

The 8th Annual NIH Pain Consortium Symposium on Advances in Pain Research: Integrated Self-Management Strategies for Chronic Pain

WORKSHOP SUMMARY

Natcher Conference Center
National Institutes of Health
Bethesda, Maryland
May 29-30, 2013

For Administrative Use
Revised June 30, 2013

This workshop summary was prepared with Federal funds from the National Institutes of Health (contract number HHSN261200900025I). The statements, conclusions, and recommendations contained in this document reflect opinions of the meeting participants and are not necessarily intended to represent the official position of any Federal agency, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

Suggested Citation: *The 8th Annual NIH Pain Consortium Symposium on Advances in Pain Research: Integrated Self-Management Strategies for Chronic Pain*. Workshop Summary of the meeting held on May 29-30, 2013, National Institutes of Health, Bethesda, Maryland. Lauren Brum and Silvia Paddock (Eds.). Bethesda, MD: National Institutes of Health, June 2013.

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ABBREVIATIONS AND ACRONYMS

Acronym	Definition
ABPP	American Board of Professional Psychology
ACPA	American Chronic Pain Association
AMI	amitriptyline
APS	American Pain Society
ASMP	Arthritis Self-Management Program
ATT	attention control
BP	blood pressure
BPSMP	Back Pain Self-Management Program
CBO	community-based organization
CBT	cognitive behavioral therapy
CC	Warren Grant Magnuson Clinical Center
CD	compact disc
CDSMP	Chronic Disease Self-Management Program
cLBP	chronic low back pain
CNS	central nervous system
CoEPE	Center of Excellence in Pain Education
DDS	Doctor of Dental Science
DHHS	Department of Health and Human Services
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DPT	Doctor of Physical Therapy
DTI	diffusion tensor imaging
EF	executive function
FAAN	Fellow of the American Academy of Nursing
FDA	U.S. Food and Drug Administration
FIC	John E. Fogarty International Center
fMRI	functional magnetic resonance imaging
HCO	health care organization
HCP	health care provider
HTN	hypertension
IASP	International Association for the Study of Pain
IBD	inflammatory bowel disease
IBS	irritable bowel syndrome
ICs	Institutes and Centers
IOM	Institute of Medicine
IPRCC	Interagency Pain Research Coordinating Committee
LL	limb loss
MPT	movement pattern training
MS	multiple sclerosis
MSN	Master of Science in Nursing
NCCAM	National Center for Complementary and Alternative Medicine
NCI	National Cancer Institute
NEI	National Eye Institute
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging

Acronym	Definition
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHHD	The Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Disorders
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NNT	number needed to treat
NRS	numeric rating scale
NYC	New York City
OA	osteoarthritis
OAK	osteoarthritis of the knee
OBSSR	Office of Behavioral and Social Sciences Research
OCS	orthopedic clinical specialist
ORD/ODP	Office of Rare Diseases, Office of Disease Prevention
ORWH	Office of Research on Women's Health
OSPA	Office of Science Policy Analysis
OTT	Office of Technology Transfer
PA	physical activity
PAHD	pre-arthritic hip disease
PAR	participatory action research
PC	Pain Consortium
PedMIDAS	Pediatric Migraine Disability Assessment
PFC	prefrontal cortex
PROMIS	Patient-Reported Outcomes Measurement Information System
PT	physical therapy or physical therapist
PTSD	post-traumatic stress disorder
RCT	randomized controlled trial
RN	registered nurse
RTF	research task force
SCI	spinal cord injury
SM	self-management
SMART	specific, measurable, attainable, relevant, time-bound
SSRI	serotonin-selective reuptake inhibitor
STAR	Staying Active with Arthritis
TIPS	Telephone Intervention for Pain Study
TIVR	therapeutic interactive voice response
VA	Veterans Affairs
VBM	voxel-based morphometry

EXECUTIVE SUMMARY

INTRODUCTION

On May 29-30, 2013, the National Institutes of Health (NIH) Pain Consortium (PC) convened *The 8th Annual NIH PC Symposium on Advances in Pain Research*, with a specific emphasis on integrated Self-Management (SM) strategies for chronic pain.

This yearly symposium helps the PC in its mission to develop a comprehensive and forward-thinking pain research agenda for the NIH, to identify key opportunities in pain research, and to foster multi-disciplinary and trans-NIH initiatives.¹ Currently more than 20 NIH Institutes and Centers (ICs) and offices participate in the PC and this yearly symposium.²

The NIH has recently identified SM as an important pillar of future management for the treatment of pain. This gathering of an expert group of scientists, patient advocates and clinicians to discuss the state of the art and future challenges of SM was thus timely for providing important guidance for future pain SM and treatment strategies.

This symposium also aligned well with the recommendations contained in the 2011 Institute of Medicine (IOM) report *Relieving Pain in America*, which called for a comprehensive strategy for pain prevention, treatment, management, and research on a population level.³ Achieving this goal requires a multidisciplinary approach and increased patient involvement through SM strategies.

SM AS A STRATEGY FOR CHRONIC PAIN CARE

SM is defined as actions taken by the patient to manage or minimize the impact of a chronic condition on everyday life.⁴ The term management is key; by skillfully handling the disease condition, the individual can get back to life even while in pain. The basic tenets of SM include:

- active participation by the patient
- treatment of the whole person, not just the disease
- empowerment of the patient

SM is employed in the treatment of many chronic disease states, including pain, diabetes, cardiovascular disease, and arthritis. These SM therapies come under many names and forms including cognitive behavioral therapy (CBT), physical therapy (PT), chronic disease self-management programs (CDSMP), meditation, and hypnotherapy. Each therapy uses a combination of skills to allow patients to successfully manage their disease, including:

- pain medication management
- coping skills
- relaxation techniques
- problem solving
- enhancement of the patient's social network

- goal setting
- managing emotions
- exercise

The skills needed are determined by the physical and psychological status of the participants. Because of the chronic nature of pain and other conditions, SM is considered not only a strategy, but also an outcome. Success in chronic pain therapy is measured not as pain elimination, but as functioning in spite of pain.

RESEARCH HIGHLIGHTS

Implementation of SM strategies in community health care settings

Presenters in the first session highlighted innovative ways to disseminate SM into the community health care setting, and presented evidence that SM therapy can be adapted for use in the home environment. Presenters discussed the use of mobile devices, including Smartphones, for facilitating wide dissemination of SM therapy, and the benefits of capturing patient data electronically in real time using a technology platform familiar to patients. Engaging the interested patient population by incorporating their suggestions and recommendations can increase attendance and retention during SM therapy. One team sought to recreate the dynamic interaction between the therapist and patient but on a mobile device, and it achieved a high level of patient satisfaction. A meta-analysis on the effectiveness of SM provided further reliable evidence for its benefits, even though effect sizes are often in the small to medium range. It was noted that more evidence-based research is needed to expand and sustain the delivery system for SM care.

Tailored SM strategies for patients and caregivers

Presenters in the second session focused on the implementation of SM therapies for special populations, including cancer, pediatric, and disabled patients. It was noted that chronic pain care occurs within a social context, and caregivers will need to be involved to ensure sustained results from SM therapy. SM tools in the pain coping process are also necessary and relevant for the caregiver, with increased caregiver functioning and confidence expected to result in improved outcomes for the patient. For example, special interventions regarding medication access, storage, and use might be especially welcome for cancer patients and their caregivers. SM therapy might fill a critical need among children with chronic migraines because there are no Food and Drug Administration (FDA)-approved medications for pediatric migraine, and there is conclusive evidence for SM therapy's effectiveness for this disorder. Effect sizes were large and may lead to an imminent change in treatment standards to include SM for this population. Individuals with disabilities may face heightened difficulties accessing and maintaining SM therapies, underscoring the importance of caregivers or home-based therapists in their treatment. Techniques such as telephone-based therapy and disability-specific information can be used to make SM therapy accessible for disabled people. Obtaining patient feedback can be a powerful tool in tailoring SM therapy for specific populations.

Predictors and indicators of outcomes in integrated SM

Presenters in the third session provided critical reviews of current outcomes, new opportunities that involve advanced technologies, and practical considerations when moving SM into the "real world." SM is not only a means to manage chronic pain, but also an outcome of chronic pain management. In this

sense, identifying predictors and indicators of outcomes of SM therapy can greatly improve the chances of SM success. Changes in brain structure resulting from SM therapy and other biological markers were mentioned as possibly useful in the future for predicting response to SM therapy. Telephone-based therapy can sustain the effectiveness of SM therapies over time. Discussion touched on concrete strategies necessary to ensure dissemination and sustainability of SM therapies in the current health care system. Innovations continue to improve the implementation of SM in clinical practice.

FUTURE CHALLENGES

The speakers identified the greatest challenge for the future as the diffusion and widespread application of sustainable SM interventions while retaining effectiveness for the target population. Meeting this challenge requires innovations in SM therapy structure and delivery as well as restructuring the current health-care model to accommodate integration of SM. The participants of this symposium emphasized the effectiveness of collaboration between research, policymakers, and practitioners in successfully implementing SM in target populations and highlighted the need for further transdisciplinary efforts.

Several key areas of research and opportunities for the future were identified consistently:

- **Innovation**
- **Dissemination**
- **Sustainability**

These three elements were also highlighted as areas that require further advancement for the successful integration of SM into the current health care system.

Innovation

In the successful SM therapies reviewed during this symposium, investigators used innovative tools to make the therapy accessible and relevant to the participants. Some innovations involved novel and technology-based delivery systems to make SM therapy more widely accessible. These delivery systems include the use of mobile devices (painCOACH intervention), Smartphones (Staying Active with Arthritis, or STAR, study), and web-based interventions (Living Well with Fibromyalgia). Virtual reality is also being explored as an effective tool for SM therapies for patients in pain.

While integrating the benefits of new technologies into the treatment regimes, the SM interventions critically assessed the impact of the use of these devices on the patient therapist relationship. Several studies made considerable efforts to recreate the important therapeutic interaction established between a therapist and patient. This can be accomplished through integration of interactions with therapists in the treatment protocol, or—in a more cost-efficient manner—through the use of a virtual coach (e.g., painCOACH) or customized recordings from a therapist (Therapeutic Interactive Voice Response, or TIVR).

Additional innovations involved the SM treatment strategy itself as well as novel techniques such as meditation and hypnotherapy for the treatment of chronic pain.

Sustainability

Multiple speakers identified sustainability as a key challenge for SM therapies. Speakers agreed that the current health care model based on surgical procedures and medication is not adequate for the treatment of chronic pain, and emphasized the consistent effectiveness of SM strategies and the benefits of being able to reduce medications in the long term. Methods to improve sustainability include interventions that follow the patient intermittently for longer periods of time. Several tools that allow long-term follow-up at low costs (e.g., TIVR) have been demonstrated to provide an effective link to the patient on a monthly basis, which resulted in the maintenance of beneficial behaviors over time.

