



# National Pain Strategy

**A Comprehensive Population Health-Level Strategy for Pain**



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## EXECUTIVE SUMMARY

In 2010, 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 resulting 2011 IOM 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.<sup>1</sup> In response to the report, the Assistant Secretary for Health, Department of Health and Human Services (HHS) asked the Interagency Pain Research Coordinating Committee (IPRCC) to oversee creation of this National Pain Strategy (NPS). Experts from a broad array of public and private organizations explored areas identified in the core IOM recommendations—population research, prevention and care, disparities, service delivery and reimbursement, professional education and training, and public awareness and communication. A companion effort is underway to address the IOM’s call for further research to support the cultural transformation.

As articulated in the IOM report, efforts to reduce the burden of pain in the United States cannot be achieved without an expanded and sustained investment in basic and clinical research on the biopsychosocial mechanisms that produce and maintain chronic pain and development of safe and effective pain treatments. As a first step to respond to the full set of research recommendations of the IOM, the IPRCC and the NIH completed a comprehensive analysis of the existing federal pain research portfolio.<sup>1</sup> The next step is development of the Federal Pain Research Strategy which will complement the NPS. It will identify gaps in our research agenda and recommend directions for new research to guide federal entities in their support of essential pain research programs.

### **Findings and recommendations from the IOM report<sup>1</sup> guided the development of the National Pain Strategy (NPS). These included:**

- The public at large and people with pain would benefit from a better understanding of pain and its treatment in order to encourage timely care, improve medical management, and combat stigmatization.
- 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.
- Chronic pain is a biopsychosocial condition that often requires integrated, multimodal, and interdisciplinary treatment, all components of which should be evidence-based.
- Data are lacking on the prevalence, onset, course, impact, and outcomes of most common chronic pain conditions. The greatest individual and societal benefit 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 to ensure that pain assessment techniques and practices are high-quality and comprehensive.

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<sup>1</sup> The Interagency Pain Research Data Base and Summary Report can be found at: [http://iprcc.nih.gov/portfolio\\_analysis/portfolio\\_analysis-index.htm](http://iprcc.nih.gov/portfolio_analysis/portfolio_analysis-index.htm)



- Self-management programs can improve quality of life and are an important component of acute and chronic pain prevention and management.
- People with chronic pain need treatment approaches that take into account individual differences in susceptibility for pain and response to treatment, as well as improved access to treatments that take into account their preferences and are in accord with best evidence on safety and effectiveness.
- Treatments that are ineffective, whose risks 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 with 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<sup>2,3,4</sup> 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.<sup>5</sup>

**The objectives and action plans developed in this report to address the core IOM findings and recommendations are summarized below by work group topics and include:**

### **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 within the U.S. population, the NPS recommends specific steps to increase the precision of information about chronic pain prevalence overall, for specific types of pain, and in specific population groups and to track changes in pain prevalence, impact, treatment over time, to enable evaluation of population-level interventions and identification of emerging needs. It also recommends development of the capacity to gather information electronically about pain treatments, their usage, costs, effectiveness, and safety.

### **Prevention and Care**

Prevention of acute and chronic pain, especially primary prevention strategies, needs greater emphasis throughout the health care system, including delivery of long term services and supports, and in environments where injuries are likely to occur (e.g. the workplace), and among 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. The NPS 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, and minimize treatment risks and adverse effects.

## Disparities

Pain is more prevalent or disabling and/or care is inadequate in certain vulnerable populations including people with limited access to health care services, racial and ethnic minorities, people with low income or education, children, older adults, and those at increased risk because of where they live or work, or because of limited communication skills.<sup>2,3</sup> Many of these groups face additional problems of stigmatization and bias in pain care.<sup>3,4,5</sup> To eliminate disparities and promote equity in pain assessment and treatment, the NPS recommends efforts aimed at increasing understanding of the impact of bias and supporting effective strategies to overcome it; increasing access to high-quality pain care for vulnerable population groups; and improving communication among patients and health professionals.

## Service Delivery and Payment

Evidence suggests that wide variations in clinical practice, inadequate tailoring of pain therapies to individuals, and reliance on relatively ineffective and potentially high risk treatments such as inappropriate prescribing of opioid analgesics, or certain surgical interventions, not only contribute to poor quality care for people with pain, but also increase health care costs.<sup>1,6,7</sup> The NPS recommends a population-based, biopsychosocial approach to pain care that is grounded in scientific evidence, integrated, multimodal, and interdisciplinary, while tailored to an individual patient's 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 education programs have yet to give it adequate attention.<sup>8</sup> The NPS recommends steps to improve discipline-specific core competencies, including basic knowledge, assessment, effective team-based care, empathy, and cultural competency. It encourages educational program accreditation bodies and professional licensure boards to require pain teaching and clinician learning at the undergraduate and graduate levels. The NPS also recommends development of a web-based pain education portal that would contain up-to-date, comprehensive, and easily accessed educational materials. These training efforts should be made in coordination with current HHS efforts to develop tools for providers to recognize the risk factors and symptoms of opioid use disorders.<sup>ii</sup>

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<sup>ii</sup> Examples of ongoing government efforts, such as the prescriber training developed as part of opioid risk mitigation strategies appropriate prescribing of extended-release and long-acting (ER/LA) opioid analgesics is included in the FDA Blueprint for Prescriber Education that is part of the FDA-approved Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioid Analgesics. <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm> and the Secretary's Initiative on Opioids: Objectives to improve clinical decision making: <http://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths>



## 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 and its appropriate treatment. The National Pain Strategy recommends a national public awareness campaign involving public and private partners to address misperceptions and stigma about chronic pain. The learning objectives of the campaign would emphasize the impact and seriousness of chronic pain and its status as a disease that requires appropriate treatment. In addition, an educational campaign on the safer use of pain medications that is targeted to people with pain whose care includes these medications is recommended.

## Next Steps for Implementation

Sustained efforts across HHS, working through operating divisions, staff divisions, and also with non-governmental partners, will be required in order to implement the public health, clinical, and research initiatives described in this Strategy. These efforts will help to prevent pain, improve patient care and outcomes, assure appropriate patient and provider education, and advance pain-related applied research. The Office of the Assistant Secretary for Health (OASH), in conjunction with HHS operating and staff divisions, will consider the recommendations included in the Strategy and develop an implementation and evaluation plan based on this process.

## THE NATIONAL PAIN STRATEGY: A Vision

The objectives of the National Pain Strategy aim to decrease the prevalence of pain across its continuum from acute to high-impact chronic pain and its associated morbidity and disability across the lifespan. The intent is to reduce the burden of pain for individuals, their families, and society as a whole. The Strategy envisions an environment in which:

- People experiencing pain would have timely access to patient-centered care that meets their biopsychosocial needs and takes into account individual preferences, risks, and social contexts, including dependence and addiction.
- People with pain would have access to educational materials and learn effective approaches for pain self-management programs to prevent, cope with, and reduce pain and its disability.
- Patients, including those with low literacy or communication disabilities, would have access to information they can understand about the benefits and risks of treatment options, such as those associated with prescription opioid analgesics.
- All people with pain would be assured of receiving needed preventive, assessment, treatment, and self-management interventions, regardless of race, color, nationality, ethnicity, religion, income, gender, sex, age (neonatal through end of life), mental health and substance use disorders, physical or cognitive disability, sexual orientation and gender identification, geographic location, education, language proficiency, health literacy, or medical condition. All pain-related services would be provided without bias, discrimination, or stigmatization.



- Americans would recognize chronic pain as a complex disease and a threat to public health and productivity. Individuals who live with chronic pain would be viewed and treated with compassion and respect.
- Clinicians would take active 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, patient-centered 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 in the care of patients who have increased comorbidities, complexity, or are at risk for dependence or addiction.
- Clinicians would receive better education and training on biopsychosocial characteristics and safe and appropriate management of pain. Clinician's knowledge would be broadened to encompass an understanding of individual variability in pain susceptibility and treatment response, the importance of shared (patient-providers) and informed decision-making, ways to encourage pain self-management, appropriate prescribing practices, how empathy and cultural sensitivity influence the effectiveness of care, and the role of complementary and integrative medicine.
- Payment structures would support population-based care models of proven effectiveness in interdisciplinary settings and encourage multimodal care aimed at improving a full range of patient outcomes.
- 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.
- The evolution toward a public health approach to pain prevention and care would be facilitated by epidemiologic, health services, social science, medical informatics, implementation, basic, translational, and clinical research, informed by clinician/scientist interactions.
- Data on the health and economic burdens of chronic pain would guide federal and state governments and 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 of the effectiveness of policy initiatives, public education efforts, and changing treatment patterns.
- A more robust and well trained behavioral health work force would be available to support the needs of patients who suffer from chronic pain, including those at risk who need mental health care and substance abuse prevention and recovery treatment.
- The actions in this strategy would be undertaken in the context of the dual crises of pain and opioid dependence, overdose, and death in the United States. Actions to improve pain care and patient access to and appropriate use of opioid analgesics for pain management would be coordinated and balanced with the need to curb inappropriate prescribing and use practices. To achieve this balance a broad range of stakeholders including those engaged in pain care





and pain care policies, as well as those working in substance use prevention, treatment, and recovery, would be engaged as the actions of the NPS are undertaken.



## BACKGROUND

The 2010 Patient Protection and Affordable Care Act (PPACA) 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, identify and reduce barriers to appropriate care, evaluate the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain across the population, and improve pain care research, education and care. As a result, HHS, working through the NIH, commissioned an IOM study to assess the state of pain care. The IOM report, issued in June 2011,<sup>1</sup> included 16 recommendations for improvements in:

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

The IOM's emphasis on pain as a significant public health challenge, amenable to population health-level 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, HHS created the IPRCC<sup>iii</sup> to coordinate all pain research efforts within HHS and across other Federal Agencies. 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 NIH established a framework for developing a National Pain Strategy, in consultation with the Chair and Vice Chair of the IOM Committee.<sup>iv</sup>

The six key areas addressed in the National Pain Strategy are:

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

The IPRCC selected expert working group members to address each of these key areas and created an oversight panel (Appendices A and B) to guide and coordinate the working groups' interrelated efforts. Nominations for working group and oversight panel membership were solicited from professional

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

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



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 body of this report is structured to reflect the results of the work groups' deliberations. Each of the six sections includes a statement of the problem and a set of priority objectives with accompanying discrete and achievable deliverables to address the problem. The time frame for completion of deliverables is presented as short (approximately one year), medium (two to four years), and long term (within five years). Stakeholders best positioned to achieve the deliverables are identified and metrics to assess progress are suggested.

