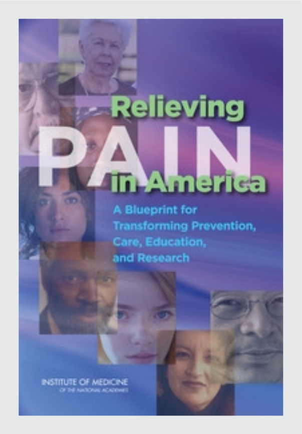

Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research

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AUTHORS

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Board on Health Sciences Policy

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

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URSULA WESSELMANN, Edward A. Ernst Endowed Professor of Anesthesiology, Professor of Neurology, University of Alabama at Birmingham, Department of Anesthesiology, Division of Pain Medicine, Birmingham, AL

LONNIE ZELTZER, Director, Pediatric Pain Program, Mattel Children's Hospital at UCLA; Professor of Pediatrics, Anesthesiology, Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine at the University of California, Los Angeles, CA

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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:

Allan Basbaum, University of California, San Francisco
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Lisa A. Cooper, Johns Hopkins Medical Institutions
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William S. Stokes, National Institute of Environmental Health Sciences
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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 **Caswell A. Evans** and **Elaine L. Larson**. 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

Protection from and relief of pain and suffering are a fundamental feature of the human contract we make as parents, partners, children, family, friends, and community members, as well as a cardinal underpinning of the art and science of healing. Pain is part of the human condition; at some point, for short or long periods of time, we all experience pain and suffer its consequences. While pain can serve as a warning to protect us from further harm, it also can contribute to severe and even relentless suffering, surpassing its underlying cause to become a disease in its own domains and dimensions. We all may share common accountings of pain, but in reality, our experiences with pain are deeply personal, filtered through the lens of our unique biology, the society and community in which we were born and live, the personalities and styles of coping we have developed, and the manner in which our life journey has been enjoined with health and disease.

The personal experience of pain is often difficult to describe, and the words we choose to describe pain rarely capture its personal impact, whether it is sudden and limited or persists over time. Severe or chronic pain can overtake our lives, having an impact on us as individuals as well as on our family, friends, and community. Through the ages, pain and suffering have been the substrates for great works of fiction, but the reality of the experience, especially when persistent, has little redeeming or romantic quality. The personal story of pain can be transformative or can blunt the human values of joy, happiness, and even human connectedness.

As a physician and a public health professional, we have experienced pain in different ways, but we also share a common bond of experience with those we have cared for professionally or personally. Those experiences shaped the way we approached the request of the Institute of Medicine (IOM) to co-chair a committee to assess the impact of pain in America. Our experiences extend from the care of individuals to evaluation of health and disease in populations, and we were joined by an outstanding group of individuals with deep knowledge of the biological, psychosocial, ethical, legal, clinical, and deeply personal aspects of pain and suffering. Over an intense 5-month period, we shared facts and figures, perceptions and realities, knowledge and assumptions, and listened carefully to each other and to the dozens of individuals and groups who provided testimony at our public meetings, as well as the thousands who shared their stories, hopes, disappointment, and anger in their written comments and testimonials. Throughout this process, we received extraordinary support from the IOM—especially from Adrienne Stith-Butler and Thelma Cox. We also benefited from the writing skills of Victoria and Neal Weisfeld. We have been enriched by all these experiences and encounters and have tried to respond to the pleas of many for recognition, understanding, and help. While we came to this study with our own expectations, we have recognized as a consequence of our shared efforts that the magnitude of the pain suffered by individuals and the associated costs constitute a crisis for America, both human and economic. We recognize further that approaching pain at both the individual and the broader population levels will require a transformation in how Americans think and act individually and collectively regarding pain and suffering. We believe this transformation represents a moral and national imperative.

Our conclusions are consonant with our individual life journeys. One of us spent decades as a pediatric oncologist and clinical scientist focused on children with catastrophic diseases. Pain and suffering were natural extensions of these disease processes and evoked sympathy and compassion from health care providers, families, and communities. But those experiences also made clear that while pain can often be controlled, it frequently cannot be eliminated, and when that is the case, it becomes more dominant for the individual than her or his underlying disease.

It also became clear that when pain could be ascribed to an underlying disease, such as cancer, it was accepted as real and treated with concern. The validation of disease made the pain socially acceptable, not shunned by the health care system or by families and communities. However, when as a pediatric oncologist one of us also experienced chronic pain in a family member whose underlying disease was less well defined, the cultural perception of and response to the pain by the health care community was dramatically different. Reactions ranged from care and compassion to judgmental opinions that lacked compassion and sometimes devolved into blaming or personalization of responsibility. The lack of a defined disease made the symptoms of pain and suffering less acceptable and more ascribed to overreaction, emotional instability, or worse. Because the pain could not be seen or measured “objectively” or interpreted within the context of the known, it was more likely to be dismissed, diminished, or avoided. The irony is that this pain and suffering, just like that of the patient with a known disease, could be life dominant—a disease in its own right.

As a behavioral scientist, one of us has worked for years with individuals, families, and communities that are trying to manage chronic disease effectively. This personal journey has made clear that for people who must deal with a heart condition, a digestive disease, a rheumatic condition, or a similar problem, pain can be a persistent companion. It can exacerbate depression, produce fatigue, hamper functioning, and diminish quality of life. It can create stress and extract high psychic and material costs in families. It also can lead to the development of unexpected personal strengths and an astonishing capacity to prevail. However, pain is a fearsome way to develop such qualities. Control of pain, and of the disease that often accompanies it, depends on the ability of individuals to garner information and assistance, of family members to give productive help, of clinicians to explore many options, and of communities to create systems to support families and clinicians. Most people living with pain, however, are not cosseted in this way, and we are woefully lacking in understanding how to offer them with the help they need or, when we do understand, in the capacity to provide it.

This is not to say that the medical community is uncaring and unwilling to help people with pain. But health care providers are subject to bias, limitations in knowledge, and differences in the systems in which they work. They are eager for new solutions and new insights, particularly with respect to chronic pain when a defined cause is lacking. Unfortunately, many health care providers lack a comprehensive perspective on pain and not infrequently interpret the suffering of others through their own personal lens. Misjudgment or failure to understand the nature and depths of pain can be associated with serious consequences—more pain and more suffering—for individuals and our society.

Our committee recognizes the need for a transformed understanding of pain. We believe pain arises in the nervous system but represents a complex and evolving interplay of biological, behavioral, environmental, and societal factors that go beyond simple explanation. Knowledge of pain needs to be enriched from the molecular and genetic to the cellular, neural network, and systems levels. It is necessary to understand how the settings and surroundings in which pain occurs and is experienced have an impact on its biology. The committee recognizes the need for new tools and metrics with which to define, diagnose, and monitor pain and its consequences, as well as for new approaches to treatment and prevention that are likely to result from novel and more interdisciplinary approaches to research. We see a need for better ways to develop, evaluate, and make available new approaches to pain management more rapidly and expeditiously. We also see the importance of approaching the individual within the broader domain of cultural diversity and of recognizing the subpopulations that are most affected by chronic pain and develop strategies to address their needs. We believe it is necessary to understand better the link between acute and chronic pain and find ways to break that link. We recognize the need to develop ever more informed health care professionals, working individually and in teams, in rural and urban settings, to address pain in the communities they serve. We believe it is necessary to understand better the true impact of pain on the workforce, our families, and the broader population and seek ways to lessen that impact. Meeting these challenges will require a cultural transformation in the way pain is perceived and managed on both the personal and societal levels.

The committee worked diligently to develop this report in an objective manner based on evidence. In doing so, we became acutely aware of the limitations of existing knowledge and the data on which it is based. We learned from our deliberations that there is crisis in the impact of and response to pain in America. Individually and collectively, we have a moral imperative to address this crisis. It is our hope that this report will help stimulate a concerted response to this crisis.

Philip A. Pizzo, *Chair*
Noreen M. Clark, *Vice Chair*
Committee on Advancing Pain Research, Care, and Education

Acknowledgments

Many 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 sponsors of this report. Funds for the committee's work were provided by the U.S. Department of Health and Human Services, National Institutes of Health. The committee thanks Amy B. Adams, who served as project officer, for her assistance during the study process.

The committee gratefully acknowledges the contributions of the many individuals who provided valuable input to its work. These individuals helped the committee understand varying perspectives on pain research, care, and education. The committee thanks those who provided important information and data at its open workshops. Appendix A lists these individuals and their affiliations. As part of its work, the committee received written testimony from thousands of individuals and organizations. This testimony helped the committee understand the experiences of persons living with pain and their family members, as well as health care providers, and the perspectives of many stakeholder organizations. Appendix B provides a summary of this input. The committee is grateful for the time, effort, and valuable information provided by all of these dedicated individuals.

The committee would like to thank the authors whose commissioned paper added to the evidence base for this study. These include Darrell J. Gaskin, Johns Hopkins Bloomberg School of Public Health, and Patrick Richard, The George

Washington University School of Public Health and Health Services. Finally, the committee thanks individuals who assisted in its work by providing data. The committee acknowledges Jennifer Madans, Charlotte Schoenborn, Vicki Burt, and colleagues from the National Center for Health Statistics, and Kevin Galloway, Army Pain Task Force.

Contents

APPENDIXES

Summary[1]

Acute and chronic pain affects large numbers of Americans, with approximately 100 million[2] U.S. adults burdened by chronic pain alone. The annual national economic cost associated with chronic pain is estimated to be $560-635 billion. Pain is a uniquely individual and subjective experience that depends on a variety of biological, psychological, and social factors, and different population groups experience pain differentially. For many patients, treatment of pain is inadequate not just because of uncertain diagnoses and societal stigma, but also because of shortcomings in the availability of effective treatments and inadequate patient and clinician knowledge about the best ways to manage pain. Some answers will come from exciting new research opportunities, but changes in the care system also will be needed in order for patients' pain journeys to be shorter and more successful. In the committee's view, addressing the nation's enormous burden of pain will require a cultural transformation in the way pain is understood, assessed, and treated. This report provides recommendations intended to help achieve this transformation.

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[1] This summary does not include references. Citations for the discussion presented in the summary appear in the subsequent report chapters.

[2] Because of a computational error, the initial publication of the report *Relieving Pain in America* contained an erroneous estimate of the number of adults who experience chronic pain in the United States. A re-analysis of the study by Tsang and colleagues (2008), as well as the independent assessment by Gaskins and Richards (Appendix C), yield an estimate of approximately 100 million U.S. adults who experience chronic pain and not 116 million as stated in the original report. The text of the report has been revised to show this corrected estimate.

Pain is a universal experience. Common chronic pain conditions affect approximately 100 million U.S. adults at a cost of $560-635 billion annually in direct medical treatment costs and lost productivity. Pain's occurrence, severity, duration, response to treatment, and disabling consequences vary from person to person because pain, like other severe chronic conditions, is much more than a biological phenomenon and has profound emotional and cognitive effects. Pain can be mild and easily handled with over-the-counter medications; it can be acute and recede with treatment; it can be recurrent over months or years; or it can be chronic and debilitating, requiring almost constant attention and accommodation.

Many shortfalls in pain assessment and treatment persist despite humanity's intimate familiarity with pain throughout history, modern appreciation for the complexity of its origins and the diversity of its effects, and the not insubstantial risk that any one person may have serious or chronic pain at some point. In general, these shortfalls arise through gaps in policy, treatment, attitudes, education, and research. Why and how these gaps might be remedied was the focus of the Institute of Medicine's (IOM's) Committee on Advancing Pain Research, Care, and Education.

CHARGE TO THE COMMITTEE AND STUDY APPROACH

Section 4305 of the 2010 Patient Protection and Affordable Care Act required the Secretary, Department of Health and Human Services (HHS), to enter into an agreement with the IOM for activities "to increase the recognition of pain as a significant public health problem in the United States." Accordingly, HHS, through the National Institutes of Health (NIH), requested that the IOM conduct a study to assess the state of the science regarding pain research, care, and education and to make recommendations to advance the field (see Chapter 1 for the committee's statement of task).

This report responds to the committee's charge by providing a blueprint for transforming the way pain is understood, assessed, treated, and prevented. It provides recommendations for improving the care of people who experience pain, the training of clinicians who treat them, and the collection of data on pain in the United States. The report does not provide an exhaustive review of the literature examining the science of pain and its diagnosis and treatment. Nor does the report present a clinical algorithm for the diagnosis and treatment of patients with pain. Rather, it describes the scope of the problem of pain and provides an overview of needs for care, education, and research. The committee's recommendations are based on both scientific evidence and expert judgment.

Several important underlying principles informed the committee's approach to its charge. These principles are presented in Box S-1.

BOX S-1
Underlying Principles

- ***A moral imperative.*** Effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions.
- ***Chronic pain can be a disease in itself.*** Chronic pain has a distinct pathology, causing changes throughout the nervous system that often worsen over time. It has significant psychological and cognitive correlates and can constitute a serious, separate disease entity.
- ***Value of comprehensive treatment.*** Pain results from a combination of biological, psychological, and social factors and often requires comprehensive approaches to prevention and management.
- ***Need for interdisciplinary approaches.*** Given chronic pain's diverse effects, interdisciplinary assessment and treatment may produce the best results for people with the most severe and persistent pain problems.
- ***Importance of prevention.*** Chronic pain has such severe impacts on all aspects of the lives of its sufferers that every effort should be made to achieve both primary prevention (e.g., in surgery for a broken hip) and secondary prevention (of the transition from the acute to the chronic state) through early intervention.
- ***Wider use of existing knowledge.*** While there is much more to be learned about pain and its treatment, even existing knowledge is not always used effectively, and thus substantial numbers of people suffer unnecessarily.
- ***The conundrum of opioids.*** The committee recognizes the serious problem of diversion and abuse of opioid drugs, as well as questions about their long-term usefulness. However, the committee believes that when opioids are used as prescribed and appropriately monitored, they can be safe and effective, especially for acute, postoperative, and procedural pain, as well as for patients near the end of life who desire more pain relief.
- ***Roles for patients and clinicians.*** The effectiveness of pain treatments depends greatly on the strength of the clinician–patient relationship; pain treatment is never about the clinician's intervention alone, but about the clinician and patient (and family) working together.
- ***Value of a public health and community-based approach.*** Many features of the problem of pain lend themselves to public health approaches—concern about the large number of people affected, disparities in occurrence and treatment, and the goal of prevention cited above. Public health education can help counter the myths, misunderstandings, stereotypes, and stigma that hinder better care.

THE NEED FOR A CULTURAL TRANSFORMATION IN THE WAY PAIN IS VIEWED AND TREATED

Pain serves a vital function as a warning sign of injury or infection, but once its warning role is over, continued pain is maladaptive. Chronic pain results in many changes in the peripheral and central nervous systems that aid in its persistence. Because of those physiological changes, some types of chronic pain are diseases in their own right.

All people are at risk of chronic pain. It can come about with age (e.g., arthritis), from genetic predisposition (e.g., migraine), as a component of another chronic disease (e.g., cancer, heart disease), as a result of surgery (e.g., severed nerves), or following an injury (e.g., low back pain, neck pain). Pain is a uniquely individual, subjective experience. Why one person suffers an injury and reports modest pain and another with a similar injury reports serious pain depends on many factors: genetic characteristics, general health status and comorbidities, pain experiences from childhood on, the brain's processing system, the emotional and cognitive context in which pain occurs, and cultural and social factors.

Because pain often produces psychological and cognitive effects—anxiety, depression, and anger among them—interdisciplinary, biopsychosocial approaches are the most promising for treating patients with persistent pain. But for most patients (and clinicians), such care is a difficult-to-attain ideal, impeded by numerous structural barriers—institutional, educational, organizational, and reimbursement-related. Costly procedures often are performed when other actions should be considered, such as prevention, counseling, and facilitation of self-care, which are common features of successful treatment. In addition, adequate pain treatment and follow-up may be thwarted by a mix of uncertain diagnosis and societal stigma consciously or unconsciously applied to people reporting pain, particularly when they do not respond readily to treatment.

In the committee's view, remediating the mismatch between current knowledge and its application will require a cultural transformation in the way clinicians and the public view pain and its treatment. Understanding chronic pain as a disease means that it requires direct treatment, rather than being sidelined while clinicians attempt to identify some underlying condition that may have caused it. It also means that health professions education programs should include a substantial amount of learning about pain and its diversity, and that people with chronic pain should be recognized by family, employers, health insurers, and others as having a serious condition. It means that people with chronic pain have an important role to play in managing their disease in an informed, productive way. And finally, it means that the biomedical research community should pursue pain research with the same vigor expended on other serious and disabling chronic conditions.

FINDINGS AND RECOMMENDATIONS

The findings and recommendations presented in this report revolve around a single conclusion:

> *Chronic pain alone affects the lives of approximately 100 million Americans, making its control of enormous value to individuals and society. To reduce the impact of pain and the resultant suffering will require a transformation in how*

> *pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess, and treat pain.*

The committee's recommendations and the findings that support them fall into four areas that serve to structure the main chapters of the report: pain as a public health challenge, care of people with pain, education challenges, and research challenges.[3]

Pain as a Public Health Challenge

Pain affects millions of Americans; contributes greatly to national rates of morbidity, mortality, and disability; and is rising in prevalence. Substantial disparities exist in the prevalence, seriousness, and adequate treatment of pain that affect the vulnerable populations of traditional public health concern. Pain exacts enormous costs both economically and in the toll it takes on people's lives. Analysis performed for the committee revealed that the annual economic cost of chronic pain in the United States is at least[4] $560-635 billion. This estimate combines the incremental cost of health care ($261-300 billion) and the cost of lost productivity ($297-336 billion) attributable to pain. The federal Medicare program bears fully one-fourth of U.S. medical expenditures for pain; in 2008, this amounted to at least $65.3 billion, or 14 percent of all Medicare costs. In total, federal and state programs—including Medicare, Medicaid, the Department of Veterans Affairs, TRICARE, workers' compensation, and others—paid out $99 billion in 2008 in medical expenditures attributable to pain. Lost tax revenues due to productivity losses compound that expense.

Finding 2-1. Pain is a public health problem. Pain is a significant public health problem. Chronic pain alone affects approximately 100 million U.S. adults. Pain reduces quality of life, affects specific population groups disparately, costs society at least $560-635 billion annually (an amount equal to about $2,000 for everyone living in the United States), and can be appropriately addressed through population health-level interventions.

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[3] The findings and recommendations are numbered according to the chapter of the report in which they appear. Thus, for example, recommendation 2-1 is the first recommendation in Chapter 2. Note that some of the findings and recommendations are presented here in abbreviated form. The full versions are included in the respective chapters.

[4] The $560-635 billion range is a conservative estimate because it excludes the cost of pain affecting institutionalized individuals (including nursing home residents and corrections inmates), military personnel, children under age 18, and personal caregivers (such as spouses who miss work while caring for people with pain), as well as the lost productivity of workers younger than 24 and older than 65. The estimate also excludes the emotional cost of pain.

Finding 2-2. More consistent data on pain are needed. While it is known that pain affects millions of Americans, the committee acknowledges the lack of consistent data with which to describe the nature and extent of the problem or to identify subpopulations that will benefit most from future interventions. Improvements in state and national data are needed to (1) monitor changes in the incidence and prevalence of acute and chronic pain; (2) document rates of treatment or undertreatment of pain; (3) assess the health and societal consequences of pain; and (4) evaluate the impact of related changes in public policy, payment, and care. Pain data need to be based on standardized questions, preferably using existing international standards, to facilitate comparisons over time and across populations. These data would be useful for a wide range of stakeholders, including policy makers, health care providers, health professions educators, professional licensing authorities, pain advocacy and awareness organizations, and researchers.

> **Recommendation 2-1. Improve the collection and reporting of data on pain.** The National Center for Health Statistics, the Agency for Healthcare Research and Quality, other federal and state agencies, and private organizations should improve and accelerate the collection and reporting of data on pain. Data should be collected in the following domains:
>
> - the incidence and prevalence of pain;
> - interference with activities of daily living and work, as well as disability, related to pain;
> - utilization of clinical and social services as a result of pain;
> - costs of pain and pain care, including indirect costs of lost employment and public- and private-sector costs for disability payments; and
> - the effectiveness of treatment in reducing pain and pain-related disability, determined through research on the comparative effectiveness of alternative treatments (including in different patient populations), to identify people most likely to benefit (or not) from specific treatment approaches.
>
> Standardized questions, fields, and protocols for surveys and electronic health records should be developed, and pain-related data should be collected at regular intervals.

Finding 2-3. A population-based strategy for reducing pain and its consequences is needed. The committee finds that, to effect changes that will reach the millions of American adults living with pain, account for differences in the experience of pain among population groups, and address selected environmental factors that contribute to the consequences of pain, a population health-level strategy is needed.

Recommendation 2-2. Create a comprehensive population health-level strategy for pain prevention, treatment, management, and research. The Secretary of the Department of Health and Human Services should develop a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and research that includes specific goals, actions, time frames, and resources. This strategy should

- Describe how efforts across government agencies, including public–private partnerships, can be established, coordinated, and integrated to encourage population-focused research, education, communication, and community-wide approaches that can help reduce pain and its consequences and remediate disparities in the experience of pain among subgroups of Americans.
- Include an agenda for developing physiological, clinical, behavioral, psychological, outcomes, and health services research and appropriate links across these domains (consistent with Recommendations 5-1 through 5-4).
- Improve pain assessment and management programs within the service delivery and financing programs of the federal government.
- Proceed in cooperation with the Interagency Pain Research Coordinating Committee and the National Institutes of Health's Pain Consortium and reach out to private-sector participants as appropriate.
- Involve the relevant federal agencies and departments (National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration, Centers for Medicare and Medicaid Services, Agency for Healthcare Research and Quality, Health Resources and Services Administration, Indian Health Service, Department of Defense, and Department of Veterans Affairs); private-sector entities (pain advocacy and awareness organizations; health professions associations; health care providers; health professions educators; private insurers; and accreditation, certification, and examination organizations); and state-level entities.
- Include ongoing efforts to enhance public awareness about the nature of chronic pain and the role of self-care in its management.

The development of this strategy should be completed by the end of 2012.

Care of People with Pain

Currently, large numbers of Americans receive inadequate pain prevention, assessment, and treatment, in part because of financial incentives that work against the provision of the best, most individualized care; unrealistic patient expectations; and a lack of valid and objective pain assessment measures. Clinicians' role in chronic pain care is often a matter of guiding, coaching, and assisting patients with day-to-day self-management, but many health professionals lack training in how to perform this support role, and there is little reimbursement for their doing so. Primary care is often the first stop for patients with pain, but primary care is organized in ways that rarely allow clinicians time to perform comprehensive patient assessments. Sometimes patients turn to, or are referred to, pain specialists or pain clinics, although both of these are few in number. Unfortunately, patients often are not told, or do not understand, that their journey to find the best combination of treatments *for them* may be long and full of uncertainty.

Finding 3-1. Pain care must be tailored to each person's experience. Pain management takes place through self-management, primary care, specialty care, and pain centers. However, the majority of care and management should take place through self-management and primary care, with specialty services being focused on recalcitrant or more complex cases. Accordingly, individualization of pain management is necessary throughout the health care system. Health care providers need to foster pain care that is patient-centered and, when necessary, comprehensive and interdisciplinary. Financing, referral, records management, and other systems need to support this flexibility.

> **Recommendation 3-1. Promote and enable self-management of pain.** Health care provider organizations should take the lead in developing educational approaches and materials for people with pain and their families that promote and enable self-management. These materials should include information about the nature of pain; ways to use self-help strategies to prevent, cope with, and reduce pain; and the benefits, risks, and costs of various pain management options. Approaches and materials should be culturally and linguistically appropriate and available in both electronic and print form.

Finding 3-2. Significant barriers to adequate pain care exist. The committee finds that multiple and significant barriers to pain care and management exist in the primary care setting.

- Enhanced continuing education and training are needed for health care professionals to address gaps in knowledge and competencies related to pain assessment and management, cultural attitudes about pain, negative and ill-informed attitudes about people with pain, and stereotyping and biases that contribute to disparities in pain care.

- Other barriers include the magnitude of the pain problem, including its extremely high prevalence, which makes effective action difficult on a national scale; certain provider attitudes and training, which impede the delivery of high-quality care; insurance coverage, because fully one-third of all Americans are uninsured or underinsured; cultural attitudes of patients, many of whom do not recognize the need to address pain early on; and geographic barriers, which place residents of rural communities at a disadvantage.
- System and organizational barriers, many of them driven by current reimbursement policies, obstruct patient-centered care. Examples of these barriers are minimal capacity for frequent visits when necessary; limited time for conduct of comprehensive assessments; inadequate patient education initiatives; difficulties in accessing specialty care; and lack of reimbursement for needed specialty care services, interdisciplinary practice, psychosocial and rehabilitative services, in-depth patient interviews and education, and time spent planning and coordinating care.
- A comprehensive, strategic approach can succeed in addressing these barriers and help close the gap between empirical evidence regarding the efficacy of pain treatments and current practice.
- Regulatory, legal, educational, and cultural barriers inhibit the medically appropriate use of opioid analgesics.

Recommendation 3-2. Develop strategies for reducing barriers to pain care. The population health-level strategy referred to in Recommendation 2-2 should include identifying and developing comprehensive approaches to overcoming existing barriers to pain care, especially for populations that are disproportionately affected by and undertreated for pain. Strategies also should focus on ways to improve pain care for these groups.

Recommendation 3-3. Provide educational opportunities in pain assessment and treatment in primary care. Health professions education and training programs, professional associations, and other groups that sponsor continuing education for health professionals should develop and provide educational opportunities for primary care practitioners and other providers to improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing.

Recommendation 3-4. Support collaboration between pain specialists and primary care clinicians, including referral to pain centers when appropriate. Pain specialty professional organizations and primary care professional associations should work together to support the collaboration of pain specialists with primary care practitioners and teams when primary care providers have exhausted their expertise and the patient's pain persists.

Recommendation 3-5. Revise reimbursement policies to foster coordinated and evidence-based pain care. Payers and health care organizations should work to align payment incentives with evidence-based assessment and treatment of pain. Optimal care of the patient should be the focus.

Recommendation 3-6. Provide consistent and complete pain assessments. Health care providers should provide pain assessments that are consistent and complete and documented so that patients will receive the right care at the right place and the right time.

Education Challenges

The optimal timing, content, and goals of patient education about pain vary with individual circumstances. Fundamental to treatment is education regarding self-management to minimize flare-ups, decrease day-to-day discomfort, and maximize functioning. In addition, public education about pain can be highly beneficial in promoting

- individual and community actions to prevent injuries,
- advocacy for appropriate acute and chronic pain treatment, and
- support for improved pain prevention and control policies.

Educational programs for the many types of health care professionals who play a role in pain prevention and treatment—nurses, psychologists, physicians, dentists, pharmacists, physical therapists, and complementary and alternative medicine practitioners—vary in the amount and quality of information on pain they contain. In medical education, pain generally has received little attention, which has contributed to the problem of undertreatment. The need for improved education about pain is especially acute for primary care providers—the front-line clinicians for most people's acute or chronic pain problems.

Finding 4-1. Education is a central part of the necessary cultural transformation of the approach to pain. The committee finds that the federal government is in a position to contribute to substantial improvements in patient and professional education about pain.

Recommendation 4-1. Expand and redesign education programs to transform the understanding of pain. Federal agencies and other

> relevant stakeholders should expand education programs to transform patient and public understanding of pain. In concert with Recommendation 2-2, federal agencies, in partnership with health professions associations, payers, pain advocacy and awareness organizations, and other relevant stakeholders, should develop education programs for patients, the public, and health care providers that are designed to promote a transformation in their expectations, beliefs, and understanding about pain, its consequences, its management, and its prevention.
>
> **Recommendation 4-2. Improve curriculum and education for health care professionals.** The Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, accrediting organizations, and undergraduate and graduate health professions training programs should improve pain education curricula for health care professionals.
>
> **Recommendation 4-3. Increase the number of health professionals with advanced expertise in pain care.** Educational programs for medical, dental, nursing, mental health, physical therapy, pharmacy, and other health professionals who will participate in the delivery of pain care should have increased capacity to train providers who can offer advanced pain care.

Research Challenges

In recent years, biomedical research has made remarkable strides in understanding of the basic biological and psychological underpinnings of pain. A principal current opportunity may be to use what has been learned across a broad spectrum of fields—from genomic and cellular through behavioral mechanisms—to develop innovative therapies that are simultaneously more targeted to the individual and more comprehensive in meeting patient needs.

From a scientific standpoint, the future of pain research is exciting because of advances in a number of relevant and diverse research fields and the development of new research techniques. This excitement is tempered, however, by knowledge that federal research dollars to address the problem of pain are in short supply and likely to decrease. Pain is a topic of interest to virtually every NIH institute and center, but not a central concern of any one of them. The committee believes one of the existing NIH institutes should be designated the lead institute for pain. The committee further believes that the NIH Pain Consortium needs to take a stronger leadership role in effecting the necessary transformation in how pain research is conducted by fostering coordination across institutes and centers, by ensuring that study section decision making on pain proposals is improved, and by exploring a range of potential public–private initiatives.

Pain research should not be confined to NIH. As this report details, pain-related research is needed across public health entities, involving, for example, the Centers for Disease Control and Prevention's epidemiological and public education expertise, the Agency for Healthcare Research and Quality's quality improvement initiatives, the Health Resources and Services Administration's expertise in professional education and service delivery for vulnerable populations, and the Centers for Medicare and Medicaid Services' research and demonstration programs related to reimbursement policies.

Finding 5-1. Research to translate advances into effective therapies for pain is a continuing need. The committee finds that significant advances have been made in understanding the basic mechanisms of nociception and pain, leading to new potential targets for future pain assessment and treatment strategies. Furthermore, recent advances in the neurosciences, biomarkers, and the behavioral sciences have validated a comprehensive approach to the management of pain that includes the individual's inherent biology, behavior, and psychological makeup and reactions, as well as environmental influences. However, data and knowledge gaps in pain research remain that have prevented such research advances from being translated into safe and effective therapies. Addressing these gaps will require a cultural transformation in the view of and approach to pain research, involving basic, translational, and clinical researchers; federal funding and regulatory agencies; and private organizations. This cultural transformation is reflected in the following recommendations.

> **Recommendation 5-1. Designate a lead institute at the National Institutes of Health responsible for moving pain research forward, and increase the support for and scope of the Pain Consortium.** The National Institutes of Health should designate a specific institute to lead efforts in advancing pain research. At the same time, the National Institutes of Health should increase financial resources and staffing support for and broaden the scope of the Pain Consortium and engage higher-level staff from the institutes and centers in the consortium's efforts. The Pain Consortium should exert more proactive leadership in effecting the necessary transformation in how pain research is conducted and funded.
>
> **Recommendation 5-2. Improve the process for developing new agents for pain control.** Academia and industry should develop novel agents for the control of pain. This does not mean simply recycling current drugs. What is required is basic and clinical science research to discover new classes of pain therapeutics and more efficient ways of developing them. Also required is that regulatory agencies, especially the Food and Drug

Administration, develop new and expeditious ways to evaluate and approve new pain therapies.

Recommendation 5-3. Increase support for interdisciplinary research in pain. Federal agencies, such as the National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Department of Defense, and Department of Veterans Affairs, as well as private funders of pain research, should increase support for interdisciplinary research and research training—across agencies and professions—on pain-related diseases and the deficiencies noted in Finding 5-1.

Recommendation 5-4. Increase the conduct of longitudinal research in pain. Public and private funders should increase support for longitudinal research in pain, including comparative effectiveness research and novel randomized controlled trials, to help ensure that patients receive care that works best in both the short and long terms.

Recommendation 5-5. Increase the training of pain researchers. With the support of training grants from the National Institutes of Health, academic institutions should increase the training of basic, translational, behavioral, population, and clinical pain researchers. This training should recognize the interdisciplinary benefits of research on pain and pain management. Agencies such as the National Center for Health Statistics, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services should support the training of researchers interested in secondary analysis of pain-related data collected by these agencies.

CONCLUSION

With the goal of providing relief for pain in America, the committee concludes this report by offering a blueprint for action toward transforming prevention, care, education, and research (Chapter 6 and Table S-1 below). This blueprint organizes the committee's recommendations into two categories. Recommendations categorized as immediate are those the committee believes should be initiated now and completed before the end of 2012. Recommendations categorized as near-term and enduring build on these immediate actions, should be completed before the end of 2015, and should be maintained as ongoing efforts. The comprehensive population health-based strategy set forth in Recommendation 2-2 should inform actions taken in response to, or consistent with, all of the other recommendations.

TABLE S-1[a] Blueprint for Transforming Pain Prevention, Care, Education, and Research

IMMEDIATE: Start now and complete before the end of 2012		
Recommendation	**Actors**	**Key Elements of Recommendation**
2-2. Create a comprehensive population health-level strategy for pain prevention, treatment, management, and research	Secretary of Health and Human Services (HHS)	Involve multiple federal, state, and private-sector entities, such as the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), Centers for Medicare and Medicaid Services (CMS), Department of Defense (DoD), Department of Veterans Affairs (VA), outcomes research community and other researchers, credentialing organizations, pain advocacy and awareness organizations, health professions associations (including pain specialty professional organizations), private insurers, health care providers, state health departments, Medicaid programs, and workers' compensation programs
3-2. Develop strategies for reducing barriers to pain care	HHS Secretary, AHRQ, CMS, HRSA, Surgeon General, Office of Minority Health, Indian Health Service, VA, DoD, large health care providers (e.g., accountable care organizations)	Key part of the strategy envisioned in Recommendation 2-2
3-4. Support collaboration between pain specialists and primary care clinicians, including referral to pain centers when appropriate	CMS, VA, DoD, health care providers, pain specialists, pain centers, primary care practitioners, pain specialty professional organizations, primary care professional associations, private insurers	The pain specialist role includes serving as a resource for primary care practitioners

TABLE S-1 Continued

Recommendation	Actors	Key Elements of Recommendation
5-1. Designate a lead institute at the National Institutes of Health responsible for moving pain research forward, and increase the support for and scope of the Pain Consortium	NIH	Involve pain advocacy and awareness organizations; foster public–private partnerships

NEAR-TERM AND ENDURING: Build on immediate recommendations, complete before the end of 2015, and maintain as ongoing efforts

Recommendation	Actors	Key Elements of Recommendation
2-1. Improve the collection and reporting of data on pain	National Center for Health Statistics (NCHS) (part of CDC), AHRQ, CMS, VA, DoD, state and local health departments, private insurers, outcomes research community, other researchers, large health care providers, designers of electronic medical records	Based on Recommendation 2-2; foster public–private partnerships; includes subpopulations at risk for pain and undertreatment of pain, characteristics of acute and chronic pain, and health consequences of pain (morbidity, mortality, disability, related trends)
3-1. Promote and enable self-management of pain	Health professions associations (including pain specialty professional organizations), pain advocacy and awareness organizations, health care providers	Requires the development of better and more evidence-based patient education products
3-3. Provide educational opportunities in pain assessment and treatment in primary care	CMS, VA, DoD, graduate medical education (GME) and continuing medical education (CME) primary care programs (backed by accreditation, licensure, and certification authorities and examiners), nurse practitioner and physician assistant training programs, researchers, health care providers	Improved health professions education requires a stronger evidence base on clinical effectiveness and more interdisciplinary training and care

continued

TABLE S-1 Continued

Recommendation	Actors	Key Elements of Recommendation
3-5. Revise reimbursement policies to foster coordinated and evidence-based pain care	CMS, VA, DoD, Medicaid programs, private insurers, health care providers, health professions associations (including pain specialty professional organizations), pain advocacy and awareness organizations	Requires the development of more evidence on clinical effectiveness and collaboration between payers and providers
3-6. Provide consistent and complete pain assessments	Health care providers, primary care practitioners, pain specialists, other health professions, pain clinics and programs, World Health Organization (WHO)	WHO should add pain to the *International Classification of Diseases*, Tenth Edition (ICD-10)
4-1. Expand and redesign education programs to transform the understanding of pain	FDA, CDC, AHRQ, CMS, Surgeon General, DoD, VA, pain advocacy and awareness organizations, health professions associations (including pain specialty professional organizations), private insurers, health care providers	Focus is on patient education and public education; includes pain prevention
4-2. Improve curriculum and education for health care professionals	CMS, HRSA Bureau of Health Professions, accrediting organizations,[b] undergraduate and graduate health professions training programs (backed by licensure and certification authorities and examiners)	CMS's role is that of payer for GME; include interdisciplinary training
4-3. Increase the number of health professionals with advanced expertise in pain care	Pain medicine fellowship programs and graduate education programs in dentistry, nursing, psychology and other mental health fields, rehabilitation therapies, pharmacy, and other health professions	Requires more effort to attract young health professionals to pain programs; also requires collaboration between educators and clinicians

TABLE S-1 Continued

Recommendation	Actors	Key Elements of Recommendation
5-2. Improve the process for developing new agents for pain control	FDA, NIH, pharmaceutical manufacturing and research industry, academically based biomedical research community, private funders of pain research	Based on Recommendation 5-1; involves developing new and faster ways to evaluate and approve new pain therapies, e.g., novel forms of patient stratification in clinical trials and novel investigative endpoints
5-3. Increase support for interdisciplinary research in pain	NIH, AHRQ, CDC, DoD, VA, pharmaceutical manufacturing and research industry, private funders of pain research, academically based biomedical research community, pain advocacy and awareness organizations	Based on Recommendation 5-1; basic, translational, and clinical studies should involve multiple agencies and disciplines; focus on knowledge gaps
5-4. Increase the conduct of longitudinal research in pain	NIH, AHRQ, CDC, DoD, VA, pharmaceutical manufacturing and research industry, Patient-Centered Outcomes Research Institute, private funders of pain research, academically based biomedical research community, outcomes research community, pain advocacy and awareness organizations	Based on Recommendation 5-1; includes translational, population health, and behavioral aspects of pain care (social and multimodal aspects, not just medications and other single modalities); focus is on real-world situations (comparative effectiveness, not just efficacy); foster public–private partnerships
5-5. Increase the training of pain researchers	NIH, NCHS, AHRQ, CMS, academic medical institutions	Includes more interdisciplinary training

[a] The committee prepared this table based on the recommendations but with a focus on their implementation. The table lists a range of potential actors and key elements of each recommendation.

[b] Accrediting organizations include the Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation, Accreditation Council for Graduate Medical Education, Commission on Dental Accreditation, Commission on Collegiate Nursing Education, National League for Nursing Accreditation Commission, American Psychological Association Committee on Accreditation, Council on Education for Public Health, Council on Social Work Education, and Council for Higher Education Accreditation (Perez et al., 2007).

1[1]

Introduction

> *I have a master's degree in clinical social work. I have a well-documented illness that explains the cause of my pain. But when my pain flares up and I go to the ER, I'll put on the hospital gown and lose my social status and my identity. I'll become a blank slate for the doctors to project their own biases and prejudices onto. That is the worst part of being a pain patient. It strips you of your dignity and self-worth.*
>
> —A patient with chronic pain[2]

Approximately 100 million U.S. adults—more than the number affected by heart disease, diabetes, and cancer combined—suffer from common chronic pain conditions (Tsang et al., 2008; see also Appendix C). Everyone is at some risk of acute or chronic pain arising from an illness, an injury, or an array of other factors, but some population groups have a much higher risk of experiencing pain and its disabling effects and receiving inadequate treatment.

Pain is a universal experience but unique to each individual. Across the life span, pain—acute and chronic—is one of the most frequent reasons for

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[1] The quotations throughout this report come from the committee's survey on pain care, testimony received at public workshops, committee member comments, and published sources, as noted. Survey responses were submitted January 31, 2011 through April 5, 2011. See Appendix B for a description of the survey.

[2] Quotation from committee survey.

physician visits, among the most common reasons for taking medications, and a major cause of work disability. Severe chronic pain affects physical and mental functioning, quality of life, and productivity. It imposes a significant financial burden on affected individuals, as well as their families, their employers, their friends, their communities, and the nation as a whole. The annual economic cost of chronic pain in adults, including health care expenses and lost productivity, is $560-630 billion annually according to a new estimate developed for this study (see Appendix C).

STUDY CONTEXT AND CHARGE TO THE COMMITTEE

Section 4305 of the 2010 Patient Protection and Affordable Care Act required the Secretary, Department of Health and Human Services (HHS), to enter into an agreement with the Institute of Medicine (IOM) for activities "to increase the recognition of pain as a significant public health problem in the United States." Accordingly, HHS, through the National Institutes of Health (NIH), requested that the IOM conduct a study to assess the state of the science regarding pain research, care, and education and to make recommendations to advance the field. The charge to the committee is presented in Box 1-1.

To conduct this study, the IOM assembled a 19-member committee, which began meeting in November 2010. Reflecting the complexity of the problem at hand, the committee included experts in pain research, pain management, pharmacology, clinical specialties (pediatrics, oncology, infectious disease, neurology, neurosurgery, anesthesiology, pain medicine, dentistry, psychology, and complementary medicine), chronic disease, clinical teaching, epidemiology, ethics, and consumer education, as well as individuals who have suffered personally from chronic pain and could reflect on the perspectives of the many people it affects.

STUDY APPROACH AND UNDERLYING PRINCIPLES

The challenges to better pain management in the United States are diverse. Some result from inadequate scientific knowledge about diagnosis and treatment and may be resolved by new research. Many of the challenges, however—those related to inadequate training and lack of understanding of the need to address the multiple physical, mental, emotional, and social dimensions of pain; to disparities in care among population groups; and to payment and policy barriers—reflect a failure to apply what is already known.

This report makes an important contribution to the field by providing a blueprint for transforming the way pain is understood, assessed, treated, and prevented. It provides recommendations for improving the care of people who experience pain, the training of clinicians who treat them, and the collection of data on pain in the United States, as well as a timetable for implementing measures to better relieve pain in America. The committee also recommends ways

BOX 1-1
Committee Charge

The Department of Health and Human Services, National Institutes of Health, has requested that the IOM convene the ad hoc committee to address the current state of the science with respect to pain research, care, and education; and explore approaches to advance the field.

Specifically, the committee will

- Review and quantify the public health significance of pain, including the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain in the United States. This effort will take a comprehensive view of chronic pain as a biological, biobehavioral, and societal condition.
- Identify barriers to appropriate pain care and strategies to reduce such barriers, including exploring the importance of individualized approaches to diagnosis and treatment of pain.
- Identify demographic groups and special populations, including older adults, individuals with co-morbidities, and cognitive impairment, that may be disparately undertreated for pain, and discuss related research needs, barriers particularly associated with these demographic groups, and opportunities to reduce such barriers.
- Identify and discuss what scientific tools and technologies are available, what strategies can be employed to enhance training of pain researchers, and what interdisciplinary research approaches will be necessary in the short and long term to advance basic, translational, and clinical pain research and improve the assessment, diagnosis, treatment, and management of pain.
- Discuss opportunities for public–private partnerships in the support and conduct of pain research, care, and education.

to help focus research and policy directives on a variety of dimensions of pain. The report does not present a clinical algorithm for the diagnosis and treatment of patients with pain. Rather, it describes the scope of the problem of pain and provides an overview of needs for care, education, and research. The committee strongly believes that an adequate understanding of pain and its effects on people’s lives must take into account the testimony of those who have experienced chronic pain. Therefore, it solicited advice and information from people with pain and their advocates both in person and through an active web portal, which received more than 2,000 submissions. The committee’s recommendations are based on scientific evidence, on this wealth of direct testimony, and on the expert judgment of its members (see Appendix A for a discussion of the data sources and methods for this study). Underlying principles that guided the committee in preparing this report and its recommendations are presented in Box 1-2.

BOX 1-2
Underlying Principles

- ***A moral imperative.*** Effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions.
- ***Chronic pain can be a disease in itself.*** Chronic pain has a distinct pathology, causing changes throughout the nervous system that often worsen over time. It has significant psychological and cognitive correlates and can constitute a serious, separate disease entity.
- ***Value of comprehensive treatment.*** Pain results from a combination of biological, psychological, and social factors and often requires comprehensive approaches to prevention and management.
- ***Need for interdisciplinary approaches.*** Given chronic pain's diverse effects, interdisciplinary assessment and treatment may produce the best results for people with the most severe and persistent pain problems.
- ***Importance of prevention.*** Chronic pain has such severe impacts on all aspects of the lives of its sufferers that every effort should be made to achieve both primary prevention (e.g., in surgery for a broken hip) and secondary prevention (of the transition from the acute to the chronic state) through early intervention.
- ***Wider use of existing knowledge.*** While there is much more to be learned about pain and its treatment, even existing knowledge is not always used effectively, and thus substantial numbers of people suffer unnecessarily.
- ***The conundrum of opioids.*** The committee recognizes the serious problem of diversion and abuse of opioid drugs, as well as questions about their long-term usefulness. However, the committee believes that when opioids are used as prescribed and appropriately monitored, they can be safe and effective, especially for acute, postoperative, and procedural pain, as well as for patients near the end of life who desire more pain relief.
- ***Roles for patients and clinicians.*** The effectiveness of pain treatments depends greatly on the strength of the clinician–patient relationship; pain treatment is never about the clinician's intervention alone, but about the clinician and patient (and family) working together.
- ***Value of a public health- and community-based approach.*** Many features of the problem of pain lend themselves to public health approaches—concern about the large number of people affected, disparities in occurrence and treatment, and the goal of prevention cited above. Public health education can help counter the myths, misunderstandings, stereotypes, and stigma that hinder better care.

In general, the committee considered the complexities of individual pain conditions and the diseases that cause pain—which vary widely in their presentation, treatment, effects, and outcomes—to be beyond the scope of this study. Nor did the study address the important issue of psychological or existential pain that exacerbates many experiences of pain. A much larger study would be necessary to address these issues. Similarly, a deep examination of the current controversies surrounding opioid abuse and diversion were beyond the committee's charge. The committee recognizes that as a result, many of the generalizations included in this report will not apply equally well to all pain conditions, although the overall direction and priorities of the report should be broadly useful.

The findings and recommendations presented in this report are intended to assist policy makers, federal agencies, state public health officials, health care providers (primary care clinicians and pain specialists), health care organizations, health professions associations, pain researchers, individuals living with pain and their families, the public, and private health funding organizations in addressing the problem of pain. The ultimate goal of this study is to contribute to improved outcomes for individuals who experience pain and their families.

This report builds on and reinforces recommendations regarding ways to improve pain care, education, and research—and the research enterprise in general—made by the IOM in past reports, as well as by other entities. As it conducted this study, the committee generally saw little evidence of progress toward these well-articulated goals and extensively documented findings of the past. Examples of such reports include

- *Approaching Death: Improving Care at the End of Life* (IOM, 1997);
- *Ensuring Quality Cancer Care* (IOM, 1999);
- *Pain and Disability: Clinical, Behavioral, and Public Policy Perspectives* (IOM, 1987);
- *A Call to Revolutionize Chronic Pain Care in America: An Opportunity in Health Reform* (The Mayday Fund, 2009);
- *New Approaches to Neurological Pain: Planning for the Future* (Harvard Medical School, Massachusetts General Hospital, and University of California, San Francisco, 2008);
- *Pain, Depression, and Fatigue: State-of-the-Science Conference* (NIH, 2002);
- *Chronic Fatigue Syndrome: State-of-the-Science Conference* (NIH, 2000);
- *The First National Pain Medicine Summit: Final Summary Report* (American Medical Association Specialty Section Council, 2010);
- *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (IOM, 2003);
- *Transforming Clinical Research in the United States: Challenges and Opportunities* (IOM, 2010); and
- *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* (NRC and IOM, 2003).

The committee hopes that this report will have an impact on the important challenge of pain, given its impact on the lives of more than a third of Americans and the economic well-being of the nation.

WHAT IS PAIN?

> *It is so much more than just pain intensity. Over time, many [patients] find the effects of living with chronic pain impact their ability to work, engage in recreational and social activities, and for some, [perform] the most basic everyday activities that people just take for granted. Not surprisingly, pain begins to chip away at their mood, often leaving them angry, frustrated, anxious, and/or depressed. Our families suffer along with us, and many relationships are forever altered.*
>
> —An advocate for people with chronic pain[3]

> *There is no visible blood test or X ray to show a trauma. I do not look sick.*
>
> —A person with chronic pain[4]

Pain is a warning, a signal that something is wrong, whether it is caused by a stove too hot to touch, a broken arm, an attack of angina, or a bout of food poisoning. In its warning role, pain is protective and sometimes even essential for survival. Its aversive quality motivates individuals to do something—to withdraw or flee, to seek help or rest or medical treatment. The reaction to a painful stimulus occurs at a deep evolutionary level and is powerfully protective. Without pain, the world would be an impossibly dangerous place. For example, some children with a rare genetic disease are born with the inability to feel pain. At first thought, these children might appear to be fortunate, but they typically have a short life span because they do not realize when they are injured or sick, and they succumb to early arthritis, wounds, and infections that children without this disease avoid.

Pain is a complex phenomenon. The unique way each individual perceives pain and its severity, how it evolves, and the effectiveness of treatment depend on a constellation of biological, psychological, and social factors, such as the following:

- *Biological*—the extent of an illness or injury and whether the person has other illnesses, is under stress, or has specific genes or predisposing factors that affect pain tolerance or thresholds;

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[3] Quotation from committee survey.

[4] Quotation from committee survey.

- *Psychological*—anxiety, fear, guilt, anger, depression, and thinking the pain represents something worse than it does and that the person is helpless to manage it (Ochsner et al., 2006); and
- *Social*—the response of significant others to the pain—whether support, criticism, enabling behavior, or withdrawal—the demands of the work environment, access to medical care, culture, and family attitudes and beliefs.

The International Association for the Study of Pain (IASP) published its widely accepted definition of pain in 1994, excerpted in Box 1-3. This useful definition has been influential in replacing earlier views that pain is strictly a physical, or biological, problem because it takes into account that emotional and psychosocial reactions to pain are clinically significant.

Most chronic diseases involve multiple physical, cognitive, and emotional factors. While chronic pain shares many attributes with other chronic diseases, it also has distinct characteristics. For example, pain, especially chronic pain, can lack reliable "objective" measures, and it has strong cultural, religious, and philosophical meanings that affect (and serve as context for) a person's pain experience. Because all people experience some degree of pain at some time, moreover, they often do not realize how chronic severe pain differs in its character and effects from the relatively mild and easily treated pain with which they are familiar.

The IASP definition emphasizes that pain is a *subjective* experience. Other people cannot detect a person's pain through their own senses: it cannot be seen, like bleeding; it cannot be felt, like a lump; it cannot be heard, like a heart arrhythmia; it has no taste or odor; and it often is not confirmed by x-ray or more sophisticated imaging procedures. No current clinical tests for pain are analogous to temperature, blood pressure, or cholesterol measurements. Clinical findings that *can* be seen—a broken bone on an x-ray, for example—do not necessarily correlate well with the severity of pain the patient perceives. People afflicted by pain may find the rough tools of language inadequate to convey the character and

BOX 1-3
Definition of Pain

An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. . . . Pain is always subjective. . . . It is unquestionably a sensation in a part or parts of the body, but it is also always unpleasant and therefore also an emotional experience.

SOURCE: IASP, 1994.

intensity of their experience and its significance to them. This can be a substantial barrier to obtaining adequate treatment (Werner and Malterud, 2003).

Figure 1-1 shows the many branching pathways pain can take. On the right side are the pathways for acute pain, one branch of which moves a person to the left side of the figure, which illustrates the erratic course of chronic pain. The figure shows that pain may be treated and controlled at a number of points in a person's experience, but also that it may persist, loop back on itself, engender related complications, and prompt an ongoing search for relief.

Pain sensation, transmission, modulation, and interpretation are functions of the central nervous system, and when abnormalities in this process occur, pain can be a neurologic disease. Increased understanding of the many physiological and psychological changes that occur in people with chronic pain has prompted the IASP and many pain experts to deem that *in many cases, chronic pain is a disease in its own right* (EFIC, 2001), a position supported by this committee.

This profound recasting means that pain requires direct, appropriate treatment rather than being sidelined while clinicians attempt to identify some underlying condition that may have caused it. Prompt treatment can derail the progression of pain from the acute to the chronic state. This recasting also means that health professions education programs should include a substantial amount of learning about pain and its diversity, and that people with chronic pain should be recognized by family, employers, health insurers, and others as having a serious disease. It means that people with chronic pain have an important role to play in managing their disease in an informed, productive way. And finally, it means that the research community should pursue pain research with the same vigor expended on other serious and disabling chronic conditions.

WHO IS AT RISK?

> *Thirteen years ago I was rear-ended in a car accident. In a split second my whole life changed, and the accident left me handicapped with chronic pain in the neck, shoulders, and head. I was thrown into a world of medical decisions of which I knew nothing and began searching for information about cervical discs, facet joints, myofascial pain, referred pain, conservative and alternative treatments and various medical procedures. . . .*
>
> — A patient with chronic pain[5]

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[5] Quotation from public testimony submitted by the American Pain Society.

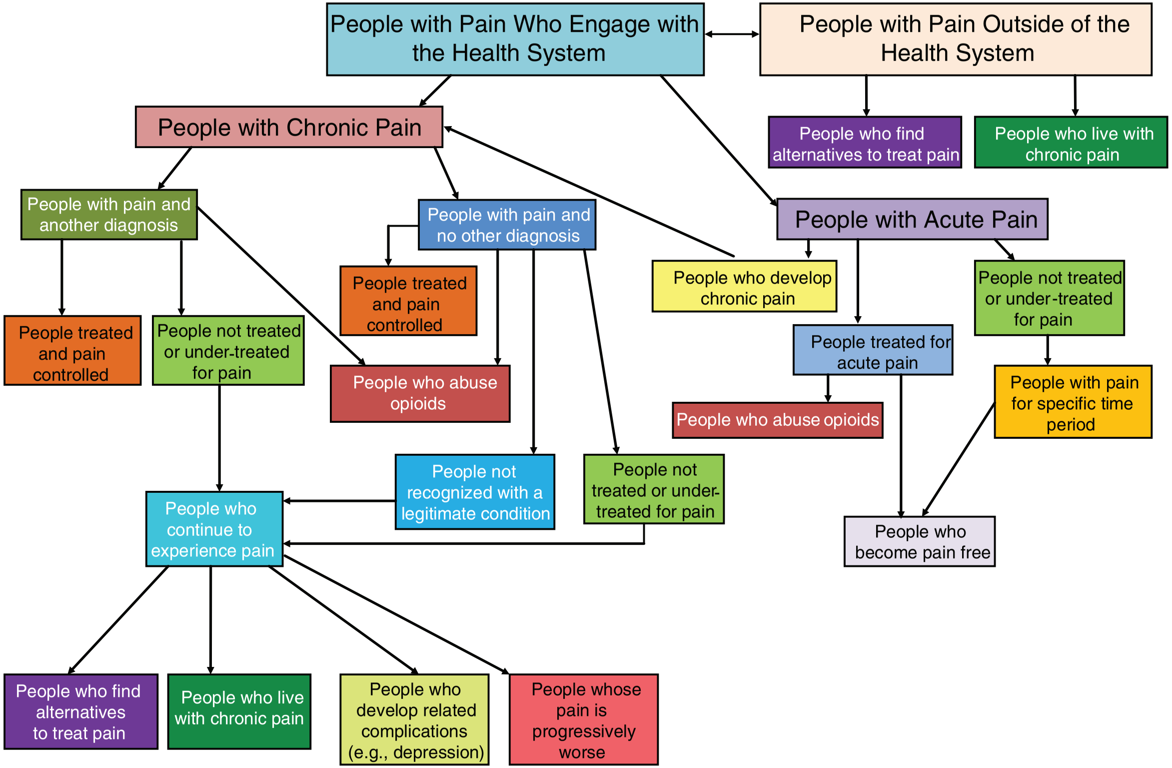

FIGURE 1-1 The picture of pain.

NOTE: People can move between and among these groupings and can be in more than one group simultaneously. Similar colors represent similar endpoints (e.g., for those within or outside the health system, or for those with chronic or acute pain).

Information about the number of people who have acute or chronic pain is far from complete. Nevertheless, as Box 1-4 illustrates, pain is pervasive and costly, and it is associated with common events and conditions, such as surgery, trauma, cancer, arthritis, migraine, and fibromyalgia, that involve large numbers of Americans (Box 1-5). Pain is common in settings such as nursing homes and other long-term care facilities. Furthermore, people who experience acute pain may go on to develop chronic, intractable pain.

BOX 1-4
Pain by the Numbers

- **100 million**—approximate number of U.S. adults with common chronic pain conditions
- **$560 to 635 billion**—conservative estimate of the annual cost of chronic pain in America
- **$99 billion**—2008 cost to federal and state governments of medical expenditures for pain
- **60 percent**—percentage of women experiencing their first childbirth who rate pain as severe; 18 percent of women who have caesarean deliveries and 10 percent who have vaginal deliveries report persistent pain at 1 year
- **80 percent**—percentage of patients undergoing surgery who experience postoperative pain; fewer than half report adequate pain relief:
  - of these, 88 percent report the pain is moderate, severe, or extreme;
  - 10 to 50 percent of patients with postsurgical pain develop chronic pain, depending on the type of surgery; and
  - for 2 to 10 percent of these patients, this chronic postoperative pain is severe
- **5 percent**—proportion of American women aged 18 to 65 who experience headache 15 or more days per month over the course of 1 year
- **60 percent**—percentage of patients visiting the emergency department with acute painful conditions who receive analgesics:
  - median time to receipt of pain medication is 90 minutes, and
  - 74 percent of emergency department patients are discharged in moderate to severe pain
- **2.1 million**—number of annual visits to U.S. emergency departments for acute headache (of 115 million total annual visits)
- **62 percent**—percentage of U.S. nursing home residents who report pain:
  - arthritis is the most common painful condition, and
  - 17 percent have substantial daily pain
- **26.4 percent**—percentage of Americans who report low back pain lasting at least a day in the last 3 months

SOURCES: (Costs) Appendix C; (Childbirth) Melzack, 1993; Kainu et al., 2010; (Surgery) Apfelbaum et al., 2003; Kehlet et al., 2006; (Headache) Scher et al., 1998; (Emergency care) Todd et al., 2007; (Emergency: headache) Edlow et al., 2008; (Nursing homes) Ferrell et al., 1995; Sawyer et al., 2007; (Low back pain) Deyo et al., 2006.

BOX 1-5
Selected Pain-Related Conditions

Common sources of acute pain
- infectious diseases (e.g., food poisoning with related gastrointestinal manifestations)
- wound infections
- untreated dental conditions
- burns
- trauma (broken bones, lacerations and other wounds)
- appendicitis
- surgery
- medical procedures
- childbirth

Common sources of chronic pain
- migraine and other serious headaches
- arthritis and other joint pain
- fibromyalgia
- endometriosis
- irritable bowel syndrome
- chronic interstitial cystitis
- vulvodynia
- trauma or postsurgical pain
- low back pain
- other musculoskeletal disorders
- temporomandibular joint disorder
- shingles
- sickle cell disease
- heart disease (angina)
- cancer
- stroke
- diabetes

Taken together, the available data suggest that all Americans have a significant chance of experiencing serious pain. Subsequent chapters of this report demonstrate that much of this pain and the attendant suffering are unnecessary and could be prevented or better managed.

The risk of both acute and chronic pain is affected by many factors, including age, race, sex, income, education, urban/rural living, and other demographic factors reviewed in Chapter 2. The likelihood of experiencing a transition from acute to chronic pain is likewise influenced by various factors, especially the adequacy of acute pain relief. The factors that influence the development of chronic pain can be assessed using a life-cycle approach (see Table 1-1). Some factors

TABLE 1-1 Life-Cycle Factors Associated with the Development of Chronic Pain*

From Birth	Childhood	Adolescence	Adulthood
Genetics, female sex, minority race or ethnicity, congenital disorders, prematurity Parental anxiety, irregular feeding and sleeping Parents' pain exposure and reactions Temperament and personality			
	Physical/sexual abuse and other traumatic events (e.g., death of a parent, witness to violence) Low socioeconomic status Emotional, conduct, and peer problems Hyperactivity Serious illness or injury, hospitalization Separation from mother Acute or recurrent pain experience		
		Changes of puberty, gender roles Education level, learning (behavioral reactions to pain) Injuries Obesity Low levels of fitness	
			Vivid recall of childhood trauma Lack of social support, accumulated stress ("allostatic load") Surgery Overuse of joints and muscles Occupational exposures, job dissatisfaction, low work status Development of chronic disease Aging

*NOTE: These factors are discussed later in this chapter and in Chapter 2.

are present from birth, some occur in childhood or adolescence, and some may not appear until later in life. And some people with many of the risk factors listed never develop chronic pain. Ways in which these factors contribute to higher rates of pain and associated disability are discussed in Chapter 2.

As part of an orientation toward prevention, both protective and risk factors for chronic pain need to be better characterized. Examples of protective factors include engaging in moderate physical activity, controlling weight, avoiding injuries, receiving pre- and postsurgical **analgesia**[6] and monitoring, and having personality traits such as resilience and positive affect. With respect to risk factors, it is important to understand that some of the factors listed in Table 1-1 clearly cannot be modified. For example, knowing that there are immutable factors (such as gender differences) in the susceptibility to chronic pain syndromes should lead to earlier intervention when acute pain occurs and greater efforts to avoid or reduce the influence of other risk factors.

IMPACT OF PAIN ON PHYSICAL AND MENTAL HEALTH

> *It made no sense to me that with all the modern miracles in medicine there was no way to relieve my pain. What I did not realize then was how complex chronic pain is. I did not know how many areas of my life and my family's lives the pain invaded.*
>
> — An advocate for people with chronic pain[7]

Although much acute and milder chronic pain is managed by people on their own or with the guidance of health professionals, severe and intractable pain may require comprehensive approaches that take into account the biological, psychological, and social factors noted previously. While many people ultimately may have their pain controlled, some will not, and repeated attempts may be required to find the right combination of therapies and self-care to achieve maximum benefit.

Understanding of the mechanisms underlying pain has changed over time and will continue to evolve with new knowledge. Research has now established that pain can cause biological changes in the peripheral and central nervous systems, as described later in this chapter. While some of these changes are adaptive and of short duration, they can become maladaptive and signal the development of chronic pain, in which case the central nervous system becomes hypersensitive and overresponsive to stimuli that normally would not be painful—a light touch

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[6] **Boldface** terms in this chapter are included in the glossary at the end of the report.

[7] Quotation from committee survey.

or a gentle breeze, for example. In a sense, the nervous system of a person with chronic pain becomes "rewired for pain."

Among the immediate consequences of severe pain, aside from the hurt itself, are "reduced mobility and consequent loss of strength, disturbed sleep, immune impairment and increased susceptibility to disease, dependence on medication, and codependence with solicitous family members and other caregivers" (Brennan et al., 2007). The consequences of **acute pain** add to the preceding list the following: reduced quality of life, impaired physical function, high economic costs (principally hospital readmissions), extended recovery time, and increased risk of developing **chronic pain** (Sinatra, 2010). In addition to an array of physical problems, severe chronic pain can engender a range of significant psychological and social consequences, such as fear; anger; depression; anxiety; and reduced ability to carry out one's social roles as family member, friend, and employee. At the same time, as knowledge about the biological processes of pain has advanced, a large, broad, and growing empirical literature has continued to inform the increasingly sophisticated understanding of key psychological and behavioral factors that influence the perpetuation, if not the development, of pain and pain-related disability. The complex relationship between pain and these factors is discussed in detail later in the chapter.

A TYPOLOGY OF PAIN

> *When they refused to treat me at the emergency room, they said, "We can't treat you for pain because we would be treating a symptom rather than the cause of a problem."*
>
> — A person with chronic pain[8]

> *Pain is more than a symptom!*
>
> — A physician who treats chronic pain[9]

Pain comes in many forms. Understanding which kind or kinds of pain a person has is a first step toward treatment. Although acute and chronic pain are considered separately below, a particular individual can experience them simultaneously.

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[8] Quotation from submission by Peter Reineke of stories from the membership of patient advocacy groups.

[9] Quotation from committee member.

Acute pain, by definition, is of sudden onset and expected to last a short time. It usually can be linked clearly to a specific event, injury, or illness—a muscle strain, a severe sunburn, a kidney stone, or pleurisy, for example. People can handle many types of acute pain on their own with over-the-counter medications or a short course of stronger analgesics and rest, and the acute pain usually subsides when the underlying cause resolves, such as when a kidney stone or diseased tooth is removed. Acute pain also can be a *recurrent* problem, with episodes being interspersed with pain-free periods, as in the case of dysmenorrhea, migraine, and sickle-cell disease.

Chronic pain, by contrast, lasts more than several months (variously defined as 3 to 6 months, but certainly longer than "normal healing") and can be frustratingly difficult to treat. Although improvement may be possible, for many patients cure may be unlikely. Chronic pain can become so debilitating that it affects every aspect of a person's life—the ability to work, go to school, perform common tasks, maintain friendships and family relationships—essentially, to participate in the fundamental tasks and pleasures of daily living. Chronic pain can be the result of

- An underlying disease or medical condition, in which case,
  - —it may continue or recur after the disease itself has been cured, as in shingles;
  - —it may simply not go away, and flare-ups may occur against a background of persistent pain, as in many instances of low back pain or osteoarthritis; or
  - —it may worsen as the disease (such as cancer) progresses.
- An *injury*, if the pain persists after the original injury heals—for example, "phantom limb" or "phantom tooth" pain, in which a person continues to feel pain in an amputated limb or missing tooth.
- *Medical treatment*, for example, after surgery, when the typical immediate acute pain, if unresolved, evolves into chronic pain or if nerve damage occurs during a procedure.
- *Inflammation,* in which pain occurs in response to tissue injury, when local nociceptors become highly sensitive even to normal stimuli, such as touch. (This is a form of *peripheral sensitization*. The overexcitement of neurons in the central nervous system is *central sensitization* and can occur with any type of pain.) This is another type of "warning" pain, this time of the need for healing, and generally disappears after the injury resolves. In conditions such as rheumatoid arthritis or gout, inflammatory pain persists as long as the inflammation does.
- ***Neuropathic pain**,* a disease of the peripheral or central nervous system that arises when a person's nerves, spinal cord, or brain is damaged or fails to function properly for any of a large number of reasons. The cause may be an underlying disease process (as in diabetes) or injury

(e.g., stroke, spinal cord damage), but neuropathic pain may not have an observable cause and can be considered maladaptive "in the sense that the pain neither protects nor supports healing and repair" (Costigan et al., 2009, p. 3).

- *Unknown causes*, in which case the pain arises without a defined cause or injury. Examples of such chronic pain conditions are irritable bowel syndrome, fibromyalgia, vulvodynia, chronic headaches, and temporomandibular disorders. For some disorders, research points to impaired central pain sensitivity and responses in these conditions, but their complex mechanisms have not yet been unraveled (Kindler et al., 2011).

WHAT CAUSES PAIN, AND WHY DOES IT SOMETIMES PERSIST?

> *Even with limitless resources, not every patient's pain can be eliminated*
>
> —Brennan et al., 2007

The following brief summary of the rapidly evolving body of research on pain—a subject with a deep literature in many disciplines—is not intended to be comprehensive. Rather, its purpose is to help readers understand the discussion in subsequent chapters of the impact of chronic pain on people's lives and the challenges of providing better pain care.

The Complexity of Chronic Pain

> *Treating a pain patient can be like fixing a car with four flat tires. You cannot just inflate one tire and expect a good result. You must work on all four.*
>
> —Penny Cowan, American Chronic Pain Association,
> an advocate for people with chronic pain[10]

In the past several decades, the long-standing belief regarding the strict separation between mind and body, often attributed to the early 17th-century French philosopher René Descartes, has given way to an appreciation of the interdependency between mind and body in health, illness, and disease and

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[10] Quotation from oral testimony to the committee.

the even broader perspective that recognizes the influence of the social environment (Marmor et al., 1994). If the Cartesian model of mind–body separation were correct, pain would be "restricted to the injury site and should be abolished after healing" (Kuner, 2010, p. 1258). Yet personal experiences, reports of clinicians who treat people with pain, and scientific research on the way pain alters the brain and nervous system indicate otherwise. A strictly biomedical approach to pain is simply too reductionist; rather, what is called for is an approach that recognizes the complexity of the pain experience. Similar to what has been learned about other chronic diseases, chronic pain ultimately affects (and is affected by) many intrinsic and extrinsic aspects of a person's life. Today, most researchers and clinicians who specialize in pain issues use the "**biopsychosocial model**" (denoting the combination of biological, psychological, and social/family/cultural contexts of pain) to understand and treat chronic pain (Gatchel et al., 2007).

In general, the early theories of how pain works failed to address key issues, many of which were described a number of years ago by Melzack and Wall (1996):

- The relationship between injury and pain varies (that is, a minor injury may produce great pain, or a significant injury may produce minor pain), as does the relationship between the extent of injury and the resulting disability.
- Non-noxious stimuli can sometimes produce pain (**allodynia**), and minor amounts of noxious stimuli can produce large amounts of pain (**hyperalgesia**).
- The locations of pain and tissue damage are sometimes different (**referred pain**).
- Pain can persist long after tissue healing.
- The nature of pain and sometimes its location can change over time.
- Pain is a multidimensional experience, with strong psychosocial influences and impacts.
- Responses to a given therapy vary among individuals.
- Earlier theories have not led to adequate pain treatments.

Over time, pain has become understood as a complex condition involving numerous areas of the brain; multiple two-way communication pathways in the central nervous system (from the site of pain to the brain and back again); and emotional, cognitive, and environmental elements—a complete, interconnected apparatus. In this sense, chronic pain resembles many other chronic diseases in that it has numerous interacting and contributing causes and multiple effects. This multiplicity of causes and effects opens up the possibility for a variety of treatment approaches. In severe chronic pain syndromes, quite a number of treatments may be attempted before the combination of physiological, cognitive, psychological, clinical, and self-care approaches that will produce the best result for a specific person is identified. Sometimes a single clinician has the requisite skills to accomplish this, and sometimes a team is required. The determination of who should care for the person with pain and the settings where that care should occur has an impact on health care delivery, as well as patients' health and well-being.

Genetic Influences

The way the central nervous system processes and transmits pain-related information can be influenced by a number of genetic factors. In general, these factors affect a person's pain sensitivity either by *increasing* the transmission of **nociception** signals to the brain and sometimes hijacking additional nerves to do so, or by *decreasing* central inhibitory signals whose purpose is to dampen the pain response. (At times, genetic influences can work exactly the opposite way as well, decreasing nociception transmission and increasing inhibitory signals.) The body's ability to release hormones, such as adrenalin (epinephrine), that stave off pain for a while is an important part of the basic "fight or flight" response. When adrenalin's effects subside, a person feels exhausted, which signals the body to rest.

Genetic factors can work in other ways as well. For example, they can affect the survival of neurons and therefore the strength of the nociceptive response; they may be at least partly responsible for differences between men and women in pain perception, tolerance, and analgesic response; and they have been shown to affect individual responses to **opioids**, including the likelihood of **addiction** (Li et al., 2008).

Nociception involves multiple steps, each accomplished by many specific molecules, such as neurotransmitters and the enzymes involved in protein synthesis. Some of these molecules increase pain sensitivity, some inhibit it, and each of them is subject to over- or underproduction as a result of genetic influences. But all must be working together properly and in balance, in all the transmission steps, to ensure that the final signal to the brain (and back) is accurate. Although these reactions may begin with a genetic proclivity, what the individual *learns* from these experiences influences and often strengthens subsequent reactions, a subtle process that establishes the basis for increasing pain **sensitization**.

Only a few pain conditions are strongly associated with a single variation in the DNA sequence of a gene; most involve multiple "risk-conferring" genes (Costigan et al., 2009). Most studies suggest that many common pain disorders—such as migraine and various types of joint pain, including low back pain—have a strong inherited component (Kim and Dionne, 2005). Efforts such as those at the Pain Genetics Lab of McGill University are focused on describing how genetic makeup can explain individual differences in pain sensitivity, response to analgesia, and susceptibility to chronic pain conditions, as well as how genes and environmental factors interact in producing these effects.

As researchers continue to unravel the workings of genetically influenced pain mechanisms, the potential emerges for new approaches to screening for and treatment of chronic pain syndromes and better targeting of therapeutics—so-called "personalized medicine." In addition, findings regarding these mechanisms may help explain why other factors, such as hormonal changes, can upset the body's delicate chemical balance and alter an individual's pain sensitivity over time.

Pain in Childhood

Researchers have studied for some time whether having pain in childhood influences the development of adult diseases and pain conditions, under the theory that the body's cumulative efforts to adapt to acute stress (a person's "**allostatic load**") eventually harm various organs, tissues, and body systems. Establishing this link also helps explain how the stresses of growing up poor, poorly educated, or in stressful environments might produce the "gradients of morbidity and mortality that are seen across the full range of income and education referred to as SES [socioeconomic status] and which account for striking differences of health between rich and poor" (McEwen, 2000, p. 111).

Psychological stressors have been shown to increase the likelihood of developing a range of serious adult diseases that involve pain, including arthritis, diabetes, heart disease, and chronic pain itself. The concept of allostatic load could explain the higher rates of some of these diseases in adults who have had early exposure to abuse or violence (Nielsen et al., 2007). Across society, "unhealthy environments are those that threaten safety, that undermine the creation of social ties, and that are conflictual, abusive, or violent" (Taylor et al., 1997, p. 411). For example, adults who have faced multiple "adversities" or suffered from anxiety or depression in childhood have a statistically significant increase in the risk of developing arthritis (Von Korff et al., 2009).

Responses to pain (physical, emotional, and cognitive) are generally learned in childhood, and these learned responses are important in understanding how adults cope with persistent pain. For example, a study of children with recurrent abdominal pain suggests that those who learn unhealthy responses to chronic pain, reflected in somatic and emotional distress, are more likely to become adults with chronic pain (Walker et al., 1995; Macfarlane, 2010). Yet some individuals are more resilient than others in the face of early adversity. It remains a question whether genetic predisposition plays a factor in these differences, in which case we need a greater appreciation of the specific psychosocial attributes involved in health outcomes (Nielsen et al., 2007).

As will be reviewed in Chapter 2, pain is not uncommon and often is undertreated in children and adolescents. And certainly we have come a long way from the era in which infants were believed not to suffer pain and so were not provided anesthesia or other pain-prevention measures for surgery and medical procedures (Schechter et al., 2002).

