

A Comprehensive Population Health-Level Strategy for Pain

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EXECUTIVE SUMMARY

In 2010, in response to a congressional mandate, the National Institutes of Health (NIH) contracted with the Institute of Medicine (IOM) to undertake a study and make recommendations "to increase the recognition of pain as a significant public health problem in the United States." The Institute's 2011 report called for a cultural transformation in pain prevention, care, education, and research and recommended development of "a comprehensive population health-level strategy" to address these issues. The Assistant Secretary for Health and Human Services (HHS) asked the Interagency Pain Research Coordinating Committee (IPRCC) to oversee creation of this resultant National Pain Strategy. Guided and coordinated by an oversight panel, expert working groups explored six important areas of need identified in the IOM recommendations—population research, prevention and care, disparities, service delivery and reimbursement, professional education and training, and public awareness and communication. The working groups comprised people from a broad array of relevant public and private organizations, including health care providers, insurers, and people with pain and their advocates.

As articulated in the IOM report, however, this cultural transformation in our efforts to reduce the burden of pain in the United States will not be achieved without sustained and indeed expanded investment into basic and clinical research studies of the biopsychosocial mechanisms that produce and maintain chronic pain and into the development of safe and effective pain treatments. As a first step in this critical direction the IPRCC has completed a comprehensive analysis of the existing federal pain research portfolio. The next steps will identify gaps in our understanding as well as directions for new research, which will guide the NIH and other federal agencies and departments in their support of these essential pain research programs.

Fundamental conclusions and implications drawn from the IOM report guided development of the National Pain Strategy, including:

- The public at large and people with pain, in particular, would benefit from a better understanding of pain and its treatment, in order to encourage timely care, improve medical management, and combat stigma.
- Increased scientific knowledge regarding the pathophysiology of pain has led to the conclusion that chronic pain can be a disease in itself that requires adequate treatment and a research commitment.
- Although pain is widespread in the population, data are lacking on the prevalence, onset, course, impact, and outcomes of most common chronic pain conditions. The greatest individual and societal benefit nevertheless would accrue from a focus on chronic pain.
- Every effort should be made to prevent illnesses and injuries that lead to pain, the progression of acute pain to a chronic condition, and the development of high-impact chronic pain.
- Significant improvements are needed in pain assessment techniques and practices to assure they are high-quality and comprehensive.
- Self-management programs can improve quality of life and is an important component of acute and chronic pain prevention and management.

- Chronic pain is a biopsychosocial condition that often requires integrated, multimodal, and interdisciplinary treatment, all components of which should be evidence-based.
- People with chronic pain need greater access to treatments that take into account their preferences and are in accord with best evidence on safety and effectiveness.
- New treatment approaches need to be developed that take into account individual differences that affect the onset of pain and response to treatment.
- Treatments that are ineffective, whose risks greatly exceed their benefits, or that may cause harm for certain subgroups need to be identified and their use curtailed or discontinued.
- Much of the responsibility for front-line pain care rests on primary care clinicians, who are not sufficiently trained in pain assessment and comprehensive, evidence-based treatment approaches.
- Greater collaboration is needed between primary care clinicians and pain specialists in different clinical disciplines and settings, including multispecialty pain clinics.
- Significant barriers to pain care exist, especially for populations disproportionately affected by and undertreated for pain, and need to be overcome.
- People with pain are too often stigmatized in the health care system and in society, which can lead to delayed diagnosis or misdiagnosis, bias in treatment, and decreased effectiveness of care.

The aforementioned expert working groups produced interrelated sets of objectives and suggested action plans in the six areas summarized below: population research, prevention and care, disparities, service delivery and reimbursement, professional education and training, and public education and communication.

Population Research

Understanding the significance of health problems in a population is a core public health responsibility. To increase the quantity and quality of what is known about chronic pain in the U.S. population, the National Pain Strategy recommends specific steps to a) increase the precision of information about chronic pain prevalence overall, for specific types of pain, and in specific population groups; b) develop the capacity to gather information electronically about pain treatments, their usage, costs, effectiveness, and safety; and c) enable tracking changes in pain prevalence, impact, and treatment over time, allowing evaluation of population-level interventions and identification of emerging needs.

Prevention and Care

Prevention of acute and chronic pain needs greater emphasis throughout the health care system, in environments where injuries are likely to occur, and for people at increased risk of developing chronic pain. When chronic pain develops, treatment should begin with a comprehensive assessment, followed by creation of a care plan that can evolve over time to address the full range of biological, psychological, and social effects of pain on the individual. That said, the National Pain Strategy recommends strengthening the evidence base for pain prevention strategies, assessment tools, and outcome measures—particularly those relevant for primary care—in part through the development of new, rigorously researched approaches. It also recommends improvements in pain self-management programs that can help affected individuals improve their knowledge, skills, and confidence to prevent, reduce, and cope with pain.

Disparities

Pain is more prevalent in a diverse set of population groups typically of interest to public health programs, including people with limited access to health care services, racial and ethnic minorities, people with low income or education, and those at increased risk because of where they live or work. These groups often face the additional problem of stigma and bias in pain care. To eliminate disparities and promote equity in pain assessment and treatment, the NPS recommends efforts that would increase understanding of the impact of bias and would support effective strategies to overcome it; an increase in access to high-quality pain care for vulnerable population groups; and improvements in communication among patients and health professionals.

Service Delivery and Reimbursement

Evidence suggests that wide variations in clinical practices, inadequate tailoring of pain therapies to individuals, and reliance on relatively ineffective and potentially high risk treatments not only contribute to poor quality care for people with pain, but also increase health care costs. The National Pain Strategy endorses a population-based, biopsychosocial approach to pain care that is grounded in scientific evidence, integrated, multimodal, and interdisciplinary while, at the patient level is tailored to individual needs. Research and demonstration efforts are needed that build on current knowledge, develop new knowledge, and support further testing and diffusion of model delivery systems.

Professional Education and Training

Although pain is one of the most common reasons for health care visits, most health profession's education programs have yet to give it adequate attention. Improvements are needed in discipline-specific core competencies, including basic knowledge, assessment, effective team-based care, empathy, and cultural competency. Educational program accreditation bodies and professional licensure boards can require pain teaching and clinician learning at the undergraduate and graduate levels. The National Pain Strategy also recommends development of a web-based pain education portal that would contain up-to-date, comprehensive, and easily accessed educational materials.

Public Education and Communication

Key to a cultural transformation in pain care is a greater understanding—among members of the public and people with pain alike—of important aspects of chronic pain. The National Pain Strategy recommends a national public awareness campaign involving many relevant public and private partners, including people with pain and their advocates, to address stigma and misperceptions about chronic pain. The learning objectives the campaign would work to achieve would emphasize the impact and seriousness of chronic pain and its status as a disease in its own right that requires appropriate treatment. In addition, a safe-use education campaign targeting people with pain whose care includes prescription medications is recommended.

THE NATIONAL PAIN STRATEGY: A Vision

If the objectives of the National Pain Strategy are achieved, the nation would see a decrease in prevalence across the continuum of pain, from acute, to chronic, to high-impact chronic pain, and across the life span from pediatric through geriatric populations, to end of life, which would reduce the burden of pain for individuals, families, and society as a whole. Americans experiencing pain—across this broad continuum — would have timely access to a care system that meets their biopsychosocial needs and takes into account individual preferences, risks, and social contexts. In other words, they would receive patient-centered care.

Further, Americans in general would recognize chronic pain as a complex disease and a threat to public health and to a just and productive society. Because of this greater understanding, significant public resources would be invested in the areas of *preventing* pain, creating *access* to evidence-based and high-quality pain assessment and treatment services and improving *self-management* abilities among those with pain. In addition, individuals who live with chronic pain would be viewed and treated with *compassion and respect*. Specifically, substantial progress in the care system would be achieved as follows:

- Clinicians would take active prevention measures to prevent the progression of acute to chronic pain and its associated disabilities.
- Clinicians would undertake comprehensive assessments of patients with chronic pain, leading to an integrated plan of coordinated care, managed by an interdisciplinary team, when needed. Treatment would involve high-quality, state-of-the-art, multimodal, evidence-based practices. While most pain care would be coordinated by primary care practitioners, specialists would be involved judiciously in the care of patients who have increased co-morbidities, complexity, or risk.
- People with all levels of pain would have access to educational materials and effective approaches for self-care and pain self-management programs that would help them prevent, cope with, and reduce pain and its disability, and they would have better information about the benefits and risks of pain management options. The information would be available to those who have low literacy or communication disabilities.
- All Americans would be assured of obtaining preventive, assessment, treatment, and self-care interventions and support, regardless of age, gender, sex, race, ethnicity, income, education,

geographic location, language proficiency, health literacy, or medical condition. All pain-related services would be provided without bias, discrimination, or stigma.

Specific advances supporting the evolution toward a public health approach to pain prevention and care would result from improvements in clinical education, public and institutional policies and population-level epidemiologic, health services, social science, medical informatics, implementation, basic and translational biomedical, and other relevant research, informed by clinician/scientist interactions.

Primary care clinicians and specialists in relevant fields need to know more about the biopsychosocial characteristics and safe and appropriate management of pain. Clinicians' knowledge of pain and pain care would be broadened to encompass an understanding of individual variability in pain susceptibility and treatment effectiveness, how pain affects communication, the importance of shared and informed decision-making, ways to encourage pain self-management under mutually agreed-upon treatment plans, how clinician empathy and cultural sensitivity influences the effectiveness of care, and the role of complementary and integrative medicine.

Chief among the supporting policy approaches would be reimbursement incentives and payment structures that support population-based care models of proven effectiveness, especially in interdisciplinary settings, and encourage multimodal care geared toward improving a full range of patient outcomes.

Timely data regarding the health and economic burdens of chronic pain would guide federal and state governments and diverse health care organizations in their efforts to work toward these objectives. Such data would lay the groundwork for enhancing the effectiveness and safety of pain care overall and for specific population groups and would enable monitoring the effectiveness of policy initiatives, public education efforts, and changing treatment patterns.

Finally, electronic data on pain assessment and treatment would be standardized, and health systems would maintain pain data registries that include information on the psychosocial/functional impact of chronic pain and the costs and effectiveness of pain management interventions. These data resources would be used in an ongoing effort to evaluate, compare, and enhance health care systems, identify areas for further research, and assess therapies for quality and value.

BACKGROUND TO THE PROJECT

The 2010 Patient Protection and Affordable Care Act (ACA), Section 4305, required the Secretary of 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." As a result, HHS, working through the NIH, commissioned an IOM study to assess the state of pain care. The resultant IOM report, issued in June 2011,¹ included 16 recommendations for improvements in:

- data collection and reporting
- the availability and effectiveness of pain care
- public, patient, and professional education about pain, and
- related preclinical, translational, and clinical research.

The IOM's emphasis on pain as a significant public health challenge, amenable to population healthlevel interventions, placed a large share of responsibility for implementing these recommendations on federal health agencies (Institute of Medicine, 2011, p. 5). Specifically, Recommendation 2-2 called for creation of "a comprehensive population health-level strategy for pain prevention, treatment, management, and research."

The following year, in response to a congressional mandate, HHS created the federal IPRCC² to coordinate all pain research efforts within HHS and across other Federal Agencies and in October 2012, the Assistant Secretary for Health asked the IPRCC to oversee the creation of the comprehensive population health-level strategy envisioned in IOM Recommendation 2-2. The IPRCC and the NIH, under the leadership of Story Landis, Director, National Institute of Neurological Disorders and Stroke, established a framework for developing a National Pain Strategy and engaging the necessary expertise, in consultation with the Chair and Vice Chair of the IOM Committee.³

Six key areas addressed in the National Pain Strategy are:

- population research
- prevention and care
- disparities
- service delivery and reimbursement
- professional education and training, and
- public education and communication

² A list of the federal agency, scientific, public, and ex-officio members of the IPRCC can be found at <u>http://iprcc.nih.gov/committee/committee-roster.htm</u>.

¹ Institute of Medicine. 2011. *Relieving pain in America: A blueprint for transforming prevention, care, education, and research.* Washington, D.C.: National Academies Press.

³ Philip Pizzo, MD, former dean, Stanford University School of Medicine; Noreen Clark, PhD, Director, Center for Managing Chronic Disease, University of Michigan (deceased).

The IPRCC selected expert working groups to address each of these areas and created an oversight panel to guide and coordinate the working groups' interrelated efforts (Appendixes A and B). Nominations for working group and oversight panel membership were actively solicited from professional societies, federal and state agencies, private foundations, advocacy organizations, and through the Federal Register (Appendix C). The goal was broad representation from relevant public and private organizations, health care providers, insurers, and people with pain and their advocates, as recommended by the IOM committee. The results of the focused deliberation of these six work groups form the body of this report, which includes objectives and steps to achieving them in the short-, medium-, and longer-term, identifies stakeholders to implement the objectives, and suggests metrics for assessing progress. The report is intended to initiate a longer-term effort to create a cultural transformation in how pain is perceived, assessed, and treated—a significant a step towards the ideal state of pain care. An ensuing strategy to address the contribution of research to this strategy will be developed by the IPRCC. Box 1 contains definitions.

