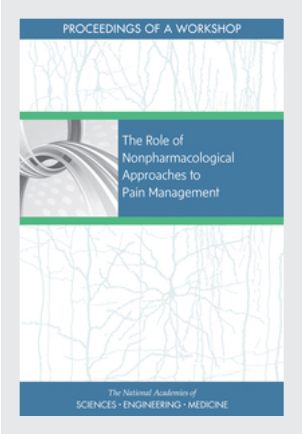

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The Role of Nonpharmacological Approaches to Pain Management

PROCEEDINGS OF A WORKSHOP

Lisa Bain, Sheena M. Posey Norris, and Clare Stroud,
Rapporteurs

Forum on Neuroscience and
Nervous System Disorders

Global Forum on Innovation in Health Professional Education

Board on Health Sciences Policy

Board on Global Health

Health and Medicine Division

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This Proceedings of a Workshop was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published proceedings as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the charge. The review comments and draft manuscript remain confidential to protect the integrity of the process.

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ROGER CHOU, Oregon Health & Science University
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Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the content of the proceedings nor did they see the final draft before its release. The review of this proceedings was overseen by **BRIAN STROM,** Rutgers, the State University of New Jersey. He was responsible for making certain that an independent examination of this proceedings was carried out in

accordance with standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the rapporteurs and the National Academies.

Contents

1

Introduction and Background[1]

Pain is a leading cause of disability globally (Dahlhamer et al., 2018; Vos et al., 2015). The dramatic increase in opioid prescriptions within the past decade in the United States has contributed to the opioid epidemic the country currently faces, magnifying the need for longer term solutions to treat pain (Rudd et al., 2016). The substantial burden of pain and the ongoing opioid crisis have attracted increased attention in medical and public policy communities, resulting in a revolution in thinking about how pain is managed, said Daniel Cherkin, senior investigator (emeritus) at the Kaiser Permanente Washington Health Research Institute. This new thinking acknowledges the complexity and biopsychosocial nature of the pain experience and the need for multifaceted pain management approaches with both pharmacological and nonpharmacological therapies, a recommendation of the 2011 Institute of Medicine report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (IOM, 2011b) and the National Academies report *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* (NASEM, 2017).

For example, Cherkin said the American College of Physicians recently recommended a dramatically new approach to managing back pain that begins with nonpharmacological treatments as first-line care (Qaseem et al., 2017). Nonpharmacological approaches are also emphasized in the

[1]The planning committee's role was limited to planning the workshop, and the Proceedings of a Workshop was prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants, and have not been endorsed or verified by the National Academies of Sciences, Engineering, and Medicine. They should not be construed as reflecting any group consensus.

Centers for Disease Control and Prevention's *Guideline for Prescribing Opioids for Chronic Pain* (Dowell et al., 2016), added Steven George, professor and director of musculoskeletal research at the Duke Clinical Research Institute. An important challenge is to find strategies to implement these guidelines effectively and efficiently in real-world practice, said Cherkin. Echoing the emphasis on implementation, Anthony Delitto, dean of the School of Health and Rehabilitation Sciences and professor of physical therapy at the University of Pittsburgh, added that implementing what is known now could make a big dent in addressing the challenges associated with pain management. Emerging models of care that provide integrated, patient-centered, evidence-based, multimodal, interdisciplinary care,[2] with systematic coordination of medical, psychological, and social aspects of care—a concept promoted by the National Pain Strategy—have been shown to decrease pain and increase function and will be important, said Robert Kerns, professor of psychiatry, neurology, and psychology at Yale University.

The magnitude and urgency of the twin problems of chronic pain and opioid addiction, combined with the changing landscape of pain management, prompted the National Academies of Sciences, Engineering, and Medicine's Forum on Neuroscience and Nervous System Disorders and its Global Forum on Innovation in Health Professional Education to convene a workshop on December 4–5, 2018, in Washington, DC. The workshop brought together a diverse group of stakeholders to discuss the current status of nonpharmacological approaches to pain management, gaps, and future directions.

WORKSHOP OBJECTIVES

The workshop was designed to provide participants with an understanding of the evidence currently available on the effectiveness and safety of nonpharmacological approaches to pain management, as well as information about emerging models of care for people living with chronic pain. In addition, the workshop explored barriers, opportunities, and policy changes needed to facilitate implementation of integrated systems of care that include nonpharmacological treatments (see Box 1-1). Workshop

[2]Defined in the National Pain Strategy as care provided by a team of health professionals from diverse fields who coordinate their skills and resources to meet patient goals.

BOX 1-1
Statement of Task

An ad hoc committee will plan and conduct a 2-day public workshop that will bring together key experts and stakeholders from government, academia, industry, health professional societies, and disease-focused organizations to discuss nonpharmacological treatments and integrative health models for pain management, and their role within the broad landscape of approaches to pain management. Invited presentations and discussions will be designed to:

- Review the current state of evidence on the effectiveness of nonpharmacological treatments and integrative health models for pain management, as well as available evidence on use patterns and patient interest. Examples may include acupuncture, manual therapies, physical therapy and exercise, cognitive behavioral therapy, tai chi, yoga, meditation, and noninvasive neurostimulation.
- Consider multimodal approaches and potential synergies between pharmacological and nonpharmacological approaches to pain management.
- Consider multimodal approaches and potential synergies between devices and nonpharmacological approaches to pain management.
- Discuss research gaps and key questions for further research.
- Examine health professions' current approaches for educating students, trainees, and practicing clinicians on nonpharmacological pain management, and discuss potential next steps to improve training and education within and across health professions.
- Explore policies, such as those related to reimbursement, that would enable broader dissemination and implementation of evidence-based nonpharmacological treatments when appropriate.

The committee will develop the agenda for the workshop, select and invite speakers and discussants, and moderate the discussions. A proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with National Academies' institutional guidelines.

presentations primarily focused on chronic pain.[3] There was limited discussion of natural products (e.g., cannabis and vitamins)—an examination of their effectiveness as treatments for pain was not within the scope of the workshop.

ORGANIZATION OF THE PROCEEDINGS

Chapter 2 provides context to the workshop, including perspectives from people living with pain and from providers about how pain is currently managed, and opportunities to reduce disparities. Chapter 3 examines the evidence available for nonpharmacological approaches to pain management and discusses future research priorities identified by individual workshop participants. Emerging models of care, including stepped, stratified, integrative, and multimodal care models, as well as the use of technology to encourage self-management, are discussed in Chapter 4. Chapter 5 highlights major current research initiatives supported by federal agencies and a nongovernmental institute in the United States that focus on pain management and reducing opioid use. Gaps in the education and training of health professionals in pain management are discussed in Chapter 6, along with opportunities to address these gaps within and across health professions to encourage the adoption and appropriate use of evidence-based approaches. Chapter 7 explores potential policy solutions to address barriers to the delivery of effective pain care. In Chapter 8, workshop participants consider potential next steps needed to advance the integration of evidence-based nonpharmacological approaches in pain care.

[3]For an in-depth discussion about pain management for people with serious illness, see the forthcoming proceedings from the complementary workshop on Pain and Symptom Management for People with Serious Illness in the Context of the Opioid Epidemic, hosted on November 29, 2018, by the National Academies' Roundtable on Quality Care for People with Serious Illness. For more information, see http://nationalacademies.org/hmd/activities/healthservices/qualitycareforseriousillnessroundtable/2018-nov-29.aspx (accessed February 9, 2019).

2

Workshop Context: Lived Experience, Provider Perspectives, and Current Patterns of Usage

Highlights

- A substantial gap exists between scientific evidence and clinical practice for pain and the decisions people make about how to manage their pain (Cherkin, Veasley).
- Practitioners, like patients, face a significant gap in measuring and understanding pain, and in assessing the effectiveness and potential harms of treatments (Ryan).
- Effective pain management requires understanding and treating the multidimensional, including biopsychosocial, aspects of pain (George, Turk).
- Placebo responses and interindividual variability in pain thresholds and response to treatment may confound evaluations of the effectiveness of pain treatments (Kroenke, Turk).
- Currently available methods of assessing pain do not fully capture an individual's experience of pain (Turk).
- Claims-based data show that nonpharmacological therapies for pain account for only a small percentage of total costs (Elton).
- When a pain patient's first point of contact is a physical therapist, chiropractor, or acupuncturist, the odds of early and long-term exposure to opiates is markedly reduced (Elton).
- Low-income populations experience higher rates of pain, disability, and comorbidities, but have less access to pain management resources, including nonpharmacological treatments (Thorn).

NOTE: These points were made by the individual speakers identified above; they are not intended to reflect a consensus among workshop participants.

LIVED EXPERIENCE AND PROVIDER PERSPECTIVES

To ensure that patient and provider experiences were central to the workshop discussions, the workshop opened with perspectives from a person living with chronic pain and a family physician. According to Christin Veasley, director of the Chronic Pain Research Alliance, chronic pain is the leading cause of disability worldwide and a major contributor to the rising number of suicides (Petrosky et al., 2018). Yet both Veasley and Daniel Cherkin noted that a substantial gap exists between the scientific and clinical understanding of pain and the decisions people make about how to manage their pain. This gap, said Veasley, arises from multiple factors: an insufficient workforce to address chronic pain; the paucity of team-based medical homes; the classification of pain disorders by symptoms rather than mechanisms; the lack of objective measures of pain; insufficient high-quality evidence about the efficacy of both pharmacological (e.g., opioids) and nonpharmacological (e.g., massage) treatments for pain; and insufficient data on risks, benefits, and cost-effectiveness of the various treatment alternatives.

Patients living with chronic pain face several decisional dilemmas, said Veasley. These include (1) how to evaluate which nonpharmacological treatment options may work when, for some approaches, little evidence exists to inform this decision; (2) how to choose the optimal combination of safe and effective treatments; and (3) how to choose the optimal modality, type, or technique within each selected treatment (e.g., the type of massage that would be most likely to provide pain relief). Veasley suggested that by developing research questions based on the decisional dilemmas faced by patients, the field could generate an evidence base, improve reimbursement, improve outcomes, and reduce uncertainty.

One reason for the low level of evidence available for nonpharmacological approaches to pain management is the variability in frequency, duration, and type among studies, said Veasley. Another problem is that in order to systematically and quantitatively review data from studies, outcomes must be assessed in a comparable manner, which is complicated by the fact that chronic pain may vary substantially from day to day and week to week and by limitations of the scales used for assessing pain. The frequent presence of comorbidities adds further complications given that patients may be receiving many different therapies for pain and nonpain conditions. All of this variability makes it hard to know exactly what is or is not working.

Moreover, she said, the experience and management of pain varies according to the underlying conditions that are contributing to a person's pain. For example, managing pain in a person with new-onset osteoarthritis is going to be very different from managing the pain of a person with diabetic neuropathy who also has obesity and a sleep disorder.

Mark Ryan, a family physician at Virginia Commonwealth University, added that providers face other challenges when trying to manage patients' pain. The national conversation on pain management did not begin to shift until the early 2000s, shortly after Ryan began his residency. The Joint Commission established standards for assessing and treating pain in 2001 (Baker, 2017; Phillips, 2000), but Ryan said it was challenging to assess pain using the scale that asks a patient to rate their pain on a scale of 0 to 10, rather than using metrics that assess global function, quality of life, or other relevant aspects of the pain experience. Practitioners, like patients, face a significant gap in measuring and understanding pain, and in assessing the effectiveness and potential harms of treatments. Moreover, treatment in the early 2000s was almost completely focused on medication, he said. The idea of integrative and comprehensive care that includes behavioral health and physical therapy was not included as part of physician training.

When Ryan moved to a rural practice in 2003, other challenges became evident, including the lack of local resources for pain management and limited access to pain management specialists. Now in his current position in Richmond, Virginia, he faces different challenges—for example, 40 percent of new adult patients in his practice lack insurance, are covered by the system's indigent care plan, and have limited access to nonpharmacological therapies. Although he can make referrals for physical therapy or other services, patients face practical barriers that limit access to those services, such as transportation challenges and concerns about taking time off work to go to appointments on a consistent basis. Outside of the health system, even insured patients face significant challenges. Examples include pain management programs that limit the type of insurance they accept, specialists who focus primarily on procedures such as nerve blocks or epidural injections, and the lack of an integrated pain service.

Concerns about opioid use have exacerbated the difficulties providers experience in caring for patients with pain, said Ryan. Taken together, these challenges have led to dissatisfied and unhappy patients with significant concerns, and dissatisfied, unhappy providers who lack the tools they need to manage their patients' pain appropriately. There are also pressures

at the health system level to manage chronic pain in an expeditious manner while also caring for patients' other primary care needs.

Ryan expressed his hope that the workshop would identify actionable and practical strategies to address pain management in primary care settings, outline evidence-based and effective approaches to chronic pain management that do not rely on opioids or other medications, and encourage research focused on improving chronic pain management in primary care settings. He also advocated for efforts to improve provider–patient communication regarding treatments and goals for managing chronic pain using collaborative and holistic approaches that encourage shared decision making.

Veasley added that a paradigm shift is needed wherein all relevant stakeholders come together at the genesis of a research project and work collaboratively throughout it to bridge the translational divide between basic science and patient care. In addition, research aims that matter to decision makers—including, patients, clinicians, and payers—are needed to ensure successful execution of rigorous science and to promote the adoption of findings into clinical care.

BACKGROUND ON PAIN AND NONPHARMACOLOGICAL PAIN MANAGEMENT

A recent analysis of the burden of disease in the United States found that 5 chronic pain conditions account for more disability than the 12 leading medical conditions (see Figure 2-1), said Kurt Kroenke, chancellor's professor of medicine at Indiana University and a research scientist at the Regenstrief Institute (Murray et al., 2013). If depression and anxiety are added to the list of pain conditions, which are comorbid in 30 to 50 percent of people with chronic pain, the burden is even greater. Moreover, most people with chronic pain have pain in multiple body sites (Kroenke et al., 2013).

The burden of pain comes not only from the individual perception of pain itself, but from how it affects other aspects of life, including social roles, vocation, and health care seeking, said Steven George. Understanding this complexity is an essential first step in both treating and managing pain.

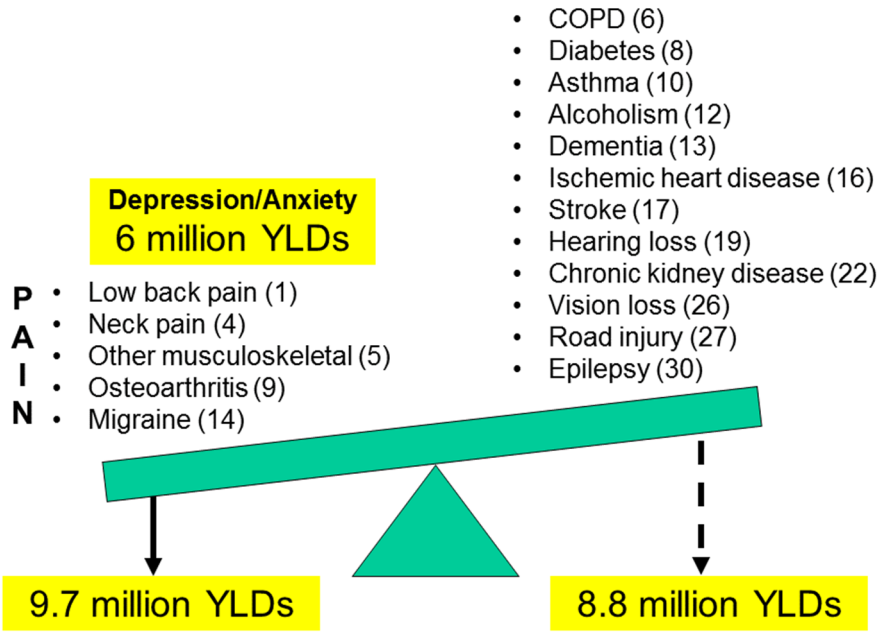

FIGURE 2-1 Years lived with disability (YLDs).
NOTES: In the United States, pain accounts for 9.7 million YLDs in comparison with 8.8 million YLDs for the 12 leading medical conditions. COPD = chronic obstructive pulmonary disease.
SOURCES: Presented by Kurt Kroenke, December 4, 2018; adapted from Murray et al., 2013.

Understanding Pain and Pain Management

George described pain using the analogy of an onion, with the layers being nociception, individual experience, and impact (see Figure 2-2). At the center of the onion is nociception, the nervous system's response to painful stimuli. Nociception is embedded within other layers of the onion that comprise the individual's experience of pain such as the beliefs, emotions, and coping strategies that introduce tremendous variability in how pain is experienced. All of these factors contribute to the impact pain has on other aspects of a person's life. It was no surprise, George added, that when the Institute of Medicine published its report *Relieving Pain in America* they concluded that pain is a major driver of health care, disability, and reduced quality of life (IOM, 2011b).

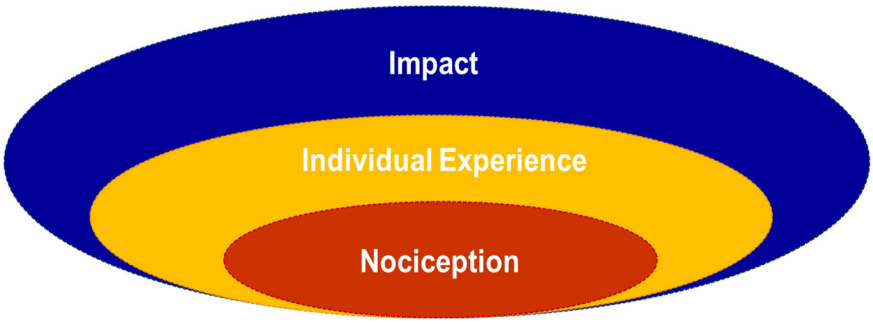

FIGURE 2-2 Understanding the layers of pain.
SOURCE: Presented by Steven George, December 4, 2018.

Treating pain is different from managing pain, said George. Individual pain treatments target nociception, while pain management addresses multiple layers. Typically, a patient's first contact with a health care provider trained in conventional medicine leads to diagnosis and drug treatment, with management of pain through nonpharmacological and other approaches only introduced later. Recent changes in the guidelines for how pain is managed aim to shorten that interlude, moving nonpharmacological care closer to the first contact point through more cohesive and integrated management pathways, said George.