Acknowledging that treatment occurs in a social context also provided clues for how to sustain SM benefits. Caregivers, such as spouses and parents, are key players in the treatment of a patient with chronic pain. By supporting the caregivers, sustainability of SM treatments is enhanced even in the absence of direct involvement of a health care provider (HCP).

Dissemination

Because SM therapies have typically fallen outside of the category of traditional medicine, dissemination is another key challenge in the implementation of SM. As the body of evidence for the success of SM in chronic pain treatment grows, its acceptance by HCPs and health care organizations (HCOs) increases. Currently, lack of reimbursement by HCOs is a major barrier to the widespread implementation of SM strategies in chronic pain care.

Research has demonstrated that pain results in structural changes to the brain and that SM strategies are able to reverse those changes. In this sense, chronic pain can be considered a biological disease and CBT a biological therapy. Reframing the discussion of SM strategies in the treatment of chronic disorders in this manner may improve acceptance of these methods by the health care system.

CONCLUSION

Now that the evidence for efficacy of SM is solid, the field must move forward and conduct pragmatic trials to address “real world effectiveness.” The current health care model itself must incorporate SM strategies as a major player in the treatment of chronic conditions. Education on SM interventions in medical and other professional schools will encourage the next generation of practitioners to engage in these efforts and, ultimately, to empower people to manage their own conditions.

WORKSHOP SUMMARY

WELCOME AND OPENING REMARKS

The Importance of Evidence-Based Research on Self-Management for Chronic Disease

Patricia A. Grady, PhD, RN, Fellow of the American Academy of Nursing (FAAN), NIH Pain Consortium Executive Committee Member and Director, National Institute of Nursing Research

The NIH Pain Consortium (PC) was established in 1996 to enhance pain research and promote collaboration among the NIH ICs.¹ The PC currently has more than 20 participating NIH ICs and is governed by an executive committee and staff. The goals of the NIH PC include:

- Develop a comprehensive and forward-thinking pain research agenda for the NIH, building on past efforts
- Identify key opportunities in pain research, particularly those that foster multidisciplinary and trans-NIH participation
- Increase visibility of pain research—both within the NIH intramural and extramural communities, and among external pain advocacy and patient groups
- Pursue the pain research agenda through public-private partnerships

The PC has implemented a number of collaborative initiatives supporting the pain research agenda. These initiatives include training and education tools, clinical research resources, and increased funding and visibility for pain research:

1. Centers of Excellence in Pain Education (CoEPEs)

In 2012, the PC awarded contracts to 12 universities to integrate pain and pain management education into their health care provider (HCP) curriculum. The resulting educational materials will be shared with a wider audience via the Internet. The first set will be available by the end of 2013.

2. Chronic Low Back Pain (cLBP) Research Task Force

cLBP is a complex condition involving multiple etiologies, symptoms, and treatments. The PC convened a research task force (RTF) of back pain experts to develop research standards for studies involving cLBP. The RTF agreed on a definition for cLBP and a sub-class scheme according to prognosis. Additionally, the RTF compiled a minimum dataset that should be required of any study involving cLBP. By standardizing terminology and methodology in cLBP research, data can be harmonized across multiple studies.

3. NIH Collaboratory⁵

Supported by the NIH Common Fund, the Collaboratory's goal is to implement cost-effective, large-scale research studies by partnering with health care delivery organizations. Two projects involving chronic pain care are currently in the pilot phase with potential to advance to clinical trials.

4. Stanford/NIH Pain Registry⁶
Stanford University and the NIH have partnered to develop a database of self-reported outcomes for chronic pain sufferers. This database will be freely available to researchers by 2014.
5. Patient Reported Outcomes Measurement Information System (PROMIS)⁷
Supported by the NIH Common Fund, this system measures patient-reported symptoms for various conditions, including pain. The database uses questions designed to assess symptoms in a consistent fashion.
6. Increased Funding for Pain Research
Pain research funding for the NIH and various PC activities has increased from \$279 million in 2008 to \$396 million in 2012.
7. Increased Visibility of Pain Research
The PC supported the compilation of high-profile articles on chronic pain in the April 2013 *Nature Collections* Compendium.

The PC has identified SM as a key opportunity in pain research for 2013. SM has been proven to be a cost-effective, long-term solution to the complex problem of chronic pain. Dr. Grady noted that speakers will address how to integrate SM care in community health care settings, tailor SM plans for special populations, identify predictors of those patients best suited for SM plans, and incorporate the patient perspective into SM strategies.

The integration of SM into chronic pain care incorporates a number of critical factors involving the patient, clinicians, and researchers. Dr. Grady emphasized that the SM strategy must account for patient factors such as the disease or condition responsible for pain, and other individual factors including the patient's psychosocial history and social environment. HCPs and researchers also face a number of significant challenges including the variability in SM approaches, the lack of randomized controlled trials (RCTs) involving SM of chronic pain, and the need for collaboration across multiple disciplines in the execution of SM.

UPDATE FROM THE AMERICAN PAIN SOCIETY

Pain SM: Barriers and Opportunities for Improved Care

David A. Williams, PhD, University of Michigan, Ann Arbor

The American Pain Society (APS)⁸ was founded in 1977 as a chapter of the International Association for the Study of Pain (IASP).⁹ The mission of the APS is to bring together a diverse group of scientists, clinicians and other professionals to increase the knowledge of pain and transform public policy and clinical practice to reduce pain-related suffering. Dr. Williams emphasized the APS's commitment to SM as an integral component of pain care. He noted that although SM of pain is supported by the Institute of Medicine (IOM), APS, and IASP, significant barriers exist that prevent the implementation of SM in routine primary and specialty care. To highlight these barriers, Dr. Williams contrasted two models of pain management: the SM and the Pain Medicine model.¹⁰

CRITERIA	SM MODEL	PAIN MEDICINE MODEL
Patient involvement	Active	Passive
Current level of HCP training	Little to none	Significant
Evidence-based efficacy	Strong for CBT and exercise	Relatively Weak
Business model	Weak	Strong
Industry support	Weak	Strong

Table 1: Comparison of the SM and Pain Medicine Models of Chronic Pain Care. SM: self-management.

Table 1 summarizes key features of the two models. The SM model of chronic pain care is supported by strong evidence for efficacy and involves the patient in his or her own care.¹¹⁻¹⁴ The Pain Medicine model, however, possesses a relatively weak basis for efficacy in chronic pain care and often fails to involve the recipient of care as an integral active participant.¹⁵⁻²⁰ Although the Pain Medicine model has weaker demonstrated efficacy, it is widely disseminated because of to a strong business model, industry support, and training in the health care professional setting.¹⁰ Dr. Williams noted that in order for the SM model to be successful, it must more fully address the following features:

1. Integration into routine clinical practice

A successful SM model must be easy to implement and cost-effective for the practitioner. Electronic therapy delivery platforms exist that utilize videoconferencing, Internet, text, and telephone. These interventions exist as professionally-led, coach-led, lay-lead or as self-guided interventions. RCTs for both guided and self-guided therapies support the efficacy of either approach.²¹⁻²³

2. A strong evidence base

For practitioners to implement the SM model, they must trust that the resource has been successfully evaluated for efficacy. Dr. Williams described his work on an Internet-based SM therapy called *Living Well with Fibromyalgia*.²³ An RCT was performed with fibromyalgia patients randomized to standard care or standard care plus the SM therapy. This study demonstrated that SM therapy was significantly better than standard care in decreasing the severity of pain and increasing physical functioning after 6 months. When comparing the number needed to treat (NNT) to achieve a greater than 30 percent reduction in pain, the SM therapy compared favorably to current FDA-approved medications for fibromyalgia.^{23,24}

THERAPY	NNT FOR 30 percent REDUCTION IN PAIN
Duloxetine	7.2
Milnacipran	19.0
Pregabalin	8.6
<i>Living Well with Fibromyalgia</i>	5.0

Table 2: Comparison of FDA-approved medications and SM therapy to reduce pain. NNT: numbers needed to treat.

3. Sustainable resources over time

Dr. Williams commented that over 50 percent of the e-Health programs evaluated by RCTs are discontinued once funding for the trial stops and the papers get published. Most funding is for the development and initial testing of programs but considerably less thought has been given to sustaining the resource for use by the public over the long term.

Dr. Williams reviewed three models with which he is involved that focus on the long-term sustainability of evidence-based e-Health interventions. The models propose (1) making SM available free-of-charge to the public and subsidized by industry, (2) commercialization of SM resources to providers and patients, and (3) using a patient-centric approach by which SM resources are selected, refined, and maintained.

- **FibroGuide.com**²⁵—offered free to the public and sustained by Eli Lilly
- **My Pain Primer**—offered to HCPs and insurance companies as a proprietary product developed and sustained by Pfizer, Inc.
- **Community Pain Center**—a patient-centric Internet resource where patients select, refine, and maintain e-Health pain management applications sustained by **Health Focus Incorporated**

For a SM resource to be successful, a strong link must exist between the HCP and the SM resource.²⁶ Construction of this link requires trust in the efficacy of the SM resources and providers and HCP staff members need to be familiar with the resources so that they can knowledgeably address patient concerns and issues related to the use of these resources. Such eHealth applications appear to be a promising solution for providing high quality SM to the many individuals suffering with chronic pain over the long term.

A PATIENT PERSPECTIVE ON PAIN SM STRATEGIES

Penney Cowan, Founder and Executive Director, American Chronic Pain Association

Cowan lives with chronic pain and has been an advocate for addressing pain-related issues for more than 30 years. She spoke about the burden of pain, goals of pain management, ways to improve communication, and 10 recommended steps for the transition from patient to person.²⁷

Cowan reminded her audience that pain is the number one cause of disability in the United States, affecting more than 100 million people and costing more than \$600 billion in lost workdays and medical costs.³ She described the experience of pain as frightening and confusing, causing the individual to become isolative and uninvolved. The current health care model creates an expectation that a pill or procedure can fix the pain. In reality, however, there may always be a certain level of inevitable pain. Those in pain are told by HCPs to “live with it” but are not given the tools to accomplish SM of their pain. Cowan emphasized that individuals must focus on their abilities and become active members of the treatment team. She described the goals of pain management as follows:

1. reduce the sense of suffering
2. improve quality of life
3. increase function

To accomplish these goals, improved communication between the individual experiencing pain and HCPs is necessary. Cowan described the pain numeric rating scale (NRS) as outdated and unable to convey the impact of pain on daily life. The ACPA has developed a quality-of-life scale explaining how pain affects a person’s ability to complete day-to-day tasks. The ACPA also provides a schematic pain log measuring multiple potential contributors to pain such as stress, fear, medications, appetite, isolation,

alcohol, and finances. The treatment team can graphically display and print these measures to help identify triggers of pain.