Box 1 Definitions Used in This Report

Acute pain – An expected physiologic experience to noxious stimuli that can become pathologic, is normally sudden in onset, time limited, and motivates behaviors to avoid actual or potential tissue injuries.

Biopsychosocial – A medical problem or intervention that combines biological, psychological, and social elements or aspects.

Chronic pain - Pain that occurs on at least half the days for six months or more.

Continuum of pain – The characterization of pain as a temporal process, beginning with an acute stage, which may progress to a chronic state of variable duration.

Disease management refers to a system of integrated, multidisciplinary interventions and communications for populations with chronic disorders in which self-care efforts are significant.

Disparities – The Disparities work group used the working definition created by Healthy People 2020, terming disparities "a particular type of health difference that is closely linked with social, economic, and/or

environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."⁴

High-impact chronic pain is associated with substantial restriction of participation in work, social, and self-care activities for six months or more.

Integrated care is the systematic coordination of medical, psychological and social aspects of health care and includes primary care, mental health care, and, when needed, specialist services.

Interdisciplinary care is provided by a team of health professionals from diverse fields who coordinate their skills and resources to meet patient goals.

Levels of care – Primary care practitioners provide routine screenings and assessment and management of common pain conditions due to headache, diabetes, arthritis, and low back pain, for example; *pain medicine specialists* provide secondary-level consultations, which can include multidisciplinary team-based care, including rehabilitation therapy and behavioral health care; *interdisciplinary pain centers* provide tertiary care through advanced pain medicine diagnostics and interventions.

Multimodal pain treatment addresses the full range of an individual patient's biopsychosocial challenges by providing a range of multiple and different types of therapies as needed.

Pain self-management programs address the systematic provision of education and supportive interventions by health care providers to strengthen patients' skills and confidence in medical management, role management, and emotional management of their health problems, including regular assessment of progress and problems, decision making, goal setting, self-monitoring, and problem solving. Specifically for pain self-management, these programs involve acquiring knowledge about pain and building skills and confidence to prevent, cope with, and reduce pain. These programs can stand alone and be individually directed, be integrated into health care settings or offered by community agencies.

⁴ <u>http://healthypeople.gov/2020/about/DisparitiesAbout.aspx</u>.

Prevention – In the pain context, *primary prevention* are efforts to reduce injuries or diseases that may result in pain. *Secondary prevention* are interventions designed to reduce the likelihood that acute pain transitions into chronic pain. *Tertiary prevention* interventions attempt to limit the development of disabilities and other complications of chronic pain after it has developed.

INTRODUCTION

The sensory and emotional experience of pain plays an important protective role in human health and well-being, by alerting a person to actual or potential physical injury. Often, painful symptoms can be self-managed while the underlying cause resolves or is treated and recovery occurs. Such instances generally require little or no professional intervention. By contrast, when acute pain does not resolve, it may be associated with a serious disease, condition, or injury that needs timely medical care. When it persists, even after any identifiable underlying cause is resolved, it may signal that pain-initiated changes in the central nervous system have occurred. If so, the chronic pain is no longer a symptom of another disorder and has become the disease itself. And, like any disease, it requires appropriate treatment.

Chronic pain is a complex biopsychosocial phenomenon that may interfere with many aspects of a person's life—ability to work, personal relationships, and both physical and mental health. Chronic pain also is linked to premature death. Unchecked, secondary psychosocial and physical problems can worsen pain reciprocally, posing escalating threats to health and well-being, and various studies indicate the suicide rate among those living with chronic pain is higher than that of the general population.

Many factors influence the way specific patients perceive pain and adapt to it, the likelihood they will seek—and get—care, and their responses to treatment. These factors include past experiences, familial and genetic factors (including race and gender), comorbidities, cultural background, psychology, economic, and environmental factors. Despite this complexity, pain education, research, and treatment historically have focused on the pathophysiological mechanisms involved in chronic pain. This approach inadvertently encourages a "magic bullet" approach to treatment, deemphasizing the many other factors that, if overlooked, may render treatment and rehabilitative efforts futile.

An estimated 100 million Americans have some level of chronic pain. Severe, disabling chronic pain in this report termed "high-impact chronic pain" (see Box 1)—affects a smaller, but significant proportion of the population. Because people with chronic pain may not seek treatment, it is important to assess the prevalence and consequences of chronic pain among people in the general population as well as those who seek medical attention. More precise assessments of the incidence, prevalence, and significance of pain in the U.S. population are needed in order to establish a reliable basis for population-wide interventions and a baseline for assessing efforts to relieve the physical, psychological, social, and economic burdens of pain.

Certain pain conditions are known to affect population groups differentially, and some groups—whether defined by age, sex, gender, race/ethnicity, geographic isolation, socioeconomic status, or other characteristics—have less access to pain prevention, assessment, and treatment services and experience worse

outcomes. These barriers reflect systemic challenges, and many are driven by current reimbursement policies, provider attitudes and training, stereotyping, and biases. In addition, chronic pain is a costly problem. It engenders high direct medical care costs, as well as costs associated with disability programs, lost productivity, and family burden. According to the IOM report's estimates, this total is between \$560 billion and \$635 billion annually.⁵

Viewing chronic pain from a public health perspective allows patients, families, clinicians, and policymakers to benefit from available public health knowledge and disease models and adds precision to the concept of pain prevention. This melding of public health mindset and individualized treatment offers the best chance to improve all Americans' access to high-quality and more cost-effective pain care. Where gaps exist, this approach may point to areas where basic biomedical and translational research is needed.

People living with chronic pain who seek care face many hurdles. Wide variability exists in clinical practices related to prevention, assessment, and treatment. Acute pain not managed properly may develop into chronic pain, and, according to the IOM report, most Americans who live with chronic pain do not receive appropriate care. What care is provided is often fragmented, without a comprehensive assessment or treatment plan, and patients may encounter difficulty obtaining the full range of potential treatments. The widespread use of unnecessary diagnostic tests and procedures and relatively ineffective and potentially harmful treatments has been linked to high health care costs.

Public health concerns related to the misuse or diversion of prescription pain medications add another layer of complexity to the management of chronic pain. As part of a public health effort over the past few decades to improve pain management, a broader prescribing of opioids led to a significant rise in adverse health consequences, including addiction, abuse, and overdose. Prescriber practices drove a steady and significant increase in the number of opioid prescriptions dispensed, rising from 76 million in 1999 to 219 million in 2011⁶. The amount per prescription, the duration of the supply, and the cumulative dose prescribed also increased.⁷ These dramatic increases paralleled rises in opioid-related substance abuse treatment admissions ⁸ and rates of opioid-involved overdose deaths, which reached over 16,000 in 2010.⁹ Studies have identified patient risk

⁵ These cost estimates were based on the U.S. adult non-institutionalized civilian population and, therefore, exclude children, prisoners, people in nursing homes or other institutional settings, and the military.

⁶ IMS Health, Vector One: National, Years 1991-1996, Data Extracted 201. IMS Health, National Prescription Audit, Years 1997-2013, Data Extracted 2014.

⁷ Kenan K. Mack K, Paulozzi L. Trends in prescriptions for oxycodone and other commonly used opioids in the United States, 2000-2010. *Open Med*.2012;6(2):41–47. <u>http://www.drugabuse.gov/related-topics/trends-statistics/monitoring-future</u>

⁸ Substance Abuse and Mental Health Services Administration. Drug Abuse Warning Network, 2007: national estimates of drugrelated emergency department visits.

⁹ Mack, K.A. Drug-induced deaths - United States, 1999-2010. MMWR Surveill Summ. 2013 Nov 22;62 Suppl 3:161-3. CDC

factors for overdose. Understanding these factors is important to enable the identification of populations at highest risk as well as for the development of interventions that target these high-risk groups.

The reluctance of many clinicians to prescribe these medications, and patients' concerns over stigmatization associated with opioids may jeopardize quality pain control in the population. Only a small percentage of practitioners and patients account for the majority of opioid-related risk through abuse of prescribing privileges and inappropriate management of prescriptions¹⁰.

Prescription opioids for management of moderate to severe pain are recommended in clinical practice guidelines for chronic pain management in selected patients. They are considered medically appropriate and safe for acute and for intractable pain that is not adequately managed with other methods, when used as prescribed. A recent conference ¹¹ to assess the safety and efficacy of long-term opioid use for chronic pain concluded that there are insufficient data to guide appropriate patient assessment, opioid selection, dosing strategies, or risk mitigation and noted the need for further research on the effectiveness of long-term opioid use for chronic pain. The panel also concluded that opioids are an essential component of optimal treatment for some patients and noted the challenge of identifying those who will benefit and are at low risk for adverse effects. The conference highlighted the need for more research and development to ensure that pain management is team based, individualized, multidisciplinary, and patient centered. Access to safe and effective care for people suffering from pain remains a priority that needs to be balanced in parallel with efforts to minimize the harms from opioids.

Effective pain control strategies emphasize shared decision-making, informed and thorough pain assessment, and integrated, multimodal, and interdisciplinary treatment approaches that balance effectiveness with concerns for safety. Opportunities for improvements in care may arise with the increasing emphasis on team-based care and care coordination, facilitated by the adoption of electronic health records, along with continued health services delivery research and implementation of better models. More effective delivery of services, supported by appropriate system characteristics and reimbursement, are essential to the "cultural transformation" called for in the IOM report, though far from the norm today.

While the development of better treatments and care models for chronic pain conditions is a high priority, at the same time, no opportunity should be lost to *prevent* the conditions and events that lead to chronic

¹⁰ Blumenschein K, Fink JL, Freeman PR, et al. Independent evaluation of the impact and effectiveness of the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER). Available at: http://chfs.ky.gov/NR/rdonlyres/

²⁴⁴⁹³B2E-B1A1-4399-89AD-1625953BAD43/0/KASPEREvaluationFinalReport10152010.pdf Accessed October 2012.

¹⁰⁹ Oregon Health Authority. Prescription drug dispensing in Oregon. October 2011-March 2012. Available at

http://www.orpdmp.com/orpdmpfiles/PDF_Files/Reports/Statewide_10.01.11_to_03.31.12.pdf.

¹¹ Pathways to prevention https://prevention.nih.gov/docs/programs/p2p/ODPPainPanelStatementFinal_10-02-14.pdf

pain and to intervene early with evidence based care, before acute pain becomes chronic. Even though pain is a leading cause of primary care visits, clinicians are generally under-trained in ways to assess and manage pain effectively. Improvements in professional education about state-of-the-art care for pain, in all its dimensions—including better communication, empathy, and cultural sensitivity—will yield significant care improvements.

A robust public education effort may lend support to individuals with pain, as well as to the dedicated clinicians, researchers, and advocates working to prevent and reduce the impact of pain among Americans. This effort will improve understanding of chronic pain and its significance among individuals, families, and society and increase knowledge about the availability of more effective treatment approaches. The U.S. health care system is evolving toward a model that is patient-centered, evidence- and outcomes-guided yet individualized, and provided through high-performance, interdisciplinary care teams. This evolution suggests that development of a National Pain Strategy is remarkably timely. However, to be successful, this model must more effectively address the common complaint of pain. Recognition of need for improvements in pain care, along with appreciation of pain's enormous human and economic burden, led the IOM Committee to develop a set of underlying principles (Box 2) that likewise informed development of this National Pain Strategy.

Box 2 IOM Committee 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 people who have it that every effort should be made to achieve both primary prevention (e.g., in surgery for 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 usefulness long-term, but believes that when opioids are used as prescribed and appropriately monitored, they can be safe and effective, especially for acute, post-operative, 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--a 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.

*Institute of Medicine, 2011, op. cit., p. 3.

Population Research

Publication of the 2011 report by the Institute of Medicine, *Relieving Pain in America*, has led to growing recognition of the impact of pain on the health, productivity, and well-being of the U.S. population. Efforts to lower the impact of chronic pain at the individual and population levels need to be guided by population-based data. At present, data are needed on the prevalence, onset, course, impact, and outcomes for most common chronic pain conditions. These data will help guide policies and initiatives of federal and state governments, and of health care organizations and insurers.

