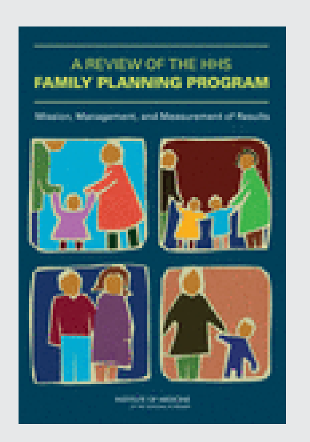

A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results

DETAILS

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A REVIEW OF THE HHS FAMILY PLANNING PROGRAM

Mission, Management, and Measurement of Results

Adrienne Stith Butler and Ellen Wright Clayton, *Editors*

Committee on a Comprehensive Review of the
HHS Office of Family Planning Title X Program

Board on Health Sciences Policy
Board on Children, Youth, and Families

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Susan C. Scrimshaw** and **Kristine M. Gebbie**. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Preface

On January 22, 2009, President Obama emphasized our country's need to "prevent unintended pregnancies . . . and support women and families in the choices they make." He clearly understands that the ability to control conception is essential "to ensuring that our daughters have the same rights and opportunities as our sons. . . ." Adequate spacing of childbearing benefits the health of children and the socioeconomic well-being of their families. Healthy families, in turn, strengthen society. Yet while family planning has been cited as one of the great public health achievements of the twentieth century, it has long been controversial. It is expressly forbidden by some religious traditions, and even the mention of contraception was banned for decades in the United States. Control of sexuality and procreation lies at the heart of the culture wars that divide the nation. To assist individuals in planning their families, we must work to find common ground to expand access to affordable contraception and accurate health information.

In this context, the resilience of Title X, the only federal program devoted exclusively to family planning, is remarkable in many ways. The program, which is directed primarily at the poor and near poor, was born in 1970 out of a conviction that all people, not just the wealthy, should be able to plan their families. President Richard Nixon showed a particular interest in family planning and in a message to the Congress in July 1969 wrote: "It is my view that no American woman should be denied access to family planning assistance because of her economic condition. I believe, therefore, that we should establish as a national goal the provision of adequate family planning services within the next five years to all those who want them but cannot afford them." From the beginning, Title X has awarded its funding on a competitive basis and to a wide variety of both public and private entities.

At the same time, the program has been under enormous pressure almost from its inception. The population in need has grown enormously in both numbers and diversity in the intervening years. The number and efficacy of contraceptive and diagnostic technologies have also grown, as have their prices. While Title X was not incorporated into state block grants in the early 1980s, in part to protect family planning from local politics, funding in inflation-adjusted dollars for the program has leveled off or declined since 1980, demonstrating the lack of strong support for the program on the national level. Congress has amended the program on several occasions, initially expanding services to adolescents and then requiring providers to encourage teens to talk with their parents, adding services for infertility, and clarifying that Title X providers are not exempt from state child abuse reporting requirements. The position of the Deputy Assistant Secretary for Population Affairs was unfilled for three years between 2000 and 2009 and had two different occupants in the last 3 years alone. The requirements for services to be offered by Title X providers have changed frequently over the years, often without a clear rationale and usually without additional funding.

Finally, the program has long been buffeted by this country's deep divisions regarding abortion. Even though Title X has never paid for abortions, abortion issues can still affect the provision of family planning services. For example, clinicians who support women's right to choose abortion worry that they are unable to provide—and that women will not be able to obtain—the advice they need under rules that limit disclosure. Those clinicians who oppose abortion feel that they are "promoting" abortion if they even mention the procedure and may decide not to provide family planning at all if required to provide abortion counseling or referral. The separation of abortion from family planning services can be particularly problematic. Indeed, the woman who has just terminated an unwanted pregnancy might be particularly receptive to contraception, and the inability to use Title X funds to address this issue at the time of abortion represents a major lost opportunity. Given the passion aroused by competing views about how family planning ought to be provided, it is hardly surprising that Title X has for years been buffeted by political and fiscal gales.

Against this backdrop of limited funding and ongoing controversy, the Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program was convened by the Institute of Medicine. The committee was composed of members with a broad range of expertise and perspectives regarding Title X, some favorable and others critical of the program. The committee's evaluation encompassed the goals of the program, its administration and management, and whether it is serving its target populations. To conduct the evaluation, the committee examined numerous documents, held 5 meetings and 3 public workshops, made 16 site visits, and commissioned 2 papers. The detailed and in-depth information and stakeholder views thus obtained served as the basis for a series of recommendations, presented in this report, for building on and enhancing the successes achieved by the Title X program.

The committee's work could not have been completed without the tireless efforts of its members and the extraordinary support of Marnina Kammersell, Thelma L. Cox, and especially Adrienne Stith Butler, our Senior Program Officer and the staff director of this study. To all of them, I extend my personal gratitude for the important work that they have completed so well. It is my hope, shared by the committee, that the new administration will use our findings and recommendations to strengthen services for family planning and reproductive health, thereby improving the lives of our nation's families and promoting equality of opportunity for women, in particular.

Ellen Wright Clayton, *Chair*
Committee on a Comprehensive Review of the
HHS Office of Family Planning Title X Program

Acknowledgments

Several individuals and organizations made important contributions to the study committee's process and to this report. The committee wishes to thank these individuals, but recognizes that attempts to identify all and acknowledge their contributions would require more space than is available in this brief section.

To begin, the committee would like to thank the sponsor of this report. Funds for the committee's work were provided by the U.S. Department of Health and Human Services, Office of Family Planning (OFP). The committee thanks Susan B. Moskosky, Director of the Office of Family Planning, and David M. Johnson, who served as project officer, for their assistance during the study process.

The committee gratefully acknowledges the contributions of the many individuals who assisted the committee in its work. The committee found the perspectives of many individuals and organizations to be valuable in understanding the Title X program. It thanks those who participated in the committee's meetings by providing important information at its open workshops. Participants included a variety of stakeholders; Title X grantees, delegates, and regional program consultants; and state and federal government representatives. Appendix A lists each of these individuals and their affiliations. As part of its review, the committee visited several sites that receive Title X funding in order to gather information about the role of Title X clinics in providing reproductive health services. These visits helped the committee understand the experiences of local administrators and service providers. In addition to clinic visits, several individuals with knowledge of the program, including Central Office staff, grantees, and regional program

consultants, were interviewed by The Lewin Group (see Appendix J) for its assessment of the administration and management of the Title X program. Appendixes F and J provide findings from these visits and interviews. The committee greatly appreciates the time and information provided by all of these knowledgeable and dedicated individuals.

Finally, the committee would like to thank the authors whose commissioned papers added to the evidence base that the committee examined. These include Julie Wolcott and Colleen Hirschkorn, The Lewin Group; and Kimberly D. Gregory, Cedars-Sinai Medical Center.

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APPENDIXES*

***The appendixes are not printed in this book but are on the CD-ROM attached to the inside back cover.**

Summary

ABSTRACT

Family planning is one of the most significant public health achievements of the twentieth century. The ability of individuals to determine their family size and the timing and spacing of their children has resulted in significant improvements in health and in social and economic well-being. The Title X federal family planning program provides these critical services to those who have the most difficulty obtaining them. Title X is a valuable program that successfully serves its target audience: low-income individuals and adolescents. In 2006, clinics supported by the program provided care to almost 5 million women, men, and adolescents, 67 percent of whom had incomes at or below the federal poverty level, and 61 percent of whom were uninsured. While the program's core goals are apparent, a secondary set of changing priorities has emerged that has not been established through a clear, evidence-based strategic process. Funding for the program has periodically grown in actual dollars, but has not kept pace with inflation, increased costs of contraceptives, supplies, and diagnostics; greater numbers of people seeking services; increased costs of salaries and benefits; growing infrastructure expenses; or rising insurance costs. The management and administration of the program generally support the achievement of its core goals, but several aspects of the program's structure could be improved to increase the ability of Title X to meet the needs of its intended population. At the same time, the extent to which the

> *program meets those needs cannot be assessed without a greater capacity for long-term data collection. The committee recommends several specific steps to enhance the management and improve the quality of the program, as well as to demonstrate its direct contribution to important end results, such as reducing rates of unintended pregnancy and infertility.*

The Title X Family Planning Program is the nation's only federal program devoted exclusively to providing family planning services. Through grants to public and nonprofit private entities, Title X funds support the provision of comprehensive family planning and related health services. These services help women and men maintain reproductive health; avoid unintended pregnancies; and determine the number, timing, and spacing of their children—all of which contribute to the health and the social and economic well-being of women, men, children, and families. By law, priority is given to low-income individuals.

The program was created in 1970 and is authorized under the Public Health Service Act, which provides for family planning services, training, research, and information and education. At least 90 percent of the program's funds must be used for family planning services. The budget for fiscal year 2008 was $300 million.

The program is administered by the Office of Family Planning (OFP) within the Office of Population Affairs (OPA) in the Department of Health and Human Services' (HHS) Office of Public Health and Science. OFP develops Title X priorities, policies, and performance measures and oversees all family planning grants. It allocates funds to 10 Regional Offices, which make awards to grantees in states and territories through a competitive process. The Regional Offices monitor program operations through site visits, Comprehensive Program Reviews, and extensive data collection, and facilitate communication between OFP and grantees.

STUDY CHARGE

In 2005, the Title X program participated in the Program Assessment Rating Tool (PART) process, which was developed and is carried out by the Office of Management and Budget (OMB). One of OMB's findings was that while several evaluations of the Title X program had been conducted, none of them had been broadly based, independent, and of sufficient quality and scope. To fill this gap and assess the overall impact of the program, OFP asked the Institute of Medicine to provide an independent evaluation of the Title X program. The specific charge to the committee is shown in Box S-1.

BOX S-1
Charge to the Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program

The HHS Office of Family Planning (OFP) has requested that the Institute of Medicine provide a critical review of the Title X Family Planning Program. The review will assess the administration and management of the program including whether the program is serving its intended target populations. The committee will also consider the extent to which the Title X program needs to reexamine the scope of its services, objectives, and operational requirements of the program.

Specifically, the committee will review and address the following questions:

- Has OFP used the PART process (including identified goals, objectives, and justification) to reflect relevant goals, outcomes, and processes needed to successfully implement and manage the Title X program?
- Does the overall Title X program meet relevant past, existing, and foreseeable future needs of the targeted population, using accepted medical, family planning, recognized and professional standards and reproductive health practices (based on the existing legislation, regulations, and guidance)?
- How do Title X program goals and objectives contribute to those of HHS?
- To what extent is the Title X program complementary versus duplicative of other public or private funding sources (e.g., Medicaid, community health centers)?

As part of this review and assessment, the committee will consider Title X documentation including legislation, regulations, previous program evaluations (such as those conducted by the Government Accountability Office, Office of the Inspector General, and Research Triangle Institute), guidance documents (Program Review Tool, Title X guidelines, Program Instructions), data management (Family Planning Annual Report guidance), Service Delivery Improvement RFAs (past and present final reports), and the PART Evaluation (level of contribution to improving service delivery).

During the committee's deliberations, four focus areas emerged that served to structure this report: (1) why family planning matters, whom the Title X program is intended to serve, and what those individuals need; (2) whether the program goals are clear and consistent and to what extent they have been achieved; (3) whether the management and administration of the program further the achievement of its goals; and (4) whether the data collected on the program are adequate for monitoring and evaluation purposes.

FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

The Importance of Family Planning

According to the Centers for Disease Control and Prevention (CDC), family planning is one of the 10 greatest public health achievements of the twentieth century (CDC, 1999). The ability to time and space children reduces fetal, infant, and maternal mortality and morbidity by preventing unintended and high-risk pregnancies (World Bank, 1993). Unintended pregnancy is associated with an increased risk of morbidity for the mother and with health-related behaviors during pregnancy, such as delayed prenatal care, tobacco use, and alcohol consumption, that are linked to adverse effects for the child (IOM, 1995). In addition to preventing unintended pregnancies, the effective use of latex condoms can reduce the transmission of sexually transmitted diseases (STDs). The availability and appropriate use of contraception can also reduce abortion rates, since a large percentage of unintended pregnancies (about one-half in 1994) result in abortion (Finer and Henshaw, 2006). Moreover, couples who are able to plan their families experience less physical, emotional, and financial strain; have more time and energy for personal and family development; and have more economic opportunities. There is also ample evidence that family planning services are cost-effective (Jaffe and Cutright, 1981; Amaral et al., 2007; Frost et al., 2008).

In 2002, nearly three-quarters of women of reproductive age in the United States (approximately 64 million women aged 15–44) received at least one family planning or related medical service (Mosher et al., 2004). Nonetheless, the rate of unintended pregnancies in the United States remains high. In 2001, 49 percent of pregnancies were unintended, a rate unchanged since 1994 (Finer and Henshaw, 2006). While unintended pregnancies occur in all age and racial/ethnic groups, they are more likely among adolescents, women in their early 20s, and poor and minority women (Finer and Henshaw, 2006). Notably, the United States has high rates of unintended pregnancy compared with other developed countries. For example, the percentage of unintended pregnancies in France is 33 percent and in Scotland 28 percent (Trussell and Wynn, 2008).

Population in Need of Title X Services

As noted, Title X targets low-income individuals; the 1978 amendment to Title X emphasized expanding services to adolescents. When the program was established in 1970, there were approximately 6.4 million adults aged 18–44 living below the federal poverty level in the United States; by 2007, that number had risen to nearly 14 million. In 1970, there were 20.1 million adolescents aged 13–17 in the United States; in 2006, there were 21.4 million. Population projections suggest that these groups will continue to grow through 2025, as will their need for care. Racial and ethnic minorities are an important population served by Title X since they are more likely to live in poverty than white Americans. Of course, not all individuals in these target populations need family planning services (because, for example, they are not sexually active or wish to become pregnant).

Barriers to Obtaining Services

Women and men may experience a number of barriers when trying to obtain family planning services. These may include a lack of awareness of the availability of services, distance to a family planning provider, difficulty in arranging transportation, limited days and hours of operation, long waiting times to schedule an appointment or receive services, poor quality of care, concerns about confidentiality, and perceived or real cost barriers (Bertrand et al., 1995; Brindis et al., 2003). In addition, the increasing number of racial and ethnic minorities in the United States leads to a growing need for culturally appropriate care, especially for sensitive services such as family planning. A further barrier to obtaining services is the fact that in 2000, approximately 17 percent of the U.S. population (47 million people) spoke a language other than English at home, and 7 percent of the population (21 million Americans) had limited English proficiency (U.S. Census Bureau, 2000d; Flores et al., 2005).

Increased Complexity and Cost of Providing Services

In the 38 years since the establishment of Title X, the health care system and overall social environment have changed in ways that have dramatically increased the complexity and cost of providing family planning services to the targeted groups. In 2007, 15.3 percent of Americans were uninsured (DeNavas-Walt et al., 2008). Among women aged 15–44, 20.8 percent lacked health insurance in 2005 (Guttmacher Institute, 2007). In addition, millions of adults are underinsured (Schoen et al., 2008), and employer-based insurance plans often do not cover basic family planning services (Klerman, 2006), although this situation has improved in the last decade.

The birth control pill, the intrauterine device (IUD), the male condom, and sterilization were the primary contraceptive methods available when Title X was enacted. New methods have since become available, including improved oral contraceptives, injectables, two new IUDs, and the contraceptive patch and ring. These safer and often more effective contraceptives are frequently more costly than earlier methods (Sonfield et al., 2008). Moreover, discontinuation rates of the various contraceptive methods vary enormously, and the more expensive long-lasting reversible methods have much higher continuation rates. Technologies such as improved Pap smears for the detection of cervical cancer, DNA-based tests for chlamydia, and STD/HIV tests also cost more than earlier tests (Dailard, 1999).

The need for the Title X program to deal with STDs has also grown. The diagnosis and treatment of STDs is an essential component of comprehensive reproductive health care and helps reduce rates of infertility—a problem Title X was directed to address by the 1978 amendment. The prevalence of STDs has changed dramatically. In particular, rates of detecting infection with chlamydia, which may be associated with subsequent infertility, have steadily increased. HIV was nonexistent at the time Title X was enacted; in 2006, CDC estimated that approximately 1.1 million persons were living with HIV infection (CDC, 2008). As part of providing preventive health services, Title X clinics must offer STD and HIV/AIDS prevention education, screening, and referral.

Conclusions

The following conclusions emerged from the committee's review of the literature on the role and history of family planning in the United States:

> *The provision of family planning services has important benefits for the health and well-being of individuals, families, communities, and the nation as a whole.*
>
> *Planning for families—helping people have children when they want to and avoid conception when they do not—is a critical social and public health goal.*
>
> *The federal government has a responsibility to support the attainment of this goal. There is an ongoing need for public investment in family planning services, particularly for those who are low income or experience other barriers to care.*

Program Goals

Clarity and Consistency of the Goals

The stated mission of the Title X program is to provide grants to public or nonprofit private entities "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)." The Program Guidelines add that Title X will "provide individuals the information and means to exercise personal choice in determining the number and spacing of their children" (OFP, 2001).

In establishing the program in 1970, Congress made clear that one major goal was to decrease the adverse health and financial effects of inadequately spaced childbearing on children, women, and their families. There was also concern at the time that the United States and the world faced serious risks due to unfettered population growth (Nixon, 1969). The program was designed to address this challenge by dramatically expanding voluntary family planning services. The federal government's continuing recognition of the contribution of family planning and reproductive health to the public well-being is evidenced by their inclusion in the nation's top health priorities as outlined in the HHS Strategic Plan and Healthy People 2010.

The program's operations are defined by (1) Program Guidelines that indicate required services, (2) annual program priorities and key issues, and (3) performance measures developed in response to the PART review. The Program Guidelines identify the clinical services that must be provided by all projects funded under the program, as well as criteria by which the quality of care is to be measured, thereby ensuring uniformity in all regions. Each Title X clinic must offer an array of 13 services, ranging from physical examination to reporting of child abuse. This expansive list poses problems, however. Most providers and program administrators wish to offer the broadest range of services possible for Title X clients, many of whom have no other source of care (Gold, 2007). Given the limited funds made available, however, all these services likely cannot be provided at a high level of quality and may not be available to all who want and need them, nor are they all appropriate for every client.

OFP disseminates an annual program announcement informing the field about the availability of funds and identifying program priorities and key issues. While the key issues have remained quite stable for the past several years, the program priorities have continually changed and expanded. The committee learned that there is no clear process for establishing these priorities and issues, nor is there an organized system for evaluating salient research findings or seeking guidance from researchers or providers about emerging needs and how the program should adapt to meet them. Many grantees therefore feel that the shifts in priorities are politically driven rather than being based on evidence or on assessments of needs or ways to improve service delivery and results.

OFP developed three long-term measures for the PART process for use in assessing the program's progress in achieving its goals (OMB, 2005):

1. Increase the number of unintended pregnancies averted by providing Title X Family Planning services, with priority for services to low-income individuals;
2. Reduce infertility among women attending Title X Family Planning clinics by identifying chlamydia infections through screening of females ages 15–24; and
3. Reduce invasive cervical cancer among women attending Title X Family Planning by providing Pap tests.

The committee concluded that the first two measures relate directly to the program's stated mission. Although less central to the program's mission, the third is worthwhile since many Title X clients have no other means of receiving these services (Gold, 2007); however, it places an additional burden on providers already dealing with very limited resources.

Achievement of the Goals

Title X has achieved a great deal in providing family planning services to its target population—low-income individuals and adolescents. Grantees provided care to 5 million family planning users in 2006—67 percent living at or below 100 percent of the federal poverty level[1] and 90 percent below 200 percent of that level (RTI International, 2008). In addition, 61 percent of clients were uninsured, 21 percent had public health insurance, and just 8 percent had private insurance (insurance status for 10 percent was not reported). In terms of age, almost one-third (32 percent) of users were aged 20–24, followed by those aged 15–19 (24 percent) and 25–29 (19 percent) (RTI International, 2008).

With regard to the above three performance measures, it is difficult to measure unintended pregnancies averted, reductions in infertility due to identifying chlamydia infections, and cases of cervical cancer prevented by providing Pap tests as a direct result of Title X services. The program can make a case that it contributes to these outcomes, but a direct effect cannot be demonstrated without building far greater capacity for long-term data collection. The desirability of establishing such a system needs to be weighed against the costs involved.

While the Title X program provides only a portion of the funds for Title X clinics, it has a special and unique role. The program covers services that other payers do not. These include the direct provision of contraceptives and other pharmaceuticals to patients, and client education and counseling. In addition, Title X covers clients who do not qualify for other

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[1] For a family of four, the 2009 poverty guideline (also known as the federal poverty level) is $22,050 (HHS, 2009).

coverage and cannot afford services, as well as expenses associated with program development and service delivery that other sources (such as Medicaid, section 330 programs, and Maternal and Child Health block grants), do not reimburse, such as overhead and infrastructure, staffing and staff training, supplies, and needs assessments and reporting.

Title X providers feel pressure to offer more and more comprehensive family planning services and comply with new program priorities without additional resources. This situation creates a tension between providing broad preventive care to fewer clients and targeting more limited services to a greater number.

Conclusions and Recommendations

The committee's findings on the clarity, consistency, and achievement of the goals of the Title X program support the following conclusions:

> *While the program's core goal and contributions to the broader goals of HHS are clear, its operational priorities have fluctuated over time without a clear rationale or grounding in science. This situation has created confusion among the program's grantees about the relative importance of the program's priorities and where to invest the limited resources available.*
>
> *The program has not engaged sufficiently in long-term strategic planning. Such planning is needed to produce directives that are evidence based and age appropriate, and to cover increasing costs.*
>
> *Although data do not currently exist to permit a comprehensive evaluation of the program, it has clearly delivered care to millions of people despite very limited resources. More funds will be needed, however, to serve the growing number of individuals of reproductive age who lack the means to obtain family planning care and to keep pace with changes and improvements in technologies.*

Based on the above conclusions, the committee offers the following recommendations:

> ***Recommendation 3-1: Reassert family planning as a core value in public health practice.*** *The Department of Health and Human Services (HHS) and Congress should recognize and support the Title X program as the leading voice for the nation's family planning effort, especially because the program's benefits apply not only to individuals and families, but also to communities and the nation.*

> ***Recommendation 3-2: Reassert and commit to the original goals of the Title X program.*** *HHS should reassert the original mission of the Title X program—helping individuals plan for pregnancy if they so desire, as well as avoid unintended pregnancy. HHS, the Office of Population Affairs, and their leadership, as well as Title X grantees, should be clearly dedicated to this mission and the goals of the Title X program, supportive of family planning as a critical public health intervention, committed to evidence-based practice, and knowledgeable about the field of family planning and reproductive health.*

> ***Recommendation 3-3: Develop and implement a strategic plan.*** *The Office of Family Planning should develop and implement a multiyear, evidence-based strategic plan that (a) reflects the mission of the Title X program and an understanding of its target population, as well as the field of family planning and reproductive health; (b) provides a vision for coordination, leadership, and evaluation; (c) addresses the family planning needs of individuals over the full reproductive lifespan; and (d) specifically references its evidence base. OPA's operation and ongoing management of the program should be guided by this plan and linked to ongoing evaluation.*

Management and Administration

The committee examined a number of issues related to the management and administration of the Title X program: the adequacy of its funding, the costs of the drugs and diagnostics Title X clinics must maintain under the Program Guidelines and the challenge for clinics of managing multiple purchasing sources, problems with maintaining continuity of products, the administrative burden on clinics, the need to review and update the Program Guidelines, the importance of ensuring transparency in program decisions and improving communication with grantees, staffing needs, and the trade-off between the benefits and burdens of local review of informational and educational materials.

Funding

As is true for much of the nation's health care system, funding for the Title X program is severely constrained (Figure S-1). Shortly after the program was established, Congress dramatically expanded its funding, which peaked in 1980. Since then, however, funding has grown in actual dollars but has not kept pace with increased costs of contraceptives, supplies, and diagnostics; greater numbers of people seeking services; inflation; increased

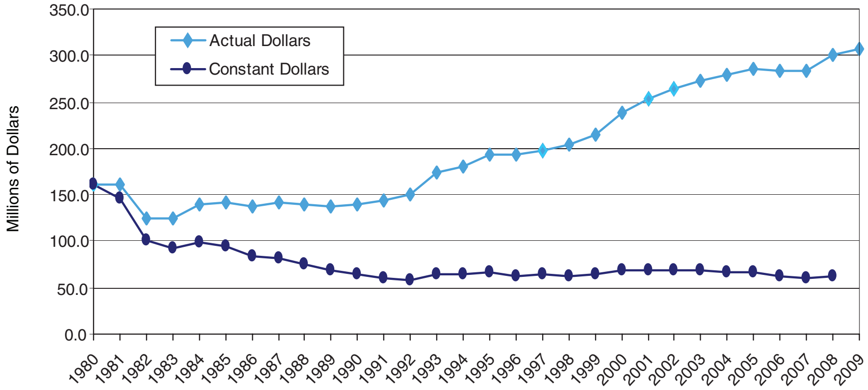

FIGURE S-1 Estimated funding for Title X when adjusted for inflation, FY 1980–2009 (actual and constant dollars, in millions).
SOURCE: Sonfield, 2009. Reprinted with permission from unpublished Guttmacher memo.

costs of salaries and benefits; infrastructure expenses; or insurance costs. Grantees identify funding and the rising costs of supplies as their greatest challenges (Sonfield et al., 2006).

Each region receives a core allocation of regular service funds made by the Central Office, based on a historical formula that measures each region's need according to three data sets—the Guttmacher Institute's Women in Need of Contraceptive Services and Supplies (Guttmacher Institute, 2008), census data, and the Bureau of Primary Care's Common Reporting Requirements. The methodology for regional allocations was last examined in 2003–2004 at the request of the Acting Assistant Secretary of Health. At that time, OFP determined that the allocations continued to reflect the need in each region accurately. According to the testimony of Title X grantees before the committee, grantees are largely unaware of how funding allocations are determined and are concerned about the lack of transparency (see below), inequities in the allocations, and the data that are used.

Costs

Under the Program Guidelines, every Title X clinic must "maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients (OFP, 2001, p. 28)." Clinics report that this is one of the strengths of the program (Gold, 2008), but that increased costs have limited the types of contraceptives they can maintain.

For example, many clinics cannot afford the cost (for both the product and related clinic services) of IUDs, implants (Implanon), and a number of other contraceptives, despite their long-term effectiveness, reliability, relatively fewer side effects, and client preferences. For cervical cancer screening, many clinics must use regular Pap tests because of the higher cost of the newer liquid-based test, which can reduce the number of tests that need to be repeated (ACS, 2006). The same is true of the recently developed test for human papillomavirus and the vaccine to prevent it.

Many Title X clinics obtain contraceptives through the Office of Pharmacy Affairs' 340B drug pricing program, consortia, cooperatives, other groups (such as the Planned Parenthood Federation), or state governments that negotiate discounted prices for bulk purchases. Coordinating or consolidating these purchasing sources could help alleviate the cost problem by maximizing the benefits of volume purchasing. Models for such an approach in the federal government include those used by the Department of Veterans Affairs and CDC (for example, the Vaccines for Children program).

Continuity of Products

Some Title X clinics have reported problems with maintaining continuity of products because the 340B program revises the list of available drugs quarterly and often obtains products with short expiration periods. Clinics must constantly monitor the list of available drugs and determine whether drugs being used by clients need to be changed. This situation disrupts continuous and hence effective use, and poses a burden for both providers and clients. Continuity of products is also compromised by the multiple purchasing sources noted above.

Administrative Burden

Title X clinics bear a significant burden in budgeting for and managing their multiple sources of funding, a burden exacerbated by the multiple funding cycles for the awarding of grants within the Title X program. Coordination of patient fees and record-keeping and reporting requirements for the numerous federal programs involved and establishment of a single funding cycle could reduce this administrative burden, as well as associated costs. Similarly, patient fee schedules and record-keeping requirements vary across federal programs and create burdens for clinics receiving Title X and other funds (e.g., 330 funding).

Program Guidelines

As noted above, some of the services required under the Program Guidelines may not be appropriate for all clients. The cancer screening requirements, for example, apply to all clients regardless of age or risk factors. Thus, for example, adolescents must have breast, rectal, and pelvic examinations and Pap smears within 6 months of becoming a Title X client, even though relevant abnormalities are rarely found in adolescents. Ensuring that the Program Guidelines are evidence based could improve the delivery of services under Title X.

Transparency and Communication

The lack of transparency regarding decisions by the Central Office and Regional Program Coordinators (RPCs) in the awarding of funds to grantees is a program challenge. OFP communicates regularly with RPCs, who in turn communicate with grantees; some Internet resources are available as well. Nonetheless, grantees often do not receive the information they desire about program decisions, nor do they feel that they have adequate input into many decisions or that their concerns reach the Central Office.

Grantees and delegates also would like more regular feedback on their performance and more constructive advice on how to improve. Some find the comprehensive program review process strenuous and overly focused on small details. Grantees also would like more opportunities to learn from other grantees about successful approaches that might be replicated.

Staffing

Staffing is a pressing concern for many grantees and delegates and is likely to become even more so given the shortage of and competition for trained medical personnel in most areas of the country, as well as the impending retirement of many nurses and nurse practitioners who staff the clinics, the increasing cost of salaries and benefits, the need for and cost of continued professional training (Murray, 2002), and efforts to revise state licensure laws to require more advanced training for practitioners (National Council of State Boards of Nursing, 2008). The need to increase the pool of qualified professionals has been an ongoing problem for the program and will become greater with the growing need for Title X services by increasingly diverse populations.

Informational and Educational Materials

During the committee's site visits, in testimony provided by grantees and delegates, and in the Membership Survey of the National Family Planning and Reproductive Health Association, several issues regarding informational and educational materials were raised. These issues include the manner in which materials developed by the OPA Clearinghouse are reviewed, the duplicative review by a delegate's advisory committee after review by the grantee responsible for the delegate, and delays or other problems in obtaining payment for materials ordered from outside sources. Grantees and delegates suggested that materials used in a related program might be distributed without additional review. Concerns were also expressed about the ability of the advisory committees (rather than professional health educators or public health personnel) to select culturally, linguistically, and literacy level–appropriate materials. Grantees and delegates indicated that some of the OPA Clearinghouse materials fail to meet those criteria—deficits that should be rectified at the Clearinghouse level.

Conclusions and Recommendations

The committee drew the following conclusions about the management and administration of the Title X program:

> *The management structure and administration of the program generally work well, but could be improved.*
>
> *Specific areas for improvement include overall funding levels, pharmaceutical and laboratory testing costs, birth control method availability, administrative burden, the evidence base for and flexibility of the Program Guidelines, transparency and communication, staffing shortages, and informational and educational materials.*

The committee offers the following recommendations for achieving these improvements:

> ***Recommendation 4-1: Increase program funding so that statutory responsibilities can be met.*** *Title X should receive the funds needed to fulfill its mission of providing family planning services to all who cannot obtain them through other sources and to finance such critical supplemental services as infrastructure, education, outreach, and counseling that many other financing systems do not cover. Consistent with legislative intent, financing for the program must also support research and evaluation, training, the develop-*

ment and maintenance of needed infrastructure, and the adoption of important new technologies.

Recommendation 4-2: Examine and, if appropriate, improve methods of allocating funds. *OFP should carefully examine and, if appropriate, improve the system used to allocate funds from OFP to regions, regions to grantees, and grantees to delegates. The transparency of these funding processes should be improved so that program participants and the public are aware of the processes for making decisions about funding allocations at each level and for commenting on those decisions.*

Recommendation 4-3: Improve the ability to purchase drugs and diagnostics at reduced prices by consolidating purchasing sources. *OFP should work with the various public and private purchasing sources for drugs and diagnostics for Title X clinics to develop a coordinated or consolidated purchasing program.*

Recommendation 4-4: Improve the continuity of products provided to clients of Title X clinics. *The 340B drug pricing program should revise its list of available drugs less frequently and make an effort to obtain drugs with longer expiration periods. Product continuity would also be enhanced by the consolidation proposed under recommendation 4-3.*

Recommendation 4-5: Reduce the administrative burden on Title X clinics. *OPA should work with other HHS agencies supporting family planning to coordinate patient fee schedules and record-keeping and reporting requirements. OPA should also adopt a single funding cycle, where possible, for the awarding of grants.*

Recommendation 4-6: Adopt a single method for determining criteria for eligible services. *The federal government should adopt a single method of determining criteria for eligible services (for example, which services are available at which percent of the federal poverty level), what copays if any are required, and how clinics should report clients seen. The current inconsistencies create an atmosphere that discourages coordination of Health Resources and Services Administration, Centers for Disease Control and Prevention (CDC), and other programs with Title X.*

Recommendation 4-7: Review and update the Program Guidelines to ensure that they are evidence based. *OFP should review the*

Program Guidelines annually and update them as needed to reflect new scientific evidence regarding clinical practice. In so doing, OFP should establish a mechanism for obtaining expert scientific and clinical advice in a systematic, transparent way. Expertise should be drawn from the clinical, behavioral, epidemiological, and educational sciences. In addition, it is important to enhance the flexibility of Title X clinics so they can meet the needs of individual patients while adhering to evidence-based guidelines and practices.

Recommendation 4-8: Increase transparency and improve communication. *OFP should increase the transparency and communication of information at all levels of the program. Such information should encompass methods for allocating program funds, the process for establishing annual program priorities, suggestions for program improvements, lessons learned through research supported by Title X and other programs, and how data are used. This information should be disseminated both vertically and horizontally.*

Recommendation 4-9: Assess workforce needs. *With the help of an independent group, OFP and other agencies within HHS should conduct an analysis of family planning workforce projections for the United States in general and for the Title X program specifically. The study should assess current and future workforce training needs and the educational system capacity necessary to meet those needs. The study should also identify ways in which these needs can be met and financed.*

Recommendation 4-10: Assess the local review of informational and educational materials. *OFP should assess whether the benefits of local review of all educational materials outweigh the burdens, including costs. OFP should develop processes that eliminate duplicative reviews while also ensuring that consumers have an opportunity for input at either the local or national level.*

Data to Monitor and Evaluate the Program

The committee developed a framework (outlined in Figure S-2) that could serve as the foundation for a more integrated and comprehensive evaluation approach to guide Title X's future efforts by linking the program's evaluation to its stated goals and priorities.

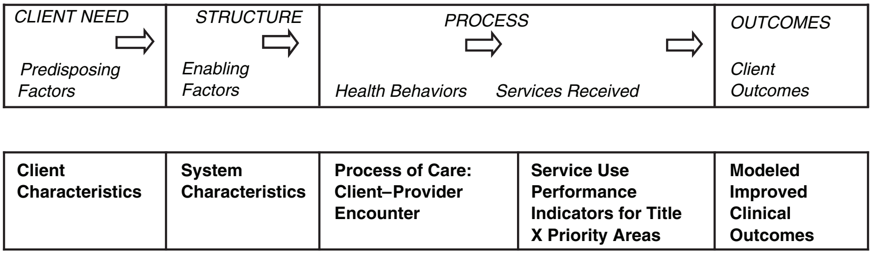

FIGURE S-2 Conceptual framework for Title X evaluation.

Current Data Sources

OFP currently uses data from a variety of sources to monitor and evaluate the program. The primary source is the *Family Planning Annual Report* (FPAR), which is based on annual uniform reporting by all Title X grantees. Another main source is the Comprehensive Program Reviews (CPRs), which are conducted approximately every 3 years by OFP's Regional Offices. The Program Review Tool, used in the CPRs, includes questions on administration, financial management, clinical services, and outreach/information. In addition, Regional Offices conduct annual grantee monitoring site visits to follow up on issues identified in the CPR, grant application, and/or needs assessment. A final data source is the National Survey of Family Growth (supported in part by Title X), which examines reproductive behaviors, health, and family planning services received.

How Data Collection Efforts Can Be Improved

The evaluation framework outlined above guided the committee's recommendations for evaluation strategies to improve the management and quality of the Title X program. The full framework (presented in the main text) lists data that are currently being collected in each of the framework's columns. The FPAR and CPR provide the most comprehensive information about the program, including key characteristics of the client population, critical system characteristics, and services performed. However, client-level data, such as knowledge and pregnancy intentions, are not obtained. Nor does OFP systematically collect data on key process and outcome variables. In addition, how Title X synthesizes and uses existing data for program planning is not clear to the committee or to grantees and delegates.

Conclusions and Recommendations

The committee's comparison of the data needed to monitor and evaluate the Title X program against the data actually collected supports the following conclusions:

> *The program does not collect all the data needed to fully monitor the program and evaluate its impact.*
>
> *A comprehensive framework for approaching program evaluation could ensure that all major aspects of the program are evaluated and the needs of clients are being met. Gathering these data will require innovative approaches—and new funding—to minimize the burden on providers.*

The following recommendations are made for meeting these data needs.

> ***Recommendation 5-1: Fund and use a comprehensive framework to evaluate the Title X program.*** *OFP should develop, fund, and use a comprehensive framework to evaluate the Title X program. The use of such a framework would allow OFP to evaluate the program on the full continuum from clinic performance and quality, to clinic management, to program outcomes. It would also help in identifying the types of data needed for evaluation purposes.*
>
> ***Recommendation 5-2: Examine the data elements of the* Family Planning Annual Report *(FPAR).*** *When revising the Program Guidelines (see Recommendation 4-7), OFP should review and clarify data elements contained in the FPAR and, where possible and useful, eliminate those that are unnecessary, particularly if additional elements are needed.*
>
> ***Recommendation 5-3: Collect additional data.*** *To help fill gaps in the Title X program's data collection systems, OFP should collect additional data in the areas of client needs, structure, process, and outcomes for use in evaluating the program's progress and its effectiveness in achieving its goals. Specifically, OFP should:*
>
> - ***Collect additional data on client characteristics.*** *Additional data sources, such as the Comprehensive Program Reviews (CPRs), should be used to supplement the FPAR data on client characteristics—for example, to obtain data on clients' knowl-*

edge about available contraceptive methods and pregnancy intentions.

- ***Collect data on system characteristics.*** *Additional data are needed on such system characteristics as the availability of interpreters to meet the needs of clients with limited English proficiency.*
- ***Collect data on the process of care.***
  - — *These data should include patients' perceptions of care. With expert consultation, selected CPR site visits could be structured to sample a limited number of clients for the purpose of obtaining generalizable results.*
  - — *With expert advice, OFP should examine the three core outcome measures identified for the PART process in relation to evidence-based guidelines and national health priorities. After determining the most appropriate measures, OFP should develop related performance metrics for clinic service to establish quality improvement standards.*
- ***Conduct research to assess program outcomes.*** *OFP should expand research aimed at evaluating program outcomes, such as the impact of the program on pregnancy planning and intention, decreased infertility, outreach to those in need of services, and the prevention of unintended pregnancy.*

Recommendation 5-4: Examine evaluation tools for outreach and education. *To assist ongoing quality improvement and effective expansion of community outreach and education, OFP should work with grantees to develop and refine evaluation tools for outreach and education that can be applied easily by delegates.*

Recommendation 5-5: Obtain scientific input on evaluation efforts. *OFP should expand its use of scientific expertise to strengthen its evaluation strategies and improve its evaluation research program, and consider expanding its use of national databases to evaluate program impacts.*

Recommendation 5-6: Communicate evaluation findings. *To ensure transparency and broad-based dissemination of information and ultimately to improve care (see Recommendation 4-8), OFP should enhance ongoing feedback and communication with grantees, delegates, clinics, and others about important evaluation findings and how they can help improve care and track progress toward the achievement of program goals.*

CONCLUDING THOUGHTS

The committee has identified a variety of ways in which the Title X program could be improved. These include focusing on the program's core mission; undertaking a strategic planning process with a longer time horizon; implementing patient-focused, scientifically based clinical practices; and enhancing evaluation and communication. While there is room for improvement, it is also important to note that the program has successfully served thousands of low-income men and women and adolescents for almost four decades. Despite increasingly limited funds and varying levels of controversy and challenge, the dedication of federal agency staff, grantees, delegates, and clinic staff to the goals and clients of the program has remained strong and made it possible for the program to deliver essential services. The committee salutes their steadfast commitment to the overall goals of family planning in general and to the Title X program in particular.

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1

Introduction

The Title X Family Planning Program, the nation's only federal program devoted exclusively to providing family planning services, is authorized under Title X of the Public Health Service Act (P.L. 91-572) (see Appendix B for the statute and Appendix C for the regulations). Created in 1970, Title X is devoted to the provision of comprehensive family planning and related health services—services that help women and men maintain reproductive health; avoid unintended pregnancies; and determine the number, timing, and spacing of their children—all of which contribute to the health and social and economic well-being of women, men, children, and families. This report presents the results of an independent evaluation of the Title X program performed by a committee convened by the Institute of Medicine (IOM).

OVERVIEW OF THE TITLE X PROGRAM

The Title X program provides grants to public and nonprofit private entities to assist in establishing and operating family planning clinics, training service providers, conducting research, and engaging in community-based education and outreach. The program is designed to provide access to contraceptive services, supplies, and information for all who want and need them. By law, however, priority is given to low-income individuals. Consistent with this basic goal, in 2006 the Title X program provided family planning and related reproductive health services to almost 5 million people, 67 percent of whom had incomes at or below the federal poverty level and 61 percent of whom were uninsured (RTI International, 2008).

The Office of Family Planning (OFP) administers the Title X program. OFP is located within the Office of Population Affairs (OPA), a part of the Department of Health and Human Services' (HHS) Office of Public Health and Science. OPA is the focal point for HHS on reproductive health issues, administering the Title X program through OFP and Title XX (funds for services to pregnant and parenting adolescents) through the Office of Adolescent Pregnancy Programs. Although the Title X program is administered by OFP, its budget line is located within the Health Resources and Services Administration. OFP develops the program's priorities, policies, and performance measures and oversees all Title X family planning grants. The Title X Act includes four major provisions: (1) family planning services, (2) training, (3) research, and (4) information and education. At least 90 percent of appropriations must be used for family planning services. The four provisions are described briefly below. Further detail about the administration and management of the program is provided in Chapter 4.

Family Planning Services

OFP allocates Title X funds to 10 HHS Regional Offices. These offices, in turn, award funds to grantees in states and territories through a competitive process. Grantees may provide family planning services and/or award funds to delegates to provide services under negotiated, written agreements with the grantees. The Regional Offices monitor program operations through site visits; Comprehensive Program Reviews; and the collection of data for the *Family Planning Annual Report* (FPAR) on characteristics of clients served, services provided, personnel providing services, and project revenues. The Regional Offices also provide feedback to grantees on their performance and communicate with OFP regarding legal and policy issues.

OFP promulgates Program Guidelines that provide grantees with an operational interpretation of the law and regulations, defining the services that must be provided by all projects funded through Title X (see Appendix D). In addition, the Program Guidelines outline other related services that may be offered, as well as requirements for equipment and supplies, medical records, and quality assurance.

Services financed in whole or in part by Title X are delivered through a wide variety of community-based clinics and sites that include state and local health departments, hospitals, university health centers, Planned Parenthood affiliates, community health centers, independent clinics, and other public and nonprofit agencies. Clinics supported by Title X provide preventive health care services, such as patient education and counseling; breast and pelvic examinations; screenings for cervical cancer, sexually transmitted diseases, and HIV; pregnancy diagnosis and counseling; contraceptive methods and/or prescriptions for contraceptive supplies and other medications; and basic infertility services (which include an initial infertility interview, education, a physical examination, counseling, and appropriate referral). Other services provided include general physical examinations, follow-up, and referrals.

Training, Research, and Information and Education

The remaining 10 percent of Title X funds goes to these three areas. Training is supported for staff of family planning clinics to strengthen overall clinic performance and patient care. Biomedical, behavioral, and health services research is aimed at improving the delivery of family planning services. Information and education includes information dissemination through a centralized clearinghouse and community-based education and outreach activities.

STUDY PURPOSE AND CHARGE TO THE COMMITTEE

In 2005, the Title X program participated in the Program Assessment Rating Tool (PART) process, which was developed and is carried out by the Office of Management and Budget (OMB) (the PART is presented in Appendix E). The purpose of the PART process is to assess and improve the performance of federal programs (OMB, 2005), with particular emphasis on identifying program strengths and weaknesses to inform funding and management decisions that will make the program more effective. As a result of the Title X PART evaluation, OMB determined that the program was strong in its overall purpose, design, and management but that performance goals for some program activities had not yet been developed. In addition, OMB determined that, while there had been several focused evaluations of the Title X program, none of them had been broadly based, independent, and of sufficient quality and scope. To fill this gap, OFP asked the IOM to provide an independent evaluation of the program, including an assessment of its overall impact. The IOM committee examined Title X's administration and management, as well as the extent to which the program's objectives and operational requirements meet the needs of its target populations. The committee also considered whether the program has adequately adapted to ongoing changes in technology, medical practice, social values and norms, and other related influences that might bear on its effectiveness. The evaluation encompassed the questions of how well the program is meeting its stated goals, how adequate the scope of services is for meeting the needs of low-income individuals, how well the program is managed at its various levels, and how it functions in relation to other public and private sources of support for family planning services. The specific charge to the committee is presented in Box 1-1.

The purpose of this report is to present the committee's assessment of the impact of the Title X program in relation to its stated goals, and to recommend ways to improve the program's effectiveness and efficiency. The committee's recommendations are based on scientific evidence and expert judgment. The findings and recommendations presented in this report are intended to assist OFP and OPA in administering the program to best meet its goals. Other audiences include policy makers, Title X grantees and delegates, those who receive services through Title X, and the general public.

BOX 1-1
Charge to the Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program

The HHS Office of Family Planning (OFP) has requested that the Institute of Medicine provide a critical review of the Title X Family Planning Program. The review will assess the administration and management of the program including whether the program is serving its intended target populations. The committee will also consider the extent to which the Title X program needs to reexamine the scope of its services, objectives, and operational requirements of the program.

Specifically, the committee will review and address the following questions:

- Has OFP used the PART process (including identified goals, objectives, and justification) to reflect relevant goals, outcomes, and processes needed to successfully implement and manage the Title X program?
- Does the overall Title X program meet relevant past, existing, and foreseeable future needs of the targeted population, using accepted medical, family planning, recognized and professional standards and reproductive health practices (based on the existing legislation, regulations, and guidance)?
- How do Title X program goals and objectives contribute to those of HHS?
- To what extent is the Title X program complementary versus duplicative of other public or private funding sources (e.g., Medicaid, community health centers)?

As part of this review and assessment, the committee will consider Title X documentation including legislation, regulations, previous program evaluations (such as those conducted by the Government Accountability Office, Office of the Inspector General, and Research Triangle Institute), guidance documents (Program Review Tool, Title X guidelines, Program Instructions), data management (FPAR guidance), Service Delivery Improvement RFAs (past and present final reports), and the PART Evaluation (level of contribution to improving service delivery).

STUDY APPROACH

During this 24-month study, the IOM committee used several methods for data collection (see Appendix A for a full description of the study methods). The committee held five meetings and three public workshops to gather information on topics related to the study charge and to hear the views of a variety of groups and individuals knowledgeable about Title X. The committee also conducted a literature review to assess evidence on populations in need of family planning services, the services provided, the role of Title X and other funding sources in providing those services, barriers to care, and best practices. In addition, the committee received documents from OFP describing the operation of the program, previous evaluations of the program, and the program's grantees and delegates. These documents included Title X's authorizing legislation, relevant regulations, program evaluations, guidance documents, annual reports, service delivery improvement reports, and the program's PART evaluation. The committee also commissioned two papers to obtain an in-depth assessment of the organization and management of the program and issues pertaining to measuring the quality of family planning services. Finally, the committee conducted 16 visits to Title X clinics to learn how services are provided in various settings and to gather the views of local administrators and service providers about the program, which yielded important data for the committee's deliberations (see Appendix F for a summary of the site visits).

ORGANIZATION OF THE REPORT

The remainder of this report is divided into four chapters. Chapter 2 provides an overview of family planning in the United States, including the importance of family planning services, key milestones, and the changing context in which the Title X program operates. Chapters 3 through 5 provide the committee's evaluation of the Title X program. Chapter 3 addresses the goals and priorities of the program and the extent to which they have been accomplished. Chapter 4 reviews the organization and management of Title X and how the program relates to other sources of funding for family planning services. Finally, Chapter 5 provides the committee's assessment of whether data collected by OFP are adequate to monitor the program and measure its outcomes, and how the Title X evaluation system can be improved. The committee's key findings are highlighted throughout these chapters, each of which ends with the committee's conclusions and recommendations. Table 1-1 shows the chapter(s) in which each element of the study charge (Box 1-1) is addressed.

TABLE 1-1 Elements of the Study Charge and Chapters Where They Are Addressed

Element of Charge	**Chapter(s)**
The review will assess the administration and management of the program including whether the program is serving its intended target populations.	3, 4
The committee will also consider the extent to which the Title X program needs to reexamine the scope of its services, objectives and operational requirements of the program.	3, 4, 5
• Has OFP used the PART process (including identified goals, objectives, and justification) to reflect relevant goals, outcomes, and processes needed to successfully implement and manage the Title X program?	3, 5
• Does the overall Title X program meet relevant past, existing, and foreseeable future needs of the targeted population, using accepted medical, family planning, recognized and professional standards and reproductive health practices (based on the existing legislation, regulations, and guidance)?	3, 4
• How do Title X program goals and objectives contribute to those of HHS?	3
To what extent is the Title X program complementary versus duplicative of other public or private funding sources (e.g., Medicaid, community health centers)?	4

2

Overview of Family Planning in the United States

According to the Centers for Disease Control and Prevention (CDC), family planning is one of the 10 great public health achievements of the twentieth century, on a par with such accomplishments as vaccination and advances in motor vehicle safety (CDC, 1999). The ability of individuals to determine their family size and the timing and spacing of their children has resulted in significant improvements in health and in social and economic well-being (IOM, 1995). Smaller families and increased child spacing have helped decrease rates of infant and child mortality, improve the social and economic conditions of women and their families, and improve maternal health. Contemporary family planning efforts in the United States began in the early part of the twentieth century. By 1960, modern contraceptive methods had been developed, and in 1970 federal funding for family planning was enacted through the Title X program, the focus of this report.

This chapter provides an overview of family planning in the United States. It begins by explaining the importance of family planning services and the crucial needs they serve. Next is a review of milestones in family planning, including its legislative history. The third section provides data on the use of family planning services. This is followed by a discussion of the changing context in which these services are provided, including changes in the populations served by Title X, changes in technology and costs, the growing evidence base for reproductive health services, and social and cultural factors. The fifth section addresses the financing of family planning. The final section presents conclusions.

WHY FAMILY PLANNING IS IMPORTANT

According to the World Health Organization (WHO), family planning is defined as "the ability of individuals and couples to anticipate and attain their desired number of children and the spacing and timing of their births. It is achieved through use of contraceptive methods and the treatment of involuntary infertility" (working definition used by the WHO Department of Reproductive Health and Research [WHO, 2008]). The importance of family planning is clear from its benefits to individuals, as well as to families, communities, and societies (AGI, 2003). Family planning serves three critical needs: (1) it helps couples avoid unintended pregnancies; (2) it reduces the spread of sexually transmitted diseases (STDs); and (3) by addressing the problem of STDs, it helps reduce rates of infertility.

These benefits are reflected in the federal government's continued recognition of the contribution of family planning and reproductive health to the well-being of Americans. Responsible sexual behavior is one of the 10 leading health indicators of Healthy People 2010, a set of national health objectives whose goal is to increase the quality of life and years of healthy life. The Healthy People indicators reflect major public health concerns. The United States has set a national goal of decreasing the percentage of pregnancies that are unintended from 50 percent in 2001 to 30 percent by 2010 (HHS, 2000). The objectives for increasing responsible sexual behavior are to increase the proportion of adolescents who abstain from sexual intercourse or use condoms if currently sexually active, and to increase the proportion of all sexually active persons who use condoms.

The 2007–2012 Department of Health and Human Services (HHS) Strategic Plan is intended to provide direction for the Department's efforts to improve the health and well-being of Americans. The provision of family planning services promotes several HHS goals, including increasing the availability and accessibility of health care services, preventing the spread of infectious diseases (through testing for STDs/HIV), promoting and encouraging preventive health care, and fostering the economic independence and social well-being of individuals and families. The contribution of Title X to these goals is discussed in Chapter 3.[1]

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[1] It should be noted that, despite the clear contributions of family planning to important public health goals, the public varies widely in its attitudes toward family planning and contraception. A large majority (86 percent) of the American public supports family planning services as part of health care for low-income women (where family planning is defined to exclude abortion) (Adamson et al., 2000). However, not everyone wants or believes in birth control. Some believe it should be available for married couples but not for unmarried people or teenagers for fear of encouraging sexual activity. Some religions, notably the Roman Catholic Church, oppose certain methods of contraception, although these strictures often are not followed by their congregants. Recent years have also seen vigorous political debates about emergency contraception (Plan B®), the rights of providers to refuse to offer care that

> ***Finding 2-1.*** *The provision of family planning services has important benefits for the health of individuals, families, communities, and societies. There is a continued need for investment in family planning and related reproductive health services, particularly for those who have difficulty obtaining these important services.*

Avoiding Unintended Pregnancy

The ability to time and space children reduces maternal mortality and morbidity by preventing unintended and high-risk pregnancies (World Bank, 1993; Cleland et al., 2006). Unintended pregnancy is associated with an increased risk of morbidity for the mother and with health-related behaviors during pregnancy, such as delayed prenatal care, tobacco use, and alcohol consumption, that are linked to adverse effects for the child. According to the Institute of Medicine (IOM) report *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families*:

> The child of an **unwanted** conception especially (as distinct from a **mistimed** one) is at greater risk of being born at low birth weight, of dying in its first year of life, of being abused, and of not receiving sufficient resources for healthy development. The mother may be at greater risk of depression and of physical abuse herself, and her relationship with her partner is at greater risk of dissolution. Both mother and father may suffer economic hardship and may fail to achieve their educational and career goals. Such consequences undoubtedly impede the formation and maintenance of strong families. (IOM, 1995, p. 1)

In 2000, approximately half of unintended pregnancies resulted in abortion (Finer and Henshaw, 2006); thus the availability and appropriate use of contraception can also reduce abortion rates (AGI, 2003).[2] In addition to preventing unintended pregnancies, effective use of contraceptives (latex condoms) can reduce the transmission of STDs (see the discussion below).

When children are adequately spaced (with conception taking place no sooner than 18 months after a live birth, or about 2.5 years between births), they are less likely to suffer complications. Such complications include low birth weight, which is associated with a host of health and developmental problems (Conde-Agudelo et al., 2006). Low birth weight and premature birth are more likely to occur to women under 18 and over 35, and to those who have already had four or more births (WHO, 1994).

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violates their beliefs, and whether teens have a right to access reproductive health care without parental involvement.

[2] By law, Title X funds cannot be used in programs that provide abortion services.

In addition to its maternal and infant health benefits, family planning can increase the involvement of partners in decisions about whether and when to have children. One of the most important aspects of helping people plan *for* pregnancy is helping them avoid unintended pregnancy. Couples who are able to plan their families experience less physical, emotional, and financial strain; have more time and energy for personal and family development; and have more economic opportunities (Cleland et al., 2006). In turn, effective family planning results in fewer strains on community resources, such as social services and health care systems (WHO, 1994).

According to the IOM report cited above, women are considered at risk of unintended pregnancy if they "(1) have had sexual intercourse; (2) are fertile, that is, neither they nor their partners have been contraceptively sterilized and they do not believe that they are infertile for any other reason; and (3) are neither intentionally pregnant nor have they been trying to become pregnant during any part of the year" (IOM, 1995, p. 28). Among the nearly 50 million sexually active women aged 18–44, 28 million (56 percent) are at risk of unintended pregnancy (Frost et al., 2008a). Given that the onset of sexual activity increasingly occurs before marriage, when the proportion of pregnancies that are unintended is greatest (see below), the highest proportion of women at risk of unintended pregnancy is found among those aged 18–29 (70 percent), although a significant proportion of women aged 30–44 (40 percent) are also at risk (IOM, 1995).

While significant advances have been made in contraceptive technology and the availability of family planning services, rates of unintended pregnancy in the United States remain high, particularly for certain segments of the population. In 2001, 49 percent of pregnancies were unintended, a rate that had not changed since 1994 (Finer and Henshaw, 2006). In 2001, unintended pregnancies resulted in 1.4 million births, 1.3 million induced abortions, and an estimated 400,000 miscarriages (Frost et al., 2008a). Notably, the United States has high rates of unintended pregnancy compared with other developed countries. For example, the percentage of unintended pregnancies in France is 33 percent and in Scotland 28 percent (Trussell and Wynn, 2008). Unintended pregnancies result in societal burden, and significant economic savings are realized through investment in family planning services. The Guttmacher Institute has estimated that every $1.00 invested in helping women avoid unwanted pregnancies saved $4.02 in Medicaid expenditures (Frost et al., 2008b).

A variety of factors contribute to unintended pregnancy, including lack of access to contraception, failure of chosen contraceptive methods, less than optimal patterns of contraceptive use or lack of use, and lack of adequate motivation to avoid pregnancy (Frost et al., 2008a). The reasons for the high rate of unintended pregnancies in the United States, particularly in relation to rates in other industrialized countries, are poorly understood.

A better understanding of these reasons from the perspective of current, former, and potential users of family planning services is needed (see Chapter 5 for discussion of the need for better data collection systems to capture client perspectives).

Unintended pregnancy is most likely among women who are young, unmarried, low-income, and/or members of racial or ethnic minorities (see Figures 2-1 through 2-3, respectively), although it occurs in significant numbers across demographic groups (IOM, 1995). Teenagers and young adults aged 18–24 have the highest rates of unintended pregnancy—more than one intended pregnancy occurred for every 10 women in this age range, which is twice the rate for women overall (Finer and Henshaw, 2006). Unsurprisingly, unintended pregnancies represent the highest proportion of all pregnancies among teenagers and young adults as well, ranging from 100 percent for those under 15, to 82 percent among those aged 15–19, to 60 percent among those aged 20–24 (Finer and Henshaw, 2006). However, teenage pregnancy rates dropped 38 percent between 1990 and 2004, from 116.8 per 1,000 to 72.2 per 1,000 among those aged 15–19 (NCHS, 2008). The pregnancy rate dropped more sharply among teenagers aged 15–17 (from 77.1 per 1,000 in 1990 to 41.5 in 2004, a 46 percent decline) than among those aged 18–19 (167.7 per 1,000 to 118.6 per 1,000, a 29 percent decline). The teenage birth rate also declined over the past two decades, from a peak of 61.8 per 1,000 in 1991 to 40.5 per 1,000 in 2005, a 35 percent decrease. The birth rate among teenagers aged 15–19 increased 3 percent between 2005 and 2006, to 41.9 per 1,000 (NCHS, 2008). Teenage pregnancy rates are currently available only through 2004, but preliminary data suggest that there may also have been an increase in the teen pregnancy rate between 2005 and 2006 (The National Campaign, 2009).

With regard to marital status, the rate of unintended pregnancy is significantly higher among unmarried women (67 per 1,000) than among married women (32 per 1,000) (Finer and Henshaw, 2006). Fully 74 percent of pregnancies among unmarried women were unintended in 2001, compared with 27 percent of those among married women (Finer and Henshaw, 2006). The rate of unintended pregnancy is also substantially higher among poor women (112 per 1,000) than among women living at or above 200 percent of the federal poverty level (29 per 1,000) (Finer and Henshaw, 2006). The proportion of unintended pregnancies is inversely related to income: among pregnant women living at or below the poverty level in 2001, 62 percent of pregnancies were unintended; in comparison, 38 percent of pregnancies were unintended among women at or above 200 percent of the poverty level (Finer and Henshaw, 2006). However, because women with higher incomes are more likely to have an abortion when they experience an unintended pregnancy, the rate of unintended births among poor women (58 per 1,000) is more than five times greater

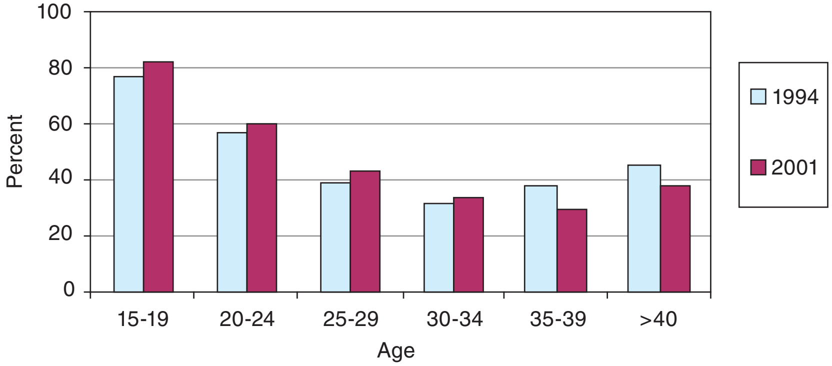

FIGURE 2-1 Percentage of pregnancies that were unintended, by age, 1994 and 2001.
SOURCE: Finer and Henshaw, 2006.

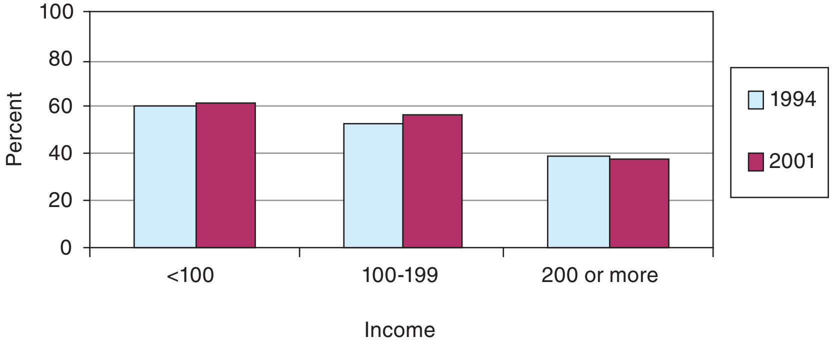

FIGURE 2-2 Percentage of pregnancies that were unintended, by income as a percentage of the federal poverty level, 1994 and 2001.
SOURCE: Finer and Henshaw, 2006.

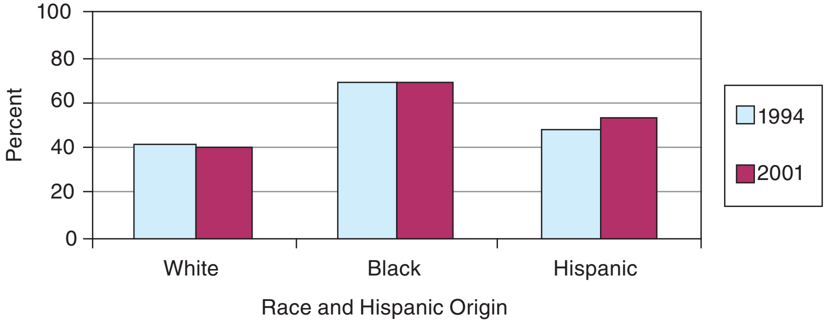

FIGURE 2-3 Percentage of pregnancies that were unintended, by race and ethnicity, 1994 and 2001.
SOURCE: Finer and Henshaw, 2006.

than that among women in the highest income category (11 per 1,000) (Finer and Henshaw, 2006). Unintended pregnancy rates are also higher among women with lower levels of education and minority women (Finer and Henshaw, 2006).

Preventing Sexually Transmitted Diseases and Reducing Infertility

In addition to preventing unintended pregnancies, Title X was designed, particularly after the 1978 amendment, to emphasize services for adolescents and infertility services. As discussed later in this chapter, the 1995 program priorities provided for expansion of reproductive health services to include screening for and prevention of STDs, including HIV/AIDS. The diagnosis and treatment of STDs is an essential component of comprehensive reproductive health care and, as noted above, also helps reduce rates of infertility.

Notable shifts have occurred in the prevalence of STDs. In 1970, gonorrhea was the most prevalent STD (see Figure 2-4). Rates of gonorrhea peaked in 1975 at 464 cases per 100,000 and declined dramatically during the 1980s and early 1990s following the implementation of the national gonorrhea control program in the mid-1970s (CDC, 2007). Rates leveled

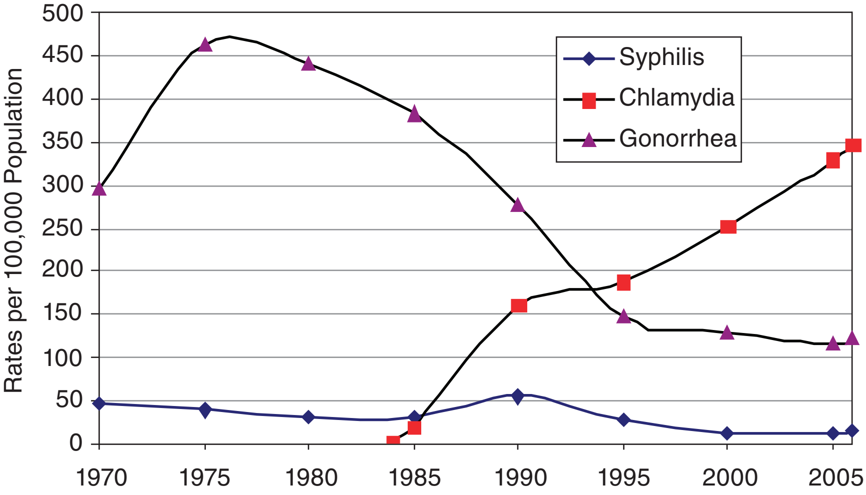

FIGURE 2-4 Rates of sexually transmitted diseases reported by state health departments per 100,000 population, United States, 1970–2006.
NOTE: Chlamydia rates were not reported until 1984.
SOURCE: CDC, 2007.

off during the past decade to a low of 112.4 cases per 100,000 in 2004, but increased in both 2005 and 2006 (to 120.9 cases per 100,000). Changes in screening and reporting practices, as well as the use of varying diagnostic tests, may mask true increases or decreases in the disease (CDC, 2007).

Rates of chlamydia (reported since 1984) have steadily increased over time, although the increase in reported infections reflects increased screening activities, improvements in diagnostic testing, stronger reporting requirements, and better reporting systems, as well as possible true increases in the disease (CDC, 2007). There is evidence that chlamydia is associated with subsequent infertility (Mol et al., 1997; Land and Evers, 2002), although it is not absolutely clear whether routine screening will reduce tubal infertility. However, screening is a CDC recommendation and Healthcare Employer Data and Information Set requirement. In 2006, there were 347 cases of chlamydia per 100,000 individuals in the civilian population.

Compared with gonorrhea and chlamydia, rates of syphilis have remained relatively low. In 2006, there were 12.5 cases of syphilis at all stages per 100,000 individuals in the United States. Nonetheless, the disease remains an important problem that is more common in the south and in urban areas in other parts of the country (CDC, 2007).

Nonexistent at the time Title X was enacted, HIV/AIDS emerged in the early 1980s, and today more than 1.2 million people in the United States are living with HIV/AIDS. While the number of new AIDS cases and deaths has declined since the early to mid-1990s, the number of Americans living with AIDS has steadily increased (see Figure 2-5).

In 2006, the CDC estimated that approximately 1.1 million persons were living with HIV infection, three-quarters of whom were men and one-quarter of whom were women. In 2006, nearly half (48 percent, or 532,000 persons) of all people living with HIV were men who have sex with men (CDC, 2008b). People exposed through high-risk heterosexual contact (which includes those who report specific heterosexual contact with a person known to have or to be at high risk for HIV infection, such as injection drug users) accounted for an additional 28 percent (305,700 persons) of all people living with HIV in 2006 (CDC, 2008b).

Minorities, particularly African Americans and Hispanics, are disproportionately affected by HIV. While African Americans make up only 12 percent of the U.S. population, they accounted for nearly half (46 percent) of all people living with HIV in the United States in 2006. The HIV prevalence rate for African Americans (1,715 per 100,000 population) was almost eight times as high as that for whites (224 per 100,000) in 2006. Hispanics, who make up 15 percent of the total U.S. population, accounted for 18 percent of people living with HIV in 2006. The prevalence rate for Hispanics (585 per 100,000) was nearly three times that for whites (CDC, 2008b).

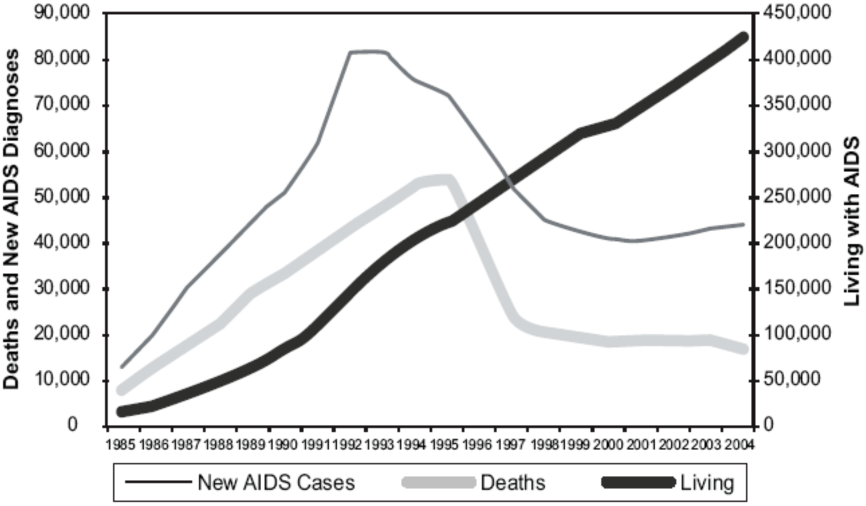

FIGURE 2-5 Estimated new AIDS cases, deaths among persons with AIDS, and people living with AIDS, 1985–2004.
SOURCE: The Henry J. Kaiser Family Foundation, 2005. This information was reprinted with permission from the Henry J. Kaiser Family Foundation. The Kaiser Family Foundation is a nonprofit private operating foundation, based in Menlo Park, California, dedicated to producing and communicating the best possible information, research, and analysis on health issues.

As shown in Figure 2-6, the HIV prevalence rate is far higher among men than women regardless of race or ethnicity. Nonetheless, women are also severely affected, particularly African American and Hispanic women, who experience HIV prevalence rates 18 and 4 times the rate for white women, respectively (CDC, 2008).

> ***Finding 2-2.*** *A significant number of people remain at risk for unintended pregnancy, sexually transmitted diseases, and infertility, and therefore are in need of family planning services.*

MILESTONES IN FAMILY PLANNING

The United States saw a dramatic decline in maternal and infant mortality, as well as the total fertility rate,[3] during the twentieth century. These

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[3] The total fertility rate reflects the total number of live births per 1,000 women aged 15–44.

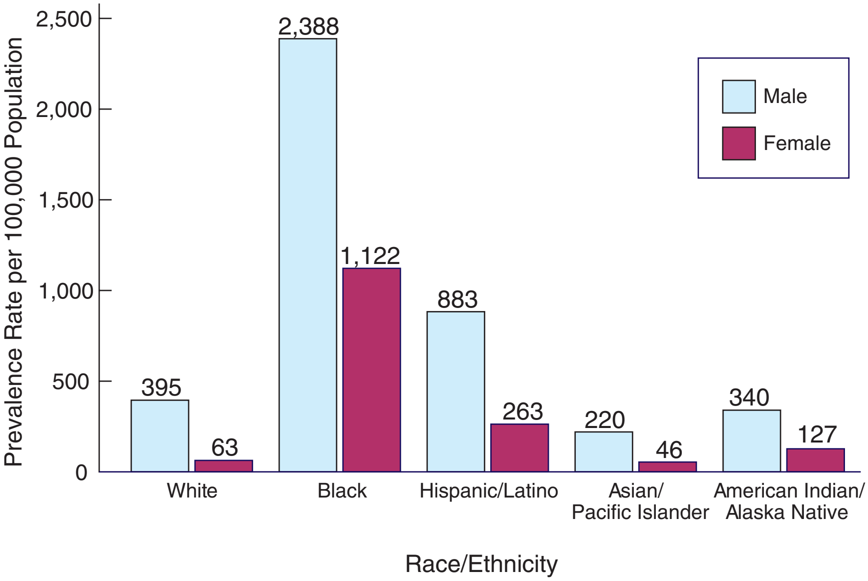


FIGURE 2-6 Estimated HIV prevalence rate per 100,000 population by race and ethnicity and gender, United States, 2006.
SOURCE: CDC, 2008b.

declines are associated with the achievements in family planning that took place in this country during that period.

At the beginning of the twentieth century in the United States, the subject of birth control was not openly discussed. For example, anti-obscenity laws, including the federal Comstock law (March 3, 1873, Ch. 258, § 2, 17 Stat. 599), banned the discussion or distribution of contraceptives. These laws were not declared unconstitutional until 1972 (*Eisenstadt v. Baird,* 405 U.S. 438). Nonetheless, public interest in and acceptance of birth control increased greatly between 1920 and 1960. Three primary factors fueled these rapid shifts in attitude toward family planning: (1) the changing role of women in American society; (2) concern about population growth; and (3) the availability of new, highly effective contraceptive methods, such as the birth control pill and intrauterine devices (IUDs). Figure 2-7 provides an overview of milestones in family planning in the United States.

The women's movement, which gained ground during the late eighteenth and early nineteenth centuries, centered largely on women's suffrage until the right to vote was won in 1920. The birth control movement was founded around that time by a public health nurse, Margaret Sanger, who argued that women had the right to control their own bodies and fertility,

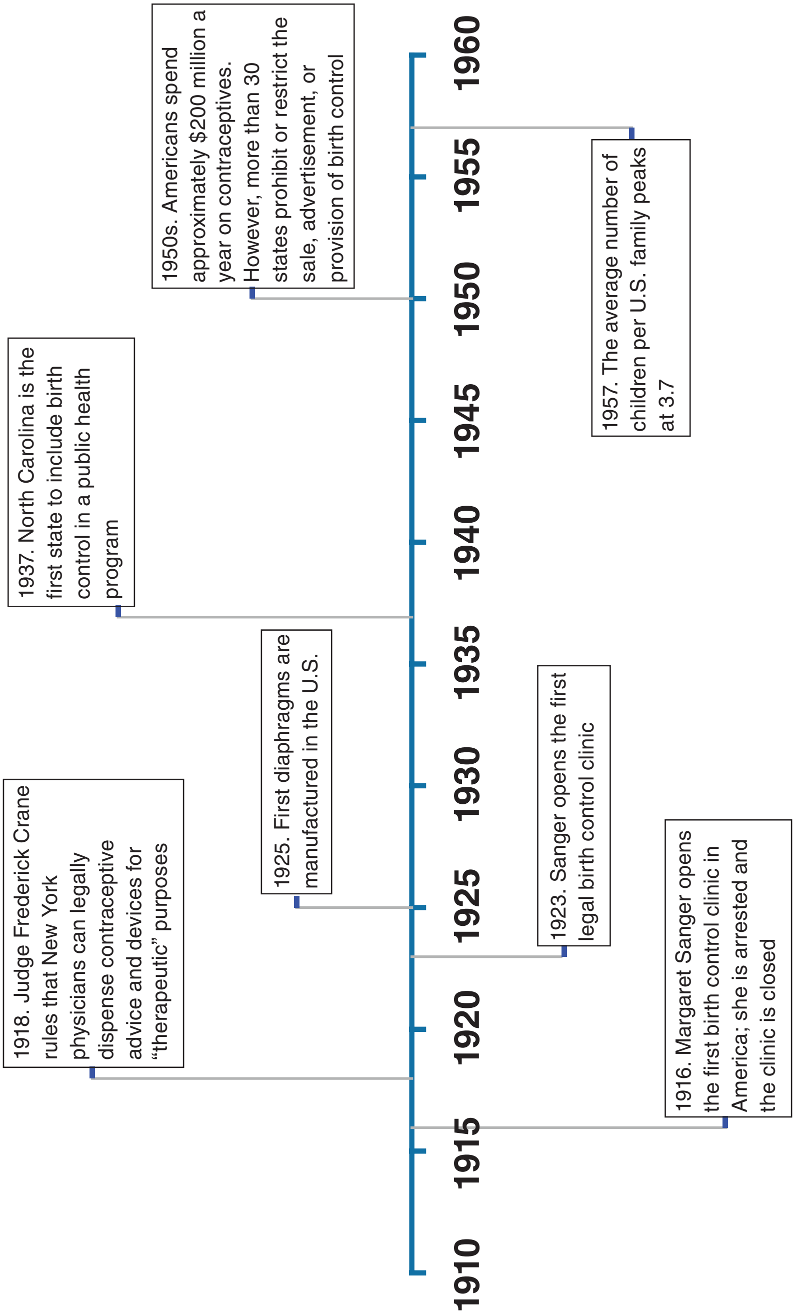
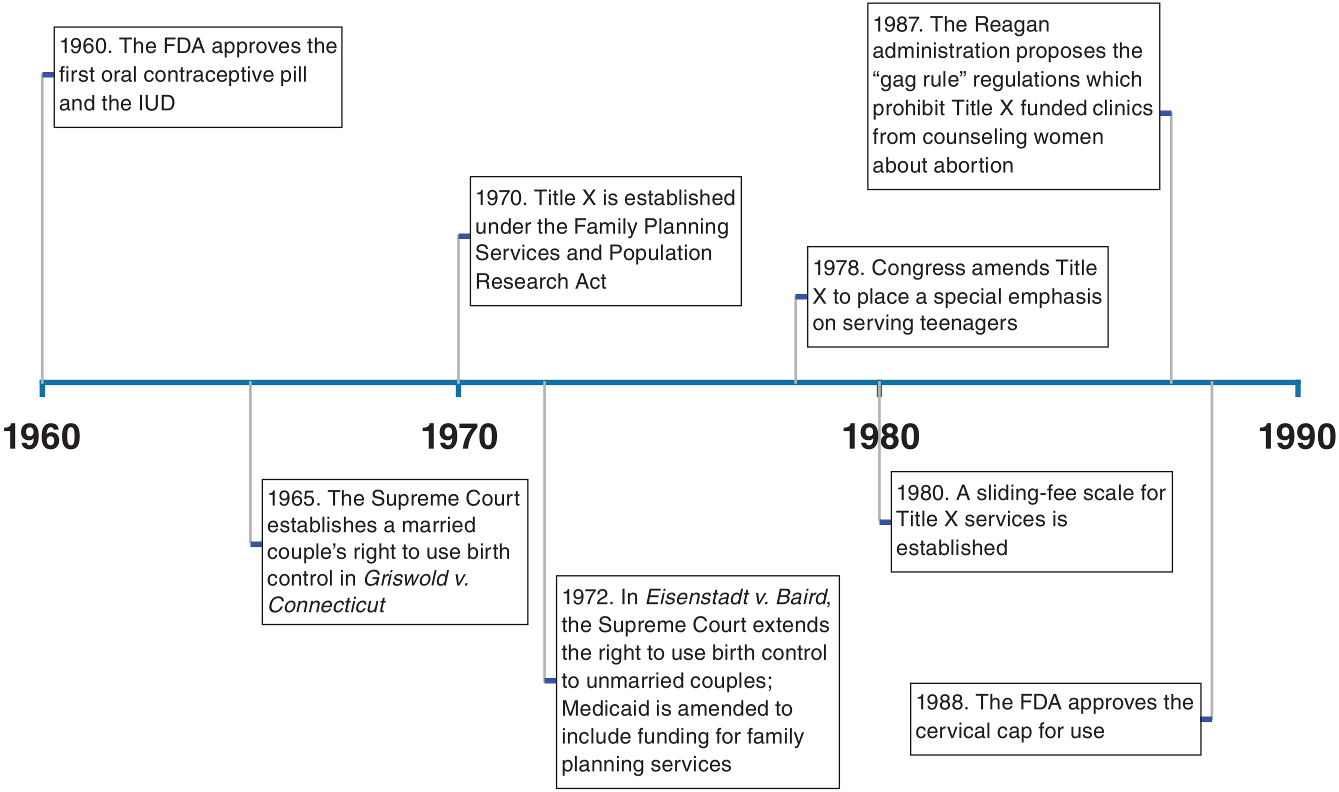


FIGURE 2-7 Milestones in family planning in the United States (Part 1 of 3, continues).
SOURCES: AGI, 2000; AMA, 2000; PBS, 2003.



1960. The FDA approves the first oral contraceptive pill and the IUD

1965. The Supreme Court establishes a married couple's right to use birth control in *Griswold v. Connecticut*

1970. Title X is established under the Family Planning Services and Population Research Act

1972. In *Eisenstadt v. Baird*, the Supreme Court extends the right to use birth control to unmarried couples; Medicaid is amended to include funding for family planning services

1978. Congress amends Title X to place a special emphasis on serving teenagers

1980. A sliding-fee scale for Title X services is established

1987. The Reagan administration proposes the "gag rule" regulations which prohibit Title X funded clinics from counseling women about abortion

1988. The FDA approves the cervical cap for use

FIGURE 2-7 Continued: part 2 of 3.

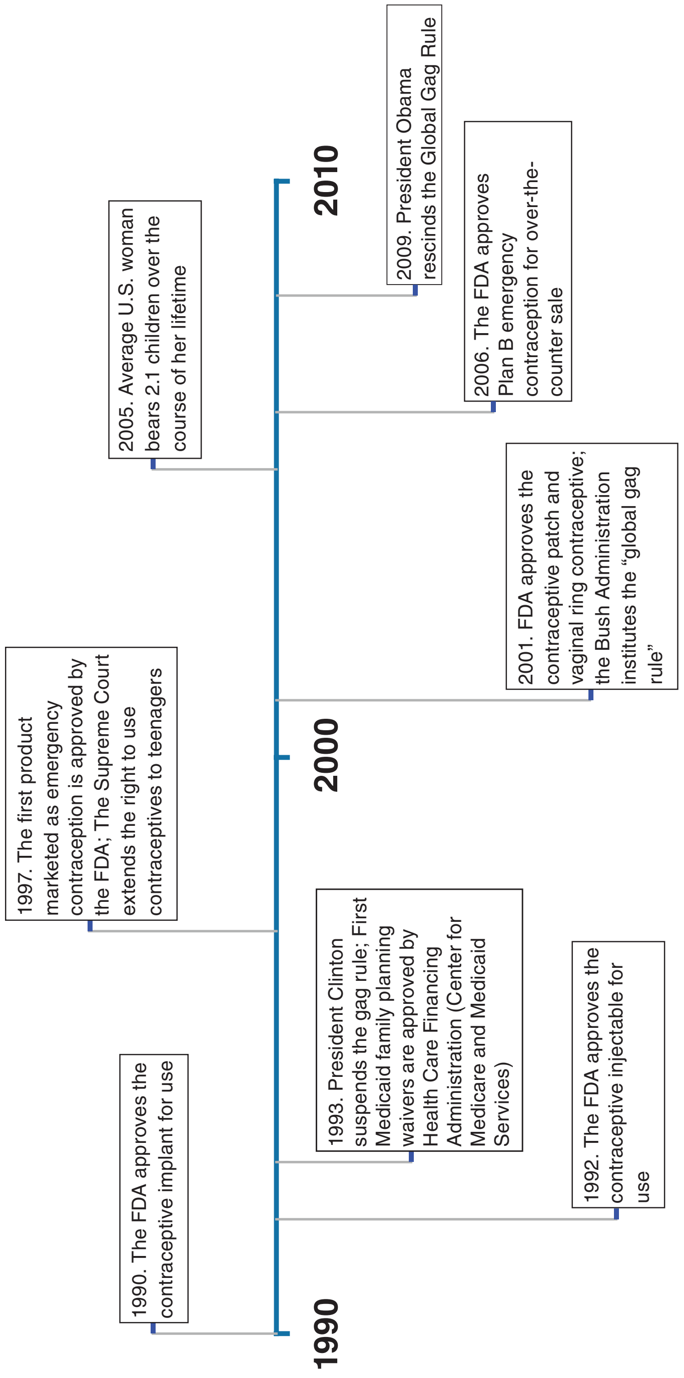


FIGURE 2-7 Continued: part 3 of 3.

and that access to birth control was necessary to achieve gender equality. Sanger opened the first birth control clinic in the United States in 1916 and continued to be a strong advocate for the birth control movement throughout the next half century (Wardell, 1980; PBS, 2003).

In 1935, Title V was enacted by Congress as part of the Social Security Act. With roots in the establishment of the Children's Bureau in 1912, the Title V legislation authorized the creation of Maternal and Child Health programs, which were dedicated to promoting and improving the health of mothers and children. In 1943, the Emergency Maternity and Infant Care Program was enacted (P.L. 78-156). This program provided payment and services for pregnant wives and infants of low-ranking men in the armed forces. Several other developments and changes to the program occurred over the next several decades.

The strong population growth the country experienced as a result of the postwar baby boom in the late 1950s (see Figure 2-8) also had a significant effect on American attitudes toward family planning (Barnes, 1970). Studies conducted in the decades after World War II revealed that women were having more children than they desired (Gold, 2001). Low-income women in particular were found to be at risk for unintended pregnancies, largely because they lacked adequate access to contraception, while unplanned births, as discussed above, were associated with increased poverty and dependence on public services (Gold, 2001). The groundwork laid by the establishment of maternal and child health programs was important for the development of family planning programs. Helping individuals avoid pregnancy is an important aspect of enabling them to plan for pregnancy and also an important strategy in improving maternal and child health.

The Food and Drug Administration's (FDA's) approval of the birth control pill in 1960 marked a significant turning point in the availability of effective and reversible contraceptive methods. Previously, couples had relied on less effective methods, such as condoms, diaphragms, withdrawal, and the rhythm method (Westoff, 1972). The birth control pill was adopted quickly by American women, and by 1970 approximately 22 percent of married women of reproductive age (nearly 6 million women) were using oral contraceptives (Westoff, 1972). The availability and use of the highly effective IUD also grew during this period.

Today, contraceptive technology and options, including long-term methods, are advancing rapidly and increasing in number. More effective methods have been developed, including the combined pill (most recent FDA approval in 2003), Seasonale oral contraceptive (FDA approved in 2003), the contraceptive patch (FDA approved in 2001), the vaginal contraceptive ring (FDA approved in 2001), the contraceptive injectable (most recent [Lunelle] FDA approval in 2000), the sterilization implant (FDA approved in 2002), and the lovenorgestrel-releasing IUD Mirena (FDA approved in

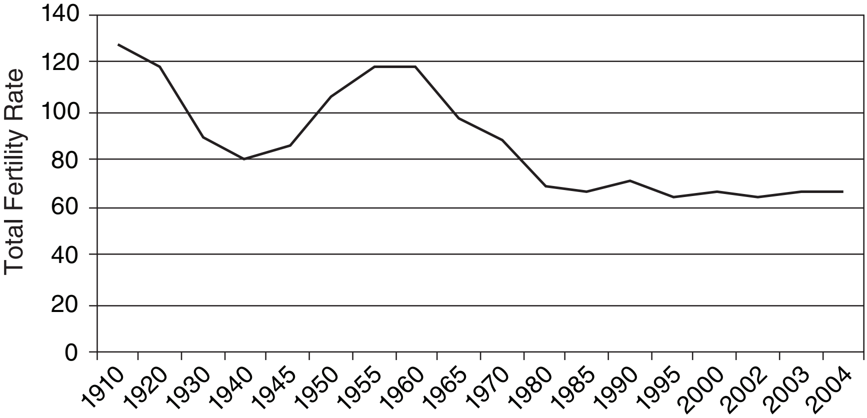


FIGURE 2-8 Fertility rate, United States, 1910–2004.
NOTE: The fertility rate reflects the total number of live births, regardless of age of the mother, per 1,000 women aged 15–44.
SOURCE: NCHS, 1975, 2007.

2000). However, the high cost of some of these options, particularly long-term methods, may prohibit their use by many women (see the discussion of changes in technology and costs later in this chapter).

The impact of family planning and contraceptive use in helping couples achieve their desired family size and timing is reflected in the reduction in the national total fertility rate (live births per 1,000 women aged 15–44) shown in Figure 2-8. Between 1900 and 2004, the rate decreased from 127 to 66 (NCHS, 1975, 2007; Darroch, 2006).

The first federal family planning grants were funded in 1964 through the Office of Economic Opportunity as part of President Lyndon B. Johnson's War on Poverty. The genesis and popularity of these grants reflected, in part, the recent and increasing availability of new reversible methods of contraception as outlined above. In the mid-1960s, however, it became evident that, because the modest funds from these grants were controlled by the states, the family planning programs developed with these funds varied greatly in their accessibility, eligibility requirements, and services provided. This realization added to the growing interest in having a federal program that could make grants directly to public and private entities within a state, bypassing the state governments.

President Richard Nixon showed a particular interest in family planning. In a message to the Congress in July 1969, he wrote: "It is my view that no American woman should be denied access to family planning assistance because of her economic condition. I believe, therefore, that we should establish as a national goal the provision of adequate family planning services within the next five years to all those who want them but cannot afford them" (Nixon, 1969).

As discussed in Chapter 1, the Title X Family Planning Program, established in 1970 under Title X of the Public Health Service Act and signed into law by President Nixon, provides grants for family planning services, training, research, and informational and educational materials. In enacting Title X, Congress emphasized that many poor women desired family planning but were unable to obtain it. The program was also intended to decrease the adverse health and financial effects of inadequately spaced childbearing on children, women, and their families (S. Rep. 91-1004, 91st Cong., 2d Sess., [July 7, 1970]; H.R. Rep. No. 91-1472, 91st Cong., 2d Sess., [September 26, 1970]).

Title X has often been affected by the strongly held differences of opinion in this country regarding the acceptability of abortion. The program has been forbidden to pay for abortions since its inception. In the waning days of the Reagan Administration, however, the Secretary of Health and Human Services issued regulations stating that a "Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a means of family planning" (53 Fed. Reg 2922-01 [Feb. 2, 1988] codified at 42 CFR § 59.8[a][1], repealed by Presidential Memorandum on January 22, 1993 [58 Fed. Reg. 7455] 42 CFR § 59.8(a)(1)), and forbidding referral of a pregnant woman to an abortion provider even if she specifically requested it (53 Fed. Reg 2922-01 [Feb. 2, 1988] codified at 42 CFR § 59.8[b][5], repealed by Presidential Memorandum on January 22, 1993 [58 Fed. Reg. 7455]) (42 CFR § 59.8(b)(5)). Title X providers were also forbidden to advocate for or support abortion in a host of ways and were required to be "physically and financially separate" from any abortion activities (53 Fed. Reg 2922-01 [Feb. 2, 1988] codified at 42 CFR § 59.9, repealed by Presidential Memorandum on January 22, 1993 [58 Fed. Reg. 7455]) (42 CFR § 59.9). These regulations were upheld by the Supreme Court in 1991 in *Rust v. Sullivan* (500 U.S. 173) against challenges that they were inconsistent with the statutory language of Title X and violated the constitutional rights of providers and patients, but were repealed shortly after President Clinton took office (58 Fed. Reg. 7455 [January 22, 1993] 59 Fed. Reg. 57560-1, November 14, 1994). In 2000, the following language was adopted (65 Fed. Reg. 41278 [July 3, 2000]; 65 Fed. Reg. 49057 [August 10, 2000]):

> Each project supported under this part must: . . .
> (5) Not provide abortion as a method of family planning. A project must:

> (i) Offer pregnant women the opportunity to be provided information about each of the following options:
> (A) Prenatal care and delivery;
> (B) Infant care, foster care, or adoption; and
> (C) Pregnancy termination.
> (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates that she does not wish to receive such information and counseling. 45 CFR § 59.5(a)(5)

The Bush Administration promulgated new regulations, stating that recipients of federal funds may not force clinicians with religious or conscientious objections to abortion to mention or counsel patients about that option or penalize these providers for refusing to do so. The regulations also imposed new requirements for documentation of nondiscrimination against religious objectors. However, a notice of rescission has been published by the Obama Administration (74 Fed. Reg. 10207, March 10, 2009).

Additional funding for family planning services for low-income individuals became available when Congress amended the Medicaid program in 1972 (AGI, 2000). The amendment required all state Medicaid programs to cover family planning services and established two additional Medicaid provisions intended to improve access to such services (Gold et al., 2007). The amendment required that states provide family planning services and supplies to all individuals who desire them and are eligible for Medicaid without cost sharing, and established a special matching rate of 90 percent for those services and supplies. Although Title X was the primary public funding source for family planning in the years after its introduction, Medicaid soon assumed that role (Sonfield et al., 2008a). (See the discussion of financing of family planning services later in this chapter, and Chapter 3 for discussion of the unique role of Title X funding.)

THE USE OF FAMILY PLANNING SERVICES

According to CDC, nearly three-quarters of women of reproductive age (approximately 45 million women aged 15–44) received at least one family planning or related medical service in 2002 (Mosher et al., 2004). Among women who have ever had intercourse, 98 percent have used at least one method of contraception (Mosher et al., 2004).

Contraceptive use is common among women aged 15–44. In 2002, almost two-thirds (62 percent) of women in this age group reported using one or more forms of contraception; the remaining 38 percent were not currently using a contraceptive method for such reasons as being pregnant or postpartum, trying to get pregnant, or not being sexually active (Chandra et al., 2005). Among those reporting using contraception in the month of interview, the most common methods cited were the contraceptive pill (19 percent), female sterilization (17 percent), male condoms (15 percent), male sterilization (6 percent), and withdrawal (5 percent). Other methods, including the contraceptive implant, patch, diaphragm, periodic abstinence, rhythm, natural family planning, sponge, cervical cap, and female condom, were reported by 4 percent; the 3-month injectable Depo-Provera by 3 percent; and an IUD by 1 percent (Chandra et al., 2005). Women may have reported multiple methods used concurrently.

Figure 2-9 illustrates the percentage of women aged 20–44 who reported current use of a contraceptive method in 2002, by percent of the federal

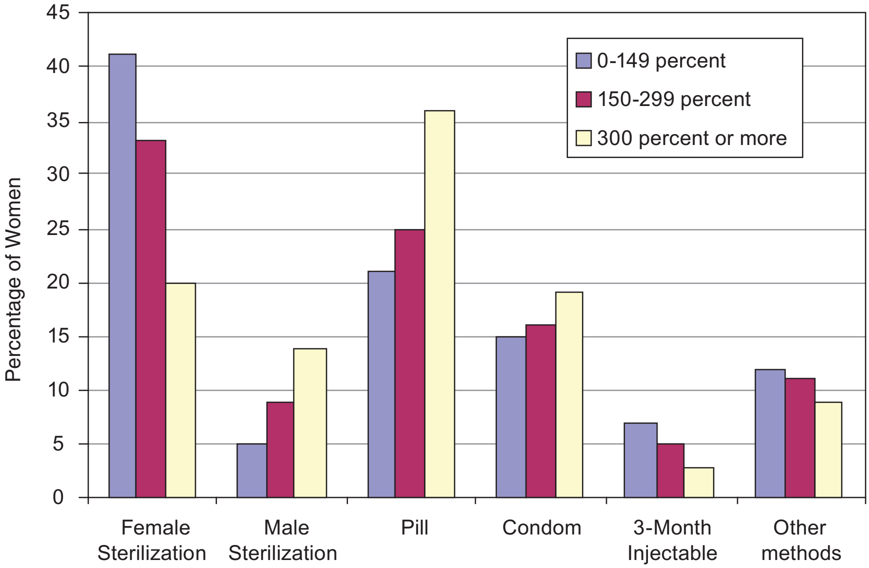


FIGURE 2-9 Percentage of women aged 20–44 currently using a method of contraception, by primary method and percent of federal poverty level (FPL), United States, 2002.