A large therapeutic armamentarium for pain exists, including medications, surgical procedures, physical modalities, and complementary and multidisciplinary approaches, said Dennis Turk, director of the Center for Pain Research on Impact, Measurement, & Effectiveness (C-PRIME) at the University of Washington. The problem, he said, is that for any of these approaches, evidence of effectiveness is modest (Moore, 2013). Kroenke added that the limited effectiveness of pharmacological treatments is true for both opioids and non-opioids (Krebs et al., 2018). While opioids and non-opioids both showed modest benefits in a recent randomized controlled trial for people with moderate to serve chronic pain or hip or knee osteoarthritis, opioids have higher rates of side effects. Moreover, Kroenke noted that in multiple trials for different types of chronic non-neuropathic pain, there is insufficient evidence supporting cannabis as an analgesic (Hill, 2015; Nugent et al., 2017).

Possible explanations for the lack of substantial benefits for pain treatments include an almost exclusive reliance on the biomedical model of pain and a focus on managing pain itself rather than managing the person who has pain, said Turk. The biomedical perspective assumes that pain is

a signal of injury or some structural pathology; that removal of the problem may be possible through some mechanical fix; and that treatment consists of symptomatic relief alone. Turk used the example of fibromyalgia to illustrate the problem of approaching a pain condition with symptomatic treatment. A checklist of 43 symptoms is used to evaluate patients with fibromyalgia, and the average patient endorses 33 of these symptoms. A single treatment would almost certainly be insufficient to deal with the fatigue, pain, cognitive and emotional problems, and many other symptoms reported by patients, he said.

Placebo responses—the perceived improvement in symptoms resulting from an inactive treatment—can also complicate evaluations of the effectiveness of pain treatments. Kroenke said that placebos have been shown to reduce pain by 30 to 50 percent. Placebo responses have biological underpinnings mediated by overlapping pain circuits (Kroenke and Cheville, 2017). Although placebo effects can undermine the ability to demonstrate effectiveness of the investigational treatment in clinical trials, Kroenke said these effects should be maximized in clinical practice.

Other important factors contributing to the modest effectiveness of pain treatments is interindividual variability in pain thresholds, response to various treatments, and psychosocial characteristics that influence the experience of pain and the response to treatments, said Turk. Patients also vary in terms of the relationship between objective evidence of pathology and how intensely they experience pain (e.g., patients with the same extent of tissue pathology respond in widely different ways to the same interventions) (Gerbershagen et al., 2013). Thus, objective pathology alone makes it challenging to predict a person's pain experience and response to treatment. Furthermore, how much pain a person experiences does not necessarily equate to his or her functional limitations, Turk added.

Assessing an individual's pain is also fraught with problems, said Turk. Objective information, self-reports, functional performance, and behavioral observations may all be useful, but are poorly correlated with one another and highly variable from person to person. Turk argued that in assessing pain, biological factors are important, but must be considered along with the individual's history, attitudes, beliefs, emotions, behaviors, and emotional and financial resources. Moreover, to maximize therapeutic effectiveness, clinicians need to determine how best to facilitate, encourage, and motivate patients for self-management when a cure is not possible. In addition, Turk said the field needs to develop and evaluate new treatments and regimens that address pain and comorbidities and prevent

misuse and disability; determine what works for whom; evaluate combination treatments; and investigate strategies to facilitate maintenance and generalization of treatment benefits and relapse prevention.

Providing Complementary and Integrative Health Approaches to Different Populations in the United States

David Elton, senior vice president of clinical programs at Optum, presented claims data to describe usage patterns for pharmacological and nonpharmacological pain treatments, noting that claims-based data do not fully reflect usage because they are blind to out-of-pocket expenditures for many nonpharmacological therapies, such as acupuncture, chiropractic services, and massage, and to non-covered services such as yoga, virtual reality, and mindfulness. Claims-based data are also affected by other distortions such as incorrect coding, capitation, and other factors. Nonetheless, and keeping these caveats in mind, Elton said the data from UnitedHealthcare/Optum show that spending on nonpharmacological therapies focused on pain across commercial, Medicare, and Medicaid enrollees totaled about $3.4 billion, or 2.4 percent of all costs in 2017. He noted that Medicare and Medicaid populations encounter increased coverage constraints because most states provide limited to no coverage for acupuncture and chiropractic care.

Using a technique that takes claims data and creates "episodes of care" as a means of understanding spending by diagnostic condition, Elton showed that musculoskeletal complaints are responsible for about 16 percent of costs as well as most prescriptions for opioids and opioid-containing medicines, with back pain being the most frequent complaint.

Elton and colleagues have looked at how a person's first point of contact after the onset of back pain influences the use of nonpharmacological therapies and opioid use; although, Elton noted that they were not able to adjust for factors that might confound the association between the type of first contact point and opioid use. What they found was that when the first point of contact was a physical therapist, chiropractor, or acupuncturist, the odds of early and long-term exposure to opioids was markedly reduced. He added that while the guidelines suggest that chiropractic manipulation has an important role to play, patients receive this care only if they start with a chiropractor. The same is true for acupuncture, massage, and other nonpharmacological therapies, said Elton, calling this an unacceptable level of variation in care delivery. He added that patients' decisions

about who will be their first point of contact vary considerably due to individual preferences and how the pain manifests; however, all providers should be aware that these other therapies are indicated and preferred over opioids for most back pain.

Elton added that an economic model on the value of these therapies indicated that if the front-line use of chiropractic or physical therapy could be increased from 30 to 50 percent in 2 years, more than $200 million could be saved per year. He suggested that simple changes in coverage and practice could achieve these savings, adding that he and his colleagues will be testing this idea over the next couple of years.

Reducing Disparities in Pain Management

Managing pain is especially difficult in low-income populations for multiple reasons, said Beverly Thorn, professor emeritus of psychology at the University of Alabama. Although these populations have higher rates of pain, disability, and comorbidities, they lack access to health care resources and consequently get less treatment for pain, she said. Access limitations may also affect other subpopulations, said David Atkins, director of the Department of Veterans Affairs Health Services Research and Development Service. For example, while veterans often have physically demanding jobs that increase the incidence of chronic pain, they may also be unable to take the time off for multiple sessions of acupuncture, chiropractic, or cognitive behavior therapy (CBT).

Thorn noted that low-income populations are often excluded from clinical trials for various reasons, including low literacy. Given that the conclusions drawn from randomized clinical trials with middle-income participants may not generalize to the broader population, Thorn argued for research that focuses on modifying treatments for disadvantaged individuals. For example, she and her colleagues have adapted CBT and self-management treatments by adapting the workbooks and other tools for people with low literacy. In a randomized clinical trial of this literacy-adapted and simplified group CBT approach compared with group pain education or usual care, they showed that after treatment, participants in the modified CBT and group pain education arms had lower pain intensity scores and improved function compared with the usual care arm (Thorn et al., 2018). Interestingly, she said, individuals with the lowest literacy levels and lowest cognitive function received the most benefit from adapted CBT. Anthony Delitto added that modifications of some nonpharmacolog-

ical approaches such as exercise and yoga are also needed for certain subpopulations (e.g., older adults) who may have limited mobility, flexibility, strength, or stamina.

3

Effectiveness, Safety, and Cost-Effectiveness of Nonpharmacological and Nonsurgical Therapies for Chronic Pain

Highlights

- Although many pharmacological therapies exist for treating pain, evidence of effectiveness for chronic pain is limited for many of them (Chou, Kroenke, Turk).
- Psychosocial factors strongly predict the transition from acute to chronic pain and the severity of pain (Chou).
- New guidelines support a shift from pharmacological to nonpharmacological approaches for the treatment of pain, and there is some fair- to good-quality evidence of effectiveness of some of those treatments (Chou).
- Cost-effectiveness studies support the use of mindfulness-based stress reduction, yoga, acupuncture, and cognitive behavioral therapy in treating lower back pain (Herman).

NOTE: These points were made by the individual speakers identified above; they are not intended to reflect a consensus among workshop participants.

Over an approximate 10-year period from 2000 to 2010, there was an approximate four-fold increase in opioid prescribing, despite limited short-term benefits, lack of data on long-term benefits, and clear evidence of serious harms, said Roger Chou, professor of medicine, medical informatics, and clinical epidemiology at the Oregon Health & Science University School of Medicine. Other pharmacological treatments for pain are also associated with similarly modest benefits, said Chou, without the risk of overdose or opioid use disorder. A systematic review that he and colleagues conducted found that of the many medications evaluated for the

treatment of low back pain, only nonsteroidal anti-inflammatory drugs, opioids, muscle relaxants, and duloxetine had small and mostly short-term effects (Chou et al., 2017). The limited effectiveness and potential for harm from pharmacological treatments has fueled interest and shifted the emphasis of treatment toward nonpharmacological therapies. However, when the new guidelines from the Centers for Disease Control and Prevention (CDC) were published in 2016 recommending nonpharmacological therapy and nonopioid pharmacological therapy for chronic pain (Dowell et al., 2016), Chou said there was minimal direct evidence to support the recommendation at that time. Nonetheless, he said the steering committee for the scientific review that had been conducted believed the body of evidence was sufficient to support the recommendation.

Another driver for emphasizing nonpharmacological approaches has been the evolution in the understanding of chronic pain from a biomedical to a biopsychosocial model, said Chou. For example, psychosocial factors are known to predict more strongly the transition to chronic pain and severity than biological factors assessed with imaging studies and laboratory tests. Thus, he said, effective treatment strategies require addressing psychosocial contributors. In addition, improvements in function as well as pain are required for a treatment to be considered effective (Chou and Shekelle, 2010; Gatchel et al., 2007). Chou cited the STarT Back trial as one that demonstrated improved outcomes using this approach. The study stratified patients according to psychosocial factors that influence their risk of developing chronic low back pain, and then used a stepped-care approach to deliver more intensive cognitive behavioral therapy (CBT) informed physiotherapy aimed at reducing disability and improving function to those at higher risk (Hill et al., 2011).

Chou described the various therapies he and his colleagues have considered when developing guidelines for the nonpharmacological treatment of pain:

- CBT, a psychological treatment that focuses on restructuring maladaptive thinking patterns and replacing them with healthier behaviors.
- Biofeedback, which uses sensors that provide feedback in order to help people control processes that are usually involuntary and thus help with relaxation and coping.
- Mind–body interventions, including meditation, relaxation, mindfulness-based stress reduction (MBSR), and movement-based therapies such as yoga and tai chi.

- Exercise therapies of many different types.
- Interdisciplinary rehabilitation that combines physical and biopsychosocial approaches.
- Classic integrative alternative or complementary therapies, including manipulation, acupuncture, and massage.
- Physical modalities such as ultrasound, transcutaneous electrical nerve stimulation (TENS), low-level laser therapy, traction, and lumbar supports.

To evaluate the evidence supporting these approaches, Chou and colleagues focused on low back pain, the leading cause of disability according to the 2013 Global Burden of Disease study and a condition reported by more than half of regular opioid users (Deyo et al., 2015; Vos et al., 2015). Recent studies indicate that the prevalence of low back pain has increased in recent years, said Chou, suggesting that the current biomedical approach of using more opioids, imaging, and surgery may not be working (Buser et al., 2018).

EXAMINING THE EFFECTIVENESS AND SAFETY OF NONPHARMACOLOGICAL APPROACHES

Most of the evidence on the effectiveness of nonpharmacological pain treatments has been collected in patients with low back pain, said Chou. He noted several challenges associated with collecting these data, including the inability to mask treatments, variability in techniques and intensity of treatments, differences among providers, the small magnitude and duration of effects, interindividual variability including the presence of psychological comorbidities, maladaptive coping behaviors, fear avoidance, catastrophizing, sensitization of the central nervous system, and concomitant use of opioids. Furthermore, data on functional effects have been limited. Studies of nonpharmacological approaches have also had methodological limitations as well as factors related to professional bias, for example, if chiropractors, rather than neutral investigators, are the sole authors involved in studies of chiropractic interventions.

Chou presented data from a review published in 2007 by the American College of Physicians (ACP) and the American Pain Society (APS) (Chou et al., 2007). In 2007, there was some fair- to good-quality evidence of small to substantial benefits for many of the nonpharmacological therapies, although the evidence for physical modalities was so poor that the

committee was unable to estimate the magnitude of benefit. The result of this analysis led to the ACP/APS low back pain guidelines, which were the first national guidelines to recommend spinal manipulation, massage, yoga, acupuncture, and progressive relaxation as treatment options for low back pain. However, the analysis provided little guidance on the optimal techniques, intensity, duration, timing, or sequence of therapies, or on how to select a therapy for a particular individual, said Chou.

The subsequent analysis published in 2017 found more evidence to support yoga, tai chi, and MBSR, but still found little evidence to support the use of physical modalities, said Chou (see Table 3-1). This analysis led to the publication of updated ACP clinical practice guidelines, which recommended nonpharmacological therapies as the preferred treatment for chronic back pain (Qaseem et al., 2017).

The Agency for Healthcare Research and Quality asked Chou and colleagues to conduct another review in 2018, this time focusing on the durability of effects for noninvasive, nonpharmacological treatments for chronic pain. In this report (see Table 3-2), data from studies examining five common chronic pain conditions (low back pain, neck pain, osteoarthritis, fibromyalgia, and tension headache) were included. Interventions were compared against usual care, sham, attention control, or wait list. The

TABLE 3-1 Effectiveness and Strength of Evidence of Nonpharmacological Treatments for Chronic Pain Versus Sham, No Treatment, or Usual Care as Described in the 2017 American College of Physicians Systematic Review on Low Back Pain

Intervention	Magnitude of Effect	Strength of Evidence
Acupuncture	Moderate	Low–moderate
Exercise	Small	Moderate
Interdisciplinary rehabilitation	Moderate	Low–moderate
Massage	No effect	Low
Psychological interventions	Small–moderate–improved	Low–moderate
Spinal manipulation	No effect–small	Low
Tai chi	Moderate	Low
Yoga	Small–moderate	Low

SOURCES: Presented by Roger Chou, December 4, 2018; derived from Qaseem et al., 2017.

TABLE 3-2 Comparative Effectiveness of Noninvasive Treatments for Low Back Pain Compared with Usual Care, Sham, Attention Control, or Waitlist; Effectiveness and Strength of Evidence (SOE) of Noninvasive, Nonpharmacological Interventions on Function and Pain Over Short Term (<6 Months), Intermediate Term (≥6 to <12 Months), and Long Term (≥12 Months); Number of + Signs Indicate Strength of Evidence

Intervention	**Function** *Short-Term*	**Function** *Intermediate-Term*	**Function** *Long-Term*	**Pain** *Short-Term*	**Pain** *Intermediate-Term*	**Pain** *Long-Term*
	Effect Size SOE	Effect Size SOE	Effect Size SOE	Effect Size SOE	Effect Size SOE	Effect Size SOE
Exercise	slight +	none +	none +	slight ++	moderate +	moderate +
Psychological Therapies: CBT primarily	slight ++	slight ++	slight ++	slight ++	slight ++	slight ++
Physical Modalities: Ultrasound	insufficient evidence	no evidence	no evidence	none +	no evidence	no evidence
Physical Modalities: Low-Level Laser Therapy	slight +	none +	no evidence	moderate +	none +	no evidence
Manual Therapies: Spinal Manipulation	slight +	slight +	no evidence	none +	slight ++	no evidence
Manual Therapies: Massage	slight ++	none +	no evidence	slight ++	none +	no evidence
Manual Therapies: Traction	none +	no evidence	no evidence	none +	no evidence	no evidence
Mindfulness Practices: MBSR	none +	none +	none +	slight ++	slight +	none +
Mind-Body Practices: Yoga	slight ++	slight +	no evidence	moderate +	moderate ++	no evidence
Acupuncture	slight +	none +	none +	slight ++	none +	slight +
Multidisciplinary Rehabilitation	slight +	slight +	none +	slight ++	slight ++	none +

NOTE: CBT = cognitive behavioral therapy; MBSR = mindfulness-based stress reduction.

SOURCES: Presented by Roger Chou, December 4, 2018; from Skelly et al., 2018.

review also evaluated head-to-head comparisons; exercise was used as a standard head-to-head comparator for all conditions other than tension headache, which was compared with biofeedback. In this study, no treatments were determined to have substantial benefits; however, there was evidence for moderate long-term effects following a course of exercise therapy and slight long-term effects following psychological therapy (primarily CBT). Chou noted that for chronic low back pain, there was some evidence of persistent benefits from multidisciplinary rehabilitation, but limited benefits for other chronic pain conditions and little evidence to support the use of specific techniques, duration, intensity, or sequencing of therapies.[1]

Chou said little evidence showed whether the use of nonpharmacological therapies influenced opioid use and associated harms. Few harms were reported in trials of nonpharmacological treatment, including few serious harms with spinal manipulation, he added. David Elton reported similar findings when he and his colleagues analyzed data from people with neck pain who experienced cerebrovascular accidents (CVAs) (Kosloff et al., 2015). They concluded there was no association between the neck pain and spinal manipulation. Indeed, he said, patients with neck pain were more likely to have a CVA following treatment by a primary care provider than a chiropractor. Few studies have looked at the effect of these treatments on depression and suicidality, Chou added.

Daniel Cherkin commented that while the conclusion of most of these studies (Qaseem et al., 2017; Skelley et al., 2018) was that both pharmacological and nonpharmacological treatments were ineffective or had small average effects, responder analyses suggest about 20 percent of patients experience clinically meaningful improvements in functional outcomes. What we do not know, he said, is whether the same 20 percent would benefit from many treatments or if a different 20 percent would benefit from each specific treatment.

Kurt Kroenke agreed, but pointed out that while nonspecific effects may be discounted in trials, they are optimized in clinical practice. He suggested that the nonspecific benefits of a treatment and the role of the therapeutic relationship are underestimated. Kroenke and his colleagues have found that in clinical trials, a thorough pain history of prior treatments takes about 15 minutes, which, in itself, may be the most useful step in

[1]Following the workshop, Andrew Vickers and colleagues (2018) published a meta-analysis on the effectiveness of acupuncture for chronic pain management. See https://www.sciencedirect.com/science/article/pii/S1526590017307800 (accessed March 13, 2019).

planning to the optimal treatment strategy for the patient. Sadly, however, there is insufficient time for that in clinical practice, he said.

With regard to potential disparities, Chou said little evidence to understand differences in effectiveness among indigent or socioeconomically disadvantaged populations, despite variations in access and presence of comorbidities. Similarly, there is little evidence of age, race, or ethnicity effects, although patient expectations and beliefs can impact effectiveness and may be influenced by culture and where one lives. He agreed that more studies are needed to assess differential effectiveness in subpopulations.