A core responsibility of public health agencies is assessing the significance of health problems in the population. These calculations typically reflect a problem's incidence, prevalence, and severity (morbidity, associated mortality, and disability) in the population as a whole and in relevant groups, defined by demographic characteristics, geography, or other parameters of interest. For chronic pain, better data are needed to understand the scope of the problem and to guide action, including efforts to reduce the impact of chronic pain through primary, secondary, and tertiary prevention. Such estimates of impact are needed in order to define health care workforce and service delivery needs and priorities for insurance benefits, as well as for monitoring the quality, safety, effectiveness, and costs of relevant programs and policies. Population research is, therefore, an essential tool in the implementation of this National Pain Strategy.

The World Health Organization's International Classification of Functioning, Disability and Health (ICF) considers determinants of health and disability from the perspective of the biopsychosocial model.¹² The following ICF concepts are relevant to defining chronic pain:¹³

Impairments: Problems with body structure or function *Activities:* The execution of a task or action by an individual *Activity limitations:* Difficulties an individual may have in executing activities *Participation:* Involvement in a life situation

Participation restrictions: Problems experienced in life situation or social role involvement Three inter-related manifestations of chronic pain define its overall individual and societal impact: perception, activity limitations, and participation restrictions. Lower to intermediate levels of pain severity are less likely to significantly impact social, recreational and vocational functioning, while more severe levels are associated with activity limitations and participation restrictions. The IOM report emphasized that chronic pain is common, affecting over 30 percent of the adult population to some extent. It is therefore critically important to differentiate people with *high-impact chronic pain* from those who sustain normal activities although experiencing chronic pain. Accordingly, the pain assessment tools proposed for population research in chronic pain (Appendixes D-F) are designed to identify people in the general population who suffer from chronic pain at various levels of severity, including those who have *high-impact chronic pain* based on the degree to which pain limits their ability to participate in work, social, or self-care activities.

The pain assessment tools proposed for population research use the definitions of chronic pain and highimpact chronic pain, which are based in part on the widely used definition of chronic pain recommended by the International Association for the Study of Pain,¹⁴ modified to account for intermittent pain.

Chronic pain is pain on at least half the days for six months or more.

High-impact chronic pain is associated with substantial restriction of participation in work, social, and self-care activities for six months or more.

arthritis on the individual patient; the WHO ICF. Ann Rheum Dis 2005; 64:664-8.

¹² World Health Organization. International Classification of Functioning, Disability and Health. World Health Organization, Geneva, 2001.

¹³ For example: Tucker CA, Cieza A, Riley AW, Stucki G, Lai JS, Ustun TB, Kostanjsek N, Riley W, Cella D. Concept analysis of the Patient Reported Outcomes Measurement Information system (PROMIS) and the International Classification of Functioning, Disability and Health (ICF). *Qual Life Res* 2014, Epub ahead of print; Stier-Jarmer M, Cieza A, Borchers M, Stucki G, World Health Organization. How to apply the ICF and ICF core sets for low back pain. *Clin J Pain* 2009; 25:29-38; Leonardi M, Steiner TJ, Scher AT, Lipton RB. The global burden of migraine: measuring disability in headache disorders with WHO's Classification of Functioning, Disability and Health (ICF). *J Headache Pain* 2005; 6:429-40; and Stucki G, Ewert T. How to assess the impact of

¹⁴ International Association for the Study of Pain. (1986). *Classification of chronic pain. Descriptions of chronic pain syndromes and definitions of pain terms. Pain Suppl, 3*, S1-226.

The Problem: Improvements in data methods and measures are needed to:

(1) guide efforts to reduce the burden of chronic pain through more accurate estimates of the prevalence of chronic pain and high-impact chronic pain in the general population and within population groups defined by demographic factors (age, gender, race, ethnicity, education, and socioeconomic status) and geographic areas, including identification of risk factors that predispose towards the development of chronic pain;

(2) provide standard methods for the analysis of electronic health care data related to pain treatment, which can reveal patterns of health services utilization, including over- and under-treatment, costs, and, most important, quality of care;

(3) develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time that will enable assessment of progress, evaluation of the effectiveness of interventions at the population health level—such as public education or changes in public policy, insurance benefits, treatments, and organization of care—and identification of emerging needs.

The intent of the population research component of the National Pain Strategy is to provide methods and measures to guide progress towards achieving improved prevention (primary, secondary, and tertiary) and management of pain in the United States.

Objective 1: Estimate the prevalence of chronic pain and high-impact chronic pain in the general population and in primary care settings, both overall and for anatomically defined pain conditions and for various population groups.¹⁵

Short-term strategies and deliverables:

- Test a set of proposed pain screener questions (Appendix D) and brief self-assessment questions about high-impact chronic pain (Appendix E) in a representative population sample and among those whose pain treatment pattern suggests high-impact chronic pain is likely.
- Convene key stakeholders to review questions related to pain in current national population surveys¹⁶ and make recommendations regarding the appropriateness of standardizing, adding, or

¹⁵ Stratified by age, gender, race and ethnicity, education, socioeconomic status, health status, and indicators of biopsychosocial resiliencies and vulnerabilities.

¹⁶ Including the National Health Interview Survey (NHIS) and the National Health and Nutrition Examination Survey (NHANES), as well as Behavioral Risk Factor Surveillance System surveys, the Health and Retirement Survey, the Medicare Current Beneficiary Survey, and other regular and special supplemental population-based pain research appropriate for this purpose.

revising questions to bring these surveys in line with the NPS-proposed self-assessment questions in Appendixes D and E.

- Conduct additional evaluative studies of the NPS-proposed self-assessment questions and any alternative questions including cognitive testing and translation into other languages.
- Prepare a manuscript for submission to a peer-reviewed journal reporting the results of the test of the proposed brief pain self-assessment questionnaire.

Medium-term strategies and deliverables:

- Convene key stakeholders to refine self-assessment questions and measurement strategies and to build support for and facilitate implementation of the proposed population-based measurement and evaluation components of the National Pain Strategy.
- Incorporate a brief pain self-assessment questionnaire resulting from this process into at least one national morbidity survey and schedule initial implementation of data collection using these items.

Longer-term strategies and deliverables:

- Use the increasingly refined measures developed to evaluate longitudinal pain outcomes among Medicare, Medicaid, and other beneficiaries, including in post-acute care evaluations, the Minimum Data Set, and other comparable population-based tools.
- Stakeholders and collaborators: Agency for Healthcare Research Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), NIH, Veterans Health Administration (VHA), and other entities involved in population-based research for finalizing pain assessment questions); Centers for Medicare and Medicaid Services (CMS) and other entities concerned with the impact of pain, such as public and private health insurers, employers, and researchers; health care provider and professional organizations; patient advocacy organizations and people with pain.
- *Metrics:* Agreement reached on a brief set of validated pain-related questions and their incorporation into population research going forward.

Objective 2: Refine and employ standardized electronic health care data methods to determine the extent to which people with common pain conditions, including those from vulnerable groups, receive various treatments and services, the costs of these services, and the extent of use of treatments that best evidence

suggests are underused, overused, effective, and ineffective.

Short-term strategies and deliverables:

- Carry out proof-of-concept analyses with large health care databases to identify patterns of pain treatment among people in specified diagnostic clusters¹⁷ (Appendix F) and their associated costs. This activity would provide insights regarding disparities in pain care, as well as how different reimbursement models affect both patterns of treatment and costs.
- Prepare a manuscript for submission to a peer-reviewed journal reporting the results of the proof-ofconcept analyses of health care data on diagnostic clusters and pain treatment indicators and related recommendations.
- Encourage the Centers for Medicare and Medicaid Services to make adequate pain measures a component of its incentive programs for establishing "meaningful use" of electronic health records, an action deemed especially helpful in monitoring care for vulnerable populations.

Medium- to longer-term strategies and deliverables:

- Refine the initially proposed diagnostic clusters and treatment indicators, including adaptation of the diagnostic clusters to ICD-10 nomenclature.
- Convene key stakeholders to consider standardization and widespread use of the resulting diagnostic clusters and treatment indicators in population research using electronic health care data. Ideally, the resulting analyses would be accompanied by evidence-based characterization of treatment indicators (Appendix G), including the relative value of specific pain treatments, as emphasized in the Service Delivery and Reimbursement section
- Establish a pain research network to study risk factors for the initiation and maintenance of chronic pain and high-impact chronic pain and patterns of pain treatment using the diagnostic clusters and pain treatment indicators.¹⁸ Use the network to develop data on trends in pain treatment in different population groups, including evidence of under-treatment, and costs of specific pain treatment services and to identify opportunities and priorities for primary prevention.

¹⁷ Diagnostic clusters refer to clinical groups of painful conditions, grouped on the basis of anatomical location of the pain rather than diagnostic specificity. They allow analysis of electronic data on use of health services for common pain conditions in clinically meaningful groups (e.g., back pain, headache).

¹⁸ Recognizing that these categories are subject to continued refinement based on experience, new research findings, and external factors, such as the implementation of ICD-10.

- Stakeholders and collaborators: For the proof-of-concept analyses and the pain research network: AHRQ, Office of the National Coordinator for Health Information Technology (ONC), NIH, and other relevant entities; evidence-based practice centers in universities; relevant primary care and specialty professional societies; CMS, DoD, VHA and other public and private sector health care financing and delivery systems that have large patient and health maintenance organizations; health insurers; patient advocacy organizations; and people with pain.
- *Metrics:* quantity, quality, and usefulness of publications arising from the research network; adoption of diagnostic cluster and pain treatment indicator methodology within and outside government-funded programs.

Objective 3: Develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time that will enable assessment of progress, evaluation of the effectiveness of interventions at the population health level—such as public education or changes in public policy, payment, and care—and identification of emerging needs. Apply these metrics to evaluate the effectiveness of primary, secondary and tertiary prevention interventions. These initiatives may include public policy initiatives, demonstration projects in the organization or reimbursement of care, or public education efforts.

Short -term strategies and deliverables:

- Set measurable goals for reducing the prevalence of high-impact chronic pain and for increasing the value of health care and preventive services for chronic pain to be incorporated into Healthy People 2020.
- Coordinate across the federal agencies that gather data related to primary prevention strategies (primarily injury prevention and improved management of certain chronic conditions).

Medium-term strategies and deliverables

- Develop approaches to assessing pain's impact in longitudinal studies that consider pain perceptions, activity limitations, and participation restrictions in work, social and self-care roles, work productivity, utilization of disability benefits and other services, family effects, and utilization and costs of health care services.
- Evaluate outcomes of Healthy People 2020 chronic pain to inform and guide appropriate objectives/questions for a dedicated chronic pain objective to be included in HP 2030.

Longer-term strategies and deliverables:

- Encourage health care providers and insurers to use data developed under these initiatives and the collaborative relationships established to:
 - o guide enhancements to health care and preventive services and
 - evaluate the effectiveness of interventions at the population health level, such as public policy initiatives, demonstration projects in the organization or reimbursement of care, or public education efforts.¹⁹
- *Stakeholders and collaborators: CDC, DoD, NIH, VHA,* and other relevant public and private entities that collect data on pain and its treatment, disability program utilization, and other public benefits; employer and employee organizations; AHRQ, CMS, DoD, VHA, and other relevant public and private entities involved in health services research, care delivery, financing, and program evaluation; and patient advocacy organizations and people with pain.
- *Metrics:* extent of adoption of the pain assessment and treatment metrics and their use in assessing programmatic interventions; adoption of the proposed measures in the Healthy People data tools and reporting system; extent of use in program planning, implementation, and evaluation at the community, state, and federal levels.

Prevention and Care

Preventable causes of acute and chronic pain should be identified and addressed throughout the health care delivery system. When acute pain from injury or disease is present, or when a persistent pain state has developed, clinicians should assess and comprehensively manage it using practice guidelines based upon best available evidence of effectiveness. Current opportunities to manage the continuity of care during transitions across health care settings and to expand real-time access to a carefully selected and synthesized body of relevant evidence should be enhanced in order to improve coordination of care and optimal use of resources.

¹⁹ Washington State's Bree Collaborative (see <u>http://www.breecollaborative.org/about</u>) provides a model for such collaboration. For example, the Bree Collaborative recently developed strategies to enhance the value of health care for low back pain (see <u>http://www.breecollaborative.org/topic-areas/spine</u>).

To date, the quality and quantity of evidence guiding clinical approaches to the prevention, assessment, and treatment of pain have lagged behind that for treatment of other major disease and public health burdens, such as cancer, infectious diseases, and cardiovascular disease. Given that acute pain can progress to chronic pain which is a disease in itself, certain principles, are clear:

- evidence-based care approaches should follow the public health prevention model and address primary, secondary, and tertiary prevention
- evidence-based pain care should involve an interdisciplinary team approach and cover the different levels of pain care—from prevention to self-care to acute to chronic pain management—as needed, and
- high-quality pain care should be available in all settings and at all levels of care, from primary care to interdisciplinary pain care centers, as the intensity of pain management efforts increases.