NOTE: "Other methods" include Norplant™, Lunelle™, contraceptive patch, emergency contraception, IUD, diaphragm, female condom, foam, cervical cap, Today sponge, suppository, jelly or cream, rhythm, natural family planning, withdrawal, or some other method. Since this figure shows the reported primary method of contraception, the use of certain methods, such as condoms in conjunction with the pill, is understated.

SOURCE: Chandra et al., 2005.

poverty level. The incidence of female sterilization is strongly correlated with poverty. It is the contraceptive method reported most commonly by women living below 149 percent of the federal poverty level (41 percent), as well as those living at 150–299 percent of that level (33 percent). By contrast, among those earning above 300 percent of the federal poverty level, 20 percent reported using female sterilization. The pill is the most popular method cited by those with incomes at or above 300 percent of the federal poverty level (36 percent), and the second most popular among women at lower income levels (Chandra et al., 2005).

Figure 2-10 shows the percentage distribution of women aged 15–44 by current contraceptive status and race and ethnicity. Women of Hispanic or Latina origin and black women reported greater rates of female sterilization, while white women were more likely than Hispanic or black women to report relying on male sterilization as their primary form of contra-

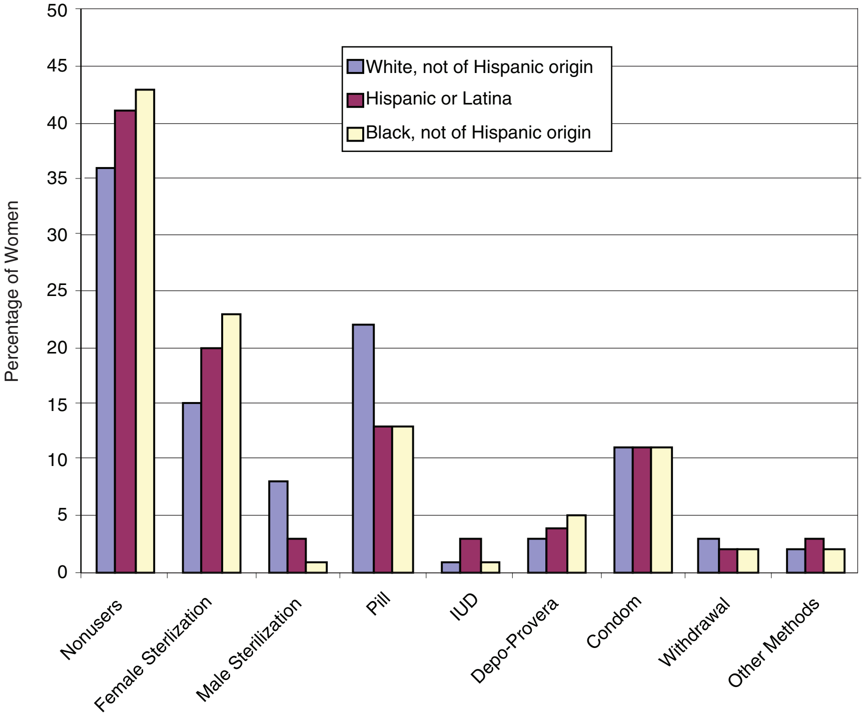


FIGURE 2-10 Percentage distribution of women aged 15–44, by current contraceptive status and race and ethnicity, United States, 2002.
SOURCE: Chandra et al., 2005.

ception. White women reported significantly higher use of the contraceptive pill (22 percent) as compared with black (13 percent) and Hispanic (13 percent) women. Hispanic women were more likely to use an IUD as a contraceptive method. Condom use did not appear to vary by race and ethnicity (Chandra et al., 2005). The reasons for these differences in contraceptive methods, which may reflect social, economic, or cultural factors, are not fully understood and warrant further exploration.

THE CHANGING CONTEXT IN WHICH FAMILY PLANNING SERVICES ARE PROVIDED

In the 38 years since the establishment of Title X, the health care system and the overall social environment of the United States have changed in ways that dramatically increase the complexity and cost of providing family planning services to the groups served by the program. The numbers of individuals requiring publicly funded family planning services have undergone substantial shifts and grown dramatically overall. Social changes, particularly sexual values and social norms regarding sexual activity and reproductive health services, have affected the desire for and delivery of services. Technological advances have expanded the number and quality of contraceptive options available to women, leading to rapidly changing standards of care and increased costs. The greater diversity of people in need also increases the complexity of providing appropriate care. Changes in the financing of health care have left an ever-growing number of people in need of family planning services, despite the infusion of new funds from Medicaid. This section reviews these changes in the social and health care landscapes to provide a clearer picture of the ongoing need for and challenges facing the Title X program.

Changes in Populations Served by Title X

As noted earlier, while the Title X program is designed to provide access to services for all who want and need them, special emphasis is placed on low-income individuals and adolescents. The population of low-income individuals is disproportionately comprised of racial and ethnic minorities. According to a recent estimate, of the 36.2 million women in need of contraceptive services and supplies (sexually active and able to become pregnant, but not wishing to become pregnant), 17.5 million needed publicly funded services because they had incomes below 250 percent of the federal poverty level or were younger than 20 (Guttmacher Institute, 2008b). This figure represents an increase of 7 percent since 2000. While men are identified as a group to be served by Title X, they make up only a small percentage of Title X clients.

When the program was established in 1970, approximately 6.4 million people aged 18–44 (3.9 million women and nearly 2.5 million men) were living below the federal poverty level (see Figure 2-11). The number of adults living in poverty peaked in 1993 at 15.1 million. After a steady decline for several years, the number of poor Americans began to rise again in 2001. In 2007, 13.8 million Americans aged 18–44 (8.2 million women and 5.6 million men) lived in poverty. (While these absolute numbers more than doubled between 1970 and 2007, the percentage living in poverty among all people aged 18–44 increased more gradually, from 9 to 12.5 percent.)

Although projections of the number of people living in poverty are not provided by the Census Bureau, Figure 2-12 indicates that the total number

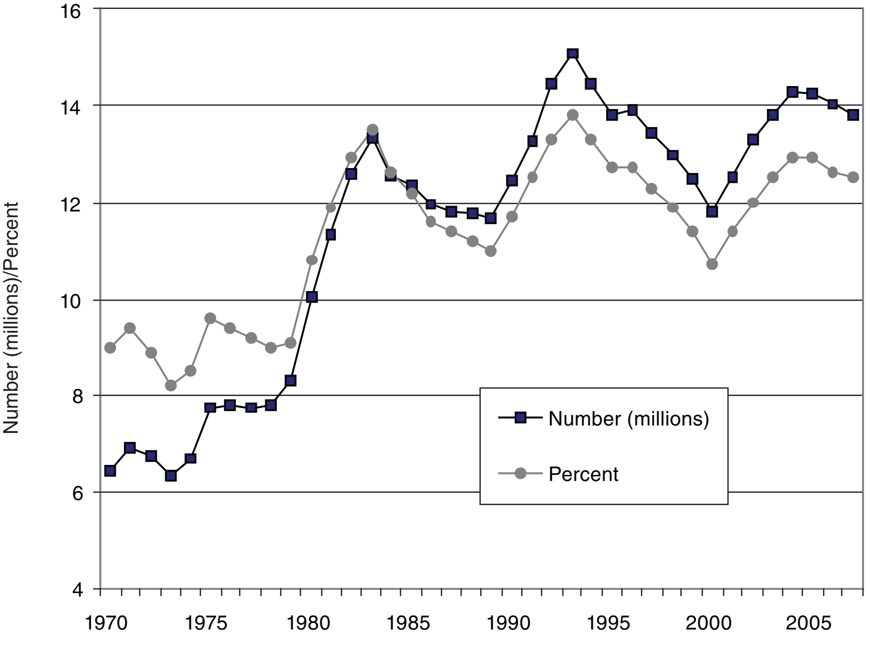


FIGURE 2-11 Number and percent of people aged 18–44 living in poverty, 1970 to 2007.
NOTES: Data prepared by Census Survey Processing Branch/Housing and Household Economic Statistics Division. For information on confidentiality protection, sampling error, and definitions, see www.census.gov/apsd/techdoc/cps/cpsmar08.pdf.
SOURCE: Based on the current population survey, 1971 to 2008 Annual Social and Economic Supplements.

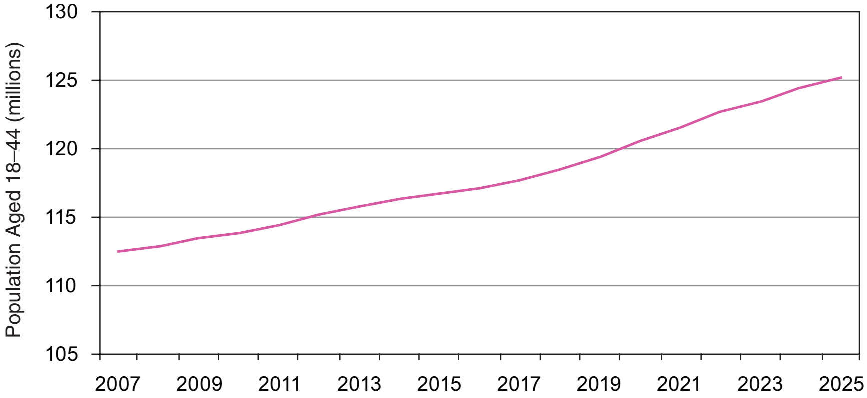


FIGURE 2-12 Projections of numbers of U.S. adult residents aged 18–44, 2007–2025.
SOURCE: U.S. Census Bureau, 2008b.

of adults aged 18–44 is expected to grow over the next 20 years—from 112 million in 2007 to 125 million in 2025. One would expect the number of people in need of publicly funded family planning services to rise accordingly, especially in light of current economic conditions. Specific subpopulations—adolescents, racial and ethnic minorities, immigrants, and the undocumented population—are discussed in turn below.

Adolescents

Providing family planning services to adolescents is a crucial function of Title X programs; the 1978 amendment to Title X emphasized expanding services to this population. As discussed above, the rate of unintended pregnancy is higher in this group compared with women in other age groups. The adolescent population has changed dramatically in the past several decades (see Figure 2-13). In 1970, there were approximately 20.1 million adolescents between the ages of 13 and 17 in the United States. By 1975, this number had increased to 21.3 million. From the late 1970s through the 1980s, the population of teens declined, reaching a low point of 16.7 million in 1990. Since then, the number of teens has steadily increased. In 2006, the last year for which population estimates are currently available from the Census Bureau, there were 21.4 million adolescents aged 13–17. The ratio of male to female adolescents remained constant throughout the period 1970–2006, with males making up 51 percent of the adolescent population and females 49 percent. Projections for 2008, which are based on Census

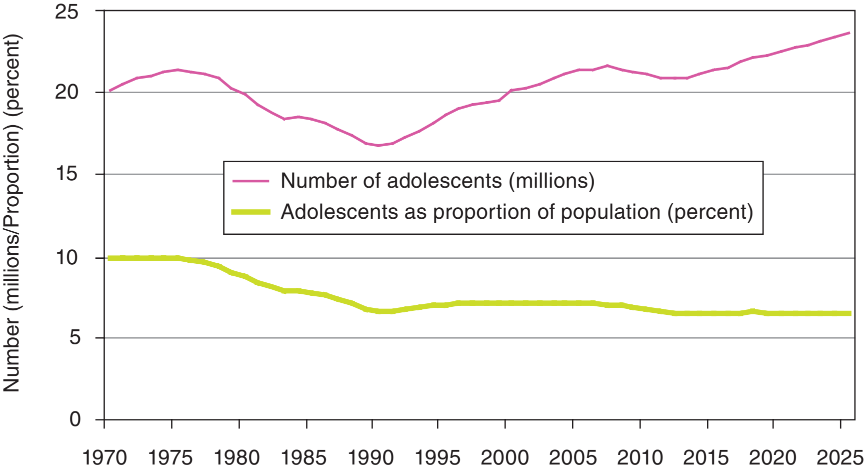


FIGURE 2-13 Estimates and projections of number of adolescents aged 13–17 and adolescents as a proportion of the total population, 1970–2025.
SOURCES: U.S. Census Bureau, 2008b, 2009a,b.

2000, suggest that the adolescent population will decrease from 2008 to 2012 (from 21.5 to 20.9 million), and then steadily increase from 2013 to 2025 (from 20.9 to 23.6 million). As shown in Figure 2-13, the proportion of the total U.S. population represented by adolescents has decreased since 1970, but has hovered at about 7 percent since the late 1980s and is expected to remain steady at around this level over the next 20 years. Nonetheless, as the absolute number of adolescents continues to rise, so, too, will their need for care.

The adolescent population is more racially and ethnically diverse than the general population, with greater percentages of African Americans, Hispanics, and American Indians than are found among the population as a whole (NAHIC, 2003). African American and Hispanic adolescents are significantly more likely than same-age peers of other racial/ethnic groups to have family incomes at or below the federal poverty level (NAHIC, 2003). Adolescents also have unique health needs stemming from the developmental and mental health factors associated with this age period. They are often using contraception for the first time and so need extra attention to ensure success. Moreover, adolescents may be more likely than adults to engage in risky behaviors that can have adverse health effects. Some adolescents, particularly those who are uninsured or underinsured (see the discussion of the uninsured below), may have little access to primary medical care and may instead rely for care on school health centers, publicly funded clinics, and hospital emergency departments. Finally, confidentiality is a particularly common concern among adolescents that requires a unique response from health care providers. (See the further discussion of adolescents in the section on serving populations that are the focus of Title X in Chapter 4.)

Racial and Ethnic Minorities

As noted earlier, the population of low-income individuals is disproportionately composed of racial and ethnic minorities. Changes in the definitions of various racial and ethnic groups in the United States make it somewhat difficult to assess trends. (Starting with the 2000 Census questionnaire, race and Hispanic ethnicity were recorded separately.) Nonetheless, marked shifts have clearly occurred in the racial and ethnic composition of the U.S. population (see Figure 2-14). In 1980, Hispanics made up 6.5 percent of the total U.S. population; by 2000, this proportion had risen to approximately 12.6 percent (CensusScope, 2001). In 2007, 20 million Hispanics (of any race) of reproductive age (18–44) were living in the United States, 3.8 million (18.9 percent) of whom were living below 100 percent of the federal poverty level (U.S. Census Bureau, 2008a). The proportion of black non-Hispanics remained relatively stable, increasing from 11.5 to

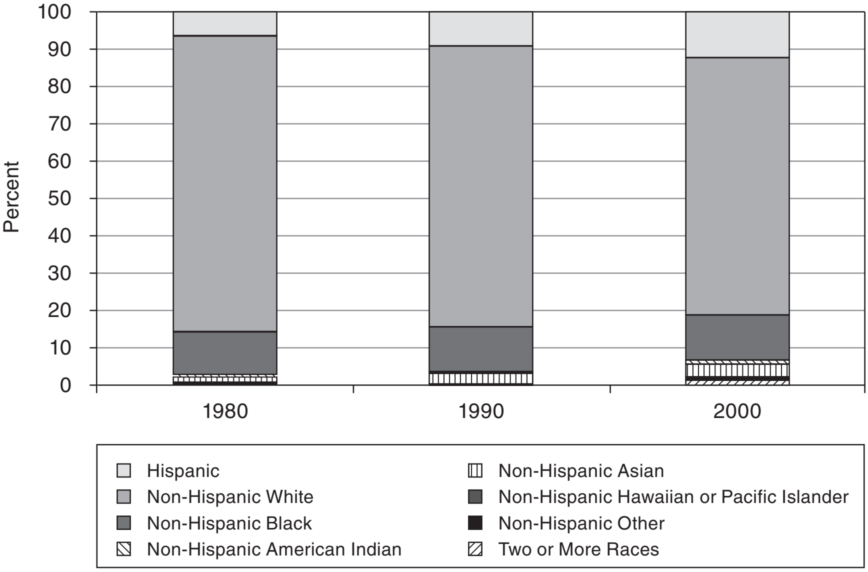


FIGURE 2-14 Race and ethnicity selections, U.S. Census, 1998–2000.
SOURCE: CensusScope, 2001.

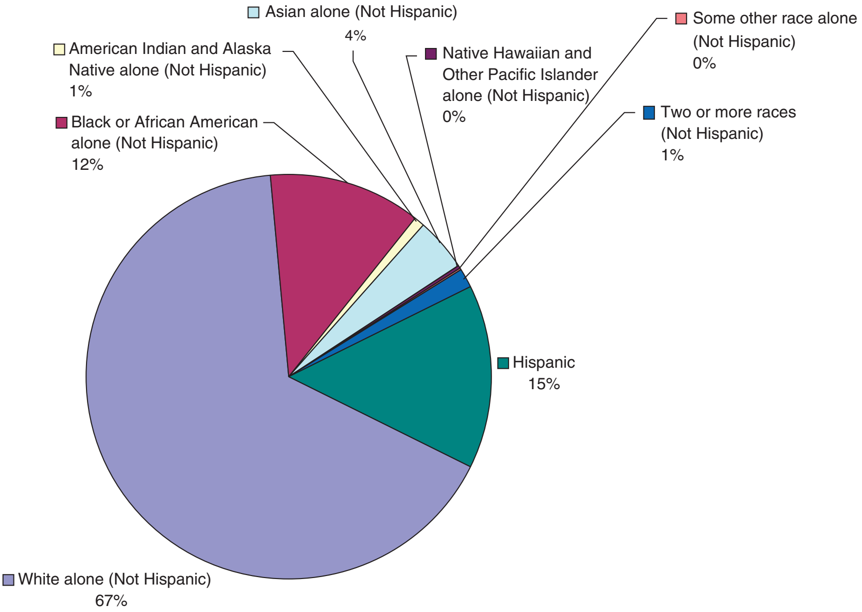


FIGURE 2-15 Racial distribution of the U.S. population by Hispanic or Latino origin, 2006.
SOURCE: U.S. Census Bureau, 2006.

slightly over 12 percent between 1980 and 2000 (CensusScope, 2001). In 2007, 14.6 million African Americans (who did not report any other race category, including Hispanic) of reproductive age (18–44) were living in the United States, 3.2 million (21.7 percent) of whom were living below 100 percent of the federal poverty level (U.S. Census Bureau, 2008a). The Asian population grew from 1.5 percent to 3.6 percent between 1980 and 2000 (CensusScope, 2001). In 2007, 5.8 million Asians (who did not report any other race category, including Hispanic) of reproductive age (18–44) were living in the United States, 563,000 (9.7 percent) of whom were living below 100 percent of the federal poverty level (U.S. Census Bureau, 2008a). The American Indian population remained at less than 1 percent in 2000 (CensusScope, 2001).

Figure 2-15 shows the 2006 racial distribution of the U.S. population for both people of Hispanic origin and those who did not identify themselves as Hispanic or Latino. In 2006, 67 percent of the U.S. population self-identified as white, not of Hispanic origin, while 12 percent self-identified as black or African American, not of Hispanic origin (U.S. Census Bureau, 2000). An additional 4 percent self-identified as Asian, not

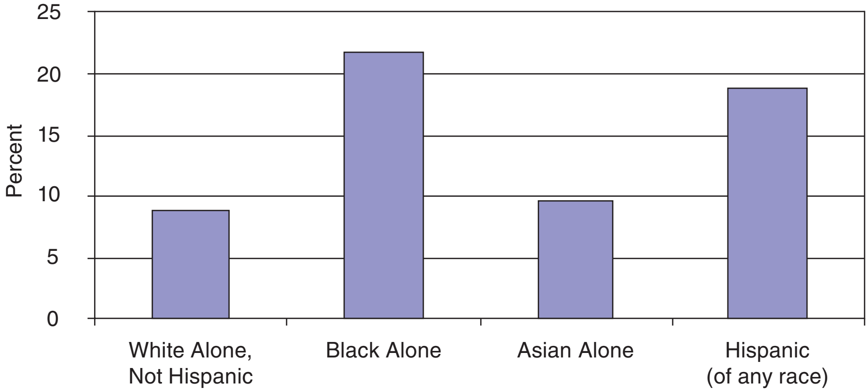


FIGURE 2-16 Percentage of people aged 18–44 living below 100 percent of the federal poverty level, by race and ethnicity, 2007.
SOURCE: U.S. Census Bureau, 2008a.

of Hispanic origin. Within the 15 percent of the population that identified themselves as being of Hispanic or Latino origin, the most common racial designation was white (53 percent of the population), followed by some other race alone (40 percent) and two or more races (7 percent) (U.S. Census Bureau, 2000).

A greater proportion of racial and ethnic minorities lived in poverty compared with white Americans (see Figure 2-16). Compared with 8.8 percent of white non-Hispanics, 21.7 percent of non-Hispanic blacks, 9.7 percent of non-Hispanic Asians, 21.5 percent of Hispanics (of any race) had incomes below the federal poverty level in 2007 (U.S. Census Bureau, 2008a). Despite the lower *percentage* of non-Hispanic whites living in poverty, this population made up almost half of those living in poverty because it represents two-thirds of the overall population.

Immigrants

In 2003, the most recent year for which data are available, there were approximately 33.5 million "foreign born" individuals living in the United States, representing 11.7 percent of the population (U.S. Census Bureau, 2003). The U.S. Census Bureau uses the term "foreign born" to refer to anyone who is not a U.S. citizen at birth, including naturalized U.S. citizens, lawful permanent residents, temporary residents (such as foreign students), refugees, and those who are present illegally (undocumented) in the United States. Because the Current Population Survey (CPS) conducted by the Census Bureau is intended to represent all residents of the United States living in households (persons in institutions are excluded), undocumented immigrants are assumed to be included in the data. However, because the CPS includes no questions intended to determine legal status, undocumented immigrants cannot be identified from CPS data (see the section on the undocumented population below).

Both the number of foreign born persons in the United States and their proportion of the American population have risen since Title X was enacted in 1970 (see Figure 2-17). In 2003, approximately 30 percent of foreign born persons currently residing in the United States (9.2 million) were women aged 15–44 (U.S. Census Bureau, 2003).

Among the 33.5 million foreign born persons living in the United States in 2003, the most common region of birth was Latin America (52.3 percent), followed by Asia (27.3 percent); Europe (14.2 percent); and "other areas," including Africa, Oceania, and North America (6.2 percent) (U.S. Census Bureau, 2003). The majority of those born in Latin America were originally from Mexico.

Foreign born persons who become naturalized citizens of the United States are less likely to have household incomes below the federal poverty level than citizens born in the United States (13.2 percent of native U.S. citizens aged 18–44 were living below the poverty level in 2007, as compared with 9.1 percent of naturalized U.S. citizens) (see Figure 2-18). In contrast, a significantly higher proportion (20.4 percent in 2007) of foreign born persons aged 18–44 who are not citizens have household incomes below the poverty level (based on the 2007 American Community Survey Public Use Microdata Sample [http://factfinder.census.gov/home/en/acs_pums_2007_1yr.html]).

Undocumented Population

The number of undocumented individuals has grown significantly in the past 20 years. While U.S. government agencies do not count this population or define its demographic characteristics, others have provided estimates of its size. According to the Pew Hispanic Center, 11.9 million unauthorized migrants were residing in the United States in 2008, representing about one-third of the country's foreign born and 4 percent of its total population (Pew Hispanic Center, 2008). This undocumented population was composed primarily of individuals from Mexico (59 percent). Approximately 22 percent were from other Latin American countries, 12 percent were from Asia, 4 percent had immigrated from Europe and Canada, and 4 percent were from elsewhere (Pew Hispanic Center, 2008). According to 2004 data, the undocumented population resided across the country, with 68 percent living in eight states: California, Texas, Florida, New York, Arizona, Illinois, New Jersey, and North Carolina (Pew Hispanic Center, 2008). Women

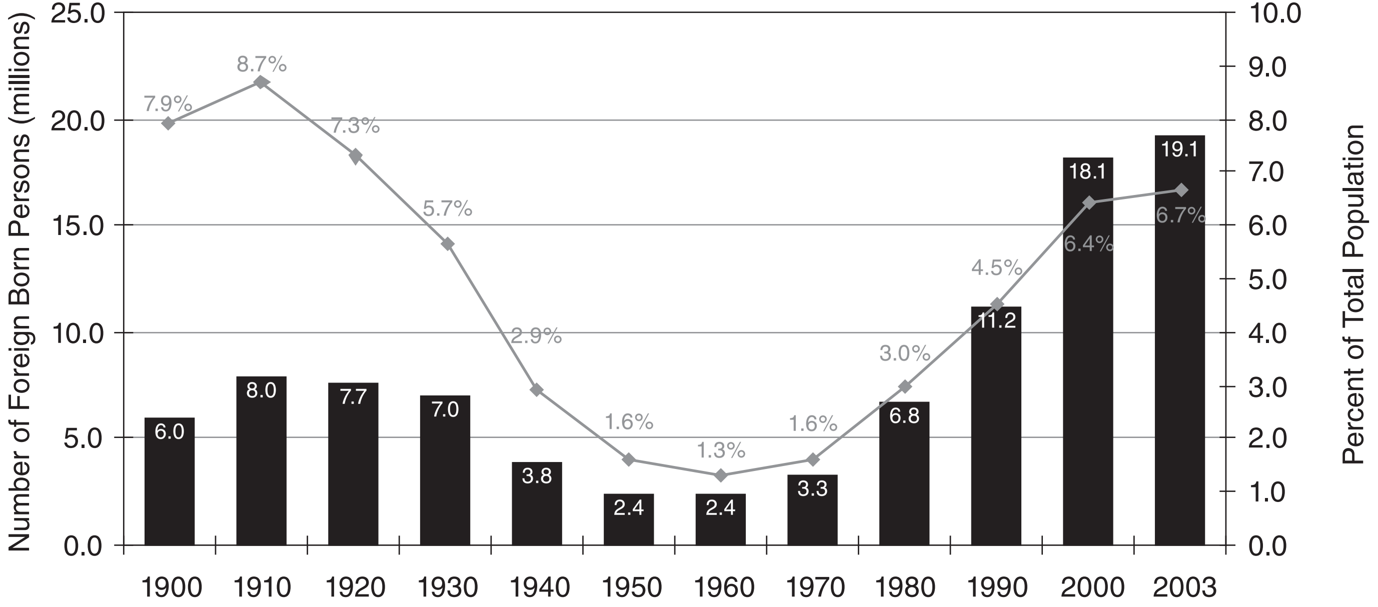


FIGURE 2-17 Foreign born persons aged 15–44 in the United States, number and percent of the total population, 1900–2003.
NOTE: These numbers reflect the civilian noninstitutionalized population aged 15–44 living in the United States; institutionalized persons, including those in correctional facilities and nursing homes, are excluded from the Current Population Survey.
SOURCES: U.S. Census Bureau, 2003; Gibson and Jung, 2006.

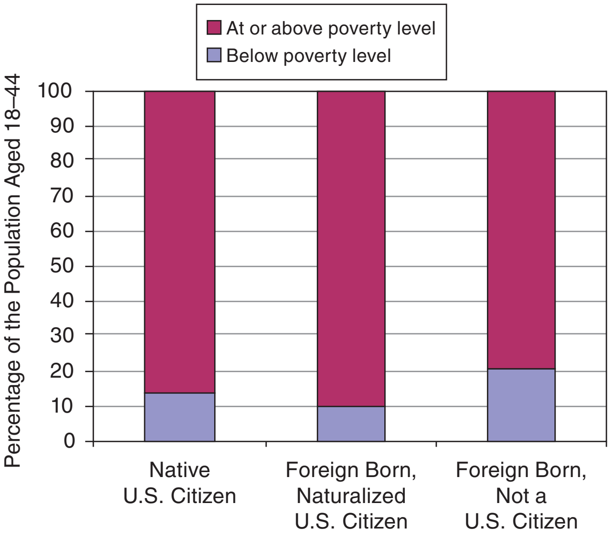


FIGURE 2-18 Poverty status of the population aged 18–44 by origin of birth and U.S. citizenship status, 2007.
SOURCE: Based on the 2007 American Community Survey Public Use Microdata Sample (http://factfinder.census.gov/home/en/acs_pums_2007_1yr.html).

aged 18–39 made up 29 percent (3 million) of undocumented persons, and children under 18 represented 17 percent (1.7 million) (Pew Hispanic Center, 2005).

> ***Finding 2-3.*** *Populations in greatest need of family planning services—low-income individuals and adolescents—have grown dramatically in the last 40 years in absolute numbers, in diversity, and in the complexity of their needs. Their demand for care is likely to continue to grow.*

Changes in Technology and Costs

Since 1970, the number of contraceptive methods available to men and women has increased. The birth control pill, the IUD, the male condom, and sterilization were the primary methods available when Title X was enacted. Additional, more effective and safer methods have since become available, including improved oral contraceptives and IUDs, injectables, the contraceptive patch, and the contraceptive ring (see Table 2-1 for an overview of family planning methods and their effectiveness).

TABLE 2-1 Summary of Contraceptive Efficacy: Percentage of Women Experiencing an Unintended Pregnancy During the First Year of Typical Use and the First Year of Perfect Use of Contraception and the Percentage Continuing Use at the End of the First Year, United States

Method	% of Women Experiencing an Unintended Pregnancy Within the First Year of Use		**% of Women Continuing Use at One Year**[c]
	Typical Use[a]	**Perfect Use**[b]	
No method[d]	85	85	
Spermicides[e]	29	18	42
Withdrawal	27	4	43
Fertility awareness–based methods	25		51
Standard-days method[f]		5	
2-day method[f]		4	
Ovulation method[f]		3	
Sponge			
Parous women	32	20	46
Nulliparous women	16	9	57
Diaphragm[g]	16	6	57
Condom[h]			
Female (Reality)	21	5	49
Male	15	2	53
Combined pill and progestin-only pill	8	0.3	68
Evra patch	8	0.3	68
NuvaRing	8	0.3	68
Depo-Provera	3	0.3	56
IUD			
ParaGuard (copper T)	0.8	0.6	78
Mirena (LNG-IUS)	0.2	0.2	80
Implanon	0.05	0.05	84
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.1	100

Emergency contraceptive pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.[i]

Lactational amenorrhea method: LAM is a highly effective, temporary method of contraception.[j]

---

[a] Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, periodic abstinence, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 National Survey of Family Growth, corrected for underreporting of abortion; see the text for the derivation of estimates for the other methods.

notes continued

TABLE 2-1 Continued

[b] Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method.

[c] Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.

[d] The percentages becoming pregnant in columns 2 and 3 are based on data on populations who do not use contraception and women who cease using contraception to become pregnant. Among such populations, about 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

[e] Foams, creams, gels, vaginal suppositories, and vaginal film.

[f] The ovulation and 2-day methods are based on evaluation of cervical mucus. The standard-days method avoids intercourse on cycle days 8 through 19.

[g] With spermicidal cream or jelly.

[h] Without spermicides.

[i] The treatment schedule is one dose within 120 hours after unprotected intercourse and a second dose 12 hours after the first (one dose is one white pill). Both doses can be taken at the same time. Plan B is the only dedicated product marketed specifically for emergency contraception. The FDA has in addition declared the following 22 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel or Ovral (one dose is two white pills); Levlen or Nordette (one dose is four light-orange pills); Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (one dose is four white pills); Tri-Levlen or Triphasil (one dose is four yellow pills); Jolessa, Portia, Seasonale, or Trivora (one dose is four pink pills); Seasonique (one dose is four light-blue-green pills); Empresse (one dose is four orange pills); Alesse, Lessina, or Levlite (one dose is five pink pills); Aviane (one dose is five orange pills); and Lutera (one dose is five white pills).

[j] To maintain effective protection against pregnancy, however, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeedings is reduced, bottle feedings are introduced, or the baby reaches 6 months of age.

SOURCE: Adapted from Trussell, 2007. Reprinted with permission of Ardent Media, Inc. © 2007 Contraceptive Technology Communications, Inc.

A large gap exists between typical and perfect use across contraceptive methods. Because there is less reliance on accurate use by the patient, long-term methods such as injectables and IUDs are more effective in practice than oral contraceptives or condoms at preventing pregnancy. Greater knowledge clearly is needed regarding the most effective ways to support successful method use for shorter-term contraceptives. More effective and long-term contraceptives are more expensive to provide. Comprehensive data on prices paid by providers and clinics for contraceptive supplies are limited, as confidentiality agreements with manufacturers prohibit the disclosure of this information (Sonfield et al., 2008a). However, the limited data available indicate that the patch and vaginal ring generally cost publicly funded family planning agencies more ($11 and $26 per patient per cycle, respectively, in 2005) than the most commonly used oral contraceptives among Title X clients ($2 per cycle) (Lindberg et al., 2006).

In addition to the cost of contraceptive supplies, the cost of diagnostic tests has increased significantly. Federal regulation of clinical laboratories (Clinical Laboratory Improvement Amendments Act of 1988, P.L. 100-578) contributed to increased costs for Pap tests (Dailard, 1999). Costs are also greater for new technologies such as improved Pap smears for the detection of cervical cancer and human papillomavirus, DNA-based tests for chlamydia, and STD/HIV tests.

The Growing Evidence Base for Reproductive Health Services

Guidelines for reproductive health services issued by professional societies and organizations reflect advances in medical technology and increased understanding that various groups (such as those with low incomes and adolescents) have unique reproductive health and other health care needs. These guidelines are intended to disseminate current clinical and scientific advances. They are issued on a variety of topics by several organizations, most notably the American College of Obstetricians and Gynecologists. Other bodies issuing guidelines, policy statements, opinions, and statements regarding reproductive health services include the Society for Adolescent Medicine, the American Academy of Pediatrics, and WHO. Examples of guidelines that are relevant to family planning are listed in Box 2-1. These guidelines represent the recommendations of experts in the field, and therefore should play an important role in shaping the delivery of family planning services, particularly to the extent that they have a sound evidence base.

Social and Cultural Factors

The many guidelines identified above reflect the recognition that effective family planning requires more than the existence of effective biomedical interventions. Family planning by nature requires close attention to social and cultural factors as well. Women and men may experience a number of sociocultural barriers to accessing family planning services, including distance to a family planning provider, difficulty in arranging transportation, limited days and hours of service operation, costs to receive services, long waiting times either to schedule an appointment or to be seen by a provider, poor quality of care, concerns about confidentiality, language barriers for those with limited English proficiency, lack of awareness of the availability of services, and perceived or real cost barriers (discussed further below) (Bertrand et al., 1995; Brindis et al., 2003).

BOX 2-1
Examples of Guidelines for Reproductive Health Care

American College of Obstetricians and Gynecologists

- 2008—Routine Human Immunodeficiency Virus Screening
- 2008—Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome and Women of Color
- 2007—Intrauterine Device and Adolescents
- 2007—Brand Versus Generic Oral Contraceptives
- 2006—Primary and Preventative Care: Periodic Assessments
- 2006—Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign
- 2006—The Initial Reproductive Health Visit
- 2006—Psychosocial Risk Factors: Perinatal Screening and Intervention
- 2006—Routine Cancer Screening
- 2006—Breast Concerns in the Adolescent
- 2006—Evaluation and Management of Abnormal Cervical Cytology and Histology in the Adolescent
- 2006—Role of the Obstetrician-Gynecologist in the Screening and Diagnosis of Breast Masses
- 2005—Racial and Ethnic Disparities in Women's Health
- 2005—Health Care for Homeless Women
- 2005—The Importance of Preconception Care in the Continuum of Women's Health Care
- 2005—Meningococcal Vaccination for Adolescents
- 2004—Prenatal and Perinatal Human Immunodeficiency Virus Testing: Expanded Recommendations
- 2004—Sexually Transmitted Diseases in Adolescents
- 2004—Guidelines for Adolescent Health Research
- 2004—Cervical Cancer Screening in Adolescents
- 2004—The Uninsured
- 2003—Induced Abortion and Breast Cancer Risk
- 2003—Tool Kit for Teen Care—Lesbian Teens
- 2003—Tool Kit for Teen Care—Contraception

Society for Adolescent Medicine

- 2006—Abstinence-Only Education Policies and Programs
- 2006—HIV Infection and AIDS in Adolescents—Update
- 2004—Emergency Contraception
- 2004—Protecting Adolescents: Ensuring Access to Care and Reporting Sexual Activity and Abuse
- 1981—Reproductive Health Care for Adolescents

American Academy of Pediatrics

- 1998—Counseling the Adolescent About Pregnancy Options

World Health Organization

- 2007—Provider Brief on Hormonal Contraception and Bone Health
- 2007—Provider Brief on Hormonal Contraception and Risk of STI Acquisition
- 2005—WHO Statement on Hormonal Contraception and Bone Health

Women in rural areas may have particular difficulty finding and obtaining family planning services (Frost et al., 2001). Some special populations, such as homeless women (Wenzel et al., 2001) and those who are incarcerated, may be especially likely to face access and cost barriers. Among teenagers, concern about confidentiality is the most significant barrier to obtaining family planning services (NRC, 2008). Additional barriers for adolescents may include community disapproval of their use of family planning, stigma related to obtaining contraceptives, lack of knowledge about the existence of publicly funded clinics, a perceived lack of affordable services, ambivalence, a history of sexual abuse, and fears of side effects (Frost and Kaeser, 1995; Brindis et al., 2003).

Medical barriers can also inhibit the use of family planning services. These barriers include service providers basing care decisions on outdated information or contraindications (IUDs, for example, are underutilized in the United States in part because of outdated information regarding the risks of this contraceptive method [Morgan, 2006]); process or scheduling impediments, such as physical exams that clients must undergo before receiving contraceptives; service provider qualifications or regulations that unnecessarily limit the types of personnel who can provide a service; provider bias toward a particular method or procedure; inappropriate management of side effects; and regulatory barriers (Bertrand et al., 1995).

Providing Culturally Appropriate Care

The increasing numbers of racial and ethnic minorities in the United States highlight the importance of providing culturally appropriate care to these populations. HHS's Office of Minority Health has issued Standards for Culturally and Linguistically Appropriate Services (CLAS) in health care, which are directed primarily at health care organizations. Fourteen standards include culturally competent care, language access services, and organizational supports for cultural competence (see Box 2-2). Some of the standards are required for all recipients of federal funds (standards 4, 5, 6, and 7); others are recommended for adoption as mandates by federal, state, and national accrediting organizations (standards 1, 2, 3, 8, 9, 10, 11, 12, and 13); and one is suggested for health care organizations to adopt voluntarily (standard 14).

Patient-centered care is also an important goal to improve the functioning of the health care system generally. It is particularly important for the delivery of care for underserved populations, including low-income individuals, the uninsured, immigrants, and racial and ethnic minorities (Silow-Carroll et al., 2006). Patient-centered care is defined as "providing care that is respectful of and responsive to individual patient preferences,

BOX 2-2
National Standards on Culturally and Linguistically Appropriate Services (CLAS)

1. Health care organizations should ensure that patients/consumers receive from all staff members effective, understandable, and respectful care that is provided in a manner compatible with their cultural health beliefs and practices and preferred language.
2. Health care organizations should implement strategies to recruit, retain, and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area.
3. Health care organizations should ensure that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery.
4. Health care organizations must offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation.
5. Health care organizations must provide to patients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services.
6. Health care organizations must assure the competence of language assistance provided to limited English proficient patients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the patient/consumer).
7. Health care organizations must make available easily understood patient-related materials and post signage in the languages of the commonly encountered groups and/or groups represented in the service area.
8. Health care organizations should develop, implement, and promote a written strategic plan that outlines clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services.
9. Health care organizations should conduct initial and ongoing organizational self-assessments of CLAS-related activities and are encouraged to integrate cultural and linguistic competence-related measures into their internal audits, performance improvement programs, patient satisfaction assessments, and outcomes-based evaluations.
10. Health care organizations should ensure that data on the individual patient's/consumer's race, ethnicity, and spoken and written language are collected in health records, integrated into the organization's management information systems, and periodically updated.
11. Health care organizations should maintain a current demographic, cultural, and epidemiological profile of the community as well as a needs assessment to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.

continued

BOX 2-2 Continued

12. Health care organizations should develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and patient/consumer involvement in designing and implementing CLAS-related activities.
13. Health care organizations should ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by patients/consumers.
14. Health care organizations are encouraged to regularly make available to the public information about their progress and successful innovations in implementing the CLAS standards and to provide public notice in their communities about the availability of this information (see http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15).

needs, and values, and ensuring that patient values guide all clinical decisions" (IOM, 2001, p. 40).

Beach and colleagues (2006, p. vii) note that proponents of "the patient-centeredness movement, [as well as] pioneers of cultural competence recognized that disparities in health care quality may result not only from cultural and other barriers between patients and health care providers but also between entire communities and health care systems." Patient-centeredness and cultural competence represent different aspects of quality. Patient-centeredness focuses on better individualized care through improved relationships with the health care system, while the aim of cultural competence is to increase equity and reduce disparities in health care by focusing on people of color or those otherwise disadvantaged. The merging of these movements would help support the current push to develop "patient-centered medical homes" (Bergeson and Dean, 2006; The Patient Center Primary Care Collaborative, 2008) and provide "inter-professional education for collaborative patient-centered practice" (Health Canada, 2008).

In 2000, Approximately 17 percent of the U.S. population (47 million people) spoke a language other than English at home; 7 percent of the population (21 million Americans) had limited English proficiency (Flores et al., 2005; U.S. Census Bureau, 2008d). Meeting the needs of those who are limited English proficient is a challenge for the health care system.

Adequate communication between patients and their providers is essential to high-quality medical care. Many clinics have staff, including clinicians, who can converse with clients in their own language. In addition, evidence suggests that access to trained interpreters helps improve patient–provider communication, patient satisfaction, and health outcomes, and that quality of care is compromised when interpreters are not provided for those who need them (Flores, 2005). HHS's *Guidance Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* requires agencies that receive federal funding from HHS to ensure that such clients have access to the services provided by the agency (HHS, 2004b). An additional challenge that may affect adequate communication is a patient's basic literacy in his or her native language. The cost of making interpreter services available and hiring bilingual staff may be a challenge for agencies.

Serving the Undocumented Population

The Personal Responsibility and Work Opportunity Act of 1996 limits federal Medicaid coverage for noncitizens. Coverage is limited to legal immigrants; no coverage is provided for the undocumented. (Legal immigrants must have arrived in the United States before 1996 or have resided here for at least 5 years.) However, hospitals must provide emergency medical services to the undocumented, including labor and delivery services (Kullgren, 2003). There have been no large-scale studies of births to undocumented women. However, a recent study describes birth outcomes for undocumented women in the state of Colorado (Reed et al., 2005). It indicates that, compared with the general population, undocumented mothers were younger, less educated, and more likely to be unmarried. While their infants had better birth outcomes (lower rates of low birth weight and preterm birth) than infants in the general population, they were at greater risk for certain abnormalities (including infant anemia, birth injury, fetal alcohol syndrome, hyaline membrane disease, seizures, and requirements for assisted ventilation) (Reed et al., 2005). Undocumented mothers also experienced higher-risk pregnancies and more complications of labor.

Many in the health care community argue that government's failure to pay for primary and preventive health care services for undocumented noncitizens under the federal Medicaid program places a heavy burden on institutions that care for immigrant populations and also threatens the public's health (Kullgren, 2003). The limitations on care mean that many immigrant women have no prenatal care and thus receive their first pregnancy-related medical attention when they are about to deliver. Such an absence of prenatal care may result in avoidable problems with a woman's pregnancy or delivery and the health of the woman or her child. There are efforts at the state level to provide reproductive health services to undocumented populations. For example, the state of California recognizes the value of family planning care for this population and its cost-effectiveness, and uses state dollars to support this care when the federal government does not reimburse for these services under the state's 1115 waiver.

Kullgren (2003) argues that this restriction of health services jeopardizes legal immigrants' and citizens' access to care by making it necessary to review immigration documents, thereby increasing administrative costs and reducing the efficiency-of-care provision. Moreover, failing to cover preventive care for the undocumented while requiring hospitals to provide them with emergency care, which is typically more expensive, prevents resources from being used in the most cost-effective manner. Finally, limiting access to care undermines efforts to control the spread of disease among the general population and compromises the ethical obligations of clinicians.

> ***Finding 2-4.*** *Providing the many effective methods of birth control now available requires careful attention to the complex social and cultural factors that affect access and utilization.*

FINANCING OF FAMILY PLANNING

Financing for reproductive health services comes from a variety of sources. As noted earlier, the proportion of public funds for family planning contributed by Title X has decreased over the last several decades. In 1980, Title X was the source of 44 percent ($162 million) of all public dollars spent for contraceptive services and supplies (AGI, 2000); by 2006, Title X accounted for just 12 percent ($215.3 million) of public funding (Sonfield et al., 2008a). Medicaid expenditures on family planning followed the opposite trajectory, accounting for 20 percent ($70 million) of total funding in 1980 (Gold et al., 2007) but increasing to 71 percent ($1.3 billion) by 2006 (Sonfield et al., 2008a).

In large measure, the growth of Medicaid's role in family planning has been driven by state-initiated expansions of these services. To date, 27 states have sought and received permission from the Centers for Medicare and Medicaid Services, the federal agency that administers Medicaid, to expand eligibility under the program specifically for family planning (Guttmacher Institute, 2008a). While the expansion efforts in six states are limited and extend eligibility only to individuals who are otherwise losing Medicaid coverage, efforts in the remaining 20 states extend eligibility for family planning based solely on income, regardless of whether the individual has ever been enrolled in Medicaid. Most of these latter states set the income eligibility ceiling for Medicaid-covered family planning services at the same level used to determine eligibility for pregnancy-related care, generally at or near 200 percent of the federal poverty level—well above the usual state-set income ceilings (The Henry J. Kaiser Family Foundation, 2008).

State efforts to expand eligibility for family planning under Medicaid have infused new funding into the system. Two-thirds of the growth in family planning spending nationwide from 1994 to 2006 occurred in states that initiated broadly based Medicaid family planning expansions during that period (Sonfield et al., 2008a). As a result, those states have twice the resources per woman in need of programs in other states.[4] Between 1994 and 2001, family planning clinics in states with income-based waivers increased the number of clients served and also increased by one-quarter the proportion of women who received needed family planning care, while clinics in states without waivers experienced no increase at all (Frost et al., 2004). Although the expansion of Medicaid has infused new funds into family planning, tremendous unmet need remains. In 2005, while 12 percent of women (7.4 million) aged 15–44 were enrolled in Medicaid, 20.8 percent (12.9 million) remained uninsured (Guttmacher Institute, 2007). Title X offers critical services not offered under other insurance programs (see Chapter 3).

Some of the unmet need for family planning services may be attributable to increasing gaps in health insurance coverage. The increased cost of insurance has been affected by several factors, including technological advances in medicine, pharmaceutical development, and the aging population (Heffler et al., 2001). The growing cost of health insurance in turn has led to an increase in the number of people who are uninsured. In 1987, 12.9 percent of Americans lacked health insurance; that figure rose to 15.3 percent in 2007 (see Figure 2-19) (DeNavas-Walt et al., 2008). Among women aged 15–44, 20.8 percent were uninsured in 2005 (Guttmacher Institute, 2007).

A high proportion of the uninsured are young: 18 percent are below age 18 and 58 percent below age 34 (U.S. Census Bureau, 2008e). Adults aged 18–34 are disproportionately uninsured relative to their representation in the overall population. This is most likely because younger adults have lower incomes than older adults and are more likely to have jobs without health insurance benefits. Figure 2-20 presents the percentages of the uninsured and of the total population by age group among those below 100 percent of the federal poverty level. While children and the elderly have among the highest rates of poverty, they have the lowest rates of uninsurance because of targeted government programs, such as the State Children's Health Insurance Program and Medicare. Thus the population most in need of family planning is least likely to have health insurance coverage.

Those with full-time, year-round employment and an annual income greater than 200 percent of the federal poverty level are most likely to have health insurance (Custer and Ketsche, 2000). However, health insurance

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[4] Unpublished Guttmacher Institute tabulations.

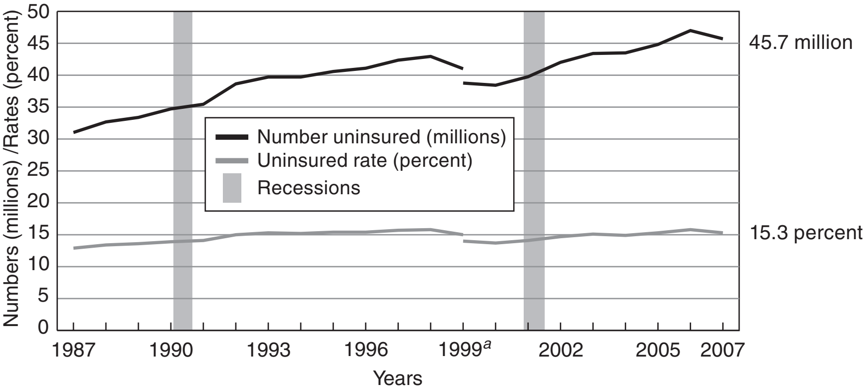

FIGURE 2-19 Number of uninsured and uninsured rate, 1987–2007.
[a]Implementation of Census 2000–based population controls occurred for the 2000 Annual Social and Economic Supplement, which collected data for 1999. These estimates also reflect the results of follow-up verification questions that were asked of people who responded “no” to all questions about specific types of health insurance coverage in order to verify whether they were actually uninsured. This change increased the number and percentage of people covered by health insurance, bringing the Current Population Survey (CPS) more in line with estimates from other national surveys.
NOTES: Respondents were not asked detailed health insurance questions before the 1988 CPS. The data points are placed at the midpoints of the respective years.
SOURCE: DeNavas-Walt et al., 2008.

coverage has become less stable even for those who are employed (National Coalition on Health Care, 2009). Rapidly rising health insurance premiums have prevented many, particularly small, businesses from offering coverage to their employees (DeNavas-Walt et al., 2008). The increase in the number of uninsured has occurred to a large degree among working adults. The percentage of working adults ages 18 to 64 without health coverage was 20.2 percent in 2006 (DeNavas-Walt et al., 2008).

In addition to the population of uninsured Americans, millions of adults are underinsured: they have insurance, but their medical costs are high relative to their income. Being underinsured is defined as either (1) having out-of-pocket medical expenses for care amounting to 10 percent of income or more; (2) for low-income adults (below 200 percent of the federal poverty level), having medical expenses amounting to at least 5 percent of income; or (3) having deductibles equal to or exceeding 5 percent of income (Schoen et al., 2008). Schoen and colleagues estimate that in 2007, approximately 25 million people aged 19–64 were underinsured—a 60 percent increase

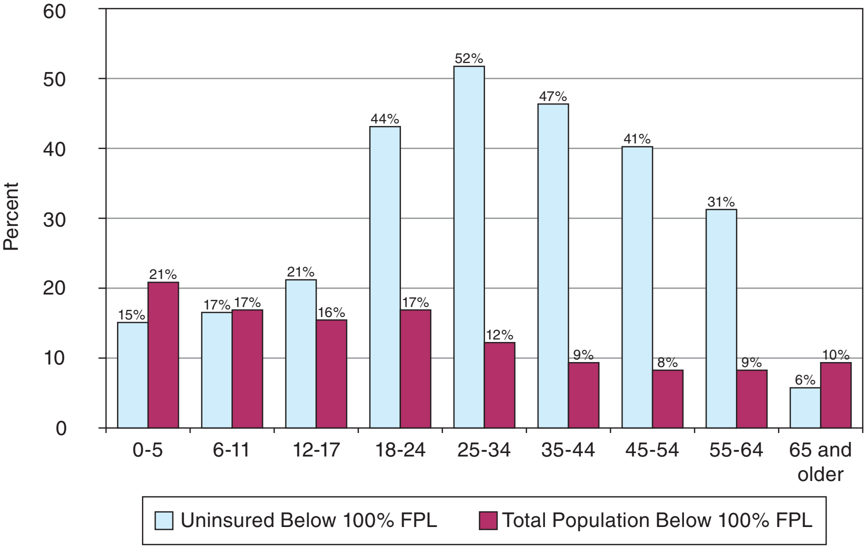

FIGURE 2-20 Percentage of uninsured and total U.S. population below 100 percent of the federal poverty level (FPL), by age, 2007.
SOURCE: U.S. Census Bureau, 2008e.

since 2003. In total, the authors report that 42 percent of adults under age 65 are uninsured or underinsured.

Even those who have employer-based insurance may find that basic family planning services are not a covered benefit. In 2003, 7 percent of health plans did not cover an annual obstetrical and gynecologic visit, 12 percent did not cover oral contraceptives, 13 percent did not provide payment for sterilization, and 28 percent did not cover all major types of contraceptives. Health maintenance organizations were more likely to cover contraceptives and sterilization than were preferred provider organizations or point-of-service plans (Klerman, 2006). This situation has improved in recent years, and by 2008, 24 states required insurers that cover prescription drugs to also provide coverage for any FDA-approved contraceptive (National Conference of State Legislatures, 2009); however, it is important to recognize that state mandates do not apply to self-insured plans. Women find it particularly difficult to obtain coverage in the individual insurance market. They are frequently charged higher premiums than men and have difficulty finding affordable coverage for maternity care. They can also have difficulty finding affordable coverage for prescription drugs, such as contraceptives.

CONCLUSIONS

The following conclusions emerged from the committee's review of the literature on the role and history of family planning in the United States:

> *The provision of family planning services has important benefits for the health and well-being of individuals, families, communities, and the nation as a whole.*
>
> *Planning for families—helping people have children when they want to and avoid conception when they do not—is a critical social and public health goal.*
>
> *The federal government has a responsibility to support the attainment of this goal. There is an ongoing need for public investment in family planning services, particularly for those who are low income or experience other barriers to care.*

3

Title X Goals, Priorities, and Accomplishments

The mission of the Title X program as stated in statute (see Appendix B) is to provide grants to public or nonprofit private entities "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)." According to the Title X Program Guidelines (see Appendix D), the program's mission is "to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children" (OFP, 2001, p. 2).

Clinics supported by the Title X program provide basic contraceptive care; related preventive health services, such as patient education and counseling; breast and pelvic examinations; screenings for cervical cancer and sexually transmitted diseases (STDs)/HIV; and pregnancy diagnosis and counseling. In addition, the Title X program helps clinics respond to patients' needs by supporting training for family planning clinic personnel, information dissemination and community-based education and outreach activities, and data collection and research to improve the delivery of family planning services. In 2006, the most recent year for which national-level data on the program are available, care was provided to almost 5 million women, men, and adolescents in clinics supported by the program (RTI International, 2008). Consistent with the congressional directive to give priority to low-income individuals, 67 percent of Title X clients have incomes below 100 percent of the federal poverty level, and 90 percent have incomes below 200 percent of that level (RTI International, 2008).

While the core mission of the program has remained clear over the years, a shifting and expanding set of operational priorities, along with a growing number of individuals requesting care and increasing expenses with no significant expansion in funding, has made it difficult for the program to fulfill that mission. This chapter begins by reviewing the original goals of the program and amendments to the law. It then examines shifts in program emphasis since 1970 and the problems associated with these shifting emphases. The third section presents the committee's findings regarding the extent to which the program has fulfilled its mission and goals. The final section offers conclusions and recommendations.

ORIGINAL GOALS AND AMENDMENTS TO THE LAW

In establishing the Title X program, Congress made clear that one major goal was to decrease the adverse health and financial effects on children, women, and their families of inadequately spaced childbearing (S. Rep. 91-1004, 91st Cong., 2d Sess., July 7, 1970; H. Rep. No. 91-1472, 91st Cong., 2d Sess., September 26, 1970; Family Planning Services and Population Research Act of 1970, P.L. 91-572 [1970]). Congress also emphasized that services offered through Title X were to be thoroughly voluntary. The Senate commented that the program "is properly a part of comprehensive health care and should consist of much more than the dispensation of birth control devices" (S. Rep. 91-1004, 91st Cong., 2d Sess., July 7, 1970, p. 10). The Senate cited with apparent approval the recommendations of a prominent family planning director for:

1. Medical services, including consultation, examination, prescription, and continuing supervision, supplies, instruction, and referral to other medical services as needed.
2. Outreach/follow-up systems, including patient identification, contact, recruitment, appointment support, follow-up, and continuing education.
3. Planning, evaluation, development, and coordination, including application of modern management technology to a goal-oriented program.
4. Financial management to assure a cost-effective, efficiently run program.
5. Research, both of an operational and a clinical nature, to be built into the medical and evaluation systems.
6. Social and ancillary services, including such necessary and supportive services as gonorrhea screening and social as well as medical services for teenagers.

7. Community education, to bring to the various parts of the community an understanding of the goals and importance of the program.

It is important to add that when the Title X program was established, it also reflected current concern that the United States and the world faced serious risks as the direct result of unfettered population growth (Nixon, 1969) (see also Chapter 2). Indeed, the formal name of the bill was the "Family Planning Services and Population Research Act of 1970." The new legislation was designed to address the population challenge directly by dramatically expanding voluntary family planning services. Before the introduction of modern contraceptive methods, many women, particularly low-income women, had more children than they desired (H. Rep. No. 91-1472, 91st Cong., 2d Sess., September 26, 1970; e.g., comments of Rep. Hawkins, Cong. Rec. H37369 and Rep. Kyros, Cong. Rec. H37381-2, November 16, 1970). The basic rationale for the new law was that through an aggressive effort by the government to make family planning services fully available and affordable, couples would have only the number of children they desired, and that as a result, the rate of U.S. population growth would decrease and ultimately stabilize (Nixon, 1969).

The optimism evident when the program was enacted is worth noting as well. Family planning was presented as a highly effective approach to reducing a broad range of maternal and infant health problems and as essential to abolishing poverty (Congressman Hawkins, Cong. Record-House 37369, November 16, 1970). Its overall benefits to communities and, indeed, the nation were cited with enthusiasm—a perspective that has repeatedly been affirmed (IOM, 1995). Supporters specifically mentioned the widespread and growing use of oral contraceptives and intrauterine devices (IUDs) and the pressing need to give low-income women the same access as more affluent women and couples to these methods and to family planning counseling and education more generally (Hearings before the Subcommittee on Health of the Committee on Labor and Public Health, December 8–9, 1969, and February 19, 1970; e.g., comments of Rep. Hawkins, Cong. Rec. H37369 and Rep. Kyros, Cong. Rec. H37381-2, November 16, 1970). As Senator Tydings of Maryland stated in 1969, "The right to plan to size one's family is an inalienable individual right, as important as the right to a job and a decent education in this country" (Hearings before the Subcommittee on Health of the Committee on Labor and Public Health, December 8–9, 1969, and February 19, 1970). Congress emphasized the importance of training for practitioners, research to strengthen the evolving field, the development of educational methods, and accountability to Congress. Supporters argued that by increasing public investment in family planning services, training, and research, the United States would not only meet a major domestic need but also serve as an international leader in addressing population pressures (Nixon, 1969).

> ***Finding 3-1.*** *Family planning is a fundamental component of health care.*

Congress has amended the law on several occasions, three of which involved substantive changes. Changes made in 1975 (1) increased reporting requirements to "address and assess the availability and adequacy of family planning services for the general population, and identify the deficiencies in the provision of services to certain groups and subgroups" (Conf. Rep. No. 94-348, 94th Cong., 1st Sess., July 11, 1975); (2) clarified the definition of "low-income family" to maximize inclusiveness; and (3) required that family planning projects "offer a broad range of acceptable and effective family planning methods (including natural family planning methods)" (P.L. 94-63, 89 Stat. 304, July 29, 1975).

Congress amended the law again in 1978 to make clear its intent that services be provided to adolescents, to address infertility services, and to protect providers who conscientiously object to abortion or sterilization (P.L. 95-613, 92 Stat. 3093, November 8, 1978). In 1981, Congress added a requirement that adolescents be encouraged to talk with their parents about family planning (P.L. 97-35, August 13, 1981). However, Congress specifically rejected requiring parental notification and, significantly, chose to retain Title X as a categorical grant program rather than rolling it into block grants to states as was common at that time (H. Conf. Rep. 97-208). In addition, yearly appropriations were to include provisions that grantees must comply with state laws requiring reporting of "child abuse, child molestation, sexual abuse, rape, or incest" (HHS, 2004a).

Shortly after the program was established, Congress dramatically expanded its funding, which peaked in 1980. Since then, however, real funding has declined significantly in relation to inflation; to the increase in the U.S. population (now almost twice as large as in 1970); and to the increasing costs of medical services and supplies, especially the more effective methods of family planning, such as IUDs. Taking inflation alone into account, funding for Title X in constant dollars was 62 percent lower in fiscal year (FY) 2008 than in FY 1980 (Sonfield, 2009) (see the further discussion of program funding in Chapter 4).

SHIFTS IN PROGRAM EMPHASIS

Within its statutory framework, Title X has developed (1) Program Guidelines that indicate required services, (2) annual program priorities and key issues, and (3) performance measures developed in response to the Program Assessment Rating Tool (PART) review (see Chapter 1). To learn more about these three systems and about the program's operations, the committee conducted a series of site visits and public workshops during which grantees, delegates, and other stakeholders provided their perspectives on the strengths of and challenges facing Title X. The information thus gathered indicated to the committee that, despite the program's many accomplishments and the optimism that clearly existed at its outset, several problems undermine its ability to achieve its goals. In particular, many Title X grantees suggested that the program's specific operational priorities lack clarity and frequently change without either an orderly process or a basis in strong science or basic public health principles. To understand this concern in greater depth, the committee carefully examined the Program Guidelines, the annual program priorities and key issues, research and training priorities, program leadership, and the PART process.

Program Guidelines

The Program Guidelines set out clearly the scope of services that must be provided by all clinics funded by the program, as well as criteria by which the quality of care is to be measured to ensure uniformity across all regions. The guidelines were last updated in 2001. According to the guidelines, each Title X clinic must offer the following:

- Client education and counseling, including specialized counseling;
- History, physical assessment, and laboratory testing, including breast and cervical cancer screening;
- Fertility regulation, including provision of contraceptive methods and/or prescriptions for contraceptive supplies and other medications;
- Basic infertility services;
- Pregnancy diagnosis and counseling;
- Adolescent services, including abstinence counseling and counseling to minors on how to resist attempts to coerce them into engaging in sexual activities;
- Reporting of child abuse, child molestation, sexual abuse, rape, or incest;
- Identification of estrogen-exposed offspring;
- Gynecological services;
- STD and HIV/AIDS prevention education, screening, and referral;
- Genetic information and referral;
- Health promotion and disease prevention; and
- Postpartum care.

This expansive list poses problems. While most providers and program administrators wish to offer as broad a range of services as possible for Title X clients, many of whom have no other source of care, the limited amount of funding available means that not all these services can be provided at a high level of quality to all who want them. Nor are all mandated services appropriate for all clients. Some of these requirements might be eliminated, or they might be prioritized (for example, categorized as essential, highly desirable, or optional). A related issue, the need to update the guidelines, is discussed in Chapter 4.

Annual Program Priorities and Key Issues

In addition to the general program requirements outlined in the Program Guidelines, the program is subject to annual program priorities that change and expand frequently, sometimes in response to congressional mandate or directives of the Office of Inspector General. Each year the Office of Family Planning (OFP) establishes these program priorities, which are published in the annual announcements of funding availability issued by the Office of Population Affairs (OPA), and applicants must address them in their annual requests for support (see Box 3-1 for the 2009 priorities). Several priorities appear each year, while others are added or deleted. For example:

- In 1995, a call was made for applicants to propose ways to increase the involvement of male partners, focus on HIV prevention and STD and cancer screening and prevention, and attend to both training and retaining nurse practitioners specializing in women's health.
- In 1996, increasing outreach to males was added.
- In 1999, the priorities included expanding and enhancing partnerships with entities that have "related interests and work with similar priority populations."
- In 2001, an emphasis on clinical services for difficult-to-reach populations, such as the uninsured or underinsured, substance abusers, migrant workers, and the homeless, became a priority.
- In 2003, abstinence education was added to the list of priorities, and persons with limited English proficiency were added to the difficult-to-reach populations that grantees are to address.
- In 2003, applicants were directed to encourage family participation in the decisions of minors to seek family planning services by including activities that promote positive family relationships; they were also directed to partner with faith-based organizations.
- In 2006, ensuring compliance with state laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape,

BOX 3-1
2009 Program Priorities

1. Assuring the delivery of quality family planning and related preventive health services, where evidence exists that those services should lead to improvement in the overall health of individuals, with priority for services to individuals from low-income families;
2. Assuring access to a broad range of acceptable and effective family planning methods and related preventive health services that include natural family planning methods, infertility services, and services for adolescents, including adolescent abstinence counseling. The broad range of services does not include abortion as a method of family planning;
3. Providing preventive health care services in accordance with nationally recognized standards of care. This includes, but is not limited to, breast and cervical cancer screening and prevention services; sexually transmitted disease (STD) and HIV prevention education, testing, and referral; and, other preventive health services;
4. Assuring compliance with State laws requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest;
5. Encouraging participation of families, parents, and/or legal guardians in the decision of minors to seek family planning services; and providing counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities; and
6. Addressing the comprehensive family planning and other health needs of individuals, families, and communities through outreach to hard-to-reach and/or vulnerable populations, and partnering with other community-based health and social service providers that provide needed services.

or incest was added to the list of priorities. In addition, programs were encouraged to provide counseling to minors on how to resist attempts to coerce them into engaging in sexual activities.

New directions in service priorities are often announced with little advance notice and without a clearly articulated rationale. These changing mandates pose a number of challenges. Given static funding levels, they have required grantees to adjust existing services to meet the new priorities. Some grantees feel that the Central Office does not elicit enough input from them and from delegates about how decisions regarding priorities will affect them[1] (The Lewin Group, 2009). As a result, according to testi-

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[1] Grantees have an opportunity to express their concerns at the national grantee meeting hosted biennially by the Central Office, but this venue does not allow for such communications at an individual level. This situation is improved somewhat by the attendance of Central Office staff members at annual regional meetings (time and money permitting), which grantees consider a very effective way of communicating information directly (The Lewin Group, 2009).

mony heard by the committee, many grantees have the impression that the shifts are often politically driven and not based on an orderly assessment of population needs or ways to achieve more effective service delivery or improved outcomes.

In addition to the program priorities, OFP lists key issues in the annual funding announcement (see Box 3-2 for the key issues for 2009). OFP states that these issues have implications for and should be considered by Title X service providers. The key issues have remained the same for the past several years.

The committee learned that there is no strategic process for establishing or revising the program priorities or key issues. It also appears that there is no organized system within the program for evaluating the latest scientific evidence, or for seeking advice and guidance from the scientific community or from program providers about emerging needs and how the program

BOX 3-2
2009 Key Issues

1. Cost of contraceptives and other pharmaceuticals;
2. Efficiency and effectiveness in program management and operations;
3. Management and decision making through performance measures and accountability for outcomes;
4. Linkages and partnerships with community-based and faith-based organizations;
5. Addressing CDC's "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings," and incorporating "ABC" concepts for HIV prevention counseling (that is, "A" for extramarital abstinence; "B" for be faithful in marriage or committed relationships; and "C" for correct and consistent condom use). For individuals at increased risk for contracting or transmitting HIV, the message should include "A," "B," and "C" (added in 2003);
6. Compliance with HIPAA (Health Insurance Portability and Accountability Act) and the Infant Adoption Awareness Act (added in 2003);
7. The use of electronic technologies, such as electronic grants management capabilities, electronic health information infrastructures, electronic access to health quality information, and similar electronic systems (added in 2006);
8. Data collection (such as the *Family Planning Annual Report* [FPAR]) for use in monitoring performance and improving family planning services;
9. Service delivery improvement through translation into practice of research outcomes that focus on family planning and related population issues; and
10. Utilizing practice guidelines and recommendations, developed by recognized national professional organizations and federal agencies, in the provision of evidence-based Title X clinical services.

could or should adapt to meet them. During testimony at the committee's public workshops, program administrators reported that changing program priorities impede orderly program functioning and also add significant stress to the application process.

Research Priorities

As 90 percent of Title X funds must be devoted to services, a very small portion of the funds are used for research. Even so, OPA issues an annual announcement on the availability of research funds and seeks applications. The committee examined the research portfolio of the Title X program (see Appendix I), keeping in mind the intent of Congress that the program's research efforts would serve to improve the delivery of family planning services. OPA determines research priorities in a variety of ways, both internal and external. Internal processes include meetings among OPA staff members to determine priorities, as well as more informal means. External processes include working groups convened by OPA to help identify research gaps and needs. For example, in 2004 OPA contracted with the Urban Institute to convene and consult with an expert panel. This effort resulted in a document entitled *Future Directions for Family Planning Research: A Framework for Title X Family Planning Delivery Improvement Research* (see Chapter 5 for further discussion of the findings of this panel). OPA also takes note of field and other formative research that may indicate particular directions that would strengthen the Title X program's overall delivery of services. This type of information, for example, led OPA to determine that the program needed to focus on how to serve males more effectively. Neither relevant research communities nor family planning providers themselves (Title X recipients or others) are consulted in any systematic way about the issues they believe require research. Perhaps more important, the committee learned that OPA has no formal advisory structure or board to assist in identifying research priorities over time or assess the many research ideas that arise.

National Training Priorities

The overall Title X training priority is "providing training to Title X providers on improving clinic efficiency in an effort to address increasing costs of health care without sacrificing quality" (OPA, 2007). Each regional training center is awarded special funding for this purpose. In addition to focusing on the main priority, grantees are expected to provide training to help providers in:

1. Addressing clinical training needs of Title X providers and collaborating with the National Family Planning Clinical Training Center;
2. Encouraging family participation in the decision of minors to seek family planning services and providing counseling to minors on how to resist attempts to coerce minors into sexual activities, and complying with state laws requiring the notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest; and
3. Integrating HIV prevention activities into Title X services.

Training priorities are determined by training needs that cut across regions. However, there has been little assessment of the effectiveness of training in achieving these goals.

Program Leadership

A number of people who testified before the committee reported concern about the OPA leadership (particularly the Deputy Assistant Secretary for Population Affairs), which has changed frequently in recent years (see also the section titled "Effect of Political Issues on Program Administration and Management" in Appendix J). Since 1994, the leadership has turned over 12 times (personal communication from OFP, September 2, 2008). For 3 of the last 8 years, the office of the Deputy Assistant Secretary for Population Affairs was vacant and managed by federal career leadership. Some who have held this position have lacked relevant medical, public health, or family planning experience (Lee, 2006, 2007). Some also have had no history of commitment to the full mission of Title X, such as providing family planning services to minors, a situation that has created uncertainty among grantees regarding the direction of the program and its priorities. Some speakers who testified before the committee argued that the program has not been adequately protected from controversies rooted in the nation's ongoing "culture wars" about such sensitive issues as abortion (which Title X funds do not support), parental consent for contraceptive services to minors, and sexual activity among unmarried individuals. The importance of shielding the Title X program from polarization on such issues was emphasized in 1969 by then Representative, now former President George H. W. Bush, who stated:

> We need to make population and family planning household words. We need to take sensationalism out of this topic so that it can no longer be used by militants who have no real knowledge of the voluntary nature of this program, but rather are using it as a political steppingstone. If family planning is anything, it is a public health matter. (115 Congressional Record H4207 [February 24, 1969] [statement of Rep. Bush])

> ***Finding 3-2.*** *The political and social pressures and arguments that surround Title X have adversely affected the program's operations and eroded morale among those who operate the program.*

Program Assessment Rating Tool (PART) Process

The committee examined the PART process to gain further insight into the program priorities of Title X and their stability over time. For the Title X PART process, OFP stated that the program's purpose is to:

> provide individuals the medical, educational and social services necessary to (1) exercise personal choice in determining the number and spacing of their children, and (2) ensure their reproductive health and well-being (through prevention of STDs, HIV and routine cancer screenings), with a priority given to low-income persons. By increasing utilization of family planning services within underserved populations, and by providing preventive health care that prevents the acquisition and spread of STDs and HIV, the program seeks to improve the health of individuals who would otherwise not have access to family planning and related preventative health services. (OMB, 2005, Section 1.1)

OFP developed three long-term measures intended to reflect the purpose of the program and its progress in achieving its goals. As noted in the 2005 PART, "these long-term measures are linked to Healthy People 2010 and are responsive to both the Health Resources and Services Administration's (HRSA's) long-term plan and the HHS Strategic Goals and Objectives, reflected in the FY HRSA budget/performance integration plan" (OMB, 2005, Section 2.1). The measures are as follows:

1. Increase the number of unintended pregnancies averted by providing Title X Family Planning services, with priority for services to low-income individuals;
2. Reduce infertility among women attending Title X Family Planning clinics by identifying chlamydia infections through screening of females ages 15–24; and
3. Reduce invasive cervical cancer among women attending Title X Family Planning by providing Pap tests.

OFP's choice of these three long-term measures reflected guidance from the Office of Management and Budget (OMB), which suggested that the measures (1) reflect health outcomes; (2) be obtainable and capable of being documented; and (3) reflect the mission of the program, as well as federal and nonfederal clinical and preventive health practice and guidance. All of these measures reflect routine clinical care delivered by all Title X grantees and relate directly to the program's goal of offering services that enable individuals to freely choose the number and spacing of their children (personal communication from OFP, September 2, 2008).

The committee concluded that the first and second measures relate directly to the program's stated mission. The third measure is also worthwhile given that many of the women who receive care through Title X often have no other means of receiving these services. However, this measure appears less central to the program's basic mission, and it places an additional burden on programs that already have very limited resources for the services they deliver. Moreover, it is unclear whether all three measures are to be given equal weight across all clinics funded by Title X. The adequacy of these measures for judging the impact of the Title X program is discussed later in this chapter and in Chapter 5.

In Summary: Unclear Priorities

In investigating the clarity and evolution of the goals and priorities of the Title X program, the committee heard about a number of concerns: the expansive list of required services in an environment of limited resources, the variations in annual program priorities without a clear basis in science or a strategic planning process for their determination, the need to respond to congressional concerns that are often driven by political pressures rather than scientific developments, the impact of the complex political environment, and the PART measures. Taken together, these concerns explain why the committee repeatedly heard that the program's priorities are not clear to those responsible for the provision of Title X–funded services.

> ***Finding 3-3.*** *Title X's core mission of providing high-quality family planning care, especially to low-income women and adolescents, is clear. However, the program's operational priorities are less clear; are not stable; and are not developed or revised through a focused, evidence-based process of strategic planning.*

The lack of clarity about program priorities exacerbates the challenges of limited funding. Absent additional money, specifying new responsibilities or priorities by definition means that some current activities or priorities must be sacrificed. Managing constant change is also difficult for grantees. These concerns are compounded by the overall growth in the number of individuals in need of publicly subsidized family planning services and the increasing cost of more effective contraceptives and diagnostics (see the discussion later in this chapter). In the face of these challenges, program leaders and providers in the field note the lack of a sufficient analytic, evidence-based system within the Title X administrative structure (national or regional) that can help them decide what to add and where to cut back to address new priorities.

FULFILLMENT OF THE PROGRAM MISSION AND GOALS

This section reviews what is known from currently available data about how well Title X fulfills its mission to provide individuals with the information and means to exercise personal choice in determining the number and spacing of their children. It also presents the committee's assessment of the extent to which the program fulfills its goals as articulated by the three long-term outcome measures outlined above—reducing unintended pregnancies, reducing the rate of infertility by screening for chlamydia, and reducing the rate of invasive cervical cancer by providing Pap tests. The committee also provides an assessment of a fourth measure focused on efficiency—maintaining the cost per family planning client below the medical care inflation rate. The third subsection examines the contribution of the Title X goals to overall HHS goals.

Fulfillment of the Title X Mission

Clients Served by Title X

In 2002, the last year for which national-level data are available, slightly more than half of women (56 percent) of reproductive age received family planning or related medical services from private health care providers. Approximately 22 percent reported using publicly funded clinics—subsidized by federal, state, or local governments or private nonprofit organizations—including Title X–funded facilities (Mosher et al., 2004). Other facilities, such as hospitals, university health centers, and military heath centers, provided care for 2 percent of women. It should be noted that data limitations make it impossible to determine whether care received in publicly funded clinics was paid for with Title X or other funds. For example, a woman may have a portion of her visit paid for by Medicaid while other aspects of her care may be paid for by Title X (or by other federal, state, or local funding that the clinic may receive). Therefore, it is possible to compare only the characteristics of all women served at Title X clinics with those of all women served by other public clinics that receive no Title X funding (for example, community health centers, hospital outpatient clinics).

Of the 13.5 million women who obtained family planning and related medical services from a public clinic in 2002, 5.4 million, or 40 percent, received these services from a Title X clinic. This represented a 29 percent

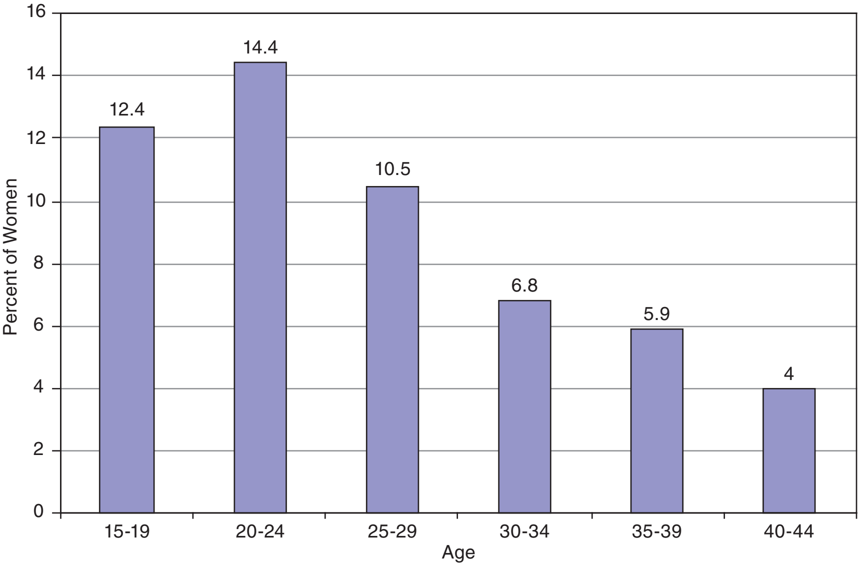

FIGURE 3-1 Percentage of women, by age, who received at least one family planning or medical service from a Title X clinic in the 12 months prior to interview, 2002.
NOTE: Family planning services included (1) a birth control method or prescription for a method; (2) a checkup or medical test related to using a birth control method; (3) counseling about birth control; (4) counseling about getting sterilized; (5) emergency contraception or the "morning-after pill," or a prescription for it; (6) counseling or information about emergency contraception or the "morning after" pill; and (7) a sterilizing operation. Medical services included (1) a pregnancy test; (2) an abortion; (3) a Pap smear; (4) a pelvic exam; (5) prenatal care; (6) postpregnancy care; and (7) counseling, testing, or treatment for a sexually transmitted disease.
SOURCE: Mosher et al., 2004.

increase from 1995 (from 4.2 million to 5.4 million women) (Mosher et al., 2004). Women aged 15–44 who used Title X–funded clinics tended to be young, poor, and from racial and ethnic minority groups (see Figures 3-1 to 3-3, respectively). Small shifts have occurred in recent years in the distribution of users of Title X services by race (RTI International, 2008). The percentage of Title X clients who are white remained relatively constant at about 65 percent between 1999 and 2006, while the percentage of Title X clients who are black decreased from 22 percent to 19 percent during the same period. In 1999, 17 percent of users reported Hispanic or Latino ethnicity; this figure increased to 25 percent in 2006 (RTI International, 2008).

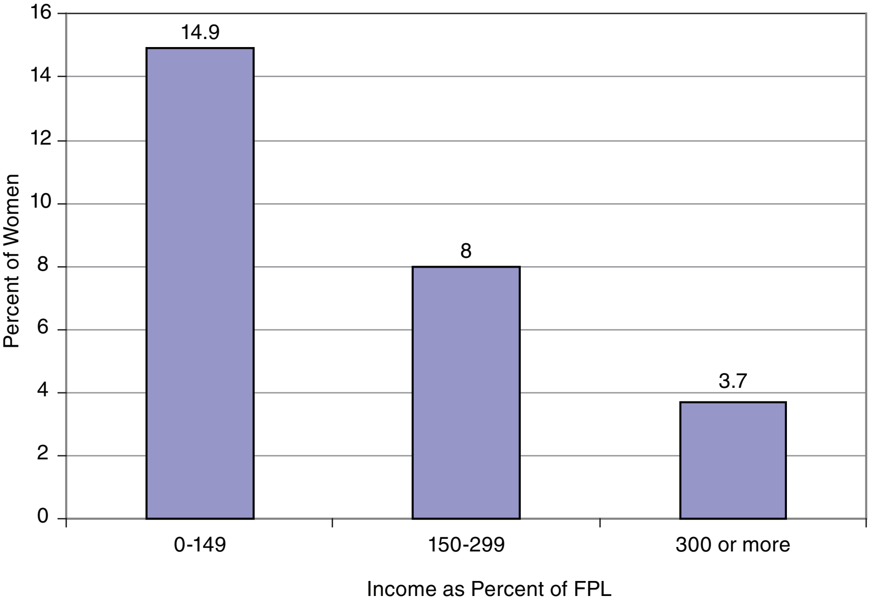

FIGURE 3-2 Percentage of women, by income as percent of the federal poverty level (FPL), who received at least one family planning or medical service from a Title X clinic in the 12 months prior to interview, 2002.
NOTE: Family planning services included (1) a birth control method or prescription for a method; (2) a checkup or medical test related to using a birth control method; (3) counseling about birth control; (4) counseling about getting sterilized; (5) emergency contraception or the “morning-after pill,” or a prescription for it; (6) counseling or information about emergency contraception or the “morning after” pill; and (7) a sterilizing operation. Medical services included (1) a pregnancy test; (2) an abortion; (3) a Pap smear; (4) a pelvic exam; (5) prenatal care; (6) postpregnancy care; and (7) counseling, testing, or treatment for a sexually transmitted disease.
SOURCE: Mosher et al., 2004.

Extent to Which Title X Is Serving Its Intended Population

In accordance with its core mission, Title X has made great strides in providing family planning services to its target population. The continued need for Title X services for low-income individuals is reflected in the high rate of unintended pregnancies in the United States and the higher risk for such pregnancies among low-income women (see Chapter 2). In 2006, 17.5 million women were in need of publicly funded contraceptive services and supplies (Guttmacher Institute, 2008b). Of these women, 29 percent (5.1 million) were under age 20, and 71 percent (12.4 million) were poor

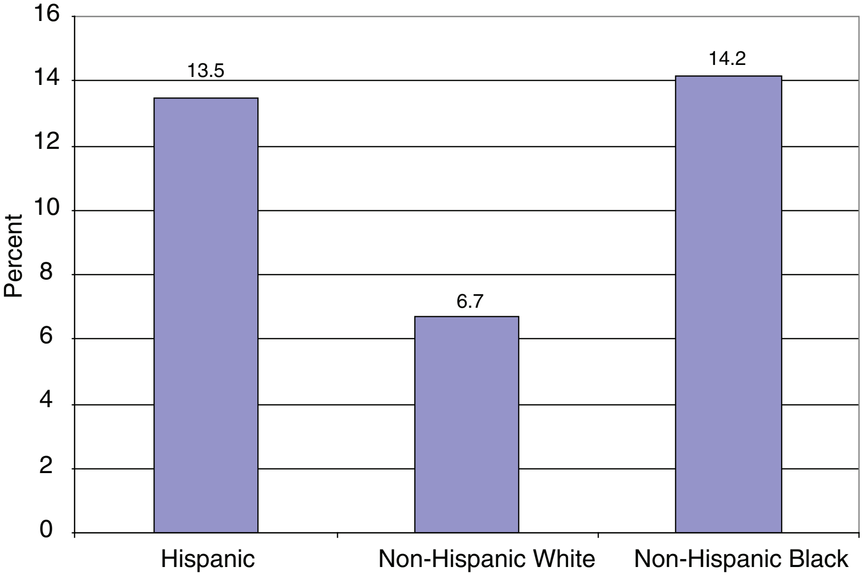

FIGURE 3-3 Percentage of women, by race and ethnicity, who received at least one family planning or medical service from a Title X clinic in the 12 months prior to interview, 2002.
NOTE: Family planning services included (1) a birth control method or prescription for a method; (2) a checkup or medical test related to using a birth control method; (3) counseling about birth control; (4) counseling about getting sterilized; (5) emergency contraception or the "morning-after pill," or a prescription for it; (6) counseling or information about emergency contraception or the "morning after" pill; and (7) a sterilizing operation. Medical services included (1) a pregnancy test; (2) an abortion; (3) a Pap smear; (4) a pelvic exam; (5) prenatal care; (6) postpregnancy care; and (7) counseling, testing, or treatment for a sexually transmitted disease.
SOURCE: Mosher et al., 2004.

or low income. Title X grantees served almost 5 million family planning users in 2006 (RTI International, 2008). In 2001, Title X clinics "met 28% of the national need for publicly funded family planning services, an 11% increase from 1994" (Frost et al., 2004, p. 213).[2] In the 26 states with fam-

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[2] Women are defined as being in need of publicly funded contraceptive services and supplies if "they are of reproductive age (13–44), have ever had sexual intercourse, and are able to become pregnant but do not wish to do so. Those with an income below 250% of the federal poverty level or who are younger than 20 (and thus presumed to have a low personal income) are considered in need of publicly funded contraception" (Gold et al., 2007, p. 9).

ily planning Medicaid waivers, Title X clinics documented greater success in meeting needs, showing a 30 percent increase in met need between 1994 and 2001 (Frost et al., 2004). Since both the total American population and the population of women without health insurance have increased over the past several years (see Chapter 2), the committee believes that Title X is an important source of care for the growing number of those in need. Of the approximately 45.7 million people without health insurance in 2007, approximately 57 percent (26 million) were of reproductive age (18–44) (DeNavas-Walt et al., 2008). Across different age groups, the proportion of women who were uninsured in 2007 was 22.6 percent (among those aged 18–20), 28.8 percent (aged 21–24), 21.7 percent (aged 24–34), and 16.2 percent (aged 35–44) (Fronstin, 2008).

According to the 2006 FPAR, more than two-thirds (67 percent) of clients served in Title X clinics were at or below 100 percent of the federal poverty level, and 90 percent were below 200 percent of that level—evidence that the program is caring for its priority population (RTI International, 2008). In 2006, 61 percent of clients at Title X clinics were uninsured; 21 percent had public insurance such as Medicaid; and 8 percent had private insurance (insurance status for 10 percent was not reported). There was great regional variation in these numbers due to differences in Medicaid eligibility across states (RTI International, 2008). Among Title X users, 95 percent were female, and 5 percent were male. The number of males served, while relatively small, more than doubled between 1999 and 2006, increasing from 127,098 to 272,409 (RTI International, 2008).

> ***Finding 3-4.*** *The Title X program plays a major role in providing family planning services and closely related preventive health services, particularly to younger women who live at or near the federal poverty level.*

As discussed in Chapter 2, the intended population for Title X services (adults at or below 100 percent of the federal poverty level and adolescents) has grown over the past 30 years. At the same time, however, funding for the program, adjusted for inflation, has decreased. As illustrated in Figure 3-4, the combined number of adults aged 18–44 living in poverty and adolescents aged 13–17, representing those potentially in need, grew from 30 million in 1980 to 35.5 million in 2007 (U.S. Census Bureau [custom tabulations plus analysis of tables from Population Estimates data]). During that same period, Title X appropriations (in constant dollars) declined from $162 million in 1980 to $60.4 million in 2007 (see the discussion of funding and costs of supplies in Chapter 4) (Sonfield, 2009). Given the existence of Medicaid, Medicaid waivers, state funds, Maternal and Child Health block grants, Social Services block grants, Temporary Assistance

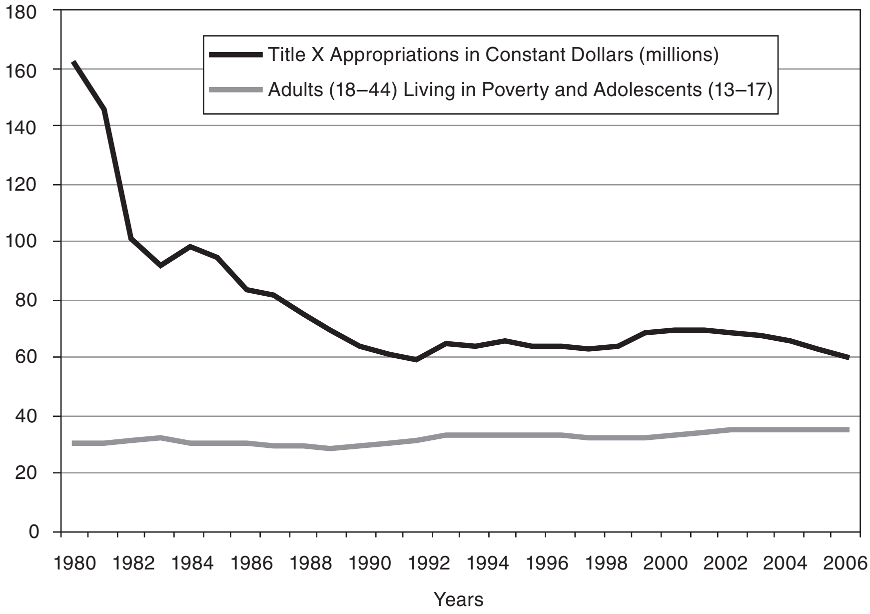

FIGURE 3-4 Title X appropriations in constant dollars and combined number of adults (18–44) living in poverty and adolescents (13–17), 1980–2007.
NOTE: Constant dollars based on the Consumer Price Index for medical care (calendar year average).
SOURCES: Sonfield, 2009; U.S. Census Bureau (custom tabulations plus analysis of tables from Population Estimates data).

for Needy Families, and some private insurance, not all the need is unmet; however, a portion certainly is (see the discussion in Chapter 4 on other sources of public funding for family planning services).

Fulfillment of the Program Goals

As discussed earlier, in response to the PART process, the Title X program has identified three specific goals it hopes to achieve in serving its target population: reducing unintended pregnancies, reducing the rate of infertility, and reducing the rate of invasive cervical cancer. OPA believes the measures needed to assess progress toward achieving these goals are obtainable and documentable, and that they reflect health outcomes and the mission of the program, as well as broader preventive heath practices.

TABLE 3-1 Target Versus Actual Number of Unintended Pregnancies Among Title X Recipients, 2003–2011

Year	Target	Estimated
2003	Baseline: 1,116,315	
2004	1,012,655	1,125,300
2005	964,000	978,845
2006	963,500	975, 080
2007	1,142,608	968,868
2008	981,000	Fall 2009
2009	978,000	Spring 2010
2010	976,000	Spring 2011
2011	974,000	Spring 2012

NOTE: The dates shown in the right column for 2008–2011 indicate when the actual numbers will be available.
SOURCE: OMB, 2009.

Reducing Unintended Pregnancies

One of Title X's key goals is reducing the number of unintended pregnancies by ensuring access to a broad range of family planning services and methods. It has been estimated that the unintended pregnancy rate in the United States would be 31 percent higher without the services provided in clinics and centers that receive Title X funding (Gold et al., 2009). The Title X program has a clear baseline for the number of unintended pregnancies, established in 2003, with specific quantified targets for 2004–2011 (see Table 3-1).

The methodology used by OFP to estimate the decrease in the number of unintended pregnancies is discussed in Chapter 5. As shown in Table 3-1, OFP estimates that there were 968,868 unintended births in 2007 and projects that this number will continue to decrease. Although the estimated number of unintended births has decreased and is lower than the targets, the committee believes that OFP should consider reducing its targets. The further reduction in unintended births can be achieved by delivering more effective contraceptive methods in a culturally sensitive manner. Furthermore, new research is needed to determine the broad array of factors that contribute to unintended pregnancy.

Reducing the Rate of Infertility by Screening for Chlamydia

Chlamydia infections may contribute significantly to the infertility of young adult women unless adequate screening and treatment services are available. Because of the disease's characteristics, especially the fact that women can be infected but unaware of their subclinical infection,

TABLE 3-2 Target Versus Actual Number of Chlamydia Screenings Among Female Clients of Title X Clinics Ages 15–24, 2005–2011

Year	Target	**Actual**
2005	Baseline: 1,349,884	
2006	1,398,000	1,353, 319
2007	1,398,000	1,361,901
2008	1,352,000	Fall 2009
2009	1,349,000	Spring 2010
2010	1,347,000	Spring 2011
2011	1,345,000	Spring 2012

SOURCE: OMB, 2009.

annual screening has become a standardized Healthcare Employer Data and Information Set measure for sexually active adolescents (ages 15–24) (USPSTF, 2007). The Centers for Disease Control and Prevention (CDC) has partnered with the Title X program and provided funding for additional chlamydia screenings and treatment, reflecting the priority it places on preventing infertility and its recognition of the critical role of Title X grantees in reaching many of the same clients CDC is interested in serving. As an indicator of the performance of Title X's clinics, the ability to screen this age group effectively and in compliance with national standards is a key quality measure.

As illustrated in Table 3-2, in 2006 Title X clinics performed chlamydia screening for approximately 1.4 million clients aged 15–24 (OMB, 2009), the age group at highest risk of this disease, numbering approximately 42 million in the United States (U.S. Census Bureau, 2007). While the FPAR provides information on the numbers of screens conducted, it is currently not feasible to track individuals longitudinally and match clients who were screened with those who were found to have a positive screen and received treatment. As a result, it is difficult to assess how successful the program has been in treating chlamydia infections.

Overall, more sensitive and noninvasive chlamydia screenings of both men and women have resulted in larger numbers of individuals being screened and more accurate reporting of the actual incidence of this disease. While screenings are clearly increasing, however, it is not possible to link screening to decreased infertility given the data systems maintained by OPA. Establishing this link would require a significant investment in tracking and following clients until they were ready to become pregnant.

Reducing the Rate of Invasive Cervical Cancer by Providing Pap Tests

While OFP has no historical data available on this measure, and national standards for prevention of and screening for invasive cervical cancer are

TABLE 3-3 Number of Pap Tests Performed and Target Versus Actual Number of Title X Clients Found to Have Invasive Cervical Cancer Following Pap Tests, 2005–2011

Year	Pap Tests	Target	Actual
2005	2,447,498	Baseline: 808	
2006	2,326,153	809	799
2007		809	798
2008		800	Spring 2009
2009		798	Spring 2010
2010		796	Spring 2011
2011		795	Spring 2012

NOTE: The number of pap tests performed was identified from the 2005 and 2006 FPARs produced by RTI International. All other information was found in the 2009 *Family Planning Program Assessment Details*.
SOURCES: RTI International, 2006, 2008; OMB, 2009.

evolving, OFP is moving toward establishing targets for this performance measure. The baseline of clients who are diagnosed with invasive cervical cancer is approximately 800 new cases on an annual basis (see Table 3-3). Given the age and ethnic/racial profile of these clients, OFP anticipates similar outcomes for the next 5 years. However, these targets are likely to change over time as the number of Latina women, who have a greater incidence of cervical cancer, increases (Ries et al., 2008); as the program documents more specific data on the actual number of clients screened and detected as having invasive cervical cancer; and as the human papillomavirus vaccine is more widely implemented. As discussed earlier, the committee considers this performance measure to be less central to the program's mission than the previous two.

Maintaining the Actual Cost per Family Planning Client Below the Medical Care Inflation Rate

In accordance with the PART process, OFP established an efficiency measure—to keep the cost per client below the medical care inflation rate. According to the PART review, "Over the past several years the Family Planning program has continued to demonstrate both increasing efficiencies and cost effectiveness. The Title X service sites have seen more users per site while requiring less revenue per user. Between 1998 and 2002, the total adjusted revenue per user in Title X projects decreased 5%. During this same time period, the average number of users per service site, across all regions, increased 11%" (OMB, 2005, section 4.3). According to HRSA's 2009 performance appendix, there was a "small decrease (1.49%) in overall users between 2004 and 2006 [that] suggests a continuing leveling off trend in client numbers, following the more substantial gain experienced between 2000–2001 when additional funds were provided to the Program" (HRSA, 2008, p. 141).

