National Institutes of Health
HEAL Initiative

HEAL Pain Strategic Planning

Subcommittee Co-Chairs:
John Farrar, MD, PhD & Claudia Campbell, PhD

OPTIMIZING INTERVENTIONS TO IMPROVE PAIN MANAGEMENT SUBCOMMITTEE

PUBLIC VIRTUAL SESSION

MONDAY, NOVEMBER 25TH, 2024

Introductory Remarks

Definition of Optimization

An act, process, or methodology of making something (such as a design, system, or decision) as fully perfect, functional, or effective as possible. - Wikipedia

"Optimization ensures that the **right patient** gets the **right treatment** at the **right time**." –Hope Chang (PharmD), 2023

"Treatment optimization aims to deliver the **best possible treatments or combinations of treatments** to affected populations. The value of recommended interventions is judged by their **long-term efficacy, safety, tolerability, adherence, and convenience**. Finding the best possible treatments at a cost that allows universal access represents the intersection of the goals of clinical practice and public health, and this is the ultimate objective of treatment optimization." –Flexner, et al., 2013

Methods for generating priority topics

- Initial brainstorming and generating topic ideas
  - Optimal modes of pain management – multimodal approaches
  - Key components of effective treatments – types and risk/ benefits
  - Individualized treatments
  - Resilience/ pain resolution/prevention of chronification

- Common themes were merged and synthesized into subtopics

- Member selected assignments to subtopics

- Subtopic meetings to refine priority statement(s) and generate slides

- Established "Parking lot" for relevant topics with less enthusiasm or handled by other groups but we felt should be acknowledged.

Pain Treatment Optimization Subcommittee

Enhancing Care Delivery Strategies

-Meryl Alappattu, PhD – University of Florida

-Katie Butera, PhD – University of Delaware

-David White (PWLE) – Advisor, NIH HEAL Patient

Engagement Working Group

Pain Treatment Optimization Subcommittee

Prevention Across the Lifespan
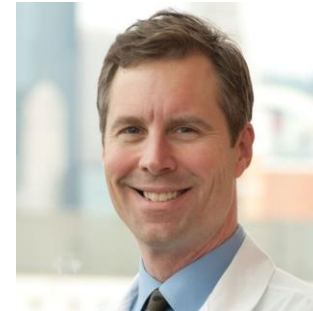
-Jennifer Rabbitts, MD – Stanford University

-John Farrar, MD, PhD – University of Pennsylvania

-Joletta Belton (PWLE) – Advisor, MyCuppaJo

Pain Treatment Optimization Subcommittee

Cross-Cutting Values

-Adam Hirsh, PhD – Indiana University

-Jeffrey Dusek, PhD – UC Irvine

-Joletta Belton (PWLE) – Advisor, MyCuppaJo

HEAL Pain Tx Optimization Workshop

11:00-11:10 am	Welcome, Rob Gereau/Kathleen Sluka, Introductory Remarks
11:10 - 11:15am	Subcommittee Co-leads Overview and Agenda
11:15-11:40 am	Joletta Belton, David White; Lived Experience Presentations
11:40-12:00 pm	Meryl Alappattu/Katie Butera, Enhancing Care Delivery
12:00-12:20 pm	Fenan Rassu/Renee Manworren, Personalized Medicine
12:20-12:40 pm	Jennifer Rabbitts/John Farrar, Prevention
12:40:1:00 pm	Break
1:00 - 1:20 pm	Jennifer Gewandter, Treatment Combinations
1:20- 1:40 pm	Adam Hirsh, Cross-cutting Values
1:40-2:10 pm	Discussion of Scientific Presentations
2:10-2:40 pm	Subcommittee panel discussion of priority areas
2:40-2:55 pm	Synthesis and adjournment
3:00 pm	Adjourn

Optimizing Interventions to Improve Pain Management:
one story among millions of stories

Joletta Belton

The specific **pain** diffuses like a **malignant mist** throughout the experienced world.

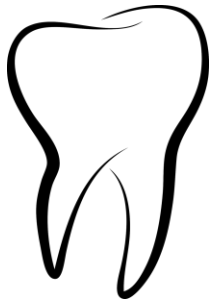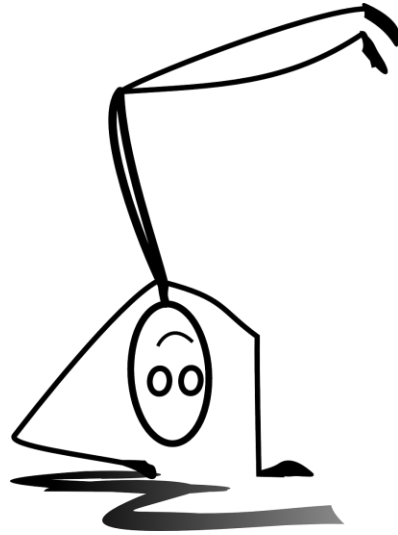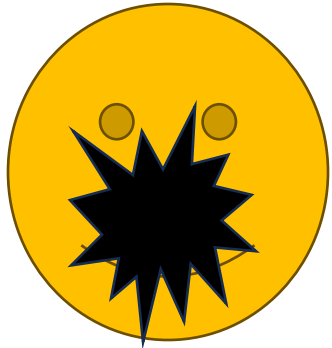Drew Leder, *The Experiential Paradoxes of Pain*

Conflicting messages within and across disciplines

Nothing more we can do

Soula Mantalvanos

Muscle relaxants
Physical therapy
Injections
Surgery
Physical therapy
Chiropractic
Acupuncture
Massage*
Yoga*
Posture therapy*
Products up the wazoo*
Exercise*

'Your 2'oclock hip is here...

DETROIT -VS- EVERYBODY

4 surgeries under anesthesia
No pain problems

Same person for all of these surgeries, only 1 became chronic pain…

Event requiring surgery

- Compound tib/fib fracture

- 4 broken noses (2 surgeries)

- Wisdom teeth

- Hip pain

- Pelvic pain

- Breast cancer

Not to mention countless other sprains, strains, muscle tears, illnesses, traumas with no pain issues, both before and after chronic hip pain

op·ti·mize

verb

make the best or most effective use of (a situation, opportunity, or resource).

Focus on whole-person, patient-centric research

HEAL researchers are meeting people where they are: conducting research with a whole-person, patient-centric focus.

Work With Communities to Bring Research to Life

HEAL research teams incorporate the experience and perspectives of community members, people with lived experience of pain or addiction, and scientists, and these partnerships are making a difference.

Target the Biology of Pain and Addiction

HEAL research is using a targeted approach to explore the underlying biology of pain, addiction, and conditions that accompany both, such as mental illness, and to disrupt the processes that lead to these conditions.

Address Health System Challenges and Inequities

HEAL research is targeting systems that provide care for people of all ages who experience pain, opioid use disorder, or both.

Enhancing the trustworthiness of pain research: A Call to Action.   DOI: 10.1016/j.jpain.2024.104736

Table 1 Core Values for trustworthy research and desired universal actions and behaviours.