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 step toward the ideal state of pain care. An ensuing companion strategy to address the crucial contribution of research to the NPS objectives also is being developed by the IPRCC.



## Box 1 contains definitions of terms frequently used in this report.

### Box 1 Definitions

**Acute pain** is 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** refers to a medical problem or intervention that combines biological, psychological, and social elements or aspects.

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

**Complementary health approaches** are mind and body practices and natural products of non-mainstream origin, including chiropractic and osteopathic manipulation, meditation, massage, relaxation, yoga, acupuncture, and naturopathic medicine.

**Continuum of pain** is 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** refers to the definition created by Healthy People 2020,<sup>v</sup> 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.” The work group recognizes that this definition is not tailored to the unique nature of pain and, further, that age disparities in this report include those faced by children from infancy to adolescence and those in older adulthood.

**High-impact chronic pain** is associated with substantial restriction of participation in work, social, and self-care activities for six months or more. This term is introduced in the NPS for development of research tools that will allow population level data collection on the degree to which pain interferes with peoples’ lives.

**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.

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<sup>v</sup> [http://www.healthypeople.gov/sites/default/files/PhaseI\\_0.pdf](http://www.healthypeople.gov/sites/default/files/PhaseI_0.pdf)



***Integrative health care*** incorporates complementary approaches into mainstream health care to achieve health and wellness.

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

***Intractable pain*** is defined as pain that is not relieved by appropriate treatment.

***Levels of care*** are offered by *primary care* practitioners, who 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* who provide secondary-level consultations, which can include multidisciplinary team-based care, including rehabilitation therapy and behavioral health care; and *interdisciplinary pain centers* which 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 that may include medical, surgical, psychological, behavioral, and integrative approaches as needed.

***Opioid Use Disorder*** occurs when recurrent use of prescription opioid analgesics (opioid based pain relievers) and /or illegal opioids such as heroin, causes clinically and functionally significant impairment and failure to meet major responsibilities at work, school, or home. Diagnosis is based on inability to control or reduce use, social impairment, tolerance and other physiological signs, and pharmacological criteria.

***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 include a broad range of complementary health approaches. These programs can stand alone and be individually directed, be integrated into health care settings, or offered by community agencies.

***Prevention*** as it relates to pain addresses three tiers. *Primary prevention* includes efforts to reduce injuries or diseases that may result in pain. *Secondary prevention* includes 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

Acute pain is an unpleasant, though normal sensory experience in response to a noxious stimulus and plays an important protective role by alerting a person to actual or potential physical injury. Painful symptoms often can be self-managed while the underlying cause resolves and recovery occurs. Such instances generally require little or no professional intervention. Acute pain does not always resolve as expected however, especially if it is associated with a serious disease or condition, or begins with an injury that does not receive timely or appropriate medical care. When pain persists after the underlying cause is resolved, it may signal that pain-initiated changes in the central nervous system have occurred. If so, this chronic pain is no longer a symptom of another disorder and has become the disease itself.<sup>9</sup>

The persistence of pain creates a complex biopsychosocial phenomenon that may interfere with many aspects of a person's life—ability to work, social activities, and both physical and mental health.<sup>10,11</sup> Secondary psychosocial and physical problems in turn, can worsen pain, posing escalating threats to health and well-being<sup>12</sup> and chronic pain has been linked to premature death.<sup>13</sup> These overwhelming challenges of living with chronic pain contribute to a suicide rate that is higher than that of the general population.<sup>14,15</sup> Many factors influence the way individual patients perceive and cope with pain and the likelihood they will seek and receive care and respond to treatment. Past experiences, familial and genetic factors (including race, sex, and gender), comorbidities, cultural background, and psychological, economic, and environmental factors all play a role.<sup>16,17</sup> Despite the complexity of pain and its care, pain education, research, and treatment historically have focused narrowly 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 result in futile treatment and rehabilitation. Other factors affect quality of patient care throughout the continuum of pain and are exemplified by wide variations that exist in clinical practices related to pain prevention, assessment, and treatment. Care is often fragmented and lacks a comprehensive assessment or treatment plan, and patients may encounter difficulty accessing the full range of potential treatments.<sup>6</sup> According to the IOM report, most Americans who live with chronic pain do not receive appropriate care.<sup>1</sup>

Chronic pain and its treatment can be a lifelong challenge at the individual level and is a significant public health problem. Population level surveys indicate that between 11% and 40% of the U.S. population report some level of chronic pain, with millions suffering from daily, severe, and disabling pain.<sup>18,19,20,21</sup> Some population groups, whether defined by age, sex, gender, race/ethnicity, geographic isolation, socioeconomic status, occupation, or other characteristics are differentially affected by certain pain conditions, have less access to pain prevention, assessment, and treatment services, and experience worse outcomes.<sup>3,4</sup> Nationwide, patients face many systemic hurdles to appropriate care, including those driven by provider attitudes, biases and stereotyping of patients.<sup>5,6</sup> Inadequate provider training and payment policies may contribute to unnecessary diagnostic tests and procedures and ineffective, risky treatments.<sup>6,7</sup> These situations likely contribute to the high health care costs associated with chronic pain. High direct medical care costs, as well as costs associated with disability programs,



lost productivity, and family burden all contribute to the IOM annual cost estimate of \$560 billion to \$635 billion.<sup>vi,22,23</sup>

More precise assessments of the incidence, prevalence, and disability associated with pain in the U.S. population and subpopulations are needed to establish a reliable basis for population-wide interventions, and a baseline to assess treatments for the physical, psychological, social, and economic burdens of pain, as well as barriers to quality care. 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 a public health mindset and personalized treatment offers the best chance to improve all Americans' access to high-quality and more cost-effective pain care. Public health concerns related to the misuse or diversion of prescription opioid pain medications and risk for dependence and overdose with long term opioid prescribing add another layer of complexity to the management of chronic pain and need to be considered during development of policies and programs related to pain management. As part of a public health effort over the past few decades to improve pain management, the broader prescribing of opioids led to a significant rise in adverse health consequences, including misuse, addiction, and overdose deaths. Prescribing practices, marketing, and misleading information on safety drove a steady and significant increase in the number of opioid prescriptions dispensed, rising from 76 million in 1999 to 219 million in 2011.<sup>24</sup> The amount per prescription, the duration of the supply, and the cumulative dose prescribed also increased.<sup>25</sup> These dramatic increases paralleled rises in opioid-related substance abuse treatment admissions<sup>26</sup> and rates of opioid-involved overdose deaths, which reached 28,647 in 2014.<sup>27,28</sup> Certain behaviors and risk factors that make people vulnerable to prescription opioid pain medication abuse or overdose have been identified.<sup>29</sup> Understanding these factors is important to enable identification of populations at highest risk and for development of and improved access to interventions that target these high-risk groups.

Programs to curb inappropriate prescribing practices and prescription opioid abuse must be balanced with the use of and access to these drugs for appropriate and quality pain management. Primary care physicians treat the majority of chronic pain patients and some primary care physicians report reluctance to prescribe opioids for chronic non-cancer pain because of concerns over dependence, addiction and abuse behaviors.<sup>30,31,32,33</sup> Pharmacy shortages and regulated dispensing policies<sup>34</sup> might result in inadequate treatment for those patients where the benefits of opioids outweigh the risks. While all patients who are on opioid therapy for chronic pain are at risk for opioid use disorder, limited recent studies have shown that most (74-96%) of these patients use their prescriptions without suffering from opioid addiction.<sup>35,36,37</sup> All people with pain should receive adequate care.

In some clinical contexts, opioids can help manage pain when other pain medicines have not or are not expected to provide enough pain relief. A recent conference to assess the safety and efficacy of long-term opioid use for chronic pain found no studies on their long term effects (more than one year) on pain, function, or quality of life. While the report states clearly that there are some patients for whom opioids are the best treatment for their chronic pain, it concluded that further research is needed to guide appropriate patient assessment, opioid selection, dosing strategies, and risk mitigation. However, for

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<sup>vi</sup> 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.



many more, there are likely to be more effective approaches.<sup>38</sup> The Centers for Disease Control and Prevention is developing a guideline for opioid prescribing for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Improving the way opioids are prescribed through clinical practice guidelines will help to improve the safety of treatment and reduce risks associated with long-term opioid therapy including abuse, dependence, overdose, and death. Providers also need better training in safer and more effective prescribing practices, recognizing risks of adverse effects, and approaches to proactively facilitate access to addiction treatment for patients at risk. These efforts represent areas in need of more research and development to ensure that pain management is team based, personalized, multidisciplinary, patient-centered, and available to those who need it.

Access to safe and effective care for people suffering from pain remains a priority that needs to be balanced in parallel with efforts to curb inappropriate opioid prescribing and use practices. A population with improved pain prevention and care and less pain would mitigate the need for prescription opioid analgesics. This need for balance underscores the importance of engaging with a broad range of stakeholders, including those engaged in pain care and pain care policies, as well as those working in opioid abuse prevention and treatment, as the actions of the NPS are undertaken.

The NPS recognizes that opportunities to prevent the conditions and events that lead to chronic pain, such as those associated with the work place and lifestyles must not be missed. Furthermore, evidence-based strategies to intervene early to prevent acute pain from becoming a chronic condition and the research to develop them are needed. It notes that effective pain care must emphasize shared decision-making, informed pain assessment, and integrated, multimodal, and interdisciplinary treatment approaches that balance effectiveness with safety. These objectives require a better trained workforce. Even though pain is a leading cause of primary care visits, clinicians are generally under-trained in ways to assess and effectively manage pain. Improvements in professional education about state-of-the-art care for pain, in all its dimensions, including better communication, empathy, cultural sensitivity, and risk management will yield significant care improvements. In parallel with provider training, a robust public education effort may lend support and knowledge to people with pain, and to the 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 care model that is patient-centered, evidence- and outcomes-guided yet personalized, and provided through high-performing, interdisciplinary care teams. This evolution suggests that development of a National Pain Strategy is timely. Opportunities for improvements in care may arise with the increasing emphasis on team-based care and care coordination, facilitated by the adoption of health information technology, including electronic health records (EHRs) continued health services delivery research, and implementation of better models. More effective delivery of services, supported by appropriate health care system features and payment are essential to the “cultural transformation” called for in the IOM report.