Nerve Pathways

A frequently cited hypothesis that links all the various influences on pain, known as the "**neuromatrix theory**," is that pain is "produced by the output of a widely distributed neural network" that is "genetically determined and modified by sensory experience" throughout life (Melzack, 2005, p. 1378). According to this theory, pain is the output of the neural network, and not "a direct response to sensory input following tissue injury, inflammation, and other pathologies" (Gatchel et al., 2007, p. 584). Although pain most often is triggered by such sensory inputs, it need not be.

The neuromatrix theory enables new thinking about chronic pain syndromes, such as fibromyalgia, that do not have an obvious cause but are associated with changes in the central nervous system. These changes are possible because the brain and nerves are not a fixed system but neuroplastic—that is, capable of adapting (in this case, in a negative way) at the level of the neuron; at the network level, where processing of pain inputs occurs; and at the structural level, which "can account for the long-term persistence of changes that arise in pathological pain states" (Kuner, 2010, p. 1259). Considerable progress has been made in the development of theories about the origins of pain, including the gate control theory, as well as in the development of new scientific knowledge, including the role of central sensitization. These advances have finally made it possible to begin to unravel the mechanisms of various chronic pain syndromes and phenomena such as phantom limb pain. The neuromatrix theory, not relying on direct sensory input, is especially important in this regard.

The Brain's Role

Until recently, understanding of the mechanisms of pain generation and transmission from the spinal cord to the brain has been based primarily on studies using animal models. The recent introduction of increasingly sophisticated, noninvasive neuroimaging technologies has made the human central nervous system available for direct examination and comparison between healthy subjects and people with chronic pain. The ultimate goal is to use these neuroimaging techniques to develop more effective and safer approaches to pain management.

Several imaging techniques have been used to investigate pain, including:

- electrophysiological methods, such as the electroencephalogram (EEG) and magnetoencephalogram (MEG);
- radiological methods, such as positron emission tomography and single-photon emission computerized tomography; and
- magnetic resonance techniques, such as magnetic resonance spectroscopy (MRS), structural magnetic resonance imaging (MRI), diffusion tensor imaging (DTI), and functional magnetic resonance imaging (fMRI).

These neuroimaging techniques can be categorized as structural (revealing anatomical information, e.g., MRI, DTI), biochemical (revealing information regarding the local chemical environment, e.g., MRS), or functional (revealing signal changes related to neuronal activity, e.g., EEG, MEG, fMRI).

Functional neuroimaging techniques, particularly fMRI, have begun to revolutionize our understanding of the brain's role in the perception and modulation of pain and provide a glimpse into the brain's response to a nociceptive stimulus, thereby enabling correlation of brain activity with the person's perceptions (Borsook and Becerra, 2006). A large number of brain regions, including the prefrontal cortex, amygdala, hypothalamus, hippocampus, primary and secondary somatosensory cortex, and others, have been identified as being involved with pain processing and modulation.

Functional neuroimaging also has yielded information about the brain regions involved in the cognitive and emotional factors that modulate pain, including attention (Petrovic et al., 2000), anticipation (Koyama et al., 2005), fear/anxiety (Ochsner et al., 2006), empathy (Ochsner et al., 2008), reward (Younger et al., 2010a), placebo (Wagner et al., 2004), and direct control (deCharms et al., 2005). Such studies have demonstrated that pain evokes a response in multiple areas of the brain—a "distributed network"—consistent with the variety of physical, affective, cognitive, and reflexive reactions to pain that people experience. Additionally, the involvement of multiple brain areas and their independent, parallel organization for transmission of nociceptive information are "quantitatively related to subjects' perceptions of pain intensity" (Coghill et al., 1999, p. 1939). These same brain regions also have been observed to undergo plastic changes as a consequence of chronic pain, changes that are visible only now because of these new technologies.

Researchers also have used structural neuroimaging to characterize anatomical changes in the brains of people with chronic pain. Although structural imaging yields no direct information about neural function, it provides indirect information about how chronic pain affects central plasticity and identifies the anatomical differences between people with chronic pain and those who are healthy. For instance, researchers have demonstrated abnormal gray matter changes in the brains of people with chronic low back pain, fibromyalgia, and temporomandibular disorders (Apkarian et al., 2004; Kuchinad et al., 2007; Younger et al., 2010b). Structural imaging can be used to track longitudinal changes due to disease severity and progression and can characterize changes following treatment.

While there is great interest in understanding the function and structure of individual brain regions, researchers increasingly are appreciating that the manner in which these brain regions are connected (i.e., networked) may be more important in understanding pain. For example, a growing body of research is focused on examining resting state functional connectivity changes in the human brain. The theory is that the brain defaults to an intrinsic pattern of brain networks when at wakeful rest. Several abnormal resting state brain networks have been identified in various chronic pain conditions, such as fibromyalgia and diabetic neuropathic pain (Cauda et al., 2009a,b, 2010; Napadow et al., 2010).

To overcome the limitations posed by using a single neuroimaging technique, researchers now are combining multiple techniques. Recent advances allow researchers to gather both EEG and fMRI data simultaneously, combining the high temporal resolution of the former with the high spatial resolution of the latter. Future research on chronic pain will witness the integration of structural, functional, chemical, and resting state network methods to build a more complete picture of the brain. Combined use of these methods has shown promise in the evaluation of other brain-related illnesses, and each adds a unique angle to the investigation of brain structure and function.

Basic research employing neuroimaging has shown which areas of the brain respond to specific nociceptive stimuli in people with acute pain sensitivity and with neuropathic pain. Such findings open up the possibility for new, more targeted treatments. Already, researchers have used biofeedback approaches to train people with chronic pain to control the activation of pain-related brain areas while watching fMRI pictures of their brains in action, resulting in decreased pain perception (deCharms et al., 2005). Again, while still early in development, such a treatment approach suggests opportunities to tailor pain management, in this case under the person's direct control, to the specific activity patterns of his or her own brain.

Emotional Context

Genetic influences on nociception and the mechanisms associated with the brain's response are far from the complete story of how individuals actually experience pain and the ways it affects their functioning. Numerous studies have shown the impact that emotions—in part the product of temperament and in part the result of background and acculturation—can have on the experience of pain, both acute and chronic (see, for example, Turk and Monarch, 2002; Vlaeyen and Crombez, 2007; Fernandez and Kerns, 2008). Negative emotions can increase the perception of chronic pain, while pain has a reciprocal effect on mood states. A good example of this interrelationship is that unrelenting pain is an important cause of and contributor to depression and anxiety; as the pain cycle progresses, depression and anxiety increase pain and pain-related disability and reduce quality of life (Bair et al., 2008; Gureje, 2008). To illustrate, greater anxiety and other psychological conditions can increase the self-reported severity of postsurgical pain (Kehlet et al., 2006), as well as increase the amount of analgesia required, the likelihood of serious complications, and the length of hospitalization.

At the same time, positive emotions are associated with better outcomes in people with chronic pain with respect to improvements in their ability to cope with pain and in their social functioning (Park and Sonty, 2010). Positive emotions also are associated with better responses to treatment, reduced disability and impairment of physical functioning, and improved health-related quality of life and coping (Fisher et al., 2004; Karoly and Ruehlman, 2006).

The negative emotional correlates of chronic pain frequently become more apparent the longer pain persists, even for individuals who wish to be "positive." For example, emotional distress may be compounded as pain interferes with work, with important social and recreational activities, and with family and social relations. People with chronic pain may come to believe that, despite their being frequent users of the health care system, the system offers them neither cure nor adequate relief. They may believe that others, including family and clinicians, will disbelieve the extent of their pain or dismiss it as "all in your head," or believe they are a malingerer or a complainer, especially if a sufficient, objective physiological component of their condition cannot be identified. They may withdraw from social interactions and work, become isolated, and thereby experience even greater functional disability (Boersma and Linton, 2006). In this way, a downward spiral of unrelieved pain and loss of social functioning is established.

It is hardly surprising that people experience significant emotional distress when they have persistent pain and related symptoms that impair their ability to function and impede their overall quality of life, often for years. People with many chronic diseases experience comparable emotional consequences. This is not to suggest that the emotional distress caused the pain in the first place. Nevertheless, there may be some individuals whose lifetime history of emotional problems predisposes them to develop persistent pain following an illness or trauma, such as an automobile accident or surgery.

Many people suffer from both persistent pain and a broader mental health disorder. An estimated 40 to 50 percent of people with chronic pain have mood disorders, but the direction of causality is not completely clear and can, in some instances, go either way. Most studies suggest that depressive disorders, for example, tend to occur *after* chronic pain begins (Fishbain et al., 1997); however, many people so affected have a prior history of depression. In one study of people with chronic disabling occupational spinal cord disorders, some 65 percent were found to have at least one current psychiatric disorder, and 56 percent had a major depressive disorder (Dersh et al., 2006).

One factor that has been suggested as breaking the link between depression and chronic pain is the belief that one can exert some control over the pain. (The latter findings are consistent with research findings on stress in general: that it is not stressful events, per se, that produce ill effects, but the individual's judgments or appraisals of those events, particularly a perceived lack of control [McEwen, 1998].) The neurotransmitter serotonin is associated with both pain and depression, and some researchers have theorized that a common genetic trait or susceptibility is linked to pain and both depression and anxiety.

Some people with chronic pain fear that movement and exercise will increase their pain or lead to a dire consequence, even paralysis. In fact, at least for people with chronic low back pain, the opposite is generally true, and for that reason, physical therapy is often part of a comprehensive treatment plan. Helping people overcome their fear of reinjury is an important intervention because, regardless of biomedical findings, this fear is the best predictor of disability for people with low back pain, about two-thirds of whom avoid activities they are capable of doing because they believe they might injure their back (Crombez et al., 1999). For people with low back pain, concern about the physical demands of their job has a greater impact than actual reported pain levels on work-related disability and lost work days.

Anger is a common correlate of chronic pain, and not an illogical one considering the debilitating effects of the disease, confusion in diagnosis and prognosis, frustrations of trial and error in finding the best treatment or combination of treatments, frequent misunderstanding and skepticism by others (including health care providers), impacts on close personal relations, and the like. People understandably desire an immediate "cure" or significant relief, but often no treatments can accomplish this; instead, they are offered a lengthy rehabilitation effort and advice on managing their disability. These circumstances can trigger powerful emotional responses that interfere with rehabilitation and adjustment. In one study, 62 percent of people with chronic pain expressed anger toward health care providers, 39 percent toward significant others, 30 percent toward insurance companies, and so on, but the most frequent target of their anger—among some 74 percent—was themselves (Okifuji et al., 1999).

Ultimately, explicit assessment of the emotional context of pain is necessary to inform a comprehensive, individualized treatment plan. Given the particularly high co-occurrence of psychiatric disorders among people with chronic pain in particular, specific effort to establish and treat any diagnosed clinically significant mood and anxiety disorders (or other psychiatric conditions) is important, even though many of these mood disorders are secondary to the experience of chronic pain. Likewise, it may be important to provide a greater measure of pain assessment and treatment to patients in psychiatric hospitals, substance abuse treatment centers, and other mental health settings as a routine practice. That is, an **interdisciplinary** approach to diagnosis and management is important, even if coordinated by a single health care provider. Put another way, "Failure to follow a biopsychosocial approach to treatment will likely contribute to prolonged disability in a substantial number of these chronic pain patients" (Dersh et al., 2006, p. 459).

Cognitive Context

People both ascribe meaning to and seek meaning in pain, acute or chronic. Physical and psychological responses to a painful stimulus occur in a context of meaning that affects how pain is perceived—for example, as a dangerous warning sign, a punishment, or a trial to overcome.

People acquire **beliefs** about pain over a lifetime of experiences and cultural exposures. Whether they regard their pain as a signal of impending damage or disability, a short-term or permanent condition, controllable or uncontrollable, or whether they believe they must reduce their activity level in response—all these beliefs influence their reactions. In the case of chronic pain, beliefs also affect how well people adjust to pain and whether they actively attempt to cope with it (Balderson et al., 2004). In fact, beliefs, anticipation, and expectation are better predictors of pain and disability than any physical pathology (Turk and Theodore, 2011).

The public's fear of cancer, for example, is exacerbated by the concomitant fear of having to face unmanageable pain, which affects decision making about medical treatments (Aronowitz, 2010). Thus, many people with cancer interpret brief pain episodes against the frightful backdrop of a serious disease. Negative interpretations may contribute, as one example, to the finding that cancer patients who believed their post–physical therapy pain was due to their cancer reported greater pain intensity than those who attributed this pain to some other cause (Smith et al., 1998).

Research has identified a particular style of thinking—"**pain catastrophizing**"—as a common maladaptive cognitive response to the experience of pain, particularly chronic pain. When people "catastrophize" their pain—that is, when they tend to ruminate about their pain, magnify pain sensations, and feel helpless about their ability to manage it (in other words, when they believe pain will lead to far worse outcomes than it will)—they not only increase their pain and dysfunction but also slow their recovery and adjustment. Therefore, these catastrophic beliefs must be assessed and addressed (Sullivan et al., 2001; Keefe et al., 2009). Pain catastrophizing interacts closely with the pain-avoidance fears described earlier:

> When pain is perceived following injury, an individual's idiosyncratic beliefs will determine the extent to which pain is catastrophically interpreted. A catastrophic interpretation of pain gives rise to physiological (arousal), behavioral (avoidance), and cognitive fear responses. The cognitive shift that takes place during fear enhances threat perception (e.g., by narrowing of attention) and further feeds the catastrophic appraisal of pain. (Gatchel et al., 2007, p. 603)

Research has shown that correcting harmful and pain catastrophizing beliefs through a treatment plan that includes **cognitive-behavioral therapy** improves outcomes (Smeets et al., 2006; Buse and Andrasik, 2010). A variety of cognitive-behavioral strategies have been used to build people's skills in coping with pain, combining education in how beliefs, feelings, and behavior affect pain with training and practice in skills such as relaxation, goal setting, and thinking in new ways (Keefe et al., 2009). Some approaches to reducing pain catastrophizing provide information plus exposure to feared activities to demonstrate that the person's fears of further injury do not inevitably materialize when physical activities are undertaken.

Because believing one has control over chronic pain decreases the incidence of depression, some clinicians attempt to increase that sense of control and coping

(Keefe et al., 2009). Some people who have been told their pain is chronic have difficulty accepting this diagnosis, and their lives become dominated by attempts to become pain free. The search for total pain relief, while understandable, can lead to doctor shopping; fragmented care; and repeated trials of surgeries, medications, or unproven remedies (Roper Starch Worldwide, 1999). The failure of these repeated (and common) pain treatment efforts undoubtedly undermines the sense of control clinicians may be trying to encourage.

Emphasis increasingly is being placed on encouraging acceptance of some pain and self-management efforts that can improve function and quality of life even if all pain cannot be eliminated. An approach that emphasizes participation in daily activities despite pain and fosters a willingness to have pain present without responding to it may aid in reducing the "distressing and disabling influences of pain" (McCracken et al., 2005, p. 1335).

Self-efficacy is a psychological construct related to that of control. Believing that one can perform a task or respond effectively to a situation predicts pain tolerance and improvements in physical and psychological functioning. Research therefore suggests that "a primary aim of CLBP [chronic low back pain] rehabilitation should be to bring about changes in catastrophic thinking and self-efficacy" (Woby et al., 2005, p. 100). Likewise, greater self-efficacy improves pain, functional status, and psychological adjustment (Keefe et al., 2004). Researchers posit several explanations for why self-efficacy works to control pain, including that people who expect success are less likely to be stymied when confronting the challenge of pain.

The goals of self-management and self-efficacy reinforce the benefits that accrue when people take a role in managing their pain, and treatment should include efforts to help them perform that role effectively. However, clinicians must take into account that people have unique capacities and cannot be held to a single, universal expectation for self-management. From acute to chronic pain, the salience of individual, subjective responses is paramount.

THE NEED FOR A CULTURAL TRANSFORMATION

> *For at least two decades, most major medical journals and the lay media have recognized that many patients have needless pain.*
>
> ——Von Roenn et al., 1993

Barriers to improved pain care exist at multiple levels: at the system level, where changes are needed in reimbursement policy and research emphasis, for example; at the clinician level, where improvements are needed in clinical education and practice; and at the level of the public and the individual person in pain, where greater awareness is needed of the significance of pain, as is more education about self-management and appropriate treatment. At all levels, the focus should be on prevention. Overcoming the barriers to improved pain care will, in the committee's view, require a cultural transformation. This transformation will lead to a greater awareness of the impact of pain on individuals and society, wider support of efforts to understand and prevent pain, a greater commitment to assessing and treating pain effectively, and enhanced recognition of the highly individual ways in which people experience pain and respond to treatment.

Overview of Barriers to Improved Pain Care

This section provides a brief overview of the barriers to improved pain care. A more detailed discussion is contained in Chapter 3.

System-Level Barriers

Although there may be much more to learn about pain and its management, scientific knowledge has advanced to the point where much is understood about the biological–cognitive–emotional aspects of pain and quite a bit about ways to treat it. Throughout the health system in general, however, exist barriers to achieving the ideal of comprehensive and interdisciplinary approaches to health care, including pain management (IOM, 2009). Many of these barriers are institutional, educational, organizational, and reimbursement-related. These same structural barriers channel the health system's attention to procedure-oriented treatments rather than prevention, but preventing pain (for example, acute pain following surgery or dental procedures) and preventing the transition from acute to chronic pain should be top clinical priorities.

In the United States, clinical services (and research endeavors) generally are organized along disease-specific lines. Thus there are departments of neurology and neurosurgery, cardiology centers, free-standing surgeries, orthopedic and cancer hospitals, and so on. Acute and chronic pain are features of each of these specialties; in a sense, however, because pain belongs to everyone, it belongs to no one. The existing clinical (and research) silos prevent cross-fertilization of ideas and best practices. Although academically based pain clinics implement the comprehensive, interdisciplinary approaches to pain assessment and treatment that appear to work best in managing chronic pain, they are few in number and increasingly constrained by a reimbursement system that discourages interdisciplinary practice.

Clinician-Level Barriers

Clinicians can, in theory, draw on many disciplines in addressing the pain-related needs of individuals and families: physicians of several specialties, nurses, psychologists, rehabilitation specialists (physiatrists, physical therapists, and occupational therapists), clinical pharmacists, and complementary and alternative medicine practitioners (chiropractors, massage therapists, and acupuncturists, for example). Yet while a substantial amount of acute and chronic pain can be relieved with proper treatment by a single clinician or the appropriate mix of trained professionals, providers encounter a number of barriers to appropriate pain care:

- Well-validated evidence-based guidelines on assessment and treatment have yet to be developed for some pain conditions, or existing guidelines are not followed.
- Health care professionals are not well educated in emerging clinical understanding and best practices in pain prevention and treatment.
- Should primary care practitioners want to engage other types of clinicians, including physical therapists, psychologists, or complementary and alternative medicine practitioners, it may not be easy for them to identify which specific practitioners are skilled at treating chronic pain or how they will do so.
- A lack of understanding of the importance of pain management exists throughout the system, starting with patients themselves and extending to health care providers, employers, regulators, and third-party payers.
- Regulatory and law enforcement policies constrain the appropriate use of opioid drugs.
- Restrictions of insurance coverage and payment policies, including those of workers' compensation plans, constrain the ability to offer potentially effective treatment.
- Additional basic and clinical research is needed on the underlying mechanisms of pain, reliable and valid assessment methods, the development of new treatments, and the comparative effectiveness of existing treatments.

Patient-Level Barriers

Adequate pain treatment and follow-up may be thwarted by a mix of uncertain diagnosis and the societal stigma that is applied, consciously or unconsciously, to people reporting pain, particularly if they do not respond readily to treatment. Questions and reservations may cloud perceptions of clinicians, family, employers, and others: *Is he really in pain? Is she drug seeking? Is he just malingering? Is she just trying to get disability payments?* Certainly, there is some number of patients who attempt to "game the system" to obtain drugs or disability payments, but data and studies to back up these suspicions are few. The committee members are not naïve about this possibility, but believe it is far smaller than the likelihood that someone with pain will receive inadequate care. Religious or moral judgments may come into play: *Mankind is destined to suffer;*

giving in to pain is a sign of weakness. Popular culture, too, is full of dismissive memes regarding pain: *Suck it up; No pain, no gain.*

When people perceive a lack of validation or other negative attitudes in their clinicians, they are more likely to be dissatisfied with treatment and change doctors, as is the case with about half of people with noncancer pain. In a survey of more than 2,600 Americans with chronic, severe, noncancer pain conducted in 1998 (Roper Starch Worldwide, 1999), 47 percent reported that they had changed doctors, and the largest subgroup of these respondents (22 percent) had done so three times or more. Among the top reasons cited for changing doctors were “doctor didn’t take pain seriously enough” (29 percent) and “doctor didn’t listen” (22 percent), although the most common reason was “still had too much pain” (42 percent). Changing doctors may help if the next clinician is more skilled or empathetic or has better ideas for treatment, or it may hurt if all the change accomplishes is to interrupt the continuity of care.

Additional patient-level barriers are specific to particular demographic groups disproportionately undertreated for pain, such as children, older adults, women, rural residents, individuals with less education or lower incomes, and people belonging to certain racial and ethnic groups. These issues are discussed in Chapter 2.

The Necessary Cultural Transformation

Proponents of international efforts to improve pain treatment have said that “the unreasonable failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right” (Brennan et al., 2007, p. 205). The IASP and its European Federation have urged the World Health Organization (WHO) to recognize that “pain relief is integral to the right to the highest attainable level of physical and mental health” (WHO, 2004), paralleling language found in the WHO Constitution.

With the passage of the Patient Protection and Affordable Care Act in March 2010, the U.S. health care system may undergo profound changes, although how these changes will evolve over the next decade is highly uncertain. Health care reform or other broad legislative actions may offer new opportunities to prevent and treat pain more effectively. Both clinical leaders and patient advocates must pursue these opportunities and be alert to any evidence that barriers to adequate pain prevention and treatment are increasing.

To remediate the mismatch between knowledge of pain care and its application will require a cultural transformation in the way clinicians and the public view pain and its treatment. Currently, the attitude is often denial and avoidance. Instead, clinicians, family members, employers, and friends inevitably must rely on a person’s ability to express his or her subjective experience of pain and learn to trust that expression, and the medical system must give these expressions credence and endeavor to respond to them honestly and effectively.

Conclusion. *Chronic pain alone affects the lives of approximately 100 million Americans, making its control of enormous value to individuals and society. To reduce the impact of pain and the resultant suffering will require a transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess, and treat pain.*

- *Understanding the experience and impact of pain:*
  - *—Pain is a major problem for individuals, families, and society, with an increasing prevalence, cost, and impact on quality of life and health status.*
  - *—The experience of both acute and chronic pain is unique and varies widely among individuals. Pain is influenced by genetics, early life experiences, mood and psychological state, coexisting medical conditions, and environments.*
  - *—National surveys and numerous research studies have shown that pain is more prevalent and less likely to be adequately treated in certain population groups, including the elderly, women, children, and racial and ethnic minorities.*
  - *—While pain sometimes can serve as a warning sign that protects individuals from further harm, chronic pain is harmful and impairs productivity and quality of life.*
  - *—When acute pain persists and becomes chronic, it may in some cases become a disease in its own right, resulting in dysfunction in the central nervous system and requiring a comprehensive treatment approach.*
- *Improving the assessment and treatment of pain:*
  - *—Ongoing pain has been underreported, underdiagnosed, and undertreated in nearly all health care settings.*
  - *—Individuals with pain that reduces quality of life should be encouraged to seek help.*
  - *—Because there are multiple contributors to and broad effects of chronic pain, comprehensive assessment and treatment are likely to produce the best results.*

Finding 1-1. To achieve vital improvements in the assessment and treatment of pain will require a cultural transformation. The committee finds that, to adequately address the impact and experience of pain in the United States, government agencies, private foundations, health care providers, educators, professional associations, pain advocacy groups and organizations that raise public awareness, and payers must take the lead in achieving a cultural transformation with respect to pain. This transformation should improve efforts to prevent, assess, treat, and better understand pain of all types. The recommendations presented in this report are intended to help achieve this transformation.

ORGANIZATION OF THE REPORT

Chapters 2 through 5 describe the public health challenge of pain, the practice and educational barriers to prevention and treatment, and issues for further research. In each chapter, the committee offers its findings and recommendations.

The public health challenge is discussed in **Chapter 2**, which establishes the rationale for considering pain as a public health problem. This chapter describes the magnitude of pain's impact on Americans, including the population as a whole and, where data are available, high-risk subgroups.

Chapter 3 provides an overview of treatments; describes the major treatment modalities; addresses several issues in pain care practice, including aspects of opioid use; elaborates on selected barriers to effective pain care; and presents pain care models.

Chapter 4 examines the need for improvements in education about chronic pain and its treatment for patients and families, the public, and clinicians.

Chapter 5 defines the challenges in pain research, from basic biomedical and pharmacologic research to the development of new research tools. The current organizational structure and funding for pain research are reviewed, and opportunities for public–private partnerships are described.

Finally, **Chapter 6** organizes the recommendations presented in Chapters 2 through 5 into a blueprint for action to address the tremendous burden of pain in America.

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2

Pain as a Public Health Challenge

> *Public health is what we, as a society do collectively to assure the conditions for people to be healthy.*
>
> —IOM, 1988, p. 19

Pain can be conceptualized as a public health challenge for a number of important reasons having to do with prevalence, seriousness, disparities, vulnerable populations, the utility of population health strategies, and the importance of prevention at both the population and individual levels.

First is the extent of the problem: pain affects tens of millions of Americans and contributes substantially to morbidity, mortality, disability, demands on the health care system, and significant economic burdens for the nation. The prevalence of chronic pain is growing and likely to continue to do so. (See Chapter 1.)

Second, there are substantial disparities in pain prevalence and seriousness and rates of undertreatment across population groups. Inadequately treated pain is more common in vulnerable populations—including the elderly, children, racial and ethnic minorities, and others—that are a traditional concern of public health agencies and programs.

Third, because pain is ubiquitous across the population, imposes a differential burden on vulnerable subgroups, and is affected by conditions in the social, physical, and economic environments, a comprehensive pain prevention and management strategy at the population health level is needed. It is not sufficient to treat pain merely on a case-by-case basis in physicians' offices and other health care settings.

Fourth, pain is costly to the nation—not just in terms of health care expenditures and disability compensation but also in terms of lost school days, lost productivity and employment, reduced incomes, and, indeed, lost potential and quality of life.

Fifth, pain raises societal issues that extend beyond individuals and their suffering. Specifically, the opioid medications that are effective for many people with pain also are subject to misuse and abuse, and ensuring that they are available for those who need them and not available to abusers necessitates cross-governmental efforts at all levels.

Sixth, the public's health is greatly influenced by the graduates of the nation's health professions training programs, many of which are heavily supported with public monies. From initial education through continuing education programs, health professionals need to learn more about the importance of pain prevention, ways to prevent the transition from acute to chronic pain, how to treat pain more effectively and cost-effectively, and how to prevent other physical and psychological conditions associated with pain.

Seventh, the ability to reduce pain's impact on the public's health can be strengthened as a result of new knowledge generated by the nation's vital research establishment through basic, clinical, and translational research; epidemiologic studies; and analysis of care patterns and costs.

Finally, public health offers an infrastructure and a forum for developing strategies for preventing and addressing pain. Multiple federal agencies—such as the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health, Agency for Healthcare Research and Quality (AHRQ), Surgeon General, and Departments of Veterans Affairs and Defense—can interact with state and local public health agencies and private-sector partners to develop and implement public education efforts and other population-based interventions.

The Department of Health and Human Services' (HHS) vision and strategic framework on multiple chronic conditions is an example of a multipronged effort to accomplish much of what a coordinated national initiative on pain might do (HHS, 2010b). The starting point for the HHS initiative was recognition of the high human and economic costs of multiple chronic diseases, many of which include a substantial pain component. Problems that result from having several chronic diseases mirror in many ways the challenges experienced by people with severe chronic pain: "poor functional status, unnecessary hospitalizations, adverse drug events, duplicative tests, and conflicting medical advice" (HHS, 2010b, p. 2). The kind of systems thinking and stakeholder involvement that went into the HHS strategic framework parallels what the public health community could accomplish in pain care.

This is not to say that the committee believes pain management services should be the sole responsibility of any one public health entity or of public health personnel. Instead, the committee acknowledges the understanding promulgated in *The Future of the Public's Health in the 21st Century* that a contemporary public health system calls for "the contributions of other sectors of society that have enormous power to influence health" (IOM, 2002a, p. 2). With respect to improving pain management, those sectors include

- *the health care delivery system*, for pain prevention, assessment, treatment, and follow-up;
- *health professions educational institutions*, for improvements in education, mentoring, and modeling of good pain care;
- *businesses and employers*, which influence group health insurance coverage policies;
- *the research establishment*, for stimulating new understandings of pain that may lead to prevention, early intervention, and new treatments that are more effective and less problematic;
- *state and federal policy makers*, who must craft policies related to patient safety, dispensing of opioid drugs, regulation of clinicians' scope of practice, workers' compensation programs, drug marketing, insurance coverage of pain services, and many others;
- *voluntary health organizations*, especially those consumer-oriented groups devoted to pain conditions, but also groups for which pain is a significant problem for their primary constituents, such as the American Cancer Society, the American Diabetes Association, the National Alliance on Mental Illness, and many others;
- *the pharmaceutical and device industries,* as they attempt to develop new, more effective, and more targeted analgesics;
- *accrediting and licensing bodies,* which set the educational and practice standards for clinicians; and
- *the news and information media*, which can affect public opinion and increase understanding of acute and chronic pain.

The variety of entities potentially involved in a broad-based effort to improve pain prevention and management across U.S. society offers promising opportunities for the kinds of public–private partnerships envisioned in the charge to this committee (see Chapter 1).

Recently released goals and objectives for Healthy People 2020—"the health agenda for the nation," issued by HHS—appear to anticipate a larger public health role in pain management. Under the Medical Product Safety topic is a new objective—"Increase the safe and effective treatment of pain"—although this objective does not explicitly frame a comprehensive or strategic approach to pain, and three of its four subparts remain under development (Box 2-1).

BOX 2-1
Healthy People 2020 Pain Relief Objectives

Medical Product Safety (MPS) Objective 2: *Increase the safe and effective treatment of pain*

MPS 2.1	Reduce the proportion of patients suffering from untreated pain due to a lack of access to pain treatment
MPS 2.2	Reduce the number of non-FDA-approved pain medications*
MPS 2.3	Reduce serious injuries from the use of pain medicines
MPS 2.4	Reduce deaths from the use of pain medicines

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*This is the only objective that, as of Healthy People's December 2010 release, was not considered "developmental"; however, the committee was unable to obtain a list of non-FDA-approved pain medications from the FDA.

Medical Product Safety Objective 2.2—"Reduce the number of non-FDA-approved pain medications"—needs additional clarification. The intent of this objective is not to address "off-label" uses of drugs for pain,[1] but to focus on drugs whose use predated current strict FDA oversight and that the FDA has never approved. The committee was unable to obtain a list of these drugs from the FDA and believes that decisions to withdraw specific medications could have unintended consequences that would be detrimental to patients. Therefore, such decisions should be evidence based, transparent, and made in consultation with clinicians who treat people with pain.

Only two other Healthy People 2020 objectives relate to pain. One focuses on reducing disability from arthritis and the other on reducing nonmedical use of prescription drugs, including pain relievers (HHS, 2010a).

Pain—especially severe, chronic pain—interferes with multiple aspects of the individual's life and has many consequences. The remainder of this chapter begins by summarizing data from national surveys, as well as independent research studies, to provide insight into the large number of people with pain

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[1] Many FDA-approved medications are used for pain "off-label" (that is, they are approved drugs, but not approved specifically for pain or approved only in specified doses), and these constitute a significant share of clinicians' pain care resources, especially for children and the elderly, groups usually omitted in clinical trials. Off-label use of prescription drugs, in general, is common; an estimated 21 percent of office-based physicians' overall use of commonly prescribed drugs is off-label (Radley et al., 2006). Examples of drugs used off-label for pain care are antiseizure drugs used for migraine and nerve pain, antidepressants for chronic pain, beta-blockers for migraine, and opioids for people with only mild or infrequent pain (Consumers Union, 2007).

conditions and the differential impacts of pain on various population groups. The chapter then examines the seriousness of pain by describing its effects on daily activities, productivity, and quality of life, as well as its link with suicide; this section also includes a discussion of differences in the seriousness of pain by race/ethnicity and sex. Finally, the chapter reviews data on the financial costs of pain and its treatment before turning to a discussion of an expanded focus on public health's role in pain prevention and treatment.

SCOPE OF THE PROBLEM

> *I have been told to "suck it up"; I have been asked if I was having trouble at home; I have been accused of being a "druggy" (drug seeking female). I have also found some practitioners who could "read the tea leaves," so to speak, and TELL ME how much pain I must be in, based on my physical exam.*
>
> —A person with chronic pain[2]

> *Neuropathic pain has reached an epidemic. More than 6 million Americans have unrelenting nerve pain. Now it will increase tremendously because of the epidemic of diabetes.*
>
> —Tina Tockarshewsky, The Neuropathy Association,
> an advocate for people with chronic pain[3]

Data Sources and Limitations

Obtaining a definitive picture of the extent and significance of pain is difficult. Current data on the incidence, prevalence, and consequences of pain are not consistent or complete, in part because in many cases pain is treated as a symptom, and what is collected is data on underlying conditions or events (see Box 2-2). For example, data on health care utilization are organized by diagnoses (e.g., arthritis or spinal disorders), but the extent to which the *pain* of these conditions drove people to the health care system is unclear. Similarly,

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[2] Quotation from response to committee survey.

[3] Quotation from oral testimony to the committee, November 2010.

BOX 2-2
Key Shortcomings of Data on Pain Prevalence in the United States

- There is no standardization of methods, definitions, and survey questions regarding pain used in population-based studies across and within agencies.
- Existing international standards for questions on some aspects of pain (e.g., low back pain) are not used by U.S. population-based health surveys, hindering cross-national comparisons.
- National population-based health surveys usually do not include people in the military or those living in nursing homes, chronic care facilities, or corrections facilities.
- In most cases, pain-related questions in national population-based health surveys are asked only of adults.
- Available data relate to only a few conditions (e.g., arthritis, low back pain).
- General items on pain (e.g., pain in the last month) do not describe types of pain.
- Acute and chronic pain are not distinguished in available data.
- Longitudinal data on consequences of pain are not available, and the data often are old.
- Complete data for population subgroups are unavailable because of these weaknesses (although some differences among subgroups—women, American Indians, those with lower levels of education or income—appear clear).

the reason for a physician visit is recorded as, for example, “knee symptoms” or “back symptoms,” and while some or all of these visits may have been prompted by pain, it is impossible to know. In constructing the picture of pain provided in this chapter, the committee could not rely solely on large epidemiologic studies or clinical trials. Such data simply are not available to describe the full impact of pain from different causes, in different population groups, or with different impacts. Instead, the committee assembled a variety of types of data from different types of sources that, taken together, suggest the broad outlines of the problem.

Furthermore, data on pain from different U.S. federal sources often do not agree. They are based on different survey questions and methodologies; some sources rely solely on self-report, while others also check medical records. Seeking insights from cross-national studies can be helpful, but the possibility of cultural differences in pain expression and expectations of treatment cannot be ignored, nor can differences in data collection methods that could affect comparisons. Moreover, since chronic pain in particular has a lengthy trajectory, longitudinal data on its consequences—medical, financial, social, and otherwise—would be a valuable resource, but these data are not available. As a result of such limitations, the profile in this chapter cannot be said to be complete, but rather strongly suggestive of the dimensions of pain in the United States.

The major sources of U.S. population health data including information on pain are two large, ongoing surveys conducted by the National Center for Health Statistics (NCHS), an agency within CDC. The first is the National Health Interview Survey (NHIS), an ongoing, cross-sectional household interview survey of approximately 35,000 U.S. households collectively containing about 87,500 persons. It is large enough to enable analysis of health information for many demographic and socioeconomic groups. The second is the National Health and Nutrition Examination Survey (NHANES), which collects data through in-person interviews and physical examinations of a representative sample of about 5,000 Americans annually. The NHANES includes demographic, socioeconomic, dietary, and health-related questions; medical, dental, and physiological measurements; and laboratory tests.

Data from national population-based surveys such as the NHIS are very limited in scope. For example, arthritis and pain questions included in the NHIS 2009 adult questionnaire were restricted to eight pain sites, asked about pain during the past 30 days, and did not distinguish between acute and chronic or persistent pain or among types of arthritis (e.g., rheumatoid arthritis, gout). Patterns in the prevalence of these pain conditions based on the NHIS questions may not reflect differences in levels of activity limitation, quality of life, or access to appropriate pain care. Most important, pain-related conditions such as lupus, sickle-cell disease, ankylosing spondylitis, and other conditions may not be captured in these data.

Moreover, both the NHIS and the NHANES use samples of civilian, non-institutionalized populations. They do not include people with chronic pain who are in the military or live in corrections facilities, nursing homes, or other chronic care facilities.

In addition to the NHIS and NHANES, the Medical Expenditure Panel Survey (MEPS), a project of AHRQ, surveys U.S. families and individuals, their medical providers (doctors, hospitals, pharmacies, etc.), and employers. The MEPS collects data on the use of health services, their costs, how they are paid for, and health insurance coverage. Pain data are obtained from both self-reports and providers' reports. Given the limitations of and the very high-level picture provided by these national data sets, this chapter includes findings from a large number of smaller-scale, independent studies in an attempt to round out the picture of pain and its effects.

Overall Prevalence

The most prominent feature of pain that qualifies it as a public health problem is its sheer prevalence, as well as its apparent increase (discussed in the next section). Of course, estimates of the current prevalence of pain in a population vary depending on the definitions and methods used. Nevertheless, an interna-

TABLE 2-1 Age-Adjusted Rates of U.S. Adults Reporting Pain in the Last 3 Months, Selected Causes, 2009

Cause of Pain	U.S. Average, Adults 18 and Over (%)
Severe headache or migraine	16.1
Low back pain	28.1
Neck pain	15.1
Knee pain	19.5
Shoulder pain	9.0
Finger pain	7.6
Hip pain	7.1

SOURCE: CDC and NCHS, 2010.

tional group of researchers using the World Health Organization's (WHO) World Mental Health Survey instrument in 10 developed countries has estimated that some 37 percent of adults in these populations (age-standardized) have common chronic pain conditions (Tsang et al., 2008). In the United States, the prevalence rose to 43 percent, amounting to approximately 100 million adults in 2010—a conservative estimate as neither acute pain nor children are included.

Recent NCHS data suggest substantial rates of pain from various common causes. The percentage of Americans 18 and older who, in 2009, reported pain during the 3 months prior to the survey is shown in Table 2-1. Low back pain was the most frequently reported pain condition. A review of multiple epidemiologic studies of pain prevalence in various populations reveals two clear and consistent messages:

- Musculoskeletal pain, especially joint and back pain, is the most common single type of chronic pain.
- Most people with chronic pain have multiple sites of pain (Croft et al., 2010).

Rising Rates of Chronic Pain

An increase in pain prevalence has been recorded for some types of pain in the U.S. population,[4] and chronic pain rates are likely to continue to rise, for at least five reasons.

First, the aging of the U.S. population means that a growing number of Americans will experience the diseases with which chronic pain is associated—diabetes, cardiovascular disorders, arthritis, and cancer, among others (Cherry et al., 2010).

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[4] Rising rates of chronic pain are not unique to the United States. A U.K. report, for example, notes that the prevalence of chronic pain is rising sharply: "chronic pain is two to three times more common now than it was 40 years ago" (U.K. Department of Health, 2009, p. 34).

Second is the rising prevalence of obesity, which is associated with chronic conditions that have painful symptoms (diabetes-associated neuropathy, for example), as well as orthopedic problems, including cartilage degradation (Richettel et al., 2011). As a result, more Americans will have joint replacement surgeries and at younger ages (Harms et al., 2007; Changulani et al., 2008); these surgeries, in themselves, can cause acute and sometimes persistent pain that interferes with a full recovery and a resumed quality of life. While it may be readily understood that increased weight places a greater burden on a person's bones and joints—back, knees, hips—obesity also is associated with higher rates of other types of pain, notably migraine (Peterlin et al., 2009).

Third, progress in saving the lives of people with catastrophic injuries related to work, sports, vehicle crashes, or military combat who in previous times would have died creates a group of relatively young people at high risk of lifelong chronic pain. Similarly, modern medicine can help many people with serious illnesses survive longer, but the cost of survival may be debilitating pain. As one example, cancer chemotherapy can cause neuropathic pain.

Fourth, all surgical patients are at risk of both acute and chronic pain as a result of their procedure. Today, about 60 percent of surgical procedures in U.S. community hospitals are performed on an outpatient basis, and persistent problems with adequate pain control after ambulatory surgery are well documented. People may be discharged before their level of pain can be adequately assessed, or they may be unable to implement the prescribed pain management strategy at home. The greatest risk is that undermanaged acute postsurgical pain may evolve into chronic pain (Rawal, 2007; Schug and Chong, 2009).

Fifth, greater public understanding of chronic pain syndromes and the development of new treatments may cause many people who have not sought help or who previously gave up on treatment to reenter the health care system. Likewise, those who gain health care coverage under the recent health care reform legislation may newly seek care. In the past, many of these people were invisible to the system, so while their emergence does not affect the true number of people with chronic pain, it increases the size of the population under management.

A study of chronic low back pain conducted in North Carolina found "an alarming increase in the prevalence of chronic [low back pain] from 1992 to 2006 . . . across all population subgroups." The prevalence for the total population studied more than doubled over the period, from about 4 to more than 10 percent, and for women (all ages) and men aged 45-54, prevalence nearly tripled (Freburger et al., 2009). Although these data are from a single state, a similar growth pattern has been seen in national data for users of the Department of Veterans Affairs health system, which show an annualized increase in prevalence of low back pain of about 5 percent per year, larger than increases in three other conditions studied (depression, diabetes, and hypertension) (Sinnott and Wagner, 2009). Further evidence of rising pain prevalence in the United States, based on NHANES data, is shown in Table 2-2. (The NHANES collected these data only through 2004.)

TABLE 2-2 Trends in Pain Prevalence, United States, 1999-2004

People Who Reported Pain in Previous Month	NHANES 1999-2000 (%)	NHANES 2001-2002 (%)	NHANES 2003-2004 (%)
Age 20 and over	22.2	25.7	27.7
Ages 20 to 44	15.7	19.5	19.6
Ages 45 to 64	28.5	31.7	35.6
Age 65 and over	33.1	34.2	36.3
Men	19.4	23.8	24.8
Women	24.8	27.4	30.4
White (not Hispanic)	24.4	28.6	30.6
Black (not Hispanic)	17.5	21.5	19.1
Mexican American	16.3	13.3	19.6
Below 100% of poverty level	26.3	28.6	29.0
100% to <200% of poverty level	25.4	30.7	29.0
≥200% of poverty level	20.0	23.6	27.9

SOURCE: Unpublished data from the National Health and Nutrition Examination Survey, 1999-2004.

In nearly every demographic group, there has been a steady increase in reporting of pain prevalence across these surveys.

The potential impact of the growing prevalence of pain on the health care system is substantial. Although not all people with chronic low back pain are treated within the health care system, many are, and "back problems" are one of the nation's 15 most expensive medical conditions. In 1987, some 3,400 Americans with back problems were treated for every 100,000 people; by 2000, that number had grown to 5,092 per 100,000. At the same time, health care spending for these treatments had grown from $7.9 billion to $17.5 billion. Thorpe and colleagues (2004) estimate that low back pain alone contributed almost 3 percent to the total national increase in health care spending from 1987 to 2000. While about a quarter of the $9.5 billion increase could be attributable to increased population size, and close to a quarter was attributable to increased costs of treatment, more than half of the total (53 percent) was attributable to a rise in the prevalence of back problems.

DISPARITIES IN PREVALENCE AND CARE IN SELECTED POPULATIONS

An important message from epidemiologic studies cited by Blyth and colleagues (2010) is "the universal presence across populations of characteristic subgroups of people with an underlying propensity or increased risk for chronic pain, in the context of a wide range of different precipitating or underlying diseases and injuries" (p. 282). These vulnerable subgroups are most often those of concern to public health.[5] Increased vulnerability to pain is associated with the following:

- having English as a second language,
- race and ethnicity,
- income and education,
- sex and gender,
- age group,
- geographic location,
- military veterans,
- cognitive impairments,
- surgical patients,
- cancer patients, and
- the end of life.

Many of these same groups also are at risk of inadequate treatment. Unfortunately, there have been no systematic national studies of rates of undertreatment among population groups, and the picture of undertreatment must be assembled from disparate pieces and small-scale studies. These assemblages do not provide a comprehensive view, but are consistent across population groups and settings. In fact, "most studies that have evaluated the potential for disparities in pain treatment on the basis of racial or ethnic differences have found them" (Portenoy et al., 2004, p. 326). Clearly, however, there is a need for more assessment of individual and group-related factors involved in seeking treatment for pain. Factors that discourage people from seeking treatment might include not only the typical and well-documented access barriers, such as lack of a usual source of care, but also "low levels of trust in clinicians, poorer expectations of treatment outcomes, language barriers and communication difficulties" (Dobscha et al., 2009, p. 1078). Under health care reform, increased access to health insurance may reduce rates of undertreatment, but the number of clinical, provider, and patient factors involved complicates the situation.

English as a Second Language

Census 2000 indicated that nearly three-quarters of Asian Americans spoke a language other than English at home, and almost 4 million Asian Americans were "low-English proficient" (Ro et al., 2009). Language problems are faced by many other groups as well. The largest group with such problems is the Hispanic population, with 28.1 million who speak Spanish at home and 13.8 million who speak English "less than very well" (Shin and Bruno, 2003). Non-English

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[5] The nomenclature used for different national, ethnic, and racial groups in this section of the report is that of the original sources.

speakers confront significant problems, especially relatively recent immigrants who are isolated by both language and culture when they encounter the complex U.S. health care system. They often are expected to follow complex home care and medication instructions, but the reasoning behind these directives may be both unclear and unfamiliar to them (Fadiman, 1997). Even for people whose first language is English, rates of health literacy are low (see Box 2-3).

Race and Ethnicity

Data weaknesses previously discussed are particularly important when one is examining racial and ethnic disparities, and only limited data are available on the prevalence of pain in certain population subgroups. Nonetheless, research

BOX 2-3
Health Literacy

Beyond shortcomings in conventional literacy and English-language ability is the problem of limited health literacy, which is widespread and not confined to any one group or level of educational attainment, but compounded for individuals who have difficulties with English. At an Institute of Medicine workshop on medication use and health literacy, a participant underscored the problem of limited English proficiency in the populations served by many safety net providers (IOM, 2010).

To be "health literate" means that people can understand instructions on prescription drug bottles, health education brochures, and doctors' directions and that they can negotiate complex health care systems. "Health literacy is not simply the ability to read. It requires a complex group of reading, listening, analytical, and decision-making skills, and the ability to apply these skills to health situations" (National Network of Libraries of Medicine, http://nnlm.gov/outreach/consumer/hlthlit.html). A person's health literacy level is "the product of a complex set of skills and interactions on the part of the individual, the health-care system, the education system, and the cultural and societal context" (IOM, 2004, p. 59).

Problems with understanding medication instructions contribute to the estimated 1.5 million preventable adverse drug events that occur each year. Improved information about drugs merits special attention according to the National Action Plan to Improve Health Literacy, released in 2010. "Individuals with limited health literacy skills are at particular risk for misunderstanding medical information" on product labels and package inserts (HHS and ODPHP, 2010. p. 19). Drugs for pain management are not exempt from these difficulties.

Specific to pain, a recent systematic review of evidence on health literacy interventions reported a study showing that people "with inadequate health literacy had higher probabilities of having activity limitations . . . and greater pain related to physical health than those with adequate health literacy" (HHS and AHRQ, 2011a, p. 38).

suggests that cultural perspectives strongly influence reports of pain in general (Morris, 2003), as well as within specific racial/ethnic groups. Data also are needed with which to examine the quality of pain care provided to vulnerable subgroups, particularly longitudinal data that might document the rate of transition from acute to chronic pain. Still, the available data substantiate undertreatment of pain among racial and ethnic minorities for a wide range of settings and types of illness or injury (Anderson et al., 2009), although a few studies suggest that disparities in pain care may be decreasing (Quazi et al., 2008). These disparities also are seen for women versus men (as discussed in the section on sex and gender).

African Americans

A robust finding across studies is that African Americans report greater pain than whites after surgery and in association with a variety of conditions, including AIDS, angina pectoris, arthritis, and headache, as well as some musculoskeletal conditions (Edwards et al., 2001). In the NHANES, blacks reported rates equal to those of whites for face/teeth pain and 1.5 times the rate of whites for abdominal pain; they were less likely than whites to report chronic pain in the back, legs/feet, arms/hands, and chest (Hardt et al., 2008). Some researchers believe the clinical differences found in many studies are attributable at least in part to greater pain sensitivity and lower pain tolerance among African Americans. However, differences in definitions of pain, disease severity, assessment, population characteristics (e.g., age), and physician management may confound these findings, inasmuch as pain response is influenced by complex interactions of numerous factors—biological, emotional, and cultural.

In general, the pain literature has not explored the experiences of diverse populations, much less subpopulations of racial and ethnic groups, with respect to acute, chronic, or cancer pain. Relatively few experimental studies have been conducted to test possible racial and ethnic differences in pain sensitivity under controlled conditions, or to enable valid conclusions about the relevance of pain experiences under experimental conditions and the pain experiences of patients treated in pain centers (under relatively controlled circumstance) or in everyday clinical practice. Pain may be experienced very differently when associated with illness or disability than under time-limited laboratory conditions.

One experimental study in 337 subjects did find that African Americans reported higher levels of clinical pain and less pain tolerance than white subjects (Edwards et al., 2001). In that study, the differences found could not be attributed to such other factors as demographic profile; the duration, location, or number of sites of pain; previous surgeries; medication use; or psychological factors, such as depression, anxiety, or overall affective states. Prior studies had ruled out other possible explanations, including "personality, anxiety, education, family history of pain, attentional variables and peripheral mechanisms of nociception" (Edwards et al., 2001, p. 320). Although underlying differences in pain response between blacks and whites were not explained by this study, the researchers hypothesized that they might be attributable to such factors as coping strategies, which vary among different cultures; social learning; attitudes; and a long-standing pattern of lower trust in medical research based on a grim history of exploitative research (Washington, 2006). In addition, minorities (as well as women) are at risk for poor physician–patient communication.

As more is learned about the role of various physiological factors in the body's reaction to pain, including comorbidities and the genetic factors described in Chapter 1, these factors also may be found to affect differences between blacks and whites in pain perception and tolerance. However, too few genetic studies, like experimental pain studies generally, involve sufficient numbers of minority subjects, much less subgroups, to generate conclusions that might enable better targeted treatments.

Affecting the prevalence of pain in a population is the extent to which it is assessed and treated. Lower rates of clinician assessment of pain and higher rates of undertreatment have been found for African Americans in all settings and across all types of pain (Green et al., 2003a).

Undertreatment of pain among African Americans has been well documented. For example, children with sickle-cell anemia (a painful disease that occurs most often among African Americans) who presented to hospital emergency departments (EDs) with pain were far less likely to have their pain assessed than were children with long-bone fractures (Zempsky et al., 2011).

In general, moreover, a number of studies have shown that physicians tend to prescribe less analgesic medication for African Americans than for whites (Bernabei et al., 1998; Edwards et al., 2001; Green and Hart-Johnson, 2010). A study that used a pain management index to evaluate pain control found that blacks were less likely than whites to obtain prescriptions for adequate pain relief, based on reported pain severity and the strength of analgesics provided. Because such an index is a way to quantify a person's response to pain medication alone, it is likely that people in this study did not receive other types of treatment for pain either.

Surgery is a frequent treatment for chronic joint pain. Data from the Health and Retirement Study were used to assess the need for joint replacement surgery (hip or knee) in almost 15,000 adults aged 60 and older; 2 years later, the same individuals were reassessed to determine whether the surgery was actually performed. African Americans who needed the surgery during the first assessment were less than half as likely to have undergone it than were whites; those without a college education were about two-thirds as likely to have received it. Such differences in surgery rates, which were not explained by differences in access to medical care or the amount of disability, perpetuate disproportionately high pain levels and disability among vulnerable groups (Steel et al., 2008).

Similarly, African Americans (and people of lower socioeconomic status) were found to be less likely to receive treatment or compensation in a St. Louisarea study of outcomes of 1,475 workers' compensation claims for low back injuries. Less treatment and compensation were associated with lower satisfaction with the workers' compensation process, and lower satisfaction led to increased postsettlement disability among these workers. "Given that the function of Workers' Compensation is to reduce disability from work-related injuries, the current results suggest that the system produces inequitable outcomes for these groups," the authors conclude (Chibnall and Tate, 2005, p. 39).

A number of striking examples of African Americans' lower likelihood of pain assessment and management were collected for the Institute of Medicine's (2003) report *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. These examples illustrate the pervasiveness of undertreatment of African Americans across settings, even in circumstances that appear "counterintuitive" (Barr, 2008).

One such study of patients with long-bone fractures in an urban Atlanta, Georgia, ED found that blacks were 1.7 times more likely than whites to receive no pain medication (Todd et al., 2000). Some years earlier, the same investigators had performed a comparison of ED treatment of long-bone fractures in whites and Hispanics in Los Angeles and found that Hispanics (discussed in the next section) were twice as likely as whites (non-Hispanics) to receive no ED pain medication (Todd et al., 1993). In the Atlanta study, medical records revealed that blacks and whites expressed their painful symptoms at similar rates (54 percent and 59 percent, respectively), which showed that the lower rate of receiving medication was not due to group differences in revealing pain or desire for relief, but "because the doctor didn't order the medication" (Barr, 2008, p. 188). Such reports of ED undertreatment of blacks persist (Minick et al., in press).

Another counterintuitive example, in a different setting—nursing homes—found that among residents with cancer who were in daily pain, African Americans had a 63 percent greater likelihood of receiving no pain medication than whites (non-Hispanic) (Bernabei et al., 1998).

Racial and ethnic stereotyping by clinicians has been shown to affect prescribing patterns (Burgess et al., 2006). In one study, physicians presented with clinical vignettes of patients that differed by race (black or white), verbal behavior ("challenging" or "nonchallenging"), and nonverbal behavior (confident versus dejected versus angry) indicated they would be significantly more likely to increase the strength of opioid prescriptions for black patients exhibiting "challenging" verbal behavior (for example, asking for a medication by name, exhibiting anger); by contrast, they would be somewhat more likely to increase dosages for white patients exhibiting "nonchallenging" behavior (Burgess et al., 2008). These results indicate the complexity of the relationship among patient race and behavior and physicians' decisions about treatments.

Unequal Treatment cites three types of provider factors that might help account for such disparities in care: "bias (or prejudice) against minorities; greater clinical uncertainty when interacting with racial and ethnic minority patients;

and beliefs (or stereotypes) held by the provider about the behavior or health of minorities" (IOM, 2003, p. 9). (It should be noted that a number of the patterns of undertreatment cited above also occur among women and the elderly, both discussed below.) When people perceive discrimination in their lives, that perception in and of itself is associated with greater pain according to a survey of older African American men (Burgess et al., 2009).

Hispanics

Hispanics are at high risk for pain and pain undertreatment, given their lower education and income levels and higher rates of overweight, lack of health insurance, lack of a usual source of care, limited English proficiency, and poor communication with health care providers.

Similar to differences within the Asian American population discussed below, there are important variations in rates of pain-related conditions among Hispanic subgroups. A secondary analysis of pain prevalence using age-adjusted NHANES data to estimate the prevalence of current, nonminor pain showed that Mexican Americans, who constitute the largest Hispanic group in the United States, are less likely to report chronic limb pain, back pain, or face/teeth pain than either blacks (non-Hispanic) or whites (non-Hispanic) (Hardt et al., 2008). The only category of chronic pain that Mexican Americans reported at a rate equal to that of whites was abdominal pain. Puerto Ricans and those born in the United States and having higher degrees of acculturation, including greater English proficiency, have the highest rates of chronic back and neck problems (Bui et al., 2011).

The secondary analysis of NHANES data cited above also found that Mexican Americans reported *widespread pain* only about half as often as blacks (non-Hispanic) or whites. The confidence intervals around the prevalence estimates for the three population groups are fairly wide, but based just on the percentages, the data suggest that only about 2 percent of Mexican Americans (men and women) report widespread pain, compared with black men (more than 3 percent), black women (4 percent), white men (just under 3 percent), and white women (5 percent).

Some comparisons of Hispanics and whites with comparable serious health problems have found that Hispanics report more pain. Depression is associated with more pain reports in both groups, although it does not erase the differences in pain reports for Hispanics. These differences have been attributed to "cultural differences in the acceptability and the expression of distress" (Hernandez and Sachs-Ericsson, 2006). Findings such as these, as well as the association between acculturation and back and neck pain noted above, underscore the importance of the comprehensive approach to assessing pain explored in Chapter 1. Such an approach emphasizes not only understanding biological conditions that give rise to pain (e.g., injury, disease), but also psychological factors (e.g., coping strategies, beliefs) and social factors (e.g., cultural norms) that may shape the way pain is experienced and expressed to others.

Finally, Hispanics, like African Americans, experience disparities in pain care. A study focusing on differences in emergency care for Hispanics, for example, found that for all injuries combined (long-bone, back, migraine), Hispanics (as well as blacks) were significantly less likely to be provided with an opioid drug (Tamayo-Sarver et al., 2003). The authors of this study hypothesize that "differences in patient assertiveness, physician perception of the patient, and social distance may contribute to differences in physician-patient communication and trust that are responsible in part for the racial/ethnic disparities in analgesic prescription" (p. 2071). Likewise, Bernabei and colleagues (1998) found that Hispanic cancer patients, like African Americans and Asians (see below), experienced an excess risk (relative to whites) of receiving no analgesia.

Asian Americans

NHIS data suggest that Asian Americans overall have lower self-reported pain prevalence than non-Hispanic whites (CDC and NCHS, 2010). However, Asian American communities in the United States represent many different national origins, cultures, languages, traditions, and ethnicities. Important variations exist among these subgroups. The few available data for Native Hawaiians and Pacific Islanders, for example, suggest high rates of low back pain. Likewise, data from the 2006 NHIS revealed that migraines and severe headaches were more likely to be reported by adults who were Vietnamese (13 percent) or Filipino (11 percent) than by those who were Chinese (7 percent) (Barnes et al., 2008). Moreover, there are more differences within than among these population groups.

In general, the differential in self-reported pain prevalence for Asian Americans is attributable to cultural factors such as stoicism and reluctance to report pain (a sign of weakness) or accuse health professionals of inadequate care (respect). Also, Asian Americans may request less pain medication or stop using it because of fears of side effects. Analyses of Chinese patients (the largest Asian subgroup in the United States), for example, suggest that barriers to cancer pain care may include low English proficiency, the belief that pain will be a burden to family members, and "deeply-rooted values and beliefs of stoicism and fatalism which inhibit pain expression" (Dhingra, 2008, p. 29).

At the same time, survey data from 2001 indicate that a lack of good doctor–patient communication may be part of the problem. Compared with whites, Asian Americans were less likely to believe their doctor understood their background and values (62 percent for whites versus 50 percent for Asian Americans), listened to everything they had to say (69 percent versus 47 percent), or involved them in decisions about their care as much as they wanted (80 percent versus 60 percent) (Ngo-Metzger et al., 2004). More recent data suggest that such poor communication persists. Even among those who have had at least some college education, Asians are more likely than blacks or whites to have had poor communication with health professionals (AHRQ, 2011). The difficulties associated with having English as a second language discussed above are a factor in this problem.

American Indians and Alaska Natives

American Indians and Alaska Natives have repeatedly been found to have markedly higher rates of reported pain overall and for specific sites (e.g., severe headache or migraine, low back pain, neck pain, joint pain) (CDC and NCHS, 2010; Jimenez et al., 2011). They also have high rates of diseases and health conditions, such as diabetes, arthritis, and obesity, that often produce significant pain (Moulton et al., 2005). For example, the 2007 age-adjusted death rate for diabetes mellitus among American Indians and Alaska Natives was 37.2 per 100,000, compared with 22.5 for the population as a whole (CDC and NCHS, 2010). Some evidence that certain autoimmune rheumatic diseases are more prevalent in American Indians than in Alaska Natives or the non-Indian population suggests that at least some of the difference in prevalence rates may be genetic (Kramer et al., 2002).

In the Health and Retirement Study,[6] which interviewed people aged 51-61, more than 15 percent reported that "pain made it difficult to do normal work." American Indians reported the highest rates of difficulty (25 percent), although they were less likely than other groups to report their pain as severe (Kramer et al., 2002).

The Indian Health Service (IHS) serves the nation's American Indian and Alaska Native population of 2.9 million spread across the continent in tribal and nontribal, urban and rural areas but has only one pain clinic, according to the Health Policy Research Director of the InterTribal Council of Arizona, Inc. (Wilner, 2008). Some 58 percent of American Indians and Alaska Natives live in urban areas, not on reservations, and may have less access to IHS programs, where they would be more likely to find culturally competent care. IHS's Urban Indian Health Program (UIHP) comprises 34 nonprofit programs nationwide, with an additional 18 cities having American Indian populations large enough to support a UIHP.[7]

In traditional American Indian culture, healing involved the whole community, but modern medicine is more likely to involve a patient–clinician or, at best,

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[6] The University of Michigan's Health and Retirement Study is a longitudinal study that surveys more than 22,000 Americans aged 50 and older every 2 years. Supported by the National Institute on Aging and the Social Security Administration, it studies labor force participation and health transitions near the end of people's working lives and into retirement.

[7] IHS programs are chronically underfunded—the agency estimates that its funding is only 22 percent of what is needed for primary care services (HHS and IHS, 2011).

a family–clinician relationship. Various cultural attributes may lead to underreporting of pain in particular tribes or groups, hindering clinicians in adequately assessing the severity of reported pain.

In-depth interviews with a small group (45) of urban American Indians with joint or musculoskeletal pain revealed that, although 70 percent had discussed their pain symptoms with a doctor, they often did not describe their level of pain or dysfunction directly but "in a subtle, guarded manner" (Kramer et al., 2002, p. 592). When asked what they would most like doctors to know about treating American Indians, the interviewees, who represented some 30 tribal affiliations, spoke openly about their cultural practice of minimizing pain complaints and noted that they generally "do not readily ask for help, discuss pain, or disclose the intensity of a painful episode." This finding suggests a strong likelihood of underdiagnosis and undertreatment of pain in this population.

Income and Education

Higher pain rates among U.S. racial and ethnic minority groups can be traced in part to strong income and educational gradients in pain prevalence, with less pain being reported as a person's educational and income levels rise. The far right columns in Tables 2-3 and 2-4 show the ratio between the lowest and highest prevalence for each pain condition. For example, a person with no high school diploma or general equivalency degree (GED) is 1.33 times more likely to suffer from severe headache or migraine than a person with some college or more. Again, low back pain is the most common condition reported, regardless of education.

TABLE 2-3 Age-Adjusted Rates of U.S. Adults* Reporting Pain in the Last 3 Months, Selected Causes, by Education, 2009

Cause of Pain	No High School Diploma or GED (%)	High School Diploma (%)	Some College or More (%)	Ratio between Highest and Lowest Education Groups
Severe headache or migraine	19.9	16.2	14.9	1.33
Low back pain	35.0	32.2	27.4	1.28
Neck pain	18.4	16.9	15.3	1.20
Knee pain	23.4	21.7	20.3	1.15
Shoulder pain	11.4	10.6	9.2	1.24
Finger pain	10.2	9.2	7.7	1.32
Hip pain	9.0	8.6	7.3	1.23

*Those aged 25 and older.

SOURCE: CDC and NCHS, 2010.

TABLE 2-4 Age-Adjusted Rates of U.S. Adults Reporting Pain in the Last 3 Months, Selected Causes, by Poverty Level, 2009

Cause of Pain	Below 100% of Poverty Level (%)	100-199% of Poverty Level (%)	200-399% of Poverty Level (%)	400% or More of Poverty Level (%)	Ratio between Highest and Lowest Income Groups
Severe headache or migraine	22.0	19.5	16.3	12.5	1.76
Low back pain	35.4	32.7	28.4	23.9	1.48
Neck pain	20.8	17.0	14.7	13.1	1.59
Knee pain	23.2	22.0	20.4	16.8	1.38
Shoulder pain	12.3	10.2	9.2	7.5	1.64
Finger pain	9.5	9.4	7.9	6.4	1.48
Hip pain	9.5	7.8	7.2	5.9	1.61

SOURCE: CDC and NCHS, 2010.

A similar pattern holds for income levels. The greatest discrepancy between low- and high-income Americans for the eight types of pain listed in Tables 2-3 and 2-4 is for migraine.

To the extent that pain interferes with completion of education or full employment, it may contribute to lower educational and income status. Or, referring back to the discussion of allostatic load in Chapter 1, the cumulative burdens of high-stress environments in childhood may contribute to both a higher likelihood of pain and lower achievement levels. A well-documented set of U.K. studies of the influence of occupational rank on health found that people in the lowest-ranking jobs (clerical and manual labor) had a death rate 3.5 times that of those in the administrative ranks, as well as similarly higher rates of serious diseases—heart disease, stroke, lung cancer, injuries, and suicide (Russo, 2011). The influence of social class held even when data were controlled for various risk factors, such as smoking. These results provide further evidence of the impact of allostatic load on health.

Education, employment, and poverty are commonly used measures of socioeconomic status and the broader construct of "social class." These three factors work together to help explain health disparities by race and ethnicity. Socioeconomic status can be measured at the individual, family/household, and neighborhood levels. It influences a person's health status in many ways, including the likelihood of having chronic pain, and "increasing neighborhood [socioeconomic status] improves the chronic pain experience for both blacks and whites" (Fuentes et al., 2007, p. 1160). Indeed, "population-based studies have consistently shown that chronic pain occurrence is inversely related to socioeconomic status" (Blyth, 2010, p. 22).

The associations among race, neighborhood socioeconomic status, medical care, and chronic pain are "important factors in initiating and maintaining racial disparities in health" (Williams and Jackson, 2005, p. 325). Accounting for both social class (education, employment, and poverty) and race may produce the most accurate perspective on health disparities (Kawachi et al., 2005). According to Kawachi and colleagues, "Even if racial disparities in health outcomes could be eliminated, most blacks [and some other minority groups] would still have worse health than the U.S. average because of their class position" (p. 346), which suggests that efforts to eliminate health disparities should not concentrate on racial and ethnic inequalities alone.

With regard to the income and education components of social class, a survey by Portenoy and colleagues (2004) found a higher prevalence of disabling pain among people with incomes of $25,000 or less (odds ratio 1.71 [p = .001]) and less than a high school education (odds ratio 1.72 [p = .001]) than among respondents with higher income and education levels. These disadvantages (along with being unemployed) remained significant even after controlling for other demographic factors. In this study, neither African American race nor Hispanic ethnicity predicted the likelihood of having disabling pain, although individuals from those groups were more likely to have the socioeconomic disadvantages that predicted pain.

Sex and Gender

Across nations, women consistently report a higher prevalence of chronic pain than men (Croft et al., 2010) and are at greater risk for many pain conditions (Fillingim et al., 2009). In the NHANES, in every ethnic/racial category, women reported widespread pain more often than men (Hardt et al., 2008).

Sex and gender differences in pain and pain perception are associated with numerous conditions. Women are likely to have more pain from certain diseases; for example, women with cancer report greater pain severity than men, as well as higher rates of depression. Both of these differences are statistically significant (Green et al., 2011). A number of chronic pain syndromes occur only in women, and others occur predominantly (80 to 90 percent) in women. These conditions include chronic fatigue syndrome (estimated at 1-4 million people affected nationally), endometriosis (6.3 million), fibromyalgia (6 million), interstitial cystitis (1 million), vulvodynia (6 million), and temporomandibular disorders. In total, perhaps 50 million women have one or more of these conditions, which frequently co-occur (Campaign to End Chronic Pain in Women, 2010; TMJA, 2010).

Common types of pain that affect both men and women vary markedly in prevalence by sex (Table 2-5). U.S. women's rates of headache and some categories of joint pain are considerably higher than men's.

These differences have been found in both clinical and experimental settings (Fillingim et al., 2009). In experimental studies, women have shown both lower

TABLE 2-5 Age-Adjusted Rates of U.S. Adults Reporting Pain in the Last 3 Months, Selected Causes, by Sex, 2009

Cause of Pain	Males (%)	Females (%)	Ratio
Severe headache or migraine	10.1	21.9	2.17
Low back pain	26.0	30.1	1.16
Neck pain	12.6	17.5	1.39
Knee pain	18.3	20.5	1.12
Shoulder pain	9.2	8.7	0.95
Finger pain	5.9	9.2	1.56
Hip pain	5.3	8.7	1.64

SOURCE: CDC and NCHS, 2010.

thresholds and less tolerance for pain, linked in part to hormone levels (Fillingim et al., 2009; IOM, 2011). Differences in chronic pain rates may occur because of "hormonal fluctuation, criterion effects, differences in body size, skin thickness, blood pressure, social expectations, cognitive variation, method of stimulation, and differences in psychological traits such as anxiety and depression" (Derbyshire, 2008, p. 1).

At least three theories have been proposed to explain the marked differences in pain experience by sex and gender:

- a gender-role theory that assumes it is socially more acceptable for women to report pain,
- an exposure theory that suggests women are exposed to more pain risk factors, and
- a vulnerability theory proposing that women are more vulnerable to developing musculoskeletal pain (Picavet, 2010).

Of these, the vulnerability theory is best supported by scientific evidence, including the potential role of sex hormones in nociception, as well as differences in psychological reactions and coping strategies.

Adverse drug effects and complications also are more common in women than men (Snidvongs and Holdcroft, 2008). Responses to analgesia may vary for many potential reasons: hormonal factors, physiology, psychological and sociocultural factors, and possibly genetic factors related to metabolism of therapeutic medications. Thus, "the possibility of sex and gender differences in the context of pain treatment—especially when analgesics are prescribed—cannot be dismissed" (Fillingim et al., 2009, p. 462). Greater understanding of the causes of the sex and gender differences in analgesia responses may reveal promising targets for improvements in therapeutic interventions (Paller et al., 2009).

Like the racial/ethnic groups discussed above, women experience disparities in pain care. In addition, some of the sex-linked conditions cited earlier are not well understood, and women with these conditions have faced not only severe pain, but also misdiagnoses, delays in correct diagnosis, improper and unproven treatments, gender bias, stigma, and "neglect, dismissal and discrimination" from the health care system (Campaign to End Chronic Pain in Women, 2010, p. 4).

Age Group

Disparities in pain prevalence and care have been documented for both children and the elderly.

Children

Children experience acute and chronic pain associated with routine childhood illnesses (ear infections, for example) and injuries (musculoskeletal injuries, abuse, burns), as well as with chronic diseases that emerge in childhood (sickle-cell anemia, cystic fibrosis) or usually are associated with older populations (cancer, HIV infection). Some diseases (diabetes, fibromyalgia) have "juvenile" forms. Neuropathic pain in children is increasingly recognized but still relatively rare (Walco et al., 2010). Most data on the prevalence of pain in pediatric populations focus on just one or two disease subpopulations, limiting information on pain prevalence among children in general (Goldstein and Sakae, 2010). As children move through adolescence, however, the prevalence of many types of pain approaches adult rates.

Children suffer from many of the common types of pain, such as headaches, that adults experience. NHANES data indicate that 17 percent of U.S. children aged 4-18 experience frequent or severe headaches, including migraine, over the course of a year. Before puberty, boys and girls have headaches at approximately the same rate, but after age 12, the rate of recurrent and severe headaches rises among girls. As in adults, other physical conditions—in this case, asthma, hay fever, and ear infections—occur more frequently in children and teens with recurrent headaches (42 percent) than in those without (25 percent) (Lateef et al., 2009).

Good pain management in children often is not achieved. The path to identifying an effective treatment begins with recognition of the problem—the diagnosis. However, researchers involved in most studies of headache in children, for example, comment on both the underdiagnosis of the condition, even when it is serious, and the significant impact headaches have on children's lives (Lopez and Rothrock, 2010; Winner, 2004).

Once children's pain is recognized, moreover, it often is undertreated for various reasons, and the consequences may include behavioral changes and adverse effects on child development (Howard, 2003). One factor contributing to undertreatment is that prescribing pain medications for children requires "creativity and adaptability" (Gregoire and Finley, 2007, p. 95) given the lack of evidence-based recommendations for children and adolescents for many pain medications. Clinicians may be unsure how to convert adult doses to child doses that will be both safe and efficacious,[8] and in line with the recognition that "children are not just small adults," they may hesitate to prescribe certain psychoactive medications for children, whose bodies and brains are still developing. Well-publicized instances of antidepressants and other medications being linked to teen suicide have led to further caution.

Research has documented numerous examples of situations in which children may not receive appropriate pain care:

- *In the regular ED*—In one academic medical center studied, very few children undergoing a laceration repair received antianxiety medication or procedural sedation, which often are indicated (Brodzinski et al., 2010).
- *In the pediatric ED*—A study of pediatric ED care provided to 180 children with long-bone fractures or second- or third-degree burns found that almost two-thirds (65 percent) of those under 2 years of age and almost half (48 percent) of those aged 6-10 received no analgesia (Alexander and Manno, 2003).
- *When the condition is unexpected*—Girls with endometriosis, a condition that is usually diagnosed in women aged 25-30, often are undiagnosed and undertreated.

Moreover, the same disparities in care experienced by adults also may affect racial and ethnic minority children with pain (Linton and Feudtner, 2008). For example, one study found that Latino children undergoing an adenoidectomy or tonsillectomy received less opioid medication than their white, non-Hispanic counterparts (Jimenez et al., 2010). If a child is part of a discernible ethnic, religious, or racial group, the clinician may either stereotype the group's attitude toward pain or encounter cultural aspects of pain, such as stoicism; either way, the clinician may fail to focus on the individual child's needs (Finley et al., 2009).