The baseline for efficiency—measured as the cost per Title X client in a given year relative to the cost in 2004 increased by the rate of medical inflation between 2004 and that year—was established in 2004, with targets provided for 2005–2013. To calculate the efficiency measure, the total revenue from all Title X clinics is divided by the number of unduplicated Title X users. The result is compared with the change from the previous year and with the increase in the consumer price index (CPI) for medical care. The baseline was established at $193.92 per client (see Table 3-4). According to HRSA, "In 2006 the actual cost per client was $215.56, $8.41 less than the targeted projection. This resulted in cost avoidance of approximately $42 million in client costs. The program has consistently met or come under the annual target for this measure and historically has kept its increase in total cost per client below that of the CPI for medical care costs" (HRSA, 2008, p. 143).

The committee does not believe, however, that revenue per client is the same as cost per client. To determine whether cost per client has increased at a lower rate than overall medical care inflation, OFP would have to control for the mix of patients seen (women, men, adolescents), as well as the major reason for the clinic visit (e.g., to obtain contraception or counseling). The committee questions whether the efficiency demonstrated by the program has come at the expense of quality and/or access. As discussed above, the target population for Title X services continues to grow, while funding for the program in constant dollars has continued to decline.

TABLE 3-4 Measure of Efficiency: Target Versus Actual Cost per Title X Client in Relation to Medical Care Inflation, Actual and Projected, Fiscal Years 2004–2013

Year	**Target**	**Actual**
2004	Baseline: $193.92	
2005	$214.61	$200.81
2006	$223.97	$215.56
2007	$233.73	$229.32
2008	$243.92	Fall 2009
2009	$245.55	Spring 2010
2010	$265.62	Spring 2011
2011	$277.18	Spring 2012
2012	$289.25	Spring 2013
2013	$301.85	Spring 2014

SOURCE: OMB, 2009.

Testimony before the committee revealed that Title X providers feel pressure to provide more comprehensive family planning care, serve increasing numbers of clients, and comply with new program priorities that are frequently introduced, but receive no additional resources for these purposes. While the committee agrees that the efficient use of resources is essential, an efficiency measure should take into account such factors as the cost of more effective contraceptive techniques and the challenges of serving an increasing and more diverse population.

Contribution of Title X Goals to HHS Goals

As discussed in Chapter 2, public health leaders in the federal government continue to recognize the contribution of family planning services to the public's health and well-being, as well as to the fulfillment of national health objectives as reflected in a number of HHS goals. HHS's goals are embodied in its current *Strategic Plan—FY 2007–2012* and the goals of various agencies within the Department, and in the broader context of Healthy People 2010, a set of national health objectives for 2000–2010 focused on improving the public's health (www.healthypeople.gov). The goals of Title X are consistent with these HHS goals, to which the program contributes significantly.

HHS Strategic Plan

The Strategic Plan identifies four goals to guide HHS's actions toward helping Americans live longer, healthier, and better lives: health care affordability and access; public health promotion and disease prevention; promotion of the economic and social well-being of individuals, families, and communities; and scientific research and development.

Affordability and Access. The clinical, educational, and counseling services that are provided at no or low cost by Title X clinics help improve affordability and access to "efficient, high-quality health care services" and "appropriate information for informed choices" (Goal 1). The location of clinics throughout the country in both rural and medically underserved areas furthers HHS's interest in reaching out to vulnerable and underserved populations.

Training provided to Title X personnel helps address the Strategic Plan's objective of "recruit[ing], develop[ing], and retain[ing] a competent health care workforce" (Objective 1.4). Title X training can ensure that program staff obtain current information about the latest family planning developments, maintain their professional competency, and develop skills that meet their patients' needs (such as cultural competency).

Public Health Promotion and Disease Prevention. Title X contributes to health promotion and disease prevention across the lifespan (Goal 2) by providing education on a range of health issues, healthy family functioning, and prevention of domestic violence, as well as medical services that detect chronic and infectious diseases (including cardiovascular disease, cancers, HIV/AIDS, and other STDs) that are the focus of this goal.

Economic and Social Well-Being. Family planning services under Title X were developed to decrease the adverse health and financial effects on children, women, and their families of inadequately spaced and unplanned childbearing. In fulfilling that goal of the Title X program, these services also contribute to the fulfillment of HHS's goal of promoting "the economic and social well-being of individuals, families, and communities" (Goal 3). HHS notes that this goal embodies "moving disadvantaged families to work and economic self-sufficiency," which is enhanced by family planning that helps families choose when to have children (see Chapter 2 for a discussion of the benefits of family planning). Protecting the safety and fostering the well-being of children and youth is another objective under this goal (Objective 3.2). The overall Title X goal of preventing teenage pregnancy is critical to the achievement of this objective (although Title X clinics provide services beyond the abstinence education activities emphasized by HHS in this objective).

Scientific Research and Development. Although only a small percentage of Title X–funded activities involve research, the investment of those funds furthers HHS's goal of scientific research and development (Goal 4), in particular, communicating and transferring research results into clinical, public health, and human service practice (Objective 4.4).

CDC Health Protection Goals

Agencies within HHS have also articulated goals for the nation's health, the achievement of which is supported by Title X's accomplishments (see, e.g., HRSA, n.d.; OPHS, 2007; OMH, 2008). CDC, for example, has established Health Protection Goals (which include a number of strategic goals and objectives), intended to support improvements in people's lives by accelerating health impact and reducing health disparities. One of the four strategic goals under the Health Protection Goals is Healthy People in Every Stage of Life, encompassing services that address many objectives in several life stages. In connection with Start Strong (which targets infants and toddlers aged 0–3), Title X's services help promote healthy pregnancy and birth outcomes; foster social and physical environments that support the health, safety, and development of infants and toddlers; and prevent infectious diseases and their consequences in this age group (Objectives 1, 2, 5) by helping people space their pregnancies.

For adolescents, Title X advances CDC's Achieve Healthy Independence objectives by promoting access to and receipt of recommended quality, effective, evidence-based preventive and health care services, and preventing STDs/HIV and unintended pregnancies and their consequences among adolescents (Objectives 17, 20). For adults aged 20–49, Title X furthers the objectives of CDC's Live a Healthy, Productive, and Satisfying Life by promoting access to and receipt of recommended quality, effective, evidence-based preventive and health care services, and promoting reproductive and sexual health for adults. Achieving these objectives in turn promotes social, emotional, and mental well-being for adults and prevents chronic and infectious diseases and their consequences (Objectives 24–28).

Healthy People 2010

There are Leading Health Indicators under Healthy People 2010[3] designed to measure Americans' health in the areas of greatest concern (HHS, 2000). Two of these indicators—responsible sexual behavior and access to health care—are particularly furthered by Title X family planning services.

Responsible Sexual Behavior. The indicator of responsible sexual behavior has the goal of reducing unintended pregnancies and STDs, including HIV/AIDS. The broad objectives for increasing responsible sexual behavior are to increase the proportion of adolescents who abstain from sexual intercourse or use condoms if currently sexually active and to increase the proportion of all sexually active persons who use condoms. There are numerous additional measurable objectives regarding increasing the use of contraception, increasing the proportion of pregnancies that are intended, and reducing STDs.[4] By making available a broad range of contracep-

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[3] Physical activity, overweight and obesity, tobacco use, substance abuse, responsible sexual activity, mental health, injury and violence, environmental quality, immunization, and access to health care.

[4] For example, increase the proportion of pregnancies that are intended (9-1); reduce the proportion of births occurring within 24 months of a previous birth (9-2); increase the proportion of females at risk of unintended pregnancy (and their partners) who use contraception (9-3); reduce the proportion of females experiencing pregnancy despite use of a reversible contraceptive method (9-4); reduce pregnancies among adolescent females (9-7); increase the proportion of sexually active, unmarried adolescents aged 15–17 who use contraception that both effectively prevents pregnancy and provides barrier protection against disease (9-10); increase the proportion of adults in publicly funded HIV counseling and testing sites who are screened for common bacterial STDs (13-12); increase the proportion of all sexually transmitted disease clinic patients who are being treated for bacterial STDs (chlamydia, gonorrhea, and syphilis) and who are offered provider referral services for their sex partners (25-19) (HHS, 2000).

tives, testing for STDs, and providing education and counseling regarding reproductive health, including abstinence, Title X arguably contributes to improving outcomes in this area, although it is not feasible to demonstrate this fully without long-term data (see the discussion in Chapter 5).

Access to Health Care. The indicator of access to health care encompasses objectives of increasing the proportion of persons with health insurance and a specific source of ongoing care and increasing the proportion of pregnant women who begin prenatal care in the first trimester. Title X clinics provide a source of ongoing care and help women obtain early prenatal care through early diagnosis of pregnancy, counseling, and provision of such clinical care or referral to other facilities.

> ***Finding 3-5.*** *The Title X program's key elements enable it to play a critical role in achieving the overall goals of HHS through the program's focus on (1) making contraceptive and reproductive health services accessible and affordable, thus helping to prevent unintended pregnancies and the spread of sexually transmitted diseases, and (2) promoting the health and social well-being of individuals and families by allowing individuals to plan for families.*

CONCLUSIONS AND RECOMMENDATIONS

The committee's findings on the clarity, consistency, and achievement of the goals of the Title X program support the following conclusions:

> *While the program's core goal and contributions to the broader goals of HHS are clear, its operational priorities have fluctuated over time without a clear rationale or grounding in science. This situation has created confusion among the program's grantees about the relative importance of the program's priorities and where to invest the limited resources available.*
>
> *The program has not engaged sufficiently in long-term strategic planning. Such planning is needed to produce directives that are evidence based and age appropriate, and to cover increasing costs.*
>
> *Although data do not currently exist to permit a comprehensive evaluation of the program, it has clearly delivered care to millions of people despite very limited resources. More funds will be needed, however, to serve the growing number of individuals of reproductive age who lack the means to obtain family planning care and to keep pace with changes and improvements in technologies.*

Based on the above conclusions, the committee offers the following recommendations:

> **Recommendation 3-1: Reassert family planning as a core value in public health practice.** *The Department of Health and Human Services (HHS) and Congress should recognize and support the Title X program as the leading voice for the nation's family planning effort, especially because the program's benefits apply not only to individuals and families, but also to communities and the nation.*

The program's leaders should clearly articulate the content and rationale for family planning care for all Americans and work with the Secretary of HHS and other agencies within HHS to disseminate these core ideas widely. They should stress the program's public health value and ties to various federal goals (such as Healthy People 2010 and the HHS Strategic Plan).

> **Recommendation 3-2: Reassert and commit to the original goals of the Title X program.** *HHS should reassert the original mission of the Title X program—helping individuals plan for pregnancy if they so desire, as well as avoid unintended pregnancy. HHS, the Office of Population Affairs (OPA), and their leadership, as well as Title X grantees, should be clearly dedicated to this mission and the goals of the Title X program, supportive of family planning as a critical public health intervention, committed to evidence-based practice, and knowledgeable about the field of family planning and reproductive health.*

The Title X program materials and the program's implementation are focused strongly on preventing pregnancy, often to the exclusion of the broader vision of family planning, which includes planning *for* families as well. An important part of achieving healthy pregnancies is addressing preconception and interconception health and care, increasing the knowledge and skills needed to avoid unintended pregnancy, performing infertility assessment, and screening and treating STDs and HIV/AIDS. This broader focus, while undoubtedly requiring more resources, is supported by CDC's recent emphasis on preconception and interconception care and planning for pregnancy. Among other benefits, this broader focus underscores the "family" in "family planning" and makes clear that the health and well-being of children and families depend in part on making family planning services and information available to adults and adolescents.

> **Recommendation 3-3: Develop and implement a strategic plan.** *The Office of Family Planning (OFP) should develop and implement a multiyear, evidence-based strategic plan that (a) reflects the mission of the Title X program and an understanding of its target population, as well as the field of family planning and reproductive health; (b) provides a vision for coordination, leadership, and evaluation; (c) addresses the family planning needs of individuals over the full reproductive lifespan; and (d) specifically references its evidence base. OPA's operation and ongoing management of the program should be guided by this plan and linked to ongoing evaluation.*

The strategic plan should be developed with input from a diverse group of experts assembled for the purpose. This group should include individuals who administer and operate programs funded under Title X; representatives of Title X clients; and a variety of outside experts and scientists with knowledge of the family planning field, reproductive health more broadly, public policy, and strategic planning. Attention should be paid to geographic, racial, ethnic, and gender diversity. It will also be important to include input from grantees as well as from federal agencies whose work relates to reproductive health, including CDC, the Agency for Healthcare Research and Quality (AHRQ), HRSA, and the Centers for Medicare and Medicaid Services (CMS). It would also be useful to solicit the views of other sectors whose work is—or should be—related in some way to family planning. These include, for example, the fatherhood and marriage communities, Head Start and other early intervention sectors, and those who work in the area of adoption as well as in family violence prevention. Many of these sectors have an important presence in states and communities, and many also are represented at the federal level in HHS, especially in the Administration for Children and Families. Because family planning has so many important benefits for children and families, such ties are potentially very important, and strategic planning offers a concrete vehicle for these sectors to learn more about and be supportive of each other. The strategic plan should accomplish at least the following:

- Clearly articulate the basic focus and components of the Title X program. Where practical and useful, core services and functions should be distinguished from those that are less central to fulfilling the program's mission of providing comprehensive family planning services, especially to low-income individuals. The plan should specifically address what services the program can realistically require grantees to provide given limited funding and the presence of multiple funding sources for family planning services (see also the section on funding of grantees and delegates in Chapter 4).

- Specify a process by which emerging issues, problems, and opportunities in the field of family planning will be identified in the future and how the program can make needed adjustments in an orderly fashion based on broad consultation and relevant evidence. This process must include explicit consideration of the cost (both in actual dollars and in terms of other services that would be forgone) and programmatic implications of any changes being seriously considered.
- Address the ways in which the program should find additional ways to link efforts and resources with those of other agencies within the federal government, including at a minimum CDC, AHRQ, HRSA, and CMS.
- Outline a robust, ongoing system for increasing the amount of scientific and research expertise brought to bear on the overall operation of the program (see also the discussion of this issue in Chapter 5).

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Program Management and Administration

As briefly outlined in Chapter 1, Title X of the Public Health Services Act established four areas for grants and contracts by the Secretary of Health and Human Services: family planning services, training, research, and informational and educational materials. Grants for family planning services can be made to states, and grants or contracts for these services can go to public or nonprofit private entities. Grants and contracts can also go to public or nonprofit private entities and individuals for training, research, and information and education. The budget for the Title X program was $300 million in fiscal year (FY) 2008. By statute, at least 90 percent of that appropriation must be used for family planning services.

The Title X program has been implemented through regulations (42 CFR 59; see Appendix C) that detail the requirements for recipients of Title X funds. The program is administered by the Office of Family Planning (OFP) (also referred to as the Central Office) within the Office of Public Health and Science, Office of Population Affairs (OPA), at the Department of Health and Human Services (HHS) and a decentralized system of 10 Regional Offices through which funds are provided to grantees in all states, the District of Columbia, and U.S. territories.

This chapter examines the administrative and management structure of the Title X program, the services and other program activities it encompasses, and its role in relation to other public or private funding sources. The information provided was drawn from Title X documents (for example, the Program Guidelines) and the commissioned paper authored by The Lewin Group, Inc. (see Appendix J this volume). In preparing this paper, The Lewin Group conducted a limited scan of published literature, government and private-sector reports, and other information. It also conducted a series of interviews with Central Office staff, regional program staff, and Title X grantees and delegates, focusing on the administration and management of the program. This chapter also draws on testimony provided to the committee at its public workshops by current and former grantees, as well as regional program staff, and on information obtained during the committee's site visits (see Appendix A for a description of the workshops and lists of participants). The first six sections review in turn the roles and relationships of the Central Office, Regional Offices, grantees, and delegates; the application process for grants and contracts; the types and distribution of grantees and delegates; and the services provided by, oversight of, and funding of grantees and delegates (including coordination with other federal sources of funding for family planning services). The chapter then presents the committee's assessment of the program's management and administration. The final section offers conclusions and recommendations.

CENTRAL OFFICE, REGIONAL OFFICES, GRANTEES, AND DELEGATES: ROLES AND RELATIONSHIPS

OFP, the Central Office, is responsible for the overall administration of the Title X program. As noted above, it is located in OPA, the primary division of HHS that advises the Secretary and Assistant Secretary for Health on reproductive health. OPA is headed by the Deputy Assistant Secretary for Population Affairs, whose responsibilities include implementation of the Title X program and the Adolescent Family Life and Research program, authorized under Title XX of the Public Health Services Act.

OFP develops national priorities and initiatives, policy, performance measures, budget requests, spending plans, and funding announcements for the program. It also coordinates and collaborates with other agencies within HHS (e.g., the Office of Women's Health, the Centers for Disease Control and Prevention [CDC], the Office of Minority Health); oversees and monitors grants and contracts that are national or cross-regional in scope (e.g., training grants regarding male family planning and reproductive health with the University of North Carolina, clinical training with the University of Missouri, and the National Training Center with Cicatelli Associates; research[1]; and the OPA Clearinghouse); responds to requests for

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[1] Research grants and contracts may be used for research in biomedical, contraceptive development, behavioral, and program implementation fields related to family planning. Research projects involve data analysis and related research and evaluation on issues of interest to the family planning field, as well as research on specific topics related to service delivery improvement. OFP has a standing announcement for service delivery improvement research, which encompasses quality of care, including the effectiveness, efficiency, timeliness, and equity of family planning services; reproductive health care of adolescents; reproductive health care of

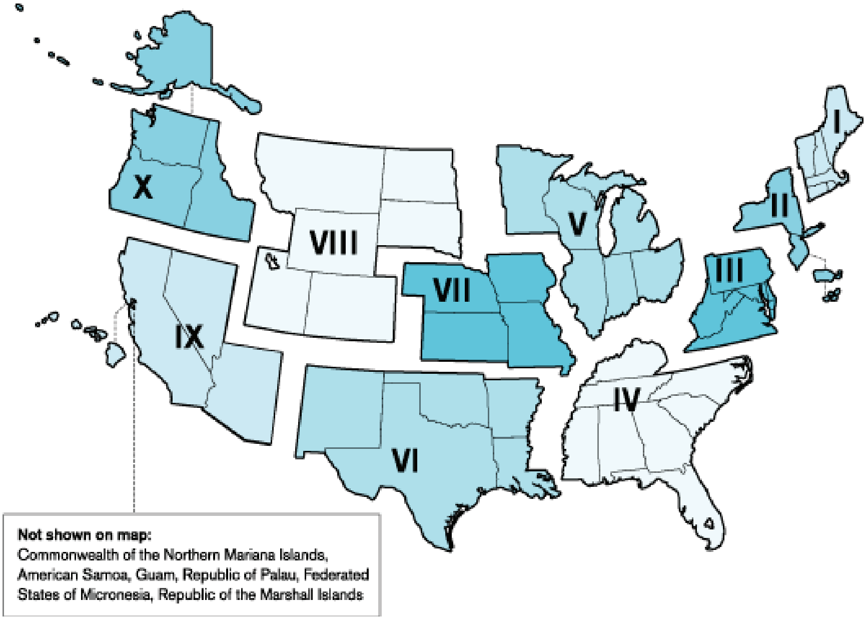

FIGURE 4-1 Public health service regions.
SOURCE: OPA, 2008b.

information; and provides leadership and direction for the Regional Offices that oversee family planning grants.

In each of the Public Health Service Regions (see Figure 4-1), a Regional Health Administrator (RHA) is authorized to oversee the Title X program at the regional level through a memorandum of understanding (MOU) with the Central Office.[2] The Central Office provides additional information and guidance to the Regional Offices through monthly conference calls and ongoing e-mail and telephone communication. It has developed an array

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males; family planning services to couples; organizational approaches to integrated services; translation of research into practice; increasing costs and their impact; and the effectiveness of Title X informational and educational activities. In addition to research covered by the standing announcement, research is currently being conducted through cooperative agreements with three grantees to analyze data on family planning needs and services over time using well-established formulas and databases; develop tools to assess and improve the quality of care in family planning clinics based on clinic data collection by a network of service providers; and analyze an array of national survey data sets to better understand the determinants of unintended pregnancy and childbearing.

[2] The RHA also oversees other HHS programs with a similar decentralized structure, such as those of the Office of Women's Health.

of Internet-based communication resources. Each Regional Office is also assigned a liaison at the Central Office who serves as a point of contact for any questions or issues.

Under the RHA, a Regional Program Consultant (RPC) carries out day-to-day program management and relationships with grantees, assisted by the regional family planning staff. The RPC selects grantees for family planning services and regional training,[3] subject to RHA and OFP approval, oversees and monitors their performance, and is the liaison between OFP and grantees, as discussed more fully below.

Grantee agencies, which are selected through a competitive process delineated in 42 CFR 59 and *The Program Guidelines for Project Grants for Family Planning Services* (OFP, 2001; see Appendix D), are responsible for delivering family planning services and developing networks of care. Grantees have legal and financial responsibility and accountability for the funds awarded and for the performance of the activities approved for funding (OFP, 2001).

Grantees may offer services directly and/or contract with delegate agencies to provide services under a negotiated, written agreement (OFP, 2001). Delegate agencies for family planning services must be appropriately licensed health care facilities that agree to provide services in accordance with Title X guidelines and applicable federal, state, and local laws; report data for the *Family Planning Annual Report* (FPAR); maximize third-party revenue (e.g., Medicaid); and participate in site visits by the grantee and the Regional Office.

If services are provided by a delegate agency, grantees are responsible for monitoring the quality, cost, accessibility, acceptability, and performance of the services provided under the grant to ensure compliance with Title X guidelines; making sure that required data and other reports are provided; and reviewing and approving delegates' informational and educational materials. Grantees and delegate agencies can operate one or more clinics and provide services other than family planning (e.g., general medical or prenatal care), although these other services are not funded by Title X (see The Lewin Group, 2009 [Appendix J], Figure J-1 and Table J-1, for the organizational structure of the Title X program and a summary of the responsibilities at each management level).

In 2006 (the last year for which national data are currently available), 88 grantees[4] and 4,480 clinic sites offered Title X family planning services,

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[3] Each region manages one General Training and Technical Assistance grant, with grantees selected through a competitive process. In some regions, grantees are public or private entities that focus exclusively on training and education or training centers developed within the organizational structure of a Title X services grantee (e.g., Center for Health Training—Region IX and Family Planning Council of Southeast Pennsylvania—Region III).

[4] For a listing of the grantees, see the 2007–2008 Directory (OPA, 2008a).

operating in nearly 75 percent of the counties in the United States (RTI International, 2008). Clinics that received Title X funding provided services to almost 5 million clients in that year (RTI International, 2008).

APPLICATION PROCESS

Grantee Requirements

The Title X statutory language, regulations, and Program Guidelines establish the requirements for entities to become grantees. By statute, public or nonprofit private entities can receive grants or contracts to offer family planning services, provide training, conduct research, and develop and distribute informational and educational materials.

Providers of family planning services must offer a "broad range of acceptable and effective medically approved family planning methods" and provide services without coercion and "in a manner which protects the dignity of the individual" (42 CFR § 59.5 [a]). If a clinic offers only a single method or an "unduly limited number" of methods, it cannot receive a grant but can participate as a delegate agency in a project (an activity supported by Title X funds) that offers a broad range of services (Program Guidelines, section 3.1). Projects that receive funds must provide for specified medical and social services, informational and educational programs, and training for personnel, as well as coordination with and referral to other health care providers (42 CFR § 59.5 [b]). (See the discussion below regarding services provided.)

Before applying for Title X funding, potential grantees must assess the need for family planning services in the service area. They must provide data regarding the population in need of the services, maternal and infant health statistics, barriers to care, existing services, and the need for additional services to meet community/cultural needs, as well as identify the high-priority populations and target areas for the services to be offered (OFP, 2001).

Grantee Selection

As noted above, grantees are selected through a competitive bidding process, in accordance with HHS objective review procedures.[5] The Pro-

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[5] HHS objective review is the Department's formal review and evaluation process: "an initial screening of an application is conducted to ensure it provides adequate information and complies with the requirements set forth in the agency's funding opportunity announcement. After the initial screening is complete, the application is submitted to an ad hoc independent panel of peers or experts, a standing review committee, or a group of field readers for review in accordance with the evaluation criteria included in the funding opportunity announcement.

gram Guidelines specify that applications must include a needs assessment; a narrative description of the project and how the applicant intends to conduct it; a budget and justification for requested funds; standards and qualifications for personnel and facilities; project objectives that are "specific, realistic and measurable"; and "other pertinent information as required" (OFP, 2001, p. 4).

To invite applications, OPA publishes Notices of Availability of Funds delineating these basic requirements, as well as additional information regarding priorities and issues that applicants should consider and evaluation criteria. The notices are published online at www.grants.gov.

Applications for service grants are submitted to the Office of Grants Management for Family Planning Services at the Central Office, but applications are reviewed and decisions made about the awarding of grants, their duration, and their amount at the regional level. The region's Objective Review Committee (ORC) evaluates applications according to the following criteria in the Title X statute:

- Whether the project plan provides for requirements set forth in Title X regulations (maximum 20 points)
- Extent to which services are needed locally (maximum 20 points)
- Adequacy of facilities and staff (maximum 20 points)
- Capacity to make rapid and effective use of federal assistance (maximum 10 points)
- Need of applicant (maximum 5 points)
- Availability of other, nonfederal resources within the community (maximum 10 points)
- Number of patients and number of low-income patients (maximum 15 points)

The same scoring methodology is used by all 10 regional ORCs, but there are differences in how the above criteria are applied and used in funding decisions.

While applications are reviewed using the ORC process, competition rarely occurs among grantees since there are few applications for any given award, and there is almost no grantee turnover (less than 2 percent per year). However, according to OFP, there is more competition currently than in the past. As discussed more fully below, 57 percent of grantees are governmental (state or territory departments of health), and 43 percent

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The review groups are made up of qualified subject matter experts with in-depth knowledge of program issues directly relating to the agency's mission. Once the application review is complete, written recommendations are provided to program management staff and the agency's leadership, who make the final determination regarding funding" (HHS, 2006).

are nongovernmental entities that have been providing services for several decades (RTI International, 2008). Most regions have added or replaced, on average, one to two new grantees over the past 10 years (The Lewin Group, 2009). Once the ORC review process has been completed, the RHA and RPC determine the duration of the grant and the amount of funding.

Grantee Funding

Each region receives a core allocation of regular service funds by the Central Office, based on a historical formula that measures each region's need according to three data sets—the Guttmacher Institute's Women in Need of Contraceptive Services and Supplies (hereafter referred to as Women in Need) (Guttmacher Institute, 2008b), census data, and the Bureau of Primary Care's Common Reporting Requirements.[6] The Lewin Group notes that precise information is unavailable on the formula and weighting of each data set (The Lewin Group, 2009).

In the early 1980s, the Central Office considered changing the regional allocations, but Congress included in its appropriations bill language that prevented such changes (see discussion, Methodology for Allocating Regular Service Funds, Appendix J). Since then, both the regular service funds and any subsequent budget increases have been allotted to each region according to its established percentage. In 2003–2004, OFP, at the request of the Acting Assistant Secretary of Health, reexamined its methodology for regional allocations (The Lewin Group, 2009). At that time, OFP determined that the allocations continued to reflect the need in each region accurately. No further efforts have been initiated to evaluate or change the basic funding formula.

The RHA and RPC have discretion to determine how funds will be distributed to grantees within their region. While they set forth a methodology for distribution of funds in the annual regional work plan, The Lewin Group (2009) reports that most methodologies were established some time ago and are used infrequently, as most grantees remain the same from year to year. It is only when a new grantee is added to a region that the methodology may be used. In all the regions examined by The Lewin Group, awards were based on the ORC score, the FPAR, and Women in Need. However, the regions varied in the weight they gave

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[6] The HHS Bureau of Primary Care's Common Reporting Requirements are the guidelines for annual reporting designed for community health centers. These requirements also were used as the guidelines for reporting on Title X until 1995, when the FPAR was instituted (The Lewin Group, 2009 [see Appendix J]).

to these data, and some grants were based largely on past awards to the grantees.[7]

According to the testimony of Title X grantees before the committee, grantees are largely unaware of how funding allocations are determined and are concerned about the lack of transparency, inequities in the allocations, and the data that are used. In testimony provided during one of the committee's public workshops, for example, a participant indicated that the distribution of funds in one of the Title X regions resulted in payments of less than $50 per user to some grantees and more than $200 per user to other grantees. The participant stated that "some degree of variation is both expected and appropriate, but a large discrepancy is not warranted," and that allocations appear to be influenced by political considerations. Another example cited is that one grantee may have two clinics and receive $400,000, while another grantee in the same region may support 140 clinics and receive $2.1 million. The Lewin Group (2009) notes grantee concerns about the lack of adjustment for population shifts and the limitations of basing allocations on data from Women in Need rather than on the number of people being served. These discrepancies lead grantees to believe that good performance is not being incentivized appropriately because some groups are receiving more money for serving fewer clients. (Such discrepancies may reflect geographic distribution, as it is more expensive to operate clinics in more remote areas. They may also reflect patient populations with different needs; for example, a homeless woman who uses drugs may require more and more expensive services than a 25-year-old married woman who is seeking contraception. However, data do not exist to support these or other explanations.) Greater transparency is also needed as to the criteria for determining the length of a grant (The Lewin Group, 2009).

In addition to regular service funds, grantees receive supplemental expansion funds, regional priority funds, directed supplements, other external funding for targeted programs, and special project funds. These funds

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[7] The Lewin Group reports that one region makes decisions on the allocation of regular service funds based on performance (using FPAR data [e.g., numbers of users, HIV tests, Pap tests] and grantee quarterly reports); a historical formula to assess the needs of the community (e.g., Women in Need, state and federal health statistics, needs assessments, National Survey of Family Growth); the number of Title X program users and the size of the grantee; and the resources and history of the grantee in the Title X program. Another region uses a more mathematical methodology for calculating regular service fund grants (or regional project priority funds) (50 percent of funding is based on the grantee's immediate past award, 30 percent on the number of women served previously who are at 100 percent of the federal poverty level and below [FPAR data], and 20 percent on Women in Need). A third region makes decisions about allocations by reviewing FPAR data on the clients/populations being served, the ORC score, the grant application plan, and the income level of the population served. Its decision-making process is more subjective. A fourth region simply allocates 90–100 percent of the immediate past award to the grantee (The Lewin Group, 2009 [see Appendix J]).

are allocated separately, using both competitive and other methods, and are awarded at different times during the year from regular service funds.

Based on its proposal and the amount of the final award, a grantee determines the delegate agencies and clinic locations and how much funding will be made available to each to ensure the best access geographically and by population. The Lewin Group (2009) reports that some grantees use the annual needs assessment to identify areas with an unmet need for family planning services, but that there is significant variability in the methodology used by grantees in distributing funds to delegates. Although most grantees pay delegates/clinics a standard base amount for basic costs plus a per patient rate, there is wide variation in those base amounts. The Lewin Group cites the examples of one grantee whose base amount is $80,000 and another whose base amount is $5,000, although these variations may reflect numbers of clients served. The percentage of the previous year's funding that is guaranteed by grantees also varies considerably. The Lewin Group provides examples of the different methodologies employed by Title X grantees (see Box 4-1).

The Lewin Group reports that in recent years, many delegates have attempted to simplify their methodologies for allocating grants to delegates/clinics. One means used was to include a per patient calculation in the formula. The Lewin Group notes that even delegates and clinics that experienced a loss of funds under a new methodology were supportive of the change because it introduced greater transparency and fairness into the allocation process and helped confirm that the right clients were being served.

GRANTEES AND DELEGATES: TYPES AND DISTRIBUTION

Grantees vary by state and include governmental entities (state, local, and territorial health departments), as well as nongovernmental entities, including hospitals, university health centers, nonprofit organizations (such as Planned Parenthood affiliates and faith-based organizations), community health centers (CHCs) of various types, independent clinics, and other federally qualified health centers (FQHCs).[8] Some states have only governmental grantees (e.g., Virginia, Colorado), some have only nongovernmental grantees (e.g., Pennsylvania, California), and others have a mix of the two (e.g., New York, New Jersey).[9]

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[8] FQHCs include all organizations receiving grants under Section 330 of the Public Health Service Act (e.g., CHCs, migrant health centers, health care for the homeless programs, and public housing primary care programs), certain tribal organizations, and FQHC look-alikes.

[9] For a list of grantees and delegates, visit www.hhs.gov/opa/familyplanning/grantees/services/fpdirectory07.pdf.

BOX 4-1
Examples of Methodologies Used by Grantees to Distribute Funds to Delegates

Grantee A

- Standard base of $500,000 paid to delegate agencies for basic costs

plus

- Per client allocation based on number of non-Medicaid patients seen in the previous year

Grantee B

- Women in Need (weighted 10%)
- Previous allocation (all health districts have been receiving money almost since the beginning) (weighted 50%)
- 3-year case load (numbers) (weighted 40%)
- Also apply 10% variability to accommodate shifts in case load

Grantee C

- Allocate more funding to agencies serving higher numbers of uninsured, low-income teenagers (less than 135% of the federal poverty level)
- Take into account all of a program's income from fees and public and private insurance
- Set goals for how much money agencies should be generating or used in the previous year, whichever is higher
- Use the per patient rate for allocations based on the number of patients expected to be seen and those actually seen (e.g., if a clinic is budgeted for $100,000 to see 1,000 patients, it is paid $100 for every patient seen; if it ends up seeing fewer patients, it owes money back; if it sees more patients, the grantee owes it money)

Grantee D

- 75% of funding is maintained (no delegate will lose more than 25% of funding; none one can increase funding by more than 33%)
- Base starting amount is $80,000
- Take into account:
  - — Number of users
  - — Number of warning letters (compliance)
  - — Number of special populations served
  - — Number of adolescents under age 17 served
  - — Chlamydia screenings (e.g., aligned with CDC guideline)

SOURCE: The Lewin Group, 2009.

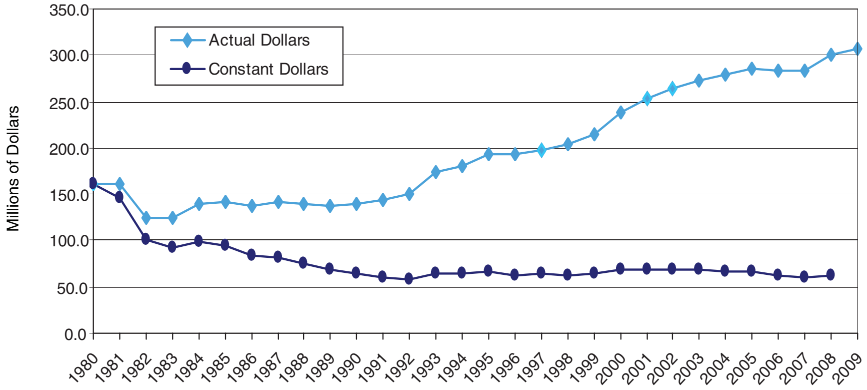

FIGURE 4-2 Estimated funding for Title X when adjusted for inflation, FY 1980–2009.
SOURCE: Sonfield, 2009. Reprinted with permission from unpublished tabulations from the Guttmacher Institute.

The number and distribution of grantees by type have changed significantly since the inception of the Title X program. In the 1980s, many HHS programs became block grants to the states. Although Title X did not become a block grant itself, funding was reduced (by approximately 23 percent in 1982; see Figure 4-2), and grant applications from state health departments received priority consideration. This shift resulted in a decrease in the number of grantees from more than 400 to less than 100, the majority of which were state grantees.[10] In 2006, 57 percent of grantees were governmental (state, local, or territorial departments of health), and 43 percent were nongovernmental (RTI International, 2008).

As noted earlier, some grantees provide family planning services themselves, but most contract with delegates in whole or in part. The delegates of state health department grantees may all be governmental entities, such as local health departments (e.g., Virginia), or they may be a mix of governmental and nongovernmental organizations. Nongovernmental delegates (of governmental and nongovernmental grantees) include hospitals, university medical centers, community action programs, CHCs, school health programs, and nursing service organizations. Some delegates provide only family planning–related services, while others offer a wider range of health care services. Some focus on particular client popula-

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[10] For example, the state department of health became the single grantee for the state of Texas in 1982, and 38 previous grantee organizations became delegates of that state agency, which at the time was not a direct provider of family planning services.

tions (e.g., teens, specific minority groups), while others serve broader populations.

As noted above, most current grantees have been Title X grantees for many years. Most of the state health departments that emerged as grantees from the consolidation of grants at the state level in the early 1980s have remained in that role. Among nongovernmental organizations, grantees are often refunded through many cycles. They have demonstrated understanding of the needs of the geographic area to be served, success in developing networks of care and serving patients in their communities, the interest and skills necessary to carry out the subcontracting required, and the ability to meet OFP standards in collecting data and monitoring the performance of delegates. Continuing with high-performing grantees ensures continuity in service delivery through a well-established and -functioning network. The lack of new applicants that characterizes most jurisdictions may relate to the numerous requirements that grantees must meet, including the infrastructure that must be provided; larger organizations that are able to manage these requirements are more likely to enter the process (Dalton et al., 2005). According to OFP, new grantees are usually selected when a new area of unmet need is identified or when one grantee is folded into another. A grantee rarely chooses to withdraw from the program (this occurs just once every 3–4 years) or is defunded for poor performance.

One of the key roles of grantees is to create networks of service delivery that can best meet the needs of the populations to be served; as noted, they usually do so through delegates that run clinics. While delegates or clinic sites may change over time, for the most part the clinics remain stable and provide a regular source of care for their clients. However, there has been no evaluation of the potential barriers experienced by service providers who are not part of the present network of providers in applying for inclusion.

Despite almost no additional resources being provided, the Central Office recently encouraged grantees to increase their competition for delegates. While some grantees engage in this process regularly, others do not. For example, state health department grantees whose only delegates are local health departments often argue that competition is unnecessary. Other grantees worry that, given the severely limited resources available, competition will cause delegates to drop out of the system when they reassess the cost/benefits of continuing as a Title X provider. There is no one right answer as to whether asking grantees to engage in competition for delegates is beneficial or necessary; the decision should be based on the individual situation of each grantee in light of the best way to meet the needs of the target populations and maintain and improve access to care.

SERVICES PROVIDED BY GRANTEES AND DELEGATES

The Title X regulations establish services that grantees must provide, while the Program Guidelines, last updated in 2001, specify in detail what those services should include and how grantees must maintain their operations (e.g., financial management; facilities and accessibility to services; personnel; training; reporting; the review of educational and informational materials; community participation, education, and project promotion; publications and inventions; and clinic management) (see also Chapter 3). The Program Guidelines apply to all clinical family planning services provided by a recipient of Title X funds, even if services are not paid for by those funds and even if those funds represent only a small portion of a grantee's or delegate's budget (see the discussion below). The Program Guidelines set a high bar in defining a comprehensive family planning program and establishing standards of care.

Mandated services include providing "clinical, informational, educational, social and referral services relating to family planning to clients who want such services," as well as "a broad range of acceptable and effective medically approved family planning methods and services on-site or by referral." The Program Guidelines specify that "projects should make available to clients all methods of contraception approved by the Federal Food and Drug Administration" (OFP, 2001, p. 13).

Clinical Services

Clinical services and their delivery are delineated in detail and include obtaining informed consent, taking a personal and family medical and social history, performing examinations and any necessary clinical procedures, conducting laboratory testing, performing follow-up, and making referrals. Specific provisions apply to fertility regulation, infertility services, pregnancy diagnosis and counseling, adolescent services, and identification of estrogen-exposed offspring, as well as related services such as gynecological services and screening and treatment for sexually transmitted diseases (STDs), including HIV/AIDS. The Program Guidelines specify what services in each of these areas should entail, along with some of the underlying reasons for their inclusion. Also delineated are specific services for females and males.

Education, Counseling, and Outreach

The Program Guidelines specify the provision of education and counseling services (section 8.1-2) (OFP, 2001). In the area of education, a range of topics is to be covered, from information about family planning and contraception to more general information regarding health screening, disease prevention (e.g., nutrition, exercise, smoking cessation), and reproductive anatomy and physiology. Counseling is required on the results of physical exams and laboratory studies; effective use of contraceptive methods and their benefits, efficacy, and possible side effects; return visits and emergency services; and STDs/HIV. The Program Guidelines require that education and counseling be documented in the client's health record. The strong emphasis on education and counseling sets the Title X program apart from other public funding sources and is thought by many providers and commentators to contribute to better informed and more satisfied patients (Gold, 2007). Grantees and delegates (as well as educators, trainers, health care providers, and members of the public) can obtain educational materials free of charge from the OPA Clearinghouse, which collects, develops, and distributes publications on family planning, sexual health, and reproductive health. (The Clearinghouse also provides a database and directory of family planning grantees, delegates, and clinics, and provides referrals to clinics and government sources of information pertaining to family planning and related health issues.)

The committee recognizes the value of educating and counseling clients. It is possible, however, that the numerous requirements in this area may be a hindrance to meeting the needs of individual clients. Clinics are required to provide education and counseling about all methods of contraception at every visit, even when a client already has a preference for a particular method or when certain methods are more appropriate than others given the information the client has provided about his or her circumstances. Moreover, excessive information may interfere with clients' ability to understand or retain the information they need (Mayeaux et al., 1996; Safeer and Keenan, 2005) and imposes a burden on clinic staff, whose time is already limited.

Educational materials used by Title X clinics must be approved by the grantee's and delegate's advisory committee before being distributed to ensure their suitability for the population or community and the purposes of Title X (42 USC § 300a-4(c), 42 CFR § 59.6). The review requirement applies to all materials, regardless of their source (including the OPA Clearinghouse) or their use by any other grantee. (See the discussion of this requirement in Chapter 3.)

Educational requirements for Title X providers are not limited to providing resources to patients. Title X clinics must also provide for "community education programs . . . to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial" (OFP, 2001, p. 12).

Several means are used to assess outreach and education activities. First, each delegate must set its own outreach and education targets in its annual work plan, and reports actual performance to the grantee annually. The grantee conducts an annual site visit to each delegate at which the materials and records of the activities are reviewed. This information is also reviewed during the OPA Title X site visits. In addition, all of the materials used in outreach and education efforts are required to be reviewed and approved by the Information and Education Committee (see the section below on information and educational materials). The grantee and the OPA site visit teams review these committee minutes and the related materials during each site visit. In addition, many grantees regularly convene the leaders of outreach and education at each delegate agency to share experiences and discuss what is working. In terms of reporting to OPA, the annual reapplications submitted by grantees contain progress reports from all delegates on their activities compared with their work plans, including the number and type of outreach and education activities. Considerable effort is made to evaluate the Title X outreach and education activities through attendance, the location of activities (to indicate target populations reached), and client satisfaction surveys. However, pre- and post-questionnaires to measure knowledge/attitude are used infrequently along with other quality measures, and there is some question as to whether the important education and outreach work of Title X is adequately captured in the program's overall evaluation plan.

> ***Finding 4-1.*** *There is a need to examine the adequacy and ease of use of tools that could be used by delegates to measure the quality of outreach and education efforts.*

OVERSIGHT OF GRANTEES AND DELEGATES

Grantee performance is monitored by the Regional Offices through Comprehensive Program Reviews (CPRs) performed every 3 years, annual site visits, and the FPAR. The CPR evaluates the grantee's financial, administrative, educational, and clinical structure and activities, using the Program Review Tool. It is conducted by the RPC; other regional staff; and outside independent consultants with expertise in the clinical, administrative, financial, and community outreach and information components of the Title X program. Consultants are professionals with direct experience with Title X and may previously have served, for example, as nurses in Title X clinics or have worked for grantee or delegate agencies. In addition to visiting the grantee's offices, the review team visits one to three delegate agencies and/or clinics overseen by the grantee (although grantees have primary responsibility for monitoring delegates and clinics).

The annual site visit serves as a follow-up on areas identified for improvement. It is generally conducted by the RPC and also, in some cases, by another staff member or one or more consultants if an outstanding issue relates to a consultant's area of expertise (e.g., grant management, finance). Grantees also make annual site visits to monitor the performance of delegates.

The FPAR is submitted by grantees, with input being provided by delegates as necessary regarding clients served and services provided (see Appendix G for the FPAR data elements). The report includes demographic, social, and economic characteristics of clients (including health insurance coverage and limited English proficiency); use of family planning methods; screening for cervical and breast cancer and STDs; utilization of family planning and related preventive health services; utilization of health personnel; and revenues. The FPAR is the only source of uniform reporting by all grantees.

There is wide variation in the methods used by grantees for data collection (The Lewin Group, 2009). Some grantees collect all data by hand. A few have developed their own electronic system with the assistance of the Central Office and the collaboration of all delegates and clinics. Several grantees prefer to contract with data service organizations. The data provided by these reviews and reports and their adequacy for monitoring and assessing the program are addressed in Chapter 5.

Grantees conduct a full needs assessment during their competitive application process (usually every 5 years) based on a very detailed compilation and analysis of community health and socioeconomic data. Examples of these data include a wide variety of health status indicators, birth rates, abortion rates, and public health insurance enrollment. The analysis is updated annually and helps inform decisions regarding priorities for the next year's activities.

FUNDING OF GRANTEES AND DELEGATES

Congress has mandated that 90 percent of Title X appropriations be used to support Section 1001, the establishment and operation of voluntary family planning programs. Thus in FY 2008/2009, $270 million of the $300 million appropriation will be used to support clinical services. As described above, those funds are distributed to the grantees, which may then distribute them to delegates.

Title X funds represent only a portion of grantee and delegate budgets, and for some only a small fraction. Program regulations stipulate that "no grant may be made for an amount equal to 100 percent for the project's estimated costs" (42 CFR §§ 59.7 (c)). Title X clinics may also receive funds from Medicaid, Maternal and Child Health (MCH) block grants (Title V of the Social Security Act, 42 USC § 501 et seq.), state and local appropriations, the State Children's Health Insurance Program, Social Services block

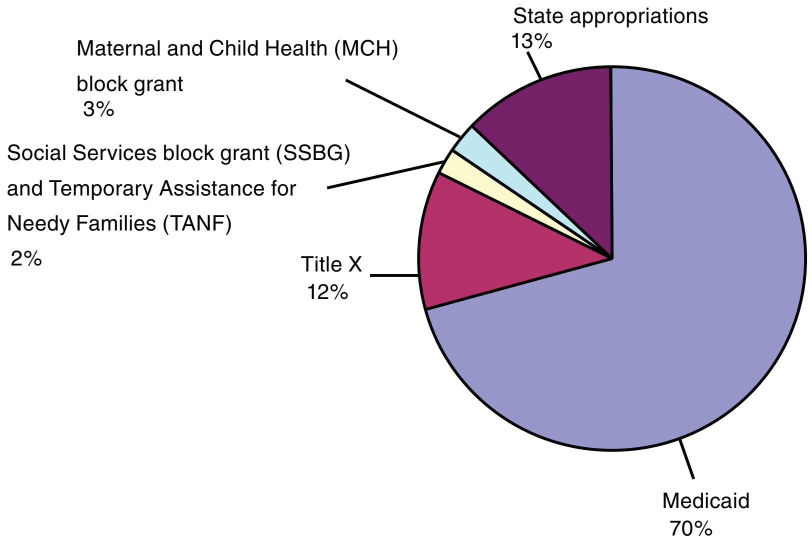

FIGURE 4-3 Sources of public funding for family planning services, 2006.
SOURCE: Sonfield et al., 2008a.

grants, and Temporary Assistance for Needy Families (TANF)[11] (see Figure 4-3). Most clinics also have patients who are covered by private insurance or who pay out of pocket for services,[12] and some receive charitable donations.

Non–Title X Family Planning Funding Sources

Medicaid and Medicaid Waivers

As noted earlier, while Title X remains the centerpiece of family planning, funding for family planning services through the Medicaid program now exceeds that from Title X. The federal government pays 90 percent of each state's Medicaid expenditures for family planning services and sup-

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[11] Social Services block grants, through Title XX of the Social Security Act, provide funds to state social services agencies to reduce individuals' dependence on public assistance and can be spent for family planning services. TANF, which was created by the Welfare Reform Law of 1996 and became effective July 1, 1997, provides assistance and work opportunities to low-income families by granting states the funds and flexibility to develop and implement their own welfare programs.

[12] Even though Title X was created to provide services to low-income women, services are available to all, regardless of income.

plies and requires only a 10 percent match with state funds. In FY 2006, Medicaid funding for family planning services was estimated at $1.3 billion for *all* health care provider settings (Sonfield et al., 2008a). Of this amount, Title X clinics alone received $320 million in Medicaid payments, slightly more than the $262 million allotted in Title X grant funds (RTI International, 2008).

As discussed in Chapter 2, in 1993, the Medicaid Waiver program was instituted to allow states to waive normal Medicaid eligibility requirements to cover family planning services for those low-income individuals who otherwise would not qualify. To date, 27 states have implemented some form of the Waiver program (Guttmacher Institute, 2009). A 2003 federally funded evaluation of the Medicaid Waiver program in six states reported significant cost savings to both the federal and state governments (Gold, 2004). Moreover, a 2006 study estimated that, if the Waiver program were implemented nationally, federal and state savings of $1.5 billion annually would be realized by the third year (Frost et al., 2006).

In addition to its macro-level benefits, the Medicaid Waiver program has had a positive influence programmatically by enabling Title X grantees and providers to serve greater numbers of clients. Some stakeholders believe that Title X and the Medicaid Waiver program complement one another as a more comprehensive effort to serve those in greatest need (Gold, 2007). The Waiver program has provided a dependable source of revenue for clinics, helping to ensure overhead. Without reimbursement from the Medicaid Waiver program, many Title X clinics would not be able to continue operation given constant increases in the costs of staff and supplies. However, unlike Title X, the Waiver program has a strict set of requirements and limits coverage to the core services that are needed to promote effective contraceptive use, rather than more comprehensive reproductive health (Sonfield et al., 2008b).

Section 330

Section 330 of the Public Health Service Act governs the operation of FQHCs, such as CHCs, which provide a broad scope of primary and preventive health care services, including reproductive health services (BPHC, 2008b). CHCs are private, nonprofit, community-based health centers located in high-need or medically underserved areas that function as major safety-net providers for low-income and/or uninsured Americans. More than 1,000 CHCs operate more than 6,000 delivery sites in all states, territories, and the District of Columbia. Since 2000, federal investments in CHCs, most often by the Bureau of Primary Health Care (BPHC) at HHS, have doubled to more than $2 billion today (BPHC, 2008c). BPHC funding of family planning services was estimated at $5.8 million in FY 2006 (RTI

International, 2008). By law, CHCs are required to offer prenatal care, screening for breast and cervical cancer, voluntary family planning, and other basic services provided by an obstetrician or gynecologist. In 2007, 95 percent of CHCs provided family planning services. Some CHCs receive Title X funding to supplement their budget for reproductive health services. However, CHCs operate according to an independent set of requirements, some of which do not fit well with Title X.

Maternal and Child Health and Social Service Block Grants

The MCH (Title V of the Social Security Act) and Social Services (Title XX of the Social Security Act) federal block grants are provided directly to and controlled by state governments. MCH grants typically go to state departments of health, while Social Services grants go to state social services agencies (Sonfield et al., 2008a). Federal law permits states to use both grants for family planning services. However, in using MCH block grant funding, states are required by law to contribute 3 state dollars for every 4 federal dollars; there are no such requirements for Social Services funds. In FY 2006, MCH and Social Services block grants provided close to $23 million and more than $28 million, respectively, for family planning services (RTI International, 2008).

Although traditionally, family planning was an important part of the MCH block grant program's overall mission, the federal government has encouraged state MCH programs to move away from supporting direct patient care, including that for family planning (Gold and Sonfield, 1999). Most states now use MCH grants to fund population-based services (e.g., surveillance, immunizations) or program infrastructure.

In contrast, the Social Services block grant program has tremendous flexibility to provide support across the spectrum of social services programs (Gold and Sonfield, 1999). In the past, family planning was the only medical service for which it was applied as a supplement to other funding. However, severe budget cuts in the mid-1990s left the program financially crippled, and as a result, most clinics receiving Title X funding no longer receive Title XX funds. In some states, funding lost from the Social Services grant cuts was replaced by TANF grants (also provided directly to states) used to administer the state's welfare programs. Similar to Social Services grants, TANF funds could be used to supplement funding of family planning programs. However, TANF requirements are quite stringent, and many grantees therefore eliminated use of the grants for their family planning programs. In fact, none of the Title X grantees currently receive Social Services or TANF funds. For family planning services overall, TANF grants amounted to $10.5 million in FY 2006 (RTI International, 2008).

State Funding

Some states provide limited funding for family planning activities through state appropriations outside the context of Medicaid or the block grants. Specifically, many states' Medicaid agencies use state appropriations to provide medical services, including contraceptive services, to people who do not meet Medicaid eligibility criteria (e.g., certain immigrants). One study estimated that in 2006 independent state appropriations for family planning services reached $241 million (Sonfield et al., 2008a). Five states (California, Florida, New York, North Carolina, and Oklahoma) accounted for 57 percent of all state appropriations.

For example, in addition to federal Title X funding, New York State has two programs for family planning services. The Family Planning Benefit Program covers family planning services for low-income citizens and those with satisfactory immigration status (SIS). The Family Planning Extension Program covers services for women losing their Medicaid coverage after a pregnancy. This program provides 2 years of family planning coverage for low-income citizens and those with SIS. Using state-only funds, the Family Planning Extension Program provides family planning for undocumented women, but only during the postpartum period. No other state has a comprehensive plan to provide family planning services to undocumented women with state-only funding.

Some clinics also receive limited funding from local governments. In states with Waiver programs, some Title X grantees believe that county or local support was better prior to the program's implementation. After its implementation, many local governments cut supplemental budgets based on the perception that clinics had sufficient funding with the new federal dollars, forgetting two important facts: (1) clinics are serving more clients because of the Waiver program; and (2) the Waiver program does not reimburse clinics for 100 percent of costs, especially when a visit goes beyond use of contraception.

Generally, state appropriations account for at least 10 percent of all family planning funding in 20 states. It is important to note that, for close to 30 years (since 1980), state appropriations for family planning services have remained flat.

Summary

In summary, Medicaid now pays for approximately 70 percent of publicly funded family planning services, with Title X accounting for approximately 12 percent, state and local governmental funds 13 percent, MCH block grants 2 percent, and Social Services block grants and TANF 3 percent (Guttmacher Institute, 2008a) (see Figure 4-3). Yet while Title X represents a small proportion of public funding for family planning services, it plays a unique role. It covers services that other payers do not, clients who do not qualify for other coverage and cannot afford services, and expenses associated with program development and service delivery that other sources do not pay for directly. Providers mentioned these benefits of the program repeatedly during the committee's site visits.

Title X Funding

Additional Services Covered by Title X

Clinics receive most of their non–Title X funds through fee-for-service reimbursement programs that pay only for specific clinical services. Title X funds are not subject to such limitations and can be used to cover additional clinical services,[13] office staff, the provision of contraceptives and other pharmaceutical products, and client education and counseling that are not reimbursed by other sources. In this way, Title X can complement these other sources to ensure the full range of services and activities necessary to optimize outcomes for all clients. Title X also provides funds for grantees and delegates to carry out community education and outreach and other activities that meet local needs.

Populations Covered by Title X

With Title X funds, clinics are able to provide reproductive health care services to people who otherwise would be unable to access or afford them. These include people who do not qualify for government-supported medical care (such as Medicaid, MCH, Social Services block grants, TANF), who lack insurance, or who face other legal or practical impediments to obtaining care.

Critical to achieving the program's goal of providing family planning services to lower-income individuals is making those services available at no cost to persons with incomes up to 100 percent of the federal poverty level and at discounted prices to those whose income is less than 250 percent of that level (42 CFR § 59.5(a)(8)). In most states, eligibility for publicly funded health care programs for adults, such as Medicaid, requires significant documentation[14] and income limits are set much lower than 250 percent of the poverty level. The median U.S. income eligibility threshold for unemployed parents, for example, is 41 percent of the federal

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[13] Examples are treatment of STDs or urinary tract infections, which is not included in the Medicaid family planning expansion in some states.

[14] Medicaid established new documentation requirements in 2006.

poverty level, while the median threshold is 68 percent for working parents (The Henry J. Kaiser Family Foundation, 2009).

As increasing numbers of people lack health insurance (see Chapter 2), Title X clinics also provide access to family planning services for those who may not be at the lowest income levels but are unable to afford health care. Because of the relative openness of the program to low-income individuals as compared with the other sources and providers of family planning services, RPCs and grantees reported that access to family planning and annual screening for STDs are better in Title X clinics. (While the majority [67 percent] of clients of Title X clinics had family incomes at or below the federal poverty level[15] in 2006, and 90 percent of clients were at or below 200 percent of that level [RTI International, 2008], the regulations stipulate that persons whose income exceeds 250 percent of the poverty level are to be charged "fees designed to recover the reasonable cost of providing services" [42 CFR §§ 59.5 (a)(8), (b)(5)].)

Eligibility for Title X funding also requires that services be provided without respect to "religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status" (42 CFR § 59.5(a)(4)). Title X clinics therefore meet the reproductive health care needs of adolescents, men, recent legal immigrants, and the undocumented,[16] who might otherwise forego family planning services.

The provision of services to adolescents is a particularly important aspect of Title X. Most teens have limited knowledge of health care services, and many will not seek their parents' involvement when they want to obtain contraception. They are also likely to seek care only when they feel that their confidentiality will be protected (Ford et al., 2004; English and Ford, 2007). By ensuring confidentiality and not requiring parental consent (although minors must be encouraged to involve their parents), Title X clinics play a special role in providing care for adolescents. The clinic services also are especially suited to the special needs of adolescents. Most teens lack basic information about their health in general and reproductive health and birth control in particular, and many do not receive this information in their schools. The education and counseling provided by Title X clinics fill this important gap. In one-on-one encounters at Title X clinics, teens receive information they do not receive elsewhere. Because Title X personnel are sensitive to issues affecting teens' attitudes and influences on their sexual behavior (including their level of sexual experience, possible early childhood sexual exposure or abuse, and peer pressure), they

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[15] In 2009, the federal poverty level for the 48 contiguous states and the District of Columbia was $10,830 for a family of one and $22,050 for a family of four.

[16] Legal immigrants are not eligible for Medicaid for their first 5 years of residency.

can effectively discuss issues facing these young patients and spend more time with them than providers in other settings.

Other Expenses Covered by Title X

Title X grants are not limited to specific expenses but allow recipients flexibility to pay for overhead and infrastructure (facilities, equipment, information technology), staffing and staff training, supplies, and costs associated with needs assessments and reporting. This support is critical to keeping the clinics functioning and to meeting patients' needs. The area of staffing is particularly important. Title X has covered not only medical staff, but also educators, social workers, staff with expertise in providing culturally and linguistically appropriate services, and staff who can work outside of normal business hours so that clinics can be open in the evenings or on weekends.

> ***Finding 4-2.*** *While family planning services are funded through a variety of sources, which may vary from state to state, Title X plays a special role by covering services that other payers do not, clients who do not qualify for other coverage and cannot afford services, infrastructure, and expenses associated with program development and service delivery that other sources do not reimburse.*

ASSESSMENT OF THE PROGRAM'S MANAGEMENT AND ADMINISTRATION

This section provides the committee's assessment of the strengths and weaknesses of the Title X program's management and administration, and challenges faced by the program in providing services to its target populations.

Central and Regional Offices: Structure and Relationships

As discussed earlier, the Central Office establishes the framework for the Title X program, its policies, and its priorities. Although Regional Office staff expressed concern about the frequent changes in OPA leadership (see Chapter 3), grantees view the senior OFP staff as dedicated and experienced, with both substantive knowledge of family planning service delivery and institutional memory regarding program operations and requirements. The OFP staff have provided a high degree of continuity and stability for the program, and regional staff regard them as responsive, communicative, and supportive (The Lewin Group, 2009). RHAs/RPCs value their regular communications with the Central Office by e-mail and telephone, although grantees reported that more written guidance would be helpful. Reliance on verbal communication has sometimes resulted in confusion or additional time required to obtain clarification (The Lewin Group, 2009).

In addition to the senior professional staff, each Regional Office is assigned a liaison at the Central Office who serves as the first point of contact for any questions or issues. These liaisons vary in their level of experience with and knowledge of the Title X program, and this can affect their ability to assist their respective Regional Offices (The Lewin Group, 2009).

Regional Offices and Grantees: Structure and Relationships

Staff and participants at the federal, regional, and state levels generally view the decentralized, regional structure of the Title X program as beneficial. It allows program administration to be responsive to local conditions and the specific needs of communities (including differences in populations and cultures); strengths, needs, and weaknesses of grantees; and state political climates. The program structure also allows for the development of training that addresses the needs of regional staff.

The relationship dynamic between RPCs and grantees varies widely among regions. According to The Lewin Group (2009), many grantees find their relationship with their RPC to be positive and transparent. Regular communication is maintained, and the RPCs serve as communication sources of programmatic and financial information. Other grantees perceive less openness in their relationship with their RPC. Communication is less frequent, and grantees believe their messages to the Central Office are diluted, and that their RPC does not advocate adequately for them.

Attention from the Central Office to problems of grantees and RPCs is also inconsistent. The RPCs discuss problems and other issues among themselves (often during a conference call prior to their monthly conference call with the Central Office). However, the issues raised fail to be resolved because the necessary leadership from the Central Office is not forthcoming (The Lewin Group, 2009).

Placing most of the decision-making authority with the RPCs results in a number of inconsistencies in how policies and regulations are interpreted and audits and reviews are conducted.[17] Regions also vary in the degree of

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[17] Independent consultants, who, as noted earlier, often participate in the CPRs, do not receive uniform training in carrying out these reviews. Therefore, they may differ in the way they interpret the Title X guidelines and grade grantees (e.g., how clinics should ask for client donations, what increments are used on the sliding fee scale). According to The Lewin Group (2009), the result is inconsistencies in how grantees are evaluated, not only for that CPR, but also for their performance longitudinally and against other grantees regionally and nationally.

coordination with other programs (such as the Office of Minority Health and the Office of Women's Health, both of which also are under the direction of the RHA) (The Lewin Group, 2009). Finally, the level of expertise of regional staff varies. RPCs do not receive formal training for their position and differ in the extent of their experience with the delivery of family planning services.

> ***Finding 4-3.*** *The regional system for managing and administering the Title X program often serves varying needs across regions effectively and is an important function of the program, but there is room for improvement.*

Grantees and Delegates: Service Delivery

The network of clinics supported by Title X delivers crucial family planning services for communities and populations that are underserved and would otherwise lack medical care. According to the 2002 National Survey of Family Growth, a Title X–supported clinic was the primary source of reproductive care for 9.6 percent of female respondents who obtained any sexual or reproductive health care service. A greater number, 12.8 percent, of women who received such a service obtained it primarily from a public clinic that received Title X funding (Frost, 2008).

Interviews during the committee's site visits revealed that clinic staff generally have both family planning expertise and dedication to the mission of Title X. Their knowledge of their communities enables them to develop and effectively deliver the range of services required by the Program Guidelines in ways that meet local needs. They are also in a position to work with schools and other health and social service agencies in their localities to ensure that target populations are reached and that clients' other needs are met.

> ***Finding 4-4.*** *The network of clinics supported by Title X is a critical part of the health care safety net in the United States.*

The available services, however, may not be able to meet all of the family planning needs of clients or meet them in a timely way. Some clinics cannot provide all the required Title X services in one visit. For example, during a site visit to a local health department that receives Title X funds, staff mentioned the need to refer patients to other facilities for HIV testing or have them return when such testing was being provided in the STD clinic. Some providers, particularly in rural areas, are not open on many or most days. Similarly, because of funding and staffing challenges (discussed more fully below), many clinics reported that they cannot offer services to all who want them, and even if they can provide appointments, clients may have to wait longer than the 2 weeks stipulated by the Title X program.

Challenges for Grantees

Title X grantees face numerous challenges that impact their ability to provide services and that may be difficult to overcome because of the current management and administrative structure. These challenges relate to the following:

- Overall funding limitations and rising costs
- Management of multiple funding sources
- Program guidelines
- Procedural requirements
- Communication
- Staffing
- Informational and educational materials
- Challenges of serving populations that are the focus of Title X
- Provision of culturally appropriate care
- Provision of services that meet client needs

Funding Limitations and Rising Costs

As is true for much of the nation's stressed health care system, funding for the Title X program is severely constrained. Shortly after the program was established, Congress dramatically expanded its funding, which ultimately peaked in constant dollars in 1980. Since then, however, funding has declined significantly (see Figure 4-2 earlier in this chapter). According to findings from surveys of Title X grantees, as well as testimony heard by the committee, funding and rising costs are by far the greatest challenges facing grantees and have been for many years (Sonfield et al., 2006). While funding has increased in actual dollars, it has not kept pace with the increased costs for salaries and benefits, contraceptives and other pharmaceuticals, clinic supplies, laboratory tests, infrastructure (e.g., rent, utilities, information technology), or insurance, or with the increased numbers of people seeking services (Sonfield, 2009). Taking inflation into account, funding for Title X in constant dollars was 62 percent lower in FY 2008 than in FY 1980 (Sonfield, 2009).

A 2005 survey of 14 Title X grantees revealed that their expenditures on contraceptive supplies increased by approximately 26 percent between 2001 and 2004, while their Title X grants increased by approximately 11 percent (Sonfield et al., 2006). As a result of rising prices, some clinics have created waiting lists for some contraceptive methods (AGI, 2000). A small sample of Title X programs also reported that their expenditures on diagnostics more than doubled between 2001 and 2004 (Sonfield et al., 2006); however, there was notable variation in these expenditures among respondents, with some reporting decreases and others increases of 150 percent or more. Under the Program Guidelines, a Title X clinic must "maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients" (OFP, 2001, p. 28). Clinics report that this is one of the strengths of the program (Gold, 2008), but that increased costs have limited the types of contraceptives available.

While the shortfalls in funding have forced clinics to be more efficient and cut waste, the committee learned from its site visits and the testimony of grantees and delegates that they have also led to more limited clinic hours, the closing of clinic sites, reduced availability of certain (more expensive) types of contraceptives, reduced staffing, curtailed outreach efforts, and reduced community and clinic educational programs. New funds made available typically are directed at new mandates or increased numbers of users and cannot be used to address funding gaps in existing programs. As one clinic representative told committee members:

> The main problem with the program is that there are not enough funds. The problem was underscored this year when additional funds would be made available only if they were associated with an increased volume. Given that they were running very close to the bone this did not seem sensible.

> ***Finding 4-5.*** *Title X has inadequate financial resources to provide comprehensive care to patients and communities at a high level of professional standards or to exercise leadership in family planning.*

Many Title X clinics obtain contraceptive products through the Office of Pharmacy Affairs' 340B drug pricing program[18]; consortia, cooperatives, or other groups of individual providers (such as Planned Parenthood); or state governments that negotiate discounted prices for bulk purchasing. According to the testimony of grantees, the ability to access less expensive contraceptives and other pharmaceuticals through the 340B program entices clinics to join and remain in the Title X program.

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[18] The 340B drug pricing program, established in 1992, limits the cost of covered outpatient drugs to certain federal grantees (such as Title X grantees), FQHC look-alikes, and qualified disproportionate share hospitals (42 USC § 340B). Under the program, the Pharmacy Services Support Center and Prime Vendor Program assist eligible entities with information and technical assistance and drug price negotiation services, respectively. Testimony of Ann P. Ferrero, HHS, HRSA, May 19, 2008.

While the 340B program does provide considerable cost savings, Title X clinics noted many problems in maintaining continuity of products because the program revises its list of available drugs quarterly and often obtains products with short expiration periods. One clinic representative noted that price fluctuations and frequent changes in the availability of certain drugs can lead to increases in the overall costs of providing services because clients must return to the clinic to change their prescription.[19] Moreover, clients' adherence and satisfaction may suffer if products or methods they prefer or with which they are familiar became unavailable (see Appendix F). The administrative cost of contraceptive purchasing is also an issue for many grantees. For entities participating in the 340B program, for example, the quarterly revisions mean they must constantly monitor the list of available products.

Costs also have prevented clinics from using the most advanced contraceptives and diagnostics as they are almost always more expensive than older versions. For example, providers noted that the relatively high cost of intrauterine devices, Implanon, and other more modern contraceptives (for both the product and related clinic services) put these products out of reach for many clinics even though some clients prefer them, and they are more effective and reliable in the long term. For cervical cancer screening, many clinics are limited to regular Pap tests because of the higher cost of the newer liquid-based test, which reduces the number of tests that need to be repeated (ACS, 2006).[20] The recently developed test for human papilloma virus and the vaccine to prevent it likewise are too expensive for most grantees and delegates to provide.

There are ways to purchase reduced-price drugs. For example, federal purchasing programs are used by the Department of Veterans Affairs and CDC (for the Vaccines for Children program and for diagnostics for HIV and chlamydia).

> ***Finding 4-6.*** *The costs of drugs and diagnostics are high and rising. The Title X program is not optimizing its leverage to contain these costs.*

Management of Multiple Funding Sources

As discussed earlier, Title X clinics rely on funds from a number of sources, necessitating coordination and management of multiple funding sources at the federal, state, and local levels to operate a comprehensive

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[19] A product may become unavailable after just a few months since the list changes quarterly.

[20] According to American Cancer Society guidelines, screening should be done every year with the regular Pap test or every 2 years using the newer liquid-based Pap test.

reproductive health program. In general, grantees reported that they have found ways to make funding sources work together. They also reported that free-standing and private-sector clinics are perceived to face greater challenges in coordination of funding.

The inclusion of a financial audit in the CPR provides adequate oversight of the coordination and use of multiple funding sources. Financial consultants that serve on the review team evaluate accounting records and the management of funding. The consultants are regarded highly for their ability to identify issues (such as a grantee not funneling fee-for-service reimbursements back into the Title X program) and to provide constructive and educational guidance to grantees. From the standpoint of funding, RPCs and grantees identified no obvious areas of duplication or lack of coordination.

Most coordination-related issues pertain to the differences among programs' operational requirements, which can affect access to care. Especially pronounced are the differences in requirements associated with program administration and clinical services among Title X, CHCs (under federal 330 rules), and the Medicaid Waiver program. RPCs and grantees see no need to have different rules for these three programs. Moreover, because Medicaid is a state-driven program, each state may implement different rules for use of the funds. For example, in Arizona, the Medicaid Waiver program is used to cover postpartum services (including sterilization services) for individuals at or below 100 percent of the federal poverty level. In California, the Medicaid Waiver program has been instituted with much broader application for those at 200 percent of the poverty level (Sonfield et al., 2008b). Because of these variations, Title X may serve different purposes in different states, adding to the complexity RPCs may experience in reviewing grant applications for their region. In general, the solution has been for RPCs to work closely with grantees to improve program management, but there is great need to better define strategies that can enhance program coordination to ensure that all funds are used most efficiently.

While there is always uncertainty as to when appropriated funds will be available (because of frequent delays in passing appropriations bills before the start of the fiscal year), the Title X program could alleviate some administrative burden by better coordinating the funding cycles for various Title X funds (such as regular and supplemental expansion funds). Coordinating the many requirements for the multiple federal programs involved in the provision of family planning services could reduce the administrative burdens and costs borne by grantees and delegates. These requirements include sliding fee schedules; documentation related to income, residential address, and citizenship; verification of third-party insurance coverage; and reporting (see also the section on procedural requirements below and the section on coordination of Title X and other sources of funding for family planning services in Appendix J). Additional factors posing administrative challenges include different state requirements for parental consent for treatment of minors, equity requirements (not every program pays for every service), restriction of services under the Medicaid Waiver program (individuals with third-party health insurance of any kind are disqualified from participation in the program, even if that insurance exempts coverage of family planning services [Sonfield et al., 2008b]), and limited access to community-based providers for individuals covered under Medicaid managed care (see the above-referenced section in Appendix J). As the Centers for Medicare and Medicaid Services moves states toward the medical home model of care coordination among providers, it is unclear how family planning services will be affected. Some states, such as Iowa, are developing collaborative networks of safety net providers, including CHCs, free clinics, rural health clinics, family planning agencies, maternal and child health clinics, and local departments of health, to ensure broad access to and coordination of care (Iowa Department of Public Health, 2008). While family planning services are an included benefit under Medicaid rules, other states may promote the use of primary care providers for such services.

The Program Guidelines

In specifying required medical services, the Program Guidelines state that for the physical assessment of a female, "an initial complete physical examination, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts, abdomen, pelvis, and rectum should be performed" (OFP, 2001, p. 21). Clinics must also "provide and stress the importance of . . . blood pressure evaluation; breast exam; pelvic examination; . . . pap smear; colo-rectal cancer screening in individuals over 40; and STD and HIV screening, as indicated" (OFP, 2001, p. 21). The Program Guidelines additionally require counseling regarding these preventive services and establish time frames for their provision. This broad range of services is mandated because "for many clients, family planning programs are their only continuing source of health information and clinical care" (OFP, 2001, p. 21).

While this range of services is certainly important for the overall and long-term health of patients at various points in their lives, it goes beyond what is essential for effective family planning. For example, breast and colorectal cancer screening is valuable for early detection of these cancers, but these services are not an essential component of reproductive health care, especially for people early in their reproductive years. According to testimony heard by the committee (and discussed in Chapter 3), the breadth of the requirements in an environment of limited resources creates a tension between providing broad preventive care to fewer clients and offering targeted family planning services to a greater number.

The Program Guidelines also include services that may not be appropriate for all clients and are not in accord with current professional clinical recommendations. The cancer screening requirements apply to all patients at a Title X clinic, regardless of age or risk factors. This means, for example, that adolescents seen at Title X clinics must have breast, rectum, and pelvic examinations and Pap smears within 6 months of becoming a patient, even though relevant abnormalities are rarely found in adolescents. Likewise, the American College of Obstetricians and Gynecologists (ACOG) does not recommend cervical cytology screening for young women until approximately 3 years after initiation of sexual intercourse, but no later than age 21 (ACOG, 2006). Some Title X clinic staff expressed concern to the committee about this requirement; they believe that patients should not be required to have pelvic examinations before initiating hormonal methods as this requirement creates a barrier for some individuals.

Other screenings prescribed in the Program Guidelines that are inconsistent with professional clinical guidelines include yearly Pap tests for many adult women over age 30 and colorectal screening. ACOG recommends that for "women aged 30 years and older who have had three consecutive negative cervical cytology screening test results and who have no history of cervical intraepithelial neoplasia (CIN) grade 2 or CIN 3, are not immunocompromised and are not HIV infected, and were not exposed to diethylstilbestrol in utero may extend the interval between cervical cytology examinations to every 2 to 3 years" (ACOG, 2003). Similarly, the American College of Physicians' clinical guidelines for colorectal cancer screening and surveillance prescribe that "screening programs should begin by classifying the individual patient's level of risk based on personal, family, and medical history, which will determine the appropriate approach to screening in that person. Men and women at average risk should be offered screening for colorectal cancer and adenomatous polyps beginning at age 50 years" (Winawer et al., 2003).

During the committee's site visits and in workshop testimony, RPCs and grantees also noted that under the Program Guidelines, there is little room for regions or grantees to implement innovative approaches or to experiment with potential program improvements (see also The Lewin Group, 2009). Any deviations from the required services, including those stemming from service providers' professional judgment, can result in negative comments during site visits and reviews.

By not reviewing and updating the Program Guidelines for clinical, behavioral, and educational services to reflect the most current professional standards, OPA is creating a critical problem for health professionals in Title X clinics that represents a serious failing of the program. Providers are being asked to choose between offering services that comply with the Program Guidelines and those that are best professional practices. The delay in adopting the most up-to-date standards means that the program not only fails to serve patients as well as it should, but also imposes unnecessary costs in some instances.

> ***Finding 4-7.*** *Requirements outlined in the Program Guidelines include services that may not be appropriate for all clients and are not in accord with current evidence-based professional clinical recommendations. Some of the requirements go beyond what is essential for effective family planning. These unwarranted requirements result in inefficient use of limited resources and may also deter individuals from seeking care.*

A possible policy direction is making the Title X guidelines (updated as the committee recommends) the standard used by all federal health programs, including the 330 program. The committee notes further that many Title X delegates (e.g., CHCs) provide comprehensive care and have other sources of income that should be used to pay for services beyond those essential for effective family planning. Likewise, Title X recipients that focus on providing family planning should develop networks to refer patients who have other health care needs.

Procedural Requirements

Procedural requirements of OPA and the other entities that govern the functioning of Title X grantees present additional administrative challenges. These include procedures for applications and allocations, program review, and reporting.

The OPA requirements for proposals are the same for governmental and nongovernmental entities. As noted earlier, in many states the state health department is the sole grantee. Requiring them to use the same competitive bid process as that required for nongovernmental entities imposes undue costs on the state health departments and appears unnecessary given their defined roles and long-term participation in the program. State grantees have recommended that OPA consider different allocation processes for the different types of applicants. They have suggested that state agencies could provide a revised justification for renewed funding and that OPA could review a state's performance during a project period to determine whether any funds were misspent and ensure that funds were received by the right delegates/clinics (The Lewin Group, 2009). Absent indications that a state health department is having problems delivering care, providing grants to state agencies for longer uniform periods (e.g., 5 years instead of the variable 3–5 years) would also allow for better long-term planning and cost savings. Long-term nongovernmental grantees could make similar arguments. The committee believes a simplified application process for grantees demonstrating continued good performance would be beneficial, as would providing funding for longer periods. In light of the considerable stability of the service delivery network that has been created through Title X, these measures would reduce the administrative burden for all involved.

Most Title X grantees must deal with multiple entities regarding program requirements, funding, licensing, and oversight. Inconsistencies in requirements add to the administrative burdens and costs faced by clinics. For example, when a delegate is an FQHC (330 program), there are different fee scales and different data collection requirements for Title X and the 330 program. These inconsistencies are burdensome for patients as well; for example, it appears that in certain situations, some women must submit information so the clinic can check to see which funding source covers them, as well as which exams, requirements, and paperwork are necessary. The requirements of these programs could and should be coordinated.

Communication

Some grantees have found their relationship and communication with the Central and Regional Offices to be a source of frustration. While OFP communicates regularly by e-mail and conference calls with RPCs, who in turn communicate with grantees, the process does not provide grantees with information they desire about program decisions. In addition, grantees do not believe that they have adequate input into such decisions or that their concerns reach the Central Office. This lack of transparency regarding decisions by the Central Office and RPCs is a major concern for grantees. Changes in service requirements and new priorities are announced without the grantees having an opportunity to offer their views or provide information about the impacts of the changes on current services. As noted previously, grantees also believe they are inadequately informed about how funding decisions are made.

In addition, grantees and delegates reported that they would like more feedback on their performance on a regular basis and more constructive advice on how to improve. While the CPRs provide an opportunity for communication about performance, some grantees said the process would be more useful in improving their programs if it had a less detailed focus and if it were less punitive and more educational and supportive in nature (The Lewin Group, 2009).

The FPAR and other information submitted to OFP can also provide a basis for feedback to grantees and delegates. However, OFP does not inform grantees about how their performance compares with that of others or provide them with information on how other grantees have addressed problems they have encountered. Grantees would like more opportunities to learn from other grantees about successful program implementation approaches that might be replicated.

> ***Finding 4-8.*** *There is a lack of transparency and communication regarding how decisions affecting program requirements are made and how funding allocations and the duration of grants are determined.*

Staffing

Staffing is a pressing concern for many grantees and delegates. It is likely to become even more so given the shortage of and competition for trained medical personnel in most areas of the country, as well as the impending retirement of many nurses and nurse practitioners who staff the clinics, the increasing cost of salaries and benefits, the need for and cost of continued professional training (Murray, 2002), and efforts to promote nursing training at the doctoral level (AACN, 2008). There has also been a trend toward increased training for entry into practice for nurse practitioners, who make up a significant proportion of medical professionals. As with other professions (such as pharmacy, which now requires a "practice doctorate"), and on recommendations from the Institute of Medicine (2003), a "doctor of nursing practice" is slated to be the training requirement for new nurse practitioners by 2015. This requirement is expected to involve one additional year of training over the length of training for the current masters-prepared nurse practitioner. The enhanced skills gained through this training will benefit patients who rely on Title X services for much of their comprehensive health care by better equipping these clinicians with "interdisciplinary, information systems, quality improvement and patient safety expertise" (AACN, 2006, p. 5, 2008). At the same time, there are some unanswered questions about this additional training requirement, such as whether it will exacerbate shortages in the available nurse practitioner workforce and how it might affect the cost of hiring nurse practitioners.

The limited pool of qualified professionals has been an ongoing problem for the Title X program.[21] This problem will become greater with the

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[21] Earlier, Title X funded certificate Women's Health Care Nurse Practitioner education programs located in geographically diverse regions (at Planned Parenthood in Philadelphia, Emory University Medical School in Atlanta, University of Texas Southwestern Medical School in Dallas, and Harbor UCLA in Los Angeles) to provide access for participants from Title X programs. These programs graduated more than 4,000 nurse practitioners. They closed in 2005 because of changes in licensing and accreditation, which mandated a masters degree in

growth in demand for Title X services, including services that can meet the needs of increasingly culturally and linguistically diverse populations (see the section on providing appropriate care below).

Recruitment and retention is the most pressing concern. Most clinical care is provided by nurse practitioners who have advanced nursing training at the master's level (CDC, 2004). In 2006, midlevel health care providers, who include nurse practitioners, physician assistants, and certified nurse midwives, made up 51 percent of the full-time medical staff at Title X–funded clinics (RTI International, 2008). As heard in testimony before the committee, those clinics compete for medical professionals with other types of health care organizations, but generally are not in a position to offer competitive salaries and benefits. The shortage of personnel is particularly acute in rural areas.

The costs of recruiting and retaining staff who can address the needs of Title X clients, including those who can provide culturally appropriate care, have increased. In a 2001 Guttmacher investigation of 12 Title X clinics, respondents indicated that the demand for language assistance for clients with limited English proficiency increased their costs of doing business (Gold, 2003). According to the 2006 FPAR, such clients represented 13 percent of Title X users (RTI International, 2008). Staff that can assist these clients are needed at every level of service, from intake to clinical encounters. However, increased competition, particularly for nurse practitioners, makes attracting these individuals to family planning clinics increasingly difficult.

> ***Finding 4-9.*** *Title X is currently facing difficulties in recruiting and retaining staff who can meet the increasingly complex needs of diverse populations. These needs will grow in the future.*

Informational and Educational Materials

During the committee's site visits, in testimony provided by grantees and delegates, and in the Membership Survey of the National Family Planning and Reproductive Health Association (NFPRHA), several issues regarding informational and educational materials were raised. These issues include the manner in which materials developed by the OPA Clearinghouse are reviewed, the duplicative review by a delegate's advisory committee after review by the grantee responsible for the delegate, and delays or

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nursing for nurse practitioners. Subsequently, OPA/Title X funded two programs—an online clinical specialty course designed to provide clinical competency–based family planning education for nurse practitioners (offered until 2006) and the current preceptorship program, which is offered through the National Clinical Training Grantee.

other problems in obtaining payment for materials ordered from outside sources. Grantees and delegates suggested that materials used in a related program might be distributed without additional review. Concerns were also expressed about the ability of the advisory committees (rather than professional health educators or public health personnel) to select culturally, linguistically, and literacy level–appropriate materials. Grantees and delegates indicated that some of the OPA Clearinghouse materials fail to meet those criteria—deficits that should be rectified at the Clearinghouse level.

Challenges of Serving Populations That Are the Focus of Title X

With growth in the overall population and expected parallel growth in the low-income population, cutbacks and gaps in health insurance, the large number of adolescents with unmet needs for family planning services, increased prevalence of STDs, and other societal changes (discussed in Chapter 2), the demand for family planning services has increased. While funding is a core issue that affects the ability of Title X clinics to provide care for all who seek it, the situation poses particular challenges concerning the special needs of target populations such as adolescents, men, and people with limited English proficiency. Common to all of these groups is the need for specialized outreach to overcome barriers to their seeking clinic services. Grantees noted problems in meeting the costs of outreach and having staff available for the purpose given the personnel cutbacks resulting from limited funds. One grantee interviewed during a site visit lamented the lack of funds for advertising or conducting studies to determine what works to bring people to the clinic. Some grantees and delegates have tried to reach target populations by developing partnerships with other social and human service providers or schools, but they would like to do more.

Adolescents pose special problems because of their lack of knowledge about reproductive health and the services they might use. As discussed above, the Title X program provides education and counseling to address this deficiency and meet the needs of individual patients. If these beneficial services are to be made available, resources must be committed to ensure sufficient time for provider–patient sessions and appropriate staff training.

Another challenge regarding the provision of services to adolescents is the required clinical examination, in particular the requirement that providers perform a pelvic exam within 6 months of the patient's first visit. As discussed above, grantees expressed concern that this requirement may deter teens from seeking services or continuing as clients. Under ACOG's current guidelines, adolescents may make several gynecological visits before they have an internal examination, during which time they may develop trust in the provider.

The "ABC" approach to counseling for HIV prevention (Abstinence, Being faithful, and Condoms) is also viewed by some grantees as an impediment to the provision of services to adolescents. Respondents to the NFPRHA survey indicated that the ABC approach is unrealistic, noting the difficulty of providing effective counseling on abstinence to sexually active teens who are seeking contraceptives. ACOG takes a different approach, arguing that having a confidential discussion about the patient's general health, dating relationships, and intimacy and sexual activity and encouraging the sharing of information are important for providing appropriate health care to adolescents (ACOG, 2004).

Many studies have found that, especially for teens, the most effective approach to preventing unintended pregnancies is to address broader aspects of young people's lives, such as their investments in education, civic service, and youth development. In a review of more than 150 studies, for example, researchers from Child Trends identified approaches that have had a positive impact on teenagers' reproductive health behaviors. Among these approaches were those that combined sexuality education for older children with positive activities such as participating in voluntary community service and youth development programs (Manlove et al., 2002). Kirby (2007) found that comprehensive programs, which include education about delaying sexual activity and decreasing the number of sexual partners as well as information about contraception, were considerably more effective overall than those focused on abstinence-only education in encouraging positive reproductive health behaviors and showed no significant negative effects. In addition, many private foundations are investing in research aimed at identifying ways to improve the family planning and reproductive health care available to low-income women, including teens.

Although men represent a small percentage of Title X clients (approximately 5 percent), adolescent and young adult males are at particular risk for STDs and sexual activity that results in unintended pregnancies, and benefit from receiving formal instruction about birth control methods. Studies have shown that efforts to target this population can significantly improve knowledge of contraception, pregnancy risk, and sexual responsibility, which presumably leads in turn to positive reproductive health impacts for males and females (Danielson et al., 1990; Armstrong et al., 1999; Brindis et al., 2005). Efforts are under way at clinics around the country to explore means of reaching out to men in need of reproductive health services (Brindis et al., 1998). Yet Title X providers disagree about the emphasis the program should place on serving men, as opposed to focusing on the primary goal of meeting the contraceptive needs of women.

Provision of Culturally Appropriate Care

Offering culturally and linguistically appropriate care and education raises many concerns for Title X clinics, ranging from providing medical care that is in accordance with a patient's cultural norms to communicating effectively with patients who have limited English proficiency. The demand for assistance to clients in many languages is increasing in communities nationwide (Gold, 2003). Culturally sensitive interpreters can provide translation to ensure that adequate and essential communication takes place between a patient and his or her provider. Evidence indicates that using such trained interpreters not only improves communication but also increases patient satisfaction and health outcomes, while quality of care is compromised when needed interpreter services are not provided (Flores, 2005). As discussed in Chapter 3, HHS's *Guidance Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* also requires agencies that receive federal funding from HHS to ensure that clients with limited English proficiency have access to services the agencies provide. However, the cost of providing such interpreters (or the alternative of "language lines") is high if staff members are unable to speak the patients' languages. Recruiting and retaining staff, including clinicians who can provide culturally and linguistically appropriate care, is a continuing challenge. Grantees are concerned, too, that some of the Title X educational requirements may not account for cultural differences or language barriers (NFPRHA survey 4).

Provision of Services That Meet Client Needs

The Program Guidelines establish requirements for the package of services that all patients must receive. As discussed above, however, grantees are concerned that the requirements force them to offer too many unnecessary and time-consuming services that patients may not want, and therefore do not allow them to individualize services to meet patients' needs in line with scientifically based best practices. In the area of education and counseling in particular, clinic personnel should have the flexibility to make decisions regarding issues to discuss, taking into account current evidence-based guidelines and professional norms. They should be able to focus on the information pertinent to a patient's condition or concerns in a personally and culturally sensitive way. Such a patient-appropriate approach would also allow staff to devote more time to responding to patients' questions, rather than delivering a litany of prescribed information that may not be relevant.

Although counseling is labor-intensive, some patients may require counseling about a range of life issues and circumstances that impact on their reproductive health to enable them to be more effective contraceptive users. For example, when working with teenagers, providers should assess and counsel across a range of life issues that directly affect sexual behaviors and contraceptive use. This assessment should include a careful review of the circumstances surrounding sexual behavior and choice of partners, the ability to negotiate with partners, substance use and its impact on contraceptive practice, and whether an abuse history or sexual assault leaves a teenager more vulnerable. Among adult women, too, many of these factors, particularly abuse and intimate partner violence, require assessment and may result in the need for counseling and referral. While providers are asking for greater flexibility and individualization in their approach to patient-centered care, it is important for the Program Guidelines to ensure that patients receive appropriate services based on a proper assessment of their history and current circumstances.

Serving low-income working women presents additional challenges in many localities, given that, according to testimony heard by the committee, limited funding and staffing have resulted in restricted hours for some clinics. For these women, many of whom cannot take time away from their employment, the lack of evening or weekend hours creates a barrier to care. The committee notes that some clinics do use Title X funds to cover the added costs of operating outside of normal business hours.

Some grantees and delegates would also like to do more, either on-site or through off-site clinics, to meet the needs of other high-risk populations, such as the homeless, substance users, those with disabilities, and those who are incarcerated. However, such expanded services would require additional resources. The program structure and funding also limit the ability of Title X clinics to provide important services relevant to healthy pregnancies and birth outcomes. These services include pre- and interconception care (to improve, respectively, the health of women who are considering pregnancy and attention to issues between pregnancies that may affect birth outcomes).[22]

CONCLUSIONS AND RECOMMENDATIONS

The committee drew the following conclusions about the management and administration of the Title X program:

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[22] These services include prevention and management, emphasizing health issues that require action before conception or very early in pregnancy for maximal impact, such as obesity/weight management, adult immunizations, supplements (folic acid), mental health care, and treatment of infectious and chronic diseases (e.g., hypertension, diabetes) that could impact pregnancy and fetal health (CDC, 2006; Lu et al., 2006).

The management structure and administration of the program generally work well, but could be improved.

Specific areas for improvement include overall funding levels, pharmaceutical and laboratory testing costs, birth control method availability, administrative burden, the evidence base for and flexibility of the Program Guidelines, transparency and communication, staffing, shortages, and informational and educational materials.

The committee offers the following recommendations for achieving these improvements:

Recommendation 4-1: Increase program funding so statutory responsibilities can be met. *Title X should receive the funds needed to fulfill its mission of providing family planning services to all who cannot obtain them through other sources and to finance such critical supplemental services as infrastructure, education, outreach, and counseling that many other financing systems do not cover. Consistent with legislative intent, financing for the program must also support research and evaluation, training, the development and maintenance of needed infrastructure, and the adoption of important new technologies.*

Recommendation 4-2: Examine and, if appropriate, improve methods of allocating funds. *OFP should carefully examine and, if appropriate, improve the system used to allocate funds from OFP to regions, regions to grantees, and grantees to delegates. The transparency of these funding processes should be improved so that program participants and the public are aware of the processes for making decisions about funding allocations at each level and for commenting on those decisions.*

Recommendation 4-3: Improve the ability to purchase drugs and diagnostics at reduced prices by consolidating purchasing sources. *OFP should work with the various public and private purchasing sources for drugs and diagnostics for Title X clinics to develop a coordinated or consolidated purchasing program.*

Recommendation 4-4: Improve the continuity of products provided to clients of Title X clinics. *The 340B drug pricing program should revise its list of available drugs less frequently and make an effort to obtain drugs with longer expiration periods. Product continuity would also be enhanced by the consolidation proposed under Recommendation 4-3.*

Having a consolidated pharmaceutical program for Title X grantees would provide potential cost savings through bulk purchasing, as well as improved continuity of products. Having a more consistent and cost-effective program would benefit both clinics and patients.

> **Recommendation 4-5: Reduce the administrative burden on Title X clinics.** *OPA should work with other HHS agencies supporting family planning to coordinate patient fee schedules and record-keeping and reporting requirements. OPA should also adopt a single funding cycle, where possible, for the awarding of grants.*

Title X clinics bear a significant burden in budgeting for and managing their multiple sources of funding, a burden exacerbated by the multiple funding cycles for the awarding of grants. Coordination of patient fees and record-keeping and reporting requirements for the numerous federal programs involved and establishment of a single funding cycle could reduce this administrative burden, as well as associated costs. Improvement in coordination for various federal programs may require changes to legislation directed at involved agencies.

> **Recommendation 4-6: Adopt a single method for determining criteria for eligible services.** *The federal government should adopt a single method of determining criteria for eligible services (for example, which services are available at which percent of the federal poverty level), what copays if any are required, and how clinics should report clients seen. The current inconsistencies create an atmosphere that discourages coordination of Health Resources and Services Administration, Centers for Disease Control and Prevention (CDC), and other programs with Title X.*

> **Recommendation 4-7: Review and update the Program Guidelines to ensure that they are evidence based.** *OFP should review the Program Guidelines annually and update them as needed to reflect new scientific evidence regarding clinical practice. In so doing, OFP should establish a mechanism for obtaining expert scientific and clinical advice in a systematic, transparent way. Expertise should be drawn from the clinical, behavioral, epidemiological, and educational sciences. In addition, it is important to enhance the flexibility of Title X clinics so they can meet the needs of individual patients while adhering to evidence-based guidelines and practices.*

Because the required services extend beyond those included in evidence-based professional guidelines, resources are not being used most efficiently, and the program is missing opportunities for patient-centered care. In addition, outdated Program Guidelines can result in clinical practices that fail to meet current standards for medical care and for education and counseling. The latter include recommendations for screening and provision of information about disease prevention (such as those of the U.S. Preventive Services Task Force, ACOG, the American College of Physicians, the American Cancer Society, and the American Academy of Pediatrics), for education (such as those of the Sexuality and Information and Education Council of the United States), and specifically for the delivery and safe use of contraceptives (of the World Health Organization in its Medical Eligibility Criteria). OFP has issued service orders (for example, regarding cervical cytology) that direct grantees and delegates to use guidelines of professional societies. These service orders are not always disseminated promptly, however, and in any event leave delegates with conflicting requirements. Incorporating such evidence-based recommendations in a timely way and promptly communicating them to grantees and delegates (through, for example, regular conference calls as well as the Internet in order to disseminate up-to-date information to all levels of program staff) could improve the effective and efficient delivery of services under Title X, as could allowing greater flexibility in service provision. Finally, timely updated guidelines could be used for all federal health care programs. In this way, clinical and quality advances achieved in Title X could be used to inform other HHS family planning efforts.