Element	Core Value	Universal Actions and Behaviours
Governance and Integrity	Demonstrate high standards of research integrity and governance.	•Value, follow and promote the principles of research integrity.•Comply with best standards of research governance.•Consider markers of integrity and good governance as key quality indicators for research.
Equity, Diversity and Inclusivity	Design, undertake and report equitable, diverse and inclusive research.	•Prioritise inclusivity, diversity and equity in the design, conduct and reporting of research.•Value and promote anti-discriminatory practices as a key quality indicator for research.•Cultivate equitable diverse and inclusive research environments/ communities.
Patient and Public Involvement and Engagement (PPIE)	Undertake research in partnership with the public and people with lived experience.	•Embed Patient and Public Involvement and Engagement throughout the research process.•Value Patient and Public Involvement and Engagement practices as a key quality indicator for research.
Methodological Rigour	Design and conduct research to optimise methodological rigour (appropriate to the question). Report research completely and transparently.	•Value, conduct, educate and promote high quality, methodologically rigorous research.•Avoid and call attention to Questionable Research Practices.
Transparency and Openness	Make research as open and transparent as possible.	•Value and promote transparency of methods and compliance with accepted best standards of reporting.•Adopt and promote Open Research practices and FAIR principles as the norm. "As open as possible, as closed as necessary." [42,69]
Balanced Communication	Communicate research with appropriate balance.	•Report all planned results regardless of the findings.•Make clear the distinction between exploratory and confirmatory research.•Make clear the distinction between reasonable interpretation of the data and speculation.•Be aware of markers of unbalanced communication and call attention to them.
Data Authenticity	Identify and exclude inauthentic data from the literature.	•Be vigilant to markers of potential inauthentic data and research misconduct, call attention to them and take action.•Commit to timely action to remove inauthentic data from the literature.•Commit to timely correction of errors in the published literature.

PAIN®

Patient engagement in pain research: no gain without the people in pain

Blair Hamilton Smith[a,b], Joletta L. Belton[b,c]

By bringing scientific knowledge together with the knowledge gained from lived experience, better research questions may be asked, even at a molecular or mechanistic level, and more innovative and transformative treatments may be discovered.

Dave's Story

David M. White, PWLE, NIH HEAL Patient Engagement Working Group

Developing HEAL Pain Strategic Research Priorities: Optimizing Interventions to Improve Pain Management Workshop

November 25, 2024

My extremely condensed CKD journey

Diagnosed with ESKD in 2009

Not exactly a model patient when I started dialysis; my first care plan meeting completely changed my outlook

Six years of dialysis (four different modalities in two years), deceased donor kidney transplant in 2015

Advocating for better care for people living with serious illnesses since 2012
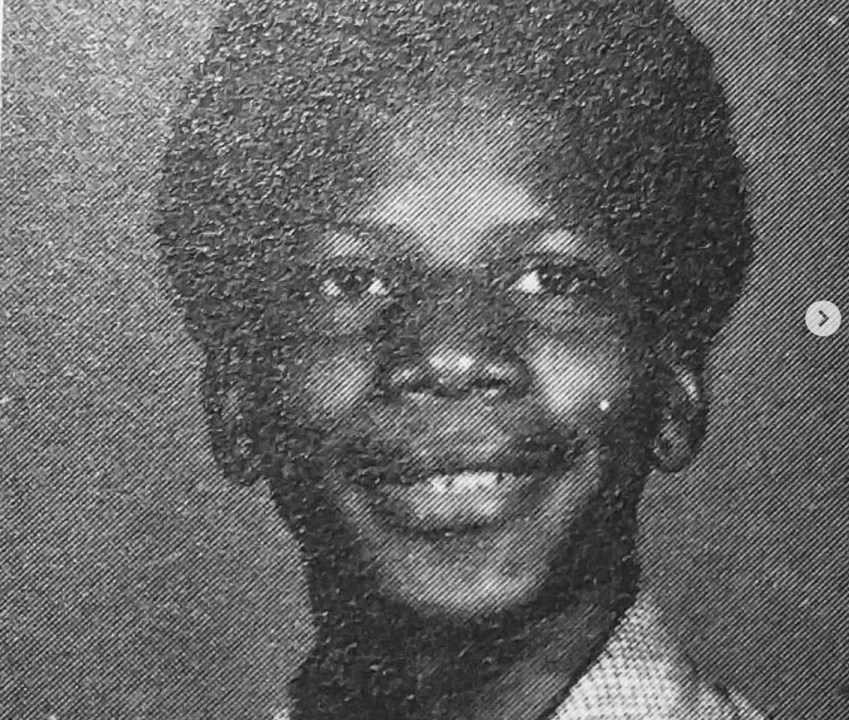
Things got better...

when I started to LISTEN.

New year's eve 2010

New year's day 2011
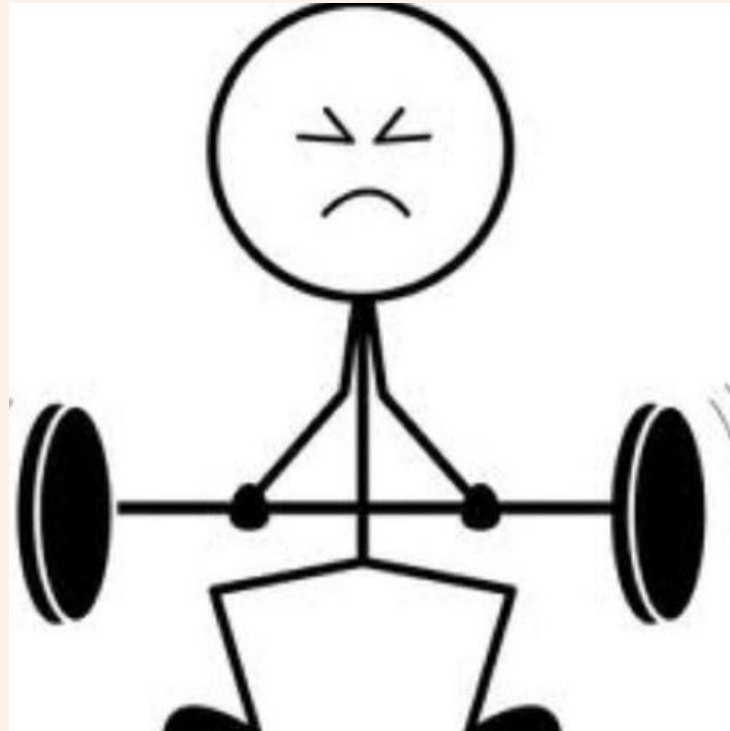
2017
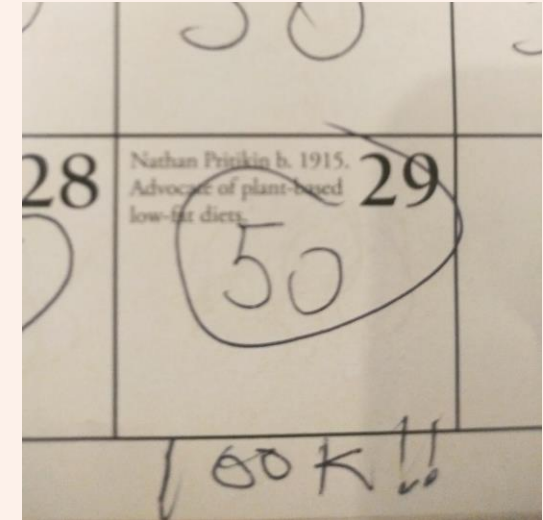
2022
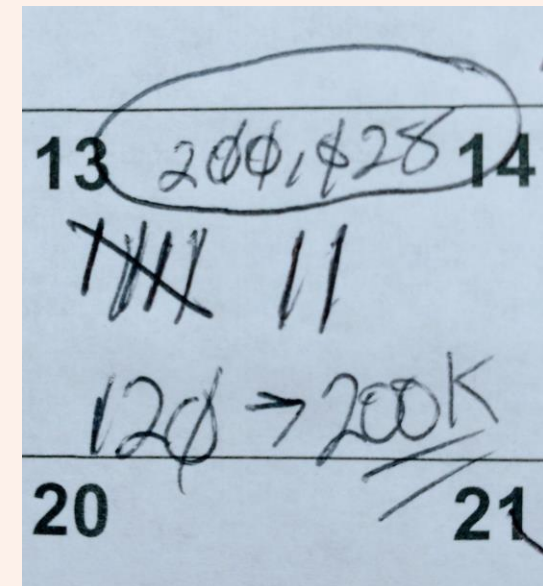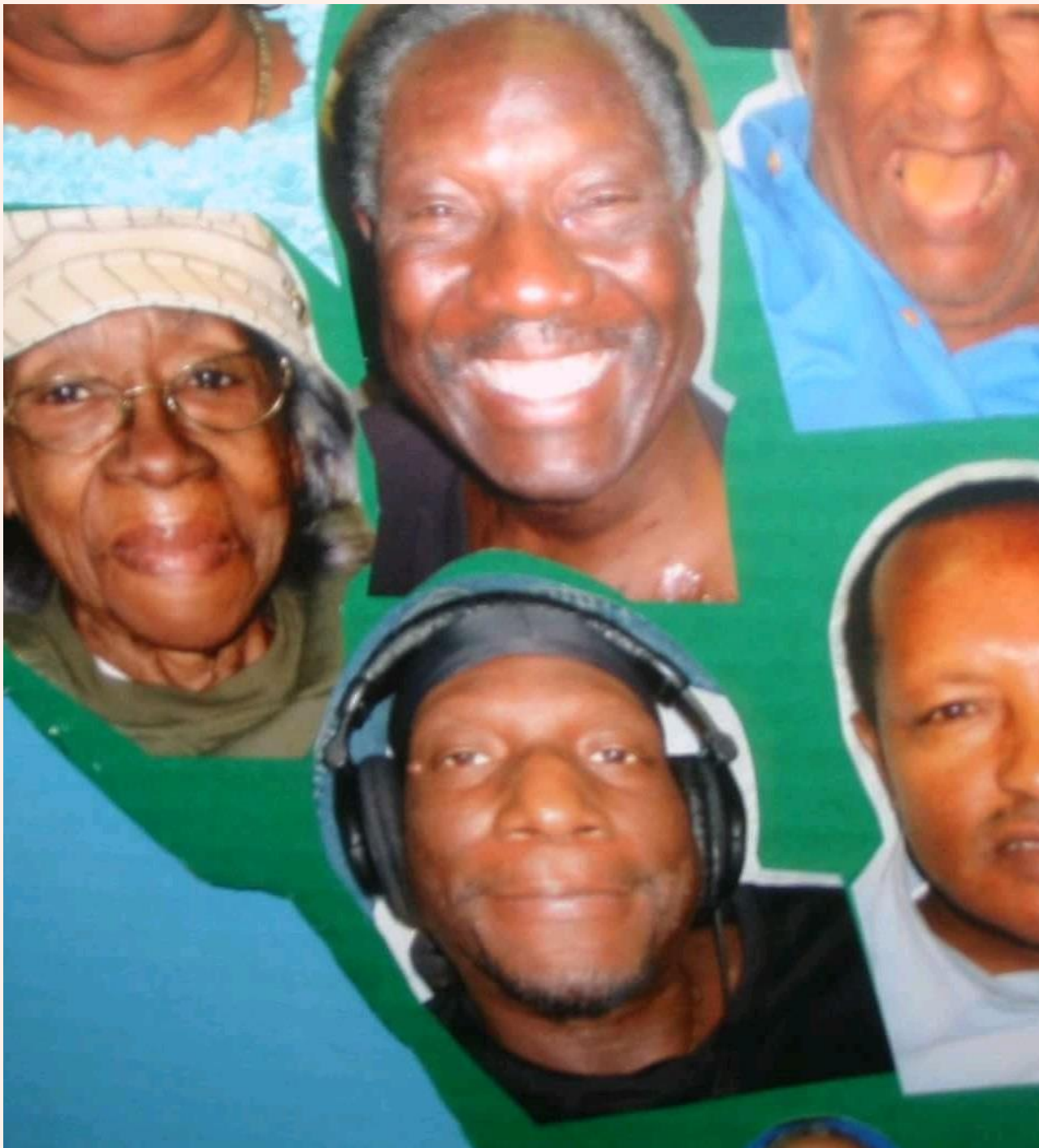
16-gauge needles