The Elderly

Data on the prevalence of chronic pain among older adults living outside institutions range from 18 to 57 percent. Much of the variation derives from

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[8] The Best Pharmaceuticals for Children Act of 2007 extends patent protection for pediatric medications as an incentive for the pharmaceutical industry to research and manufacture drugs for children, and expands National Institutes of Health research on children (Politis, 2005; *Best Pharmaceuticals for Children Act Reauthorization of 2007,* Public Law 110-85, Title V, part of the Food and Drug Administration Amendments Act [September 27]).

different definitions of chronic pain. Most researchers who use a definition of chronic pain similar to "persistent or recurrent pain for at least 3-6 months" have found chronic pain in about half of individuals surveyed (Thomas, 2010, p. 186). Across studies, the association of pain with age is not uniform; some studies do not find an association, and some attribute it to greater reporting of symptoms. However, more severe pain and pain that interferes with activities do appear to increase in frequency with age.

Experimental studies show that older populations have "a modest and somewhat inconsistent age-related decline in pain sensitivity to mild noxious stimuli," which might lead to underreporting of milder pain symptoms (Gibson, 2006, p. 2). However, both experimental and clinical studies have shown that elderly people are more vulnerable to severe or persistent pain and that the inability to tolerate severe pain increases with age.

Some of the specific causes of pain in older people include

- *joint pain* (mostly osteoarthritis), which has a significant negative impact on health-related quality of life;
- *postsurgical pain,* with people aged 65 and older being 2.6 times more likely to have surgery than those aged 45-64 (Hall et al., 2010);
- *chronic disease,* as the prevalence of chronic diseases that can cause pain rises with age; and
- *conditions associated with aging*, such as shingles (which about one of three U.S. residents will acquire at some point in life), about half of which occur among people 60 and older (CDC, 2011).

Also at risk of severe pain are elderly people with musculoskeletal disorders, such as degenerative spine conditions and arthritis, or with nighttime leg pain, pain from claudication (leg weakness), or cancer.

Factors affecting the severity of pain in the elderly include

- complex manifestations of pain;
- underreporting of pain;
- concurrent problems and multiple diseases (comorbidities), which complicate diagnosis and treatment;
- higher rates of medication side effects; and
- higher rates of treatment complications (American Geriatrics Society, 2009).

In general, these same factors also contribute to the documented undertreatment of pain in the elderly, along with the lack of an evidence base concerning the pharmacokinetic and pharmacodynamic changes that occur with aging (Barber and Gibson, 2009). Similar to the situation with children in the past, elderly people rarely are included in clinical trials of medications, so clinicians have inadequate information about appropriate dosages and potential interactions with medications being taken for other chronic diseases (Barber and Gibson, 2009).

A study of more than 13,000 people with cancer aged 65 and older discharged from the hospital to nursing homes found that, among the 4,000 who were in daily pain, those aged 85 and older were more than 1.5 times as likely to receive no analgesia than those aged 65-74; only 13 percent of those aged 85 and older received opioid medications, compared with 38 percent of those aged 65-74 (Bernabei et al., 1998). (A similar excess risk of receiving no analgesia was found among African Americans, Hispanics, and Asians compared with whites.)

Geographic Location

Comprehensive, academically based pain treatment centers are relatively few in the United States and, understandably, not available to most residents living outside major cities. At the same time, many aspects of rural life—especially farming and ranching—are hazardous (Table 2-6). The federal Bureau of Labor Statistics combines agriculture, forestry, fishing, and hunting in a single occupational category that has by far the highest rate of fatal occupational injuries of any other category—more than twice the rate of the mining and transportation industries, for example. This finding suggests a high rate of serious injuries as well, which carry the risk of concomitant pain (DOL and BLS, 2010).

Military Veterans

There are more than 23 million U.S. military veterans, about a quarter of whom receive health care services through the Department of Veterans Affairs.

TABLE 2-6 Age-Adjusted Rates of U.S. Adults Reporting Pain in the Last 3 Months, Selected Causes, by Place of Residence, 2009

Cause of Pain	Residence within Metropolitan Statistical Area (MSA) (%)	Residence outside MSA (%)	Ratio Non-MSA/MSA
Severe headache or migraine	15.5	19.3	1.25
Low back pain	27.1	33.3	1.23
Neck pain	14.6	17.7	1.21
Knee pain	18.8	23.0	1.22
Shoulder pain	8.6	10.7	1.24
Finger pain	7.4	8.9	1.20
Hip pain	6.6	9.1	1.38

SOURCE: CDC and NCHS, 2010.

The Iraq and Afghanistan conflicts have challenged the Department of Defense and the Department of Veterans Affairs with a large, new cohort of injured service members and veterans. "Painful musculoskeletal conditions are by far the most common diagnosed medical problems among these veterans, far surpassing the prevalence of other medical and mental health disorders" (Kerns and Dobscha, 2009, p. 1161).

Further, the prevalence of musculoskeletal pain has been found to increase each year following deployment, especially for women (Haskell et al., in press). Pain was assessed in a group of more than 91,000 veterans receiving care from the Department of Veterans Affairs who were discharged from the military between October 1, 2001, and November 30, 2007. Some 43 percent reported "any" pain, and among those reporting pain, 63 percent (more than 25,000 men and women) reported moderate to severe pain (Haskell et al., 2009).

Tremendous advances in military medicine have allowed large numbers of seriously injured service members to survive despite wounds that in past wars would have been fatal (President's Commission on Care for America's Returning Wounded Warriors, 2007). State-of-the-art burn care and postamputation care have saved lives and restored functioning for many catastrophically injured service members, as has improved care for traumatic brain injuries.

The urban character of the Iraq war, combined with long and multiple deployments, has exposed service members not just to more injuries but also to new and extraordinary stressors (Gironda et al., 2006). One result is unprecedented rates of posttraumatic stress disorder (PTSD).

Many wartime injuries are associated with severe pain. Burns are extremely painful, and the treatment for severe burns may take a decade of successive surgeries and rehabilitation; amputees may suffer from "phantom limb pain"; and PTSD, traumatic brain injury, and chronic pain co-occur, complicating treatment of all three conditions. In a study population recruited from a Department of Veterans Affairs' Polytrauma Network site, 42 percent of veterans had concurrent chronic pain, PTSD, and persistent postconcussive symptoms (Lew et al., 2009). In fact, the authors said, each of these conditions "rarely occurs by itself" (p. 701). The most common pain locations were the back (58 percent) and head (55 percent).

The demographics of deployed service members also have changed. The military services now include many more women, as well as Reserve and National Guard units that generally comprise older men (Gironda et al., 2006). As discussed earlier, increased age and female sex are both linked to higher pain rates in the population at large. In the first year after their last deployment, a comparison of male and female veterans found that the females were less likely to report pain, but those who did so were more likely to report moderate to severe pain and less likely to report persistent pain (Haskell et al., 2009). By 7 years after deployment, women were significantly more likely than men to report back, musculoskeletal, and joint problems (Haskell et al., in press).

The Department of Veterans Affairs also serves veterans of the Persian Gulf and Vietnam wars, many of whom are in their 60s and early 70s, as well as even older veterans from the Korean conflict and World War II. The latter groups are prey to all the pain-related problems of the elderly in addition to any lasting disabilities associated with their military service.

People with Cognitive Impairments

People with cognitive impairments, including dementia, may be unable to convey information to clinicians about their pain. The usual assessment of pain relies heavily on self-report—"the gold standard for measuring pain in research and clinical care"—and for the most severely affected, other means must be used to assess pain (Ersek et al., 2011). Reports from proxies (family members, friends, caregivers), health history (if known), and observation may have to substitute for first-person evidence

Nearly 1.5 million Americans live in the nation's nursing homes according to the 2004 National Nursing Home Survey (NNHS) (Jones et al., 2009). The most common primary diagnosis for these residents is diseases of the circulatory system (25 percent), followed by mental disorders (22 percent) and diseases of the nervous system (16 percent), which include Alzheimer's disease (11 percent). Combining the percentages for mental disorders and Alzheimer's disease suggests that a third of nursing home residents have a serious condition that might interfere with self-reports of pain. This is likely an underestimate inasmuch as some level of mental disorder might be found among residents with many other conditions considered "primary"—for example, the approximately 5 percent of those the survey identified as having acute but ill-defined cerebrovascular disease.

A frequently cited study of the prevalence of pain in nursing home residents found that, despite the prevalence of cognitive deficits, 62 percent had complaints of pain (primarily musculoskeletal), while 21 percent were "unable to make their needs known" (Ferrell et al., 1995). A trained study team nurse conducted all the resident interviews and attempted to determine pain status, taking care "to give subjects ample time to complete each task" (p. 594). The authors suggest that cognitive impairments are "a substantial barrier to pain assessment and management," (p. 591), but working with a variety of scales, assessment could be accomplished in residents with mild to moderate impairments.

Data from the NNHS suggest that about a quarter of nursing home residents report or show signs of pain (Sengupta et al., 2004). Some of the differences in recorded pain rates across studies are likely attributable to how the data were gathered. In contrast to the study by Ferrell and colleagues described above, the NNHS interviewers did not talk to patients directly, but interviewed designated staff reportedly familiar with the residents and their care.

How persistent (versus prevalent) is pain in nursing homes? A study of all 2.2 million residents of U.S. nursing homes in 1999 used the Centers for Medicare and Medicaid Services' (CMS) Minimum Data Set in an attempt to answer this question. Residents with "persistent pain" were defined as those who were in pain at an initial measurement point who were still having "daily moderate or excruciating pain" at a second assessment 60 to 180 days later (Teno et al., 2001). The results indicated that nationally, nearly 15 percent of residents still in a nursing home at the time of the second assessment were in persistent pain, and more than 41 percent of those who had been in pain at the first assessment were in severe pain 60 to 180 days later. In most states (41), 39-46 percent of nursing home residents were in persistent pain. This figure is substantially higher than the NNHS or CMS estimates. Even so, Teno and colleagues (2001) believe it is an underestimate because the data were reported by staff, not by residents themselves.

Three factors combine to make the adequate treatment of pain among the large proportion of nursing home residents with dementia and other cognitive deficits a significant concern. First are demographic shifts that are producing a growing number of elderly: in 2000, more than 12 percent of Americans were 65 and older, a rate expected to reach nearly 20 percent by 2030 (Chapman et al., 2006). The growth is especially important among the "oldest old," who are most responsible for the rising prevalence of dementia (Brookmeyer et al., 2011). Second is the increase in pain levels among the elderly from multiple causes, described above, which should affect people similarly regardless of whether they have dementia (Weiner et al., 1999); that is, there is no reason to think that people with dementia are exempt from these other sources of pain. And third is the finding from research showing the lower likelihood that people with cognitive impairments, especially dementia, will ask for and receive pain medication (Buffum et al., 2007).

Nursing home residents with versus those without dementia are less likely to report or show signs of pain (Sengupta et al., 2010), with rates of reported pain prevalence declining as the severity of cognitive impairment increases (Reynolds et al., 2008). Among residents at the most severe level, only 10 percent are reported to be "in pain." The Sengupta et al. and Reynolds et al. studies differ in their conclusions as to whether dementia affects treatment; however, undertreatment of pain in this population could lead to further health and mental health problems among residents, increased demands on facility staff and families, and higher costs of care. There is every reason to believe that pain in nursing home residents with dementia is a serious problem requiring attentive management.

Surgical Patients

Ironically, chronic pain often results from interactions with the health care system. Ten to 50 percent of people undergoing common surgical operations (groin hernia repair, breast and thoracic surgery, leg amputation, and coronary artery bypass surgery) develop persistent pain, and for 2-10 percent of them, the pain is severe (Kehlet et al., 2006). Inadequately treated pain after heart surgery, for example, inhibits healing and increases the risk of myocardial ischemia, stroke, and bleeding, among other complications, through such mechanisms as increased heart rate, systematic vascular resistance, and circulating stress-related hormones (catecholamines). Every effort should be made to avoid nerve damage in surgery, and actions to control pain after surgery should be initiated early, especially if pain is acute, because acute postsurgical pain increases the risk of developing a chronic pain syndrome (Kehlet et al., 2006).

Cancer Patients

Although the incidence of some common cancers has declined population-wide, longer survival times and the growing number of Americans who are elderly, in whom cancer incidence is highest, may overwhelm these recent declines. The prevalence of cancer in 2010 was estimated at 13.8 million Americans and projected to be 18 million in 2020, with the growth due primarily to the increased size of the over-65 population (Mariotto et al., 2011).

Most people with advanced cancer (60-85 percent) report pain (Green et al., 2011), with prevalence depending on the type of cancer and its stage. In a recent survey of people with cancer, 44 percent overall had experienced pain with the disease. This was the case for breast cancer (58 percent), colorectal cancer (41 percent), lung cancer (56 percent), multiple myeloma (100 percent), and prostate cancer (28 percent). Most of the people in this survey were cancer free or in remission; nevertheless, about one in five had current pain. In 44 percent of respondents, pain was “flares only,” meaning that they experienced sharp increases in pain over their usual background level, usually of short duration. Frequently, flares were associated with activity (42 percent).

A meta-analysis of 52 studies of pain among people with cancer likewise indicated the high prevalence of pain in this population. Some 64 percent of people with metastatic or advanced-stage disease had pain, as did 59 percent of those undergoing anticancer treatment and 33 percent who had completed curative treatment (van den Beuken-van Everdingen et al., 2007). Other studies have shown generally comparable results (Green et al., 2011). Because increasing numbers of people with cancer survive, the United States will have a significant and growing number of people with residual pain even after successful cancer treatment.

With respect to pain care, analysis of 26 international studies showed that across nations, nearly half of cancer patients’ pain was undertreated. Higher-income countries such as the United States performed better than other countries, a finding attributed to better clinician education, stronger pain treatment programs, and insurance coverage of medications. However, the eight U.S.-specific studies analyzed found a wide range of reported undertreatment, from 8 to 65 percent, with a weighted mean of 39 percent (Deandrea et al., 2008).

People at the End of Life

Preventing and relieving pain and other symptoms experienced when a person is approaching death is an essential obligation of health care professionals. Yet "too many dying people suffer from pain and other distress that clinicians could prevent or relieve with existing knowledge and therapies" (IOM, 1997, p. 2). Approximately two-thirds of people with advanced cancer experience pain, and almost three-quarters of those admitted to hospitals report pain at the time of admission. Studies of people in palliative care units reveal that "pain often is the dominant symptom" (Paice, 2010, p. 161).

Hospice and palliative care programs place great emphasis on pain management and achieve significantly improved patient outcomes (Higginson and Evans, 2010). Frequently they must rely on opiate medications at levels that would be inappropriate in other, nonterminal situations. Even in these settings, however, pain is still common. A third of people enrolled in hospice reported pain at the last hospice care visit before death (CDC and NCHS, 2010). Given the relatively short lengths of enrollment in hospice for many people, this statistic suggests that many people do not receive the full potential benefit of this service. One study of 106,500 hospice decedents found that, regardless of length of stay, a consistent 5-7 percent of patients wanted more help with pain management (Teno et al., 2007).

Teno and colleagues (2007) suggest that, rather than length of stay per se, it is "the perception of being referred 'too late'" (p. 123) that is associated with greater unmet needs, more family concerns, and lower satisfaction with care. About twice as many bereaved family members who believed the hospice enrollee had been referred "too late" reported that the decedent did not receive an appropriate amount of help with pain compared with those who thought referral came "at the right time" (10 percent versus 5 percent).

THE SERIOUSNESS OF PAIN

> *The pain level from this thing is in the 10 category, and I don't say 10 lightly. There is no way to function. It involves clawing at the air and screaming into a pillow for 24 hours at a crack. . . . Years and years.*
>
> —A person with chronic pain[9]

Understandably, pain prevalence estimates decrease as the severity of pain and its effects increases. Studies across countries suggest that approximately

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[9] Quotation from response to committee survey.

25 percent of people suffer moderate or severe pain. In the United States, about 10 percent have severe disabling chronic pain (Croft et al., 2010). No simple clinical test can assess a person's subjective experience of pain. Seriousness depends on self-report and to some extent can be inferred from pain's impact on a person's activities of daily living, ability to work, and quality of life. The seriousness of pain also is manifest in the observed link between chronic pain and the risk for suicide. This section reviews the evidence on these manifestations of the seriousness of pain, as well as differences by race/ethnicity and sex in the risk for disabling pain.

Effects on Activities of Daily Living

The NHIS asks Americans who have had pain in the last 3 months whether they had any difficulty with basic activities or experienced limitations in complex activities as a result of their pain (Table 2-7). The most common reported cause of disability was any type of joint pain, followed by low back pain. Disabling knee pain was reported by almost 40 percent, and headache and neck pain each reportedly caused disability in about a third of respondents.

Effects on Productivity

Pain has long been recognized as having a widespread adverse effect on America's workforce. More than half of 29,000 respondents to the American Productivity Audit telephone survey reported experiencing headache or musculoskeletal pain-related conditions during the previous 2 weeks (Stewart et al., 2003). One in 8 respondents said their pain caused a loss of productive time, and

TABLE 2-7 Extent of Pain-Related Disability among Adults with Pain in the Last 3 Months, United States, 2009

Type of Pain	Difficulty with Basic Actions[a] (%)	Complex Activity Limitation[b] (%)
Severe headache or migraine	31.0	33.5
Low back pain	51.6	55.0
Neck pain	30.2	34.4
Knee pain	37.3	38.6
Shoulder pain	17.7	21.4
Finger pain	14.3	16.3
Hip pain	15.0	18.4

[a] Defined as having difficulties in one or more of the following areas: movement, emotional, seeing, hearing, or cognition.
[b] Defined as having limitations in one or more of the following areas: self-care, social, or work.
SOURCE: CDC and NCHS, 2010.

1 in 14 said this lost work time exceeded 2 hours. On average, respondents reported that their reduced performance amounted to 3.6 hours per week (Stewart et al., 2003).

The economic analysis conducted for this study found that people with severe pain missed an average of 5.0-5.9 more days of work per year than people with no pain. The components of the cost of lost productivity included days of work missed ($11.6-12.7 billion), hours of work lost ($95.2-96.5 billion), and lost wages of ($190.6-226.3 billion). (The methodology used to develop these estimates is described in Appendix C.)

Effects on Quality of Life

Severe or migraine headaches have significant personal and societal impacts. Increasing evidence suggests that people with headaches have poor health-related quality of life; they also can experience serious functional impairments as a result of the headaches themselves and their unpredictable occurrence (Kalaydjian and Merikangas, 2008). These disruptions include impaired ability to work, go to school, participate in family life, and engage in leisure activities.

Migraine often occurs in conjunction with several other physical conditions, such as asthma, epilepsy, and chronic musculoskeletal pain, as well as with mood and anxiety disorders. Adults with severe headaches/migraine are significantly more likely than those without to suffer from comorbid conditions. In one study, for example, 85 percent of headache sufferers had at least one significant physical condition, compared with 69 percent of nonsufferers, and 15 percent of those with headaches reported major depression, compared with 5 percent of nonsufferers (Kalaydjian and Merikangas, 2008). Only 18 percent of those with severe headaches rated their general health as “excellent,” compared with 27 percent of those without headaches. Research has consistently documented the relationship between migraine and poorer health-related quality of life and shown quality of life to be inversely proportional to the frequency of migraine occurrence (Terwindt et al., 2000).

These findings in adults have parallels in adolescents, with adolescents aged 13-17 with migraine reporting greater reductions in physical well-being and total quality of life relative to those with tension headaches (Milde-Busch et al., 2010). Another study that used a quality-of-life instrument designed for children (PedsQL 4.0) concluded that the quality of life of children with migraine, compared with that of healthy children, was adversely affected in all areas of functioning (physical health; psychosocial health; and emotional, social, and school functioning)—a level of impact the authors equated to that experienced by children with rheumatoid diseases or cancer (Powers et al., 2003). The significance of pain at a young age includes effects on school attendance; decreased academic performance; reduced participation in athletic and social activities; social stigma; impaired ability to establish and maintain peer relationships; sleep disturbances;

impact on quality of life; and higher levels of distress, anxiety, and depression (Lateef et al., 2009; Palermo, 2009). In addition, early pain experiences may lay the groundwork for illness or chronic pain in adulthood.

At the other end of the age spectrum, studies of older adults also find decreased quality of life for those in severe pain. For example, one study found significant differences for adults over 65 between those who had pain and those who did not with respect to satisfaction with life and health-related quality of life. More severe pain also led to social isolation (Simsek et al., 2010).

Cancer patients with current pain, compared with those without pain, reported statistically significant decreases in general health, physical functioning, and role and social functioning. Similarly, those who had had pain since their diagnosis, compared with those who had not, were less worried about the harmful effects of pain treatment and more likely to report depression, as well as every category of impact on functioning that was measured (general health and physical, emotional, cognitive, role, and social functioning), as well as additional symptoms (fatigue, trouble sleeping, loss of appetite) (Green et al., 2011).

Effects on the Risk of Suicide

The risk of suicide among people with chronic pain appears to be about double that of control groups, with the lifetime prevalence of suicide attempts by chronic pain sufferers ranging from 5 to 14 percent in various studies (Tang and Crane, 2006). Establishing a link between persistent, severe pain and suicide is complicated, however, by the need to take into account the psychological comorbidities described in Chapter 1.

A 2006 review of the literature found eight suicide risk factors for people in chronic pain. Four were specifically pain-related factors: type, intensity, and duration of pain, and insomnia. Four were psychological factors: helplessness and hopelessness about pain, the desire to escape from pain, pain catastrophizing and avoidance, and deficits in problem-solving ability (Tang and Crane, 2006).

Most research on the association between suicide and pain has taken place in clinical settings among people who had chronic pain and were most likely not representative of the general population. Studies also have had unclear comparison groups. A recent population-based study used data on nearly 5,700 adults representative of the U.S. population to investigate pain and suicide (Ilgen et al., 2008). In this study population, 29 percent of the subjects had chronic pain, back or neck pain, frequent or severe headaches, or other nonarthritis pain. All of these conditions "were consistently related to suicidality" (p. 523), with chronic severe headaches having the strongest association. People with chronic headaches were 4.3 times more likely than those without such headaches to think about suicide, 4.6 times more likely to plan suicide, and 6.5 times more likely to have attempted suicide in the previous 12 months. Those with "other" chronic pain also were more likely than those without such pain to have thought about (2.5 times as likely), planned (3.5 times), and attempted (6.2 times) suicide (Ilgen et al., 2008).

Once these data were adjusted for other physical problems and for recent psychopathology that increases suicide risk (e.g., depression, anxiety disorders, substance abuse), the higher risk for people with pain generally remained, especially for people with multiple sources of pain. People having two or more types of chronic pain were "almost three times more likely to report a suicide attempt" (p. 523) than people without pain. The strong association between suicidality and chronic headaches remained after the adjustment described.

These findings mirror those of a recent population-based study among Canadians, which likewise found that the presence of one or more chronic pain conditions was associated with suicide ideation and attempts and that migraine had the strongest association with both, even after adjusting for mental disorders (Ratcliffe et al., 2008). In addition, the study showed that the presence of chronic pain significantly increased the association with suicide ideation and attempts among people with a mental disorder.

Clinicians serving people with multiple pain conditions and serious and persistent headaches should be aware of this heightened risk. At present, suicide prevention efforts tend to focus on people exhibiting psychiatric symptoms or recent suicide attempts, not on pain as an independent risk factor for suicide (Ilgen et al., 2008).

Finally, according to the National Violent Death Reporting System, 20 percent of all suicide deaths in 2008 in the 17 states that system monitors were among former or current military personnel. Almost 40 percent of these victims had some physical health problem believed to have played a part in the decision to commit suicide (CDC and NVDRS, undated). This data set—although the nation's most comprehensive on the issue of suicide—does not cover all states, nor does it ask specifically about pain as a contributing factor. However, the association between self-reported pain severity and suicide among veterans has been confirmed in other research (Ilgen et al., 2010). After controlling for demographic and psychiatric characteristics, Ilgen and colleagues determined that veterans with severe pain were one-third more likely to die by suicide than those without pain or with only mild or moderate pain.

Differences in the Seriousness of Pain by Race/Ethnicity and Sex

Statistically significant differences by race/ethnicity and sex have been found with respect to the impact of cancer pain on measures related to quality of life, with diminished quality reported for both blacks and women (Green and Hart-Johnson, 2010). Past research has found that African Americans with low back injuries, compared with whites with such injuries, report higher rates of problems with physical functioning and with carrying out family/home responsibilities, social and occupational activities, self-care, and basic life-supporting activities

(Jerome and Gross, 1991; Tait and Chibnall, 2005). Even when pain affects lower percentages of blacks than whites, blacks may show higher rates of related conditions, such as depression, PTSD, or sleep disorders (Green et al., 2004).

Contrary to some other findings, a telephone survey of a nationally representative sample of 454 white (non-Hispanic), 447 African American (non-Hispanic), and 434 Hispanic adults in the United States found that the prevalence of "frequent or persistent pain" for 3 months or longer during the previous year was roughly similar across the three groups. These results contributed to "a variety of conflicting findings related to the racial and ethnic influences on the effects of chronic pain" (Portenoy et al., 2004, p. 326). Approximately a third of subjects in all three groups had "disabling pain," which the authors defined as both of high severity and greatly interfering with daily functioning. In this study, factors with a statistically significant association with a higher likelihood of disabling pain were female sex, income under $25,000, failure to graduate from high school, and divorce. Of these, income and education were most important. Many, but not all, of the factors associated with a lower likelihood of disabling pain were the obverse of these: younger age, income over $25,000, being employed, suburban residence, and a college or graduate degree. Those at least risk of disabling pain were in the highest income group and had the most education. (See also the discussion of income and education earlier in this chapter.)

As a hypothesis to explain their finding that race did not predict the likelihood of disabling pain, Portenoy and colleagues note that "Hispanic and African American subjects were significantly more likely to have those characteristics identified as predictors of disabling pain than white subjects" (p. 325). They add, "Given the complex interactions between demography, culture, and other factors, additional studies are needed to clarify the degree to which the adverse effects[10] of chronic pain can be explained by race and ethnicity or the mediating variables with which they associate" (p. 326). Undertreatment, they suggest, may be one such potential mediating variable (see the discussion of undertreatment earlier in this chapter), along with group differences in the likelihood of seeking treatment or the choice of provider (primary care versus specialist, for example), concerns about pain medications, and so on.

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[10] In this study, "adverse effects" included disturbed sleep, exhaustion or fatigue, inability to concentrate, loss of appetite or weight gain, or loss of sex drive; depressed mood, anxiety, irritability, or feeling stressed; and inability to work, participate in sports, do household chores, take care of family members, or socialize with friends or family.

THE COSTS OF PAIN AND ITS TREATMENT

> *Our current health insurance companies are dictating medication prescriptions for patients based on their own guidelines. People are suffering because they cannot afford to pay for medications out-of-pocket or the exorbitant co-pays required.*
>
> —A nurse[11]

Costs to the Nation

The rising cost of health care is the greatest challenge facing the nation's health care system and the public programs that pay for health services. Estimating the total national toll of pain on the U.S. economy is problematic, and estimating even costs within the health care component of the economy is difficult because the costs of pain are bound up with the costs of treating many other conditions and therefore difficult to disentangle. The abundant methodological challenges in calculating the costs of pain include

- how to determine the number of people with pain during a given time interval;
- how to classify types of pain, such as by body part or severity;
- how much of an increase in health care costs is attributable to pain when people with pain often present, and are simultaneously treated for, many health problems, some of which may be related to pain;
- the extent to which people with pain may be underrepresented in various data collection efforts;
- the degree to which pain contributes to missed days or hours of work and to the loss of a capacity to perform work that the person otherwise would perform;
- the degree to which pain causes work-related disabilities and the costs of managing those disabilities; and
- the costs of noneconomic impacts of pain, such as suffering, tolls on families, and children's developmental consequences.

A regression analysis performed for this study and based on data from the MEPS for 2008 revealed that the annual cost of pain in the United States is *$560-635 billion*[12] in 2010 constant dollars (see Appendix C). This estimate combines the

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[11] Quotation from response to committee survey.

[12] The findings, methods, and limitations of this economic study are described in Appendix C.

incremental cost of health care ($261-300 billion) and the cost of lost productivity ($11.6-12.7 billion) attributable to pain. The $560-635 billion range is a conservative estimate because it excludes the costs of pain affecting institutionalized individuals (including nursing home residents and corrections inmates), military personnel, children under age 18, and personal caregivers (such as spouses who miss work while caring for people with pain), as well as the lost productivity of workers younger than 24 and older than 65. The estimate also excludes the emotional cost of pain. Even with these omissions, the estimate of the annual U.S. cost of pain given in Appendix C is higher than published estimates of the annual costs of heart disease, cancer, and diabetes; however, because different methods were used to derive these estimates, they are not strictly comparable. The analysis found that moderate pain, severe pain, joint pain, arthritis, and functional disability were all strongly associated with an increased probability of higher health expenditures.

Prior to this analysis, the National Institutes of Health used its own estimate, developed in the late 1990s, of $100 billion as the total U.S. cost of pain, including health care expenses, lost income, and lost productivity (NIH and NCCAM, 2010). Additionally, interesting estimates of the annual costs of several pain-related conditions have been developed by various researchers using different methodologies. These estimates include the following:

- headache—$14 billion, only $1 billion of which consists of health care costs (Hu et al., 1999), partly because most people with migraine stop seeking medical care for the condition (Silberstein, 2010);
- arthritis—$189 billion, less than half ($81 billion) of which is for health care costs (Yelin et al., 2007);
- low back problems—$30 billion (Soni, 2010);
- spine problems—$2,500 average in incremental medical costs (Martin et al., 2008);
- spine surgical procedures—$1 billion in Medicare expenditures (Dartmouth Atlas of Health Care, 2006);
- back pain—$100-200 billion in decreased wages and lost productivity (Freburger et al., 2009); and
- headache, arthritis, backache, and other musculoskeletal conditions—$61 billion (Stewart et al., 2003).

Disability from all causes has been estimated to cost $300 billion annually, with the pain-related conditions of arthritis and back/spine problems being the top two causes of disability (CDC, 2009).

A 2007 estimate of the national cost of pain also has been developed for Australia. The cost to that nation is estimated[13] at US$26.8 billion, or US$1,288

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[13] AU$34.3 billion in 2007 (Access Economics, 2007), with a 1.28 currency exchange rate in January of that year.

per capita. In comparison, the analysis commissioned for this study found the cost of pain to be $1,842-2,072 per capita in 2008, which is 43-61 percent higher than the Australian figure. A major factor in this difference is the high cost of U.S. health care; in 2003, the per capita cost of health care was more than twice as high in the United States as in Australia (Kaiser Family Foundation, 2007).

The cost of pain to the federal government is immense. The federal Medicare program bears fully one-fourth of U.S. medical expenditures for pain. In 2008, this amounted to at least $65.3 billion, or 14 percent[14] of all Medicare costs. In total, federal and state programs—including Medicare, Medicaid, the Department of Veterans Affairs, TRICARE, workers' compensation, and others—paid out $99 billion in medical expenditures attributable to pain. Lost tax revenues due to productivity losses compound that expense (Gaskin and Richard, 2011 [see Appendix C]).

Pain prevention therefore offers the prospect of substantial savings in U.S. health care costs. The analysis conducted for this study found that on average, a person with moderate pain generates health care expenditures $4,516 higher than those for a person without pain. A person with severe pain generates health expenditures $3,210 higher than those for a person with moderate pain. The precise reasons for these large cost differences are unclear; to the extent that they reflect differential utilization of health services due to pain, however, the potential cost savings if pain were prevented or treated more effectively are enormous.

Finally, as noted previously, people with chronic pain are frequent users of complementary and alternative medicine (CAM) services. The costs of these services—which often must be paid, at least in part, out of pocket—are difficult to measure or compare with those of conventional care. Washington State, where private insurance coverage of all licensed CAM providers is mandated, offers a unique opportunity to use insurer claims data to compare costs for those who use CAM for at least part of their care and those who do not. Such a study was performed on 2002-2003 data for insured individuals with back pain, fibromyalgia, and menopause symptoms, matching 26,466 CAM users with 13,025 nonusers on a 2:1 basis. Overall, CAM users had lower average expenditures than nonusers ($3,797 versus $4,153). Their outpatient expenses were higher, but offset by lower expenses for inpatient care and imaging. People who had the heaviest disease burdens accounted for the highest levels of savings, an average of $1,420. The study findings are suggestive, but limited because they do not reveal long-term costs or health outcomes (Lind et al., 2010), and longer-term studies would help clarify these potential savings.

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[14] Using information provided in Appendix C, to compute the 14 percent figure, start with $261.1 billion as the low, or Model 1, estimate of medical expenditures for pain, from Table C-5. Multiply this by 25 percent as the share borne by Medicare, from Table C-6. Divide this product, $65.3 billion, by total Medicare 2008 expenditures of $465.7 billion, from Martin and colleagues (2011).

Costs to Families

The social costs of pain, especially chronic pain, affect not only the person in pain but also friends, coworkers, and especially the family. As noted by Martel (2011, p. 2), "The family is more than a collection of individuals. That is, the whole is greater than the sum of its parts. One must view the family as an entity in its own right with its own 'life.'" And pain makes everything about that life different.

Family members find that their relationship with their loved one changes, and to the extent that they must take on new roles (as caregiver and morale booster) and greater responsibilities in the family (e.g., grocery shopping, chores, errands), the burden on them increases. They may observe not just physical but also psychological changes. Often "a person in pain withdraws emotionally from the spouse or partner and other family members. A family member's negative reaction to this withdrawal is a natural response" (Rome, 2011, p. 1).

A pilot study involving 75 pediatric patients and their families attempted to measure the economic cost to families of having a child with serious pain (of several common types) and the effect of treatment in a multidisciplinary pediatric pain outpatient clinic (Ho et al., 2008). In the 3 months prior to treatment in the multidisciplinary clinic, the pediatric patients used a variety of physician services and received other services, such as physical therapy and mental health services, in both inpatient and outpatient visits, accumulating mean outpatient visit charges of $1,761 and mean inpatient charges of $7,020 (both with large standard deviations). This high utilization produced lost school days and lost workdays for parents. In the 6 months after enrollment in the multidisciplinary clinic, the children made fewer visits to specialists and mental health providers for their condition, had fewer x-rays, and incurred lower health care costs. All differences were statistically significant ($p \leq 0.01$). Likewise, medical appointments consumed less family time and resulted in somewhat fewer missed workdays. Average outpatient care charges were reduced to $560 and average inpatient charges to $546, again with large standard deviations. The reduction in inpatient charges also was highly statistically significant ($p \leq 0.01$).

In the long term, pain may change nearly every aspect of family life, and to the extent that the person in pain cannot work, the family's financial stability may be threatened. Heightened stress may affect the children, who do not understand why their parent is withdrawn, irritable, and no longer the willing playmate of the past. One study showed that parents of children being treated in a pediatric rheumatology clinic were highly likely to have chronic pain conditions themselves and that higher levels of parental pain and related disability were reflected in higher levels of pain in the children. The parents' pain experiences predicted the children's reaction to their own pain and the development of maladaptive coping strategies (catastrophizing) to deal with it (Schanberg et al., 2001). This study provides a good example of how social conditions (in this case family history) affect the expression and experiences of pain.

At the same time, continued emotional support is vital to the functioning of a family member in pain and to aiding in his or her rehabilitation. People who report family disharmony and lack of support do not benefit from pain treatment to the same extent as those with strong family support (Jamison and Virts, 1990). In one study, for example, those who reported having nonsupportive families were more likely to have work-related injuries; to rely on medication; and to report more pain sites, more pain behavior, and more emotional distress. By contrast, people with supportive families reported significantly less pain intensity, needed less medication, and were more active (Jamison and Virts, 1990).

POTENTIAL ROLES FOR PUBLIC HEALTH

> *Public health policy and practice, directed at primary prevention of chronic pain in populations, offers the potential to reduce the frequency of chronic pain and the impact it has on societies.*
>
> —Croft et al., 2010, pp. 353-354

This chapter has described how widespread acute and chronic pain is in the United States, affecting large segments of the population. It also has shown that pain affects subgroups of the population differently and not always as conventional wisdom might suggest. It has made clear that serious pain has significant effects on people's daily activities, disability, and quality of life and is linked to suicide. It further has shown that pain is exceedingly costly in terms of both direct health care costs and the indirect costs associated with disability, lost employment, and reduced income.

The beginning of the chapter presented eight rationales for regarding pain as a public health issue. For three of these—the extent of the problem, its differential impact on vulnerable population groups, and its costliness—the evidence discussed in this chapter is strong and persuasive. (The rationales related to problems with opioids, training, and research are discussed in Chapters 3, 4, and 5, respectively.) This section addresses the remaining two rationales—the need for prevention and for multimodal efforts—and the associated roles for public health, as well as some additional potential public health contributions.

Prevention

Perhaps the most important conclusion that can be drawn from a review of the enormous toll caused by pain relates to the need for prevention. A public health approach to prevention attends to the external, often structural, factors in the social and physical environments that affect not just individuals but populations. These are the "upstream" influences that shape conditions and behaviors that produce or exacerbate disease.

In many instances, pain prevalence could be reduced as a consequence of normal public health initiatives aimed at preventing chronic disease, injuries, and violence and promoting healthy weight, dental care, and so on—factors associated with ameliorating health problems. A prevention approach to pain, for example, would consider conditions in the work environment that contribute to back and other musculoskeletal injuries or promotion of the use of safety helmets and goggles to reduce sports injuries. It would create effective preventive systems to enable prompt response to risk factors that suggest acute pain is evolving into chronic pain. It would support the development of community-wide understanding of the nature of pain and factors that increase it so that individuals would receive the assistance they need at the right time. A public health approach also would engender organizational, professional, and personal actions to avoid reinjury and loss of self-efficacy, as well as other measures to protect health.

As suggested at the beginning of this chapter, a comprehensive public health approach to preventive measures such as these would involve people in many sectors, including health care leaders and clinicians, the individuals affected by pain and their families, disease and child advocates, academic leaders, employers, social marketers, policy makers, union leaders, workers' compensation program directors, and insurance executives. As with all preventive efforts for which it is difficult to document impact on events that "do not occur," a direct link between efforts to reduce the occurrence of specific diseases and injuries and thereby the prevalence of pain will be difficult to establish. Nevertheless, epidemiologists and economists can help in the planning stages of such public health programs to design data collection strategies that will fill some gaps in understanding of where best to target pain-prevention efforts.

In addition to general prevention programs aimed at avoiding illness and injury (of which pain is one consequence), the kinds of educational programs and behavior change support programs that are a mainstay of public health activities are obvious targets in the primary prevention of pain. Some successful examples are briefly described in Box 2-4.

Public health entities have a role in prevention because of the high utilization of publicly funded service delivery programs, such as community service programs, public housing, rural and migrant health centers, services for the homeless, the IHS, and the Native Hawaiian Health Care Systems Program. Together, these public programs serve nearly 20 million people a year. These programs, which typically serve groups at high risk for pain and its consequent disability, should provide comprehensive, interdisciplinary, state-of-the-art pain care.

Aside from its role in direct service delivery, the public health establishment reimburses for care in nonpublic settings, including hospitals, doctors' offices, and pharmacies. Together, federal, state, and local governments accounted for

BOX 2-4
Examples of Population-Based Prevention Initiatives

Prescription Drug Take-Back Programs

These programs (for example, the Drug Enforcement Administration's [DEA's] Nationwide Prescription Drug Take-Back Day and Utah's Use Only as Directed campaign) are intended to reduce the misuse and abuse of prescription pain medications. These efforts combine media and other educational efforts to promote safe use, storage, and disposal of potentially dangerous drugs, and include opportunities for the public to return "expired, unused, and unwanted prescription drugs" to collection centers.[a] According to the DEA, during a Take-Back Day held in September 2010, Americans turned in more than 121 tons of prescription drugs to state and local law enforcement partners (DEA, 2011). Although such programs do not directly affect pain prevalence, the rising rates of opioid use may lead to policy and enforcement practices that make these medications less available to people who need them.

Campaign to Reduce Back Pain Disability

A 3-year campaign in Victoria, Australia, in the late 1990s (described in more detail in Chapter 4)—Back Pain, Don't Take It Lying Down—used mass media and other means to promote several evidence-based concepts, including that disability can be improved by positive attitudes, that people with back pain should continue to participate in their usual activities, and that they can do much to help themselves. The campaign aimed to reach both the general public and health care professionals. Evaluation revealed dramatic improvements in what the public and clinicians believed about back pain, accompanied by a decline in related workers' compensation claims and health care utilization during the campaign; those beliefs have persisted over time (Buchbinder, 2010).

Suicide Prevention

A 2002 Institute of Medicine study found that since the 1980s, there have been a wide range of suicide prevention initiatives taking a population-based approach (IOM, 2002b). Examples include improved prevention programs in schools, research on programs to target high-risk people, and efforts to identify broader patterns of suicide and suicidal behavior in groups or populations. As discussed earlier in this chapter, chronic pain and depression, as well as other emotional disorders, often go hand in hand, and all of these conditions may increase the likelihood that a person has available prescription drugs that could be used for suicide. Some measures designed to protect the population at large, such as limiting the size of prescriptions, may have unintended consequences for people with chronic pain.

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[a] The Secure and Responsible Drug Disposal Act of 2010 allows people to dispose of controlled-substance medications by delivering them to authorized entities.

43 percent of national health expenditures in 2009 (Martin et al., 2011). Developing or disseminating guidelines on pain care, creating partnerships with professional societies and advocacy groups, developing quality standards around pain management, and requiring pain care content in graduate medical education and continuing education programs all can be used to improve the clinical care of people with pain and prevent the related disability and other negative consequences of inadequate care.

The rules and practices governing both service delivery and payment programs, including any changes or coverage expansions that grow out of health reform and "meaningful use" requirements for electronic health records, should be aligned with the best thinking about pain management and disability prevention. They should ensure that federally funded health services programs are supporting coordinated, consistent care across needs and helping people develop the self-care and family care skills that may improve results and quality of life. Achieving this will be challenging for geographically isolated rural and IHS providers, however, especially in the face of state and federal budget cuts.

Support for Multimodal Efforts

As suggested at the outset of this chapter, much more than conventional medical care is involved in the public health approach to health promotion and disease prevention for the population. Public health considers the systematic differences in health status and outcomes and tries to "identify and understand the factors leading to poorer outcomes" (Russo, 2011, p. 86). The multiple determinants of health in the population health model are in five interacting categories: the social and economic environment, the physical environment, genetics, medical care, and health-related behavior (Russo, 2011). With respect to pain specifically, these five factors affect not only the likelihood of experiencing pain but also the likelihood that it will progress to a chronic condition, the amount of disability that will result, and the specific needs a person (and family) will have. For example, the diverse array of public and private agencies that work to identify and prevent child abuse and sexual abuse and aggressively treat children exposed to traumatic events (including violence) can be important not only in preventing pain during childhood but also in preventing the potential occurrence of chronic pain when these children reach adulthood (NIH and NICHD, 2002).

Public entities that provide or fund health services (for example, community health centers, the Medicaid program, state mental hospitals) for people in high-risk groups must ensure that their programs effectively manage pain and that referrals to more specialized community pain resources are made appropriately. Medicare policy should encourage aggressive team management of difficult pain conditions. Special efforts should be made to ensure that state workers' compensation programs are handling claims in timely and effective ways most likely to resolve painful injuries and return people to work and normal activities.

In addition, a substantial amount of health professions education is funded through state and federal government programs—particularly graduate medical education (residency programs). State governments are in charge of setting licensing and credentialing standards for the major health professions. Although curriculum changes are notoriously difficult to achieve, public agencies can influence training institutions to increase the quality and quantity of educational content relating to pain.

Other Public Health Contributions

Several roles for public health entities in addressing the problem of pain exist beyond those described above. One such role would involve CDC, the Substance Abuse and Mental Health Services Administration, the FDA, and federal and state law enforcement agencies in reconciling the competing goals of effective pain management and avoidance of the harmful effects of opioids. This issue should be addressed within the public health structure; involve all interested parties; and be communicated clearly to health care providers, people with pain, and the public.

CDC, AHRQ, and other agencies are involved in data gathering with respect to the prevalence of pain conditions, their treatment, their costs, and resultant disability. Their information systems can be used not only for surveillance but also analytically to identify groups at greatest risk of complications for purposes of targeting interventions. They can contribute to the collection of longitudinal data on the various consequences of serious pain; the related conditions (physical and mental) common in people with pain; the progression of acute to chronic pain; and consequences over time for subgroups of the population, including children, with attention to the risk and resilience factors that influence the progression to adult pain. In addition, the current efforts of these agencies could be better defined, more current, and more consistent across data sets.

Additionally, CDC and other agency experts in health care communication might employ their skills in reaching underserved and vulnerable populations to disseminate useful messages about pain prevention, management, and self-care. Another area for prevention could be to determine whether over-the-counter pain medications require greater monitoring, regulation, or more public education with respect to the potential hazards of long-term use and the risk of interactions with other medications.

Finally, opportunities for a range of research programs involving the National Institutes of Health, the FDA, and other HHS agencies are discussed in Chapter 5. Their aim should be to support discovery through a spectrum of research and demonstration initiatives to determine the most effective strategies for reducing the disruption and the personal, financial, and social costs of pain, especially in the most vulnerable subgroups of the U.S. population.

BOX 2-5

Potential Savings from Improvements in Pain Prevention, Care, Education, and Research

Significant savings may arise through

- *better treatment of acute pain*, through education about self-management and better clinical treatment, in order to avoid the progression to chronic pain, which is more difficult and more expensive to treat and generates high health care utilization;
- *reductions in health problems and complications of other physical and mental diseases and conditions* associated with chronic pain that also are expensive to treat;
- *reductions in public- and private-sector economic costs,* such as workers' compensation, lost productivity, and lost tax revenues, and the inestimable costs to families;
- *prevention of some of the costly effects of pain,* as public health measures and patient and public education begin to bear fruit;
- *more cost-effective care of people with chronic pain* when self-management and multimodal approaches are used more often, primary care physicians are educated and empowered to treat most people with pain appropriately, and unnecessary diagnostic tests and procedures and referrals to specialists are avoided;
- *a reduced burden of opioid misuse and abuse* as other medications are used more effectively and appropriately, and other forms of treatment successfully supplement medication use; and
- *better tailoring of treatment to individuals* based on new research findings and integration of those findings into patterns of care.

Costs and Savings from a Public Health Approach

A comprehensive public health approach to improving pain research, care, and education will require some new expenditures, but these costs can be offset by concomitant savings not only in reduced human suffering, but also in "hard dollars" from multiple sources. These potential savings are described in Box 2-5.

FINDINGS AND RECOMMENDATIONS

Finding 2-1. Pain is a public health problem. Pain is a significant public health problem. Chronic pain alone affects approximately 100 million U.S. adults. Pain reduces quality of life, affects specific population groups disparately, costs society at least $560-635 billion annually (an amount equal to about $2,000 for everyone living in the United States), and can be appropriately addressed through population health-level interventions.

Finding 2-2. More consistent data on pain are needed. While it is known that pain affects millions of Americans, the committee acknowledges the lack of consistent data with which to describe the nature and extent of the problem or to identify subpopulations that will benefit most from future interventions. Improvements in state and national data are needed to (1) monitor changes in the incidence and prevalence of acute and chronic pain; (2) document rates of treatment or undertreatment of pain; (3) assess the health and societal consequences of pain; and (4) evaluate the impact of related changes in public policy, payment, and care. Pain data need to be based on standardized questions, preferably using existing international standards, to facilitate comparisons over time and across populations. These data would be useful for a wide range of stakeholders, including policy makers, health care providers, health professions educators, professional licensing authorities, pain advocacy and awareness organizations, and researchers.

> **Recommendation 2-1. Improve the collection and reporting of data on pain.** The National Center for Health Statistics, the Agency for Healthcare Research and Quality, other federal and state agencies, and private organizations should improve and accelerate the collection and reporting of data on pain. Data should be collected in the following domains:
>
> - the incidence and prevalence of pain;
> - interference with activities of daily living and work, as well as disability, related to pain;
> - utilization of clinical and social services as a result of pain;
> - costs of pain and pain care, including indirect costs of lost employment and public- and private-sector costs for disability payments; and
> - the effectiveness of treatment in reducing pain and pain-related disability, determined through research on the comparative effectiveness of alternative treatments (including in different patient populations), to identify people most likely to benefit (or not) from specific treatment approaches.
>
> Standardized questions, fields, and protocols for surveys and electronic health records should be developed, and pain-related data should be collected at regular intervals. Collection of these data will help identify subpopulations at risk for pain and undertreatment of pain; characteristics of acute and chronic pain; and the health consequences of pain in terms of morbidity, mortality, and disability, including related trends. If electronic health record systems include adequate and appropriate pain-related questions, their broader implementation will be able to facilitate the collection of consistent pain data across health care settings. Such data will help fill gaps in current knowledge regarding the prevalence,

seriousness, and trajectories of pain, as well as the effectiveness of pain treatments. This information can guide decision makers, including public and private payers, and foster more efficient and effective pain care.

Finding 2-3. A population-based strategy for reducing pain and its consequences is needed. The committee finds that, to effect changes that will reach the millions of American adults living with pain, account for differences in the experience of pain among population groups, and address selected environmental factors that contribute to the consequences of pain, a population health-level strategy is needed. A comprehensive and coordinated strategy would

- encourage and foster the prevention of pain;
- heighten national concern about pain as a health care quality and safety issue;
- use public health communication strategies to ensure that patients understand their role in managing their own pain;
- identify and attempt to remediate relevant environmental factors, especially those that adversely affect children and start them on a path to chronic pain as adults; and
- inform members of the public about what chronic pain is, how they can help loved ones who have it, and how they may be able to help prevent it for themselves and others.

Recommendation 2-2. Create a comprehensive population health-level strategy for pain prevention, treatment, management, and research. The Secretary of the Department of Health and Human Services should develop a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and research that includes specific goals, actions, time frames, and resources. This strategy should

- Describe how efforts across government agencies, including public–private partnerships, can be established, coordinated, and integrated to encourage population-focused research, education, communication, and community-wide approaches that can help reduce pain and its consequences and remediate disparities in the experience of pain among subgroups of Americans.
- Include an agenda for developing physiological, clinical, behavioral, psychological, outcomes, and health services research and appropriate links across these domains (consistent with Recommendations 5-1 through 5-4).
- Improve pain assessment and management programs within the service delivery and financing programs of the federal government.

- Proceed in cooperation with the Interagency Pain Research Coordinating Committee and the National Institutes of Health's Pain Consortium and reach out to private-sector participants as appropriate.
- Involve the following agencies and entities:
  - Federal agencies and departments
    - National Institutes of Health
    - Centers for Disease Control and Prevention
    - Food and Drug Administration
    - Centers for Medicare and Medicaid Services
    - Agency for Healthcare Research and Quality
    - Health Resources and Services Administration
    - Indian Health Service
    - Department of Defense
    - Department of Veterans Affairs
  - Private-sector entities
    - Pain advocacy and awareness organizations
    - Health professions associations
    - Health care providers (e.g., accountable care organizations)
    - Health professions educators, colleges, and training programs
    - Private insurers
    - Accreditation (e.g., Joint Commission, National Committee for Quality Assurance), certification (e.g., American Board of Medical Specialties), and examination (e.g., National Board of Medical Examiners) organizations
  - State-level entities
    - Health professions licensing authorities
    - Workers' compensation programs
    - Medicaid programs
    - State health departments.
- Include ongoing efforts to enhance public awareness about the nature of chronic pain and the role of self-care in its management.

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3

Care of People with Pain

> *Appointment after appointment, test after test, and of course, nothing to really confirm [the diagnosis]. . . . Having pain that I did not understand, as a physical therapist, fearing some dreadful disease was hard enough. . . . So, in addition to pain, I had anxiety and depression. . . . The medication that finally gave me better relief was pulled off the market recently by the FDA.*
>
> —A person with chronic pain[1]

While pain care has grown more sophisticated, the most effective care still is not widely available. Some cases of acute pain can be successfully treated but are not; others could be dealt with promptly, but agonizing delays occur. And most people with severe, persistent pain still do not receive—and often are not offered—systematic relief or the comprehensive, integrated, evidence-based assessment and treatment that pain care clinicians strive to provide.

Currently available treatments have limited effectiveness for most people with severe chronic pain. For many such individuals, pain management on a daily basis takes place outside any health care setting. They must respond to and attempt to control their own pain while they are at home, at work or school, or in their communities as they go about their lives as actively as they can, or think they can. From that vantage point, the assistance provided by health professionals

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[1] Quotation from response to committee survey.

is largely a matter of guiding, coaching, and facilitating self-management. The clinician's approach clearly must be patient-centered—that is, specific to the individual—to be effective. Because skills in guiding and coaching are not specifically emphasized in medical education, few physicians are sufficiently prepared to perform this support role, although some health professionals from other disciplines, such as nursing or psychology, may be. Worse, even those physicians and other health professionals who are sufficiently prepared encounter obstacles because of the way health care is typically organized, reimbursed, marketed, and evaluated—namely, around specialization, procedural interventions, and a hierarchy of care management.

To a great degree, as this chapter describes, effective pain care involves a number of individuals, beginning with the patient, and various treatments. First and foremost is self-management—that is, the patient's attempts to manage pain and prevent flare-ups or additional injury. Beyond self-management, the health care sector provides pain care through primary care, specialty care, and pain centers, each of which may offer diverse treatment approaches, including medications, interventional procedures, surgery, psychological therapies (not typically available in primary care), rehabilitative and physical therapy, and complementary and alternative therapies. This chapter describes these approaches in general terms. People with pain frequently consult various types of providers, often sequentially but sometimes concurrently, and use many different therapies as they seek relief, knowledge, and understanding. This chapter also examines selected issues and barriers in pain care, including how clinicians assess pain; issues around the use of opioid medications; the perverse incentives incorporated in most health insurance coverage; and patient-level issues, such as unrealistic expectations or reluctance to report pain. Finally, the chapter describes some emerging models of effective pain care, including those of the Department of Veterans Affairs, the Department of Defense, quality improvement practitioners, and award-winning programs.

The resources available to help the tens of millions of Americans with acute and chronic pain are few and stretched thin. Nor is the path to maximum achievable relief straightforward or clear of pitfalls. Small measures will not significantly improve pain care. Rather, as discussed in Chapter 1, a cultural transformation in how pain is perceived, diagnosed, and managed will be necessary to make the best care currently possible—care we know how to provide—accessible to Americans in pain.

TREATMENT OVERVIEW

> *Is it too much to ask that we, the patients, no longer be bound to a system where no one professional takes responsibility for the patient—a system of unbelievable referrals with unscientific, unproven treatments (and hope) sold to the patient by each referring physician. In many cases, patients end up worse and more and more destitute, yet they grasp for hope with each referral.*
>
> —A chronic pain advocate[2]

Numerous factors—involving the type of pain, one's background and personal traits, and the family and social environments—affect an individual's treatment plan. In many different cases, especially for people with complex, chronic pain conditions, biopsychosocial care (taking into account patients' unique biologic and genetic constitution, their psychological and emotional composition and reaction, and the societal and environmental framework within which they reside and function) has been shown to be advantageous. In all cases, a trusting relationship between patient and clinician fosters clear communication intended to improve outcomes.

Steps in Care

When confronted with pain, some people seek professional help early on, probably from a primary care clinician, while others attempt, at least initially, to handle the situation on their own. If the pain persists, however, affecting physical functioning and quality of life, a person is likely to seek treatment—and should do so—in case the pain is functioning in its warning role as described in Chapter 1.

At least initially, a clinician probably will assume pain is a symptom of some underlying condition and prescribe analgesics, while focusing on discovering what the underlying problem might be. But if a cause cannot be found, if early treatments fail to bring improvement, and if pain persists for several months, it may progress to the point where it becomes a disease in itself, that is, an abnormal condition that impairs or disrupts normal bodily functioning (this is almost always chronic pain). Then, regardless of the initiating process, cause, or underlying disease, the clinician must focus on management of the pain condition in order to assist in restoring the individual to a better state of health. This is not to

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[2] Quotation from submission by Peter Reineke of stories from the membership of patient advocacy groups.

say that all pain is a serious disease. When pain is a disease in itself, however, it requires comprehensive assessment, care planning, and treatment.

Many factors affect the initial pain experience:

- the severity, frequency, and extent of the pain itself;
- the underlying disease process or pathology, if there is one;
- genetic factors;
- people's attitudes, emotional makeup, and beliefs and the meaning of the experience for them (for example, an accident victim might associate pain with a companion's loss of life);
- knowledge and beliefs about the effectiveness and availability of treatments;
- environmental circumstances, such as the advice of family and colleagues, the burdens of work, other life stressors, and physical aspects of the home (e.g., stairs); and
- responses of physicians and other health professionals (encouragement to engage in exercise or other self-management efforts versus suspicion or denigration of the patient's coping efforts).

In sum, the pain experience has diverse contributors and wide-ranging effects. Likewise, there are numerous ways to assess and treat it. A simple medical model, in which a physician attempts to diagnose, treat, and "cure" the cause of pain, often is too limited an approach, and the physician applying this approach is stymied at the outset when the cause cannot be found. Instead, a biopsychosocial framework takes into account the rich range of potential causes, effects, and treatment strategies.

Pain care is available in many settings, and a patient's journey may include any or all of the following steps, in sequence or in any order and with any number of repeat visits with the same or new clinicians and advisors:

- *self-management,* perhaps in consultation with family and friends—whose prior experience and knowledge, whether accurate or not, will play a key role—but with little systematic guidance or intervention from a clinician;
- *primary care,* where practitioners may employ a variety of management strategies, including use of prescription drugs and suggestions for exercise, physical therapy, or weight loss, perhaps after some consultation with specialists;
- *specialist care,* from a professional in diagnosing and treating an underlying disease (cancer, heart disease) causing the pain or from a pain specialist; and
- *a pain center,* where an interdisciplinary approach may be offered.

Almost every patient is likely to engage in self-management, and almost everyone—even those consulting with a pain specialist—should benefit from the involvement of a primary care practitioner (or medical home) who is able to help coordinate care across the full spectrum of providers (IOM, 1996). Such coordination of care helps prevent people from seeking relief from multiple providers and treatment approaches that may leave them frustrated and angry and worse off both physically and mentally, and from falling into a downward spiral of disability, withdrawal, and hopelessness. Certainly, fragmentation hinders the development of a strong, mutually trusting relationship with a single health professional who takes responsibility for coordinating care. This relationship is one of the keys to successful pain treatment.

Self-Management

Self-management is almost always the first step in a person's journey to relieving pain, and is one that is returned to repeatedly. Because severe pain strongly influences virtually all aspects of a person's quality of life, and because treatment often is insufficient and involves several specialties and professions, the burden of controlling pain falls most heavily on people in pain and their families.

Self-management succeeds partly because it helps patients believe in their own capacity to control their pain (Keefe et al., 2008). Pain beliefs correlate with outcomes, and patients function better when they have some control, are not severely disabled, and avoid "catastrophizing" pain—that is, exaggerating its threat and believing they cannot control it (see also Chapter 1) (Keefe et al., 2000).

Self-management of pain may be viewed as including both informal efforts undertaken by people with pain, perhaps following the advice of nonprofessionals or written or online sources of information, and structured activity, guided by a health professional or by an established protocol and intended to enhance the person's capacity for self-management. In self-management programs, patients become educated about their condition and active participants in their treatment, "engaging in active problem-solving, decision-making, developing good use of health resources, and taking actions to manage their pain" (National Institute of Nursing Research, 2011, p. 1). To illustrate, back pain self-management efforts might include brief rests, resumption of normal activities, strengthening exercises, structured physical activity, application of heat and cold, use of over-the-counter medications and topical ointments and creams, sleep, yoga, and caution in lifting and carrying. The following examples illustrate the range of self-management options:

- A Stanford University program, initially established for patients with arthritis, includes exercise, muscle relaxation techniques, distraction, sleep aids, education about pain and negative emotions, and cooperation with clinicians and employers (Lorig et al., 2008). This program showed modest but statistically significant improvements in self-reported pain but no differences in health care utilization.

- A psychoeducational pain control program for cancer patients, using coaching by nurses, showed significant decreases in pain intensity (Miaskowski et al., 2004).
- A self-management program of cognitive-behavioral therapy and diet interventions for women with irritable bowel syndrome, using advanced practice nurses, reduced abdominal pain symptoms (Heitkemper et al., 2004).
- A model program run by pain clinicians from several disciplines encouraged new pain center patients to participate in a 2-day, 8-hour group educational program before individual counseling with a pain specialist (for which the two pain clinics involved had lengthy waiting lists). Patients received information about pain and its treatment and learned a variety of self-management skills. Half (52 percent) of the attendees decided to forego a clinical appointment and manage their pain on their own. Results indicated statistically significant increases in the use of various self-management strategies and improved satisfaction, as well as other overall positive effects (Davies et al., 2011).
- Participants in a lay-person-led self-management group intervention for back pain patients in primary care, evaluated in a randomized trial, achieved significantly less worry about their pain, more confidence in self-care, and less self-reported disability (Von Korff et al., 1998).

A substantial body of research supports the effectiveness of such programs. For example, a meta-analysis of 17 self-management education programs for arthritis found that they achieved small but statistically significant reductions in pain ratings and reports of disability (Warsi et al., 2003).

The above examples illustrate that self-management need not take place by itself but can be combined with treatment directed by a health professional. To illustrate further, pain self-management combined with the use of antidepressants led to significantly less pain in patients with both musculoskeletal pain and depression (Kroenke et al., 2009b). A program for cancer patients called "Passport to Comfort," with four education sessions on assessing and managing fatigue and pain, was found to lead to improvements in physical and psychological well-being (Borneman et al., 2011). And a program of manual therapy, exercise, and education for chronic low back pain showed a significant treatment effect, maintained at 1-year follow-up (Moseley, 2002). Such combination programs use various settings and media; a review of rates of participation in arthritis self-management programs in the San Francisco Bay area showed that small group programs were most highly attended. Convenience in scheduling and location is also important; offering self-management programs "multiple times in diverse settings and continuously over many years" produced 40 percent participation rates among the target group (Bruce et al., 2007, p. 852).

For some people with pain, education alone may be the most effective treatment by a health professional. But as Chapter 4 describes, patient education is no easy matter, especially given deficits in health literacy (see Chapter 2) and challenges in framing messages that are specific and appropriate to individual circumstances. For example, the message delivered to an adult experiencing chronic pain caused by osteoarthritis of the spine should differ markedly from that for a person with multiple myeloma, for whom a new pain can be a truly catastrophic harbinger of permanent paralysis.

Primary Care

Primary care is where people obtain accessible, comprehensive, coordinated health care. The primary care fields of medicine are general internal medicine, general pediatrics, family medicine, and (in some views) obstetrics-gynecology. Whether functioning as individual practitioners, in integrated teams of health professionals, or in what are now termed medical homes or accountable care organizations with medical and financial responsibility for the health of a patient population, primary care clinicians provide a wide range of services and assist people in making decisions about specialty services and elective procedures (see Chapter 4). Primary care physicians also are responsible for the majority of pain medicine prescriptions. Indeed, in 2007, analgesics were the drug category most frequently mentioned in data on office visits to physicians. In 2008, analgesics constituted 10.1 percent of all drugs prescribed for adults (ranking a close second to antidepressants, at 10.8 percent) (Gu et al., 2010).

It is no wonder, then, that primary care practitioners are an early step in the pain care journey, treating 52 percent of chronic pain patients in the United States based on a national mail survey of primary care physicians, physician pain specialists, chiropractors, and acupuncturists (Breuer et al., 2010). Typically, primary care is where people first report pain to the health care system; thus the primary care practitioner's response may be crucial in providing timely relief and preventing acute pain from progressing to a persistent or chronic state (Dobkin and Boothroyd, 2008). Doubtless, many primary care practitioners become extraordinarily adept at providing pain care, but this is not the uniform experience. As discussed later in this chapter, patients experience a number of barriers to optimal pain care within the primary care system.

Specialty Care

Although most people with pain do not need a pain specialist's care, the potential demand for these services far outstrips the supply. Approximately 100 million American adults have common chronic pain conditions, but only 3,488 physicians were board certified in pain care between 2000 and 2009; thus there are more than 28,500 people with chronic pain for every specialist (this figure can be compared, for example, with the U.S. average of 264 patients treated by each radiation oncologist in 2003 [Lewis and Sunshine, 2007]). As a result, most pain care must (and should) be provided by primary care practitioners. In a national survey conducted in the late 1990s, fully four-fifths of people currently experiencing severe pain said they had never been referred to a specialized pain program or clinic (American Pain Society, 1999).

Organization of the specialty. Pain medicine (the physician specialty of pain care) and pain care in general constitute a "highly active" field, distinguished by rising numbers of peer-reviewed publications and professional associations and interest groups (Dubois et al., 2009). The American Medical Association (AMA) recognizes pain medicine as a discrete specialty, represented in the AMA house of delegates by the American Academy of Pain Medicine.

Most pain physicians come to the field from anesthesiology or, to a lesser extent, physical and rehabilitation medicine, occupational medicine, and psychiatry and neurology. (The specialty breakdown of pain medicine is discussed in greater detail in Chapter 4.) Few pain specialists come from primary care disciplines. This is an unfortunate gap because greater interchange would be helpful given that, in light of the paucity of pain specialists, the bulk of clinical pain care must take place either through primary care or through routine medical care provided by the cardiologists, oncologists, and neurologists who manage most of the care for people with heart disease, cancer, and neurologic disorders, respectively.

Several health professional associations that focus on pain are influential sources of information about pain and pain care. Individuals are free to join as many associations as they wish, provided they meet the qualifications for membership. Relatively large groups (among which memberships overlap), with about 4,000 to 6,000 members each, are the American Academy of Pain Management (consisting of anesthesiologists, chiropractors, physical therapists, psychologists, and others), the American Society of Regional Anesthesia and Pain Medicine (anesthesiologists), and the International Association for the Study of Pain (researchers and physicians, whose U.S. chapter is the American Pain Society). Somewhat smaller groups include the American Society of Interventional Pain Physicians (anesthesiologists), the American Academy of Pain Medicine (physicians), and the American Back Society (physicians, chiropractors, and physical therapists). Relatively small groups include the American Headache Society (physicians), the American Society for Pain Management Nursing, and the American Academy of Orofacial Pain (primarily dentists and physical therapists).

Certification of pain specialists. Physicians already board certified in anesthesiology, physical medicine and rehabilitation, or psychiatry/neurology can become board certified in pain medicine. During the 2000-2009 decade, pain medicine certificates were issued to 1,874 anesthesiologists, 1,337 physiatrists, and 277 psychiatrists and neurologists, based on a common curriculum and a jointly developed examination administered by the American Board of Anesthesiology (American Board of Medical Specialties, 2010).

Practice patterns reflect training. A pain specialist trained as an anesthesiologist is likely to provide different perspectives and treatments from those of a psychiatrist, neurologist, or internist. For example, a study of medication care provided to fibromyalgia patients by primary care physicians, rheumatologists, neurologists, and psychiatrists found no statistically significant differences among disciplines in outcomes of care, satisfaction, or costs of care, but did find significant differences in the types of medications most often prescribed (McNett et al., 2011). The historical predominance of anesthesiology in the pain medicine field—for example, many early pain clinics were established by anesthesiologists using nerve block techniques (Manchikanti, 2000, p. 133)—may affect the scope of services available to patients.

The confusing state of pain medicine has led some physicians and organizations to support the development of a new, inclusive pain care specialty not under the aegis of any particular medical discipline (Dubois et al., 2009). Perceived advantages of creating an independent pain specialty are a more coherent voice and the ability to advocate for a consistent training curriculum and promote greater continuity of care. For example, a unified specialty would be better positioned to persuade third-party payers to adopt reimbursement practices that are aligned with best pain care practices. Other than the logistical difficulties, possible disadvantages of creating an independent pain specialty might include loss of the cross-fertilization enabled by the involvement of several specialty groups with a history of and experience with providing pain care.

Interdisciplinary teams. Ideally, most patients with severe persistent pain would obtain pain care from an interdisciplinary team, as opposed to a specialist who might focus on a narrow range of treatments and have a restricted view of how pain is affecting the patient. The interdisciplinary model incorporates assessment and diagnosis, not just therapy. It is an integrated, coordinated, and multimodal approach to care targeting multiple dimensions of the chronic pain experience—including disease management, reduction in pain severity, improved functioning, and emotional well-being and health-related quality of life—that is developed through a comprehensive evaluation by multiple specialists (usually physicians, nurses, psychologists or other mental health professionals, rehabilitation specialists, and/or complementary and alternative medicine [CAM] therapists). In the primary care setting, the team most often includes a primary care practitioner, nurse, and mental health clinician. In specialty and tertiary care settings, this team approach most often emphasizes psychological, pharmacological, and rehabilitation approaches.

An interdisciplinary approach is hardly unique to pain care. It also is used, to beneficial effect, in palliative care, rehabilitation, critical care, mental health, and geriatrics (Paice, 2005). Interdisciplinary approaches for chronic pain have been supported by numerous studies from many different countries and study populations, including

- systematic reviews of treatment and rehabilitation for low back pain (Guzmán et al., 2001; van Middelkoop et al., 2011);
- a meta-analysis of five Scandinavian studies involving low back pain, using return to work as the outcome measure (Norlund et al., 2009);
- a general examination of chronic pain in the elderly (Corran et al., 2001);
- a study of costs of treating low back pain in Belgium and the Netherlands (Van Zundert and Van Kleef, 2005);
- a Mexican study of patients with noncardiac chest pain, more than half of whom were found to have psychiatric disorders (Ortiz-Olvera et al., 2007);
- developers of consensus guidelines on managing chronic pelvic pain in Canada (Jarrell et al., 2005);
- a study of fibromyalgia treatment (Lemstra and Olszynski, 2005);
- a prospective study of treatment for complicated chronic pain syndromes in adults (McAllister et al., 2005);
- a study of family satisfaction with care for abdominal pain in children (Schurman and Friesen, 2010); and
- an examination of a disease management program for people with pain and psychiatric disorders who previously were treated with opioids (Chelminski et al., 2005).

Several examples illustrate the effectiveness of team approaches to pain care. An initiative within the Department of Veterans Affairs is testing the value of a collaborative support team involving a case manager and specialist consultant, who communicate with primary care providers by their preferred method—generally e-mail or telephone (Dobscha et al., 2007). Another example comes from England, where a randomized controlled trial found that implementing a cognitive-behavioral intervention consisting of up to six group therapy sessions was effective and cost-effective in managing subacute and chronic low back pain in primary care (Lamb et al., 2010). A Department of Veterans Affairs intervention called Assistance with Pain Treatment, led by a psychologist care manager and an internist, reduced pain among primary care patients through clinician and patient education, assessment, symptom monitoring, feedback to clinicians, and referrals to specialists (Dobscha et al., 2009). For pain associated with sickle-cell disease, useful models include day hospitals and other alternatives to emergency departments (EDs) that focus on multipronged assessment and continuous, individualized care (Benjamin, 2008). An example not involving a team per se would be a strong referral network giving primary care practitioners access to multimodal treatment resources for direct consultation and for referral of at-risk patients, including those at psychosocial risk.

Specialists often differ significantly in the ways they practice. Even in multidisciplinary settings, pain specialists may collaborate actively, or they may seldom embrace collaboration or may even exclude patients whose pain cannot be managed through the specialist's preferred modality or type of intervention. In any event, given the low numbers of pain specialists, they should serve not only as direct care practitioners but also as resources to help educate primary care practitioners about how to assist patients with relatively easy-to-manage pain.

Pain Centers

Primary care physicians and specialists who are uncomfortable treating pain or whose efforts are unsuccessful may refer patients to pain centers. In a truly interdisciplinary pain center, a coordinated team of health professionals performs a comprehensive assessment of the pain problem and its impact on the patient and family, and then implements a management plan that usually involves several therapeutic modalities. These modalities may include medications; physical therapy; psychological therapies, such as cognitive-behavioral therapy; and other treatments designed to intervene in the biological, psychological, and social aspects of the pain experience.

The number of pain centers grew in the latter part of the 20th century, largely in academic medical centers and other hospital and nonhospital settings, focused on serving patients with complex pain problems. However, not all care that takes place in pain centers is interdisciplinary, and some "pain clinics" make no attempt to provide a broad range of modalities. Indeed, formal criteria do not exist for defining what a "pain clinic," "pain center," or "pain program" is, and thus these terms can be confusing or mean different things to different providers or constituencies. The Commission on Accreditation of Rehabilitation Facilities currently accredits only about 122 pain treatment facilities offering interdisciplinary approaches. Only three of these thus far are veterans' facilities, despite the Department of Veterans Affairs' important role in pain care. The American Academy of Pain Management accredits some 46 individuals and centers (American Academy of Pain Management, 2011). A tightening of accreditation standards during the late 1990s and 2000s may have led to reductions in the number of accredited centers, although many centers function without accreditation and refer to themselves as "pain clinics," adding to the confusion. In addition, reluctance on the part of insurance carriers to reimburse multimodal pain center care can challenge the viability of some interdisciplinary pain centers.

Outcome data on the effectiveness of care provided by pain centers are severely limited, whether effectiveness is measured in terms of lower pain severity scores or improved functioning, such as return to work. Not all pain centers are subject to review or oversight, and quality likely varies markedly from center to center. The outcome data that do exist on the effectiveness of multidisciplinary pain center care show consistent benefits; for example, such care is more effective than surgery in helping people with back problems return to work and increase their activity (Boris-Karpel, 2010). Even modest benefits could be considered an impressive result given that patients usually are referred to a pain center only after other treatments have failed, and their pain is at a severe and recalcitrant level.

People generally visit pain centers after a lengthy experience with pain—7 years on average according to an early study (Flor et al., 1992). By this point, pain has permeated most aspects of a person's life and for many has led to emotional distress or psychiatric conditions, so that care clearly must address psychosocial needs (Turk et al., 2010). This is not to imply that psychological factors caused the pain; in most patients with both pain and psychiatric conditions, the pain came first (Fishbain et al., 2010). As discussed in Chapter 1, however, a preexisting mental health problem may affect pain severity (Arnow et al., 2006). In some cases, successfully treating the pain relieves the emotional distress, while in other cases both conditions require treatment.