Sharing information with patients and clinicians from the systematic evidence reviews that have been conducted has proved to be challenging because the reports are so long, said Chou. The Comparative Effectiveness Review No. 209, for example, is nearly 1,400 pages long (Skelly et al., 2018). He described two apps—MAGICapp[2] and Tableau[3]—designed to make this information more accessible by allowing users to click on particular conditions and outcomes data with different interventions. Chou said there are other efforts to make these data more informative and usable, including living systematic reviews that allow evidence reviews to be continually updated, open-access reviews, and the use of novel analytic technologies.

As reported in Chapter 2, Christin Veasley mentioned some of the reasons for the lack of strong evidence to support the use of nonpharmacological therapies. Chou added that few studies report levels of adherence to a treatment protocol, which can be a significant complicating factor. To move forward and develop the necessary evidence, Veasley said a number of questions need to be addressed, including whether a stepped or adaptive approach is needed to understand the efficacy of combined therapies; whether there are core components across nonpharmacological interventions that account for efficacy that could be standardized across studies; which research models and study designs would provide the rigor needed to generate evidence in a timely manner; and how the field can evaluate the efficacy of many types of interventions across pain conditions.

[2]For more information about MAGICapp, see https://app.magicapp.org (accessed February 6, 2019).

[3]For more information about Tableau, see https://www.tableau.com (accessed February 6, 2019).

COST-EFFECTIVENESS AND COST SAVINGS FROM A SOCIETAL PERSPECTIVE

Beyond assessing whether a new treatment improves health compared to usual care, health economists such as Patricia Herman, senior behavioral scientist at the RAND Corporation, also ask about cost-effectiveness—whether the treatment increases or reduces costs compared with usual care. If health improves but costs increase, policy makers must then decide whether the additional health benefits are worth the costs, including both costs borne by patients, payers, and health systems as well as societal costs such as low productivity, she said (see Figure 3-1). A metric that health economists use to quantify the benefit of a treatment is quality-adjusted life-years (QALYs), which combine increases in both length and quality of life, said Herman. Anything below $50,000 per QALY is generally considered cost-effective, adding that some interventions may be cost savings if, for example, a treatment reduces the need for surgery, imaging, or injections.

In 2012, Herman and colleagues published a systematic review of the cost-effectiveness of complementary therapies and integrative care (Herman et al., 2012). They reviewed studies that evaluated costs compared with usual care from the perspective of a hospital, payer, employer, or society in general. Herman noted that economic outcomes cannot be generalized across settings, but the information obtained in one setting can be adjusted to other settings through simulation modeling. Of the 28 higher quality

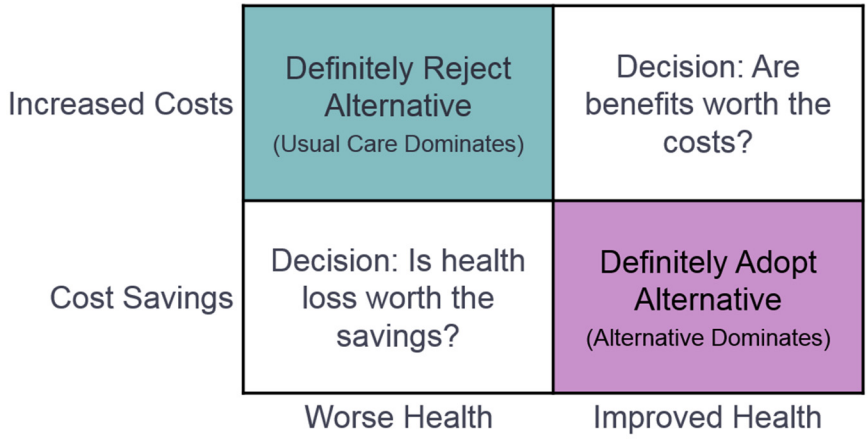

FIGURE 3-1 Cost-effectiveness decision matrix.
SOURCE: Presented by Patricia Herman, December 4, 2018.

studies identified, two-thirds had to do with pain and included a variety of interventions, including exercise, acupuncture, naturopathic care, massage, chiropractic, and other forms of manipulation. Five of these interventions were found to result in cost savings, while the costs of most of the others ranged from $3,000 to $28,000 per QALY. Only one exceeded the $50,000/QALY threshold. Evaluations of most of the low-cost interventions used a societal perspective that included productivity gains. Herman added that for some studies, costs might have been even lower if health care cost reductions had been captured over a longer period.

Another study using simulation modeling to assess the cost-effectiveness of cognitive and mind–body therapies for chronic low back pain was published in 2017 by the Institute for Clinical and Economic Review (ICER) (Tice et al., 2017). Models such as this allow researchers to fill in the gaps that exist with patient data to help understand the cost-effectiveness of interventions and to see where to target future studies, said Herman. From the perspective of the health care system and in terms of improvements in chronic pain, the ICER model indicated that two interventions—MBSR and yoga—were of high value and that two others—acupuncture and CBT—were of intermediate value. They recommended coverage for all four of those treatments, said Herman.

At RAND, Herman and colleagues have been working on a model for chronic low back pain that incorporates actual patient data on health care costs, productivity costs, and health-related quality of life for four health states: no pain, low-impact chronic pain, moderate-impact chronic pain, and high-impact chronic pain. This model allowed the researchers to carve out data from patients with different pain states to show that costs in the high-impact chronic pain group are most affected by various treatments and to determine which treatments provide the most cost savings. Thus, said Herman, the biggest benefits from a societal perspective should come from providing this group of patients with a variety of nonpharmacological interventions.

POTENTIAL RESEARCH PRIORITIES MOVING FORWARD

Chou suggested several priorities for future research on the effectiveness of nonpharmacological therapies, including

- Developing a better understanding of the long-term sustainability of intervention effects;

- Exploring whether treatments increase or decrease opioid use;
- Standardizing interventions to enable better interpretation of results; and
- Comparing nonpharmacological to pharmacological treatments.

Benjamin Kligler, director of complementary and integrative health for the Department of Veterans Affairs, added another research priority: Exploring at both a practice and systems level how best to implement new interventions and enhance access, including the best time to implement. Herman suggested additional research priorities to increase understanding of cost-effectiveness:

- Include measures of cost in all studies of effectiveness;
- Identify and target high-impact chronic pain to get the greatest impact;
- Expand the use of economic modeling using available evidence to better understand the economic impact of treatments; and
- Expand the use of simulations to enable the design of targeted trials.

4

Emerging Models of Care

Highlights

- The U.S. National Pain Strategy promoted the concept of integrated, patient-centered, evidence-based, multimodal, interdisciplinary pain care (Kerns).
- Evidence shows that diverse models of multimodal care lead to reduced pain and improved function (Kerns).
- Access to multimodal care may be limited by social factors such as poverty, education, and ethnicity as well as by coverage limitations (Kerns).
- The Department of Veterans Affairs has developed a stepped-care program that begins with self-care, followed by screening, assessment, self-management, secondary consultation, multidisciplinary rehabilitation, and advanced diagnostics and interventions if needed (Fritz, Kligler, Shaw).
- Stratified or matched care, which begin with assigning patients to risk groups based on their responses to a questionnaire, may save costs by providing care only when needed (Shaw).
- Reordering or sequencing the way care is delivered by starting with triage from a trained practitioner who provides reassurance, educational materials, and advice on self-management may improve pain management and reduce the use of opioids (Fritz).
- Treating complex and high-impact chronic pain may involve nonpharmacological interventions, particularly when pain is exacerbated by modifiable risk factors such as catastrophizing (Edwards).
- Complementary and integrative health approaches have grown in popularity and have shown effectiveness in relieving pain and improving function (DeBar).

- Placebo effects can be real and powerful and may be harnessed in pragmatic trials and studies of real-world pain treatment (DeBar).
- An array of technologies can enable the collection of high-intensity longitudinal data and may improve access to care by delivering self-management approaches directly to patients, although more evidence is needed on their effectiveness (Heapy).
- Limited evidence supports the use of multimodal approaches that combine pharmacological and nonpharmacological modalities (Kroenke).
- Neuromodulation approaches have shown modest effects in treating pain and may be improved if used in combination with other interventions (Wilson).

NOTE: These points were made by the individual speakers identified above; they are not intended to reflect a consensus among workshop participants.

The National Pain Strategy,[1] which was developed by the Interagency Pain Research Coordinating Committee in response to the Institute of Medicine report *Relieving Pain in America* (IOM, 2011b), highlighted several challenges to accessing high-quality pain care, said Robert Kerns. These challenges include the fact that pain care is often not evidence based or team based; that it is often limited to pharmacological treatment delivered by a single provider in a single setting; and that it is usually procedure oriented and incentivized for specialty care. Another challenge, said Kerns, arises from the fact that people with pain often have overlapping chronic pain conditions and other medical morbidities, especially mental health and substance use disorders.

To address these challenges, the National Pain Strategy promoted the concept of

> integrated, patient-centered, evidence-based, multimodal, interdisciplinary care, with systematic coordination of medical, psychological, and social aspects of care delivered by primary care, mental health, and sometimes specialty care providers.

Various models of care may provide integrated care, said Kerns, including stepped care, risk stratification, matched care, collaborative care, care

[1]For more information about the National Pain Strategy, see https://iprcc.nih.gov/National-Pain-Strategy/Overview (accessed February 6, 2019).

management, integrated care in a co-located setting, use of telecare and technology-assisted care, peer-delivered care by informal caregivers, and whole-health approaches that promote the uptake of complementary and integrative health (CIH) approaches.

Kerns mentioned a recent study that reviewed evidence from nine diverse models of multimodal approaches to pain management (Peterson et al., 2018). All these models provided robust evidence of improvements in measures of pain intensity and pain-related functioning. Most importantly, said Kerns, the review cited four key ingredients in effective models of care: (1) decision support to enhance provider education and treatment planning, (2) additional care coordination resources, (3) improved patient education and activation, and (4) increased access to multimodal care. He highlighted two studies that exemplify the high-quality evidence that has been obtained for multimodal pain approaches. The first of these—collaborative care delivered in five primary care clinics at one Department of Veterans Affairs (VA) Medical Center—showed significant improvements compared with usual treatment with an intervention that included "clinician education, patient assessment, education and activation, symptom monitoring, feedback and recommendations, and facilitation of specialty care" (Dobscha et al., 2009). The second, which used a stepped-care approach for affective disorders and musculoskeletal pain included pharmacotherapy, phone-delivered pain self-management, and an intervention like cognitive behavioral therapy (CBT), also showed robust effects, particularly on depression outcomes, but also on pain intensity (Kroenke et al., 2009).

Although these studies provide strong evidence to support the efficacy and effectiveness of multimodal approaches to pain management, Kerns cautioned that concerns remain about access. He advocated paying more attention to the social determinants of pain and pain management. The Centers for Disease Control and Prevention (CDC) recently published a study that showed a higher than average prevalence of chronic pain and high-impact chronic pain among women, those previously but not currently employed, less educated persons, those living in or near poverty or in rural settings, and those with public health insurance, after adjusting for age. Chronic pain was also more prevalent among non-Hispanic whites and veterans after adjusting for age (Dahlhamer et al., 2018). These social determinants are important to keep in mind, said Kerns, because they describe the same groups of people who may be disadvantaged in terms of accessing high-quality pain care.

Kerns added that delivery of integrative approaches may also be hindered by limited coverage for certain modalities. For example, a recent analysis showed that only 3 out of 15 Medicaid plans covered acupuncture or psychological interventions for low back pain (Heyward et al., 2018). However, despite these challenges, Kerns said the VA, a highly integrated health system, has successfully implemented multimodal integrative approaches; although, there is great variance across the system and still room for improvement (Carey et al., 2018). Kerns emphasized that successful implementation of these approaches will be more challenging in private practice and community settings.

Kerns called for more high quality research on the effectiveness of pain interventions, particularly using integrated approaches and reimbursement innovations. More effective strategies are also needed to disseminate and promote uptake of evidence-based findings into routine clinical practice, he said.

Giving patients a voice in choosing the type of care they receive may improve compliance and outcomes; however, David Atkins mentioned the subset of patients who might not naturally gravitate to certain types of therapies, such as CBT, even though such approaches may be best suited to their needs. He asked how studies could be designed to test whether outcomes could be improved by particular strategies to match therapies to subsets of patients based on their preferences or other characteristics. Robert Edwards, a clinical psychologist in the Pain Management Center at Brigham and Women's Hospital/Harvard Medical School, said he could envision a study using something like cluster randomization testing where one group receives treatment based on their preferences and another group receives treatment based on a risk assessment. The research question to be answered in that study would be whether the extra time and expense of assessment and phenotyping results in better long-term outcomes. Alicia Heapy, associate professor of psychiatry at Yale University School of Medicine and associate director of the Pain Research, Informatics, Multimorbidities, and Education (PRIME) Center of Innovation at the VA Connecticut Healthcare System, added that this model is consistent with the stepped-care approach, discussed below.

Lynn DeBar, senior scientist at the Kaiser Permanente Washington Health Research Institute, commented that among the biggest challenges encountered in a study aimed at bringing interdisciplinary care to patients on chronic opioid therapy were (1) getting patients interested enough in the kinds of treatments being offered, and (2) creating a culture of care

grounded in the biopsychosocial model. She added that the language practitioners use to talk about nonpharmacological therapies is important to ensure that patients believe they are being offered the best treatments possible. The facts, she said, are not nearly as compelling as the powerful experiences people share.

STEPPED CARE, STRATIFIED CARE, AND MATCHED CARE

Stepped care has been used for many conditions, purportedly to provide patients with low-risk, low-cost care early on, followed by higher risk and more invasive treatments if symptoms persist, said William Shaw, associate professor and chief in the Division of Occupational and Environmental Medicine at the University of Connecticut Health Center. Unfortunately, he said, stepped care often means starting with easy care such as pharmacological treatments before implementing more difficult approaches such as psychological treatment if the problem continues.

Shaw said the VA developed a stepped-care plan that begins with screening, assessment, and self-management, followed by secondary consultation with specialists in pain management and a third step of multidisciplinary rehabilitation or advanced diagnostics and interventions (Kerns et al., 2011). Julie Fritz, distinguished professor in the Department of Physical Therapy and Athletic Training in the College of Health, University of Utah, added that subsequently, another step was added at the beginning of the pathway that involves self-care. This step was added, according to Benjamin Kligler, when it became apparent that pain management is most successful when people are empowered to take care of their health. Shaw noted that this approach works to limit costs and reduce iatrogenic effects in health care systems such as the VA that have complete control of care. However, for the treatment of acute and subacute back pain, the stepped-care model may make it difficult to start nonpharmacological treatments early, he said. The model presumes that it takes time to establish psychological and other kinds of treatment approaches and ignores the fact that psychosocial risk factors can be assessed in a patient within hours of back pain onset.

A stratified-care model for musculoskeletal conditions may help solve this problem, said Shaw. This approach begins with the new-onset patient completing a one-page self-report questionnaire that assesses the risk of chronicity, disability, or other poor outcomes. Based on this single measure, patients can be assigned to low-, medium-, or high-risk groups that

receive conservative to more aggressive care, respectively. This approach provides early intervention for high-risk cases and may prevent unnecessary treatment, said Shaw.

The best example of the stratified-care model, he said, is the STarT Back trial, in which participants filled out a nine-item questionnaire and then were assigned to the three risk groups. Low-risk participants received advice on appropriate levels of activity, exercise, and self-help. Medium- and high-risk participants were referred for physical therapy and more intensive treatment. Outcomes for all treatment groups improved compared with the control group, said Shaw (Hill et al., 2011). The magic of this approach, he said, was the cost savings that resulted from determining at the outset who needed care and who did not.

The disadvantage of this approach is that it may be difficult to assign people to risk categories with this simple questionnaire. Shaw and colleagues proposed a matched-care model that uses a more detailed questionnaire to assess the nature of risk based on specific types of risk factors, such as mood problems, functional limitations, or workplace issues. They then assign individuals to treatment groups that match their individual problems (Shaw et al., 2013). Shaw acknowledged that this approach, which is still in an experimental phase, requires substantial resources and evidence that it improves outcomes. He suggested that a middle road is needed between specificity related to the nature of the patient's problems and the feasibility of delivering care within the payer-based systems currently in place. Edwards added that many studies would be needed before clinicians are able to match specific treatments to individual patients.

FIRST CONTACT CARE

The importance of first contact was mentioned by Steven George in Chapter 2 and was reinforced by Fritz, one of many researchers who contributed to a recent *Lancet* study focused on how to reorder the way care is delivered so that first-line treatments offered for conditions such as low back pain are grounded in a biopsychosocial framework that enhances self-management (Foster et al., 2018).

Training providers to behave differently and reforming payment policies are long-term strategies that might accomplish this goal, said Fritz. However, she advocated more strategic ways of reordering care, for example, by sequencing care and adding explicitly a step that precedes primary care and is focused on self-management and self-care. For example,

a pilot study by the National Health Service in the United Kingdom introduced a primary care triage and treatment practitioner—typically a nurse or physiotherapist—as the first contact for patients with spinal and/or radicular pain. This practitioner provided encouragement, reassurance, educational materials, and advice on self-management. Patients with signs of significant compression or inflammatory back pain were referred to primary or specialty care, while others who were nonresponsive to the first line of care or who had physical or psychological risk factors for poor prognosis were referred for evidence-based nonpharmacological treatment (Foster et al., 2018).

In the United States, Fritz said the first provider contacted for low back pain is most often a chiropractor or primary care physician. Data show that receiving care from a nonphysician, reduces the risk of opioids being either initiated or used over time (Kosloff et al., 2013; Weeks and Goertz, 2016; Wheldon et al., 2018). Claims data from her own institution also show that opioid prescription fills and long-term use of opioids are much lower when patients start their journey of care with a nonphysician provider, said Fritz (Fritz et al., 2016).

She acknowledged that selection bias may a play a role in these results, but emphasized the importance of understanding why patients choose a particular type of provider and how to encourage them to choose nonphysician providers more often. Fritz's research suggests that patients are willing to choose a physical therapist visit as the first of line care if they can be ensured that their health care providers are working together as a team and if their concerns are appropriately addressed.