Cowan described 10 steps that patients can take to transition from patient to person (in no particular order of importance):

1. **Accept the pain**—Learn about your condition. Accept that you will need to deal with the fact of pain in your life.
2. **Get involved**—Take an active role in your own recovery. Follow your doctor’s advice and ask what you can do to move from a passive role into one of partnership in your own health care.
3. **Set priorities**—Look beyond the pain to the things that are important in your life. List the things you would like to do. Setting priorities can help you find a starting point to lead you back into a more active life.
4. **Set realistic goals**—We all walk before we run. Set goals that are within your power to accomplish or break a larger goal down into manageable steps. Make sure goals are SMART (Specific, Measurable, Attainable, Relevant, Time-Bound). Take time to enjoy your successes.
5. **Know your basic rights**—We all have basic rights. Among these are the right to be treated with respect, to say no without guilt, to do less than humanly possible, to make mistakes, and to not need to justify your decisions with words or pain.
6. **Recognize emotions**—Our bodies and minds are one. Emotions directly affect physical wellbeing. By acknowledging and dealing with your feelings, you can reduce stress and decrease the pain you feel.
7. **Learn to relax**—Pain increases in times of stress. Relaxation exercises are one way of reclaiming control of your body. Deep breathing, visualization, and other relaxation techniques can help you better manage the pain you live with.
8. **Exercise**—Most people with chronic pain fear exercise. But unused muscles feel more pain than toned, flexible ones. With your doctor, identify a modest exercise program that you can do safely. As you build strength, your pain can decrease. You will feel better about yourself, too.
9. **See the total picture**—As you learn to set priorities, reach goals, assert your basic rights, deal with your feelings, relax, and regain control of your body, you will see that pain does not need to be the center of your life. You can choose to focus on your abilities, not your disabilities. You will grow stronger in your belief that you can live a normal life in spite of chronic pain.
10. **Reach out**—It is estimated that one person in three suffers with some form of chronic pain. Once you have begun to find ways to manage your chronic pain problem, reach out and share what you know. Living with chronic pain is an ongoing learning experience. We can all support and learn from each other.

By focusing on empowerment, the person experiencing pain can maintain wellness and continue with life and work. Increasing the use of SM in the treatment of chronic pain will help the individual transition from disabled patient to functioning person.

SESSION 1: SM STRATEGIES IN COMMUNITY HEALTH CARE SETTINGS

Moderator: *Wen Chen, PhD*, Program Director, National Institute on Aging

Overview: Translating Pain SM Strategies into Community Settings

M. Carrington Reid, PhD, MD, Cornell University

Dr. Reid introduced the first session by reviewing SM programs and outcome data. He used four studies involving translation of SM programs in community settings as examples for successful implementation of SM strategies utilizing community resources. He also identified current gaps in knowledge and summarized relevant research policy issues that must be addressed to increase future success of SM programs.

A PubMed search of the term “self-management” revealed a dramatic surge in the number of articles between 1985 (984 articles) and 2012 (more than 10,000 articles). There are two primary drivers of this increase in interest in SM. One is the high prevalence of chronic disease; 45 percent of individuals older than 65 years have two or more chronic conditions.²⁸ The other driver is the ineffectiveness of the current health care model to address this problem; chronic disease currently accounts for 78 percent of all health care spending. Clearly, low-cost, effective therapies are required to address the burgeoning and devastating effects of chronic disease.

Dr. Reid defined SM as “What individuals do to manage, adjust to, and minimize the impact of a chronic condition in the context of daily life.” SM involves treatment for the chronic condition and its physical and emotional consequences while maintaining meaningful life roles. Education in SM helps individuals to optimally manage their condition, minimize long-term consequences, and achieve the best possible quality of life. The core skills of SM are⁴:

- **Problem solving**—skills to solve everyday problems arising as a consequence of illness
- **Decision-making**—the ability to make sound decisions regarding chronic disease management
- **Resource Utilization** —knowledge about available resources
- **Partnership formation**—skills to build and maintain partnerships to best address illness
- **Taking action**—the ability to set and achieve goals via action plans

Building these core skills is the primary focus of SM programs, the key intervention elements of which include:

- Education about the disease
- Training of skills in:
 - Relaxation
 - Cognitive coping
 - Problem solving
 - Communication
- Weekly action plans

Well-known examples of SM therapies for pain include the Arthritis Self-Management Program (ASMP), the Back Pain Self-Management Program (BPSMP), and the Chronic Disease Self-Management Program (CDSMP). Additional SM programs are available for other chronic diseases such as diabetes, heart disease, obesity, asthma, and AIDS. Dr. Reid emphasized the importance of support from health care professionals, family members, and informal caregivers to engage in SM strategies, maintain the treatment routine, and deal with potential relapse.

The effectiveness of SM has been addressed in five meta-analyses spanning a study period of more than 45 years.^{29–32} The vast majority (90 percent) of these studies involved SM performed in a community setting. Small effect sizes were noted for measurements of pain, mood, self-reported disability, and

associated symptoms. Moderate effect sizes were identified for cognitive symptom management, exercise behaviors, and self-efficacy enhancement. Large effect sizes were associated with knowledge gained regarding the chronic condition. Overall, these studies show a definitive impact of SM on chronic pain care.

Dr. Reid next reviewed critical knowledge gaps that must be addressed in order for large-scale implementation of SM to be effective.^{29,33-35} These gaps include a lack of knowledge about whether SM is generalizable to all races and ethnicities, a high attrition rate of approximately 25 percent, problems sustaining SM programs at an agency or organizational level, and problems maintaining the effects of SM at an individual level. Dr. Reid is currently carrying out research addressing these knowledge gaps:

Study Question 1: Can program adaptation lead to improved outcomes in minority populations?

Investigators administered ASMP in three centers in New York City (NYC), each comprised of African-American, Hispanic, or non-Hispanic white seniors aged 60 years or older with self-reported arthritis. Focus groups were convened after six SM sessions, and participants were asked to provide feedback and suggestions for the program. The focus groups generated 71 unique recommendations, and program instructors contributed 15 suggestions. An Advisory Board adjudicated the recommended changes and approved them based on their importance, feasibility, and agreement with ASMP directives. As a result of these efforts, components were added to the class content, course materials, and program delivery. Examples of additions include an in-class exercise component, a discussion on spirituality as a coping mechanism, handouts on healthful eating and pain medications, and a health literacy survey at the beginning of the first class. The community-based participatory research employed in this study proved to be a feasible tool to adapt an evidence-based program in a community setting.³⁶

Study Question 2: Does the adapted program produce equivalent or superior outcomes? The adapted or original ASMP programs were administered in an RCT in eight NYC senior centers. The 201 enrolled adults were 60 years or older with self-reported arthritic pain lasting longer than 8 years. Outcomes were measured at 2 and 6 months post program administration. Both the adapted and original program produced clinically and statistically significant improvements in exercise behavior, mood, pain intensity, perceived disability, and fatigue. However, the adapted program was significantly more effective at maintaining program attendance and retention compared to the original program.

Study Question 3: Can evidence-based pain self-management programs be adapted for in-home care?

Researchers convened focus groups of in-home physical therapists (PTs)^{37,38} to review an eight session SM protocol, which was then adjudicated by an adaptation committee for feasibility. The committee recommended a six-session protocol that included pain education, goal setting, relaxation, coping skills, behavioral techniques, and relapse prevention. PTs can now be trained to deliver this home-based SM protocol to patients receiving in-home care.

Study Question 4: Are home-based SM programs effective? In an ongoing study, 600 patients 55 years or older are being enrolled in an RCT to test the home-based SM program versus usual care. Outcome measures include performance-based tests, pain intensity, perceived disability, and self-reported functional status.³⁷⁻³⁹

These four studies highlight the value of partnering with community-based organizations (CBOs) in conducting SM research. Working with CBOs provides local knowledge, community-generated ideas on how to improve the SM program, and access to a diverse population of patients with a high prevalence

of pain. These studies also demonstrate that tailoring SM within local populations results in higher satisfaction among participants, possibly leading to sustained outcomes in the long term.

Dr. Reid concluded his talk by identifying major current hurdles that must be overcome to make SM an even more effective strategy in chronic pain care:

- There is a significant lack of funding for SM programs and little reimbursement from insurance companies.
- The majority of effect sizes of SM programs remain in the low to moderate range, which may improve with increased intensity or exposure to SM programs.
- There are not enough data on the factors that determine the long-term effectiveness of SM programs.

Effects of the Chronic Disease SM Program (CDSMP)—Results of Meta-Analyses

Teresa Brady, PhD, Centers for Disease Control and Prevention, Atlanta

Quantification of the efficacy of SM is a necessary step in its acceptance in the treatment of chronic pain. Dr. Brady presented results from a meta-analysis of studies implementing Stanford's CDSMP program and summarized challenges ahead.

Although CDSMP operates under different names (e.g., *Living Well with Chronic Conditions*, *Healthy Living*, *Personal Action Toward Health*), all these programs contain the core tenets of the program, including highly interactive small group workshops led by trained laypeople. The 6-week program includes education and training on goal setting, problem solving, exercise, stress management, and communication. CDSMP is applied to a variety of chronic conditions and focuses on generalizable skills that enhance a participant's confidence (self-efficacy) and ability to manage their chronic condition(s).^{40,41}

CDSMP is unique in that the program is funded and in use across the country. All but two states have received Federal funding to disseminate CDSMP in the past 3 years. In the same time period, close to 10,000 CDSMP workshops have been attended by more than 100,000 people. In comparison, the diet support program Weight Watchers currently has more than 1 million members, so there is much work yet to disseminate this program widely.

From a public health standpoint, it is critical to know the outcomes that are impacted by delivery of an SM program. Dr. Brady reviewed results from a meta-analysis of 23 trials that met the following inclusion criteria: implementation of a CDSMP before October 2010 in an English-speaking country with at least one primary outcome variable. The 23 eligible studies included 8,688 individuals who were 75 percent female, primarily white, and had on average 12.7 years of education. Short-term (4-6 months) and long-term (12 months) outcomes in mental and physical health, health behaviors, and health care utilization were analyzed. Outcomes were reported as small, medium, and large effect sizes.⁴²

Significant long-term effects were noted at 12 months:

- increased confidence in the ability to manage the condition
- increased healthful behaviors such as exercise and stress management
- increased ability to do household and social activities
- decrease in depression and fear

- decrease in pain and shortness of breath

This meta-analysis thus indicates that CDSMP is an effective tool for enhancing self-management among people with chronic conditions. Dr. Brady acknowledged certain limitations of the analysis, including significant heterogeneity for some outcomes and limited availability of data on men and minorities. Future research priorities include the study of differential effects by patient characteristics, implementation factors, methods to identify the populations most likely to benefit, and alternative delivery modes.

Dr. Brady further expressed an interest in exploring the sustainability of effects beyond 12 months and strategies to prolong the effects of CDSMP. Measuring the impact on health care utilization directly and determining comparative effectiveness when used alone or in combination with other therapies are additional future priorities. Dr. Brady also intends to carry out an economic evaluation.

Several challenges remain for widespread and accepted use of CDSMP programs. Dissemination of these programs will require a sustainable delivery system that is fully integrated into a new model of care. This delivery system will entail integration of community interventions into clinical care and possible reimbursement of CDSMPs by HCOs.