Choice of a Treatment Approach

The choice of a treatment approach depends first and foremost on whether the pain being experienced by the patient is acute or chronic. For each of these broad categories of pain, multiple factors must then be considered.

Acute Pain

As described in Chapter 1, acute pain is of recent onset, is likely to be short in duration, and is usually caused by an identifiable injury or disease. Acute pain is most often a symptom or result of tissue injury, a surgical procedure, inflammation, childbirth, or a brief disease process (Zeller et al., 2008). When acute pain is predictable, as with surgery, childbirth, or removal of a chest tube, health professionals can reduce distress by providing patients with information about typical steps and feelings they are likely to experience (Puntillo and Levy, 2004). Diagnosing the reason for acute pain is essential for selecting an optimal treatment regimen, which should take into account factors related to the pain itself, the individual, and his or her environment (Box 3-1). Initial acute pain management may include

- pharmacologic therapy, for example, with analgesic drugs;
- advice, reassurance, or distraction delivered by a health professional;
- formal psychological interventions, including stress and tension reduction and cognitive-behavioral interventions;

BOX 3-1
Factors Affecting the Choice of Treatment for Pain

Pain-Related Factors

- the known likely source of pain, such as an arthritic joint;
- the location, intensity, frequency, duration, and recurrence pattern of the pain;
- pain descriptors, such as cramping, burning, and aching;
- situations that make the pain more or less intense; and
- impact of the pain on daily life, including eating, sleeping, activities, relationships, recreation, and attendance and performance at school or work.

Individual-Related Factors

- health status, other medical or neurological conditions, and psychological state (e.g., depression or anxiety);
- genetic factors (sometimes referred to as bioindividuality), such as a predisposition to migraines or response to specific treatments;
- age, gender, race, and ethnicity;
- patient preferences, temperament, and personality, including readiness to engage in disciplined self-management;
- history of pain, trauma, abuse, and other major life events and stressors (e.g., divorce, unemployment);
- financial means, health insurance coverage, and other factors affecting access to care;
- likely adherence to prescribed treatments, including medications, physical therapy, and diet;
- health beliefs—for example, that drugs or doctors can solve even the most difficult health problems or, conversely, that medications often prescribed for persistent pain are too dangerous;
- cultural, spiritual, and religious beliefs; and
- level of health literacy or English proficiency and cognitive, speech, hearing, or visual impairments that can affect communication with care providers.

Environmental Factors

- living and work situations and associated risks of injury and physical and emotional strain;
- the context of pain, that is, where the person is and what he or she is doing when pain occurs;
- family history and modeling of disease and wellness behavior and its reinforcement or suppression of pain behavior;
- coping resources, including support from significant others and adequate financial support;
- cultural background and involvement, community response, and support from other people;
- information obtained from the Internet, other media, and other people; and
- past experiences with health care providers.

- physical therapies, such as resting the affected part of the body, application of heat or ice, manual and massage therapies, and structured physical activity; and
- local electrical stimulation, nerve blocks, or trigger point injections to treat muscle spasms.

Chronic Pain

A common source of frustration for chronic pain patients, their families, and clinicians is that it is often impossible with today's knowledge to predict which treatment or combination of treatments will work best in an individual case, even when the factors listed in Box 3-1 are fairly well known. Many patients are not told, or do not readily comprehend, that the road to finding the right combination of treatments for them may be a long one with many different approaches to treatment until the right match is found. This lack of mutual understanding—reflecting inadequate patient–clinician communication and sometimes inadequate clinician education and training—can lead patients to change practitioners repeatedly (doctor-shop) or try a series of unsubstantiated remedies.

Mutual understanding between clinicians and patients is important in pain care. For example, a trusting relationship with a practitioner was found to improve outcomes for patients treated with a placebo for pain (Kaptchuk et al., 2008). The clinician's understanding of the impact of the painful disorder on the physical, emotional, and social aspects of the person's life is critical to making the best management and treatment decisions. Even a single structured, 30-minute communication/education session with a health professional can help a patient overcome misperceptions about pain and pain care (Smith et al., 2010). Gaining this understanding often requires a relationship with the patient beyond brief consultations, a delicate balancing act for clinicians who want to encourage realistic hope in the face of what may be a series of treatment failures.

Similarly, while people with pain should be encouraged to engage in "self-management," they should not be burdened with the impression that failing to control the pain is somehow their fault or responsibility. It is possible that more intense and focused attention to the individual, similar to care management or disease management, could point the way out of this dilemma. People who present frequently for pain care and receive many different treatments might, like other frequent users of health care, benefit from a strong commitment by a team or practitioner focused on comprehensive care, rehabilitation, and increased functioning (Gawande, 2011).

In general, an integrative approach to persistent and severe pain is beneficial, but even an integrative approach may fail large numbers of patients. In addition, the history of pain care suggests that it may be wise to temper enthusiasm for any single approach. Just as pain care has evolved in recent years from being routinely overlooked, to utilizing treatment with opioids or other single-modality interventions, to applying today's integrative model, future biomedical advances and an improved understanding of social factors will bring further changes.

One possible change, for example, is more attention to psychosocial factors. Current treatment options sometimes have only limited effectiveness; require the motivation and patience of the individual to adhere to exercise or physical therapies or other regimens that are part of a multimodal approach; and, in the case of many pain medications, have unpleasant side effects. The biopsychosocial approach, combining physical and emotional factors in assessing and treating chronic pain, offers a uniquely valuable clinical perspective (Flor and Hermann, 2004). This mind–body perspective is now generally accepted by pain researchers (Gatchel et al., 2007) and has been found useful by clinicians in various disciplines, such as osteopathic medicine (Penney, 2010), rheumatology (Johnson, 2009), and physiotherapy (George, 2008). It has improved the pain care of patients with conditions ranging from multiple sclerosis (Kerns et al., 2002) and muscular dystrophy (Miró et al., 2009) to low back pain (Guzmán et al., 2002), exercise-induced shoulder pain (George et al., 2008), and musculoskeletal pain in general (Vranceanu et al., 2009). It benefits populations ranging from children (von Baeyer, 2007)—partly because children with pain often have parents with pain (Schanberg et al., 2001)—to the elderly (Zagaria, 2008). As an example of the application of this approach, evidence that psychological factors predispose patients to persistent pain following surgery could lead to routine screening for psychological risk factors for pain and timely interventions designed to prevent their adverse effects. The growing literature showing that cultural factors influence pain and patients' engagement in pain treatments (see Chapter 2) similarly could lead to increased efforts to deliver care in more culturally appropriate and competent ways.

The committee notes how best practices evolve with new knowledge. Two examples illustrate this point. A hundred years ago, tuberculosis was a disease with a complex complement of psychosocial correlates equal to that of chronic pain today, and 50 years ago, peptic ulcers were believed to be caused by emotional stress. When tuberculosis could be cured with antibiotics and the *H. pylori* bacterium was identified as the main and treatable cause of most peptic ulcers, these diseases largely emerged from their psychosocial contexts.

Access to Pain Care

Not all Americans have the same access to pain care. As discussed in Chapter 2, significant numbers are at risk of undertreatment, especially those from racial and ethnic minorities, women, and the elderly. Lack of insurance, insurance limits, employment pressures, and other factors also can reduce access.

In addition, EDs are a common site of pain care. A busy hospital ED would appear to be one of the least promising care sites for chronic pain patients, given the multiple factors involved in assessing such pain and devising a treatment strategy and the desirability of developing a continuing patient–clinician partnership. In 2007, almost half of ED patients presented with pain that was severe (22 percent) or moderate (23 percent) (Niska et al., 2010) (chest or abdominal pain was the leading reason for the visit among those aged 15-64, while chest or abdominal pain plus shortness of breath was the leading reason for the visit among those 65 and older).

Such frequent use of EDs for pain care may in part reflect difficulties in surmounting financial, geographic, and cultural barriers affecting access to ambulatory care; for many Americans, EDs are a safety-net provider (IOM, 2007a). In addition, EDs are open all hours and are legally bound to turn no one away without a clinical assessment. They provide diagnostic and screening services (such as x-rays, head scans, and cultures), procedures (such as splints, wraps, and laceration repairs), medications, and admission to the hospital when necessary.

Other than EDs, hospitals are a site of pain care, often because of the acute pain that may follow a surgical procedure. There were 10 million inpatient surgeries and 17.4 million hospital outpatient surgeries in 2009 (AHA, 2011). Between 10 and 50 percent of people having common surgical operations—groin hernia repair, breast and thoracic surgery, leg amputation, and coronary artery bypass surgery—go on to experience chronic pain, often due to damage to nerves in the surgical area during the procedure (Kehlet et al., 2006). Today's shorter hospital stays—down, on average, from 7.2 days in 1989 to 5.4 days in 2009 (AHA, 2011)—and the trend toward outpatient surgery may not permit sufficient opportunity to assess patients' postsurgical pain or establish an appropriate course of postoperative analgesia (perhaps one that can be administered at home), shown to be effective in hip and knee replacement, for example (Schug and Pogatzki-Zahn, 2011). Hospitals also are challenged to manage the high rate of unscheduled admissions (between 14 and 26 percent) due to uncontrolled pain among cancer patients.

However, the logic of health care financing focuses some hospitals on implementing pain care initiatives to reduce lengths of stay or to prevent admissions. For example, an initiative to better manage chest pain reduced the average length of stay in one hospital from 2.36 to 1.88 days and saved the hospital almost $320,000 in the first year (Gottlieb et al., 2010). A model is being developed to predict which patients are most likely to have severe pain so that resources can be targeted toward them; they tend to be orthopedic or general surgical patients, as opposed to medical patients (Levitan, 2010), and patients with severe acute pain following surgery (Schug and Pogatzki-Zahn, 2011).

TREATMENT MODALITIES

> *We cannot successfully treat the complexity of pain without treating the whole patient. Insurance companies will pay for useless, expensive procedures and surgeries but won't pay for simple cognitive-behavioral therapy and physical rehab therapy.*
>
> —A clinical pharmacy specialist[3]

Many forms of treatment are used to help patients who present with pain. Treatment modalities frequently used by physician pain specialists and other practitioners include

- medications,
- regional anesthetic interventions,
- surgery,
- psychological therapies,
- rehabilitative/physical therapy, and
- CAM.

Medications

The range of medications used for pain is expansive (Turk et al., 2011). The most common are nonopioid analgesic drugs (acetaminophen; nonsteroidal anti-inflammatory drugs, including COX-2 inhibitors; ibuprofen; and aspirin), opioids, and a plethora of so-called "adjuvant analgesic drugs" that encompass medications used for other indications that also are used to manage pain. Most often these adjuvant medications are in the anticonvulsant (Dworkin et al., 2010) or psychotropic classes (Attal et al., 2006; Kroenke et al., 2009a). A few additional drug classes and compounds further illustrate the range: mu-opioid agonists, serotonin and norepinephrine reuptake inhibitors, and muscle relaxants (Arnold et al., 2000).

The rising rate of reported chronic pain (see Chapter 2) has been accompanied by a rise in the rate of adults reporting the use of prescription drugs for pain, the most controversial of which are the opioids. National Health and Nutrition Examination Survey (NHANES) data show that during the 7-year period 1988-1994, 3.2 percent of Americans reported using opioids for pain (2.8 percent of men and 3.6 percent of women). During the 4-year period 2005-2008, by contrast,

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[3] Quotation from response to committee survey.

5.7 percent of the population was using these drugs (5.2 percent of men and 6.2 percent of women), including 7 percent of people 65 and older.[4]

In 2007, about 2.3 billion drugs were provided or prescribed during patients' visits to their physicians, according to physician-provided reports to the National Ambulatory Medical Care Survey.[5] Aspirin (usually thought of as an analgesic, but also an antiplatelet agent) was mentioned most frequently by the physicians, associated with 55 million patient visits. Other pain medications among the 20 drugs most frequently mentioned were ibuprofen, acetaminophen-hydrocodone, and acetaminophen (Hsiao et al., 2010).

Similarly, data from the National Hospital Ambulatory Medical Care Survey indicate that in hospital EDs, the most common drug category used is analgesics, which accounted for 36 percent of drugs reported in 2007 (Niska et al., 2010).[6] The most common drugs mentioned in connection with ED visits were three analgesics: ibuprofen, acetaminophen-hydrocodone, and acetaminophen. Five other analgesics were among the top 20 drugs mentioned: keterolac, morphine, hydromorphone, acetaminophen-oxycodone, and aspirin. Acetaminophen-hydrocodone, an opioid anti-inflammatory drug compound, was mentioned in reports of 26 million physician office visits and 13 million ED visits. When patients were discharged from the ED, the leading drugs prescribed were acetaminophen (alone or with hydrocodone or oxycodone) and ibuprofen (Hsiao et al., 2010).

Issues and problems in developing new drugs for pain conditions, many of which relate to the high costs of drug development, are discussed in Chapter 5. Briefly, they include the unfavorable economics of developing drugs that may help only a small number of people, problems in finding the required animal models, lower international prices, competition from generics, high failure rates of new drugs in clinical trials, and tough new regulatory standards. Indeed, much pain medication development in the last decade has not involved novel therapies but merely reformulated existing drugs.

It is also important to recognize that some medications may actually cause pain. For example, the statins—an important class of drugs that reduces cholesterol and thus the morbidity and mortality from heart disease—were used by an estimated 8.2 million Americans aged 40 and older in 1999-2002 (Buettner et al.,

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[4] Personal communication, J. Madans, Associate Director, Science, National Center for Health Statistics, Centers for Disease Control and Prevention, February 8, 2011.

[5] The National Ambulatory Medical Care Survey is a national survey of nonfederal office-based physicians engaged primarily in direct patient care. It has been conducted continuously since 1989. Physician offices record data for a systematic random sample of patient visits, including symptoms, diagnoses, and medications ordered. See http://www.cdc.gov/nchs/ahcd.htm.

[6] The National Hospital Ambulatory Medical Care Survey collects data on the utilization and provision of services in nonfederal, short-stay hospital EDs (and other sites). ED staff complete patient record forms for a systematic random sample of patient visits, including reasons for the visit, diagnoses, and medications. See http://www.cdc.gov/nchs/ahcd.htm.

2008). Between 9 and 20 percent of statin users reported muscle pain, including lower extremity pain and low back pain. Similarly high rates were confirmed in a study using NHANES data. The additional significance of these findings is that painful side effects may reduce cardiovascular patients' willingness to adhere to their cholesterol drug regimen.

Regional Anesthetic Interventions

Regional anesthetic interventions are invasive and include a variety of treatments, such as sacroiliac joint injections; epidural steroid injections to manage radicular pain (pain radiating along a nerve as a result of irritation of the spinal nerve root, such as sciatica); cervical, thoracic, and lumbar facet joint nerve blocks; or implantation of devices that deliver analgesic medications directly to the spinal canal (Manchikanti et al., 2010).

The usefulness of some of these therapies may be doubtful. A systematic review of interventional therapies for low back and radicular pain concluded: "Few non-surgical interventional therapies for low back pain have been shown to be effective in randomized, placebo-controlled trials" (Chou et al., 2009a, p. 1078). A systematic review of 18 randomized controlled trials found no strong evidence for or against using injection therapy to treat subacute or chronic low back pain (Staal et al., 2008). However, the reviewers suggest that some specific types of patients might benefit. That said, a review of 30 trials determined that corticosteroid injections (and traction) were not found to be beneficial and are not recommended for lumbosacral radicular syndrome (Luijsterburg et al., 2007). Finally, a global discussion of pain treatments notes that the implantation procedures of spinal cord stimulation and intrathecal drug delivery systems—so-called "pain pumps"—require routine monitoring, replacement of devices over time, refilling of drug reservoirs, and a balancing of high costs and maintenance requirements against benefits (Turk et al., 2011).

Surgery

Surgical therapies overlap with interventional techniques, such as implantation of spinal cord stimulation systems and spinal analgesic infusion pumps, but include more invasive procedures, such as spinal decompression procedures (e.g., laminectomies, discectomy), disc replacement, and spinal fusion, which are used to treat neck, low back, and radicular pain. Joint replacement surgery is another frequently used surgical intervention for pain. Others include nerve decompression (e.g., for carpal tunnel syndrome or trigeminal neuralgia) and ablative surgeries that disrupt the flow of nociceptive pain in the nervous system, such as nerve section (neurectomy or rhizotomy) and cordotomy. Surgery usually is undertaken only after other treatments fail, and different procedures vary in their effectiveness (Chou et al., 2009b).

Access to high-cost treatments such as spine surgery or hip, knee, and shoulder replacement surgeries varies by race and geography. Even with less-than-universal access to these procedures, however, their frequency has grown markedly. Medicare data show that between 2000-2001 and 2005-2006, the number of hip replacements grew by 15 percent, the number of knee replacements by 48 percent, and the number of shoulder replacements by 67 percent. A portion of these surgeries results from Americans' increased longevity; people outlive their joints and need to have them replaced.

As with many other procedural interventions, wide geographic differences exist in the rates at which such procedures are performed. These differences are associated with service availability and practice patterns and preferences within the local health care system (Gawande, 2009) and are not an indicator of treatment efficacy. As Table 3-1 indicates, rates among cities varied four-fold during 2005-2006 for hip replacements, ten-fold for shoulder replacements, and nearly four-fold for knee replacements. Likewise, African Americans are only a little more than half as likely as whites to receive any of these elective procedures.

These geographic and racial differentials raise important questions about both potential overuse and underuse: Is everyone who could benefit being offered a procedure, or are some people having "a procedure that they might choose to delay or forgo if they had received balanced information on risks and benefits?" (Fisher et al., 2010, p. 1). Fisher and colleagues offer potential explanations for the differentials: that physicians in some areas may be stronger advocates for a procedure, leading to overuse; that some geographic areas may lack the skilled clinicians or sophisticated hospital facilities required, leading to underuse; or that the black–white differential may reflect individual preferences, since there is evidence that African Americans with severe osteoarthritis of the knee prefer more conservative, nonsurgical treatment (Figaro et al., 2004).

Psychological Therapies

Psychological therapies include cognitive-behavioral treatment, behavioral treatment alone, biofeedback, meditation and relaxation techniques, and hypno-

TABLE 3-1 U.S. Cities with Lowest and Highest Rates of Joint Replacement Surgeries per 1,000 Medicare Beneficiaries, 2005-2006

Procedure	Lowest Rate per 1,000 Medicare Beneficiaries	Highest Rate per 1,000 Medicare Beneficiaries
Hip replacement	Bryan, Texas (1.8)	Ogden, Utah, (7.2)
Shoulder replacement	Syracuse, New York (0.3)	Provo, Utah (3.0)
Knee replacement	Manhattan, New York (4.0)	Lincoln, Nebraska (15.7)

SOURCE: Fisher et al., 2010.

sis. These therapies reflect the biopsychosocial model of pain discussed earlier and are supported by a long line of psychological research (Kerns et al., 2011).

A meta-analysis found positive effects for psychological approaches in reducing pain intensity, improving functioning and quality of life, and curtailing depression (Hoffman et al., 2007). Another meta-analysis, limited to treatment of arthritis, also found that patients receiving psychosocial interventions reported significantly lower pain levels (Dixon et al., 2007). A 10-year study involving more than 1,000 pain patients showed that between one in three and one in seven patients benefited from a 4-week inpatient cognitive-behavioral treatment program (Morley et al., 2008). On the other hand, a meta-analysis of 30 randomized controlled trials involving chronic low back pain showed that while behavioral therapy was more effective than usual care in the short term, it was no more effective than group exercise in the intermediate to long term (Henschke et al., 2010). One brief survey of the evidence supports the notion of individualization of psychological therapies:

> There is insufficient evidence to recommend any one (psychological) therapeutic approach or modality over another. It is reasonable to consider the possibility that patients with different characteristics might derive benefits from treatments with different foci and targets. (Turk et al., 2011, p. 16)

Rehabilitative/Physical Therapy

Rehabilitative/physical therapy is undertaken in inpatient, ambulatory care, and home-based settings. Inpatient pain rehabilitation programs are interdisciplinary, include a physical medicine and rehabilitation component, and provide education as well as treatment. A meta-analysis found such programs achieved significant reductions in both pain intensity and use of pain medications (Hoffman et al., 2007). Rehabilitation methods available to patients living at home or in other settings include stretching, strengthening, and mobility exercises. Heat therapy and mechanical traction also have been used. Rehabilitative/physical therapy has increasingly been found to reduce pain even in end-of-life situations, such as advanced cancer (Chang et al., 2007), although consistent adherence to exercise regimens may be difficult for many patients. Exercise also has been shown to be effective in reducing persistent pain due to osteoarthritis of the knee (Fransen and McConnell, 2009).

A systematic review of 18 randomized controlled trials showed that physical conditioning programs "seem to be effective in reducing the number of sick days for some workers with chronic back pain, when compared to usual care" (Schonstein et al., 2003, p. 1). The programs must comprise cognitive-behavioral treatment and intensive aerobic physical training (for muscle strength, endurance, and coordination), relate to the person's work, and be directed by a physiotherapist or interdisciplinary team. The review found no evidence to support exercise programs for acute back pain.

A meta-analysis of 20 studies showed that exercise had a statistically significant effect in reducing disability for work over the long term but not over the short or intermediate term (Oesch et al., 2010). The analysts did not find support for any particular exercise approach over others. In a systematic review of 43 studies of exercise for chronic low back pain, the researchers concluded that only 6 showed statistically significant and clinically important results in improving functioning, and only 4 showed such results in reducing pain intensity (van Tulder et al., 2007). The authors comment that many studies focus only on the statistical significance of results rather than on clinical importance, so some studies misleadingly label findings as positive.

Physical modalities of therapy include physical and functional restoration techniques, massage ultrasound, and neurostimulators (such as transcutaneous electrical nerve stimulation, or TENS). Other modalities include dry land physical therapy and aquatherapy.

Complementary and Alternative Medicine

Definitions of CAM differ. For example, a study of CAM in hospices identified practices as diverse as massage therapy, supportive group therapy, music therapy, pet therapy, and guided imagery or relaxation, not all of which are usually associated with CAM (Bercovitz et al., 2011). Acupuncture, chiropractic spinal manipulation, magnets, massage therapy, and yoga often are considered CAM pain treatments. According to the National Institutes of Health's (NIH) National Center for Complementary and Alternative Medicine, additional CAM therapies used for pain include dietary supplements, such as glucosamine and chondroitin intended to improve joint health; various herbs; acupuncture; and mind–body approaches, such as meditation and yoga (NIH and NCCAM, 2010).

CAM holds special appeal for many people with pain for several reasons:

- deficits in the way that many physicians treat pain, using only single modalities without attempting to track their effectiveness for a particular person over time or to coordinate diverse approaches;
- the higher preponderance of pain in women (see Chapter 2), given that "women are more likely than men to seek CAM treatments" (IOM, 2005, p. 10); and
- a welcoming, less reserved attitude toward people with pain on the part of CAM practitioners and an apparent willingness to listen to the story of a patient's pain journey.

Whatever the reasons, pain is a common complaint presented to CAM practitioners (NIH and NCCAM, 2010). In 2007, 44 percent of people with pain or neurologic conditions sought help from CAM practitioners (Wells et al., 2010). In 2002, three-fifths of people who turned to CAM for relief of back pain found a "great deal" of benefit as a result (Kanodia et al., 2010). The National Center for Complementary and Alternative Medicine's strategic plan, released in February 2011, supports the development of better strategies for managing back pain, in particular.

However, a single CAM practice, like a single type of medical treatment, may not be as beneficial as an integrated approach. It is unclear which types of patients—defined on the basis of pain condition, attitude, or other characteristics—stand to benefit most from CAM treatments for pain.

For which pain conditions are CAM treatments most often used? In the 2007 National Health Interview Survey (NHIS), adults reported using CAM in the previous year most often to treat various musculoskeletal problems. Just over 17 percent of adults—more than 14 million Americans—used CAM for back pain/problems, almost 6 percent (5 million) for neck pain/problems, 5 percent for joint pain/stiffness (5 million), and **44 percent specifically for arthritis (3 million)**. An additional 1.5 million used CAM for other musculoskeletal problems, 1 million for severe headache or migraine, 11 million for "regular headaches," and 0.8 million for fibromyalgia (Barnes et al., 2008). Rates of reported use of CAM for these conditions had remained relatively unchanged since 2002. Even among children, NHIS data show that CAM therapies are used most often for back or neck pain (7 percent of all children).[7]

CAM treatments lie outside the traditional medical model, and research on their effectiveness for specific pain conditions is incomplete but accumulating. For example, reviews of research on acupuncture, massage, and chiropractic spinal manipulation for chronic low back pain suggest these therapies may be beneficial, whereas results are mixed as to whether the popular dietary supplements glucosamine and chondroitin sulfate can relieve osteoarthritis pain. Evidence regarding the effectiveness of static magnets, widely marketed for pain control, does not support their use. Systematic reviews show that spinal manipulation for low back pain is more effective than sham manipulation, bed rest, or traction, but not more effective than analgesics, physical therapy, exercise, or "back-school" education (Tan et al., 2007). Evidence also supports the use of massage therapy for low back and shoulder pain and suggests it may benefit patients with fibromyalgia and neck pain.

Acupuncture appears to affect several mechanisms in the brain and spinal cord, including those involved in pain and inflammation. A systematic review supports its use in postoperative pain management (Sun et al., 2008). Likewise, a German clinical trial involving more than 3,000 patients with chronic low back pain found that acupuncture improved functioning (Witt et al., 2006). A system-

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[7] Consensus standards have been developed for identifying core outcome domains for pediatric pain studies because children have different ways of expressing pain intensity or experiencing changes in functioning (McGrath et al., 2008).

atic review of 11 studies suggests that acupuncture may be clinically valuable in treating tension headaches (Linde et al., 2009).

Research on acupuncture has been controversial. Of interest, a systematic review of 23 clinical trials found moderate evidence that acupuncture and sham acupuncture are, in roughly equal measure, more effective than no treatment for chronic low back pain (Yuan et al., 2008). This finding is consistent with evidence from a rigorous German study (Haake et al., 2007). The success of sham acupuncture, in which needles are inserted in the body but not at acupuncture points and usually not with stimulation, has led to debates among researchers and clinicians about the value of placebos (Berman et al., 2010) (see the next section). Some critics of studies finding a lack of efficacy for acupuncture contend that the study findings are based only on criteria of Western medicine, not those of traditional Chinese medicine (Chiang et al., 2010).

Evidence on the effectiveness of CAM in treating children's pain is not yet robust, although the available findings suggest that hypnosis, music therapy, acupuncture, laughter therapy, and massage therapy have been beneficial for acute procedural pain in children (Evans et al., 2008). A systematic review found sufficient evidence to support only one CAM approach in children—the use of self-hypnosis/guided imagery/relaxation for recurrent headache (Tsao and Zeltzer, 2005). A review of 23 randomized controlled trials and 8 meta-analyses on acupuncture for children found "evidence of some efficacy and low risk," with the greatest effectiveness found in preventing postoperative nausea (Jindal et al., 2008, p. 431). The authors caution, however, that "because acupuncture's mechanism is not known, the use of needles in children becomes questionable" (Jindal et al., 2008, p. 432). A study of 45 children found their expectations for benefits from CAM to be fairly low, and those of their parents only somewhat higher (Tsao et al., 2005).

Note on the Use of Placebos

Placebos conceivably could be considered a form of treatment of pain, especially in light of the shortcomings of other modalities or other benefits they bring in their own right. Even though placebos are believed to have no specific pharmacologic effects, researchers and clinicians have found that some people with pain have reduced symptoms after taking them and that at times, a placebo performs as well as—or better than—other treatments (see the above discussion of sham acupuncture). Furthermore, a placebo effect has been observed in the management of a variety of nonpain disorders, suggesting that placebos have an effect that is yet to be fully understood on a scientific basis. A recent survey showed that many physicians already use placebos, in one form or another, in clinical practice (Tilburt et al., 2008), although the ethics of such use, when it involves deception, are rigorously disputed (Nichols et al., 2005). Certainly placebo should not be used as a diagnostic tool or to validate whether a patient's reported pain "is real or not."

Neuroimaging studies show that placebos reduce activation of opioid neural transmission in pain-sensitive regions of the brain, which suggests that they do have biological effects (Qiu et al., 2009). According to Tracey (2010, p. 1277), the "placebo effect" is "a genuine psychobiological event attributable to the overall therapeutic context in which a treatment is given, which itself comprises many factors such as patient-physician interaction and treatment environment."

One factor in the success of a placebo—or any pain treatment, for that matter—is the prescriber's empathy or skill in communicating with the patient. Evidence suggests that for patients treated with placebo pills, a positive relationship with a practitioner improves outcomes (Kaptchuk et al., 2008) and, in a sense, engages the brain to help in pain control by instilling optimism and confidence. Because placebo use could undermine trust, Kaptchuk and colleagues (2010) told patients they were receiving a placebo, and the treatment still produced statistically significant improvements in terms of mean global improvement scores, reduced symptom severity, and adequate relief at both an 11-day midpoint and 21-day endpoint (Kaptchuk et al., 2010).

SELECTED ISSUES IN PAIN CARE PRACTICE

> *It's a relief to finally have names for my conditions after suffering most of my life with a myriad of symptoms.*
>
> — A woman with fibromyalgia, vulvodynia, and interstitial cystitis[8]

Issues in pain care discussed in this section of the chapter are difficulties in measuring pain, the adequacy of pain control in hospitals and nursing homes, pain and suffering at the end of life, access to opioids and concerns about their use, insurance incentives, and the reporting of pain.

Difficulties in Measuring Pain

As discussed in Chapter 1, the experience of pain is influenced by a range of physical, psychosocial, and behavioral factors. There is growing consensus that these factors include many of those listed earlier in Box 3-1: (1) genetic composition; (2) physical pathology associated with a trauma or disease; (3) alterations in the peripheral and central nervous system attributable to the initial insult (peripheral and central sensitization); (4) psychological contributors, including prior pain his-

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[8] Quotation from submission by Peter Reineke of stories from the membership of patient advocacy groups.

tory and available coping resources (e.g., emotional support, financial resources, acquired coping skills); and (5) environmental influences (e.g., response by significant others, disability compensation, features inherent in the workplace). All of these factors likely interact and are important considerations in measuring pain.

The general goals of a pain evaluation, from both the clinician's and the patient's point of view, are to (1) arrive at a medical diagnosis, (2) determine whether additional diagnostic testing is needed, (3) make a judgment about the extent to which medical data adequately explain the patient's symptoms and the severity of his or her apparent incapacitation, (4) determine whether there is any appropriate treatment (i.e., treatment directed toward reversing a pathophysiologic process) that has a reasonable chance of helping, (5) determine whether there are any symptomatic treatments that should be prescribed if a reversal of pathophysiology is not possible, and (6) establish the objectives of treatment. The depth of assessment in these areas will depend on the circumstances. For example, a trauma patient in an ED will receive a much different assessment from that of a person with a 5-year history of back pain being evaluated at an interdisciplinary pain clinic.

A large number of measures have been developed with which to assess mood and physical functioning. Reliable and validated self-report measures of pain and of emotional and physical functioning are available for different populations. These measures are age- and disease-appropriate and appropriate at the level at which patients—for example, children or nursing home residents—are able to communicate. In addition to self-report measures, clinicians make their own careful observations of the patient, and, depending on circumstances, may call on other clinicians, such as physical or occupational therapists, to evaluate objective factors such as range of motion.

Health professionals' general awareness of the importance of pain and recognition of the need to ask patients about it have been buttressed by efforts of the Joint Commission to establish and enforce pain management standards (Phillips, 2000). Beginning in 2001, following the lead of pain medicine professional associations and the Department of Veterans Affairs, the then Joint Commission on Accreditation of Healthcare Organizations introduced a new hospital accreditation standard that requires monitoring of patients' pain level as a "fifth vital sign." This means that physicians and nurses are expected to measure hospital patients' pain as regularly as they measure the four traditional vital signs: blood pressure, pulse rate, temperature, and respirations.

Under this approach, patients are asked to assess their pain on a numeric scale from zero (no pain) to 10 (worst possible pain). These pain intensity scores indicate whether, and how quickly, pain needs to be treated and can be tracked over time to assess healing and effects of treatment. The Joint Commission's effort quickly led to clinically appropriate increases in opioid use in postanesthesia care units (Frasco et al., 2005). It also led many health facilities to implement routine efforts to relieve patients of pain immediately, identify and address causes of pain, initiate treatments other than medication, and prevent postsurgical acute pain from developing into chronic pain.

The full impact of the fifth vital sign approach is not entirely clear, however, as studies have indicated effects ranging from beneficial and limited outcomes to negative consequences. While adherence to the standard has improved satisfaction with pain management, adverse drug reactions have increased (Vila et al., 2005). In selected trauma care centers, overmedication with opioids and sedatives—attributed by the researchers to compliance with the new standard—reportedly contributed to higher mortality rates, usually resulting from too great a reduction in blood pressure or compression of the airway (Lucas et al., 2007). In a veterans' outpatient clinic, monitoring pain as a fifth vital sign failed to improve pain management as the assessment was not followed up with recommended treatment, even for patients reporting substantial pain (Mularski et al., 2006). Similarly, in a study of eight veterans' facilities in the Los Angeles area, documentation of pain—necessary for pain care planning—was frequently absent from the medical records of patients with moderate and severe pain (Zubkoff et al., 2010). Taken together, these studies suggest the need to exercise careful clinical judgment based on a comprehensive patient assessment instead of merely monitoring pain (meeting, in a sense, the letter of the law and not the spirit), using opioids to the exclusion of other treatment approaches, or routinely using these powerful medications when their use is not clinically indicated.

Measuring pain intensity alone offers little insight into the quality or character of an individual's pain experience (Ballantyne et al., 2009). Besides the fifth vital sign approach, clinicians use multiple mechanisms to measure pain. Assessing how much patients' pain bothers them and affects functioning—that is, the extent to which pain interferes with activities of daily living, work, and other aspects of daily life—can be as or even more useful (see Chapter 2). Using changes in functioning to assess pain also may yield more consistent results across populations than descriptions of pain, which are more heavily influenced by culture (see Chapter 2). Efforts are now under way to use health-related quality-of-life measures to assess pain (Vetter, 2007).

While some clinicians rely primarily on either intensity measures or measures of functioning, advocates of indices of functioning generally recognize that they should be used only in conjunction with other measures. Exclusive reliance on measures of functioning and other "objective" measures of pain could result in insufficient attention to a person's emotional response to pain, thereby alienating those who might already feel that the health care system is not responding adequately to their needs. Assessments of changes in function also must be tailored to the health care setting. For example, the ability to participate in rehabilitation and recovery activities is key to assessing changes in function in postoperative hospital care, the ability to perform activities of daily living is key in nursing homes, and social functioning is often central in outpatient settings. One difficulty that arises is that some people, such as those who are paralyzed, frail, terminally ill, or developmentally disabled, have only limited functioning to begin with.

Despite the many variables involved in people's responses to pain, different measures of pain can yield consistent results. For low back pain, high degrees of correlation have been found among three different types of measures: a patient's global assessment of response to therapy (often a score given by the patient from zero to 4), a well-validated questionnaire about the extent of pain-related disabilities, and use of a "visual analog" or graphic rather than a numeric scale to report pain levels (Sheldon et al., 2008).

Both intensity scores and indices of functioning, then, have limitations as measures of pain. Moreover, it remains unclear whether subjective measures of pain are fully informative. The lack of a single, universally accepted metric confounds clinicians' efforts to assess an individual patient's progression and response to treatment and researchers' efforts to evaluate treatment modalities through clinical, cost-effectiveness, comparative effectiveness, or even health services research. Thus there exists a clear need for more objective measures for pain.

Adequacy of Pain Control in Hospitals and Nursing Homes

Hospitalized patients experience both acute and chronic pain; patients often experience acute pain following a surgical procedure, or they suffered from chronic pain prior to admission. In a recently reported national survey, most inpatients gave high marks to hospitals' efforts to control their pain, whether acute or chronic (Hospital Care Quality Information from the Consumer Perspective, 2010). In a survey administered nationwide to 2.4 million patients discharged from 3,773 hospitals, 68 percent of patients who said they needed medicine for pain reported their pain was "always" well controlled, and 24 percent said it was "usually" well controlled. The same survey found equivalently high levels of satisfaction with other aspects of hospital care. (These "Hospital Compare" data derive from postdischarge surveys, so they exclude the experiences of patients who died during their hospital stay.) The survey is seen as providing a basis for improving pain care in hospitals (Gupta et al., 2009).

In another national survey, 67 percent of hospitalized patients reported that staff "always" managed pain well, 60 percent reported that staff "always" responded when help was needed, and 58 percent reported that staff "always" explained medicines and their side effects (Commonwealth Fund, 2008). An additional study found that 90 percent of hospital patients receiving medication for postsurgical pain were satisfied with their pain relief, although the researchers nevertheless concluded that "additional efforts are required to improve patients' postoperative pain experience" (Apfelbaum et al., 2003, p. 534).

The Joint Commission's fifth vital sign standard was initiated because hospital staff's underrecognition of pain was believed to be a prominent cause of pain undertreatment. Since the standard was promulgated, staff recognition of pain appears to have been improving steadily. Even soon after the standard was in place, researchers testing its effects found that hospital staff recognized the presence of pain in 90 percent of patients experiencing it. At that time, attending physicians and house staff were more likely to recognize patients in pain (75 percent and 85 percent of patients, respectively) than were nurses (54 percent), regardless of patients' pain levels. However, there was no association between documentation of pain in team members' notes and patients' satisfaction with pain management, or between pain score and patient satisfaction (Whelan et al., 2001). Much has likely improved since this early study, but it underscores that pain assessment is only the first step; it is what is done with that information that makes a difference to patients.

As discussed in Chapter 2, evidence indicates that nursing homes undertreat pain, especially in cognitively impaired and minority residents (Reynolds et al., 2008; Teno et al., 2001; Hutt et al., 2006). Previous research and expert opinion suggest that 45 to 80 percent of U.S. nursing home residents experience pain that contributes substantially to functional impairment or reduces quality of life (Ferrell, 1995; American Geriatrics Society, 1998). Factors implicated in poor pain care by nursing homes include

- cognitively impaired residents' inability to articulate pain and some residents' belief that their pain is untreatable or should be tolerated as just part of getting old;
- insufficient knowledge about and training in pain and ways to reduce it among health professionals and other staff members working in long-term care settings;
- the lack of standardized tools for assessing and treating pain in nursing homes;
- health professionals' concerns about side effects of medications, especially opioids, in frail individuals and possible adverse interactions with other drugs being taken (Reisman, 2007); and
- possible reluctance of residents and families to complain to the institution's staff.

Pain and Suffering at the End of Life

Pain and suffering are related but distinguishable concepts and not inextricably linked (Turk and Wilson, 2009). If pain is a complex biopsychosocial phenomenon, associated with tissue damage, suffering might best be described as "a specific state of distress that occurs when the intactness or integrity of the person is threatened or disrupted" (Cassell, 1999, p. 531). Quite commonly, however, pain and suffering co-occur in the context of terminal illness. Hospice pioneer Cecily Saunders coined the term "total pain" to describe this linkage (Clark, 2000). Opioids and other pain management strategies are important in addressing pain associated with terminal illness, but clinicians should be aware of the risk of exacerbating suffering when pain assessment and management lead to medical approaches alone without sufficient consideration of psychosocial and spiritual sources of distress (Kuupelomaki and Lauri, 1998).

Surveys of family members of people who have recently died find a wide range of satisfaction with pain management, associated with the place of care (Teno et al., 2004). When asked about the survey item, "Patient did not receive any or enough help with . . . pain," 18 percent of family members of patients who had died in home hospice care answered "yes," compared with 32 percent of family members who answered "yes" when their loved one had died in a nursing home without the benefit of hospice care. This result indicates that even in hospice and palliative care settings, the management of pain may be challenging, and implies that comprehensive approaches to assessment and management that address pain-related suffering are important.

Access to Opioid Analgesics and Concerns About Their Use

> *If I asked for prescription pain relief, I was treated like a common criminal. It was a terrible time in my life.*
>
> —A person with chronic pain[9]

Although opioid analgesics often are indicated for chronic severe pain, people with such pain and institutions such as nursing homes can have difficulty obtaining them for various reasons. Sometimes it is a clinician's reluctance to prescribe; sometimes it is a pharmacy's reluctance to carry the medications, ostensibly to protect against theft. The rise in opioid abuse, overdoses, and deaths over the past decade is of growing concern and may make it more difficult for people who need opioids for pain control to obtain them.

The April 2011 White House comprehensive action plan on prescription drug abuse notes that ". . . any policy in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use" (The White House, 2011, pp. 1-2). While most of the plan's provisions relate to substance abuse, it does include some measures to assess the adequacy and effectiveness of pain treatment and to "facilitate appropriate prescribing, including development of Patient-Provider Agreements and guidelines" (The White House, 2011, p. 4).

The same day the White House action plan was released, the Food and Drug Administration (FDA) announced that it will require an Opioids Risk Evaluation

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[9] Quotation from response to committee survey.

and Mitigation Strategy (REMS) (Okie, 2010; FDA, 2011) for all extended-release and long-acting opioid medications. Under the FDA requirement, manufacturers must develop education programs for all physicians prescribing these drugs that cover proper pain management and patient selection, as well as patient education programs in safe use and medication disposal. It is important that education programs mandated under the REMS approach not be so burdensome as to keep physicians from prescribing these medications altogether—particularly for those in severe pain or at the end of life.

Patient Access to Opioids

A reasonable degree of access to pain medication—such as the stepped approach of the World Health Organization's Pain Relief Ladder for cancer—has been considered a human right under international law since the 1961 adoption of the U.N. Single Convention on Narcotic Drugs (Lohman et al., 2010; WHO, 2011). Similarly, countries are expected to provide appropriate access to pain management, including opioid medications, under the International Covenant on Economic, Social, and Cultural Rights, which guarantees "the highest attainable standard of physical and mental health" (Brennan et al., 2007, p. 213).

In the United States, many pain experts agree that physicians should prescribe opioids when necessary regardless of outside pressures as an exercise of their "moral and ethical obligations to treat pain" (Payne et al., 2010, p. 11). For some time, observers have attributed U.S. patients' difficulty in obtaining opioids to pressures on physicians from law enforcement and risk-averse state medical boards. Federal and state drug abuse prevention laws, regulations, and enforcement practices have been considered impediments to effective pain management since 1994, when the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]) adopted clinical practice guidelines on cancer pain (Jacox et al., 1994a,b).

Like AHRQ, the American Medical Directors Association (nursing home physicians) and American Geriatrics Society cite delays in access to prescribed opioids for nursing home patients, including those who are terminally ill, and the American Cancer Society has recognized the frequent inaccessibility of opioids necessary for treating some pain. The American Pain Society has developed evidence-based guidelines for controlling cancer pain, including the use of opioids when other treatments fail or when severe pain relief needs must be met immediately (Gordon et al., 2005). Fourteen years ago, the Institute of Medicine Committee on Care at the End of Life called for efforts to reduce regulatory barriers to pain relief at the end of life and termed some regulatory restrictions "outdated and flawed" (IOM, 1997, p. 56).

Certainly in recent years, opioid prescriptions for chronic noncancer pain have increased sharply (Dhalla et al., 2009; Chapman et al., 2010). According to the White House action plan, between 2000 and 2009, the number of opioid prescriptions dispensed by retail pharmacies grew by 48 percent—to 257 million (The White House, 2011). But are patients who really need opioids able to get them? Twenty-nine percent of primary care physicians and 16 percent of pain specialists report they prescribe opioids less often than they think appropriate because of concerns about regulatory repercussions (Breuer et al., 2010). A survey of clinical staff in an inpatient rehabilitation hospital found that while staff held generally progressive attitudes toward the treatment of pain, there was substantial ambivalence about the use of opioids. The authors note that "significant minorities of respondents indicate a belief that chronic morphine use frequently causes sedation or mental cloudiness and that sleep or sedation can be equated with pain relief" (Loder et al., 2003, p. 67).

In the wake of criticism of state medical boards' actions against physicians who prescribed large amounts of opioids, the Federation of State Medical Boards developed a model policy in 1998—since adopted by many individual state boards—that supports use of opioids for pain management if appropriately documented by the treating physician (Federation of State Medical Boards of the United States, 2004). State medical boards generally are believed to be the best locus for sanctioning physicians for their opioid prescribing patterns, as opposed to criminal prosecution (Reidenberg and Willis, 2007). However, sanctions and prosecutions are rare: between 1998 and 2006, only 0.1 percent of practicing physicians were charged by prosecutors, medical licensing boards, or other administrative agencies with opioid-related prescribing offenses, providing "little objective basis for concern that pain specialists have been 'singled out' for prosecution or administrative sanctioning" (Goldenbaum et al., 2008, p. 2).

Effectiveness of Opioids as Pain Relievers

The effectiveness of opioids as pain relievers, especially over the long term, is somewhat unclear:

- In a meta-analysis of randomized controlled trials involving noncancer pain, researchers concluded that the "relative effectiveness and risk or benefit of opioids compared with other nonopioid drugs are still to be determined" (Furlan et al., 2006, p. 1593).
- A meta-analysis of 43 studies of short-term opioid use among people over age 60 with chronic noncancer pain found reductions in pain intensity and improvements in physical functioning, but decreases in mental health functioning (Papaleontiou et al., 2010).
- A meta-analysis of studies involving back pain did not show that opioids reduced pain, but the researchers concluded that these drugs "may be efficacious for short-term pain relief" (Martell et al., 2007, p. 116). They also found that substance use disorders are common in patients taking

opioids for back pain, with as many as one-fourth of these patients showing aberrant medication-taking behavior.

- Opioid use in a veterans' setting increased among patients aged 18-30 from 3 percent in 2003 to 4.5 percent in 2007. According to the researchers, however, "Our study did not show an improvement in median pain scores following initiation of long-acting opioid therapy, and only one-quarter of patients showed response" (Wu et al., 2010, p. 138).
- A systematic review of the use of nontramadol opioids in osteoarthritis patients concluded that the drugs should not be used routinely for that condition (Nuesch et al., 2009).

The long-term effects and effectiveness of opioid therapy are far from certain (Noble et al., 2008), and opioid therapy lasting longer than 90 days is characterized by diversity in the prescribed medications, dosages, and frequency of use (Von Korff et al., 2008). Some patients taking opioids on a long-term basis develop *greater* sensitivity to painful stimuli, a condition known as opioid-induced hyperalgesia (Chu et al., 2008). Changes in the functioning of sex hormones and the immune system also have been caused by long-term opioid use. Further, opioid use has been found to cause changes in gray matter that are not reversed an average of 4.77 months after cessation of use (Younger et al., 2011).

The research findings noted above need to be set against the testimony of people with pain, many of whom derive substantial relief from opioid drugs. This tension perhaps reflects the complex nature of pain as a lived experience, as well as the need for biopsychosocial assessments and treatment strategies that can maximize patients' comfort and minimize risks to them and society. Regardless, *the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.*

Need for Education

As discussed in Chapter 4, patterns of opioid prescribing may reflect a need for better education of physicians in this area. In 2010, the American Pain Foundation (APF) sponsored a national online survey of 400 board-certified U.S. primary care physicians who "fairly commonly" prescribe opioids and found continued misperceptions about misuse and abuse of opioids (American Pain Foundation, 2010a). More than half of the physicians surveyed (56 percent) believed that few of their patients misuse or abuse their prescriptions, suggesting that almost half believed this might be a problem. However, data from a 2009 survey conducted by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) indicate that some 5 million Americans used pain relievers nonmedically in the month prior to the survey and that these medications generally were the result of a medical prescription (SAMHSA, 2010). The APF's chief executive officer said of his organization's study, "These survey results highlight common misunderstandings about these medications, which can be addressed in the health care provider's office" (American Pain Foundation, 2010b, p. 1).

Abuse of Opioids

Ironically, while many people with pain have difficulty obtaining opioid medications, nonmedical users appear to obtain them far too easily (Arnstein and St. Marie, 2010), so much so that the diversion of opioid analgesics has become a national public health problem (FDA, 2010). Recent data on opioid abuse are disturbing. In the "Monitoring the Future" study of youth drug use and abuse for 2010, 1 in 12 high school seniors reported at least some nonmedical use of the opioid Vicodin and 1 in 20 of OxyContin (Johnston et al., 2011). And in 2007, the number of deaths for all age groups from opioid drug use—14,459—was almost twice the number involving cocaine and more than 5 times the number involving heroin (CDC, 2010b,c).

The 2009 SAMHSA survey further found that in the previous year, there had been some 2.2 million new users (12 years of age or older) of these drugs for nonmedical purposes. The average age of new users was 21 years. New nonmedical users (12 or older) of a single prescription opioid—OxyContin—numbered 584,000, up 22 percent in just one year. More than half (55 percent) of nonmedical users of prescription pain relievers obtained the drugs they used most recently "from a friend or relative for free"—that is, they did not buy or steal them. In four of five of these cases, the friend or relative obtained the drugs from just one doctor; that is, the person was not doctor-shopping to obtain multiple prescriptions. Finally, 18 percent of these nonmedical users obtained the drugs they used most recently through a prescription from their own doctor.

In a few states, unscrupulous activities by entities that identify themselves as pain clinics have included distribution of opioid medications in large quantities to drug abusers, many of whom end up as overdose victims (Collins, 2010; Horswell, 2010). Regulators and legislators are attempting to close or revamp these facilities, partly by developing or demanding tougher rules addressing standards of care, inspection, accreditation, and training (Gentry, 2011). Insufficiently regulated sources of opioids also include online distributors.

Opioid medications present some risk of abuse by patients as well. A structured review of 67 studies found that 3 percent of chronic noncancer pain patients regularly taking opioids developed opioid abuse or addiction, while 12 percent developed aberrant drug-related behavior (Fishbain et al., 2008). A recent analysis revealed that half of patients who received a prescription for opioids in 2009 had filled another opioid prescription within the previous 30 days, indicating that they were seeking and obtaining more opioids than prescribed by any single physician (NIH and NIDA, 2011).

In some geographic areas, opioid use is especially prevalent. In Utah in 2008, a Behavioral Risk Factor Surveillance System survey found that one in five adults had been prescribed an opioid during the past year, and 72 percent of these individuals reported having leftover medication, which potentially could be diverted for nonmedical use (CDC, 2010a).

Current voluntary strategies to reduce opioid abuse include

- the clinician's assessment in a history and physical exam that includes psychosocial factors, family history, and risk of abuse;
- the clinician's regular monitoring of the progress of patients on opioids and assessment for aberrant behavior that may indicate abuse;
- random urine drug screening and pill counts for patients at risk;
- state prescription drug monitoring programs (the U.S. Justice Department and other agencies have cooperated in forming an interstate information exchange for such programs);
- new drug formulations intended to prevent abuse by (1) hindering the extraction of active ingredients through physical barrier mechanisms, (2) releasing agents that neutralize the opioid effects when products are tampered with, and (3) introducing substances that cause unpleasant side effects when drugs are consumed to excess (Fishbain et al., 2010); and
- removing unused drugs from home medicine cabinets and disposing of them at "drug take-back" events (see Box 2-4 in Chapter 2) (Office of National Drug Control Policy, 2010).

Another control strategy that has gained traction is opioid "contracts" or "treatment agreements" between health care providers and patients, under which medication use by high-risk patients is closely monitored. In a study of a primary care clinic's use of such contracts, three-fifths of patients adhered to the agreement (with a median follow-up of 23 months) (Hariharan et al., 2006). However, many pain experts have concluded that pain agreements/contracts do not necessarily improve the treatment of pain or minimize diversion and abuse of prescription drugs, particularly when used indiscriminately. A systematic review of the literature found only weak evidence to support either pain contracts or urine tests as a strategy for reducing opioid abuse (Starrels et al., 2010). Thus far at least, few primary care physicians prescribing opioids for chronic noncancer pain appear to be using urine testing or other strategies to reduce the risk of opioid abuse (Starrels et al., 2011). Clearly, this is an area where future research is needed.

Opioid Use and Costs of Care

Opioid use may increase the costs of care. An analysis of Medicaid data found that total costs for patients with opioid abuse or dependence were **68 per-**

cent higher than costs for a matched set of control patients (McAdam-Marx et al., 2010). Further, opioid abuse is associated with comorbidities that increase direct medical costs (Ghate et al., 2010). A "conservative estimate" of the cost to society of prescription opioid abuse in the United States is $9.5 billion in 2005 dollars (CDC, 2010b).

Insurance Incentives

The coverage policies of third-party payers can affect the quality and comprehensiveness of care received by people with pain. Payers in fee-for-service systems have a well-documented tendency to reimburse procedures more generously than psychosocial care or other nonprocedural treatments (Bodenheimer et al., 2009). This tendency generally is believed to contribute to the nationwide shortage of primary care physicians; to reduce value and cost-effectiveness in health care overall; and, with respect to pain management, to result in the overuse of some procedures and underuse of evidence-based strategies. Put another way, "Evidence is compelling that Americans receive a substantial amount of care that is inappropriate" (IOM, 2009, p. 89).

On the whole, payers do not encourage interdisciplinary team care, which, as discussed earlier, often is an effective pain management strategy. Further, payers frequently limit reimbursement for or do not cover psychosocial and rehabilitative care, which are essential components of comprehensive care. Some payers, such as state workers' compensation programs, pay low rates for mental health care, and many insurers place lifetime or other limits on such care. Rehabilitation services also face insurance limits, especially under Medicare. In addition, many CAM therapies that are widely used in pain management often are not covered by health insurance.

These reimbursement limitations threaten the financial viability of comprehensive pain centers, even in hospitals. To illustrate, analysts for the Center for Studying Health System Change demonstrated a distortion in incentives by showing that the Virginia Mason Medical Center (VMMC), an integrated health care system in Seattle, Washington, would *lose money* by improving low back pain care and reducing costs:

> Low back pain posed the most immediate fiscal challenge to VMMC. . . . VMMC believed that care could be improved by evaluating patients more quickly and by convincing physicians not to order MRIs for uncomplicated patients. A spine clinic was created that offered same-day access for an assessment visit. The plan is expected to reduce average commercial reimbursement per episode from $2,290 to $807 . . . with a reduction in margin from a $90 surplus to a $175 loss. (Ginsburg et al., 2007, p. 2)

Similarly, the analysts demonstrated how VMMC would suffer financially for improving the effectiveness and cost-effectiveness of migraine headache care:

> Analysis of claims data suggested that expensive drugs prescribed for migraines were often dispensed in quantities that were too large and led to waste. Moreover, patients could avoid emergency department (ED) visits and expensive imaging procedures by having small "rescue" prescriptions on hand to take with onset of a migraine. . . . But ED visits (for insured patients) and MRIs are both profitable, with commercial margins of $180 and $450, respectively. Roughly 5 percent and 7 percent of VMMC members with a migraine diagnosis had ED visits or MRIs, respectively, so reducing these percentages (there is not a specific target) cost the organization positive margins that are used to cross-subsidize other services. (Ginsburg et al., 2007, p. 3)

At the primary care level, too, insurance incentives may inadvertently (albeit directly) discourage effective pain care. Evaluation and management codes, used to calculate payments for primary care visits, typically do not promote extensive one-on-one conversations with patients that can lead to effective, individualized care planning. Under current reimbursement approaches, it may be unreasonable to expect primary care practitioners to devote extensive resources to managing pain in patients simultaneously experiencing multiple health problems, such as diabetes, a history of family violence, and fibromyalgia. One way (among many) to help counter these skewed incentives would be to establish quality-of-care standards incorporating principles of biopsychosocial, interdisciplinary, multimodal pain care or evidence on the clinical effectiveness of different modalities. Currently, the National Committee for Quality Assurance's Healthcare Effectiveness Data and Information Set (HEDIS), which comprises standards for managed care organizations and certain providers of care, begins to recognize the importance of pain care (NCQA, 2011, p. 8). HEDIS indicators of cost of care include "relative resource use for people with acute low back pain," and the following HEDIS measures of effectiveness of care involve pain care, at least to some extent:

- disease-modifying antirheumatoid drug therapy for rheumatoid arthritis;
- osteoporosis management for women who have had a fracture;
- avoidance of overuse of imaging studies for low back pain, as such studies have been determined to be appropriate only for patients with severe progressive neurological deficits or signs or symptoms of a serious or specific underlying condition (Chou et al., 2011);
- some drug-monitoring practices (antidepressant medication management, annual monitoring for patients on persistent medications, medication reconciliation postdischarge, potentially harmful drug–disease interactions in the elderly, and use of high-risk medications in the elderly); and
- physical activity in older adults.

The HEDIS process and other mechanisms for monitoring the quality and cost-effectiveness of care provide opportunities for the pain management community. Within participating health care systems and institutional providers, pain management clinicians can work to improve pain care, thereby helping their institution meet the evolving standards of care. In the meantime, pain management experts—including consumers—can encourage monitoring programs to give greater attention to pain care when developing standards.

The Medicare program, too, could reasonably focus attention on pain as a quality-of-care issue. Some unique attributes of pain in the elderly that might be addressed by such quality measures include

- difficulty using certain pain intensity scales;
- increased vulnerability to neuropathic pain (but decreased vulnerability to acute pain involving visceral pathology);
- prolonged recovery from tissue and nerve injury; and
- differences, compared with younger adults, in relationships among psychosocial factors (Gagliese, 2009).

The Reporting of Pain

Unlike the majority of medical complaints, pain is presented to practitioners in venues throughout the health care system and to diverse categories of people outside the system. Members of many groups play a role in pain care, starting from when they first hear about a person's pain or notice it on their own. Any truly comprehensive program to improve pain care must therefore take into account the wide array of people who may be in a person's network, providing information and advice that may or may not be constructive.

Of course, a person's complaint or report is only one sign that pain is a problem; as discussed earlier, loss of functioning and interference with daily life also indicate the presence of pain. Frequently, it is a person's significant other or another close contact who observes a pain-related change. The response of this observer can be an important determinant of whether timely and effective treatment occurs.

Perhaps most frequently, people report pain to a primary care practitioner (family physician, general internist, general pediatrician, obstetrician-gynecologist, nurse practitioner, or physician assistant) or to a physician specialist (an orthopedist, oncologist, general surgeon, gastroenterologist, rheumatologist, psychiatrist, dermatologist, or other medical or surgical specialist) while being seen for a presumably "underlying" condition suspected of causing the pain. Thus, for example, people with chronic or recurring headaches may consult a neurologist. Depending on the severity of the pain, its site, local access to clinicians, insurance coverage, lifestyle, and pattern of health care use, people also may bring the complaint to one or more of the following:

- hospital EDs;
- medical center-based or free-standing ambulatory care clinics;
- physiatrists (physicians specializing in physical and rehabilitation medicine) or physical therapists;
- dentists;
- psychotherapists, including psychiatrists, clinical psychologists, clinical social workers, and psychiatric/mental health nurses;
- pharmacists;
- chiropractors;
- podiatrists;
- occupational health nurses;
- school nurses;
- substance abuse clinics and drug and alcohol counselors; and
- massage therapists, acupuncturists, and various other CAM practitioners (and vendors).

At acute-care hospitals, inpatients experiencing the onset of pain seek relief from attending physicians, hospitalists, bedside nurses, and pain and palliative care teams. Nursing home residents report their pain to nurses and nursing assistants, physical and occupational therapists, medical directors, and patient activity coordinators.

As noted earlier, the formal health care system is not alone in receiving complaints of acute or persistent pain or noticing pain in others (Thernstrom, 2010). For example:

- People experiencing pain talk to their families, friends, and colleagues, trading suggestions and lessons learned.
- Workers mention the problem to their supervisors and colleagues, who may offer a referral or suggest remedies, or may observe the problem on their own.
- Athletes and people who exercise regularly at a gym consult athletic trainers.
- Victims of natural disasters and disease outbreaks see physician volunteers, public health nurses, and emergency relief workers.
- Students bring their problems to teachers, coaches, and resident housing fellows.
- Active members of congregations seek guidance from clergy and other religious and spiritual advisers.
- Today, many people seek answers through individual research conducted on the Internet or in libraries or published medical guides kept on household bookshelves.
- People also pay attention to popular magazines, newspaper columns, television talk shows, and televised medical dramas.

The consuming nature of severe pain leads people down many pathways in search of information, ideas, and of course relief of pain. As a result, suffering individuals are likely to receive conflicting and outdated information and advice that are not applicable to their individual situation, and may also be exposed to myths about pain and its treatment. Wider access to authoritative information about pain would help not only physicians and other health professionals but also many other categories of people respond appropriately to a person's pain.

As noted in Chapter 2, although many people report pain in various ways, many others do not complain at all even when it would be appropriate for them to do so (Keefe et al., 2005). Cultural factors that may impede the reporting of pain include

- a belief that pain has a divine purpose and should be endured as an expression of faith;
- resignation to pain as something that cannot be alleviated;
- concern that complaining about pain will be regarded as a sign of moral or physical weakness;
- fear that pain will be regarded as completely psychological and hence not "real";
- confidence that pain is a single, limited mechanism that will not disrupt other aspects of health or quality of life;
- an aversion to drugs—especially medications commonly used to relieve pain that may be addictive—coupled with the belief that these drugs are likely to be prescribed; and
- among people whose main language is not English, linguistic differences that may confound the description of pain.

The nature of the patient's relationship with a particular health professional also may impede the reporting of pain because of the patient's

- expectation that pain management is outside the professional's scope of practice;
- suspicion that the professional is uninterested in pain—a suspicion that may reflect the professional's time pressures, lack of competence in pain treatment, or biases against or unfamiliarity with certain demographic groups of patients;
- discomfort in communicating with the professional about sensitive topics or a belief that the professional will respond only to extreme expressions of pain;
- previous negative experience with clinicians who trivialized pain, a belief that nothing can be done about the pain, or a desire for the professional to concentrate on an underlying disease; or
- limited communication skills.

BARRIERS TO EFFECTIVE PAIN CARE

> *A physician told me last week, "We don't usually prescribe any pain medication for fibromyalgia patients." My answer: "I'm surprised more of them don't commit suicide."*
>
> —A person with fibromyalgia[10]

Based on the discussion in this and other chapters, the committee identified several important barriers to adequate pain care in the United States. These include the magnitude of the problem, provider attitudes and training, insurance coverage, cultural attitudes of patients, geographic barriers, and regulatory barriers.

Magnitude of the Problem

Approximately 100 million American adults experience pain from common chronic conditions, and additional millions experience short-term acute pain (Chapter 2). Many people could have better outcomes if they received incrementally better care as part of the treatment of the chronic diseases that are causing their pain. A nationwide health system straining to contain costs will be hard pressed to address the problem, however, unless early savings can be clearly demonstrated through reduced health care utilization and disability and fewer dollars wasted on ineffective treatments. The high prevalence of pain suggests that it is not being adequately treated, and undertreatment generates enormous costs to the system and to the nation's economy (see Chapter 2).

Provider Attitudes and Training

A number of barriers to effective pain care involve the attitudes and training of the providers of care. First, health professionals may hold negative attitudes toward people reporting pain and may regard pain as not worth their serious attention. As discussed in detail in Chapter 2, patients can be at a particular disadvantage if they are members of racial or ethnic minorities, female, children, or infirm elderly. They also may have less access to care if they are perceived as drug seeking or if they have, or are perceived to have, mental health problems. A literature review showed that people with pain, especially women, often have attitudes and goals that are different from, and sometimes opposed to, the attitudes and goals of their practitioners; patients seek to have their pain legitimized,

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[10] Quotation from response to the committee survey.

while practitioners focus on diagnosis and therapy (Frantsve and Kerns, 2007). Consumers testified before the committee that patients often believe practitioners trivialize pain, which makes them feel even worse. Researchers working with patient focus groups have noted the "perceived failures of providers to fully respect, trust, and accept the patient, to offer positive feedback and support, and to believe the participants' reports of the severity and adverse effects of their pain" (Upshur et al., 2010, p. 1793).

Primary care practitioners often experience negative emotions—such as frustration, lack of appreciation, and guilt—in caring for people with pain. For example, even when 71 percent of primary care clinicians affiliated with the Department of Veterans Affairs felt confident of their ability to treat chronic pain, 73 percent said that patients with chronic pain are a major source of frustration (Dobscha et al., 2008). Efforts to improve primary care practitioners' patient-centered communication skills, including demonstrating empathy and encouraging shared decision making, may help reduce this burden of negative emotions. Improving communication skills also could strike at the root cause of practitioners' negative emotions by improving the effectiveness of pain treatment (Matthias et al., 2010). But "because physicians are oriented toward achieving cures, a chronic pain patient's attending physician will sooner or later experience frustration" (Jackson, 2010, p. 37). Clinicians who become frustrated when they cannot "cure" or substantially relieve someone's pain lose sight of the fact that even limited relief from the burden of pain may enable a person to revive skills, renew social interactions, and meet additional requirements of daily living—in themselves positive contributors to a person's relief. Modest gains in pain relief that bring a person back toward a more normal life are vital clinical accomplishments.

Second, the profession and culture of medicine generally focus on biological rather than psychosocial causes and effects of illnesses. Medicine traditionally emphasizes mind–body dualism, views pain as a symptom, focuses on disease instead of illness, and has a bias toward cure rather than care—all perspectives that impede use of the biopsychosocial model, discussed earlier in this chapter, that best suits care for severe chronic pain (Crowley-Matoka et al., 2009). Typically, patients are encouraged to describe their experience only briefly and in terms most familiar to physicians, rather than present a narrative that fully explains the impact of pain in their lives (Morris, 2002). In the medical milieu, the cognitive and emotional experience of pain may not be sufficiently recognized.

A third important barrier to pain care is the need for expanded formal training in medical, nursing, and other health professions educational programs, as well as enhanced continuing education. Most people in pain are cared for by primary care physicians who likely received little initial training or experience in best practices in pain management. Even physicians in specialties such as oncology may be unaware of current models of pain care, unable or unwilling to assemble an interdisciplinary team when needed, unsure of how to proceed, and prevented by organizational or reimbursement policies from spending the time necessary to get to the bottom of a particular case. Surgeons do not routinely practice techniques to prevent acute (and potentially chronic) postoperative pain. And preventive approaches are underutilized almost universally. The nation also may have too few pain specialists. In addition, there are inadequate opportunities in the professional education system for interdisciplinary education about pain. Training should address gaps in knowledge; strengthen competencies related to pain assessment and management; and counter negative and ill-informed attitudes about people with pain, stereotyping, and bias. Chapter 4 addresses these and other education issues in detail.

Additionally, although pain is one of the most common reasons people seek treatment, clinicians may not ask about or thoroughly investigate pain. As discussed earlier, in part this is because patients do not raise the issue or downplay it for a variety of reasons, often cultural (Narayan, 2010). If the subject of pain is not raised in the clinical encounter, it surely cannot be adequately addressed. If health care providers do not know how to solicit information about a person's experience with pain or how to treat pain when described, that is a failure of training; if they do know how to do so and yet do not, that is a failing of a different kind.

Fourth, evidence-based protocols and guidelines exist to assist primary care practitioners in treating people with chronic pain. The American College of Physicians (internal medicine physicians) and American Pain Society have issued a general guideline for treating low back pain (Chou et al., 2007). Guidelines on specific forms of treatment, such as medications for older patients, also are available to primary care practitioners (American Geriatrics Society, 2009). However, such protocols are used only rarely to treat pain in primary care practice. In one study, which used a protocol that classified pain patients by degree of disability, most participating primary care physicians reported increased confidence in treating pain after gaining familiarity with the protocol, but (as with clinical protocols in general) many physicians expressed reluctance to consult this or any other pain algorithm (Jamison et al., 2002).

Although protocols to guide primary care practitioners in providing pain care exist, there appear to be no evidence-based protocols to guide them in facilitating self-management and patient education. Yet as an article geared to family physicians points out with regard to chronic disease in general:

> Support of patient self-management is a key component of effective chronic illness care and improved outcomes. Self-management support goes beyond traditional knowledge-based patient education to include processes that develop problem-solving skills, improve self-efficacy, and support application of knowledge in real-life situations that matter to patients. This approach also encompasses system-focused changes in the primary care environment. Family physicians can support self-management by structuring patient-physician inter-

> actions to identify problems from the patient perspective, making office environment changes that remove self-management barriers, and providing education individually and through available community self-management resources. (Coleman and Newton, 2005, p. 1503)

Finally, as discussed earlier, interdisciplinary, team approaches can facilitate high-quality pain care. Despite their demonstrated benefits, however, such team approaches are not consistently used in pain care.

In short, current clinical systems are not well designed to deal with severe acute and chronic pain. System and organizational barriers, such as the lack of capacity for frequent visits when necessary and the lack of time to conduct comprehensive assessments and patient education, obstruct individualized care. Much more could be done to educate clinicians, patients, and the public about pain and pain management, but education alone will be ineffective in the absence of systems that permit—or encourage—them to act on that knowledge. Overcoming these barriers will require changes to current reimbursement policies, discussed below.

Insurance Coverage

Costly team care, expensive medications, and procedural interventions—all common types of treatment for pain—are not readily obtained by the 19 percent of Americans under age 65 who lack health insurance coverage (Holahan, 2011) or by the additional 14 percent of under-65 adults who are underinsured (Schoen et al., 2008). Together, these groups make up one-third of the nation's population. Lack of insurance coverage also may contribute to disparities in care. An inability to pay for pain care is especially prevalent among minorities and women (Green et al., 2011). As discussed above, even for people with insurance coverage, third-party reimbursement systems tend not to cover or to cover well psychosocial services and team approaches that represent the best care for people with the most difficult pain problems. Surmounting this barrier may require coordinated action by advocates for improvement.

Cultural Attitudes of Patients

Myths and stereotypes about chronic pain, people with chronic pain, and the drugs used to combat it are prevalent. Chapter 4 addresses the public and patient education efforts that might reduce some of these attitudinal barriers. Moreover, as discussed earlier, many patients do not report pain to health professionals for various reasons. They may have been rebuffed by clinicians in the past. Perhaps their clinician has tried (albeit unsuccessfully) to address the problem, and they want to be a "good patient" and not report the failure. They may fear the pain signals a serious problem they do not want to acknowledge or confront, or they may not want to distract the clinician from treating an underlying condition (Gunnarsdottir et al., 2002; Narayan, 2010). They may worry that they will be told they need surgery and not want to undergo it. Or they may harbor a tradition of stoicism. The military, for example, long has fostered an attitude of "no pain, no gain," which has prevented service members from obtaining needed pain care (Office of the Army Surgeon General, 2010); such a culture of stoicism likewise characterizes certain ethnic groups (Meghani and Houldin, 2007; see also Chapter 2). A 1993 survey of physicians with pain care responsibilities found that 62 percent believed their own patients' reluctance to report pain was one of the principal barriers to better pain management (Von Roenn et al., 1993). Twenty years later, it is unlikely that this perception has changed significantly.

Geographic Barriers

As noted in Chapter 2, America's rural areas have shortages of primary care physicians and certainly have few pain care specialists. As a result, military veterans, farm workers, people who are chronically ill, and others living in rural areas are deprived of competent pain management or, like some wounded warriors from the Iraq and Afghanistan wars, must move with their families to an area where they can find suitable care (President's Commission on Care for America's Returning Wounded Warriors, 2007).

Regulatory Barriers

As described extensively in the preceding discussion of opioid use, regulatory and enforcement practices can reduce access to opioid analgesics for people with pain. These practices cause some practitioners to fear being unfairly prosecuted for prescribing opioids (Sullivan, 2004) and perhaps to stop prescribing them altogether. One aspect of this problem surfaced in the aftermath of Hurricanes Katrina and Rita in the Gulf Coast in 2005. Then, a lack of adequate electronic networking or efficient information exchange across databases prevented many dislocated hurricane victims from obtaining timely access to their usual and properly prescribed medications. Improved public health emergency planning efforts would allow patients with opioid prescriptions for severe pain (and other patients taking controlled substances as prescribed) who are displaced during a public health emergency to have their prescriptions filled without undue and harmful delays.

MODELS OF PAIN CARE

> *I fell on the ice at work two years ago, and have three areas needing surgery. . . . [The workers' compensation system] keeps people in pain longer, it frustrates them, and injuries go untreated, frequently get worse, and become chronic. The system is so worried about fraud, that the victims with real pain and real issues do not get the treatment they need.*
>
> —A person with chronic pain[11]

This section describes the Department of Veterans Affairs and Department of Defense models of pain care, as well as some additional models.

Department of Veterans Affairs

Care of America's military veterans provides an important large-scale model against which to assess current and future pain care services. Pain is a major issue in the veterans' system: at least half of all male veterans who obtain primary care through the Department of Veterans Affairs and as many as three-fourths of all women veterans report pain (LaChappelle et al., in press) (see also Chapter 2).

Relatively early, in 1998, the department developed a brief but comprehensive National Pain Management Strategy that called for national coordination and national standards, including use of the fifth vital sign approach described earlier (VHA, 1998). The strategy represented an attempt to develop a comprehensive, multicultural, integrated, and systemwide effort to reduce acute and chronic pain associated with a wide range of injuries, illnesses, and conditions affecting veterans, including terminal conditions, and to improve veterans' quality of life. Implementation of the strategy succeeded in reducing the prevalence of severe pain, increasing pain care planning, and increasing the distribution to patients of educational materials about pain (Cleeland et al., 2003).

Recently, after determining that large numbers of returning veterans of the Iraq and Afghanistan wars were experiencing persistent pain, the department issued a detailed Pain Management Directive (VHA, 2009). The department's model has the potential to be far-reaching as a result of the number of Americans the department serves (5 million armed service veterans and 400,000 family members) and the number of facilities it operates (some 153 medical centers, 882 clinics, 136 nursing homes, and 45 residential rehabilitation facilities, as well as numerous other programs throughout the nation) (Congressional Budget Office, 2007). The directive prescribes a stepped approach to pain care such

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[11] Quotation from response to the committee survey.

that increasingly aggressive modalities are introduced as milder methods fail to provide relief. The three steps are primary care, specialty care, and accredited pain centers. The model provides for management of most pain conditions in the primary care setting. Primary care practitioners' efforts are supported by timely access to secondary consultations with specialists in pain medicine, behavioral health, physical medicine and rehabilitation, and palliative care. The approach recognizes that primary care practitioners treating veterans have shown a high level of interest in treating pain but low satisfaction with their ability to provide optimal care, and so are ripe for learning and support mechanisms to improve their ability to treat pain (Dobscha et al., 2008).