CARE FOR PATIENTS WITH COMPLEX AND HIGH-IMPACT CHRONIC PAIN

Nonpharmacological interventions have shown promise in treating patients with complex and high-impact chronic pain, said Edwards. One reason for this is that there are many clearly delineated risk factors for developing and maintaining high-impact chronic pain, including psychosocial risk factors such as catastrophizing. In the context of pain, Edwards defined catastrophizing as a negative cognitive and emotional response characterized by rumination about pain, magnification of the threat value of pain, and feelings of helplessness. Many studies have shown that the highest catastrophizing patients get the least benefit from pharmacological treatment and are most likely to discontinue treatment, he said (e.g., Toth

et al., 2014). Just as important, said Edwards, catastrophizing changes with treatment and shapes treatment-related outcomes. For example, in one study examining the effectiveness of tai chi for reducing pain and disability, about one-third of the effect on pain and two-thirds of the effect on disability were attributed to a reduction in catastrophizing (Hall et al., 2016).

Edwards and colleagues have been studying the neural mechanisms that may contribute to catastrophizing's effects on pain. They have found that patients who selectively activate brain networks associated with catastrophizing also report the most severe daily pain and have the greatest self-reported catastrophizing (Lee et al., 2018). Catastrophizing also appears to contribute to the maladaptive network connectivity that is observed in patients experiencing chronic pain.

Importantly, catastrophizing is a modifiable risk factor, noted Edwards. CBT, for example, has been shown to reduce both catastrophizing and pain in patients with fibromyalgia (Lazaridou et al., 2017). Some evidence suggests that the benefits of CBT are greatest in patients with high baseline catastrophizing scores, who are the most resistant to pharmacological treatment (Schutze et al., 2018). Recent research indicates that high catastrophizing may be associated with enhanced benefit from certain interventions and reduced benefit from others, which suggests that this phenotype may be useful as a factor for selecting personalized treatments, said Edwards (Schreiber et al., 2018).

INTEGRATIVE CARE

In 1991, the National Institutes of Health established the Office of Alternative Medicine, which was renamed the National Center for Complementary and Alternative Medicine in 1998 and renamed again in 2014 as the National Center for Complementary and Integrative Health (NCCIH). The evolution in the name of the center reflects the recognition that although interest in alternative approaches has increased over the past 20 years, there is an even greater interest in integrating them with conventional care, said DeBar.

Complementary approaches include the use of natural products and mind and body practices (NCCIH, 2018). A 2012 survey by the National Health Interview Survey showed that among mind and body practices, yoga, chiropractic and osteopathic manipulation, and meditation were

most popular. Other mind and body approaches include acupuncture, massage, tai chi, and the Alexander technique[2] (Clarke et al., 2015). A more recent study showed that these practices continue to grow in popularity, said DeBar. From 2012 to 2017, the number of adults over age 18 using yoga grew from 9.5 to 14.3 percent (Clarke et al., 2018).

The Agency for Healthcare Research and Quality set a somewhat higher bar in a recently published comparative effectiveness review by looking at short-, intermediate-, and long-term treatment effects of these approaches, said DeBar. For low back pain, yoga, manipulation, massage, and acupuncture were shown to improve function and decrease pain intensity at least in the 1- to 6-month range (Skelly et al., 2018). A limitation of this research, according to DeBar, is that many (if not most) people with pain have chronic overlapping pain conditions, yet researchers have tended to examine effectiveness in a siloed manner. One exception she cited was a study conducted by Davis and colleagues (2016), who demonstrated that the symptom cluster of sleep disturbance, pain, anxiety, depression, and low energy and fatigue—the SPADE pentad—correlated with functional outcomes in a stepped-care intervention program.

Complementary and integrative health modalities have also been studied in more partitioned ways, disconnected from conventional care, said DeBar. For example, Cherkin and colleagues conducted a series of rigorous clinical trials that examined the effectiveness, compared to usual care, of acupuncture, massage, yoga, and mindfulness-based stress reduction for the treatment of low back pain (Cherkin et al., 2009, 2011, 2016; Sherman et al., 2011). Interestingly, said DeBar, all these modalities showed similar impacts. She suggested that perhaps these effects derive from non-specific contextual effects of the care experience rather than specific characteristics of the intervention. Which modality is selected may be less important than what is available to patients in a particular area or what they are excited about and will commit and adhere to, said DeBar. There might be ways to sequentially employ both active and passive modalities in clinical trials.

DeBar said there have been some provocative studies indicating that the placebo effect is real and can be powerful both for pharmacological and nonpharmacological therapies. She pointed to a study by Crum and colleagues that demonstrated how in the real world, psychological and so-

[2]An educational process aimed at retraining poor movement and posture habits.

cial forces of healing contribute to and underlie the magnitude of a treatment effect (Crum et al., 2017). We should harness those effects, said DeBar, particularly in pragmatic trials and studies of real-world treatments.

Karen Sherman, senior scientific investigator at the Kaiser Permanente Washington Health Research Institute and affiliate professor of epidemiology at the University of Washington School of Public Health, recommended future research priorities for CIH. First, she advocated including more trials in older adults even though their interest in CIH may differ from younger adults. Chronic pain conditions associated with comorbid conditions are relatively more common in older adults, and standard treatments may work less effectively or be associated with worse side effects in seniors. Nonpharmacological approaches may reduce these adverse events, said Sherman. Currently, many randomized controlled trials of chronic pain treatments, including CIH interventions, exclude older adults, especially the oldest old and those who are institutionalized, she said, noting that CIH interventions may need to be modified for these populations. Sherman also recommended:

- Conducting studies on implementing and disseminating various mind–body and self-care therapies, which can increase self-efficacy, but often are unreimbursed and require sustained, consistent practice.
- Determining the optimal combinations of treatments and establishing principles for combining and/or sequencing treatments.
- Exploring the effectiveness of CIH treatments in people who use opioids.

USING TECHNOLOGY TO SUPPORT ACCESS, SELF-MANAGEMENT, AND CARE PROCESSES

A diverse array of technologies offer the potential to improve access to care by delivering self-management approaches to patients, according to Heapy. These technologies range from text messaging and other mobile apps to virtual reality and artificial intelligence, and include wearable devices, interactive voice response systems, and telemedicine, she said. They have the capacity to collect high-intensity, longitudinal data, which Heapy said has been shown to be valid and reliable and less vulnerable to recall bias than data collected farther from the time the pain occurred. Some of these technologies have adapted theory- and evidence-based interventions in which small to moderate effects have been demonstrated, such as CBT

and mindfulness approaches. Heapy described others as "modular treatments," where multiple approaches are combined to promote self-monitoring, goal setting, skill acquisition, education, assessment, patient–provider communication, and social support. Superimposed on these diverse technologies are differences in the amount of contact that patients have with clinicians.

Heapy said that while these technologies appear promising, limited quality evidence is available regarding the effectiveness of these interventions relative to in-person care; which technologies are best or which components are most important or effective; and to what extent clinician contact increases engagement and improves outcomes and the necessary frequency of that contact (McGuire et al., 2017). Greater understanding of how these treatments work is also needed, she said, as well as the temporal sequence of changes, causal factors that are related to changes, and common mechanisms that may underlie the effectiveness of different treatments. To improve the quality of evidence, researchers have recommended conducting more randomized controlled trials with fewer single-arm studies, reducing variability across studies to enable comparability, and focusing on interventions with a theoretical basis, said Heapy (McGuire et al., 2017; Sundararaman et al., 2017; Wethington et al., 2018). She added that cost-effectiveness studies are also needed of interventions using these technologies. Heapy advocated including clinical experts and end users in the development of technology-based treatments and adapting treatments for special and underserved populations, including older adults.

Little is known about how to implement technology-assisted treatments for pain either to the patient directly or within a health system as part of routine care, said Heapy. Internet-based interventions for anxiety and depression are the most well developed. A recent study of Internet-based CBT found general agreement among therapists and service managers on the need for technology-assisted interventions to increase access, but skepticism existed from referring providers about the quality of interventions (Folker et al., 2018). There were also concerns about the need for additional therapist training to deliver these treatments. Heapy suggested that hybrid implementation and effectiveness trials might achieve two aims with one trial.

Many questions remain about how to advance the use of technology-assisted treatments and integrate these treatments into existing care, said Heapy. Among these: Who will pay for these treatments? Will treating patients across state lines raise licensure issues? How can risk be managed (e.g., for patients at risk for suicide)? How can patient data confidentiality

be ensured (Hill et al., 2018; McGuire et al., 2017)? Heapy added that there is a need to systematically examine barriers and facilitators to treatment at the patient, provider, and system levels. Education and marketing are also needed to explain to patients how and why nonpharmacological approaches such as CBT may help, and to providers why early referral is important, she said. Heapy added that partnerships will be needed between investigators and commercial entities to address these concerns and develop a consensus, and that integrated health systems like the VA, the military health system, and Kaiser Permanente have an important role to play because they have the infrastructure, electronic health records, and large expert workforces capable of developing, testing, and implementing novel treatments into care.

MULTIMODAL APPROACHES TO PAIN MANAGEMENT

According to Kurt Kroenke, there is some, but limited, evidence to support combining pharmacological and nonpharmacological modalities to treat pain. He cited several combination trials that focused on pain or pain and depression. A study that compared the combination of the antidepressant nortriptyline plus stress management to either therapy alone or placebo, for example, showed that the combination was marginally more effective than monotherapy (Holroyd et al., 2001). The ESCAPE trial (Evaluation of Stepped Care for Chronic Pain) in veterans of the Iraq and Afghanistan conflicts combined medication with self-management strategies for the first 12 weeks, followed by 12 weeks of CBT. The results showed statistically significant reductions in pain-related disability and pain severity (Bair et al., 2015). Another study conducted by Kroenke and colleagues compared analgesics, mood treatments, and self-management to automated self-management only (see Kroenke et al., 2018, for study design and sample characteristics). Interestingly, they found that about one-third of participants in the usual care arm worsened over the 12-month trial period compared with about one-sixth of participants in the active arm, said Kroenke. This suggests that patients may actually be harmed if they are not offered the right combination of nonpharmacological and optimized analgesia treatments, which he said is often not currently feasible in primary care.

Kroenke noted that it is difficult to unbundle the effects of the different components in a combination trial to assess synergistic effects. Other fac-

tors that make studying combinations of modalities difficult are the numerous medication and nonpharmacological options with only modest benefit and the multiple common pain conditions against which those treatments could be tested. Adding devices to the equation further complicates the situation. However, "imperfect treatments do not justify therapeutic nihilism, and a broad menu of partially effective treatment options maximizes the chance of achieving at least partial amelioration of chronic pain," said Kroenke in a recent editorial (Kroenke and Cheville, 2017, p. 2366). He suggested that future research on combined modalities should examine patient preferences, optimal sequencing, differential effectiveness for chronic pain versus site- or mechanism-specific pain, long-term effectiveness, and alternative trial designs.

NEUROMODULATION

Neuromodulation—the alteration of nerve activity through targeted delivery of a stimulus to a specific neurologic site—represents another nonpharmacological approach to the treatment of pain, said Richard Wilson, associate professor of physical medicine and rehabilitation at Case Western Reserve University and director of the Division of Neurological Rehabilitation at the MetroHealth Rehabilitation Institute of Ohio. The stimulus may be electric current or chemical and can be delivered either invasively or non-invasively, he said, with the goal to reduce pain and improve function and quality of life.

Among invasive approaches, Wilson said spinal cord stimulation is one of the most commonly used methods for pain control. In this modality, electrodes are surgically placed within the spinal canal in close proximity to the spinal cord and then connected to an implantable pulse generator. Dorsal root ganglion stimulation is a newer form in which the electrode is placed near the dorsal root ganglion to deliver more precise stimulation, he said. Other invasive methods he described include peripheral nerve stimulation (PNS), in which electrodes are placed underneath the skin and connected to an implanted pulse generator. This approach, said Wilson, has been used to reduce chronic head pain. A less invasive option involves placement of an electrode underneath the skin and connecting it to an external stimulator, which can provide long-term benefits.

Brain stimulation may also be achieved through both invasive and noninvasive approaches, said Wilson. In transcranial direct current stimu-

lation (tDCS), electrodes are placed on the scalp. A current flowing between two electrodes stimulates the brain tissue underneath. With transcranial magnetic stimulation (TMS), a coil placed outside the skull generates a current within brain tissue that can alter brain activity. Among invasive neuromodulatory approaches, deep brain stimulation requires neurosurgery to plant an electrode within brain tissue to deliver more precise stimulation.

Wilson said there is evidence supporting the use of tDCS and PNS to treat migraine, and for TMS to treat phantom limb pain, neuropathic pain, and spinal cord injury (Boldt et al., 2014; Chen et al., 2015; Corbett et al., 2018; O'Connell et al., 2018; Shirahige et al., 2016). Some evidence also suggests that spinal cord stimulation may be more effective than other treatments for failed back surgery syndrome (Frey et al., 2009).

All these approaches have modest or small effects, said Wilson. He suggested that a multimodal approach using interventions that target different mechanisms or that have different mechanisms of action might provide better pain relief. For example, exercise and neuromodulation reduce pain in different ways. To treat knee osteoarthritis, Wilson hypothesized that exercise may reduce pain by improving biomechanics, altering endogenous pain mechanisms, and possibly promoting neuroplasticity. Concurrent treatment with tDCS, meanwhile, may improve somatosensory function and stimulate the cortex. The hope is that these effects might be additive or synergistic, said Wilson; however, there is little evidence at this point to guide how to use these approaches in practice.

He cited three randomized controlled trials of combined modalities for pain. The first showed that spinal cord stimulation and physical therapy were more effective than either approach alone in the treatment of complex regional pain syndrome (Kemler et al., 2000, 2004). Another trial showed that tDCS plus aerobic exercise was better than either alone for fibromyalgia. A third showed that tDCS plus exercise is better than exercise and sham stimulation for low back pain.

Wilson's lab has developed a treatment for hemiplegic shoulder pain after stroke that involves placing an electrode between the middle and posterior deltoids of the affected shoulder and delivering electrical stimulation from an external stimulator every 30 seconds for 6 hours per day for 3 weeks. They compared this approach to physical therapy designed to improve range of motion and strength and showed that both groups had reduced pain, with greater improvement in the PNS group (Wilson et al., 2014). As a next step, Wilson and colleagues are now conducting a randomized controlled trial to test combining these two approaches. One group will get the multimodal approach, another will get PNS and sham

physical therapy (physical therapy aimed at something other than shoulder pain), and a third will get sham stimulation and physical therapy. They have added other important outcomes to this trial to help them understand mechanisms and patient variables that influence response (e.g., catastrophizing, fear avoidance, or anatomic abnormalities).

Wilson mentioned one other example of multimodal research: a study comparing mirror therapy compared to tDCS for phantom limb pain (Pinto et al., 2016). Mirror therapy uses mirrors to create the illusion of movement in the phantom limb, which leads to a reorganization of cortical networks. Understanding mechanisms such as this will help investigators learn how to improve these approaches in future trials and understand which combination of treatments will likely yield the greatest effects, said Wilson.

5

Major Current Research Initiatives and Priorities

Highlights

- The National Institutes of Health (NIH) HEAL (Helping to End Addiction Long-Term[SM]) Initiative represents a transagency effort to accelerate scientific efforts aimed at addressing the opioid crisis and supports research across the spectrum from discovery to implementation (Porter, Shurtleff).
- The Pain Management Collaboratory, a partnership of several federal agencies, has a robust clinical research program, including a focus on pragmatic trials, and has launched demonstration projects to study effectiveness and implementation (Kerns, Shurtleff).
- The NIH Office of Behavioral and Social Sciences Research's mission includes advancing and coordinating the behavioral and social sciences at the NIH and supports the integration of behavioral and social sciences research into trans-NIH activities such as those addressing the opioid crisis through nonpharmacologic approaches (Smith).
- The National Center for Medical Rehabilitation Research funds research focused on how people adapt to disability, including the use of technologies to enhance function and manage chronic pain (Cernich).
- The Patient-Centered Outcomes Research Institute has two major initiatives focused on nonopioid treatment options for pain (Goertz).

- The Department of Veterans Affairs has a long history of providing integrated care and supports a large research portfolio that includes projects investigating nonpharmacological treatments for pain (Atkins).
- Pain-focused research priorities of the Department of Defense military health system include implementation of evidence-based and effective care into practice and reducing opioid misuse (Schoomaker).
- The National Center for Complementary and Integrative Health recently issued a Request for Application that will support studies testing different models of care (Weber).

NOTE: These points were made by the individual speakers identified above; they are not intended to reflect a consensus among workshop participants.

In response to a mandate of the 2010 Patient Protection and Affordable Care Act, the National Institutes of Health (NIH) asked the Institute of Medicine (IOM) to examine the state of the science regarding pain research, care, and education, which led to the 2011 IOM report *Relieving Pain in America* (IOM, 2011b). One of the outcomes of that report was the development of a National Pain Strategy[1] and the creation of the Interagency Pain Research Coordinating Committee (IPRCC).[2] In 2016, the U.S. Food and Drug Administration asked the National Academies to provide an update on the science of pain research, care, and education; characterize the opioid epidemic and evidence on strategies to address it; and identify actions and research questions needed to respond to the epidemic since publication of the 2011 IOM report. In response to this request, the National Academies published the report *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* (NASEM, 2017).

The focus on pain at the federal level has resulted in many initiatives aimed at supporting research to advance pain management and combat the opioid epidemic. Several participants at the workshop highlighted many of these efforts.

[1]For more information about the National Pain Strategy, see https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf (accessed February 6, 2019).

[2]For more information on IPRCC, see https://iprcc.nih.gov (accessed February 6, 2019).

NIH HEAL INITIATIVE

The NIH HEAL (Helping to End Addiction Long-Term[SM]) Initiative[3] was launched in 2018 as a transagency effort to accelerate scientific efforts aimed at addressing the opioid crisis, said Linda Porter, director of pain policy and planning at the National Institute of Neurological Disorders and Stroke (NINDS). According to David Shurtleff, deputy director of the National Center for Complementary and Integrative Health (NCCIH), a portion of the HEAL Initiative is an offshoot of the NIH Health Care Systems Research Collaboratory,[4] a program established in 2012 to engage health care delivery organizations as research partners in pragmatic and implementation studies (see Figure 5-1). The Collaboratory's experience in conducting clinical trials allowed NIH to move forward with the HEAL Pragmatic and Implementation Studies for the Management of Pain (PRISM) to reduce opioid prescribing. These projects must be embedded in health care systems and are supported by a coordinating center that helps them design studies and reach milestones, said Shurtleff. They address three key issues: (1) systems change to improve adherence to evidence-based guidelines for pain management; (2) integration of evidence-based approaches for pain management into health systems; and (3) informing national coverage determination decisions through partnerships with the Centers for Medicare & Medicaid Services.