The Problem: Chronic pain may begin with an injury, or procedure that evolves into a persistent painful condition. Often, however, the cause of its onset is uncertain, and the mechanisms by which it persists are complex. There is a great need to better understand the factors that cause pain to become persistent and to develop and apply measures to prevent acute pain from transitioning to a chronic state. Opportunities to prevent acute to chronic pain progression depend not only on the nature of the initial insult and treatment, but also upon various patient-related risk factors. While there is much more to be learned about chronic pain prevention and treatment, existing knowledge could be used more effectively to reduce substantially the numbers of people who suffer unnecessarily. Most people who have pain do not receive appropriate assessments or evidence-based care that is coordinated across providers and individualized for specific higher-risk situations. A robust basic, translational, and health services research effort is needed to validate the effectiveness of pain prevention and management strategies already in use, and to develop new ones.

The intent of the Prevention and Care component of the National Pain Strategy is to advance evidence-based, culturally sensitive and individualized prevention and care of pain, using the biopsychosocial model and providing value determined by accepted, validated, and systematically collected outcomes.

Objective 1: Characterize the benefits and costs of current prevention and treatment approaches. A thorough benefit-to-cost analysis of current prevention and treatment approaches, including self-management methods and programs, should be performed to identify and create incentives for use of interventions having high benefit-to-cost ratios. Conversely, treatments with little absolute benefit or a low benefit-to-risk ratio should be identified through clinical studies and efforts made to dis-incentivize their use. In judging the benefit of many treatments, clinicians and payers should bear in mind that an individual may belong to a specific population group in which the treatment may be either more beneficial (or more risky) than in the population at large.

Short-term strategies and deliverables:

- Perform a benefit-to-cost analysis of methods to prevent and treat pain for which the best available evidence suggests benefit. Such an analysis may help guide the choice between therapies that are equally efficacious but whose cost differs.
- Prepare a manuscript for submission to a peer-reviewed journal reporting the results of the benefitto-cost analyses of current prevention and treatment approaches and related recommendations.
- Develop a best-estimate synthesis of causes of preventable injuries nationwide, including both workplace and non-workplace related accidents and physical trauma by:
 - \circ Identifying areas where more evidence is needed (for example, occupational injuries may be substantially underreported²⁰)
 - Reviewing existing programs for primary prevention and the evidence for their effectiveness, and
 - Estimating the number of people with chronic pain whose condition is preventable as a first step in developing more robust preventive efforts.
- Begin research efforts geared toward development of new prevention and treatment methods likely to have high benefit-to-cost ratios.

Medium-to-longer term strategies and deliverables:

- Incorporate the most effective and cost-efficient treatments into practice guidelines and other best practices efforts (for example, the Physician Quality Reporting System), with inclusion of standards-based clinical decision support to enable providers and patients to make decisions in line with best practice guidelines. followed by:
 - Assessment of insurer practices that either deny payment for effective and cost-efficient treatments for patients who could benefit from them or continue to reimburse less effective ones.
- Development of a framework for measuring treatment outcomes on pain, level of disability, and the full range of psychosocial impacts.
- *Stakeholders and collaborators: AHRQ, ONC,* the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, the VHA, and other relevant federal and private entities; public, including CMS, and private insurers; patient advocacy organizations and people with pain.

²⁰ U.S. Government Accountability Office. 2009. Enhancing OSHA's records audit process could improve the accuracy of worker injury and illness data. GAO-10-10, p. 19. See also Figures 12 and 13. Accessed June 27, 2014, from http://www.gao.gov/assets/300/298510.pdf.

Metrics: the level of integration of effective, cost-efficient pain treatments into the health care system and the impact on outcomes for people with pain; extent of dissemination of these results to health care providers, payers, and policymakers.

Objective 2: Develop nation-wide pain self-management programs.²¹ Despite evidence to support teambased, pain self-management programs for pain, their implementation has lagged, which represents an unmet opportunity to provide people with pain the appropriate skills, education, and resources to play an active role in managing their pain, which includes understanding when clinical consultation is needed. These programs should be integrated into the health care system to bolster their use and prevalence and to guide patients through the several levels of pain care. Goal setting (action planning), problem solving, decision making and psychosocial aspects of care should be included in the programs.

Short-term strategies and deliverables:

- Perform an environmental scan of pain self-management programs that²²
 - cover the continuum of prevention and pain; foster skills to prevent, cope with, and reduce pain; and provide people having pain with the practice and confidence to utilize the core self-management skills of goal setting (action planning), problem solving, and decision making
 - are offered in differing health care settings, by community agencies, patient advocacy organizations, or that stand alone, and
 - are culturally neutral, allowing each group or individual to self-tailor the intervention, and are available in multiple languages, as well as in audio versions for those with low literacy.

Medium-term strategies and deliverables:

- Evaluate the efficacy of existing pain self-management programs and support research and development of new programs and models, as necessary, to address the continuum of pain.
- Leverage existing programs, such as the extensive self-management tools for patients with chronic disease.²³

²¹ See definitions, Box 1. In addition, to meet people's various circumstances and learning preferences, self-management programs must be offered in multiple models (in groups of varying sizes, electronically via smartphone or computer, by mail, or by telephone).
²² Specific programs that warrant an evaluation include the American Chronic Pain Association's program, Stanford Patient Education Research Center Programs, CDC's osteoarthritis program, and model falls prevention programs.

²³ Examples of program models include: Stanford's Patient Education Research Center: CDC's Arthritis Self-Management Program; the University of New Mexico's telehealth program, ECHO; the A Matter of Balance program developed by Boston University; or the National Institute of Neurological Disorders and Stroke's program for pediatric migraine, under development.

• Develop new types of patient tools for pain management and provider feedback using, for example, mobile applications, that also integrate with electronic health records (EHRs), personal health records (PHRs)/patient portals, wearable devices, and other technologies.

Longer-term strategies and deliverables:

- Implement, evaluate, and disseminate nationally evidence-based pain self-management programs that are effective, as documented by high-quality research methods, and that have developed materials and a structure enabling them to be transferred to one or more additional sites.
- Encourage the inclusion of evidence-based programs as covered benefits under public and private integrated health systems, including the VHA, especially for people with indicators or risk factors for transitioning to chronic pain.
 - Include information on effective pain self-management programs in various health information directories, such as <u>http://www.health.gov/</u>

and non-governmental resources for patients.

- Through various means, direct those with the indicators or risk factors for transitioning to chronic pain to effective self-management programs.
- *Stakeholders and collaborators:* AHRQ, DoD, and VHA in collaboration with HRSA (as appropriate to their statutory priorities and within their authority), and other relevant federal agencies, the Patient-Centered Outcomes Research Institute (PCORI) and private entities that support health care assessments and outcomes monitoring; professional organizations; public and private payers, health care provider organizations, and other potential funders (to ensure a vigorous and widely supported effort); patient advocacy organizations; and people with pain.
- *Metrics:* outcomes data obtained by leveraging established tools, such as the NIH and Department of Defense's collaborative PASTOR/PROMIS system, the NIH Pain Consortium, Stanford University's Collaborative Health Outcomes Information Registry (CHOIR), and those developed by the Joint Commission; and by innovative use of data from electronic health records

Objective 3: Develop standardized, consistent, and comprehensive pain assessments and outcome measures across the continuum of pain. Pain assessment should be multifaceted and include self-report, as

well as clinician examination. Assessment and outcomes measures should include relevant pain, physical, psychological, and social domains of functioning that conform to the biopsychosocial model of pain, as well as patient-reported outcomes and patient-defined goals. Assessments and outcomes should be used for point of care decision-making by clinicians, longitudinal outcomes monitoring, estimations of value of alternative treatment approaches, and practice-based effectiveness studies.

Short-term strategies and deliverables

- Develop comprehensive quality assessments and outcome measures for the continuum of pain.
 - Establish expert working groups to survey and identify gaps in available assessment and outcomes tools for the continuum of pain, including both general assessments and conditionspecific modules, especially taking into consideration their usefulness for primary care providers and for population research.²⁴
 - Conduct research and developmental studies to create new assessment tool models identified as needed.
 - Integrate appropriate pain self-assessment tools into EHR patient portals to aid providers and patients in clinical decision making.
 - Recommend ways to integrate outcomes measures into existing assessment systems, as necessary.

Medium-term strategies and deliverables

- Disseminate existing assessment tools and outcome measurement systems that prove most effective and are easily managed, and create incentives for using them.
- Conduct pilot studies of new models that emerge from research.

Longer-term strategies and deliverables

- Evaluate the benefits and costs of improved, standardized assessment tools and outcome measures.
- *Stakeholders and collaborators:* AHRQ, CDC, CMS, NIH, and other relevant federal and private entities including PCORI; public and private insurers; professional organizations (especially primary care); pain advocacy organizations; and people with pain.

Metrics: the extent of adoption of improved assessment tools and outcome measurement systems.

²⁴ The NIH Task Force on Research Standards for Chronic Low Back Pain is an example of such a task force.

Disparities

The IOM report, a large body of research, patient reports and other sources indicate that substantial disparities in pain occurrence, assessment, treatment, and outcomes are common; U.S. data indicate a greater prevalence of pain conditions among specific population groups typically of interest to public health programs. The Healthy People definition of disparities, included in the Background section of the strategy, describes these groups. When this section of the National Pain Strategy discusses bias, stigma, and discrimination, it is referring to all higher-risk groups that comprise vulnerable populations.

While many factors affect an individual's experience of pain and willingness to seek or adhere to treatment, and while more comprehensive efforts are needed to prevent pain in higher risk groups, this section of the National Pain Strategy focuses on improving the quality of pain care for vulnerable populations, especially as it may be affected adversely by provider attitudes and behavior that result in discrimination, bias, or stigma, which themselves can lead to or exacerbate pain. Examples of patient groups and conditions for which bias has been reported are diverse and widespread and include: women exhibiting pain from chronic fatigue syndrome, fibromyalgia, and other conditions; elderly patients in nursing home settings; minority patients with sickle cell disease or pain associated with human immunodeficiency virus (HIV) infection

Pain care disparities are complex, due to myriad contributing factors within and outside the health care sector. Eliminating disparities and promoting equity in pain care cannot be achieved without increased access to high-quality pain treatment, developing strategies and expectations for equitable assessment and treatment of pain, and appropriate supporting programs and services (such as disability programs) for people with pain. Also needed is improved communication between service providers and people with pain and their families.

The Problem: A significant problem facing vulnerable populations arises from conscious and unconscious biases and negative attitudes, beliefs, perceptions, and misconceptions about higher-risk population groups (e.g. gender or racial bias) or about pain itself. If held by clinicians, social service program administrators, or other decision-makers, these attitudes can negatively affect the care and services they provide. For example, inappropriate or inadequate treatment may result if clinicians fail to understand or to accept that individuals differ in pain sensitivity and treatment response due to a wide range of factors. People with pain who encounter these biases can feel stigmatized, which may decrease their willingness to report pain in a timely way, participate in decisions about their care, adhere to a recommended treatment plan, or follow a self-care protocol. This perception also may negatively affect their psychological state.

An additional barrier to eliminating pain disparities is the lack of sufficient knowledge of behavioral and biological issues (e.g., genomic variability, pharmacokinetic and pharmacodynamic differences) that affect pain onset and management and data to understand patterns of pain and its treatment in higher risk and vulnerable populations.

The intent of the disparities component of the National Pain Strategy is to improve the quality of pain care and reduce barriers for all minority, vulnerable, stigmatized, and underserved populations at risk of pain and pain care disparities.

Objective 1: Reduce bias (implicit, conscious, and unconscious) and its impact on pain treatment by improving understanding of its effects and supporting strategies to overcome it.

Short-term strategies and deliverables:

- Document and expand the evidence base of adverse effects of clinician bias on the pain experience for use in developing, validating and implementing, clinician and public education, policy recommendations, and health system reforms:
 - Conduct a baseline survey of health care providers to assess their biases, attitudes, beliefs, knowledge, and behavior regarding pain among people from vulnerable populations.
 - Convene an expert group to review evidence on the impact of health care provider bias in decision-making on the pain experience (including effects on patients and treatment effectiveness) and the strategies to overcome bias (at the patient, clinician, institutional, and health system levels) and to identify gaps in knowledge. The gaps should serve as a starting point to formulate a research strategy to improve clinician education, pain care and management, and direct pain policy.

Medium-term strategies and deliverables:

- Convene an expert group to assess the role of health care provider bias in decision-making regarding integrated, multimodal, and interdisciplinary pain care, including analgesic and psychological treatment.
- Convene an expert group to assess the state of the science and promote a better understanding of biological variability, including genetic and other influences, affecting pain sensitivity and treatment response across diverse populations.
- Disseminate the proceedings of the groups to clinicians who treat pain through a manuscript in a relevant journal and other appropriate means.
- Based on the workshop recommendations and identification of evidence gaps, federal agencies should develop and support pilot projects in bias reduction.