## IOM underlying principles that informed development of this National Pain Strategy (Box 2)

### 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 can have 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., workplace ergonomics) 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 stigmatization that hinder better care.

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



## REPORTS FROM THE WORKING GROUPS

### Population Research

The 2011 IOM report 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. The quality and quantity of information being gathered on pain and its treatment needs to be improved in order to collect essential data 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, 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, mortality, and disability) in the population as a whole, across the lifespan, 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 an essential tool in the implementation of the NPS.

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.<sup>39</sup> The following ICF concepts are relevant to defining chronic pain:<sup>40,41,42,43</sup>

***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.<sup>25</sup> The IOM report emphasized that chronic pain affects to some extent, and estimated that over 100 million adults in the U.S.<sup>1</sup> It is important to differentiate people with *high-impact chronic pain* from those who maintain 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 high-impact 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,<sup>44</sup> modified to account for intermittent pain.

***The Problem:*** Population level data on prevalence, onset, course, impact, and outcomes are not adequate to guide policies, and practices to improve pain care. 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, sex, 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 and metrics 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; (analyses should consider the need to gather information on use of self-care practices and complementary approaches that are not captured through health records);

(3) develop a system of metrics for tracking changes in pain prevalence, impact, treatment and barriers to 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; (analyses should consider the need to track and account for lack of access to services).

***The intent of the Population Research section*** is to provide methods and metrics to guide progress toward 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.***<sup>vii</sup>

*Short-term (approximately one year) strategies and deliverables:*

- Engage active population researchers to test a set of proposed pain screener questions (Appendix D) and brief self-assessment questions about high-impact chronic pain (Appendix E) in an existing and 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 surveys<sup>45</sup> and make recommendations regarding the appropriateness of standardizing, adding, or revising questions to bring these surveys in line with the NPS-proposed self-assessment questions in Appendixes D and E.

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<sup>vii</sup> Stratified by age, sex, gender, race and ethnicity, education, socioeconomic status, health status, and indicators of biopsychosocial resiliencies and vulnerabilities



- 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 tests of the proposed brief pain self-assessment questionnaire.

*Medium-term (two to four years) 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.

*Long-term (within five years) strategies and deliverables:*

- Use the increasingly refined measures developed to evaluate longitudinal pain outcomes including post-acute care evaluations, the Minimum Data Set, and other comparable population-based tools, from among populations covered through Medicare, Medicaid, and then those privately insured.
- Modify the measures as needed to evaluate longitudinal pain outcomes among vulnerable and special populations (including workers in high risk occupations, pediatric populations, those exposed to early trauma, individuals with physical and cognitive disabilities, and older adults).

*Federal Stakeholders:*

- Administration for Community Living (ACL), Agency for Healthcare Research Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), NIH, National Prevention Council (NPC), Veterans Health Administration (VHA)

*Collaborators:*

- public and private health insurers
- researchers
- health care provider and professional organizations
- patient advocacy organizations and people with pain

*Metrics:* The screener tool should be validated through a larger population level study (short-term). The progress of the refinement of the assessment tool by expert panels (medium-term) and its incorporation into national morbidity surveys and its application to determining longitudinal pain outcomes among public and private health care beneficiaries (long-term) should be monitored.



**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 evidence has shown are effective and underused or ineffective and overused.**

*Short-term (approximately one year) strategies and deliverables:*

- Carry out proof-of-concept analyses with large public and private health care databases to identify patterns of pharmacological and non-pharmacological treatments among people in specified diagnostic clusters<sup>viii</sup> (Appendix F) and their associated costs. This activity would provide insights regarding disparities in pain care, as well as how different payment models affect both patterns of treatment and costs across a sampling of the general population.
- Prepare a manuscript for submission to a peer-reviewed journal reporting the results of the proof-of-concept analyses of health care data on diagnostic clusters and pain treatment indicators and related recommendations.
- Encourage CMS to issue rules to make adequate pain control measures, including clinical quality measures, a component of its Medicare and Medicaid incentive programs for establishing meaningful use of electronic health record (EHR) technology, an action deemed especially helpful in monitoring care for vulnerable populations.

*Medium-term (two to four years) 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 Payment section.

*Long-term (within five years) strategies:*

- 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.<sup>ix</sup> Use the network to develop data, including EHRs and patient reported outcomes, on trends in pain treatment in different population groups (including vulnerable populations) including and costs of specific pain treatment services and to identify opportunities and priorities for primary prevention.

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<sup>viii</sup> 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).

<sup>ix</sup> 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.



*Federal Stakeholders:*

- ACL, AHRQ, CDC, CMS, DoD, Indian Health Service (IHS), Office of the National Coordinator for Health Information Technology (ONC), NIH, NPC, VHA

*Collaborators:*

- evidence-based practice centers in universities
- relevant primary care and specialty professional societies
- long-term services and supports providers
- public and private sector health care financing and delivery systems that have large patient and health maintenance organizations and support research
- public and private health insurers
- patient advocacy organizations; and people with pain

*Metrics:* The progress of the refinement of the diagnostic clusters and related treatment indicators, their incorporation into ICD-10 nomenclature and their standardization and use in population research should be monitored (medium-term). The adoption of diagnostic cluster and pain treatment indicator methodology within CMS and outside government-funded programs should be assessed (long-term). The development of the research network and its subsequent progress in generating quality data on trends in pain treatment in population subgroups, associated costs of specific pain treatment services should be evaluated (long-term).

***Objective 3: Develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time to assess progress, evaluate the effectiveness of interventions at the population health level—such as public education or changes in public policy, payment, and care—and identify emerging needs. Apply these metrics to evaluate the effectiveness of primary, secondary and tertiary prevention interventions.***

*Short-term (within one year) 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 (two to four years) 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 objectives to inform and guide appropriate objectives/questions for a dedicated chronic pain objective to be included in HP 2030.

*Long-term (within five years) strategies and deliverables:*



- Encourage health care providers, including long-term services and supports and insurers to use data developed under these initiatives and the collaborative relationships established to guide enhancements to health care and preventive services.
- Encourage health care providers and insurers to use data developed under these initiatives and the collaborative relationships established to evaluate the effectiveness of interventions at the population health level, such as public policy initiatives, demonstration projects in the organization or payment for care, or public education efforts.<sup>x</sup>

*Federal Stakeholders:*

- ACL, AHRQ, CMS, CDC, DoD, IHS, NIH, NPC, VHA

*Collaborators:*

- entities that collect data on pain, pain treatment, use of disability programs, and public benefits
- employer and employee organizations
- public and private sector health care financing and delivery systems that have large patient and health maintenance organizations and support research
- patient advocacy organizations, and people with pain

*Metrics:* The extent of adoption of the pain assessment and treatment metrics and their use in assessing programmatic interventions should be assessed. The adoption of the proposed measures in the Healthy People data tools and reporting system should be monitored and expanded (ongoing). The extent of use of diagnostic clusters in program planning, implementation, and evaluation at the community, state, and federal levels should be assessed.

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<sup>x</sup> For example, the Bree Collaborative recently developed strategies to enhance the value of health care for low back pain (see <http://www.breecollaborative.org/topic-areas/spine>)<sup>14</sup> Washington State's Bree Collaborative provides a model for such collaboration.



## 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.

The quality and quantity of evidence needed to guide appropriate and comprehensive clinical approaches to the prevention, assessment, and treatment of pain across the lifespan is inadequate, in part because of the complex nature of pain. Given that acute pain can progress to chronic pain, which is a disease in itself, certain principles are clear:

- Evidence-based care should follow the public health prevention model and address primary, secondary, and tertiary prevention.
- Evidence-based pain care should involve an interdisciplinary team approach that includes the patient, and family when appropriate, and covers the different levels of pain care—from prevention to self-care to acute to chronic pain management—as needed.
- High-quality pain care should be available to all and in all settings and at all levels of care, from primary care to interdisciplinary pain care centers, to functional rehabilitation settings, and nursing homes as the intensity of pain management efforts increases.

***The Problem:*** Chronic pain can affect people of any age and may begin with an injury, disease process, or procedure that evolves into a persistent painful condition. Often, the cause of its onset is uncertain however, 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 and its transition 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 learn 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 personalized for specific higher-risk situations.<sup>1</sup> A robust basic, translational, and health services research effort is needed to validate the effectiveness of pain prevention and management strategies already in use across the spectrum of care settings, and to develop new ones.

***The intent of the Prevention and Care section*** is to advance evidence-based, culturally sensitive and personalized 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 work place injury prevention programs, self-management methods and programs for prevention and care, should be performed to identify and create incentives for use of interventions having high benefit-to-cost ratios.





Conversely, approaches and 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 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. Providers and payers should tailor care to address such individual variation in patient response.

*Short-term (approximately one year) strategies and deliverables:*

- Perform a benefit-to-cost analysis of existing methods and programs to prevent and treat pain for which the best available evidence suggests benefit (and for which benefits outweigh risks). 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 benefit-to-cost analyses of current prevention and treatment approaches and related recommendations.

*Medium-term (two to four years) strategies and deliverables:*

- Develop a best-estimate synthesis of causes of preventable injuries nationwide, including both workplace and non-workplace related injuries and physical trauma by:
  - Identifying areas where more evidence is needed (for example, linking work relatedness to EHRs, evaluate occupational injuries that may be substantially underreported<sup>46</sup>).
  - Reviewing existing programs for primary prevention, the evidence for their effectiveness and the barriers to their implementation.
  - 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 dissemination of existing effective programs and development of new prevention and treatment methods likely to have high benefit-to-cost ratios.

*Long-term (within five years) strategies and deliverables:*

- Incorporate the most clinically effective and cost-efficient treatments into practice guidelines and other quality-related efforts, 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 clinically effective and cost-efficient treatments for patients who could benefit from them or insurer practices that continue to pay for less effective treatments.
  - Development of a patient-centered framework for measuring treatment outcomes on pain, level of disability, and the full range of psychosocial impacts.