Staying Active with Arthritis (STAR): An Intervention Guided by Self-Efficacy

Elizabeth Schlenk, PhD, RN, University of Pittsburgh

Successful SM programs in a community setting must be easily integrated and translatable into clinical practice. Innovations in SM delivery mechanisms facilitate its dissemination into widespread clinical practice. Dr. Schlenk described the preliminary results of the STAR study, in which patients used Smartphones to document and communicate their progress during an individually delivered physical activity (PA) intervention.

The target population for this study includes patients with osteoarthritis of the knee (OAK) and hypertension (HTN). More than 9 million Americans have OAK, and half of them have comorbid HTN.^{43,44} PA in individuals with OAK and HTN has been associated with clinically significant increases in function, strength, and fitness walking, and decreases in pain and blood pressure.⁴⁵⁻⁴⁸ However, only 15 percent of individuals with OAK are physically active. The STAR study assessed a 6-month, home-based PA intervention with regard to exercise, walking ability, functionality, blood pressure, and pain.

The study design was an RCT with two groups: one group received physical therapist-led PA education and RN support (SM group), while the other group received general education on aging and RN support (attention control). The 24-week study was divided into 6 weeks of face-to-face SM training or general education by phone, followed by 9 bi-weekly telephone support calls by an RN. In the 6-month follow-up period, an RN evaluated both groups during three phone calls.

Tracking how much exercise study participants engage in has always been a significant challenge for researchers. In the STAR study, patients were provided with Smartphones with a study-specific application to keep track of their exercise. The resulting data can be updated wirelessly in real time and filtered by individual or sorted by exercise.

So far, 107 patients (73 percent female) have been enrolled with a mean age of 65 years. At baseline, they had mild knee and body pain and moderate self-efficacy to self-manage arthritis pain. A baseline

analysis of self-efficacy and pain demonstrates that higher self-efficacy tends to correlate with less knee and body pain. This result lends confidence to the hypothesis that increasing self-efficacy through an SM program might lead to improved outcomes for the patient. If successful, the STAR program will be evaluated for integration into clinical practice. Dr. Schlenk concluded that the STAR study shows how to integrate new and innovative tools in the delivery of an SM program for potential use by HCPs.

Internet-based Pain Coping Skills Intervention for Osteoarthritis (OA)

Christine Rini, PhD, University of North Carolina, Chapel Hill

Internet-based SM programs are another example of the innovative use of technology for the dissemination of SM programs to manage pain. Dr. Rini described her work on the development of PainCOACH, an interactive, Internet-based pain SM program for people with OA. OA is the most common type of arthritis, affecting approximately 27 million individuals in the United States.^{49,50}

Dr. Rini emphasized that the optimal management of OA involves pharmacological and non-pharmacological therapies. Pain SM programs have small but reliable effects on pain and function and potentially larger effects on psychological and behavioral outcomes. These programs also lack the side effects of pharmacological interventions.^{51,52}

The development of an Internet-based SM program for the pain management of OA involved combining the benefits of in-person therapy with the ease of delivery through an Internet-based system. The benefits of in-person therapy include the supportive interactions that build a therapeutic relationship and the learning that takes place by observing other's experiences. But this type of therapy demands a lot of resources and a significant time commitment by a highly trained therapist. Internet-based SM programs are cost-effective and easily scalable. Disadvantages of this form of therapy include the lack of face-to-face interactions and the fact that access to the Internet may be limited in some populations.

In order to combine benefits of both in-person and Internet-based approaches PainCOACH was developed with the help of focus groups and iteratively incorporating recommendations in subsequent versions. Dr. Rini and her colleagues implemented a pilot study. An RCT, to be completed by July 2013, constitutes the final test for the program. Investigators designed the final version of PainCOACH to recreate the personal connection of in-person therapy through the use of a virtual coach. This critical element enhanced the sense of support and accountability for the participants. The Internet platform was designed for touch screens and requires minimal reading and simple navigation. A typical session involves reviewing the previous session, training a new skill, practice and exploration of the experience, and setting goals for the week. The program contains a total of eight sessions at a pace of one session per week, with each session taking 35 to 45 minutes. The COACHchat function allows participants to share their own experiences and read about other people's efforts.

Preliminary results from 28 individuals who had completed the RCT on program-issued iPads show that most participants (93 percent) found the platform easy to use. They also were confident using Pain COACH (89 percent). A large percentage of individuals further reported improved outcomes on mood (86 percent), relationships (71 percent), physical health (86 percent), and outlook on life (82 percent). Certain outcomes, however, suggested the need for further refinement before conducting a larger trial: 18 percent of patients found it difficult to figure out the best way to practice skills, 36 percent found it difficult to find time, and 39 percent found it difficult to remember to practice.

Dr. Rini concluded that preliminary results of the PainCOACH RCT suggest the promise of the program for improving various physical and mental health outcomes. Patients also reported comfort with the program, supporting the Internet as a valid SM delivery system. Future efforts with the PainCOACH program include refining the program based on the RCT findings, following up for longer periods, measuring the impact on medication use, and studying cost-effectiveness. Adding booster sessions or ongoing access to the website may promote long-lasting benefits of this program. Integration into primary care and/or free access to the website may help to make PainCOACH widely available.

Discussion

Several questions regarding the translation of SM into community settings related to strategies to improve the efficacy of SM. It is possible that other interventions or medications may augment the beneficial effects of SM. Panel members noted that upcoming trials would address whether additional therapies offer increased benefit. A critical issue for SM therapy involves the achievement of long-lasting benefits to manage pain that may last a lifetime. Panel members agreed that longer-term studies would be necessary to answer this question. It is clear that social networks will be vital in reinforcing the tenets of SM. Similarly, the panel noted that although improvements in retention do not always correlate with improved outcomes in the short term, it might be a critical component for sustaining outcomes in the long term.

Panel members also explored the issues of technology use and acceptance by elderly populations. Panel members were unanimous in their experience of older adults being very open to trying new technologies. When Smartphones and iPads were used, participants received instructions and technical support where necessary. In general, older participants proved very adaptive and comfortable using technology.

An audience member noted that the enrollment numbers and retention levels for the presented studies were surprisingly high. Panel members explained that in the group programs, individuals tended to motivate each other. Where PA was involved, panel members noted that PA became part of the participants' routines and meaningful in their lives.

The panel members also discussed the role of psychiatry/psychology versus neurology. Traditionally, neurologists treat physical pain, while psychiatrists and psychologists treat mental health disorders. This traditional model would have to be challenged in order to implement SM in a health care setting. An interdisciplinary approach involving multiple HCPs will be necessary for the success of SM programs.

The lack of adverse event reporting in SM trials was also discussed. Adverse event reporting is typically required for trials involving pharmacological agents but not for those involving therapy-based interventions. Panel members agreed that adverse events are not adequately reported and expressed the need for this kind of reporting in future RCTs of SM programs.

SESSION 2: TAILORED SM STRATEGIES FOR PATIENTS AND CAREGIVERS

Moderator: *Ann O'Mara, PhD, RN, FAAN*, Head of Palliative Care Research, National Cancer Institute

Overview: Understanding How Patients and Their Caregivers Cope with Pain: Implications for Behavioral Assessment and Training in Pain Coping Skills

Francis Keefe, PhD, Duke University Medical Center

Dr. Keefe reviewed internal and external factors that influence a patient's ability to deal with pain and how both sets of factors are potential targets for individual tailoring of SM therapies.

Stress and coping theory defines pain as a stressor, although outcomes are different between animals and humans. In animals, pain elicits a stress response similar to other stressors. The level of pain correlates with the intensity of the response. In humans, however, the level of pain does not necessarily correlate with the intensity of the response, and the ability to cope with pain is highly variable. The human model incorporates a coping and appraisal step in evaluating persistent pain. This extra step might account for the large variability in individual coping mechanisms. Appraisals can include evaluation of the pain for threat, harm, and challenge, and are affected by situational factors, including genetics, health, and social environment.

Pain catastrophizing is an example of an internal factor that influences coping ability. It is "the tendency to focus on and exaggerate the threat value of painful stimuli and negatively evaluate one's own ability to deal with pain."⁵³ In studies with chronic non-malignant pain, persons who catastrophized reported more severe pain, showed more pain behavior, reported more depression, and took more medication. In a study of pain following knee replacement surgery, patients who catastrophized were 4.5 times as likely not to achieve clinically significant pain relief.

The neuronal mechanisms of catastrophizing do not involve the sensory aspects of pain, but rather the affective nature. In individuals who catastrophize, the cortical vigilance network is engaged during mild pain, but diminished prefrontal cortex (PFC) modulation impedes disengaging from and suppressing pain.⁵⁴ While catastrophizing has a trait component, it is by no means static and varies with time and situation. According to Dr. Keefe, individuals who catastrophize are uniquely receptive to psychosocial interventions and are among the top responders following this kind of therapy.

External factors that affect a patient's ability to cope with pain include caregivers. Coping with pain occurs in a social context; seeing a loved one in pain has repercussions on the caregiver(s), which in turn influences the patient. Caregivers, similar to patients, also vary in their ability to cope with stress and have their own background and situational factors. Pain communication between spouses has been shown to be critical in the management of a person's pain. Patients who held back pain from their spouse reported more pain and dysfunction, and spouses who held back how their partner's pain affected them reported more stress. The caregivers of a person in pain are targets for SM therapy in the pain coping process.

Delivering psychosocial interactions to influence the patients and their caregivers is a key step in SM therapies. Innovations in this area will be necessary to make these interventions both effective and sustainable. Examples of these innovations include the use of daily pain assessment through questionnaires on mobile devices. By tracking pain daily, retrospection bias can be avoided, and triggers and trends may be identified. SM therapies can also be delivered by telephone or via the Internet to patients and caregivers. Virtual reality also has been proven to help individuals who have difficulty disengaging from pain.⁵⁵ Sensory immersion in what appears to be a garden, night sky, or other environment can result in a significant reduction in pain.

In conclusion, the understanding of pain processing and coping has advanced tremendously in the past 25 years. Pain can be reliably measured and coping skills for the patient and caregiver can be integrated into the treatment plan. These approaches have the possibility of improving the patient's quality of life and lessening the suffering of many individuals.