Longer-term strategies and deliverables:

- Conduct demonstration projects based on the results of the pilot projects, to further test bias reduction strategies. These studies should be carried out in health care systems or other large population-based service delivery systems.
- Develop, implement, and evaluate policy recommendations and guidelines on bias reduction for clinicians, based on the recommendations of the work groups and the outcomes of the demonstration projects.
- *Stakeholders and collaborators:* AHRQ, Office of Minority Health, NIH, and other relevant public and private entities; professional organizations, health care providers; and other policymakers; community representatives and patient advocacy organizations; and people with pain.
- *Metrics:* extent of implementation of policy recommendations and guideline adoption; eventually, a repeat survey could assess any changes in health care provider practices and patient outcomes.

Objective 2: Improve access to high-quality pain services for vulnerable population groups.

Short-term strategies and deliverables:

- Promote awareness of current patient and provider resources that link people with chronic pain to care (e.g., programs and health centers, behavioral health providers, nursing homes, hospices, and clinician specialists).
- Develop demonstration projects of ways to improve access to current resources, including projects to determine the potential of patient-centered medical homes to serve people living with chronic pain who are at risk for disparities in care.

Medium-term strategies and deliverables:

- Develop an interactive web-based gateway to information and resources for patients and families, which could include a pain specialist locator, a link to <u>http://healthfinder.gov/</u>, and self-care tools.
- Develop demonstration projects to assess the usefulness of the information gateway in improving access to high-quality pain care among vulnerable populations.
- Promote and disseminate use of high-quality telemedicine consultations and training programs for hard-to-reach populations and for clinicians who do not practice where multidisciplinary colleagues are available.²⁵

Longer-term strategies and deliverables:

- Promote and disseminate effective models from the demonstration projects (new access models, web-based tools) through various means, and provide financial incentives to adopt them.
- *Stakeholders and collaborators:* CMS, OMH, Indian Health Service (IHS) and other relevant public and private entities (for promoting awareness within existing programs, developing demonstration projects, and evaluating existing tools); other public and private health care provider organizations (especially public-funded centers and clinics, patient-centered medical homes, and accountable care organizations); professional organizations; community representatives, patient advocacy organizations, and people with pain (to aid in assessing the information gateway, individual tools, and other web-based information products).

²⁵ Examples are the University of New Mexico's Project ECHO and the University of Washington's telemedicine program.

Metrics: changes in prevalence of untreated or inadequately treated pain among vulnerable groups in demonstration project models; number of users of the information gateway and telemedicine consultation service and their feedback.

Objective 3: Facilitate communication among patients and health professionals.

Short-term strategies and deliverables:

• Create an expert group to review and make recommendations on effects of disparities in pain care, in order to heighten national awareness, reduce the stigma of pain and support a national research agenda. Disseminate findings to the general public, researchers, health care providers, and professional organizations.

Medium- and longer-term strategies and deliverables:

- Improve the quality and certification standards of translation services for patients with low English proficiency or who have low literacy, health literacy, or communications disabilities, consistent with culturally and linguistically appropriate services (CLAS) standards.
- Develop guidelines specific to pain care, consistent with CLAS standards.
- *Stakeholders and collaborators:* AHRQ, OMH and other relevant federal agencies; health care credentialing agencies (certification standards and guidelines); health professional training programs and licensing bodies (promoting cultural competency).
- *Metrics:* increased number of staff and quality translation services in pain care settings; establishment of reimbursement models for payment of direct translation and interpreters; increased dissemination of high-quality educational materials about pain in multiple languages and at various literacy levels.

Objective 4: Improve the quality and quantity of data available to assess the impact of pain on higherrisk population groups, including data on group members' access to high-quality pain care and the costs of disparities in pain care.

Short-term strategies and deliverables:

- Develop data standards and definitions that enable tracking of pain prevalence and treatment in the full range of vulnerable populations. These standards and definitions could be applied to electronic health records, population-level surveys, and relevant clinical research.
- Create an expert group to assess the current costs of pain care disparities, including costs that result from health care utilization, lost work or educational opportunities, and use of disability and other benefits.

Medium- and longer-term strategies and deliverables:

- Develop additional data standards for national surveys and electronic health records needed to include disability and functional status relevant to pain.
- Use current and new data standards as developed above to enable national studies of pain undertreatment among vulnerable populations and to assess progress toward eliminating it.

Stakeholders and collaborators: AHRQ, CDC, ONC, NIH, and other relevant public and private entities (for research using new or existing data sets and data collection standards); the pain research community, patient advocacy organizations, and people with pain (for input on data needs, adequacy, and usability).

Metrics: increase in the number of studies conducted and published using improved data and information on the impact of pain in vulnerable populations.

Service Delivery and Reimbursement

A primary objective in enhancing the delivery of quality pain care is to make optimal pain management tailored to the individual available to all. Wide variation in clinical practice and in patients' responses to therapies, along with repeated use of relatively ineffective and potentially risky treatments, has been linked to poor quality and high costs of pain care. Because commonly used single-modality treatments often fail as first-line therapies for chronic pain, attention among leaders in the field has shifted to improving pain assessment and delivery of integrated, multimodal, interdisciplinary care that is effective and safe. The IOM report reflected this shift by advocating consistent and complete pain assessments, reimbursement reform to foster coordinated interdisciplinary care, and greater support for primary care clinicians to deliver the most effective, safe, and timely care, including more opportunities for consultations with pain specialists. The recommendations of this workgroup support a framework for which the advances in prevention and care outlined in that section of the report can be provided to all individuals with pain.

The National Pain Strategy likewise endorses a population-based, disease management²⁶ approach to pain care that is delivered by integrated, interdisciplinary, patient-centered teams and is consistent with real-world experience. To succeed, the care model must shift from the current fragmented fee-for-service approach

²⁶ *Disease management* refers to a system of integrated, multidisciplinary interventions and communications for populations with chronic disorders in which self-care efforts are significant. (Disease Management Association of America. Disease State Management Definition. Accessed at www.dmaa.org/dm_ definition.asp, March 30, 2006.)

to one based on better incentives for prevention (primary, secondary, and tertiary) and for collaborative care along the continuum of the pain experience—from acute to chronic pain across the lifespan, including at the end of life—at all levels of care and in all settings.

The Problem. Access to high-quality integrated care based on clinical evidence is hindered by many challenges, including a payment system that does not support optimal care. Pain management often is limited to pharmacological treatment offered by a single primary care practitioner or to procedure-oriented and incentivized specialty care that is not coordinated and not aligned with the best available evidence or expected outcomes. This situation is especially relevant for people with high-impact chronic pain, where integrated care is likely to be most effective. Even when interdisciplinary care is provided, creating and executing a care plan is often fragmented, with poor communication among clinicians and without consideration of patient preferences. The clinician or team's choice of therapy may be based on practice experience or on insurance coverage, rather than one informed by a comprehensive pain assessment, clinical evidence or best practices.

More quality research is needed on the effectiveness of pain interventions, integrated care, models of care delivery, and reimbursement innovations. Also needed are more effective methods to disseminate research findings and incentives to incorporate them into clinical practice. The number of level-I studies (e.g. high-quality randomized controlled trials or prospective studies) in pain is low. Patient-reported outcomes are rarely collected outside of clinical trials. Observational data and registry studies sometimes lack detail and relevant outcomes. There is a need to increase the rate of drug discovery and to raise the level of evidence for treatments in the management of pain and improve the adoption of evidence-based pain management in clinical practice.

The incongruity between high-quality care recommendations and real-world clinical practice is only partly the result of limited evidence to support existing clinical guidelines, however. Current reimbursement practices complicate development of a population-based approach that would use integrated, interdisciplinary, patient-centered teams. Payers tend to provide incentives for mono-therapy and interventional procedures instead of services that conform to the biopsychosocial model of care and incorporate pain self-management programs,²⁷ patient and family education, patient decision making, coordinated team-based medication management, counseling, cognitive-behavioral therapy, physical medicine and rehabilitation, and complementary health approaches. Current reimbursement mechanisms (see Appendix H) tied to the fee-for-

²⁷ Self-management includes nutrition and weight control, exercise and conditioning, sufficient sleep, mindfulness meditation and relaxation, engagement in meaningful activities, family and social support, and assuring a safe environment

service payment system also generally fail to support more value-driven approaches (for example, the stepped model of pain care ²⁸ and other emerging models of coordinated care).

Further hurdles to quality pain care delivery are lack of access to and reimbursement for medications, managed primarily by retail pharmacies and third-party payers. Although analgesics should not be the sole intervention for most pain conditions, medications, including opioids, may be essential for improved quality of life. Rationing, medication shortages, and inadequate reimbursement for medication management and monitoring decrease patients' access to medications, causing considerable hardship, especially for vulnerable populations.

The overall, long-term intent of this component of the National Pain Strategy is to promote coordinated care across the continuum of pain in order to conform to the biopsychosocial model and provide value, as defined by outcomes of care.

Objective 1: Define and evaluate integrated, multimodal, and interdisciplinary care for people with acute and chronic pain, and end of life pain, which begins with a comprehensive assessment, creates an integrated, coordinated, evidence-based care plan in accord with individual needs and preferences and patient-centered outcomes, and is supported by appropriate reimbursement incentives.

Short-term strategies and deliverables:

• Convene expert stakeholders to promote interest in and greater understanding of the shortcomings in quality of care and the high costs of current pain treatment approaches, the existence of more effective models, and the steps that can be taken toward achieving high quality care and outcomes.

Medium-term strategies and deliverables:

- Solicit proposals through the Center for Medicare and Medicaid Innovation for pilot projects that evaluate emerging and innovative models of integrated care for chronic pain conditions.
- Engage stakeholders and potential collaborators to conduct rigorous evaluations of pilot projects in pain care, especially approaches using the stepped model of pain care, the biopsychosocial model,

²⁸ The *stepped model of pain care* (Appendix I) is a progression from self-management to primary care to specialty care to interdisciplinary pain care. The model is geared to outcomes and value, because, when treatment on one level of care produces satisfactory results for the patient, there is no need to progress to the next, more costly and intensive level. High-impact chronic pain, which suppresses a person's overall quality of life and ability to function, optimally is treated at the higher levels.

team-based care, pain self-management approaches, and care planning based on comprehensive pain assessments.

Longer-term strategies and deliverables:

- Monitor and evaluate outcomes of the pilot projects.
- Implement and evaluate optimal models in federal, state, and private provider contexts.
- *Stakeholders and collaborators:* CMS, DoD, IHS, VHA, and other public and private entities that provide health care benefits (including PCORI; primary and specialty care clinicians; professional accreditation entities; integrated health care systems; large private third-party payers; pain advocacy organizations: and people with pain.
- *Metrics:* Positive outcomes from pilot projects on measures of physical, psychological, and functional improvement for patients, as well as cost savings relative to conventional care; incorporation of validated, successful models into health care systems and clinical practice.

Objective 2: Enhance the evidence base for pain care and integrate it into clinical practice through defined incentives and reimbursement strategies, to ensure that the delivery of treatments is based on the highest level of evidence, is population-based, and represents real-world experience.

Short-term strategies and deliverables

- Develop and implement population-based studies designed to be cost-effective, represent real-world settings, including primary care practices and pain self-management programs, and include representative samples of patients that will provide practical approaches for assessing therapeutic effects. Evidence-based outcomes from these studies can be analyzed through available pain data registries, electronic health records, population surveys, and other appropriate data sources, including the tools recommended in the Population Research section.
- Leverage existing pain registries or initiate development of suitable new pain registries to track outcomes, including patient-reported outcomes, of the pilot projects in Objective 1, and develop, standardize and integrate process and outcomes measures into electronic health records, which may then be compiled across networks.

Medium-term strategies and deliverables:

- Compile results of the pilot projects in Objective 1, the population-based studies mentioned above, and those from the large national databases recommended in the Population Research section that are relevant to treatment choices.
- Disseminate these results to clinical audiences, quality improvement initiatives, public-private partnerships, patient and advocacy organizations, and others, in order to encourage implementation of more appropriate, evidence-based care.
- Inform the design of these research projects and integrate their findings with data obtained in the national survey activities described in the population research section of the National Pain Strategy.