Generalized pain

CRAMPS

Life-changing care planning

Self-management

Interactions with NPs

Advocacy

Clinical trial participation

Hospital.

July 3, 2015 · Washington D.C. ·

Good Morning! Post-Kidney Transplant Day Four is off to a great start. Thank you all for the prayers and positive vibes. Listening to "Machinehead" right now -- 'breathe in, breathe out'

52

23 Comments

Dear Mr. David White,

Congratulations! Thank you for your interest in serving as a member of the PCORI Advisory Panel on Patient Engagement. We received a large number of applications from highly qualified individuals, and we were impressed by their enthusiasm and commitment.

We are pleased to extend this formal invitation to you to serve as a member of the PCORI Advisory Panel on Patient Engagement for a term length of 2 years. Please reply to this email by accepting PCORI's invitation by 5 pm EDT today. Additionally, please complete and send back to us the PCORI

Outline

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PATIENT VOICE

Appropriate Use of Opioids in Patients with Kidney Diseases

White, David M.

Author Information ⌄

OPEN

Metrics

In this issue of the *Clinical Journal of the American Society of Nephrology*, Ishida *et al.* report on an investigation using data from the US Renal Data System to investigate the effects of opioids on patients on hemodialysis ([1]). The timely findings of Dr. Julie Ishida and her colleagues regarding the effects of opioid use on patients on hemodialysis confirm a need for more nephrology-related pain management research. Dr. Ishida's team concluded that there is a correlation between higher opioid dosages and the likelihood of a patient on hemodialysis suffering an adverse event, and that

HOPE Trial Patient Advisors

Helping People on Dialysis Manage Pain

Caroline Wilkie
Punta Gorda, FL

Scientific and Data Research Center

Robert Grindstaff, MD
Nashville, TN

Vanderbilt University Medical Center

Dave White
Hillcrest Heights, MD

Hennepin Healthcare

Joel Williams
Bloomington, MN

Hennepin Healthcare

Nina Quintana
Chicago, IL

University of Illinois at Chicago

Dawn Edwards
Jamaica, NY

The Rogosin Institute

Found 1 result for *The design and baseline characteristics for the HOPE Consortium ...*

Save   Email   Send to   Display options

FULL TEXT LINKS

ELSEVIER
OPEN ACCESS

The design and baseline characteristics for the HOPE Consortium Trial to reduce pain and opioid use in hemodialysis

ACTIONS

❝ Cite

Collections

Laura M Dember [1], Jesse Y Hsu [2], Leah Bernardo [3], Kerri L Cavanaugh [4], David M Charytan [5], Susan T Crowley [6], Daniel Cukor [7], Ardith Z Doorenbos [8], David A Edwards [9], Denise Esserman [10], Michael J Fischer [11], Manisha Jhamb [12], Steven Joffe [13], Kirsten L Johansen [14], Sahir Kalim [15], Francis J Keefe [16], Paul L Kimmel [17], Erin E Krebs [18], Natalie Kuzla [19], Rajnish Mehrotra [20], Puneet Mishra [21], Bethany Pellegrino [22], Jennifer L Steel [23], Mark L Unruh [24], David M White [25], Jonathan G Yabes [26], William C Becker [27]; HOPE Consortium

Affiliations + expand

SHARE

Scientific Presentations

ENHANCING CARE DELIVERY MODELS

Meryl Alappattu, PhD, DPT

Katie Butera, PhD, DPT

David White (PWLE)

CRITICAL NEED TO DELIVER EVIDENCE-BASED PAIN MANAGEMENT IN REAL-WORLD HEALTH-SETTINGS

- Nonpharmacological interventions are safer and can be more effective than opioids

- Undertreatment of pain disproportionately affects underserved populations

- More rigorous designs needed to optimize structuring and timing of non-pharmacologic interventions

CURRENT LIMITATIONS

- Interventions and delivery models with promising efficacy are not necessarily successful when translated to clinical settings (Shi and Wu, 2022)

- Variations in practices for organizing/delivering nonpharmacologic pain management (George et al., 2020)

- Limited clinician adoption of evidence-based interventions; lack of adherence to recommended practice guidelines (Rutten et al, 2010; Muslem et al, 2022)

PROPOSED RESEARCH PRIORITIES

1. Utilize advanced trial designs (e.g., SMART) to determine optimal combinations and/or sequencing of pain management interventions and to explore predictors of success/responsiveness across patients.