> **Recommendation 4-8: Increase transparency and improve communication.** *OFP should increase the transparency and communication of information at all levels of the program. Such information should encompass methods for allocating program funds, the process for establishing annual program priorities, suggestions for program improvements, lessons learned through research supported by Title X and other programs, and how data are used. This information should be disseminated both vertically and horizontally.*

In light of the limited funding and opportunities for regional or national meetings, the Internet could be used to facilitate communication among grantees and RPCs across regions. Greater use of online systems could help a great deal in disseminating information, such as updates on clinical practices, from the Central Office to RPCs, grantees, and delegates, as well as exchanges among grantees and from grantees to both RPCs and the Central Office. For example, this type of communication is used by the program's national and regional training grantees, which have Internet-based service, resource, and training tools.[23] A website could be developed to provide

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[23] See http://www.hhs.gov/opa/familyplanning/grantees/training/index.html.

information about policies, service requirements, changes in the Program Guidelines, and program improvements, as well as training for staff. Information useful for quality improvement could be included (see Chapter 5). Interactive components could facilitate communication at all levels.

> **Recommendation 4-9: Assess workforce needs.** *With the help of an independent group, OFP and other agencies within HHS should conduct an analysis of family planning workforce projections for the United States in general and for the Title X program specifically. The study should assess current and future workforce training needs and the educational system capacity necessary to meet those needs. The study should also identify ways in which these needs can be met and financed.*

Given the current and predicted personnel needs throughout the program, national efforts to address the problem are appropriate. NFPRHA has suggested a workforce study to develop strategies for addressing recruitment and retention issues, including alternative staffing options. Outreach and collaboration with nurse practitioner training programs should be explored. As efforts are made to revise state licensure laws to require practitioners to have more advanced training (National Council of State Boards of Nursing, 2008), they must be fully evaluated for their impact on available staffing, and plans must be made to deal with shortages. To address the immediate problem, efforts should be made to ensure that current staff members receive the training needed to maintain their professional credentials under state laws and professional certification programs. The Title X training priorities have focused on program-specific issues to help grantees comply with changes in program priorities (see Chapter 3). Greater effort should be made to develop training modules that not only inform participants about program issues, but also meet continuing education requirements for nurse practitioners, certified nurse midwives, and others who staff Title X clinics. This goal could be advanced through the priorities for training in the MOU between OFP and the Regional Offices. New means of providing training should also be explored. Internet-based programs could make training available to a broader audience at lower cost. Specific attention also should be given to clients' language issues when considering workforce needs.

> **Recommendation 4-10: Assess the local review of informational and educational materials.** *OFP should assess whether the benefits of local review of all educational materials outweigh the burdens, including costs. OFP should develop processes that eliminate duplicative reviews while also ensuring that consumers have an opportunity for input at either the local or national level.*

5

Collection of Data to Measure Program Outcomes

Under the auspices of the Office of Population Affairs (OPA), the Office of Family Planning (OFP) uses a variety of measures to provide programmatic information that is both timely and responsive to a wide range of stakeholders concerned with the program's scope, quality, and reach. This chapter addresses the ability of these measures to assess the program's goals, processes, and outcomes. It begins by summarizing the Office of Management and Budget's (OMB) Performance Assessment Rating Tool (PART) evaluation process for Title X. It then presents a series of evaluation questions and an evaluation framework used by the committee to assess the sources and types of data collected by OFP. Next is a review of current sources of data for program assessment. The committee's evaluation framework is then used to assess OFP's measures and goals. This is followed by an assessment of the data collection infrastructure for the Title X program. The chapter ends with conclusions and recommendations for improving the Title X evaluation system as a whole, drawing on recommendations from earlier groups as well as this committee.

PART PROCESS FOR EVALUATING TITLE X

There have been several evaluations of specific aspects of the Title X program, including both government reviews and evaluations conducted by nongovernmental organizations at the request of OPA (see Appendix H for a summary of findings and recommendations from these evaluations). The present study was prompted by OMB's evaluation of Title X under the PART process (OMB, 2005) (the PART is presented in Appendix E). The program received a rating of Moderately Effective (rating categories include Results Not Demonstrated, Ineffective, Adequate, Moderately Effective, and Effective). The highest scores were achieved in the areas of Program Purpose and Design and Program Management, with lower scores in the areas of Strategic Planning and Program Results/Accountability. The committee concurs that strategic planning is an area for improvement (see the discussion and recommendations in Chapter 3).

As required by the OMB evaluation process, OFP defined three long-term annual performance measures, described in Chapter 3: (1) increasing the number of unintended pregnancies averted by providing Title X family planning services, with priority for services to low-income individuals; (2) reducing infertility among women attending family planning clinics by identifying chlamydia infection through screening of females aged 15–24; and (3) reducing invasive cervical cancer among women attending family planning clinics by providing Pap tests according to nationally recognized standards of care. In addition to defining these three long-term measures, OFP had earlier developed, implemented, and established targets for all annual and long-term performance goals, including its efficiency measure, which is to maintain the actual cost per client below the medical care inflation rate. These measures, along with quality-of-care indicators, are assessed in this chapter.

COMMITTEE'S EVALUATION QUESTIONS

The committee examined two key issues. The first is what data collection infrastructure is currently in place for the Title X program. The second is how the data collection effort and its infrastructure can be improved. The following questions, which emerged from the committee's charge, the PART process, and previous program evaluations, framed the committee's assessment of the measures around these two issues:

- What types of data are being used by OFP for monitoring and assessing the Title X program?
- Does the existing portfolio of data collection approaches adequately capture Title X's activities?
- What modifications should be made to the data collection system and planning?

COMMITTEE'S EVALUATION FRAMEWORK

To answer the above questions, the committee developed an evaluation framework that focuses on Title X's primary mission—to provide individuals the information and means to exercise personal choice in determining the

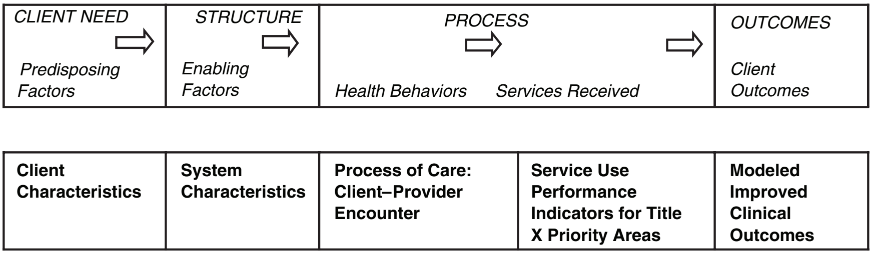

FIGURE 5-1 Conceptual framework for Title X evaluation.

number and spacing of their children (see Figure 5-1). The committee's conceptual framework structures this final chapter. Discussion of how the framework can be used to evaluate the program is detailed below.

The committee believes such a framework can help establish a more integrated and comprehensive evaluation approach for Title X by linking the program's assessment to its stated goals and priorities. Consistent with Title X's commitment to ensuring adequate quality of care, the committee's evaluation framework draws on well-tested models for evaluation of the quality and utilization of health services—Donabedian's Quality Model (Donabedian, 1968, 1980) and Andersen's Health Care Utilization Model (Andersen and Davidson, 2007). The use of this framework offers an opportunity to place the discussion of quality of care within the broader context of national and various state health policies and Title X financing as enabling factors for the Title X program, patient care, and education and outreach.

The goal of the framework is to help OFP maintain a cohesive and proactive evaluation program focused on quality improvement and the ability to document outcomes. The framework provides a logic model emphasizing measures linking (1) the clients to be served; (2) the resources, facilities, and personnel required to serve them (structure); (3) the services actually provided (process); and (4) the results of those services (outcomes). Having such a model allows planners to determine returns on various investments or interventions. The committee acknowledges the challenging task of identifying, at a minimum, meaningful and prioritized short- and longer-term outcomes that are valid indicators and can readily be measured in a clinic setting. As with any data collection, it is necessary to recognize the resource and staff costs associated with complete and timely data collection at the local level. Moreover, longer-term outcomes may be difficult to capture adequately without significant investments in client tracking and data collection.

The committee's framework encompasses:

- *Client need, or predisposing factors* (column 1)—These factors include characteristics of clients that motivate them to use services and that Title X should consider in defining its profile of services.
- *Structure, or enabling factors* (column 2)—These system characteristics enable patient access to health care services and facilitate the delivery of quality services important to client outcomes.
- *Process, or health behaviors/services received* (column 3)—These process factors pertain to the interaction between clients and providers, as well as the services received and how they align with established service use performance indicators for the Title X priority areas.
- *Outcomes* (column 4)—These factors refer to improvements in clinical outcomes that occur as a result of clients' interactions with the system of services and outreach.

Depending on the evaluation question, measures relevant to the Central Office, Regional Offices, grantees, delegates, clients, populations in need, and barriers to care may be included in the data collection. For example, Title X's Central Office may be interested in answering questions pertaining to overall trends in the numbers and profiles of clients served across the country. At the delegate level, there may be interest in questions that pertain to comparisons among similar types of delegates or to contrasts among different types of delegates in various geographic areas.

CURRENT SOURCES OF DATA FOR PROGRAM ASSESSMENT

OFP currently uses a variety of data sources for monitoring and assessing the Title X program (see Chapter 4). The *Family Planning Annual Report* (FPAR) is the primary source of annual, uniform reporting by all Title X grantees (see Appendix G for the FPAR data elements). Information from the FPAR is important to OPA for several reasons. First, FPAR data are used to monitor compliance with statutory requirements, regulations, and operational guidance set forth in the Program Guidelines, which include giving priority in the provision of services to low-income persons (Section 1006(c) of Title X of the Public Health Service Act, 42 USC § 300) and ensuring that Title X grantees and their subcontractors provide a broad range of family planning methods and services (Section 1001(a) of Title X of the Public Health Service Act, 42 USC § 300).

Second, OPA uses FPAR data to comply with accountability and federal performance requirements for recipients of Title X family planning funds as required by the 1993 Government Performance and Results Act (GPRA).

Current GPRA performance goals for the Title X program include as priorities the provision of family planning services to low-income individuals, access to and utilization of cervical and breast cancer screening, and access to on-site HIV testing at Title X–funded clinics.

Finally, the program relies on FPAR data to monitor performance, respond to inquiries about the program from policy makers and Congress, and support program planning. The FPAR allows OPA to assemble comparable and relevant program data to answer questions about the characteristics of the populations served by Title X clinics, utilization of the services offered, the composition of revenues, and program impact. FPAR data are the basis for objective grant reviews, program evaluation, and assessment of program technical needs (RTI International, 2008).

Each year, FPAR data are analyzed to produce the *Family Planning Annual Report National Summary.* This report provides analyses of the FPAR measures by demographics; social and economic profile; method use, by gender; and cervical, breast, and sexually transmitted disease (STD) screening. It also includes information on staffing, family planning encounters, and revenue. The Research Triangle Institute (RTI) conducted analyses of the FPAR measures to produce the 2006 National Summary (RTI International, 2008).

Although the committee anticipated that its site visits and the testimony of grantees and delegates would elicit reports of the burden imposed on clinic staff by meeting the FPAR requirements, a more complex picture emerged. Many interviewees reported that complying with FPAR requirements was not burdensome, especially after they switched to electronic health records. Others, however, indicated it was difficult to meet these requirements; indeed, the committee was told that the FPAR requirements deterred some clinics from seeking Title X funding.

> ***Finding 5-1.*** *Sites vary in their capacity to meet the FPAR data collection requirements.*

Another source of information that OFP uses to evaluate the Title X program is the Comprehensive Program Review (CPR), conducted every 3 years by OFP's Regional Offices. This review is intended to ensure that grantees are complying with Title X policy and program requirements, as well as OMB regulations. The Program Review Tool (PRT) used in these CPRs contains key questions on administration, financial management, clinical services, and outreach/information (see Appendix J, Table J-2, for data collected by the PRT). Grantee-monitoring site visits are then conducted by the Regional Offices to check on compliance and to follow up on issues identified previously in the CPR, grant application, and/or needs assessment. The CPR activities suggest that there is considerable system capacity for and commitment to evaluation. The question the committee raises is whether this capacity could be used more strategically to strengthen the evaluation and performance of the program. OFP might further structure this evaluation visit, with input from evaluation experts, RPCs, grantees, and delegates. This group would define core goals and provide tools/approaches that would be used during site visits.

> ***Finding 5-2.*** *The Comprehensive Program Review represents an underutilized opportunity for systematic assessment across the Title X program.*

Another source of data is the National Survey of Family Growth (NSFG), which Title X partially supports on an annual basis. This large-scale survey asks a nationally representative group of women a series of questions related to reproductive behavior and health. Key variables most relevant to Title X include (1) whether family planning medical or contraceptive services were received, (2) contraceptive(s) received, (3) type of family planning medical services received, (4) type of setting where services were received (e.g., hospital, health maintenance organization facility, community clinic), (5) location (i.e., name, address) of the facility, (6) whether the location was clients' regular source of care, (7) how the service was paid for (e.g., copayment, Medicaid, insurance, free), and (8) whether services were paid for by clients on a sliding-scale basis.

Data on the Title X program that may be useful for evaluation purposes are also available from several other sources. These include, for example, contracts that are funded by HHS 1 percent evaluation funds, the Service Delivery Improvement grant program, family planning research cooperative agreements, and demonstration projects aimed at addressing key program initiatives (see Appendix I).

In 2008, OPA spent approximately $9 million on research and evaluation activities. The goal is to identify emerging needs in family planning, as well as to develop and evaluate service innovations that respond to identified needs, with the implied intent of disseminating findings to grantees. Findings from OPA-funded research are also important for monitoring service delivery needs and the provision of care by clinics funded under the program.

> ***Finding 5-3.*** *The National Survey of Family Growth and other research grant programs funded by OPA hold potential for more targeted research to enhance evaluation agendas for Title X. Monitoring to ensure wider dissemination of OPA-supported research findings to the provider community and use of these findings is key to ongoing efforts to improve service delivery.*

APPLYING THE COMMITTEE'S FRAMEWORK TO ASSESS OFP'S MEASURES AND GOALS

The committee used the evaluation framework presented in Figure 5-1 to evaluate whether the measures currently used by OFP adequately assess the program's progress and effectiveness in meeting its goals. The primary data sources reviewed were the FPAR and to a lesser degree the CPR/PRT. Table 5-1 shows the data currently being collected that are relevant to each of the framework's domain columns. Also listed are indicators and approaches the committee recommends be added (presented in italics).

The evaluation framework was also used to guide the committee's recommendations for improving the evaluation of Title X patient care and counseling, as well as to help in identifying emerging needs for outreach and education. OFP's collection of data elements is much stronger for some columns of the framework than others. On the one hand, OFP already collects data on key characteristics of clients served, several critical system characteristics, and services performed. On the other hand, OFP does not systematically collect data on key process and outcome variables.

The next section reviews the strengths and gaps under each of the framework's domains—client need, structure, process, and outcomes. Recommendations for filling the identified gaps are presented at the end of the chapter.

ADEQUACY OF THE DATA COLLECTION INFRASTRUCTURE

Client Need

Consistent with column 1 of the committee's evaluation framework, a key goal of the Title X program is to provide services to low-income, uninsured individuals; ethnically/racially and linguistically diverse women and men; and adolescents. Individuals with certain predisposing factors clearly are at risk of being unable to obtain needed reproductive health services. They include those without the economic means to pay for services, low-income individuals whose insurance plans do not cover contraceptive services, those who are linguistically and geographically isolated, those with limited knowledge regarding available contraceptive methods, and those who may have limited support in planning for the number and spacing of their children. Thus it is critical that the FPAR clearly identify the extent to which the program is reaching its target populations.

Strengths

The FPAR successfully captures information on the key characteristics of Title X clients, and the data collected suggest that the program is reaching

TABLE 5-1 Committee's Evaluation Framework Applied to the Title X Program

CLIENT NEED ⇨ *Predisposing Factors*	*STRUCTURE* ⇨ *Enabling Factors*	*PROCESS* ⇨ *Health Behaviors*	⇨ *Services Received*	*OUTCOMES* *Client Outcomes*
Client Characteristics	**System Characteristics**	**Process of Care: Client–Provider Encounter**	**Service Use Performance Indicators for Title X Priority Areas**	**Modeled Improved Clinical Outcomes**
DERIVED FROM FPAR 1. Income 2. Insurance 3. Age 4. Gender 5. Ethnicity (Latino) 6. Users with limited English proficiency 7. Race 8. Income—percent of poverty guidelines 9. Insurance covers family planning *NEW PROPOSED MEASURE TO BE COLLECTED BY CPR/PRT* *1. Client knowledge, intendedness, visit agenda* DERIVED FROM CPR/PRT 1. No. of clients	DERIVED FROM FPAR 1. Title X funding/other revenue for each clinic 2. Title X program requirements 3. Ratio of staffing to patient encounters a. No. of full-time equivalents (FTEs) who are medical versus other clinical service providers b. Nonclinical service providers 4. Limited information re interpreters during visits (not necessarily staff) 5. No. of delegates supported by Title X 6. Service planning sites supported by Title X	DERIVED FROM FPAR 1. Mandated care is state of the art DERIVED FROM CPR/PRT Administrative data: 1. Range of client services offered by qualified staff 2. Procedural outline to offer client services and document them in the client's medical record 3. Written plan for client education 4. Report that counseling, history, and exam services comply with Title X requirements 5. Quality assurance program ongoing	DERIVED FROM FPAR 1. Enumeration of services provided, including screenings, testing, and contraceptives 2. No. of users receiving testing and other services; no. of positive test results *EXAMPLES OF SERVICE USE PERFORMANCE INDICATORS DEFINED BY FAMILY PLANNING COUNCILS OF AMERICA* *1. Increased family planning services to low-income clients to decrease number of unintended pregnancies* *a. 80% of contracepting male and female clients who return to clinic continue any method for 10–14 months unless seeking a pregnancy* *b. 90% of female clients seeking contraception do not report a positive pregnancy test within 15 months of receiving contraception*	NEW PROPOSED MEASURE TO BE COLLECTED BY CPR/PRT 1. *Low-income women achieve their family planning goals (Gregory, 2009 [see Appendix K])* DERIVED FROM PART AND NSFG POPULATION DATA 2. Decreased number of unintended pregnancies, particularly among low-income individuals

TABLE 5-1 Continued

Client Characteristics	**System Characteristics**	**Process of Care: Client–Provider Encounter**	**Service Use Performance Indicators for Title X Priority Areas**	**Modeled Improved Clinical Outcomes**
	DERIVED FROM CPR/PRT Administrative data: 1. No. of clinic sites 2. Compliance with administrative requirements for Title X site structure, having written goals and an evaluation plan, facilities, staffing, policy for language assistance, etc. 3. Personnel and clinic management systems 4. Client care protocols 5. Training and technical assistance 6. Financial management system 7. Systems to involve the community	*NEW PROPOSED MEASURES TO BE COLLECTED BY CPR/PRT* *1. Evaluate monthly the range of contraceptive products available, including emergency contraception, to assess budget impact* *2. Wait time for scheduling visit by reason for visit* *3. Continuity of care at the same site if needed* *Patient-based measures* *4. Care is patient-centered and respectful* *5. Clear information is offered (bilingual counseling offered for those with limited English proficiency)* *6. Patients feel welcomed by reception and clinical staff during all calls and visits* *7. Services are perceived as confidential*	*2. Increased screening of females aged 15–24 for chlamydia infection* *a. 75% of female clients under 25 receive at least one test for chlamydia within 14 months* *b. 100% of all female clients with a positive test for chlamydia are retested at the first visit that takes place 90 days or longer after treatment; 95% of those who are retested test negative* *3. Increased services to reduce invasive cervical cancer (such as HPV immunization and Pap tests, to be defined by an expert committee); benchmarks to be determined using evidence-based guidelines* *4. Increased screening for HIV/AIDS (to be added if recommended by an expert panel); benchmarks to be determined using evidence-based guidelines*	3. Reduced infertility among women by identifying chlamydia infections through screening of females aged 15–24 4. Reduced invasive cervical cancer among women by providing Pap tests

NOTE: Italicized text represents indicators and approaches the committee recommends be added to OFP's data collection system.

its target populations. Important demographic data provided by the FPAR include each client's income, insurance coverage, gender, race/ethnicity, and age and the number of users with limited English proficiency. In addition, the PRT used by the Regional Office or its designated representative collects relevant data as part of the CPR conducted every 3 years. These data include the total number of clients served, as well as the number served by each Title X delegate. In January 2005, Title X revised the FPAR to include new data elements, such as user health insurance coverage status, English proficiency, and contraceptive use by males (RTI International, 2006). These data elements help answer a variety of questions pertaining to the profile of the clients using Title X services.

Gaps

The FPAR does not provide client-level data on knowledge and pregnancy intendedness. For example, if a clinic wanted to improve its education and support activities, it would need to collect data on clients' knowledge of available contraceptive methods and their pregnancy intendedness. However, the clinics are not required to collect this information. OPA should explore the feasibility of gathering these data at the time of the CPR. It might be possible to use the CPR and site visit cycle to sample clients' knowledge and intentions related to their visit agendas at the time of their clinic encounters if the representatives were provided the tools, through expert advice, necessary to obtain more information about knowledge, pregnancy intention, and satisfaction with provider interaction. These results then could be reviewed by the site visit team at the time of the CPR.

It would be useful if the FPAR could collect more group-specific data in order to detect the effect of small changes in the performance indicators based on race and ethnicity, age and gender, level of income, and level of education. For example, this type of data could include unduplicated number of family planning users by age and gender; ethnicity and race; income level; limited English proficiency; primary contraceptive method; and number of gonorrhea, syphilis, HIV, and chlamydia tests. If there were a decline in the percentage of African American users, it would be useful to determine by group-specific data whether the decline was among teenagers, young adults, or older users who might have high STD rates and might not prefer birth control pills as their primary method. This information could help target outreach to be more specific and provide better program direction. It would also be possible to identify any racial disparity in who, for example, obtains a Pap test or has an STD, or high infertility rates based on age, income, or educational level.

It would also be useful to know the proportion of unmet need within the Title X target population, both overall and in different regions of the country. This information, along with pregnancy intendedness information, could help inform Title X outreach planning for different regions. However, the collection of these data would require a new data collection instrument. Any expansion of the CPR to accomplish these goals would need to be scientifically valid, conducted in a way that preserves client confidentiality, and required for all grantees. To date, OFP has relied primarily on the NSFG to gather population-level data, and it might be possible for the NSFG to collect these types of data. Other data currently collected under cooperative agreements with OPA specifically examine the population in need of publicly funded family planning and how much of that need is met by family planning clinics, whether funded through Title X or not, at the state and county levels. The use of these data should also be explored.

> ***Finding 5-4.*** *OFP collects the data needed to affirm that it serves the target populations for the Title X program. Data needed to affirm client knowledge and pregnancy intendedness; resources available to support clients' childbearing decision making; and the proportion of unmet need within the Title X target populations, both overall and in different regions of the country, are not being collected. However, these data could be gathered by sampling clients served or expanding the NSFG instead of requiring that this information be obtained on every client served.*

Structure

A client's ability to access quality services and the processes used to offer services are influenced by public policy; funding; staff training and availability; and facility factors such as location, hours of operation, comfort, and privacy.

Strengths

FPAR. To ensure that there is adequate and appropriate staffing, the FPAR documents the number of full-time equivalents, categorized as medical versus other clinical service providers and as nonclinical service providers. Data on the number of family planning encounters are also required. Together, these data provide the needed ratio of staffing to patient encounters. The FPAR also collects data on the sources of revenue for each Title X clinic so that federal grants, payment for services, and other sources of revenue are itemized. These data provide an opportunity to (1) calculate and compare the staff load within and across clinics, and (2) construct a cross-sectional and longitudinal profile of revenue sources and track how required service changes or expansions relate to gaps in available revenue. Additional data elements include total number of delegates, clinic sites, and subcontractors supported through Title X, as well as service planning sites. All of these elements should continue to be measured in their current format.

CPR. The CPR gathers substantial information about compliance with administrative requirements, such as commitment to voluntary participation in services, confidentiality of services, and appropriate facilities. This information is obtained from written goals, objectives, policies for quality language assistance, and the like. The CPR also assesses whether clinic management is consistent with Title X guidance, whether there are written protocols for client care, and whether the required continuing education has been completed. In addition, the CPR examines the financial management system, as well as the quality of educational and informational program components. (The regulations require that grantees have a community board and a community education program, and provide for community participation in the development or selection of materials.)

> ***Finding 5-5.*** *Both the FPAR and CPR collect important data needed to evaluate the adequacy of the Title X clinic structure and compliance with administrative guidelines to meet program goals.*

Gaps

While both the FPAR and CPR collect substantial information on structural factors in clinic settings, it is not clear how the two sources are used to inform each other. For example, although the FPAR collects some information on the number of family planning users who have limited English proficiency, more specific information is needed about the availability or quality of interpreters or the bilingual nature of staff to determine whether the needs of these clients at any given clinic are being met. It is not clear from reviewing the PRT whether or how an assessment could be conducted using current data on the availability of interpreters for each patient requiring such services. Additional analyses are needed to compare client characteristics and the enabling factors or system characteristics that are in place by region and by type of delegate.

Financial information is thorough in the PRT, but it is not clear whether a profile of revenue sources, both cross-sectionally and longitudinally, is used to track how the required services change in relation to available revenue. For example, did a site's inadequate revenue limit the type of contraceptives or the number of months' supply of contraceptives that clients could receive in certain periods of the year?

> ***Finding 5-6.*** *The Title X data collection tools gather key information on structure, such as revenue, staffing, and other enablers for services and number of services. However, it is unclear that these data are used effectively to examine the relationships between financing and services.*

Process

A critical ingredient once clients access care is the type of care they receive. Title X mandates require delivery of state-of-the-art care and identify specific services that must be provided, including screenings, testing, and contraceptive provision (Table 5-1, column 3).

Strengths

The PRT includes a variety of measures aimed at documenting that protocols are in place for delivering high-quality care. Thus, checklists elicit information on such factors as whether the full range of family planning services and Food and Drug Administration–approved contraceptive methods are provided to eligible clients by qualified and trained personnel. In addition, client chart protocols documenting the array of services provided during the initial visit are required, and there are extensive requirements for client consent; protocols for emergency care; and referrals, for example, for prenatal care. The PRT also notes whether clinic protocols are in place, such as those for follow-up for women and their partners when a chlamydia test is positive. The FPAR collects data on the number of Pap tests performed that had an atypical squamous cells or high-grade squamous intraepithelial lesion or higher result, as well as the number of family planning users who obtained a clinical breast exam and were referred for further evaluation. The number of tests provided for chlamydia, gonorrhea, syphilis, and HIV is also collected.

Gaps

A weakness of both the FPAR and the CPR is that neither systematically gathers information directly from clients about their family planning agenda or their experience at the clinic. Without this information, it is difficult to know the extent to which clients achieved their family planning agendas; whether their visits were client-centered; to what extent their most important reproductive counseling, education, and support needs were met by the visit; whether they felt services were confidential and offered respectfully; whether the information offered was clear, particularly when an interpreter was needed; or how welcomed clients felt during initial and follow-up phone calls, as well as in their interactions with reception staff, clinicians, and counselors during their visits. The lack of this information leaves a gap in the evaluation of the quality of care provided by Title X clinics. While the committee acknowledges that patient agendas are not the only consideration when public health matters, such as preventing the spread of STDs, are involved, it is useful to determine even in a representative sample of clients whether clients had negative experiences or were required to receive services that would deter their return. Various methods, including telephone interviews, surveys, and community focus groups, could be used to collect data directly from clients.

Although the FPAR captures client service data, it collects no specific quality measures for those services. The FPAR does not appear to collect data on many aspects of the process of care, such as the length of wait time to schedule a visit for different types of care (emergency contraception, initial family planning, pregnancy testing, fertility counseling, HIV testing) or what contraceptive methods are available at the time of a client's family planning visit. This latter issue is a critical one given that some of the most effective, long-lasting methods are more expensive, and the committee heard testimony that tight clinic budgets often limit the availability of these methods for clients who most need and desire them. Equally important, the reporting system does not capture the length of time a client's contraceptive supply can last before a return visit for refills (if needed) is necessary. This, too, is a critical issue since barriers to accessing desired methods relate to adherence and subsequent pregnancy prevention. Given OFP's commitment to quality performance indicators, these data gaps are especially noteworthy.

There are other important indicators of quality for which the FPAR does not collect information. These include compliance with age- and gender-specific screening protocols; the extent to which appropriate tailoring of protocols occurs, given both client characteristics and client-identified needs; the wait time before clients receive test and other screening results and follow-up when merited by results; and continuity of care. For example, do clients see the same clinician in subsequent visits when possible, so that continuity is maximized?

While the FPAR does identify specific services that must be provided, including screenings, clinical tests such as laboratory tests and Pap smears, and contraceptive provision and collects data regarding the number of abnormal test results, data are not available on referral and treatment provided as a consequence of those results. Thus, while the FPAR reports service use, reporting on the numbers alone does not provide sufficient data on the process of care.

The PRT currently offers little insight into the individualization of care based on the different characteristics of clinics or client populations. For example, while outreach may be required to market clinic services to targeted populations in some areas, it may not be needed at all for a clinic that has more patients than it can comfortably serve. Similarly, efficiency indicators in one clinic may not apply in another where the client population comprises adolescents who require more time for education and exams, or where the understanding and needs of clients who lack English language proficiency require special attention. It is important to document how counseling and education efforts are tailored to respond to the client and his or her partner's childbearing decision making. This issue is particularly critical as the program serves ethnically/racially and culturally diverse clients. Their values regarding the overall number and timing of their children need to be considered in assessing the role Title X can play in ensuring the availability of appropriate services, including planning for desired children and avoiding unintended childbearing.

To minimize the burden on staff of collecting information on the above process indicators, a plan for stratified random sampling by type of visit and test results could be designed with the assistance of an external group of scientific and clinical advisors. One possibility would be to integrate this data collection into the CPR. Having different types of Title X sites gather client information nationwide in a staggered fashion would make it possible to collect clinic-specific feedback from a restricted number of clients at any one time and also contribute to a national data picture. A multimethod approach would provide useful and complementary information, as suggested by Gregory (2009). As noted above, different methods could be used to collect data directly from clients, including telephone interviews, surveys, exit interviews, and community focus groups, depending on the specific evaluation question and the sampling plan for clinics selected to capture different types of clients and visits. In addition, standardized patients could participate and observe the complete trajectory of patient contact, from the initial phone call for an appointment through the completed service delivery, as suggested by Gregory.

> ***Finding 5-7.*** *A number of indicators of the quality of the process or services provided are not systematically addressed by either the FPAR or CPR.*

In addition to considering gaps in data needed to evaluate the process of care, it is necessary to consider whether clinics have sufficient quality improvement indicators. One example would be service use performance indicators for Title X priority areas. As noted above, clinics enumerate the number of times they offer specific services in their FPAR. However, these data are not translated into a quality improvement indicator that clinics could use to compare performance for the current and previous years. This would not be intended as an outcome measure but more as a formative evaluation indicator to improve the quality of service delivery.

As noted earlier, OFP identified three performance measures through the PART process: (1) increasing family planning services to low-income clients to decrease the number of unintended pregnancies, (2) increasing screening of females aged 15–24 for chlamydia infection to reduce infertility, and (3) increasing Pap tests to reduce invasive cervical cancer. It is important to acknowledge the difficulty of connecting process indicators with outcomes. Nevertheless, the service performance indicators associated with these outcomes are valuable antecedents as quality improvement tools in themselves.

To address quality improvement and management issues, OFP could establish benchmarks or standards for each of its priority outcome measures. Table 5-1 provides examples of service use performance indicators for the Title X priorities using benchmarks from the Performance Measurement System (PMS) developed by the Family Planning Councils of America, Inc. (FPCA) and partially funded by OFP. OFP could closely examine the FPCA PMS as well as other potential benchmarks and related outcome measures with the assistance of an external panel of experts. Relevant Healthcare Employer Data and Information Set (HEDIS) and Centers for Disease Control and Prevention (CDC) standards and goals could be used to reevaluate the benchmarks against which service quality can be measured. By using longitudinal within-clinic return visit data, clinics (especially those with electronic systems) could begin providing a broader picture of service performance quality directly linked to OFP goals.

As an example, the goal of reducing infertility through chlamydia screening offers an opportunity for specific antecedent benchmarks against which service provision can be evaluated. According to the 2006 FPAR, 56 percent of all Title X female clients were aged 15–24; of those female clients 24 years and younger, only 51 percent were tested for chlamydia (RTI International, 2008), although HEDIS recommendations require that 100 percent of sexually active women in this age group be screened. To achieve the goal of reducing infertility among women, incremental targets for reaching national standards for rates of chlamydia testing and screening among women aged 15–24 could be established. Rates for follow-up with treatment and for remaining negative at a follow-up visit also need to be tracked against benchmarks based on national standards (recognizing that whether one is negative on follow-up depends on both treatment and intervening exposure). Since some older women and men may be tested for chlamydia, OFP could consider how these groups fit into the Title X priorities. OFP might consider altering this goal to focus on the reduction of STDs among the groups most likely to be at risk, since the primary goal is to achieve reductions in infertility. Data could also be added to determine what percentage of users are treated for STDs. As STDs are a reportable disease, local and state health departments have the results of positive STD tests and treatment. Family planning agencies could consider linking through information technology to local and state health departments for this information.

As part of this process, expert consultation will be needed to determine whether the performance measures themselves should be modified. OFP's goal of reducing cervical cancer through Pap tests deserves further review by an expert panel in light of HEDIS and CDC recommendations (see also Chapter 3). Guidelines for Pap tests were revised in 2002 and now state that a Pap test is not indicated until a woman has been sexually active for 3 years or reaches age 21, whichever occurs first. Guidelines for management of abnormal Pap tests were revised in 2007. Follow-up of abnormal Pap tests for adolescents in particular changed significantly. Unless there is a very abnormal test (i.e., high-grade lesion or worse), the follow-up should be at 1 year. Both of these changes have led to a decrease in Pap tests required, yet a gap continues to exist between program requirements and recommended practice.

OFP could use an expert committee of clinicians and scientists to examine its primary approach to reducing cervical cancer. A goal of early immunization with the human papillomavirus vaccine for Title X female clients up to age 26 and age-appropriate Pap screening for other female clients should be considered. This could be accomplished in conjunction with the Vaccines for Children program. With the input of an expert panel, benchmarks for the immunizations and follow-up could be established, similar to those for chlamydia testing, and parallel national goals could be incorporated. With respect to the possible addition of an outcome related to HIV/AIDS, in 2006 CDC revised its guidelines to recommend that all individuals aged 13–64 in health care settings undergo HIV screening. HIV-positive status has crucial implications for pregnancy planning, as well as early intervention for the disease itself. According to the 2006 FPAR, Title X providers performed 1.3 HIV tests for every 10 family planning users. This is a measurable item that should have greater importance in the Title X program. OFP could therefore consider adding a goal regarding HIV testing and include this goal in its discussions of measures and benchmarks for service performance quality improvement.

OFP could evaluate quality of care using national guidelines and benchmarks. Particular attention should be paid to how guidelines vary with the age of the client. For example, while OFP currently requires that adolescents receive breast examinations, the U.S. Preventive Services Task Force has concluded that the evidence is insufficient to recommend for or against routine clinical breast exams alone to screen for breast cancer, especially among the young (USPSTF, 2003). According to the National Breast and

Cervical Cancer Early Detection Program, 85 percent of breast cancers are identified in women over age 50. Mammograms detect 90 percent of breast cancers; the sensitivity of a clinical breast exam is 40–69 percent. Because the majority of Title X users are in an age group at low risk of breast cancer, mandating clinical breast examinations is of limited benefit and may deter some young women from seeking care. Data on this service would therefore no longer be collected if the Title X care guideline changed on the basis of scientific input.

An important question is whether closing these data collection gaps would add to the burden on clinics. As more Title X clinic sites shift to electronic health records, they will be able to perform longitudinal data analysis when provided with appropriate software and training. FPCA reports that with software and training, eight beta sites found the process relatively easy to implement and valued the additional data (Testimony by Dorothy Mann, May 19, 2008). The power of this approach is that it encourages each clinic to assess whether it is meeting national benchmarks set by OFP in keeping with HEDIS, CDC, and other federal agencies, thereby closing an important quality improvement feedback loop at the clinic level. Further, it becomes possible to analyze these data nationally and at the clinic level in terms of the demographics of the clients served. The rates at which low-income clients meet the benchmarks could be a particular focus of the within- and across-clinic analysis of outcome measures.

> ***Finding 5-8.*** *The three core measures identified by OFP through the PART process are insufficient for successfully implementing and managing the Title X program or assessing outcomes.*

Outcomes

An important product of OMB's evaluation of OFP was that OFP identified the above three outcomes for evaluating the impact of Title X on population health. The committee recognizes both the difficulty and importance of defining and measuring these outcomes. For this assessment, the committee placed the greatest emphasis on the goal of increasing family planning services to low-income clients to decrease the number of unintended pregnancies since this is the predominant reason for visiting a family planning clinic. As discussed above, the committee suggests that OFP revisit the outcomes selected for evaluating the program's impact on population health.

Decreasing Unintended Pregnancies

While OFP can document the extent to which family planning services are provided to low-income clients, an important but much more difficult task is estimating the decrease in the number of unintended pregnancies associated with those services. As noted above, OFP estimates the decrease in the number of unintended pregnancies using a methodology originally developed in 1977 (Jaffe and Cutright, 1977). This methodology has evolved over time as better behavioral and utilization data at both the national and clinic levels have become available. The model estimates the number of unintended pregnancies by examining the current use of contraceptive methods by women visiting Title X clinics, the failure rates associated with those methods, and estimates of changes in contraception practices if Title X clinics were to close. A number of different estimates of the increase in unintended pregnancies are produced (five in the most recent paper by Frost et al., 2008b), depending on the assumptions made about how contraceptive behavior would change (including "would give up prescription contraception altogether" and "using contraception in the same way as comparable women who do not attend Title X clinics").[1] OPA bases its estimates on the average of the four most realistic scenarios. While the committee agrees that this approach is a reasonable one for estimating the number of unintended pregnancies, it recommends that OFP provide data on the particular assumptions used to make these estimates. In addition, techniques should be developed to increase the robustness of these estimates and their sensitivity to the quality of the services provided. Three specific improvements in methodology and data collection would enhance OFP's understanding of the effectiveness and cost-effectiveness of Title X services:

- *Estimates should rely on program-specific data on contraceptive methods dispensed and be sensitive to the types and quantity of methods used in Title X clinics rather than on the distribution found in the NSFG.* Use of data on the provision of contraceptives by Title X programs would allow the analyses to reflect changes in methods dispensed, quantities dispensed, and method continuation. The committee anticipates that more sensitive evaluation methods would encourage quality improvement, as well as increases in clients served. This approach has been used in evaluations of the California Medicaid Waiver Program (Foster et al., 2004, 2006).
- *There is room for improvement in modeling the absence of the Title X program.* Research on contraceptive use in the absence

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[1] The Frost et al. paper actually models the impact of publicly funding family planning clinic services, not Title X clinics specifically. However, it is transferable to an examination of Title X clinics only.

of public funding could be improved, for example, by examining method use prior to program inception among new Title X clients or by asking a sample of Title X clients what they would do if subsidized services were unavailable. This information could be included in sensitivity analyses.

- Cost savings should be adjusted to differentiate between costs that were entirely prevented through use of contraceptives provided by Title X clinics and those that were merely delayed. Although significant research would be needed to yield reliable estimates, failure to make this adjustment results in overestimation of costs averted (Amaral et al., 2007).

Finally, given the importance of the problem, multiple models and approaches for estimating the number of unintended pregnancies averted through Title X would be useful to explore and compare.

Strategic Use of OPA/OFP Research Funding to Demonstrate Outcomes

Findings from Title X–funded research are disseminated in a number of ways. Summaries of the research are posted on the OPA website; research grant recipients make formal presentations at the biennial Title X national grantee meetings and other national conferences/meetings; and researchers publish their results in peer-reviewed journals (see Appendix I for a sample of peer-reviewed publications resulting from OPA-funded research).

It is noteworthy that in the almost 40 years that Title X's research program has been in place, too little remains known about how best to promote and encourage contraceptive use among both men and women. In a recent review, Kirby (2008) found that there is a significant lack of research and evaluation on interventions to promote the use of family planning methods, a lack that severely limits the nation's ability to help couples both plan for pregnancy and prevent unintended pregnancy. Given the nation's high rate of unintended pregnancy, this knowledge gap is particularly troubling.

An important resource for OFP is the Title X research program's ability to target relevant issues regarding both outcomes and service delivery. OPA and OFP should carefully evaluate the currently funded research program to ensure that it frames the mission and use of targeted research effectively. The goal is to fund research on concerns, issues, and interventions whose results will have value for subsequent decisions and dissemination among the Title X network. For example, OFP may want to consider targeting research to evaluate program initiatives it has piloted to determine whether wider dissemination of those initiatives is merited.

Part of the Title X research effort should involve collaborating with other federal agencies to determine unmet need among the Title X target population. Addressing this question will require additional data sets on nonusers of Title X clinics, describing family planning needs and indicators for target populations in the region. OFP should apply some of its research funds to using data available through other existing national databases more effectively. It should study the value of the current items available from the NSFG and evaluate the merits of adding other items if needed. Other systematic national population surveys should be examined for the potential to augment the FPAR outcome evaluation. The more directly items collected by these additional national surveys can be tied to the priority outcomes for Title X, the greater the opportunity for comparisons will be.

The committee also suggests that OFP consider regional evaluations whereby data from a variety of sources can be compared to identify the extent to which Title X is contributing to key outcomes and whether new initiatives appear to be helpful. Projects that take advantage of claims data from Medicaid and other third-party payers in some counties and regions offer unique opportunities for comparison with data collected on Title X clients.

The 2006 FPAR data suggest additional analyses and probes to help evaluate the program's impact on preventing unintended pregnancy. According to these data, 85 percent of women attending Title X clinics were using a birth control method. The percentages of use by method were as follows:

- Oral contraceptives, 39 percent
- Condoms, 16 percent
- Injectable, 12 percent
- Patch, 4 percent
- IUD, 2 percent
- Sterilization, 2 percent
- Vaginal ring, 2 percent
- Abstinence, 1 percent

Each of these methods differs in its profile of discontinuation and failure rates. For example, oral contraceptives have a probability of failure rate of 8.7 percent of users at 1 year, while the every 3 months injectable (Depo-Provera®) has a failure rate of 6.7 percent of users at 1 year. These failure rates are highest among those under age 30, especially low-income teenagers. Given that long-acting methods such as the IUD or the implant are more effective and cost-effective, it would be useful to track not only the availability of these methods at each family planning clinic visit, but also their prescription rate at the visit.

Lastly, the 2006 FPAR reports that 15 percent of women using Title X services were not using birth control, were pregnant, or wanted to be. The FPAR provides very little information about this group. To help evaluate

OFP's progress in helping women achieve their family planning goals, it would be useful to understand more about whether the majority of these women were planning to become pregnant and what role Title X played in helping them with the spacing of subsequent pregnancies.

CONCLUSIONS AND RECOMMENDATIONS

The committee's comparison of the data needed to monitor and evaluate the Title X program against the data actually collected supports the following conclusions:

> *The program does not collect all the data needed to fully monitor the program and evaluate its impact.*
>
> *A comprehensive framework for approaching program evaluation could ensure that all major aspects of the program are evaluated and the needs of clients are being met. Gathering these data will require innovative approaches ~~an~~d new funding ~~to~~ minimize the burden on providers.*

The following recommendations are intended to help OFP strengthen its ability to meet its goals through improved data collection. These recommendations are based on recent literature reviews and reports on quality in the provision of family planning services (Sonenstein, 2006; Becker et al., 2007), papers commissioned by the committee (Gregory, 2009; The Lewin Group, 2009 [see Appendixes K and J, respectively]), previous reports commissioned by OFP (Sonenstein et al., 2004; RTI International, 2005a,b), the committee's site visits (see Appendix F), and testimony provided to the committee during public workshops. The challenge is to move an evaluation agenda and process forward without imposing an undue burden on clinic providers, clients, and regional administration. The committee therefore recommends that a formal planning process be undertaken by OFP.

> **Recommendation 5-1: Fund and use a comprehensive framework to evaluate the Title X program.** *OFP should develop, fund, and use a comprehensive framework to evaluate the Title X program. The use of such a framework would allow OFP to evaluate the program on the full continuum from clinic performance and quality, to clinic management, to program outcomes. It would also help in identifying the types of data needed for evaluation purposes.*

The development and use of a comprehensive framework to evaluate Title X would make it possible to explore the interactions among various contributing factors and outcomes, as well as the completeness of different measures for each set of factors. It is important to providing funding for data collection, analysis, and use rather than diluting service dollars.

> **Recommendation 5-2: Examine the data elements of the *Family Planning Annual Report* (FPAR).** *When revising the Program Guidelines (see Recommendation 4-7), OFP should review and clarify data elements contained in the FPAR and where possible and useful, eliminate those that are unnecessary, particularly if additional elements are needed.*
>
> **Recommendation 5-3: Collect additional data.** *To help fill gaps in the Title X program's data collection systems, OFP should collect additional data in the areas of client needs, structure, process, and outcomes for use in evaluating the program's progress and its effectiveness in achieving its goals. Specifically, OFP should:*
>
> - **Collect additional data on client characteristics.** *Additional data sources, such as the Comprehensive Program Reviews (CPRs), should be used to supplement the FPAR data on client characteristics—for example, to obtain data on clients' knowledge about available contraceptive methods and pregnancy intentions.*
> - **Collect data on system characteristics.** *Additional data are needed on such system characteristics as the availability of interpreters to meet the needs of clients with limited English proficiency.*
> - **Collect data on the process of care.**
>   - *These data should include patients' perceptions of care. With expert consultation, selected CPR site visits could be structured to sample a limited number of clients for the purpose of obtaining generalizable results.*
>   - *With expert advice, OFP should examine the three core outcome measures identified for the PART process in relation to evidence-based guidelines and national health priorities. After determining the most appropriate measures, OFP should develop related performance metrics for clinic service to establish quality improvement standards.*
> - **Conduct research to assess program outcomes.** *OFP should expand research aimed at evaluating program outcomes, such as the impact of the program on pregnancy planning and intention, decreased infertility, outreach to those in need of services, and the prevention of unintended pregnancy.*

> **Recommendation 5-4: Examine evaluation tools for outreach and education.** *To assist ongoing quality improvement and effective expansion of community outreach and education, OFP should work with grantees to develop and refine evaluation tools for outreach and education that can be applied easily by delegates.*

It is important to acknowledge that in many ways, the outreach and education responsibilities (and opportunities) encompassed by Title X often receive less attention than other aspects of the program because of the pressing needs of the clinical care system and the lack of resources. However, the expertise in reproductive health that exists in so many communities across the country needs to be utilized to fuller advantage. The increasing leadership role for OFP and the Title X system of services that the committee recommends (see Chapter 3) extends to outreach and education responsibilities (and opportunities). In addition to clinic services, Title X grantees and delegates devote considerable effort to responding to the needs of their communities through outreach and education programs. As discussed in Chapter 4, there is a need to examine the evaluation of these important activities. The current tools used to evaluate the program tend to document quantity and client satisfaction, both of which are important. The question is whether more can be done to extend and evaluate outreach and education efforts. Can more be done to develop easily implemented strategies and tools for promoting and evaluating the quality of these efforts and their impact on such outcomes as knowledge, attitudes, and intentions related to preventing unintended pregnancy and associated preventive health issues, such as prevention of STDs?

> **Recommendation 5-5: Obtain scientific input on evaluation efforts.** *OFP should expand its use of scientific expertise to strengthen its evaluation strategies and improve its evaluation research program, and consider expanding its use of national databases to evaluate program impacts.*

A group of scientific experts should be established for the program, representing knowledge of public health practices and principles; the relevant clinical specialties, including primary care, obstetrics and gynecology, and adolescent health; health education, behavioral science, and health services research; epidemiology; and ethnography. This group could serve multiple functions (see also Recommendation 4-7 in Chapter 4) by reviewing standards of care annually, assessing relevant FPAR and CPR measures and samples, and helping to identify an OFP research agenda. That agenda could (1) explore how the Title X program can reduce unintended pregnancies more effectively; (2) be linked directly to improving the nation's family planning service system; and (3) ensure coordination with other federal research efforts that address common issues of quality assurance, clinical guidelines, and related matters. This group could have systematic input into the quality improvement indicators collected and strategies for increasing clinic feedback and information exchange. Lastly, this group could assist OFP in addressing the recommendations offered in this report.

Expert and clinic site consultation would also be helpful in addressing the key question of how OFP should better use the data it currently collects. As discussed, OFP relies on different but complementary sources of data, as well as data collection strategies, as part of its national evaluation system. This multiplicity is vital as any one source of data may be unable to provide the level of information necessary—each having its strengths and limitations. The ways in which OFP synthesizes and uses existing data for program planning, including process data and service delivery improvement research funded by OPA, are not fully transparent.

As discussed in Chapter 3, grantees expressed concern regarding their perception that new service priorities often appear to be announced without explanation of how they were established or how they relate to an overall strategic plan. Furthermore, there appears to be a gap between requiring new priorities and adapting the existing data collection system to capture and document the program's success in responding to these priorities. If the data collection system is not incorporating new program priorities, the efforts of grantees to respond to those priorities may not be fully captured. The FPAR was last modified in 2005 (to include new data elements, such as user health insurance coverage, English proficiency, contraceptive use by males, summary Pap [abnormal] and confidential HIV [positive] test results, and disease-specific information on STD screening). While it is unrealistic to modify the FPAR frequently, it may be realistic to require a more limited set of data elements for programs engaged in implementing new priorities to determine whether those priorities are being implemented fully and having the desired impact. Soliciting both scientific and clinic-based input on these questions would be useful.

> **Recommendation 5-6: Communicate evaluation findings.** *To ensure transparency and broad-based dissemination of information and ultimately to improve care (see Recommendation 4-8), OFP should enhance ongoing feedback and communication with grantees, delegates, clinics, and others about important evaluation findings and how they can help improve care and track progress toward the achievement of program goals.*

During the committee's site visits with Title X clinics, as well in testimony at public workshops, several providers expressed a desire for more feedback and information on the FPAR. The committee recommends that OFP consider a variety of ways to meet this need (see Recommendation 4-8). Feedback on clinic performance and data trends via webpages and web broadcasts could offer additional information to clinics. Equally important, it could help clinic staff understand the significance of their work on collecting FPAR data.

CONCLUDING THOUGHTS

The committee has identified a variety of ways in which the Title X program could be improved. These include focusing on its core mission; undertaking a strategic planning process with a longer time horizon; implementing patient-focused, scientifically based clinical practices; and enhancing evaluation and communication. There is also a need to coordinate requirements of relevant federal agencies with Title X. The committee acknowledges that the current systems used by OFP to collect program data have significant strengths. Recognizing that more resources will be required, the committee believes there are opportunities to utilize data that are already available, as well as to improve the collection of those data in ways that are sensitive to the needs of both grantees and clients while also contributing to quality improvement efforts.

Although there is room for improvement, it is important to note that the Title X program has successfully served low-income women and men and adolescents. Despite increasingly limited funds, the dedication of federal agency staff, grantees, delegates, and clinic staff to the goals and clients of the Title X program has made it possible to deliver essential services that have helped individuals, families, communities, and the nation.

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Appendixes

Appendix A

Data Sources and Methods

The Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program was asked to provide a critical review and assessment of the Title X program. The purpose of this study was to examine Title X administration and management, and to assess whether the Title X objectives and operational requirements meet the needs of the program's target populations and have been adapted to ongoing changes in technology and medical practice, social changes, and other related influences that affect these populations since the program was created in 1970. To provide a comprehensive response to its charge, the committee examined data from a variety of sources. These data sources included a review of recent literature, input provided during a series of public workshops, commissioned papers, and site visits to selected recipients of Title X funds. The study was conducted over a 24-month period.

The committee comprised 16 members with expertise in family practice, obstetrics and gynecology, adolescent health, behavioral science, demography, program administration and evaluation, health services research, health economics, law, and policy. The committee held five 2-day meetings in December 2007, February 2008, May 2008, August 2008, and October 2008.

LITERATURE REVIEW

The committee used several strategies to identify literature and other documents relevant to its charge. First, it conducted a search of four bibliographic databases to obtain articles from peer-reviewed journals: PubMed, PsycINFO, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and Sociological Abstracts and Social Service Abstracts. The searches focused on Title X and U.S. family planning services, using the keywords *Title X*, *public funding*, *national family planning programs*, *family planning*, *reproductive health services*, *maternal health services*, *women's health services*, *student health services*, *adolescent health services*, *evaluation studies*, *Medicaid*, and *community health centers*. From approximately 2,000 articles, staff identified those relevant to the committee's charge and created an EndNote database. Second, Title X documentation—including legislation, regulations, previous program evaluations (see Appendix D for a review), guidance documents (Program Review Tool, Title X Program Guidelines, Office of Population Affairs [OPA] Program Instructions), *Family Planning Annual Report* (FPAR) guidance, products resulting from Service Delivery Improvement Requests for Applications (RFAs) (past and present final reports), and the Program Assessment Rating Tool (PART) evaluation—were added to the committee's EndNote database. The previous program evaluations were also used to identify relevant articles and documents. Finally, committee members, meeting participants, and the public submitted articles and reports. In total, the committee's database of relevant documents included more than 200 articles and reports.

PUBLIC WORKSHOPS

The committee hosted three public workshops to gather additional information on specific aspects of its charge. These workshops were held in conjunction with the committee's December 2007 and February and May 2008 meetings. The first workshop was intended to provide an overview of the structure and purpose of the Title X program and the committee's charge, which was discussed by representatives from the study's sponsors. Several invited stakeholders shared their perspectives on Title X, particularly with respect to the scope of its services and how well it is serving its target populations. The second workshop focused on a variety of topics, including the place of Title X in a state's overall health system and the perspectives of organizations that represent grantees and of current and former grantees and delegates. The third workshop addressed the role of Title X regional program consultants, drug pricing and its impact on the cost of operating Title X programs, and the measurement of quality in family planning services. Each workshop was open to the public. Individuals were invited to present information to the committee, answer questions from the committee and the audience, and participate in subsequent discussions. The agendas for these meetings are presented in Boxes A-1 through A-3.

BOX A-1
Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program

The National Academies Keck Building
500 Fifth Street N.W., Room 101
Washington, DC

Thursday, December 6, 2007

AGENDA

1:00 p.m. **WELCOME AND INTRODUCTIONS**
Ellen Wright Clayton, M.D., J.D.
Chair

1:15 p.m. **OVERVIEW OF THE OFFICE OF POPULATION AFFAIRS AND TITLE X**
Susan Orr, Ph.D.
Acting Deputy Assistant Secretary for Population Affairs

SPECIFIC ASPECTS OF TITLE X
Susan B. Moskosky, M.S., R.N.C.
Director, Office of Family Planning
Office of Population Affairs

DELIVERY OF STUDY CHARGE
Susan Orr, Ph.D.
Acting Deputy Assistant Secretary for Population Affairs

2:15 p.m. **DISCUSSION OF STUDY CHARGE**

2:45 p.m. **GENERAL DISCUSSION**

3:15 p.m. **BREAK**

STAKEHOLDER PERSPECTIVES

3:30 p.m. *Mary Jane Gallagher*
President and CEO
National Family Planning and Reproductive Health Association

3:40 p.m. *Rachel Benson Gold*
Director of Policy Analysis and Washington Office Operations
Guttmacher Institute

3:50 p.m. *Dorothy Mann*
Executive Director
Family Planning Council, Inc.

4:00 p.m. **DISCUSSION**

5:00 p.m. **RECEPTION**

BOX A-2

Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program

The National Academy of Sciences Building
2100 C St. N.W.
Washington, DC
Room 150

Monday, February 11, 2008

PERSPECTIVES ON TITLE X

AGENDA

WELCOME AND INTRODUCTIONS

1:00 p.m. *Ellen Wright Clayton, M.D., J.D.*
Chair, Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program

PERSPECTIVES ON TITLE X FROM A STATE OFFICIAL: HOW DOES TITLE X FIT INTO A STATE'S OVERALL HEALTH SYSTEM?

1:15 p.m. *Joan Henneberry, M.S.*
Executive Director
Colorado Department of Health Care Policy and Financing
Former Director, Colorado Family Planning Program

1:30 p.m. **Q & A**

PERSPECTIVES ON TITLE X FROM ORGANIZATIONS REPRESENTING GRANTEES: STATE FAMILY PLANNING ADMINISTRATORS AND FAMILY PLANNING COUNCILS OF AMERICA

1:45 p.m. *Rian Frachele*
Vice President, State Family Planning Administrators
Section Manager, Women's and Reproductive Health
Office of Family Health, Public Health, Oregon Department of Human Services

2:00 p.m. *Cindy Stewart, CAE*
President, Family Planning Councils of America
President and CEO, Family Health Council of Central Pennsylvania, Inc.

2:15 p.m. **Q & A**

2:45 p.m. **BREAK**

PERSPECTIVES ON TITLE X FROM CURRENT GRANTEES AND DELEGATES

3:00 p.m. *Juliana Gonzales*
Title X Family Planning Program Coordinator
El Buen Samaritano Episcopal Mission
Austin, TX

3:15 p.m. *Mark Hathaway, M.D., M.P.H.*
Outreach Director for OB/GYN Services
Washington Hospital Center
Clinical Director for Title X and Associate Medical Director for OB/GYN Services
Unity Health Care, Inc.
Washington, D.C.

3:30 p.m. *David Greenberg, Ph.D.*
President and CEO
Planned Parenthood of the Columbia Willamette, Inc.
Portland, OR

3:45 p.m. **Q & A**

PERSPECTIVES ON TITLE X FROM A FORMER GRANTEE

4:15 p.m. *Michael Bloom, M.P.A.*
CEO, North Colorado Health Alliance
Former CEO, Sunrise Community Health

4:30 p.m. **Q & A**

4:45 p.m. **GENERAL DICUSSION**

5:15 p.m. **ADJOURN**

RECEPTION FOR COMMITTEE, PRESENTERS, AND GUESTS

BOX A-3
Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program

The National Academies Keck Building
500 Fifth Street, N.W.
Washington, DC
Room 101

Monday, May 19, 2008

PUBLIC MEETING

AGENDA

WELCOME AND INTRODUCTIONS

8:30 a.m. *Ellen Wright Clayton, M.D., J.D.*
Chair, Committee on a Comprehensive Review of the HHS Office of Family Planning Title X Program

PERSPECTIVES ON TITLE X FROM REGIONAL PROGRAM CONSULTANTS

8:45 a.m. *Evelyn Glass, M.S.P.H.*
Regional Program Consultant
Region VI

9:00 a.m. *Jill Leslie*
Regional Program Consultant
Region VIII

9:15 a.m. **Q & A**

DRUG PRICING AND THE IMPACT ON TITLE X PROGRAMS

9:35 a.m. *Jimmy R. Mitchell, R.Ph., M.P.H., M.S.*
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

COMMISSIONED PAPERS

The committee commissioned papers to provide in-depth information on two selected topics. The first paper (presented in Appendix J) reviews the organizational structure and management of the Title X program, with a focus on the relationships among the program's Central Office, Regional Offices, and grantees/delegates. It examines the effectiveness of the relationships between the Central Office and Regional Offices, mechanisms

9:55 a.m.	*Adam Sonfield, M.P.P.* Senior Public Policy Associate The Guttmacher Institute
10:10 a.m.	**Q & A**
10:30 a.m.	**BREAK**
	THE MEASUREMENT OF QUALITY IN FAMILY PLANNING SERVICES
10:45 a.m.	*Dorothy Mann* Executive Director Family Planning Council, Inc.
11:15 a.m.	**Q & A**
11:30 a.m.	**GENERAL DISCUSSION**
12:00 p.m.	**ADJOURN**

for accountability and transparency, and the effectiveness of the FPAR for management purposes.

The second paper (presented in Appendix K) assesses the quality of reproductive health services provided under the Title X program. It addresses how well the FPAR measures quality, quality initiatives undertaken by family planning programs, how the quality of services should be assessed in various settings, and the costs and benefits associated with introducing quality measures into family planning clinics.

SITE VISITS

The committee visited 16 Title X clinics to obtain perspectives on the program from administrators and service providers. The methods used and results from these site visits are summarized in Appendix F.

Appendix B

Population Research and Voluntary Family Planning Programs

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001 [300]

(a)The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family[1] participation in projects assisted under this subsection.

(b)In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c)The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary.

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[1] So in law. See section 931(b)(I) of P.L. 97-35 (95 Stat. 570). Probably should be "family."

The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d)For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973, $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976;
$115,000,000 for the fiscal year ending September 30, 1977;
$136,400,000 for the fiscal year ending September 30, 1978;
$200,000,000 for the fiscal year ending September 30, 1979;
$230,000,000 for the fiscal year ending September 30, 1980;
$264,500,000 for the fiscal year ending September 30, 1981;
$126,510,000 for the fiscal year ending September 30, 1982;
$139,200,000 for the fiscal year ending September 30, 1983;
$150,030,000 for the fiscal year ending September 30, 1984; and
$158,400,000 for the fiscal year ending September 30, 1985.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002 [300a]

(a)The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b)The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c)For the purposes of this section, the term “State” includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d)For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS

SEC. 1003 [300a-1]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH

SEC. 1004 [300a-2]

The Secretary may -

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005 [300a-3]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

SEC. 1006 [300a-4]

(a)Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b)Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c)A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that—

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge. For purposes of this subsection, the term ‘‘low-income family” shall be defined by the Secretary in accordance with such criteria as he may prescribe so as

to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008[2] [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

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[2] Section 1009 was repealed by section 601(a)(1)(G) of P.L. 105-362 (112 Stat. 3285).

Appendix C

Title X Family Planning Program Regulations

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.232 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure
45 CFR part 16—Procedures of the Departmental Grant Appeals Board
45 CFR part 46—Protection of human subjects
45 CFR part 74—Administration of grants
45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
45 CFR part 81—Practice and procedure for hearings under part 80 of this title
45 CFR part 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Service Act
45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying

[49 FR 38116, Sept. 27, 1984. Redesignated and amended at 61 FR 6131, Feb. 16, 1996]

§ 58.233 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6131, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 58.234 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

Subparts E–F [Reserved]

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a–4.

SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, *et al.*), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and

may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by §59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral

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[1] Section 205 of Pub. L. 94–63 states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both."

to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients, and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and

Human Services effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title
45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance
45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

AUTHORITY: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a–4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a–1.

SOURCE: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

§ 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a–1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

§ 59.202 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act.

(b) *State* means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.

(c) *Nonprofit* private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(d) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Training* means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

§ 59.203 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: *Provided,* That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

§ 59.204 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a–1, and 300a–4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

§ 59.205 Project requirements.

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

§ 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to

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[1] Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

(1) Return travel to the trainee's point of origin.

(2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation impelmenting such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

§ 59.210 Inventions or discoveries.

Any grant award pursuant to § 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 59.212 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) *Accounting for grant-related income*—(1) *Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.213 [Reserved]

§ 59.214 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 59.215 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:
A General.
B Cash Depositories.
C Bonding and Insurance.
D Retention and Custodial Requirements for Records.
F Grant-Related Income.
G Matching and Cost Sharing.
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

[38 FR 26199, Sept. 19, 1973]

PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

Sec.

Subpart B—Establishment of Regional Medical Libraries

SOURCE: 56 FR 29189, June 26, 1991, unless otherwise noted.

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

AUTHORITY: 42 U.S.C. 286b–2, 286b–5.

§ 59a.1 Programs to which these regulations apply.

(a) The regulations of this subpart apply to grants of funds, materials, or both, for establishing, expanding, and improving basic medical library resources as authorized by section 474 of the Act (42 U.S.C. 286b–5).

(b) This subpart also applies to cooperative agreements awarded for this purpose. In these circumstances, references to "grant(s)" shall include "cooperative agreements(s)."

§ 59a.2 Definitions.

Undefined terms have the same meaning as provided in the Act. As used in this subpart:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Project period—See § 59a.5(c).

Related instrumentality means a public or private institution, organization, or agency, other than a medical library, whose primary function is the acquisition, preservation, dissemination, and/or processing of information relating to the health sciences.

Secretary means the Secretary of Health and Human Services and any other official of the Department of Health and Human Services to whom the authority involved is delegated.

examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(1) There is an immediate health hazard involved;

(2) There is an immediate need to protect Federal funds or equipment;

(3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

(4) It is probable that the alleged incident is going to be reported publicly.

(5) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

§50.105 Institutional compliance.

Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

§50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§50.202 Definitions.

As used in this subpart:

Arrange for means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (1) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or (2) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for purposes which include the ability to consent to sterilization.

Public Health Service means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

The *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

[43 FR 52165, Nov. 8, 1978, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of § 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and § 50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled:

(2) A description of available alternative methods of family planning and birth control;

(3) Advice that the sterilization procedure is considered to be irreversible;

(4) A thorough explanation of the specific sterilization procedure to be performed;

(5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(6) A full description of the benefits or advantages that may be expected as a result of the sterilization; and

(7) Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in § 50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

(c) Suitable arrangements must be made to insure that the information specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 50.205 Consent form requirements.

(a) *Required consent form.* The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) *Required signatures.* The consent form must be signed and dated by:

(1) The individual to be sterilized; and

(2) The interpreter, if one is provided; and

(3) The person who obtains the consent; and

(4) The physician who will perform the sterilization procedure.

(c) *Required certifications.* (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter's knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

(i) The individual is already sterile at the time of the hysterectomy.

(ii) The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

(i) That the woman was already sterile, stating the cause of that sterility; or

(ii) That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance adminstered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and as applicable, either acknowledgments of receipt of hysterectomy information or certification of an exception for hysterectomies.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.210 Review of regulation.

The Secretary will request public comment on the operation of the provisions of this subpart not later than 3 years after their effective date.

APPENDIX TO SUBPART B OF PART 50—REQUIRED CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from ____________ (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a ____________. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on ____ (day), ____ (month), ____ (year).

I, ____________, hereby consent of my own free will to be sterilized by ____________ by a method called ____________. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature ____________________________
Date: ____________________________
(Month, day, year)

You are requested to supply the following information, but it is not required:

Race and ethnicity designation (please check)

Black (not of Hispanic origin) ____________
Hispanic ____________
Asian or Pacific Islander ____________
American Indian or Alaskan native ______
White (not of Hispanic origin) ____________

Interpreter's Statement

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in ____________ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter ____________________________
Date ____________________________

State of Person Obtaining Consent

Before ____________ (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation ____________, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent ______
Date ____________________________
Facility ____________________________
Address ____________________________

Physician's Statement

Shortly before I performed a sterilization operation upon ____________ (name of individual to be sterilized), on ________ (date of sterilization), ____________ (operation), I explained to him/her the nature of the sterilization operation ____________ (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(*Instructions for use of alternative final paragraphs:* Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

☐ Premature delivery
Individual's expected date of delivery: _____
☐ Emergency abdominal surgery:
(Describe circumstances): _____

Physician _____
Date _____

[43 FR 52165, Nov. 8, 1978, as amended at 58 FR 33343, June 17, 1993]

Subpart C—Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

AUTHORITY: Sec. 118, Pub. L. 96–86, Oct. 12, 1979, unless otherwise noted.

SOURCE: 43 FR 4570, Feb. 2, 1978, unless otherwise noted.

§ 50.301 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, appropriated to the Department of Health and Human Services and administered by the Public Health Service.

§ 50.302 Definitions.

As used in this subpart: (a) *Law enforcement agency* means an agency, or any part thereof, charged under applicable law with enforcement of the general penal statutes of the United States, or of any State or local jurisdiction.

(b) *Medical procedures performed upon a victim of rape or incest* means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

(c) *Physician* means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she practices.

(d) *Public health service* means: (1) An agency of the United States or of a State or local government, that provides health or medical services; and

(2) A *rural health clinic,* as defined under section 1(d)(aa)(2) of Pub. L. 95–210, 91 Stat. 1485; except that any agency or facility whose principal function is the performance of abortions is specifically excluded from this definition.

§ 50.303 General rule.

Federal financial participation is not available for the performance of an abortion in programs or projects to which this subpart applies except under circumstances described in § 50.304 or § 50.306.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.304 Life of the mother would be endangered.

Federal financial participation is available in expenditures for an abortion when a physician has found, and so certified in writing to the program or project, that on the basis of his/her professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

(Sec. 101, Pub. L. 95–205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978]

§ 50.305 [Reserved]

§ 50.306 Rape and incest.

Federal financial participation is available in expenditures for medical procedures performed upon a victim of rape or incest if the program or project has received signed documentation from a law enforcement agency or public health service stating:

(a) That the person upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;

(b) The date on which the incident occurred;

(c) The date on which the report was made, which must have been within 60 days of the date on which the incident occurred;

Appendix D

Program Guidelines for Project Grants for Family Planning Services

Program Guidelines For Project Grants For Family Planning Services

United States Department of Health and Human Services
Office of Public Health and Science
Office of Population Affairs
Office of Family Planning
4350 East West Highway, Suite 200
Bethesda, Maryland 20814

January 2001

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Attachments

A. The Law: Title X Population Research and Voluntary Family Planning Programs

B. Regulations: Grants for Family Planning Services under Title X of the Public Health Service Act

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D. DHHS Regional Offices- Regional Program Consultants For Family Planning

Resource Documents

PART I

1.0 Introduction to the Program Guidelines

This document, *Program Guidelines for Project Grants for Family Planning Services (*Guidelines), has been developed by the Office of Population Affairs (OPA), U.S. Department of Health and Human Services (DHHS), to assist current and prospective grantees in understanding and utilizing the family planning services grants program authorized by Title X of the Public Health Service Act, 42 U.S.C. 300, et seq. The Office of Population Affairs also provides more detailed guidance, updated clinical information and clarification of specific program issues in the form of periodic Program Instructions to the Regional Offices.

This document is organized into two parts. Part I (sections 1-6) covers project management and administration, including the grant application and award process. Part II (sections 7-11) covers client services and clinic management.

Reference is made throughout the document to specific sections of the Title X law and implementing regulations, which are contained in *Attachments A and B,* respectively. (Reference to specific sections of the regulations will appear in brackets, e.g., [45 CFR Part 74, Subpart C].) Federal sterilization regulations are contained in *Attachment C.* The DHHS regional offices are listed in *Attachment D.* Selected other materials that provide additional guidance in specific areas are classified as *Resource Documents.*

1.1 DEFINITIONS

Throughout this document, the word “must” indicates *mandatory* program policy. “Should” indicates *recommended* program policy relating to components of family planning and project management that the project is urged to utilize in order to fulfill the intent of Title X. The words “can” and “may” indicate suggestions for consideration by individual projects.

The "grantee” is the entity that receives a Federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The “project” consists of those activities described in the grant application and supported under the approved budget. “Delegate/contract agencies” are those entities that provide family planning services with Title X funds under a negotiated, written agreement with a grantee. “Service sites” are those locations where services actually are provided by the grantee or delegate/contract agency.

2.0 The Law, Regulations, and Guidelines

To enable persons who want to obtain family planning care to have access to such services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs" to the Public Health Service Act. Section 1001 of the Act (as amended) authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)" (*see Attachment A*). The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X [42 CFR Part 59, Subpart A] set out the requirements of the Secretary, Department of Health and Human Services, for the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act. Prospective applicants and grantees should refer to the regulations (*see Attachment B*). This document, *Program Guidelines for Project Grants for Family Planning Services*, interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

3.0 The Application Process

3.1 ELIGIBILITY

Any public or nonprofit private entity located in a state (which, by definition, includes the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands [Midway, Wake, et al.], the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services project grant [59.2, 59.3].

To promote the purposes of Section 1001 of the Act in the most cost effective and efficient manner, grants will be made to public and non-profit private entities to foster projects most responsive to local needs. A non-profit private agency, institution, or organization must furnish evidence of its non-profit status in accordance with instructions accompanying the project grant application form. Under the law, grants cannot be made to entities that propose to offer only a single method or an unduly limited number of family planning methods. A facility or entity offering a single method can receive assistance under Title X by participating as a delegate/contract agency in an approvable project that offers a broad range of acceptable and effective medically approved family planning methods and services [59.5(a)(1)].

3.2 NEEDS ASSESSMENT

An assessment of the need for family planning services must be conducted prior to applying for a competitive grant award. The needs assessment documents the need for family planning services for persons in the service area and should include:

- Description of the geographic area including a discussion of potential geographic, topographic, and other related barriers to service;
- Demographic description of the service area including objective data pertaining to individuals in need of family planning services, maternal and infant morbidity/mortality rates, birth rates and rates of unintended pregnancies by age groups, poverty status of the populations to be served, cultural and linguistic barriers to services, etc.;
- Description of existing services and need for additional family planning services to meet community/cultural needs;
- Need indicators that include rates of STDs and HIV prevalence (including perinatal infection rates) in the grantee area;
- Identification and descriptions of linkages with other resources related to reproductive health; and
- Identification and discussion of high priority populations and target areas.

Grantees should perform periodic reassessment of service needs. Competitive grant applications must include a full and updated needs assessment.

3.3 THE APPLICATION

The Department of Health and Human Services' Office of Population Affairs administers the Title X Family Planning Program through the DHHS Regional Offices. An annual announcement of the availability of Title X service grant funds sets forth specific application requirements and evaluation criteria. Applications must be submitted to the Office of Grants Management for Family Planning Services on the form required by the Department. The application forms are available from the Office of Grants Management for Family Planning Services. Assistance regarding programmatic aspects of proposal preparation is available from the Regional Office. For assistance with administrative and budgeting aspects of proposal preparation, contact the Office of Grants Management for Family Planning Services.

Unless otherwise instructed, applicants are to respond to the standard instructions contained in the application kit and to the PHS supplemental instructions. An application must contain:

- a needs assessment
- a narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the requirements of the law and regulations;
- a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested [59.4(c)(2)] and which is consistent with the terms of Section 1006 of the Act, as implemented by regulation [59.7(b)];
- a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project;
- project objectives that are specific, realistic, and measurable; and
- other pertinent information as required [59.4(c)(4)].

The application must address all points contained in section 59.7(a) of the regulations, which are the criteria DHHS Regional Offices will use to decide which family planning projects to fund and in what amount. The application shall not include activities that cannot be funded under Title X, such as abortion, fundraising, or lobbying activities.

3.4 PROJECT REQUIREMENTS

Projects must adhere to:

- Section 59.5 and all other applicable provisions of the regulations, which list the requirements to be met by each project supported by Title X.
- The applicable requirements of these *Program Guidelines for Project Grants for Family Planning Services.*
- Other Federal regulations which apply to grants made under Title X [59.10]. For assistance in identifying other relevant regulations, contact the Regional Office.

3.5 NOTICE OF GRANT AWARD

The notice of grant award will inform the grantee how long DHHS intends to support the project without requiring it to recompete for funds [59.8]. This period of funding is called the "project period." The project will be funded in increments called "budget periods." The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All grantees must comply with the applicable legislative, regulatory and administrative requirements described in the *Public Health Service Grants Policy Statement*. A copy of the *Public Health Service Grants Policy Statement* may be obtained from the Office of Grants Management for Family Planning Services.

5.0 Legal Issues

5.1 VOLUNTARY PARTICIPATION

Use by any individual of project services must be solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use or not to use any particular method of family planning. Acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other service or assistance from or participation in any other programs of the applicant [59.5(a)(2)].

Project personnel must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

5.2 CONFIDENTIALITY

Every project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11].

5.3 CONFLICT OF INTEREST

Grantees must establish policies to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others.

5.4 LIABILITY COVERAGE

Grantees and/or delegates/contractors should ensure the existence of adequate liability coverage for all segments of the project funded under the grant, including all individuals providing services. Governing boards should obtain liability coverage for their members.

5.5 HUMAN SUBJECTS CLEARANCE (RESEARCH)

Grantees considering clinical or sociological research using Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. A copy of these regulations may be obtained from the Regional Office. Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources in any segment of the project.

6.0 Project Management

6.1 STRUCTURE OF THE GRANTEE

Family planning services under Title X grant authority may be offered by grantees directly and/or by delegate/contract agencies operating under the umbrella of the grantee. However, the grantee is responsible for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by delegate/contract agencies. Grantees must therefore have a negotiated, written agreement with each delegate/contract agency and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the *Program Guidelines for Project Grants for Family Planning Services,* as well as other applicable requirements such as Subpart C of 45 CFR Part 74, or Subpart C of 45 CFR Part 92. If a delegate/contract agency wishes to subcontract any of its responsibilities or services, a written negotiated agreement that is consistent with Title X requirements and approved by the grantee must be maintained by the delegate/contractor. Delegate/contract agencies should be invited to participate in the establishment of grantee standards and guidelines.

6.2 PLANNING AND EVALUATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered. To meet these requirements, each competitive application must include a plan which identifies overall goals and specific measurable objectives for the project period. The objectives may be directed to all clients or to specific groups of clients and must be consistent with Title X objectives. The plan must include an evaluation component that addresses and defines indicators by which the project intends to evaluate itself.

6.3 FINANCIAL MANAGEMENT

Grantees must maintain a financial management system that meets the standards specified in Subpart C of 45 CFR Part 74 or Subpart C of 45 CFR Part 92, as applicable, as well as any other requirements imposed by the Notice of Grant Award, and which complies with Federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained as required.

! Charges, Billing, and Collections

A grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project. The policies and procedures should be approved by the governing authority or board of the grantee and the Regional Office.

Clients must not be denied project services or be subjected to any variation in quality of services because of the inability to pay. Billing and collection procedures must have the following characteristics:

(1) Charges must be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services must be given bills directly. In cases where a third party is responsible, bills must be submitted to that party.

(2) A schedule of discounts must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees must be waived for individuals with family incomes above this amount who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.

(3) Clients whose documented income is at or below 100% of the Federal poverty

level must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services.

(4) Individual eligibility for a discount must be documented in the client's financial record.

(5) Bills to third parties must show total charges without applying any discount.

(6) Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or delegate/contract agency level is required.

(7) Bills to clients must show total charges less any allowable discounts.

(8) Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.

(9) Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.

(10) A method for the "aging" of outstanding accounts must be established.

(11) Voluntary donations from clients are permissible. However, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements set out above.

(12) Client income should be re-evaluated at least annually.

Effective financial management will assure the short and long term viability of the project, including the efficient use of grant funds. Technical assistance in achieving this objective is available from the Regional Office. Title X projects offering services that are not required by the statute, regulations or these Guidelines should whenever possible seek other sources of funding for such services before applying Title X funds to those activities.

! Financial Audit

Audits of grantees and delegate/contract agencies must be conducted in accordance with the provisions of 45 CFR Part 74, Subpart C, and 45 CFR Part 92, Subpart C, as applicable. The audits must be conducted by auditors meeting established criteria for qualifications and independence.

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet applicable standards established by the Federal, state and local governments (e.g., local fire, building and licensing codes).

Projects must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap in Federally assisted programs and activities, and which requires, among other things, that recipients of Federal funds operate their Federally assisted programs so that, when viewed in their entirety, they are readily accessible to people with disabilities. A copy of Part 84 may be obtained from the Regional office. Projects must also comply with any applicable provisions of the Americans With Disabilities Act (Public Law 101-336).

Emergency situations may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.

6.5 PERSONNEL

Grantees and delegate/contract agencies are reminded of their obligation to establish and maintain personnel policies that comply with applicable Federal and state requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title I of the Americans With Disabilities Act. These policies should include, but need not be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures. Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to and able to deal effectively with the cultural and other characteristics of the client population [59.5 (b)(10)].

Grantees must also ensure that:

- Projects are administered by a qualified project director;
- The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning;
- Protocols exist that provide all project personnel with guidelines for client care;

- Personnel records are kept confidential;
- Licenses of applicants for positions requiring licensure are verified prior to employment and that there is documentation that licenses are kept current.

6.6 TRAINING AND TECHNICAL ASSISTANCE

Projects must provide for the orientation and in-service training of all project personnel, including the staffs of delegate agencies and service sites. All project personnel should participate in continuing education related to their activities. Documentation of continuing education should be maintained and used in evaluating the scope and effectiveness of the staff training program.

Training through regional training centers is available to all projects under the Title X program. In addition to training, grantees may receive technical assistance for specific project activities. Technical assistance is provided by contract from the OPA and administered through the Regional Office. Information on training and technical assistance is available from the Regional Office.

6.7 REPORTING REQUIREMENTS

Grantees must:

(1) comply with the financial and other reporting requirements of 45 CFR Part 74 or 45 CFR Part 92, as applicable; and

(2) comply with other reporting requirements as required by DHHS.

6.8 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members (the size of the committee can differ from these limits with written documentation and approval from the Regional Office) who are broadly representative of the community must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X. Oversight responsibility for the I&E committee(s) rests with the grantee. The grantee may delegate the I & E operations for the review and approval of materials to delegate/contract agencies.

The I&E committee(s) must:

- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- Consider the standards of the population or community to be served with respect to such materials;
- Review the content of the material to assure that the information is factually correct;
- Determine whether the material is suitable for the population or community to which it is to be made available; and
- Establish a written record of its determinations [59.6].

The committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff. However, final approval of the I& E material rests with the committee(s).

6.9 COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

Boards and advisory committees for family planning services should be broadly representative of the population served.

! Community Participation

Title X grantees and delegate/contract agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services [59.5(b)(10)].

The I& E advisory committee may serve the community participation function if it meets the above requirements, or a separate group may be identified. In either case, the grantee project plan must include a plan for community participation. The community participation committee must meet annually or more often as appropriate.

! Community Education

Each family planning project must provide for community education programs [59.5(b)(3)]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial.

! Project Promotion

To facilitate community awareness of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community [59.5(b)(3)]. Projects should review a range of strategies and assess the availability of existing resources and materials. Promotion activities should be reviewed annually and be responsive to the changing needs of the community. For more information, contact the Regional Offices.

6.10 PUBLICATIONS AND COPYRIGHT

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. The word "publication" is defined to include computer software. Grantees should ensure that publications developed under Title X do not contain information which is contrary to program requirements or to accepted clinical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the *Public Health Service Grants Policy Statement*. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable right of the Government to reproduce, publish, or otherwise use such materials for Federal purposes and to authorize others to do so [45 CFR 74.36][45 CFR 92.34].

6.11 INVENTIONS OR DISCOVERIES

Family planning projects must comply with Government-wide regulations, 37 CFR Part 401, which apply to the rights to inventions made under government grants, contracts and cooperative agreements.

PART II

7.0 Client Services

Projects funded under Title X must provide clinical, informational, educational, social and referral services relating to family planning to clients who want such services. All projects must offer a broad range of acceptable and effective medically approved family planning methods and services either on-site or by referral [59.5(a)(1)]. Projects should make available to clients all methods of contraception approved by the Federal Food and Drug Administration.

Part II of this document has been developed to assist grantees in determining those services which will be provided to fulfill the mission of Title X.

- Projects must provide services stipulated in the law or regulations, or which are required by these Guidelines for the provision of high quality family planning services.

- Projects may also provide those services that are intended to promote the reproductive and general health care of the family planning client population.

7.1 SERVICE PLANS AND PROTOCOLS

The service plan is the component of the grantee's project plan, as set forth in the competitive application, which identifies those services to be provided to clients under Title X by the project. As part of the project plan, all grantees must assure that delegate/contractors have written clinical protocols and plans for client education, approved by the grantee and signed by the service site Medical Director, which outline procedures for the provision of each service offered and which are in accordance with state laws. Clinical protocols must be consistent with the requirements of these Guidelines.

Under exceptional circumstances, a waiver from a particular requirement may be obtained from the Regional Office upon written request from a grantee. In submitting a request for an exception, the grantee must provide epidemiologic, clinical, and other supportive data to justify the request and the duration of the waiver.

7.2 PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. However, the following components must be offered to and documented on all clients at the initial visit:

Education

- Presentation of relevant information and educational materials, based upon client needs and knowledge;

Counseling

- Interactive process in which a client is assisted in making an informed choice;

Informed Consent

- Explanation of all procedures and obtaining a general consent covering examination and treatment and, where applicable, a method specific informed consent form;

History

- Obtaining of a personal and family medical and social history;

Examination

- Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

- Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

- Planned mechanism for client follow-up;
- Performance of any necessary clinical procedures;
- Provision of medications and/or supplies as needed; and
- Provision of referrals as needed.

Return visits, with the exception of routine supply visits, should include an assessment of the client's health status, current complaints, and evaluation of birth control method, as well as an opportunity to change methods. The following components must be offered to and documented on all clients at the return visit:

History

- Updating a personal and family medical and social history;

Examination

- Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

- Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

- Planned mechanism for client follow-up;
- Performance of any necessary clinical procedures;
- Provision of medications and/or supplies as needed; and
- Provision of referrals as needed.

7.3 EMERGENCIES

Emergency situations involving clients and/or staff may occur at any time. All projects must therefore have written plans for the management of on-site medical emergencies. At a minimum, written protocols must address vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties. Protocols must also be in place for emergencies requiring transport, after-hours management of contraceptive emergencies, and clinic emergencies. All project staff must be familiar with these plans. Appropriate training, including training in CPR, should be available to staff.

7.4 REFERRALS AND FOLLOW-UP

Grantees must assure that delegate/contract agencies provide all family planning services listed in Section 8.0 under "Required Services," either on-site or by referral. When required services are to be provided by referral, the grantee must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.

Agencies must have written policies/procedures for follow-up on referrals that are made as a result of abnormal physical examination or laboratory test findings. These policies must be sensitive to clients' concerns for confidentiality and privacy.

For services determined to be necessary but which are beyond the scope of the project, clients must be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies must:

- Make arrangements for the provision of pertinent client information to the referral provider. Agencies must obtain client's consent to such arrangements, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality;

- Advise client on their responsibility in complying with the referral; and

- Counsel client on the importance of such referral and the agreed upon method of follow-up.

Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care. Agencies must maintain a current list of health care providers, local health and human services departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs to be used for referral purposes. Whenever possible, clients should be given a choice of providers from which to select.

8.0 Required Services

The services contained in this section must be provided by all projects funded under Title X.

The client's written informed voluntary consent to receive services must be obtained prior to the client receiving any clinical services. In addition, if a client chooses a prescription method of contraception, a method-specific consent form must be obtained and updated routinely at subsequent visits to reflect current information about that method.

8.1 CLIENT EDUCATION

Grantees and/or delegate/contract agencies must have written plans for client education that include goals and content outlines to ensure consistency and accuracy of information provided. Client education must be documented in the client record. The education provided should be appropriate to the client's age, level of knowledge, language, and socio-cultural background and be presented in an unbiased manner. A mechanism to determine that the information provided has been understood should be established.

Education services must provide clients with the information needed to:

- Make informed decisions about family planning;
- Use specific methods of contraception and identify adverse effects;
- Perform breast/testicular self examination;
- Reduce risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV);
- Understand the range of available services and the purpose and sequence of clinic procedures; and
- Understand the importance of recommended screening tests and other procedures involved in the family planning visit.

Clients should be offered information about basic female and male reproductive anatomy and physiology, and the value of fertility regulation in maintaining individual and family health. Additional education should include information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse.

! Method-Specific Informed Consent

Written informed consent, specific to the contraceptive method, must be signed before a prescription contraceptive method is provided. Prior to implementation, informed consent forms should be approved by the service site Medical Director.

The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen. Specific education and consent forms for the contraceptive method provided must be part of the project's service plan.

The signed informed consent form must be a part of the client's record. All consent forms should contain a statement that the client has been counseled, provided with the appropriate informational material, and understands the content of both. The method-specific consent form should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method.

Federal sterilization regulations [42 CFR Part 50, Subpart B], which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.2 COUNSELING

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware and able to create an environment in which the client feels comfortable discussing personal information. The counselor must be sufficiently knowledgeable to provide accurate information regarding the benefits and risk, safety, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the various contraceptive methods. Additionally, the counselor should be knowledgeable about the other services offered by the agency. Documentation of counseling must be included in the client's record.

! Method Counseling

Method counseling refers to an individualized dialogue with a client that covers the following:

- Results of physical exam and lab studies;
- Effective use of contraceptive methods, including natural family planning (NFP), and the benefit and efficacy of the methods;
- Possible side effects/complications;
- How to discontinue the method selected and information regarding back-up

method use, including the use of certain oral contraceptives as post-coital emergency contraception;

- Planned return schedule;
- Emergency 24-hour telephone number;
- Location where emergency services can be obtained; and
- Appropriate referral for additional services as needed.

! Sexually Transmitted Disease (STD) and HIV Counseling

All clients must receive thorough and accurate counseling on STDs and HIV. STD/HIV counseling refers to an individualized dialogue with a client in which there is discussion of personal risks for STDs/HIV, and the steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STD/HIV must be given advice regarding risk reduction and must be advised whether clinical evaluation is indicated. All projects must offer, at a minimum, education about HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may also provide HIV risk assessment, counseling and testing by specially trained staff. When the project does not offer these optional services, the project must provide the client with a list of health care providers who can provide these services.

8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING

! History

At the initial comprehensive clinical visit, a complete medical history must be obtained on all female and male clients. Pertinent history must be updated at subsequent clinical visits. The comprehensive medical history must address at least the following areas:

- Significant illnesses; hospitalizations; surgery; blood transfusion or exposure to blood products; and chronic or acute medical conditions;
- Allergies;
- Current use of prescription and over-the-counter medications;
- Extent of use of tobacco, alcohol, and other drugs;

- Immunization and Rubella status;
- Review of systems;
- Pertinent history of immediate family members; and
- Partner history
    - injectable drug use
    - multiple partners
    - risk history for STDs and HIV
    - bisexuality.

Histories of reproductive function in female clients must include at least the following:

- Contraceptive use past and current (including adverse effects);
- Menstrual history;
- Sexual history;
- Obstetrical history;
- Gynecological conditions;
- Sexually transmitted diseases, including HBV;
- HIV;
- Pap smear history (date of last Pap, any abnormal Pap, treatment); and
- In utero exposure to diethylstilbestrol (DES).

Histories of reproductive function in male clients must include at least the following:

- Sexual history;
- Sexually transmitted diseases (including HBV);

- HIV; and
- Urological conditions.

! Physical Assessment (female)

For many clients, family planning programs are their only continuing source of health information and clinical care. Therefore, an initial complete physical examination, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts, abdomen, pelvis, and rectum, should be performed.

While most client services will necessarily relate to fertility regulation, family planning clinics must provide and encourage clients to use health maintenance screening procedures, initially and as indicated. Clinics must provide and stress the importance of the following to all clients:

- Blood pressure evaluation;
- Breast exam;
- Pelvic examination which includes vulvar evaluation and bimanual exam;
- Pap smear;
- Colo-rectal cancer screening in individuals over 40; and
- STD and HIVscreening, as indicated.

Following counseling about the importance of the above preventive services, if a client chooses to decline or defer a service, this should be documented in their record. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or procedures.

All physical examination and laboratory test requirements stipulated in the prescribing information for specific methods of contraception must be followed. Physical examination and related prevention services should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless if in the clinician's judgment there is a compelling reason for extending the deferral. All deferrals, including the reason(s) for deferral, must be documented in the client record. Project protocols should be developed accordingly.

! Physical Assessment (male)

Family planning clinics also may be an important source of reproductive health care for male clients. Physical examination should be made available to male clients, including height and weight, examination of the thyroid, heart, lungs, breasts, abdomen, extremities, genitals and rectum. Examination should also include palpation of the prostate, as appropriate, and instructions in self-examination of the testes. Clinics should stress the importance of the following to male clients:

- Blood pressure evaluation;
- Colo-rectal cancer screening in individuals over 40; and
- STD and HIVscreening, as indicated.

! Laboratory Testing

Specific laboratory tests are required for the provision of specific methods of contraception. Laboratory tests can also be important indicators of client health status and useful for diagnostic purposes. Pregnancy testing must be provided onsite. The following laboratory procedures must be provided to clients if required in the provision of a contraceptive method, and may be provided for the maintenance of health status and/or diagnostic purposes, either on-site or by referral:

- Anemia assessment
- Gonorrhea and chlamydia test
- Vaginal wetmount
- Diabetes testing
- Cholesterol and lipids
- Hepatitis B testing
- Syphilis serology (VDRL, RPR)
- Rubella titer
- Urinalysis

  - HIV testing

- Notification of Abnormal Lab Results

A procedure which addresses client confidentiality must be established to allow for client notification and adequate follow-up of abnormal laboratory results.

- Other Laboratory Services or Procedures

Other procedures and lab tests may be indicated for some clients and may be provided on-site or by referral.

! Revisits

Revisit schedules must be individualized based upon the client's need for education, counseling, and clinical care beyond that provided at the initial and annual visit.

Clients selecting hormonal contraceptives, intrauterine devices (IUDs), cervical caps, or diaphragms for the first time should be scheduled for a revisit as appropriate after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information or clarification. A new or established client who chooses to continue a method already in use need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

8.4 FERTILITY REGULATION

! Reversible Contraception

Currently, the reversible methods of contraception include barrier methods (female and male), IUDs, fertility awareness methods, natural family planning, and hormonal methods (injectables, implants, orals). Certain oral contraceptive regimens have been found by the Federal Food and Drug Administration to be safe and effective for use as postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. More than one method of contraception can be used simultaneously by a client and may be particularly indicated to minimize the risks of STDs/HIV and pregnancy. Consistent and correct use of condoms should be encouraged for all persons at risk for STDs/HIV.

! Permanent Contraception

The counseling and consent process must assure that the client's decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal sterilization regulations, which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.5 INFERTILITY SERVICES

Grantees must make basic infertility services available to women and men desiring such services. Infertility services are categorized as follows:

• *Level I*	Includes initial infertility interview, education, physical examination, counseling, and appropriate referral.
• *Level II*	Includes such testing as semen analysis, assessment of ovulatory function and postcoital testing.
• *Level III*	More sophisticated and complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Level II infertility services may be offered in projects with clinicians who have special training in infertility. Level III services are considered to be beyond the scope of Title X program.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Projects must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to the family planning facility. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects should have available a pregnancy test of high sensitivity. If the medical examination cannot be performed in conjunction with the laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, referral for early initiation of prenatal care should be made. Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays). For clients with a negative pregnancy diagnosis, the cause of delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.

Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- Prenatal care and delivery;
- Infant care, foster care, or adoption; and
- Pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling [59.5(a)(5)].

Clients who are found not to be pregnant should be given information about the availability of contraceptive and infertility services, as appropriate.

8.7 ADOLESCENT SERVICES

Adolescent clients require skilled counseling and age-appropriate information. Appointments should be available to them for counseling and clinical services as soon as possible.

Adolescents seeking contraceptive services must be informed about all methods of contraception. Abstinence as well as contraceptive and safer sex practice options to reduce risks for STD/HIV and pregnancy must be discussed with all adolescents. It is important not to assume that adolescents are sexually active simply because they have come for family planning services. As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively.

Adolescents must be assured that the counseling sessions are confidential and, if follow-up is necessary, every attempt will be made to assure the privacy of the individual. However, counselors should encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on resisting attempts to coerce minors into engaging in sexual activities. Title X projects may not require written consent of parents or guardians for the provision of services to minors. Nor can the project notify parents or guardians before or after a minor has requested and received Title X family planning services.

8.8 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

The children of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. As part of the medical history, clients born between 1940 and 1970 should be asked if their mothers took estrogens during pregnancy. Clients prenatally exposed to exogenous estrogens should receive information/education and special screening either on-site or by referral.