Secondary care and pain center, or tertiary, care are reserved for patients whose pain is not managed successfully at the primary care level, is more complex, or involves comorbidities, as well as for patients considered at risk for addiction or suicide, for example. Care at interdisciplinary pain centers includes advanced diagnostic and medical management, rehabilitation services for complex cases involving comorbidities (such as mental health disorders and traumatic brain injuries), and integrated services for patients with both chronic pain and substance use disorders.

The model further encompasses

- treatment goals, education of practitioners, clinical protocols, and systemwide referrals;
- systemwide data collection, including questions on pain in veteran satisfaction surveys;
- quality improvement, with increasing reliance on the department's well-regarded electronic health record;
- external evaluation, including reports of the department's Health Analysis and Information Group;
- health services research on such topics as geographic disparities and outcomes of care; and
- use of "patient-aligned care teams," usually including a nurse who coordinates services, to ensure that pain care is provided as part of the continuity of care. Teams also include practitioners in behavioral health and other specialty services.

Top-down and bottom-up elements both are included in the department's approach. Top-down elements include systemwide action by the central administration to set standards of care and monitor performance. These top-down elements reflect the organization of veterans' health as a closed system, so that referrals and practice—including adherence to stepped-care principles—can be guided by agency policy, an approach that is far more difficult to accomplish elsewhere in the pluralistic U.S. health care system. Bottom-up elements include action taken at the local level. There, champions are recruited; pain committees are formed;

and these groups work together across the system as a community of practice in a network of frequent, rapid, and informal communication.

Department of Defense

A second, related model of care is provided by the Department of Defense, particularly the Army. In May 2010, an Army task force released, and vigorously publicized, a report containing more than 100 recommendations on pain management in the areas of tools, best practices, a focus on the patient and family, and a culture of awareness. The recommendations are intended to

> . . . lead to a comprehensive pain management strategy that is holistic, interdisciplinary, and multimodal in its approach, utilizes state of the art/science modalities and technologies, and provides optimal quality of life for Soldiers and other patients with acute and chronic pain. . . . The recommendations rely heavily on an education and communication plan that crosses [Department of Defense and Veterans Health Administration] medical staff and patients. (Office of the Army Surgeon General, 2010)

To overcome the stigma that acknowledging one's pain reflects "weakness of character," the Army is emphasizing soldiers' duty to obtain treatment for pain in order to remain sufficiently fit to accomplish their assigned mission. The Navy, too, is endeavoring to coordinate pain management efforts with the Department of Veterans Affairs' stepped-care approach.

Other Models

The field of quality improvement (QI) provides another model for efforts to make pain care more effective. In health care, QI is a commitment by a provider or group of providers to improve the quality of care consistently, in measurable ways (IOM, 2007b). QI usually involves substantial effort to collect and analyze data in order to identify problems, monitor trends, and find ways to improve performance. For example, one QI approach is the "plan, do, study, act" cycle, promoted by the Institute for Healthcare Improvement.

St. Jude's Children's Research Hospital provides a model of the use of QI to improve pain care. After initially developing an institutional "pain standard of care," St. Jude's undertook a systematic evaluation of its performance in assessing and reducing pain intensity levels over 6 years (Oakes et al., 2008). The QI effort revealed patterns of success as well as continuing challenges. The researchers concluded (p. 667):

> . . . no single strategy is likely to offer optimal pain management. Quality pain management requires an interdisciplinary approach combining the talents and dedication of every member of the health care team.

Additional models of care are offered by the American Pain Society's Clinical Centers of Excellence Awards Program, which selects several pain management centers each year for recognition (American Pain Society, 2011). The Brigham and Women's Pain Management Center in Boston won awards in both 2007 and 2011. The center serves 19,000 patients annually, providing expanded psychological, social work, and pharmacy services. It also has initiated palliative care and pelvic pain programs and conducts extensive research. The other 2011 award recipients were

- *Comprehensive Pain Center of Sarasota, Florida*, a free-standing entity that provides multimodal, evidence-based services in a state where, the center's staff emphasizes, eight people die each day from prescription drug abuse;
- *Jane B. Pettit Pain and Palliative Care Center*, affiliated with Children's Hospital of Wisconsin in Milwaukee, which integrates medical and mental health services, is dedicated to quality improvement, and maintains a sickle-cell clinic;
- *Rehabilitation Institute of Washington,* in Seattle, which transitioned from an academic medical center to a free-standing facility that specializes in interdisciplinary cognitive-behavioral rehabilitation for injured workers and low back pain disability and provides language interpretive services for non-English speakers; and
- *University of New Mexico Project ECHO Pain Clinic* in Albuquerque, which serves people with complex pain who are drawn from vulnerable urban and rural underserved populations.

CONCLUSION

Because people's experience with pain touches the entire health care system and many aspects of American life, the committee believes it is an important public health and health care issue, but it is not yet an issue that our society is handling well. Multiple factors compromise the ability to provide high-quality treatment to people with pain, as this chapter has demonstrated. The diversity and importance of these factors suggest that, as discussed in Chapter 1, only a cultural transformation could substantially increase the accessibility and quality of pain care and thereby provide relief to many more Americans who need it.

FINDINGS AND RECOMMENDATIONS

Finding 3-1. Pain care must be tailored to each person's experience. Pain management takes place through self-management, primary care, specialty care, and pain centers. However, the majority of care and management should take place through self-management and primary care, with specialty services being focused on recalcitrant or more complex cases. Accordingly, individualization of pain management is necessary throughout the health care system. Health care providers need to foster pain care that is patient-centered and, when necessary, comprehensive and interdisciplinary. Financing, referral, records management, and other systems need to support this flexibility.

> **Recommendation 3-1. Promote and enable self-management of pain.** Health care provider organizations should take the lead in developing educational approaches and materials for people with pain and their families that promote and enable self-management. These materials should include information about the nature of pain; ways to use self-help strategies to prevent, cope with, and reduce pain; and the benefits, risks, and costs of various pain management options. Approaches and materials should be culturally and linguistically appropriate and available in both electronic and print form.

Finding 3-2. Significant barriers to adequate pain care exist. The committee finds that multiple and significant barriers to pain care and management exist in the primary care setting.

- Enhanced continuing education and training are needed for health care professionals to address gaps in knowledge and competencies related to pain assessment and management, cultural attitudes about pain, negative and ill-informed attitudes about people with pain, and stereotyping and biases that contribute to disparities in pain care.
- Other barriers include the magnitude of the pain problem, including its extremely high prevalence, which makes effective action difficult on a national scale; certain provider attitudes and training, which impede the delivery of high-quality care; insurance coverage, because fully one-third of all Americans are uninsured or underinsured; cultural attitudes of patients, many of whom do not recognize the need to address pain early on; and geographic barriers, which place residents of rural communities at a disadvantage.
- System and organizational barriers, many of them driven by current reimbursement policies, obstruct patient-centered care. Examples of these barriers are minimal capacity for frequent visits when necessary; limited time for conduct of comprehensive assessments; inadequate patient education initiatives; difficulties in accessing specialty care; and lack of reimbursement for needed specialty care services, interdisciplinary practice, psychosocial and rehabilitative services, in-depth patient interviews and education, and time spent planning and coordinating care. Improving pain care will improve the effectiveness and cost-effectiveness of care and generate large savings by reducing the need for

the most expensive types of treatments; reducing costly comorbidities, recognizing that patients with pain generate very large health care costs in general; avoiding costly public-sector disability payments; increasing the productivity of patients and families; and avoiding the negative effects of opioid misuse.

- A comprehensive, strategic approach can succeed in addressing these barriers and help close the gap between empirical evidence regarding the efficacy of pain treatments and current practice.
- Regulatory, legal, educational, and cultural barriers inhibit the medically appropriate use of opioid analgesics.

Recommendation 3-2. Develop strategies for reducing barriers to pain care. The population health-level strategy referred to in Recommendation 2-2 should include identifying and developing comprehensive approaches to overcoming existing barriers to pain care, especially for populations that are disproportionately affected by and undertreated for pain. Strategies also should focus on ways to improve pain care for these groups.

Recommendation 3-3. Provide educational opportunities in pain assessment and treatment in primary care. Health professions education and training programs, professional associations, and other groups that sponsor continuing education for health professionals should develop and provide educational opportunities for primary care practitioners and other providers to improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing.

Recommendation 3-4. Support collaboration between pain specialists and primary care clinicians, including referral to pain centers when appropriate. Pain specialty professional organizations and primary care professional associations should work together to support the collaboration of pain specialists with primary care practitioners and teams when primary care providers have exhausted their expertise and the patient's pain persists. Ways these organizations could work together include

- joint meetings;
- pain-related workshops and other educational opportunities sponsored by pain organizations at primary care national meetings, and awards and other forms of recognition to highlight exemplary models for how primary care clinicians and pain specialists can work together;
- discussions among health professions associations and public and private payers to facilitate such consultations; and

- clinical protocols for consultations between primary care clinicians and pain specialists, incorporating evidence-based practices. With support from specialists in creating an appropriate plan of treatment, the primary care team will be better informed about and willing to manage the patient's pain care.

Recommendation 3-5. Revise reimbursement policies to foster coordinated and evidence-based pain care. Payers and health care organizations should work to align payment incentives with evidence-based assessment and treatment of pain. Optimal care of the patient should be the focus. Medicare, Medicaid, workers' compensation programs, and private insurers should

- Create incentives to support and adequately reimburse primary care providers' delivery of integrated, interdisciplinary pain assessment and treatment, as well as advanced specialty care for people with complex pain. The committee encourages demonstration projects of the Centers for Medicare and Medicaid Services to foster models of this kind of patient-centered pain management.
- Recognize that patients with severe pain may require more frequent visits, as well as extended visits to allow for comprehensive assessment, treatment planning, and patient education. Reimbursement also should cover the physician's time and effort for coordinating pain care outside of the face-to-face patient visit.
- Consult with pain specialty organizations on ways to ensure that payment incentives are designed to encourage evidence-based best practices in the assessment and treatment of pain.
- Create a database of providers for referrals.
- Develop comprehensive pain management and research centers to promote interdisciplinary research that directly translates discoveries into effective clinical therapies.

Recommendation 3-6. Provide consistent and complete pain assessments. Health care providers should provide pain assessments that are consistent and complete and documented so that patients will receive the right care at the right place and the right time.

- Pain assessment should focus on soliciting a careful history of the pain experience, the impact of pain on functioning and quality of life and emotional suffering, and the patient's goals and values.
- Pain assessment should be multifaceted and include self-report, observations by significant others, and careful examination by the health care provider.

- In recognition of the prevalence and complexity of chronic pain and the fact that in some cases it is a disease entity in its own right, a specific disease category should be developed that would enable clinicians and researchers to better document and analyze this condition. Therefore, the World Health Organization should create a chronic pain category in the *International Classification of Diseases*, Tenth Edition.

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4

Education Challenges

> *Education, Education, Education. Educate more physicians on proper diagnosis and proper pain management. Educate the person living with pain and their family on addiction versus physical dependency and proper storage of medication. Educate the public and press about the realities of pain medication and people living with pain.*
>
> —A person with chronic pain[1]

Earlier chapters of this report reveal a disturbing discrepancy. On the one hand, pain is extremely widespread in American society, exacts a huge toll in suffering and disability, and imposes extraordinary costs on the health care system and the nation's economy (Chapter 2). On the other hand, all too often treatment is delayed, disorganized, inaccessible, or ineffective (Chapter 3). Much of this gap between need and performance results from inadequate diffusion of knowledge about pain. Many members of the public, people with pain themselves, and many health professionals are not adequately prepared to take preventive action, recognize warning signs, initiate timely and appropriate treatment, or seek specialty consultation when necessary with respect to pain. The avoidable negative consequences are that more people than necessary experience pain, acute pain often is not optimally treated and progresses unnecessarily to chronic pain,

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[1] Quotation from response to committee survey.

chronic pain is not systematically addressed, and the health and quality of life of large numbers of people are severely impaired.

Improving care for people with acute or chronic pain requires broad improvements in education, especially with regard to

- the multiple causes and effects of pain,
- the range of treatments available to help people obtain relief, and
- the need to consider chronic pain as a biopsychosocial disorder.

Education efforts should be directed to people with pain, the general public, and health professionals. Each of these audiences has distinct needs for greater knowledge, and each presents its own education challenges. In addition, education programs need to be high quality and evidence based, and in their planning draw on such sources as the successful examples highlighted in this chapter, inasmuch as the history of both patient and public education efforts is littered with failed, ineffective, and poorly implemented programs.

PATIENT EDUCATION

> *I had to relearn how to live.*
>
> —Gwenn Herman,
> Pain Connection-Chronic Pain Outreach Center, Inc.[2]

People with acute or chronic pain often are unaware of their treatment options or may hold inaccurate or value-laden beliefs about pain that obstruct the path to treatment and relief (Chapter 3). They deserve information that can help them understand and address their condition.

The optimal timing, content, and goals of patient education will vary depending upon the type of pain (acute or chronic), the availability and effectiveness of treatment, and the educational and literacy levels of the patient. Consider the case of acute pain. Although there are only limited opportunities to provide effective pain education to patients who experience unanticipated pain as a result of an injury or medical emergency, acute pain is an appropriate target of patient education. For example, the fear of pain or the experience of poorly controlled pain with outpatient procedures can affect a person's willingness to undergo needed medical or dental treatment. Education about the likelihood of pain, including its possible magnitude, is therefore important to informed decision making, includ-

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[2] Quotation from testimony to the committee, November 2010.

ing decisions about options for preventing or managing pain. There is ample opportunity to educate people who will undergo elective surgery or outpatient procedures about the likelihood and magnitude of acute pain they may experience and to inform them about the availability of methods to prevent or relieve this pain. Postoperative patients surveyed about their information needs placed a high value on information about pain and pain management plans following surgery and discharge (Kastanias, 2009).

With respect to chronic pain, the committee believes education for patients should encompass such topics as those listed in Table 4-1. While the table addresses strictly patient education, families, too, should be seen as an appropriate target for educational efforts. Education for people with chronic pain should not be a one-time effort; as pain progresses, as treatments have greater or dwindling effects, as new treatments become available, the educational process should continue. One advantage of education is that it can enable people with pain to handle many pain-related problems themselves, without having to rely on medical care.

People with chronic pain have substantial unmet educational needs. For example, while three-fourths of people with chronic pain who visited an emergency department reported a desire for information about pain treatment options or referrals to pain specialists, only half reported receiving such information (Todd et al., 2010). There is evidence that appropriate education can improve satisfaction with care and outcomes of people with pain (Merelle et al., 2008).

Sometimes, especially in cases of severe persistent pain, a person may have to learn that certain limitations and discomforts appear to be permanent. Someone facing the prospect of lifelong discomfort, disability management, and self-care challenges will require emotional support along with accurate information. The prospect of a permanent reduction in health status and quality of life is not unique to persistent pain. It also confronts people who have other chronic diseases (such as diabetes, asthma, end-stage renal disease, multiple sclerosis, and some cancer and heart disease conditions), and the rich experience of patient education about these other diseases can be mined to improve strategies and expand the supply of materials for patient education about pain. Patient education programs and materials, like treatment choices (Chapter 3), need to be age-appropriate, geared to the person's and family's level of comprehension and general health literacy, culturally and linguistically competent, and supported by timely opportunities to ask questions and receive authoritative and useful answers. Families and other personal caregivers deserve information about how to obtain stress relief—including, in the case of people who are terminally ill, respite care—because they, too, are part of the patient's milieu and need to be able to remain in peak form. Given the importance of patient education on pain, it would be useful to have educational modules—available through different media, such as Internet links (which could also benefit clinicians), pamphlets, and audio connections translated into various languages or geared to different health literacy levels or age groups—that could be selected for individual patients.

TABLE 4-1 Patient Education: Essential Topics

Essential Patient Education Topic	Reason Why the Topic Is Essential
Steps people can take on their own—such as relaxation strategies, exercises, or weight loss—to prevent or obtain relief, help prevent acute pain from progressing to chronic pain, and help prevent chronic pain conditions from worsening	To prevent pain from progressing (that is, secondary prevention), to provide quick relief, to empower people to manage their own care as appropriate, and to avoid unnecessary health care expenditures
Differences between pain that is protective (adaptive) and pain that is not protective (maladaptive)	To advise people why pain that is not protective should be treated
Reasons why the need for relief is important, especially the possibility that poorly managed acute pain will progress to chronic pain	To persuade people to obtain early treatment when necessary
When and how emergency or urgent care should be obtained	To encourage seeking immediate intervention, which sometimes can prevent pain from severely worsening
Treatment-related pain (such as postoperative pain) and major categories of available pain therapies, along with the main advantages and disadvantages of each (such as potential benefits and risks of opioids)	To enable patients to be informed consumers
Different types of health professionals who may be able to help, and how they may help	To provide information about a full range of available services, to promote individual choice
Treatments health insurers may or may not reimburse or may reimburse only partially	To equip people to make choices that are cost-effective for them and prepare them for reimbursement problems
Ways in which family, employer, colleagues, friends, school, and other contacts can help prevent the pain from progressing or becoming prolonged	To empower patients to marshal support from those who are willing and able to help them
How pain is measured, including the difference between numeric (“subjective,” or intensity) scales and functional (“objective,” or disability) assessments	To enable patients to place their pain in a context health professionals will recognize and serve as an informed member of their own health care team
The fact that pain involves a complex mind–body interaction, rather than being strictly physical (biological) or strictly emotional (psychological)	To provide patients with an understanding of the need to address both dimensions of their pain and with appropriate, rather than unrealistically high, expectations
The right to pain care, including access to medications that are medically necessary and properly used	To alert patients to the possible need to advocate on their own behalf
Self-management techniques (surveyed in Chapter 3)	To furnish patients with enough information to obtain some relief on their own and contribute meaningfully to their own care

Because severe pain affects so many aspects of a person's life, people with pain and their families can feel overwhelmed. Education can help them devise ways of improving those circumstances that can be improved and coping with more lasting restrictions. Various types of education programs evaluated or in use by voluntary health organizations have benefited people with pain, including

- information on ways to control and cope with pain (American Chronic Pain Association, 2011; American Pain Foundation, 2011; PainKnowledge.org, 2011);
- psychosocial supports for people with pain and their personal caregivers, with a strong patient education component (Porter et al., 2010); and
- encouragement in the use of self-management strategies (Oliver et al., 2001; Moseley, 2003; Trautmann and Kröner-Herwig, 2010).

As noted in Chapter 1, a person's beliefs about pain correlate with pain treatment outcomes. For example, one study found that people with cancer tend to receive inadequate analgesics and have greater pain if they harbor beliefs such as that cancer pain is inevitable, that side effects of analgesic drugs are unmanageable, that "good patients" do not complain about pain, and that pain distracts physicians from treating the cancer (Gunnarsdottir et al., 2002). Correcting such beliefs and misperceptions should be an important educational goal.

Education programs also can reduce symptoms and improve functioning. A program consisting of four educational sessions for people with cancer showed "significant immediate and sustained effects . . . on pain and fatigue barriers" among patients who received the intervention, compared with a usual care control group, as well as increased knowledge and measurable improvements in quality of life (Borneman et al., 2011, p. 197). Among people with low back pain, one-on-one education with a physiotherapist led to improved physical functioning, as measured by both straight-leg raise and forward bending. The researchers attributed approximately 77 percent of the leg-raise improvement and 60 percent of the bending improvement to a change in cognition, especially the belief that pain means tissue damage, and to reduced catastrophizing (Moseley, 2004).

Psychosocial education appears to be especially useful. In a German study involving "back schools" for rehabilitation in patients with low back pain, those who received education in the biopsychosocial model showed greater knowledge about their illness and better self-management than those who received more traditional education (Meng et al., 2011). A study of U.S. soldiers completing their training showed that a psychosocial education program improved their knowledge about the effects of low back pain—a malady frequently faced by soldiers—and their ability to cope with it (George et al., 2009).

Patient education assists people with pain and their families, as well as specific high-risk groups, such as soldiers in the example discussed above or people diagnosed with cancer. The next section addresses public education, which can help in the prevention and treatment of pain in the general population.

PUBLIC EDUCATION

> *We need respectability brought to these conditions.*
>
> —Terrie Cowley, The TMJ Association, Ltd.,
> An advocate for people with chronic pain[3]

Why educate the general public about pain? The committee identified five reasons why public education about pain could be highly beneficial:

- People who have received such education can take steps to avoid pain, such as practicing proper stretching and lifting techniques, and can engage in timely and useful self-management when pain strikes.
- Educated people can give appropriate advice and assistance to family members, friends, and colleagues of people with pain, especially by advising them to refrain from telling injured individuals to simply “bear with it” or “suck it up.”
- In interactions with health care providers, educated people can advocate for and accept appropriate treatment of acute and chronic pain they or family members experience.
- An educated public can act at the community level to minimize hazards that contribute to pain-producing injuries among students (such as in sports programs) and in the general community (such as unshoveled walkways or sidewalks in disrepair).
- Educated citizens can advocate for improved pain prevention and control policy measures, such as reasonable sports helmet requirements, lawful access to medically necessary opioid medications, and health insurer reimbursement of interdisciplinary pain care.

Data with which to measure the extent and accuracy of public knowledge about the science and treatment of pain are limited. A 2002 national telephone survey of 1,000 adults found that “most Americans have little understanding of pain and its treatment” (Partners for Understanding Pain, 2002, p. 2). Specifically, survey respondents tended to overestimate physicians’ training in pain; underestimate the extent to which pain affects people under age 65; and believe that

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[3] Quotation from testimony to the committee, November 2010.

most people complain about pain only to obtain drugs, avoid work, or garner attention. Similarly, a landmark 1997 survey of the public sponsored by the Mayday Fund found that many Americans had only limited knowledge about pain and its treatment, believing, for example, that pain medications are dangerous and should be avoided if possible (Bostrom, 1997).

Although the 1997 and 2002 surveys uncovered persistent deficits in public understanding about pain, they are insufficient to serve as a platform for a major public education effort today. The results are a decade or more old and are focused largely on opioid-related issues that continue to evolve. Additional research into public knowledge about pain would enable public health advocates to

- assess the overall need for public education,
- identify groups most in need of education and the most cost-effective ways of reaching them,
- determine appropriate content domains, and
- craft messages or lessons.

Some existing campaigns, described in Box 4-1, illustrate how public education on pain might take place. Some public health education campaigns outside the pain field illustrate the potential for producing change in pain-related behavior.

BOX 4-1
Public Education Campaigns on Low Back Pain

Australia

Low back pain costs Australia more than AU$9 billion a year (which amounts to approximately US$350-400 per resident) (Walker et al., 2003). Partly to reduce rapidly rising workers' compensation costs for back pain, the state of Victoria WorkCover Authority in the late 1990s conducted what is considered the first back pain public education campaign, Back Pain: Don't Take It Lying Down.

The 3-year, $10 million multimedia effort, centered on prime-time television advertisements, helped convince people with pain not to fear remaining physically active (Buchbinder et al., 2001a). Pre- and postcampaign evaluations showed that after the campaign, more people disagreed with certain inaccurate statements contained in the Back Beliefs Questionnaire (BBQ), such as that back trouble requires rest; that back trouble will eventually stop one from working; that there is no real treatment for back pain; and that once one has had back trouble, there is always a weakness. The desired beliefs were maintained for at least 3 years after the campaign ended and were held more widely in Victoria than in neighboring New South

continued

BOX 4-1 Continued

Wales (Buchbinder and Jolley, 2004). General practitioners' beliefs also improved, and claims for back injuries fell by 15 percent (Buchbinder et al., 2001b).

The Victoria campaign messages were disseminated through television, radio, billboards, posters, seminars, workplace visits, and news articles. The messages included the following:

- Back pain is not a serious problem.
- People with back pain should continue their usual activities and exercise, without resting for long periods or leaving work unnecessarily.
- People with back pain should maintain a positive attitude.
- X-rays are not useful, and surgery may not help.
- Employees should remain at work.

Underlying the Victoria campaign were specific, informed convictions about disease prevention. Campaign organizers focused on improving beliefs in a majority of the population that had been somewhat undecided ("had intermediate beliefs") instead of trying to improve "the poorest beliefs" held by only a few people. They also thought that influencing attitudes communitywide could produce sustained behavioral change and that even expensive mass media campaigns would ultimately be more cost-effective than one-on-one education (Buchbinder, 2008).

Scotland

Influenced by the Australian experience, National Health Service authorities in Scotland also conducted a media campaign on back pain, involving 1,777 radio announcements that reached three in five of the country's adults. The effort further included leaflets, as well as information packets distributed to health professionals and employers. The campaign produced a positive effect on public and professional attitudes, as most people became aware of the benefits of staying active for those with back pain. However, the Scottish campaign, which was far smaller in scale than its Australian counterpart, did not reduce disability claims or worker absenteeism (Waddell et al., 2007).

Norway and Canada

Back pain campaigns modeled on the Australian and Scottish efforts have taken place in parts of Norway and in the province of Alberta, Canada. The Norwegian effort was relatively small and, like the Scottish campaign, improved beliefs but not workers' compensation claims (Werner et al., 2008). The Alberta effort also was small, involving mostly radio announcements, and produced little effect on beliefs and no appreciable change in work behavior or health care utilization (Gross et al., 2010). As the evaluators of the Alberta campaign emphasized, mass media campaigns must be large in order to influence behavior significantly.

Tobacco use in the United States has fallen dramatically, for example, partly as a result of systematic public education. Between 1991 and 2009, use levels among high school students declined by 34 percent for "ever smoked cigarettes," by 29 percent for current cigarette use, and by 43 percent for current frequent cigarette use (Office on Smoking and Health, 2010). Among adults, smoking rates declined by 24 percent between 1992-1993 and 2006-2007 (Giovino et al., 2009). Local combinations of a well-designed public education campaign, community and school-based programs, strong enforcement efforts, and smoking cessation programs have reduced smoking among youth by as much as 40 percent (Campaign for Tobacco-free Kids, 2011). Mass media tobacco control campaigns are associated with both declines in youth uptake of smoking and adult smoking cessation (Wakefield et al., 2010).

The back pain campaigns described in Box 4-1 and tobacco control campaigns represent one type of public education—social marketing—which uses simple messages, advertising techniques, and other marketing approaches to persuade large numbers of people to change behavior or support changes in public policy (Kotler and Lee, 2008). Other public education strategies include more neutral informational and awareness-building efforts. Like social marketing, these efforts seek people out proactively. In the pain context, such efforts could alert people to the range of available treatments and categories of health professionals who treat pain, to available educational resources, or to the fact that pain is both a physical and a psychosocial condition. These strategies also might also focus on reducing risk factors for pain. For example, they could remind people with frequent headaches to avoid using analgesics daily or near-daily to minimize the development of medication-overuse headache (Loder, 2006).

Many educational tools are useful in reaching the public:

- website content, listservs, and social media;
- fact sheets distributed to target audiences, such as opinion leaders or community meeting attendees;
- leaflets, to raise awareness and be retained as personal references;
- informational reports and studies;
- pamphlets distributed at schools, workplaces, churches, public meetings, and other venues;
- signs at health facilities and in health professionals' offices;
- media outreach;
- coalition building among stakeholders;
- surveys of public or professional attitudes used to garner media attention;
- wellness classes at health facilities, gyms, senior centers, and adult education programs, for example;
- instructional videos; and

- attempts to influence purveyors of popular culture, such as television and movie scriptwriters.

An advantage of comprehensive educational efforts is that content can be far more complex than simple messages delivered via the mass media. Also, most of these approaches can be tailored to specific audiences, segmented by health status, risk group, demographic characteristics, language skills, or preferred educational media. Some educational initiatives could target nonhealth professionals who receive people's initial reports of pain, such as employers, teachers, and clergy (Chapter 3), or third-party payers and others who influence the course of pain care. An additional advantage of public education overall is that it can draw people into public decision-making processes, for example, by encouraging them to ask their employer to make sure that their health insurance plan sufficiently covers pain management or advocate that their local public schools have an injury prevention policy, especially in sports programs.

Illustrating the capacity of public education about health issues, the American Cancer Society (ACS) has been effective in its long-term efforts to promote cancer screening and early detection. ACS began as a public education organization in an era when cancer was rarely talked about openly, and used film and other media to engender emotion and gain support for cancer research and care (Cantor, 2007). The organization maintains a nationwide 24-hour help line and offers information about local resources, clinical trials, awareness building, smoking cessation, and specific cancers (ACS, 2011). Additionally, ACS actively advocates for public policies to increase cancer prevention, care, and research and participates in prohealth coalitions (ACS et al., 2008).

Over a shorter time frame, end-of-life educational efforts have been similarly instrumental in such areas as making more Americans aware of the importance of advance directives (Ulrich, 1999; *Patient Self-Determination Act*, Public Law 101-508, Secs. 4206 and 4751 of *Omnibus Budget Reconciliation Act of 1990*). Prominent among these end-of-life educational efforts was the Last Acts campaign, a coalition-based enterprise that engaged in multiple public and professional education initiatives (Karani and Meier, 2003). For example, one Last Acts product was a national report card indicating how well each state was protecting end-of-life decisions and ensuring high-quality care for people with terminal illnesses (Robert Wood Johnson Foundation, 2003).

Public education is undertaken by many other nonprofit organizations dedicated to combating a single disease or constellation of health conditions. Typically, their efforts mix patient (and family) and public education. Alzheimer's disease, for example, is targeted by multiple groups that have both public and patient education as part of their mission:

- The Alzheimer's Association maintains a website with access to such materials as a chartbook and a list of ten warning signs of the disease (Alzheimer's Association, 2011).
- The American Geriatrics Society's Foundation for Health in Aging administers a Patient Education Forum with online answers to such questions as: "What effect can Alzheimer's disease have on a caregiver?" and "How important is early detection and diagnosis of Alzheimer's disease?" (American Geriatrics Society, 2011).
- A California Alzheimer's disease task force adopted a statewide plan to reduce stigma, ensure that information clearinghouses have reliable information, increase access to public information, and promote public education (California Health and Human Services Agency and California Council of the Alzheimer's Association, 2011).
- The National Institute on Aging maintains an Alzheimer's Disease Education and Referral Center.

Educational efforts by these and many other organizations have helped make the country more aware of Alzheimer's disease and have assisted individuals and their families in finding information and support.

Currently, public education about pain is not conducted in a large-scale, systematic, coordinated, and strategic way as in the tobacco, cancer, end-of-life, and Alzheimer's disease examples. Some organizations, such as the American Pain Foundation and the Mayday Fund, certainly promote public awareness. Several patient-oriented groups focused on single pain conditions or issues—such as the National Fibromyalgia Association, Women with Pain Coalition, and American Chronic Pain Association—take strong advocacy positions. The issue of access to opioid medications has sparked numerous public advocacy efforts over the past two decades. But neither the federal government nor a coalition of pain organizations that could assemble more resources has designed and undertaken a campaign to increase public awareness of such topics as the pervasiveness of pain and the need to treat it, the multiple causes and effects of pain, the fact that pain involves a complex mind–body interaction, and the range of available and useful treatments. Without such an effort, it appears unlikely that public awareness of these issues will increase substantially in the near future or that the cultural transformation envisioned by this committee (Chapter 1) can be achieved.

On the federal level, informing the public about pain has not received sustained priority attention from the Centers for Disease Control and Prevention (CDC), the Office of the Surgeon General, the Agency for Healthcare Research and Quality (AHRQ), or the National Institutes of Health (NIH), although CDC, AHRQ, and NIH all have displayed an appreciation for the importance of pain. CDC, for example, has publicly released a fact sheet on pain (CDC, 2006); AHRQ conducted an early study on back pain and publicized the results (Chapter 3); and

NIH has assembled a Pain Consortium (Chapter 1). Pain also does not receive focused attention in the latest Healthy People report (Chapter 2).

Public education is a normal public health activity; indeed, "inform, educate, and empower people about public health issues" is one of the Ten Essential Public Health Services that every public health agency is expected to provide (CDC, 2011). Public education enhances the effects of each of the concentric circles of major influence on disease control: policy, community-wide environmental control measures, community awareness support and action, work and school support, clinical expertise, family involvement, and patient self-management (Clark and Partridge, 2002).

Advocacy, especially at the state level, may be an appropriate education-related activity for organizations interested in reducing the burden of pain in society. To illustrate, the Massachusetts Pain Initiative has supported state legislation to require pain assessment and management in all health facilities, extend the expiration date of scheduled drugs to comply with federal law, require pain management and prescription drug abuse training for all prescribers, and establish a prescription monitoring program task force (Massachusetts Pain Initiative, 2011).

Just as public education programs may require the combined financial resources of several organizations, advocacy efforts typically require the combined voice of a strong coalition. Given the multiple barriers to better pain prevention and care, such a combined effort may be needed to have a significant impact at the federal level; in state capitals; and with key private organizations, such as health insurers, health professions training and accreditation authorities, health professions examination boards, large health care providers, employers, schools, and sports officials. Effective, multifaceted, and coordinated advocacy is a necessary condition for cultural transformation.

Patient and public education, the two topics addressed in the first part of this chapter, help shape the *demand* for pain care. The following sections turn to the *supply* of health professionals adequately prepared to provide pain care, beginning with physicians.

PHYSICIAN EDUCATION

> *Pain management and physical rehabilitation were never addressed in my medical school curriculum nor in my family practice residency. My disability could have been avoided or lessened with timely treatment, and I could still be the provider instead of the patient.*
>
> —A physician with chronic pain[4]

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[4] Quotation from response to committee survey.

> *Did we have as students a single lecture on migraine, and did anyone tell us that migraine is not just a tiresome form of occasional headache which someone else rather boringly suffers from?*
>
> —William Gooddy, Foreword to *Migraine*, by Oliver Sacks, p. xxii.

The case for including comprehensive education about pain in medical education is powerful. People have sought out physicians for pain care for centuries. Pain treatment is an essential component of clinical practice, as recognized in state medical practice acts and by the Federation of State Medical Boards in its model Medical and Osteopathic Practice Act:

> Practice of medicine means . . . offering or undertaking to prevent or to diagnose, correct and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition of any person. . . . (Federation of State Medical Boards, 2010, p. 4).

The widespread prevalence of pain (Chapter 2) demonstrates the need for medical educators to recognize it as a common and often severe condition. Yet there are strong indications that pain receives insufficient attention in virtually all phases of medical education—the lengthy continuum that includes medical school (undergraduate medical education), residency programs (graduate medical education), and courses taken by practicing physicians (continuing medical education [CME]).

Deficiencies in preparing physicians to manage pain were documented and explored in depth during the First National Pain Medicine Summit, convened in November 2009 by the American Medical Association's Pain and Palliative Medicine Specialty Section Council (Lippe et al., 2010). The genesis of the summit was widespread concern that current knowledge about pain management is not being well integrated into medical practice and that pain care in general is "delayed and inadequate." Nearly 100 representatives of some 30 physician organizations participated in this exercise. The summit agenda was built around a two-stage Delphi, or group consensus development, process. The first stage produced strong criticism of current physician training in pain care:

- Training was seen as poor or "not leading to competency" at both the undergraduate and residency levels in all suggested areas of pain treatment. Rated highest was pharmacologic therapy training at the residency level, but even in that area, only 53 percent of respondents agreed that the training led to competency. None of the areas received a majority of "yes" votes to the question of whether adequate care was being provided in that area.

- Participants identified three top barriers to adequate pain care: workforce issues that create a shortage of competent pain care providers, a lack of knowledge among physicians and/or people with pain regarding the field of pain care medicine, and a lack of public knowledge about pain issues. All three factors were seen as barriers by more than 90 percent of respondents.
- The average score for the question, "How well does the present system of credentialing and certification ensure competency?" was 2.65 (where 1 was "not at all" and 5 was "completely").

Themes extracted from respondents' comments in the first Delphi round were used to identify five topics that became the subject of work group discussions in the second round:

- What should all physicians know about pain medicine?
- How should pain medicine be taught?
- What are the parameters that define the field of pain medicine?
- What mechanisms do we need to establish the competency of a physician who wishes to practice pain medicine?
- What are the barriers, besides the absence of competent pain medicine physicians, that prevent people from receiving adequate care?

The summit therefore may have laid the groundwork for substantial improvements in physician education about pain. The summit work group discussing the question, "What should all physicians know about pain medicine?" concluded that most medical school education still treats pain mainly as a symptom. "Cure the disease, and cure the pain" is the assumption, which ignores the emerging recognition that persistent pain requires direct treatment (Chapter 1). The group found little consistency in teaching across medical schools, among departments in the same school, and even within departments (Gallagher, 2010). Identified as chief flaws were a lack of breadth in the presentation of the topic, a lack of integration of basic science and clinical knowledge, and a lack of clinical role models—especially specialists treating chronic pain—in most academic medical centers. The results included "negative generalizations about patients with chronic pain" and "further alienation and misunderstanding of the patient and chronic pain." Moreover, this first work group observed that pain management is spread out over many clinical specialties, creating confusion about "who is in charge" of developing, documenting, and reporting best practices and pain care guidelines. As a result, there are "no standards for measuring the effectiveness of treating pain in clinical practice." The work group also noted the paucity of information about treating pain in children.

The summit work group discussing the question, “How should pain medicine be taught?” echoed the first group’s findings and focused on the need to make pain training more comprehensive, “incorporating the needs of the primary care practitioner and the pain care specialist” alike (Burchiel, 2010, p. 1452).

The work group discussing the question, “What mechanisms do we need to establish the competency of a physician who wishes to practice pain medicine?” identified the need to determine competency through medical education, assessment, and documentation through all three stages of education. Meeting this need will require oversight of education by accreditation authorities and oversight of practice by licensure and certification authorities, including greater attention to CME (Follett, 2010). This work group’s discussion suggests that improvement could be realized if organizations such as the Accreditation Council for Graduate Medical Education (ACGME) and the National Board of Medical Examiners took steps to require pain training of most residents and include questions about pain on physician licensure examinations, respectively.

Finally, the competencies work group determined that “competing, overlapping, and sometimes conflicting efforts of the various organizations involved” mean there is no “single-party” ownership of the pain medicine specialty. This makes it difficult to develop a uniform process for training, certification, and demonstration of competency, a situation further complicated by the availability of pain treatment by nonphysicians “whose variable training and certification add even more disparity to the mix” of competencies of different practitioners.

The summit findings emerged against a backdrop of continually expressed concerns that most physicians are not equipped to provide high-quality pain care. One concern is that too many physicians harbor outmoded or unscientific attitudes toward pain and people with pain (see Chapter 3). For example, physicians are described as having “pain apathy” that inhibits them from engaging in active treatment (Notcutt and Gibbs, 2010). The perspective of scholars in medical anthropology or social medicine provides a theory about this lack of interest:

> . . . in our studies over several decades, we found that “the medical gaze” soon becomes the dominant knowledge frame through medical school, that time and efficiency are highly prized, and that students and their attendings (that is, clinical educators) are most caring of patients who are willing to become part of the medical story they wish to tell and the therapeutic activities they hope to pursue. (Good et al., 2002, p. 596)

Pain may not be part of the “medical story” most physicians are interested in telling or learning about because they concentrate on other diseases and conditions.

People with pain, especially chronic pain, sometimes do find that physicians are poor listeners. In a study of physician communication with people with cancer pain, involving 17 oncologists and 84 patients, physicians were found to do most of the talking during patient visits and to interrupt most patients’ attempts to provide information or answer questions (Berry et al., 2003). The researchers concluded: "The nature of such communication may prevent the patient from sharing significant facts and experiences relevant to cancer pain and thus compromise the quality of pain management" (Berry et al., 2003, p. 374). A previous Institute of Medicine (IOM) study recommended additional training for medical students in subjects involving communication skills to "assist physicians in building therapeutic relationships with their patients and increase the likelihood that patients will follow their advice" (IOM, 2004, p. 4).

Inadequate training in pain is strongly implicated in insufficient treatment. An expert panel convened by the Mayday Fund reported:

> . . . current systems of care do not adequately train or support internists, family physicians and pediatricians, [who are] the other health care providers who provide primary care in meeting the challenge of treating pain as a chronic illness. Primary care providers often receive little training in the assessment and treatment of complex chronic pain conditions. They tend to work under conditions that permit little time with each individual and few options for specialist referrals. (Mayday Fund, 2009, p. 3)

The Mayday panel recommended that every health professional be taught "the skills to assess and treat pain effectively, including chronic pain" (Mayday Fund, 2009, p. 9). Presumably, those skills would include the application of cognitive-behavioral therapy, which also can be useful in treating conditions other than pain and should be appropriately reimbursed (Chapter 3).

Medical schools' inadequate attention to comprehensive pain education has been quantified. A recent study of 117 U.S. and Canadian medical schools found that only 4 U.S. schools offer a required course on pain (Mezei and Murinson, in press). Most schools incorporate pain into another required course. The study also found that over the 4-year course of U.S. medical school education

- the total number of pain sessions taught ranged from 1 to 28, with a mean of 9 and a median of 7; and
- the total number of pain teaching hours ranged from 1 to 31, with a mean of 11 and a median of 9.

Levels about twice as high were found at Canadian medical schools. The inadequacy of attention to pain in medical schools is reflected in students' specialty preferences. In a questionnaire administered annually to graduating medical school students, the percentage of respondents indicating pain medicine as their preferred choice of specialty stood at a flat 0.0 from 2006 through 2010 (AAMC, 2010).

What do primary care physicians themselves think of their preparation in pain management? Results of a national survey of residents completing their training at U.S. academic health centers, including training in the primary care specialties for which pain management is an essential component (internal medicine, family medicine, and obstetrics-gynecology), found that

- half the primary care respondents felt only "somewhat prepared" to counsel patients about pain management;
- as many as 27 percent felt "somewhat unprepared" or "very unprepared";
- only 21 to 26 percent felt "very prepared"; and
- in response to questions about treating specific common pain problems, only about half of the internal medicine residents rated themselves "very prepared" to diagnose and treat low back pain or headache, compared with about two-thirds of family medicine residents and a quarter or less of obstetrics-gynecology residents (Blumenthal et al., 2001).

The Association of American Medical Colleges has surveyed all medical graduates regarding whether their instruction in various areas was inadequate, appropriate, or excessive. In 2006, a quarter of graduates rated their instruction in pain management and palliative care as inadequate. The rating improved somewhat by 2010, with only 20 percent rating instruction in this area as inadequate (AAMC, 2010).

Likewise, in a survey of 1,236 practicing physicians, more than half said they felt poorly prepared to manage end-of-life or chronic pain care (Darer et al., 2004). However, physicians (and other clinical staff) working in a rehabilitation hospital appeared somewhat more confident of their competence in most pain management skills (Loder et al., 2003). In a survey in which 111 staff members participated, large majorities (between 63 and 89 percent) said they were comfortable with such tasks as engaging in basic pain assessment, providing psychological support, using thermal modalities for pain, managing pain in the elderly, and teaching relaxation techniques.

Some efforts are under way to improve pain education and training in medical schools in creative ways. For example, at the Johns Hopkins University School of Medicine, a new 4-day program in pain medicine for first-year students integrates core curriculum knowledge with emotional and reflective development (Murinson et al., 2011). Pain specialists provide instructional support, and the course emphasizes building "emotional skills." Student performance on a variety of outcome measures has been encouraging.

In CME—the end of the medical education continuum for practicing physicians—attention to pain also has increased somewhat. In 2001, California enacted legislation requiring all physicians other than radiologists and pathologists to take 12 CME units in pain management or end-of-life care; this mandatory CME provision is implemented by the state's Board of Medical Examiners through regulation (California Business and Professions Code, 2011, Sec. 2190.5). This is a one-time-only requirement, however, and so does not compel clinicians to stay abreast of developments in the field throughout their careers.

Another possible shortcoming of mandatory CME is that the relationship between CME and desired changes in practice patterns is somewhat limited. In a recent review of 105 studies, only 60 percent showed that CME produces changes in physician practice patterns (although the authors found this to be a persuasive reason to promote CME) (Davis et al., 2009). A targeted approach to CME in pain management would require it only of physicians who prescribe high levels of opioids.

One frontier of CME (and quality improvement) appears to offer promise for physicians seeking to improve their competence in pain management. Academic detailing, in which medical school professors or other nonindustry experts offer tailored instruction to clinicians, was offered by a drug and therapeutics information service to primary care physicians in Fayette County, Kentucky (May et al., 2009). Instruction, in the form of personal visits, was offered in two subjects: diabetes management and pain management. Nearly three in five physicians chose to accept visits dealing with pain management.

Education and Training of Primary Care Physicians

Not all physicians require the same amount of pain-related knowledge and skills. Because so few physicians specialize in pain management, the main source of medical care for most people with common chronic pain problems is a primary care practitioner (Chapter 3), which makes the need for medical education about pain especially important in primary care training. Yet primary care physicians do not believe that they are well prepared to manage pain:

- In a survey of 500 primary care physicians at 12 academic medical centers, only 34 percent reported feeling comfortable treating people with chronic noncancer pain (O'Rorke et al., 2007).
- A survey of 111 primary care practitioners (including physicians, medical residents, nurse practitioners, and physician assistants) at community clinics found that most felt inadequately prepared to treat pain and had low satisfaction with providing pain care, even though nearly 40 percent of adult appointments involved people with chronic pain complaints (Upshur et al., 2006).
- A survey of 279 residents in internal medicine and 326 residents in family medicine showed that only about half of those in internal medicine considered themselves adequately prepared to diagnose and treat headache or low back pain, while 62 percent of those in family medicine felt adequately prepared to treat headache and 71 percent low back pain. Greater patient exposure and contact improved residents' confidence in managing these pain conditions (Wiest et al., 2002).

Wiest and colleagues (2002) concluded that reorganization of graduate medical training programs to increase patient contact might improve residents' readiness to care for common pain conditions. However, physicians' beliefs about their ability to manage pain do not always match their actual competence, and physicians may not recognize deficits in their pain care knowledge:

> [There is] no correlation between physicians' confidence in their knowledge and abilities to manage pain and their ability to make good treatment decisions. Educators and policy-makers need to develop effective tools for self-assessment and creative ways of using these tools to helping [sic] physicians understand and remediate their knowledge and skill deficits. (Gallagher, 2003, p. 3)

A drive toward competency-based education, as supported by one of the 2009 pain summit work groups described above, is being promoted within internal medicine (Weinberger et al., 2006; Meyers et al., 2007). (General internists are one of the main categories of primary care physicians.) Recognizing pain management as part of the core competency of internal medicine could substantially improve the ability of a large group of physicians to manage pain.

Even if formal residency training programs are not altered to incorporate pain and pain management, Internet-based updates and tips might increase residents' awareness of developments in pain care (Sullivan et al., 2010; Claxton et al., 2011). Another way to improve primary care physicians' ability to manage pain would be to expand interdisciplinary education in pain so that more pain care can be delivered competently and efficiently by a primary care team instead of having to be handled by an individual physician (see Chapter 3). Given the nationwide shortage of primary care physicians, teams may deliver most primary care in the future. Further, according to Cooper (2009, p. 125), "the notion that future patients may experience regular 30-minute visits with a primary care physician is not credible." To illustrate, teams consisting of a physician, nurse, medical assistant, and patient care representative have successfully managed hypertension in 88 percent of patients (Feder, 2011), and the American Academy of Family Physicians is ambitiously supporting the development of medical homes that use teams to provide chronic care (Nutting et al., 2011). The development of accountable care organizations could further accelerate the trend toward team care (DeVore and Champion, 2011).[5]

Still, some skepticism about the potential to transform pain care through primary care teams probably is well founded. The United States has a long history of failed attempts to promote interdisciplinary teamwork (Grumbach and

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[5] A completely different model is that used in the United Kingdom under its system of "specialization in general practice" (Jones, 2006). Preliminary findings in a headache service suggested that, for patients with comparable severity of illness, outcomes from care by generalists with special training in headache management were similar to those from care by a traditional neurology service, while patient satisfaction was higher and costs were lower (Ridsdale, 2008).

Bodenheimer, 2004). Poor communication skills and technologies, a lack of appreciation of the capabilities of different disciplines, entrenched interprofessional conflicts, and inexperience in collaborating collegially across professional divides make team practice difficult. In general, professional silos allow few opportunities for meaningful interaction and joint problem solving (IOM, 2001b). The route to success in team care probably begins with interdisciplinary training so that members of different professions become comfortable with collaboration (Schuetz et al., 2010).

Training and Credentialing of Physician Pain Specialists

At present, pain medicine is recognized by the American Board of Medical Specialties (ABMS) not as a distinct physician specialty but as a subspecialty fellowship training program that can be offered by residency programs in anesthesiology, physical medicine and rehabilitation, and psychiatry and neurology. Although these pain fellowship programs could admit physicians trained in other specialties, they rarely do.

The American Board of Anesthesiology first issued pain subspecialty certificates in 1993, and the other two specialty boards followed in 2000. After completing an accredited pain fellowship, candidates are allowed to sit for an examination; if they pass, they receive board certification in pain medicine. The certification examination for all three boards is administered by the American Board of Anesthesiology (ABMS, 2010).

Between 2000 and 2009, a total of 3,488 physicians obtained board certification in pain medicine (Chapter 3). This amounts to 4 percent of all physicians obtaining certification in some field during that decade. Many who did obtain certification in pain medicine are believed to have allowed their certification to lapse because of retirement, difficulties in obtaining desired reimbursement for specialty pain care, or other factors.

The American Board of Pain Medicine (ABPM) also certifies physicians in the field of pain medicine. ABPM is not a member of ABMS, but state medical boards in California and Florida deem it to be equivalent to ABMS for purposes of recognizing a physician as board certified in pain medicine—entitled, therefore, to advertise as a board-certified specialist and to seek insurance reimbursement at specialist rates. Whereas ABMS pain certification is subsidiary to the three fields of anesthesiology, physical medicine and rehabilitation, and psychiatry and neurology, ABPM certification is held out as a free-standing, or "primary," specialization.

Approximately 2,150 physicians have been certified in pain medicine by ABPM since 1991. Some pain specialists hold both ABMS and ABPM certificates. Thus, in light of lapsed certificates, the actual number of certified, currently practicing pain specialists may be in the range of 3,000 to 4,000.

These small numbers, set against the large number of Americans with pain conditions, clearly demonstrate that referral to a pain specialist is not easily accomplished.

Simultaneously with the effort to establish pain fellowship training in the 1990s and early 2000s, interest was growing in palliative care, and certification somewhat similar to the pain medicine certification is provided in that field. Although broadly concerned with symptom relief in terminal, progressive illnesses, palliative care necessarily involves a substantial degree of pain treatment. Both fields address pain and other symptom control; physician–patient communication; fatigue; and psychosocial issues, such as depression and social problems (IOM, 2001a, p. 60). An IOM report published in the 1990s (IOM, 1997, pp. 287-288) contributed to the development of the palliative care field. Recommendations from that report included the following:

- Educators and other health professionals should initiate changes in undergraduate, graduate, and continuing education to ensure that practitioners have relevant attitudes, knowledge, and skills to care well for people who are dying.
- Palliative care should become, if not a medical specialty, at least a defined area of expertise, education, and research.

ABMS approved hospice and palliative care subspecialties in 2006 and began awarding certificates in 2008 for ten medical specialties: anesthesiology, emergency medicine, family medicine, internal medicine, obstetrics and gynecology, pediatrics, physical medicine and rehabilitation, psychiatry and neurology, radiology, and surgery.

In addition, since 2006 the United Council for Neurologic Subspecialties (UCNS) has offered subspecialty certification in headache medicine to qualified candidates who pass an examination. UCNS is sponsored by five parent organizations, including the American Academy of Neurology and the American Neurological Association. UCNS also accredits headache medicine fellowship programs. Beginning in 2012, only physicians who have completed an accredited headache medicine fellowship will be allowed to sit for the UCNS headache medicine certification examination. As of 2010, 294 physicians had passed this examination, and there were 12 accredited headache medicine fellowship programs (United Council for Neurologic Subspecialties, 2011). The very existence of the UCNS certification effort may reflect the lack of sufficient attention to pain care in the overall scope of graduate medical education.

In 2008, three leading academic centers, perhaps perceiving a leadership vacuum, convened a conference to discuss ways to improve pain education for physicians. Participants recommended, in part:

- finding ways to expose more neurology residents to people with chronic pain;
- recruiting the most gifted teachers and promoting use of the best teaching methods in pain education;
- identifying academic champions of pain research, whom students and residents could seek out; and
- outlining a curriculum for medical students, primary care physicians, neurologists, and pain specialists that identifies specific information necessary to help each medical professional accurately diagnose and appropriately treat or refer people with pain (Drexler, 2008).

A bright side of the picture consists of the presence of 93 pain fellowship programs—1-year programs typically sponsored by, and located at, an academic medical center (ACGME, 2011). Generally, physicians who have completed a residency in a pain-related specialty are eligible to apply for one of these fellowships. Fellowship programs are accredited by ACGME, based on rigorous standards (ACGME, 2007). But specialization in pain medicine is now such a long path, involving core residency training followed by a pain fellowship, that potentially interested physicians may be deterred from entering the field.

Most physicians who are board certified in pain medicine are anesthesiologists by prior training. In part, this reflects the early attention of the anesthesiology field to pain—attention that began with that specialty's origins, when William Morton first publicly demonstrated the effects of ether in Boston in 1846. By virtue of its historical and current ties to pain management, the specialty of anesthesiology tends, more than other specialties, to attract physicians interested in pain care. In addition, most pain fellowship training programs are anesthesiology based, so the majority of physicians interested in pain management will take advanced training in such programs. The result can be a loss of the diversity that can be advantageous for the systemwide practice of multidisciplinary pain care as practitioners from disparate medical backgrounds (e.g., neurology and physiatry) learn similar approaches to pain care. In 2007, the ACGME committee that oversees pain fellowship training redefined the training requirements to emphasize the importance of multidisciplinary care with the integration of training from the fields of neurology, psychiatry/psychology, physiatry, and anesthesiology. For a variety of reasons, however, such as reimbursement patterns or patient preferences for invasive, procedural techniques, even graduates of programs that provide multidisciplinary training may develop clinical practices that focus disproportionately on interventional (procedural) approaches to pain care (Chapter 3). If so, patients may have little opportunity to choose among treatment options to obtain the treatment most appropriate for them.

While anesthesiology has a key position in the delivery of pain care, other specialties have strong reasons to engage in pain medicine. One reason is the potentially broad range of applications of pain medicine's rapidly evolving knowledge base. For example, analysts conducting a literature review regarding the relationship between pain and psychiatry found that "psychiatric disorders are commonly associated with alterations in pain processing" and that "chronic pain may impair emotional and neurocognitive functioning" (Elman et al., 2011, p. 12). The analysts concluded that pain training among psychiatrists would enable "deeper and more sophisticated insight" into both pain syndromes and psychiatric conditions, regardless of patients' pain status. The same could be true of other specialties as well.

Promoting Physicians' Understanding of Medication Abuse and Misuse

Physicians' understanding of opioid-related issues, especially diversion of drugs for illicit purposes, is an important concern, discussed in Chapter 3. What is particularly relevant here is the existence of knowledge deficits among physicians on important topics related to opioids (e.g., Fineberg et al., 2006).

For example, prescriptions written by physicians can inadvertently enter the nonmedical, illegal market. Accordingly, physicians should assess the risk that medications they prescribe in the care of their patients could find their way into unauthorized use and counsel their patients about this possibility. Further, professional confusion and the recent rise in opioid diversion and abuse contribute to a backlash against the medical use of opioids. This backlash leads, in turn, to restrictive public policies and enforcement approaches, reduced access to opioid medications, and individual and family apprehensions about using these drugs.

Development of a standardized curriculum in pain management and opioid prescribing across disciplines has been suggested by the Nurse Practitioner Healthcare Foundation (Arnstein and St. Marie, 2010, p. 4). A foundation white paper states: "One of the main adverse consequences of the rise in prescription opioid use is the potential criminalization of pain sufferers who use opioids and the [health care professionals] who prescribe these agents to treat pain." The white paper recommends providing outcome-oriented continuing education and making pain education available to all members of health care teams, including those who are not health professionals.

NURSE EDUCATION

> *Every patient is an individual pharmacological experiment; one size does not fit all.*
>
> —A nurse in a pain management clinic[6]

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[6] Quotation from response to committee survey.

The experience of pain is an overwhelming, whole-person experience with devastating effects on the experiencing person, the family witness, and the nurse.

—Nurse educator Betty Ferrell (2005)

Nurses provide bedside care to people with pain in hospitals and nursing homes, in patients' homes, at schools and workplaces, in physicians' offices, in public health and patient education programs, and as advanced practice nurses (a category that includes nurse practitioners, clinical nurse specialists, certified nurse midwives, and nurse anesthetists). Nursing leaders emphasize their profession's focus on the "whole patient," a helpful perspective when one is considering the complex interplay of factors involved in caring for people with acute and chronic pain. Nurses are educated to take into account that the "human response to a health problem may be much more fluid and variable" than suggested by the medical diagnosis and a greater key to recovery than a single medical treatment (ANA, 2011, p. 1). Moreover, nurses are trained to be attentive to the needs of families, who play a vital role in the care of people with chronic pain.

More specifically, nurses with baccalaureate degrees are charged with responsibility for providing care that incorporates many components of high-quality pain care. A recent report of the American Association of Colleges of Nursing states:

> Baccalaureate-prepared nurses provide patient-centered care that identifies, respects, and addresses patients' differences, values, preferences, and expressed needs (IOM, 2003). Patient-centered care also involves the coordination of continuous care, listening to, communicating with, and educating patients and caregivers regarding health, wellness, and disease management and prevention. The generalist nurse provides the human link between the healthcare system and the patient by translating the plan of care to the patient. A broad-based skill set is required to fill this human interface role. (American Association of Colleges of Nursing, 2008, p. 8, citing IOM, 2003)

To the extent that such psychosocially oriented care is delivered to people with chronic pain early in their course of treatment, it may have a particularly salutary effect in preventing serious problems—such as the progression from acute to chronic pain—later on. The report also outlines expectations for students' clinical experiences within baccalaureate programs. These clinical experiences should be "focused on developing and refining the knowledge and skills necessary to manage care as part of an inter-professional team" and should take place "across the range of practice settings" (American Association of Colleges of Nursing, 2008, pp. 4, 34).

Pain management now is considered an essential responsibility for nurses, and nursing organizations acknowledge the need for "prompt, safe, and effective pain management." The nursing profession views pain as a complex and multidimensional experience (Lewis et al., 2011) that responds subjectively to both physical and psychological stressors (LeMone et al., 2011). In a joint position statement, the American College of Emergency Physicians, American Pain Society, Emergency Nurses Association, and American Society for Pain Management Nursing enunciated 14 core principles regarding pain management (American College of Emergency Physicians et al., 2010). Two of these principles refer to educational issues:

- Clinician education and resources [should] support optimal pain management.
- Research and education are encouraged to support widespread dissemination of evidence-based analgesic practices.

Elsewhere among these principles, the need to rely on evidence-based practices is reinforced. Despite these well-articulated goals for nursing education, however, shortfalls persist. A survey of 111 nurse practitioners and physician assistants working in community clinics, surveyed about the adequacy of their training for pain management, rated it 0.5 on a scale of 0 to 4 (Upshur et al., 2006).

Numerous actions demonstrate the nursing profession's commitment to high-quality pain care. In 2006, the house of delegates of the American Nurses Association passed an "Improving Pain Management" resolution (Trossman, 2006). And in 2005, the American Nurses Credentialing Center began administering a certification examination in pain management for generalist nurses (ANA, 2005).

Recognition of the need to sensitize and educate nursing students about pain management has been based on evidence and expert opinion. College students surveyed were found to have "many misconceptions" about pain management that must be addressed before education specific to pain management is attempted (McCaffery and Ferrell, 1996), although efforts to overcome personal biases and opinions are not universally successful. For example, nurses' personal opinions about patients' pain levels have been shown to affect their clinical behavior (McCaffery et al., 2000).

One important construct, interprofessional education, is intended to increase the effectiveness of the care received from both physicians and nurses. An example of an initiative intended to foster improved interdisciplinary teamwork is that of the Centers of Excellence in Primary Care Education program of the Department of Veterans Affairs, which recently awarded grants to five of the department's medical centers and collaborating organizations (Department of Veterans Affairs, 2011). The funded centers will "develop and test innovative approaches to prepare physician residents and students, advanced practice nurse and undergraduate nursing students, and associated health trainees for primary care practice in the

21st Century." The projects are designed to promote shared decision making; interprofessional collaboration; quality improvement; and longitudinal relationships among students, patients, and teachers. These projects may well contribute to enhancing pain care, a central focus of veterans' services (Chapter 3).

In other, nonfederal settings, state laws that restrict the scope of practice of nurse practitioners and other advanced practice nurses may impede the delivery of primary care (IOM, 2010). Given that responsibility for most pain care falls heavily on primary care practitioners, and too few primary care physicians exist to shoulder that burden, nurse practitioners are likely to play an increasingly important role.

One innovation in nursing pain education consists of pain resource nurse (PRN) programs. Initially developed at the City of Hope National Medical Center, PRN programs are intended to create a cadre of well-trained nurse coaches and mentors to promote nurses' use of best-practice pain strategies. PRN training includes in-person coursework, regular follow-up in-service training, newsletters, ongoing peer support, and other forms of education. This approach has been found to produce significant improvements in nurses' knowledge and attitudes about pain care, as well as improved patient satisfaction with pain control and a reduction in the prevalence of pain (Paice et al., 2006). However, some participants in PRN programs have expressed frustration with "the slow pace of change and improvement, the lack of visible signs of their success, and the ongoing nature of the work" (McCleary et al., 2004, p. 34). Institutional support is considered key to the success of the PRN initiative.

OTHER HEALTH PROFESSIONS EDUCATION

> *If dentists couldn't offer "pain-free" dentistry, no one would go to them!*
>
> —A dental educator[7]

Many health professions are involved in pain care. Although a comprehensive survey of the pain-related educational preparation of all health professions is beyond the scope of this report, the committee identified a few particularly noteworthy efforts.

Psychology

Psychologists, in particular, have addressed the need for professional education about pain management. An ad hoc subcommittee of the multidisciplinary

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[7] Quotation from committee member.

International Association for the Study of Pain (IASP) developed a core curriculum for educating psychology students about pain (IASP, 1997, p. 1), which still appears progressive 14 years later. The subcommittee declared:

> All pain has a psychological component and psychological factors are important at all stages of pain (whether the problem is acute, recurrent or chronic) and have a major role in the prevention of unnecessary pain-associated dysfunction in a wide range of settings from primary prevention to terminal care.

IASP's detailed curriculum encompasses

- nociceptive mechanisms,
- experimental and clinical pain measurement,
- the psychological impact of different types of pain,
- psychological and behavioral assessment of the individual with pain,
- the psychosocial impact of pain,
- pain syndromes particularly influenced by sex and gender,
- life-span issues,
- health care seeking,
- the economic and occupational impact of pain-associated disability,
- psychological and psychiatric treatment,
- pharmacological and invasive pain management procedures,
- interdisciplinary treatment programs,
- prevention and early intervention,
- treatment outcome and evaluation, and
- ethical standards and guidelines.

The Health Psychology Network, an online educational source for psychologists, includes chronic pain as one of eight areas in which it offers information about evidence-based treatments (Health Psychology Network, 2011). Similarly, the American Psychological Association's website targets pain as one of seven types of disorders or health problems that need additional attention from policy makers (American Psychological Association, 2011).

As is true with other health professions, it would be useful to encourage more psychologists to provide pain care and to conduct pain-relevant research. As the profession of psychology has matured in the past half century, specialization, and even subspecialization, among practicing psychologists have increased. Most psychologists who claim a specific expertise in pain management have pursued specialty training in clinical health psychology (France et al., 2008), which is dedicated to developing scientific knowledge at the interface between behavior and health and to delivering high-quality services based on that knowledge. Education and training programs in clinical health psychology emphasize approaches and experiences that are entirely consistent with some of the core principles of pain management emphasized in this report, including adherence to the biopsychosocial model, integration of science and practice, interdisciplinary methods, and explicit attention to culture and diversity.

Education and training in the specialty of clinical health psychology, and by extension pain psychology, follow a graded and sequential series of learning experiences beginning with doctoral training programs in clinical or counseling psychology, followed by internship training and specialty training at the postdoctoral level (Kerns et al., 2009). On an entirely volunteer basis, some psychologists pursue specialty board certification in clinical health psychology following a more intensive process of continuing education and training beyond the doctoral degree. However, only recently has the American Psychological Association begun to accredit specialty training in clinical health psychology at the postdoctoral level. Even so, pain psychology remains a subspecialty within the broader field of clinical health psychology, and there are no explicit criteria for credentialing psychologists with specific expertise in pain management.

Despite an apparently robust market for psychologists with this expertise, the field has been slow to expand its capacity for education and training of psychologists with competencies in pain management. One of the key challenges is that doctoral training programs in clinical and counseling psychology may not have faculty with this interest and expertise, thus limiting students' exposure to the field, including clinical practicum experiences and participation in research laboratories or clinical research settings. The few students who do develop this interest and expertise are likely to pursue internship and postdoctoral training in the subspecialty area in academic medical environments that support this training. In the past 10 years, for example, the Department of Veterans Affairs has continued to expand its predoctoral and postdoctoral psychology training programs, and with this expansion and an increased emphasis on system improvements in pain management for veterans (see Chapter 3), a growing number of training opportunities for psychologists interested in pain management have emerged. A small and growing number of subspecialty training opportunities in pain psychology, focused on pain-relevant rehabilitation and health services research, also have begun to emerge.

Dentistry

The Commission on Dental Accreditation (CODA) states that dental school "graduates must be competent in providing oral health care within the scope of general dentistry, as defined by the school, for the child, adolescent, adult, and geriatric patient . . . including anesthesia, and pain and anxiety control. . . ." (CODA Standard 2-25e, 2007). Pain management and control, particularly for acute and postoperative pain, remain a core curriculum component that, historically, has affected the relationship between dental procedures and pain.

As a specialty, dentistry has long recognized the fear of the dental experience. Dental education programs have therefore taken steps to decrease the pain associated with dental care through several approaches, aided by the advent of new anesthetics (local anesthesia, intravenous [IV] sedatives, and inhalation agents such as nitrous oxide). In addition the American Dental Association (ADA) and several other dental organizations have held comprehensive workshops on pain control. And through the active work of dental educators and the dental community, *Guidelines for Teaching the Comprehensive Control of Pain and Sedation to Dentists and Dental Students* provides training guidelines for predoctoral dental programs, postdoctoral (residency) programs, and continuing dental education (ADA, 2007). These efforts have allowed dentistry to evolve from a specialty restricted to extracting problematic teeth; to one that restores and maintains a person's natural teeth; to one that promotes prevention of caries and periodontal disease and the recognition that dental care can have an effect on a person's overall health.

As an example of postgraduate (residency) training that includes specific competencies in pain management and anxiety control, oral and maxillofacial surgery residencies typically include 4 months of training as an anesthesiology resident. Residents must demonstrate competence in outpatient ambulatory surgeries utilizing IV sedation techniques and pain control. Acute pain control is managed aggressively and has improved the overall experience of the patient.

Unfortunately, the development of chronic pain of the temporomandibular joint (TMJ) or the orofacial region is poorly understood, and that type of pain is poorly controlled. Management approaches vary among practitioners and may highlight a variable etiology. However, there is growing evidence that the negative affective, cognitive, and psychosocial state of chronic pain is universal, whether it be non-neuropathic/nociceptive pain (TMJ chronic pain) or neuropathic pain (trigeminal neuralgia), which suggests that cognitive-behavioral therapy may help (Gustin et al., 2011).

Although predoctoral programs and continuing education in chronic orofacial pain are limited, the ADA recently established accreditation standards for postgraduate training in orofacial pain. A particular emphasis in this advanced training program is the incorporation of interprofessional care.

Physical and Occupational Therapy

Rehabilitation therapies are an important part of pain care (Chapter 3). Historically, however, physical therapists were not well prepared to help manage pain. In a survey of 119 physical therapists who belonged to the American Physical Therapy Association's Section on Orthopaedics, all but 4 percent said they preferred not to work with patients likely to have chronic pain, 72 percent said their entry-level education in pain management was very inadequate or less than adequate to handle orthopedic patients, and pain knowledge scores were found to be low (Wolff et al., 1991). In a faculty survey of slightly more than

100 accredited physical therapy education programs in North America, the modal amount of time spent on pain in the curriculum was 4 hours; most respondents nevertheless believed pain was adequately covered, except for pain in the elderly and children and cognitive-behavioral therapy (Scudds et al., 2001). Similarly, in a survey of 201 seniors in occupational therapy programs, the mean score on a 10-item test about pain was 61 percent (Rochmann, 1998). And in an Australian-based study of 35 recent occupational therapy graduates, the combined score on a test including 69 questions about pain knowledge and attitudes was only 53 percent (Strong et al., 1999).

Pharmacy

Another health profession that has focused on pain is pharmacy. To improve the use of analgesics to achieve "good therapeutic outcomes for patients," some pharmacists and physicians have created drug therapy management teams, or even collaborative practice models (Brushwood, 2001). A few states authorize collaborative practice in which physicians consult pharmacists about the use of opioid medications, and both practitioners share accountability.

Complementary and Alternative Medicine (CAM)

Because complementary and alternative therapies are widely used in pain care (see Chapter 3), the education of CAM practitioners is an important component of health professions education about pain and pain management, although systematic reviews of this training are scant. In general, education and training of CAM practitioners are less formal than is the case for physicians, nurses, and other conventional health professionals, in part because of the lack of accreditation standards for CAM education programs, the existence of many small proprietary training programs, and a chaotic set of state licensure regulations for CAM practitioners (Kreitzer et al., 2009). Thus, for example, substantial variation has been found in pain education among chiropractors and acupuncturists (Breuer et al., 2010).

Few educational programs in state-licensed CAM fields involved in pain care—chiropractic, acupuncture, naturopathic medicine, traditional Chinese medicine, and massage therapy—appear to focus specifically on pain and pain management. However, several interdisciplinary undergraduate and graduate degree or certificate programs have emerged that allow for a focus on pain in CAM practice. For example, a collaborative program sponsored by Tufts University School of Medicine and the New England School of Acupuncture provides an opportunity for master's students in acupuncture to enroll in a multidisciplinary pain management program at Tufts (White House Commission on Complementary and Alternative Medicine Policy, 2002). Several organizations representing CAM practitioners and others who offer pain treatment (e.g., the American

Holistic Medical Association, American Association of Orthopaedic Medicine, and American Association of Naturopathic Physicians) are able to contribute to the education of relevant stakeholders.

CONCLUSION

Curricula for all health professions are full, and advocates of many important causes compete for a greater share of students' and clinicians' valuable educational time. Yet despite the large role that care of patients with pain will play in their daily practice, many health professionals, especially physicians, appear underprepared for and uncomfortable with carrying out this aspect of their work. These professionals need and deserve greater knowledge and skills so they can contribute to the necessary cultural transformation in the perception and treatment of people with pain.

FINDING AND RECOMMENDATIONS

Finding 4-1. Education is a central part of the necessary cultural transformation of the approach to pain. The committee finds that the federal government is in a position to contribute to substantial improvements in patient and professional education about pain.

> **Recommendation 4-1. Expand and redesign education programs to transform the understanding of pain.** Federal agencies and other relevant stakeholders should expand education programs to transform patient and public understanding of pain. In concert with Recommendation 2-2, federal agencies, in partnership with health professions associations, payers, pain advocacy and awareness organizations, and other relevant stakeholders, should develop education programs for patients, the public, and health care providers that are designed to promote a transformation in their expectations, beliefs, and understanding about pain, its consequences, its management, and its prevention. Programs should
>
> - be endorsed by expert pain health professions organizations;
> - strive to increase awareness of the significance of pain, its prevention, the need to address acute and chronic pain in timely and effective ways, the biological and psychosocial aspects of pain, and the need for comprehensive assessment of pain, as well as to instill a balanced understanding of available treatments;
> - incorporate materials such as fact sheets and information that can be made widely available, including on the Internet; and
> - be specifically and appropriately targeted to patients, the public, and providers to ensure understanding of the concepts being imparted.

Recommendation 4-2. Improve curriculum and education for health care professionals. The Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, accrediting organizations, and undergraduate and graduate health professions training programs should improve pain education curricula for health care professionals.

- Accrediting organizations, such as the Liaison Committee on Medical Education and American Psychological Association Committee on Accreditation, should establish specifically identifiable standardized curriculum requirements for pain education.
- The Centers for Medicare and Medicaid Services should provide financial support for advanced training in pain management.
- The Bureau of Health Professions should provide financial support for training grants for the education of practitioners in pain assessment and management.
- Undergraduate and graduate health professions training in programs whose graduates will participate in pain care should include pain education.
- Relevant accrediting organizations (such as residency review committees and the Accreditation Council for Graduate Medical Education) should establish specifically identifiable and standardized curriculum requirements for pain education in graduate training programs, such as primary care programs.
- Training should include education in interprofessional settings.
- Assessment of pain knowledge should be included in examinations for licensure (e.g., the U.S. Medical Licensing Examination), certification (the American Board of Medical Specialties), and recertification.
- Health care professionals should engage in ongoing pain education through postgraduate continuing education programs.

Recommendation 4-3. Increase the number of health professionals with advanced expertise in pain care. Educational programs for medical, dental, nursing, mental health, physical therapy, pharmacy, and other health professionals who will participate in the delivery of pain care should have increased capacity to train providers who can offer advanced pain care.

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5

Research Challenges

> *We want the best damn science this country can give us.*
>
> —Terrie Cowley, The TMJ Association, Ltd.,
> an advocate for people with chronic pain[1]

The last several decades have seen remarkable strides in understanding of pain processes, as well as in assessment and, to some extent, treatment of pain, with new techniques and technologies being applied to one of humanity's oldest problems. Important new insights into the basic science of pain—from genetics and molecular biology, to neural networks and neuroimaging, to the role of psychosocial factors—are unraveling pain's mysteries. Some of these new insights have been highlighted earlier in this report. At the same time, the preceding chapters demonstrate that much remains to be learned. For example:

- The section in Chapter 1 describing the current understanding of how pain works delineates the many physical and psychosocial attributes of pain and shows not only how far we have come but also how much more there is to learn about the biological, psychological, sociological, and environmental aspects of pain and its diagnosis, treatment, and prevention.
- The description in Chapter 2 of the increasing prevalence of pain, the extent to which it affects various population groups, and its societal costs

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[1] Quotation from testimony to the committee, November 2010.

and effects on families reveals that data on pain are spotty and conflicting and provide only a partial picture of pain's impact.
- The discussion of treatment approaches and system issues in Chapter 3 reveals a number of gaps and conflicting public policies regarding the management of pain.
- Chapter 4's discussion of shortfalls in education about pain with respect to promoting the application of even existing knowledge suggests the need for robust translational research and heightened efforts to understand how to educate and reach patients and the public more effectively with useful messages about pain and its management.