Pain Control Program Intervention for Cancer Pain Patients and Their Caregivers

Christine Miaskowski, MSN, PhD, FAAN, University of California, San Francisco

Tailoring of an SM program for a target population can be achieved by improvement of the program itself through "learning from non-responders." In this method, feedback from non-responders provides critical insight regarding additions to a therapy that can make it more effective. Dr. Miaskowski reviewed a study completed in 2001 that employed a medication-assisted SM therapy. The non-responders informed the design of a new study that is currently under way.⁵⁶

The patient cohort for the 2001 study involved cancer patients who experienced severe pain caused by bone metastasis. The RCT included a 6-week intervention (PRO-SELF©) with three home visits and three phone calls during which the family caregiver was present. Tools included medication education, a pain management diary, and a pillbox. Outcomes were changes in pain scores and increases in opioid use. Although pain scores decreased significantly, only 50 percent of patients were identified as responders.⁵⁷

An analysis of non-responders resulted in the identification of certain characteristics that were not addressed with the PRO-SELF© intervention, including difficulties in the following areas:

- obtaining prescribed medication
- accessing information
- tailoring prescribed medications to meet individual needs
- managing side effects, particularly constipation
- experiencing cognition deficits due to medication
- dealing with new or unusual pain
- managing multiple symptoms simultaneously

To overcome these difficulties, a new intervention was developed called PRO-SELF© PLUS Program, which contained the following additions or revisions to the original SM program^{58,59}:

- focus on knowledge deficits in medication use
- evaluation of the management of difficulties on a daily basis
- intervention time increase from 6 to 10 weeks
- aggressive management of side effects, including constipation
- accounting for pain history in medication management

The patient cohort (54 percent female) in the 2013 trial of PRO-SELF PLUS was, on average, 60 years old with a mean education of 15.5 years. Pain levels for this cohort were high with a mean NRS score of 4.5 for average pain and a mean NRS score of 7.5 for worst pain. Patients reported an average of 16 symptoms at a time, and daily life was affected 5 out of 7 days each week. The results from this study are not yet available, but 12 years after the original PRO-SELF study, it is clear that major challenges still exist for the patient attempting to self-manage cancer pain.

Some challenges involve pain medication management within a complex health care system, including obtaining medications. Insurance policies may not cover relevant medications, and some pharmacies may not carry them. Other challenges for the SM of cancer pain involve lifestyle considerations, including continuing with home life or work while in pain, understanding what is being prescribed, and remembering to take medications at the proper time. Organization of medications in the home is critical because a patient may be taking a total of 15 different medications daily, all with their own dosing regimens. Safe storage is also a concern, especially with the rise in prescription drug abuse.

Considerations made during the design of the revised study underscored the complexity in management of cancer pain and the need for a comprehensive, multidimensional assessment of the patient and home environment for a program to be successful.

Combined Behavioral and Pharmacological Treatment for Pediatric Chronic Migraine

Scott Powers, PhD, American Board of Professional Psychology (ABPP), Cincinnati Children's Hospital

Developing an SM Program for chronic migraine in children presents a number of significant challenges. There are no FDA-approved medications for the prophylactic treatment of migraine in pediatric populations, and integration of parents into care is a vital component of the treatment of a child with any chronic condition. It is estimated that chronic migraine affects 1 percent of all children. It is estimated that more than 50 percent of children with migraine become adults with migraine.

Dr. Powers described the design of an RCT to evaluate the effectiveness of CBT combined with the use of Amitriptyline (AMI) for the treatment of pediatric chronic migraine. Although AMI is used off-label, it is considered the standard of care for the treatment of migraine in children. Investigators designed the trial to be a two arm study of AMI + CBT or AMI + Attention Control and Education Therapy (ATT). Children enrolled in the study were 10 to 17 years old and diagnosed with chronic migraine. In addition, children had an average of 15 or more headaches per month resulting in a disability score greater than 20 on the Pediatric Migraine Disability Assessment (PedMIDAS). Children in this study were excluded if they had ever been diagnosed with a psychiatric disorder, such as psychoses and bipolar disorder, were on other anti-migraine medications, or had PedMIDAS scores greater than 140. The final cohort had 64 children in the AMI + CBT arm and 71 in the AMI + ATT arm. The average age was 14 years, and 79 percent of the participants were female. At baseline, these children averaged 21 headache days and had a mean PedMIDAS score of 68 (severe grade of disability).

The CBT program used in this study consisted of standard SM principles with tailoring for children and parents, including:

- headache management principles
- exercise
- regular meals and sleep (no caffeine)
- biofeedback-assisted relaxation training
- recognizing negative thoughts and using calming statements
- problem-solving skills
- parent coaching and reinforcement of coping

After an initial medical and psychosocial assessment, children were randomized into one of the two arms, and treatment proceeded for 20 weeks. Treatment during the first 8 weeks comprised weekly sessions. Then individual sessions continued to occur monthly for 3 months. The children were followed for 1 year at 3-month intervals. The treatment arms were then evaluated for safety, efficacy, and sustainability at the 20 week endpoint and over the one-year follow-up period. Measured treatment credibility and integrity was high for both arms.

Final AMI doses averaged 1 mg/kg/day, and six children dropped out of the study. There were no serious or unexpected adverse events. Both treatment arms were considered to be safe for the pediatric patients.

The primary endpoint of the study was headache days and the key secondary endpoint was disability. Both treatment arms reduced headache days significantly, but the AMI + CBT arm was superior to the AMI + ATT arm. After the treatment period, two-thirds of patients in the AMI + CBT arm had a greater or equal to 50 percent reduction in the number of headache days. This result was sustained during the follow-up period of 1 year. In fact, measurements of the primary endpoints continued to improve over time. At the end of the year follow-up, children in the AMI + CBT arm had less than six headache days per month.

Treatment regimes in both arms of the study were successful in reducing the level of disability. The AMI + CBT arm was, again, superior. At the end of the treatment period, three-fourths of patients in the CBT arm had PedMIDAS scores less than 20, and this trend continued throughout the follow-up period with little to no disability (PedMIDAS scores 5-10) by the end of the year.

These results from the first proven RCT of a treatment for chronic migraine in the pediatric population demonstrate that AMI + CBT therapy is safe, effective, and sustainable. Given the measured clinical impact, this suggests a new standard of care. The trial further supports the value of tailored CBT for a population that is young, requires parental support, and has few proven pharmacological interventions. Translating this work into practice is a work in progress. Dr. Powers noted a need for more trained providers and integration into neurology practices. Furthermore, evidence-based SM programs will only be widely disseminated if insurance companies cover them.

Pain SM Programs for Individuals with Disabilities and Chronic Disease

Dawn M. Ehde, PhD, University of Washington

A patient whose pain is secondary to a disability or neurological condition often encounters significant barriers in accessing SM programs for the treatment of pain. Specifically, individuals with limb loss (LL), multiple sclerosis (MS), or spinal cord injury (SCI) are often unable to attend group SM sessions because of pain or difficulty accessing transportation. Chronic pain is a significant problem for many people with acquired disabilities and affects 40-80 percent of people with LL, MS, or SCI. Pain relief for these patients is rare, and only few (10-15 percent) have tried SM for pain.⁶⁰⁻⁶²

Dr. Ehde described the design of the Telephone Intervention for Pain Study (TIPS), an RCT to evaluate the effectiveness of telephone-delivered CBT for patients with LL, MS, or SCI. The study had two treatment arms: telephone-based CBT or telephone-based pain education. Patients had LL, MS, or SCI with an average pain intensity greater than four on the NRS. The pain originated with or preceded the onset of the disability and lasted longer than 6 months. Patients were excluded if they suffered from severe cognitive impairment or had previously participated in CBT. The final cohort included 188

patients, 39 percent with SCI, 43 percent with MS, and 18 percent with LL. Patients were 52 years old on average, and 57 percent were female. The CBT component of this study included standard SM components in addition to several modifications specific for those with disabilities:

- relaxation training adapted for disability
- behavioral activation and goal-setting
- pacing
- cognitive therapy
- in-session rehearsal of skills, readings, and homework
- manuals provided in multiple formats—compact disc (CD), large print, paper
- deliberate queries about the ability to physically and cognitively complete homework
- therapists help to overcome challenges to homework completion
- manuals use disability-specific examples

Patients were randomized and participated in 8 weekly sessions of 1 hour with 15-minute booster calls at 2, 4, 8, 12, and 24 weeks and follow-up calls at 3, 6, and 12 months post treatment. The primary outcome of this RCT was pain intensity, and the secondary outcomes included pain interference and depression.

Both treatment arms were significantly able to reduce pain intensity; 30 percent of the CBT arm reported at least 30 percent reduction in pain, while 28 percent of the education arm achieved this goal. CBT was superior with regard to pain interference and reduction in depression. The results were sustained at 6 and 12 months. TIPS thus proved to be effective in the primary and secondary outcomes outlined in the study. The study also demonstrated that simple pain education led to significant reduction of pain intensity in patients with disabilities.

Treatment satisfaction was high with 98 percent of participants stating that they would recommend TIPS to a friend. Patients saw the following benefits of TIPS:

- easier and convenient (53 percent of participants)
- no need to travel or drive (47 percent)
- physically more comfortable (24 percent)
- access to care that would normally not be available in a small town

About 70 percent of participants noted no drawbacks of the phone-based intervention, although 24 percent would have wanted some in-person interaction.

This study supports the feasibility of telehealth for disabled individuals and shows that the therapeutic alliance is maintained. Further use of telehealth is being explored for brain injury patients in the Veterans Affairs (VA) hospitals, patients in rural areas with little access to health care, and patients with other comorbid conditions.

Discussion

Discussion centered on study design, factors that determine outcomes, and medication use. It is, for example, unclear whether educational arms are appropriate as controls in these kinds of studies, or whether a placebo would be more informative. The panel members agreed that although a placebo

would yield more data on the true efficacy of the SM program, it is not always ethical or feasible to include a placebo control. Educational controls usually involve a professional trained in psychology who was likely to inadvertently offer a level of support and care. By the simple act of communication, those providing education were giving patients a place to diffuse unhealthy thoughts and behaviors. It is likely that the mere presence of a warm, caring person leads to improved outcomes.

An audience member asked why people who catastrophize pain tend to respond best to SM programs. The mechanisms behind this phenomenon are unknown.

Another audience member questioned whether holding back pain information in couples might be a proxy for the health of the relationship or the mental health of the patient. Interestingly, the effect sizes of changes following CBT in distressed couples are large, suggesting that interventions in communication behaviors are possible and worthwhile.

Medication effectiveness in patients for pain has proven to be highly variable. The literature on analgesic drugs implies that most agents are capable of reducing pain by about 30 percent; however, there are wide ranges in the pain response as well as side effects experienced by patients.

Medication use was a factor in the decision not to include children with depression in Dr. Powers's study of chronic pediatric migraine. Although the adult literature describes major depression as a comorbid condition of migraine; the literature on children with migraine describes anxiety but not depression as a typical comorbid factor. Dr. Powers further noted that AMI + CBT may not be adequate to properly treat a child or adolescent with major depressive disorder.

SESSION 3: PREDICTORS AND INDICATORS OF OUTCOMES IN INTEGRATED SM STRATEGIES

Moderator: *Bridgett Rahim-Williams, PhD, MPH, MA*, Senior Research Fellow, NIMHD

SM as Means and End in Chronic Pain Care

Mark Sullivan, MD, PhD, University of Washington

SM is usually defined as a strategy to achieve an outcome, but it may be more valuable to reframe SM as both a strategy and an outcome. Dr. Sullivan emphasized that pain intensity reduction is neither sufficient nor necessary for success in chronic pain care, while SM of pain is vital to increased quality of life. Dr. Sullivan described three ways in which SM can be considered an outcome:

1. SM is the final phase of care for an illness that has no cure.
2. SM is not simply a means to pain relief. It may be judged adequate by the patient without achieving any particular level of pain relief.
3. SM itself is a valuable and essential goal as a form of patient empowerment.