The HEAL Initiative is divided into two components: First, to develop and implement therapies for opioid use disorders, including a focus on neonatal opioid withdrawal; and second, to better understand the neurobiology of pain and accelerate development of new approaches to treat both acute and chronic pain, said Porter. On the pain side, the HEAL Initiative has devoted resources to build infrastructure and incentivize partners to develop new analgesics, including small molecules, natural products, biologics, and devices. This infrastructure will include human- and animal-based tissue screening platforms to support early-stage drug development; new and refined animal models that better reflect the human condition; and clinical research networks to support clinical trials, said Porter. Biomarker discovery and validation will be woven throughout all HEAL programs on

[3]For more information on the NIH HEAL Initiative, see https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative (accessed February 6, 2019).

[4]For more information on the NIH Collaboratory, see http://rethinkingclinicaltrials.org (accessed February 6, 2019).

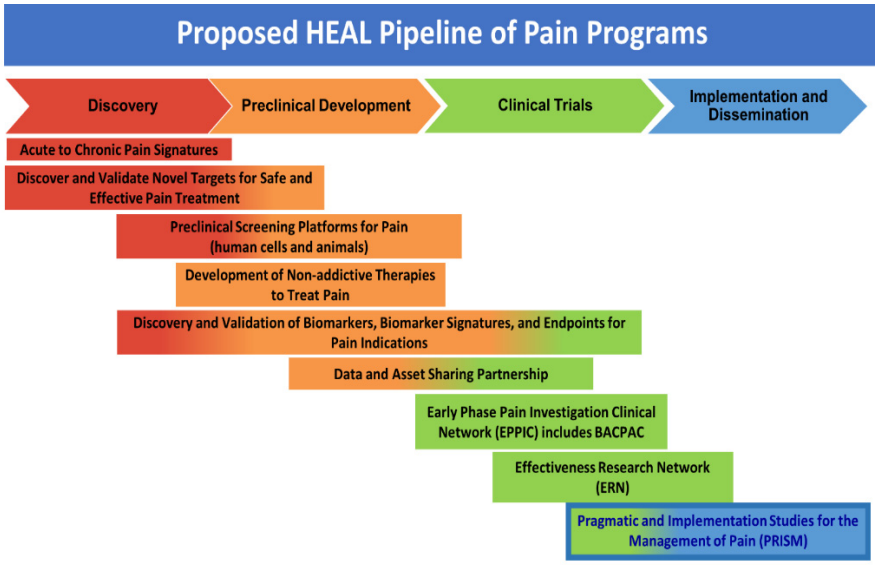

FIGURE 5-1 The National Institutes of Health (NIH) HEAL (Helping to End Addiction Long-Term[SM]) Proposed Pipeline of Pain Programs. The transagency NIH HEAL Initiative supports research across the spectrum from discovery to implementation.
SOURCE: Presented by David Shurtleff, December 4, 2018.

both the pain and addiction sides, she added, noting that biomarkers will be defined broadly to include anything from phenotypic characteristics to blood biomarkers and predictive signatures. A Common Fund program to identify signatures of the transition from acute to chronic pain[5] is included as part of the HEAL Initiative.

Porter mentioned two other consortia relevant to the workshop discussions that are folded into the HEAL Initiative: The NIH Back Pain Consortium (BACPAC)[6] and the Pain Management Effectiveness Research

[5]For more information on the Acute to Chronic Pain Signatures (A2CPS) program, see https://www.nih.gov/news-events/news-releases/nih-research-program-explore-transition-acute-chronic-pain (accessed February 6, 2019).

[6]For more information on the NIH Back Pain Research Consortium (BACPAC), see https://www.niams.nih.gov/grants-funding/funded-research/nih-back-pain-consortium-bacpac-research-program (accessed February 6, 2019).

Network (ERN).[7] She said BACPAC will provide opportunities to look at integrative care, while the Pain Management ERN will support comparative effectiveness research trials for many different modalities, including nonpharmacological therapies.

National Center for Complementary and Integrative Health

NCCIH plays a prominent role in the pragmatic aspects of the HEAL Initiative, said Shurtleff. He described a clinical research pipeline that funds studies across the continuum from basic and mechanistic work through translational research, intervention, refinement, and optimization; efficacy and effectiveness; and pragmatic studies and dissemination. These studies are designed to elucidate how natural products and mind–body treatments work, whether the impact can be measured reliably in humans, what modifications might enhance impact adherence, how treatment effectiveness compares with other treatments or controls, and how effective the treatment is likely to be in real-world conditions. Shurtleff added that natural products account for about half of the NCCIH research investment.

Wendy Weber, branch chief for clinical research in the Complementary and Integrative Health Branch, Division of Extramural Research at NCCIH, mentioned a forthcoming Request for Applications that has since been announced, specifically calling for research studies within health systems that will test different models to determine how best to change care to better adhere to the current guidelines, implement services, and overcome access barriers.[8]

NIH Pain Management Collaboratory

The Pain Management Collaboratory[9] is a partnership among NIH, the Department of Defense (DoD), and the Department of Veterans Affairs (VA) that supports pain-focused pragmatic clinical trials of nonpharmacological approaches embedded in the VA and military health systems, said

[7]For more information on the NIH HEAL Pain Management Effectiveness Research Network, see https://painconsortium.nih.gov/Funding_Research/NIH-HEAL-Effectiveness-Research-Program-Pain (accessed February 6, 2019).

[8]For more information on the RFAs associated with PRISM, see httpts://nccih.nih.gov/grants/heal (accessed February 13, 2018).

[9]For more information on the Pain Management Collaboratory, see https://painmanagementcollaboratory.org (accessed February 6, 2019).

Robert Kerns. Shurtleff said they have successfully launched 11 demonstration projects and are looking ahead to how they will implement new treatment approaches into care when and if they demonstrate effectiveness.

Kerns noted that they have encountered a challenge related to the capacity for conducting this kind of research in primary care settings within a large, integrated health system like the VA. Given the many competing demands in these settings, organizational leaders, leaders in the primary care setting, or clinicians and staff do not necessarily consider research a priority, he said. Patient and clinician education and messaging will be key factors to spark the interest of practicing clinicians and increase the likelihood that they will stay engaged with this research, Kerns added. Access issues add to the difficulty of designing pragmatic trials in many of these health systems as well, said Fritz.

Office of Behavioral and Social Science Research

The NIH Office of Behavioral and Social Science Research (OBSSR)[10] was created by Congress in recognition of the importance of behavioral and social sciences to the NIH mission. OBSSR was created more than 20 years ago to encourage the advancement and coordination of behavioral and social sciences research at NIH. The current OBSSR strategic priorities include increasing the synergy between basic and applied research; enhancing the methods, measures, and data infrastructures to encourage a more cumulative "behavioral and social sciences; and facilitating the adoption of behavioral and social sciences research findings in health research and practice." OBSSR also helps to encourage and support the integration of behavioral and social sciences into trans-NIH activities, including those addressing the opioid and pain crises; to communicate with various stakeholders about behavioral and social sciences research, said Wendy B. Smith, associate director of OBSSR. For example, in 2018 as part of the NIH Cutting Edge Series to Combat the Opioid Crisis, OBSSR help lead the coordination of a meeting in collaboration with the National Institute on Drug Abuse (NIDA), NCCIH, NINDS, and the National Institute on Minority Health and Disparities that invited experts with a wide variety of experience and expertise to identify social and behavioral research contributions and priorities to help address the opioid and pain

[10]For more information about OBSSR, including funding opportunities, see https://obssr.od.nih.gov (accessed February 6, 2019).

crises, said Smith. This meeting included a panel focused on incorporating nonpharmacological approaches for the treatment of opioid abuse and chronic pain management and included discussions about the importance of both implementing these new methods as well as de-implementing methods that are not found to be effective.[11] To address the objectives of the OBSSR strategic priorities, the central functions of the Office include focusing on communicating results, coordinating efforts across institutes and centers, training the next generation of behavioral and social scientists, shaping scientific policies and procedures to facilitate the OBSSR agenda, and conducting evaluation activities that help address important research gaps and track progress, Smith added.

National Center for Medical Rehabilitation Research

Within the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Center for Medical Rehabilitation Research (NCMRR)[12] funds rehabilitation research and coordinates related efforts across NIH and other federal agencies, said Alison Cernich, director of NCMRR. People with disabilities are often prescribed opioids for pain and are at higher risk for chronic pain due to inactivity, inability to move certain body parts, spasticity, and contractures, she said. Thus, NCMRR's research funding priorities include examining how people adapt to disability by using devices and technologies that enhance function, manage chronic pain, and access effective nonpharmacological treatments for pain such as fitness facilities. As an example of the importance of this research, Cernich noted that recent surveys indicate that 78 to 80 percent of fitness facilities lack access for people with disabilities, which not only prevents them from gaining the benefits of nonpharmacological and multimodal approaches to pain management, but also leads to social isolation. NCMRR also supports research aimed at identifying objective and real-world measures of pain and function, developing multimodal approaches to managing pain and disability, and promoting the continued effective treatment of pain when children make the transition to adult care, said Cernich.

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[11]For a summary of the OBSSR meeting Contributions of Social and Behavioral Research in Addressing the Opioid Crisis, see https://www.nih.gov/heal-initiative/full-summary-contributions-social-behavioral-research-addressing-opioid-crisis (accessed February 6, 2019).

[12]For more information about NCMRR, including funding opportunities, see https://www.nichd.nih.gov/about/org/ncmrr (accessed February 6, 2019).

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

The Patient-Centered Outcomes Research Institute (PCORI)[13] was created in 2010 to fund comparative clinical effectiveness research guided by and using data obtained from patients, caregivers, and the broader health care community, said Christine Goertz, chief operating officer of the Spine Institute for Quality and vice chair of the PCORI Board of Governors. PCORI also is mandated to provide the public, patients, and clinicians with information about the evidence gathered in funded studies and implementing the results of their research, said Goertz.

PCORI has had two major initiatives focused on nonopioid treatment options, the prevention of unsafe prescribing, and the management of long-term prescription opioid use. As of November 2018, Goertz said PCORI had awarded nearly $94 million to fund comparative effectiveness research studies on managing or treating noncancer pain, including the use of nonpharmacological therapies such as CBT, physical therapy, manual therapy, exercise, mindfulness, and acupuncture as well as education, self-management, and system-level interventions such as integrative care coordination.

DEPARTMENT OF VETERANS AFFAIRS

The VA manages the largest federal health system in the United States, providing integrated care to 6 million patients each year at more than 160 hospitals and more than 1,000 other care sites, said David Atkins. He added that because both chronic pain and opioid use are higher in military veterans than in other population groups, the VA is a good place to study pain care; for a large organization such as the VA, the biggest challenges is how to deliver evidence-based and patient-centered multimodal care in a reliable, scalable, accountable, and affordable way.

Nonetheless, progress has been made, said Atkins. As of 2015, 93 percent of VA medical centers offer at least two CIH modalities, he said, noting that chiropractic care has been standard in the VA for more than a decade. Massage and mindfulness approaches are also widely used by vet-

[13]For more information about PCORI, including funding opportunities, see https://www.pcori.org (accessed February 6, 2019).

erans, who have a high burden of comorbid mental health disorders, substance abuse, and social isolation—all factors that can influence the pain experience, said Atkins.

In fiscal year 2018, the VA research portfolio consisted of 151 projects, including studies exploring nonpharmacological approaches such as biobehavioral, technology, activity, and CIH-based interventions. Atkins said that evidence gaps remain, particularly with regard to delivering these interventions across a broad organization, identifying well-qualified providers, implementing multimodal care in a primary care setting, and demonstrating both effectiveness and cost-effectiveness of different therapies.

DEPARTMENT OF DEFENSE

The DoD military health system, which provides cradle-to-grave care for 9.5 million beneficiaries, including combat and noncombat personnel, families, and retirees, also funds and conducts research and develops and implements policies, according to Eric Schoomaker, Lieutenant General, U.S. Army (retired) and former U.S. Army Surgeon General and Commanding General of the U.S. Army Medical Command. DoD research initiatives and priorities related to pain management focus on translating and implementing evidence-based and effective care into practice and tackling opioid overuse and misuse while recognizing the need for opioids in combat settings, he said. Indeed, Schoomaker suggested that the shift in focus from pain to opioids over the past few years may need rethinking because more than 75 percent of patients with opioid use disorder start with problems in pain management. He noted that DoD initiatives must align with other federal agencies, especially the VA.

Schoomaker referenced the 2010 DoD published task force report that recommended a comprehensive pain management strategy, citing good evidence of effectiveness for CIH modalities, especially yoga and tai chi.[14] He questioned why payers are still debating whether these modalities should be covered and why the provider community has not embraced them, especially in light of the cumulative evidence of their effectiveness (as discussed in Chapter 3), the absence of evidence for effectiveness for the most commonly used therapy for chronic pain—chronic opioids—and

[14]To read the Office of the Army Surgeon General's Pain Management Task Force report, see http://www.dvcipm.org/site/assets/files/1070/pain-task-force-final-report-may-2010.pdf (accessed February 6, 2019).

the relative safety of CIH while opioid use, misuse, and diversion have spawned an unprecedented national public health crisis (further explored in Chapter 7). Schoomaker added that since the task force report was published, DoD has recognized acupuncture, biofeedback, meditation, music therapy, mindfulness meditation, medical massage, and chiropractic as evidence-based complementary and alternative therapeutic modes.

6

Education and Training of Health Professionals in Pain Management

Highlights

- Clinicians often receive inadequate pre- and post-licensure training about pain and its treatment (Fishman).
- Interprofessional education and collaboration are essential components of integrative medicine (Kligler).
- Several organizations have developed free curricula, including competency-based curricula, to facilitate interprofessional education (Darnall, Fishman, Kligler, Thomas).
- Addressing misconceptions and reducing stigma are important goals of interprofessional curricula (Thomas).
- Immersion programs, internships, and fellowships offer creative approaches to promote interprofessional pre- and post-licensure training (Anderson, Baker, Fishman).
- Turf, ignorance, and economics present barriers to the implementation of collaborative, team-based, patient-centered, pain care in clinical practice (Goldblatt).
- Many excellent models to promote collaborative practice exist including those that involve interfaculty education, intra-agency collaborations and exchange programs. In addition, there are programs that address social factors (or the social determinants) that affect the pain experience (Goldblatt, Harrell, Kligler, Watt-Watson).

NOTE: These points were made by the individual speakers identified above; they are not intended to reflect a consensus among workshop participants.

Throughout the workshop, many participants emphasized the need to change health care practice to integrate nonpharmacological management of pain, with important implications for implementation and dissemination that need to be considered, said Kim Dunleavy, clinical associate professor and director of Professional Education and Community Engagement in the Department of Physical Therapy at the University of Florida. Every group that has looked at the problem of inadequate or inappropriate pain management has recognized that clinicians receive inadequate pre- and post-licensure training about pain and the treatment of pain (IOM, 2011b), said Scott Fishman, Fullerton Endowed Chair in Pain Medicine and professor of anesthesiology and psychiatry at the University of California, Davis. Adding to this problem are interprofessional and interdisciplinary silos and the fact that while each discipline includes pain in its curricula, pain is not the primary focus of any of them, he said. Benjamin Kligler concurred about the importance of interprofessional education and collaboration, noting that they are essential components of integrative medicine. Integrative medicine, he said, reaffirms the important

> relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and uses all appropriate therapeutic lifestyle approaches and disciplines to achieve optimal health and healing.[1]

One of the biggest barriers to interprofessional education and health care is physicians who resist the idea of working collaboratively with other practitioners, said Kligler.

Belinda Anderson, founding director of the Institute for Health and Wellness at Monmouth University, added that immersion approaches might be far more effective than didactic approaches in bringing people from disparate professions together. Selling this idea to different professions may require different strategies, she said. In addition to informing practitioners from the various professions about how and why a particular complementary approach may be beneficial, she said it is equally important to let them know about the training and qualifications of the practitioners of that approach. Creative approaches are also needed to encourage CIH professionals to collaborate with mainstream practitioners,

[1]For more information about integrative medicine, see imconsortium.org (accessed March 11, 2019).

she said. Educating patients about self-care and these different therapeutic interventions is also important, said Anderson.

With medical information increasing at such a rapid rate, data overload presents a significant challenge for providers. Thus, building complexity and changeability into interprofessional education curricula through the use of big data approaches, artificial intelligence, and telemedicine is essential, said Anderson. Learning health care systems that provide feedback to practitioners about successful and unsuccessful interventions may also help change behavior and practice, said David Shurtleff.

INTERPROFESSIONAL EDUCATION MODELS

Fishman advocated a competency-based education model that employs competencies as goals. He led an interprofessional project that included physicians, nurses, pharmacists, acupuncturists, physical therapists, and other health care professionals to build consensus about core competencies for pain management. Based on the domains of the International Association for the Study of Pain Curricula, they developed and reached consensus about the competencies of the important goals for all students: Every student who graduates from a health professional program should know what pain is and how to recognize it and should understand how to safely and effectively treat pain within the scope of their practice. In addition, he said, they need to understand how the patient's context affects their pain (Fishman et al., 2013). Fishman said the model has been embraced by many national and international professional organizations.

Fishman and colleagues were invited by the National Board of Medicine Examiners to review the U.S. Medical Licensing Exam to see how well it aligned with the core competencies they identified (Fishman et al., 2018). He and his team were surprised to find that 15 percent of the questions on the exam directly tested on pain. However, almost 90 percent of the questions that directly tested aspects of pain knowledge focused on recognition of pain. Fishman said that while recognizing pain is obviously important, without understanding pain or how to treat it safely and effectively, or the context in which it occurs, may create the conditions where clinicians reach for what is known and accessible, which typically means opioids and other pharmacological approaches. While he believes the National Board of Medicine Examiners will change the test as a result of this study, even more important is to convince accreditors of schools and li-

censing organizations to require that schools demonstrate they are educating students with clear competency-based goals for comprehensive pain education within their curricula.

Kligler and colleagues, with a grant from the Health Resources and Services Administration, established the National Center for Integrative Primary Healthcare (NCIPH)[2] and developed a standardized curriculum in integrative primary health care. In developing this program, they looked at shared competencies across different professions, realizing right away that shared competencies exist because every one of those professions put the patient first. The 30-hour online course they developed, called Foundations in Integrative Health, identified a set of core competencies and developed educational materials in integrative health (Kligler et al., 2015). The Department of Veterans Affairs (VA) has developed a set of free educational materials for interdisciplinary pain teams and a course called Whole Health for Pain and Suffering.[3] Beth Darnall, clinical professor in the department of anesthesiology, perioperative and pain medicine at Stanford University, added that the International Association for the Study of Pain also has free curriculum outlines available online.