This chapter focuses primarily on clinical and translational research opportunities—opportunities to fill the needs and gaps in pain research by building on new discoveries. A number of prestigious organizations have been engaged in devising new strategies for pain research, and the committee did not attempt to readdress the specific recommendations of these groups. Rather, it focused its deliberations on what is needed to make pain research initiatives a reality and to enhance translational research—research based on interactions and feedback loops between researchers and clinicians on the one hand and between patients and researchers on the other—so as to bring new discoveries to patients more rapidly. Similar interactions are needed among educators, communication specialists, and researchers to enable more effective public dissemination of information (with feedback) about pain and its management. The overall goals are to expedite the process of translating scientific findings into patient care in tandem with the development of new knowledge and to gain insights that will lead to future progress in diagnosis and treatment.

Of note, the National Institutes of Health (NIH) recognized the breadth of areas for new knowledge development related to pain when it developed its 2011 request for "new and innovative advances . . . in every area of pain research." Annex 5-1 at the end of this chapter reproduces NIH's descriptions of these vital areas of research and the kinds of research questions of interest under the following broad topics:

- molecular and cellular mechanisms of pain,
- genetics of pain,
- biobehavioral pain,
- models of pain,
- diagnosis and assessment of pain,
- pain management,
- epidemiology of pain,
- health disparities, and
- translational pain research.

The committee considered NIH's specification of topics to be comprehensive, and instead of attempting to repeat the effort to identify specific topics for research, focused its deliberations on what is needed to optimize pain research initiatives. Nor did the committee address in detail overall workforce needs because NIH has stated plans for its own effort in that area later in 2011.

The U.S. research establishment is not alone in placing increasing emphasis on the need for improvements in pain knowledge. The International Association for the Study of Pain (IASP) has made October 2010 to October 2011 the "Global Year Against Acute Pain," highlighting a number of research-related problems that are barriers to better acute pain treatment, including

- incomplete, sporadic, or nonstandard pain assessment;
- limited transferability of results derived from randomized controlled trials (RCTs) to clinical practice;
- other problems in evidence transfer, including general barriers to implementing evidence-based and outcome-driven practices;
- failure to capture short- and long-term quality outcomes that might be correlated with the adequacy of acute pain control; and
- disproportionately low expenditures for basic, translational, and clinical research relative to the burden of acute pain (IASP, 2010).

In the United Kingdom, the British Pain Society is working toward developing chronic pain patient pathways, and its efforts are proceeding in parallel with the interests of the U.K. Department of Health's Chronic Pain Policy Coalition and experts working with the National Institute for Health and Clinical Excellence, with the aim of hosting a Pain Summit in November 2011. Additionally, the Royal College of General Practitioners has established pain as one of four new clinical priorities for the years 2011 to 2013 (Baranowski, 2011).

The committee finds the new knowledge that may be developed under these international initiatives exciting but is aware that there also is a significant problem with respect to the appropriate use of currently available therapeutic modalities, and is concerned about the slow pace and unsystematic way in which important basic research results are adopted (or not) into medical practice. The concern is that "the current clinical research enterprise in the United States is unable to produce the high-quality, timely, and actionable evidence needed to support a learning health care system" (IOM, 2010, p. 7). Efforts are under way to address these issues by improving and diversifying research methods, expanding research targets, streamlining the organization and funding of research, encouraging collaboration among research teams and disciplines, and promoting public–private partnerships, but gains have been slow.

Because of the biopsychosocial complexity of the pain process (Chapter 1) and the variable ways in which different individuals and population groups are affected, assessed, and managed (Chapter 2), and because of the lack of specific scientific assessment tools and biomarkers with which to identify underlying processes, it is difficult to determine what treatment will work best for individual patients without a frustrating and debilitating period of trial and error. At this time, diagnostic tools, as well as treatment approaches for many chronic pain syndromes, are often empirical, and the metrics for defining pain, along with the endpoints for determining a therapeutic response, are not well measured or properly considered in the evaluation of therapeutic interventions. A more multifactorial approach that takes into account the individual's genetics, biology, social and cultural history, and psychological and environmental factors is needed, along with objective metrics for defining response.

In this context, this chapter examines research challenges in the following areas: expanding basic knowledge, moving from research to practice, improving and diversifying research methods, building the research workforce, organizing research efforts, obtaining federal research funding, and fostering public–private partnerships.

EXPANDING BASIC KNOWLEDGE

> *The complexity of the "pain web" in the brain indicates the difficulty that comes with evaluating a multidimensional experience such as pain and pain affect. . . . Patients present with one or more actual pain generators, a wide range of past life experience in dealing with pain and suffering, and with their own natural proclivities and resources for handling their pain burden. Successful clinical and research outcomes must be capable of addressing or controlling for such wide variability.*
>
> —Director of a pelvic pain specialty center[2]

Long-term investments in multiple basic science disciplines—physiological, cognitive, and psychological—are essential to the development of targeted pain therapies and safer, more effective pain management strategies. This section examines in depth one promising basic research area—biomarkers and biosignatures—because results of this research could be useful in their own right and because other types of research could be strengthened by incorporating biomarker and biosignature data. This discussion is followed by a review of other active areas of basic research that may ultimately lead to improved pain management and a synopsis of opportunities in psychosocial research.

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[2] Quotation from response to committee survey.

Biomarkers and Biosignatures

Biomarkers are used to identify individuals at risk for disease, diagnose a condition, assess its progress, or predict its outcome. They are "quantitative biological measurements that provide information about biological processes, a disease state, or . . . response to treatment" (IOM, 2008, p. 1). Two or more biomarkers used in combination are termed a "biosignature." In the pain context, combining information from neuroimaging and circulating molecular markers, for example, can improve the sensitivity and specificity of diagnosis relative to that attainable from either method alone—vital information for treatment (Woolf, 2010).

Promising biomarkers for pain research come from a broad range of rapidly expanding fields, including proteomics, metabolomics, immune modulation, inflammatory processes, central neuroimaging, and neurocognitive processes, as well as new knowledge about the interactions among organ systems. Since up to half of the variation in the pain experience appears to be a result of individual biological factors, genetic markers are an obvious target for biomarker development (Kim and Dionne, 2005). Another active and needed area of research is the integration of biomarkers across the multiple dimensions of basic, behavioral, and environmental sciences to improve the understanding of what causes, amplifies, and maintains pain.

To be sure, biomarker development faces a number of challenges. In general, biomarkers specific to neurological and psychiatric disorders have been difficult to identify, and clinical testing has been "plagued by factors such as patient heterogeneity, lengthy trial durations, subjective readouts, and placebo responses" (IOM, 2008, p. 11). The complexity of the brain, limited access to brain tissue, and the blood-brain barrier pose additional difficulties. An important nonphysiologic barrier to biomarker development is the lack of incentives for academic, industry, or government research programs to pursue promising biomarker candidates.

Moving biomarkers from basic to clinical research also may be a challenge. As discussed in Chapter 1, the experience of pain involves the interaction of many different physical, psychological, and cognitive processes, and a person's report of pain is inherently subjective. Clinicians seeking to use an objective measure of pain (a biomarker) risk implying to the patient that they do not believe the patient's report. If biomarkers were validated (and perceived by patients) as aids in identifying promising beneficial treatments rather than "substantiating" or "verifying" patients' pain reports, they might have a useful and accepted role in pain care. Most valuable would be their potential to obviate the need to conduct lengthy hit-or-miss trials of different therapies before identifying the one that works best for a given individual (Woolf, 2010).

Finally, biomarkers potentially could play a role in pain prevention by identifying individuals at high risk for whom special effort should be made to avoid triggering events or situations and to intervene promptly when they occur. This function would be analogous to that of using genetic testing to identify people at elevated risk for heart disease or cancer.

Other Promising Basic Research

Knowledge about the way nociception and pain work at basic biological, genetic, and pathophysiologic levels has advanced rapidly in the past 20 years—knowledge that should facilitate the discovery of new analgesics through new approaches related to the following:

- *Genetics*—The scientific understanding of the role of genes and gene polymorphisms in pain mechanisms is increasing. The potential exists to carry out genomewide screens for genes associated with pain in model organisms.
- *Ion channels*—Research on ion channels has intensified over the last several years in an effort to explain their role in the development and maintenance of chronic pain syndromes. For instance, investigators have identified several subtypes of voltage-gated sodium channels—a substrate by which products of inflammation and growth factors trigger chronic pain states. These channels can be nonselectively blocked by lidocaine, mexiletine, lamotrogine, carbamazepine, and amytriptyline—all drugs used to treat chronic pain. Unfortunately, their nonselectivity results in significant side effects. Now, researchers and pharmaceutical companies are developing drugs that block more selectively those peripheral and central nervous system sodium channels that change their expression in chronic pain states. Similar efforts are under way to characterize the role of other transient receptor potential (TRP) ion channels.
- *Glial cells*—The glial cell has traditionally played a supporting role to the neuronal cell in acute and chronic pain. More recently, investigators have reevaluated the glial cell's importance as an initiator and maintainer of chronic pain states through its role in linking the immune, inflammatory, and nervous systems. Researchers have discovered that some types of glial cells[3] have a major impact on chronic neuropathic pain, challenging the old treatment paradigm of reducing neuronal activity to reduce pain. Indeed, targeting glial cells may result in a new class of therapies that are disease modifying rather than simply palliative.
- *Stem cells*—Use of stem cells to create neurons might enable study of the response of human cells to new drugs, in vitro, early in the drug development process (Woolf, 2010). This field is in a nascent stage but holds promise.

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[3] Schwann cells, satellite cells in the dorsal root ganglia, spinal microglia, and astrocytes.

- *Neuroimaging*—Researchers have used neuroimaging tools—functional magnetic resonance imaging (fMRI), positron emission tomography (PET), and magnetoencephalography (MEG)—to investigate the central nervous system correlates of the human pain experience. Although pain is a subjective experience, the brain regions and systems responsible for that experience can now be identified and characterized, including brain regions responsible for the pain-modulatory effects of attention/distraction, anticipation, fear, anxiety, depression, placebo, and cognitive control. Neuroimaging also yields valuable information regarding central abnormalities in pain processing in chronic pain conditions and the effects of therapeutic agents on central neural systems. In short, neuroimaging opens windows into the brain's functioning.
- *Veterinary science*—Further opportunities should be sought to learn from the significant clinical veterinary studies of pain treatment in animals that experience conditions analogous to human pain disorders.

Opportunities in Psychosocial Research

In the psychosocial realm, there is a need for multidisciplinary research to develop and test novel theories that can explain how biological, psychological, and social factors interact to influence pain. Given the growing interest in tailoring of treatments, a particularly important research opportunity is to develop a way to subgroup patients (phenotyping) based on genetic and demographic factors, pain mechanisms, symptoms, and psychosocial adjustment to pain. Phenotyping studies should include measures that not only capture persistent psychological traits (e.g., personality traits) but also measure more dynamic processes, such as changes in mood, thoughts, beliefs, expectations, and coping efforts.

Conclusion

Focusing and integrating all of the above efforts would move pain research a step closer to personalized medicine. "Collectively, these [developments] will enable us to identify the mechanisms responsible for pain in each individual, the most appropriate treatment and the side effect hazards" (Woolf, 2010, p. 1246).

MOVING FROM RESEARCH TO PRACTICE

> *Each condition is being researched separately, which dilutes the effort. We won't understand any of them very well or why someone has one and not the other. Almost 80 percent of patients with vulvodynia also fit diagnostic criteria for TMJ. They have allergies and chronic headache long before they have a TMJ problem. "You have this, and two years later you have that."*
>
> —Terrie Cowley, The TMJ Association, Ltd.,
> an advocate for people with chronic pain[4]

A consistent, general direction of both basic and clinical and both physiological and psychological pain research is toward more personalized approaches to pain. Tailoring pain interventions to the specific makeup of the individual is attractive not only because it would presumably enable more effective treatment and avoid some of the serious downsides of current treatment options, but also because it might, finally, provide a viable strategy for prevention of pain. Further, personalized approaches might enable clinicians to address simultaneously the underlying causes of several pain syndromes, which sometimes cluster in a single individual. This section describes important challenges in moving from research to practice, including the difficulty of developing new analgesics, shortfalls in applying evidence-based psychosocial approaches in practice, and the need for interdisciplinary approaches.

The Difficulty of Developing New Analgesics

From 2005 to 2009, only a few of the nearly 100 new drugs approved by the U.S. Food and Drug Administration (FDA) were for chronic pain conditions, specifically arthritis and fibromyalgia (FDA and CDER, 2011). Furthermore, other than the recently introduced capsaicin patch for postherpetic neuralgia, no new therapeutic agents have been approved that represent truly novel approaches to pain management. Instead, most drugs approved recently are variations on existing molecules (e.g., pregabalin, duloxetine, nonsteroidal anti-inflammatory agents) or repackaged existing molecules (e.g., the many versions of extended-release opioids). It is ironic and concerning that "many major pharmaceutical companies are leaving the pain market" (Woolf, 2010, p. 1241), despite the growing need for more diverse pain products and an increasing population of people with serious pain conditions (see Chapter 2).

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[4] Quotation from testimony to the committee, November 2010.

Current pharmaceutical-based treatments for acute, severe, and chronic pain commonly rely on two classes of drugs: opioids (which have major side effects and carry a large risk of abuse and misuse [Chapter 3]) and nonsteroidal anti-inflammatory drugs, such as the COX inhibitors (which carry the risk of renal failure, heart attack, and other serious complications). As advances in basic research raise the possibility of more personalized approaches to pain care, the "one-drug-fits-all" approach to treatment may finally be replaced by more targeted therapeutics. But personalized approaches will have profound implications for "changing the current analgesic drug development model" (Woolf, 2010, p. 1246). A significant challenge will be to rethink current regulatory strategies, which typically do not differentiate among the classes of patients for which a drug is approved. Rethinking also will be required with respect to treatment strategies.

The appreciation that pain can become a chronic disease in and of itself through aberrant activity of the central nervous system should curtail the search for underlying disease pathology and redirect treatment efforts toward the malfunctioning nervous system itself—a "mechanism-based therapeutic approach" rather than a "strictly symptom-based approach" (Farrar, 2010, p. 1285). Thus far, however, "although considerable progress has been made in identifying pathophysiologic mechanisms of acute and chronic pain, this knowledge has not translated to the development of analgesic medications with improved efficacy, safety, and tolerability" (Dworkin et al., 2011, p. S107). In part this is because the very attributes that make personalized approaches to pain management possible also may inhibit incentives for pharmaceutical companies to develop those approaches. The economics of developing a product akin to an "orphan drug" that would work in a small number of people are unfavorable in the extreme given the high cost of both bringing a drug to market and identifying the relatively few clinicians and individuals who can benefit from it.

Recognizing the challenge to drug regulation posed by these expanding opportunities, the FDA has launched a Regulatory Science Initiative that includes a modernization of its evaluation and approval processes so as to give people access to innovative products when they need them.[5] Specifically, one priority for this initiative is to accelerate the delivery of new medical treatments by "increasing the practical value of basic discoveries" so that "patients have access to the most cutting-edge medical treatment possible" (FDA, 2010b, p. 4). One of the reasons the FDA offers to justify accelerated drug development is the need for pain medications with less abuse potential than the opioids. A personalized drug ideally would work well for the intended person but have minimal effects on others and therefore would be less attractive as a drug of abuse. To make new pain treatments available expeditiously will require improved pain models, measurement tools (including patient-reported assessments), and clinical trial designs.

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[5] The FDA defines "regulatory science" as the science of developing new tools, standards, and approaches for assessing the safety, efficacy, quality, and performance of FDA-regulated products.

Shortfalls in Applying Psychosocial Approaches in Practice

Much of what is known about psychosocial factors and pain has come from studying patients in medical specialty clinics and specialized pain treatment programs. Less is known about the psychosocial aspects of pain in general clinical practice. Although some large, nationally representative data sets (e.g., Medicare and Medicaid, the Department of Veterans Affairs, Kaiser Permanente, insurance industry claims data sets) include some measures of pain and its potential psychological impact, these data sets have only recently begun to be explored (Zerzan et al., 2006; Haskell et al., in press), and their potential for yielding answers to questions regarding health services has yet to be realized.

A variety of psychosocial treatment protocols for managing pain are available, and evidence of their clinical and cost-effectiveness has continued to accumulate over time (Kerns et al., 2008, 2011). Paradoxically, these protocols are not widely used, in large part because third-party payers are unwilling to pay for them despite the positive evidence. Another reason these interventions have not been adopted more broadly is because too little is known about such basic questions as their optimal timing and dosing and their additive effects when combined with other treatments (Keefe et al., 2005). These evidence-based approaches cover a range of activities that are

- *self-regulatory* (e.g., hypnosis [Jensen, 2009] and biofeedback);
- *behavioral* (e.g., weight loss [Sellinger et al., 2010], structured exercises, and exposure to daily activities that patients fear will increase their pain or contribute to additional injury [Bell and Burnett, 2009]); and
- *cognitive-behavioral* (e.g., training in coping skills, cognitive restructuring, problem-solving training [Morley et al., 1999; Hoffman et al., 2007]).

Over the past decade, a major effort has been made to test the efficacy and cost-effectiveness of psychosocial approaches in patients with chronic pain conditions (e.g., chronic low back pain and migraine headaches) and persistent disease-related pain (Gatchel and Okofuji, 2006; Hoffman et al., 2007; Morley et al., 2008). In general, meta-analyses and systematic reviews of these approaches demonstrate modest short-term improvements in pain and functioning compared with standard care (pharmacological and medical interventions). (Longer-term studies are still to come.) However, the psychosocial interventions produce fewer adverse effects and often are carried out at lower cost (Turk, 2002). Meta-analysis of such interventions for chronic low back pain, for example, revealed a small and statistically significant effect for all the interventions across all outcome domains for as long as 5-year follow-up (Hoffman et al., 2007).

Although meta-analyses of psychosocial interventions for pain often examine and comment on the methodological rigor of the studies they include, they give relatively little attention to the quality of the intervention protocols (e.g., number and content of sessions, extent of therapist training, ongoing supervision, uptake and implementation of the techniques by the participant)—factors that may be critical to the success of treatment. Nevertheless, a number of studies included in these analyses have found that many, though not all, people exposed to these protocols show significant improvements in measures of pain, physical functioning, and psychological distress (Gatchel and Okofuji, 2006; Dixon et al., 2007; Hoffman et al., 2007). The protocols themselves use various combinations of the types of activities listed above. Perhaps their most common feature is an emphasis on helping people with chronic pain learn to manage their pain and their lives despite residual discomfort. The public's awareness and understanding of the nature of these interventions and their potential benefit, as well as such factors as patients' motivation to engage in these treatments, are potentially important targets for further investigation (Jensen et al., 2003; Kerns et al., 2006).

To date, relatively few studies have attempted to test the effectiveness of these protocols in primary care settings, where the vast majority of pain management occurs, or with patients having comorbid conditions, such as obesity, diabetes, or depression. Furthermore, most studies have tested the efficacy of psychologist-delivered interventions, so that much less is known about the interventions' performance when delivered by physicians, nurses, physical therapists, social workers, or other health professionals (Keefe et al., 2005).

To bridge the gap between current research knowledge and clinical application, more needs to be learned about the effectiveness of psychosocial protocols in primary care settings. Only recently have investigators begun to develop and test innovative strategies for delivering in the primary care setting psychosocial interventions designed to promote self-management of chronic pain. In two important studies in this area, for example, psychologists or nurse care managers closely monitored patient symptoms and functioning and provided patient education and cognitive-behavioral therapy, and they encouraged adoption of a pain self-management approach in the context of more comprehensive care programs (Dobscha et al., 2009; Kroenke et al., 2009). In the study by Dobscha and colleagues, the broader intervention involved provider education and training plus support in the application of a biopsychosocial model of chronic pain treatment. At the same time, it de-emphasized the medicalization of chronic pain.

The Need for Interdisciplinary Approaches

The team approach to care of people with complex chronic conditions envisioned in the development of medical homes and accountable care organizations may lead to new care delivery models. Although the physical mechanisms of some pain disorders may be identified and adequately treated medically, more comprehensive interdisciplinary treatment and related research are currently the best alternative for those with chronic pain when the underlying mechanisms are unclear or those for whom demonstrated medical treatments do not exist. Interdisciplinary research can provide insight into the combinations of treatments—pharmacological, physical, psychosocial—most likely to achieve the optimal result (Dobscha et al., 2009; Kroenke et al., 2009).

Collaborative research is essential if pain care is to become truly interdisciplinary, multidimensional, and multimodal. Involvement of primary care clinicians will facilitate the translation of new pain assessment and management protocols, including psychosocial protocols, into clinical practice.

IMPROVING AND DIVERSIFYING RESEARCH METHODS

> *Pain treatment needs to be individualized and often combined, [which] presents challenges to research design and statistical analysis; however, in reality, many who live with pain use a variety of pain management strategies simultaneously to achieve their goals.*
>
> —An advocate for people with chronic pain[6]

Numerous barriers impede the development of improved and innovative ways to treat chronic pain. Among them are the need for new diagnostic measures for pain and the need for improved clinical research methods to determine the efficacy of treatments. Comparative effectiveness research (CER), improved clinical trial designs, and the development of biomarkers and biosignatures (discussed previously) are among the strategies that can help overcome these barriers. They would be particularly useful if augmented by detailed pain-related information, such as the severity and sites of pain, pain-related disability, genetic profiles, and psychosocial information, collected in a systematic way through observational research and available through well-designed clinical databases and pain registries. Additionally, since pain can involve multiple sites and frequently is accompanied by a constellation of other symptoms and reported health- and mental health-related conditions (for example, sleeplessness, gastrointestinal discomfort, fatigue, and respiratory complaints, as well as psychosocial maladies), research is needed to document and assess this full spectrum of pain-associated problems. This information would enable the development of interventions that would address all aspects of the pain condition (Natvig et al., 2010).

Meta-analyses of RCTs of currently approved chronic pain treatments have found that they produce relatively small (less than 30 percent) improvements in pain intensity compared with placebo. Moreover, fewer than half of people treated

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[6] Quotation from response to committee survey.

have more than half their pain reduced (Turk, 2002). Efforts to demonstrate analgesic efficacy have repeatedly failed, even among commonly used analgesics, including opioids (Chapter 3), despite a long history of human experience with using various forms of these agents for pain control. According to Dworkin and colleagues (2011, p. S108), "the explanation for failures of RCTs of efficacious analgesic treatments is currently unknown." Potential contributing factors include trial designs, methodological features, outcome measures, data analysis methods, and variations in populations studied, as well as the possibility that the drugs being studied are truly ineffective (Dworkin et al., 2011). These trials unfortunately have revealed little about the large number of nonresponders and what differentiates them from people in whom the tested drugs do make a difference.

Thus the search is ongoing not only for more effective and less risky treatments, but also for improved research methods. This section starts with a discussion of RCTs and their limitations for pain research and then describes initiatives to address those limitations. It then examines the potential usefulness in pain research of other research methods: CER; observational studies, databases, and registries; and psychosocial research. With respect to the latter, new, more sophisticated methods of data analysis are needed to build understanding of individual differences in pain and its psychosocial impact and to test causal or explanatory models of the role of psychosocial factors in the maintenance, magnification, and development of persistent pain.

Randomized Controlled Trials: The Gold Standard

RCTs have long been regarded as the gold standard for understanding the *safety* and *efficacy* of health care interventions, especially drugs. RCTs have a number of strengths, and they continue to play an important role in the development, evaluation, and regulatory approval of new treatments and interventions. Compared with alternative research methods, they carefully control for potentially confounding factors (internal validity)—hence their ability to provide specific answers to questions related to the efficacy of new treatments, compared with alternatives and with placebo, as well as questions about appropriate dosages of the treatment being tested.

However, there are significant problems with RCTs as used in the pain field, including their limited ability to predict *effectiveness* (external validity)—that is, how well a drug will perform in real-life populations (Dworkin et al., 2011). In particular, older adults—the age group in which pain is most prevalent—are often excluded from RCTs (Zulman et al., 2011). Yet this may be the age group for which predicting the effects of pain medications may be most important and difficult because of age-related organ system dysfunction, coexisting chronic conditions, and the probability that elders are taking multiple other medications. RCTs typically also have excluded people with comorbid psychological disorders, those with pain conditions other than that being studied, and those taking other medications. The clinical reality is, of course, that many people with chronic pain also have psychological symptoms (Chapter 1), have multiple types of pain, and take various medications for these conditions. As a result of these tight exclusion criteria, people enrolled in clinical trials are unlikely to represent the typical population of people with pain seen in a primary care clinic or pain center.

Some RCTs enroll relatively few subjects, and as a consequence, adverse outcomes (which may prove to be important) may go undetected. Moreover, comparator treatments included in RCTs often do not represent current best practices in care. For example, combinations of medications are common in clinical practice but rarely used in RCTs. RCTs have other disadvantages as well:

- They are expensive and administratively cumbersome and suffer from difficulties in recruiting sufficient numbers of subjects.
- Many RCTs are of relatively short duration (typically 4 to 14 weeks), whereas people with chronic pain may need to use a medication for many months to years. This is a critical shortcoming in trials of analgesics. Perhaps nowhere is this latter issue more of a problem than with prescription opioids. To date, there still has been no accurate assessment of the long-term safety and effectiveness of chronic opioid therapy (Martell et al., 2007).
- RCTs may be terminated early if initial results suggest serious toxicity (in which case termination is probably appropriate), but also if they indicate potentially dramatic benefits that researchers believe should be made available to everyone in the study. When trials are terminated early, less is known about the drug and its potential usefulness over the longer term.

In short, RCTs generally manage their study population very closely, but given the diverse biological, psychological, demographic, social, and clinical characteristics of people with pain, such trials may not be the best or the only way to evaluate new analgesic agents or therapeutic approaches. In the future, answering the many research questions about pain treatment likely will require novel research designs that can better align the strengths of RCTs with the design requirements of pain studies. What is needed is a balance of different, complementary research approaches.

Initiatives to Address Limitations of Clinical Trials

According to the FDA (2010a), "Many experts in analgesic drug development believe that it is the design of the clinical trials that is at fault in [the disappointing results in trials of new analgesics] and that better trial designs will yield more successful results." As discussed in Chapter 1, the slow translation of basic science findings into novel therapeutics is a major problem, and there is growing concern about the lack of innovation in the design and conduct of clinical trials that could improve the testing of potential therapies. Specific initiatives focused on pain have been making important contributions toward improving the consistency of pain outcome measures and resolving study design issues and problems inherent in the conduct and reporting of clinical trials. An important target of future research is a better understanding of how to increase the sensitivity of clinical trials, as well as new approaches to regulatory science that could enhance the efficiency of product approval while continuing to emphasize safety.

Over the last 20 years, several initiatives have been undertaken to address issues in the design of RCTs for pain-related disorders. Starting in 1992, the Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT) project was developed as an international organization of experts in outcome measurement for rheumatoid arthritis and osteoarthritis. The Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain and function scale grew out of this collaboration and has become the standard for most arthritis studies.

Since 2002, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), with industry funding, has been developing "consensus reviews and recommendations for improving the design, execution, and interpretation of clinical trials of treatments for pain" (IMMPACT, undated, website home page). Participants include representatives from academia, industry partners, U.S. government agencies (the FDA, NIH, the Department of Veterans Affairs), and consumer support and advocacy groups. IMMPACT has created databases to assist researchers in evaluating methods used in past RCTs related to osteoarthritis and neuropathic pain; in development are additional databases on fibromyalgia, back pain, and acute postsurgical pain. IMMPACT's recommendations and systematic reviews, as with those of its pediatric counterpart, Ped-IMMPACT, have helped guide the design of trials, clinical research, and a national survey, and its research reports and articles are widely published and cited in both specialty and general journals.

With its pivotal role in the approval of safe and effective therapies for pain, the FDA has undertaken new initiatives to support research on how to improve clinical trials. The Clinical Trials Transformation Initiative, a public–private partnership founded by the FDA's Office of Critical Path Programs and Duke University, now involves more than 50 organizations in efforts to identify practices that will "increase the quality and efficiency of clinical trials" (https://www.trialstransformation.org/).

Recently, the FDA provided seed money for a new effort—the Analgesic Clinical Trials, Innovations, Opportunities, and Networks (ACTION) initiative—described as "a collaborative effort designed to bridge gaps in the discovery and development of safe and efficacious analgesics" (FDA, 2010a). It has two key objectives: to initiate and foster collaborations among stakeholders in pain research in order to share data, best practices, and innovative thinking; and to leverage resources to speed the development of analgesic drugs. Its goal is to seek new ways of analyzing and standardizing trial data and to establish public–private partnerships to support projects aimed at improving trial design.

The initial activities of ACTION involve developing a standardized data submission template to facilitate analysis of clinical trial data; initiating analyses of factors, such as placebo group response rates, that may influence assay sensitivity using group data available through the FDA; and conducting a scientific workshop focused on improved efficiency of clinical trials. Future research objectives are to

- conduct analyses of databases created from clinical trials of analgesics from all available sources, including those submitted to the FDA as part of the drug approval process;
- develop and test novel methods for analyzing endpoints of analgesic trials;
- improve methodologies for the standardization of data collected in clinical trials and harmonization of data from completed trials of pain treatments; and
- establish an ACTION public–private partnership to provide an infrastructure for ongoing support of additional projects to inform analgesic development and trial design (Dworkin et al., 2011).

The sustainability of ACTION will depend on its ability to secure additional funding from a variety of public and private sources.

In short, the intent of all these initiatives is to enable improvements in trial design that may reduce the level of confounding results and speed the development of improved pain treatments. Ongoing support for these efforts will have an important impact on improving the availability of evidence-based therapeutic options for pain care.

Comparative Effectiveness Research, Observational Studies, and Psychological Research

CER is the generation and synthesis of evidence that can be used to compare the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care (IOM, 2009). Research on both existing and novel forms of pain management might benefit from using CER techniques to assess the relative effectiveness of various treatments overall and in specific populations. The results of CER are intended to assist consumers, clinicians, purchasers, and policy makers in making informed decisions that will improve health care at both the individual and population levels (IOM, 2009). Most gaps in the literature on chronic pain involve uncertainties regarding treatments for specific types of patients—those with comorbidities, specific genotypes, different disease stages, and so on.

In some countries, formal CER programs have been established to help national health authorities decide whether to reimburse for particular procedures (Satvat and Leight, 2011). That is explicitly not the goal of CER in the United States, although in a constrained economic environment, disallowing payment for treatments that clearly are ineffective or for costly treatments that clearly are of limited or questionable benefit may be an inevitable future step.

CER uses a number of different research methodologies, including RCTs, but also observational studies, as no single research approach can answer all questions about interventions and outcomes. CER that involves analyses of archival data from electronic health care databases and electronic health records holds great promise (see below). Such data are currently used extensively in pharmacoepidemiology and health services research. Although they are not as well controlled as RCTs, observational studies have a number of potential advantages: (1) they often use databases having large sample sizes with extended follow-up over long periods of time; (2) they can identify and track specific study populations; (3) they reflect routine, community-based clinical practice and can measure actual medication use; (4) subjects are managed according to standards of community practice, in academic health centers, or with clinical protocols; (5) the data may be sufficiently rich to allow researchers to focus on informative drug–drug and dosage-level comparisons; (6) they may include historical, demographic, disease-related (e.g., duration of symptoms), comorbidity, and psychosocial variables that may affect treatment response; and (7) they have the potential to capture information on important adverse effects treated by clinicians.

Increasingly, genomic and pharmacokinetic data can be included in health care databases and used to identify patient characteristics and treatments associated with better and more cost-effective outcomes. With these approaches, patient care and research needs can be collected in a common data set. By providing valid information about what works and in whom, CER serves as a key to individualized care and future innovation in personalized therapies (Garber and Tunis, 2009).

Not only pain management but also pain prevention and public health strategies can be investigated and enriched through CER. For example, population-based approaches can be used to assess targeted public education; regulatory mechanisms; and changes made to physical environments to prevent injuries in workplaces, schools, homes, athletic fields, and roadways. The use of CER to assess public health approaches usually requires a comprehensive research design that relies on observational studies or modeling approaches rather than RCTs partly because it is difficult to isolate a single social variable to determine the causes of changes in rates of illness or injury (Teutsch and Fielding, 2011).

CER also holds promise for informing pain-related public policy. To date, however, it has been used almost exclusively to test medical and surgical treatments for pain. For these studies to be useful in informing policy decisions at both the individual and population levels, their focus needs to be expanded so as to test the effects of psychosocial interventions for pain relief relative to one another and to other medical, rehabilitative, and complementary and alternative medicine (CAM) approaches.

Observational Studies, Databases, and Registries

Many databases can be used for the observational studies that support CER research, but three are particularly useful: large administrative databases, principally the Medicare database, which covers tens of millions of people; databases from health plans that use electronic medical records (for example, the Department of Veterans Affairs and the 16 organizations in the HMO Research Network); and the FDA's Sentinel Initiative on drug safety, which has access to millions of patient records. A growing area of importance is the emphasis on personal electronic medical records and the collection of specific data in carefully planned registries, such as those used for cancer patients. Large databases can be used to evaluate comparative safety as well as comparative effectiveness. They also can aid in comparing postintervention expenditures and utilization across different treatments, a topic of interest to insurers. Each has advantages, such as those cited above, as well as disadvantages. For example, large administrative databases contain limited information on the severity of the patient's illness and details on patient and treatment characteristics often available only in text form and are not easily exportable.

Condition-specific pain registries have been created—such as PainCAS™ (http://www.pain-cas.com/) and the National Data Bank for Rheumatic Diseases (http://www.arthritis-research.org/)—that contain various amounts of detail on patients, treatments, and outcomes (Wolfe and Michaud, 2011). This type of database usually contains details limited to one condition or syndrome and may not contain other valuable and important information, such as patient comorbidities and signs, symptoms, and physical findings that might affect the effectiveness and clinical outcomes of pain treatment.

Harnessing the growing amounts of clinical data currently stored within isolated health care systems and provider offices clearly holds potential for expanding the evidence base on the effectiveness of pain treatments. The development of systems to allow individual patients and physicians to access important medical information independently of any specific medical care system holds promise for the future. It offers the possibility of evaluating treatments and outcomes using observational study designs across the full spectrum of patients and practice settings and identifying heterogeneity in treatment effects among subpopulations. Wide geographic variation in the use of therapies (for example, joint replacement surgery) and new analgesics creates natural experiments that can reduce the biases usually associated with observational studies. These data sources also may provide efficient sampling frames for recruitment to large practical clinical trials or cluster randomized trials.

A relatively recent approach, practice-based evidence (PBE), was developed to overcome some of the limitations described above and has been used to determine which interventions are associated with better outcomes for specific types of patients in the actual practice of care (Horn et al., 2005; Horn and Gassaway, 2010). PBE uses the Comprehensive Severity Index (CSI®, http://www.isisicor.com/CSI_Flyer_p1.html), which is based on objective clinical findings rather than diagnostic codes to control for patient differences (Ryser et al., 2005).

A Chronic Pain PBE Registry© is being created in New York City, based initially on detail on thousands of patients treated in four pain clinics in three academic institutions (the Weill Cornell Medical College-New York Presbyterian Hospital, the Memorial Sloan-Kettering Cancer Center, and the Hospital for Special Surgery). In addition to the advantages cited above, this registry includes longitudinal scoring of severity of illness for all conditions for each patient, a wealth of detail on treatments, and information on outcomes that are measured by both patients and their providers.

If this type of registry proves useful, expansion to other locales or even nationally would be useful, although expensive. There is a need for greater development and use of such patient outcome registries that can support point-of-care treatment decision making, as well as for aggregation of large numbers of patients to enable assessment of the safety and effectiveness of therapies. These registries could help create "learning systems" that would provide clinicians with information about treatment success or failure on an ongoing basis, along with probability "filters" for information that might be particularly useful in the care of an individual patient.

The large databases and diverse populations offered by health system-wide research, combined with biosignature data on patients' individual characteristics, could contribute to the development of personalized medicine approaches that would take into account the wide variability in people's responses to pain and pain treatment. At present, researchers cannot differentiate among the various potential pain processes that may be occurring in a given person. Expecting a population of people whose pain etiology is heterogeneous to respond in the same way to a potential new analgesic in a clinical trial is a likely cause of some of the disappointing results that have been seen. In many cases, moreover, several biological processes are in play simultaneously, making it difficult to detect benefits from a treatment that has an impact on only one or a few of those processes (Farrar, 2010).

A principal reason why targeted therapy, based on genomic and other factors specific to individuals, has not become more widespread is the absence of clear, reproducible evidence for both its predictive power and its impact on patient outcomes. However, genomic approaches as applied to pain treatments are still in an early stage of investigation. As such information becomes increasingly available, the opportunity to test its usefulness across larger populations will depend on the quality and availability of individual-level data. The development of standardized approaches to collection, recording, storage, and access for such data, designed so that the privacy of the individual is carefully protected, is essential to achieving the goal of improved individualized pain care.

Psychosocial Research

Psychosocial research holds promise for greatly increasing the ability to understand and treat people with pain. Over the past several decades, significant progress in the development of research methods for assessing and treating pain has closed important gaps in understanding of how individuals perceive, react to, and adjust to pain, as well as how they respond to treatment. These approaches are relatively new and have not yet influenced health policy significantly or been widely adopted in clinical practice.

Assessment of Dimensions of Pain

Reliable and well-validated self-report measures are now available for assessing the experience of pain in adults and children, including pain intensity and other key dimensions. Valid and reliable self-report measures of emotional state and physical functioning also are available, including measures of pain's impact on different levels and types of activity (e.g., Western Ontario-McMaster Osteoarthritis Scale [Bellamy et al., 1988]; Fibromyalgia Impact Questionnaire [Bennett et al., 2009]).

One limitation of self-report measures is that some people, because of developmental or cognitive limitations, are unable to describe their pain verbally. To address this limitation, standardized observation methods for assessing pain-related behavior are now available—for example, assessments of facial expressions related to pain in neonates and people with advanced dementia (Hadjistavropoulos et al., 2007; McGrath et al., 2008) or movement patterns connoting the presence of pain (Keefe, 2000).

Clinicians often find it helpful to understand how a person with pain rates noxious stimuli that are of a known intensity and duration. Reliable and well-standardized psychophysical protocols for testing reactions to controlled noxious stimuli (quantitative sensory testing) are being used to study differences in pain perception by sex and gender, race and ethnicity, age, and other important variables (Walk et al., 2009; Maier et al., 2010).

A significant barrier to improving the diagnosis, evaluation, and monitoring of pain is the need for new assessment methods that can be integrated more easily into clinical practice and used in epidemiological studies. Clinicians often view self-report measures as too time-consuming for routine use, especially in busy primary care settings. Many of these current measures are therefore employed primarily in interdisciplinary pain specialty practices. Even there, their use may be limited to a one-time administration prior to treatment. Reluctance to use these measures for periodic reassessment prevents learning about changes in the pain experience and responses to treatment that could lead to treatment refinements and improved outcomes. It also inhibits development of the clinician–patient relationship so vital to effective pain treatment.

The Patient Report Medical Outcomes Reporting System (PROMIS), part of the NIH Roadmap for Medical Research, represents an important step (see http://www.nihpromis.org/). The goal of PROMIS is to develop and validate patient-reported measures that can be used to quantify clinical outcomes such as pain in adults and children (Fries et al., 2005; Revicki et al., 2009). Using sophisticated computer adaptive testing (CAT) methods, PROMIS will provide clinicians and researchers with short, valid, individually tailored, and easy-to-use methods for measuring pain in a wide variety of clinical and research settings. According to the PROMIS website, "Not only can the reports be used to design treatment plans, but also can be used by patients and physicians to improve communication and manage chronic disease" (NIH, undated-b).

Assessment of Psychological Traits and States Related to Pain Adjustment

Research conducted over the past two decades has led to a variety of reliable and valid self-report measures that can be used to assess psychological traits and states related to pain, as well as expectations, beliefs, and thoughts about pain and its impact (DeGood and Cook, 2011). These measures enable more precise characterization of how people adjust to their pain, and some of them can predict the development of pain-related disability and response to treatment (Linton and Hallden, 1998; Jensen et al., 2007).[7] Incorporating self-report measures of psychosocial adjustment into clinical practice prevents overly simplistic thinking about adjustment to pain and can lead to a new appreciation of the impact of pain and the need to address its psychological and social contexts.

A number of psychological markers have been demonstrated to predict chronic pain and related disability. For example, Carragee (2005), Jarvik et al. (2005), and their colleagues have reported that psychological distress is a better predictor of the development of chronic back pain and pain-related disability than physical pathology up to a year following initial assessment. Similarly, Klenerman and colleagues (1995) found that fear of pain and further injury was a better predictor than injury-related variables of prolonged disability following back injuries.

Over the past decade, structured psychiatric interview methods have been shown to offer another standardized and reliable way of assessing adjustment to pain (Sullivan and Brennan-Braden, 2011). Although more time-intensive than self-report, these methods may provide more accurate and reproducible results

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[7] Examples include the Brief Pain Inventory, Multidimensional Pain Inventory, and Western Ontario and McMaster Universities Osteoarthritis Index: http://www.rheumatology.org/practice/clinical/clinicianresearchers/outcomes-instrumentation/WOMAC.asp (Kerns et al., 1985; Cleeland and Ryan, 1994).

when used in persons with persistent pain and potentially co-occurring and treatable emotional disorders, such as those involving mood, anxiety, posttraumatic stress, substance use, and sleep difficulties.

Ongoing Assessment and Monitoring of Pain and Pain-Related States

Pain and related psychosocial processes are dynamic and vary considerably over time. A key step in capturing these dynamic processes is to make greater use of newly developed daily diary methods (Stone et al., 2003; Broderick et al., 2008). Sophisticated data analysis methods then can be applied to the diary entries to assess how day-to-day changes in pain are related to changes in mood, stress, or cognition. Daily diary methods avoid problems with recall and capture potentially important pain-related processes closer to their real-time occurrence.

Although pain diaries often are used in clinical practice, new methods for collecting and analyzing the data are underutilized (Heapy et al., 2007; Turk and Melzack, 2011). As a result, major opportunities for understanding patients' pain trajectories more fully and customizing treatment to their day-to-day adjustment to pain are being missed. Electronic methods for collecting, analyzing, and displaying data will make this activity less expensive and more widely available (Turk and Melzack, 2011).

BUILDING THE RESEARCH WORKFORCE

> *I wouldn't wish this on anyone, but if researchers could go through just one day of life as I live it, maybe they would understand how devastating this is. . . . There is no hope for people with R.S.D. [reflex sympathetic dystrophy]. "Just learn to live with it" is NOT acceptable! Please help us.*
>
> —A person with chronic pain[8]

In the future, many discoveries in pain research will require teams of researchers with diverse backgrounds who can integrate multilayered data into systems models. Increasingly, accomplishing this integration will require expertise in bioinformatics to help analyze and interpret massive data sets. Currently, a significant barrier to advances in pain research is the lack of scientists working in this arena. The field needs a larger and broader array of basic, clinical, behavioral, and social scientists from diverse disciplines, as well as veterinary clinical specialists, engineers, and researchers from the physical sciences.

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[8] Quotation from response to committee survey.

New training mechanisms are needed to make research on pain more accessible to scientists in many disciplines through exposure in graduate or medical school education and inclusion in comprehensive continuing education courses. The gathering of evidence on best practices in pain management for nurses is led at the federal level by the National Institute for Nursing Research, and pain is regarded as one of the most difficult challenges in health care for both nursing researchers and clinicians. Training models should better orient basic and applied pain researchers to the multidisciplinary nature of the development, amplification, and maintenance of chronic pain and pain-related disability. Along these lines, established curricula on pain are available (for example, the IASP curriculum), but they have not been widely used in the training of pain clinicians and researchers.

ORGANIZING RESEARCH EFFORTS

> *The population affected and the readiness of the science together should determine where the research money goes. Pain research needs investments to get from its infancy to adolescence. When a field is in its infancy and researchers think the chances of getting funding are very low, that discourages applications.*
>
> —Peter Reinecke, an advocate for people with chronic pain[9]

A Road Not Taken

Although there is much more to be learned about pain from many research perspectives, much of what we already know is not applied well or consistently in clinicians' day-to-day interactions with people in pain. As noted earlier, because pain is a feature of so many health conditions, no one "owns" it in the same way that a large cadre of cardiologists or oncologists and national research institutes focuses on heart, lung, and blood conditions or cancer. The relatively small group of physician pain specialists, although acquiring increasing coherence, has not been concentrated in one field, but spread across the disciplines of anesthesiology, physiatry, psychiatry and neurology, occupational medicine, and palliative care. Nor are there large numbers of generous funders and foundations supporting pain research, or patient advocacy groups with the visibility, national network, and financial resources of the American Heart Association or American Cancer Society to press for more research and training and public awareness of what quality pain care should be.

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[9] Quotation from testimony to the committee, November 2010.

For these reasons, it might appear logical for the committee to have suggested creation of a pain institute within NIH that could develop a research strategy and coordinate the disparate pain-related efforts currently spread across various institutes and centers, which are not working as quickly or effectively as the opportunities being created by new science might allow. In not making such a recommendation, the committee was guided by several factors:

- The National Institutes of Health Reform Act of 2006 (PL 109-482) caps the number of institutes and centers at 27, its current complement.[10] Effecting a change in that legislative rule would be difficult.
- The 2006 act also gives the NIH director expanded authority to manage the agency, and he recently approved a new National Center for Advancing Translational Sciences. The goal of that center, which is to speed the translation of therapies from the laboratory to the bedside, is certainly compatible with committee's views with respect to advances in pain assessment and treatment.
- In a 2003 report on the organization of NIH, a National Research Council and Institute of Medicine (NRC/IOM) committee commented, "An organization's ability to make effective changes is influenced by a multiplicity of factors, including structure, strategy, and systems" (p. 4), encompassing both its formal and informal processes. The goal of increased and better coordinated pain research is not necessarily dependent on having a unique institute or center, but could result from a stronger strategy and systems to support that goal. With respect to establishing new institutes or centers, the NRC/IOM committee recommended that a public process be established "to evaluate scientific needs, opportunities, and consequences of the proposed change and the level of public support for it. For a proposed addition, the *likelihood of available resources to support it should also be assessed* [emphasis added]" (p. 7). The Scientific Management Review Board is designed to carry out that public process. The committee acknowledges elsewhere in this chapter the high probability of declining funds for pain research.
- The potential for a more robust set of pain-related research activities does exist, coordinated across NIH institutes and centers by the NIH Pain Consortium and across NIH and other federal agencies by the Interagency Pain Research Coordinating Committee, currently in formation. Further, the NIH request for proposals ("Mechanisms, Models,

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[10] In fall 2010, NIH Director Francis S. Collins accepted the NIH Scientific Management Review Board's (SMRB) recommendation to merge the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism into a single new institute, thereby reducing the number of institutes and centers by one. Soon thereafter, he also decided, again based on an SMRB recommendation, to fill that slot with a new $722 million National Center for Advancing Translational Sciences, a proposal now before Congress.

> Measurement, and Management in Pain Research Funding Opportunity Announcement"), included at the end of this chapter as Annex 5-1, provides a thorough and thoughtful overview of the breadth of research opportunities in the pain field.

Therefore, instead of recommending the creation of a pain institute, a proposal the committee believed would not produce either a pain institute or any other desired result, the committee focused on ways to reenergize and strengthen current activities, a goal the committee believed was both more practical and achievable. The committee's recommendations to this end are designed to ensure clearer responsibility and accountability for pain research, working within the existing organizational structure.

Organizational Alternatives

A number of efforts are under way to organize research efforts, particularly clinical trials, differently to make them logistically easier to mount, more economical, and more useful. A number of these efforts involve interorganizational networks and cooperation (see Box 5-1 for an example).

An important example is the NIH Common Fund, housed within the office of the NIH director. It supports cross-cutting, trans-NIH programs that involve the participation of at least two NIH institutes or centers, encouraging collaboration among researchers who have worked on similar problems in the past. Previously, NIH researchers worked exclusively in their organizational silos, missing opportunities for shared insights and for the development of common, best methods (NIH, undated-c). Indeed, an early Common Fund science advance described by NIH is one that involves the development of "new tools to correct brain activity," which is expected to contribute to new treatments for several brain disorders, including chronic pain.

Programs the Common Fund supports are known collectively as the NIH Roadmap for Medical Research. Roadmap programs are generally short-term, 5- to 10-year programs that are "expected to have exceptionally high potential to transform the manner in which biomedical research is conducted" (NIH, undated-c). They are developed through a strategic planning process that involves multiple stakeholders. This process has led to the identification of three themes under which Roadmap projects fall: New Pathways to Discovery, Research Teams of the Future, and Reengineering the Clinical Research Enterprise. Funded initiatives respond to one or more of these major themes and attempt to

- foster high-risk/high-reward research,
- enable the development of transformative tools and methodologies,
- fill fundamental knowledge gaps, or
- change academic culture to foster collaboration.

BOX 5-1
The Department of Veterans Affairs' Pain Research Program

Since 1998, the Department of Veterans Affairs has had a National Pain Management Strategy intended to develop a systemwide approach to reducing pain and suffering and improving the quality of life for veterans (see Chapter 3). A key feature of the initiative is support for basic and applied research on pain management, especially for conditions prevalent among the nation's 23 million military veterans.

The department's Office of Research and Development and the Pain Management Program have collaborated to promote basic laboratory, clinical science, health services, and rehabilitation research and development services. The number of pain-relevant projects increased from 10 in 2000 to 47 in 2007, while funding for pain-relevant research increased by 27 percent.

The expanded level of research continues, with numerous projects focused on the needs of veterans from the wars in Iraq and Afghanistan and the characteristic injuries they incur. Several of these projects involve collaboration between the Departments of Veterans Affairs and Defense. Painful musculoskeletal conditions are by far the most commonly diagnosed medical problems among this cohort of veterans.

In further support of the strategy, the department's Health Services Research and Development Service has funded a Pain Research, Informatics, Medical Comorbidities, and Education Center to improve understanding of the complex interactions among pain, the associated chronic diseases, and various behavioral health factors, as well as to develop new, efficacious interventions. A national Pain Research Working Group comprising more than 50 representatives of the department and a few external collaborating investigators in pain and pain management focuses, in part, on disseminating research findings "with relatively direct practice and policy implications" (Kerns and Dobscha, 2009, p. 1162).

The PROMIS initiative, described previously, is a good example of how the general Roadmap purposes can be adapted and applied to the needs of pain patients and the clinicians who serve them.

Pain is a topic of interest for virtually every NIH institute and center and should benefit from this type of collaboration. The NIH Pain Consortium was established in an effort to make this happen. The consortium has identified the following goals:

- to develop a comprehensive and forward-thinking pain research agenda for NIH that builds on past efforts;

- to identify key opportunities in pain research, particularly those that provide for multidisciplinary and trans-NIH participation;
- to increase visibility for pain research within and outside NIH, such as among pain advocacy and patient organizations; and
- to pursue the pain research agenda through public–private partnerships, wherever applicable (NIH, 2007).

Participating in the NIH Pain Consortium are 15 institutes, four centers, and four offices under the Office of the NIH Director. The committee commends the efforts of the NIH Pain Consortium to foster pain research. However, the committee believes there needs to be a transformation in how pain research is conducted and that the Pain Consortium should take an even more proactive leadership role in effecting that transformation. NIH should increase staffing support for the Pain Consortium and engage higher-level staff from the institutes and centers, and the consortium should hold more frequent, regular, structured, and productive meetings to advance basic, translational, and clinical pain research and to monitor funding levels and the overall portfolio of pain research funding. One possibility, reflected in the committee's recommendations, is the identification of a single lead institute or center to coordinate this work, establish a consistent strategy, and maintain momentum. The National Institute of Neurological Disorders and Stroke is one strong lead-agency candidate, but not the only one.

In 2004, NIH created a Blueprint for Neuroscience Research, in which 13 institutes, two centers, and one office participate (NIH, undated-a). One of the priorities for the blueprint is the Grand Challenge on Pain, which supports research "to understand the changes in the nervous system that cause acute, temporary pain to become chronic nerve pain (neuropathic pain)." The blueprint is encouraging collaboration among researchers in the pain field and those nonpain experts with expertise in neuroplasticity. The committee recognizes the importance of the NIH blueprint and encourages NIH to increase collaborative pain research through this mechanism.

With or without the participation of one of the above NIH initiatives, the development of clinical research networks (CRNs) to conduct RCTs or other types of clinical research is one approach that can be used to spread the costs of trials across institutions, gather larger pools of patients to participate in studies, and otherwise achieve economies and accelerate the drug development process (IOM, 2010). Encouraging clinicians who work with people with pain to participate in clinical research might improve rates of integration of new findings into everyday medical care and help focus projects on issues of immediate clinical need and potential application, such as more usable psychosocial evaluation tools.

OBTAINING FEDERAL RESEARCH FUNDING

> *If you think research is expensive, try disease.*
>
> —Mary Lasker (NIGMS, 2011)

Investigators seeking funds for pain research projects, at least in the past, have faced a number of significant hurdles, which the new funding opportunity program (Annex 5-1) may or may not help resolve. As discussed in Chapter 1 and earlier in this chapter, because pain is "everybody's business," in a sense it becomes no one's. Although several NIH study sections review pain grant applications, the expertise is not focused and may be spread too thin to be effective. Nor is pain any institute's or center's primary agenda. As noted below, the study sections are working with a very small portion of the NIH budget, which is likely to shrink further as the funding for biomedical research becomes more constrained. Simply put, the current review and funding processes are suboptimal. The NIH Pain Consortium should to take steps to optimize the process for reviewing pain grants.

NIH provides about a third of all biomedical research funding in the United States. The agency's interest in a topic has ripple effects, stimulating interest in laboratories and science training programs around the country. Between 1997 and 2004, when the NIH budget hit its high-water mark, funding nearly doubled, from $15.6 billion to $30.4 billion (in constant 2008 dollars). After 2004, funding declined slightly each year, reaching $28 billion in 2009. President Obama's NIH budget request for fiscal year (FY) 2012 is just under $32 billion. Because of large past commitments requiring ongoing funding, little of that amount can support new efforts.

The reversal of annual growth in congressional appropriations for NIH during the mid-2000s affected funding for pain research, which has consistently represented a very small part of the NIH budget—0.61 percent in 2007. An analysis of NIH grant awards from 2003 to 2007 indicates that in the first year, 2003 to 2004, NIH funding allocated to pain research increased by 12 percent, but in the three succeeding years, it declined by an average of 9.4 percent per year, while overall NIH funding declined an average of only 1.9 percent per year (Bradshaw et al., 2008). Consideration needs to be given to expanding NIH funding of pain research, given the magnitude of the problem of pain (approximately 100 million adults affected by chronic pain alone) and its related costs (at least $635 billion per year) (see Chapter 2 for a full discussion). Research and innovation, including efforts focused on pain prevention, may be the most cost-effective approach to tackling the problem in all its dimensions.

Current pressures to reduce federal spending suggest that large NIH budget expansions are unlikely in the foreseeable future. This trend will naturally encourage the institutes and centers to concentrate on their primary missions, which are *not* pain, meaning that money for new pain research will most likely be in increasingly short supply. As a result, this area of investigation may be a casualty of competing priorities. The impending merger of the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism may further exacerbate the situation as their existing programs are consolidated.

According to the analysis by Bradshaw and colleagues (2008), in 2007 NIH awarded 586 grants for primary pain research. In most years examined, clinical research grants outnumbered basic research grants and exceeded them in dollars spent. Of the total funding for pain research in 2007 ($181 million), $78 million supported basic science and $102 million clinical research. In testimony provided to the committee, it was reported that NIH pain-related expenditures for 2009-2010 were approximately $320 million. Unfortunately, the increase over the 2007 funding level includes a one-time influx of economic stimulus funds from the American Recovery and Reinvestment Act, and therefore is unlikely to be sustained going forward. The NIH staff involved in pain research does not favor a specific dollar commitment for pain research lest it become an "entitlement," not linked to quality benchmarks or measurable criteria. This point of view must be balanced against the magnitude of the pain problem and the need for prompt and sustained research efforts to address it.

Finally, although workforce development is not a primary focus of the committee's work, the committee recognizes that new investigators can be attracted to the field—and current ones motivated to remain in it—only if funding for research and career development is predictable.

FOSTERING PUBLIC–PRIVATE PARTNERSHIPS

> *The kind of far-reaching progress anticipated for biomedical research in the 21st century will require even more research collaboration among public and private sectors.*
>
> —NIH, undated-d[11]

Current Partnership Activities

Efforts to promote public–private partnerships will likely be important in building and sustaining the capacity for pain-relevant research. There are several

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[11] http://commonfund.nih.gov/publicprivate/.

examples of existing important partnerships that could be expanded. One particularly effective collaboration over the past decade has been IMMPACT (described earlier in this chapter), which has yielded multiple consensus reports designed to foster improvements in clinical trial design and execution and in interpretation of pain treatment studies. Recently, the FDA supported the creation of ACTION, a public-private partnership (also described earlier) that will expand the efforts initiated by IMMPACT. Although the goals and objectives of IMMPACT and ACTION relate directly to promoting the development of analgesics, their indirect effect has been to promote knowledge and consensus on a broad array of methodological, measurement, and trial design issues relevant to research more broadly.

Another partnership example can be found within the Department of Veterans Affairs. A majority of the department's facilities are closely affiliated with schools of medicine and nursing and associated health professionals, and the strong public interest in veterans and their known high prevalence of painful disorders encourages an explicit focus on pain and pain management. Collaborative funding opportunities involving the Department of Veterans Affairs, the Department of Defense, and NIH, among other public agencies, should be explored.

A few private foundations, notably the Mayday Fund, have long supported research, including psychological research, related to pain. In the past year, Mayday partnered with the Patrick and Catherine Weldon Donaghue Medical Research Foundation to sponsor Project STEP, which systematically examines the efforts of the Department of Veterans Affairs to implement a stepped pain care model. Most recently, Mayday provided partial support for an examination of efforts to enhance pain care in a federally qualified health center (FQHC). In addition, a recent Mayday Fund report (The Mayday Fund, 2009) includes a number of forward-thinking recommendations relevant to pain research involving

- the need for coordinated health information technology systems across payers and providers to permit tracking of pain conditions, treatments, and outcomes and to facilitate improvements in quality of care;
- the need for increased funding for pain research "to a level that is commensurate with the size of a public health problem that affects millions of people" (p. 10); and
- the need for studies to determine best practices in treating specific types of chronic pain.

Recommendations such as these inherently involve cross-sector partnerships and multiple constituencies.

Public–private partnerships are especially appropriate when problems fall outside the normal scope of activities of either the basic sciences or industry. Basic scientists may develop candidate biomarkers, for example, but lack the resources and incentives to proceed with the intensive effort involved in translating them into "practical, reliable, and well-characterized tools ready for clinical use" (IOM, 2008, p. 11). At the same time, the scanning efforts necessary to produce candidate entities may be too far removed from industry's search for marketable products.[12]

NIH launched its own agency-wide program for public–private partnerships (the PPP Program) in 2005 within the Office of the NIH Director as a result of work on the NIH Roadmap, in collaboration with the Foundation for the NIH. The Roadmap is focused on areas in which NIH institutes and centers can build on existing strengths and create synergies through cross-cutting projects. The PPP Program is a logical extension of that approach, expanding the techniques and goals of collaboration outside the walls of NIH.

According to the home page for the PPP Program website, public–private partnerships will "provide additional models for conducting biomedical research in an increasingly complex world." The PPP Program's mission is to be a central resource within NIH to facilitate collaborations—that is, to aid in establishing, sustaining, coordinating, and advising NIH and potential public- and private-sector partners with respect to, as the home page says, the "formation of partnerships that leverage NIH and non-NIH resources" (NIH, 2010).

NIH already has almost 30 years' experience with public–private partnerships, dating from creation of the National Cooperative Drug Discovery Group within the National Cancer Institute (NCI) in 1982, an approach subsequently adopted by four other institutes. The NCI program aims to

- support multidisciplinary team research to discover new targeted anti-cancer therapies;
- address the need for new therapies with greater selectivity;
- use new technologies to speed discovery (i.e., molecular targets, compound libraries, high-throughput screening, imaging);
- protect intellectual property; and
- foster high-risk, translational research with a potentially high payoff.

Although the makeup of multidisciplinary teams for pain would, of course, be different and perhaps more diverse than that of such teams for cancer, the above list provides a good summary of what public–private partnerships in the field of pain management might hope to accomplish.

A new opportunity for enhancing public–private partnerships to improve pain care can be found in the new Patient-Centered Outcomes Research Institute,

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[12] A public–private partnership for biomarkers—the Biomarkers Consortium—has been developed. It involves the Foundation for the National Institutes of Health as the managing organization, NIH, the FDA, Pharmaceutical Research and Manufacturers of America, the Centers for Medicare and Medicaid Services, and the Biotechnology Industry Association, with a large number of for-profit companies and nonprofit organizations serving as contributing members (http://www.biomarkersconsortium.org/).

established by the Patient Protection and Affordable Care Act of 2010 (Public Law 111-148, Secs. 6301 and 10602). This independent, nonprofit organization is intended to support CER projects and other investigations that will help patients and clinicians make better health care decisions. Its board of governors includes physicians, industry representatives, public officials, consumer representatives, and others appointed by the Comptroller General of the United States. Its processes are required to be transparent and to involve substantial public input. The institute will be more likely to make pain-related research a priority if advocates for improved pain care reach out to this agency and make a strong case for such research.

Potential Projects for Public–Private Partnerships

The discussion in this chapter points to a number of areas ripe for public–private partnerships, whereby different parties can bring their strengths to the table. One is the concept of multicenter clinical trials to enable the involvement of sufficient numbers of participants with specific pain pathologies; a second is involvement of private clinicians in the trial process to facilitate knowledge transfer to daily practice; a third is the FDA's desire to develop new regulatory science approaches through which it can work more closely with the scientific community and industry; and a fourth is to balance the pharmaceutical industry's market-driven process for determining research priorities with a process driven by consumer needs, which could take greater account of the pain treatment needs of children, the elderly, and disease or population groups that are too small to attract industry. (The FDA's effort to encourage pediatric studies is an example of how this is being done [Politis, 2005].)

New public–private partnerships could help leverage resources to target high-priority, if not expensive, research questions and initiatives. CER is another high-priority research need that almost certainly will require public–private partnerships and the combining of financial and other resources. Partnerships could expedite the development of treatment approaches that employ advanced technologies, such as web-based treatment and support programs or the use of cell phone applications to enhance maintenance of treatment of regimens. Finally, the development and dissemination of provider and patient/family educational resources (see Chapter 4) is another obvious target for such partnerships.

Other potential partnerships could involve

- working with international research organizations on epidemiologic and human behavior studies in an attempt to understand the reasons for the apparent increased prevalence of chronic pain in many countries, including the United States;
- working with the pharmaceutical industry and the pain research community to increase understanding of genetic or other variations in patho-

physiology that affect individual responses to nociception and pain treatment and the biomarkers or biosignatures that characterize those responses;

- working with industry, clinicians from multiple disciplines, and pain advocacy and awareness organizations to apply knowledge about individual differences in pain perception, persistence, and responses to treatment to support the development of personalized strategies for pain management, including pharmacogenomic approaches;
- working with proprietors (public or private) of large health care and pharmacy databases to determine what information they can provide to inform research on the comparative effectiveness of pain treatments, as well as additional data elements that could feasibly be added, and where there are gaps in information, supporting multiorganizational pain patient registries;
- working across NIH institutes and centers, the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), clinicians treating pain patients, and patient advocacy groups to produce and publicize evidence-based reviews of currently used pain treatments (including surgery) and their effectiveness[13] in order to discourage unnecessary or ineffective treatments that delay appropriate care, encourage greater use of treatments known to be effective, and address barriers to more effective pain care;
- working with the pharmaceutical industry, the FDA, and patient advocates to ensure that accurate information about pain and its self-management is included in drug inserts and on appropriate NIH websites in order to foster public education;
- working with private foundations, voluntary health organizations (e.g., the Arthritis Foundation, the American Cancer Society), or other funders to provide full or partial funding for promising grant applicants that miss NIH cutoff points or for new investigators, workshops or training experiences targeting promising new pain investigators, and more forceful advocacy for additional pain research funding;
- working with the above groups and with academic institutions to develop a national network that would support and encourage ongoing mentoring, including such activities as laboratory visits and ongoing e-mail/telephone contact, and fostering new collaborations between successful senior and midcareer investigators and younger investigators;

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[13] Examples are the American Urological Association's review of currently available treatments for interstitial cystitis (http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/ic-bps/diagnosis_and_treatment_ic-bps.pdf) and the American Academy of Neurology's guideline on diabetic neuropathy (http://www.aan.com/go/practice/guidelines).

- researchers in health care, health policy, and health economics working with CMS, NIH, the FDA, the Department of Veterans Affairs, the Department of Defense, private insurers, health professions associations, consumer groups, integrated health care systems, accountable care organizations, and academic medical centers to compare outcomes of care for various pain treatments and assess which are most effective for specific groups of patients and under what circumstances (use of these more effective treatments should be encouraged, while use of ineffective treatments should be discouraged); and
- investigators working with public health entities, pain advocacy and awareness organizations, physicians, and others to explore the effectiveness of alternative public health strategies, approaches to public and patient education and clinician–patient communication, and ways in which system changes could support better pain care.

Each of the above examples suggests a somewhat different mix of partners. Such variation is highly desirable, not only because it engages a wider range of organizations in thinking about pain care but also because it avoids overreliance on a small group of industry partners.

FINDINGS AND RECOMMENDATIONS

Finding 5-1. Research to translate advances into effective therapies for pain is a continuing need. The committee finds that significant advances have been made in understanding the basic mechanisms of nociception and pain but that much remains to be learned, underscoring the importance of continued support for basic and clinical research. At the same time, the advances achieved to date have led to new potential targets for future pain assessment and treatment strategies. Furthermore, recent advances in the neurosciences, biomarkers, and the behavioral sciences have validated a comprehensive approach to the management of pain that includes the individual's inherent biology, behavior, and psychological makeup and reactions, as well as environmental influences. However, data and knowledge gaps in pain research remain that have prevented such research advances from being translated into safe and effective therapies:

- There is a need for further understanding of the basic behavioral and environmental mechanisms and their interactions that cause, amplify, and maintain pain. Integration across the multiple layers of biological and behavioral sciences is needed to examine and develop systems models that can be used to improve the understanding and treatment of pain (i.e., across the domains of the gene, protein, synapse, neuron, circuit, network, brain, behavior, family/social/work/education environment, and culture).

- Advances in dissemination sciences could be used more effectively to help translate treatments found to be efficacious in clinical trials into clinical practice.
- The mechanisms and factors that lead acute pain to persist and become chronic are not understood.
- Gaps exist in basic, clinical, and epidemiological research on pain and pain management. Filling these gaps could help define the prevalence of recurrent and chronic pain conditions and populations at risk.
- Research is needed on the development, testing, and dissemination of effective psychoeducational interventions to support patients and their families.
- The long-term efficacy and safety of existing pain therapies (including chronic opioid therapy) are not well understood.
- Gaps exist in understanding of the influence of the role of the placebo group response and its impact on clinical pain management trials.
- Gaps exist in understanding the most effective ways of educating pain clinicians and researchers.
- Barriers in regulatory science prevent the efficient evaluation and approval of potentially effective therapies for clinical use.
- In the committee's opinion, current processes within the National Institutes of Health for the review of grants pertaining to pain are suboptimal in that many topics in pain research do not fit within existing study sections, and expertise for the review of submitted proposals is inconsistent.

Addressing these gaps will require a cultural transformation in the view of and approach to pain research, involving basic, translational, and clinical researchers; federal funding and regulatory agencies; and private organizations. This cultural transformation is reflected in the following recommendations.

> **Recommendation 5-1. Designate a lead institute at the National Institutes of Health responsible for moving pain research forward, and increase the support for and scope of the Pain Consortium.** The National Institutes of Health should designate a specific institute to lead efforts in advancing pain research and increase the support for and broaden the scope of its existing Pain Consortium. The committee recognizes that the primary physiologic processes that underlie pain involve the nervous system, which would make the National Institute of Neurological Disorders and Stroke a rational choice to take on this lead role, but also recognizes that the decision may depend on other factors best addressed by the organization's leadership. The designated institute should

- Include pain as a major component of its mission.
- Assume leadership of the NIH Pain Consortium and the NIH Interagency Pain Research Coordinating Committee.
- Assume responsibility for assessing the effectiveness of the National Institutes of Health in moving pain research forward.
- Identify funding needs.

At the same time, the National Institutes of Health should increase financial resources and staffing support for and broaden the scope of the Pain Consortium and engage higher-level staff from the institutes and centers in the consortium's efforts. The Pain Consortium should exert more proactive leadership in effecting the necessary transformation in how pain research is conducted and funded. The consortium should

- Hold more frequent, regular, structured, and productive meetings to advance interdisciplinary basic, translational, and clinical pain research.
- Take steps to improve the process for reviewing grant proposals related to pain. Study sections should be expanded to add individuals with pain expertise. The expansion effort should include
  - —identifying gaps in areas of pain research not met by existing study sections,
  - —ensuring that these gaps are filled by reviewers with appropriate expertise, and
  - —publishing on the Pain Consortium's website a list of study sections that review pain research.
- Work with pain advocacy and awareness organizations to help identify public needs with regard to pain treatment and management.
- Work to improve and expand public–private partnerships between academia and the for-profit (e.g., pharmaceutical and device industries) and not-for-profit (e.g., foundations and professional organizations) entities that foster research, education, and treatment for pain.

Recommendation 5-2. Improve the process for developing new agents for pain control. Academia and industry should develop novel agents for the control of pain. This does not mean simply recycling current drugs. What is required is basic and clinical science research to discover new classes of pain therapeutics and more efficient ways of developing them. Also required is that regulatory agencies, especially the Food and Drug Administration, develop new and expeditious ways to evaluate and approve new pain therapies. Examples include new methods for patient stratification in clinical trials, as well as more appropriately defined diagnostic and therapeutic endpoints (e.g., biomarkers and new surrogate markers of response).

Recommendation 5-3. Increase support for interdisciplinary research in pain. Federal agencies, such as the National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Department of Defense, and Department of Veterans Affairs, as well as private funders of pain research, should increase support for interdisciplinary research and research training—across agencies and professions—on pain-related diseases and the deficiencies noted in Finding 5-1. This research should include teams of researchers comprising both traditional pain researchers and people from different fields (e.g., engineering, mathematical and computer modeling, systems biology, genomics, dissemination sciences, comparative effectiveness [or outcomes] research). It also should include teams with members from basic, translational, and clinical areas of expertise. Funding should focus on areas that represent gaps in pain knowledge and understanding.

Recommendation 5-4. Increase the conduct of longitudinal research in pain. Public and private funders should increase support for longitudinal research in pain, including comparative effectiveness research and novel randomized controlled trials, to help ensure that patients receive care that works best in both the short and long terms.

- The cohorts studied should include real-world patients with pain (i.e., those likely to have comorbid conditions in addition to pain, such as depression, anxiety, obesity, and hypertension) and not be restricted to overly homogeneous but atypical patient groups.
- The studies should use appropriate pain metrics and coding of the types of pain treatments tested.
- Public and private funders of pain research should collaborate with medical specialty and other health professions associations, federal agencies, and private industry to develop pain outcome registries involving real-world patients. Large prospective registries will enable investigators to identify more readily pain treatments and patient characteristics that result in beneficial outcomes or harms.
- Public–private partnerships could support a core infrastructure for interdisciplinary clinical trials in pain treatment (similar to that which exists in the children's oncology field). Funding could be provided for a statistical and coordinating center, for some key investigative leaders, and for conduct of meetings at least yearly to identify and implement trials of new care models and interdisciplinary treatment strategies for specific pain populations.

- Studies also should evaluate the effectiveness or potential utility of interventions at the population health level, such as public policy initiatives, demonstration projects in the organization and reimbursement of care, and public education efforts.

Recommendation 5-5. Increase the training of pain researchers. With the support of training grants from the National Institutes of Health, academic institutions should increase the training of basic, translational, behavioral, population, and clinical pain researchers. Specific support should be provided for pre-and postdoctoral fellows and junior investigators to promote increased education in pain and collaborative research agendas for investigators. This training should recognize the interdisciplinary benefits of research on pain and pain management. Agencies such as the National Center for Health Statistics, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services should support the training of researchers interested in secondary analysis of pain-related data collected by these agencies.

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ANNEX 5-1
MECHANISMS, MODELS, MEASUREMENT, AND MANAGEMENT IN PAIN RESEARCH FUNDING OPPORTUNITY ANNOUNCEMENT

RESEARCH OBJECTIVES

New and innovative advances are needed in every area of pain research, from the microperspective of molecular sciences to the macro perspective of behavioral/social sciences. Although great strides have been made in some areas, such as the neural pathways of pain, chronic pain and the challenge of its treatment have remained uniquely individual and largely unsolved. Proposals that seek to improve the understanding of the causes, costs, and societal effects of both acute and chronic pain and the relationships between the two are highly encouraged. Studies on the mechanisms underlying the transition from acute to chronic pain are also needed. Additionally, proposals that link such understandings to the development of better approaches to therapeutic interventions, including complementary and alternative medicine (CAM) interventions, and management of acute and chronic pain are in keeping with the current translational focus of NIH and are encouraged.

The following topic-areas are not intended to be comprehensive or exhaustive. Synergistic studies that reach across two or more of these areas are encouraged. Interdisciplinary and multidisciplinary research is especially encouraged, as is research that involves specific cooperation between basic and clinical scientists. These pain research areas also cut across Institutes and Centers (ICs) and programs and should not be viewed as restricted to only one specific IC.