Longer-term strategies and deliverables

- Expand the pilot pain registries to incorporate over time, findings from other studies, including randomized controlled trials, pragmatic trials, and other high-quality research methods.
- Convene expert stakeholders from appropriate disciplines to consider the outcomes of the pilot studies on emerging models of service delivery and reimbursement and to discuss adoption of consistent clinical guidelines on pain care across clinical specialties.
- Use population-based data to inform national policy for opioid use and monitoring, including comparative effectiveness of opioids versus other forms of treatment, effectiveness of state prescription drug monitoring and point-of-care interventions to prevent abuse and misuse, and the effects of regulatory and enforcement policies (Food and Drug Administration and Drug Enforcement Agency), on abuse, misuse, and access to opioid medications.
- *Stakeholders and collaborators:* AHRQ, CDC, DoD, NIH, VHA, and other relevant public and private entities that support population-level research: PCORI; private payers, private agencies and software experts developing electronic medical records and other relevant programs, integrated health systems, and; health professions organizations, including credentialing bodies; primary care and specialty clinicians; pain advocacy organizations; and people with pain.
- *Metrics:* incorporation of validated, successful models and practices from the pilot projects into provider practices and health care systems; outcomes of evaluated interventions and care, including patient and family assessments and costs, as compared to usual treatment; adoption of evidence-based practice guidelines for multiple disciplines.

Objective 3: Tailor reimbursement to promote and incentivize high-quality, coordinated pain care through an integrated biopsychosocial approach that is cost-effective, comprehensive, and improves outcomes for people with pain.

Short-term strategies and deliverables:

- Identify and invest in the development of models of care that deliver high-value pain care that simultaneously maximizes patient benefit and minimizes risk and costs.
- Identify, measure, and control variations in pain care that lead to low-quality or high-cost care.

- Develop new tools to facilitate payment for higher quality pain care.²⁹
- Define, identify, and engage eligible pain care clinicians willing to participate in quality and utilization reporting, including those participating in existing programs, such as the Medicare Physician Quality Reporting System.

Medium-term strategies and deliverables:

• Develop and test methodologies for defining episodes of care related to pain conditions to inform payment models and identify where pain should be included as a critical outcome of existing episode-based payment models.

Longer-term strategies and deliverables:

- Develop and support pilot projects to test and rigorously evaluate the impact of reimbursement innovations on pain care quality measures and cost savings.
- Disseminate results of the pilot projects to public and private payers for consideration in updating their reimbursement policies and practices.
- Develop clinical quality measures and clinical decision support for pain care.
- Make clinical quality measures for pain and associated decision support part of incentive programs.
- Stakeholders and collaborators: relevant federal agencies and other entities (including AHRQ, CMS, DoD, National Library of Medicine (NLM), ONC, and VHA), accountable care organizations; state Medicaid programs; integrated health care systems; private payers; private agencies and software experts developing electronic medical records and other relevant programs, health service researchers; primary care and specialty clinicians; private payers, professional organizations; health care quality organizations (including the National Quality Forum); pain advocacy organizations; and people with pain.
- *Metrics:* proportion of payments under the demonstrations that successfully support integrated care data; development of quality measures for integrated pain care, outcomes of care, including patient and family assessments, and impact on costs (for the demonstrations).

²⁹ An example would be episode groupers, which are software programs that organize claims data into clinically coherent episodes based, typically, on diagnosis. As designed for use by the Centers for Medicare and Medicaid Services and other payers, they help in identifying high-cost providers and also could be used for reimbursement purposes, much as diagnosis-related groups have been used in hospital reimbursement.
Professional Education and Training

Pain is one of the most common reasons for health care visits. Nonetheless, most professional health care education programs devote little time to education and training about pain and pain care. Given "strong indications that pain receives insufficient attention in virtually all phases of medical education," the IOM report found "[e]ducation is a central part of the necessary cultural transformation of the approach to pain" and recommended improvement in the curriculum and education for health care professionals.³⁰

To assure the needed improvement, education and training must allow learners to achieve disciplinespecific core competencies, which include empathy and cultural sensitivity, across a broad range of disciplines and prepare them to provide high quality team-based care for pain. Demonstration of competency in pain assessment, safe and effective pain care, and the risks associated with prescription analgesics should be a requirement for licensure and certification of health professionals and should be considered in curriculum review for accreditation of health professional training programs. These training enhancements should be developed in collaboration with relevant accrediting bodies and certifying boards to promulgate their use. Sub-specialty training and certification should include training in effective team management for patients with the most complex pain conditions.

The Problem: The high prevalence of pain across the population and its impact on individuals and families creates a significant responsibility for health care professionals. Despite the need to address this public health problem, many health professionals, especially physicians, are not adequately prepared and require greater knowledge and skills to contribute to the cultural transformation in the perception and treatment of people with pain. Education and training of health professionals in the complex etiology, prevention, assessment, safe and effective treatment of pain, and risks associated with poor pain management is insufficient, in part because educators lack access to valid information about pain and pain care. Core competencies in pain care are not fully developed and generally do not inform undergraduate (pre-licensure) curricula in health professions schools or graduate training programs, even those in pain medicine. As a result, practitioners may rely primarily on procedural or pharmacological approaches that alone are not effective and may have significant unintended adverse consequences such as addiction and medication misuse for which many health care providers lack skills and knowledge to identify and manage.

³⁰ IOM, 2011, p. 191, Finding 4-1, and Recommendation 4-2.

Moreover, cultural bias exists in the medical community against people with pain, especially those with chronic pain, which can negatively affect patient care and reinforce pain stigma. This bias and the documented decline in empathy as medical training progresses³¹ may be interrelated, in the case of pain care, and exacerbated by knowledge deficits, frustration with the limited effectiveness of usual treatments for chronic pain, and the complex nature of pain and pain care.

The intent of the professional education and training component of the National Pain Strategy is to anchor an attitudinal transformation toward pain and a reorganization of pain management by the health care system, in the education and training of health professionals. The mission includes grounding the pain-related education and training of physicians, nurses, clinical pharmacists, dentists, clinical health psychologists, physician's assistants, nurse practitioners, and other health professionals in core competencies, and making available easily accessible, evidence based information for educators to work toward this goal.

Objective 1: Develop, review, promulgate, and regularly update core competencies for pain care education and licensure and certification at the undergraduate and graduate levels.

Short-term strategies and deliverables:

- Convene an expert group that includes all relevant undergraduate health professions to review, revise, and promote the set of interdisciplinary core competencies that have been developed for undergraduate education in pain and pain care (Appendix J). The expert group should devise plans to incorporate the competencies into their programs, beginning with selected sites for piloting curricular changes. The relevant accrediting, certification, and licensing entities should be involved at early planning and subsequent phases of this strategy.
- Examine subspecialty training and certification in pain medicine through the planned effort of the Accreditation Council for Graduate Medical Education (ACGME), to assure that pain specialists are effectively trained to lead clinical teams in managing the most complex and challenging patients with acute and chronic pain and to provide needed support for formal and informal clinical medical education. Enhance team management training in currently existing ACGME- accredited programs (e.g. ACGME pain medicine residency requirements). Extend this examination to include nursing,

³¹ Neumann, M., F. Edelhäuser, D. Tauschel, M.R. Fischer, M. Wirtz, C. Woopen, A. Haramati, and C. Scheffer. 2011. Empathy decline and its reasons: A systematic review of studies with medical students and residents. *Acad Med* 86(8): 996-1009.

clinical pharmacy, clinical health psychology, and other relevant health professional training schools and programs.

• Solicit input from the public, including people with pain, professional organizations, and students, to enhance clinical empathy, cultural competency, and expanded patient-centered communication for people with pain, based on impact, feasibility, and ease of dissemination.

Medium-term strategies and deliverables:

- Promulgate interdisciplinary core competencies for undergraduate education for use in professional licensure examinations and educational accreditation standards.
- Convene an expert group from pain-relevant primary care specialties, including internal medicine, family medicine, pediatrics, obstetrics/gynecology to develop and promote core primary care competencies by building on the interdisciplinary core competencies and to approach ACGME regarding incorporation into relevant ACGME program requirements; participation from equivalent groups and accreditation boards in advanced practice nursing and physician assistant fields should be integrated into this process.
- Convene accrediting (e.g. ACGME, LCME) and certifying organizations and related groups to develop consensus and an implementation plan on the depth with which competency in pain care is integrated into health professions education, accreditation, and certification.
- Develop empathy-enhancing projects based on the solicited input.

Medium- and longer-term strategies and deliverables:

- Publish and promulgate core competencies in graduate education and training in primary care, through a work group convened for this purpose and in collaboration with relevant accrediting bodies.
- Develop and review, promote, and publish core competencies in pain care in relevant specialties, replicating the same general process used in primary care.
- Commission a baseline evaluation of the use of core competencies in undergraduate, graduate primary care and graduate specialty education and training, evaluate them over time to determine progress, and regularly update them.
- Evaluate the projects for enhancing empathy to determine their suitability for widespread use, and implement them accordingly.

Stakeholders and collaborators: CDC, FDA, Substance Abuse and Mental Health Service Administration (SAMHSA), and VHA, in collaboration with HRSA (as appropriate to their statutory priorities and within their authority) and other relevant federal agencies, and accreditation, certification, and licensing entities, including ACGME and Residency Review Committees, Association of American Medical Colleges, Liaison Committee on Medical Education, American Board of Medical Specialties, American Osteopathic Association, Coalition for Physician Accountability, Commission on Collegiate Nursing Education, Accreditation Commission for Education in Nursing, the Department of Education, the United Council for Neurological Subspecialties, selected specialty accreditation and certification bodies for physicians and nurses, related professional associations, equivalent groups in dentistry, clinical pharmacy, physical therapy, physician assistants, clinical health psychology and other relevant health

professions); pain advocacy organizations, and opioid use disorder advocacy organizations; and people with pain.

Coordinate with ongoing activities across HHS (including FDA, SAMHSA) on health care provider prescriber knowledge and skills for safe prescribing practices and identification of risks for opioid use disorder.

Metrics: validity and reliability of core competencies.

Objective 2: Develop a pain education portal that contains a comprehensive array of standardized materials to enhance available curricular and competency tools. The portal will serve as a central, comprehensive source for pain education materials and will be monitored regularly and updated as new evidence-based guidelines and resources are available. The need for knowledge and skills that address how clinician empathy influences the effectiveness of care should be included in the available educational materials. *Short-term strategies and deliverables:*

- Convene expert stakeholders to survey current resources, link to other relevant electronic artifact portals, and determine the content for a pain education portal. The portal would contain evidence-based and/or peer reviewed best practices material about pain care and pain for use by educators and learners.
- Develop and evaluate a pilot portal that leverages the NIH Pain Consortium Centers of Excellence in Pain Education Coordination Center contract.

Medium-term strategies and deliverables:

- Launch the portal.
- Reconvene stakeholders to develop an annual survey to measure individual school's progress in teaching about pain. Systematic reviews of studies about pain education would be a starting point in developing the content of the survey.
- Conduct the initial survey of schools.

Longer-term strategies and deliverables:

- Monitor and keep updating the portal, which would be fully developed over a five-year horizon.
- Repeat the survey of schools and otherwise monitor pain education to assure that core competencies are taught.

Stakeholders and collaborators: AHRQ, CDC, FDA, NLM, ONC, SAMSHA, and other entities (including the DoD and VHA) (to leverage current resources, e.g. AHRQ's; United States Health Knowledge Information Data Base) develop content and architecture and strategies to monitor and promote the portal); professional organizations, and educators (to help develop survey and portal content); pain advocacy organizations; and people with pain.

Coordinate with resources developed across HHS, including FDA, SAMHSA, on health care provider prescriber educational resources for safe prescribing practices and identification of risks and care for opioid use disorder.

Metrics: Results of the annual survey of schools, to be promptly reported; use of the portal (such as frequency of access and downloading of materials) and user ratings; use of the survey results.

Public Education and Communication

The Institute of Medicine considered education central to a cultural transformation in pain care and recommended expanded and redesigned programs aimed at increasing public and patient understanding of pain. A national pain awareness campaign could draw on the experience of numerous federal agencies that have managed communications campaigns about public health topics as diverse as childhood immunizations, tobacco control, HIV/AIDS, depression, and nutrition.

Such campaigns generally involve numerous public and private partner organizations, each able to reach different segments of the population, use multiple media (including entertainment and social media), and require careful planning, research on audience segments' attitudes and beliefs and receptivity to test messages, and evaluation. A campaign with multiple components, heavy media buys, and other activities can be quite costly, which underscores the importance of focus and solid strategy development.

The National Pain Strategy envisions a significant effort to increase public awareness about pain and recommends two campaigns.³² The priority campaign is an extensive public awareness campaign about pain, and the secondary campaign would promote safe medication use by patients. Both should integrate health literacy principles and cross-cultural awareness and be tailored to specific audiences segmented by health status, demographic and cultural characteristics, and preferred informational media. These campaigns should be undertaken in such a way that they do not compete.

³² In general, the planning and implementation for the campaigns follow the stages outlined in the National Cancer Institute's Making Health Communication Programs Work (<u>http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook/page1</u>).