*Federal Stakeholders:* ACL, AHRQ, CDC, CMS, ONC, National Institute for Occupational Safety and Health, Occupational Safety and Health Administration, VHA, and other relevant federal entities



*Collaborators:*

- private health insurers
- employers, labor unions and trade associations
- patient advocacy organizations, and people with pain

*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 should be assessed at five years, which ideally could be compared with baseline data to determine any short-term trends.

**Objective 2: Develop nationwide pain self-management programs.**<sup>xi</sup> Despite evidence to support team-based, self-management programs for pain their implementation has lagged. This is a missed 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 systems and other services' networks to bolster their use and prevalence and to guide patients through multiple levels of pain care. Goal setting (action planning), problem solving, decision making and psychosocial aspects of care should be included in the programs. Team based programs should be multidisciplinary including integrative health professionals, patient-centered, developed with provider input and monitoring, and paralleled with clinical care when needed.

*Short-term (approximately one year) strategies and deliverables:*

- Perform an environmental scan of pain self-management programs<sup>xii</sup> that:
  - cover the continuum of prevention and pain care; foster skills and integrative health self-management approaches 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 (e.g. aging services providers), patient advocacy organizations, or that stand alone.
  - are culturally neutral and sensitive, allow for tailoring of the intervention as needed for special populations, apply across the lifespan to include children and older adults, and are available in multiple languages and formats.

*Medium-term (two to four years) 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.

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<sup>xi</sup> 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).

<sup>xii</sup> Specific programs that warrant an evaluation include the American Chronic Pain Association's program, Stanford Patient Education Research Center Programs, and model falls prevention programs. Existing models from integrative healthcare disciplines also should be evaluated.



- Leverage existing programs, such as the extensive number of self-management tools for patients with chronic disease.<sup>xiii</sup>
- Develop new types of patient tools for pain management and provider feedback using, for example, mobile applications, that also integrate with EHRs, personal health records/patient portals, wearable devices, and other technologies.

*Long-term (within five years) 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 Patient Centered Medical Homes and the VHA, especially for people with indicators or risk factors for transitioning to chronic pain.
  - Disseminate broadly, information on effective pain self-management programs through various health information directories, such as <http://www.health.gov/> and non-governmental resources for patients.
  - Through various means, direct those with indicators or risk factors for transitioning to chronic pain to effective self-management programs.

*Federal Stakeholders:* ACL, AHRQ, CMS, DoD, IHS, VHA in collaboration with the Health Resources and Services Administration (HRSA, as appropriate to their statutory priorities and within their authority), and other relevant federal agencies

*Collaborators:*

- private entities that support health care assessments and outcomes monitoring
- the Patient-Centered Outcomes Research Institute (PCORI)
- professional organizations, including those representing rehabilitation medicine, athletic trainers, and licensed complementary and integrative health fields
- public and private payers
- health care provider organizations, and other potential funders
- patient advocacy organizations, and people with pain

*Metrics:* The short-term progress of the programs should be assessed through data on the outcomes for people with pain and collected through established tools, such as the NIH and Department of Defense's collaborative Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcomes Information System PASTOR/PROMIS, 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 EHRs. The level of integration of

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



and payment for effective pain self-management into the health care system should be assessed at five years, which ideally could be compared with baseline data (environmental scan).

**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 outcome measures should include relevant pain, physical, psychological, emotional, 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 accommodate patient communication challenges (e.g. through behavioral symptoms measures), be used for point-of-care decision-making by clinicians, longitudinal outcomes monitoring, estimations of value of optional treatment approaches, and practice-based effectiveness studies.

*Short-term (approximately one year) 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 condition-specific modules, as well as opportunities to leverage outcome data from existing resources such as registries, especially taking into consideration their usefulness for primary care providers and for population research.<sup>xiv</sup>
  - Conduct research and developmental studies to create new assessment tools and identify models.
  - Integrate appropriate pain self-assessment tools into EHRs, patient portals, and other forms of health information technology (health IT) to aid providers and patients in clinical decision making.
  - Recommend ways to integrate outcomes measures into existing assessment systems, as necessary.

*Medium-term (two to four years) 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.

*Long-term (within five years) strategies and deliverables:*

- Evaluate the benefits and costs of improved, standardized assessment tools and outcome measures.
- Assess health insurer practices to improve appropriate use of pain treatments, including opioid and non-opioid therapies.

*Federal Stakeholders:* ACL, AHRQ, CDC, CMS, FDA, ONC, NIH, and other relevant federal entities.

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<sup>xiv</sup> The NIH Task Force on Research Standards for Chronic Low Back Pain is an example of such a task force.



*Collaborators:*

- public and private health insurers
- PCORI
- professional organizations (especially primary care)
- National Committee for Quality Assurance (NCQA) and other relevant health care systems accrediting bodies
- pain advocacy organizations, and people with pain

*Metrics:* The extent of adoption of improved assessment tools and outcome measurement systems into existing assessment systems, provider practices, EHRs, patient portals, and other forms of health IT should be monitored annually over five years. The costs and benefits of the tools should be evaluated at five years.



## Disparities

Pain care disparities are complex, due to myriad contributing factors within and outside the health care sector. Elimination of disparities and equity in care cannot be achieved without increased access to high-quality treatment, development of strategies and expectations for equitable assessment and treatment of pain, and creation of appropriate supporting programs and services (such as effective patient communication strategies, and disability and addiction services as needed) for people with pain. A more robust and well trained workforce is needed to address the need for access to quality care for all people with pain and especially for those in vulnerable populations. Specific needs include expansion of the nation's behavioral health workforce to support the needs of patients with chronic pain and those at risk for substance use and mental health disorders. Also needed is improved communication between service providers and people with pain and their families.

The IOM report, extensive research, and patient reports indicate that substantial disparities in pain prevention, occurrence, assessment, treatment, and outcomes are common; U.S. data indicate a greater prevalence of pain conditions among specific population groups. The Healthy People 2020 current definition of health disparities is included in the Background section of the strategy.

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 behaviors that result in discrimination, bias, or stigmatization, which themselves can lead to or exacerbate pain. When this section of the NPS discusses bias, stigmatization, and discrimination, it is referring to all higher-risk groups that comprise vulnerable populations. Examples of patient groups and conditions for which bias has been reported are diverse and widespread and include: women experiencing pain from chronic fatigue syndrome, fibromyalgia, and other conditions; people who are on prescription opioids for intractable pain; children—especially infants and others who cannot communicate; older adults—especially those in nursing home settings who have limited communication; people with substance use and mental health disorders; and patients with sickle cell disease or pain associated with human immunodeficiency virus (HIV) infection.

**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. sex, gender, age, disability, ethnic, or racial bias) or about pain itself.<sup>6,47,48,49</sup> 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 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 that arise from age (infancy through older adults), genomic variability, pharmacokinetic and pharmacodynamics differences, which affect pain onset, chronicity, and management and data to understand patterns of pain and its treatment in higher risk and vulnerable populations.



*The intent of the Disparities section* is to improve the quality of pain care and reduce barriers for all 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 (approximately one year) strategies and deliverables:*

- Document 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, using quantitative and qualitative research design, of health care and social services 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 effects of health care, long-term services and supports, and social services provider bias in decision-making regarding integrated, multimodal, and interdisciplinary pain care, strategies to overcome bias (at the patient, clinician, institutional, and health system levels), and to identify gaps in knowledge. These gaps should support a research strategy to improve clinician education, pain care, and direct pain policy.
  - 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.

*Medium-term (two to four years) strategies and deliverables:*

- Disseminate the proceedings of these groups to health care and social service providers, policy makers, and other stakeholders through a manuscript in a relevant journal and other appropriate means.
- Develop pilot projects, designed to reduce bias in pain care at the provider, health care, long-term services and supports, and social service systems levels, using the conclusions of the expert groups.
- Conduct demonstration projects to evaluate bias reduction strategies in health care systems or other large population-based service delivery systems, based on the results of the pilot projects.

*Longer-term (within five years) strategies and deliverables:*

- Develop, implement, and evaluate policy recommendations and guidelines on bias reduction for health care, long-term services and supports, and social service providers, based on outcomes of the demonstration projects.

*Federal Stakeholders:* ACL, AHRQ, HRSA, Office of Minority Health (OMH), NIH

*Collaborators:*

- professional medical organizations



- researchers (including social sciences)
- health care, long-term services and supports, and social services providers (including licensed practitioners who provide integrative and complementary health approaches)
- state and federal policymakers
- community representatives
- patient advocacy organizations and people with pain

*Metrics:* Identified knowledge gaps on effects of provider bias in health care outcomes should be included in a long term research strategy. Practices to reduce bias, based on demonstration projects, should be incorporated into health care, long-term services and supports, and social service systems. The extent of implementation of policy recommendations and guideline adoption should be assessed at five years through a follow-up survey to determine changes in health care, long-term services and supports, and social service provider biases, attitudes, beliefs, knowledge, and behavior.

***Objective 2: Facilitate communication among patients and health professionals.***

*Short-term (approximately one year) strategies and deliverables:*

- Convene an expert group to review and make recommendations on effects of disparities in pain care and means to heighten its national awareness.
- Disseminate findings of the review group to the general public, researchers, health care and social services providers, and professional organizations.

*Medium-term (two to four years) strategies and deliverables:*

- Improve the health literacy of people with pain through promotion and dissemination of the National Action Plan for Health Literacy and the National CLAS standards to relevant health care providers and health care systems.
- Perform an environmental scan for existing communication guidelines that are specific to pain care and relevant to patients with limited English proficiency or health literacy, communications disabilities, or age related communication limitations.

*Long-term (within five years):*

- Develop needed communication guidelines in accord with the gaps from the environmental scan, that are consistent with the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards: [www.thinkculturalhealth.hhs.gov](http://www.thinkculturalhealth.hhs.gov) ).<sup>xv</sup>

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<sup>xv</sup> Title VI of the Civil Rights Act of 1964 requires federally assisted programs to take reasonable steps to provide meaningful access for persons who have limited English proficiency which may include the provision of language assistance services at no cost to the person being served. Section 504 of the Rehabilitation Act of 1973 and Title II of the Americans with Disabilities Act of 1990 require that recipients ensure that communication with individuals with disabilities is equally effective as communication with persons without disabilities.