9.0 Related Services

The following related health services, which can improve quality of care, may be offered if skilled personnel and equipment are available.

9.1 GYNECOLOGIC SERVICES

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of health care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine. More complex procedures, such as colposcopy, may be offered, provided that clinicians performing these services have specialized training.

9.2 SEXUALLY TRANSMITTED DISEASES (STD) AND HIV/AIDS

The increasing incidence and prevalence of STDs, particularly among adolescents, requires that family planning projects increase their efforts to provide education and information about the more common STDs and HIV/AIDS. Projects should make available detection and treatment of the more common STDs. At-risk clients should be urged to undergo examination and treatment as indicated, either directly or by referral. When treatment is provided on-site, appropriate follow-up measures must be undertaken.

Gonorrhea and chlamydia tests must be available for clients requesting IUD insertion. Tests for gonorrhea, syphilis, chlamydia and HIV should be provided as indicated by client request or evidence of increased risk for infection.

Grantees and/or delegate contract agencies must comply with state and local STD reporting requirements.

9.3 SPECIAL COUNSELING

Clients should be offered appropriate counseling and referral as indicated regarding future planned pregnancies, management of a current pregnancy, and other individual concerns (e.g., substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) as indicated. Preconceptional counseling should be provided if the client's history indicates a desired pregnancy in the future.

9.4 GENETIC INFORMATION AND REFERRAL

Basic information regarding genetic conditions should be offered to family planning clients who request or are in need of such services. Extensive genetic counseling and evaluation is beyond the scope of the Title X program. Referral systems should be in place for those who require further genetic counseling and evaluation

9.5 HEALTH PROMOTION/DISEASE PREVENTION

Family planning programs should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease. Programs are encouraged to assess the health problems prevalent in the populations they serve and to develop strategies to address them.

9.6 POSTPARTUM CARE

Family planning programs may provide postpartum care in collaboration with local agencies or institutions which provide prenatal and/or intrapartum care. If a family planning program undertakes responsibility for postpartum care, such care should be directed toward assessment of the woman's physical health, initiation of contraception if desired, and counseling and education related to parenting, breast feeding, infant care, and family adjustment.

10.0 Clinic Management

10.1 EQUIPMENT AND SUPPLIES

Equipment and supplies must be appropriate to the type of care offered by the project. Projects are expected to follow applicable Federal and state regulations regarding infection control.

10.2 PHARMACEUTICALS

Agencies must be operated in accordance with Federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project.

10.3 MEDICAL RECORDS

Projects must establish a medical record for every client who obtains clinical services. These records must be maintained in accordance with accepted medical standards and State laws with regard to record retention. Records must be:

- Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;
- Signed by the clinician and other appropriately trained health professionals making entries, including name, title and date;
- Readily accessible;
- Systematically organized to facilitate prompt retrieval and compilation of information;
- Confidential;
- Safeguarded against loss or use by unauthorized persons;
- Secured by lock when not in use; and
- Available upon request to the client.

! Content of the Client Record

The client’s medical record must contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical impression or diagnosis, and warrant the treatment and end results. The required content of the medical record includes:

- Personal data;
- Medical history, physical exam, laboratory test orders, results, and follow-up;
- Treatment and special instructions;
- Scheduled revisits;
- Informed consents;
- Refusal of services; and
- Allergies and untoward reactions to drug(s) recorded in a prominent and specific location.

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral, and follow-up. The record must allow for entries by counseling and social service staff. Projects should maintain a problem list at the front of each chart listing identified problems to facilitate continuing evaluation and follow-up. Client financial information should be kept separate from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.

! Confidentiality and Release of Records

A confidentiality assurance statement must appear in the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality [59.11]. HIV information should be handled according to law, and kept separate whenever possible. When information is requested, agencies should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care.

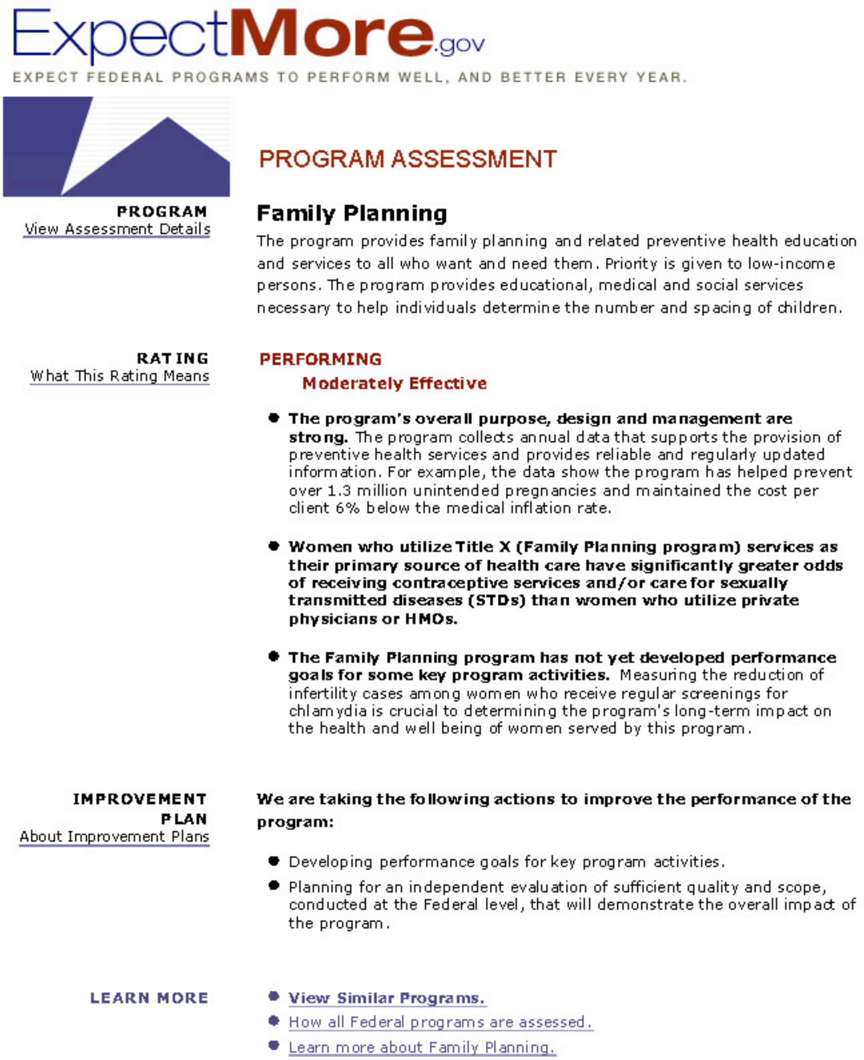
10.4 QUALITY ASSURANCE AND AUDIT

A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality assurance system should include:

- An established set of clinical, administrative and programmatic standards by which conformity would be maintained;
- A tracking system to identify clients in need of follow-up and/or continuing care;
- Ongoing medical audits to determine conformity with agency protocols;
- Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;
- Periodic review of medical protocols to insure maintenance of current standards of care;
- A process to elicit consumer feedback; and
- Ongoing and systematic documentation of quality assurance activities.

Appendix E

Family Planning Program Assessment Rating Tool



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EXPECT FEDERAL PROGRAMS TO PERFORM WELL, AND BETTER EVERY YEAR.

PROGRAM ASSESSMENT

PROGRAM
View Assessment Details

Family Planning

The program provides family planning and related preventive health education and services to all who want and need them. Priority is given to low-income persons. The program provides educational, medical and social services necessary to help individuals determine the number and spacing of children.

RATING
What This Rating Means

PERFORMING
Moderately Effective

- **The program's overall purpose, design and management are strong.** The program collects annual data that supports the provision of preventive health services and provides reliable and regularly updated information. For example, the data show the program has helped prevent over 1.3 million unintended pregnancies and maintained the cost per client 6% below the medical inflation rate.
- **Women who utilize Title X (Family Planning program) services as their primary source of health care have significantly greater odds of receiving contraceptive services and/or care for sexually transmitted diseases (STDs) than women who utilize private physicians or HMOs.**
- **The Family Planning program has not yet developed performance goals for some key program activities.** Measuring the reduction of infertility cases among women who receive regular screenings for chlamydia is crucial to determining the program's long-term impact on the health and well being of women served by this program.

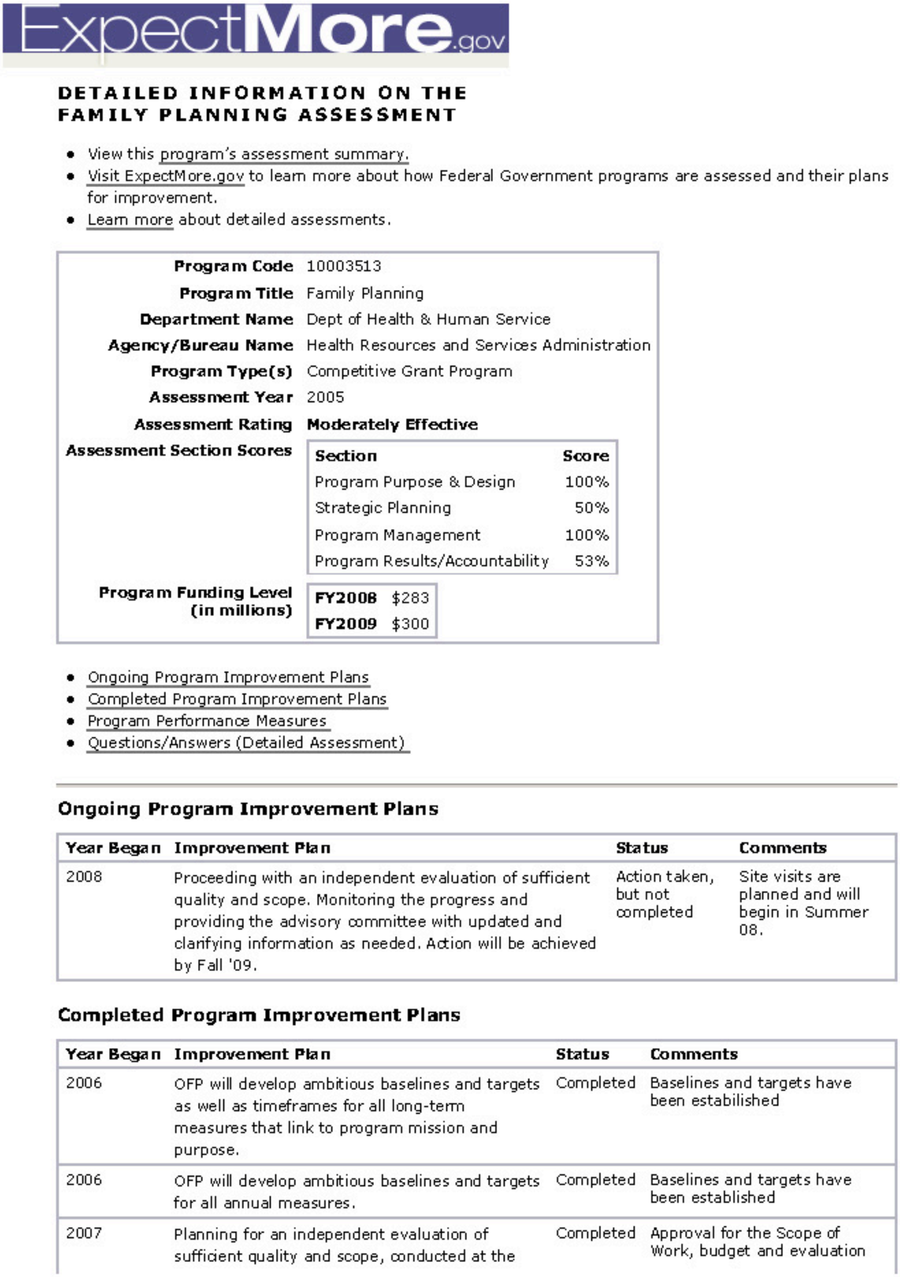
IMPROVEMENT PLAN
About Improvement Plans

We are taking the following actions to improve the performance of the program:

- Developing performance goals for key program activities.
- Planning for an independent evaluation of sufficient quality and scope, conducted at the Federal level, that will demonstrate the overall impact of the program.

LEARN MORE

- **View Similar Programs.**
- How all Federal programs are assessed.
- Learn more about Family Planning.



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DETAILED INFORMATION ON THE FAMILY PLANNING ASSESSMENT

- View this program's assessment summary.
- Visit ExpectMore.gov to learn more about how Federal Government programs are assessed and their plans for improvement.
- Learn more about detailed assessments.

Program Code	10003513
Program Title	Family Planning
Department Name	Dept of Health & Human Service
Agency/Bureau Name	Health Resources and Services Administration
Program Type(s)	Competitive Grant Program
Assessment Year	2005
Assessment Rating	**Moderately Effective**

Assessment Section Scores

Section	Score
Program Purpose & Design	100%
Strategic Planning	50%
Program Management	100%
Program Results/Accountability	53%

Program Funding Level (in millions)

FY2008	$283
FY2009	$300

- Ongoing Program Improvement Plans
- Completed Program Improvement Plans
- Program Performance Measures
- Questions/Answers (Detailed Assessment)

Ongoing Program Improvement Plans

Year Began	Improvement Plan	Status	Comments
2008	Proceeding with an independent evaluation of sufficient quality and scope. Monitoring the progress and providing the advisory committee with updated and clarifying information as needed. Action will be achieved by Fall '09.	Action taken, but not completed	Site visits are planned and will begin in Summer 08.

Completed Program Improvement Plans

Year Began	Improvement Plan	Status	Comments
2006	OFP will develop ambitious baselines and targets as well as timeframes for all long-term measures that link to program mission and purpose.	Completed	Baselines and targets have been estabilished
2006	OFP will develop ambitious baselines and targets for all annual measures.	Completed	Baselines and targets have been established
2007	Planning for an independent evaluation of sufficient quality and scope, conducted at the	Completed	Approval for the Scope of Work, budget and evaluation

	Federal level, that will demonstrate the overall impact of the program. Action will be achieved by Spring '07.		plan has been approved. The contract with an independent agency has been initiated
2007	Proceeding with an independent evaluation of sufficient quality and scope. Monitoring the completion of contract negotiations between Department entities, the Program and the Independent Contractor. Action will be achieved by Fall '07.	Completed	

Program Performance Measures

<table>
<tr><th>Term</th><th>Type</th><th></th></tr>
<tr><td>Long-term</td><td>Outcome</td><td>Measure: Reduce invasive cervical cancer among women attending Title X family planning clinics by providing Pap tests.

<i>Explanation:</i>Baselines will be established and targets determined after receipt of 2005 Family Planning Annual Report Data (April 2006).

<table>
<tr><th>Year</th><th>Target</th><th>Actual</th></tr>
<tr><td>2005</td><td>Baseline</td><td>808</td></tr>
<tr><td>2006</td><td>809</td><td>799</td></tr>
<tr><td>2007</td><td>809</td><td>798</td></tr>
<tr><td>2008</td><td>800</td><td>Fall 2009</td></tr>
<tr><td>2009</td><td>798</td><td>Spring 2010</td></tr>
<tr><td>2010</td><td>796</td><td>Spring 2011</td></tr>
<tr><td>2011</td><td>795</td><td>Spring 2012</td></tr>
</table></td></tr>
<tr><td>Long-term</td><td>Outcome</td><td>Measure: Reduce infertility among women attending Title X family planning clinics by identifying Chlamydia infection through screening of females ages 15-24.

<i>Explanation:</i>Baselines will be established and targets determined after receipt of 2005 Family Planning Annual Report Data (April 2006).

<table>
<tr><th>Year</th><th>Target</th><th>Actual</th></tr>
<tr><td>2005</td><td>Baseline</td><td>1,349,884</td></tr>
<tr><td>2006</td><td>1,398,000</td><td>1,353,319</td></tr>
<tr><td>2007</td><td>1,398,000</td><td>1,361,901</td></tr>
<tr><td>2008</td><td>1,352,000</td><td>Fall 2009</td></tr>
<tr><td>2009</td><td>1,349,000</td><td>Spring 2010</td></tr>
<tr><td>2010</td><td>1,347,000</td><td>Spring 2011</td></tr>
<tr><td>2011</td><td>1,345,000</td><td>Spring 2012</td></tr>
<tr><td>2012</td><td>1</td><td>Spring 2013</td></tr>
<tr><td>2013</td><td>1</td><td>Spring 2014</td></tr>
</table></td></tr>
<tr><td>Long-term</td><td>Efficiency</td><td>Measure: Maintain the actual cost per Title X family planning client below the medical care inflation rate.

<i>Explanation:</i>Performance will be reported upon receipt of 2005 Family Planning Annual Report Data (April 2006).

<table>
<tr><th>Year</th><th>Target</th><th>Actual</th></tr>
</table></td></tr>
</table>

2004	Baseline	$193.92
2005	$214.61	$200.81
2006	$223.97	$215.56
2007	$233.73	$229.32
2008	$243.92	Fall 2009
2009	$254.55	Spring 2010
2010	$265.62	Spring 2011
2011	$277.18	Spring 2012
2012	$289.25	Spring 2013
2013	$301.85	Spring 2014

Long-term Outcome

Measure: Increase the number of unintended pregnancies averted by providing Title X Family Planning Services, with priority for services to low income individuals.

*Explanation:*Performance on measure will be reported based on 2008 Family Planning Annual Report Data. Annual progress toward meeting long-term target will be reported based on 2005 Family Planning Annual Report Data (April 2006).

Year	Target	Actual
2003	Baseline	1,116,315
2004	1,012,655	1,125,300
2005	964,000	978,845
2006	963,500	975,080
2007	1,142,608	968,868
2008	981,000	Fall 2009
2009	978,000	Spring 2010
2010	976,000	Spring 2011
2011	974,000	Spring 2012
2012	1	Spring 2013
2013	1	Spring 2013

Questions/Answers (Detailed Assessment)

Section 1 - Program Purpose & Design

Number	Question	Answer	Score
1.1	**Is the program purpose clear?** *Explanation:* The purpose and mission of the Family Planning program is to provide individuals the medical, educational and social services necessary to 1) exercise personal choice in determining the number and spacing of their children and 2) ensure their reproductive health and well-being (through prevention of STDs, HIV and routine cancer screenings), with a priority given to low-income persons. By increasing utilization of family planning services within underserved populations, and by providing preventative health care that prevents the acquisition and spread of STDs and HIV, the program seeks to improve the health of individuals who would otherwise not have access to family planning and related preventative health services. *Evidence:* Evidence for this answer can be found in the following documents: ?? Family Planning Services and Population Research Act of 1970 (Public Law 91-	YES	20%

	572) ?? Title X of the Public Health Service Act (42 USC 300 et. seq.) ?? Regulations: [42CFR Part 59, Subpart A] ?? Family Planning FY 2006 Performance Plan ?? Program Guidelines for Project Grants for Family Planning Services (Mission statement, p.2, 2nd paragraph) ?? OPA Website, OFP homepage: opa.osophs.dhhs.gov		
1.2	**Does the program address a specific and existing problem, interest, or need?** *Explanation:* According to the U.S. Census Bureau, of the approximately 45 million people who are currently without health insurance, approximately 50% (26.4 million) are within the reproductive ages of 18-44. Subsequently, millions of Americans do not have regular access to preventative health services and education necessary to make informed decisions about their reproductive health. Almost 50% of pregnancies in the U.S. are unintended and 40% of women who are not seeking pregnancy and not using a method of contraception account for 53% of unintended pregnancies. Each year, publicly-subsidized family planning services help women avoid an estimated 1.3 million unintended pregnancies. *Evidence:* Evidence for this answer can be found in the following documents: 1) Family Planning FY 2006 Performance Plan (GPRA) (Performance Goal1 and p. 8, Goal I.C. Frost, J., Frohwirth, L., & Purcell, A. 2) "The Availability and Use of Publicly Funded Family Planning Clinics: U.S. Trends, 1994-2001" (Perspectives on Sexual and Reproductive Health, 2004. 36(5), 206-216) 3) Henshaw, S. "Unintended Pregnancy in the United States" (Family Planning Perspectives, 1998. 30(1), 24-29;46) 4) "Contraceptive Needs and Services, 2001-2002" (The Alan Guttmacher Institute, 2004) 5) Issues in Brief, 2004 Series, No. 3, "Preventing Unintended Pregnancy in the United States.	YES	20%
1.3	**Is the program designed so that it is not redundant or duplicative of any other Federal, state, local or private effort?** *Explanation:* Title X is the sole federal program dedicated to the provision of family planning services for those who do not qualify for Medicaid and who are otherwise unable to afford adequate health insurance. Title X supported clinics play a vital role in providing services to individuals who are poor but not covered by Medicaid because they 1) are not poor enough to qualify, 2) do not have a child or 3) they do not have a private physician who is willing to accept Medicaid clients. While private and non-profit organizations, as well as other Federal programs, such as Community Health Centers (CHC), provide varying levels of family planning services, none of them were designed to provide the breadth and quality of reproductive health care as that which is provided by the Family Planning program. The Family Planning program is unique in its both its purpose and ability to enable uninsured (and underinsured) individuals to make informed reproductive choices and remain in good health so that they experience successful outcomes in future pregnancies. *Evidence:* Evidence for this answer can be found in the following documents: ?? Issues in Brief - Community Health Centers and Family Planning ?? Frost, J., Frohwirth, L., & Purcell, A. "The Availability and Use of Publicly Funded Family Planning Clinics: U.S. Trends, 1994-2001" (Perspectives on Sexual and Reproductive Health, Vol. 36, Number 5, Sept./Oct. 2004, 206-216) ?? Frost, J. "Public or Private Providers? U.S. Women's Use of Reproductive Health Services (Family Planning Perspectives, 2001. 33(1):4-12) ?? Use of Contraception and Use of Family Planning Services in the United States: 1982-2002. Advance Data	YES	20%

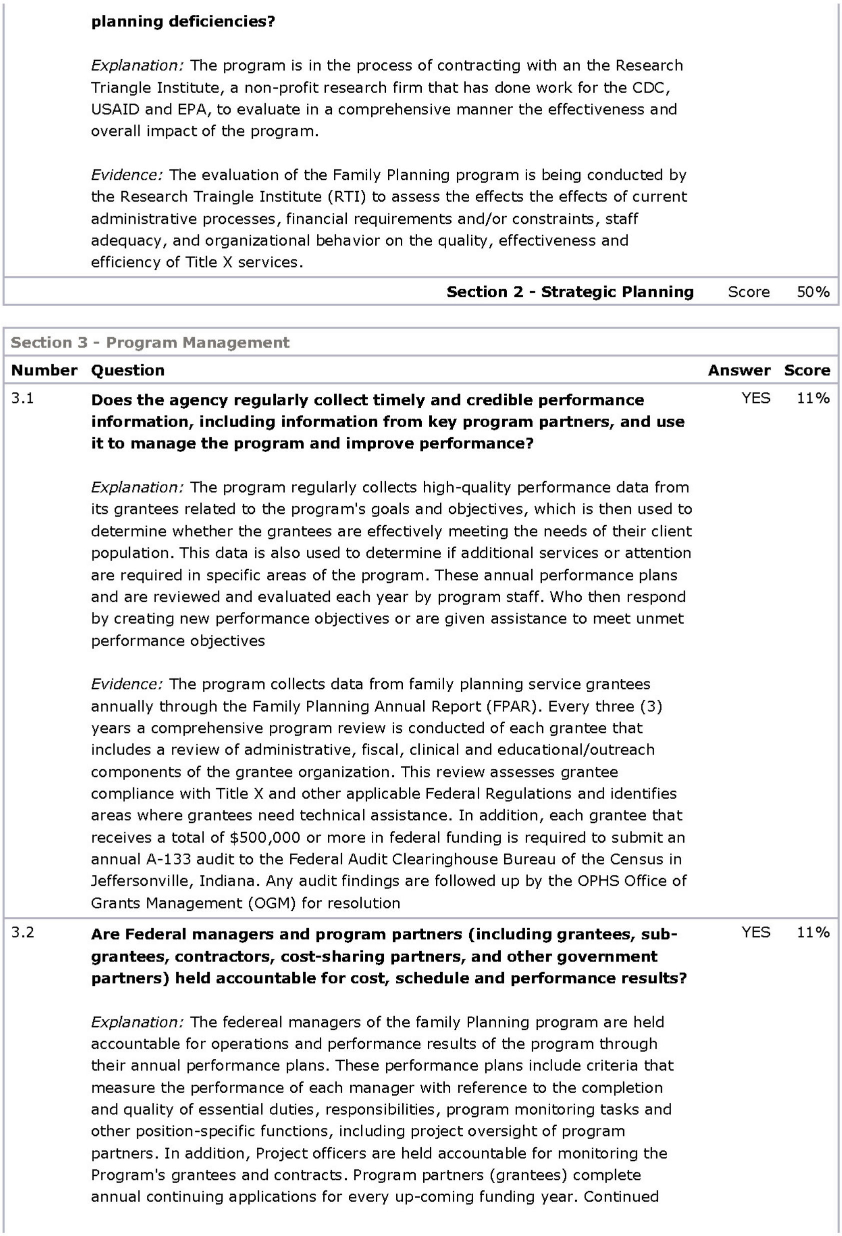
	No. 350 (2004)		
1.4	**Is the program design free of major flaws that would limit the program's effectiveness or efficiency?** *Explanation:* The Title X Family Planning program is intended to provide accessible, high-quality, and community-based family planning services to all who want and need them- with priority given to low-income persons who would otherwise not have access to such care. The program accomplishes this by awarding grants and/or contracts, on a competitive basis, to public or not-for-profit community-based providers who possess a good understanding of their communities' needs. Because the purpose of the program is to provide direct health services to an underserved population, issuing grants or contracts to local clinics to provide these services is the most efficient way to achieve the program's intended purpose. Title X funds also represent only approximately 25% of their grantees' revenues. This ensures that these clinics receive buy in from other State and local organizations that have an interest in providing family planning services to low-income communities. *Evidence:* Evidence for this answer can be found in the following documents: ?? Program Guidelines for Project Grants for Family Planning Services ?? Federal Register Announcements - FY05 Services, FY05 General Training, FY 05 Service Delivery Improvement Research ?? OPA Clearinghouse Publications List ?? FY 2005 Regional MOU and Work Plan Guidance ?? Frost, J., Frohwirth, L., & Purcell, A. "The Availability and Use of Publicly Funded Family Planning Clinics: U.S. Trends, 1994-2001" (Perspectives on Sexual and Reproductive Health, Vol. 36, Number 5, Sept./Oct. 2004, 206-216)	YES	20%
1.5	**Is the program design effectively targeted so that resources will address the program's purpose directly and will reach intended beneficiaries?** *Explanation:* The Family Planning program is designed in a manner that ensures resources are being used directly and effectively to meet the program's purpose. As the program was developed to provide family planning services to all who need and want them, with priority given to low-income individuals, the program's services are provided at no cost to individuals at or below 100% of the Federal Poverty Level (FPL). For those just above the FPL, the program utilizes a sliding fee scale for those individuals between 101% and 250% of the FPL. According to the 2003 Family Planning Annual Report (FPAR), over two-thirds (67%) of clients served in Title X clinics were at or below 100% of the FPL, and 90% were below 200% of the FPL, indicating that the program's family planning services are being provided to it's priority populations. *Evidence:* Evidence for this answer can be found in the following documents: ?? 2003 FPAR - Table A-5 ?? Program Review Tool ?? FY 2005 Regional MOU ?? Title X Statute ?? Title X Regulations ?? Program Guidelines for Family Planning Services (2001) ?? FY 2005 Family Planning Services Announcement 90% Appropriations Language	YES	20%
	Section 1 - Program Purpose & Design	Score	100%

Section 2 - Strategic Planning

Number	Question	Answer	Score
2.1	**Does the program have a limited number of specific long-term performance measures that focus on outcomes and meaningfully reflect**	YES	12%

	the purpose of the program? *Explanation:* The Office of Population Affairs' (OPA) Office of Family Planning has developed three long-term measures that directly reflect the core purpose of the program and reflect the program's progress in achieving meaningful health outcomes. These long-term measures are linked to Healthy People 2010 and are responsive to both HRSA's long-term plan and the HHS Strategic Goals and Objectives as reflected in the FY 2006 HRSA budget/performance integration plan. *Evidence:* The program's long-term measures are as follows: 1) Increase the number of unintended pregnancies averted by providing Title X Family Planning services, with priority for services to low-income individuals 2) Reduce infertility among women attending Title X Family Planning clinics by identifying Chlamydia infection through screening of females ages 15-24. 3) Reduce invasive cervical cancer among women attending Title X Family Planning clinics by providing Pap tests.		
2.2	**Does the program have ambitious targets and timeframes for its long-term measures?** *Explanation:* The program has a clear baseline and specific quantified targets for one of its long-term measures (averting unintended pregnancies by ensuring access to a broad range of family planning services and methods), and is presently developing baselines and targets for its other two long-term measures. Because the baselines and targets for these two measures will not be available until Spring 2006, and therefore not available for inclusion in the FY 2007 Budget, this question must be answered "no". *Evidence:* Evidence for this answer can be found in the following documents: ?? FPAR 2003 ?? Proposed long-term objectives for Title X ?? Title X budget and performance plan for FY 2006 ?? Appropriations language Title X FY 2005 ?? Issues in Brief, 2004 Series, No. 3, "Preventing Unintended Pregnancy in the United States"	NO	0%
2.3	**Does the program have a limited number of specific annual performance measures that can demonstrate progress toward achieving the program's long-term goals?** *Explanation:* In order to measure their progress annually in achieving their long-term goals, the Family Planning program will simply break down its long-term measures into annual targets. Therefore their annual measures will look identical to their long-term measures (sited in the evidence section of question 3.1), with the exception that each measure will have annual targets. The program already has yearly targets in place for its "unintended pregnancies averted" measure, and are in the process of developing baselines and annual targets for its other two measures. *Evidence:* Evidence for this answer can be found in the following documents: ?? FPAR 2003 ?? Title X budget and performance plan for FY 2006 ?? HRSA and HHS Strategic Goals and Objectives ?? Revised FPAR forms and instructions ?? AGI Estimates of the number of unintended pregnancies averted among all women and women under age 20 attending Title X family planning clinics 2000-2003	YES	12%
2.4	**Does the program have baselines and ambitious targets for its annual measures?**	NO	0%

	Explanation: The program does have a baseline and ambitious targets for one of the above annual measures (increasing the number of unintended pregancies averted) and is presently developing baselines and targets for its other two annual measures. Because the baselines and annual targets for these two measures will not be available until Spring 2006, and therefore not available for inclusion in the FY 2007 Budget, this question must be answered "no". *Evidence:* Evidence for this answer can be found in the following documents: ?? Title X statute and regulations ?? FPAR 2003 (trend table) ?? Title X budget and performance plan for FY 2006		
2.5	**Do all partners (including grantees, sub-grantees, contractors, cost-sharing partners, and other government partners) commit to and work toward the annual and/or long-term goals of the program?** *Explanation:* All of the program's partners are committed to and work toward the annual and long-term goals of the program. The memorandum of understanding (MOU) with the Regional Offices is a written commitment to the stated annual program goals and priorities. The program priorities define the context for program activities that contribute to achieving long- and short-term goals, and define program requirements for grantees. Grantees commit to and report on achievement toward annual program goals in the annual continuation grant applications and on the FPAR. Grantees are required to use a competitive process to distribute funds to sub-recipients that is consistent with Title X requirements, and commit to monitor sub-recipients and hold them accountable for performance *Evidence:* Evidence for this answer can be found in the following documents: ?? Federal Register Notices - Availability of Funds for Family Planning Services Projects, 2003, 2004, 2005 ?? Family Planning Program Priorities, Legislative Mandates, and Key Issues ?? Title X statute and regulations ?? Competing Application Guidance for Title X Services Grants ?? Review Criteria for Title X objective review of Title X services project applications ?? Application kit contents	YES	12%
2.6	**Are independent evaluations of sufficient scope and quality conducted on a regular basis or as needed to support program improvements and evaluate effectiveness and relevance to the problem, interest, or need?** *Explanation:* Independent evaluations of sufficient scope and have not been conducted on a regular basis. While several independent evaluations have been conducted recently (and over the course of the program), all were narrow in scope and did not attempt to assess the overall impact of the program. *Evidence:*	NO	0%
2.7	**Are Budget requests explicitly tied to accomplishment of the annual and long-term performance goals, and are the resource needs presented in a complete and transparent manner in the program's budget?** *Explanation:* The program does not make clear the impact of its budget on its expected performance nor does it provide evidence as to how its requested resources/funding enable it to achieve its annual and long-term goals. *Evidence:* FY 2006 Family Planning program Congressional Justification	NO	0%
2.8	**Has the program taken meaningful steps to correct its strategic**	YES	12%



	planning deficiencies? *Explanation:* The program is in the process of contracting with an the Research Triangle Institute, a non-profit research firm that has done work for the CDC, USAID and EPA, to evaluate in a comprehensive manner the effectiveness and overall impact of the program. *Evidence:* The evaluation of the Family Planning program is being conducted by the Research Traingle Institute (RTI) to assess the effects the effects of current administrative processes, financial requirements and/or constraints, staff adequacy, and organizational behavior on the quality, effectiveness and efficiency of Title X services.		
	Section 2 - Strategic Planning	Score	50%

Section 3 - Program Management

Number	**Question**	**Answer**	**Score**
3.1	**Does the agency regularly collect timely and credible performance information, including information from key program partners, and use it to manage the program and improve performance?** *Explanation:* The program regularly collects high-quality performance data from its grantees related to the program's goals and objectives, which is then used to determine whether the grantees are effectively meeting the needs of their client population. This data is also used to determine if additional services or attention are required in specific areas of the program. These annual performance plans and are reviewed and evaluated each year by program staff. Who then respond by creating new performance objectives or are given assistance to meet unmet performance objectives *Evidence:* The program collects data from family planning service grantees annually through the Family Planning Annual Report (FPAR). Every three (3) years a comprehensive program review is conducted of each grantee that includes a review of administrative, fiscal, clinical and educational/outreach components of the grantee organization. This review assesses grantee compliance with Title X and other applicable Federal Regulations and identifies areas where grantees need technical assistance. In addition, each grantee that receives a total of $500,000 or more in federal funding is required to submit an annual A-133 audit to the Federal Audit Clearinghouse Bureau of the Census in Jeffersonville, Indiana. Any audit findings are followed up by the OPHS Office of Grants Management (OGM) for resolution	YES	11%
3.2	**Are Federal managers and program partners (including grantees, sub-grantees, contractors, cost-sharing partners, and other government partners) held accountable for cost, schedule and performance results?** *Explanation:* The federeal managers of the family Planning program are held accountable for operations and performance results of the program through their annual performance plans. These performance plans include criteria that measure the performance of each manager with reference to the completion and quality of essential duties, responsibilities, program monitoring tasks and other position-specific functions, including project oversight of program partners. In addition, Project officers are held accountable for monitoring the Program's grantees and contracts. Program partners (grantees) complete annual continuing applications for every up-coming funding year. Continued	YES	11%

	funding is dependent on the level of progress toward meeting goals, objectives and deliverables for the past project year and for inclusion of specific, measurable, achievable, realistic and time-framed (SMART) objectives for the up-coming project year. *Evidence:* The Performance plans for managers and staff are re-assessed annually. They are based on a three-tiered performance scale. This system was implemented in FY 2004 and results have not yet been evaluated. Additional evidence can be found in the: 1) Federal Register Notice for a sample grant 2) Sample Staff Annual Performance Plan 3) FY 2005 MOU and Work Plan Guidance		
3.3	**Are funds (Federal and partners') obligated in a timely manner and spent for the intended purpose?** *Explanation:* Program funds are obligated consistently with the overall program plan as quarterly spending plans are developed by the Program at the beginning of each fiscal year. Year end obligations have historically reflected a lapsed balance of less than 1 percent of the appropriation. The Program distributes funding to the regional offices no more than 60 days after receiving the Program's appropriation. In the instance when the Federal government is operating under a continuing resolution (CR) and the budget start date for a specific grantee falls within the time of the CR, the grantee is provided with funding based on half of the previous year's base funding. The remaining portion is distributed once the Federal budget has been signed and the full appropriation has been received by the Program. All Program partners (grantees and contractors) are required to complete an annual FSR 90 following the close of their budget period. *Evidence:* Evidence for this answer can be found in the following documents: ?? Sample Notice of Grant Award ?? Sample Financial Status Report - Long and Short Form ?? Budget Distribution Report ?? Title X Statute and Regulations	YES	11%
3.4	**Does the program have procedures (e.g. competitive sourcing/cost comparisons, IT improvements, appropriate incentives) to measure and achieve efficiencies and cost effectiveness in program execution?** *Explanation:* The program has taken (and is in the process of taking) several steps that will allow it to both measure and achieve efficiencies and cost effectiveness in program execution. 1) The program outsources performance-based contracts for technical assistance, objective review committees, FPAR compilation and meeting logistics, in which compensation is based on the delivery of services or products depending on the scope of work. 2) The program also has a new efficiency measure with baseline and targets. *Evidence:* The Program is able to measure and set targets for the average cost per client using the FPAR data and comparing the annual rate of growth of actual expenditures to the baseline amount forecasted using the Consumer Price Index (CPI) for medical care prices. This monitoring will use 1999 data as the baseline figure. This monitoring will use 1999 data as the baseline figure. The baseline figure will be reexamined at five (5) year intervals (e.g. baseline year 1999 - target year 2004, baseline year 2000 - target year 2005, etc.).	YES	11%
3.5	**Does the program collaborate and coordinate effectively with related programs?** *Explanation:* The program collaborates with several other related government programs and agencies which enables the program to maximize its resources	YES	11%

	and improve its capacity to achieve its goals. The agencies with which the Family Planning program collaborates are CDC, HRSA, ACF, Ryan White HIV/AIDS program and CMS. *Evidence:* The Family Planning program works with CDC on the prevention and treatment of STDs, and promotion of reproductive health through HIV testing and prevention. Coordination with HRSA's 340B program aids in decreasing the cost of pharmaceuticals for the FP program's grantees. The program also collaborates with the Admin. for Children and Families' (ACF) Infant Adoption Awareness Training Program (IAATP) to assist Title X grantees with providing accurate information about adoption.		
3.6	**Does the program use strong financial management practices?** *Explanation:* The Office of the Inspector General audit of the financial statement audit for the Department of Health and Human Services in FY 2004 reflected an unqualified or "clean" audit for the Department, the sixth clean consecutive opinion for the departmental financial statement audit. The audit does not cite any material internal control weaknesses specific to the Program. None of the agency-wide material weaknesses identified in the report has a direct relation to the Family Planning Program. The Program also completed the Improper Payment Improvement Act risk assessment. The Program used the GAO Internal Control Management and Evaluation Tool to evaluate the control environment. The Program determined the risk of improper payments to be low. Spending plans guide the timely obligation of funds to Program grantees. Financial management of all OPHS office budgets reside in the Office of the Assistant Secretary for Health. *Evidence:* Evidence for this answer can be found in the following documents: ?? Department-wide Independent Auditor's Report on Financial Statements and Management Response ?? Improper Payment Risk Assessment ?? Federal Manager's Financial Integrity Act (FMFIA) Report	YES	11%
3.7	**Has the program taken meaningful steps to address its management deficiencies?** *Explanation:* There are no management deficiencies for the program to correct. *Evidence:*	NA	%
3.CO1	**Are grants awarded based on a clear competitive process that includes a qualified assessment of merit?** *Explanation:* All grants awarded by the Family Planning program are awarded on a competitive basis. In addition, each application is reviewed by an Objective Review Committee (ORC) made up of an independent and diverse group familiar with family planning and the specific subject area. Prior to the review of each application, the members of the ORC are required to complete a conflict of interest form. The applications, including the proposed project and budget plans, are individually reviewed and scored by the ORC based on the established evaluation criteria which are published in the Federal Register announcement. *Evidence:* Evidence for this explanation can be found in the following documents: ?? ASAM Review and Corrective Action Plan ?? Sample RFA ?? ORC documents ?? Application Checklist ?? Continuing Application Guidance ?? Conflict of Interest Form	YES	11%

3.CO2	**Does the program have oversight practices that provide sufficient knowledge of grantee activities?** *Explanation:* The Program, decentralized with family planning program staff in each of the 10 Public Health Service (PHS) regions conduct annual site visits in addition to comprehensive program reviews of administrative, fiscal, clinical and educational components once every three years. These site visit and program review reports are submitted to the Program's Central Office upon completion. Additionally, the grantees are required to complete an annual continuing application for each budget year of their approved project period. Financial Status Reports (FSRs) are required of each program grantee within 90 days following the end of the budget period. Future funding within their project period is contingent on successful completion of a continuation application which includes progress on the past project year, future performance goals and objectives and supporting evidence on challenges, and proposed solutions for actual and possible challenges. *Evidence:* Evidence for this answer can be found in the following documents: 1) FY 2005 MOU and Work Plan Guidance 2) Non-competing and continuing application guidance (progress report formats) 3) Program Review Tool	YES	11%
3.CO3	**Does the program collect grantee performance data on an annual basis and make it available to the public in a transparent and meaningful manner?** *Explanation:* The Program grantees provide data annually to OFP in the form of the FPAR. The Program uses the data in conjunction with other publicly available reports to determine the patterns and trends regarding program funding, service availability, use, access, quality and other measures that assess the performance of the Program. The FPAR forms and instructions as well as the most recent final report are posted on the OPA web page. The Program's annual performance plan is also posted on the OPA web page. Continuing grant applications which are required annually also include performance information which details the progress toward stated performance goals and objectives. The Program also makes available evaluation reports from specific studies regarding the performance of the Program and its partners. *Evidence:* Evidence for this answer can be found in the following documents: ?? FPAR reports ?? Continuing application guidance ?? Program's website: http://opa.osophs.dhhs.gov/titlex/ofp.html	YES	11%
	Section 3 - Program Management	Score	100%

Section 4 - Program Results/Accountability

Number	**Question**	**Answer**	**Score**
4.1	**Has the program demonstrated adequate progress in achieving its long-term performance goals?** *Explanation:* While the program has developed three new long-term goals, it is only able to demonstrate progress towards one of those goals (number of unintended pregnancies averted), as there exists no historical data available for the other two measures (reducing infertility among women attending Title X Family Planning clinics by identifying Chlamydia infection through screening of females ages 15-24 and reducing invasive cervical cancer among women attending Title X Family Planning clinics by providing Pap tests).	SMALL EXTENT	7%

	Evidence: Evidence for this answer can be found in the following documents: ?? Family Planning Annual Report: 2003 Summary ?? Title X Funding History. http://opa.osophs.dhhs.gov/titlex/ofp-funding-history.html ?? Systematic Evidence Review Number 3: Screening for Chlamydia Infection, Agency for Healthcare Research and Quality, U.S. Preventive Services Taskforce		
4.2	**Does the program (including program partners) achieve its annual performance goals?** *Explanation:* The program's annual measures are the same as its long-term measures- except with targets set annually, and hence the program is only able to demonstrate annual performance in regards to one of its three annual goals. The measure for which the program does have long-term historical data clearly demonstrates that the program has annually exceeded its targets for the number of unintended pregnancies averted through the provision of Title X Family Planning Services. *Evidence:* Evidence for this answer can be found in the following documents: ?? Family Planning Annual Report: 2005 Instructions and Forms ?? Family Planning Annual Report: 2003 Summary ?? GPRA measures ?? Cervical Cancer (PDQ??): Screening, National Cancer Institute, www.nci.nih.gov/cancertopics/pdq/screening/cervical/HealthProfessional/page1	SMALL EXTENT	7%
4.3	**Does the program demonstrate improved efficiencies or cost effectiveness in achieving program goals each year?** *Explanation:* Over the past several years the Family Planning program has continued to demonstrat both increasing efficiencies and cost effectiveness. The title X service sites have seen more users per site while requiring less revenue per user. Between 1998 and 2002, the total adjusted revenue per user in Title X projects decreased 5%. During this same time period, the average number of users per service site, across all regions, increased 11%. The continuing efficiency and cost effectiveness of Title X programs is demonstrated through ongoing success in meeting the need for publicly funded family planning services in the United States. In 2001, Title X clinics met 28% of the national need for publicly funded family planning services, an 11% increase from 1994. In states employing income-based Medicaid waivers for family planning, the increasing success of Title X clinics was even greater, with a 33% increase in met need from 1994 to 2001. *Evidence:* Evidence for this answer can be found in the following documents: ?? Total adjusted revenue per user in Title X projects decreased 5% from $55.04 per user in 1998 to $52.47 per user in 2002. Adjusted Title X revenue per user decreased 1% from $13.62 per user in 1998 to $13.51 per user in 2001. - AGI FPAR summaries, 1998 to 2002 (see RTI report p. 25) ?? AGI FPAR summaries, 1998 to 200,(see RTI report p 49) ?? Frost JJ, Frohwirth L and Purcell A (2004). The availability and use of publicly funded family planning clinics: U.S. trends, 1994-2001. Perspectives on Sexual and Reproductive Health, 36 (5).	YES	20%
4.4	**Does the performance of this program compare favorably to other programs, including government, private, etc., with similar purpose and goals?** *Explanation:* The program Title X program services compare favorably with other publicly funded family planning services in regards to the types and quality of care the program provides (see evidence column to the right). However, because there have been no independent studies that have evaluated	LARGE EXTENT	13%

	the overall impact of the program, it is difficult at this time to compare the overall effectiveness of Title X clinics relative to other public, private or non-profit groups. *Evidence:* In the provision of contraceptive services, the mean number of contraceptive methods offered in Title X funded agencies is significantly higher than the number offered by agencies receiving no Title X funds. In addition, a significantly higher proportion of Title X-funded agencies (90%) provide oral contraceptives on-site, compared to agencies receiving no Title X funding. Woman utilizating Title X services as their primary source of health care also have significantly higher odds of receiving contraceptive services and/or STD related care than women utilizing private physicians or HMOs.		
4.5	**Do independent evaluations of sufficient scope and quality indicate that the program is effective and achieving results?** *Explanation:* While there has not been an independent evaluation of sufficient quality and scope conducted at the federal level that demonstrates the overall impact of the program, there have been several studies conducted by independent contractors that have focused on varying aspects of the program. These studies have demonstrated that the program has been implementing aspects of the program that play a key role in the enabling the program to achieve its primary goals and objectives. *Evidence:* An April 2005 Report issued by the Office of the Inspector General that the FP program had informed, and periodically reminded, Title X greantees of their responsibilities regarding State requirements for reporting and notification of child abuse, molestation, sexual abuse, rape and incest. A 2004 evaluation conducted by the Assistant Secretary for Administration and Management (ASAM) rewarded the Family Planning Services grant review protocol the Best Program for grant monitoring. Recently, the program contracted with the Research Triangle Institute, Inc. to conduct an assessment of Title X program evaluation needs.	SMALL EXTENT	7%
	Section 4 - Program Results/Accountability	Score	53%

Appendix F

Committee Site Visits

The committee conducted 16 site visits to Title X grantees and delegates during April–July 2008 to gather information about the experiences of local administrators and service providers with the Title X program. Approximately 4,600 sites receive Title X funds. The sites visited were selected to reflect various geographic regions, clinic types (including health departments, community health centers, hospital and academic centers, and Planned Parenthood health centers), and patient demographics (including race and ethnicity). Sites were chosen based on convenience sampling and were not considered to be a representative sample of Title X sites. The following sites were visited:

- Adagio Health Aliquippa, Aliquippa, Pennsylvania;
- Charlottesville/Albemarle Health Department, Charlottesville, Virginia;
- Fred Leroy Health and Wellness Center, Omaha, Nebraska;
- Harbor UCLA Medical Center, Torrance, California;
- La Clinica De La Raza, Oakland, California;
- Midwife Center for Birth and Women's Health, Pittsburgh, Pennsylvania;
- Mobile County Health Department, Mobile, Alabama;
- New York Presbyterian Hospital, New York, New York;
- Orange County Health Department, Orange, Virginia;
- People's Community Clinic, Austin, Texas;
- Planned Parenthood of Middle and East Tennessee, Nashville, Tennessee;

- Planned Parenthood of Mid-Michigan, Ann Arbor, Michigan;
- Planned Parenthood of Wisconsin Inc., Madison, Wisconsin;
- Trousdale County Health Department, Hartsville, Tennessee;
- Unity Health Care, Washington, DC; and
- University of Nebraska Medical Center Family Planning Clinic, Omaha, Nebraska.

One or two committee members conducted each half-day visit. They followed one of several loose interview guides (see Boxes F-1 through F-4), which varied based on the type of site, to assist them in gathering information. The questions in sections I and II of the interview guides were provided to the sites for completion prior to the visits. Committee members interviewed senior administrators, Title X coordinators, and service providers. The committee was interested in obtaining information about each program (including services provided, demographics of patients served and the surrounding community, and staffing), financing (for example, proportion of Title X versus other funding), and grantee and delegate perspectives on the Title X program.

Staffing varies greatly among the sites—from 2 to 40 full-time employees. The percentage of the sites' funding provided by Title X ranges from 4 percent to 75 percent, but is less than 15 percent for most sites. Title X funds are used for a mix of staff, services, goods, administrative costs, and facility costs. A summary of the strengths and weaknesses of the Title X program cited by interviewees is presented below, followed by a summary of the interviewees' perceptions of the *Family Planning Annual Report* (FPAR) and additional findings.

STRENGTHS AND WEAKNESSES OF TITLE X

In general, the interviewees emphasized that Title X is an extremely beneficial program. Most noted that Title X funds allow them to provide services they would otherwise struggle to offer, including the direct provision of contraceptive methods. They appreciate that Title X funds are more flexible than many other funding sources and can be used to cover such expenses as staffing, overhead, outreach, and patient education. Interviewees also said that Title X increases access for underserved populations, including adolescents and the uninsured. Some of the administrative features and requirements of the program were also cited as strengths. For example, one interviewee noted that "the counseling requirements make the nurse ask questions she might have otherwise overlooked." The interviewees generally reported positive relationships between grantees and delegates.

At the same time, interviewees had many suggestions for improving the program. Several reported finding the goals and priorities of the

BOX F-1
Title X Site Visits to Hospital-Based Centers

I. Site information (should be completed by the site prior to the visit)

1. Location (city, state)
2. Hours/days of operation
3. Geographic market (rural, urban, suburban)
4. Annual visits (number)
5. Demographics (clients served annually)
   a. median age and range
   b. % female
   c. average income
   d. race/ethnicity
6. How are patients referred to your center?
7. Highest volume (days/times)
8. Staffing
   a. Number of staff
   b. Types of staff (e.g., case manager, social worker, nurses, residents, physicians)
   c. Staff case load
9. Tools (electronic or otherwise) used in the work
10. Recent/current process improvement efforts/projects
11. Are there any current reports on performance, productivity, etc.?
12. Does the site work in conjunction with other clinics or other organizations that provide family planning services?

II. Finances (should be completed by the site prior to the visit)

13. Income—How is your organization funded (breakdown by percentages)?
    a. Federal %
       i. Title X funds %
       ii. Medicaid funds %
       iii. MCH grants %
       iv. TANF %
       v. Social services block grants %
    b. State appropriations %
    c. Grants %
    d. Gifts %

continued

BOX F-1 Continued

  - e. Private payer %
  - f. Out of pocket/self-pay %
  - g. Uncompensated care %
  - h. Functions of staff

14. Expenses—What do Title X funds pay for?
    - a. Budget for staff
    - b. Budget for services (e.g., medical operations, education, outreach)
    - c. Budget for goods (e.g., labs and associated costs, pharmaceuticals and dispensing costs)
    - d. Administrative costs
    - e. Facility costs (purchase/rent, maintenance)

III. Site Concerns

Begin by asking each interviewee: what are the two most important things you would like to share about your experiences with Title X.

IV. Services

15. Range of services
    - a. What types of services do Title X funds provide?
      - ___ Education
      - ___ Counseling
      - ___ History, physical assessment, labs
      - ___ Fertility regulation (contraception)
      - ___ Infertility services
      - ___ Pregnancy diagnosis and counseling
      - ___ Adolescent services
      - ___ GYN services
      - ___ STD and HIV/AIDS
      - ___ Special counseling (future pregnancies, substance use, sexual abuse, domestic violence)
      - ___ Health promotion/disease prevention
      - ___ Postpartum care
      - ___ Other (please list)
    - b. Who else provides these services in the community?
16. Scheduling
    - a. How are urgent vs. emergent patients scheduled (priority matrix)?
    - b. Appointment wait time (how many days or weeks?)

17. Quality
    - a. Do staff follow any standing clinical protocols or care pathways?
    - b. What quality metrics are evaluated at the site?

18. Referral and Follow-up
    - a. Are patients classified based on any risk factors? If so, what risk factors?
    - b. What is the mechanism for post-visit follow-up?

BOX F-1 Continued

V. Perspectives on Title X

19. What are benefits/strengths of the Title X program?

20. What are drawbacks or weaknesses of the program?

21. What do Title X funds allow you to do that other funding sources do not?

22. What changes or improvements (administrative, service provision, etc.) would you suggest for the program?

23. How do Title X requirements (e.g., child abuse reporting) affect the provision of services?

24. How do you implement the mandate to encourage parental involvement?

25. Describe hard-to-reach groups in your area and describe any efforts at outreach.

26. Describe the ease/burden of collecting information for FPAR. What elements seem unnecessary? What additional elements would you include?

27. How does the administrative structure work from your perspective? What is your relationship (communication) with the grantee and/or RPC?

28. How have any funding limitations affected the number of patients served or the care that is delivered? (e.g., hours of operation, decreasing type or amount of services)

29. Have you identified/developed any best practices for service delivery or outreach?

30. Are there any training or workforce issues (finding and retaining adequately trained staff in sufficient numbers to provide services)?

31. Do you see Title X requirements as a barrier to participation for certain family planning providers? How?

32. How does your program intersect with the hospital's administration?

33. Does your program coordinate with other clinics or organizations that provide family planning services?

34. Additional comments

BOX F-2
Title X Site Visits to Community Clinics

I. Site information (should be completed by the site prior to the visit)

1. Location (city, state)
2. Hours/days of operation
3. Geographic market (rural, urban, suburban)
4. Annual visits (number)
5. Demographics (clients served annually)
    a. median age and range
    b. % female
    c. average income
    d. race/ethnicity
6. How are patients referred to your clinic?
7. Highest volume (days/times)
8. Staffing
    a. Number of staff
    b. Types of staff (e.g., case manager, social worker, nurses, residents, physicians)
    c. Staff case load
    d. Functions of staff
9. Tools (electronic or otherwise) used in the work
10. Recent/current process improvement efforts/projects
11. Are there any current reports on performance, productivity, etc.?
12. Does the site work in conjunction with other clinics or organizations that provide family planning services?

II. Finances (should be completed by the site prior to the visit)

13. Income—How is your organization funded (breakdown by percentages)?
    a. Federal %
        i. Title X funds %
        ii. Medicaid funds %
        iii. MCH grants %
        iv. TANF %
        v. Social services block grants %
    b. State appropriations %
    c. Grants %
    d. Gifts %

BOX F-2 Continued

- e. Private payer %
- f. Out of pocket/self-pay %
- g. Uncompensated care %

14. Expenses—What do Title X funds pay for?
    - a. Budget for staff
    - b. Budget for services (e.g., medical operations, education, outreach)
    - c. Budget for goods (e.g., labs and associated costs, pharmaceuticals and dispensing costs)
    - d. Administrative costs
    - e. Facility costs (purchase/rent, maintenance)

III. Site Concerns

Begin by asking each interviewee: what are the two most important things you would like to share about your experiences with Title X.

IV. Services

15. Range of services
    - a. What types of services do Title X funds provide?
        - ___ Education
        - ___ Counseling
        - ___ History, physical assessment, labs
        - ___ Fertility regulation (contraception)
        - ___ Infertility services
        - ___ Pregnancy diagnosis and counseling
        - ___ Adolescent services
        - ___ GYN services
        - ___ STD and HIV/AIDS
        - ___ Special counseling (future pregnancies, substance use, sexual abuse, domestic violence)
    - b. Who else provides these services in the community?

16. Scheduling
    - a. How are urgent vs. emergent patients scheduled (priority matrix)?
    - b. Appointment wait time (how many days or weeks?)

17. Quality
    - a. Do staff follow any standing clinical protocols or care pathways?
    - b. What quality metrics are evaluated at the site?

18. Referral and Follow-up
    - a. Are patients classified based on any risk factors? If so, what risk factors?
    - b. What is the mechanism for post-visit follow-up?

continued

BOX F-2 Continued

V. Perspectives on Title X

19. What are benefits/strengths of the Title X program?

20. What are drawbacks or weaknesses of the program?

21. What do Title X funds allow you to do that other funding sources do not?

22. What changes or improvements (administrative, service provision, etc.) would you suggest for the program?

23. How do Title X requirements (e.g., child abuse reporting) affect the provision of services?

24. How do you implement the mandate to encourage parental involvement?

25. Describe hard-to-reach groups in your area and describe any efforts at outreach.

26. Describe the ease/burden of collecting information for FPAR. What elements seem unnecessary? What additional elements would you include?

27. How does the administrative structure work from your perspective? What is your relationship (communication) with the grantee and/or RPC?

28. How have any funding limitations affected the number of patients served or the care that is delivered? (e.g., hours of operation, decreasing type or amount of services)

29. Have you identified/developed any best practices for service delivery or outreach?

30. Are there any training or workforce issues (finding and retaining adequately trained staff in sufficient numbers to provide services)?

31. Do you see Title X requirements as a barrier to participation for certain family planning providers? How?

32. Does your clinic operate within a larger group of community centers? If so, how do you coordinate with other clinics in your area to provide reproductive health services?

33. Do you work in conjunction with other organizations (other than community-based clinics) that provide family planning services?

34. Additional comments

BOX F-3
Title X Site Visits to Health Departments

I. Site information (should be completed by the site prior to the visit)

1. Location (city, state)

2. Hours/days of operation

3. Geographic market (rural, urban, suburban)

4. Annual visits (number)

5. Demographics (clients served annually)
    a. median age and range
    b. % female
    c. average income
    d. race/ethnicity

6. How are patients referred to your department?

7. Highest volume (days/times)

8. Staffing
    a. Number of staff
    b. Types of staff (e.g., case manager, social worker, nurses, residents, physicians)
    c. Staff case load
    d. Functions of staff

9. Tools (electronic or otherwise) used in the work

10. Recent/current process improvement efforts/projects

11. Are there any current reports on performance, productivity, etc.?

12. Does the site work in conjunction with other health departments or organizations that provide family planning services?

II. Finances (should be completed by the site prior to the visit)

13. Income—How is your organization funded (breakdown by percentages)?
    a. Federal %
        i. Title X funds %
        ii. Medicaid funds %
        iii. MCH grants %
        iv. TANF %
        v. Social services block grants %
    b. State appropriations %
    c. Grants %
    d. Gifts %

continued

BOX F-3 Continued

- e. Private payer %
- f. Out of pocket/self-pay %
- g. Uncompensated care %

14. Expenses—What do Title X funds pay for?
    - a. Budget for staff
    - b. Budget for services (e.g., medical operations, education, outreach)
    - c. Budget for goods (e.g., labs and associated costs, pharmaceuticals and dispensing costs)
    - d. Administrative costs
    - e. Facility costs (purchase/rent, maintenance)

III. Site Concerns

Begin by asking each interviewee: what are the two most important things you would like to share about your experiences with Title X.

IV. Services

15. Range of services
    - a. What types of services do Title X funds provide?
        - ___ Education
        - ___ Counseling
        - ___ History, physical assessment, labs
        - ___ Fertility regulation (contraception)
        - ___ Infertility services
        - ___ Pregnancy diagnosis and counseling
        - ___ Adolescent services
        - ___ GYN services
        - ___ STD and HIV/AIDS
        - ___ Special counseling (future pregnancies, substance use, sexual abuse, domestic violence)
        - ___ Health promotion/disease prevention
        - ___ Postpartum care
        - ___ Other (please list)
    - b. Who else provides these services in the community?

16. Scheduling
    - a. How are urgent vs. emergent patients scheduled (priority matrix)?
    - b. Appointment wait time (how many days or weeks?)

17. Quality
    - a. Do staff follow any standing clinical protocols or care pathways?
    - b. What quality metrics are evaluated at the site?

18. Referral and Follow-up
    - a. Are patients classified based on any risk factors? If so, what risk factors?
    - b. What is the mechanism for post-visit follow-up?

BOX F-3 Continued

V. Perspectives on Title X

19. What are benefits/strengths of the Title X program?

20. What are drawbacks or weaknesses of the program?

21. What do Title X funds allow you to do that other funding sources do not?

22. What changes or improvements (administrative, service provision, etc.) would you suggest for the program?

23. How do Title X requirements (e.g., child abuse reporting) affect the provision of services?

24. How do you implement the mandate to encourage parental involvement?

25. Describe hard-to-reach groups in your area and describe any efforts at outreach.

26. Describe the ease/burden of collecting information for FPAR. What elements seem unnecessary? What additional elements would you include?

27. How does the administrative structure work from your perspective? What is your relationship (communication) with the grantee and/or RPC?

28. How have any funding limitations affected the number of patients served or the care that is delivered? (e.g., hours of operation, decreasing type or amount of services)

29. Have you identified/developed any best practices for service delivery or outreach?

30. Are there any training or workforce issues (finding and retaining adequately trained staff in sufficient numbers to provide services)?

31. Do you see Title X requirements as a barrier to participation for certain family planning providers? How?

32. How do the services you provide with Title X funds fit into the public health structure in your area? Does the site work in conjunction with other health departments or organizations that provide family planning services?

33. Additional comments

BOX F-4
Title X Site Visits to Planned Parenthood

I. Site information (should be completed by the site prior to the visit)

1. Location (city, state)

2. Hours/days of operation

3. Geographic market (rural, urban, suburban)

4. Annual visits (number)

5. Demographics (clients served annually)
   a. median age and range
   b. % female
   c. average income
   d. race/ethnicity

6. How are patients referred to your clinic?

7. Highest volume (days/times)

8. Staffing
   a. Number of staff
   b. Types of staff (e.g., case manager, social worker, nurses, residents, physicians)
   c. Staff case load
   d. Functions of staff

9. Tools (electronic or otherwise) used in the work

10. Recent/current process improvement efforts/projects

11. Are there any current reports on performance, productivity, etc.?

12. Does the site work in conjunction with other planned parenthood clinics or other organizations that provide family planning services?

II. Finances (should be completed by the site prior to the visit)

13. Income—How is your organization funded (breakdown by percentages)?
    a. Federal %
       i. Title X funds %
       ii. Medicaid funds %
       iii. MCH grants %
       iv. TANF %
       v. Social services block grants %
    b. State appropriations %
    c. Grants %
    d. Gifts %

BOX F-4 Continued

  - e. Private payer %
  - f. Out of pocket/self-pay %
  - g. Uncompensated care %

14. Expenses—What do Title X funds pay for?
    - a. Budget for staff
    - b. Budget for services (e.g., medical operations, education, outreach)
    - c. Budget for goods (e.g., labs and associated costs, pharmaceuticals and dispensing costs)
    - d. Administrative costs
    - e. Facility costs (purchase/rent, maintenance)

III. Site Concerns

Begin by asking each interviewee: what are the two most important things you would like to share about your experiences with Title X.

IV. Services

15. Range of services
    - a. What types of services do Title X funds provide?
      - ___ Education
      - ___ Counseling
      - ___ History, physical assessment, labs
      - ___ Fertility regulation (contraception)
      - ___ Infertility services
      - ___ Pregnancy diagnosis and counseling
      - ___ Adolescent services
      - ___ GYN services
      - ___ STD and HIV/AIDS
      - ___ Special counseling (future pregnancies, substance use, sexual abuse, domestic violence)
      - ___ Health promotion/disease prevention
      - ___ Postpartum care
      - ___ Other (please list)
    - b. Who else provides these services in the community?

16. Scheduling
    - a. How are urgent vs. emergent patients scheduled (priority matrix)?
    - b. Appointment wait time (how many days or weeks?)

17. Quality
    - a. Do staff follow any standing clinical protocols or care pathways?
    - b. What quality metrics are evaluated at the site?

18. Referral and Follow-up
    - a. Are patients classified based on any risk factors? If so, what risk factors?
    - b. What is the mechanism for post-visit follow-up?

continued

BOX F-4 Continued

V. Perspectives on Title X

19. What are benefits/strengths of the Title X program?
20. What are drawbacks or weaknesses of the program?
21. What do Title X funds allow you to do that other funding sources do not?
22. What changes or improvements (administrative, service provision, etc.) would you suggest for the program?
23. How do Title X requirements (e.g., child abuse reporting) affect the provision of services?
24. How do you implement the mandate to encourage parental involvement?
25. Describe hard-to-reach groups in your area and describe any efforts at outreach.
26. Describe the ease/burden of collecting information for FPAR. What elements seem unnecessary? What additional elements would you include?
27. How does the administrative structure work from your perspective? What is your relationship (communication) with the grantee and/or RPC?
28. How have any funding limitations affected the number of patients served or the care that is delivered? (e.g., hours of operation, decreasing type or amount of services)
29. Have you identified/developed any best practices for service delivery or outreach?
30. Are there any training or workforce issues (finding and retaining adequately trained staff in sufficient numbers to provide services)?
31. Do you see Title X requirements as a barrier to participation for certain family planning providers? How?
32. How does your clinic coordinate with other Planned Parenthood clinics in your area to provide services? Do you work in conjunction with other organizations that provide family planning services?
33. Have you had any challenges with the media (related to receiving Title X or other federal funds)?
34. Additional comments

program to be unclear, as well as overly influenced by political factors rather than evidence-based research. By far the most commonly cited issue was that Title X has insufficient funding in general. Interviewees reported needing increased funds for contraceptives, staffing for screening for sexually transmitted diseases/HIV, community education, outreach, advertising, interpretation services, and sterilization services. The increasing cost of contraceptives was cited as a particular problem for clinics in light of their already overburdened finances. Several interviewees also reported that the lack of funding necessitates low salaries, making it difficult for them to recruit and retain staff. One respondent suggested that the payment scale needs to be readjusted to impose less financial burden for clients with incomes just above the federal poverty level.

Interviewees also expressed the view that the significant administrative burden associated with Title X participation is incommensurate with the often small percentage of their funding provided by Title X. One interviewee said the problem was underscored this year when additional funds were made available only if a clinic had an increased volume of patients. Moreover, interviewees reported having difficulty meeting Title X's "unfunded mandates," which they described as multiplying each year in the form of annual program priorities that require additional service components with no additional funding. Interviewees also expressed frustration with requirements to follow Title X program guidelines that are outdated and do not reflect current best practices as outlined by professional organizations, such as the American College of Obstetricians and Gynecologists. One interviewee stated further that the guidelines do not allow for differences among individual clinics, and that the number of requirements for each visit are unrealistic based on staff-to-client ratios. Moreover, this interviewee noted that the clinic's client volume has been increasing yearly, while its staff has been decreasing because of limited funds and despite the need to provide more services to more people.

FAMILY PLANNING ANNUAL REPORT

While a number of interviewees cited no difficulties with the FPAR, several said it imposes an administrative burden that could potentially be alleviated. Many interviewees suggested that some aspects of the FPAR are "outdated" and do not reflect current best practices, or are framed so narrowly that clinics' responses are meaningless. For example, one question asks what family planning methods patients used but does not allow multiple answers; questions about race are similarly problematic because patients often do not fit neatly into one racial category. While most believe the data collected for the FPAR to be useful, some think the collection process could be streamlined so that grantees, delegates, and the Office of Family Planning would have easier access for reporting and management purposes. For example, one delegate suggested that it is unnecessary for data to be collected separately by the site and by the county, and that using the "unduplicated patients" designation does not make sense because on average Title X patients make more family planning visits than paying clients. Some respondents also noted that completing the FPAR is very labor-intensive. One delegate said it takes 2 of 14 full-time staff members a full week to complete the FPAR. Several interviewees said they did not understand why many elements of the FPAR are required, and expressed a desire to gain such an understanding and to know how OPA uses that information. The interviewees did say that electronic reporting was a significant positive change.

ADDITIONAL FINDINGS

Difficult-to-Reach Groups

While the client population varies depending on the location of the Title X site, several interviewees reported that difficult-to-reach groups include women aged 20–40 who have no health problems, as well as older women who may think they are less fertile than they used to be and thus no longer need to worry about contraception. Another interviewee noted that the "undocumented, homeless, poor, and children in foster care are the most hard-to-reach in the neighborhood." The gay, lesbian, bisexual, and transgender population was also cited as being difficult to reach. In addition, many interviewees reported having a difficult time getting males to come to their clinics, and some said they would like guidance on how to address this problem.

Follow-up Care

Most interviewees reported having detailed procedures for following up with clients to report laboratory results. However, they did not appear to have procedures in place for following up with patients to determine the effectiveness of the family planning services provided (e.g., the number of unplanned pregnancies, continuation of use of birth control methods, whether patients are seeing other providers if they are not being seen at the clinic). Interviewees agreed that this information would be desirable but that gathering it would take more staff time than is available.

Cultural Sensitivity

Several interviewees reported that, although cultural sensitivity is extremely important, it can be difficult to respect clients' personal beliefs while trying to satisfy Title X requirements. This issue was cited in relation to requirements for Pap tests for women who do not wish to undergo a complete physical exam, which may include women who are virgins, as well as Muslim and Hispanic women. Language issues were also frequently discussed during the interviews. Many clinics cited difficulty with recruiting and retaining multilingual staff; this is a particular problem for small clinics that may have only a few staff members. Many respondents had one or two bi- or multilingual staff members and a phone service that provided access to an interpreter for a wider range of languages.

Best Practices

Best practices identified during the site visits included holding a Friday Clinic during which there are no scheduled appointments, and women without health insurance are welcomed; providing a warm and inviting clinic environment; offering a “Quick Start” program through which the clinic is able to provide birth control pills immediately and then arrange appointments within 3 months; engaging the local community to build trust and maintaining those relationships; cross-training personnel, which allows for growth through acquisition of advanced skills; and holding events such as a fish fry and health fair in the parking lot to reach out to the community. Most committee members found that the staff at the sites they visited were really concerned about providing high-quality care to their patients, and that in general, they were meeting that goal to the extent possible in light of the barriers to care summarized above.

On-site Medication

Several interviewees reported that they appreciate the fact that Title X enables clinics to keep medications on site because they can start clients on contraceptives or other medications immediately. However, at least one respondent objected to the Title X requirement for dispensing since some clients would be more comfortable picking up prescriptions from a pharmacy.

Scheduling

Most interviewees reported that they could generally arrange appointments within the 2-week period required by Title X. However, many reported that waits are significantly longer in their communities (presumably because of a lack of provider capacity). One respondent noted that there is usually a 6- to 8-week wait for new patient appointments and annual exams, although patients who have problems or need contraceptive refills can get an appointment for an “expedited visit” more quickly. Few interviewees provided information regarding client wait times at the clinic; however, those who did so said that patients were generally seen within about a half-hour of arriving at the clinic.

Appendix G

Family Planning Annual Report Data Elements

The *Family Planning Annual Report* (FPAR) is the data collection tool used by the Office of Family Planning (OFP) within the Office of Population Affairs (OPA), which administers the Title X program. Annual submission of the FPAR is required of all Title X grantees in order to obtain comparable data about the Title X family planning program and its users. The following tables, which represent the data elements requested in the FPAR, are excerpted from the *Title X Family Planning Annual Report: Forms and Instructions* (OFP, 2007).

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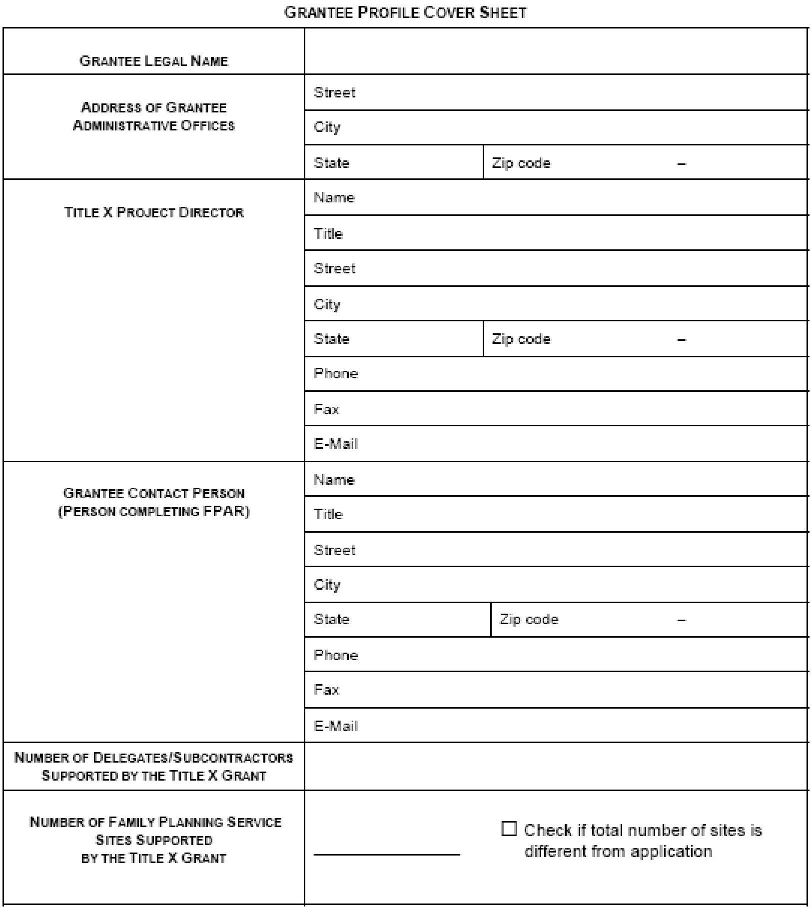
- Table 7: Unduplicated Number of Female Family Planning Users by Primary Method and Age
- Table 8: Unduplicated Number of Male Family Planning Users by Primary Method and Age
- Table 9: Cervical Cancer Screening Activities
- Table 10: Clinical Breast Exams and Referrals
- Table 11: Unduplicated Number of Family Planning Users Tested for Chlamydia by Age and Gender
- Table 12: Number of Gonorrhea, Syphilis, and HIV Tests
- Table 13: Number of Family Planning Encounters by Type of Provider
- Table 14: Revenue Report



GRANTEE PROFILE COVER SHEET

GRANTEE LEGAL NAME		
ADDRESS OF GRANTEE ADMINISTRATIVE OFFICES	Street	
	City	
	State	Zip code –
TITLE X PROJECT DIRECTOR	Name	
	Title	
	Street	
	City	
	State	Zip code –
	Phone	
	Fax	
	E-Mail	
GRANTEE CONTACT PERSON (PERSON COMPLETING FPAR)	Name	
	Title	
	Street	
	City	
	State	Zip code –
	Phone	
	Fax	
	E-Mail	
NUMBER OF DELEGATES/SUBCONTRACTORS SUPPORTED BY THE TITLE X GRANT		
NUMBER OF FAMILY PLANNING SERVICE SITES SUPPORTED BY THE TITLE X GRANT	____________	☐ Check if total number of sites is different from application

TABLE 1
UNDUPLICATED NUMBER OF FAMILY PLANNING USERS BY AGE AND GENDER

	AGE GROUP (YEARS)	FEMALE USERS (A)	MALE USERS (B)	TOTAL USERS (SUM COLS A + B) (C)
1	Under 15			
2	15–17			
3	18–19			
4	20–24			
5	25–29			
6	30–34			
7	35–39			
8	40–44			
9	Over 44			
10	**TOTAL USERS (SUM ROWS 1 TO 9)**			

TABLE 2
UNDUPLICATED NUMBER OF FEMALE FAMILY PLANNING USERS BY ETHNICITY AND RACE

	RACE	HISPANIC OR LATINO (A)	NOT HISPANIC OR LATINO (B)	UNKNOWN/ NOT REPORTED (C)	TOTAL FEMALE USERS (SUM COLS A + B + C) (D)
1	American Indian or Alaska Native				
2	Asian				
3	Black or African American				
4	Native Hawaiian or other Pacific Islander				
5	White				
6	More than one race				
7	Unknown/not reported				
8	**TOTAL FEMALE USERS (SUM ROWS 1 TO 7)**				

Table 3
Unduplicated Number of Male Family Planning Users by Ethnicity and Race

	Race	Hispanic or Latino (A)	Not Hispanic or Latino (B)	Unknown/ Not Reported (C)	Total Male Users (Sum Cols A + B + C) (D)
1	American Indian or Alaska Native				
2	Asian				
3	Black or African American				
4	Native Hawaiian or other Pacific Islander				
5	White				
6	More than one race				
7	Unknown/not reported				
8	**Total Male Users (sum rows 1 to 7)**				

Table 4
Unduplicated Number of Family Planning Users by Income Level

	Income as Percent of the HHS Poverty Guidelines	Number of Users (A)
1	100% and below	
2	101%–150%	
3	151%–200%	
4	201%–250%	
5	Over 250%	
6	Unknown/not reported	
7	**Total Users (sum rows 1 to 6)**	

Table 5
Unduplicated Number of Family Planning Users by Principal Health Insurance Coverage Status

	Principal Health Insurance Covering Primary Medical Care		Number of Users (A)
1	Public health insurance covering primary medical care		
2	Private health insurance covering primary medical care **(sum rows 2a to 2c)**		
2a	(Optional) Coverage for all or some family planning services		▨
2b	(Optional) Coverage for no family planning services		▨
2c	(Optional) Coverage unknown for family planning services		▨
3	Uninsured (no public or private health insurance)		
4	Unknown/not reported		
5	**Total Users (sum rows 1 to 4)**		

Table 6
Unduplicated Number of Family Planning Users with Limited English Proficiency (LEP)

		Number of Users (A)
1	***Number of users*** with limited English proficiency (LEP)	

TABLE 7
UNDUPLICATED NUMBER OF FEMALE FAMILY PLANNING USERS BY PRIMARY METHOD AND AGE

PRIMARY METHOD		UNDUPLICATED NUMBER OF FEMALE USERS BY AGE									TOTAL FEMALE USERS (SUM COLS A TO I)
		< 15 (A)	15–17 (B)	18–19 (C)	20–24 (D)	25–29 (E)	30–34 (F)	35–39 (G)	40–44 (H)	> 44 (I)	(J)
1	Female sterilization										
2	Intrauterine device (IUD)										
3	Hormonal implant										
4	1-Month hormonal injection										
5	3-Month hormonal injection										
6	Oral contraceptive										
7	Hormonal/contraceptive patch										
8	Vaginal ring										
9	Cervical cap/diaphragm										
10	Contraceptive sponge										
11	Female condom										
12	Spermicide (used alone)										
13	Fertility awareness method (FAM)										
14	Abstinence										
15	Other method										
16	Method unknown										
NO METHOD											
17	Pregnant or seeking pregnancy										
18	Other reason										
RELY ON MALE METHOD											
19	Vasectomy										
20	Male condom										
21	TOTAL FEMALE USERS (SUM ROWS 1 TO 20)										

TABLE 8
UNDUPLICATED NUMBER OF MALE FAMILY PLANNING USERS BY PRIMARY METHOD AND AGE

PRIMARY METHOD		UNDUPLICATED NUMBER OF MALE USERS BY AGE									TOTAL MALE USERS (SUM COLS A TO I) (J)
		< 15 (A)	15–17 (B)	18–19 (C)	20–24 (D)	25–29 (E)	30–34 (F)	35–39 (G)	40–44 (H)	> 44 (I)	
1	Vasectomy										
2	Male condom										
3	Fertility awareness method (FAM)										
4	Abstinence										
5	Other method										
6	Method unknown										
NO METHOD		▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
7	Partner pregnant or seeking pregnancy										
8	Other reason										
9	RELY ON FEMALE METHOD(S)										
10	TOTAL MALE USERS (SUM ROWS 1 TO 9)										

TABLE 9
CERVICAL CANCER SCREENING ACTIVITIES

SCREENING ACTIVITY		NUMBER OF USERS OR NUMBER OF TESTS (A)
1	***Unduplicated number of users*** who obtained a Pap test	
2	***Number of Pap tests*** performed	
3	***Number of Pap tests*** with an ASC or higher result	
4	***Number of Pap tests*** with an HSIL or higher result	

TABLE 10
CLINICAL BREAST EXAMS AND REFERRALS

SCREENING ACTIVITY		NUMBER OF USERS (A)
1	***Unduplicated number of users*** who received a clinical breast exam (CBE)	
2	***Unduplicated number of users*** referred for further evaluation based on their CBE	

TABLE 11
UNDUPLICATED NUMBER OF FAMILY PLANNING USERS TESTED FOR CHLAMYDIA BY AGE AND GENDER

		NUMBER OF USERS	
	AGE GROUP (YEARS)	FEMALE USERS (A)	MALE USERS (B)
1	Under 15		
2	15–17		
3	18–19		
4	20–24		
5	25 and over		
6	**TOTAL USERS (SUM ROWS 1 TO 5)**		

TABLE 12
NUMBER OF GONORRHEA, SYPHILIS, AND HIV TESTS

		NUMBER OF TESTS		TOTAL TESTS (SUM COLS A + B) (C)
	TEST TYPE	FEMALE (A)	MALE (B)	
1	Gonorrhea			
2	Syphilis			
3	HIV – All confidential tests			
4	HIV – Positive confidential tests	▨	▨	
5	HIV – Anonymous tests	▨	▨	

TABLE 13
NUMBER OF FAMILY PLANNING ENCOUNTERS BY TYPE OF PROVIDER

	PROVIDER TYPE	NUMBER OF FTEs (A)	NUMBER OF FAMILY PLANNING ENCOUNTERS (B)
1	**CLINICAL SERVICES PROVIDERS**	▨	
1a	Physicians		▨
1b	Physician assistants/nurse practitioners/ certified nurse midwives		▨
1c	Other clinical services providers (e.g., registered nurses)		▨
2	**NON-CLINICAL SERVICES PROVIDERS**	▨	
3	**TOTAL FAMILY PLANNING ENCOUNTERS (SUM ROWS 1 + 2)**		

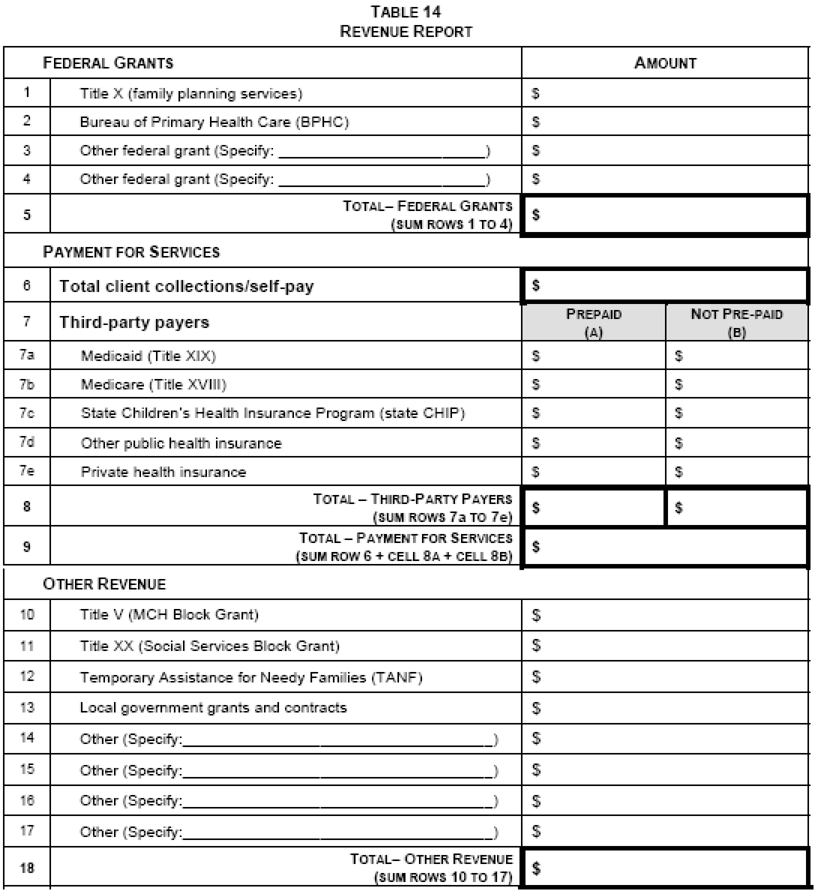


TABLE 14
REVENUE REPORT

	FEDERAL GRANTS	AMOUNT	
1	Title X (family planning services)	$	
2	Bureau of Primary Health Care (BPHC)	$	
3	Other federal grant (Specify: ________________________)	$	
4	Other federal grant (Specify: ________________________)	$	
5	TOTAL– FEDERAL GRANTS (SUM ROWS 1 TO 4)	$	
	PAYMENT FOR SERVICES		
6	**Total client collections/self-pay**	$	
7	**Third-party payers**	PREPAID (A)	NOT PRE-PAID (B)
7a	Medicaid (Title XIX)	$	$
7b	Medicare (Title XVIII)	$	$
7c	State Children's Health Insurance Program (state CHIP)	$	$
7d	Other public health insurance	$	$
7e	Private health insurance	$	$
8	TOTAL – THIRD-PARTY PAYERS (SUM ROWS 7a TO 7e)	$	$
9	TOTAL – PAYMENT FOR SERVICES (SUM ROW 6 + CELL 8A + CELL 8B)	$	
	OTHER REVENUE		
10	Title V (MCH Block Grant)	$	
11	Title XX (Social Services Block Grant)	$	
12	Temporary Assistance for Needy Families (TANF)	$	
13	Local government grants and contracts	$	
14	Other (Specify:__________________________________)	$	
15	Other (Specify:__________________________________)	$	
16	Other (Specify:__________________________________)	$	
17	Other (Specify:__________________________________)	$	
18	TOTAL– OTHER REVENUE (SUM ROWS 10 TO 17)	$	

SOURCE: OFP, 2007.

REFERENCE

OFP (Office of Family Planning). 2007. *Title X family planning annual report: Forms and instructions*. Washington, DC: HHS. http://www.hhs.gov/opa/familyplanning/toolsdocs/fpar_forms_instructions_reissued_oct2007.pdf (accessed March 31, 2009).

Appendix H

Summary of Previous Title X Evaluations and Reviews

Several evaluations of specific aspects of Title X have been conducted. These include both government reviews and evaluations conducted by nongovernmental organizations at the request of the Office of Population Affairs (OPA) or the Office of Family Planning (OFP). The purpose, scope, primary findings, and major recommendations from these assessments are summarized below, in chronological order.

GENERAL ACCOUNTING OFFICE

In 1981, the U.S. General Accounting Office (GAO) provided testimony before Congress summarizing the major findings from a series of GAO reviews of family planning activities under Title X. Between 1970 and 1981, GAO issued eight reports to Congress and one to the District of Columbia's Department of Human Services. The reports did not provide a comprehensive evaluation of the effectiveness of Title X, but concluded that the program had not served many in the target population effectively. This conclusion was based on a series of interviews conducted with welfare recipients, many of whom desired to use family planning services but were unaware of the existence of local clinics, as well as interviews with a sample of clinic clients that suggested high client turnover (GAO, 1981). Several areas for improvements in program management were identified. They included streamlining services for clients using oral contraceptives and collecting fees more aggressively; consolidating and improving coordination of the four different programs administered by the Department of Health and Human Services (HHS) that fund family planning services; improving data collection and monitoring of grantees; improving procedures for grants and contracts awards; and ensuring the appropriate use of funds authorized for program implementation research. GAO indicated that these improvements could reduce costs or enhance the effectiveness and efficiency of Title X.

ASSISTANT SECRETARY FOR ADMINISTRATION AND MANAGEMENT

In 2004, the Office of Grants Management and Policy, under the direction of the Assistant Secretary for Administration and Management, conducted a review of the family planning grant program pre-award activities, which include selection of instruments, development of the program announcement, solicitation of applications, review of applications, and monitoring of post-award activities (Office of Grants Management and Policy, Assistant Secretary for Administration and Management, 2004). The evaluation focused on how the program complied with HHS regulations and policies, whether the pre-award process effectively maximized competition, and whether post-award administration was adequate.

Results of the evaluation identified areas for improved compliance, such as utilizing the grants.gov system more fully, improving filing of communication with grantees, and standardizing the maintenance and organization of grant files. In terms of competition, it was recommended that term limits for grant application reviewers be established, that supplemental requests across regions be reviewed to ensure objectivity, and that OPA review practices to ensure that competition is maximized. Several recommendations were also made in the area of post-award administration, including forwarding copies of site visit reports, as well as the protocols used and the documentation provided, to the grants office for inclusion in the official grant file; developing a post-award monitoring instrument to record contact with grantees; verifying and documenting that appropriate financial monitoring is conducted; and developing a mechanism to verify that organizations eligible for new or continuation grants are up to date with applicable audit requirements. Some additional recommendations outside of the main focus areas were also made, such as establishing a specific amount of time a reviewer could serve under the same program. The protocol used to conduct program reviews of grantees was identified as a best practice.

RESEARCH TRIANGLE INSTITUTE

In 2005, the Research Triangle Institute (RTI) provided a review of evaluations relevant to the Title X program to assess evaluation activities, determine evaluation needs and topics, and identify approaches to guide future evaluations (RTI International, 2005a,b). After identifying

490 potentially relevant published and unpublished studies and excluding studies such as those that were not evaluations or were not specific to the Title X program, the RTI review included 29 published and 39 unpublished studies. The majority (69 percent) of the reviewed studies focused on the financing, costs, organizational structure, and operations of the Title X program. The remaining 31 percent of the studies focused on utilization and demand characteristics of reproductive health care. The studies were further grouped under various topics within these major categories, as well as by evaluation type, population studied, and geographic location of the evaluation. The review also identified differences found between published and unpublished studies; for example, published studies were more likely to be output, process, and outcome evaluations, while the majority of unpublished studies were process evaluations and needs assessments.

RTI noted a lack of studies in several areas that are highly relevant to the Title X program. Few of the studies reviewed examined demand for and utilization of family planning services; organizational or operational issues related to service provision; or supply and demand issues for racial and ethnic minorities, migrants, people with limited English proficiency or low literacy, the uninsured and underinsured, young men, or other high-risk populations (for example, homeless individuals). No studies examined the effects of family and school ties on adolescents' sexual behavior, partnerships with community- or faith-based providers that work with vulnerable populations, education in extramarital abstinence, and HIV/AIDS risk prevention counseling—topics from the 2005 list of program priorities.

A systematic examination of the quality of each of the studies included in the review was undertaken, and the gaps and needs thus identified were discussed. Recommendations were made for OPA to encourage researchers to conduct studies in areas where research is currently lacking, as well as to establish guidelines to improve the quality of unpublished studies. Other recommendations included taking steps to make it easier to identify relevant published Title X studies (for example, by encouraging the use of Title X identifiers in data collection efforts and creating a dedicated medical subject heading term for Title X), as well as implementing a system to catalogue OPA-funded evaluations. Additional suggestions were made for strengthening the quality and impact of Title X program evaluations, including forming an external Title X evaluation work group to, among other things, establish priorities for national and cross-regional evaluations; encouraging the use of logic models as part of the design and implementation of demonstration or other pilot project initiatives; encouraging support for and involvement in the collection and analysis of Title X–relevant national-level data; and encouraging Regional Training Centers to collaborate on the development of a methodology for evaluating training needs for cross-regional OPA initiatives.

OFFICE OF THE INSPECTOR GENERAL

After concern was raised that organizations receiving Title X funds might not be fully complying with state reporting laws regarding sexual abuse, the Office of the Inspector General (OIG) reviewed the process used by OPA to inform and monitor grantees with respect to these requirements. The OIG assessment included a review of documents issued by OPA and its grantees, including Program Guidelines, assessment tools, and training materials; a written survey of the 10 Regional Offices; and structured in-person and telephone interviews with representatives from the OPA Central Office, regional program consultants, and representatives from each of the Regional Training Centers. OIG concluded that "OPA has informed and periodically reminds Title X grantees of their responsibilities regarding State child-abuse and sexual-abuse reporting requirements in its reviews and site visits of grantees" (OIG, 2005, p. 1).

HEALTH SYSTEMS RESEARCH, INC.

In 2005, Health Systems Research, Inc. assessed clinical specialty training for Title X clinical service providers (Health Systems Research, Inc., 2005). OPA requested the assessment to help improve clinicians' capacity to provide effective and high-quality family planning services. The assessment consisted of a literature review, a workgroup meeting, and interviews with the two Title X clinical specialty training programs (each of which provides training for half of the country's regions). The staffing challenges identified included an aging provider population, difficulty in recruiting and retaining providers, and inadequate funding. Training challenges identified included "a lack of hands-on training opportunities, difficulties in finding preceptors, complex client needs and changing demographics, difficulty recognizing and assessing training needs, and funding, geographic, and timing issues." (Health Systems Research, Inc., 2005, p. 1).

Suggested strategies for addressing training challenges included (1) using the existing infrastructure to expand training opportunities (for example, by standardizing training technologies and sharing information about model programs); (2) utilizing alternative resources (for example, by collaborating with other federal training programs that provide training in similar areas); (3) building a new infrastructure to provide more opportunities for training (for example, by creating a pool of clinical trainers that could travel to sites to provide training, or by establishing model clinics in each region); and (4) addressing recruitment and retention issues (for example, by providing salary adjustments for clinicians with advanced training). Recommendations were also made regarding the key components of an ideal program for Title X clinical specialty training, including creating roles for "key players" (such as a pool of expert clinical trainers who would travel among clinics to provide training or the staff of a national coordinating center); developing training content, including a national standardized curriculum covering the Title X core competencies and service requirements; enhancing the delivery of clinical training to increase accessibility and maximize the use of resources; and creating a national coordinating body to assess training needs and develop a standardized evaluation that would be conducted on an ongoing basis.

PROGRAM ASSESSMENT RATING TOOL

As described in Chapter 1, the Office of Management and Budget (OMB) performed an evaluation of Title X under the Program Assessment and Rating Tool (PART) process (OMB, 2009). The program received a rating of Moderately Effective. The program subsequently developed three long-term measures that are reported on annually: (1) increasing the number of unintended pregnancies averted by providing Title X family planning services, with priority for services to low-income individuals; (2) reducing infertility among women attending family planning clinics by identifying chlamydia infection through screening of females aged 15–24; and (3) reducing invasive cervical cancer among women attending family planning clinics by providing Pap tests according to nationally recognized standards of care.

In addition to requesting the present evaluation, OFP has developed performance goals for key program activities in response to the PART process. The program has developed, implemented, and established targets for all annual and long-term performance goals, including its efficiency measure, which is to maintain the actual cost per client below the medical care inflation rate.

REFERENCES

GAO (U.S. General Accounting Office). 1981. *Results of GAO reviews of family planning activities under Title X of the Public Health Service Act*. Washington, DC: GAO.

Health Systems Research, Inc. 2005. *Assessment of clinical specialty training for Title X clinical service providers: Executive summary.* Washington, DC: Health Systems Research, Inc.

Office of Grants Management and Policy, Assistant Secretary for Administration and Management. 2004. *Review of grants management practices, policies, and procedures in the Office of the Assistant Secretary for Public Health and Science (OPHS), Office of Population Affairs (OPA), Family Planning Services Program, CFDA 93.217*. Washington, DC: U.S. Department of Health and Human Services.