The National Institutes of Health (NIH) Pain Consortium's Centers of Excellence in Pain Education (CoEPEs)[4] has also developed modules to promote prelicensure training on pain, according to the David Thomas, leader of the program and health scientist administrator in the Division of Epidemiology, Services, and Prevention Research at the National Institute on Drug Abuse (NIDA). One goal of these modules is to address misconceptions, such as the idea that pain is in your head, or that if you treat a disease the pain goes away. Through the presentation of case studies, the modules also hope to reduce the stigma around pain, including the common belief that patients who present with pain are drug seekers or simply complainers.

The case studies approach also provides opportunities to learn about how to manage specific types of pain, said Thomas. For example, at a sickle cell disease (SCD) meeting, Thomas heard the story of a woman coping with pain related to the disease. SCD, said Thomas, is a condition where racism and ignorance collide. The woman's story led to the creation

[2]For more information about NCIPH, see http://nciph.org (accessed February 6, 2019).

[3]For more information and to download a Whole Health for Pain and Suffering course brochure, see https://wholehealth.wisc.edu/courses-training/whole-health-for-pain-and-suffering (accessed February 6, 2019).

[4]For more information about the CoEPEs, see https://painconsortium.nih.gov/Funding_Research/CoEPEs (accessed February 6, 2019).

of an interactive module on the collaborative management of pain associated with SCD. Thomas said he believes that the gap in pain education results from society's lack of caring for people in pain. Although empathy for people in pain goes down in medical school, he said, empathy can be taught, and can pay dividends in terms of sustaining clinician's interest in caring for people in pain (Chen et al., 2012; Hegazi and Wilson, 2013).

Addressing Gaps in Pain Education

To address the education gaps both in pre-licensure and post-licensure training, Fishman said we need to make some of the current NIH research funding available to study the impact of the education gap on the current opioid crisis as well as the impact of retaining our students and clinicians. Accreditors also need to be brought on board. Otherwise, he said, there will be generations of clinicians on the front line, particularly in primary care, who have not received adequate training in pain management. To fill this gap, he and his colleagues at the University of California, Davis, have developed a fellowship program using telementoring for retraining primary care clinicians; and to make this training more widely accessible have also instituted a "train the trainer" primary care fellowship.

Health professions with curricula that cover all these competency domains still face challenges in training students to synthesize this information into a comprehensive way to treat patients with chronic pain, said Nancy Baker, associate professor of occupational therapy at Tufts University. The best way to do this, she said, would be through internships; however, such internships are rare, in part because there are few sites that focus on the treatment of chronic pain. In addition, when an occupational therapist does gain this expertise, there are few jobs available. This "catch 22" is a problem for many other health professions, said Baker. To address this challenge, she suggested creating post-professional training programs to provide additional training for therapists with excellent skills but little specific training in pain. She and her colleagues at Tufts have created an online training course for working therapists to increase their understanding of chronic pain and how to treat it.

Moving from Classroom to Practice

In 2010, the Lancet Commission published a report on health professionals for a new century, emphasizing the importance of patient-centered, collaborative, team-based care, said Elizabeth Goldblatt (Frenk et al.,

2010). Shortly thereafter, she said, the IOM published a report on the future of nursing—the largest segment of the health care workforce—which emphasized the need for all health professionals to practice up to their full scope of training (IOM, 2011a). Those seminal reports led to the formation of the National Academies' Global Forum on Innovation in Health Professional Education, while at the same time the Interprofessional Education Collaborative (IPEC)[5] was getting starting with its 6 original members that has now expanded to 21, and includes the Association of Chiropractic Colleges, said Goldblatt.

To create inclusive and collaborative team-based, patient-centered pain care, all mainstream/conventional health professionals are now required to receive training in interprofessional education and collaborative practice, according to Goldblatt. Practitioners of five CIH approaches—acupuncture/East-Asian medicine, chiropractic, naturopathic medicine, massage therapy, and direct-entry midwifery—are licensed and have accreditation bodies recognized by the Department of Education. Others such as yoga or Ayurveda medicine,[6] while highly credible, are not yet licensed in the United States, said Goldblatt. Models are emerging to promote integrated health care using blended classrooms and collaborative clinics where health care professionals can gain deep knowledge about other professions and learn how to work together. Goldblatt mentioned there is a wealth of information on the National Center for Interprofessional Practice and Education (NEXUS) website, which provides evidence-based resources across the education-to-practice continuum.[7]

Practitioners in medical and allied health professions also need to learn self-care since many of these professionals (e.g., dental hygienists, physical therapists, and occupational therapists) suffer from chronic occupation-related pain, said Monika Gross with the Poise Project and Alexander Technique for Pain Management. She also suggested creating a new class of health care professionals for persons skilled in advocacy and translation.

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[5]For more information about IPEC, see https://www.ipecollaborative.org/about-ipec.html (accessed February 6, 2019).

[6]Ayurveda medicine is the ancient Indian medical system that "relies on a natural and holistic approach to physical and mental health." It "combines products (mainly derived from plants, but may also include animal, metal, and mineral), diet, exercise, and lifestyle." For more information, see https://nccih.nih.gov/health/ayurveda/introduction.htm (accessed March 7, 2019).

[7]For more information about NEXUS, see https://nexusipe.org (accessed February 6, 2019).

Working as consultants to health systems, these individuals could help translate curricula from one institution to another.

COLLABORATIVE PRACTICE: A TEAM-BASED APPROACH FOR PAIN MANAGEMENT

Creating egalitarian collaborative teams to provide patient-centered care remains a challenge, said Goldblatt. Turf, ignorance, and economics (TIE) all present barriers, despite the benefits that collaborative, team-based care can provide for patients and often can reduce stress for providers. Evidence of the benefits gained from collaborative practice can help build bridges across disciplines, said Goldblatt, adding that successful teams require respect and trust for all practitioners on a team and a clear understanding of the strengths and limitations each one brings.

The importance of collaborative practice in the treatment of pain and addressing the opioid epidemic mirrors what became evident in the early years of the HIV/AIDS epidemic, said Margaret Chesney, professor of medicine at the University of California, San Francisco. Then, like now, there were dual epidemics—treating patients while at the same time stopping the spread of the disease—both of which demanded attention to a wide array of medical and social factors, said Chesney. Specialists in infectious disease, oncology, dermatology, pulmonology, and others were called in for their expertise; and psychologists were also needed to help patients manage the stress of coping with the disease. All providers became integral parts of the collaborative team, she said. Moreover, because adherence to the complex and individualized medication regimens was so important to prevent development of drug-resistant virus, patients were not only the center of the team, they led the team, said Chesney. It was "their adherence to care" that the team needed to encourage. Wanting to avoid adding new medications to deal with the side effects of their antiviral treatment, patients began educating her and other clinicians about side effect management, including acupuncture, massage, dietary interventions, supplements, and other nonpharmacological approaches they had sought out. The collaborative team also expanded to include communities, when it became clear that providing housing and other resources would also be necessary to stop the epidemic. Anderson added that including social scientists and psychologists on the team can be especially helpful in elucidating the importance of social determinants of health.

The Department of Defense's (DoD's) Pain Management Task Force, which was mentioned in Chapter 5, also recognized the importance of collaborative practice, said Chester (Trip) Buckenmaier III, Colonel, U.S. Army (retired) and program director and principal investigator for the Uniformed Services University of the Health Sciences Defense and Veterans Center for Integrative Pain Management (DVCIPM) under the Department of Military Emergency Medicine. The ultimate goal of collaborative practice, said Buckenmaier, is to enable an individualized process and team approach that bridges the different treatment silos. Keeping silos and connecting them with the patient at the center of the activity is important, he said, adding that, in the operating room, the silo of anesthesiology is essential.

Combating prejudice against what are considered alternative treatment approaches can interfere with development of collaborative teams, noted John Chae, vice president of research at MetroHealth. Using as an example the field of physical medicine and rehabilitation (PM&R), he suggested that prejudice could be overcome with science. PM&R evolved to what is now a more mainstream approach in part because of the emergence of the biopsychosocial model as well as an embrace of science, he said. However, Kligler noted a tension that exists between pushing for research using conventionally established methods of proof and the use of other types of research methodologies. Patient-Centered Outcomes Research Institute (PCORI), for example, has successfully promoted the use of alternative methodologies, he said.

Collaborative Practice Models

Several models of collaborative practice were presented at the workshop. Some of these use case studies to discuss various aspects of pain management and treatment of opioid use disorder. Eric Schoomaker suggested that to explore management of opioid use disorder, a case involving traumatic amputation would be appropriate since wounded warriors are the most grievously wounded and do not want to be further disabled by opioids. Other models immerse patients in a well-functioning social group to leverage the importance of social, cohort, and kinship functions in managing chronic pain. Daniel Carr, past president of the American Academy of Pain Medicine and professor of public health and community medicine at Tufts University, suggested that these programs might inadvertently be providing something akin to family therapy.

University of Toronto Interfaculty Pain Curriculum

Judy Watt-Watson, professor emeritus at the University of Toronto, described an interfaculty prelicensure pain curriculum[8] at the University of Toronto that has been mandatory for students in six training programs since 2002: dentistry, medicine, nursing, pharmacy, occupational therapy, and physical therapy (Hunter et al., 2008; Watt-Watson et al., 2004). Physician assistants were also recently added, she said.

The 20-hour program is completed over 3 days through a combination of online modules, large and small multiprofessional sessions, and concurrent clinically focused sessions that the students choose. Students are assigned to an interprofessional group of 30 people that is further divided into 10-person interprofessional teams to discuss several patient cases and develop appropriate patient-focused pain management plans. A facilitator on each team guides the team to ensure respect for the role of the different professions in patient care as well as the need for collaboration and future referrals to colleagues outside of their own profession, said Watt-Watson. Meanwhile, students learn about the relationship between pain and the social determinants of health.

Watt-Watson noted that an outcome of the curriculum is that many of the health science departments are now including more pain content in their curricula. As a result, students' baseline knowledge is greater and overall scores for pain knowledge and beliefs between pre-test and post-test assessments increased by only 7 percent in 2018 as compared to 17 percent in 2002. Recently, they have conducted curriculum mappings to identify overlaps and gaps, which along with the many other evaluations, allow them to adapt the program in an iterative fashion. They also have published a pain interprofessional curriculum decision model to share with other institutions what they have learned through the development and evolution of this program, said Watt-Watson (Watt-Watson et al., 2017).

SHOW/Crossroads Model

At the Biomedicine Campus in Phoenix, Arizona, the student-led clinic Student Outreach for Wellness (SHOW) has partnered with Crossroads, the largest substance abuse recovery residential center in the Southwest, to provide community-based interprofessional direct care and health

[8]For more information, see http://sites.utoronto.ca/pain/research/interfaculty-curriculum.html (accessed March 11, 2019).

promotion services,[9] said S. Liz Harrell, chief medical officer of integrated care at Crossroads and Doctor of Nursing Practice Faculty at the Arizona State University College of Nursing and Health Innovation.

SHOW provides a learning laboratory that uses an interprofessional team-based approach to deliver care to vulnerable populations, said Harrell. The program is run by students and guided by interprofessional faculty from 12 different professional programs. Crossroads has been operating since 1960, originally as a halfway house before transitioning to become a residential substance use treatment program. Their recognition of the need for additional primary care services led to the partnership with SHOW, said Harrell. The SHOW/Crossroads clinic is expected to open in 2019 and will use an interdisciplinary team approach that focuses on holistic restoration.

Other Innovative Programs to Promote Interprofessional Care

Kligler described an exchange program between students from the Albert Einstein College of Medicine and the Pacific College of Oriental Medicine, which gives students the opportunity to learn about each other's practices and how they can be used in a complementary fashion to improve patient care (Anderson et al., 2012). Kligler also mentioned an acupuncture fellowship at Beth Israel in New York that trained licensed acupuncturists to work in inpatient hospital settings. In interviews conducted with the acupuncturists, physicians, and nurses, Kligler said he and his colleagues found that when nurses and physicians saw the benefits to their patients, they recommended acupuncture even if they did not know how it worked. The acupuncturists, meanwhile, felt like outsiders in conventional health care settings, and had to learn more about how hospitals function, said Kligler.

The VA also has some excellent programs in complementary and integrative care, added Kligler. For example, the Empower Veterans Program[10] brings together social work, chaplaincy, physical therapy, and teachers of mindfulness in a 10-week program for veterans with high impact chronic pain. Participation in the program has yielded improved pain outcomes, decreased opioid use, and decreased suicidal thinking, said Kligler.

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[9]For more information, see https://showazgeneral.wixsite.com/showazclinic (accessed March 11, 2019).

[10]To learn more about the Empower Veterans Program, see https://www.atlanta.va.gov/services/Empower_Veterans_Program.asp (accessed February 6, 2019).

Another innovative program called Central City Concern in Portland, Oregon, addresses the social determinants of physical and mental illnesses as well as addiction among the homeless through a comprehensive approach that provides naturopaths, acupuncturists, chiropractors, working with a variety of mainstream health care providers while also offering housing, job training, and job placement, said Goldblatt.

Models have also been developed for sustaining both education and care delivery programs after initial grant funding runs out, said Harrell. Given that there is no business model for care programs, she is in the process of building such a model that others can use to replicate. On the education side, Watt-Watson noted that sharing specific curriculum content can be challenging because of copyrights held by the universities where the curricula were developed.

Michele Maiers, executive director of research and innovation at Northwestern Health Sciences University, summed up the discussion by citing the need to customize models of interprofessional and transdisciplinary education to the specific needs of the communities served, including the learning communities. Moreover, she said, in planning for the future it will be important to consider the next generation of health care providers. Most of them are millennials who are recognized as being highly collaborative with extensive communication networks, said Maiers, adding that they also want to be part of creating new models from the ground up.

Leslie Davidson, chair of the department of clinical research and leadership at the George Washington University School of Medicine and Health Science and an occupational therapist who specializes in traumatic brain injury and neurology, added that pain is not a sensation, but a perception which can be described as a complex phenomenon attributed to the confluence of ever-shifting internal and external variables. Consequently, the treatment of pain is equally complex, with patients at the center requiring a collaborative approach from practitioners with a range of skills. Davidson said,

> implementing collaborative practice requires practitioners to consider multiple aspects of a patient's pain experience. For example, pain may be particularly debilitating for different reasons depending on the current circumstances and life stressors of the individual.

She cited a recent book titled *Not for Long: The Life and Career of the NFL Athlete* by Robert W. Turner II, an assistant professor in her depart-

ment, who described how the lives of professional football players are affected by years of playing the sport. The pain they experience every day and the functional limitations imposed by the pain, frequently lead to depression that may increase their sense of pain and hopelessness, said Davidson. Other important considerations include the roles, priorities, and the sense of purpose or meaningful activity of the person who experiences pain. It is critical for those who participate on their care team to understand how the person expresses their pain, how pain can be treated to increase their quality of life, and whether the pain is acute, sub-acute, or chronic, said Davidson. She added that it is essential that the care team understands and explores what situations or activities are most painful, and the patient's level of readiness to participate in a treatment plan. Davidson said,

> With this more complete understanding of the patient's pain experience a treatment plan can be devised, that may include occupational therapy, physical therapy, sleep hygiene, cognitive behavioral therapy (CBT), yoga therapy, nutrition, maintaining and activity journal, intimacy counseling, meditation, and other approaches. Simplification of the pain experience is a surefire way to set up a recipe for treatment failure.

7

Policies to Address Barriers to the Use of Evidence-Based Nonpharmacological Approaches to Pain Management

Highlights

- Delivering more effective pain care through the expanded use of nonpharmacological therapies will require policy changes that promote awareness, acceptance, availability, accessibility, and affordability (Saper).
- Novel systems and tools have been developed to gather evidence regarding multidimensional aspects of patients' pain, treatment effects, and patient preferences and expectations, which can inform efforts to revise policies (Buckenmaier, Darnall).
- To change the culture of pain management, educational programs should target not only providers, but patients and payers as well (Bonakdar, Cowan, Darnall).
- Flexible policies are needed that allow providers to deliver the right treatments to the right people, and that equip people to self-manage their pain as much as possible without demonizing the need to receive medical treatment, including opioids when appropriate (Darnall).
- Reimbursement reform is needed to address the discordance between evidence-based practices and payment structures, ensure providers have adequate time for a complete pain assessment, and enable clinicians rather than payers to determine optimal treatment approaches (Carr, Cowan, Herman).
- Large health systems such as the Department of Veterans Affairs (VA) and Kaiser Permanente have successfully implemented complementary nonpharmacological care approaches and can serve as models for other health systems (Goldberg, Lisi).
- Patients should be at the center of policy decisions (DeBar, Heapy, Kerns).

- Profound differences in the cost of opioids versus nonpharmacological care, along with cultural expectations, evidence, and ease of controlling coverage, are key drivers of coverage disparities; health systems and payers are exploring alternative care, coverage, and reimbursement models to increase the use of nonpharmacological approaches (Alexander, Elton, Ling, Livingston).

NOTE: These points were made by the individual speakers identified above; they are not intended to reflect a consensus among workshop participants.

Chapter 6 discussed efforts to address the problem of inadequate pain education through the development of interprofessional curricula. However, inadequate education is but one of many barriers to the delivery of effective pain care (Kligler et al., 2018). To help lower these barriers and accelerate change toward greater use of nonpharmacological therapies, policy changes will be needed as well as evidence to support those policy changes, according to Robert Saper, director of integrative medicine in the Department of Family Medicine at Boston Medical Center and associate professor at the Boston University Schools of Medicine and Public Health.

Saper noted that much of the heightened focus on pain management at the policy level has been fueled by the opioid epidemic and its sequelae; for example, policies and regulations that promote medication-assisted treatment ensure the availability of detox facilities, and decrease opioid prescribing. However, he suggested that policies also need to look upstream at pain itself.

BARRIERS AND POTENTIAL OPPORTUNITIES TO THE IMPLEMENTATION OF NONPHARMACOLOGICAL CARE: PATIENT, CLINICIAN, EDUCATOR, AND HEALTH CARE SYSTEM PERSPECTIVES

Both barriers and opportunities to implement evidence-based nonpharmacological approaches to pain treatment can be captured by what Saper calls the five As: awareness, acceptance, availability, accessibility, and affordability. Awareness and acceptance are relevant to all stakeholder groups (e.g., patients, providers, educators, health systems, and payers), he said, while availability, accessibility, and affordability are especially

important to patients, providers, health systems, and payers. While workshop participants focused their comments on nonpharmacological approaches, some of the issues raised and opportunities discussed may be relevant to all pain management.