The term SM is not meant to suggest that therapy occurs without the involvement of HCPs. The Chronic Care Model states that the patient, doctors, and health care system are all engaged in the self-care effort. This model requires more collaboration and integration between providers and patients. HCPs need more than CBT training to provide support for SM; providers need to encourage and support the patient to be more responsible for their own care.

Dr. Sullivan described two prerequisites for the success of a SM program: importance and confidence.⁶³ Medicalization of pain care can undermine self-care by reducing its importance. If more procedures or more medications are the only tools offered for pain, then SM will be deemed unimportant.⁶⁴⁻⁶⁶ Likewise, pharmacological treatment of pain can also undermine self-care by decreasing patient confidence.⁶⁷ Having the confidence to manage pain is necessary for patient success.

Dr. Sullivan compared the acceptance of pain to the five-step grieving process:

1. **Denial**—“I am not going back to work until this back pain is gone.”
2. **Anger**—“I do not deserve this awful pain in my neck.”
3. **Bargaining**—“If you give me some more oxycodone, then I can go to PT.”
4. **Depression**—“This pain is never going to get better; I can’t do anything fun.”
5. **Acceptance**—“Even if I hurt, I still like taking care of my grandchildren.”

Dr. Sullivan equated acceptance of pain with re-invention of the self. Patients invariably want to return to their former lives and resist the suggestion that they cannot do this. Healing in chronic pain occurs through a reinvention of the self by including pain as only a part of the whole person.

Opioid use for the treatment of pain is an excellent example of SM as a strategy as well as an outcome. The opioid epidemic has rekindled interest in therapies that have less adverse effects. Trials of SM programs that support tapering of opioid use for pain are valuable for many reasons:

- Opioid therapy has long-term risks.
- There are doubts about the efficacy of long-term opioid therapy.
- 43 percent of patients want to cut down or stop opioid therapy.
- There is a 90 percent failure rate in tapering in individuals with opioid use disorders.
- Self-care, not medication, is the foundation for effective chronic non-cancer pain care.

To evaluate the effectiveness of an SM program to support tapering of opioid drugs, a pilot RCT is underway with two trial arms: one arm includes a tapering SM intervention and one arm does not support tapering. About 50 patients are to be enrolled who are currently taking over 50 mg of morphine or equivalent medication.

The SM intervention includes CBT training as well as taper visits with a physician’s assistant. Patients will attempt to taper 10 percent of the original dose per week until a 30 percent reduction is reached, followed by tapering 10 percent of the new dose. Tapering will occur first with long-acting opioids followed by short-acting ones to give participants a sense of control when encountering breakthrough pain.

After randomization, patients will complete 22 weekly taper visits including CBT training. The primary outcome for this study is the daily dose at 22 and 34 weeks.

Although trial results are not yet available, it is possible to assemble a list of potential predictors of tapering success. A history of substance abuse, depression, anxiety, post-traumatic stress disorder (PTSD), or insomnia is a possible barrier to successful tapering of opioids. Also, the patient’s readiness and confidence will improve the likelihood of tapering. The types of pain and medications used will also likely influence the outcome of this trial.

Dr. Sullivan observed that chronic illness changes the nature and role of self-care. It is no longer just a strategy, but also an outcome for long-term pain management. There is currently a conflict between specialty medical pain care, which relies on procedures and medications, and self-care. Dissemination of SM programs is limited under the current health care system because of costs and access.

Neurobiological Mechanisms Underlying Effectiveness of CBT in Irritable Bowel Syndrome (IBS) Patients: Lessons from Anxiety Disorders

Emeran A. Mayer, MD, University of California, Los Angeles

The effectiveness of CBT has been demonstrated for various chronic pain syndromes as well as for disorders of mood and affect, even though significant individual variations in the responsiveness to this type of intervention exists. Identifying biomarkers which predict treatment responsiveness would increase the cost effectiveness of such therapies.¹² Structural and/or functional brain changes (“brain signatures” have been proposed as possible biomarkers for chronic pain, and may be useful as moderators of CBT outcome.

Alterations in evoked brain responses (measured as Blood Oxygenation Level Dependent [BOLD] signal) to painful stimuli or to the expectation of such stimuli have been reported in various chronic pain conditions, including IBS, fibromyalgia and chronic back pain.^{68–70} In IBS, it has been shown that the expectation of an aversive visceral stimulus can elicit similar brain responses as the actual distension, and that the group difference in brain responses between IBS and healthy subjects can largely be explained by the difference in responses during pain expectation.⁷¹ More recently, alterations in intrinsic brain oscillations (“resting state activity”) and connectivity in the absence of any stimulus have been reported in similar brain regions,⁷² as well as regional alterations in cortical thickness. When viewed together, the observed structural and functional changes are consistent with alterations in brain circuits concerned with detection of saliency, corticolimbic modulation and emotional arousal.⁷³ Based on these findings and the well documented effectiveness of CBT approaches to chronic visceral pain, it has been suggested that CBT may be associated with a normalization of some of these brain signatures.

To address whether CBT changes the brain structurally in persistent pain, investigators performed an RCT involving 43 women with fibromyalgia.⁷⁴ Women were assigned to either a 12-week CBT plan or a wait-list control group. Responses to pressure pain were evaluated by functional magnetic resonance imaging (fMRI). The group receiving CBT experienced larger symptomatic improvement, but did not note any changes in the perception of experimental pain. Those receiving CBT also demonstrated an increased functional connectivity between the PFC and thalamus as well as increased activation of ventro- and dorsolateral brain regions. These results are consistent with a model that predicts that CBT changes the connections between structures involved in the processing of pain.

Another trial to assess brain correlates of CBT involved an RCT of 42 women with IBS.⁷⁵ Participants were assigned to either a 7-week hypnotherapy plan or an education control group. Responses to visceral pain and its expectation were evaluated by fMRI. Both groups demonstrated symptom improvement, improvements in the expectation of pain, and concomitant brain structural changes.

In subjects with mood disorders, medications such as serotonin-selective reuptake inhibitors (SSRIs) on the one hand and CBT on the other hand have both similar as well as distinct brain correlates. Similar to the studies described above, CBT or medication can normalize the impaired cortico-limbic-pontine networks involved in persistent pain and affective disorders. Both CBT and medication have been shown to strengthen prefrontal regions and the inhibitory control of affective circuits.

More studies are needed to confirm if brain signatures can be used to monitor or predict therapeutic outcomes. In addition, it will be possible to evaluate different types of CBT for their effects on brain signatures, and these effects can be examined for their sustainability after treatment. The Neuroimaging Core of the UCLA Center for Neurobiology of Stress has established a brain image and metadata repository to facilitate the identification of robust brain signatures in various chronic pain conditions.⁷⁶

Can Integrated Pain Management Strategies of CBT and Relapse Prevention Alter CNS Function and Structure?

Magdalena Naylor, MD, PhD, University of Vermont

A key goal of SM is the long-term maintenance of skills and strategies that allows the patient to manage chronic pain. Although CBT is effective for chronic pain management, the maintenance of coping skills is variable and usually declines within several weeks after the SM program ends. In order to improve the outcomes of long-term SM, Dr. Naylor and her colleagues evaluated the effectiveness of Therapeutic Interactive Voice Response (TIVR), a phone-based intervention.⁷⁷

TIVR was created as an extension of CBT group therapy and is based on a relapse prevention model of behavior change. The CBT phase included:

- relaxation techniques
- ways to challenge pain beliefs
- increased self-monitoring by using a pain diary
- setting treatment goals
- cognitive coping strategies
- strategies to enhance social support

Knowledge of the patient was then used to create personalized prerecorded messages during the post-treatment phase. The participants entered responses using their telephone keypad. Investigators structured the TIVR intervention as follows:

- **Component 1**—Self-monitoring 21-item Daily Questionnaire
- **Component 2**—Prerecorded didactic skills review
- **Component 3**—Prerecorded behavioral skills practice
- **Component 4**—Monthly therapist feedback

A total of 51 individuals in chronic pain were randomized to CBT therapy with or without monthly TIVR and evaluated for pain, PA, and decreases in opioid use at 4 and 8 months post treatment.

Compared with controls, individuals receiving TIVR experienced superior outcomes in pain relief, PA, and decreased opioid use. Even though CBT therapy had ended, decreases in opioid use continued through 8 months, while increases in opioid use occurred in the control group. These results indicate that TIVR is an effective tool in maintaining CBT's beneficial outcomes.

Dr. Naylor noted that the personalized therapist feedback is the most labor-intensive portion of the TIVR program. She described the results of a subsequent study designed to ascertain whether full or partial TIVR is necessary to maintain CBT outcomes. One hundred fifty-one individuals with an average of 11

years of chronic pain were randomized to CBT with 4 months of a full TIVR program, partial TIVR program with no personalized message, and no TIVR program. Follow-up analyses were conducted at 4, 8, and 12 months post therapy and included effects on pain, depression, and self-efficacy.

Both TIVR programs proved effective at maintaining the CBT outcomes of decreased pain and depression, and improved self-efficacy. However, the full TIVR program was significantly superior to the partial program at improving depression, control of pain, and self-efficacy of pain management. These results indicate that the personalized messages were valuable in maintaining and improving the mental status of patients in chronic pain. Clearly, a personal touch, even if delivered by pre-recorded message, is a key component in maintaining the therapeutic alliance between a participant and his or her HCP.

It has been demonstrated that CBT modifies both the dysfunctional neural circuitry and decreased gray matter found in chronic pain patients.⁷⁸ Dr. Naylor tested the hypothesis that CBT might be able to reverse the gray matter changes seen in patients with chronic pain. She used voxel-based morphometry (VBM) to analyze brain changes before and after CBT treatment. Individuals participating in CBT for chronic pain showed increases in the amount of gray matter in the dorso-lateral PFC. In addition, this increase in gray matter correlated with decreased pain catastrophizing and improved coping skills.

Patient Utilization of Pain SM Strategies

Stephen T. Wegener, PhD, ABPP, Johns Hopkins University

Dr. Wegener agreed with the previous speakers that a significant evidence base now exists for the utility of professionally delivered, individually administered CBT-based SM intervention for the management of chronic pain. He further noted a growing evidence base for the utility of CBT-based SM interventions as a secondary prevention strategy against the development of chronic pain and disability. A remaining challenge is the diffusion and widespread application of sustainable CBT-based SM interventions while retaining effectiveness for the target population.

Significant improvements in several areas of SM interventions have created a more favorable environment for the use of SM in chronic pain care:

- **Health care environment**—The increase in chronic pain incidence is causing a shift toward low-cost, effective alternative strategies. More HCPs and health care organizations are now including SM in pain care. In the Participatory Action Research (PAR) Model, SM is a key part of pain care involving a prepared HCP team interacting with informed and motivated patients.⁷⁹
- **Accumulation of research data**—Research data are accumulating to shape interventions, and infrastructures are maturing to support adequately powered effectiveness studies.
- **Knowledge of behavior change**—In a meta-analysis of behavior change techniques, SM methods such as self-monitoring of behavior, risk communication, and social support were highly effective at eliciting a beneficial behavioral change. Harnessing the motivators of behavior change has made SM highly effective in improving chronic pain outcomes.