OIG (Office of the Inspector General). 2005. *Federal efforts to address applicable child abuse and sexual abuse reporting requirements for Title X grantees.* http://www.oig.hhs.gov/oei/reports/oei-02-03-00530.pdf (accessed April 2, 2009).

OMB (Office of Management and Budget). 2009. *Detailed information on the family planning assessment*. http://www.whitehouse.gov/omb/expectmore/detail/10003513.2005.html (accessed March 6, 2009).

RTI International (Research Triangle Institute International). 2005a. *Review and synthesis of evaluations relevant to the Title X program*. Research Triangle Park, NC: RTI International.

RTI International. 2005b. *Synthesis of data relevant to the Title X program*. Research Triangle Park, NC: RTI International.

Appendix I

Title X– and OPA-Funded Research

Section 1004 of the Title X Act authorizes the Secretary of Health and Human Services to award grants and enter into contracts for research projects in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population. Research funded by the program includes Title X Service Delivery Improvement research—applied research aimed at generating knowledge that will enable the program to improve the delivery of reproductive health services to women and men who need them. Research is also conducted through cooperative agreements. The purpose of these agreements is to analyze data on family planning needs and services over time, develop tools for assessing and improving the quality of care in clinics, and analyze national survey data to better understand the determinants of unintended pregnancy and childbearing (www.hhs.gov/opa/ore/research/index.html [accessed August 19, 2008]). In addition to these grants, the Office of Population Affairs uses 1 percent funds from the Department of Health and Human Services (HHS) to contribute to the National Survey of Family Growth (NSFG) and Adolescent Health Surveys.

SERVICE DELIVERY GRANTS AND COOPERATIVE AGREEMENTS

The awards listed below are categorized by fiscal year (FY). These include grants made under the Service Delivery Improvement research standing announcement and through cooperative agreements (three were awarded in FY 2004). Note that grants were not awarded in FY 2002 and FY 2003.

Fiscal Year 2008

Integration of Family Planning Services into an STD Clinic Setting

Grantee Organization:
Denver Health and Hospital Authority
Denver Public Health Department
Denver, CO
Principal Investigator: Judith Shlay, M.D.
Project Period: 9/01/2008–8/31/2011

This study will investigate how providing integrated family planning with STD clinical services in an STD clinic affects quality of care, cost of services, staff duties, clinic flow, clients' family planning needs, satisfaction with services, and incidence rates of STDs and pregnancies. The study will specifically (1) assess the feasibility and replicability of the clinical processes used by clinicians to provide family planning services in an STD clinic setting, (2) assess and compare the costs of providing family planning and STD services in separate clinical settings and through separate programs to the costs of an integrated program, (3) establish computerized procedures to identify clients eligible for family planning services in an STD clinic, and (4) assess the need for family planning services among all clients seen for STD clinical services. In addition, the study will evaluate the effectiveness of a reminder system that notifies staff of a person's eligibility to receive family planning services; and compare rates of STDs and unintended pregnancies among clients seen in the clinic.

Sexual and Reproductive Health Outreach for Young Women of Color: A New Approach

Grantee Organization:
The Trustees of Columbia University
Columbia University Health Sciences Center
New York, NY
Principal Investigator: Debra Kalmuss, Ph.D.
Project Period: 9/01/2008–8/31/2011

The study will develop innovative and practical ways to embed sexual and reproductive health (SRH) referrals, as well as promotional information and messages, into workforce development (WFD) programs; train WFD program staff to interview men about their use of and/or need for SRH care and how to make care referrals; train staff at Title X clinics how to enhance their facilities and services to be gender sensitive to men, based on the results of a male friendliness needs assessment; and implement and evaluate the efficacy and sustainability of the capacity building outreach model in promoting men's SRH utilization. The proposed research will occur with two WFD programs that serve low-income Hispanic and African-American males seeking new job training, and two Title X clinics.

Increasing Family Planning Utilization Among Hispanic Teen and Young Adult Women

Grantee Organization:
Child Trends
Washington, DC
Principal Investigator: Jennifer Manlove, Ph.D.
Project Period: 9/01/2008–8/31/2011

The specific aim for the project is to reduce the high rate of teen and unintended pregnancies among Hispanics in the United States. This will be accomplished by using quantitative, qualitative and applied research methods to better assess who is or is not accessing family planning services and why. The project work will be performed in three stages. In Stage 1, the project will analyze family, individual, and community factors associated with the utilization of family planning services using data from several cycles of the National Survey of Family Growth. For Stage 2, focus groups will be conducted in three target cities with Hispanic female teens and young adults to gather group insights into their decisions to access or not access services. The project will also include three focus groups with clinics and service providers to discuss the challenges of reaching Hispanic clients. In Stage 3, project staff will work with a clinic or provider in each of the target cities to assess how the programs can use the study's findings; translate the findings; and construct implementation guidelines for the broader family planning practitioner community.

Fiscal Year 2007

Medicaid Family Planning Waivers: Service Delivery, Use, and Intended Pregnancy

Grantee Organization:
Emory University
Rollins School of Public Health
Atlanta, GA 30322
Principal Investigator: Kathleen Adams, Ph.D.
Project Period: 9/30/2007–9/29/2010

Six states will be study sites for examining the effects of changes in the organization and delivery of family planning services through Medicaid section 1115 waivers on three key outcomes—(1) access to services, (2) use of contraceptive/preventive services, and (3) unintended pregnancy. In each state, the aim will be to test whether the state's waiver reduced barriers and increased use of services and thereby reduced unintended pregnancy. Overall, variation in the impact of waivers across states and across different subgroups, such as married women, teens and minority women, will be analyzed. Both quantitative analyses (PRAMS and BRFSS data sets available from CDC) and qualitative research (informant interviews and focus groups) will be carried out. A synthesis of states' concerns, approaches, successes/failures and client perceptions of the waivers will be generated. A key goal of the analyses is to elucidate the pathways whereby sexually active women not desiring to become pregnant are or are not served under the delivery systems each state has in place under its waiver. The six states are Arkansas, Illinois, New York, California, Washington, and Wisconsin; the project will provide a case study for each of these states.

Sexual and Reproductive Health Services: Reaching Latino Men in Rural Areas

Grantee Organization:
Oregon State University
Department of Public Health
Corvalis, OR 97331
Principal Investigator: S. Marie Harvey, Dr.P.H.
Project Period: 9/30/2007–9/29/2010

The objective of this research project is to increase understanding of the sexual and reproductive health needs of heterosexual Latino men who live in rural areas. In this two-part study, the focus is on Latino men in the new settlement areas of rural Oregon. Study 1 will consist of in-depth interviews of a convenience sample of 80 men to assess their attitudes and behavior pertaining to sexual activity and contraception, and their perceptions of their needs and of the barriers to accessing services and to determine how their attitudes and behaviors vary by age, type of sexual partner and acculturation. Study 2 will include in-depth interviews with administrators and practitioners from publicly funded family planning agencies who serve Latinos in rural areas. The specific aims of Study 2 are to (a) explore experiences providing family planning and HIV/STI prevention services to Latino males; (b) identify barriers and facilitators to serving male Latinos; (c) explore advantages and disadvantages of integrating men into sexual and reproductive health services for family planning agencies and for male clients; (d) identify preferred context for providing sexual and reproductive health services to men (e.g., couples, male only, traditional family setting or other contexts); and (e) explore how agencies can build their capacity to improve sexual and reproductive health services for Latino males.

Couples-Based Family Planning Services: Is There a Need?

Grantee Organization:
The Guttmacher Institute
New York, NY 10038
Principal Investigator: Rachel Jones, Ph.D.
Project Period: 9/30/2007–9/29/2010

The project aims to improve contraceptive use and reduce unintended pregnancy among Title X family planning clients by providing information on a new and mostly untested programmatic strategy of fostering joint decision-making around family planning through couples-oriented services. Three interrelated activities are proposed:

1. Provide a national overview of the extent to which Title X female and male clients, 18–44 years of age, as well as the clients' partners, express a desire for programs oriented to couples designed to improve joint decision making around contraceptives and method selection;
2. Explore the issue from the point of view of providers, to determine what strategies clinics have so far adopted in terms of couples-oriented counseling or services, as well as perceived need for and barriers to implementing such programs; and
3. Disseminate findings to relevant audiences to inform public discussion about the potential for contraceptive counseling and services targeting couples in order to foster or promote joint decision making around contraceptive use.

The sampling approach is based on 80 randomly drawn clinics from a universe of U.S. clinics. Individual clients will receive and complete surveys at the clinic site and be provided survey forms to take to partners; the sample size of clients is expected to be 2,500 women and 125 men. Clients' openness to a couples approach will be analyzed by relationship type (married, co-habiting, neither married nor co-habiting) and by racial/ethnic groupings. Staff at sampled clinics will complete a provider survey on couples-oriented services as well.

The Fort Peck Sexual Health Project:
A Contextual Analysis of American Indian Men

Grantee Organization:
Montana State University
Department of Health and Human Development
Bozeman, MT 59717
Principal Investigator: Elizabeth Lynne Rink, Ph.D.
Project Period: 9/30/2007–09/29/2009

The study will elucidate the individual, social and environmental factors that most greatly influence American Indian men's sexual and reproductive health. Individual characteristics to be examined include: knowledge of contraceptive methods and sexually transmitted infections (STIs); perceptions of pregnancy; perceived risk of STIs; perceptions of abstinence, monogamy and contraceptive use. Social dynamics to be examined are: relationships with family; relationships with peers; culture; religion; and relationships with sexual partners. The relevant environmental factors will include: characteristics of family planning services, access to family planning services, and utilization of family planning services. The target population for this project is American Indian men ages 18–24 years living on the Fort Peck Indian Reservation in northeastern Montana. The research plan includes a Community Based Participatory Research (CBPR) approach and qualitative research methods. CBPR will entail engaging the Fort Peck Indian Reservation as full and equal partners in the research project, by establishing an 8–10 member community advisory board to provide oversight and coordination of the project. Qualitative research methods will include (1) 12–15 key informant interviews with health care professionals and (2) 112 in-depth interviews with American Indian men. Research results will be used to design effective, culturally sensitive, family planning intervention strategies for American Indian men.

Fiscal Year 2006

CONnecting with Teens About Contraceptive Use (CONTAC-U)

Grantee Organization:
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street
Baltimore, MD 21205
Principal Investigator: Kathleen M. Cardona, Dr.P.H., M.P.H.
Project Period: 09/01/2006–08/31/2009

Project Description: The objective of this study is to develop and evaluate a clinic-based intervention intended to increase contraceptive use and consistency of use, and reduce 1-year pregnancy rates among adolescents. Specifically, the plan is to design an easily replicable, technology-based and adolescent-friendly means of continuing contact to enhance contraceptive protection, while encouraging parental involvement. This will involve all female clients under age 20 who present to the youth center in Baltimore City over an 18 month period. Individualized methods counseling sessions will be provided to clients who will be contacted at regular intervals beginning 2 weeks post-enrollment and then at least monthly to discuss issues related to method use, and appointment reminders. One technological innovation is clients' use of text-messaging, e-mail, or phone as a means of clinic contact. A second innovation is the use of a new web-based database to be designed for this project, which will permit contacts to be scheduled, initiated, and recorded, and which will enable the clinic to provide regular, longitudinal follow-up. Clients will also be encouraged to identify a parent or key adult to participate in order to learn about contraceptive options and how to communicate with the teen to reinforce appropriate use of contraception.

Chlamydia and Race/Ethnicity in Title X Region X Female Clients Age 15–24 Years

Grantee Organization:
Center for Health Training
1809 7th Avenue, Suite 400
Seattle, WA 98101
Principal Investigator: David Fine, Ph.D.
Project Period: 9/01/2006–08/31/2007

Project Description: The research goal for this project is to explore, assess, and begin to address possible racial/ethnic disparities in chlamydia (CT) screening, prevalence and prevention services in Title X family planning clinics using existing data sets. Specific aims are to (1) assess racial and ethnic disparities in chlamydia screening coverage among Title X Region X family planning (FP) clinic female clients aged 15–24, from 2004–2005; (2) assess racial and ethnic disparities in chlamydia positivity among Region X FP clinic female clients aged 15–24 from 1997–2005; and (3) assess an enhanced array of behavioral, demographic, and socioeconomic status measures in relation to race/ethnicity and chlamydia positivity in a sample of FP clinic female clients age 15–24. Data sources to be used for specific aims #1 and #2 include (1) a two-year (2004–2005) data set from the Region X Title X FP client information system that captures patient characteristics and service provision for all Title X encounters; and (2) data from the Infertility Prevention Project (IPP) for the assessment of racial and ethnic disparities in chlamydia positivity. Data for specific aim #3 will come from recruiting female FP clients (375 CT+/375 CT-) age 15–24 from clinics where race/ethnic disparities were found based on results from specific aim #2.

Disparities in Reproductive Health Care Access Among Vulnerable Populations

Grantee Organization:
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709
Principal Investigator: Christina Fowler, Ph.D., M.P.H.
Project Period: 09/01/2006–08/31/2008

Project Description: This study proposes a comprehensive and systematic examination of disparities in reproductive health service access across multiple vulnerable populations. The objective of this project is to examine whether disparities in access to family planning and other reproductive health services exist for vulnerable groups of women and men, specifically non-Hispanic black and Hispanic, relative to non-Hispanic white; poor (<100% of federal poverty level [FPL]) and near-poor or low income (100%–199% of FPL), relative to nonpoor (>200% of FPL); teens (aged 15–19) and young adults (aged 20–24), relative to older adults (aged 25–44); and residents of nonmetropolitan counties and metropolitan suburban counties, relative to residents of metropolitan urban counties. Data from the 1995 (women) and 2002 (women and men) National Survey of Family Growth (NSFG), will be used to analyze whether group differences exist in service utilization, quality, and contraceptive use and to assess the role of Title X clinics in reducing differences. The IOM's 1993 Model of Access to Personal Health Care Services, adapted to reproductive health care, will guide the study.

Impact of Pack Supply on Contraceptive Continuation

Grantee Organization:
Columbia University Medical Center
630 West 168th Street
New York, NY 10032
Principal Investigator: Katherine J. O'Connell, M.D., M.P.H.
Project Period: 09/30/2006–09/29/2009

Project Description: The objective of this project is to determine whether providing an enhanced, seven-month supply of oral contraception (OC) versus the standard 7-month supply of OC results in less contraceptive discontinuation. It is believed that an extended initial supply of contraception requires fewer visits to obtain refills and may remove a common obstacle to method continuation. The proposed strategy is a randomized trial to compare two approaches to the initial supply of hormonal contraception in women aged 29 and under who receive family planning care at a publicly funded clinic (n = 750). The approaches are (1) a standard 3-month supply of OC, versus (2) an enhanced 7-month supply of OC. Interviews will be conducted at a 6-month follow-up to determine OC continuation rates and adverse events. The researchers believe that the approach of extending the initial supply of contraception has the potential to improve rates of OC, particularly among adolescents who are at the highest risk of early discontinuation, and by removing a obstacle to method continuation, would ultimately help to reduce the rate of unintended pregnancy.

Fiscal Year 2005

How Well Do Family Planning Providers Link Their Low-Income Clients to Primary and/or Specialty Care?

Grantee Organization:
University of Alabama-Birmingham
1530 3rd Avenue South
Birmingham, AL 35294
Principal Investigator: Janet M. Bronstein, Ph.D.
Project Period: 09/30/2005–09/29/2007

Project Description: The specific aims of this project are (1) to examine the range of referral facilitation activities provided in family planning settings serving low-income women; (2) to explore the factors associated with family planning clients' decisions to seek and ability to receive care for other medical conditions, including the role played by referral facilitation and discussions of the problem at the family planning visits; and (3) to compare the level of concern about the ability to refer family planning clients for needed primary and specialty care between clinicians who do and do not provide family planning care to clients with Medicaid coverage for these services. Family planning providers who participate in and clients who are enrolled in Medicaid family planning demonstration programs in Alabama and Arkansas are the populations under study. Data for this project will be collected through three surveys: (1) a survey of family planning clinicians to assess referral practices; (2) a survey of these clinicians' family planning clients, to examine their care-seeking behavior for general health problems and the role played by their family planning providers; and (3) a survey of office physicians who are authorized as Medicaid family planning providers but are seeing few or no Medicaid clients.

Men's Reproductive and Sexual Health Practices, Attitudes and Service Utilization

Grantee Organization:
Columbia University Medical Center
60 Haven Avenue, Suite B-2
New York, NY 10032
Principal Investigator: Debra S. Kalmuss, Ph.D.
Project Period: 09/30/2005–09/29/2008

Project Description: The objective of the proposed study is to examine men's reproductive and sexual health (RSH) practices, attitudes, and service utilization in order to inform the development of programs for adolescent and older men. The research plan is to employ both quantitative and qualitative methods to examine men's RSH status, attitudes and practices and how they vary across race/ethnic, socioeconomic, age, and marital/relationship status in order to increase the utilization of RSH services for men. The quantitative approach would use national data from Cycle 6 of the National Survey of Family Growth (NSFG) supplemented by two data sets targeting high-risk groups of males aged 18–30 from northern Manhattan and the Bronx. The qualitative component—use of focus groups—is intended to obtain a more in-depth understanding of men's perceptions regarding utilization, such as barriers to men's use of RSH and possible strategies to increase men's utilization of such services. The final step in the proposed study will involve the translation of research findings into suggestions for program development and/or enhancement.

Improving Services for Latina Women and Their Partners: A CAPACITIES Approach

Grantee Organization:
Georgetown University, Department of OB/GYN
3900 Reservoir Road, NW
Washington, DC 20007
Principal Investigator: Rebecka Lundgren, M.P.H.
Project Period: 09/30/2005–09/29/2008

Project Description: This intervention research, which will be conducted collaboratively by the Institute for Reproductive Health, Georgetown University, and Planned Parenthood of San Diego and Riverside Counties, will determine whether including the Standard Days Method (SDM) as an option for clients results in an increased focus on the couple in counseling for all methods of contraception; whether incorporating a couple perspective into services results in improved satisfaction with and use of services; whether it increases couple communication and participation in family planning use and decision-making; and whether it results in improved used of and satisfaction with family planning methods. SDM is a simple, effective fertility awareness-based method that is being offered in programs around the world, including a growing number in the United States. The importance of addressing couples may be particularly relevant for Latinos, given cultural considerations.

Couples and Contraceptive Practice

Grantee Organization:
Family Planning Council
260 S. Broad Street, Suite 1000
Philadelphia, PA 19102-5076
Principal Investigator: Paul Whittaker, Ph.D.
Project Period: 09/30/2005–09/29/2008

Project Description: The Family Planning Council proposes to conduct a mixed methods investigation to study the feasibility and effectiveness of couples-focused contraceptive services, which will use an integrated complement of ethnographic and quantitative methods to attain three aims. The first is to compare the attitudes, subjective norms, and behavioral beliefs of young adult men and women regarding the involvement of intimate partners in contraception decisions and the influence of these partners on contraceptive use. The second is to identify the attitudes, subjective norms, and behavioral beliefs of Title X providers regarding the current and potential provision of couples-focused contraception services. The third is to develop and field-test the potential utility of a culturally relevant couples-focused intervention that promotes informed contraception decisions and effective contraception use.

Fiscal Year 2004 (Cooperative Agreements)

Family Planning Needs and Services in the United States

Grantee Organization:
The Alan Guttmacher Institute
120 Wall Street
New York, NY 10005
Principal Investigator: Jennifer Frost, Dr.P.H.
Project Period: 09/30/2004–09/29/2009

Project Description: The goal of the proposed project is to provide core information and analyses that program planners and providers can use to improve the delivery of quality family planning services, and through this, to increase the success with which U.S. women and their partners prevent unplanned pregnancies. This project will use existing national-, state-, and county-level data, and collect new data when necessary, to answer the following questions: How many women in the United States are in need of subsidized family planning services? To what extent is this need being met? How well are these women being served? What challenges are posed by an increasingly diverse population base? How is financing for family planning changing? What return do we get for our investment in publicly funded family planning services? These data will allow programs to be monitored and services to be adjusted to ensure that those who need and want subsidized family planning and related preventive reproductive health services are able to obtain them.

Child Trends/OPA Cooperative Agreement for Family Planning Research

Grantee Organization:
Child Trends
4301 Connecticut Ave., N.W., Suite 100
Washington, DC 20008
Principal Investigator: Jennifer Manlove, Ph.D.
Project Period: 09/30/2004–09/29/2009

Project Description: The aim of this project is to examine family, individual, peer, partner, and community factors to better understand sexual experience and activity, contraceptive use and effectiveness, unintended childbearing and unmet family planning service needs. In addition, studies are planned of nonvoluntary sexual experiences, the male role in reproductive health decisions, and parental involvement on important reproductive health matters. These analyses will help clinic staff identify those most in need of services and provide insights into how to implement challenging family planning policy initiatives. The project will comprehensively analyze relevant data from several national data sources (National Vital Statistics System; Youth Risk Behavior Survey; National Survey of Family Growth; National Longitudinal Study of Adolescent Health or Add Health; National Survey of Adolescent Males; and National Longitudinal Survey of Youth 1997). Research products in the form of Research Briefs and Fact Sheets will be made available.

Strengthening the Capacity of Family Planning Agencies to Improve the Quality of Family Planning Services: Cooperative Agreement for Research to Improve the Delivery of Family Planning Services

Grantee Organization:
Johns Hopkins University School of Hygiene and Public Health
2007 E. Monument Street
Baltimore, MD 21205
Principal Investigator: Freya Sonenstein, Ph.D.
Project Period: 09/30/2004–09/29/2009

Project Description: The proposed project, which addresses a significant gap in our knowledge about quality of family planning services in this country, will be conducted by a team of researchers from Johns Hopkins University in collaboration with a small network of Title X grantees. The project has the following aims: to develop approaches that assess the quality of service delivery; to develop a toolbox of approaches to improve quality of services; and to test interventions aimed at quality improvement. The emphasis is on developing (1) feasible and practical approaches to measuring quality of care in Title X clinics with attention to client–provider interactions; (2) a demonstration network that could help develop a research infrastructure among Title X grantees; and (3) dissemination processes that promote science-based practices. Serving a mix of clients, including individuals with limited English proficiency, varying ethnic and racial identities, and men as well as women, the network of agencies will make it possible to test approaches to measure and improve services for diverse populations with varying needs.

Fiscal Year 2001

Enhanced Family Planning in an STD Clinic

Grantee Organization:
Johns Hopkins University, School of Medicine
720 Rutland Avenue
Baltimore, MD 21305
Principal Investigator: Emily Erbelding, M.D., M.P.H.
Project Period: 9/2001–9/2003

Project Description: This project will evaluate the impact of enhanced STD outreach worker services on the reproductive health outcomes in a cohort of women receiving STD care and contraceptive care in inner city STD clinics. Outcomes will be compared to those of a control cohort of women who are enrolled for a similar range of contraceptive services but do not receive the outreach intervention. The study will measure rates of unintended pregnancy and new STDs among female STD patients in a system with contraceptive public health outreach compared to standard care.

Women Leaving Prison: Two Models of Family Planning Service Delivery

Grantee Organization:
Rhode Island Hospital
593 Eddy Street
Providence, RI 02903
Principal Investigator: Jennifer Clarke, M.D.
Project Period: 9/2001–9/2003

Project Description: The researchers will evaluate a current Title X-funded family planning program for incarcerated women in Rhode Island who are soon to be released from prison. Clients will be surveyed to determine factors associated with and barriers to seeking family planning services. The study will compare two modes of delivering family planning services to women being released from prison. The first model will evaluate an innovative program that involves initiating family planning education for incarcerated women and then arranging post-release connection to a clinic for family planning services. The second model will examine a model in which education and contraceptive methods are offered to women prior to their release from prison and then arranging a post-release connection to a clinic for family planning and reproductive health care. Behavioral and biological outcomes will be assessed when testing both these models.

Improvement in Northern Manhattan to Two Underserved Populations: Males and Recent Immigrants

Grantee Organization:
New York Presbyterian Hospital
60 Haven Avenue, B-3
New York, NY 10032
Co-Principal Investigators: Roger Vaughan, Ph.D., and Lorraine Tiezzi, M.S.
Project Period: 10/2001–9/2003

Project Description: This project will identify and explore the enabling factors for, and barriers to, health care seeking behavior among a recent immigrant Hispanic population and among Hispanic males in New York City. The project will conduct several case-control studies at different health care access points (including reproductive health care) available to recent immigrants and males. Structured interviews will be conducted among a sample of older adolescents, young adults and older adults who have demonstrated health care needs and who accessed health care, and among a control group who did not access health care. Structured interviews will also be conducted with parents, as well as with the health care providers in the school-based clinics and the community-based family planning clinics.

Barriers to Family Planning Services Among Mexican Immigrants in California: Gender, Power and Culture

Grantee Organization:
University of California, San Francisco
Department of Obstetrics, Gynecology and Reproductive Sciences
3333 California Street, #315
San Francisco, CA 94118
Principal Investigator: Catherine Maternowska, Ph.D., M.P.H.
Project Period: 1/2001–12/2002

Project Description: This project focuses on understanding the complex sociocultural factors that influence reproduction and the use of family planning services in Mexican immigrant communities. The research project has three broad aims: (1) to uncover factors that influence the use of family planning services among male and female Mexican immigrants in California; (2) to discern if these factors differ among rural (largely migrant) and urban populations; and (3) to understand providers' behavior and their perceptions of Mexican immigrants in an effort to determine how services can be made more accessible. A sample of Mexican men and women of childbearing age will be recruited for interviews from two groups—clients in the California Family Planning, Access, Care and Treatment Program (Family PACT) and non–Family PACT clients. Interviews will address respondents' fertility histories, contraceptive knowledge and attitudes, financial, time, and health care resources, access to medical care, as well as social and legal networks. The project will also study family planning provider attitudes regarding the Mexican immigrant population and perceptions of their needs.

Project to Assess the Impact of Increasing Costs on the Delivery of Family Planning and Reproductive Health Services

Grantee Organization:
Cicatelli Associates, Inc.
505 Eighth Avenue, Suite 2001
New York, NY 10018-6505
Principal Investigator: Susan Gadon
Project Period: 9/2001–9/2002

Project Description: Cicatelli Associates, Inc. (CAI) will conduct a case study approach to explore the impact of increasing costs and other factors on the delivery of family planning and reproductive health services over a 5–10-year period. The project will work with a sample of Title X family planning grantees and provider agencies to conduct an in-depth review and analysis of purchasing records, clinic operations, and other records to extract information required to determine the effect that changing costs have had on the delivery of family planning services. A relative value cost methodology will be utilized for each participant agency to determine the unit cost of service by CPT codes. CAI will develop cost of service reports providing in-depth information on the impact of changing costs, as well as other contributing factors, affecting the delivery of family planning services.

FISCAL YEAR 1983–2000 AWARDS

Service Delivery Improvement grants for FY 1983–2000 are listed below, organized according to the following topic areas: increasing cost of family planning services, family planning client behavior, adolescent family planning clients, male family planning clients, targeting of family planning services, organization/management of family planning services, role of private physician, natural family planning, infertility services, counseling services, and cross-national studies.

Increasing Cost of Family Planning Services

Project to Assess the Impact of Increasing Costs on the Delivery of Family Planning and Reproductive Health Services

Grantee Organization:
Cicatelli Associates, Inc.
505 Eighth Avenue, Suite 2001
New York, NY 10018-6505
Principal Investigator: Susan Gadon
Project Period: 9/2001–9/2002

Project Description: Cicatelli Associates, Inc. (CAI) will conduct a case study approach to explore the impact of increasing costs and other factors on the delivery of family planning and reproductive health services over a 5–10-year period. The project will work with a sample of Title X family planning grantees and provider agencies to conduct an in-depth review and analysis of purchasing records, clinic operations, and other records to extract information required to determine the effect that changing costs have had on the delivery of family planning services. A relative value cost methodology will be utilized for each participant agency to determine the unit cost of service by CPT codes. CAI will develop cost of service reports providing in-depth information on the impact of changing costs, as well as other contributing factors, affecting the delivery of family planning services.

Family Planning Client Behavior

Assessing Family Planning and Reproductive Health Needs and Services in the United States

Grantee Organization:
The Alan Guttmacher Institute
120 Wall Street
New York, NY 10005
Principal Investigator: Jacqueline E. Darroch, Ph.D.
Project Period: 7/01/1999–6/30/2004

Project Description: The objectives of this project include the following: (1) to document the nation's need for publicly funded reproductive health and family planning services, service providers' capability and success in meeting those needs with attention to the demographic and socioeconomic characteristics of those in need; (2) to investigate emerging issues and significant trends in publicly funded reproductive health and family planning service delivery, with special attention to the Title X family planning program; (3) to monitor federal and state funding and policies that affect reproductive health family planning service delivery, including funding provided under Medicaid and other major sources and through managed care mechanisms; and (4) to disseminate information and analyses that will enable policy makers, providers and other individuals and organizations to improve the quality and reach of reproductive health and family planning services in the United States.

Improving Condom Use for STD Prevention by Clinic Patients

Grantee Organization:
Family Health Council of Central PA
1017 Mumma Road
P.O. Box 360
Camp Hill, PA 17001-0360
Principal Investigator: Laraine Winter, Ph.D.
Project Period: 1/1998–12/2000

Project Description: The aim of this study was to evaluate an intervention to increase condom use among partners of family planning clinic patients. Using a prospective cohort design, the study was conducted in three family planning clinics in Pennsylvania and Maryland. A sample of 2,100 female family planning patients under age 30 received one of three counseling strategies—the skill training condition, a control condition with standardized condom education, and a second control condition in which a list of suggestions was added to the standard condom education. The intervention, which was designed to enhance the subjects' negotiation skills in getting partners to use condoms, consisted of a counseling based social skill training exercise which targeted social barriers to condom use. Patients were first required to identify obstacles to their condom use, and with the help of a counselor devised plans to overcome each obstacle. At the end of their clinic visit, patients were invited to take as many free condoms from a basket of 50 as they wished and complete a questionnaire which assessed intention to use condoms, attitudes, knowledge, number of condoms taken, and frequency of sexual intercourse. Demographic information and STD infection status were gathered from the clinic's Patient Input and Clinic Report Forms. Twelve months later, at the annual clinic visit, patients answered questions about their condom use since the intervention. Also, patient medical charts were examined for evidence of new STD infections since the intervention.

Norplant, Depo Provera, the Pill: Influences and Outcomes

Grantee Organization:
Family Planning Council of Southeastern Pennsylvania
260 South Broad Street, Suite 1900
Philadelphia, PA 19102-3865
Investigator: Kay A. Armstrong
Project Period: 10/1993–9/1996

Project Description: This study involved clinicians and clients at five Title X funded family planning clinics in Southeastern Pennsylvania and focused on the three major methods of hormonal contraception: Norplant, Depo-Provera, and oral contraceptives. It examined two issues: (1) clinician influences on clients' contraceptive decision making with a particular focus on the choice of the three hormonal methods, and (2) behavioral compliance outcomes associated with the use of each of the three methods.

Family Planning in Clinic Discontinuation

Grantee Organization:
Family Planning Council of Southeastern Pennsylvania
260 South Broad Street, Suite 1900
Philadelphia, PA 19102-3865
Investigator: Roberta Herceg-Baron, M.A.
Project Period: 10/1983–3/1985

Project Description: This project examined the complete clinic histories of over 13,000 women in Pennsylvania and follow-up interviews were conducted with a subsample to obtain answers to the following questions: (1) What are the rates and patterns of clinic discontinuance among family planning clients? (2) To what extent are personal, clinic, and community attributes associated with the rate of discontinuance? (3) What are the reasons for clinic discontinuation and what sources are used subsequently by women still desiring family planning care?

Family Planning Performance: Acceptance and Drop-Out

Grantee Organization:
Johns Hopkins University
School of Hygiene and Public Health
Department of Population Dynamics
615 North Wolfe Street
Baltimore, MD 21205
Principal Investigator: Dr. Lien P. Chow, M.D.

Project Period: 10/1983–9/1985

Project Description: Two major data sources were utilized to study family planning services in Maryland, with emphasis on the study of clinic acceptors and dropouts. First, computerized data files on all new acceptors in Maryland (except Baltimore) for the past 5 years were assessed to ascertain if the program was increasing its numbers of those it is designed to serve and to analyze the characteristics of dropouts. Second, follow-up interviews of 1,500 women were conducted to determine subsequent contraceptive behavior and fertility and to obtain additional data not available on medical records.

Choice of Family Planning Services Among Poor Women

Grantee Organization:
University of Florida
Department of Psychology
Gainesville, FL 32611
Principal Investigator: Lawrence J. Severy, Ph.D.
Project Period: 10/1983–9/1986

Project Description: This project surveyed 1,000 low-income women in need of family planning services in north central Florida to examine the utility of the expectancy-value model in predicting both choice of provider (private physicians, family planning clinics, or other) and change in providers over an 18-month period. The results can alert providers as to whether there are misperceptions about their service delivery systems which can be addressed.

Family Planning Needs of Underserved Women: Contraception, Patient Education, and Reproductive Health

Grantee Organization:
University of Southern California
School of Medicine
Department of Medical Education
KAM Room 200
1975 Zonal Avenue
Los Angeles, CA 90033
Principal Investigator: Robert C. Mendenhall, Ph.D.
Project Period: 9/1985–6/1987

Project Description: The study identified low-income women who, while at the risk of unintended pregnancy, were not receiving clinic or private family planning care; determined what are the barriers to service utilization for them; and assessed deficits of clinic providers in their efforts to reach such clients. Approximately 600 low income Los Angeles women from different ethnic groups and poverty levels were surveyed, and those survey data were linked with information from providers located in the same "district" as the surveyed women.

Rural Family Planning Services: An Interactionist View

Grantee Organization:
Cornell Institute for Social and Economic Research
Cornell University
123 Day Hall
Ithaca, NY 14853
Principal Investigator: Burton Mindick, Ph.D.
Project Period: 1/1985–12/1986

Project Description: This project will look at how person and clinic situation interrelate to influence family planning effectiveness in a rural setting. A three-county area in Central New York State is the geographical location of the study; data will be obtained from approximately 900 subjects: women of childbearing age attending family planning clinics, a comparable group of women receiving noncontraceptive services, and provider personnel serving the two groups of women. Over-time measures will be taken on both clients and clinics. Qualitative, as well as quantitative, data will be sought. A theoretical model of adaptive coping behavior will guide the analysis, which will employ multivariate techniques.

Adolescent Family Planning Clients

Adolescents' Motivation to Prevent Pregnancy

Grantee Organization:
Child Trends
4301 Connecticut Avenue, N.W., #100
Washington, DC 20008
Principal Investigator: Barbara W. Sugland, Sc.D.
Project Period: 6/1995–5/1998

Project Description: The goal of this study was to develop a conceptual framework for explaining the determinants of pregnancy risk-taking behavior among youth. To fulfill this aim, the investigators conducted focus groups among a sample of European-American, African-American, and Hispanic-American youth aged 16–19 to determine youth perceptions about the decision-making process concerning pregnancy risk-taking behavior; and held concept mapping groups to provide insights into how youth conceptualize the decision-making process for pregnancy risk-taking behavior.

Tailoring Family Planning Services to the Needs of Teens

Grantee Organization:
Family Health Council of Central PA
1017 Mumma Road
P.O. Box 360
Camp Hill, PA 17001-0360
Principal Investigator: Laraine Winter, Ph.D.
Project Period: 7/1994–3/1998

Project Description: This study followed approximately 2,000 teen (under 18) female clients of two inner-city Pennsylvania clinic sites and evaluated an intervention strategy designed to improve clinic outcomes for these young women in the areas of contraceptive use, contraceptive knowledge, continued clinic attendance, and pregnancy prevention. Using an intervention strategy referred to as the New Adolescent Approach, the experimental protocols emphasized extended counseling, addressed clients fears and worries, and provided more clinic supervision. Its ultimate goal was to improve the delivery of services to young women who visit family planning clinics.

Abuse Dimensions of Teen Contraception and STD Prevention

Grantee Organization:
The Center for Health Training
400 Tower Building
1809 Seventh Avenue
Seattle, WA 98101
Principal Investigator: David N. Fine, Ph.D.
Project Period: 3/1992–2/1995

Project Description: Using a sample of 400 subjects (200 abused and 200 nonabused) drawn from Title X clinics in Region X, this project investigated the prevalence of sexual abuse (nonvoluntary sexual experience) among the family planning clinics and examined the relationship between sexual abuse and contraceptive compliance and sexually transmitted disease prevention. Another aim of the project was to determine the most effective approach for obtaining client abuse histories and to develop strategies for improving services to sexually active adolescents who are at risk for contraceptive noncompliance.

Influencing Adolescent Male Contraceptive Behavior and Attitudes

Grantee Organization:
Children's Hospital National Medical Center
Department of Adolescent Medicine
Washington, DC 20010
Principal Investigator: Lawrence J. D'Angelo, M.D.
Project Period: 7/1/1988–6/30/1992

Project Description: The purpose of this longitudinal study was to investigate the attitudes and behaviors of adolescent males towards contraception. The specific aim of this project, which involved a sample of 500 sexually-active adolescent males aged 11–21 from Title X clinics, was to provide answers to the following questions: (1) Can the attitudes and behaviors of sexually active males be changed either through an educational program or the availability of free condoms? (2) How do the attitudes of non-sexually active adolescent males compare with those of their sexually active peers? (3) What psychosocial variables affect attitudes and behaviors? (4) Has AIDS influenced contraceptive attitudes and behavior?

Effects of Psychosocial Factors on Teen Contraception

Grantee Organization:
University of Texas
Health Science Center at Dallas
Southwestern Medical School
5323 Harry Hines Blvd.
Dallas, TX 75235
Principal Investigator: Judith B. Keith, Ph.D.
Project Period: 10/1986–9/1988

Project Description: The goal of this project was to obtain a more comprehensive understanding of adolescent contraceptive behavior by utilizing a multivariable framework that included psychosocial and cognitive determinants of contraceptive use. Several kinds of data were collected over a 6-month period on 200 unmarried, nulliparous adolescent women attending a clinic serving lower-income black and Hispanic adolescents. The data were analyzed with regard to differences between contracepting and noncontracepting adolescents and between those behaving consistently and inconsistently in the contraceptive area.

Male Family Planning Clients

Reproductive Health Screening of Male Adolescents

Grantee Organization:
Kaiser Foundation Hospitals
Center for Health Research
4610 S.E. Belmont
Portland, OR 97215
Principal Investigator: Ross Danielson, Ph.D.
Project Period: 10/1984–9/1987

Project Description: This project tested the impact on adolescent males' subsequent sexual and contraceptive activity of providing reproductive health information and counseling in combination with the delivery of routine medical care in a HMO setting. Approximately 1,000 males, who were 15–17 years of age and who scheduled routine HMO appointments, were recruited for the study.

The Male Role in Adolescent Contraception

Grantee Organization:
Children's Hospital National Medical Center
Department of Adolescent Medicine
111 Michigan Avenue, N.W.
Washington, DC 20010
Principal Investigator: Lawrence D'Angelo, M.D.
Project Period: 9/1985–8/1986

Project Description: This study sought to determine factors affecting use or nonuse of contraceptives, particularly condoms, through interviews of 500 males, aged 11–19, attending a general medical clinic in an urban hospital setting.

Other Research: A second grant was awarded to Dr. D'Angelo in June 1988 to evaluate the impact of an educational strategy on both sexually active and non-sexually-active adolescent males, as well as the impact of a free condom distribution arrangement on the former.

Males' Use of Public Health Contractive Services

Grantee Organization:
University of Illinois
College of Medicine at Rockford
Department of Community Medicine
1601 Parkview Avenue
Rockford, IL 61107
Principal Investigator: Michael Glasser, Ph.D.
Project Period: 4/1987–3/1988

Project Description: The purpose of this research was to obtain a better understanding of the male experience in using public family planning services, as a basis for designing a program to better serve the needs of male clients. Data were obtained from all men utilizing the family planning services of the Winnebago County Public Health Clinic in Rockford, Illinois, during a 6-month period. The project sought answers to basic questions such as "Who are male clinic users, why do they use the clinic, and how satisfied are they?" Specific comparisons were made between males who visit the health department primarily to receive condoms and males who attend the scheduled family planning visits of their female partners.

Targeting of Family Planning Services

Improving Family Planning and Reproductive Health Services for Individuals with Limited English Proficiency

Grantee Organization:
Center for Health Training
1809 7th Ave., Suite 400
Seattle, WA 98101-1341
Principal Investigator: David Fine, Ph.D.
Project Period: 9/01/2002–8/31/2004

Project Description: The aim of this research project is to increase understanding as to how to effectively meet the specific and unique family planning and reproductive health service needs of individuals with limited English proficiency (LEP). The research will consist of a descriptive and exploratory study of the individual, family, clinic and community factors that affect access to family planning and other health services by individuals with LEP. The objectives will also include developing and testing outreach and communication strategies at selected clinics. The research will be conducted at Title X family planning clinics and community-based organizations that represent urban and rural communities in Washington state, particularly in areas with high concentrations of Hispanics and Asian Pacific Islanders.

Meeting the Needs of Substance Abusers: A Title X Service Delivery Model

Grantee Organization:
Family Planning Council, Inc.
260 South Broad Street, Suite 1000
Philadelphia, PA 19102-5076
Principal Investigator: Linda Hock-Long, Ph.D.
Project Period: 9/01/2002–8/31/2004

Project Description: The goal of this project is to implement and evaluate the delivery of Title X funded reproductive health services to an underserved population of substance abusers who are not currently in treatment. The study will examine the changes required of service providers as they expand from one intervention approach (i.e., substance abuse services) to a more comprehensive package of services that include reproductive health services. The investigators will collaborate with two substance abuse organizations, one which provides services to men and women over 18 years of age, and another which provides health promotion programs for hard-to-reach youth ages of 13 to 25. The objective is to build upon the harm reduction outreach model these two substance abuse programs already have in place and integrate the delivery of reproductive health services. Through street outreach, clients will be recruited at mobile van services that are already provided and at centralized service centers where comprehensive clinical and support services are provided. This research will provide insight into how difficult it is to address multiple problems.

Enhanced Family Planning in an STD Clinic to Improve STD Services

Grantee Organization:
Johns Hopkins University, School of Medicine
720 Rutland Avenue
Baltimore, MD 21305
Principal Investigator: Emily Erbelding, M.D., M.P.H.
Project Period: 9/2001–9/2003

Project Description: This project will evaluate the impact of enhanced STD outreach worker services on the reproductive health outcomes in a cohort of women receiving STD care and contraceptive care in inner city STD clinics. Outcomes will be compared to those of a control cohort of women who are enrolled for a similar range of contraceptive services but do not receive the outreach intervention. The study will measure rates of unintended pregnancy and new STDs among female STD patients in a system with contraceptive public health outreach compared to standard care.

Women Leaving Prison: Two Models of Family Planning Service Delivery

Grantee Organization:
Rhode Island Hospital
593 Eddy Street
Providence, RI 02903
Principal Investigator: Jennifer Clarke, M.D.
Project Period: 9/2001–9/2003

Project Description: The researchers will evaluate a current Title X–funded family planning program for incarcerated women in Rhode Island who are soon to be released from prison. Clients will be surveyed to determine factors associated with and barriers to seeking family planning services. The study will compare two modes of delivering family planning services to women being released from prison. The first model will evaluate an innovative program that involves initiating family planning education for incarcerated women and then arranging post release connection to a clinic for family planning services. The second model will examine a model in which education and contraceptive methods are offered to women prior to their release from prison and then arranging a post release connection to a clinic for family planning and reproductive health care. Behavioral and biological outcomes will be assessed when testing both these models.

Improvement in Northern Manhattan to Two Underserved Populations: Males and Recent Immigrants

Grantee Organization:
New York Presbyterian Hospital
60 Haven Avenue, B-3
New York, NY 10032
Co-Principal Investigators: Roger Vaughan, Ph.D., and Lorraine Tiezzi, M.S.
Project Period: 10/2001–9/2003

Project Description: This project will identify and explore the enabling factors for, and barriers to, health care seeking behavior among a recent immigrant Hispanic population and among Hispanic males in New York City. The project will conduct several case-control studies at different health care access points (including reproductive health care) available to recent immigrants and males. Structured interviews will be conducted among a sample of older adolescents, young adults and older adults who have demonstrated health care needs and who accessed health care, and among a control group who did not access health care. Structured interviews will also be conducted with parents, as well as with the health care providers in the school-based clinics and the community-based family planning clinics.

Barriers to Family Planning Services Among Mexican Immigrants in California: Gender, Power, and Culture

Grantee Organization:
University of California, San Francisco
Department of Obstetrics, Gynecology and Reproductive Sciences
3333 California Street, #315
San Francisco, CA 94118
Principal Investigator: Catherine Maternowska, Ph.D., M.P.H.
Project Period: 1/2001–12/2002

Project Description: This project focuses on understanding the complex sociocultural factors that influence reproduction and the use of family planning services in Mexican immigrant communities. The research project has three broad aims: (1) to uncover factors that influence the use of family planning services among male and female Mexican immigrants in California; (2) to discern if these factors differ among rural (largely migrant) and urban populations; and (3) to understand providers' behavior and their perceptions of Mexican immigrants in an effort to determine how services can be made more accessible. A sample of Mexican men and women of childbearing age will be recruited for interviews from two groups—clients in the California Family Planning, Access, Care and Treatment Program (Family PACT) and non–Family PACT clients. Interviews will address respondents' fertility histories, contraceptive knowledge and attitudes, financial, time, and health care resources, access to medical care, as well as social and legal networks. The project will also study family planning provider attitudes regarding the Mexican immigrant population and perceptions of their needs.

Improving Family Planning to Southeast Asian Refugees: A Study of Their Knowledge, Attitudes, and Practices

Grantee Organization:
University of Californian-SF
School of Medicine
126 Medical Sciences Bldg.
San Francisco, CA 94143
Principal Investigator: Donald H. Minkler, M.D.
Project Period: 10/1983–3/1985

Project Description: The focus of this study was an assessment of the family planning needs of Indochinese refugees presently in California who are seeking self-sufficiency in the United States. Data from official records and interviews of refugees were used to describe fertility patterns, family planning attitudes, and service utilization. Cross-cultural barriers to utilization of family planning services were analyzed, and a cost-benefit analysis was conducted to identify cost-efficient models for the delivery of family planning services to monolingual, cost-cultural groups.

Child Care Adequacy and Family Planning Practices: A Study of the Fertility Patterns and Contracepting Behaviors of Low-Income Child Housing and Child Neglecting Mothers

Grantee Organization:
The Baltimore City Department of Social Services
Division of Policy and Resource Development
1510 Guilford Avenue
Baltimore, MD 21202
Principal Investigator: Susan J. Zuravin, Ph.D.
Project Period: 12/1983–5/1985

Project Description: This project examined the relationship of child abuse and neglect and contraceptive use and childbearing patterns. Among the project objectives was the development of recommendations about family planning strategies that could address problem areas identified in this study.

Family Planning Needs of the Child Welfare Population

Grantee Organization:
Humanalysis, Inc.
74 Henry Street
Suite 139
Saratoga Springs, NY 12866
Principal Investigator: Denise F. Polit, Ph.D.
Project Period: 10/1985–3/1987

Project Description: Information to inform strategies for meeting the family planning needs of female adolescents in the child welfare population were obtained from several sources: (1) a national survey of state policies and practices regarding family planning and sexuality counseling in this population; (2) interviews of 150 girls, aged 13–18, who were child welfare clients in metropolitan areas of Missouri; and (3) interviews of the girls' caseworkers and parents/guardians or foster parents.

Organization/Management of Family Planning Services

Reassessing United States Family Planning and Reproductive Needs

Grantee Organization:
The Alan Guttmacher Institute
120 Wall Street
New York, NY 10005
Principal Investigator: Jacqueline E. Darroch, Ph.D.
Project Period: 5/1/1994–4/30/1999

Project Description: The objective of this project was to provide information intended to help assess the current family planning system by (a) analyzing the current status of the nation's public family planning providers, including numbers and locations of service sites, staffing, services offered and fees charged; (b) estimating the need for publicly funded family planning services; (c) documenting the numbers of clinics and clients served according to county, state and region; (d) describing the characteristics of family planning clients; (e) documenting the public funds spent on family planning services; (f) analyzing private physician contraceptive service delivery; and (g) describing linkages between family planning clinics and STD clinics and school-linked health services. The information was expected to be useful in the development of services and policies aimed at reducing the level of unintended pregnancy, as well as suggesting means to improve other areas of reproductive health.

Integration of Contraceptive Services into an STD Clinic

Grantee Organization:
Johns Hopkins Hospital
Infectious Diseases Division
600 N. Wolfe Street
Baltimore, MD 21205
Principal Investigator: Edward W. Hook, M.D.
Project Period: 4/1/1987–3/31/1990

Project Description: The primary goal of this study was to investigate the benefits of integrating contraceptive services in inner-city STD clinics. It involved a prospective study of the benefits of offering free on-site contraceptive counseling and services at STD clinics in terms of (1) contraceptive acceptance and continuation rates, (2) detection of STDs among contraceptive acceptors returning for follow-up visits, and (3) the cost-effectiveness of adding contraceptive services in this manner.

An Assessment of Family Planning Service Delivery in South Carolina

Grantee Organization:
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201
Principal Investigator: Harold D. Gabel, M.D.
Project Period: 10/1983–9/1984

Project Description: This project developed indicators of family planning service effectiveness, which were then related to cost, productivity, and characteristics of service delivery organizations. Resulting analyses were used as a basis for developing model interventions in clinic-level delivery organizations to improve efficiency and effectiveness.

A Mathematical Model for Family Planning Clinic Staffing

Grantee Organization:
University of South Carolina
College of Business Administration
Columbia, SC 29208
Principal Investigator: Lori Sharp Franz, Ph.D.
Project Period: 1/1984–12/1984

Project Description: This project developed a mathematical staff planning and resource allocation model to assist decision makers in multiclinic family planning programs or districts. The model, which was tested with actual data from South Carolina Family Planning Districts, may provide planning and allocation methods such as assigning itinerant staff and scheduling individual clinic operations to meet client demand with minimal cost and staff time.

An Integrated Services Model: Family Planning and Pediatrics

Grantee Organization:
University of Texas Southwestern Medical Center at Dallas
Department of Obstetrics and Gynecology
Division of Maternal Health/Family Planning
5323 Harry Hines Blvd.
Dallas, TX 75235
Principal Investigator: Stephen F. Heartwell, Dr.P.H.
Project Period: 10/1984–9/1986

Project Description: The study examined quality of care, recruitment and retention of patients, appointment keeping, clinic costs and efficiency, repeat pregnancies and other factors as they are affected by combining family planning with post-partum and new infant assessment so that mothers may receive these services at a single clinic appointment.

Effects of the Integration Model on Family Planning Programs

Grantee Organization:
The Center for Health Training
400 Tower Building
1809 7th Avenue
Seattle, WA 98101
Principal Investigator: Susan DeLisle, M.P.H.
Project Period: 10/1986–11/1987

Project Description: This project studied how integration of family planning services with other services affects the character of family planning service provision. It described and compared DHHS Regions I and X using the quality-assurance guidelines of Dimensions of Care (clinical appropriateness, continuity, efficiency, comprehensiveness, accessibility, and accountability). Regional databases, computerized and archival, were utilized.

Role of Private Physician

Private Physician Family Planning Services in the United States

Grantee Organization:
The Alan Guttmacher Institute
111 Fifth Avenue
New York, NY 10003
Principal Investigator: Margaret Terry Orr, Ph.D.
Project Period: 10/1983–9/1984

Project Description: This project analyzed data previously obtained from a large national sample of private physicians (obstetricians/gynecologists, general and family practitioners, and general surgeons). The analysis focused on (1) describing the role of private physicians in providing contraceptive and infertility services to poor women and (2) estimating the cost of family planning services obtained by poor women from private physicians.

Family Planning Services for Economically Disadvantaged Women: Utilization, Cost, and Patient Satisfaction

Grantee Organization:
University of Southern California
School of Medicine
Department of Medical Education
KAM Room 200
1975 Zonal Avenue
Los Angeles, CA 90033
Principal Investigator: Robert C. Mendenhall, Ph.D.
Project Period: 10/1983–3/1985

Project Description: The study involved interviewing low-income Los Angeles–area women concerning source of family planning care and satisfaction with such care. Interview responses were augmented with data supplied by identified physicians and clinics, to provide comparative pictures of private and clinic-provided family planning care. The results may enable family planning clinics to initiate improvements to increase clients' acceptability of the services offered.

Natural Family Planning

Factors Affecting the Choice of Natural Family Planning

Grantee Organization:
International Population Center
San Diego State University
San Diego, CA 92182-3083
Principal Investigator: John R. Weeks, Ph.D.
Project Period: 9/1987–8/1988

Project Description: The aim of this study was to identify possible stumbling blocks to wider utilization of NFP, particularly in Title X settings. Specifically, it assessed the extent to which knowledge of and attitudes toward NFP on the part of family planning clinic administrators, clinic service providers, and physicians in private settings affect the availability of NFP services, controlling for program characteristics, client characteristics, and the sociodemographic background of respondents. Questionnaires were sent to 1,000 providers in Los Angeles and San Diego counties; the results were analyzed and then translated into a set of policy recommendations for removing existing barriers.

Infertility Services

Infertility Services in the United States: Need, Accessibility, and Utilization

Grantee Organization:
The Alan Guttmacher Institute
111 Fifth Avenue
New York, NY 10003
Principal Investigator: Jacqueline D. Forrest, Ph.D.
Project Period: 10/1984–9/1985

Project Description: This project utilized several data sets to estimate (1) need for infertility services among poor women and (2) their ability to access such services from various sources, including family planning agencies.

Counseling Services

Computerized Contraceptive Counseling Aid

Grantee Organization:
University of Wisconsin-Madison
425 North Charter
Madison, WI 53706
Principal Investigator: Betty A. Chewning, Ph.D.
Project Period: 1/1/1988–6/30/1991

Project Description: The objective of this project was to evaluate the potential of a computerized contraceptive counseling aid to improve Title X family planning services for women under age 20. Specifically, it evaluated (1) the receptivity of Title X clients and staff to the computerized aid; (2) whether the computer aid could strengthen the contraceptive knowledge, satisfaction, and confidence of clients in using a method; (3) whether the computer can reduce sexual risk-taking by promoting consistent use of the selected contraception; (4) the computer's ability to encourage the male partner's support for the client's choice; and (5) whether the computer aid can improve contraceptive compliance.

The Effectiveness of Contingency Planning Counseling

Grantee Organization:
Columbia University
Center for Population and Family Health
60 Haven Avenue, B-3
New York, NY 10032
Principal Investigator: Pearila B. Namerow, Ph.D.
Project Period: 10/1984–3/1987

Project Description: Approximately 1,500 young adult family planning clients were studied in a randomized clinical trial of an innovative counseling approach which involved the use of a written plan to deal with contingencies that may affect birth control use over time. Effects on continued clinic attendance, use of contraception at last coitus, consistency of contraceptive use, and unintended pregnancy were examined at 6- and 12-month intervals.

Aid for Contraceptive Decision Making

Grantee Organization:
University of Wisconsin
Sonderegger Center
School of Pharmacy
425 North Charter
Madison, WI 53706
Principal Investigator: Betty A. Chewning, Ph.D.
Project Period: 11/1985–12/1986

Project Description: This project developed and assessed the content and software of a computerized counseling aid to be used in conjunction with and prior to seeing a health provider. The counseling aid was designed to help the female client gather accurate information regarding tradeoffs associated with different contraceptives, clarify her priorities and select a method which best fits her preferences and circumstances.

Other Research: A second grant was awarded to Dr. Chewning in June 1988 to evaluate the developed computerized counseling aid in clinic settings.

Strategies of Counseling and Follow-up in Family Planning Clinics

Grantee Organization:
Family Planning Council of Southeastern Pennsylvania
260 South Broad Street
Suite 1900
Philadelphia, PA 19102-3865
Principal Investigator: Kay A. Armstrong, M.S.
Project Period: 11/1985–10/1987

Project Description: This project was conducted to determine which of three counseling approaches—directive, anticipatory, and information (with and without a follow-up component)—is most effective in promoting clinic continuity and contraceptive compliance. Data were obtained from approximately 3,500 clients of six comparable family planning clinics in Southeastern Pennsylvania at the initial visit and 9 months later.

Cross-National Studies

An International Comparison of Unintended Pregnancy, Contraceptive Practice and Family Planning Services

Grantee Organization:
The Alan Guttmacher Institute
111 Fifth Avenue
New York, NY 10003
Principal Investigator: Jacqueline D. Forrest, Ph.D.
Project Period: 10/1985–9/1987

Project Description: This study searched the experiences of other countries to learn how family planning can be delivered in the United States more efficiently and effectively. Existing quantitative and qualitative data on 22 developed countries were assembled to provide an overview and frame of reference for in-depth study of four countries—the United States, the United Kingdom (England and Wales), Canada, and the Netherlands.

Family Planning Services Delivery: Danish Experience

Grantee Organization:
Transnational Family Research Institute
8307 Whitman Drive
Bethesda, MD 20817
Principal Investigator: Henry P. David, Ph.D.
Project Period: 11/1985–10/1987

Project Description: Population subgroups whose family planning needs are underserved in the United States, but better met in Denmark were the focus of this study, with an emphasis on identifying successful service delivery features that are transferable from Denmark to the United States. Focus group discussions with Danish users, providers, and policymakers were conducted.

PEER-REVIEWED RESEARCH FROM TITLE X–FUNDED RESEARCH

The Office of Research and Evaluation requested from grantees and compiled published peer-reviewed research from the past several years. There were 5 grantees funded in 2001, 4 each year during 2005–2007, and 3 cooperative agreements funded in 2004, totaling 20 grantees. The 5-year Alan Guttmacher Institute (AGI) project funded from 1999 to 2004 was also included in the request sent to current and former grantees (overall total 21). The list below includes responses from 6 of the 21 individual grantees that have had at least one peer-reviewed publication.

1. Men's Reproductive and Sexual Health Practices, Attitudes, and Service Utilization
Grantee: Columbia University Medical Center

> Kalmuss, D., and C. Tatum. 2007. Patterns of men's use of sexual and reproductive health services: Results from cycle 6 of the national survey of family growth. *Perspectives on Sexual and Reproductive Health* 39(2):74–81.
>
> Kalmuss, D., B. Armstrong, M. Franks, G. Hecker, and J. Gonzalez. 2008. Evaluation of a community-based sexual health intervention for young adult Latino and African-American men. *Journal of Men's Health* 5(4):318–326.

2. Family Planning Needs and Services in the United States
Grantee: Guttmacher Institute

> Frost, J. J. 2008. Trends in U.S. women's use of sexual and reproductive health care services, 1995–2002. *American Journal of Public Health* 98(10).
>
> Frost, J. J., L. B. Finer, and A. Tapales. 2008. The impact of publicly funded family planning clinic services on unintended pregnancies and government cost savings. *Journal of Health Care for the Poor and Underserved* 19(2008):778–796.
>
> Lindberg, L. D., J. J. Frost, C. Sten, and C. Dailard. 2006. The provision and funding of contraceptive services at publicly funded family planning agencies: 1995–2003. *Perspectives on Sexual and Reproductive Health* 38(1):37–45.
>
> Lindberg, L. D., J. J. Frost, C. Sten, and C. Dailard. 2006. Provision of contraceptive and related services by publicly funded family planning clinics, 2003. *Perspectives on Sexual and Reproductive Health* 38(3):139–147.

3. Child Trends/OPA Cooperative Agreement for Family Planning Research
Grantee: Child Trends

Manlove, J., E. Terry-Humen, and E. Ikramullah. 2006. Young teenagers and older sexual partners: Correlates and consequences for males and females. *Perspectives on Sexual and Reproductive Health* 38(4):197–207.

Manlove, J., S. Ryan, and K. Franzetta. 2007. Risk and protective factors associated with the transition to a first sexual relationship with an older partner. *Journal of Adolescent Health* 40:135–143.

Manlove, J., E. Terry-Humen, L. Mincielli, and K. Moore. Forthcoming. Outcomes among children of teen mothers at kindergarten entry and through adolescence: Analyses of recent data. In *Kids having kids updated edition: Economic costs and social consequences of teen pregnancy.* Edited by R. Maynard and S. Hoffman. Washington, DC: Urban Institute Press.

Manlove, J., E. Ikramullah, and E. Terry-Humen. Forthcoming. Condom use and consistency among U.S. teen males. *Journal of Adolescent Health*.

Ryan, S., K. Franzetta, J. Manlove, and E. Holcombe. 2007. Adolescents' discussions about contraception or STDs with partners before first sex. *Perspectives on Sexual and Reproductive Health* 39(3):149–157.

Ryan, S., K. Franzetta, J. Manlove, and E. Schelar. 2008. Older sexual partners during adolescence: Links to reproductive health outcomes in young adulthood. *Perspectives on Sexual and Reproductive Health* 40(1):17–26.

4. Strengthening the Capacity of Family Planning Agencies to Improve the Quality of Family Planning Services

Grantee: Johns Hopkins University

Becker, D., M. A. Koenig, Y. M. Kim, K. Cardona, and F. Sonenstein. 2007. The quality of family planning services in the United States: Findings from a literature review. *Perspectives on Sexual and Reproductive Health* 39(4):206–213.

5. Women Leaving Prison: Two Models of Family Planning Service Delivery

Grantee: Rhode Island Hospital

Clarke, J. G., C. Rosengard, J. S. Rose, M. R. Herbert, J. Peipert, and M. D. Stein. 2006. Improving birth control service utilization by offering services prerelease vs. postincarceration. *American Journal of Public Health* 96(5):841–845.

Clarke, J. G., M. R. Herbert, C. Rosengard, J. S. Rose, K. M. DaSilva, and M. D. Stein. 2006. Reproductive health care and family planning needs among incarcerated women. *American Journal of Public Health* 96(5):834–839.

6. Assessing Family Planning and Reproductive Health Needs and Services in the United States
Grantee: Alan Guttmacher Institute

Donovan, P. 1996. Taking family planning services to hard-to-reach populations. *Family Planning Perspectives* 28(3):120–126.

Finer, L. B., J. E. Darroch, and S. Singh. 1999. Sexual partnership patterns as a behavioral risk factor for sexually transmitted diseases. *Family Planning Perspectives* 31(5):228–236.

Finer, L. B., J. E. Darroch, and J. J. Frost. 2002. U.S. agencies providing publicly funded contraceptive services in 1999. *Perspectives on Sexual and Reproductive Health* 34(1):15–24.

Finer, L. B., J. E. Darroch, and J. J. Frost. 2003. Services for men at publicly funded family planning agencies, 1998–1999. *Perspectives on Sexual and Reproductive Health* 35(5):202–207.

Forrest, J. D., and R. Samara. 1996. Impact of publicly funded contraceptive services on unintended pregnancies and implications for Medicaid expenditures. *Family Planning Perspectives* 28(5):188–195.

Frost, J. J. 1996. Family planning clinic services in the United States, 1994. *Family Planning Perspectives* 28(3):120–126.

Frost, J. J. 1998. Clinic provision of contraceptive services to managed care enrollees. *Family Planning Perspectives* 30(4):156–162.

Frost, J. J. 2001. Public or private providers? U.S. women's use of reproductive health services. *Family Planning Perspectives* 33(1):4–12.

Frost, J. J., and M. Bolzan. 1997. The provision of public-sector services by family planning agencies in 1995. *Family Planning Perspectives* 29(1):6–14.

Frost, J. J., N. Ranjit, K. Manzella, J. E. Darroch, and S. Audam. 2001. Family planning clinic services in the United States: Patterns and trends in the late 1990s, *Family Planning Perspectives* 33(3):113–122.

Frost, J. J., L. Frohwirth, and A. Purcell. 2004. The availability and use of publicly funded family planning clinics: U.S. trends, 1994–2001. *Perspectives on Sexual and Reproductive Health* 36(5):206–215.

Gold, R. B., and C. Richard. 1998. Lessons learned: The managed care experiences of family planning providers. *Journal of Public Health Management and Practice* 4(6):1–13.

Gold, R. B., and A. Sonfield. 1999. Family planning funding through four federal-state programs, FY 1997. *Family Planning Perspectives* 31(4):176–181.

Landry, D. J., and J. D. Forrest. 1996. Public health departments providing sexually transmitted disease services. *Family Planning Perspectives* 28(6):261–266.

Landry, D. J., and J. D. Forrest. 1996. Private physician's provision of contraceptive services. *Family Planning Perspectives* 28(5):203–209.

Lindberg, L. D., F. L. Sonenstein, L. Ku, and G. Levine. 1997. Young men's experience with condom breakage. *Family Planning Perspectives* 29(3):128–131, 140.

Murphy, J. J., and S. Boggess. 1998. Increased condom use among teenage males, 1988–1995. *Family Planning Perspectives* 30(6):276–280, 303.

Sollom, T., R. B. Gold, and R. Saul. 1996. Public funding for contraceptive, sterilization and abortion services, 1994. *Family Planning Perspectives* 28(4):166–173.

Sonfield, A., R. B. Gold, and J. J. Frost. 2004. U.S. insurance coverage of contraceptives and the impact of contraceptive coverage mandates, 2002. *Perspectives on Sexual and Reproductive Health* 36(2):72–79.

OPA LARGE-SCOPE EVALUATION EFFORTS

Through OPA's Office of Research and Evaluation, evaluation projects are carried out under contracts funded by HHS 1 percent evaluation funds. The evaluation activities cover a wide range of issues.

OPA collaborates with other federal agencies in efforts related to family planning and reproductive health. OPA is one of the major funding contributors to the NSFG, which is conducted by the National Center for Health Statistics. The NSFG has completed six cycles and currently proceeds on a continuous interviewing basis. OPA also has funded several research initiatives at the National Institute of Child Health and Human Development. It provides support for the National Longitudinal Study of Adolescent Health.

A number of comprehensive final 1 percent evaluation reports are relevant to Title X. They include Healthy People 2010 content related to family planning and STDs/HIV, documents outlining Food and Drug Administration approval of the hormonal contraceptive skin patch and hormonal vaginal contraceptive ring, the *Family Planning Annual Report*, and reports on parent involvement strategies in programs serving adolescents and on statutory rape.

In 2007, OPA and the Administration for Children and Families cosponsored an Abstinence Education Evaluation Conference for the abstinence education community. In addition, OPA contracted with The Lewin Group to conduct the Developing Theoretical Frameworks for Abstinence Education project. The goal of this project is to develop theoretical frameworks that can help explain primary and secondary abstinence for adolescents and provide likely mechanisms for behavior change.

Appendix J

Organization, Funding, and Management of the Title X Program

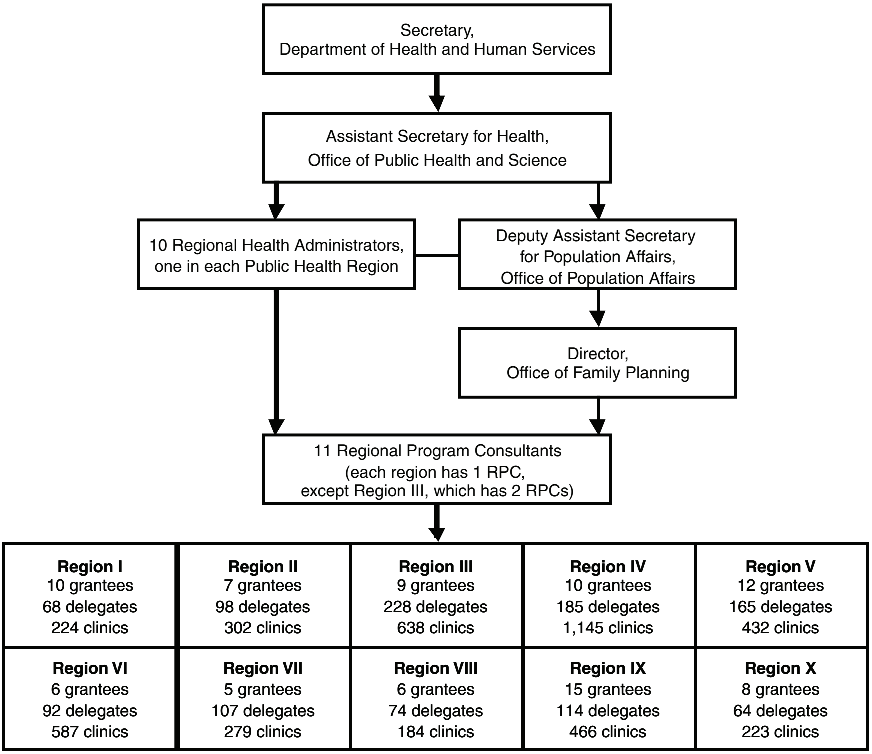
The Lewin Group

Although the first federal grants to support family planning were made in 1965, the formal structure for operation of a national family planning program did not occur until Congress enacted Title X of the Public Health Service Act of 1970 (P.L. 91-572). This legislation established the decentralized structure for the program's organization, funding, oversight, and management that remains in place today.

PROGRAM ADMINISTRATION

The program's operational structure consists of a Central Office and 10 Regional Offices, grantees, delegates of the grantees, and clinical service sites. The Office of Family Planning (OFP), also referred to as the Central Office, administers the Title X program at the federal level and is responsible for establishing administrative policy.[1] OFP is part of the Office of Population Affairs (OPA), located within the Office of Public Health and Science at the U.S. Department of Health and Human Services (HHS). OPA is headed by the Deputy Assistant Secretary for Population Affairs (DASPA), to whom the Director of OFP reports.

A Regional Health Administrator (RHA) in each of the 10 Public Health Service Regions is authorized to oversee the Title X program at the regional level through a memorandum of understanding (MOU) with the Central Office.[2] Regional Program Consultants (RPCs) carry out the day-to-day program management and allocation of funding to grantees (i.e., entities that assume legal and financial responsibility for performing Title X activities). Grantees may be state or local health departments, nonprofit



Region I 10 grantees 68 delegates 224 clinics	**Region II** 7 grantees 98 delegates 302 clinics	**Region III** 9 grantees 228 delegates 638 clinics	**Region IV** 10 grantees 185 delegates 1,145 clinics	**Region V** 12 grantees 165 delegates 432 clinics
Region VI 6 grantees 92 delegates 587 clinics	**Region VII** 5 grantees 107 delegates 279 clinics	**Region VIII** 6 grantees 74 delegates 184 clinics	**Region IX** 15 grantees 114 delegates 466 clinics	**Region X** 8 grantees 64 delegates 223 clinics

FIGURE J-1 Title X program organizational structure.
SOURCE: [3,4]

organizations (e.g., Planned Parenthood, faith-based organizations), community health centers (CHCs), and other federally qualified health centers (FQHCs).[a] Grantees may operate clinics or negotiate an agreement with a contract agency (delegate) that will provide services. Delegate agencies and clinics may be CHCs, student health centers, Planned Parenthood agencies, hospitals, other nonprofit health care providers, or state or local health departments.[3,4] Figure J-1 depicts the organizational structure of the Title X program. Table J-1 provides a summary of responsibilities for each management level.

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[a] FQHCs include all organizations receiving grants under Section 330 of the Public Health Service Act (e.g., community health centers, migrant health centers, health care for the homeless programs, and public housing primary care programs), certain tribal organizations, and FQHC look-alikes.

TABLE J-1 Responsibilities for Each Administrative Level of the Title X Program

Title X Entity	**Primary Responsibilities**
Central Office	• Administers program at national level • Sets policy and develops national priorities and initiatives • Coordinates and collaborates with other offices within HHS and Office of Public Health and Science (OPHS) • Oversees research and educational aspects of program • Oversees and monitors grants and contracts that are national or cross-regional in scope (e.g., OPA Clearinghouse, National Family Planning Training Center) • Creates budget requests and annual spending plan • Develops Family Planning Services Announcement for *Federal Register* • Develops performance measures • Develops funding announcements • Communicates with Regional Offices • Plans OFP national meetings
Regional Health Administrator	• Oversees management of RPC and regional family planning staff • Final authority on allocation of Title X base service funding grants, special project grants, regional priority funds • With Central Office, signs off on regional training grant allocations
Regional Program Consultant	• Oversees and monitors regional family planning service grantees (e.g., through grant reviews, annual site visits, Comprehensive Program Reviews, regular communication with grantees via phone and e-mail) • Oversees and monitors family planning training and technical assistance (TA) grantees (e.g., approves training plan, facilitates TA for providers in region) • Communicates with Central Office • Supports and oversees regional areas of special focus (e.g., HIV prevention, male-related projects) • Participates in OFP national meetings • Provides record of all official correspondence with grantees to Office of Grants Management for filing (e.g., site visit reports, corrective action plans)
Grantee	• Selects, arranges contract with, monitors, and reimburses delegate agencies • Coordinates TA for delegates (if applicable) • Guarantees provision of data for *Family Planning Annual Report* (FPAR) by clinics or delegates • Participates in Comprehensive Program Reviews and annual site visits • Reviews and approves educational and informational materials used by delegates or clinics
Delegate	• Provides services in accordance with Title X guidelines and applicable federal, state, and local laws • Reports FPAR data • Participates in site visits by grantee and Regional Office
Clinic	• Provides services in accordance with Title X guidelines and applicable federal, state, and local laws

SOURCES: [1,2]

The decentralized, regional structure through which the Title X program is administered is seen by staff at the federal, regional, and state levels as advantageous because it places a majority of decision-making authority in the hands of the RPCs, who are most familiar with the specific needs of their region as well as the strengths, needs, and weaknesses of their grantees. The decentralized structure allows RPCs to administer the Title X program most effectively by taking into account differences in populations and cultures and selecting grantees that are best able to meet the needs of a particular state or geographic region within a state. Most grantees feel strongly that decision-making authority should remain in the hands of the RPCs rather than the Central Office.

Still, some regional staff and grantees attribute variation among regions in large part to the personalities of those working in the Regional Offices. For example, in some regions, the RPC works closely with the Office of Minority Health and the Office of Women's Health, both of which also are under the direction of the RHA, while in other regions, these programs operate without any coordination. Other points of variation are attributed to differences in state regulations regarding family planning clinics. For example, the forms and process a clinic uses to obtain patient consent for a particular procedure may be dictated by specific state regulations.

The level of communication and the relationship between RHAs and RPCs is relatively consistent among regions. RPCs tend to find their RHA very responsive and attentive to the needs of the Regional Office and of the Title X program. While RHAs have final approval of all allocations to grantees, the extent to which they are involved in the programmatic work of the regional family planning office varies. For example, some RHAs attend regional Title X meetings hosted by the Regional Office and work actively to promote cooperation among related offices in the region. Although the RHAs are the official supervisor responsible for performance reviews, day-to-day communication and management of the Title X program occur between the RPC and the Central Office.

The Central Office communicates regularly with the Regional Offices through monthly conference calls and ongoing e-mail and telephone communication. The monthly conference calls are open to RPCs and usually cover process-related topics (e.g., directed supplements, preparation for a national meeting, Title X priorities). In some instances, the Central Office may use the conference call to address a specific issue, such as clinic efficiency.[b] RPCs find the topic-specific conference calls quite helpful and expressed interest in holding more of them on a variety of topics, such

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[b] So far, one call of this nature has been scheduled; it concerned grants management, and it replaced the regularly scheduled conference call for that month.

as performance measurement, innovations in contraception, and research related to service delivery improvement.

Each Regional Office is assigned a liaison at the Central Office who serves as the first point of contact for any questions or issues. The Central Office is highly regarded as responsive, communicative, and supportive by all regional staff. However, the Central Office may not always have the time and/or money to create written guidance for the Regional Offices and instead may communicate guidance orally; this results in confusion or additional time spent seeking clarification by the Regional Offices. Additionally, the Central Office liaisons assigned to each Regional Office vary in terms of seniority and knowledge of the Title X program, which can affect the extent to which the liaison is able to assist his or her assigned Regional Office. Of further note, RPCs receive no formal training for their position.

One hour before their monthly conference call with the Central Office, the RPCs hold a regularly scheduled call among themselves to discuss common issues (e.g., setting a sliding fee scale) and/or provide new Regional Office staff with pertinent information. All Regional Office staff members (e.g., program officers, administrative assistants) are invited to be on the call. These calls are important because they provide Regional Office staff members with an opportunity to communicate outside the presence of the Central Office and to share insights and issues with each other. Yet without more overt leadership and decision-making authority that comes from the Central Office, they serve as a forum in which issues surface but are not resolved.

The relationship dynamic between RPCs and grantees varies widely among regions. Many grantees describe a very positive relationship with their RPC, citing their relationship as open, effective, transparent, and positive. In these relationships, the RPCs are in regular communication[c] with grantees and even schedule regular conference calls to address current questions or issues. These grantees see their RPC as someone to whom they can go with programmatic and financial questions. However, some grantees feel that they do not experience the level of openness and communication that they need and want from their RPC.

While some RPCs solicit input and information from grantees to convey to the Central Office, the line of communication between grantees and the Central Office is not direct. There is a sentiment among many grantees that the messages they would like to convey to the Central Office are diluted, and the RPCs do not advocate enough on their behalf. Specifically, some grantees feel that the Central Office does not elicit enough

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[c] Regional Offices also are in and are required to maintain a log of official contact (e.g., phone calls, site visits), which is forwarded to the Office of Grants Management (OGM) at the end of the fiscal year.[1]

input from grantees and delegates about the ramifications of its decisions. Opportunities to voice concerns directly are limited to the national grantee meeting hosted by the Central Office every 2 years; however, formalities of this meeting do not offer grantees substantial time to communicate with the Central Office individually. As an adjunct, Central Office staff members sometimes are able to attend the annual regional meetings (time and money permitting), which grantees consider a very effective way to communicate information directly.

Grantees communicate with delegates and/or clinics on a regular basis. Some grantees divide their delegate agencies and/or clinics into groups according to geographic region and assign specific staff members to communicate with those delegates. In addition, many grantees host in-person conferences at least once a year to update delegates and/or clinics on administrative, clinical, and policy topics related to Title X and family planning. With a few exceptions, delegate agencies and clinics do not have regular communication or interaction with the RPC or the Central Office.

PROGRAM MANAGEMENT AND OVERSIGHT

Several tools facilitate the program's day-to-day management, regular monitoring, and ongoing improvement. These tools include the development of Central Office and Regional Office work plans, Comprehensive Program Reviews and annual site visits, the *Family Planning Annual Report* (FPAR), and regional training programs.

Work Plans

Day-to-day management and strategic planning for the Title X program are founded on the annual development of Central Office and Regional Office work plans and budget plans. The Central Office work plan is an internal document comprised of all grant announcements, administrative and training activities, and research projects for that year. Prior to its implementation, the plan must be approved by the Assistant Secretary of Health. If situations arise that require the Central Office to depart significantly from the work or budget plan, it is required to develop an addendum that also must be approved by the Assistant Secretary.[d]

Before the start of the fiscal year, each Regional Office submits its work plan to the Central Office. Areas to be covered in the regional work plan are outlined by the DASPA in the Regional Memorandum of Agreement and

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[d] Changes to the spending plan that involve less than a few thousand dollars do not need to be approved by the Assistant Secretary of Health.

Work Plan Guidance sent to RHAs each year. Specifically, regional work plans must include the following:

- Funding methodology, including how service grants and regional priority funds will be distributed within the region
- A list of Comprehensive Program Reviews and site visits scheduled in the region for the coming fiscal year
- A list of service and training meetings that the region plans to hold with grantees (e.g., annual regional meetings, meetings with grantees following the award of a grant), where possible including agendas for these meetings
- Travel plans for Regional Office staff members, including priority level, project cost, and purpose of travel
- Grantee training plans, including the location, date, and format of the training; the national priorities addressed by the training; the names of the people conducting the training; and the total number and type of trainees who will be present (e.g., nurse practitioners, administrators, medical doctors)
- Regional objectives and efforts related to national Title X priorities, legislative mandates, HHS priorities,[e] and other key issues, along with specific regional outputs linked to each priority

In general, RPCs find regional work plans to be a valuable tool for strategic planning and program management. Often, previous years' work plans serve as reference documents for future planning and monitoring activities. Sections of the work plan that address grantee performance, program outcomes, and meeting planning were identified as especially useful. However, some limitations associated with the regional work plans also were cited. Because so much of each region's work is prescribed, there is little flexibility in the content of the work plans from one year to another. In many instances, the same work plan is used each year, with modifications based on the guidance from the Central Office and/or the needs of the region. Thus, some offices view the work plans as additional paperwork that could be moderated if multiyear plans were developed.

Comprehensive Program Reviews and Annual Site Visits

Site visits by Regional Offices to grantees and by grantees to delegates and clinics serve as the primary mechanism for oversight of the Title X pro-

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[e] Examples of HHS priorities include health information technology (e.g., making sure secure, interoperable electronic records are available to patients and clinicians), Medicare prescription drug access, and pandemic preparedness.[5]

gram. Regional Offices use two types of site visits to monitor grantees: the Comprehensive Program Review, performed every 3 years; and the annual site visit, used as a follow-up to areas identified for improvement. Grantees perform annual site visits to a selected number of their delegate agencies and clinics. Reports on the Comprehensive Program Reviews and annual site visits are held in the individual grantee's official grant file at the Health Resources and Services Administration's (HRSA's) Grants Office. In addition, a copy of the Comprehensive Program Review report is held at OFP.

Comprehensive Program Reviews

Regional Offices are required to conduct an on-site Comprehensive Program Review of each grantee every 3 years to evaluate the grantee's financial, administrative, educational, and clinical structure and activities.[1] Specific goals of the Comprehensive Program Review are to:

- Ensure compliance with Title X program laws, regulations, and guidelines.
- Assess grantees' progress with regard to carrying out the plan outlined in their approved Title X grant application.
- Validate activities reported on by the grantee (e.g., expenditure of funds, scope of services).
- Identify technical assistance and training needs.
- Identify grantee strengths that might be useful to other grantees.
- Ensure proper use of Title X funds by grantees.
- Provide grantees with an opportunity to identify issues in delivering services and in carrying out program requirements that might be common to all grantees.
- Provide grantees with an update on the program and emphasize program priorities.

The Comprehensive Program Review team consists of the RPC; other Title X–related program officers; and independent consultants with expertise in the clinical, administrative, financial, and community outreach and information components of the Title X program. Consultants are professionals with direct experience with Title X and may have served previously as nurses in Title X clinics or have worked for grantee or delegate agencies. In addition to visiting the grantee's offices, the review team visits one to three delegate agencies and/or clinics overseen by the grantee (although grantees have primary responsibility for monitoring delegates and clinics).

The review is conducted using the Program Review Tool, which was last revised in January 2003.[6] The tool initially was created as a standardized document, and a few regions have made slight modifications to it. The document is divided into four sections (i.e., administration, finance, clinical, and community outreach and information) and directs consultants to mark grantees as "compliant" or "noncompliant" in several different areas.[f] The financial review assesses compliance with federal regulations published under 2 Code of Federal Regulations (CFR) Part 230, *Cost Principles for Non-Profit Organizations* (OMB Circular A-122).[7] The administrative, clinical, and community outreach aspects of the Title X program are evaluated for compliance with the OFP *Program Guidelines for Project Grants for Family Planning Services*.[3] For any areas in which the grantee is found to be noncompliant, a corrective action plan is prescribed that outlines the steps required of the grantee to achieve compliance.[1] Some issues identified may be addressed through technical assistance and training at the Regional Training Center (RTC). Table J-2 provides a summary of the key areas covered in the Program Review Tool.

Many RPCs feel that the Comprehensive Program Reviews are the most helpful and collaborative mechanism through which they are able to monitor and oversee grantees. They provide Regional Offices with an opportunity to interact with grantees on an individual basis and to see first-hand where grantees excel and where additional guidance is needed. However, financial and time constraints and the large number of delegate and clinic sites significantly limit the number of service sites that the review team can visit. Some RPCs believe that the ability to visit a greater number of delegates and clinics would enhance their oversight capabilities.

Also, because independent consultants do not receive uniform training, they may vary in their interpretation of certain Title X guidelines and grading of grantees (e.g., how clinics should ask for client donations, the increments used on the sliding fee scale). This creates inconsistencies in the evaluation of a grantee, not only for the current Comprehensive Program Review, but also for evaluations of the grantee's performance longitudinally and against other grantees in the region and nationally.

Some grantees do not share positive sentiments about Comprehensive Program Reviews, indicating that they find the process strenuous and overly focused on small details rather than the larger picture. As such, they do not

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[f] Subcategories address more specific aspects of the program, each of which is marked as "must," "should," or "optional." For example, in the administration section, the first section asks the consultant to mark whether or not the grantee complies with the regulation for client voluntary participation. In the sections underneath, the consultant is asked to comment on items such as whether services are provided solely on a volunteer basis and whether project personnel are informed of the potential for prosecution under federal law if they coerce anyone to undergo abortion or sterilization procedures.

TABLE J-2 Summary of Areas Evaluated for Compliance with the Program Review Tool

Administration	Clinical	Financial Management
• Needs Assessment • Project Requirements • Grant Administration • Voluntary Participation • Privacy and Confidentiality • Conflict of Interest • Human Subject Clearance • Structure of the Grantee • Planning and Evaluation • Facilities and Accessibility of Services • Personnel • Training and Technical Assistance • Reporting Requirements • Review and Approval of Information and Educational Materials • Community Participation, Education, and Project Promotion • Publications and Copyright • Inventions or Discoveries	• Client Services • Service Plans and Protocols • Procedural Outline • Emergencies • Referrals and Follow-Up • Client Education • Counseling • History, Physical Assessment, and Laboratory Testing • Fertility Regulation • Infertility Services • Pregnancy Diagnosis and Counseling • Adolescent Services • Identification of Estrogen-Exposed Offspring • Gynecologic Services • Sexually Transmitted Diseases, HIV, and AIDS • Special Counseling • Genetic Information and Referral • Health Promotion/Disease Prevention • Postpartum Care • Equipment and Supplies • Pharmaceuticals • Medical Records • Quality Assurance and Audit • Infertility Prevention Project	• Budgetary Control Procedures • Accounting Systems and Reports • Purchasing/Inventory Control/Property Management • Charges, Billing, and Collection Procedures • Liability Coverage

believe that the reviews have improved their program.[g] They would like the Regional Offices and reviewers to adopt a less punitive, more educational and supportive approach that positions the review as an opportunity for learning.

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[g] As a basis for comparison, Bureau of Primary Health Care (BPHC)–supported health centers undergo accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[8] The process, which includes both a survey and a review, accounts for both the BPHC statutory requirements and applicable JCAHO standards. The survey generally takes 2–3 days and is conducted by a clinician and administrator from JCAHO.

Annual Site Visits

In years in which a grantee is not subject to a Comprehensive Program Review, the Regional Office conducts an annual site visit to each grantee. These site visits provide another mechanism for Regional Offices to follow up on any item identified for improvement or corrective action in the Comprehensive Program Review, grant application, and annual needs assessment for training programs, or identified by the grantees themselves. The site visit also may entail an abbreviated review of grantee compliance with 2 CFR Part 230 and the OFP Program Guidelines. Generally, the annual site visit is conducted by the RPC and potentially another staff member; in some cases, one or more consultants may be hired to participate if an outstanding issue relates to a consultant's area of expertise (e.g., grants management, finance).

Grantees also conduct annual site visits to their delegate agencies and clinics to ensure compliance with federal regulations and the Program Guidelines. While grantees are afforded the freedom to design the tools (forms, documents) for their site visits, they must address all areas of Title X operation and management that are part of the Comprehensive Program Review (Table J-2). Thus, there is some variability among grantees in the tools they use when conducting site visits. Some grantees use the same tables and checklists used in the Comprehensive Program Review, while others develop an abbreviated, modified version.

Areas covered during site visits include, but are not limited to, the following. Delegates and clinics must be in compliance with rules governing privacy and confidentiality under the Health Insurance Portability and Accountability Act (HIPAA), rules for client voluntary participation in Title X programs, and rules regarding the use of Title X clients in research. They must perform the required annual needs assessment to determine areas for additional training. A conflict of interest policy, written agreements with subcontractors providing services, and a mechanism for periodic self-evaluation and ongoing improvement must be maintained. Service facilities must provide safe, clean environments for patient care. They must comply with state and federal requirements for personnel, financial and programmatic reporting, and review and approval of educational and informational materials.

From the clinical perspective, delegates and grantees also must maintain written protocols for emergencies (e.g., vaso-vagal reactions, shock), as well as patient referrals to other providers. Grantees may conduct chart reviews to ensure that patients receive appropriate education and counseling about family planning, contraception, infertility, pregnancy, and sexually transmitted diseases (STDs), as indicated. They are assessed to ensure that medical history taking, physical examinations, and laboratory testing are consistent with clinical guidelines and that medical records are kept in accordance with Title X regulations. In addition, a grantee will shadow a variety of clients (with their consent) through the clinic process to observe eligibility, provision of clinical services, counseling/education, and provision of birth control methods.

Family Planning Annual Report

Federal regulations under 45 CFR Part 74 stipulate that all Title X service grantees must submit an annual report to OFP/OPA.[9] The submissions are synthesized into the FPAR—the only source of annual, uniform, national-level data on Title X program users, service providers, family planning and related services, and sources of revenue.[10] FPAR data are used at all levels of the program (i.e., Central Office, Regional Office, grantee, delegate) to monitor compliance with statutory and federal performance requirements, guide planning and resource allocation decisions, respond to inquiries from policy makers and Congress about the program, and assess the impact of program activities on key reproductive health outcomes (e.g., unintended pregnancies averted, incidence of STDs).[10] In addition to a national report, each individual region receives an FPAR that contains more detailed data on that region.

To fulfill the FPAR reporting requirements, service grantees must collect and compile specific data, most of which is collected by delegates/clinics during patient-level family planning encounters (i.e., in-person appointments). Clinic providers collect the data manually or electronically using a standardized encounter form called the clinic visit record (CVR). The CVR facilitates efficient data collection and formulation of concise and comprehensive records of Title X services, patient contraceptive practices, and relevant social and demographic information.[11] All data provided by service grantees are deidentified to protect the privacy of individual patients who receive Title X services.

The FPAR is considered a valuable tool for management, strategic planning, and financial planning purposes. It provides good, useful data that capture the characteristics of the patient population being served, their preferences in family planning, their geographic shifts, and whether the target populations are being reached. This information is important for practical assessments of consistency between the program goals a grantee cited in its grant application and the services it is actually providing. The data also allow for more directed analyses helpful in managing resources. For example, one Regional Office uses FPAR data to evaluate cost per user across Title X clinics, delegates, and grantees. In another example, a grantee prefers to use FPAR data to assess patient case loads at state departments of health.

However, there are several limitations to the FPAR data. First, the FPAR does not provide data on the effect of Title X services on patient outcomes over time. For example, the FPAR currently collects information on the number of patients with an abnormal Pap test or STD but does not track those patients over the next 18 months to assess whether they return to the clinic, obtain all necessary medical treatment, and remain disease free during this period. In addition, the FPAR does not track the nonclinical services provided by the program (e.g., outreach), which some RPCs cite as a limitation on the FPAR's usefulness. For example, data are collected on the number of persons served with limited English proficiency, but not on whether the patients' language needs were met. Performance measures, as exemplified above, are necessary for more extensive quality-related analyses that should be funded and undertaken at the national level by OFP/OPA.

With these limitations, the FPAR functions predominantly as a data tool to meet federal regulatory requirements. Even though there has been much discussion of the potential use of the FPAR for quality assessments of Title X services, the current data elements do not provide a true mechanism for measuring quality of care. Moreover, some of the data collected for the FPAR are considered unnecessary and useless, such as breast exams on girls ages 14–15. To address this issue, RPCs and grantees expressed the need to add more patient outcome–oriented data and performance measures. Some specific areas suggested for measure development were community education/outreach and results of chlamydia screening (similar to Pap tests). Also highlighted was the need to incorporate a more longitudinal analysis in the FPAR to allow year-to-year comparisons. Integrating a few key new performance measures into the FPAR would eliminate duplication of efforts and make the FPAR a more complete assessment tool.

The second issue is that grantees must use multiple methods to collect all FPAR data. While the utility of the FPAR improved significantly in recent years following the 2005 revision to the report's data elements, the change also increased the labor-intensiveness of data collection. Specifically, with new reporting guidelines, not all information is collected at the time of the patient's visit (e.g., Pap test results), necessitating substantial additional manual work to match all data for a particular patient. OPA has plans to further improve the FPAR by moving toward collection of a smaller, cleaner data set based on more sentinel patient information. Widespread implementation of electronic health records (EHRs) would facilitate this type of data collection. A recommended resource for identifying additional performance measures is the *Family Planning Councils of America Family Planning Performance Measurement System: Phase II Final Report*.

Currently, there is wide variation in the methods that grantees use for data collection. Some grantees are collecting all data by hand. A few grantees have developed their own electronic system, with the assistance of the Central Office and the collaboration of all delegates and clinics. Several grantees prefer to contract with data services organizations, such as Ahlers and Associates,[h] a nonprofit health care management and software company with a web-based family planning reporting system. Tracking current and future FPAR data and performing high-value quality-of-care analyses would be easier with EHRs.

Third, because of the high capital investment required, only a few delegate agencies and clinics have EHRs; most commonly, EHRs are associated with an FQHC, large nonprofit agency, or state department of health. Other delegates are at varying points in exploring the possibility of implementing EHRs. It was suggested by many grantees that OPA undertake a more extensive analysis to study how other health-related government agencies, including community health centers and the Veterans Health Administration, have addressed EHR cost and investment issues. In addition, OPA would need to study methods for meeting the substantial need for technical assistance to train delegates and grantees in use of EHRs and data analysis for quality improvement.

Training Programs

OPA invests a fair amount of money in training and development, allocating to each region funding for its RTC. The RTCs provide learning opportunities to delegates, grantees, and Title X providers and other staff. They conduct both individual delegate/grantee training programs and those that are more regional in scope. In addition to the RTCs, OFP/OPA holds an annual training conference to update Title X RPCs and grantees on important areas of family planning. The August 2008 training conference focused on financial aspects of program management and included presentations by representatives from GrantSolutions and the HRSA Grants Management Office. More recently, OPA funded development of a National Family Planning Clinical Training Center (NFPCTC) that will streamline training activities across the Title X program. Because the NFPCTC is fairly new, it is too early to judge its effectiveness. Thus, this section focuses on RTCs.

Training program topics are set according to the educational priorities of the Central Office and/or the DASPA, as well as needs assessments conducted by grantees and delegates. Often, educational priorities are politically driven (e.g., ABCs: abstinence, be faithful, use condoms; family

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[h] The Ahlers Family Planning Reporting System is an automated data system that collects client and visit information from family planning agencies, calculates billing, and produces reports for the agency and state. The system is designed to meet federal reporting requirements, as well as to provide management information.

involvement for teenagers) without scientific evidence to support them. In contrast, RPCs and grantees agree that topics that could significantly improve use of Title X services include understanding how to help women choose birth control methods and how to make contraceptive use more effective.

Along with OPA training priorities, per Title X regulations, grantees undertake a needs assessment each year to identify areas for training and improvement. This provides RPCs and grantees with some flexibility in training topics. The needs assessment survey has 80 different topics and asks grantees what type of training they need. The results are used to customize training for the grantee (e.g., patient wait time, need to conduct patient flow analysis).

All RPCs and grantees interviewed stated that they are pleased with the quality of the training programs conducted by the RTCs. The consultants contracted (via competitive application) to manage the RTCs are highly regarded among RPCs and grantees. They are considered to be knowledgeable in the spectrum of topics important to family planning and often compile best practice documents that are very useful. RPCs and consultants work together to balance the amount of training among grantees to ensure that everyone's needs are met. There is usually a good balance between identifying problems in the region and training according to OPA priorities. As with other aspects of the Title X program, however, there is never enough funding for grantee training as consultants can be expensive, and there is a cap on how much money a region may allocate to its RTC.