*Federal Stakeholders:* ACL, AHRQ, HRSA, OASH: ODPH, OMH, Substance Abuse and Mental Health Services Administration (SAMHSA)

*Collaborators:*

- health care, long-term services and supports, and social service providers' credentialing agencies (certification standards and guidelines) and accrediting bodies (NCQA and other relevant health care systems accrediting bodies)
- health professional training programs and licensing bodies (to promote cultural and linguistic competency)
- patient advocacy organizations and people with pain

*Metrics:* The establishment of payment models for payment of direct translation and interpreters should be tracked and linked to the number of staff and quality translation services available in pain care settings.

**Objective 3: Improve the quality and availability of data to assess the impact of pain and under or overtreatment for vulnerable populations, and the costs of disparities in pain care.**

*Short-term strategies (approximately one year) and deliverables:*

- Develop data standards and definitions to track pain prevalence and treatment across vulnerable populations. These standards and definitions could be applied to EHRs, population-level surveys, and relevant clinical research

*Medium-term (two to four years) strategies and deliverables:*

- Convene 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.

*Long-term (within five years):*

- Use current and new data standards as developed above to enable national studies of inappropriate, under- and over-treatment among vulnerable populations, and to assess progress toward eliminating it.

*Federal Stakeholders:* ACL, AHRQ, CDC, HRSA, NIH, ONC

*Collaborators:*

- 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:* The number of studies published using the data standards and definitions developed to assess prevalence and treatment outcomes should be monitored. Data mining based on these standards and definitions from EHRs, population surveys and clinical studies should be tracked to assess effectiveness of dissemination.



**Objective 4: Improve access to high-quality pain services for vulnerable population groups.**

*Short-term (approximately one year) strategies and deliverables:*

- Conduct an environmental scan of current patient resources that link people with chronic pain to appropriate care (e.g., health centers, long-term services and supports, social services, and behavioral health providers, and clinician specialists).
- Promote awareness of these resources through stakeholder agencies (e.g. websites, social media) and professional organizations (e.g. websites, membership).
- Develop demonstration projects of ways to improve access to current resources (including means to determine the potential of patient-centered medical homes to serve people who are at risk for disparities in care and aging and disability resource centers).

*Medium-term (two to four years) strategies and deliverables:*

- Develop a web-based portal of resources to link patients and families to appropriate care (leverage <http://healthfinder.gov/>, <http://eldercare.gov/>) and self-management tools.
- Develop demonstration projects to evaluate the web-based portal in improving access to high-quality care among vulnerable populations.
- When appropriate, promote and disseminate telehealth for hard-to-reach populations and for clinicians who do not practice where multidisciplinary colleagues are available.
- Coordinate with ongoing efforts to expand the behavioral health workforce capacity for psychological needs related to pain care, mental and substance use disorders, through HHS sponsored programs to attract new students to the field.<sup>xvi</sup>

*Long-term (within five years) strategies and deliverables:*

- Promote and disseminate effective models from the demonstration projects (access models, web-based tools), and provide incentives to adopt them.
- Develop, test, evaluate, and promote provider-facing clinical decision support tools to identify patients who are vulnerable to disparities in care, and to make treatment and referral decisions that prevent/reduce disparities.

*Federal Stakeholders:* ACL, CMS, DoD, HRSA, IHS, OMH, VHA

*Collaborators:*

- private entities to promote awareness of existing programs, develop demonstration projects, and evaluate existing tools
- health care, long-term services and supports, and social service systems
- professional medical organizations
- community representatives
- patient advocacy organizations, and people with pain

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<sup>xvi</sup> Examples can be found at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2741399/>



*Metrics:* The frequency of access to the information gateway portal and telehealth consultation should be tracked annually and outcomes of the demonstrations projects should be used to improve the gateway and the effectiveness of the telehealth programs.

### Service Delivery and Payment

A primary objective in enhancing the delivery of quality pain care is to make optimal and personalized pain management accessible to all. Wide variation in clinical practice and in patients' responses to therapies, along with inappropriate or repeated use of relatively ineffective and potentially risky treatments (e.g. prescription opioids and certain procedural/surgical interventions), has been linked to poor quality outcomes and high costs of pain care.<sup>1,6</sup> Given that 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.<sup>1,6</sup> The IOM report reflected this shift by advocating consistent and complete pain assessments, payment 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 the IOM report can be provided to all individuals with pain.

Insurance policies have been shown to affect consumer choices of treatments and their adherence to treatment regimens. Payment policies also can affect the clinical strategies adopted by health care providers. Payment policies for different procedures and products, formulary placement of drugs, and managed care arrangements all can affect the choices made by patients and physicians about managing chronic pain. The structure of payment and coverage arrangements can therefore exert powerful effects on how pain is managed.

Patients suffering from chronic pain may have access to complementary and alternative strategies for pain management, but these strategies have diverse economic implications. For example, consider acupuncture, cognitive behavioral therapy (CBT) and use of various prescription opioids. Many insurance plans do not cover acupuncture, and if they do provide coverage, subject it to strict duration limits. Moreover, these treatments are time consuming, must often occur during "work hours" and may require substantial cost sharing (e.g., \$20 to \$50 per visit in the case of CBT). The cost to consumers of prescription opioid products varies according to the specific drug and its placement on the prescription drug formulary. Some generic products (e.g., methadone) have out-of-pocket costs of as little as \$10 to \$15 for a 30-day supply. Brand name drugs may have higher out of pocket costs in the range of \$20 to \$35 for a 30-day supply. Thus, consumers in many insurance plans may gravitate to prescription drugs over complementary or alternative treatments, creating risks for subsequent problems with opioid dependency.

Providers frequently are very constrained in the time they can spend with individual patients. The typical primary care visit is approximately 17 minutes in duration, and fees permitted for brief office visits are fixed. Such visits usually involve attending to a number of clinical issues as well as trying to develop a rational, individualized pain treatment regimen. Capitation schemes create incentives for clinicians to minimize the total resources devoted to addressing complex problems such as pain control. In pay-for-performance systems additional payments are earned based on favorable outcomes being



achieved. In pain management, there are no such systems. Providing referrals for acupuncture or CBT may require primary care providers or specialists to provide clinical services with which they have little experience. Specifically, monitoring such services for referred patients may be difficult, and patient outcomes are more uncertain and require more clinician time to assess. These complexities can create situations where clinical choices for physicians and patients are weighted towards use of prescription drugs.

Ideally, clinicians might face neutral economic consequences as a result of choosing among effective pain control strategies. This could allow reimbursement for longer visits when selecting a therapy that involves more clinician time and less prescription opioid use. Exploring coverage and payment mechanisms that align consumer and provider interests in choosing cost-effective treatment strategies that balance risks and benefits of care for individuals can make an important contribution to implementing an HHS pain management strategy.

The National Pain Strategy endorses a population-based, disease management<sup>xvii</sup> 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 to one based on person-centered care, 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. Pain management often is limited to pharmacological treatment offered by a primary care practitioner or to procedure-oriented and incentivized specialty care that is neither coordinated nor aligned with best available evidence or expected outcomes.<sup>1,7</sup> 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 and collaboration among clinicians and without consideration of patient preferences.<sup>1,7</sup> The clinician or team's choice of therapy may be based on practice experience or 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 interventions, integrated care, models of care delivery, and payment innovations. Also needed are more effective methods to disseminate research findings and incentives to incorporate them into clinical practice. Level-I studies (e.g. high-quality randomized controlled trials or prospective studies) in pain are limited. 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 for research to enhance drug discovery for safer opioids and non-opioid analgesics, to raise the level of evidence for treatment approaches, and to improve evidence for clinical guidelines.

The incongruity between high-quality care and real-world clinical practice is however, only partly the result of limited evidence to support existing clinical guidelines. Current payment practices complicate use of integrated, interdisciplinary, patient-centered teams. Payers tend to cover mono-therapy

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<sup>xvii</sup> *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](http://www.dmaa.org/dm_definition.asp), March 30, 2006.)



and interventional procedures instead of prevention programs and services that conform to the biopsychosocial model of care. Payment often is not provided for pain self-management programs, patient and family social services support, patient decision making, patient education on the biopsychosocial effects of pain, team-based medication management, psychological counseling, cognitive-behavioral therapy, physical medicine and rehabilitation, and complementary and integrative health approaches. Current payment mechanisms (Appendix H) tied to the fee-for-service payment system generally fail to support more value-driven approaches (for example, the stepped model of pain care and other emerging models of coordinated care).

Further hurdles to quality pain care delivery are lack of access to and payment for medications managed primarily by retail pharmacies and third-party payers. Although analgesics should not be the sole intervention for most pain conditions, they may be essential for improved quality of life. Rationing, medication shortages, and inadequate payment for medication management and monitoring, and the high cost of abuse deterrent formulations decrease patient's access to medications and cause considerable hardship, especially for vulnerable populations.<sup>3,6</sup>

*The intent of the Service Delivery and Payment section* is to create a payment and delivery environment that facilitates coordinated care across the continuum of pain and throughout the lifespan 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 payment incentives.**

*Short-term (approximately one year) strategies and deliverables:*

- Perform an environmental scan to assess quality of care and costs of current treatment approaches and identify the existence of more effective models.
- Convene expert stakeholders to develop strategies to address 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 (two to four years) strategies and deliverables:*

- Solicit proposals through the Center for Medicare and Medicaid Innovation for evaluating emerging and innovative models of integrated care for chronic pain conditions.
- Conduct rigorous evaluations of these models through independent evaluators, and others that have been initiated but not yet evaluated, especially those using the stepped model of pain care, the biopsychosocial model, team-based care, pain self-management approaches, and care planning based on comprehensive pain assessments based on a biopsychosocial model that includes the etiology of pain.
- Monitor and evaluate outcomes of the models tested.

*Long-term (within five years) strategies and deliverables:*

- Evaluate optimal models in federal, state, and private provider contexts and implement as appropriate.

*Federal Stakeholders:* ACL, CMS, DoD, HRSA, IHS, VHA



*Collaborators:*

- primary and specialty care clinicians, neuro- and orthopedic surgeons, and licensed integrative health care practitioners)
- professional accreditation entities
- integrated health care systems
- large private third-party payers
- pain advocacy organizations, and people with pain

*Metrics:* Metrics used to determine positive outcomes from models on measures of physical, psychological, and functional improvement for patients, as well as cost savings relative to conventional care should be used as a measure of progress. Incorporation of validated, successful models into health care systems and clinical practice should be monitored and assessed.