Improving the Understanding of Pain

As mentioned in Chapters 2 and 3, an incomplete understanding of pain hinders the delivery of optimal pain care. To overcome this barrier, Daniel Carr said the first step is to recognize pain, particularly chronic pain, as a disease per se. This would call on the field to raise its evidence base to be comparable with those of other diseases such as cancer and cardiovascular disease, he said.

To achieve this, especially in the realm of interventional pain medicine, Carr suggested broadening the sources or types of evidence and the manner in which data are analyzed and synthesized. He also called for balancing procedure-centric guidelines with patient-centric guidelines that stratify and prioritize resources for patients at risk. Guidelines, regulations, laws, and regulatory policies should respect the diversity of populations and the variability of individuals and should be consistent with the National Pain Strategy and the Federal Pain Research Strategy, he said. Finally, Carr suggested revisiting the Centers for Disease Control and Prevention (CDC) guidelines to examine unintended consequences of their implementation and generalization (Carr, 2018).

Better data are needed, said Beth Darnall, including better phenotyping and data on treatment effects and patient preferences and expectations. She said there is an imperative to invest in the implementation of learning health care systems; for example, the Stanford Collaborative Health Outcomes Information Registry (CHOIR) provides a platform for pragmatic research and for the implementation of scalable, digital behavioral pain medicine treatments that can be deployed at low or no cost. CHOIR allows providers to track multidimensional aspects of a patient's pain over time, discuss with patients which symptoms have the most impact, and then engage them in different dimensions of treatment. For example, Darnall and her colleagues have developed a perioperative digital behavioral pain medicine treatment called My Surgical Success to help patients learn how to self-manage pain after surgery.

The tools commonly used to assess pain intensity also fail to represent patients' experience of pain (Ballantyne and Sullivan, 2015), added Chester (Trip) Buckenmaier. Recognizing this, DVICPM developed a Department

of Defense (DoD) Pain Scale, which retains the 0-to-10 numbering system commonly used, but defines each number with functional language and asks four additional questions to capture the impact of pain on activity, sleep, mood, and stress—aspects of the pain experience that are meaningful to patients (Buckenmaier et al., 2013). Buckenmaier said he thinks that by measuring the right factors, treatments such as acupuncture and massage can actually compete with opioids in terms of effectiveness. He added that the DoD has also established the Pain Assessment Screening Tools and Outcomes Registry (PASTOR),[1] leveraging both the DoD Pain Scale and the National Institutes of Health (NIH) Patient Reported Outcome Measurement Information System (PROMIS) instruments to collect data and help identify best practices (Cook et al., 2014).

Reforming Education and Changing Culture

Education gaps regarding pain assessment and pain management were discussed in Chapter 6. Robert Bonakdar, director of pain management at the Scripps Center for Integrative Medicine, said education reform is needed not only for providers, but for patients and payers as well. He said culture change is also needed. Bonakdar advocated a national education campaign with clear messaging about the benefits of nonpharmacological interventions. He suggested supporting this with a national clearinghouse of educational materials that are evidence based and shown to have a real-world impact, possibly with case studies.

The need for changes in pain education was reiterated by Carr as well as Penney Cowan, founder and chief executive officer of the American Chronic Pain Association. Cowan called for mandatory education in pain management for all health care providers across the board. Carr suggested flipping the pain curriculum from a bottom-up to a top-down approach to change the emphasis from nociceptive mechanisms to social determinants and dimensions of pain (Carr and Bradshaw, 2014). Bonakdar added that education for providers should also be expanded to include courses on nutrition, prevention, and provider empathy.

Darnall said scalable methods need to be developed and applied to improve education for clinicians and patients. By leveraging technology, she suggested that some of the solutions discussed earlier could be applied

[1]For more information about PASTOR, see https://www.dvcipm.org/clinical-resources/pain-assessment-screening-tool-and-outcomes-registry-pastor (accessed February 6, 2019).

more broadly to achieve both short- and long-term impacts. Darnall also advocated for dedicated funding to scale up matriculation and professional training to meet patient demand. This might involve cross-institutional collaborations as well as community-based professional pain education incentivized with reimbursement models, she said.

Improving Access to Pain Care Through Policy

To access a balanced approach to pain management, people with pain need health care that is patient-centered and helps them move from being a passive patient to an active participant, said Cowan. That means including the patient voice in everything, from bedside to bench or bench to bedside. Bonakdar also supported the idea raised earlier of using pain navigators or educators to help patients access optimal care.

Darnall added that flexible policies are needed that allow providers to deliver the right treatments to the right people, and that equip people to self-manage their pain as much as possible without demonizing the need to receive medical treatment, including opioids when appropriate. Carr agreed, adding that stigmatization and marginalization of patients being treated for pain is a significant barrier to care (Carr, 2016).

Reforming Reimbursement Policies

Discordance between evidence-based best practices and payment structures, such as inadequate coverage for multidisciplinary therapy including behavioral therapy and medication-assisted therapy, further hinder delivery of optimal pain care, said Carr. Another way that reimbursement policies block optimal care is by not allowing providers adequate time to do a complete assessment, said Cowan. She called for adequate reimbursement of providers' time to allow for a complete assessment of a person's pain. Cowan also called for changes in prior authorization for many pain management treatments to allow for more flexible and targeted treatment options.

Patricia Herman added that costs to patients extend far beyond copays and reimbursement. There are costs to individuals in terms of taking time off work to visit a practitioner or to receive training for self-care, which then needs to be integrated into daily activities, that need to be considered when revising guidelines, she said. She emphasized that chronic pain is chronic. Some of the course of pain management should be entrusted to

patients and their providers, said Herman, and not prescribed by payer guidelines that might not match patients' needs.

Cowan suggested changes in policies regarding opioid prescribing that take treatment decisions out of payer's hands and give that authority back to providers. She added that if a provider is going to stop opioid treatment, the tapering protocol should be designed according to the individual patient's needs. However, if the patient is functioning well and has a good quality of life, opioids may be a long-term part of their complete pain management, said Cowan.

Implementing Integrative Pain Management

Harley Goldberg, retired physician executive at the Northern California Kaiser Permanente Medical Care Program, shared experiences he had when implementing complementary approaches in a closed health care system that combines both delivery of and payment for services. Evidence of the efficacy of acupuncture did not drive inclusion of the modality into the system, he said. Rather, the health care system agreed to incorporate complementary approaches when presented with usage data showing that a brief acupuncture program of four to six treatments resulted in declined usage in every single clinical department except for chronic pain. Goldberg added that in a single-payer system like Kaiser, adding clinicians in one area means subtracting them somewhere else, which complicates the implementation of a new program. In addition, integrating ancillary providers and adjunctive treatments into the system presents operational challenges, he said. The solution at Kaiser was to build new programs into existing programs, said Goldberg. For example, mind–body medicine programs were built into their very mature patient education program as well as some psychology, behavioral medicine, and primary care modules, he added.

Anthony Lisi, chiropractic program director for the Veterans Health Administration, described some of the VA policy and practice initiatives that have enabled implementation of nonpharmacological painmanagement. In 2001, a law[2] was passed requiring the VA to begin including chiropractic care as a covered service, and in 2004 a directive was issued to start providing chiropractic care in-house at VA facilities as well as in the community. Use of chiropractic services grew slowly at first, but has accelerated in recent years. Additionally, in 2014, the VA established the

[2]Public Law 107-35, the Department of Veterans Affairs Health Care Programs Enhancement Act.

Integrative Health Coordinating Center. The Comprehensive Addiction and Recovery Act of 2016 further mandated expansion within the VA of nonpharmacological approaches, particularly those in the complementary and integrative realms, said Lisi.

According to Lisi, there are now approximately 170 chiropractors providing care at 99 VA facilities, and the use of chiropractic care has grown an average of about 18 percent per year since 2005 (Lisi and Brandt, 2016). Within the VA, chiropractic clinics can be implemented in physical medicine and rehabilitation, pain medicine, or primary care, and all three models have worked well, although with different dynamics, he said. Lisi added that chiropractic users in the VA tend to be younger and more likely to be female, which matches the priority population of Iraq and Afghanistan veterans who, in comparison with veterans of previous wars, are also younger, more likely to be female, and more likely to have chronic musculoskeletal pain and mental illness as their main complaints.

In 2016, the VA Health Services Research & Development Service held a state-of-the-art conference on nonpharmacological approaches for the management of chronic musculoskeletal pain. Lisi said that among the results of that conference was the recommendation to deliver several nonpharmacological approaches for pain widely within the VA, and specifically to deliver those therapies early in the course of pain care rather than only after other approaches had failed (Kligler et al., 2018). He noted that the recommended approaches—cognitive behavioral therapy (CBT), acceptance and commitment therapy, mindfulness-based stress reduction, physical exercise, tai chi, yoga, acupuncture, manipulation, and massage—were listed by therapy, not by discipline. In other words, it comes back to putting the patient first as opposed to the provider first, said Lisi.

Recently, acupuncture has been offered in the VA, and while previously only physicians and chiropractors with acupuncture training were authorized to provide acupuncture therapy, licensed acupuncturists were recently approved as well. The VA has partnered with DoD to provide battlefield acupuncture training, said Lisi. More than 2,000 VA providers, including physician assistants and nurse practitioners, have since been trained to perform ear acupuncture, which involves inserting small needles at specific points in the ears to relieve pain, said Lisi (Levy et al., 2018). He added that the number of veterans receiving acupuncture increased greatly in recent years.

In 2014, Lisi and colleagues assessed the implementation of chiropractic care (Lisi et al., 2014). They identified several barriers and some facilitators, which he said may be applicable to other services. The three main

barriers were negative perceptions by individual physicians, lack of funding (because the original VA mandate was unfunded), and lack of guidance on how to implement the service, said Lisi. Conversely, the strongest facilitator was having a positive perception of individual physicians and decision makers. New funding initiatives and central office guidance have also helped to expand chiropractic care, he said. Interestingly, neither patient preferences nor the degree of evidentiary support was identified as a barrier or facilitator, said Lisi.

Along with colleagues at Yale and the Pain Research, Informatics, Multimorbidities and Education (PRIME) Center at the VA Connecticut Healthcare System, Lisi has also examined opioid use among veterans. They found that the percentage of the population likely to fill an opioid prescription was much lower after a chiropractic visit compared with before the visit (Lisi et al., 2018).

Placing Patients at the Center of Policy Decisions

Lynn DeBar noted that one cannot discuss quality without some kind of patient-centered outcome. Robert Kerns added that the experience of clinicians in health care systems and organizations is also important. Wen Chen from the NCCIH commented about the difficulty for patients to know what to do first. She asked if there is evidence to support recommending one approach over another and if not, how researchers might design studies to gather this evidence. Alicia Heapy said she believes there are many different ways for patients to improve. The most important thing, she said, is that patients have the opportunity to engage in treatments and continue receiving that treatment if they believe it is providing benefits. For that to happen, she said, a system is needed that makes it easy for patients to obtain care and for providers to make referrals. Providers need to be educated about the value of providing nonpharmacological treatments early, Heapy added.

THE PAYER PERSPECTIVE: INSURANCE COVERAGE AND REIMBURSEMENT

With public attention focused on both the opioid epidemic and the care of people in pain, policy makers have the unique opportunity to scrutinize the role coverage and reimbursement policies can play in reducing the overuse of opioids and improving quality of care for those in pain, said

Caleb Alexander, founding co-director of the Center for Drug Safety and Effectiveness and associate professor of epidemiology and medicine at the Johns Hopkins Bloomberg School of Public Health. One of the biggest myths about the opioid epidemic is that there is a conflict between these two goals; however, Alexander said there is no conflict. Strengthening coverage, reimbursement, quality, and access to nonpharmacological treatments is the place to start, he said.

Eight years ago, DoD published a report that concluded there was good evidence for the use of many nonpharmacological modalities, especially yoga, massage therapy, mindfulness meditation, and tai chi for back pain, in contrast to the use of chronic opioids and highly invasive and potentially destructive surgical approaches, said Eric Schoomaker (Office of the Army Surgeon General, 2010). He wondered why coverage of nonpharmacological treatments is still being debated in some circles. One reason, said Roger Chou, is that for primary care providers, ordering an imaging test or prescribing an opioid may be easier and take less time. He added that even if physicians want to refer their patients to psychologists, acupuncturists, or other providers of nonpharmacological treatments, they may have difficulty finding a provider who will provide the right treatment and take the patient's insurance. Moreover, Chou said, there is no system to vet these providers and the paperwork required from Medicaid and other payers may be onerous.

Revising Coverage Policies to Improve the Treatment of Pain

There are wide disparities among insurers in coverage and adoption of nonpharmacological treatments for pain, said Alexander. Profound differences in cost are one driver of this disparity, he said. Whereas a typical course of physical therapy may call for 6 to 12 visits and a $30 copay per visit (Heyward et al., 2018), the median cost of a 30-day supply of generic opioids is only about $10 (Lin et al., 2018). Costs matter not only to patients, but to policy makers too, said Alexander. In many states, constraints on Medicaid budgets make it extremely difficult for them to add new benefits. He added that there have been mixed data regarding the degree to which various treatments pay for themselves.

A few years ago, Oregon's Health Evidence Review Commission identified a problem in the state's Medicaid coverage for back pain, said Catherine Livingston, associate medical director of the Commission. Back pain was not a funded diagnosis, said Livingston, which essentially meant that patients could see their primary care providers and get opioids, but no

other treatments were covered. Given the evidence supporting the use of nonpharmacological therapies for back pain, Livingston said they convened a public multidisciplinary task force to develop a new back pain coverage paradigm that includes coverage for all the therapies that have been shown to be effective, including CBT, spinal manipulation, acupuncture, physical therapy, occupational therapy, nonopioid medications, yoga, interdisciplinary rehabilitation, supervised exercise, and massage. Recognizing the likelihood of implementation barriers, she said they added an "if available" caveat to the policy. Simultaneously, they created a guideline to limit the use of treatments that do not have evidence of efficacy (e.g., TENS and epidural steroid injections) or that have evidence of harm, such as opioids.[3] They also added a risk stratification component using the STarT Back tool mentioned in Chapters 3 and 4.

Livingston said that PCORI and the National Institute on Drug Abuse (NIDA) are studying the impact of this new policy and should have results in a few years. She added that while this was a very expensive change in policy, the Commission believed it was the right thing to do and implemented it. Other challenges raised by this policy include workforce issues such as licensing and credentialing; educating providers, patients, and plan medical directors; and implementation issues related to meeting requirements and tapering opioids, said Livingston.

In Chapter 2, David Elton said that when the first point of contact is a chiropractor or physical therapist, opioid use is markedly reduced and suggested that substantial savings could be realized if physical therapists and chiropractors replaced primary care providers or specialists as first line providers. He and his colleagues at Optum have shown that for the treatment of back pain, the conservative care pathway that begins with chiropractic, physical therapy, or acupuncture is the most aligned with prevailing pain treatment guidelines and the least fragmented, yet only 30 percent of patients start on this pathway. Meanwhile, he said, only about 2 percent of specialists or medical physicians refer patients to conservative (i.e., low-risk and low-cost) care (see Figure 7-1).

Elton's group wants to increase the percentage of patients starting with conservative care to more than 50 percent in the next 2 years and at the same time increase the percentage of referrals from physicians to conservative care to around 10 percent. Actuaries have estimated that this

[3]For more information, see https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports-Blog.aspx?View=%7b2905450B-49B8-4A9B-AF17-5E1E03AB8B6B%7d&SelectedID=197 (accessed March 12, 2019).

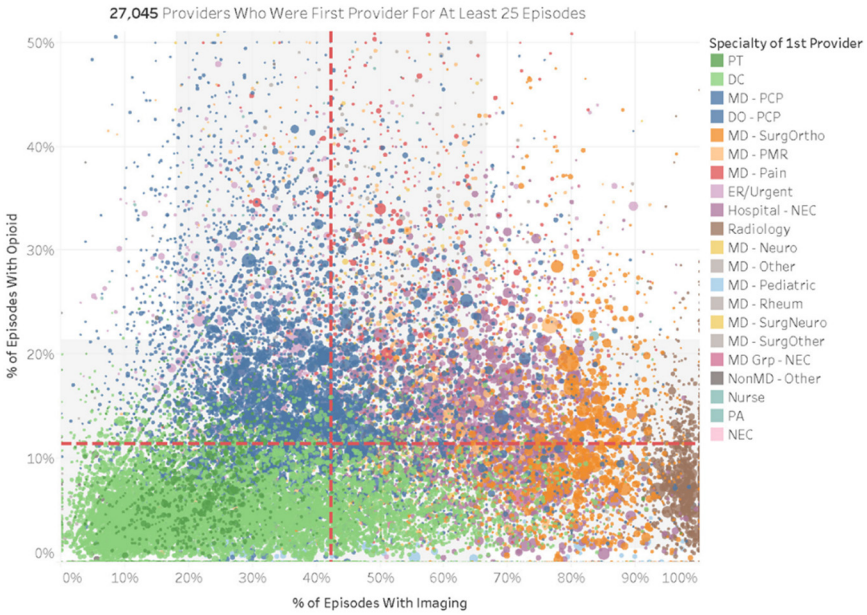

FIGURE 7-1 Imaging and opioid use for nonsurgical spine episodes. The graph displays the likelihood of receiving an opioid or imaging study at any time during an episode of back pain based on the specialty of the first provider.
SOURCE: Presented by David Elton on December 5, 2018.

would reduce annual medical expenditures by about $230 million and opioid prescribing for back pain by about 25 percent, said Elton. The call to action, he said, is to make this happen now. No more research or data are needed to support this change, Elton said.

One way to help achieve this goal, he said, would be to have out-of-pocket costs (i.e., copays and deductibles) for conservative care reduced or eliminated. Providing consumers with tools and resources to help them understand available options based on the characteristics of their pain and their own personal preferences could help guide them toward choosing conservative care when appropriate, or more aggressive care when needed, he said.