2. Support for pragmatic research initiatives critical to:

   a) Implement care delivery models showing previous efficacy (e.g., stratified care, stepped-care)

   b) Identify barriers and facilitators of intervention delivery across various health systems

   c) Ensure intervention access for underserved populations.

3. Identify and evaluate effective models of telehealth, hybrid care, and AI-driven interventions

RESEARCH PRIORITY #1: Utilize advanced trial designs (e.g., SMART) to determine optimal combinations and/or sequencing of pain management interventions and to explore predictors of success/responsiveness across patients.

Why use a Sequential Multiple Assignment Randomized Trial (SMART) design?

- Many interventions require decisions such as, "If a patient is unresponsive to initial treatment, what should we do next?" or "Once the patient recovers, what is needed to prevent relapse?"

- A treatment's effect may be impacted by what comes before or after.

- Provides insight regarding a) best sequencing of treatments, b) best timing for treatment alteration, and c) what information can be used to guide clinical decision-making

Skolasky RL et al. *BMC Musculoskelet Disord,* 2020.
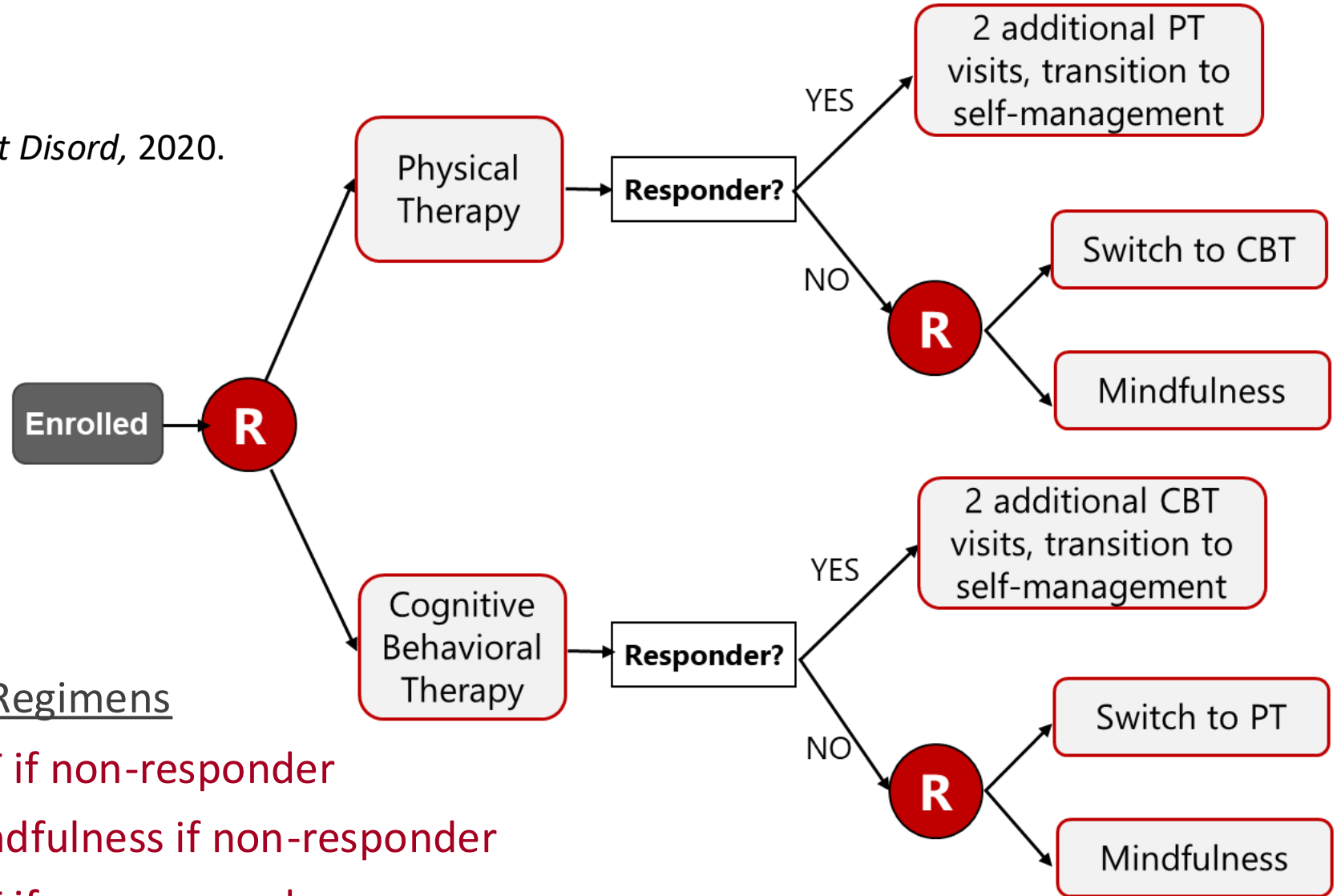
Tested 4 Dynamic Treatment Regimens

1) Start with PT, Switch to CBT if non-responder

2) Start with PT, Switch to Mindfulness if non-responder

3) Start with CBT, Switch to PT if non-responder

4) Start with CBT, Switch to Mindfulness if non-responder

RESEARCH PRIORITY #2: Expand support for pragmatic research initiatives, which are critical for a) implementing care delivery models showing previous efficacy; b) identifying barriers and facilitators of intervention delivery across various health systems; and c) ensuring intervention access for underserved populations.

Examples of care delivery models to test using pragmatic approaches

- **Stratified Care:** Matches treatment to a patient's initial risk or severity
- **Stepped Care:** Starts with low-intensity care, escalating as needed
- **Sequenced Care:** Delivers treatments in a pre-planned order

AIM-Back Trial
George et al., *Pain Med*, 2020.