**Objective 2: Enhance the evidence base for pain care and integrate it into clinical practice through defined incentives and payment 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 (approximately one year) strategies and deliverables:*

- Perform an environmental scan to assess barriers to quality care (e.g. identify outcomes of current insurers' practices of prior authorization, fail first protocols, and caps on treatments, and pharmacy benefit managers).

*Medium-term (two to four years) strategies and deliverables:*

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

*Long-term (within five years) strategies and deliverables:*

- Integrate and disseminate study results:
  - Compile and integrate outcomes of the population-based studies (above), the models tested (Objective 1), and those from the large national databases recommended in the Population Research section that are relevant to treatment choices.
  - 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.



- Disseminate their results to clinicians, quality improvement initiatives, public-private partnerships, patient and advocacy organizations, and others, to encourage implementation of more appropriate, evidence-based care.
- 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 payment 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 programs 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 Administration), on abuse, misuse, and access to opioid medications.
- Assess the impact of potential changes in policies on opioid use and opioid use disorder.

*Federal Stakeholders:* ACL, AHRQ, CDC, DoD, FDA, HRSA, NIH, VHA

*Collaborators:*

- private entities that support population-level research, including PCORI, private payers, integrated health systems
- private agencies and software experts developing electronic medical records and other relevant programs
- health profession organizations
- health, long-term services and supports, and social service provider organizations
- credentialing bodies for primary care and specialty clinicians
- pain advocacy organizations and people with pain

*Metrics:* The incorporation of validated, successful models and practices from the pilot projects into provider practices and health care systems should be assessed. The outcomes of evaluated interventions and care, including patient and family assessments and costs, as compared to usual treatment should be assessed. The adoption of evidence-based practice guidelines for multiple disciplines should be assessed.

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

*Short-term (approximately one year) strategies and deliverables:*

- Identify and invest in the development and implementation of models of care that deliver high-value pain care that both maximizes patient benefit and minimizes risk and costs and accounts for potential need for long term and enduring care.



- Identify alternate strategies to serve those most likely to lack access to these innovative models and those with unique needs such as patients with or at risk for addiction, those who have suffered psychological trauma, pediatric populations, and older adults.
- Identify, measure, and recommend means to control variations in pain care and access to pain care that lead to low-quality or high-cost care.
- Develop new tools to facilitate payment for higher quality pain care.<sup>xviii</sup>
- Define, identify, and engage eligible pain care clinicians and health, long-term services and supports, and social service providers willing to participate in quality and utilization reporting that includes pain measures, including those participating in existing programs, such as the Medicare Physician Quality Reporting System, the Advancing Excellence campaign<sup>xix</sup> and all of the other quality reporting systems that CMS hosts.

*Medium-term (two to four years) 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.
- Develop clinical quality measures and clinical decision support for pain care.
- Assess their impact on outcomes of care to define further refinement of these tools and then discontinue support for tools that are not effective in improving safety or quality, while promoting those that do.

*Long term (within five years) strategies and deliverables:*

- Develop and support pilot projects to test and rigorously evaluate the impact of payment innovations on pain care quality measures and cost savings. Include evaluation of adverse effects of payment innovations on evidence-based invasive interventions, devices and novel technologies, high cost drugs and access to quality pain care. Develop a plan for assessment of longer term outcomes of the pilots such as cumulative health care costs and comparison of long-term disability to productivity.
- Disseminate results of the pilot projects to public and private payers for consideration in updating their payment policies and practices.
- Make clinical quality measures for pain care and associated decision support part of incentive programs.

*Federal Stakeholders:* ACL, AHRQ, CMS, DoD, HRSA, National Library of Medicine (NLM), ONC, VHA

*Collaborators:*

- accountable care organizations
- state Medicaid programs

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<sup>xviii</sup> 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 & Medicaid Services and other payers, they help in identifying high-cost providers and also could be used for payment purposes, much as diagnosis-related groups have been used in hospital payment.

<sup>xix</sup> [www.nhqualitycampaign.org](http://www.nhqualitycampaign.org)





- integrated health care systems
- private agencies and software experts developing electronic medical records and other relevant programs
- health service researchers
- primary care, licensed integrative health care providers, and specialty clinicians, including surgeons
- long term services and supports and social services providers
- private payers
- professional medical organizations
- health care quality organizations
- pain advocacy organizations and people with pain


*Metrics:* The proportion of payments under the demonstrations that successfully support integrated care data should be monitored and assessed. The development of quality measures for integrated pain care, outcomes of care, including patient and family assessments, and impact on costs (for the demonstrations) should be assessed. The impact of clinical decision support on safety, quality, and outcomes of care should be assessed to guide further refinement of effective clinical decision support tools and allow for identification and discontinuation of support for tools that are not effective in improving safety, quality, or outcomes of care.



## Professional Education and Training

Pain is one of the most common reasons for health care visits.<sup>1,50</sup> Nonetheless, most health care professions' education programs devote little time to education and training about pain and pain care.<sup>9</sup> Given "strong indications that pain receives insufficient attention in virtually all phases of medical education," the IOM report found "education 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.<sup>51</sup>

To assure the needed improvement, education and training must allow learners to achieve discipline-specific 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 (including specific training on safe opioid prescribing practices), the risks associated with prescription analgesics, communication of these risks to patients, and prescriber education 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.

Efforts to enhance health care provider knowledge and skills for safer prescribing practices and identification of risks for opioid use disorder should be coordinated with ongoing activities across HHS including the Secretary's Initiative on Prescription Opioids, the pending CDC Guideline for Prescribing Opioids for Chronic Pain, the FDA approved Risk Evaluation and Mitigation (REMS) for Extended-Release and Long-Acting Opioid Analgesic Products, the Office of Disease Prevention and Health Promotion's (ODPHP) [Pathways to Safer Opioid Use](#), SAMHSA's [Providers' Clinical Support System for Opioid Therapies](#), and HHS's [Behavioral Health Coordinating Council](#) .

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, long-term services and supports, and social service 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.<sup>9</sup> Education and training of health, long-term services and supports, and social service 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, long-term services and supports, and social service 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.



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 stigmatization.<sup>6,21</sup> This bias and the documented decline in empathy as medical training progresses<sup>52</sup> 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 and risks associated with treatments.

*The intent of the Professional Education and Training section* is to anchor an attitudinal transformation toward pain and a reorganization of pain management by the health care system across all care settings and in the education and training of health professionals. The mission includes grounding the pain-related education and training of physicians, nurses, advanced practice nurses, clinical pharmacists, dentists, podiatrists, clinical health psychologists, social workers, physician's assistants, nurse practitioners, physical and occupational therapists, behavioral health specialists for mental health and substance use disorders, and other health, long-term services and supports, and social service 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 pre-licensure<sup>xx</sup> (undergraduate) and post-licensure (graduate) levels.**

*Short-term strategies and deliverables:*

- Convene an expert group that includes all relevant pre-licensure health professions to review, revise, and promote the set of interdisciplinary core competencies that have been developed and widely accepted for pre-licensure education in pain and pain care<sup>53</sup> (Appendix J). The expert group should develop a set of learning objectives to be achieved by the core competencies, devise plans to incorporate the competencies into their programs, beginning with selected sites for piloting curricular changes, and evaluate the effects of the core competencies. The relevant accrediting, certification, and licensing entities should be involved at early planning and subsequent phases of this strategy.
- Examine current specialist 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 through the planned effort of discipline-specific accrediting and certifying bodies related to nursing, clinical pharmacy, clinical health psychology, and other relevant health, long-term services and supports, and social service professional training schools and programs.

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<sup>xx</sup> Pre-licensure (undergraduate) level refers to a health professional currently enrolled in their degree program (e.g. bachelor, master, doctorate) and not yet licensed. Post-licensure (graduate/postgraduate) refers to a health professional who holds a degree in their discipline, has obtained their license and may be enrolled in a clinical residency or training fellowship program (graduate/postgraduate).



- 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 (include empathy and cultural sensitivity) for pre-licensure education, 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, as well as advanced practice nursing and physician assistant fields to develop and promote core primary care competencies by building on the existing undergraduate (short term) interdisciplinary core competencies and to approach ACGME regarding incorporation into relevant ACGME program requirements.
- Convene accrediting (e.g. ACGME, LCME) and certifying entities and related groups relevant to health care providers who provide pain management within the scope of their practice, 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.
- Publish and promulgate core competencies in post-licensure fields, including primary care education and training, through the work group convened for this purpose and in collaboration with relevant accrediting bodies.

*Long-term (within five years) strategies and deliverables:*

- Convene an expert group from pain care specialties to 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 pre-and post-licensure primary care and 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.

*Federal Stakeholders:* CDC, FDA, SAMHSA, and VHA, in collaboration with HRSA (as appropriate to their statutory priorities and within their authority)

*Collaborators:*

- relevant state and federal accreditation, certification, and licensing entities for physicians, nursing, dentistry, clinical pharmacy, physical therapy, physician assistants, clinical health psychology, long-term services and other relevant health disciplines
- relevant professional organizations for physicians, nursing, dentistry, clinical pharmacy, physical therapy, physician assistants, clinical health psychology, long-term services and other relevant health disciplines
- pain advocacy organizations and people with pain



- addiction and opioid use disorder advocacy organizations

*Metrics:* The validity and reliability of core competencies should be evaluated through the pilot projects based on the learning objectives developed by the expert group. The incorporation of core competencies into pre- and post-licensure disciplines should be tracked on an annual basis.

***Objective 2: Develop a pain education portal that leverages current activities and contains a comprehensive array of standardized materials to enhance available curricular and competency tools to address management across the continuum of pain and across the lifespan.*** 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. The portal also should support an expanded knowledge base among providers to assess, identify, and refer individuals at risk for mental health and substance use disorders to behavioral health specialty care when needed.<sup>54</sup>

*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 assessment and care for use by educators and learners across all health, long-term services and supports, and social service settings and for all patients, including vulnerable populations.
- Develop and evaluate a pilot portal that leverages the NIH Pain Consortium Centers of Excellence in Pain Education and the AHRQ's U.S. Health Knowledge Information Database.

*Medium-term strategies and deliverables:*

- Coordinate efforts and existing resources to launch the publically accessible portal and broadly disseminate and promote its availability and use.
- Reconvene stakeholders to develop an annual survey to measure each school's progress in teaching about pain and to develop learning objectives to assess effects of enhanced pain education. 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.