The Problem: Pervasive stigma and misperceptions about pain are a root cause of significant and costly barriers to treatment and make it difficult for people with chronic pain to live productively and with dignity. Education is key to unlocking a necessary cultural transformation in the understanding of chronic pain, its care and treatment. In part, these problems arise because of the lack of high-quality, evidence-based communications campaigns that:

- Increase public awareness and knowledge about the pervasiveness of chronic pain, its complexity, and the importance of access to prompt and effective treatments
- Change cultural attitudes about chronic pain, debunking stereotypes and myths related to people with chronic pain and various pain treatment options and emphasizing the value of pain self-management programs in enabling people to live better with chronic pain
- Foster coalitions involving federal agencies, health care professionals and institutions, training and accreditation agencies, insurers, employers, foundations, patient advocate organizations, and others to participate in such campaigns and promote core messages, and
- Provide provider, public and patient education on the safe use of pain medications, including awareness of the risks for opioid misuse disorders that are associated with prescription pain medications.

The intent of the public education and communication component of the National Pain Strategy is to assure that chronic pain is recognized as a serious public health issue in the United States and that people with chronic pain have timely access to appropriate, safe pain care

Objective 1: Develop and implement a national public awareness and information campaign about the impact and seriousness of chronic pain, in order to counter stigma and correct common misperceptions.

Short-term strategies and deliverables:

- Select a broadly representative advisory panel of stakeholders, to include patients with pain and members of their families, advocacy groups, professional societies, policy groups, and others, as described below.
- Define campaign objectives, including intended audiences, advisory structure, and budget (potential learning objectives are in Appendix K).
- Develop requests for proposals for strategic communications firms to develop and conduct the campaign, review proposals, and select a firm (a separate firm may be engaged to conduct the evaluation).
- The selected firm would, as needed:
 - review available psychographic information regarding attitudes about pain (in the general population, in population subsets of interest, and in key stakeholder groups) and commission additional research, including surveys
 - review available evidence about settings, channels, and activities best suited to reach these audiences, and commission additional research
 - o review existing information and educational materials
 - \circ develop a communications strategy for each targeted audience, and

- work with the advisory board to identify and recruit partner organizations and define their roles in the campaign.
- Based on this preliminary work, develop and pretest messages and materials, using, wherever possible, information developed by other components of the National Pain Strategy

Medium-term strategies and deliverables

- Implement the program, including partner participation strategies, spokesperson training, and program-related services (e.g., pain self-management programs suggested in the Prevention and Care section), media (news, entertainment, social) strategies, and promotional materials.
- Monitor audience reach and feedback and partner engagement; adjust strategies as necessary.

Longer-term strategies and deliverables

- Conduct an outcome evaluation to assess campaign effectiveness, as measured by changes in public opinion related to the campaign's learning objectives (e.g., the percent who agree "chronic pain is a disease").
- Prepare a report based on the campaign evaluations for submission to a peer-reviewed scientific journal.
- As funds are available, continue to implement, assess, and adapt campaign components, as needed, and report on campaign outcomes in a peer-reviewed journal.

Stakeholders and collaborators: relevant federal agencies; public health organizations; professional organizations; insurers; human resources professionals; clinicians; patient advocacy organizations; and people with pain.

Metrics: the outcome evaluations would provide current data on public attitudes and those of relevant demographic or other subgroups.

Objective 2: Develop and implement a national educational campaign encouraging safe medication use, especially opioid use, among patients with pain.

Short-term strategies and deliverables:

- Identify an HHS team and select an advisory board with broad representation, including people with pain, as well as experts in health communications and public relations, to develop, plan, implement, and evaluate the campaign. The selected team would:
 - define the advisory structure and budget
 - o review existing information and educational materials
 - review available research on attitudes, knowledge, and medication practices of patients with chronic pain who take opioid medications
 - review available evidence about settings, channels, and activities best suited to reach these patients, and commission additional research, as needed
 - o develop a communications strategy, and

- o identify and recruit partner organizations.
- Align campaign messages and approaches with ongoing HHS efforts to promote safe and appropriate use of prescription medications, such as electronic prescribing of controlled substances (EPCS).
- The campaign should cover the learning objectives and outcomes outlined in Appendix L.
- Based on this preliminary work, develop and pretest messages and materials.

Medium-term strategies and deliverables

• Implement the program, including partner participation strategies, spokesperson training, programrelated services (e.g., a hotline), media (news, entertainment, social) strategies, and promotional materials.

• Monitor campaign reach and feedback and partner engagement; adjust strategies as necessary. *Longer-term strategies and deliverables*

- Conduct an outcome evaluation through nationally representative surveys and when appropriate through pre- and post-test surveys, using outcome measures tailored to the learning objectives to assess campaign effectiveness.
- Conduct a five- to 10-year progress assessment of the issue of safe use of pain medications.
- Prepare reports based on the campaign evaluations for submission to a peer-reviewed scientific journal.
- Continue to implement, assess, and adapt campaign components, as needed, and report on campaign outcomes in a peer-reviewed journal.

Stakeholders and collaborators: relevant federal agencies/offices, including FDA, ODPHP, SAMHSA, public health organizations; professional organizations; insurers; human resources professionals; clinicians; credentialing bodies (e.g., the Federation of State Medical Boards), major retail pharmacy chains, the National Association of Boards of Pharmacy, professional pharmacy organizations and pharmacists; pain patient advocacy organizations; and people with pain.

Metrics: the outcome evaluations would provide current data on the medication practices of patients with pain, which ideally could be compared with baseline data to determine any short-term trends.

APPENDIXES

- A. List of oversight panel members
- B. List of working group members, expert consultants, and staff
- C. Member nomination process and conflict of interest disclosure
- D. Chronic pain screener questions
- E. Operational questions for determining high-impact chronic pain
- F. Diagnostic clusters for population pain research
- G. Pain treatment indicators: Health care services for pain measurable with electronic health care data
- H. Public and private payer coverage and reimbursement methodologies for pain-related treatments
- I. The Stepped Care Model of pain care
- J. Core competencies for pain education
- K. Public education general campaign learning objectives

L. Learning objectives and potential outcome measures for an educational campaign on safe use of pain medications

Appendix A. List of Oversight Panel Members

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Appendix C. Member nomination process and conflict of interest disclosure

The National Pain Strategy (NPS) is a nationwide plan to address the core recommendations of the Institute of Medicine's (IOM) report, <u>Relieving Pain in America</u>, on pain prevention, treatment, management, education, and research. The entity charged by HHS to address the IOM recommendations is the Interagency Pain Research Coordinating Committee (IPRCC), which was established under the Patient Protections and Affordable Care Act and, as such, is subject to rules and guidelines of the Federal Advisory Committee Act (FACA). The IPRCC's Task Force of experts, established to develop the NPS plan, also falls under the FACA rules and guidelines.

The Task Force is organized into six thematic working groups and an oversight panel and comprises approximately 80 members, with broad representation and expertise in accord with the recommendations of the IOM committee. Screening and selection of the NPS Task Force members was a multi-step process, performed according to FACA's requirements. A call for nominations was made through distribution to advocacy groups, professional societies, website notification, and email distribution. It was published as a Federal Register Notice as well. Candidates were selected based on expertise and knowledge, and the overall Task Force representation fulfilled IOM recommendations. A working group of the IPRCC screened and approved the slate of working group members.

Nominees were informed of the nature of conflicts of interests that would preclude their service and were required to disclose any potential conflicts and the nature of the conflicts. They were also required to disclose whether they were registered lobbyists, which precludes service under FACA. Conflict of interest disclosures were reviewed by the FACA Committee Management Officer and the IPRCC's Designated Federal Officer. If potential conflicts were identified, the nominee's conflict situation was reviewed by the NINDS Deputy Ethics Counselor to determine eligibility for service on the working group.

The working groups were advised of the needs and guidelines to protect the confidentiality of discussions to develop the NPS. Requests from all outside entities to present or provide unsolicited information to the working groups during the process were directed to the IPRCC's Designated Federal Officer.

Appendix D. Chronic pain screener questions

Definition	Item	Criteria
Pain on at least half the days for 6 months	 Over the last six months, on about how many days have you had pain? I have not had pain I have had pain, but on less than half the days I have had pain on more than half the days, but not every day I have had pain every day, but not all the time I have had pain all day, every day, without break 	Chronic pain is pain on at least half the days over the past six months.
Chronic pain severity (mild, moderate, severe)	In the past 7 days, how would you rate your pain on average? 0=No pain 10= Worst imaginable pain	Mean or sum of the three 0-10 pain ratings.
	In the past 7 days, how much did pain interfere with <u>your</u> <u>day-to-day activities</u> ?	<u>Mean Sum</u>
	0=No interference 10=Completely interferes	Mild < 4 < 12
	0-100 interference 10-Completery interferes	Moderate $4 \text{ to} < 7$ 12 to 20
	In the past 7 days, how much did pain interfere with <u>your</u> <u>enjoyment of life</u> ? 0=No interference 10=Completely interferes	Severe 7 to 10 21 to 30
		NOTE: If only two pain ratings are available, divide by the sum by two and multiple by 3 to obtain an estimated sum score.

Appendix E. Operational questions for determining high-impact chronic pain

• • •	with chronic pain (as determined by screener questions in Appendix operationally defined by enduring participation restrictions because	· • •
Participation restrictions because of pain	 Over the past 6 months because of pain I have had trouble doing my usual work (including work for pay, work around the home, volunteer work). Never Rarely Sometimes Usually Always I have had trouble doing my regular social and recreational activities (such as visiting friends, going to the movies, 	At least one item
	attending clubs or religious activities). Never Rarely Sometimes Usually Always	rated "usually" or "always"
	I have had trouble taking care of myself (for example dressing, bathing, or feeding myself).	
	Never Rarely Sometimes Usually Always	

Appendix F. Diagnostic clusters for population pain research

1. Back pain
2. Neck pain
3. Limb/extremity pain, arthritis disorders (including osteoarthritis and joint pain)
4. Fibromyalgia and wide-spread muscle pain
5. Headache
6. Orofacial, ear, and temporomandibular disorder pain
7. Abdominal pain and bowel pain
8. Chest pain
9. Urogenital, pelvic, and menstrual pain
10. Fractures, contusions, sprains and strains
11. Other painful conditions.
This includes sickle cell disease, complex regional pain syndrome, systemic lupus
erythematosus, acquired deformities (excluding spinal disorders), spinal cord injury,
Lyme disease, Neuropathic pain. Note: Cancer pain is included here, but relevant
diagnostic codes need to be identified.

Type of service	Sub-types	Notes	Identification
Professional	Primary care visits		Provider codes in
services			combination with
	Pain specialist visits	Differentiate type of specialist (e.g. neurology,	Diagnostic Clusters.
		orthopedic surgery, rehabilitation medicine,	
		anesthesiology, rheumatology)	
	Physical therapy visits		
	Occupational therapy visits		
	Psychologist visits		
	Chiropractic visits	These may not be routinely available in many	
	Alternative/complementary	electronic health care databases.	
	care visits		
Oral medications	Opioids	Differentiate short-acting and extended release.	National Drug
		Chronic use may be defined by 70+ days supply in a	Classification (NDC)
		90 day period, receiving 6+ dispensings in a year, or	codes) in combination
		other indication of sustained use.	with Diagnostic Clusters
	NSAIDS	Only available when prescribed, not over-the-counter.	when necessary
	Sedatives, anti-anxiety	Chronic use may be defined by 45+ days supply in a	
	agents, sleep medications	90 day period or other indication of sustained,	
	and muscle relaxants	frequent use.	
	Tryptans		
	Anticonvulsants		
	Antidepressants	SSRI, SNRI, Tricyclic antidepressants and other	
		heterocyclic medications may be differentiated.	