While a favorable health care environment and increased knowledge of behavior change have thus increased the acceptability of SM in chronic pain care, the delivery of SM interventions remains a formidable barrier to widespread dissemination. In order for SM in pain care to become widely used, it

must be easily implementable and sustainable in health care practice while simultaneously maintaining effectiveness.

Another key component to dissemination is timing of the intervention. There is little data to support when a patient is most receptive to SM interventions. As an example of the importance of timing, Dr. Wegener described the SM program called NEXT STEPS: Managing Life after Trauma. Although interest in such a program seemed high, only 16 out of 5,000 invited individuals came to the first class. Timing and engagement of the patient population is clearly a critical factor in the success of SM programs.

The ideal delivery vehicle for SM would be both effective and low-cost. Dr. Wegener described a model with preliminary data involving a computer-based SM program coupled with PT for musculoskeletal pain in occupational workers (Take Charge of Pain Program). The use of computers in implementing SM will facilitate meeting the criteria of effectiveness and low costs. In this cohort, high levels of early acute pain put the patient at risk for poor outcomes, such as lost work, disability, and chronic pain. Dr. Wegener described the importance of intervening before the acute pain turns into a chronic problem.

The computer-based intervention consisted of seven 20-minute sessions of classic SM principles including:

- knowledge acquisition
- problem solving
- skill acquisition
- self-monitoring
- identifying and building on existing strengths

Patients were encouraged to complete the SM sessions during the PT appointment to increase retention in the program.

A total of 260 patients were randomized to receive rehabilitative therapy with or without computer-based SM. Inclusion criteria included an acute injury less than 3 months ago with a pain level greater than 5 on the NRS. The patients' ages averaged 45 years, and 70 percent were male. The following outcomes were measured at 3 and 6 months post therapy: pain intensity, physical functioning, and psychosocial functioning. More than half of the patients dropped out of the program; 44 percent of participants completed all seven computer-based SM lessons. Outcome results will be forthcoming.

The examples provided illustrate the importance and sensitivity of timing for the delivery and sustainability of SM programs. Dissemination is both a barrier and an opportunity for SM in the care of chronic pain. There is a wide variety of platforms that can be harnessed for the delivery of SM, including phones, text messages, computers, and film. The challenge will be to deliver SM on the right platform at the right time to the right patient population.

Discussion

Discussion centered on methodology, treatment outcomes, and the relationship between pharmacological therapy and SM.

Panel members clarified that sleep is an important factor in SM therapy, and they considered sleep to a useful, measurable outcome. Although sleep was not explicitly mentioned as an outcome, the panel members have included sleep parameters as part of their trials.

Panel members discussed methods of accessing Internet-based therapies. Dr. Wegener commented that most patients preferred to complete the therapy at home but he also noted that the time to complete SM at home was significantly longer than in the therapist's office. It may be that distractions in the home that are not present in a doctor's office are responsible for the increased time to complete the task.

Dr. Mayer was asked whether he intended to examine structural changes in the brains of children following CBT. He acknowledged the importance of such a trial, but noted that as of now, there is no funding for imaging studies in children following CBT. He also noted that the PFC is not fully formed until 18 or 20 years of age and questioned whether CBT interventions might change the trajectory of development in children.

The importance of helping patients manage opioid medications was emphasized. The panel members stated that steady-state around-the-clock analgesia used to be the standard of care for chronic pain. This model, however, may be less effective at controlling pain long-term, and may in fact lead to increased sensitivity to pain (i.e., hyperalgesia). The current medical advice is to treat pain on an as-needed basis to give patients a sense of control over their pain. By removing the long-acting opioid medications, pain can be controlled with fewer medications per day while still giving flexibility to the patient.

Panel members discussed the reasons behind the increase in CBT in the past 10 years. They agreed that although the incidence of chronic pain has increased, drug development for pain medications has stalled. Ultimately, opioids are not a viable solution for a lifetime of pain treatment. Instead, these drugs are self-perpetuating and undermine SM strategies. Dr. Mayer commented that chronic pain also can be described as a disease of the brain. Because CBT alters brain structure, it can be considered as much a biological therapy as medication. By reframing the use of CBT as a biological therapy, it may become a more accepted mode of intervention in the treatment of chronic pain.

INTRODUCTION TO THE JUNIOR INVESTIGATOR PRESENTATIONS

Catherine Bushnell, PhD, Scientific Director, Intramural Research, NCCAM

A number of NIH junior investigators were invited to present posters at this meeting. They are typically supported by NIH fellowships, career development awards, or their first independent investigator research grant. The following three presenters were selected from among the invited posters as particularly outstanding. One of these three will then be selected to receive the Mitchell Max Award for Research Excellence, an award that has been presented annually since 2009.

Movement Pattern Training for Pre-Arthritic Hip Disease

Marcie Harris-Hayes, PT, Doctor of Physical Therapy (DPT), MSCI, Orthopedic Clinical Specialist (OCS), Washington University School of Medicine

Pre-arthritic hip disease (PAHD) is defined as joint pain and loss of function with no radiographic evidence of arthritis.^{80,81} Several risk factors (e.g., abnormal bone structure, intense activity, muscle

performance, and movement patterns) have been suggested for PAHD, which is a precursor to OA.^{82,83} The number of surgeries to treat PAHD has grown significantly in recent years. Dr. Harris-Hayes described a prospective study designed to identify differences in individuals with and without PAHD, and to evaluate the effectiveness of an SM program involving movement pattern training (MPT) reduce pain and improve function in people with PAHD. Differences in movement were evident between individuals with PAHD; these differences in movement are further associated with specific outcome scores.⁸⁴

The primary goal of the treatment phase of the RCT was to assess whether 6 weeks of a rehabilitative MPT SM program would be able to improve pain, strength, and hip movement. Individuals aged 18-40 years with chronic PAHD are currently being recruited with a goal cohort size of 80. Of the 16 individuals currently enrolled, 14 are female and the average age is 27.3 years.

The RCT consists of randomization into an immediate MPT program versus a 6-week waiting period with follow-up sessions at 6 and 12 months. The MPT program includes six 1-hour sessions in education and instructions on how to modify abnormal movement patterns. Patients are encouraged to continue PT on their own after instruction ends. Primary outcomes include self-reported adherence and a modified Harris Hip score indicative of hip mobility, pain, and functional disability.

For those that have completed the MPT program, a 10 percent improvement in hip scores was noted at 6 and 12 months. Improvements in pain and functionality were also evident. These preliminary results indicate that MPT is effective in improving pain and mobility and that these effects are sustainable over the study period. Recruitment is ongoing and results will inform future clinical trials.

An audience member asked whether certain sports may be associated with PAHD. Dr. Harris-Hayes replied that hockey, soccer, and ballet are being investigated as possible triggers of PAHD.

Pain, Executive Function, and Structural Brain Correlates in Children with and without Chronic Abdominal Pain

Christine Mrakotsky, PhD, Boston Children's Hospital and Harvard Medical School

Chronic pain has been associated with functional, structural, and chemical changes in the brain. In children, chronic pain has developmental implications for executive functions (EFs) including:⁸⁵

- **Behavior regulation**
 - emotional control
 - inhibitory control
 - self-awareness

- **Cognitive functions**
 - planning and strategizing
 - problem-solving
 - attention
 - follow-through and execution
 - monitoring

Chronic abdominal pain is a hallmark symptom of inflammatory bowel disease (IBD) and is the most common complaint in school-age children.^{86,87} Neural connections between the brain and gut are well documented, and in fact, 61 percent of IBD patients are depressed.^{88,89} Chronic pain of the gut can cause

changes in brain and behavioral outcomes. IBD in adults has been associated with reductions in gray and white matter but no data exist for brain changes in the pediatric IBD patient.

Dr. Mrakotsky described the results of two trials evaluating how IBD pain affects EFs and brain structure. The first study examined the EFs of 148 children ages 8-16 years with and without IBD at baseline and 6 months. Pain severity was associated with poorer EFs regardless of disease status; healthy individuals in acute pain had poorer EFs. Pain was also associated with more emotional problems such as anxiety and depression regardless of disease status. The disruption of EFs was most prominent in IBD patients.

The second study determined the disrupting effects of IBD pain in both gray and white matter. Thirty-five children ages 9-14 with or without IBD were examined by diffusion tensor imaging (DTI), which maps white matter fiber tracts and brain connectivity. DTI results demonstrated that IBD patients with acute pain show reduced white matter integrity compared to healthy controls. Those children with lower EFs also presented with lower brain volume and a smaller nucleus accumbens, an area involved in EFs.

Results of these two studies indicate that pain in children results in structural changes of the brain involved in EFs. Given that reduced EFs lead to maladaptive coping strategies, EFs themselves may be a target for SM intervention in children with IBD.

The panel discussed the potential reversal of brain structural changes following pharmacological or SM therapy as a valuable research avenue. An audience member noted that disruption of school due to pain episodes could contribute to disruptions in EFs.

Brief Meditation Training for Migraineurs Affects Emotional and Physiological Stress Reactivity

Amy Wachholtz, PhD, University of Massachusetts Medical School and UMass Memorial Medical Center

Migraines result in a significant amount of pain and reduce the quality of life for more than 13 percent of the U.S. population.⁹⁰ They are related to increases in emotional and physiological stress. Reducing stress may, therefore, lead to fewer headaches.¹² Dr. Wachholtz and her colleagues designed a specific SM program involving meditation to test the hypothesis that decreased reactivity to stressors might reduce the number and intensity of migraines.

The study cohort included 88 patients with migraine who had never practiced meditation. Of these patients, 80.7 percent were female, matching the epidemiological profile of migraine. Participants were randomized to the meditation or education control groups. Treatment included 4 weekly 90-minute group sessions with meditation training and meditation practice for 20 minutes per day. Education controls were given information on migraine demographics and treatment options.

Anxiety levels were assessed by the State Anxiety Inventory and galvanic skin response; migraines were assessed in a headache journal. Outcomes were measured at baseline, post-trial period, and 4 weeks post-trial period.

Meditation significantly reduced the number of headaches by 50 percent. This effect was maintained 4 weeks post trial. Meditation reduced emotional and physiological stress reactivity by 10 percent and 40 percent, respectively, and was sustained during the post-trial period. Patients in the education control group actually experienced a transitory increase in state anxiety at the immediate post-trial evaluation, possibly because of focusing on their disability during the intervention.

These results indicate that meditation is a useful and cost-effective tool in the management of chronic migraine pain. Interesting avenues of future research include examining different kinds of meditation, whether there are gender differences, and how long meditation-mediated outcomes can be sustained.