*Long-term (within five years) strategies and deliverables:*

- Monitor and continue to update the portal, which would be fully developed over a five-year horizon. Conduct an annual online survey to solicit feedback on quality and utility of the portal.
- Repeat the survey (five year intervals) of schools and otherwise monitor pain education to assure that core competencies are taught.

*Federal Stakeholders:* AHRQ, CDC, DoD, FDA, HRSA, NIH, NLM, ONC, SAMHSA, VHA (to develop content and architecture and strategies to monitor and promote the portal)

*Collaborators:*



- professional medical organizations
- educators (to help develop survey and portal content)
- pain advocacy organizations and people with pain

*Metrics:* Frequency of access to, and downloads from the portal should be monitored and reported annually. Feedback from the annual online survey of the portal should be used to update and improve its quality and utility. Results of the annual survey of school's progress should be promptly reported. Progress in enhancing educational content on core competencies should be linked to achievement of learning objectives.



## 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 costly, which underscores the importance of focused strategy development.

The National Pain Strategy envisions a significant effort to increase public awareness about pain and recommends two campaigns. The priority campaign is an extensive public awareness campaign about pain, to reach all people including patients, their caregivers, and health care, long-term services and supports, and social service providers, and the secondary campaign would promote safer medication use by patients. Both should use a scientific approach, 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.<sup>xxi</sup> These campaigns should be undertaken in such a way that they do not compete.

***The Problem:*** Pervasive stigmatization 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 and treatment risks. 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, long-term services and supports, and social service professionals and institutions, training and accreditation agencies, insurers, employers, foundations, patient advocate organizations, and others to participate in such campaigns and promote core messages.
- Deliver provider, public and patient education on risks and benefits of pain treatments and safer use of pain medications, including awareness of the risks for opioid use disorders that are associated with these prescription pain medications.

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



*The intent of the Public Education and Communication section 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 management.*

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

*Short-term strategies and deliverables:*

- Perform an environmental scan of existing relevant campaigns on chronic conditions and assess their impact in order to draw on successes in the design of this campaign.
- Establish a broadly representative advisory panel of stakeholders, to include patients with pain and members of their families, advocacy groups, professional societies, policy groups.
- Define campaign learning objectives (suggested concepts are in Appendix K), intended audiences, advisory structure, and budget.
- Develop requests for proposals from 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.
  - review existing information and educational materials.
  - develop a communications strategy based on behavior change theories for each targeted audience.
  - 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, feedback and partner engagement; adjust strategies as necessary.

*Long-term (within five years) 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.
- Prepare a report based on the campaign evaluations for submission to a peer-reviewed scientific journal.





- As funds are available, continue to monitor, implement, assess, and adapt campaign components, as needed, and report on campaign outcomes in a peer-reviewed journal.

*Federal Stakeholders:* ACL, CDC, FDA, NPC, OASH (ODPHP, Office of the Surgeon General, Regional Health Administrators)

*Collaborators:*

- public health organizations
- professional organizations
- private and public insurers
- human resources professionals
- health care providers
- patient advocacy organizations and people with pain
- employee assistance programs

*Metrics:* the outcome evaluations would provide data on changes in public (and those of relevant demographic or other subgroups) attitudes based on campaign learning objectives, which are to be developed by the advisory panel, which ideally could be compared with baseline data to determine any short-term trends and refined and updated over time to maintain the campaign messaging based on achievements of the learning objectives.

***Objective 2: Develop and implement a national educational campaign to promote safer use of all medications, 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.
  - review existing information and educational materials.
  - review available research on attitudes, knowledge, and medication practices of patients with chronic pain who take prescription medications, especially opioids.
  - review available evidence about settings, channels, and activities best suited to reach these patients, and commission additional research, as needed.
  - develop a communications strategy.
  - identify and recruit partner organizations.
- Align campaign messages and approaches with ongoing HHS efforts to promote safer and more appropriate use of prescription medications by patients and prescribers, such as:
  - promoting appropriate, safer, and effective use of opioids to manage chronic pain through the interactive tool [Pathways to Safer Opioid Use](http://health.gov/hcq/trainings/pathways/)<sup>xxii</sup>
  - electronic prescribing of controlled substances (EPCS).
  - facilitating use of state prescription drug monitoring programs.

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<sup>xxii</sup> <http://health.gov/hcq/trainings/pathways/>



- promoting clinical prescribing guidelines, such as the pending CDC Guidelines for Prescribing Opioids for Chronic Pain and the FDA Medication Guide for ER/LA Opioids (REMS<sup>xxiii</sup>).
- Cover the learning objectives and outcomes outlined in Appendix L in the campaign.
- Develop and pretest messages and materials based on preliminary work.

*Medium-term strategies and deliverables:*

- Implement the program, including partner participation strategies, spokesperson training, program-related 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.

*Long-term (within five years) 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.
- Continue to implement, assess, and adapt campaign components as needed.
- Conduct a five year progress assessment of the issue of safer use of pain medications.
- Prepare reports based on the campaign evaluations for submission to a peer-reviewed scientific journal.

*Federal Stakeholders:* CDC, FDA, NPC, OASH (ODPHP, Office of the Surgeon General, Regional Health Administrators), and SAMHSA

*Collaborators:*

- public health organizations
- professional organizations
- health, long-term services and supports, and social services providers
- public and private insurers
- human resources professionals
- health care providers
- credentialing bodies
- major retail pharmacy chains
- National Association of Boards of Pharmacy
- professional pharmacy organizations and pharmacists
- pain patient advocacy organizations and people with pain
- addiction and opioid use disorder advocacy organizations

*Metrics:* the outcome evaluations would provide current data on the medication practices of patients with pain based on campaign learning objectives, which ideally could be compared with baseline data

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<sup>xxiii</sup> <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>



to determine any short-term trends and refined and updated over time to maintain the campaign messaging based on achievements of the learning objectives.



## APPENDICES

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- 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 payment methodologies for pain-related treatments
- I. The Stepped Care Model of pain care
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- K. Public education general campaign learning objectives
- L. Learning objectives and potential outcome measures for an educational campaign on safe use of pain medications
- M. Conflicts of Interests/Financial Disclosures



## 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, [\*Relieving Pain in America\*](#), 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 ACA 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												
<p>Pain on at least half the days for 6 months</p>	<p>Over the last six months, on about how many days have you had pain?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> I have not had pain</li> <li><input type="checkbox"/> I have had pain, but on less than half the days</li> <li><input type="checkbox"/> I have had pain on more than half the days, but not every day</li> <li><input type="checkbox"/> I have had pain every day, but not all the time</li> <li><input type="checkbox"/> I have had pain all day, every day, without break</li> </ul>	<p>Chronic pain is pain on at least half the days over the past six months.</p>												
<p>Chronic pain severity (mild, moderate, severe)</p>	<p>In the past 7 days, how would you rate your pain on average?</p> <p>0=No pain      10= Worst imaginable pain</p> <p>In the past 7 days, how much did pain interfere with <u>your day-to-day activities</u>?</p> <p>0=No interference      10=Completely interferes</p> <p>In the past 7 days, how much did pain interfere with <u>your enjoyment of life</u>?</p> <p>0=No interference      10=Completely interferes</p>	<p>Mean or sum of the three 0-10 pain ratings.</p> <table border="0" style="width: 100%;"> <thead> <tr> <th></th> <th style="text-align: center;"><u>Mean</u></th> <th style="text-align: center;"><u>Sum</u></th> </tr> </thead> <tbody> <tr> <td>Mild</td> <td style="text-align: center;">&lt; 4</td> <td style="text-align: center;">&lt; 12</td> </tr> <tr> <td>Moderate</td> <td style="text-align: center;">4 to &lt; 7</td> <td style="text-align: center;">12 to 20</td> </tr> <tr> <td>Severe</td> <td style="text-align: center;">7 to 10</td> <td style="text-align: center;">21 to 30</td> </tr> </tbody> </table> <p>NOTE: If only two pain ratings are available, divide by the sum by two and multiple by 3 to obtain an estimated sum score.</p>		<u>Mean</u>	<u>Sum</u>	Mild	< 4	< 12	Moderate	4 to < 7	12 to 20	Severe	7 to 10	21 to 30
	<u>Mean</u>	<u>Sum</u>												
Mild	< 4	< 12												
Moderate	4 to < 7	12 to 20												
Severe	7 to 10	21 to 30												



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

Among people with chronic pain (as determined by screener questions in Appendix D), high-impact chronic pain is operationally defined by enduring participation restrictions because of pain, including:		
Participation restrictions because of pain	<ul style="list-style-type: none"> <li>• <b><i>Over the past 6 months because of pain...</i></b>  I have had trouble doing my usual work (including work for pay, work around the home, volunteer work).  Never Rarely Sometimes Usually Always</li> <li>• I have had trouble doing my regular social and recreational activities (such as visiting friends, going to the movies, attending clubs or religious activities).  Never Rarely Sometimes Usually Always</li> <li>• I have had trouble taking care of myself (for example dressing, bathing, or feeding myself).  Never Rarely Sometimes Usually Always</li> </ul>	At least one item rated “usually” or “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.



**Appendix G. Pain treatment indicators: Health care services for pain measurable with electronic health care data**

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



		anatomical site (e.g. laminectomy, fusion, discectomy for back surgery).	Diagnostic Clusters when necessary
	Injections, blocks and infusions	Differentiate 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 stimulation, deep brain stimulation		
Inpatient care	Surgical admission		Diagnostic codes identifying primary reason for admission
	Non-surgical admission		



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

<b>Public &amp; Private Payer Coverage of Pain-Related Treatments</b>						
<b>Payer</b>	<b>Pain-related Treatments</b>					
	<b>Medications</b>	<b>Regional Anesthetic Interventions</b>	<b>Surgery</b>	<b>Psychological Therapies</b>	<b>Rehabilitative/Physical Therapy</b>	<b>Complementary and Alternative Medicine (CAM)</b>
<b>Medicaid</b>	X	No state specific data found	X	X	X	X <sup>5</sup>
<b>Medicare</b>	X	X	X	X <sup>3</sup>	X <sup>4</sup>	X <sup>5</sup>
<b>Private Insurers (BCBSM example)</b>	X	X	X	X	X	X
<b>Veterans Health Administration (VHA)</b>	X	X	X	X	X	X <sup>6</sup>
<b>U.S. Department of Defense (DoD)/TRICARE<sup>1</sup></b>	X	X	X	X	X	X <sup>7</sup>
<b>Federal and State Workers' Compensation Programs<sup>2</sup></b>	<i>State:</i> X <i>Federal:</i> X	<i>State:</i> X <i>Federal:</i> X	<i>State:</i> X <i>Federal:</i> X	<i>State:</i> No state specific data found <i>Federal:</i> X	<i>State:</i> X <i>Federal:</i> X	<i>State:</i> No state specific data found <i>Federal:</i> X



**“X” indicates the payer offers coverage for procedure(s) within the treatment category**

<sup>1</sup> TRICARE is the health care program of the DoD Military Health System and is administered through managed care support contracts. The program offers service members and their families three main health plan options (TRICARE Prime, TRICARE Standard, and TRICARE Extra) that allow them to receive care from private health care providers.