MOLECULAR AND CELLULAR MECHANISMS OF PAIN

Improved treatments of acute and chronic pain conditions require a thorough understanding of the processes underlying the transmission and perception of painful stimuli. Discovery of the molecules, cells, and neuronal pathways involved in nociception/pain perception and affective aspects of pain are critical. Molecular and cellular studies, when coupled with studies in animal models and clinical research, will provide a comprehensive basis for the development of new pharmacological, behavioral, and technology-based treatments for chronic pain disorders, and/or research on the mechanisms of action of therapies effective for chronic pain. Hormones, neurotransmitters and their receptors, ion channels, G-protein coupled receptors, neuropeptides, and neurotrophic factors are just a few of the molecules of interest in pain studies. Molecular mechanisms and nervous system circuitry involved in facilitation and inhibition of pain signaling and in the development of hypersensitive pain states are important targets of pain research. Neurons, glial cells, and keratinocytes all play important roles in pain sensation and approaches examining their individual functions and their interactions are vital for understanding pain processes. Research is encouraged but not limited to science in the following areas:

- Mechanisms that underlie sex differences in the pain experience.
- Cellular and molecular mechanisms involved in pain processing, modulation, and perception.
- Molecules and processes that target cellular mechanisms involved in signaling, modulation, and perception of pain, as well as changes in these processes over the developmental life course, to enhance innovative therapeutic development.
- Ontogeny and neuropharmacology of the pain system.
- Endogenous and environmental factors that alter pain during the course of development, in response to injury, and related to disease processes.
- Mechanisms of hypersensitivity including both central and peripheral mechanisms of hyperalgesia and allodynia.
- Endogenous molecules that modify pain perception and analgesic treatments.

GENETICS OF PAIN

Clinical studies have identified polymorphisms at several gene loci that are associated with differential sensitivity to experimental pain. Inbred strains of mice also show differential pain responses in models of neuropathic and inflammatory pain. These studies strongly suggest that genetics plays an important role in pain mechanisms. Chronic pain conditions are complex disorders where environmental and genetic influences interact to affect sensitivity to noxious stimuli and relief from pain. Polymorphisms and mutations in mitochondrial DNA may also play a role in modulating pain, especially in muscles and peripheral nerves. Elucidating the genetic contributions to the individual variability in pain sensitivity and perception is of much interest. Research is encouraged but not limited to science in the following areas:

- Genes and gene variants involved in the complex processes of pain perception.
- Utilization of pharmacogenetics to identify gene variants with potential to inform treatment providers which pain medications may be most effective for the individual needing therapy, with the fewest side effects.
- Use of gene therapy to ameliorate chronic pain.
- Gene polymorphisms and gene–environment interactions that predict pain development or treatment response.
- Epigenetic mechanisms underlying chronic pain conditions.

BIOBEHAVIORAL PAIN

The experience of pain is a complex interaction of biological, cognitive, behavioral, sociocultural, spiritual, and environmental factors. Pain etiology, severity, tolerance, exacerbation, maintenance, and treatment are all significantly influenced by this complex of acknowledged but poorly understood interactions. Comorbid conditions that alter affect, such as mood disorders, can induce or exacerbate pain. Although it is recognized that psychological factors, such as expectation or stress, significantly contribute to pain tolerance and treatment efficacy, the physiological mechanisms of these effects are poorly understood. Physiologic responses such as autonomic arousal, muscle tone and activity, skin thermal receptor activation, and cardiopulmonary reactivity, are perceived as painful in some behavioral and sociocultural environments, but not in others. The elucidation of these complex interactions will enable better assessment of pain in clinical settings, more effective therapeutic approaches, greater ability to prevent pain onset, and potentially will increase the individuals ability to self-manage pain.

Research is encouraged but not limited to science in the following areas:

- Adaptation to pain and ways to incorporate this adaptation into treatments.
- Mechanisms and process variables that are responsible for the efficacy of behavioral and CAM interventions for pain. This research includes studies to better understand the effect of patients' expectations and beliefs, psychophysiological states (e.g., anxiety, relaxation, stress), adherence, and specific cognitive (e.g., imagery) and sociocultural (e.g., support systems) components in behavioral and CAM interventions to treat pain.
- Biobehavioral techniques for optimizing adherence to pain management. Identify barriers to adherence to pain management strategies.
- Sensory, cognitive, and affective aspects of acute and chronic pain in individuals across the developmental lifespan.
- Development of methods for assessing relative contributions of biological, psychological, behavioral, and environmental predictors of the course of pain, pain dysfunction, and response to treatment for pain.
- Interactions of pain and sleep, their combined impact on function and illness recovery, and interventions that target these interactions.
- Relationships among a variety of emotional states (e.g., anger, fear, anxiety and depression), which are associated with acute and chronic pain conditions, and how these affective states modify the experience of pain and treatment outcomes.
- Interaction of biological markers, central nervous system mechanisms, and drug, behavioral, and CAM interventions.
- Mechanisms that underlie gender and cultural differences in the pain experience.

MODELS OF PAIN

There are many factors responsible for pain experienced by patients. Current animal models of pain have been useful in understanding the mechanisms of pain and developing interventions that target these particular mechanisms. However, many of the existing animal models do not adequately reflect clinical pain conditions and, in particular, chronic pain disorders. The development of new animal models is necessary in order to discover the underlying mechanisms of pain perception as well as the mechanisms of analgesia that will prove useful in treating patients. Innovative clinical modeling studies are also needed to advance our understanding of these underlying mechanisms. Research is encouraged but not limited to science in the following areas:

- New animal models and refinement of existing animal models.
- New measures of pain in animals that are noninvasive and objective, and that permit a behavioral or functional assessment of pain and pain treatment outcomes.
- Use of transgenic animals in the study of pain mechanisms.
- Studies in patients with chronic pain conditions that develop, test, and validate new models of these chronic disorders.
- Computational models that predict development of pain and/or treatment responses.
- Computer simulations of pain that overcome ethical concerns and expand the range of studies possible.
- Objective measures of spontaneous pain in validated animal models of chronic pain conditions.

DIAGNOSIS AND ASSESSMENT OF PAIN

Most healthcare system interactions are initiated by persons with complaints of pain. To date, direct patient report is the basis of most pain assessments. Yet many patients, including the very young, persons with cognitive, sensory, psychiatric, or physical disabilities, those rendered unresponsive by their physiologic state (e.g., drug intoxication, severe brain injury), and those persons who by culture, education, language, or communication skills may be unable to effectively respond using currently validated assessment tools. To study, model, predict, prevent, diagnose, treat, or manage pain effectively, sensitive multimodal measurement tools are needed. Pain assessment techniques must be valid and reliable and provide sensitivity, both with single and repeated measurements, and allow for the assessment of acute, chronic, persistent, and breakthrough pain. Severity/intensity, type/location/source (i.e., somatic, visceral, neuropathic), and duration (acute, chronic, persistent, breakthrough) are key components to assess.

Assessment should include diagnostic as well as outcomes measures. Research is encouraged but not limited to science in the following areas:

- Refinement of existing physiologic techniques for measuring pain for greater sensitivity and specificity.
- New, outcome-specific techniques for different populations.
- Sensitive assessment tools that are not language (neither receptive nor production) dependent.
- Refinement of pain measurements that can account for or predict the trajectory or course of pain, as well as the changes in pain over time.
- Predictive biomarkers of pain that are sensitive to rapid changes in pain.
- Develop pain assessments that are sensitive across both developmental and cognitive spectrums, especially assessments of pain in children and in older adults with declining cognitive function.
- New technologies to improve pain assessment in all populations, but especially in those persons with limited language abilities.

PAIN MANAGEMENT

The prevalence of pain and inadequate pain management in patients is well documented. It is estimated that 75 percent of patients with advanced cancer experience moderate to severe pain; an IOM report states that 40 percent of people at the end of life have severe, unrelieved pain. A number of advances have been made in the treatment of chronic pain, most notably the neuroactive medications, counter-stimulation methods, and cognitive-behavioral therapies. However, adoption of these advances remains modest. Many patients report that they are reluctant or afraid to report their pain, are unaware of available pain management modalities, or do not adhere to pain treatment when available. Health care providers undertreat pain, fearing patient addiction, drug interactions, or adverse events. In addition, research findings consistently show the heterogeneity of response to treatment, even for pain of the same type and etiology.

Due to the biobehavioral nature of pain, pain management should engage interdisciplinary teams and involve both pharmacologic and nonpharmacologic approaches. Research is encouraged but not limited to science in the following areas:

- Interventions involving combinations and sequencing of pharmacological, nonpharmacological, and behavioral interventions to manage pain in progressive, incurable diseases.
- Interventions to reduce pain that are customized to the group (i.e., targeted), as well as to the individual (i.e., tailored).
- New methods to manage pain in cognitively impaired individuals or those unable to verbalize their pain.

- Interventions to manage co-occurring symptoms related to pain such as depression and fatigue.
- Role of pain and pain management approaches in improving rehabilitation outcomes and preventing functional decline.
- Methods for optimizing maintenance and stability of treatment in patients with advancing disease or with pain from multiple contributing disease processes.
- Novel interventions to manage pain in progressive, incurable, nonmalignant diseases.
- Interventions to improve management of side effects related to pharmacological pain therapy.
- New techniques for managing pediatric pain.
- Models of therapy in those with uncontrolled pain and/or breakthrough pain.
- Pain management strategies at the end of life.
- Long-term (i.e., physiologic, behavioral, or developmental) effects of pharmacologic treatment during the neonatal period and childhood.
- Clinical trials to establish best pain management practices.

EPIDEMIOLOGY OF PAIN

One goal of this FOA is to stimulate innovative investigations that enhance our understanding of the incidence, prevalence, and correlates of pain within and across populations. Epidemiology is one of the fields of science recognized for its contribution to understanding of physical and mental disorders. However, epidemiologic information concerning pain disorders is not well developed. Research is encouraged but not limited to science in the following areas:

- Incidence and natural history of pain disorders and their correlates over time.
- Interplay of environmental (e.g., familial and/or neighborhood quality and resources), physical (e.g., comorbid medical disorders that are a result of, or a cause of pain), behavioral (e.g., comorbid mental and substance use disorders), and social or socioeconomic (e.g., loss of employment—including issues of secondary or tertiary gain, social isolation, lack of mobility, dependence on others for basic caretaking) factors.
- Risk factors, including age, ethnicity, family history, gender, genetic predisposition, lifestyle, occupation, pre- or coexisting mental and physical disorders, and socioeconomic status (SES); and the mechanisms that are associated with the occurrence, maintenance, and remission of pain conditions.
- Impact of pain on an individual's SES and the resulting health consequences (e.g., obesity, deconditioning, mental disorders, substance

abuse) controlling for the effect of the cultural and socioeconomic influence of the community.

- Prevalence of and methods for self-management of pain within and across cultural, racial, ethnic populations, and populations of special interest such as persons with disabilities, across developmental age groups.
- The effect changes in practice or policy have on the measures of pain, e.g., effect of the increase in the amount of opioid prescriptions on the natural course of pain using aggregate population measures.
- Creation and adoption of innovative epidemiologic and statistical methodologies and study designs to further the understanding of pain disorders. Also use these techniques to maximize the analytic yield from new and existing data sets.
- Interrelationship of psychiatric disorders (e.g., borderline personality, histrionic, antisocial) and chronic pain, and relate these findings to pharmacological and behavioral therapies.
- Comorbid disorders and pain, including descriptive studies of risk and protective processes, and interventions aimed at relieving adverse consequences associated with comorbid disorders and pain.

HEALTH DISPARITIES

The Institute of Medicine reported significant racial and ethnic disparities with regard to the socioeconomic, health, and quality-of-life impacts of pain. Racial and ethnic minorities tend to be under treated for pain when compared with non-Hispanic whites. There is also evidence for racial/ethnic differences in pain care for various types of pain. Persons with disabilities report greater levels of pain and less benefit from treatment than do those without disabilities. Little other data exists as to pain disparities in persons with disabilities, the homeless, or persons living in frontier/extremely rural areas. It is clear that many factors contribute to these health disparities, including patient preferences, differences in attitudes toward and response to treatments, access to and accessibility of health care providers, and health care system factors. This program announcement invites research applications that seek to address the underlying causes of these disparities and suggest ways to address and remedy them. In particular, clinical investigations and appropriate clinical trials relevant to health disparity issues are of interest. Research is encouraged but not limited to science in the following areas:

- Differences in care for various types of pain, acute postoperative pain, treatment-related pain, cancer pain, or chronic nonmalignant pain, in various settings (i.e., health clinics, physician and dental offices, institutional settings including long-term care facilities, assisted living facilities, or emergency departments), and management of pain at the end of life.

- Differences in the factors contributing to pain disparities including patient-related (e.g., communication, attitudes), health care provider-related (e.g., decision making), and health care system-related (e.g., access to pain medication) factors.
- Differences in perceptions of pain and responses to pain and how these differences impact appropriate treatment management of pain.
- The nature and extent of disparities in the delivery of pain treatment in diverse populations.
- Existing and potential barriers to quality pain care and management including patient-related barriers, health care provider-related barriers, health care system-related barriers, and sociocultural barriers.
- Novel, evidence-based interventions to improve training for health care providers and educational interventions for minority patients.
- Measures of pain perception for those with cognitive impairment, or limited health literacy and from varied cultures.
- Assessment of the global impact, including societal and medical consequences, of pain related disparities on both individuals and society, and the potential impact of pain-related disability.
- Diverse cultural beliefs about and actions taken for pain and its management including self-care and that of lay *caregivers*.
- Treatment and management strategies for chronic pain in diverse populations.
- Means to identify population differences in pain perception and processing by addressing the incidence, severity, and consequences of pain in these and the general populations, and in specific disease states.
- New diagnostic tools for different pain mechanisms, and objective measures of treatment response that have validity in diverse populations.
- The prevalence and effectiveness of the use of nonpharmacological and novel (e.g., virtual reality) therapies for pain treatment in diverse populations such as ethnic minority groups and persons with disabilities.
- Pain management for special populations including infants, children, elderly, cognitively impaired, disabled, chronically and/or terminally ill, and patients with psychiatric diagnoses.

TRANSLATIONAL PAIN RESEARCH

The translation of laboratory-based, scientific discoveries into practical, clinical applications is a current priority for NIH. Such translational research has a reasonable probability of leading to practical outcomes within the foreseeable future and likewise resultant clinical findings should stimulate new areas of basic research. Inherent in translational research is the recognition of both efficacy (i.e., does the intervention work in a controlled setting) and effectiveness (i.e., does the intervention work in the natural environment) research. Effective translational research is extremely important in pain research and is needed to bridge the inherent differences in approach between basic studies of pain and the clinical study of pain conditions. Accordingly, proposals directed toward translational pain research are of particular interest. Research is encouraged but not limited to science in the following areas:

- Novel pharmacological and non-pharmacological pain treatments.
- Improved treatment protocols and adjunctive therapies that promote greater effectiveness, patient adherence, or patient tolerance.
- Characteristics (e.g., gender, race, age, type of pain) that predict which patient populations will benefit most or least from various pain treatments.
- Barriers to effective pain treatment.
- New technologies for use in the study and treatment of pain in the natural environment of the patients daily living.
- Clinical studies to inform, develop, and validate new animal models of chronic pain conditions; i.e., a bedside-to-bench approach.
- Design and development of small molecule mimics and other advanced pharmacological approaches.

6

A Blueprint for Transforming Pain Prevention, Care, Education, and Research

> *Progress occurs when courageous, skillful leaders seize the opportunity to change things for the better.*
>
> —Harry S Truman

This report has provided an overview of the causes, impact, prevalence, and scope of pain; presented pain as a public health problem; identified barriers to high-quality and accessible pain care; delineated specific groups that may be undertreated for pain; outlined strategies for improving the training of pain researchers; and described opportunities for public–private partnerships and collaborations in pain research, care, and education. The report has also identified challenges in educating patients, the public, and providers with respect to pain and examined the current state of basic knowledge about pain and ways in which pain research is funded and organized. In reviewing the evidence in these areas, the report has identified knowledge gaps, barriers, opportunities to move the field forward, and ways to transform how pain is understood and treated.

The committee's goal in preparing this report was to provide a broad overview of the topics included in its charge (see Chapter 1, Box 1-1) and delineate a direction and priorities for achieving change. The committee recognizes that other groups, such as the Interagency Pain Research Coordinating Committee and the Pain Consortium of the National Institutes of Health (NIH), will make use of the broad direction provided by this report and undertake their own processes to improve the understanding of pain and its treatment.

As discussed in Chapter 2, pain is experienced by virtually everyone yet is unique in its perception and experience for each person. Accordingly, broad recommendations such as those offered by the committee can yield general change, but not improvement that will be palpable to every affected individual. A standard clinical algorithm for diagnosing and treating every patient lies well beyond the scope of this report (and may not be achievable in any event). The committee did not analyze the complexities of individual pain conditions and diseases associated with pain. Nor did it analyze in depth the controversies surrounding opioid abuse and diversion. However, the committee hopes that its findings and recommendations will be transformative for the lives of many of the approximately 100 million American adults experiencing chronic pain and those with acute pain as well.

The committee determined that transforming pain prevention, care, education, and research will require carefully planned and coordinated actions by numerous leaders and organizations. Many actors should contribute to the formation of a new national pain strategy. For example, the NIH Pain Consortium should be strengthened and its activities expanded. A comprehensive strategy will ensure that actions to address the problem of pain will be both efficient and effective.

The recommendations in this report are designed to assist policy makers; federal agencies within and outside the Department of Health and Human Services; state and local health departments; primary care practitioners; pain specialists; other health professionals; health care provider organizations; health professions associations; private insurers; researchers; funders; educators; pain advocacy and awareness organizations; the public; and, most important, people living with pain and their families, friends, and colleagues. The ultimate goal is to improve outcomes of care and return people to their maximum level of functioning. The basis for the committee's recommendations consists of scientific evidence, direct testimony, and the expert judgment of the committee's diverse membership. Principles underlying the recommendations were presented in Chapter 1 (Box 1-2). They include

- pain management as a moral imperative,
- chronic pain as sometimes a disease in itself,
- the value of comprehensive treatment,
- the need for interdisciplinary approaches,
- the importance of prevention,
- wider use of existing knowledge,
- recognition of the conundrum of opioid use,
- collaborative roles for patients and clinicians, and
- the value of a public health- and community-based approach.

This chapter organizes the recommendations presented in Chapters 2 through 5 into a blueprint for action by identifying them as either immediate or near-term and enduring. The immediate recommendations are those the committee believes should be initiated now and completed before the end of 2012. The near-term and enduring recommendations build on these immediate actions, should be completed before the end of 2015, and should be maintained as ongoing efforts. Table 6-1 presents the recommendations in these two categories, along with the relevant actors and the recommendations' key elements. (Note that the numbering scheme used in Chapters 2 through 5 is preserved here.)

The committee wishes to emphasize that the comprehensive population health-based strategy set forth in Recommendation 2-2 should inform actions taken in response to, or consistent with, all of the other recommendations. The strategy should be comprehensive in scope, inclusive in its development, expeditious in its implementation, and practical in its application. Most important, the strategy must be far-reaching. As evidenced in this report, pain is a major reason for visits to physicians, a major reason for taking medications, a major cause of disability, and a key factor in quality of life and productivity. Further, pain costs the country $560-635 billion a year according to a new, conservative estimate developed as part of this study. Given the burden of pain in terms of human lives, dollars, and social consequences, actions to relieve pain should be undertaken as a national priority.

REFERENCE

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TABLE 6-1[a] Blueprint for Transforming Pain Prevention, Care, Education, and Research

IMMEDIATE: Start now and complete before the end of 2012		
Recommendation	**Actors**	**Key Elements of Recommendation**
2-2. Create a comprehensive population health-level strategy for pain prevention, treatment, management, and research	Secretary of Health and Human Services (HHS)	Involve multiple federal, state, and private-sector entities, such as the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), Centers for Medicare and Medicaid Services (CMS), Department of Defense (DoD), Department of Veterans Affairs (VA), outcomes research community and other researchers, credentialing organizations, pain advocacy and awareness organizations, health professions associations (including pain specialty professional organizations), private insurers, health care providers, state health departments, Medicaid programs, and workers' compensation programs
3-2. Develop strategies for reducing barriers to pain care	HHS Secretary, AHRQ, CMS, HRSA, Surgeon General, Office of Minority Health, Indian Health Service, VA, DoD, large health care providers (e.g., accountable care organizations)	Key part of the strategy envisioned in Recommendation 2-2
3-4. Support collaboration between pain specialists and primary care clinicians, including referral to pain centers when appropriate	CMS, VA, DoD, health care providers, pain specialists, pain centers, primary care practitioners, pain specialty professional organizations, primary care professional associations, private insurers	The pain specialist role includes serving as a resource for primary care practitioners

TABLE 6-1 Continued

Recommendation	Actors	Key Elements of Recommendation
5-1. Designate a lead institute at the National Institutes of Health responsible for moving pain research forward, and increase the support for and scope of the Pain Consortium	NIH	Involve pain advocacy and awareness organizations; foster public-private partnerships

NEAR-TERM AND ENDURING: Build on immediate recommendations, complete before the end of 2015, and maintain as ongoing efforts

Recommendation	Actors	Key Elements of Recommendation
2-1. Improve the collection and reporting of data on pain	National Center for Health Statistics (NCHS) (part of CDC), AHRQ, CMS, VA, DoD, state and local health departments, private insurers, outcomes research community, other researchers, large health care providers, designers of electronic medical records	Based on Recommendation 2-2; foster public–private partnerships; includes subpopulations at risk for pain and undertreatment of pain, characteristics of acute and chronic pain, and health consequences of pain (morbidity, mortality, disability, related trends)
3-1. Promote and enable self-management of pain	Health professions associations (including pain specialty professional organizations), pain advocacy and awareness organizations, health care providers	Requires the development of better and more evidence-based patient education products
3-3. Provide educational opportunities in pain assessment and treatment in primary care	CMS, VA, DoD, graduate medical education (GME) and continuing medical education (CME) primary care programs (backed by accreditation, licensure, and certification authorities and examiners), nurse practitioner and physician assistant training programs, researchers, health care providers	Improved health professions education requires a stronger evidence base on clinical effectiveness and more interdisciplinary training and care

continued

TABLE 6-1 Continued

Recommendation	Actors	Key Elements of Recommendation
3-5. Revise reimbursement policies to foster coordinated and evidence-based pain care	CMS, VA, DoD, Medicaid programs, private insurers, health care providers, health professions associations (including pain specialty professional organizations), pain advocacy and awareness organizations	Requires the development of more evidence on clinical effectiveness and collaboration between payers and providers
3-6. Provide consistent and complete pain assessments	Health care providers, primary care practitioners, pain specialists, other health professions, pain clinics and programs, World Health Organization (WHO)	WHO should add pain to the *International Classification of Diseases*, Tenth Edition (ICD-10)
4-1. Expand and redesign education programs to transform the understanding of pain	FDA, CDC, AHRQ, CMS, Surgeon General, DoD, VA, pain advocacy and awareness organizations, health professions associations (including pain specialty professional organizations), private insurers, health care providers	Focus is on patient education and public education; includes pain prevention
4-2. Improve curriculum and education for health care professionals	CMS, HRSA Bureau of Health Professions, accrediting organizations,[b] undergraduate and graduate health professions training programs (backed by licensure and certification authorities and examiners)	CMS's role is that of payer for GME; include interdisciplinary training
4-3. Increase the number of health professionals with advanced expertise in pain care	Pain medicine fellowship programs and graduate education programs in dentistry, nursing, psychology and other mental health fields, rehabilitation therapies, pharmacy, and other health professions	Requires more effort to attract young health professionals to pain programs; also requires collaboration between educators and clinicians

TABLE 6-1 Continued

Recommendation	Actors	Key Elements of Recommendation
5-2. Improve the process for developing new agents for pain control	FDA, NIH, pharmaceutical manufacturing and research industry, academically based biomedical research community, private funders of pain research	Based on Recommendation 5-1; involves developing new and faster ways to evaluate and approve new pain therapies, e.g., novel forms of patient stratification in clinical trials and novel investigative endpoints
5-3. Increase support for interdisciplinary research in pain	NIH, AHRQ, CDC, DoD, VA, pharmaceutical manufacturing and research industry, private funders of pain research, academically based biomedical research community, pain advocacy and awareness organizations	Based on Recommendation 5-1; basic, translational, and clinical studies should involve multiple agencies and disciplines; focus on knowledge gaps
5-4. Increase the conduct of longitudinal research in pain	NIH, AHRQ, CDC, DoD, VA, pharmaceutical manufacturing and research industry, Patient-Centered Outcomes Research Institute, private funders of pain research, academically based biomedical research community, outcomes research community, pain advocacy and awareness organizations	Based on Recommendation 5-1; includes translational, population health, and behavioral aspects of pain care (social and multimodal aspects, not just medications and other single modalities); focus is on real-world situations (comparative effectiveness, not just efficacy); foster public–private partnerships
5-5. Increase the training of pain researchers	NIH, NCHS, AHRQ, CMS, academic medical institutions	Includes more interdisciplinary training

[a] The committee prepared this table based on the recommendations but with a focus on their implementation. The table lists a range of potential actors and key elements of each recommendation.

[b] Accrediting organizations include the Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation, Accreditation Council for Graduate Medical Education, Commission on Dental Accreditation, Commission on Collegiate Nursing Education, National League for Nursing Accreditation Commission, American Psychological Association Committee on Accreditation, Council on Education for Public Health, Council on Social Work Education, and Council for Higher Education Accreditation (Perez et al., 2007).

Glossary

Acute pain: Pain that comes on quickly, can be severe, but lasts a relatively short time. (1)[1]

Addiction: A primary, chronic, neurobiologic disease whose development and manifestations are influenced by genetic, psychosocial, and environmental factors. It is characterized by behavior that includes one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. (2)

Allodynia: Pain due to a stimulus that does not normally provoke pain. (3)

Allostatic load: The cumulative physiological cost to the body of chronic exposure to the stress response. (4)

Analgesia: Absence of pain in response to a stimulus that would normally be painful. (5)

Beliefs: Assumptions about reality that shape the interpretation of events and, consequently, the appraisal of pain. (6)

Biopsychosocial model: A framework that accounts for the biological, psychological, and social dimensions of illness and disease. The biopsychosocial model

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[1] Numbers in parentheses indicate the respective references listed at the end of this glossary.

provides a basis for the understanding and treatment of disease, taking into account the patient, his/her social context, and the impact of illness on that individual from a societal perspective. The model states that ill health and disease are the result of interaction among biological, psychological, and social factors. (7)

Chronic pain: Ongoing or recurrent pain lasting beyond the usual course of acute illness or injury or, generally, more than 3 to 6 months and adversely affecting the individual's well-being. A simpler definition for chronic or persistent pain is pain that continues when it should not. (8)

Cognitive-behavioral therapy: An empirically supported treatment focusing on patterns of thinking that are maladaptive and the beliefs that underlie such thinking. Cognitive-behavioral therapy is based on the idea that our thoughts, not external factors, such as people, situations, and events, cause our feelings and behavior. As a result, we can change the way we think to improve the way we feel, even if the situation does not change. (9)

Hyperalgesia: Increased pain from a stimulus that normally provokes pain. (10)

Interdisciplinary: Refers to efforts in which professionals from several disciplines combine their professional expertise and understanding to solve a problem.

Neuromatrix theory: Proposes that pain is a multidimensional experience produced by characteristic "neurosignature" patterns of nerve impulses generated by a widely distributed neural network—the "body-self neuromatrix"—in the brain. These neurosignature patterns may be triggered by sensory inputs, but they may also be generated independently of them. (11)

Neuropathic pain: Pain caused by a lesion or disease of the somatosensory nervous system. (12)

Nociception: The neural processes of encoding and processing noxious stimuli. (13)

Opioid: Any compound that binds to an opioid receptor. Includes the opioid drugs (agonist analgesics and antagonists) and the endogenous opioid peptides. (14)

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. (15)

Pain catastrophizing: An individual's tendency to focus on and exaggerate the threat value of painful stimuli and negatively evaluate his/her ability to deal with pain. (16)

Referred pain: Pain subjectively localized in one region although due to irritation in another. (17)

Self-efficacy: Beliefs that individuals hold about their capability to carry out actions in a way that will influence the events that affect their lives. (18)

Sensitization: An increased response of neurons to a variety of inputs following intense or noxious stimuli. (19)

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Appendix A

Data Sources and Methods

The Committee on Advancing Pain Research, Care, and Education was asked to assess the current state of the science with respect to pain research, care, and education and explore approaches to advancing the field. The purpose of this study was to review the public heath significance of pain; identify barriers to appropriate pain care and strategies for reducing those barriers; identify populations undertreated for pain; identify tools and strategies for enhancing training of pain researchers; and examine opportunities for public–private partnerships to support pain research, care, and education. To respond comprehensively to its charge, the committee examined data from a variety of sources. These sources included a review of the recent literature, public input obtained through a series of meetings, a commissioned paper, and written public comments on aspects of the study charge. The study was conducted over a 10-month period.

DESCRIPTION OF THE STUDY COMMITTEE

The study committee comprised 19 individuals with expertise in pain research, pain management, pharmacology, the behavioral sciences, clinical specialties (pediatrics, oncology, infectious disease, neurology, neurosurgery, anesthesiology, pain medicine, dentistry, and complementary medicine), chronic disease, clinical teaching, epidemiology, ethics, and consumer education, as well as those who have suffered personally from chronic pain and could reflect the perspectives of the many people affected by pain. See Appendix D for biographical sketches of the committee members. The committee convened for five 2-day meetings in November 2010, January 2011, February 2011, March 2011, and April 2011.

LITERATURE REVIEW

Several strategies were used to identify literature relevant to the committee's charge. First, a search of bibliographic databases, including MEDLINE and PsycINFO, was conducted to obtain articles from peer-reviewed journals. In addition, WorldCat and the New York Academy of Medicine's Grey Literature database was searched for books, reports, and other types of grey literature. The searches focused on pain epidemiology, assessment, treatment, education, and training. The keywords used included *pain* and *diagnosis, treatment, management, analgesics, drug prescriptions, complementary therapies, practice patterns, public health, epidemiology, chronic disease, acute pain, communication barriers, physician-patient relations, caregivers, health services accessibility, health knowledge and attitudes, health care delivery, education (medical, continuing, graduate, internship and residency, nursing, pharmacy, psychology, public health professional, nonprofessional, non-medical, professional development, professional standards), curriculum, ethnic groups, population groups, aged, child, cognition disorders, women, sex factors, comorbidity, disparities, racial and ethnic differences, stereotyping, psychology, research (behavioral, biomedical, genetic, translational, interdisciplinary, qualitative, empirical), food and drug administration, department of veterans affairs, military medicine, department of defense,* and *public-private sector partnerships*. Staff sorted through approximately 3,500 articles to identify those that were relevant to the committee's charge and created an EndNote database. In addition, committee members, meeting participants, and the public submitted articles and reports on these topics. The committee's database included more than 2,600 relevant articles and reports.

PUBLIC MEETINGS

The committee hosted four public meetings to obtain additional information on specific aspects of the study charge. These meetings were held in conjunction with the committee's November, January, February, and March meetings. The committee determined the topics and speakers for the public meetings. The committee also held open forums at each public meeting at which members of the public were encouraged to provide testimony on any topics related to the study charge.

The first meeting was intended to focus on a discussion of the committee's task. Representatives from the study's sponsors reviewed and discussed the charge to the committee. The second meeting focused on data collection on pain and opportunities for public–private partnerships. The third meeting featured speakers who discussed cultural and anthropological views on pain and financing of pain care. The final meeting addressed the basic science of pain and its translation to clinical practice, as well as the regulation of pain drugs. At each meeting, the committee heard testimony and comments from a broad range of stakeholders, including individuals living with pain, family members of people living with pain, health care providers, representatives of the pharmaceutical industry, and individuals representing pain advocacy groups. The committee found this input to be highly informative for its deliberations. Agendas for the four meetings are presented in Boxes A-1 through A-4.

In addition to testimony at these meetings, the committee solicited public input on topics relevant to its charge through its website. More than 2,000 individuals provided written testimony. A summary of these comments can be found in Appendix B.

COMMISSIONED PAPER

The committee commissioned a paper on the economic burden of pain. The specific aim of this work was to provide an assessment of the economic and societal costs of pain and pain care, including such topics as health care expenditures, out-of-pocket costs, costs related to lost work or unemployment, and other individual-level impacts (see Appendix C).

BOX A-1
Committee on Advancing Pain Research, Care, and Education

The National Academies Keck Building
500 Fifth Street N.W.
Washington, D.C.

AGENDA FOR PUBLIC SESSIONS
Monday, November 22, 2010
Room 201

1:00 p.m. **WELCOME AND INTRODUCTIONS**

Philip A. Pizzo, M.D.
Chair

1:15 p.m. **DELIVERY OF STUDY CHARGE**

Lawrence A. Tabak, D.D.S., Ph.D.
NIH Principal Deputy Director

1:30 p.m. **DISCUSSION OF STUDY CHARGE WITH SPONSOR**

2:30 p.m. **ADJOURN OPEN SESSION**

Tuesday, November 23, 2010
Room 100

9:00 a.m. **WELCOME AND COMMITTEE INTRODUCTIONS**

Philip A. Pizzo, M.D.

9:15 a.m. **STAKEHOLDER PERSPECTIVES**

Tina M. Tockarshewsky
President and CEO
The Neuropathy Association

Terrie Cowley
President
The TMJ Association, Ltd.

Peter Reinecke
Principal
Reinecke Strategic Solutions, Inc.

Gwenn Herman, LCSW-C, DCSW
Executive Director
Pain Connection
Chronic Pain Outreach Center, Inc.

Malcolm Herman, Esq.
The American Pain Foundation

Romy Gelb-Zimmer, MPP
Associate Director
Federal Regulatory and Payment Policy
American Academy of Nurse Anesthetists

Robert J. Saner
Principal
Powers, Pyles, Sutter & Verville PC

11:30 a.m. **ADJOURN**

BOX A-2
Committee on Advancing Pain Research, Care, and Education

The National Academies Keck Building
500 Fifth Street N.W.
Washington, D.C.

AGENDA FOR PUBLIC SESSION
Tuesday, January 4, 2011
Room 101

10:00 a.m. **WELCOME AND INTRODUCTIONS**

Philip A. Pizzo, M.D., Chair

10:10 a.m. **PUBLIC COMMENTS**

Michael Ashburn, M.D., M.P.H.
American Pain Society (APS) *and*
American Society of Anesthesiologists (ASA)

11:00 a.m. **DATA COLLECTION ON PAIN AT THE FEDERAL LEVEL**

Centers for Disease Control and Prevention, National Center for Health Statistics
Jennifer Madans, Ph.D.
Co-Deputy Director
Associate Director for Science

Veterans Health Administration
Lynette Nilan, R.N., Ed.D.
Director, Strategic Planning and Measurement
Patient Care Services

Michael E. Clark, Ph.D.
Clinical Director, Pain Rehabilitation Program
James A. Haley Veterans Hospital, Tampa

Department of Defense
CDR Necia Williams, M.C., United States Navy
Chief, Integrated Anesthesia Services
Walter Reed Army Medical Center
National Naval Medical Center

LTC Scott R. Griffith, M.D., United States Army
Consultant, Pain Management
Walter Reed Army Medical Center

12:30 p.m. **BREAK FOR LUNCH**

Committee will meet in closed session for lunch. Members of the public may obtain lunch in the cafeteria located in the third floor Atrium.

1:15 p.m. **PUBLIC–PRIVATE PATNERSHIPS**

Robert Dworkin, Ph.D.
University of Rochester Medical Center
Director, Analgesic Clinical Trial Innovations, Opportunities, and Networks (ACTION), a public-private partnership with the FDA

Story C. Landis, Ph.D.
Director, National Institute of Neurological Disorders and Stroke

2:15 p.m. **PUBLIC COMMENTS**

Andrew Bertagnolli
American Chronic Pain Association

Penney Cowan
Founder, Executive Director
American Chronic Pain Association

David St. Peter, M.D., F.H.M.
Society of Hospital Medicine and Pacira Pharmaceuticals, Inc.

Carol Drury
Associate Director
Endometriosis Association

Chip Amoe
Assistant Director, Federal Affairs
American Society of Anesthesiologists

2:45 p.m. **ADJOURN OPEN SESSION**

BOX A-3
Committee on Advancing Pain Research, Care, and Education

Hotel Monteleone
214 Royal Street
New Orleans, LA 70130-2201

AGENDA FOR PUBLIC SESSIONS
Tuesday, February 8, 2011

10:00 a.m. **WELCOME AND INTRODUCTIONS**

Philip A. Pizzo, M.D., Chair

10:10 a.m. **CULTURAL VIEWS OF PAIN**

David B. Morris, Ph.D.
Emeritus Professor of English
University of Virginia

Mary-Jo DelVecchio Good, Ph.D.
Professor of Social Medicine
Harvard Medical School

Linda Garro, Ph.D.
Professor
Department of Anthropology
University of California, Los Angeles

12:00 p.m. **COMMITTEE WILL MEET IN CLOSED SESSION FOR LUNCH**

1:00 p.m. **FINANCING AND RESOURCES FOR PAIN CARE**

Jeffrey Livovich, M.D.
Medical Director, Aetna Inc.
National Medical Policy and Operations

2:00 p.m. **PUBLIC COMMENTS**

Todd Sitzman, M.D.
Medical Director
Advanced Pain Therapy, LLC

Barbara St. Marie, MA, RN-BC, CS, ANP, GNP
Nurse Practitioner Healthcare Foundation

Harry Gould, M.D.
Professor
Department of Neurology
LSU Health Sciences Center

Dennis Paul, M.D.
Associate Professor
Department of Pharmacology
LSU Health Sciences Center

Art Morelli, M.D.
Vice President, Medical Affairs
Clovidien Pharmaceuticals

Philip A. Saigh, Jr.
Executive Director
American Academy of Pain Medicine

Angie Gravois
Patient and Nurse, Picayune, Mississippi

Janet Chambers
President
Association for Fibromyalgia and Chronic Pain

Jon Russell, M.D., Ph.D.
Associate Professor
Department of Medicine
University of Texas Health Science Center at San Antonio

3:00 p.m. **ADJOURN OPEN SESSION**

BOX A-4
Committee on Advancing Pain Research, Care, and Education

The National Academies Beckman Center
100 Academy
Irvine, CA 92617

AGENDA FOR PUBLIC SESSIONS
Monday, March 14, 2011

1:00 p.m. **WELCOME AND INTRODUCTIONS**

Philip A. Pizzo, M.D., Chair

1:05 p.m. **BASIC SCIENCE OF PAIN AND APPROACHES TO PAIN TREATMENT**

Clifford J. Woolf, M.D., Ph.D.
Professor of Neurobiology
Harvard Medical School

Howard L. Fields, M.D., Ph.D.
Professor, Neurology and Physiology
University of California, San Francisco

Frank Porreca, Ph.D.
Professor of Pharmacology and Anesthesiology
University of Arizona

2:20 p.m. Discussion

3:00 p.m. Break

3:15 p.m. **REGULATION OF PAIN DRUGS: PERSPECTIVES FROM THE FDA**

Bob A. Rappaport, M.D. (by phone)
Director
Division of Anesthesia and Analgesia Products
Center for Drug Evaluation and Research, FDA

4:00 p.m. **PUBLIC COMMENTS**

Heather Grace
American Pain Foundation/Intractable Pain Patients United
Lakewood, CA

Douglas Cook
American Pain Foundation/Intractable Pain Patients United
Lancaster, CA

Radene Marie Cook
American Pain Foundation
Lancaster, CA

5:00 p.m. **ADJOURN OPEN SESSION**

Appendix B

Summary of Written Public Testimony

The committee solicited testimony in multiple forms from people who suffer from pain, their families and caregivers, advocates from pain-related organizations, and providers who care for pain patients. In addition to direct testimony given at the public meetings described in Appendix A, the committee asked for public comments through an online survey (see Box B-1), as well as via e-mail and other written submissions. The committee received 2,022 responses. Every response was read carefully, and these comments, along with the in-person testimony described in Appendix A, greatly informed the committee's deliberations. These voices lent focus, context, and richness—as well as a sense of urgency—to the committee's discussions and the study process. Quotations from this testimony appear throughout this report. This appendix provides brief summaries and highlights of the unique challenges faced by pain sufferers and the people who care for and treat them.

The testimony of pain sufferers bears witness to the blight of pain: its magnitude and pervasiveness, the suffering it engenders, and the transforming effects it has on people's lives. The testimony attests to the difficulty of finding adequate pain care because of both the limitations of current science and barriers that prevent patients from getting the care that is possible. Health care professionals confirm this perspective, often describing patients who have had difficulty finding adequate treatment, but their responses also illuminate the difficulties providers themselves face in providing good pain treatment—especially concerns about the impact of drug enforcement policies on pain care and the difficulty of treating a multifaceted problem such as pain within the current health care delivery system. Yet for all the ways cited by both pain sufferers and health care professionals in which the current system fails to deliver the best possible care, they are united

BOX B-1
Survey Overview and Testimony Questions

To help the committee, individuals and organizations are invited to share their thoughts and concerns about pain care, including:

- barriers to and opportunities for improving pain care,
- groups that may be inadequately treated for pain,
- patient experiences in seeking treatment, and
- provider experiences providing pain care (the committee is particularly interested in the perspectives of primary care clinicians).

The committee invites individuals living with pain and their families, caregivers, health care professionals, and others interested in these issues to share their comments.

You may submit written comments in any or all of the following areas. To share your thoughts, please complete the following electronic form.

Question 1: Barriers to Pain Care
What do you see as the biggest barriers or obstacles to affordable, accessible, and effective pain care in the U.S. today?

Question 2: Improving Pain Care
What three changes in our health care system could improve pain care?

Question 3: Undertreated Groups
Are there groups of people you believe are not receiving adequate or effective pain care? If so, who are they and why do you think that?

Question 4: Experiences Seeking Treatment for Pain
If you are an individual living with pain, please describe your experiences seeking help to treat your pain.

Question 5: Experiences Providing Pain Treatment
If you are a health care professional, please tell us about your experiences in trying to provide quality pain care for your patients and problems you encounter. Please indicate if you are a primary care clinician or specialist (and what specialty).

Question 6: Additional Comments
If you have additional thoughts about advancing pain research, care, and education or would like to share that information related to the committee's work, please use the space provided below to do so. You may also email documents or articles to support your testimony to iompainstudy@nas.edu.

in agreeing that pain will truly be mastered only when we have more and better treatments than exist today.

THE IMPACT OF PAIN

Pain sufferers' survey responses testify to the terrible ways in which pain can transform one's life—the sense of loss of self, relationships, and career that can accompany chronic pain. One woman describes herself as "a shell of my former self—I lost friends, family, my job, my sanity." Another speaks of how, "on my wedding day—one of the happiest day[s] of my life—I was in so much pain, and so tired, I could barely stand." She goes on, "so now I find myself in a situation where I am forced into a life that is 'just existing.' Dreams of having a great career and large family are gone. Please help this cause. It may be too late for me to get all of my dreams back. It may be early enough to help the others that will follow."

Yet paradoxically, this affliction often appears to be invisible. "Yesterday I was lucky, the pain was kind and waited until after I got back home before showing its true colors . . . black and blue," one man writes. "No one sees the colors upon my skin. My pain is internal. It is physical. It is mental." Another writes, "my chronic pain does not show up on an MRI or in blood work. Yet it is with me 24/7 and has changed my life completely so that I am very limited in my ability to function compared to before my illness." Pain sufferers indicate a longing for objective documentation, but in its absence, experience pain as a deeply isolating state.

Perhaps as a result, one of the most characteristic experiences described by respondents—one quite different from experience with other serious diseases—is simply "not being believed" by health care professionals and others. For example, one woman reports, "after examining me and doing an ultrasound, my doctors said the only problem I had was in my head." (She was eventually diagnosed with endometriosis.) Others report being repeatedly second-guessed about their motivation: "Since 1991 I have been dealing with mistrust in motives for seeking pain care. Most doctors I encountered did not believe that my pain was severe enough to warrant more than ibuprofen."

Health care professionals report similar observations. A nurse who teaches at a hospital-based nursing school writes: "I teach students as most faculty do, that 'pain is what the patient says it is.' But when I bring them into the clinical arena they see in real practice that nurses and doctors disbelieve the patients' complaints, and treat them as drug seekers (this is especially [true for] Sickle Cell, but also chronic back pain, joint pain etc.)." A provider observes, "I have seen the misery they [patients] have gone through trying to get proper care and being denied it based on physician fears. I also have seen the success and the quality of life improvements when they finally find a doctor who will take them seriously and is willing to properly manage their pain. But isn't being in pain bad enough?"

LACK OF TIMELY TREATMENT

Both health care professionals and patients describe how a lack of timely treatment causes problems to worsen and lead to new problems. A nurse writes that "some patients get referred too late," noting that symptoms such as "RSD [reflex sympathetic dystrophy] or post-herpetic neuralgia can benefit from selective nerve blocks, if treated within the first (roughly) 6 months of symptoms, but many times it is years before a patient is referred to a specialist." One patient writes a plea to health care professionals: "Take the issue of pain serious[ly] at the beginning. Do not say it is all in our head. This does nothing other than making the original issue worse. For instance, you are in pain, [so] you become less active, you gain weight, then the joint problems start, and then the diabetes etc. sets in. If treatment was accessible in the beginning you could stop the progression."

Many pain sufferers' stories include years of misdiagnosis. While some report eventually finding effective treatment, many report that their pain remains poorly controlled and describe their journey to finding care as one beset by woe. Comments a sufferer: "The impersonal hostility of the payment system, the intellectual poverty of the research, and the cognitive poverty of my providers, combined to turn me from a spirited and capable professional with a good income and a bright future, into a needy dependent of the state with no profession, no future, and a life that is ever more bleak and limited by pain, weakness, disenchantment, and despair."

ECONOMIC BURDEN

Pain is especially devastating for those who lack the ability to shoulder the economic burden it imposes (see Appendix C). Many respondents lack health insurance and the financial resources to obtain treatment. Even when they have coverage, patients often complain about delays in treatment due to insurance or workers' compensation processes. One writes, "my company put me in the less-than-capable hands of Worker's Compensation. . . . Finally—they'd HAVE TO HELP ME. They didn't. Four more years of stalling, ignoring me, delaying every possible way."

In some cases, pain itself has caused people to lose their jobs and health insurance, thus ending their ability to obtain treatment and placing them in a downward spiral of disability and poverty. Others report having inadequate insurance coverage, such as Medicaid, which does not cover physical therapy or behavioral health. Physicians write that they are reimbursed so little for Medicaid patients with chronic pain that they see them only out of charity because other doctors refuse to treat them.

DIFFICULTIES SURROUNDING PRESCRIPTION OF OPIOIDS

One issue raised frequently by both patients and health care professionals is the difficulties surrounding opioid pain medication. Pain sufferers describe being treated like a "common criminal" and a "drug seeker" in asking for pain medication. Others express anger that fear of the Drug Enforcement Agency (DEA) is, they believe, preventing physicians from prescribing the opioid pain medication they feel they need, and describe the arduous process of searching (and in some cases failing) to find a physician who is willing to prescribe. The belief that physicians are being influenced by fear or suspicion leads some respondents to distrust their doctors when medications are withheld, even possibly for valid medical reasons. For example, survey respondents who describe their condition as "chronic daily headache" or fibromyalgia express anger at not being prescribed opioids, but in fact research finds that opioids usually are not beneficial for those conditions. Thus, a further deleterious consequence of government opioid drug policy may be the way it undermines patients' confidence in the medical integrity of the treatment their physicians provide, thereby interfering with an effective physician–patient partnership.

Opioid prescriptions are no less fraught with difficulty for health care professionals who responded to the survey. Physicians who prescribe opioids complain of facing unfair scrutiny and fearing legal repercussions. A number of physicians describe being questioned by the DEA or state board of medical examiners and asked to justify their practices—an experience that has adversely affected their willingness to continue prescribing. They point out that managing pain through medications is safer and more effective than many medical procedures and interventions, which elicit no special scrutiny. A family physician writes, "pain patients are treated like criminals, and are belittled because of their pain. Non-intervention pain physicians are treated like criminals, when they are only trying to help patients as best they can."

An acute care nurse in a hospital describes what she calls "narcophobia"—when patients are taken off their regular pain medications during hospital stays. "These patients, who have specialists in pain control in their regular lives, and who probably spent years arriving at a regimen that works, are then taken off of those drugs and told to 'suck it up.' It is very hard to watch." Another respondent writes how there is a common misconception among health care providers concerning dangers "in the utilization of long acting opioids for the management of chronic pain and the misconception that prescribing short acting opioids is 'safer' and less of a risk." A psychologist writes, "the difference between an opiate addict who does not have pain and a pain patient receiving proper opiate medication for pain management is night and day, yet these two types are approached similarly by physicians under the scrutiny of the DEA, especially on the East Coast. This is unfair to doctors and cruel punishment to patients. When, oh when, will physicians and enforcers wake up?"

Other providers take the position that the problems associated with long-term opioid use are underestimated. A pain specialist who directs a clinic writes that his data show that among patients on high-dose opioids, more than 50 percent have no history of substance abuse and take the drugs as prescribed, yet nonetheless develop medical and social problems, which improve when they are detoxed and treated with alternative analgesics. He reports feeling that prescribing physicians fail to understand that high-dose opioids rarely maintain their effectiveness over the long term: "Also, it takes 5 minutes for a doc to renew a prescription, but much longer to reduce a dose, and some skill is involved, so the incentive is just to renew or raise the dose for temporary relief." Other physicians note the prevalence of accidental death due to unintentional drug overdoses.

Provider respondents see an urgent need for a national system that would allow them to monitor opioid use. While some states, such as Utah, have developed a system that allows prescribing doctors to view all prescriptions of controlled substances written for a given patient, this mechanism is lacking in other states. In any case, a state-by-state patchwork approach does not prevent patients from simply crossing state lines to get prescriptions from multiple providers. Responding emergency room physicians point out that they face particular challenges in trying to assess whether patients for whom they have no history are legitimate or drug seeking.

Some respondents relay the feeling that the lack of a national electronic prescription monitoring system leads to opioid prescribing practices that increase the economic burden for patients, forcing people to take substantial time and spend money on gas to drive long distances and pay (in full or as a copay) to see a physician simply to get a 30-day prescription for pain medication. One man describes how his physician "was constantly trying to force me to come into the clinic, which is about fifty miles south of my home, for things like a random urine test, despite my having told him that we were extremely poor, and that there was no one to leave with my bed-ridden wife."

REIMBURSEMENT POLICIES

Some health care professional respondents noted that insurance provides perverse incentives, reimbursing for invasive procedures and high-risk surgeries while failing to reimburse for the multidimensional treatment of pain (particularly physical therapy and behavioral health treatment) known as the "biopsychosocial" treatment model, which has been shown to be most effective for chronic pain (as well as for many other chronic health conditions). Thus, as one pain specialist points out, the insurance system rewards "procedure-based care rather than patient-oriented, biopsychosocial, outcomes-based care." Numerous pain sufferers describe being driven to have surgeries that only ended up exacerbating their pain and causing greater disability.

Behavioral health treatment is vital given the prevalence of depression, anxiety, and other mental health problems among pain sufferers. A psychiatrist describes his experience that "many patients who report to primary care with complaints of pain or fibromyalgia actually have an underlying primary depressive disorder." As numerous responding pain specialists observe, the failure to address psychological problems and provide psychological support undermines effective pain treatment. A primary care physician respondent finds that for primary care physicians, "chronic pain management requires complex skills in managing psychiatric and behavioral sequellae (including addiction) for which training and reimbursement are woefully inadequate. The low reimbursement of both cognitive work and behavioral medicine in primary care creates time pressures that limit the ability to carefully assess complex, multifaceted conditions like pain." Ultimately, he writes, "for many [primary care physicians] it is easier to let the patient become dissatisfied with care so that they seek care elsewhere. . . . Research is needed into alternative reimbursement strategies that will encourage primary care physicians to accept and retain these often complex patients."

A neurologist and pain medicine specialist sums up what many providers agree are some of the primary barriers to effective pain treatment: "1) too many pain providers give one-dimensional care; 2) patients often expect simplistic answers or injections; 3) medical providers too often refer pain patients to specialists (e.g., orthopedic surgery) rather than to a comprehensive pain center; 4) multidisciplinary pain treatment is not well-developed throughout the country." Another pain specialist—and director of a pain clinic—decries how "cost cutting has led to limited access to modalities such as injections, neuromodulation, chiropractic care, mental health care, massage, and acupuncture for chronic pain." An internist notes, "it seems easier to get help with chronic diabetics or heart failure patients, but not the same kind of support for chronic pain patients."

There were some reports that providers justify invasive procedures to patients by convincing them that structural abnormalities in MRIs require surgical intervention, despite the extensive evidence that MRIs reveal many abnormalities in people who have no pain and that surgical interventions often are unnecessary and even harmful. A pain specialist writes, "The main problem I encounter are patients who have . . . been convinced by health care professionals that an invasive procedure is warranted." Another provider in the Department of Veterans Affairs (VA) system writes, "one significant problem is the overuse of diagnostic testing. Patient[s] now have an expectation of the need for imaging and surgery when they could use self care or non-invasive treatment. Current evidence suggests that imaging studies may create a level of anxiety and fear that may affect the prognosis of someone suffering from a pain syndrome." Instead, he advocates public education, such as that in Australia about staying active and not overtreating pain (see Box 4-1 in Chapter 4). Chronic pain sufferers seeking disability status or with pending litigation themselves may have perverse incentives.

NEED FOR NEW TREATMENTS

Despite the ways in which both patients and health care professionals suggest that the health care system could do better at delivering the pain care that is available today, the overwhelming consensus of both groups is that new treatments are needed. While pain sufferers and providers are aware of the disadvantages of opioid medications, they often perceive a lack of adequate alternatives. “YES, we desperately need better medications,” one woman writes. Patients complain of feeling like “an experiment” or “a guinea pig” as treatment upon treatment is attempted without success. “We need better drugs, particularly those which act on the NMDA receptor pathways, substance P antagonists, etc.,” a provider writes. “One of the biggest problems with chronic pain, is that it isn’t a single disease with a few neat endpoints. When we did a national educational effort to encourage physicians to be more aggressive on treating pain, we [got] an epidemic of accidental overdoses.” An emergency room physician comments: “We need a systematic approach, not the ad hoc methods of US medicine. The best treatment is a functional system.” A psychotherapist writes simply: “I pray for more research to get to the bottom of this illness that is affecting so many people.”

CONCLUSION

The committee is deeply grateful to all those who shared their experiences and insights. The committee is mindful, too, of the fact that their testimony only scratches the surface of the challenges faced by pain sufferers and the people who help them. In receiving this testimony, the committee tried to bear in mind a poignant admonition offered by the American Pain Foundation: “for every letter you receive, consider the other THOUSAND PEOPLE who would love to write to you, but are too ill to do so.”

Appendix C

The Economic Costs of Pain in the United States

Darrell J. Gaskin, Ph.D.
Associate Professor of Health Economics
Department of Health Policy and Management
Johns Hopkins Bloomberg School of Public Health

Patrick Richard, Ph.D., M.A.
Assistant Research Professor of Health Economics and Policy
Department of Health Policy
The George Washington University
School of Public Health and Health Services

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SUMMARY

Background

In 2008, according to the Medical Expenditure Panel Survey (MEPS), about 100 million adults in the United States were affected by chronic pain, including joint pain or arthritis. For those who suffer pain, it limits their functional status and adversely impacts their quality of life. Pain is costly to the nation because it sometimes requires medical treatment. Pain also complicates medical care for other ailments, and it hinders one's ability to work and function in society.

Objective

We estimated (1) the annual economic costs of pain in the United States and (2) the annual costs of treating patients with a primary diagnosis of pain.

Data

We used the 2008 MEPS to compute the economic costs of pain in the United States. The analytic sample was restricted to adults, ages 18 years or older, who were civilians and noninstitutionalized. To compute the annual economic cost of pain, we defined persons with pain as those who reported having "severe pain," "moderate pain," "joint pain," "arthritis," or functional limitation that restricted their ability to work. To compute the cost of medical care for patients with a primary diagnosis of pain, we examined adults who were treated for headache, abdominal pain, chest pain, and back pain in 2008.

Methodology

The annual economic costs of pain can be divided into two components: (1) the incremental costs of medical care due to pain, and (2) the indirect costs of pain due to lower economic productivity associated with lost wages, disability days, and fewer hours worked. We estimated the incremental and indirect costs using two-part models consisting of logistic regression models and generalized linear models. We also used different model specifications for sensitivity analysis and robustness. To compute the annual costs of medical treatment for patients with a primary diagnosis of pain, we summed the expenditures for medical encounters for headache, abdominal pain, chest pain, and back pain. We converted the cost estimates into 2010 dollars using the Medical Care Inflation Index of the Consumer Price Index (CPI) for medical costs and the General CPI for wages.

Results

We found that the total incremental cost of health care due to pain ranged from $261 to $300 billion. The value of lost productivity is based on three estimates: days of work missed (ranging from $11.6 to $12.7 billion), hours of work lost (from $95.2 to $96.5 billion), and lower wages (from $190.6 to $226.3 billion). Thus, the total financial cost of pain to society, which combines the health care cost estimates and the three productivity estimates, ranges from $560 to $635 billion. All estimates are in 2010 dollars.

Conclusion

We found that the annual cost of pain was greater than the annual costs in 2010 dollars of heart disease ($309 billion), cancer ($243 billion), and diabetes ($188 billion) and nearly 30 percent higher than the combined cost of cancer and diabetes.

INTRODUCTION

Millions of Americans experience persistent pain. A review of 15 studies of chronic pain among adults found that prevalence estimates ranged from 2 percent to 40 percent, with a median of 15 percent (Verhaak et al., 1998; Turk, 2002; Manchikanti et al., 2009). Data from the 2009 National Health Interview Survey (NHIS) indicate that during a 3-month period, 16 percent of adults reported having a migraine or severe headache, 15 percent reported having pain in the neck area, 28 percent reported having pain in the lower back, and 5 percent reported having pain in the face or jaw area. For those who have persistent pain, it limits their functional status and adversely impacts their quality of life. Consequently, pain can be costly to the nation because it requires medical treatment, complicates medical treatment for other conditions, and hinders people's ability to work and function in society.

Several studies have examined the economic costs of pain. The U.S. Bureau of the Census (1996) reported the total costs of chronic noncancer pain to be $150 billion annually. In 1999, a report issued by the American Academy of Orthopedic Surgeons estimated the total cost of musculoskeletal disorders at $215.5 billion in 1995 (Praemer et al., 1999). In 2001, the National Research Council and the Institute of Medicine (IOM) reported that the economic cost of musculoskeletal disorders, in terms of lost productivity, was $45-54 billion (NRC and IOM, 2001). Turk and Theodore (2011) reported that the annual cost of pharmaceuticals for pain management was $16.4 billion, and the cost of lumbar surgeries was $2.9 billion. Their estimates of the indirect costs of pain were $18.9 billion for disability compensation and $6.9 billion for productivity loss. Researchers have estimated the annual costs of migraines and rheumatoid arthritis at $14 billion each (Hu et al., 1999; Lubeck, 2001). Stewart and colleagues (2003) estimated that common pain conditions (i.e., arthritis, back, headache, and other musculoskeletal) result in $61.2 billion in lower productivity for U.S. workers. The evidence leaves no doubt that the cost of treating pain can be high.

These studies used a more exacting, piecemeal approach to compute the cost of pain than that used for our study. For example, Turk and Theodore (2011) identified per patient costs of treating pain based on information from the U.S. Workers' Compensation database and the Centers for Medicare and Medicaid Services. They computed indirect costs using data on disability compensation and estimates of lost work time for specific pain conditions from the literature. Our study is more comprehensive because our measures of pain conditions, health care costs, and indirect costs (such as missed work days and hours and wages) were drawn more rigorously from the same sample population. We used nationally representative data sets and standard econometric techniques to address sample selection issues. Our measures of pain also capture people with chronic and persistent pain that is not formally diagnosed by a physician.

We estimated the annual economic costs of pain in the United States and the annual costs of treating patients with a primary diagnosis of pain. The annual economic costs of pain can be divided into two components: (1) the incremental costs of medical care due to pain and (2) the indirect costs of pain due to lower productivity associated with lost days and hours of work and lower wages. The annual costs of treating patients with a primary diagnosis of pain are the sum of the costs of provider visits and hospital stays for which the primary diagnosis was pain and the costs of medications used to manage pain. This is a subset of the costs of medical care due to pain because unlike cancer, heart disease, and diabetes, persistent pain is not always a diagnosed condition. The medical costs for other conditions are higher for individuals who are experiencing persistent pain. These costs are not captured in the annual costs of treating patients with a primary diagnosis of pain but are captured in the incremental costs of medical care due to pain.

DATA

Sample

We used the 2008 MEPS to examine the economic burden of pain in the United States. Cosponsored by the Agency for Health care Research and Quality and the National Center for Health Statistics, the MEPS is a nationally representative longitudinal survey that covers the U.S. civilian noninstitutionalized population (Cohen et al., 1996-1997). For this analysis, we used the Household Component (HC) file of the MEPS—the core component of the survey that collects data on demographic characteristics, health expenditures, health conditions, health status, utilization of medical services, access to care, health insurance coverage, and income for each person surveyed. We combined data from the HC file with data from the Condition and Event files of the MEPS to capture the different pain management services used and associated direct medical costs. The analytic sample for the analysis of incremental health care costs was restricted to 20,214 individuals aged 18 or older. This sample is representative of all noninstitutionalized civilian adults in the United States. The analytic sample for the analysis of indirect costs was restricted to 15,945 individuals aged 24-65 to capture the active labor force in the United States. The analysis of direct medical costs was conducted at the event level. We scanned the Event files for diagnosis of pain and the Prescribed Medicine file for pharmaceuticals used to treat pain. Specifically, we identified medical expenditures associated with headache, abdominal pain, nonspecific chest pain, and back pain that occurred in several settings, including physician and nonphysician office-based visits, hospital outpatient visits, emergency department visits, and hospital inpatient stays. We also identified expenditures associated with prescription drugs. We summed the costs of medical encounters for these diagnoses and the costs of medications used to treat pain.

Key Independent Variables

We defined persons with pain as those who reported that they experienced pain that limited their ability to work, that they were diagnosed with joint pain or arthritis, or that they had a disability that limited their ability to work. The SF-12 pain question of the MEPS asked the respondent whether, during the past 4 weeks, pain interfered with normal work outside the home and housework. The joint pain question inquired whether the person had experienced pain, swelling, or stiffness around a joint in the last 12 months. The question for arthritis determined whether the person had ever been diagnosed with arthritis. The question about functional disability inquired whether the person had any work or housework limitation. We explored whether we could use information from the Event files on persons who were diagnosed with a headache, abdominal pain, chest pain, or back pain. We identified relatively few persons who had medical encounters in which pain was the primary diagnosis. Consequently, we decided not to use the Event files to determine the prevalence of pain in the population. Rather, we expected that persons suffering from these pain conditions would report having moderate or severe pain on the SF-12.

Dependent Variables

We used total expenditures as the dependent variable to predict the incremental costs of care for individuals with selected pain conditions compared with those without these conditions. Total expenditures in the MEPS include both out-of-pocket and third-party payments to health care providers but do not include health insurance premiums. Expenditures for hospital-based services include those for both facility and separately billed physician services. Total expenditures include inpatient, emergency room, outpatient (hospital, clinic, and office-based visits), prescription drugs, and other (e.g., home health services, vision care services, dental care, ambulance services, diagnostic services, medical equipment). The expenditures do not include over-the-counter purchases.

For the analysis of indirect costs, we used the annual number of days of work missed because of pain conditions, the annual number of hours of work missed because of pain conditions, and hourly wages as dependent variables to predict the productivity loss associated with the different pain conditions. Variations in the annual number of days of work missed measure workers' decisions to use sick days. Variations in the annual number of hours worked measure workers' decisions whether to work full time, part time, or overtime. Variations in the hourly earnings measure the value of the amount of work workers can perform in an hour.

Control Variables

We used a modified version of Aday and Andersen's (1974) behavioral health model of health services to estimate direct medical costs for patients with pain compared with those without any pain. This model hypothesizes that health expenditures depend on predisposing, enabling, and health need factors. In this conceptual framework, pain is a health need factor. We estimated the association between pain and health care expenditures. We predicted health care expenditures using demographic, socioeconomic status, health behavior, location, and health need measures. The demographic factors were age, gender, race, and marital status. The socioeconomic factors were education, income, and health insurance status. To measure health behaviors, we used whether respondents smoked or exercised and their obesity status. Census region and urban/rural residence were used to measure location. To measure health needs, we used whether respondents reported they were in fair or poor health and whether they had been diagnosed with diabetes or asthma. Diabetes and asthma were included because they may complicate the treatment of other conditions, and we did not want to attribute these costs to the incremental medical costs of pain. We excluded other chronic conditions, including hypertension, heart disease, emphysema, and stroke because we were concerned about the potential correlation between these other chronic conditions and the SF-12 measures of pain. We estimated preliminary models with the full complement of chronic conditions; however, some conditions were statistically insignificant. Therefore, we elected to use the most parsimonious models that adequately controlled for health needs.

The lost productivity computation was based on the human capital approach of estimating labor supply and earning models (Becker, 1973, 1974; Killingsworth, 1983). Theoretically, hours worked, wages, and labor force participation are based on a set of factors, including age, sex, race, ethnicity, education, health status, and location. We also included the size of the family the person lives with to capture some of the household characteristics that are associated with labor market outcomes.

ESTIMATION STRATEGY

As stated above, we estimated two types of costs: (1) the incremental costs of health care due to pain, computed by estimating the impact of chronic pain on the annual cost of medical care; and (2) the indirect costs of pain due to lower economic productivity associated with disability days, lost hours worked, and lost wages.

Health Care Expenditure Models

We estimated a standard two-part expenditure model to address issues of sample selection and heterogeneity and computed the economic burden for patients with the different types of pain conditions noted above compared with those without any pain (Manning, 1998; Mullahy, 1998; Manning and Mullahy, 2001; Buntin and Zaslavsky, 2004; Deb et al., 2006; Cameron and Trivedi, 2008). The first part of the model consisted of estimating logistic regression models to estimate the probability of having any type of health care expenditures. The second part consisted of using generalized linear models with log link and gamma distribution to predict levels of direct expenditures conditional on individuals with positive expenditures. We used a log link and gamma distribution to address the skew in the expenditure data. We eliminated outliers, i.e., observations with expenditures greater than $100,000. We conducted the different diagnostic and specification tests recommended by Manning (1998), Mullahy (1998), and Manning and Mullahy (2001). We estimated the models using the survey regression procedures in STATA 11, which appropriately incorporates the design factors and sample weights.

We developed three models to predict total health care expenditures and conduct sensitivity analyses for robustness, varying the degree to which we controlled for health status. In the first model, we measured pain with indicators for moderate pain, severe pain, joint pain, and arthritis. We controlled for health status using only self-reported general health status and body mass index. In the second model, we added functional disability to our pain measures. In the third model, we included diabetes and asthma in our measures of health status. We conducted sensitivity analyses using several of the chronic condition indicators available in the MEPS and found that diabetes and asthma were significant predictors of expenditures independently of the pain measures. We estimated models with and without an indicator for functional disability. We were concerned that persons with a functional disability who had chronic pain might not be captured by the other pain measures; however, we were also aware that the functional disability variable might capture people with a functional disability but no chronic pain. By conducting the computation both ways, we could see whether including functional disability in our definition of pain conditions mattered.

We computed the incremental costs of pain by using our model to predict health care costs if a person has any type of pain and subtracting the predicted health care costs if a person does not have pain (Deb et al., 2006). To perform this calculation, the probabilities of having health care costs for persons with and without pain must be taken into account. We computed unconditional levels of health care expenditures by multiplying the probabilities obtained from the first part of the model by predicted levels of expenditures from the second part of the model for individuals with and without pain. Subsequently, we computed the incremental values for each type of pain condition by taking the difference between those with and without pain. We converted the cost estimates into 2010 dollars using the medical care index of the CPI.

We computed the impact of the incremental costs of selected pain conditions on the various payers for health care services. The HC file from the MEPS contains 12 categories of direct payment for care provided during 2008: (1) out-of-pocket payments by users of care or family; (2) Medicare; (3) Medicaid; (4) private insurance; (5) the VA, excluding CHAMPVA; (6) TRICARE; (7) other federal sources (includes the Indian Health Service, military treatment facilities, and other care provided by the federal government); (8) other state and local sources (includes community and neighborhood clinics, state and local health departments, and state programs other than Medicaid); (9) workers' compensation; (10) other unclassified sources (includes such sources as automobile, homeowner's, and liability insurance and other miscellaneous or unknown sources); (11) other private (any type of private insurance payments); and (12) other public. For each payer category, we computed its proportion of total health care expenditures. We multiplied our estimate of total incremental health care costs due to pain by these proportions to estimate the impact on each payer.

Indirect Cost Models

As with the health care expenditure models, we used two-part models to estimate the indirect costs of pain. The structure of the models depended upon the dependent variables. For missed days of work, we estimated the probability of missing a work day as a result of selected pain conditions during the year. Second, we estimated a log linear regression model in which the dependent variable was the log of the number of disability days for those adults who had positive disability days.

For hours worked and wages, the first equation estimated the impact of pain on the probability that a person is working. The second equation estimated the impact of pain on the number of annual work hours and hourly wages. Combining the results from these different parts of the models, we computed the productivity costs associated with chronic pain for each of the conditions noted above. We used a standard two-step estimator for labor supply to predict lost productivity due to pain (Greene, 2005; Cameron and Trivedi, 2008). As with the incremental cost models, we multiplied the probabilities obtained from the first part of the model by predicted levels of work days missed, lost work hours, or lost wages from the second part of the model for individuals with and without pain. To compute the total cost of missed days, we multiplied the days missed by 8 hours times the predicted hourly wage rate for individuals with the pain condition. To compute the total cost of reduction of hours worked, we multiplied the total of annual hours missed by the predicted hourly wage rate for individuals with the pain condition. To compute the total cost due to a reduction in hourly wages, we multiplied the predicted hourly wage reduction by the predicted annual hours lost for individuals with the pain condition. We converted the cost estimates into 2010 dollars using the general CPI.

The approach of using a two-part model to estimate lost productivity is similar to the use of Heckman selection models, but can be used in the absence of the identifying variables required by Heckman selection models and other limited dependent variables models, such as the Tobit (see Heckman, 1979; Ettner, 1995). Additionally, we conducted a series of tests to determine the appropriate distribution for each of these models. For instance, we used a log link with Gaussian distribution to estimate the models for hours worked.

RESULTS

Incremental Costs of Health Care

Table C-1 displays the dependent and independent variables used in the analysis of the incremental costs of health care. The sample includes 20,214 individuals aged 18 and older, representing 210.7 million adults in the United States as of 2008. The mean health care expenditures were $4,475, and 85 percent of adults had a positive expenditure. The prevalence estimates for selected pain conditions were 10 percent for moderate pain, 11 percent for severe pain, 33 percent for joint pain, 25 percent for arthritis, and 12 percent for functional disability.

Adults with pain reported higher health care expenditures than adults without pain (see Table C-2). Based on the SF-12 pain measures, a person with moderate pain had health care expenditures $4,516 higher than those of someone with no pain. Persons with severe pain had health care expenditures $3,210 higher than those of a person with moderate pain. We found similar differences for persons with joint pain ($4,048), arthritis ($5,838), and a functional disability ($9,680) compared with persons without these conditions. All of these differences were statistically significant ($p < 0.001$).

The regression results of the logistic regression models and generalized linear models indicate that moderate pain, severe pain, joint pain, arthritis, and functional disability were strongly associated with an increased probability of having a health care expenditure and with higher expenditures (see Table C-3). The coefficients were all statistically significant and positive predictors of whether a person had a health care expenditure and the amount of that expenditure. The coefficients were relatively stable across the three models. The magnitude of the coefficients declined as we included functional disability, asthma, and diabetes in the models.

To interpret the coefficients on pain conditions, we exponentiated the coefficients in the logistic models to compute the odds ratio (OR) of having a health care expenditure for a person with pain relative to a person without pain. For example, the odds of having a health care expenditure increased by 70 percent for persons with joint pain relative to persons without joint pain (OR = 1.70) according to Model 1. Similarly, because the link function in the generalized linear model is a log, we exponentiated the coefficients on the pain variables to compute the percentage increase in health care expenditure for a person with pain relative to a person without pain. For example, among persons with a health care expenditure, spending for persons with joint pain was 16.2 percent higher than that for persons without joint pain based on Model 1.

The coefficients on the control variables had the expected signs. Women were more likely to have a health care expenditure and a higher expenditure than men. The likelihood of an expenditure and the level of expenditures increased with age. Blacks, Hispanics, and Asians were less likely than whites to have a health care expenditure and had lower expenditures. Socioeconomic and health factors had the expected impact. As education, income, and health insurance status increased, health care spending also increased. Health care spending increased for persons who were obese, who reported they were in fair or poor health, who had asthma, and who had diabetes.

We computed the average and total incremental costs of the selected pain conditions (see Tables C-4 and C-5). The average incremental costs of health care for selected pain conditions ranged from $854 for joint pain to $3,957 for severe pain according to Model 1. When functional disability was included in the model, its incremental costs were $3,787, while the estimates for the other pain conditions declined, particularly for severe pain, which fell to $2,573 in Model 2. We estimated that approximately 100 million persons had at least one of the pain conditions based on the 2008 MEPS. The most prevalent condition was joint pain, affecting more than 70 million adults. We estimated that the incremental costs of health care for these selected pain conditions ranged from $261 billion to $293 billion annually. The most expensive pain condition was severe pain at $89.4 billion annually. However, functional disability was the most expensive when we included it in the model—$93.5 billion in Model 2. One interesting observation is that the incremental costs of severe pain declined to $58 billion when we included functional disability.

Table C-6 shows the distribution of the incremental costs by source of payment. We estimated that private insurers paid the largest share of incremental costs, ranging from $112 billion to $129 billion. Medicare bore 25 percent of the incremental costs due to pain, ranging from $66 billion to $76 billion. Individuals paid an additional $44 billion to $51 billion in out-of-pocket health care expenditures due to persistent pain. Medicaid paid about 8 percent of the incremental costs of pain, ranging from $20 billion to $23 billion.