Testing delivery of an integrated sequence-care pathway (Figure) versus a pain navigator pathway for Veterans with back pain
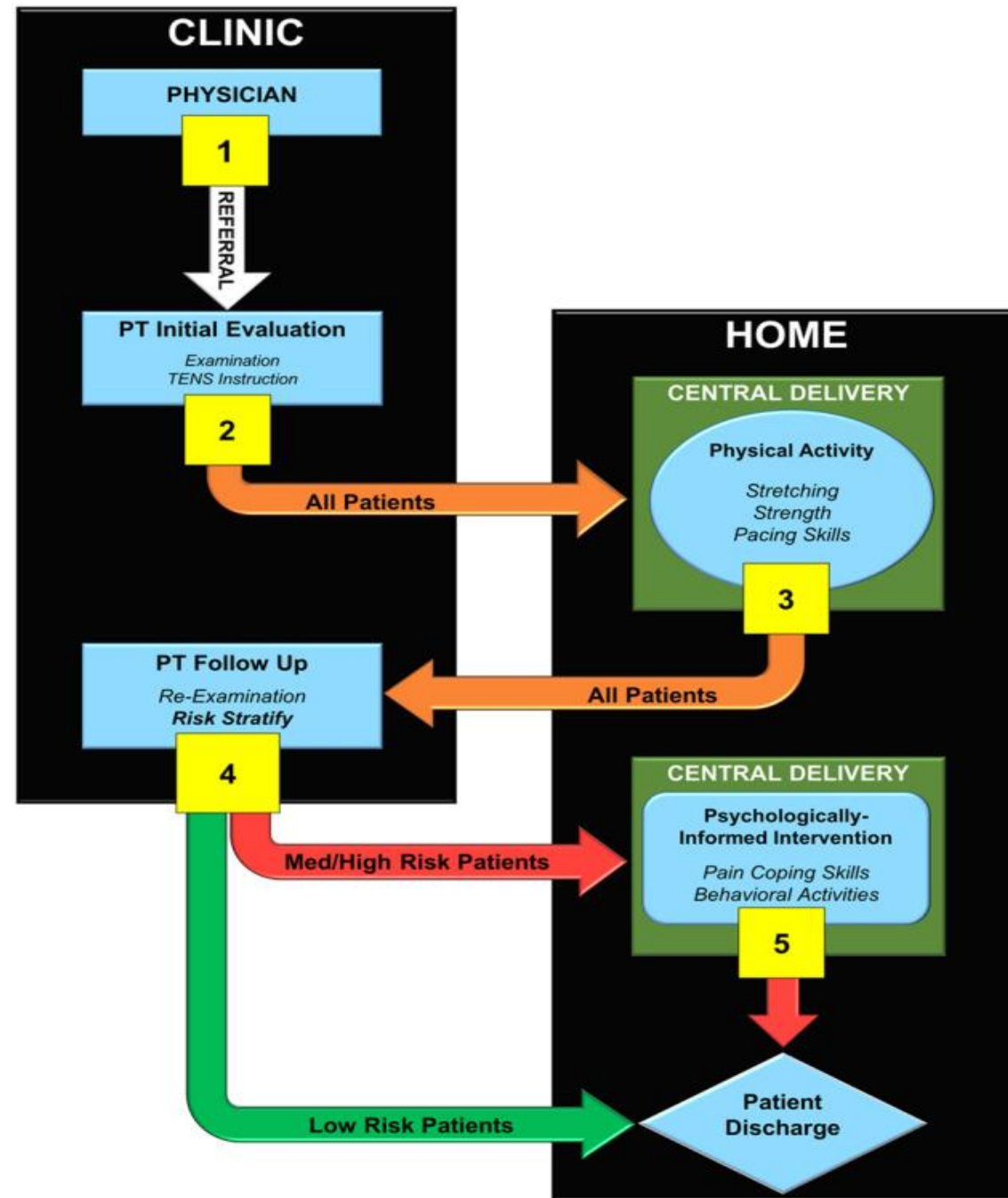
RESEARCH PRIORITY #3: Identify and evaluate effective models of telehealth, hybrid care, and AI-driven interventions to improve pain management and quality of life.

Examples of care delivery models to test using pragmatic approaches

- **Telehealth:** Consult and treatments delivered virtually

- **Hybrid/ integrated care:** Combination of In-person and virtual care

- **AI-driven care:** Use of technology (e.g. motion sensors, apps) to assist in diagnosis, assessment, and development of personalized treatment plans

  - Motion analysis

  - Remote therapeutic monitoring

  - Sole mode of treatment or in combination with hybrid/integrated care

Personalized Pain Management: Moving Beyond the Bell Curve:

HEAL Pain Strategic Planning

Fenan Rassu, PhD, Renee CB Manworren, PhD, APRN, Joletta Belton, Ausaf A. Bari MD PhD

November 25, 2024

Personalized Pain Management: Moving Beyond the Bell Curve

• Current approaches overlook individual differences

• $635B annual cost of ineffective pain management

• Treatment success varies widely between individuals
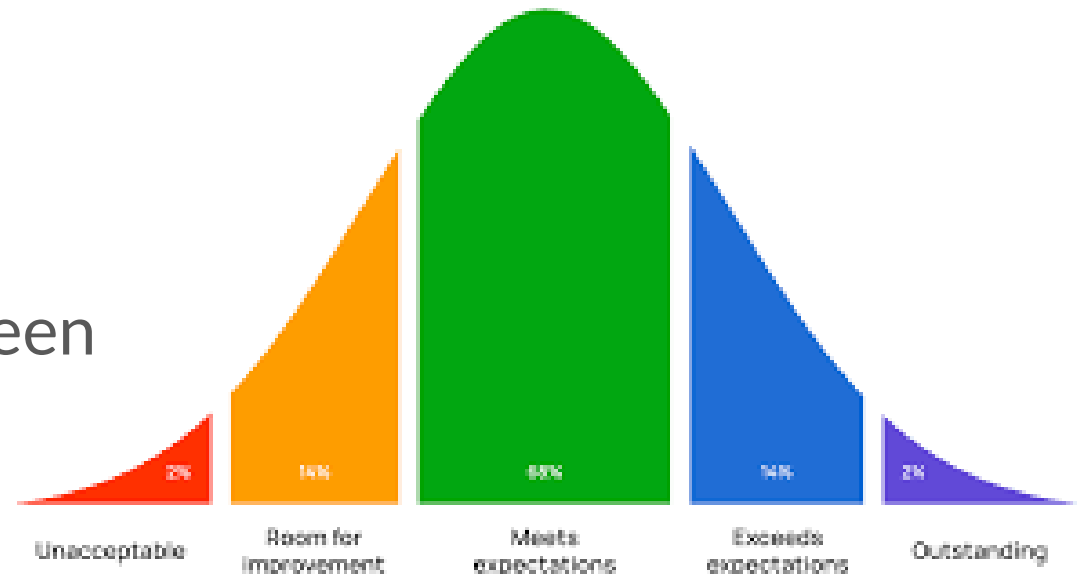
Why Personalize Pain Care Now?

• Advanced analytics capabilities

• Growing evidence for individual treatment response differences

• Demand for patient/community engagement in research and shared decision-making

One-Size-Fits All

Personalized Approach
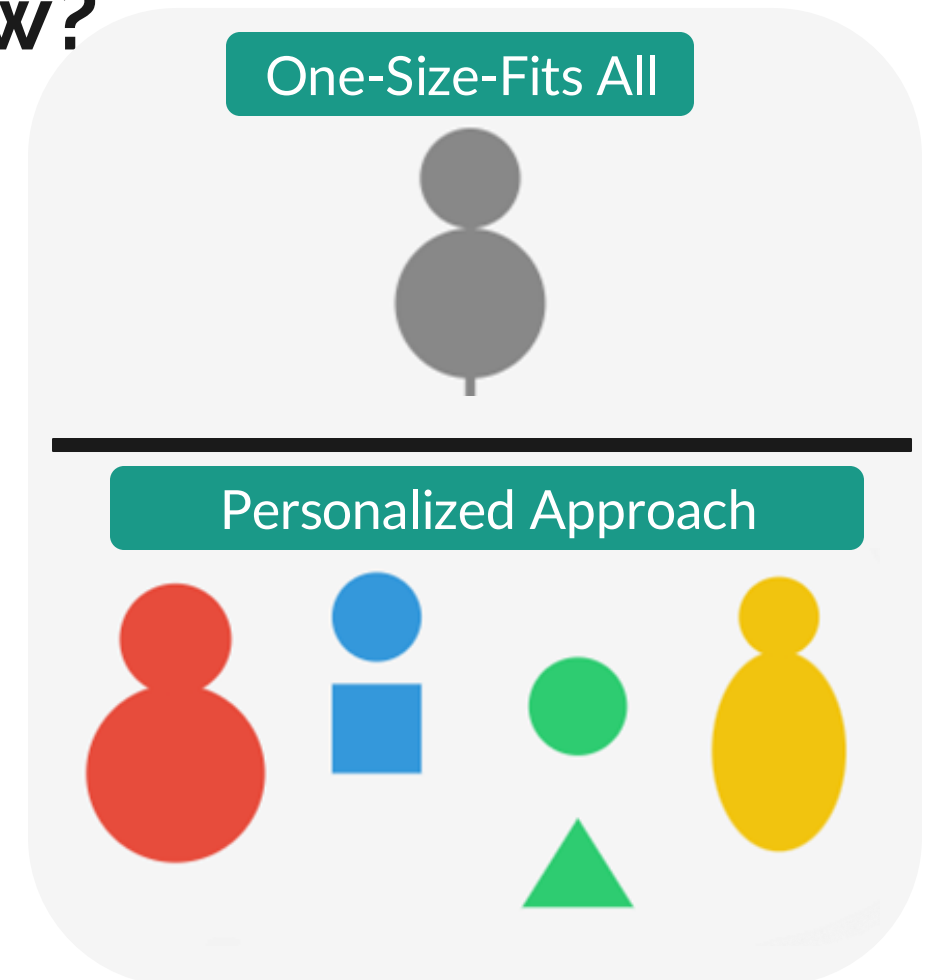
Current Challenges