Aspirin and	These will not be adequately captured by electronic	
acetaminophen	health care data because they are generally taken	
	over-the-counter	
Surgery	Differentiate anatomical site of surgery (back, hip,	Procedure codes in
	knee, shoulder, etc.) and type of surgery within	combination with
	anatomical site (e.g. laminectomy, fusion, discectomy	Diagnostic Clusters when
	for back surgery).	necessary
Injections, blocks and	Differentiate type (e.g., epidural steroid injections,	
infusions	selective nerve root blocks, trigger point injections,	
	facet point injections, sympathetic nerve root blocks,	
	joint injections, peripheral nerve blocks).	
TENS, spinal cord		
stimulation, deep brain		
stimulation		
Surgical admission		Diagnostic codes
Non-surgical admission		identifying primary
		reason for admission
	acetaminophen Surgery Injections, blocks and infusions TENS, spinal cord stimulation, deep brain stimulation Surgical admission	acetaminophenhealth care data because they are generally taken over-the-counterSurgeryDifferentiate anatomical site of surgery (back, hip, knee, shoulder, etc.) and type of surgery within anatomical site (e.g. laminectomy, fusion, discectomy for back surgery).Injections, blocks and infusionsDifferentiate type (e.g., epidural steroid injections, selective nerve root blocks, trigger point injections, facet point injections, sympathetic nerve root blocks, joint injections, peripheral nerve blocks).TENS, spinal cord stimulationInjections, blocks selective nerve root blocks, trigger point injections, surgical admission

Public & Private Payer Coverage of Pain-Related Treatments								
Payor	Pain-related Treatments							
	Medications	Regional Anesthetic Interventions	Surgery	Psychological Therapies	Rehabilitative/Physical Therapy	Complementary and Alternative Medicines (CAM)		
Medicaid	х	No state specific data found	х	х	х	X ⁵		
Medicare	х	x	Х	X ³	X ⁴	X ⁵		
Private Insurers (BCBSM example)	х	x	x	x	х	х		
Veterans Health Administration (VHA)	х	x	х	х	х	X ⁶		
U.S. Department of Defense (DoD)/ TRICARE ¹	х	x	x	x	х	x ⁷		
Federal and State Workers'	State: X Federal: X	State: X Federal: X	State: X Federal: X	<i>State:</i> No state specific data found	State: X Federal: X	<i>State:</i> No state specific data found		

Appendix H. Public and private payer coverage and reimbursement methodologies for pain-related treatments

Compensation Programs ²				Federal: X		Federal: X		
"X" indicates the payer	"X" indicates the payer offers coverage for procedure(s) within the treatment category							
					port contracts. The program off ve care from private health care			
become ill in the course the congressionally appr	of their federal employm	ent. FECA covers all m ees' Compensation Fu	edical costs associated nd. In contrast, state v	d with the treatment of the vorkers' compensation pro	rovides medical benefits to emp e work-related injury or illness. ograms are regulated by the stat	FECA benefits are paid out of		
³ In 2014, Medicare ben percent.	eficiaries will be responsil	ble for paying a 20% c	oinsurance for outpati	ent psychological counseli	ng services. In previous years th	ne coinsurance was 35-40		
				or 2014, Medicare has a \$2 ot to institute a therapy ca	1,920 annual cap for physical an p.	nd speech therapy and a		
					ipulation of the spine to treat a covered other CAM services, inc			
⁶ Every VHA provider ha	s a specific requirement t	o make chiropractic se	ervices available onsite	2.				
⁷ While some military m under TRICARE.	edical facilities may offer	services like acupunct	ure and chiropractic c	are, these are reserved for	active duty members only. CAN	vi services are largely excluded		
Congress: Complementa Comprehensive Policy O	ry and Alternative Medic	ine within the Military ne Military Health Care	Health System, 2011;	Department of Defense, R	BSM; TRICARE; VHA; Departmer eport to the Congress: The Imp ederal Employees' Compensatio	lementation of a		

Public & Private Reimbursement Methodologies for Pain-Related Treatments							
Payor ¹	Pain-related Treatments						
	Medications	Regional Anesthetic Interventions	Surgery	Psychological Therapies	Rehabilitative/Physical Therapy	Complementary and Alternative Medicines (CAM)	
Medicaid ²	States use varied methods. Most estimate the acquisition cost for a prescription drug and add a dispensing fee.	No state specific data found	Varies by state	35 states use fee-for-service to reimburse for psychologist services for individuals enrolled in adult Medicaid.	 33 states use fee-for-service to reimburse for occupational therapy services for individuals enrolled in adult Medicaid. 35 states and DC states use fee-for-service to reimburse for physical therapy services for individuals enrolled in adult Medicaid. 	26 states use fee-for services to reimburse for chiropractic services for individuals enrolled in adult Medicaid.	
Medicare	Medicare Part D sponsors negotiate prices with pharmacies and manufacturers. The negotiated price includes the ingredient cost and dispensing fee.	Fee-for-Service	Fee-for-Service and Prospective Payment System	Fee-for-Service	Fee-for-Service (Outpatient Facility) and Prospective Payment System (Inpatient and Nursing Facility)	Fee-for-Service	
Private Insurers (BCBSM example)	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service	

Veterans Health Administration (VHA) ³	VA negotiates pricing and purchases directly from wholesalers and manufacturers.	Global Budget	Global Budget	Global Budget	Global Budget	Global Budget
U.S. Department of Defense (DoD)/ TRICARE ⁴	DoD negotiates prices with pharmacies and manufacturers.	Fee-for-Service	Fee-for-Service and Prospective Payment System	Fee-for-Service	Fee-for-Service and Prospective Payment System	Fee-for-Service
Federal and State Workers' Compensation Programs ⁵	<i>State:</i> Varies by state <i>Federal:</i> Based on the Average Wholesale Price (AWP) for prescription drugs plus a dispensing fee, or on the Usual and Customary charge amount (whichever is less).	<i>State:</i> Fee-for- Service <i>Federal:</i> Fee- for-Service	<i>State:</i> Varies by state <i>Federal:</i> Fee-for- Service and Prospective Payment System	<i>State:</i> Fee-for- Service <i>Federal:</i> Fee-for- Service	<i>State:</i> Varies by state <i>Federal:</i> Fee-for-Service and Prospective Payment System	<i>State:</i> Fee-for- Service <i>Federal:</i> Fee-for- Service

¹ All payers appear to be relying largely on single modality approaches.

² In July 2011, almost 75% of Medicaid beneficiaries were enrolled in a managed care program. Benefits that are not included in a state's managed care contract are often provided on a fee-for-service basis or by a non-comprehensive prepaid health plan.

³ The VHA, within the Department of Veterans Affairs, is appropriated a fixed amount of funds by Congress. Those funds are distributed to 23 regional service networks. The amount distributed to each region is determined by the Veterans Equitable Resource Allocation (VERA) system, an allocation method based on the number of patients served in the region and the severity of their conditions. VHA facilities do bill third-party payers (e.g., private insurance) for nonservice-connected care. The funds generated from third-party payers go to the billing VHA facility. The VHA does reimburse for care provided at non-VHA facilities, using fee-for-service, when a veteran is unable to access care at a VHA facility in emergencies, if a covered service cannot be provided at a VHA facility, or due to geographic inaccessibility.

⁴ Reimbursement rates for TRICARE are generally aligned with Medicare. Health care providers who are employed at military medical facilities are salaried, like the VHA, and do not receive reimbursements from TRICARE for the care they provide.

⁵ Reimbursement rates for the services covered by FECA are determined by the Department of Labor's Office of Workers' Compensation Programs fee schedule, which are generally aligned with Medicare. Similar to FECA, fee-for-service is the most common payment method among state workers' compensation programs. Payments made under state programs are generally greater than Medicare payments.

Sources: Kaiser Family Foundation, State Facts, Medicaid Benefits, 2011; Centers for Medicare & Medicaid Services; BCBSM; Congressional Research Service, Military Medical Care: Questions and Answers, January 2014; Congressional Research Service, Health Care for Veterans: Answers to Frequently Asked Questions, February 2014; Government Accountability Office, Access to Civilian Providers under TRICARE Standard and Extra, June 2011; U.S. Department of Labor, OWCP Medical Fee Schedule 2013.



Appendix J. Core competencies for pain education

Core competencies for pain management from an inter-professional consensus summit have been endorsed widely and supported by national healthcare organizations across the major health professions. These may serve as a starting point for accrediting and credentialing organizations to help guide educators to develop and revise curriculum that advances care for effectively preventing and managing pain.

Box 1 Pain management domains and core competencies

Domain one

Multidimensional nature of pain: What is pain?

This domain focuses on the fundamental concepts of pain including the science, nomenclature, and experience of pain, and pain's impact on the individual and society.

- 1. Explain the complex, multidimensional, and individual-specific nature of pain.
- 2. Present theories and science for understanding pain.
- 3. Define terminology for describing pain and associated conditions.
- 4. Describe the impact of pain on society.
- 5. Explain how cultural, institutional, societal, and regulatory influences affect assessment and management of pain.

Domain two

Pain assessment and measurement: How is pain recognized?

This domain relates to how pain is assessed, quantified, and communicated, in addition to how the individual, the health system, and society affect these activities.

- Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population.
- Describe patient, provider, and system factors that can facilitate or interfere with effective pain assessment and management.
- 3. Assess patient preferences and values to determine pain-related goals and priorities.

4. Demonstrate empathic and compassionate communication during pain assessment.

Domain three

Management of pain: How is pain relieved?

This domain focuses on collaborative approaches to decision-making, diversity of treatment options, the importance of patient agency, risk management, flexibility in care, and treatment based on appropriate understanding of the clinical condition.

- Demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care.
- 2. Identify pain treatment options that can be accessed in a comprehensive pain management plan.
- 3. Explain how health promotion and self-management strategies are important to the management of pain.
- 4. Develop a pain treatment plan based on benefits and risks of available treatments.
- 5. Monitor effects of pain management approaches to adjust the plan of care as needed.
- 6. Differentiate physical dependence, substance use disorder, misuse, tolerance, addiction, and nonadherence.
- Develop a treatment plan that takes into account the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life.

Domain four

Clinical conditions: How does context influence pain management?

This domain focuses on the role of the clinician in the application of the competencies developed in domains 1-3 and in the context of varied patient populations, settings, and care teams.

- 1. Describe the unique pain assessment and management needs of special populations.
- 2. Explain how to assess and manage pain across settings and transitions of care.
- Describe the role, scope of practice, and contribution of the different professions within a pain management care team.
- Implement an individualized pain management plan that integrates the perspectives of patients, their social support systems, and health care providers in the context of available resources.
- 5. Describe the role of the clinician as an advocate in assisting patients to meet treatment goals.

Appendix K. Public education general campaign learning objectives

To increase public awareness about pain and people with pain, the committee recommends developing a campaign that will cover the following learning objectives (listed in order of priority):

- 1. Chronic pain is a disease.
- 2. Chronic pain is manageable.
- 3. Chronic pain is more prevalent than cancer, diabetes, and heart disease combined.
- 4. Chronic pain is real.
- 5. Most Americans will experience chronic pain or care for someone with chronic pain.
- 6. People in chronic pain deserve respect, compassion, and access to timely treatment.
- 7. Many people in chronic pain nevertheless live productive lives.
- 8. Chronic pain may cause depression and depression increases the severity of pain.
- 9. Chronic pain may require a spectrum of medical treatments and/or non-medical interventions along with the active participation of people with chronic pain in their own pain care management.
- 10. Appropriate chronic pain management may involve prescription medications, which require knowledge of risks for adverse effects such as dependency and addiction.
- 11. Activity level and mood may vary depending on the intensity of chronic pain (good days and bad days).

Appendix L. Learning objectives and potential outcome measures for an educational campaign on safe use of pain medications

Learning Objectives

Increasing the number of people with chronic pain who report that they:

- 1. Talk with their clinician about their hopes and expectations and share activities of daily living or function that are important to them.
- 2. Work with their clinician to develop a plan of treatment consistent with their goals.
- 3. Know that analgesic medications can be an appropriate pain management option, but they are not the only option.
- 4. Know their prescription medication is only for them and do not share it with others.
- 5. Store their medicine in a safe place where children or pets cannot reach it.
- 6. Dispose of unused medication properly.
- 7. Take medicine only if it has been prescribed or approved by their doctor.
- 8. Do not take more medicine or take it more often than instructed. They call their doctor if their pain worsens.
- 9. Know how to understand and recognize expected and unexpected adverse effects such as dependency and addiction and to discuss risks with their doctor.
- 10. They talk to their doctor before taking prescription medications in combination with other drugs, including alcohol, sleeping pills, or anti-anxiety medication.
- 11. Have discussed with family and friends how to recognize and respond to overdose.

Potential Outcome Measures

Where possible, existing data sources should be employed to monitor measures such as:*

- 1. Proportion of patient who
 - a. discuss daily activities (quality of life) with their physician
 - b. discuss expectations about the outcomes of pain treatment and side effects with their physician
 - c. have a functional contract (defined) with their physician and discuss with their doctor appropriate alternative treatments (NSDUH)
- 2. Number of patients taking opioids who:
 - a. report storing their medication safely
 - b. do not save back medications (CPDA)
 - c. dispose of unused medication properly (CPDA)
 - d. take opioids not prescribed for them (NSDUH)
 - e. take higher doses or more frequent doses than prescribed (DAWN)
 - f. report calling their doctor if pain worsens
 - g. report mixing pain medicines with alcohol, sleeping pills, or any illicit substance (DAWN).
- 3. Number of overdoses reported in national emergency department data (DAWN).

*Potential data sources for some of these research questions are: the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health (NSDUH) and Drug Abuse Warning Network (DAWN), and Research America's National Poll on Chronic Pain and Drug Addiction (CPDA).