Frequently requested areas for training pertain to financial management, general program administration, clinical care, and interpretation and implementation of regulations at the clinical level. Specific examples of training program topics include:

- Pregnancy options counseling
- Contraception updates
- Program administration (e.g., customer service, how to approach patients about fee collections)
- Hands-on clinical skills (e.g., examination of male patients for nurse practitioners)
- STD update
- HIV update
- HIPAA

However, those interviewed identified several areas of unmet need in terms of training. Specifically, training centers need to develop a basic, comprehensive, nationwide orientation program for providers and other clinic staff about family planning (cultural competency, counseling patients effectively based on their needs, clinical and administrative efficiency, decreasing wait times). Also, there is a need for greater emphasis on the training of first-level staff (e.g., people who obtain informed consent, receptionists, community outreach, and community health care workers), who need to understand how to communicate in client-centric ways. Additional programs also are needed in how to manage Title X grants and screen for violence and violence prevention.

Centralized training does not always work for states or geographic areas that contain many rural clinics. Thus, there is great interest in expanding use of web-based distance learning programs. To date, certain RTCs have developed distance learning programs for their respective regions; however, the information in these programs typically is available only to grantees within the region and has not been shared widely across the Title X program. To advance learning among providers, it is important to institute a tool that consolidates information created at the local level. RPCs and grantees interviewed stated the importance of the national training center in serving as the clearinghouse for all training tools (e.g., compiling of different modules, resources), including distance learning information.

The main factor substantially limiting the ability of grantees to participate in training programs is the cost of travel. A few delegates and grantees have been very resourceful in working around the travel funding issue by implementing polycoms in all health departments for videoconferencing training sessions.

Some grantees also identified the need for uniform training of RPCs and RHAs in the principles of family planning and evidence-based medicine and how to interpret clinic guidelines. For example, some grantees feel there is wide variation in advice given by RPCs in different regions, particularly in terms of what clinics can and cannot do in obtaining consent and what services are offered.

Also, consultants who participate in the objective review committees responsible for reviewing grantee applications do not receive uniform training or any training at all. This results in wide variation in how consultants assess clinics, particularly with regard to financial status. Implementation of standardized training would enable consultants to provide more consistent evaluations of grant applications.

EFFECT OF POLITICAL ISSUES ON PROGRAM ADMINISTRATION AND MANAGEMENT

The DASPA's status as a political appointee is one of the most significant issues affecting the Title X program. As a political appointee, the DASPA typically manages the Title X program according to the overall political agenda of the presidential administration that made the appointment. Each new DASPA brings new ideas and new priorities for the program. If the DASPA is associated with an administration that does not approve of family planning, the Title X program can be subject to substantial changes that may shift funds to programmatic areas that are ineffective, freeze funding despite increases in program costs, or limit program resources in other ways. Even DASPAs associated with administrations that support family planning can develop plans to change operational or programmatic aspects of the Title X program (e.g., centralization).

Often, multiple DASPAs are appointed within the time frame of an administration. For example, from 2006 to 2008, three different DASPAs were appointed by the George W. Bush Administration. Over the years, several DASPAs even have gone so far as to attempt to retract the funding-related decision-making authority of the RHAs. Although the original language of the Title X statute provides decision-making authority to the DASPA, the Secretary of HHS transferred this authority from the DASPA to the RHAs in the 1980s. This transfer has helped maintain the integrity of the funding processes associated with the Title X program.

Other DASPAs have initiated activities that have increased the amount of cost sharing by Title X clients when clinic sliding fee scales were already in place for this purpose. One proposal would have changed the cost-sharing requirements of those at 100 percent of the federal poverty level. This would have increased the financial burden on the poorest of the poor, who should not have to choose between buying milk or contraceptives.

Another political factor affecting DASPAs is the well-funded private-sector and nonprofit groups involved in family planning. Their advocacy and lobbying efforts may have a strong influence on proposed legislation or administration policies.

Constant change with each political administration is highly disruptive, burdensome, and time-consuming for all Title X participants. OPA leadership becomes a "moving target" of inconsistency, with the Director of OFP providing the only source of stability. Suggested better approaches to Title X leadership are either to restructure the DASPA's position as a nonpolitical, civil service position or establish requirements that the DASPA be an individual who supports family planning.

PROGRAM FUNDING ALLOCATIONS

Several sources of federal and state funding provide support for family planning services, including Title X, Medicaid, Social Services block grants, Maternal and Child Health (MCH) block grants, and, more recently, the State Children's Health Insurance Program (SCHIP) and Temporary Assistance for Needy Families (TANF). Historically, the Title X program provided the highest proportion of funding for family planning services, followed by

Medicaid. In 1993, the Medicaid Waiver program was instituted, allowing states to waive normal Medicaid eligibility requirements to cover family planning services for those low-income individuals who otherwise would not qualify. Thus, in the last two decades, Medicaid has taken the lead in financial support of family planning services. However, Title X remains the only program dedicated solely to family planning. (The various sources of funding for family planning services are detailed below.)

Although the Title X program has achieved many programmatic successes, it has been challenged financially throughout its duration. This section describes the Title X funding process, highlighting some of the differences among regions and challenges in managing multiple funding cycles and sources of funding.

Historical Overview of the Title X Budget and Structural Changes

Funding for Title X was established under the Family Planning Services and Population Research Act of 1970 with a budget of $6 million, and it grew rapidly in the following decade as clinics proliferated throughout the country.[12] By 1980, the Title X budget was $160 million.[13] However, funding for the Title X program decreased significantly in the 1980s as part of the broader Reagan Administration initiative to reduce federal spending on all social service programs.[12]

The Reagan Administration block grant initiative had a significant effect on both the administrative structure and funding of the program. The initiative aimed to streamline and consolidate administration of social services programs and reduce funding across the board by 25 percent. Title X funding dropped to $120–140 million and remained flat until 1992. OPA also undertook an initiative to consolidate[i] the number of grantees under state departments of health. If the state chose not to serve as the Title X grantee, then the contract would be awarded to a single grantee serving the state or another geographically defined area designated by OPA.

Although the Clinton Administration provided steady increases in Title X funding to $254 million by 2000, the program budget remained underfunded. One study estimated that in 2000, funding was actually 58 percent lower than the $162 million allocated in 1980 when adjusted for inflation.[14]

Financial pressures on the Title X program continue today, due to increasing demand for services, expanding scope of services, rising costs of services and supplies, and the changing dynamics of health care delivery

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[i] By the 1980s, some grantees had developed “consortiums” to oversee many clinic sites, as is the case today. However, there also were a number of grantees operating a single or very few clinics, which created a significant administrative burden on OPA.

and financing. Currently, the fiscal year (FY) 2008 Consolidated Appropriations Bill provides \$299.9 million for the Title X program, an increase of \$16.8 million from the previous fiscal year. If keeping pace with inflation, the program budget would be funded at \$759 million.[15] Figure J-2 displays Title X program funding as compared with inflation-adjusted rates.

Title X Funding Resources

According to the Title X statute, at least 90 percent of funds must be used for clinical services as defined in Section 1001; the remaining 10 percent may be used for administration, training, informational materials, and research. The budget is sectioned accordingly. Box J-1 summarizes and defines the different Title X funds.

Over the past 30 years, the allocation of Title X funds has depended on a complex, multilevel set of processes. At the federal level, methodologies used by the Central Office to determine allocations to each region are different for each type of funds. Each region may use its own methodology to allocate funds to grantees. Regions also consider the level of funding

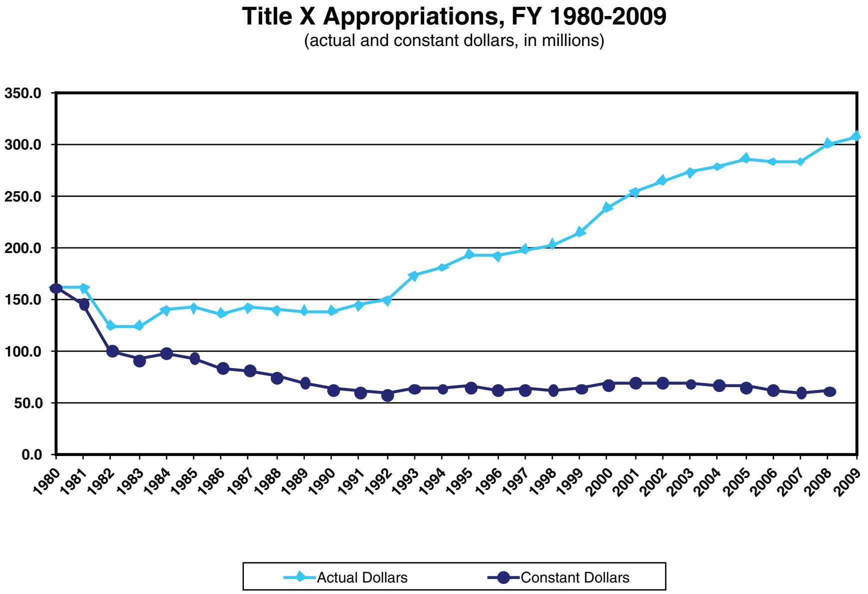

FIGURE J-2 Estimated funding for Title X when adjusted for inflation.
SOURCE: Reprinted with permission from unpublished tabulations from the Guttmacher Institute.[34]

BOX J-1
Summary of Title X Program Funds

SERVICE FUNDS

Title X dollars for clinical services (90 percent of the total budget) are allocated from the Central Office to each Regional Office through four different types of funds.

- Regular service funds, also called base funding
- Supplemental services expansion funds, used to distribute increases in Title X funding
- Regional project priority funds, used at regional discretion to address specific needs in that area
- Male reproductive health project funds to support initiatives to increase male participation in reproductive health programs

GENERAL TRAINING AND TECHNICAL ASSISTANCE FUNDS

Remaining dollars for administration and training (10 percent of the total budget) cover the costs of overall program management (e.g., personnel, travel, rent), as well as regional training and technical assistance. Regions receive these resources via three funding sources:

- Training base fund to support the operation of a regional training center and training grantee
- Priority set-aside funds, used for training priorities established by OPA
- Technical assistance base to cover costs for grantee training in specific areas identified through an annual needs assessment

ADDITIONAL FUNDS

All regions also receive other family planning–related funds from HHS for special initiatives, which they may distribute to Title X service grantees. The purpose of the supplemental grants is to integrate screening and preventive services for HIV/AIDS and STDs. Minority AIDS Initiative funds provide supplemental funding for HIV/AIDS screening and counseling in efforts to support broad implementation of the Centers for Disease Control and Prevention's (CDC's) Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. As part of the National Infertility Prevention Program, grantees also may receive CDC funds for chlamydia screening and treatment to reduce the incidence of the STD and its complications (pelvic inflammatory disease, infertility) if left untreated.

requested by grantees, the populations they intend to serve, and clinical services they intend to provide as listed in their grant application. Each region's planned distributions to grantees are described in its budget plan submitted annually to the Central Office. In turn, grantees also may employ their own methodologies for funding delegate agencies and clinics. Thus, the current funding levels and mechanisms vary by region and grantee. The specific methodologies for distribution for each type of funds are described below to the extent that information was available.

Methodology for Allocating Regular Service Funds

Allocations from the Central Office to Regional Offices. For the regular service funds, allotments are based on a historical formula that measures each region's need according to three data sets—Guttmacher Women in Need, census data, and the Bureau's Common Reporting Requirements[j] (BCRR, the pre-FPAR equivalent). The exact formula and weighting of each data set are not available, but this process resulted in each region (and state or designated geographic area) receiving a percentage of the total Title X budget. At one point in the early 1980s, the Central Office considered changing the regional allocations; however, Congress passed language in the FY 1987 appropriations bill that prevented changes in the percentages allocated to each region. Hence, throughout the program's operation, the regular service funds *and* any subsequent budget increases have been allotted to each region according to its established percentage.

In 2003–2004, at the request of the Acting Assistant Secretary of Health, the Central Office undertook an internal exercise to reexamine the methodology for regional allocations. Using current data derived from the Guttmacher Women in Need report, census data, and the FPAR, it was found that the current allocations to each region continued to match up very well, and no further efforts have been initiated to evaluate or change the base funding. Actual monetary values provided to each region are available in the FPAR.

Allocations from Regional Offices to Grantees. Similar to the process described above, the Regional Offices use historical, preset, percentage-based calculations for allocating regional funds to specific geographic areas. Regular service funds are allocated to grantees through a competitive process managed by the Regional Offices. The Regional Office issues a Request

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[j] The Bureau's Common Reporting Requirements are the HHS Bureau of Primary Health Care's guidelines for annual reporting designed for community health centers. The BCRR was also used as the guideline for reporting on Title X until 1995, when the FPAR was instituted.

for Proposals (RFPs) announcing the level of funding available for the competition in a designated geographic area (e.g., state of Connecticut, $2.5 million). The grant applications are evaluated by that region's Objective Review Committee (ORC) according to criteria established in the Title X statute. OFP includes information on the scoring of the criteria in the RFP. The same scoring methodology is used by all 10 regional ORCs (see Box J-2).

The RPC and RHA determine the length of the grant award—2–5 years, depending on the ORC score:

- Score of 95–100 points: 5 years
- Score of 85–94 points: 3 years
- Less than 85 points: 2 years

Once grant applications have been scored by the ORC and winners have been announced, the Regional Office calculates disbursements for regular service funds according to the methodology of its choosing or past award amounts. Most of the methodologies were established some time ago. In noncompetitive years, grantees complete an application annually to receive funds for the remainder of the project period.

Among Regional Offices, there are some commonalities and differences not only in the data used for these disbursements, but also in the way that regions may weight the data. Commonly used data include the ORC score, the FPAR, and Women in Need. Differences are notable in the percentage of the grant that is attributable to past awards. Some examples of the regional variations are provided below.

BOX J-2
Criteria and Scoring for Award of Regular Service Funds

- Project plan provides for requirements set forth in Title X regulations (maximum 20 points)
- Extent to which services are needed locally (maximum 20 points)
- Adequate facilities and staff (maximum 20 points)
- Capacity to make rapid and effective use of federal assistance (maximum 10 points)
- Need of applicant (maximum 5 points)
- Availability of other, nonfederal resources within the community (maximum 10 points)
- Number of patients and number of low-income patients (maximum 15 points)

One region makes decisions on the allocation of regular service funds based on performance and a historical formula. Performance criteria include FPAR data (e.g., numbers of users, numbers of HIV and Pap tests) and grantee quarterly reports. The historical formula provides a means with which to assess the needs of the community (e.g., Women in Need, state and federal health statistics, needs assessments, National Survey of Family Growth), the number of Title X program users, and the size of the grantee. Also taken into consideration are the resources and history of the grantee within the Title X program (most are returning applicants).

Another region uses a more mathematical methodology for calculating regular service fund grants (or regional project priority funds):

- 50 percent of funding is based on the grantee's immediate past award
- 30 percent is based on the number of women served previously who are at 100 percent of the federal poverty level and below (FPAR data)
- 20 percent is based on Guttmacher Women in Need data

A third region makes decisions about allocations by reviewing FPAR data on the clients/populations being served, the ORC score, the grant application plan, and the income level of the population served. The decision-making process is more qualitative than quantitative.

A fourth region simply allocates 90–100 percent of the immediate past award to the grantee.

Generally, there is no grantee turnover; 57 percent of grantees are governmental (state or territory departments of health), and 43 percent are nonprofit organizations that have been providing services for several decades. As such, there is rarely competition among grantees. Most regions have added, on average, one to two new grantees over the past 10 years. Much more turnover occurs at the delegate level, in terms of both lost and gained delegate agencies.

Although each region maintains some sort of methodology for allocating its base funding to grantees, these methodologies actually are employed infrequently, as most grantees remain the same from year to year. Generally, it is only when another grantee is added to a region that the methodology may be used.

RPCs believe that the strength of the Title X program is founded on a structure that maximizes flexibility in regional administration and management of the program, including that pertaining to the allocation of funds to grantees. They also believe that there are many ways of achieving the same programmatic success, and what works for one region may not work for another.

Allocations from Grantees to Delegates/Clinics. Most of the variability in allocations throughout a region occurs at the level of the delegate/clinic. Once grantees have been awarded Title X funds, they contract with delegate agencies or provider organizations (e.g., clinics) and negotiate which clinical locations will participate in the Title X program. Most often, grantee selections of delegates/clinics are undertaken through a competitive process with a scoring mechanism typically based on the budget available, the applicant capabilities, and the applicant statement of work. Additional factors taken into consideration include delegate/clinic past performance (i.e., whether they do a good job providing services, results of site visits, compliance with OPA rules) and familiarity with the health care infrastructure of the geographic area.

Although grantees have some leeway in deciding how many delegate/clinic locations will receive funding, they must ensure that funding is distributed appropriately throughout the geographic area associated with the grant award. One way that some grantees accomplish this is by using the annual needs assessment of their geographic area to identify areas with an unmet need for family planning services.

There is significant variability in methodologies used by grantees to distribute funds to delegates/clinics. Most grantees use a standard base amount paid to delegates/clinics to cover basic costs plus a per patient rate based on a selected data set. However, the base amount can vary considerably from one grantee to another. For example, one grantee uses a base amount of $80,000, while another uses $5,000. The funding amounts guaranteed to delegates/clinics relative to previous awards also can vary widely. One grantee may guarantee 50 percent of the previous year's funding, while another may guarantee 75 percent. Table J-3 provides some examples of the different methodologies employed by Title X grantees.

For many grantees, these methodologies are the product of a conscious effort in the last decade to simplify the process and calculations for allocating grants to delegates/clinics. Among grantees, delegates, and clinics, the most highly regarded change in methodology is the inclusion of a per patient calculation in the formula. Even delegates and clinics that lost some funds with the new calculations were supportive because of the transparency and fairness of the allocation process and confirmation that the right patients were being served. Thus, grantees have found this method to be very effective in supporting family planning services where they are most needed and in demand.

Methodology for Allocating Other Service Funds

Supplemental Expansion Funds. Although traditionally the Central Office has integrated supplemental expansion funds into the larger budget for

TABLE J-3 Examples of Methodologies Used by Grantees to Allocate Regular Service Funds to Delegates and Clinics

Grantee A	Grantee B
• Standard base of \$5,000 paid to delegate agencies for basic costs plus • Per client allocation based on number of insured and uninsured, non-Medicaid patients seen in previous year	• Women in Need (weighted 10 percent) • Previous allocation (all health districts have been receiving funds almost since the beginning) (weighted 50 percent) • 3-year case load (numbers) (weighted 40 percent) • 10 percent variability applied to accommodate shifts in case load
Grantee C	**Grantee D**
• Allocate more funding to agencies serving higher numbers of uninsured, low-income teenagers (less than 135 percent of federal poverty level) • Take into account all of a program's income from fees and public and private insurance • Set goals for how much money agencies should be generating or used in the previous year, whichever was higher • Use per patient rate for allocations based on the number of patients expected to be seen and those actually seen (e.g., if a clinic is budgeted for \$100,000 to see 1,000 patients, it is paid \$100 for every patient seen; if it ends up seeing fewer patients, it owes money back; if it sees more patients, grantee owes it money)	• 75 percent of funding is maintained (cannot lose more than 25 percent of funding, and funding cannot increase by more than 33 percent) • Base starting amount is \$80,000 • Takes into account: — Number of users — Number of warning letters (compliance) — Number of special populations served — Number of adolescents under age 17 — Chlamydia screenings (e.g., aligned with CDC guideline)

regular service funds, a different approach was employed for the 2007 increase: \$15.8 million of the \$16.8 million overall increase was allocated through a separate process based on regional size and number of clients served as reported in the 2005–2006 FPAR.[k] Small regions received \$1.3 million, medium-sized regions received \$1.6 million, and large regions received \$1.9 million. In contrast with previous budget increases, use of the 2007 funds was restricted. Grantees had to compete for the funds and could use them only for expansion of family planning services to individuals not currently being served.[1] Funds could be awarded for any aspect of grantee Title X program operation, including the purchase of additional supplies

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[k] There was \$1 million set aside for research and development of additional data collection capabilities.

BOX J-3
Criteria for Award of Supplemental Expansion Funds

- Description of targeted area and justification for additional services (25 points)
- Relative need for funds (25 points)
- Project plan of strategies to expand service delivery (20 points)
- Description of clinical efficiency strategies used to maximize resources (20 points)
- Capacity of the proposed project to make rapid and effective use of resources (10 points)

(e.g., contraceptives) or payments for additional staff members, as long as such requests were tied to anticipated increases in Title X clients.

Applications were reviewed by the RPC, who made recommendations to the RHA. Examples of data of interest to the Regional Offices include the projected number of new clinic users, calculations of cost per user over the course of the 3-year project period, and FPAR data. Many grantees indicated that they did not overcommit to increasing users during the first year of the award to allow time for program implementation. Most increases in users were planned for years 2 and 3. The criteria for awarding supplemental expansion funds are provided in Box J-3.

The new requirement that delegates must compete for supplemental funding is challenging for small, rural communities. There tend to be sole or few providers of family planning services in these communities, so competing for funds means competing for less money than in larger areas with multiple delegates. In addition, it is more challenging to increase the number of users given the greater distances that patients must travel for services.

Regional Project Priority Funds. The Central Office allocates regional project priority funds through equal allotments of $472,000 to each region. This approach is intended to equalize the smaller and larger regions. If project priority funds were allocated only by percentages, the larger regions would receive most of the resources. These funds may be used at regional discretion to support specific regional priorities and/or needs, Title X program priorities, legislative mandates, and efforts to address key issues.[1]

Until 2005, regions received separate funds to support male adolescent clinic projects ($30,000) and information, education, and communication activities ($30,000). However, in 2006 those funds became part of the region's base funding. Regions are allotted the additional project priority funds, and are allowed substantial flexibility in how the funds will be used to continue activities in these or other areas.

Regions can vary in the way the RPC and RHA determine allocations for regional project priority funds. Use of a competitive process is optional, but encouraged by the Central Office. Many regions simply fold regional project priority funds into the regular service funds, while others prefer to develop their own criteria for assessing grantee applications. For example, one region bases allocations on the ORC score, data on special initiatives (e.g., STDs), and previous performance. Another region uses the eight questions highlighted in Box J-4 as criteria for evaluating grantees interested in receiving regional project priority funds.

Still, a few regions use a more formulaic methodology for determinations. One region's methodology includes:

- Description of proposed use of funds (15 percent)
- Extent of unmet need (30 percent)
- Lack of other resources (30 percent)
- Grantee performance (15 percent)
- Grantee budget (10 percent)

For existing grantees, funding often remains at the previous rate, unless there is evidence that the funds have not been used wisely or that the number of clients has decreased. For new applicants, examples of criteria for evaluation may include percentage of federal poverty level of users, number of non-English speakers, socioeconomic status of users, number of providers/geographic area, state and county statistics, and data from the National Infertility Prevention Program. Regions that have unused funds at the end

BOX J-4
Example of Criteria Used for Distribution of Regional Project Priority Funds

- Briefly summarize need and plan, including time frame
- Briefly describe if and how budget relates to plan
- Measurable goals to track
- Suggestions for other project metrics
- How likely (from reviewer perspective) project will experience success
- Whether project identifies potential new service delivery partner
- Questions that might be addressed to grantee for clarity of intention and direction for this project
- Other comments

of the year may issue a notification to request applications from grantees. Applications should be as descriptive as possible (e.g., funds to address increased cost of providing service, funds to meet OPA priority).

General Training and Technical Assistance Funds. The Central Office provides each region with funds for training and technical assistance programs. Three types of such funds are available: training base funds, priority set-aside funds, and technical assistance funds. The training base funds, totaling $4.7 million in FY 2008, support the 10 RTCs as authorized under the Public Health Service Act. Regional allocations range from $385,000 to $555,000, depending on the size of the region. Consultants interested in managing the RTCs compete for awards and are scored according to the criteria published in the RFP. Recently, this competitive process was centralized by OFP.

In addition to the training base funds, each region receives $50,000 in priority set-aside funds and $30,000 in technical assistance funds. These funds are not competed. Instead, for the set-aside funds, OFP provides the criteria for RPC and RHA use in evaluating applications. The technical assistance funds are discretionary, with allocations determined by RPCs.

Directed Supplements, External Funding of Targeted Programs, and Special Projects. Directed supplements and other external sources of funding are awarded only to existing Title X service grantees (not new grantees). Three types of such funds are available to those that qualify. Two of the programs (male reproductive health funds and HIV/AIDS screening and counseling funds) are directed supplements that depend wholly on Title X funds. The third program—for chlamydia screening—is funded entirely by CDC.

The male reproductive health funds are 100 percent Title X and are part of the service funds; however, because they target a specific population, they also are considered a directed supplement. These funds must be used only to support initiatives that aim to increase male participation in reproductive health programs. For HIV/AIDS screening and counseling services, a portion of the Title X funds is combined with funds provided through the Minority AIDS Initiative fund.

CDC funds chlamydia screening and treatment at Title X service sites through a completely separate process. When CDC instituted the National Infertility Prevention Program to support chlamydia screening, legislative provisions allotted 50 percent of funds for use in STD programs and 50 percent for use in family planning programs. Funds are supplied directly to delegate agencies and clinics from CDC; OPA does not function as an intermediary and does not monitor chlamydia screening programs. Rather, the program operates as a collaboration between CDC and OPA, with grantees reporting data to both agencies.

RPCs and grantees are highly supportive of the directed supplements they receive and believe that the Title X program has ultimately benefited significantly from a closer association with public health. However, grantees also stated that they would prefer to receive the funds as part of the regular service funds rather than as a directed supplement. Typically, directed supplement funds are awarded very late in the overall Title X project period (e.g., August 2008 for project year 2008). The grantees provide services regardless of when they receive the funding. As long as they meet the overall Title X program goals (male reproductive health, HIV/AIDS screening/counseling, chlamydia screening), they do not see the purpose of separating the directed supplements from regular service funds. (Issues related to multiple funding cycles are discussed in the next section.)

In addition to directed supplements, OPA may issue funds for special research projects, such as the ABC[1] model of counseling. Because of the significant shortfalls in funding just to provide basic family planning services, many grantees remain concerned about the restrictions and requirements associated with funds for special projects. In some regions, many clinics have been closing or decreasing hours in the past few years to stay open. As such, OPA's first goal should be maintaining core services and funding supplies (e.g., OPA should be spending more money on IUDs). Many believe that a better approach would be to put all the funds into one fund and allow grantees to distribute them for clinical services under Section 1001 of the Title X statute as they see fit.

Key Challenges in Title X Allocations

Funding Cycles

One of the most challenging aspects of Title X funding is the coordination and management of the multiple funding and project cycles at the federal, regional, and state levels. When Congress passes the annual appropriations bill, the Central Office releases all service and training funds (i.e., regular service funds and regional project priority funds) to the regions. Typically, appropriations are made in accordance with the federal fiscal year (October 1–September 30). As stated previously, once regions receive their funding, they begin the process for grantee allocations.

If there is a delay in reaching an agreement on the appropriations, Congress may issue a continuing resolution that allows government programs

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[1] As noted earlier, ABC refers to a model for family planning counseling services based on extramarital abstinence, being faithful in marriage or committed relationships, and consistent and correct condom use. The ABC model was designated as a Title X priority area by the DASPA appointed by the George W. Bush Administration.

to be funded as a portion of the previous year's appropriation (for up to 6 months) until the current year's funding is available. However, delays in appropriations can interfere with grantee planning and use of service funds. Because the same financial resources are not available, Regional Offices and grantees conserve funds by limiting travel and training expenses. In some extreme cases, grantees may not be able to expand or maintain certain aspects of clinical services (e.g., they may have to decrease staff hours for family planning services).

At the level of the grantee, the dynamics of the funding process can be very complicated. Each grantee maintains one account with the federal government, through which the different service funds and training funds are made available at different times throughout the year. A grantee's budget period (annual funding period) and project period (total contract period, e.g., 3 years) can vary substantially from those of other grantees within a given region. Each grantee is designated a specific start date for both its budget period and project period as identified in the notice of its grant award. Yet this date may or may not coincide with the dates when the different funds are made available to the grantee. For example, a grantee's budget and project start date may be January 1, but the date for availability of the supplemental services expansion funds may be August 1. Each grantee also may have grants being competed in different years. For example, a grantee may compete for supplemental services expansion funds in 2008 and recompete for regular service funds in 2009 and HIV funds in 2010. Grantees that are a state department of health also are subject to state funding periods that may or may not align with the federal timetable.

Thus, the Title X program funding cycles tend to be out of sync with many grantees' budget and project periods and, in some instances, federal reporting periods. This creates a perpetual situation in which grantee funds must be carried over from one budget year to another. While the amount of the carryover may be small (e.g., $62,000), it involves a time- and labor-intensive process that takes resources away from clinical services and staff training.

This process was established initially to balance the workload associated with reviewing grant applications throughout the year. Considering that there are 88 grantees receiving funds in the Title X program, the workload would be high if all grant applications arrived at the Regional Offices and OPA grants office simultaneously.

However, this approach also has resulted in a process that can be perceived as fragmented and difficult to coordinate. In addition, management of all these cycles requires significant time and resources. For example, one region has 5 grantees with a December 31 start and 10 grantees with a July 1 start. The Regional Office must hire two sets of ORC consultants, doubling all costs. The process also creates a significant amount of paperwork that could be streamlined.

Several solutions were suggested by those interviewed. One method of streamlining processes without changing federal funding cycles has been to coordinate the budget and project periods of all grantees within a region. One region already has instituted this approach using a June 1 start date. Given a date midway through the fiscal year, grantees are assured full funding for their budget period regardless of whether there is a delay in appropriations. Grantees in this region also have found it easier to manage all of their sources of funding. Another solution is for the federal government to create a universal start date for projects. Many interviewed indicated a willingness to make the trade-off between having more work at one point during the year and having two or more different sets of start dates. A third suggestion was to institute 5-year project periods more broadly, especially for grantees that have been providing family planning services for an extended time. Lastly, OPA could evaluate the strategies used by CHCs and other public health programs to coordinate budget and project periods.

Transparency

Many grantees feel that OPA should gather all stakeholders to simplify regional allocation methodologies and funding processes across the board. Such revisions should be an outgrowth of an independent evaluation of funding distributions. In addition, all expressed concern about the lack of transparency at the OPA and regional levels in the methodologies used to determine allocations to grantees. Some grantees feel that Central Office allocations have not been adjusted sufficiently to shifts in the population. Another point of concern is the lack of transparency in revealing publicly to grantees what other grantees are receiving. As a result, some question the equity of allocations among grantees. For example, one grantee may have two clinics and receive $400,000, while another grantee in the same region may support 140 clinics and receive $2.1 million. Thus, grantees believe that good performance is not being incentivized appropriately because some groups are getting more money for serving fewer clients. Greater transparency also is needed as to the criteria for determining a specific grant length and why the designated length was awarded to a particular grantee.

Some grantees believe that there are notable limitations in basing allocations on data from Women in Need. For example, there is no way to know whether women identified will use Title X services. Rather, some believe that funding should be based solely on how many people are being served.

Competition

The Title X competitive process is designed to create opportunities for new grantees, clinics, and consultants, as well as stable networks of care. In general, grantees have mixed feelings about the competitive grant application process. Some grantees think the application process is better than that for other HRSA programs, even though they feel unnecessarily restricted by the application page limits (i.e., 50 pages for competitive applications, 30 pages for noncompetitive applications). Several grantees also indicated a desire for more guidance in the application process.

Some grantees would like OPA to consider different allocation processes for the different applicant types, especially since some state departments of health have been providing family planning services for almost 40 years. These grantees would like OPA to develop one process for state departments of health and long-serving nonprofit and private-sector grantees, and another process for newer nonprofit and private-sector organizations. For example, instead of competing for funds, state departments of health and long-standing grantees could provide a revised justification for renewed funding, and in addition, OPA could review the state's project period performance to determine whether any funds were misspent, as well as to ensure that funds were received by the right delegates/clinics.

Competing Local Priorities

Some grantees are further challenged by competing local priorities, such as state-based financial obligations to invest in health information technology systems using a portion of Title X funds. These obligations can have an impact on the amount of funds available for clinical services. For example, a technology company contracted by one state to build a state-wide health information technology (HIT) network requires payment of $300–400 per person per month for each professional in the health department who uses a computer. While a state-wide HIT system is considered a good and necessary investment, it can have an impact on the ability of state health clinics to purchase contraceptives.

Coordination of Title X and Other Sources of Funding for Family Planning Programs

As noted above, several past and current sources of federal and state funding have provided support for family planning services, including the Title X program, the Medicaid Waiver program, the federal 330 program, MCH block grants, Social Services block grants, and TANF. Funds from CDC can be used only for its STD prevention program. Title X, the federal 330 program, and the Medicaid Waiver program are the predominant sources of family planning support in today's health system. The discussion in this section is based on a limited scan of the published literature, government and private-sector reports, and other information. To supplement those findings and to provide context based on the experiences of those involved in the Title X program, Lewin also interviewed four RPCs and three grantees.

Overview of Non–Title X Family Planning Funding Sources

As stated earlier, Title X of the Public Health Service Act provides the only focused support (both historically and presently) for family planning through grants to 38 state agencies and 39 private-sector nongovernmental organizations that collectively serve all 50 states, territories, and the District of Columbia.[17] Because of the relative openness of the program to low-income individuals as compared with the other sources and providers of family planning services, RPCs, grantees, and clients consider access to family planning and annual screening to be better in Title X clinics.

As noted, while Title X remains the centerpiece of family planning, funding for family planning services through the Medicaid Waiver program now marginally exceeds that of Title X. To date, 27 states have implemented some form of the waiver program.[18] The federal government pays 90 percent of each state's Medicaid expenditures for family planning services and supplies and requires only a 10 percent match with state funds. In FY 2006, Medicaid funding for family planning services was estimated at $1.4 billion for all health care provider settings.[17] Of this amount, Title X clinics alone received $320 million in Medicaid payments, slightly more than the $262 million allotted in Title X grant funds.[19] A 2003 federally funded evaluation of the Medicaid Waiver program in six states found significant cost savings to both the federal and state governments.[20] Moreover, this study estimated that if the waiver program were implemented nationally, federal and state savings of $1.5 billion would be realized annually by the third year.

In addition to macro-level benefits, the Medicaid Waiver program has had a positive influence programmatically by enabling Title X grantees and providers to serve greater numbers of clients. Some stakeholders believe that Title X and the Medicaid Waiver program complement one another as a more comprehensive effort to serve those in greatest need.[21] The waiver program has provided a dependable source of revenue for clinics, helping to ensure overhead. Without reimbursement from the Medicaid Waiver program, many Title X clinics would not be able to continue operation given the constant increase in the costs of staff and supplies. However, unlike Title X, the waiver program has a strict set of requirements and limits coverage to the core services that are needed to promote effective contraceptive use rather than more comprehensive reproductive health.[22]

Section 330 of the Public Health Service Act governs the operation of FQHCs (e.g., CHCs), which provide a broad scope of primary and preventive care health services, including reproductive health services.[23] CHCs are private, nonprofit, community-based health centers located in high-need or medically underserved areas that function as major safety-net providers for low-income and/or uninsured Americans. There are more than 1,000 CHCs operating more than 6,000 delivery sites in all states, territories, and the District of Columbia. Since 2000, federal investments in CHCs, most often by the Bureau of Primary Health Care (BPHC) at HHS, have doubled to more than $2 billion today.[24] BPHC funding of Title X family planning services was estimated at $5.8 million in FY 2006.[19] By law, CHCs are required to offer prenatal care, screening for breast and cervical cancer, voluntary family planning, and other basic services provided by an obstetrician or gynecologist. In 2007, 95 percent of CHCs provided family planning services. Some CHCs receive Title X funding to supplement their budget for reproductive health services. However, as with the Medicaid Waiver program, CHCs operate according to an independent set of requirements, some of which do not fit well with Title X.

The MCH (Title V of the Social Security Act) and Social Services (Title XX of the Social Security Act) block grants are provided directly to and controlled by state governments. The MCH grants typically go to state departments of health, while the Social Services grants go to the state's social services agency.[17] Federal law permits states to use both grants for family planning services. However, for MCH grants, the law also requires states to contribute $3 for every federal $4. There are no such requirements for Social Services grants. In FY 2006, grants to Title X clinics for family planning services were estimated at close to $23 million for MCH and more than $28 million for Social Services.[19]

Although traditionally, family planning was an important part of the MCH program's overall mission, state MCH programs have shifted away from providing direct patient care for family planning.[25] Most states use MCH grants to fund prenatal care, population-based services (e.g., immunizations), or program infrastructure. For example, some MCH grantees use the grant to pay for county health department staff (e.g., nurse practitioners, public health nurses) that may also serve Title X or for outreach activities to promote AIDS prevention. Generally, grantees feel that county or local support was better prior to the Medicaid Waiver program. After implementation of the waiver program, many county commissioners cut supplemental budgets with the perception that clinics had enough funding with the new federal dollars, forgetting two important facts: (1) clinics are serving more clients because of the waiver program and (2) the waiver program does not reimburse clinics for 100 percent of costs, especially when the visit goes beyond the use of contraception.

In contrast, the Social Services block grants have tremendous flexibility in applicability across the spectrum of social services programs.[25] Family planning is the only medical service for which the grants are applied as a supplement to other funding. Severe budget cuts in the mid-1990s left the program financially crippled, and as a result, most clinics receiving Title X funding no longer receive Title XX funds. In some states, lost funding from the Social Services cuts was replaced by TANF grants (also provided directly to states) used to administer the state's welfare programs. Like the Social Services grants, TANF funds can be used to supplement funding of family planning programs. However, TANF requirements are quite stringent, and as a result, many grantees eliminated use of the grants for their family planning programs. In fact, none of the grantees interviewed for this study received Social Services or TANF funds. For the Title X program overall, TANF grants amounted to $10 million in FY 2006.[19]

Some states also provide limited funding for family planning activities through state appropriations outside the context of Medicaid or the block grants. Specifically, many states' Medicaid agencies use state appropriations to provide medical services, including contraceptive services, to people who do not meet Medicaid eligibility criteria (e.g., certain immigrants). In 2006, one study estimated that independent state appropriations for family planning services reached $241 million.[17] Five states (California, Florida, New York, North Carolina, and Oklahoma) accounted for 57 percent of all state appropriations. Generally, state appropriations account for at least 10 percent of all family planning funding in 20 states. It is important to note that for close to 30 years (since 1980), state appropriations for family planning services have remained flat.

Coordination vs. Duplication of Effort

Because no single program finances family planning adequately, grantees must combine different sources of funding and program requirements to operate a comprehensive reproductive health program. In general, the multiple sources of funding are not difficult to manage, and all grantees have found ways to make funding sources work together. It would be easier if all family planning funding came from one source, but grantees do not have an issue with coordination of the different funding sources, especially if they are affiliated with the state department of health. Free-standing and private-sector clinics are perceived as having greater challenges in coordination of funding.

The inclusion of a financial audit in the Comprehensive Program Reviews provides adequate oversight of the coordination and use of multiple funding sources. Financial consultants that serve on the review team evaluate accounting records and management of funding. The consultants are regarded highly for their ability to identify issues (e.g., a grantee not funneling fee-for-service reimbursements back into the Title X program) and provide constructive and educational guidance to grantees. From the standpoint of funding, RPCs and grantees do not feel that there is any obvious area of duplication or lack of coordination.

Most coordination-related issues pertain to the differences in each program's operational requirements, which can affect access to care. Specifically, the differences in requirements associated with program administration and clinical services are especially pronounced among Title X, CHCs (under federal 330 rules), and the Medicaid Waiver program. RPCs and grantees do not see the need to have different rules for these three programs. Moreover, because Medicaid is a state-driven program, each state may implement different rules for use of the funds. For example, in Arizona, the Medicaid Waiver program is used to cover postpartum services (including sterilization services) for individuals living at or below 100 percent of the federal poverty level. In California, the Medicaid Waiver program has been instituted with much broader application for those at 200 percent of the federal poverty level.[22] Because of these differences, Title X may serve different purposes in different states, which adds to the complexity RPCs may experience in reviewing grant applications for their region.

In general, the solution has been for RPCs to work closely with grantees to improve program management. However, there is great need to better define strategies that can enhance program coordination to ensure that all funds are used more efficiently.

Impact of the Financial Crisis

The downturn in the economy is causing state budget deficits, prompting states to cut their 2009 and 2010 budgets across the board, including those associated with health care services. In addition, foundations and wealthy individuals have lost money and have less to donate. This situation has had a direct effect on Title X grantees that are state departments of health. Typically, budget cuts result in clinic staff cuts, which in turn decrease the availability of services. With fewer staff, some clinics may close altogether, while others will decrease their hours of operation from 5 to 3 days a week. This affects clinics' ability to serve family planning clients. Furthermore, family planning clinics within state departments of health become more dependent on federal funding.

Another important outcome of the financial crisis is the fact that a greater number of individuals are in need of federally subsidized family planning services. Currently, more than 50 percent of Title X clients are nonpaying. However, growth in unemployment, home foreclosures, and high gas prices are increasing the rates of those who are uninsured and at or near the federal poverty level. Without adequate access to family planning services or increases in federal funding, pending state and private-sector budget cuts may result in increased rates of unintended pregnancy and STDs, as well as higher health system costs over the long term.

These challenges are exacerbated by the fact that, as discussed above, federal funding for Title X has remained predominantly flat for the past few decades, while the costs of clinic staff, contraceptives, and laboratory tests have continued to increase. RPCs and grantees are hopeful that the new administration will expand Title X funding and take a greater leadership role in the purchase of contraceptives.

CLINICAL SERVICES

Equity Requirements

Title X requires that services for family planning clients be equal regardless of payment type or nonpayment. This has been a significant issue among grantees and clients. Since not every program pays for every service, there is difficulty regarding what can be done for one patient compared with another. For example, clinics currently have to review all carrier formularies and rules, their client mix, and desired contraception to develop a baseline so that all clients receive equal services as required by the Title X statute. Because of the equity rule, those with private insurance or Medicaid may not be able to receive certain contraceptives (e.g., Implanon and newer IUDs) even if their insurance/Medicaid pays for them unless those same contraceptives are equally available to Title X clients. Some clinics offer the innovative contraceptives on a sliding fee scale. Other clinics may institute an open service period each month. For instance, one clinic holds an open period for clients seeking Implanon during the first week of every month or until a designated number of Title X appointments are filled. Then, the Implanon service is closed for the rest of the month. During the open period, all clients with third-party payers that cover Implanon also may receive the service until it is closed.

Although Title X funding remains inadequate, there is consensus among grantees that clinics should not have to equalize to a common denominator. Moreover, each grantee and clinic appears to be deciding independently which contraception to offer. With this disjointed approach, certain clients who could really benefit from new technology (e.g., those with cognitive impairment or those who are mentally challenged) may not have the opportunity to obtain it under the current rules. Establishing flexibility could help to increase revenues for struggling clinics, especially given the current financial crisis (see below), as well as improve access and quality of care for clients.

Another issue relates to the CHC and Medicaid requirements for using a pharmacy to fill prescriptions for contraceptives, whereas Title X stipulates that contraceptives be dispensed during the office visit. There is concern that, unless clients receive contraception directly from their clinician, they may not wait for the prescription to be filled. As a result, they may delay or avoid getting their prescription filled, increasing the risk of unintended pregnancy.

Lastly, Title X is the only program that formally emphasizes client education and counseling about family planning. Both CHCs and Medicaid should enhance family planning services by adopting the Title X education/counseling requirements.

Restricted Services Under the Medicaid Waiver Program

According to federal rules, individuals with third-party health insurance of any kind are disqualified from participation in the Medicaid Waiver program, even if that insurance exempts coverage of family planning services.[22] For those that do qualify for the waiver program, all clinical visits must be focused on contraception or infertility services. The Waiver program supports many other services considered standard care under Title X, such as a comprehensive physical exam; education and counseling; routine blood work; and testing for pregnancy, cervical cancer, and STDs.[22] However, there are limitations on the extent of coverage. The Medicaid Waiver allows only one pelvic exam per year and any return visit associated with contraception, but in many states will not cover the cost of diagnosis and treatment for an STD found during one of these return visits.[27] Currently, clinics use Title X and CDC funds to pay for some of the costs associated with STD-related services and dispense antibiotics purchased at a discount by the health department, but not all of the costs for the STD service maybe covered by these funds.

In addition, there is wide variability in access to emergency contraception (EC) under the waiver program. Some states do not cover EC, while others limit access through managed care programs, utilization controls, or prior authorization requirements, or based on the context of the clinic visit. In these instances, EC is provided to the client through Title X funds.[28]

In contrast, clients seen in CHCs may present for a certain condition but be treated for the wide spectrum of reproductive health services, including but not limited to receipt of contraceptives. Title X clients may present for any reproductive health issue (e.g., STD, pregnancy) and receive treatment as covered under Title X or be referred to an appropriate clinician for further care. There are no limits on the number of times that a client may request EC in either Title X clinics or CHCs.

RPCs and grantees stated that a more holistic view of care is needed with the Medicaid Waiver program—one that is reproductive health oriented versus just contraception oriented.

Impact of Medicaid Managed Care

In 1981, under Section 1915(b) of the Social Security Act, Congress authorized the Secretary of HHS to waive Medicaid provisions regarding free choice of provider so that state Medicaid programs could negotiate contracts with and require beneficiary enrollment in managed care organizations.[29] Over the course of the 1990s, almost all states shifted some or all of their Medicaid beneficiaries from traditional fee-for-service plans to Medicaid managed care plans.[30]

Although family planning services are generally considered to be primary care, such networks limit beneficiary choice and access to community-based providers of reproductive health services. For example, several states, most notably New York, entered into managed care contracts with religious plans that refused to include family planning services in their agreements. This left the states liable for coverage of family planning services through community-based providers as a direct medical assistance benefit.[29]

Congress amended the statute in 1986, effectively creating a "carve-out" that prohibits restrictions on managed care patients' choice of family planning providers.[31] However, the amendment has not achieved its goals of continued access to full family planning benefits because the Medicaid and other statutes did not define family planning services and supplies adequately such that it is possible to discern which managed care contract services would be subject to the free-choice rule and which would be subject to managed care network restrictions.[29] In addition, the statutes did not clarify the interpretation of important issues, for example, whether primary care gatekeepers would continue to have the authority to preauthorize services from a separate provider. As a result, the definition of family planning services and supplies was left to the states' discretion. This has resulted in variations in coverage and benefits from state to state.

As the Centers for Medicare and Medicaid Services (CMS) moves toward the medical home model of care coordination among providers, it is unclear how family planning services will be affected. Some states, such as Iowa, are developing collaborative networks of safety-net providers, including CHCs, free clinics, rural health clinics, family planning agencies, MCH clinics, and local boards of health, to ensure broad access to and coordination of care.[32] While family planning services are an included benefit under Medicaid rules, other states may promote use of primary care providers for such services. For example, South Carolina lists covered family planning services in its guide *Medical Homes Network: Policies and*

Procedures, which states: "Eligible beneficiaries should be encouraged to receive family planning services through their primary care provider or by the appropriate referral to promote integration/coordination of these services with their total medical care. However, eligible beneficiaries have the freedom to receive family planning services from any appropriate Medicaid providers without any restrictions."[33] Given the differences in approaches to Medicaid medical homes among the states, further research is needed to better assess the potential impact on beneficiary access to and confidentiality of family planning services.

Effect of Program Management and Funding on Clinical Services

Even with the limitations discussed above, the quality of care has not been affected by the current level of Title X funding. Yet there are mixed feelings about the scope of Title X services. Most RPCs and grantees believe that the scope of services is adequate and should not be increased or decreased. The current set of services is necessary to ensure quality of care and prevent downstream effects on patient health, as when a woman who comes to a Title X clinic for contraception has an STD. Furthermore, many women do not want their primary care/family practice physician to be their family planning provider. However, a few grantees felt that clinics are being asked to do too much, and this has been an issue for the past 20 years. Too many services have been added without enough funding. For example, a grantee may receive $5 million per year yet serve 150,000 patients a year, which amounts to $33 per patient.

If additional Title X dollars were available, grantees indicated an interest in using the funds to develop educational materials for clinics, provide continuing education in family planning and reproductive health to clinicians, and/or add colposcopy services.

In conclusion, those involved in the management and provision of Title X services believe that the program has served as an important safety net for millions of women, providing valuable assistance in family planning and reproductive health. The focus on quality of services, such as nonbiased, nondirectional counseling and preventive health screenings, has had a substantial impact on the lives of many people. In fact, for many women, Title X clinics are a first point of entry into the health care system. Thus, Title X is considered a critical public health program for reaching underserved populations.

However, all costs associated with Title X clinic operation continue to rise each year, while funding has remained relatively flat for several decades. Inadequate funding has significantly limited the ability of clinics to provide Title X services. Both RPCs and grantees estimate that, with current funding levels, they can meet only 45–50 percent of patient demand. Even those grantees participating in the Medicaid Waiver program are struggling to provide Title X services. One grantee estimated that, with the waiver program, only 56 percent of patient need is met. Many RPCs and grantees expressed concern about the ability to continue to provide quality services if prices continue to rise and funding remains stagnant.

In addition, when funding increases are available, grantee efforts must be directed at increasing the number of users rather than ensuring the sustainability of existing programs. For example, with the current supplemental expansion funds, some grantees can receive, at most, an additional $500,000 but must see an additional 2 million patients—an excessive requirement since they already cannot keep up with the rising costs to provide services. Moreover, the modest increases in funding seriously limit the ability of grantees to open new clinics to address unmet patient need in areas that currently do not provide Title X services.

Grantees/delegates stated that there is significant pressure on them to decrease program costs and, if necessary, eliminate aspects of their programs. For example, one grantee has not purchased patient educational materials in the past 6–7 years and recently went further by eliminating interpreter services ($40,000/year). Inadequate funding even has affected the willingness of some delegates/grantees to provide services. Some delegates/grantees, including some CHCs, have withdrawn from the Title X program as a result of limited funding and complexities involved in obtaining grants.

PRIORITY ISSUES

The main issues affecting clinic services are the cost of contraceptives and other supplies and provider recruitment and retention.

Cost of Contraceptives and Other Supplies

Currently, clinics can purchase contraceptives through HRSA's 340B program. Section 340B of P.L. 102-585 limits the cost of covered outpatient drugs to certain federal grantees (including Title X grantees), FQHC look-alikes, and qualified disproportionate-share hospitals.[16] Entities participating in the program may gain substantial savings on the cost of pharmaceuticals. However, one major drawback of the program has been the ability of pharmaceutical companies to change drug prices every quarter[m] at their own discretion. More often than not, companies have increased prices.

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[m] The 340B price for each drug can be recalculated by manufacturers on a quarterly basis. Manufacturers may lower a drug's price (below the ceiling) in the middle of a quarter, but may not raise a drug's price until the beginning of the next quarter.

Some pharmaceutical companies indicated a willingness to decrease the cost of contraceptives to pennies for low-income patients if the Title X clinic agreed to give all Medicaid patients prescriptions for contraceptives to be filled at Medicaid-approved pharmacies where they could obtain relative market prices for their products. However, several clinics did not accept this agreement because in effect, it would establish two tiers of treatment.

The continual increases in the cost of contraceptives have been the primary issue negatively affecting Title X patients who want to use birth control. The lack of funding limits the variety of contraceptive methods clinics can provide. For example, many clinics can afford to provide only oral contraceptives, even though a growing number of patients would like newer methods, such as the contraceptive patch, Depo-Provera contraceptive injection, or Implanon.

Grantees work diligently to prevent this situation and often will refer out a particular service (e.g., certain STD services, screening, and treatment) in order to supply different types of contraception. However, similar to the dilemma with contraceptives, clinics continuing to provide laboratory testing can afford to perform only certain types of tests (e.g., several clinics still are using traditional Pap smears even though newer, more accurate testing methods are available). In some instances, clinics have run out of money to pay for contraceptives (and other supplies, including laboratory tests) midyear because of unexpected increases in the following quarter. Also, the 2008 rise in gas prices resulted in fuel surcharges of $3.97 on every order of contraceptives, regardless of how many were ordered.

Those interviewed felt overwhelmingly that OPA should negotiate multiyear, national contracts for contraceptives. In addition, other critical public health–related medications should be available through Title X clinics, such as human papillomavirus (HPV) vaccines. All clinics participating in the Title X program should have the ability to purchase contraceptives at the negotiated rate. To date, OPA has not taken this route because, as most believe, certain reproductive health services, including provision of contraceptives, are politically charged. However, other federal government agencies, such as the Veterans Health Administration (VHA) and CDC, do negotiate national contracts for pharmaceuticals. The VHA negotiates prices for drugs listed on its formulary, including contraceptives. CDC has a national contract for azythromycin, used to treat chlamydia as part of its Infertility Prevention Program. Both the VHA and CDC contracts were suggested as possible models for Title X contracts.

Provider Recruitment and Retention

Currently, there is a shortage of nursing personnel for family planning programs. Physicians provide medical oversight, but midlevel practitioners (e.g., nurse practitioners, physician assistants) provide most Title X services. The recruitment and retention of nurse practitioners has been particularly difficult. Many private physician offices are hiring nurse practitioners and offer substantially higher salaries than public health programs. As a result, public-sector clinics cannot compete with private-sector salaries, especially in rural areas. Thus, as demand for private-sector nurse practitioners increases, the pool for Title X services has decreased.

Even public health departments are losing nursing staff. Historically, public health clinics were considered a desirable place to work because staff could work regular hours; however, the shift in salaries has created a lack of incentives to work in public health settings. Several states already have cut maternity care from health departments in order to conserve resources. This has affected the Title X program, as many of those patients would have come back to the health department for postpartum care and family planning services. Many health departments are left with individuals who do not quality for Medicaid.

Several other factors have the potential to significantly affect the Title X program. First, the pending new requirement that nurse practitioners obtain a doctorate of nursing practice likely will add to the financial burden on nursing personnel, who must pay for additional advanced education. It also may result in a loss of diversity in the types of providers involved in family planning. Second, pending retirements of family planning providers who have been in the field for 20–30 years will leave a large gap in the provider knowledge base. Third, when clinics loose nurse practitioners or other providers, it takes time to replace them, which can negatively affect the ability to provide services. Some clinics have had to close, and some have been taken over by FQHCs.

Because of the sizable increase in the number of FQHCs in recent years, there are fewer providers who have a family planning orientation. In particular, family planning services may receive inadequate attention from primary care providers who are not trained in the delivery of those services in a client-specific manner (i.e., using judgment to determine what is best and most appropriate for a specific person). While FQHCs used to employ nurses trained in reproductive health care, a growing proportion of these nurses are focused on other health issues (e.g., diabetes management) and may or may not be well versed in reproductive health services. This leaves grantees with concerns about whether women receiving Title X services will obtain the counseling and education they need. In addition, Title X grantees are concerned about their own ability to address public health issues (e.g., infectious disease) if they cannot attract family planning–specific staff.

Those interviewed would like to see OPA employ some of the federal government's strategies for recruiting and retaining health care workers, such as debt repayment, scholarship programs, payment supplements, grants, and continuing education funding. They also believe that it is worthwhile to consider how family planning fits within the context of the medical home model and whether there is a role for a targeted family planning program.

PROGRAM ADMINISTRATION

Copays and Sliding Fee Scale

The chief point of dissonance between Title X and other family planning programs, as well as across the spectrum of clinics operating within the Title X program, pertains to differing sliding fee schedules. Table J-4 illustrates the many different fee schedules related to family planning services in California.

Both Title X clinics and CHCs prohibit charging clients at or below 100 percent of the federal poverty level. However, Title X charges clients the full fee at 250 percent of that level, whereas CHCs charge the full fee at 200 percent of that level. Within their respective schedule ranges, both Title X clinics and CHCs can develop their own schedule of discount rates as long as there are sufficient increments. As a result, there are a multitude of different fee schedules for each program. For the Title X schedule of discounts (ranging from 100 to 250 percent of the federal poverty level), some clinics have implemented 10 percent increments, while others have implemented 20 percent or 25 percent increments; a similar approach is used by CHCs for their discount range (100–200 percent of the federal poverty level). Unlike Title X, CHCs are required to charge a copay at each visit. All third-party payers (Medicaid and private insurance) are billed the full amount by either Title X clinics or CHCs.

Challenges in coordination are most evident when a CHC receives supplemental funding for Title X services. These CHCs must operate with two different fee schedules as they are prohibited from implementing the Title X fee schedule according to federal rules. If 50 percent or more of the clinic visit is dedicated to family planning, then the visit must be billed under Title X funds. It is quite time-consuming to go through this process.

Documentation Requirements

Another key area of contention among the different funding sources of family planning programs is the wide variation in documentation requirements related to income, residential address, and citizenship. More specifically, Title X asks individuals to self-certify their income status at the point of service. Recently, OPA issued allowances for use of documentation from participation in other federal social services programs for which citizenship

TABLE J-4 Example of Different Requirements Governing Copays and the Sliding Fee Scales for Funding Sources of Family Planning Programs in California

Required	Optional	Prohibit Charge
Medi-Cal managed care based on income*	Out-of-pocket paying clients >100 percent of federal poverty level	F-PACT (CA 1115 Medicaid Waiver)
Medi-Cal fee for service (with share of cost requirements)*	Expanded Access to Primary Care (EAPC), depending on agency	Local county programs (public–private partnership, Los Angeles only)
Medicare (seniors do not need family planning, but may qualify for STD services)		Title X at ≤100 percent of federal poverty level
Other private insurance		Medi-Cal fee for service (except for those who must meet share of cost requirements first)*
Federal 330 clients >100 percent of federal poverty level		

*Medi-Cal is Medicaid in California.

is a condition for receipt of benefits (e.g., Women, Infants, and Children [WIC]). The federal 330 program requires proof of income (e.g., pay stub [last 30 days], income receipt, tax form), proof of current address (e.g., driver's license, last utility bill, rent receipt), and dependent information if applicable.[23] Title X and federal 330 statutes do not require proof of U.S. citizenship.

The most extensive documentation requirements are associated with the Medicaid Waiver program. Historically, Medicaid did not require proof of U.S. citizenship. However, the 2005 Deficit Reduction Act codified new regulations requiring proof of U.S. citizenship as a condition for Medicaid eligibility for both adults and teens.[26] Acceptable documentation for verification of U.S. citizenship may include a valid birth certificate and photo ID,[n] social security number (SSN), passport, or certificate of naturalization. CMS has written into the rules a 90-day presumptive eligibility clause that permits clinics to serve clients waiting for verification if not readily available. The one exception to this requirement applies to low-income women during pregnancy, including those undocumented.

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[n] Acceptable photo identification includes driver's license, state or federal identification card, military or merchant marine identification card, or Native American tribal documents.

Some grantees report substantial expansion of resources and service hours with implementation of the Medicaid Waiver program. Yet without the citizenship requirement, they believe that they could serve even more clients, creating greater overall cost savings (as it is less expensive to provide contraception than to pay for unplanned pregnancies, whether a woman is a U.S. citizen or not).

Increases in utilization have not been reported for all grantees. The key issues are the ability to navigate the system and access to documentation to meet program requirements. For example, one grantee (state department of health) noted a 30 percent decrease in utilization of the family planning clinic with implementation of the Medicaid Waiver program (and associated documentation requirements). Some of the decrease is attributed to first-time and re-enrolling individuals that often wait up to 6 weeks to receive their Medicaid card. To address the coverage gap during the waiting period or the possibility that documentation will not materialize, this grantee implemented an innovative program whereby state general funds are set aside to cover family planning services. In addition, the family planning clinics have access to the state's Bureau of Health Statistics online and can verify citizenship status for those born in the state. If the individual was born out of state, the Bureau acts as liaison and pays for the cost to obtain a birth certificate from the other state. While waiting for their birth certificate, clients may make a one-time-only clinic visit and receive a 30-day supply of contraception. About 30 percent of individuals receiving contraception return for a follow-up visit, while 70 percent return when they receive their birth certificate.

According to grantees, the Medicaid Waiver documentation requirements also have had a significant effect on teenagers who use clinic services. Teenagers often do not have documentation (e.g., their SSN) and do not know how to get it without asking their parents. Those who previously used the clinic without documentation may have told their friends that they could no longer receive services unless they had their birth certificate or SSN, contributing to the decline in utilization. To address this problem, clinics guide students in obtaining their documentation by having them go to the school office and request their records with their SSN since they have a legal right to view their records at any time.

Coverage Verification

Verification of third-party insurance coverage can be challenging for Title X clinics. Patients may be on/off an insurance plan from month to month depending on whether they pay the premium. Moreover, different carriers have different rules for switching providers (some are same day, while others require 30 days), and most clients do not know the details of their coverage. Thus, clinic staff must check clients' status each time they visit the clinic (as is the case with most providers). However, for small, underfunded, understaffed clinics, this can be a cumbersome and time-consuming process, requiring training of front desk staff and constant updates of the clinic computer system. Most grantees do not generate enough private-sector payments to warrant having staff dedicated to this task. Thus, many clinics just bill the insurer and hope to be reimbursed instead of calling to verify every patient. Greater attention is needed to organizing and determining payer mix and how it relates to client mix.

Parental Consent

Some states require parental consent for use of services under the federal 330 program; however, such consent is prohibited under Title X. A few CHCs have created a "work-around" by keeping the family planning clinic separate from the rest of CHC services. These CHCs have instituted policies and procedures to support this separation of services. For example, there is no blending of visits—billing must be completely closed out for one set of services and reopened for the other set of services.

REPORTING REQUIREMENTS

Reporting requirements are different for each federal program. Electronic reporting allows for mixing and matching of data elements for simplification of reporting to all. Specifically, computerized information systems have made it possible to consolidate Title X clinic data for the FPAR. Electronic practice management systems ensure that information is accurate and can be used to generate various reports for different agencies as needed. Some smaller clinics still collect data by hand and report manually.

Title X is the only program that requires reporting on family planning; STD data are reported to CDC. Duplication in reporting on family planning services may occur only when data for CHCs and Title X are contained in the same report. In comparison, each state may have different requirements for reporting on its Medicaid Waiver program. Typically, RPCs remain focused on Title X reporting but assist grantees in managing all reporting requirements if requested.

RECOMMENDATIONS

The RPCs and grantees interviewed for this study offered two recommendations for improving coordination among family planning programs.

1. *Promote the broader view of reproductive health vs. contraceptive use.*

To facilitate higher-quality care, CHCs and the Medicaid Waiver program should adopt the Title X approach to comprehensive family planning. For the most part, CHCs do provide comprehensive clinical services, yet they could improve in their emphasis on client education and counseling. Similarly, the Medicaid Waiver program needs to expand coverage beyond a single pelvic exam and visits for contraceptives to the broader view of comprehensive reproductive health. Adoption of such an approach would support not only higher-quality care but also public health.

2. *Convene a meeting of all family planning funding sources to improve coordination and identify ways of streamlining certain regulations and requirements.*

At such a meeting, each funding source could provide an overview of its program, services covered, regulatory requirements, and key issues.[o] A strategic planning session could identify areas of potential harmonization. The outcome of the meeting could be presented at the OPA-sponsored annual regional meeting for Title X.

In particular, participants in the proposed meeting could identify and agree on adoption of certain approaches throughout their respective programs. Some examples include methods of classification by age group and common budget forms. Simple adjustments such as these would make it easier for grantees to apply for grants, enhance the quality of applications, and increase applicants' familiarity with forms and processes.

The meeting also would serve as a forum to discuss possibilities for streamlining more significant policies and regulations. For example, in California, anyone aged 12 or older has access to family planning without parental consent. Ideally, this policy should be standard for all programs to enhance client education and access to care. Another topic for discussion would be the ability to verify citizenship for Medicaid eligibility at the point of care. Currently, only one state has developed a program for point-of-care verification for those born in the state. Adoption of this approach broadly in all Title X clinics and CHCs could facilitate access to care. A third topic could be expanded, joint funding and implementation of health promotion and educational campaigns such as those targeted toward prevention of unintended pregnancies and STDs. Fourth, participants could discuss the advantages and disadvantages of shifting to the same fee schedule (e.g.,

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[o] One grantee disagreed with this recommendation, citing past experiences when the federal government "got too involved in family planning."

same copay or no copay) and the legislative and policy changes needed to implement such a schedule. Fifth, it would be useful to discuss strategies certain CHCs have used for effective implementation of Title X to assist those CHCs that have been most challenged.

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ANNEX J-1

GRANTEE SITE VISIT TOOL

AGENCY SITE REVIEW RESULTS & ACTION PLAN

Agency ______________________ **Clinic Site** ____________________

Site Contact _________________________**Date of Visit** __________________

Reviewer(s) ____

Summary Report of (Check One): Delegate Agency Site Review ___ Satellite Site Review ___ Self-Review___

Programs Reviewed (Check all that apply): Family Planning ___ Circle of Care ___ HWP ___ HRC ___

	Observation
Areas of Commendation:	

Areas of Non-Compliance:	Observation	Action Plan	Reevaluation Timeline

	Observation	Response
Auditor Recommendations:		

Client Survey

Patient Name ***(Optional)***: ________________________ **Clinic Name**: ________________________ **Date**: _________

Client feedback is one way for clinics to make changes to improve the quality of care for the services they provide. Please fill out this survey and make comments if needed. Your responses are anonymous and will be treated in confidence.

For the following questions please ✎ your response *in the box that best fits your opinion.*	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The staff is friendly.					
The staff treats you with respect.					
The staff has a professional appearance.					
The staff wears nametags.					
The staff knows what they are talking about.					
The staff does not judge you.					
You are able to get the services you want.					
You got all the information needed.					
The staff explains things in a way you can understand.					
You know what to expect during a visit or exam.					
The staff takes time to listen to you.					
The staff pays attention to what is important to you.					
The staff explains what happens during a physical exam or test.					
The clinic is clean.					
There are good magazines and reading material.					
The clinic has convenient hours.					
The clinic lets you walk in for emergencies.					
It’s easy to make an appointment at the clinic.					
It’s easy to communicate with staff people on the phone.					
You don’t have to wait too long in the waiting room.					
You don’t have to wait too long in the exam room.					
The staff respects your privacy.					
The paperwork is explained to you.					
You would return to this clinic.					
You would recommend this clinic to your family/friends.					
You know when you are supposed to return to the clinic for another visit.					
The fees at this clinic are affordable.					

Comments: ____

Clinical Environment & Systems

Auditor Name: ____________________________ Clinic Name: _________________________ Client #__________

STAFFING	**Y**	**N**	**N/A**	**Comments**
Does Medical Director hold valid PA license to practice medicine? {ERR}				
Are there collaborative practice agreements in place between medical director and CRNPs? {ERR}				
Is there a documented system in place to ensure clinicians are credentialed for Colposcopy? {PR}				
Are clinicians being evaluated *clinically* on an annual basis? {PERR}				
Employee records kept confidential? {DO}				
Are the Rubella and Hepatitis B Vaccinations provided for all clinical staff? {ERR}				

Do personal records contain at a minimum: {ERR} [] Job description [] Valid license and / or certification (if applicable)? [] Current annual performance evaluation signed by employee [] Resume or application [] Documentation that personnel policies/procedures were received? [] Training/continuing education information? [] Wage and salary information, including all changes? [] Evidence of personnel actions (e.g., promotion, disciplinary action, termination)? [] Routinely trained regarding HIPPA compliance? [] Staff trained in CPR	**Comments**
Is there documentation in employee records ensuring staff are aware of meet Title X regulations regarding client participation. {ERR} [] Voluntary basis [] Not subjected to coercion to use any specific method [] Acceptance of service not a prerequisite to get non Title X funded services [] Personnel subject to prosecution if they coerce client to have abortion or be sterilized	*Comments*

Key: {ERR}= Employee Record Review, {PR} = Policy Review, {RR} = Record Review, {DO} = Direct Observation,
{PERR} = Policy & Employee Record Review

Additional Comments:
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____
____

POLICIES & PROCEDURES	**Y**	**N**	**N/A**	**Comments**
Is there a Family Planning Council Polices & Procedure (P&P) Manual on site? {DO}				
Is there evidence that the Medical Director has Signed off on P&P Manual updates? {RR}				
Is there a mechanism in place to ensure P&P updates are regularly reviewed with staff? {I}				
Is there a written policy regarding referrals? {RR}				
Physician on site or protocol in place if IM antibiotics given? {RR}				

SERVICE ACCESS	**Y**	**N**	**N/A**	**Comments**
Is there Signage posted regarding the clinic's days/hours of operation? {DO}				
Is a "Patient's Bill of Rights" posted? {DO}				
Does the agency have a system in place for collecting client feedback? {I}				
Is there Signage posted stating a client's inability to pay does not effect their receipt of service ? {DO}				
Does the agency have access to staff/services for various client language needs? {I}				
Are the next available appointments for the following services in compliance with FPC guidelines? {DO} [] Family planning (14 calendar days) [] Emergency contraception (3 calendar days) [] Pregnancy testing (7 calendar days)	*Comments*			
How are client walk-ins handled? {I}				
What mechanism is in place to contact clients that missed appointment? {I}				
Is the clinic accessible to handicapped clients? {DO}				

Key: {ERR}= Employee Record Review, {PR} = Policy Review, {RR} = Record Review, {DO} = Direct Observation,
{PERR} = Policy & Employee Record Review, {I} = Interview

Additional Comments:

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LABORATORY FOLLOW-UP	**Y**	**N**	**N/A**	**Comments**
Other than the client chart, where are laboratory test results noted (log, computer, other)? {I}				
What is the process if no laboratory test results are received by the clinic from the laboratory? {I}				
Is a system in place to track clients with abnormal lab test results? {DO} [] How does this compare to the FPC Policy? [] Are client charts flagged for abnormal results in any way				
Are clients with abnormal test results receiving at least 3 attempts at making lab follow-up contact (as per FPC Policy)? {DO}				
Is agency identifying and properly managing clients who request **"NO CONTACT"** or **"CONFIDENTIAL CONTACT"**? {I}				

CONSULTATION FOLLOW-UP	**Y**	**N**	**N/A**	**Comments**
Does agency have the ability to both identify the Need for and refer clients for: [] Prenatal care [] Abortion [] Adoption [] Mental health [] Anonymous HIV testing [] High blood pressure [] Domestic violence [] Substance abuse [] Smoking cessation [] Genetic counseling [] Sex coercion	*Comments*			
What is the process if consultation reports are not received? {I}				
Is a release of medical records routinely obtained? {I}				

GERNERAL FOLLOW-UP	**Comments**
Is there a system to track clients who need: {I} [] Deferred exams F/U for no-shows [] Depo Shot [] IUD removal after 12 years (Mirena = 5 years)	

Key: {ERR}= Employee Record Review, {PR} = Policy Review, {RR} = Record Review, {DO} = Direct Observation,
{PERR} = Policy & Employee Record Review, {I} = Interview

Additional Comments:

TELEPHONE TRIAGE	**Y**	**N**	**N/A**	**Comments**
Are telephone contacts documented in the chart?{I}				
How are incoming phone calls triaged? {I}				
After clinic hours? {I}				

CLIENT FORMS	**Comments**			
Education Materials/Handouts {DO} [] All method information [] Anatomy and Physiology [] STD/HIV [] BSE/TSE				
FPC Educational Formulary available onsite or by computer access {DO}				
Educational materials are reviewed/updated annually {I}				
Required consents {DO} [] PVA/General Consent [] HIPAA [] Method Specific [] HIV Testing	*Comments*			
Literature is in the client's primary language {DO}				

EQUIPMENT / SUPPLIES	**Comments**
Exam Room {DO} [] Drapes and gowns [] Light source [] Exam table [] Waste receptacle contaminated [] Waste receptacle non-contaminated [] Gloves/Lubricant [] Specula [] IUD equipment [] Diaphragm fitting rings	

Key: {ERR}= Employee Record Review, {PR} = Policy Review, {RR} = Record Review, {DO} = Direct Observation, {PERR} = Policy & Employee Record Review, {I} Interview

Additional Comments:

EQUIPMENT / SUPPLIES	Y	N	N/A	Comments
Contraceptive Supplies {DO} [] Birth control pills [] IUDs [] Emergency post coital pills [] Diaphragms [] Foams, VC Film, creams, jellies, sponges, etc. [] Condoms (male and female) [] NFP Materials [] Patch []Ring	*Comments*			
Do repackaged Pharmaceuticals have a standard label which includes: {DO} [] Name of drug [] quantity of drug [] strength of drug, [] expiration date, [] name and address of agency [] manufacturer's drug lot number	*Comments*			
Drug is repackaged with: {DO} [] Date of RX, [] name of patient [] directions for use [] name of prescriber	*Comments*			
Drug Logs {DO}				
Controlled substances monitored {DO}				
Supply/Drug area secured {DO}				
Prescription blanks are stored in locked area. {DO}				
An up-to-date PDR is easily accessible. {DO}				
Pharmaceutical Recall Protocol. {I}				
Miscellaneous Supplies {DO} (Accounted for and calibrated) [] Scale [] Centrifuge [] Refrigerator [] Autoclave [] Incubator [] Microscope [] BP Cuffs	*Comments*			

Key: {ERR}= Employee Record Review, {PR} = Policy Review, {RR} = Record Review, {DO} = Direct Observation,
{PERR} = Policy & Employee Record Review, {I} = Interview

Additional Comments:
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LABORTORY	**Y**	**N**	**N/A**	**Comments**
Dept of Health & Clinical Laboratory Improvement Amendants (CLIA)? {DO} *CLIA certificate should be displayed at every* Site (even though only the primary location is *listed on certificate)*				
Original Commonwealth of PA Clinical Lab Permit onsite (Each site should have their own) {DO}				
Needles/sharps disposal {DO}				
Lab cleaning and decontamination supplies {DO}				
Incubator temperature log {DO}				
Pregnancy testing equipment control and long (Weekly controls unless part of the rest) {DO}				
Urinalysis control and log (Weekly controls) {DO}				
Hemoglobin control and log (Daily controls) {DO}				
Refrigerator temperature log {DO}				
Spill clean-up policy {RR}				
Staff routinely trained regarding OSHA compliance? {DO}				
Does agency have: {RR} [] Written policy for occupational exposure? [] Is it reviewed w/staff annually? [] Accessible to employees?	*Comments*			
Food and drink in separate areas from blood and infectious materials? {DO}				
Staff protection {DO} [] Lab coats or protective clothing [] Masks [] Sink/bactericidal soap for hand washing	*Comments*			

EMERGENCY EQUIPMENT	**Y**	**N**	**N/A**	**Comments**
Written Emergency plans {RR}				
Infection control policy including guidelines for Needle stick injuries {RR}				
Ambulance/hospital back-up system {I}				
Emergency equipment/drug (present, up to date, adequate, available {DO} [] Ammonia inhalants [] IV Fluid/Pole [] Oral airway [] Tourniquet [] Syringes & Needled [] Epinephrine/Benadryl [] Mouthpiece or ambu bag [] BP Cuff [] Stethoscope [] Fire Extinguishers				
	Comments			
Periodic emergency drills documented {RR}				

Key: {ERR}= Employee Record Review, {PR} = Policy Review, {RR} = Record Review, {DO} = Direct Observation,
{PERR} = Policy & Employee Record Review, {I} = Interview

Counseling & Physical Exam Audit

Auditor Name: __________________________Clinic Name: _______________________ Client # ___________

COUNSELING

For each question ✍ all boxes that apply. Give comments if needed.	***Yes***	***No***	***N/A***	***Comments***
Did staff introduce themselves to client and call the client by name? {DO}				
Did staff attempt to assess client's level of understanding regarding information presented? {DO}				
Was **client centered** information provided to the client either verbally or in writing? {DO} [] BSE or TSE [] Reproductive anatomy and physiology [] Preconception health/pregnancy planning [] Cervical screening info as per national guidelines [] Pelvic Exam/pap test [] Drugs/Smoking/Alcohol [] Abstinence [] BCMs [] ECPs [] Safer sex [] HIV/STDs [] Intimate partner violence				*Comments:*
If client has substance abuse problem, and substance is injected, was safer injection/needle exchange discussed? {COC/HIVQUAL} {DO}				*Comments:*
Were teen issues covered as appropriate? {DO} [] Explained PE procedures [] Sex development [] Parental /family involvement [] Sexual coercion [] Info on Pap screening according to national guidelines				*Comments:*
For method of choice, were the following things reviewed? {DO} [] Method specific consent [] Usage & back up plans [] Side effects & contingency planning [] Danger signs [] Follow up schedule[] Use of method and STD/HIV prevention [] Emergency contraception				*Comments:*

Were services offered and provided in the client's preferred language? {DO}				
Did client complete an informed consent form? {DO}				
Was an attempt made to assess the client's understanding of information presented? {DO}				
Was the client's next routine appointment given? {DO}				
Did a licensed practitioner do a mental health assessment during the 12 – month period? {COC/HIVQUAL} {DO}				
Was medication adherence discussed with client? {COC/HIVQUAL} {DO}				
Was client based STD/HIV risk assessment & counseling done within past 12 – months? {COC/HIVQUAL} {DO}				

KEY: {DO} = Direct Observation, {COC/HIVQUAL} = Circle of Care

Additional Comments:

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LABORATORY

For each question ℘ all boxes that apply. Give comments if needed.	***Yes***	***No***	***NA***	***Comments***
Was a lab coat worn? {DO}				
Was client weight assessed? {DO}				
Was client's height assessed? {DO} (1st visit and method visit)				
Was client's BMI assessed? {DO}				
Was client's blood pressure assessed? {DO}				
Did staff wear gloves when working with client body fluids (blood, urine)? {DO}				

PHYSICAL EXAMINATION

For each question ℘ all boxes that apply. Give comments if needed.	***Yes***	***No***	***NA***	***Comments***
Did the clinician review the chart prior to seeing the client? {DO}				
Was the client's {DO} [] Thyroid assessed? [] Heart/Lungs assessed? [] Extremities assessed?	*Comments:*			

Did the client receive a breast examination? {DO} (if appropriate)				
Was the client's abdomen palpated? {DO} (if appropriate)				
Did the client receive (if appropriate) {DO} [] A pelvic exam [] A cervical cytology [] A bimanual exam [] Cultures and/or wet mount [] Viral load count [] Mammogram [] LEEP/ Colposcopy [] Breast U/s	*Comments:*			

FOLLOW-UP / DOCUMENTATION

For each question ✍ all boxes that apply. *Give comments if needed.*	***Yes***	***No***	***NA***	***Comments***
Following the exam were: {DO} [] Findings shared and explained? [] Instructions for treatment and/or follow-up given? [] Instructions for action to be taken in the event of a method or treatment problem? [] Processes of notification for normal and abnormal labs reviewed?			*Comments:*	
Did patient have the opportunity to have his/her questions addressed? {DO}				
Does the medical record correlate with the observation? {DO&CR}				

KEY: {DO} = Direct Observation, {CR} = Client Record

Medical Chart Review

Auditor Name: ______________________Clinic Name: ______________________ Client # ___________

CHART FORMAT	Y	N	N/A	Comments
Is the medical record legible? {RR}				
Is the medical record orderly and is information easily accessible? {RR}				
Are all visits/contacts noted dates and staff signatures? {RR}				

CONSENT FORMS	Y	N	N/A	Comments
Is a signed consent for exam and laboratory procedures present? {RR}				
Is a signed consent for the HWP present? {RR}				
Is a signed method specific consent for birth control present? {RR}				
Is a signed consent for HIV testing present? {RR}				
Is a signed HIPPA consent present? {RR}				
Is the medical/family history updated annually? {RR}				

CONTACT INFORMATION	Y	N	N/A	Comments
Is the client's contact information obtained & reviewed annually? {RR}				
Is there a documented method for confidential contact? {RR}				
Is the emergency contact information documented and updated annually? {RR}				

FEE ASSESSMENT	Y	N	N/A	Comments
Is the client's financial information kept in a separate portion of the medical record? {RR}				
Is the client's income information documented and updated at each visit? **HWP- Annually** {RR}				

Key: {RR} = Record Review, {HWP} = Healthy Women Program

Additional Comments:

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ANNEX J-2

GRANTEE CLINICAL VISIT RECORD

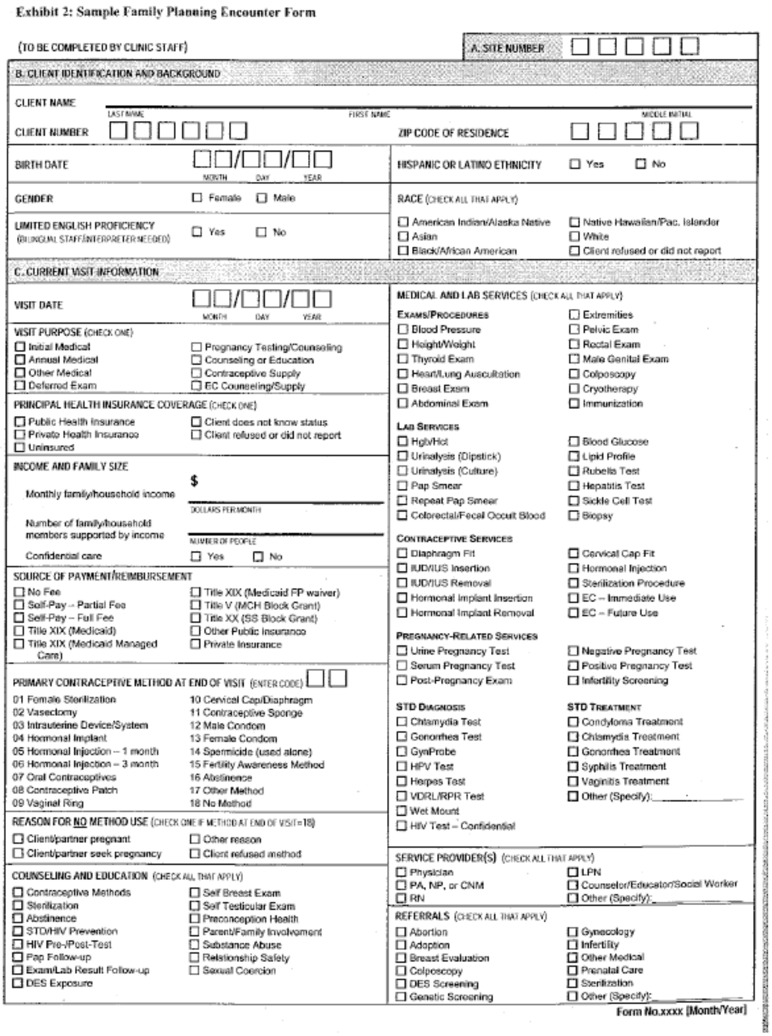

Exhibit 2: Sample Family Planning Encounter Form

(TO BE COMPLETED BY CLINIC STAFF)

A. SITE NUMBER ☐☐☐☐☐

B. CLIENT IDENTIFICATION AND BACKGROUND

CLIENT NAME ____________________
LAST NAME FIRST NAME MIDDLE INITIAL

CLIENT NUMBER ☐☐☐☐☐☐

ZIP CODE OF RESIDENCE ☐☐☐☐☐

BIRTH DATE ☐☐/☐☐/☐☐
MONTH DAY YEAR

GENDER ☐ Female ☐ Male

LIMITED ENGLISH PROFICIENCY (BILINGUAL STAFF/INTERPRETER NEEDED) ☐ Yes ☐ No

HISPANIC OR LATINO ETHNICITY ☐ Yes ☐ No

RACE (CHECK ALL THAT APPLY)
☐ American Indian/Alaska Native
☐ Asian
☐ Black/African American
☐ Native Hawaiian/Pac. Islander
☐ White
☐ Client refused or did not report

C. CURRENT VISIT INFORMATION

VISIT DATE ☐☐/☐☐/☐☐
MONTH DAY YEAR

VISIT PURPOSE (CHECK ONE)
☐ Initial Medical
☐ Annual Medical
☐ Other Medical
☐ Deferred Exam
☐ Pregnancy Testing/Counseling
☐ Counseling or Education
☐ Contraceptive Supply
☐ EC Counseling/Supply

PRINCIPAL HEALTH INSURANCE COVERAGE (CHECK ONE)
☐ Public Health Insurance
☐ Private Health Insurance
☐ Uninsured
☐ Client does not know status
☐ Client refused or did not report

INCOME AND FAMILY SIZE

Monthly family/household income $ ____________________
DOLLARS PER MONTH

Number of family/household members supported by income ____________________
NUMBER OF PEOPLE

Confidential care ☐ Yes ☐ No

SOURCE OF PAYMENT/REIMBURSEMENT
☐ No Fee
☐ Self-Pay – Partial Fee
☐ Self-Pay – Full Fee
☐ Title XIX (Medicaid)
☐ Title XIX (Medicaid Managed Care)
☐ Title XIX (Medicaid FP waiver)
☐ Title V (MCH Block Grant)
☐ Title XX (SS Block Grant)
☐ Other Public Insurance
☐ Private Insurance

PRIMARY CONTRACEPTIVE METHOD AT END OF VISIT (ENTER CODE) ☐☐
01 Female Sterilization
02 Vasectomy
03 Intrauterine Device/System
04 Hormonal Implant
05 Hormonal Injection – 1 month
06 Hormonal Injection – 3 month
07 Oral Contraceptives
08 Contraceptive Patch
09 Vaginal Ring
10 Cervical Cap/Diaphragm
11 Contraceptive Sponge
12 Male Condom
13 Female Condom
14 Spermicide (used alone)
15 Fertility Awareness Method
16 Abstinence
17 Other Method
18 No Method

REASON FOR <u>NO</u> METHOD USE (CHECK ONE IF METHOD AT END OF VISIT=18)
☐ Client/partner pregnant
☐ Client/partner seek pregnancy
☐ Other reason
☐ Client refused method

COUNSELING AND EDUCATION (CHECK ALL THAT APPLY)
☐ Contraceptive Methods
☐ Sterilization
☐ Abstinence
☐ STD/HIV Prevention
☐ HIV Pre-/Post-Test
☐ Pap Follow-up
☐ Exam/Lab Result Follow-up
☐ DES Exposure
☐ Self Breast Exam
☐ Self Testicular Exam
☐ Preconception Health
☐ Parent/Family Involvement
☐ Substance Abuse
☐ Relationship Safety
☐ Sexual Coercion

MEDICAL AND LAB SERVICES (CHECK ALL THAT APPLY)

EXAMS/PROCEDURES
☐ Blood Pressure
☐ Height/Weight
☐ Thyroid Exam
☐ Heart/Lung Auscultation
☐ Breast Exam
☐ Abdominal Exam
☐ Extremities
☐ Pelvic Exam
☐ Rectal Exam
☐ Male Genital Exam
☐ Colposcopy
☐ Cryotherapy
☐ Immunization

LAB SERVICES
☐ Hgb/Hct
☐ Urinalysis (Dipstick)
☐ Urinalysis (Culture)
☐ Pap Smear
☐ Repeat Pap Smear
☐ Colorectal/Fecal Occult Blood
☐ Blood Glucose
☐ Lipid Profile
☐ Rubella Test
☐ Hepatitis Test
☐ Sickle Cell Test
☐ Biopsy

CONTRACEPTIVE SERVICES
☐ Diaphragm Fit
☐ IUD/IUS Insertion
☐ IUD/IUS Removal
☐ Hormonal Implant Insertion
☐ Hormonal Implant Removal
☐ Cervical Cap Fit
☐ Hormonal Injection
☐ Sterilization Procedure
☐ EC – Immediate Use
☐ EC – Future Use

PREGNANCY-RELATED SERVICES
☐ Urine Pregnancy Test
☐ Serum Pregnancy Test
☐ Post-Pregnancy Exam
☐ Negative Pregnancy Test
☐ Positive Pregnancy Test
☐ Infertility Screening

STD DIAGNOSIS
☐ Chlamydia Test
☐ Gonorrhea Test
☐ GynProbe
☐ HPV Test
☐ Herpes Test
☐ VDRL/RPR Test
☐ Wet Mount
☐ HIV Test – Confidential

STD TREATMENT
☐ Condyloma Treatment
☐ Chlamydia Treatment
☐ Gonorrhea Treatment
☐ Syphilis Treatment
☐ Vaginitis Treatment
☐ Other (Specify): ____________

SERVICE PROVIDER(S) (CHECK ALL THAT APPLY)
☐ Physician
☐ PA, NP, or CNM
☐ RN
☐ LPN
☐ Counselor/Educator/Social Worker
☐ Other (Specify): ____________

REFERRALS (CHECK ALL THAT APPLY)
☐ Abortion
☐ Adoption
☐ Breast Evaluation
☐ Colposcopy
☐ DES Screening
☐ Genetic Screening
☐ Gynecology
☐ Infertility
☐ Other Medical
☐ Prenatal Care
☐ Sterilization
☐ Other (Specify): ____________

Form No.xxxx [Month/Year]

Appendix K

Measurement of Quality in the Title X Family Planning Program

Kimberly D. Gregory, M.D., M.P.H.

SUMMARY

There exist a solid evidence base for quality domains and an extensive list of potential indicators that can be used to measure quality performance in family planning programs. The *Family Planning Annual Report* (FPAR), the Family Planning Council of America Performance Monitoring System (FPCA), and Healthy People 2010 reproductive health goals are explicitly specified indicators representative of the more than 200 indicators that have been suggested in this arena. There is some consistency (or overlap) in indicators among these documents, and several of the indicators reflect goals adopted by external agencies, such as the Healthcare Employer Data and Information Set (HEDIS) measures espoused by the National Center for Quality Assurance (NCQA) (specifically breast and cervical cancer screening and screening for chlamydia). Two obvious deficiencies in the currently reported measures are:

- The lack of outcome data that are patient-specific about reproductive desires (specifically Helping patients Achieve their Reproductive Intentions [HARI]; patients should *plan for* pregnancy as well as *plan to prevent* pregnancy).
- The lack of data on provider competency and interpersonal skills or client comprehension/literacy.

The Title X program mandate specifies three long-term measures that are to be reported annually: (1) increasing the number of unintended preg-

nancies averted by providing Title X family planning services; (2) reducing infertility among women attending family planning clinics by identifying chlamydia infection; and (3) reducing invasive cervical cancer among women attending family planning clinics. Additional pertinent indicators include screening for other sexually transmitted diseases (STDs) that are treatable and preventable and have significant maternal and perinatal long-term implications (syphilis, gonorrhea, HIV). Available monitoring systems adequately address these indicators.

Future primary data collection efforts should include the following patient-centered priorities:

- Patient-specific reproductive desires/outcomes. Instead of counting visits and number of new visits, the focus should be changed to:
    - HARI: What are pregnancy plans for the year? Among those making a repeat visit, have these goals been met?
    - Percent clients not pregnant at next visit (denominator: those planning contraception)
    - Percent clients still using any method
    - Percent referrals for pregnancy termination or percent referrals for prenatal care for unintended pregnancy
    - Percent pregnant who desired pregnancy
- Patient-specific evaluation of the quality of information provided
    - Technical competence and interpersonal skills of provider
    - Client comprehension (health literacy)

This appendix addresses the measurement of the quality of reproductive health services provided under the Title X program. The discussion includes an assessment of how well the FPAR measures quality, a description of quality initiatives undertaken by family planning programs, and consideration of how the quality of services should be assessed in various settings. An assessment of the costs and benefits associated with introducing quality measures into family planning clinics is beyond the scope of this discussion because of the limited data available to inform such an assessment.

OVERVIEW OF FINDINGS AND RECOMMENDATIONS

To assess quality, there must be consensus on what quality is (e.g., how it is defined), as well as agreement on what measures are to be used to monitor and report quality. Several definitions of quality are pertinent, including those of the Institute of Medicine (IOM) and the World Health Organization (WHO) (WHO, 1998; IOM, 2001). Both emphasize proper performance of care based on current standards and knowledge, recognizing the potential for individual and societal benefit. Judith Bruce offers a family planning–specific definition of quality: "providing a range of services that are safe, effective, and that satisfy clients' needs and wants" (Bruce, 1990). For this study, the author performed a focused review of the literature and evaluated the FPARs for 2001–2006 (Frost, 2001, 2002, 2003; Frost and Frohwirth, 2005; Fowler et al., 2006; RTI International, 2006), the Title X Program Assessment Rating Tool (PART) evaluation (OMB, 2005), and an advance copy of the FPCA proposed Performance Measurement System (FPCA, 1999).

This review led to the conclusion that a full assessment of the quality of the Title X program cannot be performed at this time. Based on the limited information available, primarily the 2005–2006 FPARs, the program does appear to be doing what it set out to do; however, the extent to which its services are underused, overused, or used inappropriately (measures of poor quality) cannot be determined from these reports. Whereas the readily apparent structure and process variables appear to have face and construct validity, the outputs and outcomes need further clarification. Regional and/or population data are needed to support any claim for program effects. Think tanks and advocacy groups, such as the Alan Guttmacher Institute and the Center for Reproductive Rights, believe there is a logic model to support a causal link between family planning services and pregnancies averted and dollars saved (Center for Reproductive Rights, 2004; Dreweke, 2006). Evidence of such program impact would clearly help advance the policy mandate for more funding, more marketing, and the development of more meaningful indicators to advance the reproductive health agenda.

While there are substantial data to support a framework for both quality assessment and program evaluation within the family planning field, there are limited data on the quality of national family planning services, and there does not appear to be a national consensus about the quality domains or quality indicators that should be routinely (or periodically) monitored and reported. There is a tendency to count resources, visits, and tests, with less energy directed toward capturing data on intermediate effects or long-term impact, such as pregnancies prevented (or planned) or overall reduction in population fertility rates or STD rates.

Surprisingly, the lack of data on the quality of family planning services in the United States in general and under Title X in particular is not due to the lack of an evidence base for indicators, but to an apparent failure to capitalize on the extensive work that has been done and applied internationally in this arena. Similarly, and not surprisingly, the dearth of quality-of-care research in the area of family planning in the United States contrasts with the quality-of-care work in the medical/surgical arena, likely because family planning has historically been focused primarily on women. Despite widespread acceptance internationally, only recently have the benefits of family planning been claimed to extend to improved child, family, and world health in the United States (Cleland et al., 2006). The inclusion of reproductive health services that encompass infertility and STD/HIV screening and treatment has broadened family planning services to extend to outreach programs for men, but this, too, has been a relatively new phenomenon. The absence or relative paucity of indicators for women's health, maternity services, and child health has not gone unnoticed by health service researchers, but progress on the development of these indicators has been slow (Schuster et al., 1997; Kerr et al., 2000; Gregory et al., 2005; Korst et al., 2005). In fact, the Agency for Healthcare Research and Quality (AHRQ)—the national leader in advancing the quality agenda—specifically excludes pregnancy and children from its current inpatient and patient safety indicators (AHRQ, 2004, 2006a,b). A set of pediatric inpatient indicators was recently developed (AHRQ, 2006c).

Attempts to achieve federal accountability across all federally funded programs have spurred the development of indicators for Title X. Current efforts by the FPCA to develop consensus-based performance indicators are a step in the right direction. Efforts to capture additional measures, already defined by the Department of Health and Human Services (HHS) via Healthy People 2010, would further the cause (HHS, 2000a). Examples of representative Healthy People 2010 reproductive and STD/HIV goals that would be consistent with Title X program goals can be found in Annex K-1. Similarly, focused incorporation of selected indicators from the *Handbook of Indicators for Family Planning Program Evaluation*, which contains more than 200 indicators, would be beneficial and could elevate family planning and preventive reproductive health services in general, and the Title X program in particular, from a relatively obscure program for the poor to a more prominent national program dedicated to improving the health and well-being of women, children, and families (Bertrand et al., 1994). Glasier et al., in an editorial about family planning services and women's health, state that "unsafe sex is the 2nd most important risk factor for disability and death in the world's poorest communities, and the 9th most important in developed countries" (Glasier et al., 2006). These authors contend that reproductive health services are of poor quality and underused because discussions about sexual intercourse and sexuality make people uncomfortable. Further, they suggest that the increasing influence of conservative, political, religious, and cultural forces threatens to undermine what has been achieved to date.