- Lack of risk, recognition, and prediction models

- Lack of model integration in healthcare systems and business of providing pain care

- Limited provider training or incentives for personalized approaches

- Historical exclusion of diverse perspectives in research

Priority 1: Developing Models

• Integration of biological, psychological, functional, social determinants of health

• Integration of genomics, biometrics, wearable sensors, patient self-report and patient preferences,

• Validation in diverse populations

• Partnership with patient/community stakeholders
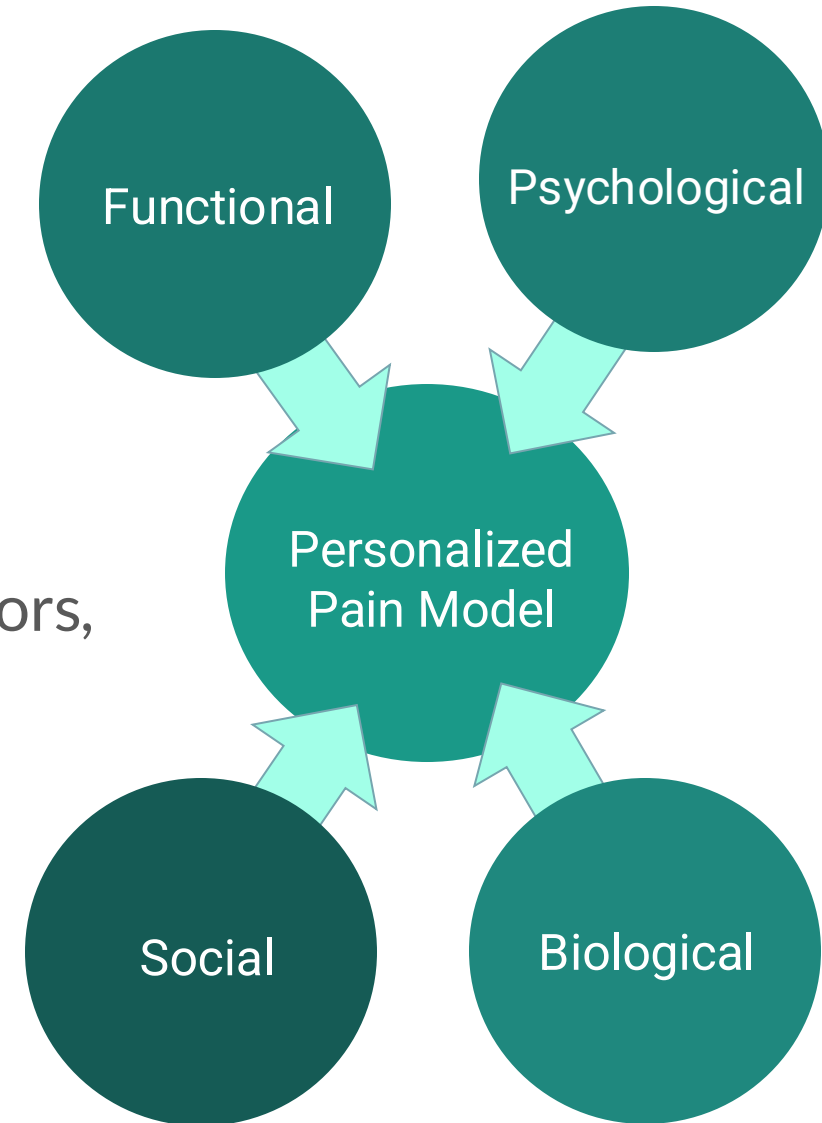
What Makes a Good Model?

- Multiple data types
(markers, profiles, determinants)

- Systematic validation process

- Real-world clinical utility
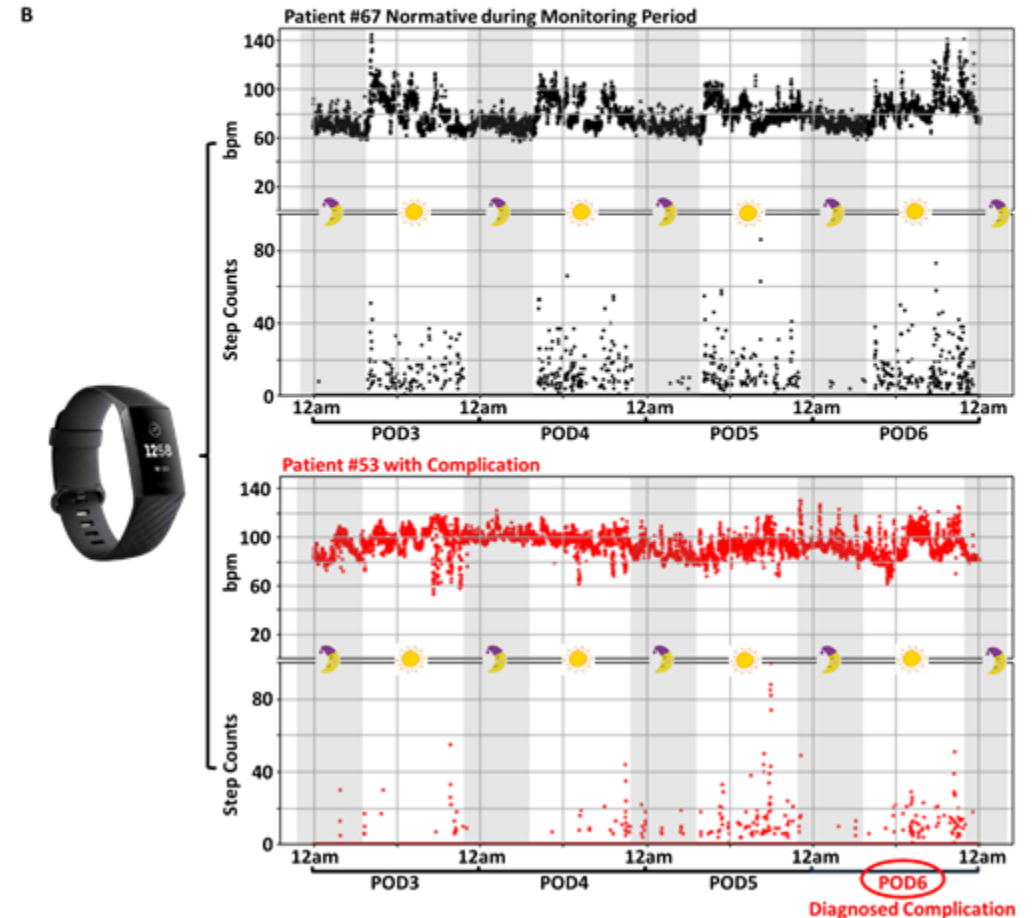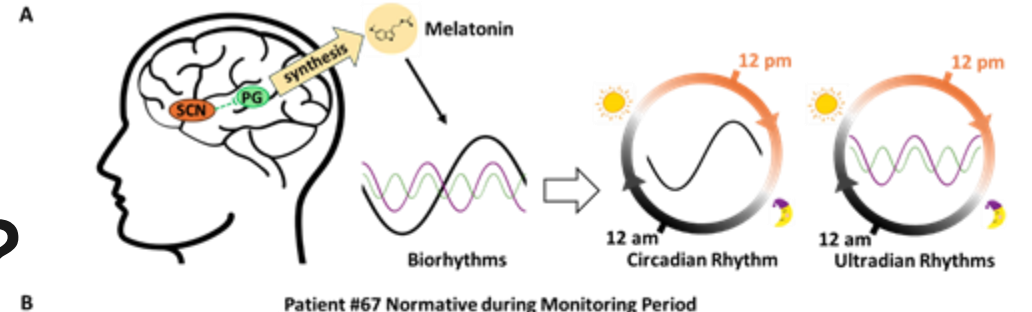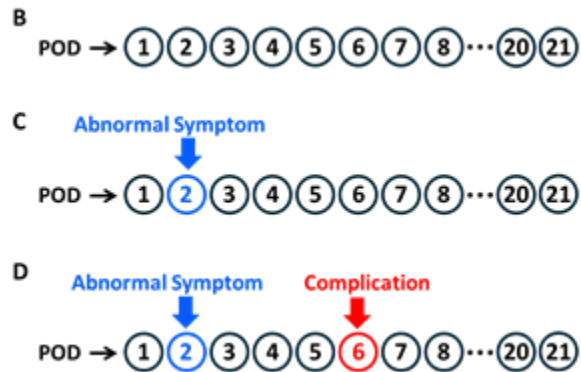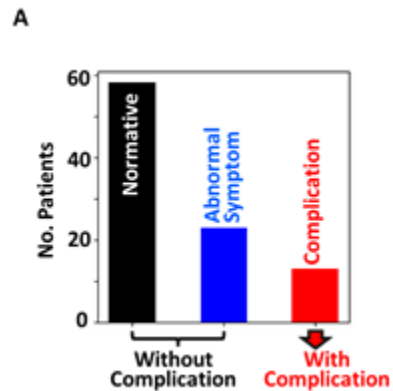
Priority 2: Create Flexible Feasible & Meaningful Assessment Frameworks