Indirect Costs

Table C-7 shows the dependent and independent variables for the analysis of incremental indirect costs. The sample was 15,945 persons ages 24 to 64, representing 156 million working-age adults. The mean number of work days missed was 2.14, and 46 percent of adults missed at least one day of work. The average number of hours the sample worked annually was 1,601, with 81 percent of adults working. The average hourly wage was $14.19. Among working-age adults, 9 percent reported having moderate pain, 10 percent severe pain, 31 percent joint pain, 21 percent arthritis, and 10 percent a functional disability.

Adults with pain reported missing more days of work than adults without pain (see Table C-8). A person with moderate pain, based on the SF-12 pain measures, missed 2.1 days more than someone with no pain. Adults with severe pain missed 2.6 days more than those with moderate pain. The differences for joint pain, arthritis, and functional disability were 1.3 days, 1.3 days, and 3.3 days, respectively. Pain was associated with fewer annual hours worked (see Table C-9). Persons with functional disability had the largest difference, working 1,203 fewer hours than persons with no functional disability. Compared with persons with no pain, persons with moderate pain worked 291 fewer hours, and persons with severe pain 717 fewer hours. We found similar differences in hours for joint pain (220) and arthritis (384). Wages were lower for persons with pain (see Table C-10). The largest difference was for persons with functional disability, followed by severe pain, moderate pain, arthritis pain, and joint pain. Persons with functional disability earned $11 an hour less than persons without functional disability.

The regression results for the indirect cost analysis are reported in Tables C-11, C-12, and C-13. As with the health care cost models, we interpreted the coefficients on the pain measures by exponentiating them. The first step models were logistic regressions, so the exponentiated coefficients on the indicator variables were ORs. The second step models were log-linear using the generalized linear model. Thus, the exponentiated coefficients were percent changes in the dependent variables. For example, in Table C-11, Model 1, the coefficients on moderate pain were 0.5 in the logistic model and 0.49 in the generalized linear model. We interpreted these coefficients as follows. Compared with a person with no pain, someone with moderate pain had 64 percent greater odds of having at least one missed day of work during the year, and having moderate pain increased the number of days missed by 63 percent. Tables C-12 and C-13 display the impact of pain conditions on the likelihood of working, the number of hours worked, and hourly wages. The pain conditions had a significant negative impact on the likelihood of working. The impact on hours worked and wages was negative but modest and in several cases insignificant. This means that the negative impact of pain conditions on hours worked and wages occurred largely through the decision to work or not. Persons with pain were less likely to work than persons without pain.

The calculated incremental costs are reported in Tables C-14 to C-19. The average incremental number of days of work missed was greatest for severe pain, with estimates ranging from 5.0 to 5.9 days. Arthritis caused the fewest days of work missed—0.1 to 0.3. Almost 70 million working adults reported having one of the pain conditions. The annual costs for the number of days missed ranged from $11.6 to $12.7 billion. More persons reported joint pain, but severe pain was more costly. Including functional disability in these models did not affect the estimates for the other pain conditions.

Pain also was associated with fewer annual hours worked. For Model 1, severe pain was associated with the largest reduction, 204 hours. However, when we included functional disability in the model, the impact of severe pain fell to 30 hours, while the reduction associated with having a functional disability was 740 hours. While the inclusion of functional disability changed the distribution of the costs, it did not change the overall estimate of the costs associated with fewer annual hours worked, which totaled about $95 to $96 billion.

The average reduction in hourly wages for selected pain conditions ranged from $0.26 an hour for joint pain to $3.76 an hour for severe pain according to Model 1. Including functional disability in the models changed the estimates substantially for the other pain conditions—from $0.05 an hour for joint pain to $1.66 an hour for severe pain. Functional disability was associated with a large reduction in wages ($9.36 an hour), which did impact the total estimate of the costs due to wage reductions. The indirect cost associated with reduced wages was $191 billion for Model 1 but $226 and $217 billion for Models 2 and 3, respectively.

Total Direct Cost for Medical Care for Pain Diagnoses

The direct cost of medical treatment for pain diagnoses was almost $47 billion (see Table C-20). The bulk of these costs was for back pain ($34 billion). Office-based services and hospital stays accounted for 36 percent and 33 percent of the total costs, respectively. The difference between the total direct cost and the total incremental health care costs was $214 to $246 billion. This indicates that most of the health care costs were attributable not to a direct diagnosis of pain but to the impact of pain on the treatment of other conditions.

In summary, we found that the total incremental costs of health care due to pain ranged from $261 to $300 billion. The value of lost productivity ranged from $11.6 to $12.7 billion for days of work missed, from $95.2 to $96.5 billion for hours of work lost, and from $190.6 to $226.3 billion for lower wages. The total annual costs ranged from $560 to $635 billion.

DISCUSSION

Persistent pain impacts 100 million adults and costs from $560 to $635 billion annually. Based on statistics published by the National Institutes of Health (NIH), the costs of persistent pain exceed the economic costs of the six most costly major diagnoses—cardiovascular diseases ($309 billion); neoplasms ($243 billion); injury and poisoning ($205 billion); endocrine, nutritional, and metabolic diseases ($127 billion); digestive system diseases ($112 billion); and respiratory system diseases ($112 billion) (National Heart, Lung, and Blood Institute, 2011) (we have converted these costs into 2010 dollars). These cost-of-condition estimates differ from our cost-of-pain estimate. NIH combined personal health care costs reported in the MEPS and the costs of premature death due to these conditions; however, the NIH estimates do not include lost productivity. We do not consider the costs of premature death due to pain because pain is not considered a direct cause of death as are heart disease, cancer, and stoke. The American Diabetes Association reported that in 2007, diabetes cost $174 billion, including $116 billion in excess medical expenditures and $58 billion in reduced productivity (ADA, 2008). (This is equivalent to $188 billion in 2010 U.S. dollars.) Unlike these diagnosed conditions, pain affects a much larger number of people, by a factor of about four compared with heart disease and diabetes and a factor of nine compared with cancer. Thus, the per person cost of pain is lower than that of the other conditions, but the total cost of pain is higher.

Our estimate of the cost of chronic pain is conservative for several reasons. First, we did not account for the cost of pain for institutionalized and noncivilian populations. In particular, the incremental health care costs for nursing home residents, military personnel, and prison inmates with pain were not included and may be substantial. Second, we did not include the costs of pain for persons under age 18. Third, we did not include the cost of pain to caregivers. For example, we did not consider time a spouse or adult child might lose from work to care for a loved one with chronic pain. Fourth, we considered the indirect costs of pain only for working-age adults. We did not estimate these costs for working persons over the age of 65 or under the age of 24. While there are persons in these age categories who are retired or continuing their education, there also are persons in both age categories who are working or willing to work. We did not capture the value of their lost productivity. Fifth, we also did not include the value of time lost for other, non-work-related activities. Sixth, we did not include other indirect costs—lost tax revenue, costs for replacement workers, legal fees, and transportation costs for patients to reach providers. Finally, in our cost estimates we did not attempt to measure the psychological or emotional toll of chronic pain.

The presence of chronic pain can lower a person's quality of life and diminish the person's enjoyment of other aspects of life.

Our analysis has a few limitations. First, it is a cross-sectional analysis, so we cannot infer causality. Second, our measures of pain are limited. We cannot estimate the impact of pain associated with musculoskeletal conditions or cancer. Third, our functional disability may include persons who do not have chronic pain. Finally, we used two-part models to control for unobserved differences between persons with pain and persons without pain. However, we recognize that the two-part approach may not fully capture the unobserved differences between the two groups and if so, our estimates of costs associated with pain will be too large.

In general, given the magnitude of the economic costs of pain, society should consider investing in research, education, and care designed to reduce the impact of pain. Eliminating pain may be impossible, but helping people live better with pain may be achievable.

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TABLE C-1 Dependent and Independent Variables Used in the Incremental Cost Models for Patients Aged 18 or Older for Selected Pain Conditions (N = 20,214, US$2010)

Categories	Means/ Proportions	Linearized Standard Errors	[95% Conf. Interval]	
Dependent Variables				
Total expenditures*	$4,475.23	$93.23	$4,291.41	$4,659.05
Any expenditures	0.85	0.00	0.84	0.86
Independent Variables				
SF-12 Measures				
No pain [reference]	0.79	0.00	0.78	0.80
Moderate pain	0.10	0.00	0.10	0.11
Severe pain	0.11	0.00	0.10	0.11
Other Measures of Pain				
Joint pain	0.33	0.01	0.32	0.35
Arthritis	0.25	0.01	0.24	0.26
Functional disability	0.12	0.00	0.11	0.12
Gender				
Male [reference]	0.48	0.00	0.48	0.49
Female	0.52	0.00	0.51	0.52
Age				
Age 18-44 [reference]	0.48	0.00	0.44	0.52
Age 45-54	0.19	0.00	0.18	0.20
Age 55-64	0.16	0.00	0.15	0.17
Age 65-74	0.09	0.00	0.08	0.10
Age 75 plus	0.08	0.00	0.07	0.09
Race/Ethnicity				
Non-Hispanic white [reference]	0.72	0.00	0.67	0.74
Black	0.11	0.01	0.10	0.13
Hispanic	0.13	0.01	0.12	0.15
Asian	0.04	0.00	0.04	0.05
Marital Status				
Married [reference]	0.55	0.00	0.53	0.56
Divorced	0.11	0.00	0.11	0.12
Widow	0.06	0.00	0.06	0.07
Separated	0.02	0.00	0.02	0.02
Never married	0.26	0.00	0.25	0.26
Education				
No high school degree [reference]	0.34	0.00	0.21	0.27
High school degree	0.50	0.01	0.49	0.51
College degree	0.17	0.00	0.16	0.18
Graduate degree	0.09	0.00	0.08	0.10

TABLE C-1 Continued

Categories	Means/ Proportions	Linearized Standard Errors	[95% Conf. Interval]	
Income				
0-199% of federal poverty level (FPL) [reference]	0.29	0.00	0.27	0.32
200-400% of FPL	0.30	0.01	0.29	0.31
More than 400% of FPL	0.41	0.01	0.39	0.42
Insurance Status				
Private insurance [reference]	0.69	0.00	0.67	0.71
Public insurance	0.16	0.00	0.15	0.17
Uninsured	0.15	0.00	0.14	0.16
Health Behaviors				
Current smoker	0.20	0.00	0.19	0.21
Physical activity	0.57	0.01	0.55	0.58
Health Conditions/Status				
Normal weight [reference]	0.36	0.00	0.35	0.39
Overweight	0.35	0.00	0.34	0.36
Obese	0.18	0.00	0.17	0.18
Over obese	0.11	0.00	0.10	0.11
Diabetes	0.10	0.00	0.09	0.10
Asthma	0.09	0.00	0.09	0.10
Health Status				
Excellent/very good/good health [reference]	0.86	0.00	0.85	0.87
Fair/poor health	0.14	0.00	0.13	0.15
Regions/Locations				
Northeast [reference]	0.18	0.00	0.13	0.23
Midwest	0.22	0.01	0.21	0.24
South	0.37	0.01	0.35	0.39
West	0.23	0.01	0.21	0.24
Non-metropolitan statistical area	0.16	0.00	0.13	0.19
Metropolitan statistical area	0.84	0.01	0.81	0.87

NOTE: Dollar amounts were adjusted for inflation as of 2010 using the Medical Care Inflation Index of the Consumer Price Index.

*Total expenditures include inpatient, emergency room, and outpatient services (hospital, clinic, and office-based visits); prescription drugs; and other (e.g., home health services, vision care services, dental care, ambulance services, and medical equipment). Expenditures do not include over-the-counter purchases.

SOURCE: Based on the 2008 Medical Expenditure Panel Survey (MEPS).

TABLE C-2 Means of Unadjusted Expenditures for Patients Aged 18 or Older for Selected Pain Conditions (US$2010)

	Weighted Means	Linearized Standard Errors	[95% Conf. Interval]		F-Test	P-Value
SF-12 Pain Measures						
No Pain	$3,225.60	82.13	$3,063.67	$3,387.53		
Moderate Pain	7,742.01	377.34	6,998.05	8,485.98		
Difference	**4,516.41**		**3,934.38**	**5,098.45**	**145.43**	**0.0000**
Severe Pain	10,952.44	371.41	10,220.17	11,684.71		
Difference	**3,210.43**		**3,222.12**	**3,198.73**	**41.77**	**0.0000**
Joint Pain						
No Joint Pain	3,055.17	82.20	2,893.01	3,217.24		
Joint Pain	7,103.02	178.42	6,751.24	7,454.79		
Difference	**4,047.85**		**3,858.23**	**4,237.55**	**475.89**	**0.0000**
Arthritis Pain						
No Arthritis	3,036.90	74.27	2,890.50	3,183.33		
Arthritis	8,875.13	233.28	8,415.19	9,335.07		
Difference	**5,838.23**		**5,524.69**	**6,151.74**	**603.49**	**0.0000**
Functional Disability						
No Disability	3,353.34	82.76	3,190.16	3,516.52		
Disability	13,033.6	377.26	12,289.79	13,777.41		
Difference	**9,680.26**		**9,099.63**	**10,260.9**	**599.76**	**0.0000**

SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey. Dollar amounts were adjusted for inflation as of 2010 using the Medical Care Inflation Index of the Consumer Price Index.

TABLE C-3 Results of Two-Part Total Expenditure Models for Patients Aged 18 or Older for Selected Pain Conditions

	Model 1^{a}		Model 2		Model 3	
	Logit	GLM	Logit	GLM	Logit	GLM
Moderate Pain	0.71***	0.42***	0.68***	0.36***	0.66***	0.37***
	(0.12)	(0.05)	(0.12)	(0.05)	(0.12)	(0.05)
Severe Pain	0.58***	0.58***	0.46***	0.43***	0.41***	0.44***
	(0.11)	(0.04)	(0.12)	(0.04)	(0.11)	(0.05)
Joint Pain	0.53***	0.15***	0.51***	0.12***	0.49***	0.11***
	(0.07)	(0.04)	(0.07)	(0.04)	(0.07)	(0.04)
Arthritis	0.49***	0.24***	0.45***	0.22***	0.42***	0.21***
	(0.09)	(0.04)	(0.09)	(0.04)	(0.1)	(0.04)
Functional Disability			0.73***	0.65***	0.65***	0.63***
			0.15	0.05	0.15	0.05
Female	0.91***	0.20***	0.92***	0.22***	0.92***	0.23***
	(0.05)	(0.04)	(0.05)	(0.03)	(0.05)	(0.03)
Age 45-54	0.23***	0.08*	0.22***	0.06	0.19**	0.03
	(0.07)	(0.04)	(0.07)	(0.04)	(0.07)	(0.04)
Age 55-64	0.56***	0.44***	0.53***	0.41***	0.45***	0.36***
	(0.09)	(0.05)	(0.09)	(0.05)	(0.09)	(0.05)
Age 65-74	0.87***	0.50***	0.86***	0.48***	0.75***	0.42***
	(0.16)	(0.06)	(0.16)	(0.06)	(0.16)	(0.06)
Age 75 and Over	1.48***	0.68***	1.43***	0.62***	1.35***	0.57***
	(0.23)	(0.07)	(0.23)	(0.07)	(0.23)	(0.07)
Black	–0.68***	–0.17***	–0.67***	–0.18***	–0.69***	–0.19***
	(0.08)	(0.05)	(0.08)	(0.05)	(0.08)	(0.06)
Hispanic	–0.73***	–0.29***	–0.71***	–0.26***	–0.70***	–0.26***
	(0.08)	(0.05)	(0.08)	(0.05)	(0.08)	(0.05)
Asian	–0.72***	–0.66***	–0.71***	–0.62***	–0.71***	–0.64***
	(0.11)	(0.06)	(0.11)	(0.06)	(0.11)	(0.06)
High School Degree	0.03	–0.03	0.03	–0.03	0.03	–0.02
	(0.06)	(0.04)	(0.06)	(0.04)	(0.06)	(0.04)
College Degree	0.48***	0.11*	0.48***	0.11*	0.49***	0.13**
	(0.1)	(0.06)	(0.1)	(0.06)	(0.1)	(0.06)
Graduate Degree	0.53***	0.17**	0.52***	0.16**	0.55***	0.17**
	(0.14)	(0.07)	(0.14)	(0.07)	(0.14)	(0.07)
Divorced	–0.20**	–0.06	–0.23**	–0.08	–0.23**	–0.09
	(0.09)	(0.06)	(0.09)	(0.05)	(0.09)	(0.05)
Widow	–0.11	–0.11*	–0.13	–0.14**	–0.13	–0.12*
	(0.21)	(0.06)	(0.21)	(0.06)	(0.21)	(0.06)
Separated	–0.31**	–0.13	–0.34**	–0.11	–0.36**	–0.15
	(0.15)	(0.1)	(0.16)	(0.1)	(0.16)	(0.1)
Never Married	–0.26***	–0.11**	–0.27***	–0.15***	–0.28***	–0.14**
	(0.06)	(0.05)	(0.06)	(0.05)	(0.06)	(0.05)
200-400% of Federal Poverty Level (FPL)	0.08	–0.03	0.09	0.02	0.08	0.02
	(0.06)	(0.05)	(0.06)	(0.05)	(0.06)	(0.05)

continued

TABLE C-3 Continued

	Model 1[a]		Model 2		Model 3	
	Logit	GLM	Logit	GLM	Logit	GLM
More Than 400% of FPL	0.44***	0.06	0.45***	0.10**	0.45***	0.11**
	(0.08)	(0.05)	(0.08)	(0.05)	(0.08)	(0.05)
Public Insurance	0.09	0.18***	0.01	0.08	–0.01	0.08
	(0.08)	(0.05)	(0.09)	(0.05)	(0.09)	(0.05)
Uninsured	–1.33***	–0.68***	–1.33***	–0.70***	–1.32***	–0.69***
	(0.06)	(0.06)	(0.06)	(0.06)	(0.07)	(0.06)
Current Smoker	–0.22***	–0.09	–0.23***	–0.10*	–0.24***	–0.09*
	(0.06)	(0.05)	(0.06)	(0.05)	(0.06)	(0.05)
Physical Activity	0.01	–0.15***	0.03	–0.11***	0.03	–0.10***
	(0.06)	(0.04)	(0.06)	(0.04)	(0.06)	(0.04)
Overweight	0.04	0.02	0.05	0.05	0.02	0.04
	(0.06)	(0.04)	(0.06)	(0.04)	(0.06)	(0.04)
Obese	0.19***	0.05	0.19***	0.06	0.14*	0.02
	(0.07)	(0.05)	(0.07)	(0.05)	(0.07)	(0.05)
Over Obese	0.16*	0.09*	0.16*	0.07	0.03	–0.01
	(0.09)	(0.05)	(0.09)	(0.05)	(0.09)	(0.05)
Fair/Poor Health	0.82***	0.54***	0.72***	0.39***	0.57***	0.33***
	(0.09)	(0.04)	(0.09)	(0.05)	(0.09)	(0.05)
Midwest	0.07	0.02	0.07	0.05	0.07	0.05
	(0.1)	(0.04)	(0.1)	(0.04)	(0.1)	(0.04)
South	–0.05	–0.02	–0.05	0.01	–0.04	0.02
	(0.07)	(0.04)	(0.07)	(0.04)	(0.08)	(0.04)
West	–0.18**	0.07	–0.18**	0.11**	–0.21**	0.11**
	(0.09)	(0.05)	(0.09)	(0.05)	(0.09)	(0.05)
Metropolitan Statistical Area	0.20***	0.06	0.20***	0.04	0.20***	0.03
	(0.07)	(0.06)	(0.07)	(0.06)	(0.08)	(0.06)
Diabetes					1.55***	0.41***
					(0.16)	(0.04)
Asthma					0.80***	0.10**
					(0.11)	(0.05)
Constant	0.95***	7.82***	0.94***	7.73***	0.92***	7.70***
	(0.12)	(0.1)	(0.12)	(0.1)	(0.12)	(0.1)
Number of Respondents[b]	21,777	17,450	21,777	17,363	21,646	17,363

NOTES: Total expenditures include inpatient, emergency room, and outpatient services (hospital, clinic and office-based visits); prescription drugs; and other (e.g., home health services, vision care services, dental care, ambulance services, medical equipment). The expenditures do not include over-the-counter purchases. Linearized standard errors are in parentheses. GLM = generalized linear model.

[a] * p <.10, ** p <0.05, *** p <.01.

[b] Logistic models were estimated on the full subsample of adults with any health care expenditure. Log-transformed generalized linear models were estimated for adults with positive expenditures. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables.

SOURCE: Based on the 2008 Medical Expenditure Panel Survey (MEPS).

TABLE C-4 Average Incremental Costs of Medical Expenditures for Selected Pain Conditions (US$2010)

Condition	Model 1	Model 2	Model 3
Moderate Pain	$2,146.31	$1,832.11	$1,861.32
Severe Pain	3,956.90	2,572.76	2,655.27
Joint Pain	854.25	686.78	649.07
Arthritis	1,234.40	1,143.65	1,110.34
Functional Disability	—	3,786.58	3,590.27

NOTES: Dollar amounts were adjusted for inflation as of 2010 using the Medical Care Inflation Index of the Consumer Price Index. This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 18 or older, representing 210,764,398 individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-5 Total Incremental Costs of Medical Expenditures for Selected Pain Conditions (in millions of US$2010 and millions of persons)

Condition	Population	Model 1	Model 2	Model 3
Moderate Pain	21.3	$45,716	$39,024	$39,646
Severe Pain	22.6	89,426	58,144	60,009
Joint Pain	70.3	60,054	48,280	45,630
Arthritis	53.4	65,917	61,071	59,292
Functional Disability	24.7	—	93,529	88,680
Total	100.0	**$261,113**	**$300,048**	**$293,257**

NOTES: Dollar amounts were adjusted for inflation as of 2010 using the Medical Care Inflation Index of the Consumer Price Index. This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 18 or older, who represented 210,764,398 individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables. One hundred million persons had at least one of the pain conditions studied. The population total for the selected pain conditions does not sum to 100 million because some persons have multiple conditions.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-6 Distribution of Total Incremental Costs of Medical Expenditures by Source of Payment (in millions of US$2010)

Source of Payment	Proportion (%)	Model 1	Model 2	Model 3
Out of Pocket	17	$44,381	$50,999	$49,845
Medicare	25	65,891	75,716	74,002
Medicaid	8	20,176	23,184	22,659
Private Insurance	43	112,260	128,999	126,079
Department of Veterans Affairs/TRICARE/ Other Federal	3	7,322	8,413	8,223
State/Other Public	1	2,960	3,401	3,324
Workers' Compensation	1	3,866	4,443	4,342
Other Sources	2	4,258	4,893	4,783
Total	100	**$261,113**	**$300,048**	**$293,257**

NOTES: Dollar amounts were adjusted for inflation as of 2010 using the Medical Care Inflation Index of the Consumer Price Index. This analysis applied the distribution of total expenditures for noninstitutionalized adults aged 18 or older to the total incremental costs due to persistent pain. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-7 Dependent and Independent Variables Used in the Indirect Cost Models for Patients Aged 24-64 for Selected Pain Conditions (N = 15,945)

Categories	Means/ Proportions	Linearized Standard Errors	[95% Conf. Interval]	
Dependent Variables				
Number of work days missed	2.14	0.08	1.98	2.30
Missed any work days	0.46	0.01	0.45	0.47
Number of hours worked	1,601.17	10.13	1,581.19	1,621.14
Hourly wages*	14.19	0.19	13.83	14.56
Any hours worked	0.81	0.00	0.80	0.82
Independent Variables				
SF-12 Measures				
No pain [reference]	0.81	0.00	0.82	0.79
Moderate pain	0.09	0.00	0.08	0.10
Severe pain	0.10	0.00	0.10	0.11
Other Measures of Pain				
Joint pain	0.31	0.01	0.30	0.33
Arthritis	0.21	0.01	0.20	0.22
Functional disability	0.10	0.00	0.09	0.10
Gender				
Male [reference]	0.48	0.00	0.49	0.48
Female	0.52	0.00	0.51	0.52
Age/Family Size				
Age 18-44 [reference]	0.28	0.00	0.31	0.25
Age 35-44	0.25	0.00	0.24	0.26
Age 45-54	0.26	0.00	0.25	0.27
Age 55-64	0.21	0.01	0.20	0.22
Family size	2.87	0.03	2.81	2.92
Race/Ethnicity				
Non-Hispanic white [reference]	0.70	0.00	0.74	0.66
Black	0.11	0.01	0.10	0.13
Hispanic	0.14	0.01	0.12	0.16
Asian	0.05	0.00	0.04	0.05
Marital Status				
Married [reference]	0.62	0.00	0.64	0.59
Divorced	0.13	0.00	0.12	0.14
Widow	0.02	0.00	0.02	0.02
Separated	0.02	0.00	0.02	0.03
Never married	0.21	0.01	0.20	0.22
Education				
No high school degree [reference]	0.22	0.00	0.25	0.18
High school degree	0.48	0.01	0.47	0.50
College degree	0.20	0.01	0.19	0.21
Graduate degree	0.10	0.00	0.09	0.11

continued

TABLE C-7 Continued

Categories	Means/ Proportions	Linearized Standard Errors	[95% Conf. Interval]	
Income				
0-199% of federal poverty level (FPL) [reference]	0.27	0.00	0.29	0.23
200-400% of FPL	0.30	0.01	0.29	0.32
More than 400% of FPL	0.43	0.01	0.42	0.45
Insurance Status				
Private insurance [reference]	0.74	0.00	0.75	0.72
Public insurance	0.09	0.00	0.09	0.10
Uninsured	0.17	0.01	0.16	0.18
Health Conditions/Status				
Diabetes	0.08	0.00	0.08	0.09
Asthma	0.09	0.00	0.08	0.10
Health Status				
Excellent/very good/good health [reference]	0.87	0.00	0.87	0.86
Fair/poor health	0.13	0.00	0.13	0.14
Regions/Locations				
Northeast [reference]	0.19	0.00	0.24	0.14
Midwest	0.22	0.01	0.21	0.24
South	0.36	0.01	0.34	0.38
West	0.23	0.01	0.21	0.24
Metropolitan statistical area	0.85	0.01	0.82	0.88

*Wages were adjusted for inflation as of 2010 using the General Consumer Price Index.
SOURCE: Based on the 2008 Medical Expenditure Panel Survey.

TABLE C-8 Means of Unadjusted Number of Work Days Missed for Adults Aged 24-64 with Selected Pain Conditions

SF-12 Pain Measures	Weighted Means	Linearized Standard Errors	[95% Conf.	Interval]	F-Test	P-Value
No pain	1.48	0.07	1.34	1.61		
Moderate pain	3.60	0.38	2.84	4.36		
Difference	**2.12**		**1.50**	**2.75**	**27.36**	**0.0000**
Severe pain	6.21	0.50	5.22	7.20		
Difference	**2.61**		**2.37**	**2.84**	**18.44**	**0.0000**
Joint Pain						
No joint pain	1.73	0.08	1.56	1.89		
Joint pain	3.05	0.17	2.72	3.39		
Difference	**1.33**		**1.16**	**1.50**	**46.75**	**0.0000**
Arthritis Pain						
No Arthritis	1.89	0.08	1.73	2.05		
Arthritis	3.14	0.19	2.77	3.52		
Difference	**1.25**	**0.11**	**1.04**	**1.46**	**35.86**	**0.0000**
Functional Disability						
No Disability	1.83	0.07	1.69	1.97		
Disability	5.09	0.48	4.14	6.05		
Difference	**3.26**		**2.45**	**4.08**	**44.30**	**0.0000**

SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-9 Means of Unadjusted Number of Hours Worked for Adults Aged 24-64 with Selected Pain Conditions

SF-12 Pain Measures	Weighted Means	Linearized Standard Errors	[95% Conf. Interval]		F-Test	P-Value
No pain	1,697.45	10.75	1,676.25	1,718.64		
Moderate pain	1,405.99	32.40	1,342.10	1,469.88		
Difference	**291.46**		**334.15**	**248.77**	**72.91**	**0.0000**
Severe pain	980.56	32.66	916.17	1,044.95		
Difference	**425.43**		**425.93**	**424.93**	**89.81**	**0.0000**
Joint Pain						
No joint pain	1,672.61	11.75	1,649.44	1,695.78		
Joint pain	1,453.11	20.14	1,413.40	1,492.83		
Difference	**219.50**		**236.04**	**202.96**	**80.35**	**0.0000**
Arthritis Pain						
No Arthritis	1,676.77	10.51	1,656.05	1,697.49		
Arthritis	1,292.52	21.88	1,249.38	1,335.65		
Difference	**384.25**		**406.67**	**361.84**	**247.70**	**0.0000**
Functional Disability						
No Disability	1,718.47	9.71	1,699.32	1,737.62		
Disability	515.02	30.59	454.70	575.33	1462.73	
Difference	**1,203.45**	**–20.88**	**1,244.62**	**1,162.29**		**0.0000**

SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-10 Means of Unadjusted Number of Hourly Wages for Adults Aged 24-64 with Selected Pain Conditions (US$2010)

SF-12 Pain Measures	Weighted Means	Linearized Standard Errors	[95% Conf.	Interval]	F-Test	P-Value
No pain	$15.22	0.22	$14.80	$15.65		
Moderate pain	11.73	0.49	10.75	12.70		
Difference	**3.50**				**45.53**	**0.0000**
Severe pain	7.58	0.33	6.93	8.24		
Difference	**4.14**		**3.83**	**4.46**	**46.40**	**0.0000**
Joint Pain						
No joint pain	14.85	0.20	14.45	15.25		
Joint pain	12.74	0.31	12.12	13.37		
Difference	**2.10**				**37.02**	**0.0000**
Arthritis Pain						
No Arthritis	14.88	0.19	14.50	15.26		
Arthritis	11.19	0.32	10.56	11.81		
Difference	**3.69**				**118.37**	**0.0000**
Functional Disability						
No Disability	15.23	0.19	14.86	15.61		
Disability	4.23	0.32	3.60	4.86		
Difference	**11.00**				**978.55**	**0.0000**

NOTE: Wages were adjusted for inflation as of 2010 using the General Consumer Price Index.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-11 Results of Two-Part Missed Days Models for Persons Aged 24-64 for Selected Pain Conditions

	Model 1		Model 2		Model 3	
Categories	Logit	GLM	Logit	GLM	Logit	GLM
Moderate Pain	0.50***	0.49***	0.43***	0.48***	0.43***	0.48***
	(0.09)	(0.12)	(0.09)	(0.12)	(0.09)	(0.12)
Severe Pain	0.79***	0.81***	0.57***	0.80***	0.56***	0.80***
	(0.09)	(0.1)	(0.09)	(0.11)	(0.09)	(0.11)
Joint Pain	0.25***	0.08	0.23***	0.06	0.23***	0.06
	(0.05)	(0.07)	(0.05)	(0.07)	(0.05)	(0.07)
Arthritis	0.20***	–0.07	0.15***	–0.06	0.13**	–0.06
	(0.06)	(0.08)	(0.06)	(0.08)	(0.06)	(0.08)
Female	0.51***	–0.05	0.52***	–0.04	0.51***	–0.04
	(0.04)	(0.06)	(0.04)	(0.06)	(0.04)	(0.06)
Family Size	–0.01	–0.01	0	–0.02	0	–0.02
	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)
Age 35-44	–0.22***	–0.02	–0.23***	–0.01	–0.23***	–0.01
	(0.06)	(0.1)	(0.06)	(0.09)	(0.06)	(0.1)
Age 45-54	–0.31***	–0.04	–0.34***	–0.05	–0.34***	–0.06
	(0.06)	(0.1)	(0.06)	(0.1)	(0.06)	(0.1)
Age 55-64	–0.09	–0.17*	–0.12	–0.17*	–0.12	–0.17*
	(0.08)	(0.1)	(0.08)	(0.1)	(0.08)	(0.1)
Black	–0.14**	0.19**	–0.13**	0.22***	–0.13**	0.22***
	(0.06)	(0.08)	(0.06)	(0.08)	(0.06)	(0.08)
Hispanic	–0.26***	0.22**	–0.22***	0.23**	–0.22***	0.23**
	(0.06)	(0.11)	(0.06)	(0.11)	(0.06)	(0.11)
Asian	–0.27***	–0.29**	–0.26***	–0.28**	–0.25**	–0.28**
	0.1	0.11	0.1	0.11	0.1	0.11
High School Degree	0.05	0.13*	0.05	0.13*	0.05	0.13*
	(0.05)	(0.07)	(0.05)	(0.07)	(0.05)	(0.07)
College Degree	0.03	0.05	0.02	0.05	0.02	0.05
	(0.06)	(0.1)	(0.06)	(0.09)	(0.06)	(0.09)
Graduate Degree	0	0.11	–0.01	0.1	–0.01	0.11
	(0.08)	(0.12)	(0.08)	(0.12)	(0.08)	(0.12)
Divorced	–0.02	0.03	–0.03	0.01	–0.04	0.01
	(0.08)	(0.1)	(0.08)	(0.1)	(0.08)	(0.1)
Widow	–0.07	–0.04	–0.09	–0.08	–0.08	–0.07
	(0.13)	(0.22)	(0.14)	(0.21)	(0.14)	(0.21)
Separated	0	–0.17	–0.02	–0.21	–0.03	–0.22
	(0.15)	(0.19)	(0.15)	(0.2)	(0.15)	(0.2)
200-400% of Federal Poverty Level (FPL)	–0.31***	0.04	–0.29***	0.05	–0.29***	0.05
	(0.06)	(0.09)	(0.06)	(0.09)	(0.06)	(0.09)
More Than 400% of FPL	–0.36***	0.02	–0.33***	0.02	–0.33***	0.02
	(0.07)	(0.09)	(0.07)	(0.09)	(0.07)	(0.09)
Public Insurance	0.54***	–0.64***	0.30***	–0.65***	0.30***	–0.65***
	(0.08)	(0.1)	(0.09)	(0.1)	(0.09)	(0.1)

TABLE C-11 Continued

	Model 1		Model 2		Model 3	
Categories	Logit	GLM	Logit	GLM	Logit	GLM
Uninsured	–0.01	–0.37***	–0.04	–0.38***	–0.03	–0.38***
	(0.07)	(0.09)	(0.07)	(0.09)	(0.07)	(0.09)
Never Married	–0.09	–0.17**	–0.1	–0.20**	–0.1	–0.20**
	(0.06)	(0.08)	(0.06)	(0.08)	(0.06)	(0.08)
Fair/Poor Health	0.63***	0.25***	0.46***	0.25***	0.43***	0.24***
	(0.07)	(0.08)	(0.08)	(0.09)	(0.08)	(0.09)
Midwest	0.05	0.04	0.07	0.02	0.07	–0.02
	(0.08)	(0.09)	(0.09)	(0.08)	(0.09)	(0.08)
South	0	–0.12	0.02	–0.12	0.03	–0.12
	(0.08)	(0.08)	(0.08)	(0.08)	(0.08)	(0.08)
West	0.08	–0.14	0.1	–0.13	0.1	–0.13
	(0.08)	(0.1)	(0.08)	(0.1)	(0.08)	(0.1)
Metropolitan Statistical Area	0.1	0.11	0.11	0.13	0.11	0.13
	(0.08)	(0.08)	(0.08)	(0.08)	(0.08)	(0.08)
Functional Disability			1.09***	0.1	1.07***	0.1
			(0.1)	(0.13)	(0.1)	(0.13)
Diabetes					0.1	0.04
					(0.08)	(0.11)
Asthma					0.27***	–0.01
					(0.08)	(0.09)
Constant	–0.42***	1.36***	–0.47***	1.35***	–0.50***	1.35***
	(0.14)	(0.17)	(0.15)	(0.17)	(0.15)	(0.17)

NOTES: Total expenditures include inpatient, emergency room, and outpatient services (hospital, clinic and office-based visits); prescription drugs; and other (e.g., home health services, vision care services, dental care, ambulance services, medical equipment). The expenditures do not include over-the-counter purchases. Linearized standard errors are in parentheses. * p <.10, ** p <0.05, *** p <.01.
SOURCE: Based on the 2008 Medical Expenditure Panel Survey.

TABLE C-12 Results of Two-Part Missed Hours Models for Persons Aged 24-64 for Selected Pain Conditions

	Model 1		Model 2		Model 3	
Categories	Logit	GLM	Logit	GLM	Logit	GLM
Moderate Pain	–0.33***	0.00	–0.15	0.01	–0.14	0.01
	(0.10)	(0.01)	(0.10)	(0.01)	(0.10)	(0.01)
Severe Pain	–0.81***	0.00	–0.31***	0.02	–0.31***	0.02
	(0.09)	(0.01)	(0.11)	(0.01)	(0.11)	(0.01)
Joint Pain	0.02	–0.02***	0.11	–0.02**	0.11	–0.02**
	(0.07)	(0.01)	(0.07)	(0.01)	(0.08)	(0.01)
Arthritis	–0.32***	–0.01	–0.21***	0.00	–0.20***	0.00
	(0.07)	(0.01)	(0.07)	(0.01)	(0.07)	(0.01)
Female	–0.82***	–0.14***	–0.91***	–0.14***	–0.92***	–0.14***
	(0.06)	(0.01)	(0.07)	(0.01)	(0.07)	(0.01)
Family Size	–0.02	0.00	–0.05**	0.00	–0.05**	0.00
	(0.02)	(0.00)	(0.02)	(0.00)	(0.02)	(0.00)
Age 35-44	0.29***	0.02**	0.32***	0.02**	0.33***	0.02**
	(0.08)	(0.01)	(0.08)	(0.01)	(0.08)	(0.01)
Age 45-54	0.00	0.03***	0.07	0.03***	0.08	0.03***
	(0.09)	(0.01)	(0.09)	(0.01)	(0.09)	(0.01)
Age 55-64	–0.82***	–0.02*	–0.81***	–0.02*	–0.78***	–0.02
	(0.10)	(0.01)	(0.10)	(0.01)	(0.10)	(0.01)
Black	0.26***	0.02**	0.22**	0.02**	0.23**	0.02**
	(0.08)	(0.01)	(0.09)	(0.01)	(0.09)	(0.01)
Hispanic	0.26***	0.03***	0.14*	0.03***	0.16*	0.03***
	(0.08)	(0.01)	(0.08)	(0.01)	(0.08)	(0.01)
Asian	–0.32**	0.03*	–0.36***	0.02*	–0.35***	0.02*
	(0.12)	(0.01)	(0.12)	(0.01)	(0.12)	(0.01)
High School Degree	0.03	–0.01	0.05	–0.01	0.05	–0.01
	(0.08)	(0.01)	(0.08)	(0.01)	(0.08)	(0.01)
College Degree	–0.02	0.00	0.00	0.00	0.00	0.00
	(0.10)	(0.01)	(0.10)	(0.01)	(0.10)	(0.01)
Graduate Degree	0.26*	0.01	0.29**	0.01	0.29**	0.01
	(0.14)	(0.01)	(0.14)	(0.01)	(0.14)	(0.01)
Divorced	0.69***	0.02**	0.80***	0.03**	0.80***	0.03**
	(0.10)	(0.01)	(0.11)	(0.01)	(0.11)	(0.01)
Widow	0.04	0.02	0.05	0.03	0.06	0.03
	(0.20)	(0.03)	(0.21)	(0.03)	(0.21)	(0.03)
Separated	0.78***	0.04**	0.83***	0.03*	0.82***	0.03*
	(0.18)	(0.02)	(0.18)	(0.02)	(0.18)	(0.02)
200-400% of Federal Poverty Level (FPL)	0.63***	0.06***	0.61***	0.06***	0.61***	0.06***
	(0.08)	(0.01)	(0.09)	(0.01)	(0.09)	(0.01)
More Than 400% of FPL	0.97***	0.10***	0.95***	0.10***	0.95***	0.10***
	(0.09)	(0.01)	(0.09)	(0.01)	(0.09)	(0.01)
Public Insurance	–2.01***	–0.17***	–1.67***	–0.17***	–1.67***	–0.17***
	(0.10)	(0.02)	(0.10)	(0.02)	(0.10)	(0.02)

TABLE C-12 Continued

	Model 1		Model 2		Model 3	
Categories	Logit	GLM	Logit	GLM	Logit	GLM
Uninsured	–0.81***	–0.08***	–0.78***	–0.08***	–0.79***	–0.08***
	(0.08)	(0.01)	(0.09)	(0.01)	(0.09)	(0.01)
Never married	ed 0.45***	0.01	0.53***	0.01	0.53***	0.01
	(0.10)	(0.01)	(0.10)	(0.01)	(0.10)	(0.01)
Fair/Poor Health	–0.69***	–0.02*	–0.28***	0.00	–0.27***	0.00
	(0.08)	(0.01)	(0.09)	(0.01)	(0.08)	(0.01)
Midwest	0.12	0.02	0.12	0.02	0.11	0.02
	(0.12)	(0.01)	(0.12)	(0.01)	(0.12)	(0.01)
South	–0.07	0.03***	–0.11	0.03***	–0.11	0.03***
	(0.09)	(0.01)	(0.10)	(0.01)	(0.10)	(0.01)
West	–0.04	0.01	–0.06	0.00	–0.06	0.00
	(0.10)	(0.01)	(0.10)	(0.01)	(0.10)	(0.01)
Metropolitan Statistical Area	–0.07	–0.03**	–0.04	–0.02**	–0.04	–0.02**
	(0.09)	(0.01)	(0.09)	(0.01)	(0.09)	(0.01)
Functional Disability			–1.98***	–0.12***	–1.98***	–0.12***
			(0.10)	(0.03)	(0.10)	(0.03)
Diabetes					–0.20*	0.00
					(0.11)	(0.01)
Asthma					0.12	0.00
					(0.11)	(0.01)
Constant	2.16***	7.60***	2.26***	7.60***	2.26***	7.60***
	(0.20)	(0.02)	(0.21)	(0.02)	(0.21)	(0.02)

NOTES: Total expenditures include inpatient, emergency room, and outpatient services (hospital, clinic and office-based visits); prescription drugs; and other (e.g., home health services, vision care services, dental care, ambulance services, medical equipment). The expenditures do not include over-the-counter purchases. Linearized standard errors are in parentheses. GLM = generalized linear model. * p <.10, ** p <0.05, *** p <.01.
SOURCE: Based on the 2008 Medical Expenditure Panel Survey.

TABLE C-13 Results of Two-Part Logistic Regression and Generalized Linear Hourly Wages Models for Adults Aged 24-64 for Selected Pain Conditions

	Model 1		Model 2		Model 3	
Categories	Logit	GLM	Logit	GLM	Logit	GLM
Moderate Pain	–0.29***	–0.05**	–0.12	–0.05*	–0.12	–0.05*
	(0.08)	(0.03)	(0.09)	(0.03)	(0.09)	(0.03)
Severe Pain	–0.77***	–0.09***	–0.26***	–0.07**	–0.26***	–0.07**
	(0.08)	(0.03)	(0.09)	(0.03)	(0.09)	(0.03)
Joint Pain	–0.04	–0.01	0.03	0.00	0.02	0.00
	(0.06)	(0.01)	(0.06)	(0.02)	(0.06)	(0.02)
Arthritis	–0.18***	–0.03*	–0.06	–0.03	–0.06	–0.02
	(0.06)	(0.02)	(0.07)	(0.02)	(0.06)	(0.02)
Female	–0.17***	–0.19***	–0.17***	–0.19***	–0.17***	–0.19***
	(0.05)	(0.01)	(0.05)	(0.01)	(0.05)	(0.01)
Family Size	–0.08***	–0.02***	–0.09***	–0.03***	–0.09***	–0.03***
	(0.02)	(0.00)	(0.02)	(0.00)	(0.02)	(0.00)
Age 35-44	–0.07	0.14***	–0.07	0.14***	–0.07	0.14***
	(0.07)	(0.02)	(0.07)	(0.02)	(0.07)	(0.02)
Age 45-54	–0.22***	0.19***	–0.20***	0.19***	–0.20***	0.19***
	(0.07)	(0.02)	(0.08)	(0.02)	(0.08)	(0.02)
Age 55-64	–0.82***	0.17***	–0.83***	0.17***	–0.82***	0.17***
	(0.08)	(0.02)	(0.08)	(0.02)	(0.08)	(0.02)
Black	0.16***	–0.10***	0.19***	–0.11***	0.19***	–0.10***
	(0.06)	(0.02)	(0.07)	(0.02)	(0.06)	(0.02)
Hispanic	0.07	–0.19***	0.01	–0.20***	0.01	–0.20***
	(0.07)	(0.02)	(0.07)	(0.02)	(0.07)	(0.02)
Asian	–0.23**	–0.05*	–0.26**	–0.05*	–0.25**	–0.05*
	(0.10)	(0.03)	(0.10)	(0.03)	(0.10)	(0.03)
High School Degree	0.13**	0.00	0.14**	0.00	0.14**	0.00
	(0.06)	(0.02)	(0.06)	(0.02)	(0.06)	(0.02)
College Degree	0.21***	0.41***	0.18**	0.41***	0.18**	0.41***
	(0.07)	(0.02)	(0.07)	(0.02)	(0.07)	(0.02)
Graduate Degree	0.11	0.59***	0.07	0.59***	0.07	0.59***
	(0.10)	(0.02)	(0.11)	(0.02)	(0.11)	(0.02)
Divorced	0.20***	–0.06***	0.33***	–0.06***	0.32***	–0.06***
	(0.07)	(0.02)	(0.07)	(0.02)	(0.07)	(0.02)
Widow	–0.46***	–0.11**	–0.35*	–0.10**	–0.34*	–0.10**
	(0.18)	(0.05)	(0.18)	(0.05)	(0.18)	(0.05)
Separated	0.14	–0.21***	0.25*	–0.21***	0.25*	–0.21***
	(0.12)	(0.04)	(0.13)	(0.04)	(0.13)	(0.04)
Never Married	0.10	–0.14***	0.21***	–0.14***	0.21***	–0.14***
	(0.07)	(0.02)	(0.08)	(0.02)	(0.08)	(0.02)
Fair/Poor Health	–0.71***	–0.10***	–0.28***	–0.09***	–0.28***	–0.08***
	(0.07)	(0.02)	(0.07)	(0.02)	(0.07)	(0.02)
Midwest	0.13	–0.08***	0.12	–0.08***	0.12	–0.08***
	(0.10)	(0.03)	(0.10)	(0.03)	(0.10)	(0.03)

TABLE C-13 Continued

	Model 1		Model 2		Model 3	
Categories	Logit	GLM	Logit	GLM	Logit	GLM
South	–0.04	–0.09***	–0.09	–0.10***	–0.09	–0.10***
	(0.08)	(0.02)	(0.09)	(0.02)	(0.09)	(0.02)
West	–0.16*	0.04	–0.20**	0.04	–0.20**	0.04
	(0.09)	(0.03)	(0.10)	(0.03)	(0.10)	(0.03)
Metropolitan Statistical Area	0.16*	0.15***	0.18**	0.15***	0.17**	0.15***
	(0.08)	(0.02)	(0.09)	(0.02)	(0.08)	(0.02)
Functional Disability			–1.95***	–0.13***	–1.95***	–0.13***
			(0.09)	(0.04)	(0.09)	(0.04)
Diabetes					–0.07	–0.05*
					(0.08)	(0.02)
Asthma					0.13	–0.01
					(0.08)	(0.02)
Constant	1.46***	2.88***	1.51***	2.89***	1.50***	2.89***
	(0.15)	(0.04)	(0.16)	(0.04)	(0.16)	(0.04)

NOTES: Total expenditures include inpatient, emergency room, and outpatient services (hospital, clinic and office-based visits); prescription drugs; and other (e.g., home health services, vision care services, dental care, ambulance services, medical equipment). The expenditures do not include over-the-counter purchases. Linearized standard errors are in parentheses. GLM = generalized linear model. * p <.10, ** p <0.05, *** p <.01.

SOURCE: Based on the 2008 Medical Expenditure Panel Survey.

TABLE C-14 Average Incremental Number of Days of Work Missed Because of Selected Pain Conditions

Conditions	Model 1	Model 2	Model 3
Moderate Pain	1.87	1.70	1.70
Severe Pain	5.92	5.01	4.99
Joint Pain	0.44	0.36	0.35
Arthritis	0.03	0.01	0.01
Functional Disability	—	1.38	1.35

NOTES: This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 24-64, who represented 156 million individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-15 Total Incremental Costs of Number of Days of Work Missed Because of Selected Pain Conditions (in millions of US$2010 and millions of persons)

Conditions	Population	Model 1	Model 2	Model 3
Moderate Pain	14.1	$2,643	$2,541	$2,540
Severe Pain	15.6	6,476	7,330	7,196
Joint Pain	49.1	2,401	1,999	1,983
Arthritis	32.9	105	40	19
Functional Disability	14.9	—	919	898
Total	69.8	$11,625	$12,728	$12,635

NOTES: Dollar amounts were adjusted for inflation as of 2010 using the General Consumer Price Index. This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 24-64, who represented 156 million individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables. To compute the total cost, we multiplied days missed by 8 hours times the predicted hourly wage rate for individuals with the pain condition. A total of 69.8 million persons had at least one of the pain conditions studied. The population totals for the selected pain conditions do not sum to 69.8 million because some persons have multiple conditions.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-16 Average Incremental Number of Hours of Work Lost Because of Selected Pain Conditions

Conditions	Model 1	Model 2	Model 3
Moderate Pain	64.43	15.28	14.03
Severe Pain	204.27	30.06	30.33
Joint Pain	28.73	7.80	7.58
Arthritis	85.74	45.48	44.45
Functional Disability	—	739.61	744.85

NOTES: This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 24-64, who represented 156 million individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-17 Total Incremental Costs of Number of Hours of Work Missed Because of Selected Pain Conditions (in millions of US$2010 and millions of persons)

Conditions	Population	Model 1	Model 2	Model 3
Moderate Pain	14.1	$11,380	$2,846	$2,618
Severe Pain	15.6	27,939	5,422	5,472
Joint Pain	49.1	19,750	5,550	5,296
Arthritis	32.9	37,472	20,530	20,090
Functional Disability	14.9	—	61,495	61,742
Total	69.8	$96,542	$95,744	$95,217

NOTES: Dollar amounts were adjusted for inflation as of 2010 using the General Consumer Price Index. This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 24-64, who represented 156 million individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables. To compute the total cost, we multiplied the total of annual hours of work missed by the predicted hourly wage rate for individuals with the pain condition. A total of 69.8 million persons had at least one of the pain conditions studied. The population totals for the selected pain conditions do not sum to 69.8 million because some persons have multiple conditions.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-18 Average Incremental Reduction in Hourly Wages Due to Selected Pain Conditions (US$2010)

Conditions	Model 1	Model 2	Model 3
Moderate Pain	$1.65	$0.99	$0.97
Severe Pain	3.76	1.65	1.66
Joint Pain	0.26	0.05	0.05
Arthritis	1.12	0.59	0.57
Functional Disability	—	9.36	9.37

NOTES: Dollar amounts were adjusted for inflation as of 2010 using the General Consumer Price Index. This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 24-64, who represented 156 million individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-19 Total Indirect Costs Associated with Reductions in Wages Due to Selected Pain Conditions (in millions of US$2010 and millions of persons)

Conditions	Population	Model 1	Model 2	Model 3
Moderate Pain	14.1	$35,795	$22,114	$21,791
Severe Pain	15.6	78,214	40,173	40,453
Joint Pain	49.1	19,959	3,709	4,293
Arthritis	32.9	56,657	30,340	29,396
Functional Disability	14.9	—	130,029	129,577
Total	69.8	$190,625	$226,365	$216,924

NOTES: Dollar amounts were adjusted for inflation as of 2010 using the General Consumer Price Index. This analysis is based on the total noninstitutionalized adult subpopulation of the United States for individuals aged 24-64, who represented 156 million individuals as of 2008. Model 2 includes functional disability in addition to all the other control variables. Model 3 includes functional disability, asthma, and diabetes in addition to all the other control variables. To compute the total cost due to a reduction in hourly wages, we multiplied the predicted change in hourly wages by the predicted annual hours of work for individuals with each of the pain condition by the total population affected by the condition. A total of 69.8 million persons had at least one of the pain conditions studied. The population totals for the selected pain conditions do not sum to 69.8 million because some persons have multiple conditions.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

TABLE C-20 Total Direct Costs for Selected Pain Conditions (in millions of US$2010)

Conditions	Office-based	Hospital Outpatients	Emergency Services	Hospital Inpatients	Prescription Drugs	Total
Headache	1,350	434	958	147	3,730	6,619
Nonspecific Chest Pain	596	1,040	948	1,930	62	4,576
Abdominal Pain	689	305	438	128	38	1,598
Back Pain	14,400	3,000	607	13,500	2,660	34,167
Total	17,035	4,779	2,951	15,705	6,490	46,960

NOTE: Dollar amounts were adjusted for inflation as of 2010 using the Medical Care Inflation Index of the Consumer Price Index.
SOURCE: Based on authors' calculations using the 2008 Medical Expenditure Panel Survey.

Appendix D

Committee and Staff Biographies

COMMITTEE MEMBERS

Philip A. Pizzo, M.D. (*Chair*), is dean of the School of Medicine and Carl and Elizabeth Naumann professor of pediatrics and of microbiology and immunology at Stanford University School of Medicine. Before joining Stanford in 2001, he was physician-in-chief of Children's Hospital in Boston and chair of the Department of Pediatrics at Harvard Medical School, 1996-2001. Dr. Pizzo is recognized for his contributions as a clinical investigator, especially in the treatment of children with cancer and HIV. He has devoted much of his distinguished medical career to the diagnosis, management, prevention, and treatment of childhood cancers and the infectious complications that occur in children whose immune systems are compromised by cancer and AIDS. Dr. Pizzo and his research team pioneered the development of new treatments for children with HIV infection, lengthening and improving the quality of life for these children. His research soon led to important clues about how to treat HIV-positive children and adults and how to manage life-threatening infections. Dr. Pizzo served as head of the National Cancer Institute's (NCI) infectious disease section, chief of NCI's pediatric department, and acting scientific director for NCI's Division of Clinical Sciences between 1973 and 1996. He is the current chair of the Council of Deans of the Association of American Medical Colleges and the immediate past chair of the board of directors of the Association of Academic Health Centers. He has been a member of the Institute of Medicine (IOM) since 1997 and has served on the Council of the IOM since 2006.

Noreen M. Clark, Ph.D. (*Vice Chair*), is Myron E. Wegman distinguished university professor, professor of health behavior and health education, professor of pediatrics, and director of the Center for Managing Chronic Disease at the University of Michigan. From 1995 to 2005, she served as dean of public health and Marshall Becker professor of public health. Dr. Clark is interested in systems, policies, and programs that promote health, prevent illness, and enable individuals to manage disease. Her work focuses on the social, psychological, and behavioral aspects of disease management and how they interact with clinical factors. Her research is directed toward people at risk for disease and its complications, as well as those who can help them: family members, clinicians, communities, and systems. Her studies of disease management have contributed to the research literature and the field of practice by demonstrating that educational interventions for patients and providers can decrease both asthma- and heart-related hospitalizations and medical emergencies and increase patients' quality of life. Interventions for respiratory disease tested by her team are used across the country and around the world. Dr. Clark currently heads exploratory studies of the management of diabetes, epilepsy, and digestive and neurological conditions, including consequences of pain, as well as physical, psychological, and social functioning. She has held many leadership positions in public health and is a member of the IOM.

Olivia D. Carter-Pokras, Ph.D., is an associate professor in the Department of Epidemiology and Biostatistics, University of Maryland, College Park School of Public Health. Prior to joining the faculty at the University of Maryland, College Park, Dr. Carter-Pokras was an associate professor in the Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine, where she currently serves as adjunct faculty. She is the previous director of the Division of Policy and Data, Office of Minority Health, Department of Health and Human Services. Dr. Carter-Pokras has conducted research on health disparities for three decades in the federal government. She has an extensive history of ensuring that the community has a voice in research conducted at the national and local levels. Dr. Carter-Pokras lectures on epidemiologic methods, cultural competency, and health disparities to medical, dental, and public health students. She is principal investigator for two National Institutes of Health (NIH)-funded grants to develop, implement, evaluate, and disseminate cultural competency and health disparities curriculum, and for a National Institute of Child Health and Human Development (NICHD) community-based participatory research grant on oral health among Latino and Ethiopian children and their mothers. She just completed a project evaluating state tobacco disparities and is research director for the new Centers for Disease Control and Prevention (CDC)-funded University of Maryland Prevention Research Center.

Myra Christopher has been president and CEO of the Center for Practical Bioethics since its inception in 1985. In addition to providing oversight to the Center, from 1998 to 2003 she served as national program officer of The Robert Woods Johnson Foundation's National Program Office for Community-State Partnerships to Improve End-of Life Care, which was housed at the Center. These roles have allowed Ms. Christopher to continue her lifelong mission to improve care for seriously ill people and their families. She consulted with the Joint Commission on patients' rights and organizational ethics standards and developed Beyond Compliance, resource materials, and a seminar for the Joint Commission that was presented across the country. She has collaborated with the National Association of Attorneys General to establish palliative care as a consumer protection issue. Since the late 1990s, Ms. Christopher has expanded the scope of her work to include the undertreatment of chronic pain and has worked with the American Pain Foundation, American Academy of Family Physicians, American Academy of Pain Medicine, Federation of State Medical Boards, Drug Enforcement Administration, and others to improve care for people living with chronic pain. Currently she is co-directing The Transformation Project: A New Initiative to Improve Advanced Illness Care. She is also principal investigator for the Pain Action Initiative: A National Strategy (PAINS). This project will assess capacity and readiness nationwide to develop a coordinated plan for improving care for the millions of Americans who struggle with chronic pain. In 2001, Ms. Christopher was named Kathleen M. Floey Chair in Pain and Palliative care at the Center for Practical Bioethics.

John Farrar, M.D., Ph.D., is associate professor of biostatistics and epidemiology, Department of Biostatistics and Epidemiology, at the Hospital of the University of Pennsylvania. His research expertise is related to pain, including the use of new pain medications, brain function in people with pain, complementary and alternative therapies, and new methodologies for understanding how patients report their pain in clinical trials. His current research includes ongoing studies of acupuncture for the treatment of pain in osteoarthritis patients and chronic fatigue in cancer patients, brain imaging of patients with pain, and studies of pain related to cancer treatment. Dr. Farrar focuses clinically on all aspects of pain and symptom therapy in cancer patients as a member of the Symptom and Palliative Care Team and as a collaborator in the development of a multidisciplinary program for the evaluation and treatment of patients with pain.

Kenneth A. Follett, M.D., Ph.D., is Nancy A. Keegan and Donald R. Voelte, Jr., chair of neurosurgery, professor and chief of the Division of Neurosurgery, interim chair of the Department of Anesthesiology, and program director for the neurological surgery residency training program at the University of Nebraska Medical Center (UNMC). In addition to his clinical, academic, and educational responsibilities in the Division of Neurosurgery, Dr. Follett is a faculty member in the UNMC Pain Medicine Fellowship Program. His clinical and research interests include pain management and functional and stereotactic neurosurgery. His research activities range from bench studies of mechanisms of nociception using electrophysiological and histological techniques in animal models to clinical studies of drugs and devices for pain therapy and movement disorders. Dr. Follett is recognized as a leader in pain management and neuromodulation therapies and has given numerous national and international presentations pertaining to these topics. He is past chair of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Pain and has held leadership positions in national pain organizations, including the American Academy of Pain Medicine (past president).

Margaret Heitkemper, R.N., Ph.D., F.A.A.N., is chairperson, Department of Biobehavioral Nursing and Health Systems, School of Nursing; Elizabeth Sterling Soule endowed chair in nursing; and adjunct professor, Division of Gastroenterology, School of Medicine, University of Washington. For the past 20 years, Dr. Heitkemper has conducted interdisciplinary research related to chronic abdominal pain and irritable bowel syndrome (IBS). Her research in this area has included both descriptive and mechanistic studies focused on the role of gender and lifestyle factors in this chronic pain condition. In addition to bench work focused on ovarian hormones and motility, Dr. Heitkemper's work has highlighted the impact of menstrual cycle comorbidities, including other pain conditions such as headache, muscle pain, and backache, and the menopausal transition on gastrointestinal symptom reports. With clinic populations, she has further described autonomic nervous system and polysomnographic sleep in women with IBS. Sleep disturbances play a role in the exacerbation of pain reports in this population. Most recently, Dr. Heitkemper's work has evolved to include genetic (SERT, COMT) and potential proteomic markers of chronic abdominal pain in children and adults with chronic visceral pain conditions. In addition, her team has conducted two randomized clinical trials of a self-management cognitive-behavioral therapy to alleviate symptom distress in men and women with IBS.

Charles E. Inturrisi, Ph.D., is professor of pharmacology at Weill Cornell Medical College. He also holds appointments with the Pain and Palliative Care Service, Memorial Sloan-Kettering Cancer Center, and the Laboratory of the Biology of Addictive Diseases at The Rockefeller University. Dr. Inturrisi's current research activities are focused on determining the comparative effectiveness of interventions used for chronic pain management. This research is examining prospectively and retrospectively the long-term outcomes of treatments for chronic cancer and noncancer pain received by patients at four New York City hospital-based outpatient pain clinics. The effectiveness information obtained will allow a determination of which patients benefit from the currently available interventions used for the management of chronic pain and the cost-effectiveness of these treatments, which should improve pain management worldwide. Dr. Inturrisi continues to have an interest in the role of glutamate receptors in injury-induced pain, opioid tolerance, dependence, and addictive behaviors. This preclinical research employs molecular genetic approaches (Cre-loxP and siRNA) to produce spatial knockouts of selected receptors and signaling proteins. These studies are intended to discover new treatments for pain and drug addiction. Dr. Inturrisi has been teaching Weill Cornell medical and graduate students about pain and opioids for the past 40 years.

Francis Keefe, Ph.D., is professor of psychiatry and behavioral sciences and director of the Pain Prevention and Treatment Research Program at Duke University Medical Center and professor of psychology and neuroscience at Duke University. Dr. Keefe has broad interests in behavioral and psychological aspects of pain and pain management. He is internationally recognized for his research on pain coping. He was the first to develop a psychometrically strong, standardized questionnaire for assessing pain coping—the Coping Strategies Questionnaire. This questionnaire, now translated into many languages, is the most widely used pain coping measure in both clinical and research settings. Dr. Keefe also is internationally recognized for developing and systematically testing novel treatment protocols for managing persistent, disease-related pain. Novel interventions currently being tested in his laboratory include several training protocols for partner-assisted coping skills for helping cancer patients and their partners manage pain and other symptoms, a perisurgical coping skills intervention to improve the outcome of spinal cord stimulation treatment for persistent pain, a web-based coping skills intervention for osteoarthritis patients, and interventions targeting obese patients with pain that combine training in pain coping skills with a lifestyle behavioral weight management program.

Robert Kerns, Ph.D., is Veterans Health Administration (VHA) national program director for pain management; director of the Pain Research, Informatics, Medical comorbidities, and Education (PRIME) Center at the Department of Veterans Affairs (VA) Connecticut Healthcare System; and professor of psychiatry, neurology, and psychology at Yale University. In his role as national program director for pain management, he has programmatic responsibility for policy development, coordination, and oversight of the VHA National Pain Management Strategy. He is a member of the Food and Drug Administration's (FDA) Arthritis Advisory Committee, and he is frequently called upon to serve as a temporary voting member of other pain-relevant FDA advisory panels. Dr. Kerns's primary areas of scholarly and academic interest are behavioral medicine and health psychology, in particular pain and pain management. He was recently awarded a VA Health Services Research and Development grant to establish the PRIME Center, which will build capacity for pain-relevant health services research at VA Connecticut and Yale University. Dr. Kerns's current research interests include evaluation of the use of technologies (the Internet, interactive voice response, videoconferencing) for the delivery of automated self-management interventions for disadvantaged and diverse populations with chronic pain (e.g., persons living in rural settings, the elderly, persons with painful diabetic neuropathy, persons with coprevalent pain and posttraumatic stress disorder, and persons with multiple sclerosis). Additional interests focus on the development of strategies for improving the quality of pain clinical trials, the development of integrative models of care for chronic pain and other chronic health problems, diversity and disparity in pain care, and related policy issues.

Janice S. Lee, D.D.S., M.D., M.S., is associate professor and vice chair in the Department of Oral and Maxillofacial Surgery at the University of California, San Francisco (UCSF), where she is she is also director of clinical and translational research. Dr. Lee is an oral and maxillofacial surgeon who treats children and adults. Her areas of expertise include facial reconstruction, maxillofacial pathology, and craniofacial anomalies. She is a member of the Craniofacial Anomalies team at UCSF Medical Center, which evaluates and treats children with congenital deformities such as cleft lip/palate, hemifacial microsomia, secondary cleft deformities, and other dentofacial deformities. Most of these conditions involve skeletal reconstruction problems, especially when a deficiency in bone exists. Dr. Lee's research is in the area of bone marrow stem cells and the effects of age on their ability to differentiate and form bone. While training at NIH, she was the maxillofacial specialist for a team evaluating and treating one of the largest populations of patients with McCune-Albright syndrome and polyostotic fibrous dysplasia, a fibro-osseous disease that affects the normal development of bone. Dr. Lee continues to see patients with these conditions at UCSF.

Elizabeth Loder, M.D. M.P.H., is chief of the Division of Headache and Pain in the Department of Neurology at the Brigham and Women's/Faulkner Hospitals in Boston and an associate professor of neurology at Harvard Medical School. She is also a senior research editor at the *British Medical Journal*. She has worked as a clinician and researcher in the headache field since completing a fellowship in headache medicine in 1990. Dr. Loder served on the board of directors of the International Headache Society from 2005 to 2009, is the winter meeting director for the Headache Cooperative of New England, and is president-elect of the American Headache Society.

Sean Mackey, M.D., Ph.D., is associate professor of anesthesia (and of neurology and neurological sciences by courtesy) at Stanford University. He also is currently chief of the Stanford Pain Management Division and Pain Fellowship Program director. As director of the Stanford Systems Neuroscience and Pain Laboratory, Dr. Mackey focuses his research on the use of advanced research techniques, such as functional and structural neuroimaging, psychophysics, and neurobehavioral assessment, to investigate the neural processing of pain and neuronal plasticity in patients with chronic pain. Dr. Mackey has served as principal investigator and investigator for multiple NIH and foundation grants investigating chronic pain and novel analgesics for acute and chronic pain. Additionally, he recently received an NIH K24 grant focused on mentoring junior investigators to have successful careers.

Rick Marinelli, N.D., M.Ac.O.M., is a naturopathic physician and acupuncturist at the Natural Medicine Clinic in Portland, Oregon. His professional practice over nearly 30 years has spanned many specialties. His foundational training in naturopathic, conventional, and oriental medicine has allowed him to apply diagnostic and therapeutic insight in choosing the best approaches for his patients. Dr. Marinelli has extensive experience in women's health care, hormone replacement therapy for men and women, the diagnosis and treatment of pain, diagnostic ultrasonography, sports medicine, aesthetic medicine, weight loss, and primary care. In addition to his practice, he has been active in community and professional service, serving, for example, as immediate past chair of the Oregon Board of Naturopathic Medicine, immediate past president of the American Academy of Pain Management, a commissioner of the Oregon Pain Management Commission and Prescription Drug Monitoring Program Advisory Commission, and founding vice president of the Naturopathic Academy of Therapeutic Injection. He also is an external affairs representative for the Academic Consortium for Complementary and Alternative Health Care.

Richard Payne, M.D., is professor of medicine and divinity at Duke Divinity School, Duke University, and Esther Colliflower director of the Duke Institute on Care at the End of Life (ICEOL). Dr. Payne is an internationally known expert in the areas of pain relief, care for those near death, oncology, and neurology. ICEOL seeks to increase knowledge and rediscover old wisdoms concerning the end of life through interdisciplinary scholarship, teaching, and outreach, emphasizing the spiritual dimension of care. As a unique teaching and research program located in a divinity school, ICEOL is particularly focused on the problem of preventing and addressing the moral and theological dimensions of pain and suffering. Prior to his appointment at Duke, Dr. Payne was chief, Pain and Symptom Management Section, Department of Neurology, at M. D. Anderson Cancer Center (1992-1998) in Houston, Texas; from 1998 to 2004, he led the Pain and Palliative Care Service at Memorial Sloan-Kettering Cancer Center in New York City, where he held the Anne Burnett Tandy Chair in Neurology. He is certified in palliative medicine by the American Academy of Hospice and Palliative Medicine and in pain management by the American Academy of Neurology and the American Academy of Pain Medicine.

Melanie Thernstrom, MFA, is the author of *The Pain Chronicles: Cures, Myths, Mysteries, Prayers, Diaries, Brain Scans, Healing, and the Science of Suffering*, a *New York Times* bestseller. In *The Pain Chronicles*, Ms. Thernstrom traces conceptions of pain from ancient Babylonia to modern brain imaging. She interweaves first-person reflections on her own battle with chronic pain, incisive reportage and medical research, and insights from a wide range of disciplines. Ms. Thernstrom also is the author of two previous books: *The Dead Girl*, a memoir, and *Halfway Heaven: Diary of a Harvard Murder*, a work of investigative journalism. She is a contributing writer for *The New York Times Magazine*. She also has written for *Vanity Fair*, *The New Yorker*, *New York*, *The Wall Street Journal*, and other publications. She has taught creative writing at Harvard University and Cornell University and in the master of fine arts program at the University of California at Irvine. Ms. Thernstrom has received fellowships from the Corporation of Yaddo, the Edward Albee Foundation, and the Virginia Center for the Creative Arts and is a member of PEN.

Dennis C. Turk, Ph.D., is John and Emma Bonica professor of anesthesiology and pain research; director of the Center for Pain Research on Impact, Measurement, and Effectiveness (C-PRIME) at the University of Washington; and a special government employee within the FDA. Prior to his current position, he was professor of psychiatry and anesthesiology and director of the Pain Evaluation and Treatment Institute at the University of Pittsburgh. He is co-director of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT). Dr. Turk has published more than 500 papers and authored or edited 16 books on pain assessment, management, and treatment; the psychological characteristics of pain sufferers; clinical trial design; and measure- and value-based health care. He is past president of the American Pain Society and currently editor-in-chief of the *Clinical Journal of Pain*.

Ursula Wesselmann, M.D., Ph.D., joined the faculty at the University of Alabama at Birmingham (UAB) as professor of anesthesiology, neurology, and psychology in 2008. She is senior scientist at the Civitan International Research Center and a faculty member of the Comprehensive Neuroscience Center at UAB. Previously, she was on the faculty of the Department of Neurology at The Johns Hopkins University, an attending physician at Johns Hopkins Hospital, and a member of the Johns Hopkins Blaustein Pain Treatment Center. Dr. Wesselmann's translational pain research laboratory is funded by NIH and focuses on the pathophysiological mechanisms of urogenital and visceral pain syndromes in females. Her clinical practice at the UAB Pain Treatment Clinic centers on the treatment of chronic urogenital and visceral pain syndromes in women.

Lonnie K. Zeltzer, M.D., is professor of pediatrics, anesthesiology, psychiatry, and biobehavioral sciences at the University of California at Los Angeles (UCLA)

School of Medicine. She is director of the UCLA Pediatric Pain Program and medical director of the Palliative Care Program at Mattel Children's Hospital, UCLA. Her program's research focuses on pediatric chronic pain; experimental pain in children; genetics and pain; end-of-life care in children, including cancer pain; complementary and alternative medicine therapies; and quality of life in survivors of childhood cancer. Dr. Zeltser has received many awards, including the 2005 American Pain Society's Jeffrey Lawson Award for Advocacy in Children's Pain Relief, and her program was a 2009 recipient of the American Pain Society's Clinical Centers of Excellence in Pain Management. She is president of the Special Interest Group on Pain in Childhood in the International Association for the Study of Pain and is on the board of directors of the American Pain Foundation. She also is chair of the American Cancer Society's Palliative Care Study Section and is on the advisory board of the Mayday Fund, a pain education and research-focused foundation. Dr. Zeltser has more than 300 publications, including her book *Conquering Your Child's Chronic Pain: A Pediatrician's Guide for Reclaiming a Normal Childhood* (HarperCollins, 2005). Her nonprofit, Whole Child LA, is dedicated to bringing mind–body pain care to the community's children (www.wholechildla.org).

IOM STAFF

Andrew Pope, Ph.D., is director of the Board on Health Sciences Policy in the IOM. He holds a Ph.D. in physiology and biochemistry from the University of Maryland and has been a member of the National Academies staff since 1982 and of the IOM staff since 1989. His primary interests are science policy, biomedical ethics, and environmental and occupational influences on human health. During his tenure at the National Academies, Dr. Pope has directed numerous studies on topics ranging from injury control, disability prevention, and biologic markers to the protection of human subjects of research, NIH priority-setting processes, organ procurement and transplantation policy, and the role of science and technology in countering terrorism. Dr. Pope is the recipient of the IOM's Cecil Award and the National Academy of Sciences President's Special Achievement Award.

Adrienne Stith Butler, Ph.D., is senior program officer in the IOM's Board on Health Sciences Policy. Recently, she served as study director for the IOM reports *The Future of Nursing: Leading Change, Advancing Health* and *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*. Previously, Dr. Stith Butler served as study director for the IOM reports *Preterm Birth: Causes, Consequences, and Prevention* and *Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy*. She also has served as a staff officer for IOM reports pertaining to diversity in the health care workforce and racial and ethnic disparities in health care. Prior to working at the IOM, Dr. Stith 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. Dr. Stith Butler, a clinical psychologist, received a doctorate 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.

Jing Xi, M.B.B.S., M.P.H., is a research associate in the Board on Health Sciences Policy. Prior to joining the IOM, she was a research fellow in the FDA's Division of Epidemiology, Center for Devices and Radiological Health. Her work at the FDA focused on a regulatory research project assessing publication bias for clinical trials of FDA-approved coronary artery stents. Ms. Xi holds an M.P.H. from the University of Michigan and an M.B.B.S. in clinical medicine from Fudan University Shanghai Medical College.

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's Recognition Award and two IOM Staff Achievement Awards.

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