<sup>2</sup> The Federal Employees’ Compensation Act (FECA) is the workers’ compensation program for federal employees and provides medical benefits to employees who are injured or become ill in the course of their federal employment. FECA covers all medical costs associated with the treatment of the work-related injury or illness. FECA benefits are paid out of the congressionally appropriated Federal Employees’ Compensation Fund. In contrast, state workers’ compensation programs are regulated by the state and provided through private insurance, state insurance funds, or self-insurance. Policies and programs vary widely among states.

<sup>3</sup> In 2014 and 2015, Medicare beneficiaries were responsible for a 20% coinsurance for outpatient psychological counseling services. Before 2014, the coinsurance was 35 to 50 percent.

<sup>4</sup> Most health plans have limitations on physical therapy and occupational therapy services. For 2015, Medicare had a \$1,940 combined annual cap for physical therapy and speech-language pathology services, and a \$1,940 annual cap for occupational therapy services. Many Medicare Advantage plans have chosen not to institute a therapy cap.

<sup>5</sup> Medicare and most state Medicaid programs only cover chiropractic services for manual manipulation of the spine to treat a subluxation (when one or more bones in the spine move out of position). A few state Medicaid programs, such as Florida and Rhode Island, have covered other CAM services, including acupuncture and massage therapy.

<sup>6</sup> Every VHA provider has a specific requirement to make chiropractic services available onsite.

<sup>7</sup> While some military medical facilities may offer services like acupuncture and chiropractic care, these are reserved for active duty members only. CAM services are largely excluded under TRICARE.

**Sources:** Kaiser Family Foundation, State Facts, Medicaid Benefits, 2011; Centers for Medicare & Medicaid Services; BCBSM; TRICARE; VHA; Department of Defense, Report to the Congress: Complementary and Alternative Medicine within the Military Health System, 2011; Department of Defense, Report to the Congress: The Implementation of a Comprehensive Policy On Pain Management by the Military Health Care System; Congressional Research Service, The Federal Employees’ Compensation Act (FECA): Workers’ Compensation for Federal Employees, June 2013.





**Public & Private Payment Methodologies for Pain-Related Treatments**

Payer <sup>1</sup>	Pain-related Treatments					
	Medications	Regional Anesthetic Interventions	Surgery	Psychological Therapies	Rehabilitative/Physical Therapy	Complementary and Alternative Medicines (CAM)
<b>Medicaid<sup>2</sup></b>	Pharmacies are reimbursed for the acquisition cost of the drug plus a dispensing fee, both of which can vary by state. For states that contract with a managed care entity (MCE) to provide drug benefits, the MCE would negotiate payments.	No state specific data found	Varies by state	35 states use fee-for-service to pay for psychologist services for individuals enrolled in adult Medicaid.	33 states use fee-for-service to pay for occupational therapy services for individuals enrolled in adult Medicaid.  35 states and DC use fee-for-service to pay for physical therapy services for individuals enrolled in adult Medicaid.	26 states use fee-for services to pay for chiropractic services for individuals enrolled in adult Medicaid.
<b>Medicare</b>	Medicare Part D plans negotiate prices with pharmacies and manufacturers. The negotiated price includes the ingredient cost and dispensing fee.	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule
<b>Private Insurers (BCBSM example)</b>	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service
<b>Veterans Health Administration (VHA)<sup>3</sup></b>	VA negotiates pricing and purchases directly from wholesalers and manufacturers.	Global Budget	Global Budget	Global Budget	Global Budget	Global Budget
<b>U.S. Department of Defense (DoD)/ TRICARE<sup>4</sup></b>	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
<b>Federal and State Workers' Compensation Programs<sup>5</sup></b>	<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



<sup>1</sup> All payers appear to be relying largely on single modality approaches.

<sup>2</sup> In July 2011, almost 75% of Medicaid beneficiaries were enrolled in some type of 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.

<sup>3</sup> 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 non-service-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.

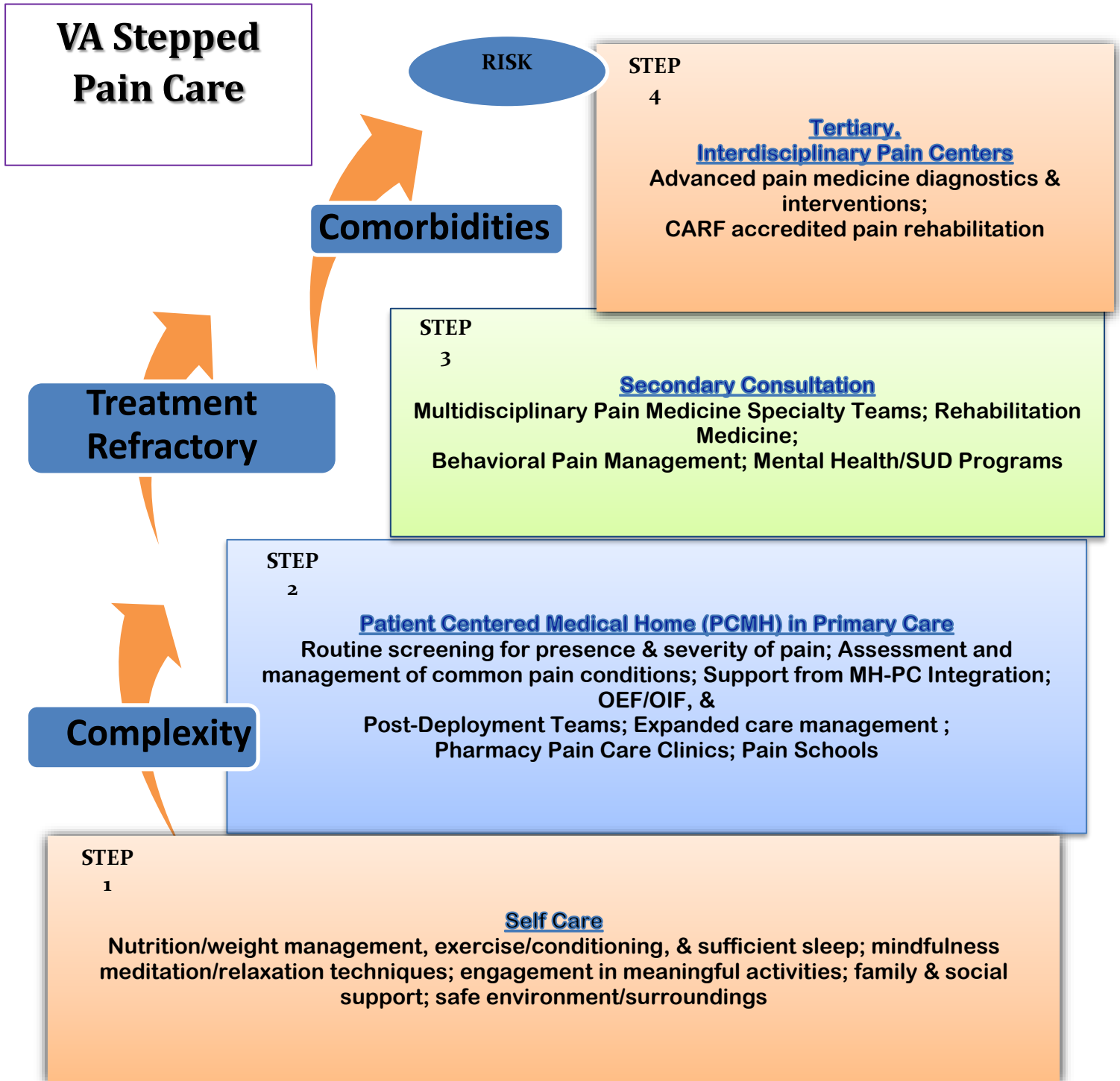
<sup>4</sup> Payment rates for TRICARE are generally aligned with Medicare. Health care providers who are employed at military medical facilities are salaried, like the VHA, and do not receive payment from TRICARE for the care they provide.

<sup>5</sup> Payment 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 I. The VA Stepped Care Model of pain care





## 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.<sup>51</sup> They provide 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.

1. 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.
2. 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.

1. 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.
7. 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.
3. Describe the role, scope of practice, and contribution of the different professions within a pain management care team.
4. 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. Suggested learning objectives for a public awareness campaign

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. The goal for chronic pain management is to alleviate pain and restore function. Patients should be aware of realistic treatment expectations.
9. Chronic pain may cause depression and depression increases the severity of pain.
10. Chronic pain may require a spectrum of medical and surgical treatments and/or non-medical interventions, including self-management strategies along with the active participation of people with chronic pain in their own pain care management.
11. Appropriate chronic pain management may involve prescription medications, which require knowledge of risks for adverse effects such as dependency and addiction.
12. Activity level and mood may vary depending on the intensity of chronic pain (good days and bad days).
13. Awareness of conditions and activities that contribute to injury, especially in the workplace, can prevent pain.



## Appendix L. Learning objectives and potential outcome measures for an educational campaign on safer 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 in selected and monitored patients and 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, including the use of naloxone.
12. Encourage family and friends to utilize Poison Control Centers as a confidential resource and to report possible opioid exposure and/or abuse by calling the Poison Help line <sup>24</sup>

### *Potential Outcome Measures*

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

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

\*A potential data source for some of these research questions is Research America's National Poll on Chronic Pain and Drug Addiction (CPDA).

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<sup>24</sup> Poison Control Hot Line (1-800-222-1222).



## Appendix M. Conflicts of Interests/Financial Disclosures

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