● Feasible implementation in practice

● Co-developed with community partners

● Guide treatment decisions and optimize treatment responses.
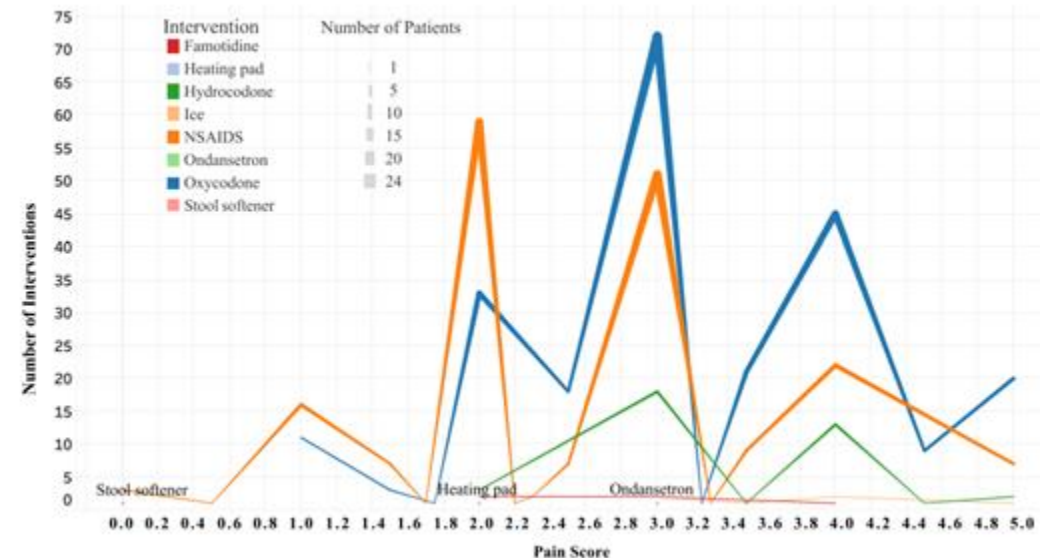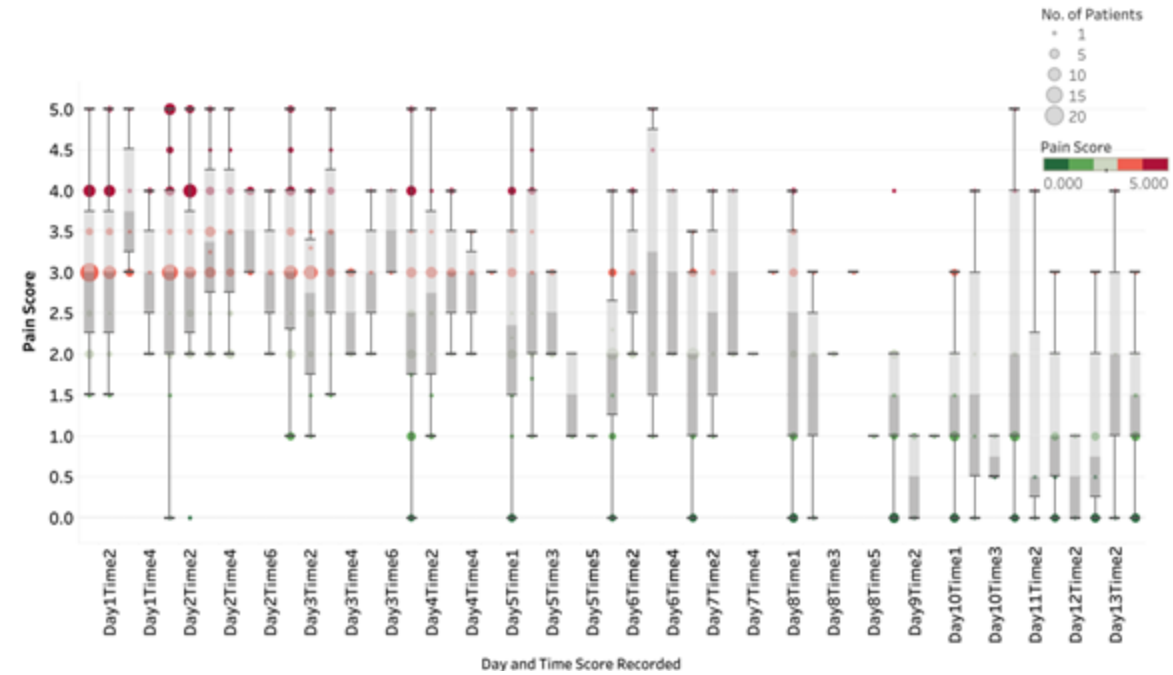
Priority 3: Support mixed methods research aimed at transitioning from managed care to implementation of personalized strategies

- Provider training needs

- Workflow integration solutions

- Learning from diverse healthcare contexts

Priority 4: Underserved & Vulnerable

• Co-development with communities

• Addressing accessibility and implementation barriers

• Test the efficacy of drugs, devices, and treatments that are sold direct to the public, but not FDA approved

• Integration of community perspectives
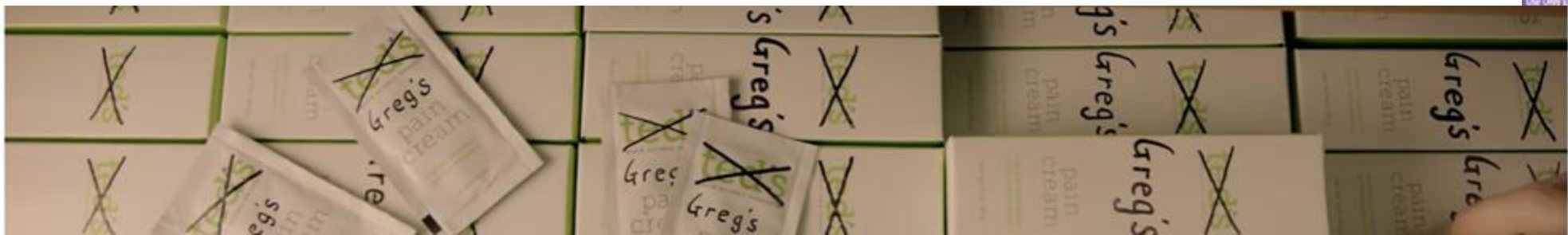
Path to Success

- Early stakeholder engagement
- Systematic validation
- Continuous feedback

Expected Impact

- Reduced trial-and-error treatment
- Efficient resource utilization
- Improved outcomes

Research Priorities

- *Proposed research priority 1:* Develop and validate comprehensive models that integrate biological (biometrics, genomics), psychological (self-report), functional (wearables), and social determinants of health to guide personalized pain management shared decision-making
- *Proposed research priority 2:* Create flexible, feasible, and meaningful assessment frameworks for capturing individual patient characteristics that guide treatment decisions and optimize treatment response.
- *Proposed research priority 3:* Support methodological studies and mixed-methods research aimed at transitioning from a managed care to implementation of a personalized pain management approaches in diverse healthcare settings
- *Proposed research priority 4:* Develop and test culturally appropriate personalized interventions for underserved and vulnerable populations, including pediatric, elderly, and rural people.