Reforming Reimbursement Policies

Value-based payment reforms through shared savings or bundling may address another barrier to the delivery of quality pain care (i.e., the

concern expressed from clinicians that reimbursement rates are too low), said Julie Fritz. Elton agreed that the rates that are paid to providers of nonpharmacological therapies might not be appropriate for the value created. Bundling payments for multiple visits over weeks or months is challenging, he said, particularly when multiple providers are involved and/or subcontractors are used for services. Optum has been developing a value-based bundled payment model, said Elton. Shari Ling, deputy chief medical officer for the Centers for Medicare & Medicaid Services (CMS), added that the CMS Innovation Center has also developed several bundled payment care initiative models and is exploring other alternative payment models as well, although no pain-specific model thus far. One possible approach would combine comprehensive primary care with an alternative payment model, she said. DeBar mentioned that there are also many small-scale natural experiments going on at coordinated care organizations to examine how services are organized and whether alternative payment models might result in better patient outcomes.

Bonakdar noted that clinicians also must grapple with denial of coverage for some nonpharmacological pain therapies such as biofeedback. Elton said the opioid epidemic has forced a lot of innovation and rethinking about legacy coverage policies for treatments such as biofeedback. To introduce coverage for a new therapy, payers and health systems need to evaluate the science supporting the approach, how it will be covered, and what the cost will be to cover it, he said. It is a long journey, but a necessary one given the urgent need for new approaches to address this epidemic, said Elton.

The Importance of Evidence in Coverage Decisions

To implement coverage changes, payers need evidence of the effects on critical outcomes such as long-term function, opioid use, use of emergency care, and ability to return to work, said Livingston. Evidence on dose response of nonpharmacological interventions is also important, she added.

The importance of evidence was reiterated by Ling. When it comes to coverage determinations for Medicare, one of the major limitations has been the absence of evidence from patient samples that reflect the Medicare beneficiary population, she said. This explains, for example, why there is a national noncoverage policy for acupuncture. She acknowledged, however, that the constraint in enrolling Medicare patients in clinical trials

stems from the Medicare statute. Strategies are needed to integrate these patients into trials, said Ling.

Ling added that as CMS shifts from volume to value in considering how and what services to cover, having a core set of outcomes that matter to the people served would be incredibly helpful. Moreover, she said, the metrics and data collected across care settings (e.g., clinicians, practices, health systems, programs, states, the entire country) all need to be standardized and aligned. She noted that this is already taking place as a result of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act).[4] Coverage is just the starting point, said Ling, adding that barriers to implementation also need to be identified and addressed. Among these are administrative barriers, which are being addressed in part through the Patients over Paperwork Initiative, launched by CMS Administrator Seema Verma in October 2017.[5]

[4]To learn more about the IMPACT Act, see https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-Measures.html (accessed February 6, 2019).

[5]To learn more about the Patients Over Paperwork Initiative, see https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html (accessed February 6, 2019).

8

Future Directions

Highlights

- To address the education gap regarding pain and pain management, efforts are underway to improve pain curricula, expand the workforce in critical areas, and change licensure and accreditation policies (Cherkin).
- To make it easier for clinicians to provide nonpharmacological care, models to remove cost and access barriers and provide support for clinicians are being studied (Cherkin).
- Pilot studies are underway to evaluate the effectiveness of multimodal treatments, and pragmatic studies and big data approaches will also likely be needed (Elton, Kligler).
- Potential next steps include identifying actions that would have the greatest impact, developing a strategy to implement those actions, designing a national public education campaign on pain and pain management, and engaging with companies moving into the health care field (Anderson, Goldblatt, Schoomaker).

NOTE: These points were made by the individual speakers identified above; they are not intended to reflect a consensus among workshop participants.

Daniel Cherkin suggested in his concluding remarks that the field is in the midst of moving "from a thousand points of blight to a thousand points of light." The points of blight are well recognized, he said, including the tremendous toll of the opioid epidemic, the continued suffering of people in pain despite the availability of treatment approaches that can relieve suffering, inadequate clinician training, poor understanding of evidence

regarding pain treatment effectiveness, continued focus on a biomedical rather than biopsychosocial approach to treating pain, poor access to effective nonpharmacological care, inadequate coverage of nonpharmacological treatments, and a shortage of qualified clinicians to deliver those treatments.

The cost of continued inaction is high, Cherkin said as he shifted his attention to the thousand points of light. First, he said, recognition of the essential role of education has resulted in efforts to improve pain curricula with a focus on team and collaborative care, expand the workforce in critical areas, and change licensure and accreditation policies. In addition, models are being developed to remove cost and access barriers and provide systems support to make it easier for clinicians to provide nonpharmacological care. Finally, many agencies are increasing research funding dedicated to improving the management of pain. Cherkin also highlighted the increasing focus on patients at the center of care management and the importance of empowering patients and supporting self-management.

Eric Schoomaker added that although people in the conventional health care world might see efforts to expand the use of complementary and integrative health approaches as an attempt to build an alternative universe, in reality the aim is to integrate emerging disruptive technologies, some of which are 4,000 years old, into conventional practice.

POTENTIAL OPPORTUNITIES FOR MOVING FORWARD

Cherkin predicted that the workshop would imbue participants with energy and confidence to take their good work in this area to the next level, knowing that they can call on other participants for advice, support, and collaboration. Anthony Delitto agreed, adding that workshop participants are already implementing many new ideas in the classroom, clinic, and community. Emerging models are ready for prime time, said Delitto, adding that he would like to see simulations give way to real-world studies in community environments.

David Elton noted that many innovative pilot studies are underway that are driven by employers. For example, some studies evaluating virtual reality with biofeedback in the office and at home to control pain (Gupta et al., 2018). Biometric data collected indicated that participants experienced better pain control and improved function at very low cost, he said.

Benjamin Kligler commented that pragmatic data and a big data approach will be needed to evaluate some combinations of approaches, such

as cognitive behavioral therapy plus acupuncture plus yoga, because it is unlikely that anyone would conduct a clinical trial to assess effectiveness of that combination. Elton said Optum Labs is working in this space to bring all stakeholders together with academic and industry researchers and provide data access to begin answering these kinds of questions. Margaret Chesney added that leveraging datasets in existing studies may also provide a head start in efforts to fill research gaps.

Another issue related to understanding the effectiveness of combined therapeutic approaches was raised by Elizabeth Goldblatt. When people experience difficult chronic pain, they frequently see multiple practitioners who may or may not be working together as a team. It is vitally important that health professionals communicate with one another to provide optimal care, she added. Roger Chou said there have been studies of coordinated care models at the Department of Veterans Affairs (VA); although implementing these models outside of VA settings has proven difficult. Elton said data from his large network suggests there are pockets of innovation where diverse providers are working together in natural networks to provide tightly integrated care. These approaches can be powerful, he said, but may be challenging to scale up in health systems where providers operate in silos.

Cherkin suggested convening a task force to identify key actions that would have the biggest, broadest, and quickest impact on removing major barriers, and then crafting a strategy to address those issues. Schoomaker agreed, adding that a campaign plan is needed to clearly define lines of efforts and principal tasks. A national campaign should include a substantial amount of public education, added Goldblatt. She and Belinda Anderson suggested reaching out and engaging big technology companies that are moving into the health care field in these efforts.

In the closing moments of the workshop, David Shurtleff urged workshop participants to take advantage of the major programs and initiatives already in place to help move these ideas forward.[1]

[1]Shortly after this workshop, 30 new funding opportunities aimed at evaluating the full spectrum of strategies for pain management were announced as part of the NIH HEAL Initiative. For more information on the NIH HEAL funding opportunities, see https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-needs-your-innovative-research-ideas-through-our-newly-announced-nih-heal-initiative-funding-opportunities (accessed February 7, 2019).

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B

Workshop Agenda

The Role of Nonpharmacological Approaches to Pain Management—A Workshop

December 4–5, 2018
National Academy of Sciences Building
2101 Constitution Avenue, NW, Washington, DC

Background:

Pain is a leading cause of disability in the United States. Given the complexity and biobehavioral nature of pain, the 2011 Institute of Medicine report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* advocated for multifaceted approaches for pain management composed of both pharmacological and nonpharmacological therapies. In 2017, the National Academies of Sciences, Engineering, and Medicine's report *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* reviewed the status of available evidence on nonpharmacological therapies for managing chronic pain. For example, cognitive behavioral therapy (CBT), a type of psychotherapy focused on restructuring negative thoughts and experiences with positive expectations, has been shown to be effective in reducing pain intensity and other psychological effects caused by pain (e.g., anxiety and depression) for low back pain, headaches, arthritis, orofacial pain, and fibromyalgia.

As a result of this national push toward the use of nonpharmacological therapies for chronic pain, increased health professional education and train-

ing will be needed to encourage the adoption and appropriate use of the evidence-based approaches. In addition, addressing policy barriers, such as those related to reimbursement for these treatments, will be important to enable broader use and dissemination. Given the changing landscape for pain management, the Forum on Neuroscience and Nervous System Disorders and the Global Forum on Innovation in Health Professional Education will bring together key stakeholders to discuss these treatments and integrative health models for pain management.

Workshop Objectives:

- Review the current state of evidence on the effectiveness of nonpharmacological treatments and integrative health models for pain management as well as available evidence on use patterns and patient interest. Examples may include acupuncture; manual therapies; physical therapy, occupational therapy, and exercise; cognitive behavioral therapy; tai chi; yoga; meditation; and neurostimulation.
- Explore the state of evidence on the effectiveness of emerging models of pain management.
- Consider multimodal approaches and potential synergies between and among pharmacological and nonpharmacological approaches to pain management.
- Consider multimodal approaches and potential synergies between and among devices and nonpharmacological approaches to pain management.
- Discuss research gaps and key questions for further research.
- Examine health professions' current approaches for educating students, trainees, and practicing clinicians on nonpharmacological pain management, and discuss potential next steps to improve training and education within and across health professions.
- Explore policies, such as those related to reimbursement that would enable broader dissemination and implementation of evidence-based nonpharmacological treatments when appropriate.

DAY ONE: December 4, 2018

8:00 a.m. Welcome and Overview of Workshop
DANIEL CHERKIN (*Co-Chair*), Kaiser Permanente Washington Health Research Institute (Emeritus)
ANTHONY DELITTO (*Co-Chair*), University of Pittsburgh

8:15 a.m. Why This Workshop Matters: Lived Experience and Provider Perspective
CHRISTIN VEASLEY, Chronic Pain Research Alliance
MARK RYAN, Virginia Commonwealth University

Session I: Nonpharmacological Approaches to Pain Management—Evidence on Effectiveness and Safety, and Emerging Models of Care

Objectives:

- Describe the treatments used for pain problems covered by insurance and patient use of complementary and integrative health approaches often not covered by insurance.
- Review evidence for the effectiveness and cost-effectiveness of nonpharmacological treatments for pain management.
- Describe the impact of psychological and social factors on patient responses to pain and pain treatments.
- Explore the state of evidence on the effectiveness of emerging models of pain management.
- Consider multimodal approaches and potential synergies between and among (1) pharmacological and nonpharmacological approaches; and (2) devices and nonpharmacological approaches to pain management, and for whom.
- Discuss research gaps and priorities for further research.

8:35 a.m. Session Overview
STEVEN GEORGE, Duke University (Moderator)

8:45 a.m. What health care services are provided to persons with pain?

- In large insured population
- In indigent (Medicaid) population
- In older adults (Medicare)

- Use of complementary and integrative health approaches in the U.S. population

DAVID ELTON, Optum

9:00 a.m. What do we know about the effectiveness and safety of nonpharmacological and nonsurgical treatments for chronic pain conditions?

- Low back pain
- Other common pain problems
- In specific populations (indigent, elderly, ethnic groups)

ROGER CHOU, Oregon Health & Science University

9:30 a.m. What is known about the cost-effectiveness of nonpharmacological and nonsurgical treatments?
PATRICIA HERMAN, RAND Corporation

9:45 a.m. Discussion

10:15 a.m. BREAK

10:30 a.m. What are the effects of psychological and social factors on patient responses to pain and pain treatments?
DENNIS TURK, University of Washington

10:45 a.m. Emerging Models of Care
Overview (deficiencies of current models; principles guiding development of new models; evidence for effectiveness of major models; and challenges for implementing in diverse settings)
ROBERT KERNS, Yale University (Moderator)

11:00 a.m. Major Models and Evidence for Effectiveness

Stepped Care, Stratified Care, and Matched Care
WILLIAM SHAW, University of Connecticut

First Contact Care
JULIE FRITZ, University of Utah

	Care for Patients with Complex and High-Impact Chronic Pain ROBERT EDWARDS, Brigham and Women's Hospital/ Harvard Medical School
	Integrative Care LYNN DEBAR, Kaiser Permanente Washington Health Research Institute
	Use of Technology to Support Access, Self-Management, and Care Processes ALICIA HEAPY, Yale University; VA Connecticut Healthcare System
11:50 a.m.	Discussion
12:30 p.m.	LUNCH
1:30 p.m.	Multimodal Approaches to Pain Management and Potential Synergies
	Pharmacological and Nonpharmacological Approaches KURT KROENKE, Indiana University
	Devices and Nonpharmacological Approaches RICHARD WILSON, Case Western Reserve University
2:00 p.m.	Discussion
2:15 p.m.	Major Current Research Initiatives and Priorities LINDA PORTER, National Institute of Neurological Disorders and Stroke DAVID SHURTLEFF, National Center for Complementary and Integrative Health WENDY SMITH, National Institutes of Health Office of Behavioral and Social Sciences Research ALISON CERNICH, National Center for Medical Rehabilitation Research, Eunice Kennedy Shriver National Institute of Child Health and Human

Development
CHRISTINE GOERTZ, Patient-Centered Outcomes Research Institute (PCORI)
DAVID ATKINS, Department of Veterans Affairs
ERIC SCHOOMAKER, Uniformed Services University of the Health Sciences, Department of Defense

3:05 p.m. Panel on Future Research Priorities
ALICIA HEAPY, Yale University; VA Connecticut Healthcare System
ROGER CHOU, Oregon Health & Science University
PATRICIA HERMAN, RAND Corporation
KAREN SHERMAN, Kaiser Permanente Washington Health Research Institute
BEVERLY THORN, University of Alabama

3:30 p.m. Discussion
Discussant: KIM DUNLEAVY, University of Florida

4:00 p.m. BREAK

Session II: Education and Training of Health Professionals in Pain Management

Objective:

- Examine health professions' current approaches for educating students, trainees, and practicing clinicians on nonpharmacological pain management.

4:15 p.m. Session Overview
ELIZABETH (LIZA) GOLDBLATT, Academic Collaborative for Integrative Health (Moderator)

4:25 p.m. Current Status of Health Professional Education in Pain Management and the Incorporation of Nonpharmacological Approaches
SCOTT FISHMAN, University of California, Davis

4:40 p.m. Discussion
Discussants: NANCY BAKER, Tufts University

DAVID THOMAS, National Institute on Drug Abuse
BENJAMIN KLIGLER, Veterans Health Administration; Icahn School of Medicine at Mount Sinai

5:30 p.m. Adjourn Day One
DANIEL CHERKIN (*Co-Chair*), Kaiser Permanente Washington Health Research Institute (Emeritus)
ANTHONY DELITTO (*Co-Chair*), University of Pittsburgh

DAY TWO: December 5, 2018

8:00 a.m. Day Two Opening Remarks
DANIEL CHERKIN (*Co-Chair*), Kaiser Permanente Washington Health Research Institute (Emeritus)
ANTHONY DELITTO (*Co-Chair*), University of Pittsburgh

Session II: Education and Training of Health Professionals in Pain Management (continued)

Objective:

- Discuss potential next steps to improve training and education for pain management within and across health professions.

8:10 a.m. Session Overview
ELIZABETH (LIZA) GOLDBLATT, Academic Collaborative for Integrative Health (Moderator)

8:20 a.m. Interprofessional Education: How do we move from classroom to practice?
MICHELE MAIERS, Northwestern Health Sciences University (Topic Moderator)

Speakers:
JUDY WATT-WATSON, University of Toronto
S. LIZ HARRELL, Arizona State University

8:50 a.m. Discussion
Discussant: BENJAMIN KLIGLER, Veterans Health Administration; Icahn School of Medicine at Mount Sinai

9:30 a.m. BREAK

9:45 a.m. Collaborative Practice: Facilitating a Team-Based Approach for Pain Management
MARGARET CHESNEY, University of California, San Francisco (Topic Moderator)

Speakers:
LESLIE DAVIDSON, The George Washington University
ANTHONY LISI, Veterans Health Administration; Yale School of Medicine

10:15 a.m. Discussion
Discussant: BELINDA (BEAU) ANDERSON, Monmouth University; Albert Einstein College of Medicine

11:00 a.m. LUNCH

Session III: Policies to Promote Evidence-Based Nonpharmacological Approaches

Objectives:
- Explore policies, such as those related to reimbursement, that would enable broader dissemination and implementation of evidence-based nonpharmacological treatments when appropriate.
- Discuss potential policy barriers and opportunities for innovation.
- Consider the research and evidence needed to advance these policies.

12:00 p.m. Session Overview
ROBERT SAPER, Boston University (Moderator)

What policies would help reduce major barriers to change?

12:10 p.m. Patient, Clinician, Educator, and Health Care System Perspectives
PENNEY COWAN, American Chronic Pain Association
ROBERT BONAKDAR, Scripps

BETH DARNALL, Stanford University
DANIEL CARR, Tufts University School of Medicine
HARLEY GOLDBERG, Kaiser Permanente (retired)
CHESTER (TRIP) BUCKENMAIER III, Uniformed Services University of the Health Sciences, Department of Defense

12:40 p.m. Discussion

12:55 p.m. Insurance Coverage and Reimbursement Perspective
SHARI LING, Centers for Medicare & Medicaid Services
CATHERINE LIVINGSTON, Health Evidence Review Commission/Oregon Health Authority
DAVID ELTON, Optum
CALEB ALEXANDER, Johns Hopkins University
PATRICIA HERMAN, RAND Corporation

1:20 p.m. Discussion

Session IV: Moving Forward

Objective:

- Synthesize and discuss key highlights from the workshop presentations and discussions and, most importantly, identify next steps and promising areas for future action and research.

1:40 p.m. Session Overview and Synthesis of Key Workshop Themes
DANIEL CHERKIN (*Co-Chair*), Kaiser Permanente Washington Health Research Institute (Emeritus)
ANTHONY DELITTO (*Co-Chair*), University of Pittsburgh

2:00 p.m. Open Discussion

2:25 p.m. Closing Remarks from the Workshop Co-Chairs

2:30 p.m. Adjourn Workshop

C

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Robert Ackley
Unaffiliated

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Optimae Rehabilitation Services

Afomeya Agonafer
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