To make this admonishment meaningful in a different social context, the average youth watches 3 hours of television daily, whereas 59 percent of adults watch television 2 or more hours (Roberts et al., 1999; Bowman, 2006). It is inevitable that most Americans will therefore encounter sexual messages given how commonly they appear on television; approximately 64 percent of all programs have sexual content based on analysis of the

2001–2002 TV season. Among programs with sexual content, there was an average of 4.4 scenes per hour. Talk about sex was more common (61 percent) than overt portrayals of sexual behaviors (32 percent). However, approximately 14 percent (or one of every seven programs) included a portrayal of sexual intercourse, depicted or strongly implied (Kunkel et al., 2003; Collins et al., 2004). Since children tend to model what they see, it is perhaps not surprising that the average age of sexual debut overall is 14.2 years (13.1 for boys, 15.0 for girls) (Sandfort et al., 2008). Moreover, the rate of premarital sex continues to be high. Fully 90 percent of women aged 15–44 responding to the National Survey of Family Growth (NSFG) in 2002 had had premarital intercourse (Mosher et al., 2004). The social marketing of sexuality is rampant, while the marketing of abstinence, contraception, and preventive reproductive behaviors is glaringly absent, despite evidence that it could be beneficial (Piotrow et al., 1997).

Based on a review of the literature and a synthesis of both national and international data regarding quality measurement in family planning, there is a solid evidence base for the quality domains that should be included, and there is no dearth of potential indicators that could be used. The FPCA Performance Measurement System, coupled with the Healthy People 2010 goals, would be an excellent start. These should be fortified with a paradigm policy shift that emphasizes planning *for* pregnancy as much as planning *to prevent* pregnancy (HARI) (Jain et al., 1992). This is entirely consistent with the IOM recommendation to adopt a social norm whereby all pregnancies are intended—clearly and consciously desired at the time of conception (IOM, 1995). Further analysis of the merits of the Title X program is needed using various methodologies, such as provider observation or simulated patients, to document technical competence and communication skills. Additionally, patient exit interviews should not be limited to satisfaction surveys or closed questions about what was discussed as is currently the trend, but should include measures verifying literacy and comprehension. Community focus groups should ascertain additional perceptions of clinic quality with less possibility of courtesy bias (Sullivan and Bertrand, 2000).

The infrastructure to implement many of these suggestions exists, as evidenced by the FPARs, the Program Guidelines, application criteria, and the Office of Population Affairs' (OPA) 2006 *Family Planning Program Priorities, Legislative Mandates, Key Issues* (HHS, 2006). However, data collection efforts by Title X clinic sites may already be burdensome, and future funding should support either quality-monitoring full-time equivalents (FTEs) or an electronic medical record (EMR) system without sacrificing support for existing services. The EMRs should be designed to capture indicator data. There should be a vision or capacity for shared information (regional health information network), given the transient nature of the poor population. The opportunity for shared patient-level data (with appropriate consent and Health Insurance Portability and Accountability Act [HIPAA] considerations) could optimize STD/HIV prevention and treatment. Additionally, a widely acknowledged strength of the Title X program is its information–education–counseling (IEC) emphasis and the associated training and audiovisual tools directed at both clients and providers. These tools, coupled with standardized protocols, could be shared across state and federal agencies, including STD clinics and public schools, as well as incorporated into medical, nursing, and residency training curricula. There is clearly stakeholder support for enhancing the quality of family planning services at the user/provider level, but broader support at the administrative and policy levels is needed to facilitate the development of a national agenda emphasizing the maternal, child, and family benefits of family planning and preventive health services in general and the Title X program in particular.

The remainder of this appendix provides an overview of the theoretical frameworks that inform this review. It also provides an assessment of how well the FPAR measures quality based on these frameworks, a description of quality initiatives undertaken by family planning programs, and an overview of how the quality of services should be assessed. The latter overview uses representative examples of available indicators, highlighting where existing indicators may need to be modified or expanded to address clients' needs and wants and the HARI principle.

THEORETICAL FRAMEWORKS

Several quality and reproductive health frameworks inform this discussion:

- Donabedian quality model: Structure–Process–Outcome Model (Donabedian, 1968)
- Bertrand et al. program evaluation model (Bertrand et al., 1994; Sullivan and Bertrand, 2000)
- International frameworks for quality family planning services
    - Bruce and Jain et al. model of quality family planning services (Bruce, 1990; Jain et al., 1992) International Planned Parenthood Federation (IPPF) framework (IPPF, 1998)
    - 1994 International Conference on Population and Development, Cairo (United Nations, 1994)
- Lu and Halfon Reproductive Health Continuum (Lu and Halfon, 2003)
- AHRQ criteria for an acceptable indicator (AHRQ, 2001)

These frameworks need to be integrated and ultimately accepted by various stakeholders.

Donabedian's Structure–Process–Outcome Model

Donabedian's model has been widely endorsed as the theoretical framework for quality measurement (Donabedian, 1968). Key representative variables critical for assessment of the quality of Title X programs using the various domains outlined by Donabedian are shown in Figures K-1 through K-3.

Structure

Where is the facility located? What are the physical and administrative barriers to accessing services? Is the site geographically convenient and accessible by public transportation? Are the hours varied enough to meet the needs of clients—for example, evening or weekend hours for people who work or teens in school? Are the building and waiting area physically appealing? Once inside, is the waiting area comfortable, are there enough chairs, and are there diversions for accompanying children? Is there an opportunity for private discussion between clients and various clinical and nonclinical staff? Both national and international studies evaluating client satisfaction have demonstrated that all of these factors may influence whether a client comes for an initial visit or returns for subsequent visits—which of necessity impacts the short- and long-term goals of initiation and continuation of contraceptive services (Alden, 2004; Zaky et al., 2007). These may be significant issues at the individual clinical sites, determining

Structure

Faculty	Staff	Infrastructure
Location?	Number of FTEs	Sociopolitics
Accessible?	FTE/MD ratio	Cultural milieu
Public transportation	Expertise of non-MDs	Technology
Convenient hours	Training opportunities	Information technology (IT)
Physically appealing?	Training requirements	EMRs
Well lit	Communication skills	Advisory board
Comfortable waiting area		Funding/revenue
Private		Competing services
		Demographics/case mix
		Marketing

FIGURE K-1 Examples of variables representing Donabedian's structure quality domain.

- Contraceptive services and counseling
- Pregnancy diagnosis and counseling (infertility)
  - — Level I: initial interview, education, physical exam, counseling and appropriate referral (mandatory)
  - — Level II: semen analysis, assessment of ovulatory function, and postcoital testing (offer if a clinician with this training is available)
  - — Level III: More sophisticated services than Levels I and II (beyond scope of Title X)
- Related preventive health services
  - — Breast and cervical cancer screening
  - — STD/HIV screening
  - — Human papillomavirus (HPV) screening (not explicitly stated, but indirectly through cervical cancer screening and specified referral criteria)

FIGURE K-2 Services that must be provided by Title X programs.

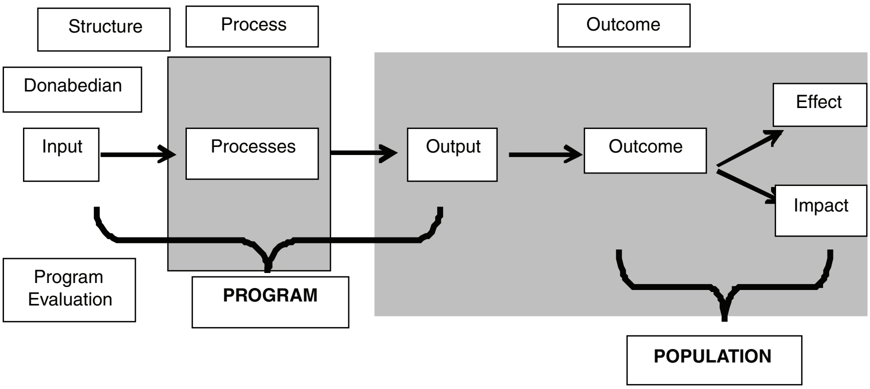

FIGURE K-3 Similarities between quality monitoring and program evaluation.

whether or not a client seeks initial or follow-up services. However, at the program level, only privacy issues are relevant from a regulatory standpoint. Staffing mix and training opportunities determine technical competence. The sociopolitical and cultural milieu can impact what methods are available (e.g., termination or emergency contraception). Ready access to information technology (IT) support can facilitate notification after positive test results and timely data acquisition for audits. The strength of the advisory board can determine additional funding options for outreach, social marketing, and facility improvement.

Process

The services that must be provided by Title X programs have been mandated by legislation (Figure K-2) (HHS, 2001, 2006). The federal Family Planning Program is authorized under Title X of the Public Health Service Act, which was created in 1970 to provide family planning and related preventive health care. The mission of Title X is to provide the information and means necessary for individuals to exercise choice in determining the number and spacing of their children (AHRQ, 2006c). In addition to providing a broad range of contraceptive supplies, counseling, and information on a confidential basis, clinics with Title X funding must provide reproductive health and preventive health services that include breast and pelvic exams to screen for breast cancer, cervical cancer, and STDs (including HIV); pregnancy diagnosis; patient education; reproductive health counseling; and appropriate social and referral services. A mechanism to determine that the information provided has been understood should be established and documented. Further, the Title X legislation authorizes funding for family planning services, training, research, information, and education. The program is administered by OPA through the Office of Family Planning (OFP). Services are intended for all who want and need them, with priority for low-income individuals. The Program Guidelines stipulate the involvement of an advisory board and community participation in the development of educational materials and project promotion.

While these are nationally legislated mandates, how these mandates get carried out is influenced by regional or local implementation strategies, largely resulting in site-specific policies and procedures (see Figure K-3). This variation is due to previously mentioned structural variables such as sociocultural or political milieus, regional demographics and/or case mix, and availability of staff and legal or licensing mandates regarding what types of providers can perform which types of services. For example, Gillian et al. found improved compliance among African American teens due to the involvement of all clinical staff in the process. All clinic employees, including clerical and professional staff, forged relationships through shared backgrounds and experiences, honesty, and additional time spent with the teens (Gilliam et al., 2007).

Outcome

See Figure K-3 and the discussion below of the Bertrand et al. (1994) program evaluation model.

Relationship Between Quality Assessment and Program Evaluation

It is difficult if not impossible to distinguish quality assessments from program evaluations when reviewing the family planning literature. Hence, Figure K-3 shows an integrated model of quality and program evaluation. Inputs and processes are conceptually equivalent to Donabedian's structure and process variables. Input examples pertinent to family planning include such items as personnel, financial resources, facilities, and equipment. Both output and outcomes are comparable to Donabedian's outcome domain. However, output specifically refers to outcomes at the program level and is usually defined by service utilization (number of visits, number of new or continuing contraceptive users). On the other hand, program outcomes defined by program effect and program impact are measured at the population level. An example of program effect is the prevalence of contraceptive use as measured in a population survey, and an example of program impact is the regional or national fertility rate or desired pregnancy rate. The maturity of the program determines the type of evaluation strategy to use—the more mature the program, the more impact one would expect to be able to demonstrate. By most standards, Title X is a mature program (more than 30 years old), but it is immature in quality assessment; hence the majority of indicators will initially be focused on processes and outputs. However, the program has been in existence long enough to be capable of demonstrating long-term impact if the correct data are made available for collection and interpretation.

International Frameworks for Quality Family Planning Services

Several authors have published extensively on quality assessment as it relates to the international family planning and reproductive health care arena. Most authors build on or adapt the Bruce (1990) and Jain et al. (1992) framework, which identifies six elements of quality:

- Choice of method,
- Information provided to the client,
- Technical competence of providers,
- Interpersonal relations between clients and providers,
- Mechanisms to encourage continuity of care, and
- Appropriate constellation of services.

Outcome measures include program readiness, the provider perspective, the services delivered, and the client perspective and the services received, with particular emphasis on client knowledge, client satisfaction, client health, and contraceptive use—both acceptance and continuation.

IPPF adopted the above framework as its model for quality after adding client acceptability to the above list and emphasizing that these criteria should be defined as clients' and providers' rights and expectations (IPPF, 1998). Table K-1 outlines the IPPF client and provider "bill of rights."

The most extensive and comprehensive framework for family planning quality indicators and program evaluation is that proposed by Bertrand et al. (1994). While intended for developing countries, it is easily applicable to the United States and includes both program- and population-level indicators. Program-based or performance indicators include those factors related to inputs, processes, and outputs, whereas population-based or outcome indicators usually reflect intermediate effect or long-term impact. Bertrand et al. define eight broad categories for program evaluation, which outline the pathways by which programs achieve impact in a given country:

- Indicators to measure the policy environment,
- Indicators to measure service delivery operations,
- Indicators to measure family planning outputs,

TABLE K-1 International Planned Parenthood Federation Framework: Clients' Rights and Providers' Needs

Client Rights	Provider Needs
Information about family planning	Training—technical and communication skills
Access to all service delivery systems and health care providers	Information on technical issues updated regularly
Choice of adopting, switch, or discontinuing methods	Infrastructure (appropriate facility and efficient organization)
Safety in the practice of family planning	Supplies of contraceptives, equipment, and educational materials
Privacy during discussions and physical examinations	Guidance from service guidelines, checklists, and supervision
Confidentiality of all personal information	Back up from other providers
Treated with dignity, courtesy, and attentiveness	Respect and recognition from coworkers, managers, clients, community
Comfort while receiving services	Encouragement to provide good quality care
Continuity of care for as long as client desires	Feedback from managers, supervisors, and clients
Opportunity to express opinions about he quality of care received	Opportunity to express their concerns relative to clinic decision making

SOURCE: Huezo, C. M., and S. Diaz. 1993. Quality of care in family planning: Clients' rights and providers' needs. In P. Senanyake and R. L. Kleinman, eds. *Family planning: Meeting challenges, promoting choices*. The proceedings of the IPPF Family Planning Congress, New Delhi, Oct. 1992. Pearl River, New York: Parthenon Publishing Group. Pp. 235-244. Reprinted with permission.

- Indicators to measure demand for children,
- Indicators to measure demand for family planning,
- Indicators to measure service utilization,
- Indicators to measure contraceptive practice, and
- Indicators to measure fertility impact.

The categories outline the pathways by which programs achieve impact in a given country (see Figures K-4 and K-5). Bertrand et al. (1994) advise that a key prerequisite for the development of a successful family planning program is the presence of a strong, viable political and administrative system. Political support should be coupled with resource allocation and permissive legal codes and regulations that affect the number, type, and distribution of methods. A comprehensive family planning service delivery program will have defined functional areas that include management, supervision, training, commodities and logistics, IEC, and evaluation. There are two primary expected results (or outputs) for a successful program: (1) adequate services from the client perspective, as defined by accessibility, quality, and acceptability; and (2) increased utilization of services, as defined by number of new and/or continuing users.

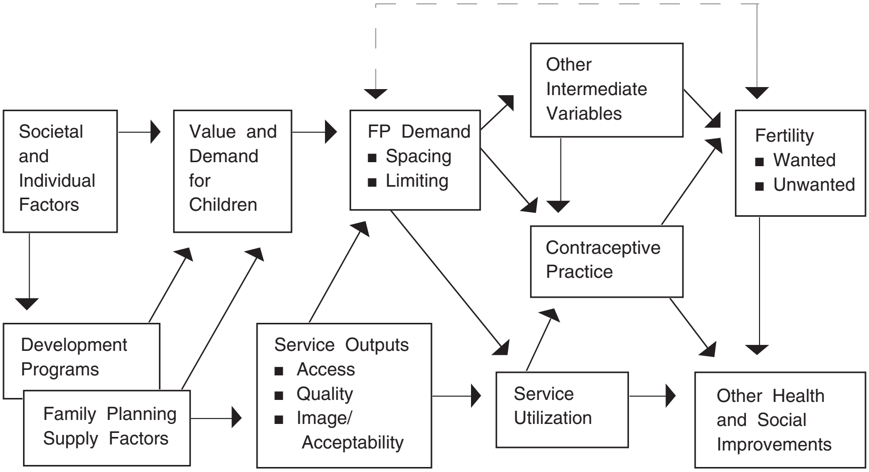

FIGURE K-4 Conceptual framework of family planning demand and program impact on fertility.
SOURCE: Bertrand, J. T., R. J. Magnani, and J. Knowles. 1994. *Handbook of indicators for family planning*. Chapel Hill, NC: MEASURE Evaluation, Carolina Population Center. http://www.cpc.unc.edu/measure/publications/pdf/ms-94-01.pdf (accessed April 18, 2008). Reprinted with permission.

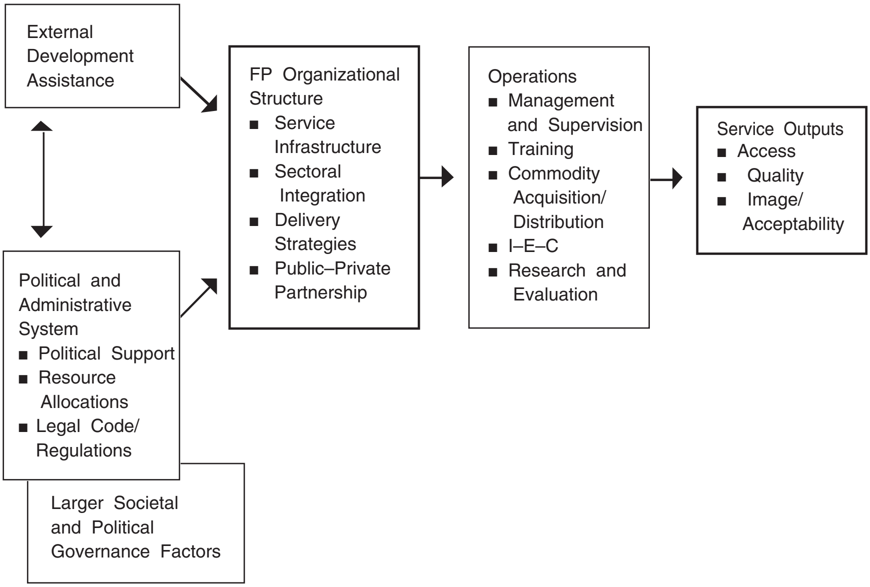

FIGURE K-5 Conceptual framework of family planning demand and program impact on fertility.
SOURCE: Bertrand, J. T., R. J. Magnani, and J. Knowles. 1994. *Handbook of indicators for family planning*. Chapel Hill, NC: MEASURE Evaluation, Carolina Population Center. http://www.cpc.unc.edu/measure/publications/pdf/ms-94-01.pdf (accessed April 18, 2008). Reprinted with permission.

Each category has a series of indicators. A detailed listing can be found in Annex K-2. It should be noted that there are approximately 200 discrete descriptive indicators that can provide trend data over time; however, they are meant to be used selectively depending on what outputs, processes, or outcomes are being assessed. In fact, field research used a modified "quick" 25 indicators with good success (Sullivan and Bertrand, 2000). The indicators and data collection method are listed in Table K-2. The research focused on indicators of quality that were related to client behaviors. It was aimed at determining the feasibility of data collection, testing the comparability of results obtained with two separate instruments (direct observation of provider and client exit interview), and determining the cost of data collection, among other things. It is among the few studies that provide information on the cost of quality assessment, and also demonstrate how the data could be used and compared within and among health systems or countries. The actual dollar amount for the costs associated with conducting the studies

TABLE K-2 Short List of Quality Indicators and Method of Data Collection

Indicator Number	Indicator	Client Exit Interview	Observation	Facility Audit
	PROVIDER			
I-1	Demonstrates good counseling skills (composite)	X	X	
I-2	• Assures client of confidentiality		X	
I-3	• Asks client about reproductive intentions (more children? when?)	X	X	
I-4	• Discusses with client which method she would prefer	X	X	
I-5	• Mentions HIV/AIDS (initiates or responds)	X	X	
I-6	• Discusses dual method use	X	X	
I-7	• Treats client with respect/courtesy	X	X	
I-8	• Tailors key information to the particular needs of the specific client	X		
I-9	• Gives accurate information on the method accepted (how to use, side effects, complications)	X	X	
I-10	• Gives instructions on when to return	X	X	
I-11	Follows infection control procedures outlined in guidelines		X	
I-12	Recognizes/identifies contraindication consistent with guidelines		X	
I-13	Performs clinical procedures according to guidelines		X	
	STAFF (other than provider)			
I-14	Treat clients with dignity and respect	X		

	CLIENT			
I-15	Participates actively in discussion and selection of method (is "empowered")	X	X	
I-16	Receives her method of choice	X	X	
I-17	Client believes the provider will keep her information confidential	X		
	FACILITY			
I-18	Has all (approved) methods available, no stockouts			X
I-19	Has basic items needed for delivery of methods available through SDP (sterilizing equipment, gloves, blood pressure cuff, specula, adequate lighting, water)			X
I-20	Offers privacy for pelvic exam/IUD insertion (no one can see)	X	X	X
I-21	Has mechanisms to make programmatic changes based on client feedback			X
I-22	Has received a supervisory visit in past ____ months			X
I-23	Adequate storage of contraceptives and medicines (away from water, heat, direct sunlight) is on premises			X
I-24	Has state-of-the-art clinical guidelines			X
I-25	Waiting time is acceptable	X		X

SOURCE: Sullivan, T. M., and J. T. Bertrand. 2000. *Monitoring quality of care in family planning by the quick investigation of quality (QIQ): County reports*. MEASURE Evaluation Technical Report Series No. 5. Chapel Hill, NC: MEASURE EVALUATION, Carolina Population Center. Reprinted with permission.

is difficult to interpret given the lack of comparability among international salary ranges. It is noteworthy, however, that the researchers interpreted the costs as reasonable, but they were considered high by the service providers, who were concerned that those funds might need to be diverted from other family planning–related resources (range $217–1,000/site).

All of the above frameworks essentially culminated in a paradigm shift away from fertility control in favor of individualized services responsive to client needs. This human rights approach was widely endorsed in 1994 at the International Conference on Population and Development in Cairo (United Nations, 1994).

Recently, assessment of family planning program quality has begun to emphasize client satisfaction. WHO has specified that clients want respect, understanding, individualized care, complete and accurate information, technical competence, access, fairness, and results (WHO, 1998). Communication standards have been emphasized internationally. Clients should be given sufficient information and counseling to be capable of making contraceptive decisions (WHO, 2004). This information should include at a minimum:

- A description and understanding of the relative effectiveness of the chosen method,
- Correct use of the method,
- How it works,
- Common side effects,
- Health risks and benefits of the method,
- Signs and symptoms that should necessitate a return to the office,
- Information on return to fertility after stopping the method, and
- Information on STD protection.

It should be noted that exit interviews on site and focused interviews in the community may reveal different pictures of quality, raising concern about the validity of exit interviews and the possibility of a positive or courtesy response bias on site (Sullivan and Bertrand, 2000; RamaoRao and Mohanam, 2003).

There has been considerable research on concepts, frameworks, measurement, and methodology, but few experimental studies have been conducted on the impact of quality services on reproductive health outcomes. Few quality interventions have been designed within a research framework capable of measuring or quantifying their effects. In a review of 15 international studies, most had methodological flaws (RamaoRao and Mohanam, 2003). Proposed explanations for these limitations included a perception that research activities were outside the normal scope of work and were burdensome and consumed limited resources. The small number of well-designed intervention studies suggests that quality can be improved and that good care has beneficial effects. The authors conclude that conceptual frameworks to examine quality have been developed and refined. The language and vocabulary used to define them have been accepted by diverse constituents. Methodological advances have been developed for data collection. A variety of interventions have been tested. Intervention tools demonstrating the most promise are those that facilitate better interaction between clients and providers through provider training in interpersonal communication and information exchange or the use of audiovisual aids. Better care has been associated with higher levels of client satisfaction and contraceptive adoption and continuation. Despite these findings, the authors acknowledge a number of gaps in the literature. These gaps should serve as stimulus for discussion when considering the development of quality indicators in the United States, where indicator development is in its infancy, but program infrastructure has been well established:

- What is the impact of decentralization on the quality of care provided or received?
- What is the level of readiness and quality of care in the private sector? Studies suggest private-sector facilities do not necessarily provide better care.
- Why do family planning clients choose to use some facilities rather than others? Is choice guided by perceptions of quality, and if so, how?
- What changes would encourage clients to continue to visit facilities and stay with existing programs? Research designs and program evaluations tend to concentrate on new users rather than the needs of existing clients. What quality attributes predict return visits or behavioral changes that support birth spacing/limiting and STD prevention?
- Many indicators have been proposed, but none have been tested on a wide scale. What is the most efficient mechanism to study new measures? Can existing infrastructure support indicator development and validation?
- Can quality be improved without extraordinary financial outlay? There is limited information on costs, cost-effectiveness, and financing.

To summarize, the international literature has established the following tenets as the elements essential for quality family planning services:

- A client-centered perspective sets the program objectives and standards.

- Interactions are information based and participatory, and allow for collaborative decision making.
- Clients have access and are treated with respect, understanding, and fairness. Clients want to be given complete and accurate information and be treated by technically competent providers (RamaoRao and Mohanam, 2003).

The Reproductive Health Continuum Model

This theoretical framework was initially proposed by Lu and Helfon and later used by the Maternal Quality Indicators Working Group to posit indicators for maternal health care quality, and is put forth here as a reminder that women are at various stages of their reproductive cycle (Gregory et al., 2005; Lu and Helfon, 2003; Korst et al., 2005). These stages include childhood, puberty, preconception, pregnancy, postpregnancy/interconception, perimenopause, and postmenopause. The postpregnancy/interconception stage includes all postpregnancy options: miscarriage, termination, and postpartum; for this model, postpregnancy also refers to post–negative pregnancy test. All of these events are critical times when a woman is interacting with a health care provider and ready for IEC about pregnancy intendedness. During the postpregnancy/interconception stage, there are special considerations if the woman or couple is planning to space or limit children. Thus, the contraceptive needs and types of counseling and preventive health services required will change over time and across different life circumstances. Family planning services and IEC messages for pubescent teens should obviously be different from those for couples actively seeing pregnancy. Likewise, divorce, death of partner or child, and involvement with a new partner will all impact where a woman is in the cycle relative to interconception and her birth spacing versus limiting needs. While specific to individuals, the model has some societal relevance as well. Social marketing of family planning and preventive reproductive health services that are consistent with national population goals should be geared toward age-appropriate cohorts (e.g., abstinence at puberty and more permanent methods at the birth-limiting phase of a women's reproductive life). An explicit understanding of national population/fertility goals is critical to judging the success of the Title X program. As America becomes more culturally diverse, the commonly espoused number of two children per family may no longer be valid.

AHRQ Framework for the Evaluation of Potential Indicators

Not all indicators get the benefit of validation prior to implementation, but it is important to recognize that there is a process by which this can be done. Ideally, the following criteria, as recommended by AHRQ, should be used to assess each of the proposed indicators:

- Importance—There is opportunity for improvement, as evidenced by substantial variation among hospitals and regions (or clinical sites). Face and construct validity must be established.
- Scientifically acceptability
  - — The variation in outcomes can be explained largely by provider/system-related factors and not by patient case mix.
  - — The indicator is well defined and precisely specified.
  - — The indicator is valid, accurately representing the concept being evaluated.
  - — The indicator is precise, adequately discriminating real differences in provider performance, and a reasonable sample size exists to detect actual differences; the indicator captures all possible cases, and bias related to case exclusion or limited data is minimal.
  - — Risk adjustment is adequate to address confounding bias.
  - — Analytical methods appear robust.
  - — The indicator is adaptable to a variety of settings.
- Usability—Statistical testing can be applied to identify when differences in performance levels are greater than would be expected by chance.
- Feasibility
  - — Data collection methods yield consistent construction and assessment of the measure.
  - — The indicator is feasible to calculate, and the benefits exceed the financial and administrative burden of implementation.
  - — Data collection and presentation mechanisms allow confidentiality to be protected.
  - — The quality of the data is known and consistent, and an audit strategy can be implemented.

HOW WELL DOES THE TITLE X FPAR MEASURE QUALITY?

What is the FPAR National Summary?

The FPAR is the only source of annual uniform reporting by all 87 Title X service grantees. It provides national-level validated data on program users, service providers, utilization of family planning and related preventive health services, and sources of revenue for the program. It provides an estimate of the impact of Title X–funded activities on key reproductive health outcomes. The Research Triangle Institute (RTI) tabulates the grantee FPARs to prepare the National Summary under a contract with OPA. Data are submitted electronically through a web-based electronic grant management system (eGrants). Data elements include facility-specific information such as number and type of providers; revenue generated, by payer source; user demographics (age, sex, race/ethnicity, insurance coverage, English proficiency); new user encounters; contraceptive use by male and female family planning users; summary abnormal Pap smears; and summary confidential HIV-positive test results and disease-specific rates for STD screening.

As currently reported, the FPAR data provide some measures of quality as related to structure and certain inputs, processes, and outputs. They could potentially be used to calculate or abstract outcomes related to effect (short-term and site-specific), but are not currently suited to determining long-term outcomes demonstrating program impact.

What Quality Measures Can Be Determined by the FPAR?

Structure (and Input) Variables

Staffing. In 2006, there were 3,937 FTEs working at Title X sites, including physicians, midlevel providers, and other clinical service providers (CSPs). Most (51 percent, or 2,014) were midlevel providers (physician assistants, nurse practitioners, or certified nurse midwives); 13 percent were physicians and the remainder CSPs. There was one MD per 4.1 midlevel providers, and the staffing composition varied across regions. Research indicates that where variations in staffing exist, there likely exist an opportunity for improvement and associated poor quality due to both under- and overutilization (Wennberg, 1999; Fisher and Wennberg, 2003). What is unknown from a quality perspective is what defines best practice as it relates to provider mix/FTE ratios. For example, some studies suggest that midlevel clinicians provide better care (Winter and Goldy, 1987). A further quality issue is whether fewer physicians imply better quality (enhanced efficiency) or worse quality (e.g., CSPs practicing beyond their scope).

Total Revenue. In 2006, grantees reported $1.1 billion in total revenue, or approximately $217 per user. Medicaid was the major source of revenue, followed by Title X (30 percent and 24 percent, respectively). Other sources included state governments, client payment (approximately 9 percent), local government, and other third parties. The proportion contributed by other sources varied across regions. Assuming a single standard of care across all payers, the question arises of the extent to which alternative revenue sources improve other inputs, such as resources available, contraception options, additional funds for outreach, and facility enhancements.

Process (and Output) Variables

Percent Limited English Proficiency (LEP). In 2006, 13 percent of clients were LEP and required oral language assistance to optimize their use of Title X services. This includes services provided by bilingual staff, a competent agency or contracted interpreter, or a family member or friend (after the client refused the agency's offer to provide a qualified interpreter at no cost). Data are needed on the quality of the bilingual translator, client comprehension after the interaction, and percent and rationale when in-house translator services were refused or not used.

Female Users by Primary Contraceptive Method at Last Encounter in Reporting Period. In 2006, 85 percent of Title X clients were using a contraceptive method, while 15 percent were not (8 percent seeking pregnancy, 7 percent other reasons). The FPAR provides a breakdown of users by method, thereby demonstrating a key family planning quality domain—options in contraceptive methods. Method use varies by age, race, and region. There is a need to understand this variation; with regard to age, it is likely to be related in part to the reproductive health continuum, with increased utilization of reversible methods during the birth-spacing years and more permanent methods during the birth-limiting years. Racial/ethnic differences are likely to be related to cultural differences. As noted above, for example, the assumption that the average number of children desired by American women is two may not be valid across racial/ethnic groups (AGI, 2000). Likewise, long-standing fears about institutional racism and discrimination have been associated with distrust and low contraceptive continuation rates among African American women (Thornburn and Bogart, 2005a,b). An additional output measure that could be calculated from the FPAR, but is not currently obvious, is the percent of women who use dual protection (another method plus condom) for STD/HIV prevention. Dual protection would impact pregnancy prevention given the percent of pregnancies that occur as a result of contraceptive failure or inappropriate use. It would also protect against STD/HIV transmission.

Male Users by Primary Contraceptive Method at Last Encounter During Reporting Period. In 2006, 92 percent of all male users of Title X services were using a contraceptive method, while 8 percent were not; 1 percent had a pregnant partner or were seeking pregnancy, and 7 percent had "other" reasons for nonuse. Fully 78 percent of users relied on male condoms, 6 percent on their partner's method, 4 percent on abstinence, 1 percent on vasectomy, and 7 percent on an unknown method. The above comments on dual method use apply to this measure as well with respect to its limitations as a quality measure.

Cervical Cancer Screening: Number of Users Who Obtained a Pap Test, Number of Pap Tests Performed, Number of Pap Tests with (ASC) or Higher. In 2006, 2.4 million Pap tests were performed, and 49 percent of Title X female family planning users were tested. Ten percent (240,702) of tests revealed precursors or cancerous conditions requiring further evaluation or treatment. By region, the screening rates were at or above the national average (49 percent). A potential advantage of this indicator is that it is a HEDIS measure, and hence some efficiency might be gained due to the need to report elsewhere. This indicator has been proposed as a PART performance measure and will be collected by the FPCA Performance Monitoring System (see below) (OMB, 2005). It addresses the Title X mission to decrease cervical cancer, and there is an existing benchmark. Variation exists among regions, suggesting an opportunity for improvement; however, all regions exceeded the national threshold. Future quality measures might include referral and treatment outcomes (see below).

Breast Cancer Screening: Number of Users Receiving a Clinical Breast Exam, Number of Users Referred for Further Evaluation. In 2006, 2.4 million users received a clinical breast exam, and 3 percent (65,157) were referred for further evaluation. Screening rates were at or above the national average (49 percent) in 7 of 10 regions. A potential advantage of this indicator is that it is a HEDIS measure, again offering the potential to gain efficiency. This indicator has been proposed as a PART performance measure and will be collected by the FPCA Performance Monitoring System (see below) (OMB, 2005). It addresses the Title X mission to decrease breast cancer, and there is an existing benchmark. Variation exists among regions, suggesting an opportunity for improvement. Future quality measures might include referral, final diagnosis, and treatment outcomes. Where feasible, information about missed cases after a clinical breast exam would also be pertinent and would enhance the feedback quality loop.

STD Screening

STD screening is a recognized goal of Title X. Only chlamydia, gonorrhea, syphilis, and HIV are reported in the FPAR. There are more than 25 STDs, but limiting reporting to these four is reasonable in this early stage of quality measurement (HHS, 2000a,b). However, future measures might include rates of diagnosis, treatment, or referral for hepatitis and HPV. Likewise, it might be useful to measure resources used; Level II infertility assessments; and costs per patient for screening, diagnosis, and treatment of more common infections, such as bacterial vaginosis, yeast, mycoplasma, and ureaplasma. These measures would be useful, especially if they could be tracked electronically, as the prevalence of these conditions diverts resources from other family planning priority areas.

Chlamydia Testing by Age Group (under 24, and 25 and Older) and Gender

In 2006, Title X clinics tested 47 percent of all female users and 52 percent of male users for chlamydia. Testing rates were highest among younger users. Overall, 51 percent of users under 24 were tested, and in five regions, testing rates were at or above the national average (which was not specified). However, testing rates in all regions were lower than that recommended by the Centers for Disease Control and Prevention (CDC) (Fowler et al., 2008). A potential advantage of this indicator is that it is a HEDIS measure, again offering potential efficiency benefits. This is a good-quality indicator in its current form. Guidelines specify contact time for notification of a positive test (2 weeks) and for documentation of a subsequent negative test, confirming a program effect (successful treatment) and program impact due to implied behavioral change (condom use) preventing reinfection (Meyers et al., 2008). Note that half of Title X clinics participate with CDC and OPA in a nationwide chlamydia prevention effort, and chlamydia screening has been endorsed by the U.S. Public Health Service Task Force and is a Healthy People 2010 objective (HHS, 2000b; AHRQ, 2007). This is an excellent example of cross-agency collaboration and national priority agenda setting and social marketing, as evidenced by the adoption of this indicator by other external quality monitoring agencies (e.g., NCQA) (NCQA, 2007).

Gonorrhea and Syphilis Testing. In 2006, Title X administered approximately 2.1 million gonorrhea tests and more than 700,590 syphilis tests. This indicator is not useful as reported. No data are reported on prevalence rates, treatment, cures, or impact on congenital infection rates (a particular concern given rates of unplanned pregnancy among Title X clients).

HIV Testing: Number of Positive Confidential Tests Performed and Number of Anonymous Tests Performed. In 2006, sites performed 652,426 confidential HIV tests, 1,337 of which were positive; 14,280 anonymous tests were performed. This is a good-quality indicator in its current form. The Program Guidelines specify the contact time for notification of a positive test (2 weeks). Future measures could report referral for follow-up, percent and extent of partner notification, and percent of condom use postdiagnosis.

Family Planning Encounters: Face-to-Face Contact with Clinical or Nonclinical FTE to Provide Family Planning and Related Preventive Health Services to Clients Who Want to Avoid Unintended Pregnancies or Achieve Intended Pregnancies. In 2006, there were 9.8 million family planning encounters (documented in the medical record). There were roughly two visits per user; 74 percent were with a CSP (nonphysician). This indicator is not useful as reported. Given the quality domain of patient-centeredness, a more useful measure should be designed that would take into account the ideal number of visits for patient need, specifically considering patient age, race/ethnicity, pregnancy plans, and contraceptive method.

Outcomes Variable

The FPAR as it currently exists does not adequately address Title X outcomes at the program (effect) or population (impact) level, but performance measures have been suggested by OPA and are in development by FPCA (see below). If the Title X program were judged by the criteria of Bruce (1990) and Jain et al. (1992) (as discussed above), it would have a high likelihood of being judged as good quality on three of their six constructs: choice of method, information provided to the client, and appropriate constellation of services (assuming clinical sites are doing what they are mandated to do). However, additional information is needed to determine quality ratings on technical competence of providers, interpersonal relations between clients and providers, and mechanisms to encourage continuity of care—especially given the current audit emphasis on new users (Bruce, 1990). With respect to the IPPF framework, assumptions of good quality could be made on only four of the ten client rights, and none of the ten provider rights (IPPF, 1998). Finally, no assessment of the quality of the Title X program could be made using the comprehensive or abbreviated version of the Bertrand et al. framework (Bertrand et al., 1994; Sullivan and Bertrand, 2000).

WHAT QUALITY INITIATIVES HAVE BEEN UNDERTAKEN BY FAMILY PLANNING PROGRAMS?

This section starts with a broad overview of the utilization of family planning services and quality assessment studies of family planning programs in the United States. It then reviews what is known about the quality initiatives that have been undertaken by Title X programs, as evidenced by the PART and the proposed FPCA Performance Measurement System (FPCA, 1999; OMB, 2005).

Who Needs Family Planning Services?

There are approximately 62 million women of reproductive age in the United States, 70 percent (43 million) of whom are sexually active and not planning to become pregnant (Mosher et al., 2004; Guttmacher Institute, 2008). Of these women, 31 percent are not using contraception because they are infertile, pregnant, trying to become pregnant, postpartum, or not sexually active; 62 percent of women are using a contraceptive method (representing 89 percent of the 42 million fertile women at risk for pregnancy). Approximately 7 percent of women at risk for pregnancy are not using a contraceptive method; 64 percent of women use a reversible method; and of the remainder, they or their partner has been surgically sterilized. Poor and low-income women are more than twice as likely as higher-income women to use the 3-month injectable method. Approximately 7.3 million women use barrier contraceptives, such as the male condom. Condom use is especially common among teens (and is the primary method for 27 percent of teenage girls), those aged 20–24, childless women, and never-married women. Condom use declines as women grow older and marry. The proportion of women who used a contraceptive method the first time they had sex nearly doubled from 43 percent in the 1970s to 79 percent in 1999–2002. This change is due mainly to an increase—from 22 percent to 67 percent—in the proportion using the male condom at first intercourse, and likely reflects heightened concern about and awareness of HIV/STD prevention. This finding supports the programmatic impact of Title X and other family planning initiatives. Condom use at first intercourse varies by age (more likely among older women) and race/ethnicity (67 percent among whites, 60 percent among African Americans, and 46 percent among Hispanics) (Mosher et al., 2004; Guttmacher Institute, 2008).

Despite these encouraging statistics, most pregnancies are still unplanned and occur among women using contraception (IOM, 1995; Schunmann and Glasier, 2006). Approximately half of women experiencing unintended pregnancies used some type of birth control during the month they conceived—albeit inconsistently or incorrectly (Dreweke, 2006). Hence, there is an ongoing need for IEC activities related to pregnancy planning, prevention, and reproductive health services. Based on data from the NSFG and other sources, 5 percent of U.S. women of reproductive age have an unintended pregnancy each year (for a rate of 51 unintended pregnancies per 1,000 women aged 15–44). Unintended pregnancy is substantially more common among women aged 18–24, unmarried and/or cohabiting women, low-income women, women who did not complete high school, and minority women. Poor women have a high rate of unintended pregnancy (112 per 1,000 women aged 15–44, or twice the national average). A poor woman is four times as likely to have an unintended pregnancy, five times as likely to have an unintended birth, and more than three times as likely to have an abortion as her higher-income counterpart (Finer et al., 2002; Mosher et al., 2004; Guttmacher Institute, 2008).

Knowing where women receive family planning services and standardizing the quality of care for these services should help improve compliance, the effectiveness of contraception, and patient satisfaction with respect to achieving needs and wants regarding reproductive intentions (HARI), and further validate Title X 's mission. More than 44 million women obtained reproductive health services in 2002. Of these women, 34.4 million (56 percent) were seen by a private physician, while 13.5 million (22 percent) were seen in a publicly funded clinic (5.4 million of these women were seen in Title X clinics), and the remainder were seen in other types of facilities. Of women seen in Title X clinics, 53 percent were at less than 300 percent of the federal poverty level (Mosher et al., 2004).

Lessons Learned from the General Family Planning Quality Assessment Literature

Improving access to family planning services, either by increasing funding or by reducing barriers related to program enrollment or to mandated physical assessments such as pelvic exams, results in increased utilization of services and increased variety of contraceptive methods available (Lindberg et al., 2006). Both access and method choice are family planning quality domains. For example, Lindberg et al. report that the number of contraceptive methods increased and agencies reduced barriers to oral and emergency contraception by liberalizing policies for provision (e.g., no pelvic exam required) between 1995 and 2003. By 2003, clinics were offering the newest methods (IUD, ring, patch); however, not every method was stocked at all facilities because of costs, suggesting that continued funding challenges limit the ability of publicly funded providers to offer all available methods to all women (Lindberg et al., 2006).

In a longitudinal study of the impact of extending Medicaid coverage for family planning services, Bronstein et al. found that expanded access was associated with an increased number of family planning users who were demographically similar to Title X users (Bronstein et al., 2007). But the growth was greatest among clients of non–Title X providers (e.g., private physicians). Access to private physicians has been inconsistently associated with quality. Patient satisfaction surveys rate this as indicative of improved quality, but objective evaluations by Bronstein et al. found that private physicians provided less comprehensive services, such as less HIV screening, and more contraception services, such as provision of oral contraceptives or sterilization. The use of risk assessment and coordination of care was, however, associated with more continuity as measured by return for care. Receiving less comprehensive care, unless specifically individualized based on risk assessment, would obviously be a measure of poor quality. Mathematical models suggest that improved access is associated with an increased number of pregnancies averted and significant cost savings, based on both pregnancy-related costs and subsequent newborn and childhood social costs. Researchers using the Markov methodology estimate that for every dollar spent on family planning, $3.58–5.33 is saved in subsequent government spending (Foster et al., 2004; Dreweke, 2006; Amaral et al., 2007).

Paine et al. performed a systematic literature review to examine the relationship between family planning services and safe and effective contraceptive use (Paine et al., 2000). Their aim was to identify features of family planning service provision that influenced use and the optimal effectiveness of user-dependent methods. The authors identified 142 articles, only 16 of which met inclusion and exclusion criteria, including a specified long-term outcome. The authors concluded that the quality of provider–client exchanges had a net incremental effect on contraceptive use, and available evidence suggests that training in communication with clients about side effects and an emphasis on client choice are key components of effective interventions. However, evidence for the effectiveness of methods to improve uptake, continuation of method use, and safe and appropriate use of contraception is scant.

In essence, providers must be client-centered and interactive and listen to clients' needs and wants. This conclusion confirms findings originally publicized and widely accepted in the international family planning arena (Bruce, 1990; IPPF, 1998; WHO, 1998; Sullivan and Bertrand, 2000; RamaoRao and Mohanam, 2003). Paine et al. (2000) acknowledge that to date, almost all quality measures have looked at outcomes immediate to the site of care, with minimal or no attempt to look at the incidence of unwanted conception among users of the services. They advise embracing a broader focus on helping "individuals to achieve their reproductive intentions in a healthful manner," endorsing the HARI concept as originally proposed by Jain et al. (1992).

The HARI index is a mathematical number defined as the proportion of clients who meet their reproductive goals:

HARI index = 100 – (% unplanned pregnancies + % unwanted pregnancies) during a specified period after the initiation of contraception
% unplanned = women who are trying to space their pregnancies
% unwanted = women who want to limit pregnancy (finished with childbearing)

This index could be calculated annually per site, but would require explicitly asking about, documenting, and monitoring each user's reproductive intentions for the year (confirmed by subsequent visits during that time period).

In this same vein, family planning programs tend to measure continuation rates or discontinuation rates among new users over a specified time period (FPAR and FPCA). Some researchers have suggested that a better indicator would be the dropout ratio, defined as the proportion of new users who are still at risk of pregnancy, do not want to become pregnant, and have quit using any family planning method. This indicator would exclude women who are past menopause, are no longer sexually active, planned a pregnancy, or switched methods, thereby taking into account the client's reason for stopping the method (WHO, 2004).

Another landmark review that informs this discussion is a recently published study conducted by Becker et al. (2007). These authors published a comprehensive review of the quality of family planning services in the United States based on documents available between 1985 and 2005. They conceptualized a framework based on Bruce (1990) (specific to family planning) and Sofaer and Firminger (2005) (health care in general) that includes eight domains: accessibility, communication and information, client–staff interactions, efficiency and effective organization of care, technical competence, structure and facilities, contraceptive method choice, and patient-centeredness (Bruce, 1990, Sofaer and Firminger, 2005). The authors identified 29 studies conducted in the United States: 15 studies were descriptive and documented levels of service quality, 10 investigated the correlates of quality, 12 examined the effect of quality on client attitudes and behavior, and 8 explored clients' preferences and values regarding family planning service delivery. The studies were not limited to Title X programs. The methodology most commonly used in the studies reviewed was surveys of women receiving the services. Other approaches included focus group discussions, interviews, medical record reviews, direct observation of client–provider interactions, surveys of providers or managers, and quasi-experimental and experimental studies. Although most studies conceptualized family planning quality as a multidimensional construct, a few explicitly defined service quality constructs; thus the domains of quality evaluated were not consistent across studies. Client–staff interactions and accessibility of services have been assessed relatively frequently, while other domains, such as provider technical quality, have been explored infrequently. A brief summary of the findings of Becker et al. (2007) by quality domain is as follows.

- **Accessibility—**Problem areas from the client perspective included barriers involving administrative accessibility, such as waiting more than a month for an initial appointment, inconvenient hours, unable to access provider by phone, and language barriers. For example, more than 25 percent of 637 federally funded programs lacked tailored services for non-English-speaking clients in 1999 (Finer et al., 2002). Ideally, this would not be an issue in Title X clinics, based on statutory requirements, but objective performance data are needed to confirm this.

- **Communication and information**—When queried, a high proportion of women reported talking to the provider about specific topics, such as the effectiveness of different contraceptives and how to use particular methods. However, studies asking clients to rate the quality of the information they received were less positive, with 14–25 percent of clients stating that they felt they did not receive sufficient information; they felt their concerns and questions were not adequately addressed; the advice was not tailored to their specific circumstances; or their concerns were dismissed, especially those related to possible contraceptive side effects.
- **Client–staff interactions**—Issues raised by clients included a lack of respect from nonclinical staff members and of privacy while waiting for an appointment. African American women were more likely to report a perceived lack of respect (Thornburn and Bogart, 2005a).
- **Efficiency and effective organization of care**—The most widely studied aspect of this domain is waiting time. A long waiting time has consistently been associated with poor quality by clients. Similarly, a lack of continuity as defined by the inability to see the same provider is associated with being rated as poor quality by clients. Not all programs have a mechanism for clients to see the same provider at each visit. A lack of follow-up mechanisms to track patients over time has also been associated with poor quality. Finer et al. found that only 53 percent of programs had a mechanism in place to contact clients who missed appointments (Finer et al., 2002).
- **Technical competence**—This domain is defined by safe, effective care that complies with accepted clinical standards. There have been only two studies conducted in this domain in the United States, but their findings suggest technical competence is high. Clearly more work is needed in this area.
- **Structure and facilities**—As previously mentioned, location, proximity, physical appeal, and waiting room comfort have been associated with good quality as judged by clients.
- **Method choice**—The range of contraceptive options varied across sites. Although oral contraceptives were the only method offered

by virtually all providers, few clients reported being unable to obtain their method of choice. However, one study using a nationally representative sample of African American women reported that a family planning provider strongly encouraged these clients to adopt a specific method of birth control that was not consistent with their preference (Thornburn and Bogart, 2005b). While choice has been deemed an important quality indicator, associated with both initiation and continuation of contraceptive use, pressure or a perceived lack of choice has been associated with early discontinuation. This is especially concerning given that, as noted above, some African American women are suspicious about birth control (Thornburn and Bogart, 2005b). Addressing patient concerns and beliefs and providing nondirective counseling might be especially pertinent and beneficial in geographic regions where conspiracy concerns are high.

- **Patient-centeredness—**The degree to which services are tailored to the needs and circumstances of individual clients has not been well operationalized. Studies that evaluated this domain were inconclusive.
- **Correlates of service quality—**Correlates of service quality were grouped into four categories: facility factors, provider factors, client factors, and consultation factors. These are comparable to the eight domains previously discussed. Facility factors were the most frequently studied. Quality ratings were generally lower for public as compared with private facilities. Hospitals and health departments received the poorest ratings from clients, while private physicians received the highest ratings. This contradicts other findings since hospitals and health departments are more likely to be Title X sites providing more comprehensive services, but they may also have longer waiting times, more rigid hours, and other administrative barriers. Female providers received higher quality ratings than males, and nonphysicians were rated more highly than medical doctors. Ratings varied by client demographics: those who were unmarried, under age 20, less educated, members of a minority, Spanish speaking, and males tended to rate services more poorly than others.
- **Quality and outcomes—**Studies looked at the relationship between family planning service quality and client attitudes and behaviors. Most explored the link between quality and clients' contraceptive use after the visit, satisfaction with the method, likelihood of returning for services, and experiencing an unintended pregnancy. Observational and prospective studies tended to find positive relationships between service quality (individualized counseling)

and contraceptive behavior. However, the evidence from quasi-experimental and experimental studies is mixed.

- **Effect of service quality on likelihood of returning for care—**Observational studies suggest there is an association between quality and returning for care.
- **Client preferences and values regarding family planning service quality—**Receiving personalized attention, having staff spend time explaining issues, being able to see the same provider at different visits, and receiving affordable care are all associated with clients' perceptions about quality.

Becker et al. (2007) conclude that there was a lack of consistency in the domains of quality studied, making it difficult to draw causal associations. They suggest that future studies should formulate more explicit definitions of quality guided by previously developed conceptual frameworks with delineated domains. The methodology should be multileveled, incorporating the perspectives of providers and managers as well as clients. Further, the authors suggest increased utilization of expert observations in the field, chart audits, simulated patient visits, and provider surveys to provide a more informative, multidimensional measure of quality at the site.

While most studies of family planning services have focused on users, examining reasons for nonuse may reveal unfavorable perceptions of services within the community or provide insight into the role of ambivalence and pregnancy intendedness. In the same way that silence is considered implied consent, ambivalence or inconsistent contraceptive use could be interpreted as a planned or wanted pregnancy. In the developed world, most unintended pregnancies arise from inconsistent or incorrect use of contraceptives. Ambivalence about pregnancy may be associated with less effective contraceptive use. In a study conducted at the time of termination, Schunmann and Glasier developed a measure of intendedness and found that women not using contraception had higher intendedness scores than those using some type of method (Schunmann and Glasier, 2006). Of those women reporting use of a method, 44 percent were using the method inconsistently or incorrectly (either condoms or oral contraceptives). Method choice was not linked to intendedness. The authors concluded that women who are ambivalent about the desire for pregnancy are less likely to use contraception and/or more likely to use it inconsistently. Hence, one of the many challenges to efforts to reduce unplanned pregnancy rates is to maximize contraceptive use among those who use contraception imperfectly. Nationwide, further gain may come from increasing awareness about ambivalence and its potential consequences, and publicly endorsing pregnancy planning and advocating that everyone specify her/his reproductive intentions.

Are There Quality Initiatives Specific to Title X Programs?

What Can PART Tell Us About the Quality of the Title X Program?

This review revealed no published peer-reviewed descriptions of quality initiatives undertaken by Title X programs. A federal evaluation of the program occurred as part of the PART evaluation conducted by the Office of Management and Budget (OMB). The purpose of the PART evaluation was to assess and improve the performance of federal programs by identifying strengths and weaknesses to inform funding and management decisions. The initial PART evaluation of Title X was done in 2005 (OMB, 2005). The program received a Moderately Effective rating, just shy of an ideal rating of Effective. Programs rated Moderately Effective have ambitious goals and are considered to be well managed. However, there is a need to improve efficiency or address some other problem in their design or management to achieve better results.

As a result of the PART evaluation, OMB determined that the program was strong in its overall purpose, design, and management, but performance goals for some key program activities had not yet been established. In addition, OMB found that, although several focused evaluations of Title X had been completed, no broad-based, independent evaluation of sufficient quality and scope had been carried out in recent years. As a result of the PART evaluation and discussions with OMB, OFP committed to improving the performance of the program by developing performance goals for key program activities and conducting an independent evaluation of sufficient quality and scope at the federal level to demonstrate the program's overall impact. In an effort to further address OMB's findings, the IOM was tasked with conducting the comprehensive evaluation of Title X documented in this report.

Since the initial PART evaluation, the program has successfully developed, implemented, and established targets for several annual and long-term performance goals, including its efficiency measure (see Chapter 3). The Title X program has specified three long-term measures that are to be reported annually: (1) increasing the number of unintended pregnancies averted by providing Title X family planning services, with priority for services to low-income individuals; (2) reducing infertility among women attending family planning clinics by identifying chlamydia infection through screening of females aged 15–24; and (3) reducing invasive cervical cancer among women attending family planning clinics by providing Pap tests according to nationally recognized standards of care. The exact methods for accomplishing these goals (e.g., specified numerators and denominators) were not identified. The program's efficiency measure is to maintain the actual cost per client below the medical care inflation rate. The 2005

PART evaluation found that the program has helped prevent more than 1.3 million pregnancies and has kept the cost per case 6 percent below the medical inflation rate (OMB, 2005).

What Can the Family Planning Council of America Performance Monitoring System (PMS) Reveal About the Quality of the Title X Program?

In 1999, in the absence of a national set of family planning indicators, FPCA decided to develop a measurement system to assess the performance of Title X grantees and delegate agencies within the FPCA network of family planning service delivery (FPCA, 1999). The proposed system was derived through a consensus process described in detail in the Phase I and Phase II final reports (not available for review as of this writing). The conceptual framework for the indicators was based on four priorities thought to be representative of a comprehensive family planning services model of care:

- Ensure the provision of high-quality clinical services.
- Enhance the skills and knowledge of clients and providers.
- Maintain a leadership role in the community through education, advocacy, and partnerships.
- Ensure the effective and efficient management and evaluation of councils and delegate agencies.

The ultimate goal of the PMS is to provide a mechanism to achieve the following objectives:

- Monitor and document the achievements of family planning providers.
- Evaluate program effectiveness and impact.
- Guide future program and policy development and implementation.
- Communicate to consumers and policy makers the outcome of an investment in family planning.
- Direct the program planning process toward improved performance of family planning providers and further improvement of health status.

Ultimately, 24 indicators were selected, representing structure, process, and output variables. It is anticipated that the chosen measures will be identified as standards of care for the broader family planning service delivery field.

The Measures. The PMS consists of a Clinical Module encompassing 17 clinical measures that evaluate performance in comparison with established benchmarks. Additionally, the system includes an optional Administrative Module with 7 measures that address operational and support services. (The Administrative Module was not provided with the advance PMS summary.) The clinically based performance measures evaluate standards of care in the following areas: Contraception/Pregnancy (CON), STD/HIV (STD), Adolescents (TEEN), Cancer Screening (CA), and Operations (OP).

A worksheet will be provided for each of the indicators, describing how the data should be collected and tabulated and giving a description of the relevant standards of care and applicable government regulations. (The worksheets were not available for review at the time of this writing; a sample was provided for CON-1.)

The PMS Pilot Demonstration. A pilot demonstration project involving 6 FPCA members and 30 delegate agencies was conducted between October 2001 and February 2002. This pilot tested the feasibility of using the performance measures and collected data to establish or substantiate benchmarks. In testing feasibility, the pilot examined the following: (1) the burden of data collection (e.g., time, resources, staff), (2) the availability of data to address the measure, and (3) whether the measure had meaning for assessing performance (validity). The results of the pilot are described in detail in the Phase II final report and informed the design of the current system. Key lessons from the pilot as described by FPCA include the following:

- Data collection was not as onerous a process as originally anticipated.
- Pilot sites perceived the information as beneficial, with the potential for use as a mechanism for ensuring quality services.
- Pilot sites identified areas where they were meeting benchmarks, as well as areas for improvement.
- The pilot process provided an opportunity to test ways in which existing data systems (e.g., billing systems) could be used to access performance data.
- Sites recognized that many of the performance measures could be incorporated into the current quality assurance and auditing process required for the FPAR.

Cursory discussions with two clinic sites corroborated these lessons with the following caveats. Data collection was perceived as burdensome by one site, taking CPSs away from other family planning services. It was not viewed as burdensome by the other site, as its delegate provided an external FTE to perform the chart audits for 7 of the 24 total indicators. The remaining data were directly abstracted from the FPAR data that were being prepared for submission.

FPCA has established a users group, composed of administrative, quality assurance, and clinical staff, which is working in the field at clinical sites to help implement the PMS by facilitating the exchange of information related to the performance measures. The PMS is intended to enhance overall program performance at the site of care. The collection of data and their measurement against established benchmarks provide an opportunity for feedback to reinforce or improve performance. Action plans can be developed to focus on areas needing improvement. New data are collected to measure improvement after the intervention. This approach essentially incorporates the Plan–Do–Study–Act (PDSA) tenets of quality improvement (Deming, 1986; Speroff and O'Connor, 2004).

The FPCA indicators reflect many of the quality dimensions previously established in the international family planning arena. Domains that appear to be missing include client-centered measures reflecting satisfaction, literacy after IEC encounters, and method choice. Likewise, there are no technical competence or provider communication measures. It is anticipated that indicators to measure these domains will be added over time.

HOW SHOULD THE QUALITY OF TITLE X SERVICES BE ASSESSED IN VARIOUS SETTINGS?

A review of the literature reveals that a theoretical framework and a multitude of quality indicators exist that can be used to assess the quality of family planning and reproductive health services in the Title X program. One can think of the indicators presented as a pyramid becoming more complex and more comprehensive as one approaches the base (see Figure K-6). At the top of the pyramid are the PART performance measures. The existing FPARs would be the next rung, but currently represent primarily descriptive indicators of structure and processes. The FPCA PMS, with its 24 indicators, will provide a mechanism to collect outputs that will yield some data on short-term program effect. Ultimately, adoption of the Healthy People 2010 reproductive health and STD benchmarks would demonstrate more significant program impact across large regions of the United States (see Appendix K-1) (HHS, 2009). Finally, individualization by site or region and selection of key representative indicators from the more than 200 indicators in the *Handbook of Indicators* (Bertrand et al., 1994) would help spur site-specific goals directed at quality improvement. Thus, deciding which indicators to use, how many to use, and across what settings will be a function of the goal of the evaluation. As suggested by Bertrand et al. (1994), if the goal is to advance political support, indicators showing the program effectiveness and selected indicators from the policy environment will be monitored and distributed among stakeholders who can influence policy. Small new sites might want to focus on needs assess-

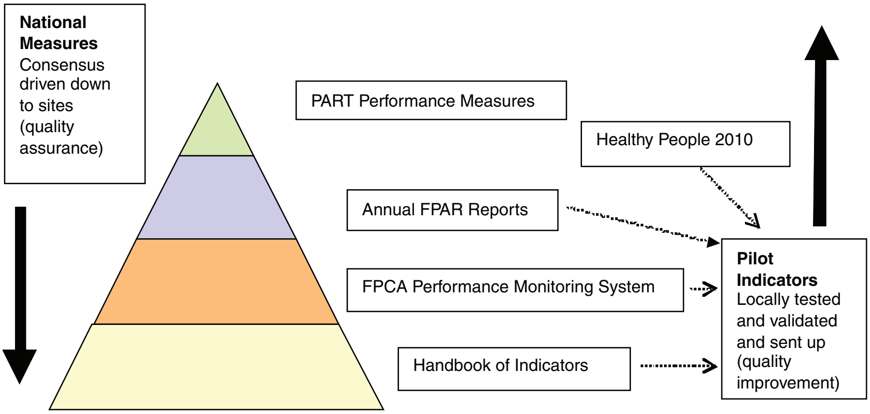

FIGURE K-6 Integration of quality assurance (program) and quality improvement (site) activities.

ments, increased volume, program revenues, technical competence, and patient satisfaction. Large, established, older sites or networks might want to emphasize networking and technical training to keep staff motivated and interested. Sites frequented primarily by teens or clients with LEP would obviously have different quality improvement interests than sites with more diverse populations.

More rapid improvement could be achieved if national measures were established for all sites to report, with recognized benchmarks or standards. These objective measures would represent quality assurance activities coming from the top down and would serve to demonstrate both short- and long-term impact over time. Additionally, there should be an opportunity for piloting site-specific and region-specific measures. In fact, sites should be encouraged or required to identify their own quality improvement initiatives consistent with the mission and goals of the program, but responsive to site-specific needs assessments (which are conducted routinely as part of the reapplication process). For example, sites with teen pregnancy problems would need to focus quality improvement activities differently from sites with birth-spacing, birth-limiting, or STD problems. It is conceivable that site-specific quality improvement indicators would be drawn from the universe of indicators and piloted and validated using the AHRQ framework of indicator development (AHRQ, 2001). Validated indicators could then be shared horizontally across sites and vertically from the bottom up with program administrators for consideration as national indicators. Further, there should be opportunities to share best practices to help understand why variation exists, provide a mechanism to minimize variation, and move more sites toward benchmark goals. The overall process could work similarly to the rapid improvement cycles and learning collaboratives currently being advocated by the Institute for Healthcare Improvement (IHI, 2003).

As these measures are introduced, further research and analysis of the merits of the Title X program should be conducted using a mix of methodologies, such as provider observation or simulated patients, to document technical competence and communication skills. Additional scientific validation of the effectiveness of these interventions is needed. Whenever possible, indicator development, data collection, and reporting should be electronic, or funding for FTE support should be included so that service resources will not be used to offset this expense. Given the transient nature of the poor population, there should be a vision or capacity for shared information (regional health information network), consistent with national goals for a health information highway (NCVHS, 2000). Additionally, a widely acknowledged strength of the Title X program is IEC training tools and clinical standards. Validation of the success of the IEC modules by both providers and clients should be confirmed; replicated across all sites; shared across state and federal agencies, including STD clinics and public schools; and incorporated into medical, nursing, and residency training curricula. Broader support at the administrative and policy levels is needed to facilitate the development of a national agenda emphasizing the maternal, child, and family health benefits of family planning and preventive health services in general and the Title X program in particular. While the presumed benefits are clear, the opportunity now exists to demonstrate the quality of family planning services within the Title X program definitively and establish a causal link with reproductive health outcomes. The American public needs to learn to plan for pregnancy from puberty on, and to acquire the skills necessary to achieve personal reproductive goals.

ANNEX K-1

HEALTHY PEOPLE 2010 OBJECTIVES

Currently, there are 13 Healthy People 2010 objectives related to reproductive health that could serve as indicators of quality for the Title X program (see Annex Table K-1):

- 9.1. Intended pregnancy
- 9.2. Birth spacing
- 9.3. Contraceptive use
  - — Contraceptive failure
  - — Emergency contraception
  - — Male involvement with pregnancy prevention
  - — Adolescent pregnancy
  - — Abstinence before age 15
  - — Abstinence ages 15–17
  - — Pregnancy prevention and STD protection
  - — Pregnancy prevention education
  - — Problems in becoming pregnant
  - — Insurance coverage for contraceptive supplies and services

There are also 19 Healthy People 2010 objectives related to STDs (see Annex Table K-2):

- *Chlamydia*—Reduce infection in those aged 15–24.
- *(GC)*—Reduce infection.
- *Syphilis*—Eliminate primary and secondary syphilis from the United States.
- *Herpes*—Decrease percent with genital infection.
- *Human papillomavirus (HPV) (developmental)*—Decrease percent with HPV (can help minimize the number of high-risk subtypes associated with cervical cancer).
- *Pelvic inflammatory disease*—Reduce proportion of females who have ever acquired PID.
- *Fertility problems*—Decrease percent of women with fertility problems associated with chlamydia and PID.
- *Heterosexual HIV (developmental)*—Reduce HIV infections in females aged 13–24 associated with heterosexual contact.
- *Congenital syphilis*—Reduce congenital syphilis.
- *Neonatal STD (developmental)*—Reduce neonatal consequences from maternal STD.

ANNEX TABLE K-1 Healthy People 2010 Reproductive Health Objectives with Targets and Baselines

Topic	Objective	Target	Baseline
Intended pregnancy	Increase percent of pregnancies that are intended	70 percent	51 percent Note: 39 percent in Canada, 6 percent in Netherlands
Spacing	Reduce percent of births occurring within 24 months of a previous birth	6 percent	11 percent
Contraceptive use	Increase use	100 percent	93 percent used People who do not use any method account for half of unintended pregnancies; rest occur to those who use intermittently or incorrectly
Contraception failure	Reduce proportion of females experiencing pregnancy despite use of a reversible contraceptive method	7 percent	13 percent Focus on consistent and correct use of a specific method
Emergency contraception (developmental)	Increase percent of health care providers that provide emergency contraception		Emergency contraception can reduce risk of pregnancy by 75 percent; in 1995, fewer than 1 percent of women reported using emergency contraception; need direct access and insurance reimbursement

continued

ANNEX TABLE K-1 Continued

Topic	Objective	Target	Baseline
Male involvement with pregnancy prevention (developmental)	Increase male involvement in pregnancy prevention and family planning efforts	Need to be culturally and linguistically sensitive in promoting condom use and addressing HIV and STD prevention, managed care marketing; emphasis on male responsibilities regarding welfare, need for rapid treatment of female partners who test positive for bacterial STD to decrease STDs, including HIV	Men make up 10 percent of total clientele in only 13 percent of clinics; an average of 6 percent of clients are male—only 2 percent of Title X clients in 1991 and 2 percent of Medicaid clients in 1990
Adolescent pregnancy	Decrease	43/1000	68/1000
Abstinence before age 15	Increase percent of teens who have never engaged in intercourse	Females 75 percent; males 75 percent	Females 62 percent; males 57 percent The later intercourse starts, the less overall exposure; need education regarding intimacy; setting limits; and resistance to social, media, peer, and partner pressure
Dual protection at ages 15–17 at first intercourse		Condoms: females 75 percent, males 83 percent; condoms +: females 9 percent, males 11 percent	Condoms: females 67 percent, males 72 percent; condoms +: females 7 percent, males 11 percent Condom use has increased, suggesting that teens do anticipate and plan for initiation; decrease in hormonal treatment

ANNEX TABLE K-1 Continued

Topic	Objective	Target	Baseline
Last intercourse		Condoms: females 49 percent, males 79 percent; condoms +: females 11 percent, males 20 percent	Condoms: females 39 percent, males 70 percent; condoms +: females 7 percent, males 16 percent Education about birth control does not prevent infections
Pregnancy prevention education		90 percent	64 percent females (tracking in men has just started)
Problems in becoming pregnant	Decrease proportion of married people unable to conceive or maintain pregnancy	10 percent	13 percent In 1995, small decline in infertility most marked in Hispanics
Insurance coverage for contraceptive supplies and services (developmental)			Institute of Medicine: one reason for unintended pregnancy is lack of coverage; half of indemnity plans and 7 percent of health maintenance organizations covered contraception in 1993; methods inconsistent; bias toward permanent surgical methods

- *Responsible teen sex*—Increase percent of adolescents who abstain from sex or use condoms if active.
- *Responsible sex on television (developmental)*—Increase number of positive messages related to responsible sexual behavior on television.
- *Hepatitis B vaccine in STD clinics*—Increase number of STD programs that offer hepatitis B vaccine.
- *Screening in detention and jails (developmental)*—Screen within 24 hours of admission and provide treatment before release.
- *Contracts to treat nonplan partners (developmental)*—Increase percent of local health departments that have contracts with managed care providers for treatment of nonplan partners.

ANNEX TABLE K-2 Healthy People STD Objectives with Targets and Baselines

Topic	Objective	Target	Baseline
Chlamydia	Reduce infection in those aged 15–24 Family planning clinics	3.0	5.0
	STD clinics	3.0	12.2
	Males	3.0	15.7
(GC)	Reduce infection	19/100 thousand	123/100 thousand
Syphilis	Eliminate primary and secondary syphilis from United States	0.2/100 thousand	3.2/100 thousand
Herpes	Decrease percent with genital infection	14 percent	17 percent
Human papillomavirus (HPV) (developmental)	Decrease percent with HPV (can help minimize the number of high-risk subtypes associated with cervical cancer)		
Pelvic inflammatory disease	Reduce proportion of female who have ever acquired PID	5 percent	8 percent
Fertility problems	Decrease percent of women with fertility problems associated with chlamydia and PID	15 percent	27 percent of women with fertility problems reported history of PID
Heterosexual HIV (developmental)	Reduce HIV infections in females aged 13–24 associated with heterosexual contact		

ANNEX TABLE K-2 Continued

Topic	Objective	Target	Baseline
Congenital syphilis	Reduce congenital syphilis	1/100 thousand	27/100 thousand
Neonatal STD (developmental)	Reduce neonatal consequences from maternal STD		
Responsible teen sex	Increase percent of adolescents who abstain from sex or use condoms if active	95 percent	85 percent
Responsible sex on television (developmental)	Increase number of positive messages related to responsible sexual behavior on television		
Hepatitis B vaccine in STD clinics	Increase number of STD programs that offer hepatitis B vaccine	90 percent	5 percent
Screening in detention and jails (developmental)	Screen within 24 hours of admission and provide treatment before release		
Contracts to treat nonplan partners (developmental)	Increase percent of local health departments that have contracts with managed care providers for treatment of nonplan partners		
Annual screening for chlamydia (developmental)	Increase percent of women under age 25 screened annually		

continued

ANNEX TABLE K-2 Continued

Topic	Objective	Target	Baseline
Screening of pregnant women (developmental)	Increase percent of pregnant women screened for STD, HIV, and (BV)		
Compliance with recognized STD treatment	Increase percent of primary care providers who treat patients with STDs who manage according to standards	90 percent	70 percent
Provider referral for sex partners (developmental)			

- *Annual screening for chlamydia (developmental)*—Increase percent of women under age 25 screened annually.
- *Screening of pregnant women (developmental)*—Increase percent of pregnant women screened for STD, HIV, and (BV).
- *Compliance with recognized STD treatment*—Increase percent of primary care providers who treat patients with STDs who manage according to standards.
- *Provider referral for sex partners (developmental)*.

ANNEX K-2

REPRESENTATIVE INDICATORS FOR EACH OF THE EIGHT BROAD CATEGORIES IN BERTRAND ET AL. (1994)

I. Policy Environment
- Existence of a policy development plan
- Number of appropriately disseminated policy analyses
- Number of awareness-raising events targeted to leaders
- Existence of a strategic plan for expanding the national family planning program
- Integration of demographic data into development planning
- Number of statements of leaders in support of family planning
- Formal population policy addressing fertility and family planning
- National family planning coordination
- Level of the family planning program within the government administration
- Levels of import duties and other taxes
- Restrictions on advertising of contraceptives in the mass media
- Absence of unwarranted restrictions on providers and users
- Quality of program leadership
- Extent of commercial-sector participation

II. Service Delivery Operations
- Management
- Training
- Commodities and logistics
- Information–education–communication (IEC)
- Research and evaluation

III. Management (illustrative indicators)
- Existence of a clear mission that contributes to the achievement of program goals
- Realization of operational targets
- Clearly defined organizational structure
- Adequacy of staffing
- Awareness of current financial position
- Access to current information on key areas of program functioning
- Access to current information on program progress
- Capacity to track commodities

IV. Training

- Number/percentage of courses that achieve learning objectives
- Number/percentage of courses that contribute to the achievement of program training objectives
- Number/percentage of courses in which the training methodology is appropriate for the transfer of skills and knowledge
- Number of trainees by type
- Number/percentage of trainees who have mastered relevant knowledge
- Number/percentage of trainees competent to provide a specific family planning service
- Number/percentage of trained providers assessed to be competent at a specified period (e.g., 6 months) post-training
- Number/percentage of trainees who apply the skills to their subsequent work

V. Commodities and Logistics

- Pipeline wastage
- Percentage of storage capacity meeting acceptable standards
- Frequency of stock-outs
- Percentage of service delivery points (SDPs) stocked according to plan
- Percentage of key personnel trained in contraceptive logistics
- Composite indicator for commodities and logistics

VI. Information–Education–Communication

- Number of communications produced, by type, during a reference period
- Number of communications disseminated, by type, during a reference period
- Percentage of target audience exposed to program messages, based on respondent recall
- Percentage of target audience who correctly comprehend a given message
- Number of contraceptive methods known
- Percent of audience who acquire the skill to complete a certain task as a result of exposure to a specific communication
- Percentage of target audience exposed to a specific message who report liking it
- Number/percentage of target audience who discuss message(s) with others, by type of person
- Percentage of target audience who advocate family planning practice

VII. Research and Evaluation

- Presence of an active research and evaluation unit
- Extent of use of a service system
- Conduct of periodic household and/or special-purpose surveys and studies
- Conduct of operations research
- Regular conduct of process evaluations
- Conduct of effectiveness, efficiency, and impact evaluations
- Use of research and evaluation results for program modification
- Dissemination of research and evaluation results

VIII. Family Planning Service Outputs

- Accessibility (illustrative indicators)
  - Number of SDPs located within a fixed distance or travel time of a given community (i.e., service density)
  - Cost of 1 month's supply of contraceptives as a percentage of monthly wages
  - Restrictive program policies on contraceptive choice
  - Percentage of the population who know of at least one source of contraceptive services and/or supplies
  - Percentage of nonuse related to psychosocial barriers

- Quality of care (illustrative indicators)
  - Number of contraceptive methods available at a specific SDP
  - Percentage of counseling sessions with new acceptors in which provider discusses all methods
  - Percentage of client visits during which provider demonstrates skill in clinical procedures, including asepsis
  - Percentage of clients reporting sufficient time with provider
  - Percentage of clients informed of timing and sources for resupply/revisit
  - Percentage of clients who perceive that hours/days are convenient

- Program Image
  - Number and type of activities to improve the public image of family planning during a reference period (e.g., 1 year)
  - Percentage of target population favorable to the (national) family planning program

- Service Utilization
  - Number of visits to SDP(s)
  - Number of acceptors new to modern contraception

  - Number of acceptors new to the institution
  - Number of new acceptors
  - Couple-years of protection (CYP)
  - Method mix
  - User characteristics
  - Continuation rates

- Contraceptive Practice
  - Contraceptive prevalence rate (CPR)
  - Number of current users
  - Level of ever (past) use
  - Source of supply (by method)
  - Method mix
  - User characteristics
  - Continuation rates
  - Use failure rates

- Fertility Impact

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Appendix L

Committee and Staff Biographies

COMMITTEE MEMBERS

Ellen Wright Clayton, J.D., M.D. (*Chair*), is Rosalind E. Franklin Professor of Genetics and Health Policy at Vanderbilt University, where she is a professor of law and pediatrics. She is also the director of Vanderbilt's Center for Biomedical Ethics and Society and is a practicing pediatrician at Vanderbilt Medical Center. Her research and teaching interests include pediatrics, medical ethics, legal and ethical issues in children's and women's health, and genetics and health policy. She has served as a member on numerous committees for the National Institutes of Health (NIH), including the Ethical, Legal, and Social Issues Working Group of the Newborn Screening Taskforce, Maternal and Child Health Bureau, Health Resources Services Administration. Dr. Clayton has served as a consultant to the Food and Drug Administration (FDA) on the topic of clinical pharmacology during pregnancy. She is a member of the Institute of Medicine (IOM) and has served on several National Academy of Sciences (NAS) committees, as well as the IOM's Health Sciences Policy Board. She has authored numerous publications in books, medical journals, interdisciplinary journals, and law journals on the intersection of law, medicine, and public health. Dr. Clayton received her M.D. from Harvard University and her J.D. from Yale University.

Ronald M. Andersen, Ph.D., is Wasserman Professor Emeritus in the departments of Health Services and Sociology, University of California, Los Angeles. He has taught courses in health services organization, research methods, evaluation, and leadership. He has studied access to medical care for his entire professional career. Dr. Andersen developed the Behavioral Model of Health Services Use, which has been used extensively nationally and internationally as a framework for utilization and cost studies of general populations, as well as special studies of minorities, low-income populations, children, women, the elderly, oral health, the homeless, and the HIV-positive population. He has directed three national surveys of access to care and has led numerous evaluations of local and regional populations and programs designed to promote access to medical care. Dr. Andersen's other research interests include international comparisons of health services systems, graduate medical education curriculum, physician health services organization integration, and evaluations of geriatric and primary care delivery. He was on the founding Board of the Association for Health Services Research and has been chair of the Medical Sociology Section of the American Sociological Association. In 1994 he received the association's Leo G. Reeder award for Distinguished Service to Medical Sociology; in 1996 he received the Distinguished Investigator Award from the Association for Health Services Research; and in 1999 he received the Baxter Allegiance Health Services Research Prize. Dr. Andersen received his Ph.D. in sociology from Purdue University.

Dyan A. Aretakis, F.N.P., M.S.N., P.N.P., is project director of the Teen Health Center of the University of Virginia Health System, which she cofounded in 1991 to offer reproductive health care to local, mainly medically uninsured adolescents. She is also a practicing family nurse practitioner at the center, which serves more than 3,600 patients each year. In her role as director, Ms. Aretakis has developed patient and peer education programs and conducted state-wide professional conferences. She has served on numerous committees and advisory boards related to child and adolescent health. She is also a frequent speaker on the topic of adolescent reproductive health for professional groups, the Medical School and the School of Nursing at the University of Virginia, and statewide conferences and associations. Ms. Aretakis holds family nurse practitioner, master of science in nursing with a specialty in pediatrics, and pediatric nurse practitioner degrees from the University of Virginia.

Jennifer S. Barber, Ph.D., is an associate professor at the Institute for Social Research and an associate professor of sociology at the University of Michigan. She studies childbearing behavior, intergenerational processes, and attitude–behavior relationships in both the United States and Nepal. In the United States, Dr. Barber is currently conducting a mixed-method data collection project, combining survey interviews with semistructured interviews and a weekly electronic journal. Her current research in Nepal focuses on intergenerational influences on family formation attitudes and behavior. She has published extensively on topics related to family relationships and childbearing, and is a member of the National Council on Family Relations and the Population Association of America. Dr. Barber holds a Ph.D. in sociology and demography from Pennsylvania State University.

Miriam A. Bender, J.D., is chief executive officer of Women's Health Virginia, a statewide nonprofit organization that promotes and improves Virginia women and girls' health and well-being. The organization focuses attention on the health needs of women and girls in Virginia; addresses women and girls' health comprehensively and as a continuous process; takes a multidisciplinary approach that includes economic, educational, cultural, environmental, social, and medical issues; and connects people and organizations in the public and private sectors and from around the state to work together. In her capacity as a practicing attorney, Ms. Bender works primarily with nonprofit organizations on issues regarding development and public policy. She previously taught at the University of St. Louis School of Law and served as associate general counsel at the U.S. Department of Agriculture and in various positions at the Federal Trade Commission. She has served on the Board of Directors of the League of Women Voters of Virginia and of Charlottesville and Albemarle County and the Virginia Citizens Consumer Council. Ms. Bender received her J.D. from Columbia University.

Regina M. Benjamin, M.D., M.B.A., is founder and CEO of the Bayou Clinic in Bayou La Batre, Alabama. She is chair-elect of the Federation of Sate Medical Boards and vice chair of the American Medical Association's (AMA's) Council on Ethical and Judicial Affairs. She is former associate dean for rural health at the University of South Alabama's College of Medicine in Mobile, where she administered the Alabama Area Health Education Centers program and previously directed its Telemedicine program. She is former president of the Medical Association of the State of Alabama. In 1998 Dr. Benjamin was the U.S. recipient of the Nelson Mandela Award for Health and Human Rights. She has also served as president of the AMA's Education and Research Foundation. She has done missionary work in Honduras and was previously on the Board of Physicians for Human Rights. Dr. Benjamin received her M.D. from the University of Alabama at Birmingham and completed her residency in family practice at the Medical Center of Central Georgia. After receiving an M.B.A. from Tulane University, she converted her solo practice in Bayou La Batre to a rural health clinic. Dr. Benjamin spent several of her early years moonlighting in emergency rooms and nursing homes to sustain her practice, which is currently recovering from the devastation of Hurricane Katrina.

Claire D. Brindis, Dr.P.H., is a professor of pediatrics and health policy at the University of California, San Francisco (UCSF) and is the director of UCSF's Philip R. Lee Institute for Health Policy Studies. She is also the co-director of the Bixby Center for Reproductive Health Research and Policy. Her research interests focus on adolescent and children's health policy and women's health. Dr. Brindis leads a multidisciplinary team evaluating California's Office of Family Planning's Family PACT (Planning, Access, Care and Treatment) program and has conducted program evaluations of teenage pregnancy and parenting programs, teenage pregnancy prevention programs, and community coalitions focused on teenage pregnancy prevention. She also serves as a frequent policy advisor to federal, state, and local policy makers and private foundations. Her writings, publications, and personal consultation in the field of adolescent pregnancy prevention have been used extensively in the planning and implementation of various state and federal initiatives. She previously served as chair of the Population, Reproductive Health and Family Planning Section of the American Public Health Association and as chair of the Board of Directors of Advocates for Youth. Dr. Brindis' educational background includes a Ph.D. in public health and behavioral sciences from the University of California, Berkeley and a masters degree in public health from the University of California, Los Angeles (UCLA).

Sarah S. Brown, M.S.P.H., is cofounder and CEO of the National Campaign to Prevent Teen and Unplanned Pregnancy. Previously, she was a senior study director at the IOM, where she completed studies on unintended pregnancy, health care reform, substance abuse among pregnant women, access to prenatal care, and prevention of low birth weight. Ms. Brown has served on the advisory boards of many national organizations, including the Population Advisory Board of the David and Lucile Packard Foundation, the American College of Obstetricians and Gynecologists, the DC Mayor's Committee on Reducing Teenage Pregnancies and Out-of-Wedlock Births, and *Teen People* magazine. She holds a masters degree in public health from the University of North Carolina.

Betty A. Chewning, Ph.D., is a professor at the University of Wisconsin School of Pharmacy and directs the Sonderegger Research Center. Throughout her research, she has sought to build on the strengths and perspectives of communities while conducting both descriptive and evaluation research related to abstinence and contraceptive education interventions in diverse populations. She created and evaluated computer-based abstinence, sexual decision making, and contraceptive modules in the Body Awareness Resource Network. Dr. Chewning analyzed the data set to identify risk and protective factors related to delayed initiation of sexual intercourse and early adoption of effective contraception by sexually active adolescents. Building on this work, she developed and evaluated the impact of a computerized contraceptive decision aid. She developed the computer program by involving low-literacy adolescents from Cabrini Green, a public housing unit in Chicago. She implemented and evaluated this program in family planning clinics in Chicago and Madison, Wisconsin. Following this work, Dr. Chewning was asked by the Great Lakes Intertribal Council to identify needs and interventions for Indian reservation youth to reduce sexual risk taking and HIV exposure. This work, as well as her earlier work, helped document protective factors that can help buffer sexual risk taking by Indian adolescents. Dr. Chewning's Ph.D. is in educational psychology, and she has done postdoctoral work in industrial engineering.

Angela Diaz, M.D., M.P.H., is the Jean C. and James W. Crystal Professor of Adolescent Health at Mount Sinai School of Medicine and Director of the Mount Sinai Adolescent Health Center. She has been providing direct medical services to children and adolescents for more than 25 years, particularly in identifying and engaging trauma-affected adolescents. The Mount Sinai Adolescent Health Center is a unique program that provides comprehensive, integrated, interdisciplinary primary care, reproductive health, mental health, and health education services to teens. Dr. Diaz is president of the Children's Aid Society Board of Trustees. She has been active in international health projects in Asia, Central and South America, Europe, and Africa. She has published numerous articles on topics including child and adolescent sexual abuse, adolescents' access to health care, and health services for immigrants. Among her many accomplishments, Dr. Diaz has been a White House Fellow, was awarded the American Academy of Pediatrics Founders of Adolescent Health Award, and received the Alexander Richman Commemorative Award for Ethics and Humanism in Medicine from the Mount Sinai School of Medicine. She served with the FDA's Pediatric Advisory Committee and with the NIH State of the Science Conference on Preventing Violence and Related Health Risk Social Behaviors in Adolescents. Dr. Diaz her M.D. at Columbia University College of Physicians and Surgeons and her M.P.H. from Harvard University.

Vivian M. Dickerson, M.D., is a clinical professor of obstetrics and gynecology at the University of California, Irvine (UCI) Medical Center. In addition, she is Executive Medical Director of Women's Health at Hoag Memorial Hospital Presbyterian in Newport Beach, California. She is certified by the American Board of Obstetrics and Gynecology, for which she is currently an examiner. Dr. Dickerson is a prolific lecturer and writer, having published numerous peer reviewed articles on topics including contraception, menopause, PMS, and obesity. Throughout her career, she has received a variety of awards and honors, including the American Medical Women's Association Gender Equity Award, the UCI College of Medicine Golden Apple Teaching Award, and the District Service Award from the American College of Obstetricians and Gynecologists. She currently serves as editor in chief for *The Female Patient*. Annually since 2001, Dr. Diaz has been named by Woodward and White as one of the Best Doctors in America. In 2004, she became president of the American College of Obstetricians and Gynecologists, the third woman ever to achieve this national honor. Dr. Dickerson graduated summa cum laude from the University of California, Santa Barbara, and subsequently spent 2 years in Togo, West Africa, as a health educator with the United States Peace Corps. Upon her return, she attended the University of California, San Diego, medical school and completed her internship and residency in obstetrics and gynecology at UCLA Cedars-Sinai Medical Center.

Stephen F. Heartwell, Dr.P.H., is Deputy Director of Domestic Programs for the Susan Thompson Buffett Foundation. The foundation concentrates its resources on activities in education, service delivery, and global development, with a focus on decreasing the rate of unintended pregnancy. Dr. Heartwell retired from the University of Texas Southwestern Medical School, Department of Obstetrics and Gynecology, after serving 35 years as professor and director of the Division of Community Women's Health Care. This division provided comprehensive women's health care services to more than 72,000 women annually in Dallas County, with a special emphasis on Title X–supported family planning services. It also provided certificate women's health care nurse practitioner education through a Title X grant for more than 20 years. The teaching and research programs of the division have received national recognition. Prior to his appointment at the University of Texas Southwestern Medical School, Dr. Heartwell held the position of assistant professor and associate director of the Institute for Health Services Research at Tulane University. He received an M.P.H. in epidemiology and a Dr.P.H. in family health and population dynamics from the Tulane University School of Public Health and Tropical Medicine.

Judith R. Lave, Ph.D., is chair of the Department of Health Policy and Management, director of the Health Administration Program, codirector of the Center for Research on Health Care, and professor of health economics at the University of Pittsburgh. She is also director of the Pennsylvania Medicaid Policy Center. Her research interests include health care financing, costs of graduate medical education, health insurance, health care for children, the economics of mental health, and the cost of illness. Prior to coming to the University of Pittsburgh, she was director of the Office of Research at the Health Care Financing Administration, now the Centers for

Medicare and Medicaid Services. Dr. Lave is a member of the IOM, where she serves on the Board of Health Care Services and the National Academy for Social Insurance and is a distinguished fellow of AcademyHealth. She is also on the Technical Advisory Group for the Pennsylvania Health Care Cost Containment Council. She was a commissioner on the Medicare Payment Advisory Commission and its predecessor commission, the Prospective Payment Assessment Commission. Dr. Lave received her Ph.D. in economics from Harvard University.

Ellen L. Rautenberg, M.H.S., is president and CEO of Public Health Solutions (formerly the Medical and Health Research Association [MHRA] of New York City, Inc.), which is dedicated to improving the health status and well-being of New Yorkers, with special emphasis on the city's high-risk, underserved populations. Among its responsibilities, Public Health Solutions has been a Title X grantee since 1982 and is a provider of reproductive health services to 20,000 low-income women through a network of seven centers. Before joining Public Health Solutions (then MHRA) in 1995, Ms. Rautenberg was executive director for special population projects at the New York Academy of Medicine, as well as an independent consultant specializing in public health policy/program development and strategic planning. She has an extensive background in the planning and management of public health programs. Between 1981 and 1990, she worked for the New York City Department of Health both as assistant commissioner for planning, evaluation, and grants and as assistant commissioner for AIDS program services. Prior to her experience in city government, Ms. Rautenberg ran the Community and Family Health Center in Baltimore, developed the perinatal health plan for central Maryland, and was a family planning counselor in Washington, DC. She is a member of the Public Health Council of New York State and of the boards of the Human Services Council of New York, the National Network of Public Health Institutes, and the Family Planning Councils of America. She is immediate past chair of the National Family Planning and Reproductive Health Association. Ms. Rautenberg holds an M.H.S. in comprehensive health planning and administration from the Johns Hopkins Bloomberg School of Public Health.

Eduardo J. Sanchez, M.D., M.P.H., is vice president and chief medical officer for Blue Cross and Blue Shield of Texas. He served as Texas commissioner of health from 2001 to 2006, initially as commissioner of the Texas Department of Health (TDH) from November 2001 through August 2004 and then as commissioner of the Texas Department of State Health Services (DSHS) from September 2004 to October 2006. As TDH commissioner, Dr. Sanchez oversaw programs such as family and community health services, mental health and substance abuse prevention and treatment, disease prevention and all-hazards preparedness, and environmental and consumer safety and regulatory programs. The Texas DSHS, a single agency made up of the state's former public health, mental health, and substance abuse agencies, has more than 11,500 employees and operates on an annual budget of more than $2.3 billion. Dr. Sanchez is a fellow of the American Academy of Family Physicians. He actively practiced in Austin, Texas, from 1992 to 2001. He also served as health authority and chief medical officer for the Austin–Travis County Health and Human Services Department from 1994 to 1998. Dr. Sanchez received an M.D. from the University of Texas Southwestern Medical School in Dallas. He holds an M.P.H. from the University of Texas School of Public Health and an M.S. in biomedical engineering from Duke University.

Jeannette E. South-Paul, M.D., is Andrew W. Mathieson Professor and Chair of the Department of Family Medicine at the University of Pittsburgh. Her research interests include measuring and eliminating health and health care disparities in maternal/child health and chronic disease, and evaluating cultural competence in clinicians and trainees. She served as a family physician in the U.S. Army for 22 years and still maintains an active family medicine practice, including maternity care, at the UPMC Matilda Theiss Health Center. During her service with U.S. Army, Dr. South-Paul served as chair of the Department of Family Medicine and vice president for minority affairs at the F. Edward Hébert School of Medicine of the Uniformed Services University of the Health Sciences. She has also served as national president of the Society of Teachers of Family Medicine and president of the Uniformed Services Academy of Family Physicians, and has chaired cultural competence and diversity committees at the American Academy of Family Physicians and the Association of American Medical Colleges, developing tools for teaching and assessing cultural competence. She also has an interest in sociocultural issues for health care and health care for special populations, and has volunteered in clinics for the uninsured both in Maryland and in Pittsburgh. Dr. South-Paul is a widely recognized speaker and author on the impact of race, ethnicity, and culture on health; cultural diversity and academic medicine; and the development of minority faculty. She holds an M.D. from the University of Pittsburgh School of Medicine and completed postgraduate training in family medicine at the Eisenhower Army Medical Center and a fellowship in faculty development at the University of North Carolina.

IOM STAFF

Adrienne Stith Butler, Ph.D., is a senior program officer in the IOM's Board on Health Sciences Policy. Previously, she was study director for the IOM report *Preterm Birth: Causes, Consequences, and Prevention.* She also served as study director for the report *Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy,* a study conducted by the Board on Neuroscience and Behavioral Health, and for the IOM reports *In the Nation's Compelling Interest: Ensuring Diversity in the Health-Care Workforce* and *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care,* studies conducted by the Board on Health Sciences Policy. Prior to working at the IOM, Dr. Butler served as James Marshall Public Policy Scholar, a fellowship cosponsored by the Society for the Psychological Study of Social Issues and the American Psychological Association (APA). In this position, based at the APA in Washington, DC, she engaged in policy analysis and monitored legislative issues related to ethnic disparities in health care and health research, racial profiling, and mental health counseling provisions in the reauthorization of the Elementary and Secondary Education Act. Dr. Butler, a clinical psychologist, received her Ph.D. in 1997 from the University of Vermont. She completed postdoctoral fellowships in adolescent medicine and pediatric psychology at the University of Rochester Medical Center in Rochester, New York.

Marnina Kammersell, M.A., is a research associate in the Board on Health Sciences Policy. Prior to joining the IOM, she was a health science policy analyst in NIH's Clinical Research Policy Analysis and Coordination (CRpac) program within the Office of Biotechnology Activities. Her work at NIH focused on the ethics, policy, and regulation of clinical trials. Ms. Kammersell previously spent time as a research assistant at The George Washington University's Center for International Science and Technology Policy, and she also served as a legislative intern for the House of Representatives' Committee on Science. She was 2005 Christine Mirzayan Fellow at the National Academies, where she worked on the *Rising above the Gathering Storm* report. She holds a M.A. in public policy with a focus on health policy from The George Washington University and a B.A. in philosophy from the University of Michigan.

Thelma L. Cox is a senior program assistant in the Board on Health Sciences Policy. During her years at the IOM, she has also provided assistance to the Division of Health Care Services and the Division of Biobehavioral Sciences and Mental Disorders. Ms. Cox has worked on numerous IOM reports, including *In the Nation's Compelling Interest: Ensuring Diversity* *in the Health-Care Workforce; Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care;* and *Ethical Issues Relating to the Inclusion of Women in Clinical Studies*. She has received the National Research Council Recognition Award and two IOM Staff Achievement Awards.