Presentation of the 2013 Mitchell Max Best Poster Award

Story C. Landis, PhD, NIH Pain Consortium Executive Committee Chair

NIH established the Mitchell Max Best Poster Award in memory of the late Mitchell Max, an NIH investigator who was passionately interested in pain-related issues. It is awarded annually to the early-stage investigator who presents the most exciting advances in pain research. The 2013 Mitchell Max Best Poster Award was given to Dr. Christine Mrakotsky for her work on pain, executive function, and structural brain correlates in chronic abdominal pain.

UPDATE ON THE INTERAGENCY PAIN RESEARCH COORDINATING COMMITTEE (IPRCC)

Linda Porter, PhD, Health Science Policy Advisor for Pain, NINDS

The Patient Protection and Affordable Care Act of 2010 included several provisions relating to pain research, including:

- **IOM conference on pain**³—to identify key research and pain policy issues
- **Engagement of the NIH PC**¹
 - Coordinate and support an active agenda for pain research across NIH ICs
 - With the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), develop and submit recommendations on pain research initiatives for the Common Fund
- **Creation of an IPRCC**⁹¹—to coordinate federal pain research across NIH and other federal agencies

The 2011 IOM report identified key research and policy activities necessary to successfully treat chronic pain:

- increase recognition of pain as a widespread health problem
- evaluate the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain in the general population, and in identified racial, ethnic, gender, age and other demographic groups that may be disproportionately affected by inadequacies in the assessment, diagnosis, treatment, and management of pain
- identify barriers to appropriate pain care
- establish an agenda for action in both the public and private sectors that will reduce such barriers and significantly improve the state of pain research, education, and clinical care in the United States

The IPRCC uses the IOM report as a guide for its research and to make recommendations for the treatment of pain. The IPRCC consists of 19 members from public and private research organizations, patient advocacy groups, and federal agencies. The research mandate for the IPRCC includes the following activities:

- develop a summary of advances in pain care research supported or conducted by the federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain
- identify critical gaps in basic and clinical research on the symptoms and causes of pain
- make recommendations
 - to ensure that the activities of the NIH and other federal agencies are free of unnecessary duplication of effort
 - on how best to disseminate information on pain care
 - on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research

In October 2012, the Assistant Secretary for the Department of Health and Human Services (DHHS) tasked the IPRCC and NIH with addressing IOM recommendation 2-2:

“Create a comprehensive population health-level strategy for pain prevention, treatment, management, and research.”

To meet this significant challenge, the IPRCC created five working groups with an oversight-working group that will address the following areas:

1. Population research
2. Professional education and training
3. Public education and communication
4. Public health: prevention, care, and disparities
5. Public health: services and reimbursement

The oversight working group will convene on June 2, 2013, and updates will be posted on the IPRCC website. The goal of this effort is to coordinate and integrate the agenda for pain research and ensure that SM is an integral part of chronic pain care.

CLOSING REMARKS AND ADJOURN

Josephine P. Briggs, MD, NIH Pain Consortium Executive Committee Member

This PC Symposium highlighted the efficacy and implementation of SM programs in the treatment of chronic pain. Dr. Briggs emphasized that now is the time to “get pragmatic” and address the real-world effectiveness of SM. Pragmatic trials would assess the validity of the SM program by:

- choosing patient populations likely to participate in the treatment
- choosing interventions that could be administered in a standard clinical setting
- using representative practitioners

Dr. Briggs noted that it is essential for a pragmatic trial to achieve a large representative patient population. A pragmatic trial is unique in that randomization is on the health care system level, not an individual level. The goal of these trials is to build a research base that informs pain care policy. Results of these trials will hopefully provide the impetus and rationale to change the health care system.

The NIH-funded Health Care Systems Collaboratory is a vehicle by which pragmatic trials can be conducted. The Collaboratory sponsors phased awards; projects have 1 year to prove its feasibility, followed by full funding. Duke University is the coordinating center for all Collaboratory projects. These awards have modest budgets and involve working closely with a major health care organization. Outcome measures are derived from electronic health records. Seven examples of projects currently funded by the Collaboratory were presented, two of which are pain-related:

1. **Nocturnal blood pressure (BP) control**—Does taking antihypertensive medications at night reduce cardiovascular events?
2. **Longer dialysis duration**—Does a system-wide change to increase dialysis duration reduce mortality?
3. **Preventing hospital-acquired infections**—Does increasing bathing procedures result in less hospital-acquired infections?
4. **Suicide prevention**—Does an intervention for patients who acknowledge suicidal thoughts reduce suicide attempts?
5. **Colorectal cancer screening**—Does a simple intervention improve screening?
6. **Lumbar image reporting**—Does a pragmatic trial of lumbar image reporting with epidemiology inform the efficacy of procedures for pain relief?
7. **Chronic pain**—Does collaborative care for chronic pain in a primary-care setting improve outcomes?

All seven projects are in the feasibility phase, and Dr. Briggs is hopeful that the network will be able to support more. A number of ideas from the consortium's presentations would benefit from this kind of large-scale analysis. Dr. Briggs concluded that cost issues are the driver of interest in health care issues and that researchers must become effective persuaders of the value of their interventions.

APPENDIX 1: AGENDA

8th Annual NIH Pain Consortium Symposium on Advances in Pain Research Integrated Self-Management Strategies for Chronic Pain

Wednesday, May 29, 2013

- 8:30 a.m. **WELCOME AND OPENING REMARKS**
The Importance of Evidence-Based Research on Self-management for Chronic Disease
Patricia A. Grady, PhD, RN, FAAN, NIH Pain Consortium Executive Committee Member
- 8:45 a.m. **UPDATE FROM THE AMERICAN PAIN SOCIETY**
Pain Self-management: Barriers and Opportunities for Improved Care
David A. Williams, PhD, University of Michigan, Ann Arbor
- 9:05 a.m. **SESSION 1: SELF-MANAGEMENT STRATEGIES IN COMMUNITY HEALTH CARE SETTINGS**
Moderator: Wen Chen, PhD, Program Director, NIA
- Overview: Translating Pain Self-management Strategies into Community Settings
M. Carrington Reid, MD, Cornell University
- 9:50 a.m. Effects of the Chronic Disease Self-management Program—Results of Meta Analyses
Teresa Brady, PhD, Centers for Disease Control and Prevention
- 10:10 a.m. Staying Active with Arthritis: An Intervention Guided by Self-efficacy Theory
Elizabeth Schlenk, PhD, RN, University of Pittsburgh
- 10:30 a.m. Internet-based Pain Coping Skills Intervention for Osteoarthritis
Christine Rini, PhD, University of North Carolina, Chapel Hill
- 10:50 a.m. **Questions and Answers**
- 11:10 a.m. **Break and Poster Session (Natcher Atrium)**
- 11:35 a.m. **Introduction to the Junior Investigator Presentations**
Catherine Bushnell, PhD, Scientific Director, Intramural Research, NCCAM
- 11:45 a.m. Movement Pattern Training for Pre-Arthritic Hip Disease
Marcie Harris-Hayes, PT, DPT, MSCI, OCS, Washington University School of Medicine
- 12:00 p.m. Pain, Executive Function, and Structural Brain Correlates in Children with and without
Chronic Abdominal Pain
Christine Mrakotsky, PhD, Boston Children’s Hospital and Harvard Medical School

- 12:15 p.m. Brief Meditation Training for Migraineurs Affects Emotional and Physiological Stress Reactivity
Amy Wachholtz, PhD, University of Massachusetts Medical School and UMass Memorial Medical Center
- 12:30 p.m. **Lunch**
- 2:00 p.m. **SESSION 2: TAILORED SELF-MANAGEMENT STRATEGIES FOR PATIENTS AND CAREGIVERS**
Moderator: *Ann O'Mara, PhD, RN, FAAN*, Head of Palliative Care Research, NCI
- Overview: Understanding How Patients and Their Caregivers Cope with Pain: Implications for Behavioral Assessment and Training in Pain Coping Skills
Francis Keefe, PhD, Duke University Medical Center
- 2:45 p.m. Pain Control Program Intervention for Cancer Pain Patients and Their Caregivers
Christine Miaskowski, MSN, PhD, UCSF
- 3:05 p.m. Combined Behavioral and Pharmacological Treatment for Pediatric Chronic Migraine
Scott Powers, PhD, ABPP, Cincinnati Children's Hospital
- 3:25 p.m. Pain Self-management Programs for Individuals with Disabilities and Chronic Disease
Dawn M. Ehde, PhD, University of Washington
- 3:45 p.m. **Questions and Answers**
- 4:10 p.m. **Presentation of the 2013 Mitchell Max Best Poster Award**
Story C. Landis, PhD, NIH Pain Consortium Executive Committee Chair
- 4:30 p.m. **Adjourn day 1**

Thursday, May 30, 2013

- 8:30 a.m. **A Patient Perspective on Pain Self-Management Strategies**
Penney Cowan, Founder and Executive Director, American Chronic Pain Association
- 8:45 a.m. **SESSION 3: PREDICTORS AND INDICATORS OF OUTCOMES IN INTEGRATED SELF-MANAGEMENT STRATEGIES**
Moderator: *Bridgett Rahim-Williams, PhD, MPH, MA*, Senior Research Fellow, NIMHD
- Self-management as Means and End in Chronic Pain Care
Mark Sullivan, MD, PhD, University of Washington
- 9:30 a.m. Neurobiological Mechanisms Underlying Effectiveness of CBT in IBS patients: Lessons from Anxiety Disorders
Emeran Mayer, MD, UCLA

- 9:50 a.m. Can Integrated Pain Management Strategies of CBT and Relapse Prevention Alter
CNS Function and Structure?
Magdalena Naylor, MD, PhD, University of Vermont
- 10:10 a.m. **Break**
- 10:30 a.m. Patient Utilization of Pain Self-management Strategies
Stephen T. Wegener, PhD, ABPP, Johns Hopkins University
- 10:50 a.m. **Questions and Answers**
- 11:10 a.m. **UPDATE ON THE INTERAGENCY PAIN RESEARCH COORDINATING COMMITTEE**
Linda Porter, PhD, Health Science Policy Advisor for Pain, NINDS
- 11:30 a.m. **CLOSING REMARKS AND ADJOURN**
Josephine P. Briggs, MD, NIH Pain Consortium Executive Committee Member

APPENDIX 2: LIST OF PARTICIPANTS

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Director, National Center for Complementary
and Alternative Medicine

Martha Somerman, DDS, PhD

Director, National Institute of Dental and
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Patricia Grady, PhD, RN, FAAN

Director, National Institute of Nursing
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Nora Volkow, MD

Director, National Institute on Drug Abuse

INVITED SPEAKERS

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Centers for Disease Control and Prevention,
Atlanta

Christine Mrakotsky, PhD

Boston Children's Hospital and Harvard
Medical School

Catherine Bushnell, PhD

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National Eye Institute (NEI)

National Heart, Lung, and Blood Institute (NHLBI)

National Institute on Aging (NIA)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

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Office of Research on Women's Health (ORWH)

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Office of Technology Transfer (OTT)

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