Pain Prevention Across the Lifespan

Jennifer Rabbitts, MD
Professor of Anesthesiology, Perioperative and Pain Medicine, Stanford University

John Farrar, MD, PhD
Professor of Epidemiology, Neurology, and Anesthesia, University of Pennsylvania

Joletta Belton, MSc
Lived Experience Partner

NIH HEAL INITIATIVE

- Prevention Priority Statement
- Where does prevention fit into HEAL
- Current Prevention Priorities and HEAL Research
- Prevention in Pediatric Pain
- Prevention in Adult Pain
- Discussion of Priority Areas

NIH HEAL INITIATIVE

HEAL research addresses urgent unmet needs across the lifespan - from infancy to adulthood. It encompasses prevention, treatment, harm reduction, and recovery support approaches for people at risk for or with opioid use disorder, as well as **prevention and management of pain**, with the goal of developing evidence-based strategies capable of providing rapid and lasting solutions to the opioid crisis.

Priority Statement

Advance **pain prevention** by evaluating **primary and secondary** strategies to reduce pain and prevent transition from acute to chronic pain across the **lifespan**. Integrating **lived experience** to assess **preventive approaches** and implement **safe and effective early treatments** for **novel cohorts, high-risk populations, and the whole population.**

Federal Pain Research Strategy:

"Prevention of onset, persistence, and related disability of chronic pain".

o Primary prevention: Avoid development of disease, remove risk factor
"preventing acute pain in the general population and in high-risk groups".

o Secondary prevention: Early detection and treatment, prevent progression
"prevention of the transition from acute to chronic pain".

o Tertiary prevention: Reduce complications of established disease
"aimed at reducing the frequency, severity and disability of chronic pain".
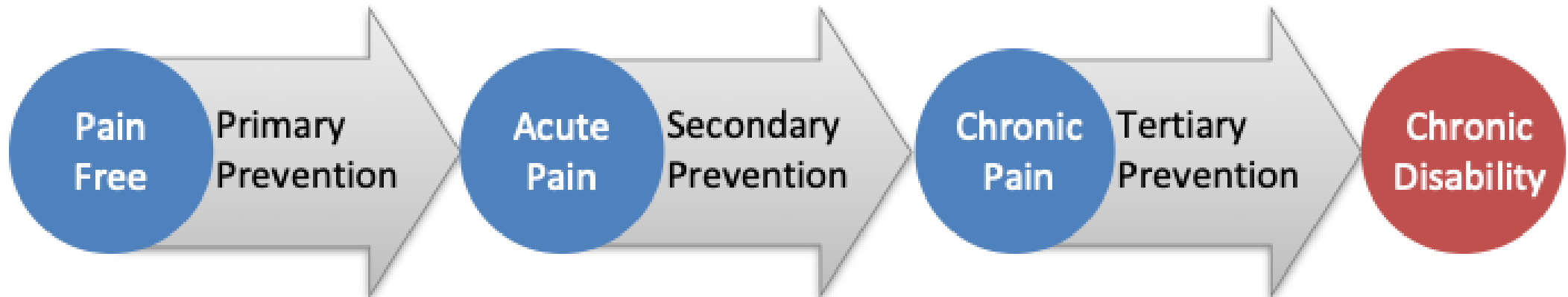
HEAL Pain Research Strategic Planning Focus Areas
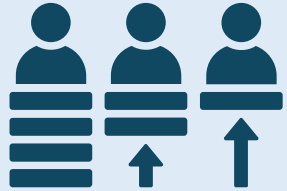
Health equity & pain across the life course

Non-addictive therapeutics development

Pain biomarkers and predictors

Optimization of interventions to improve pain

Implementation and health services
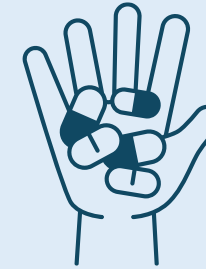
Intersection of pain and substance use disorder

Pain research workforce and training

Pain Prevention
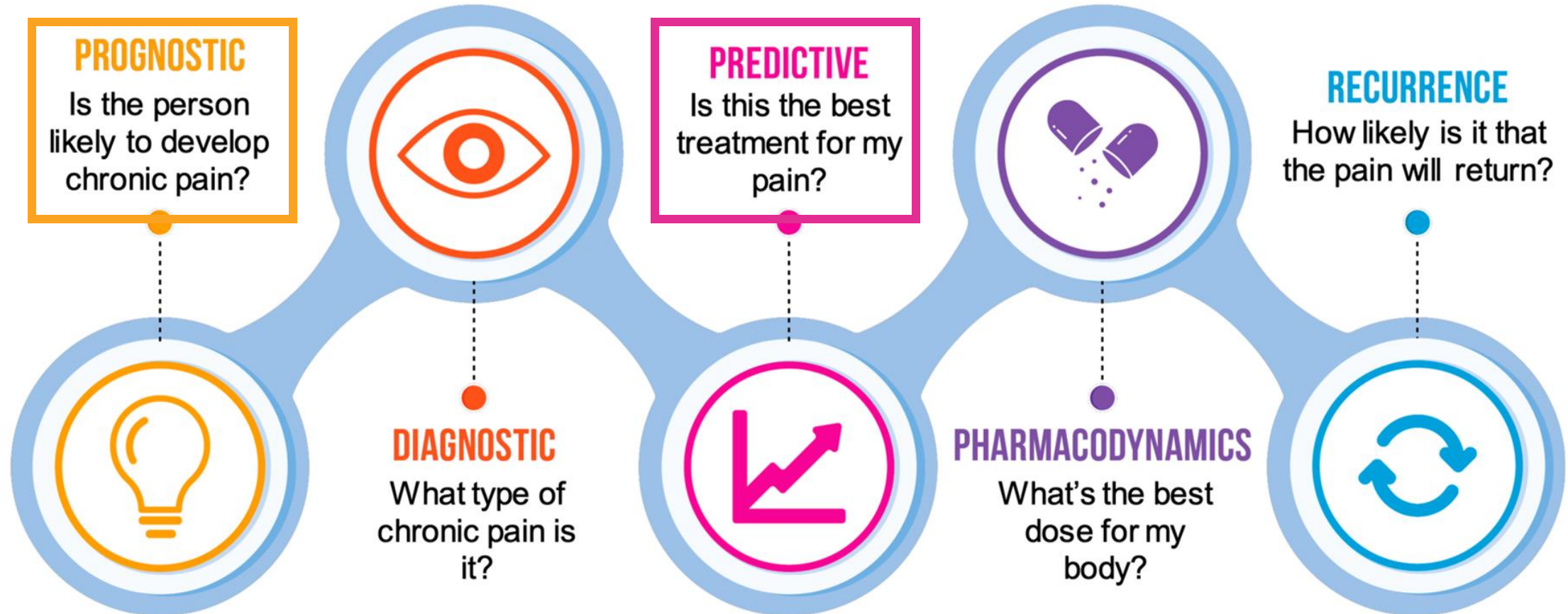
Lifespan Perspective
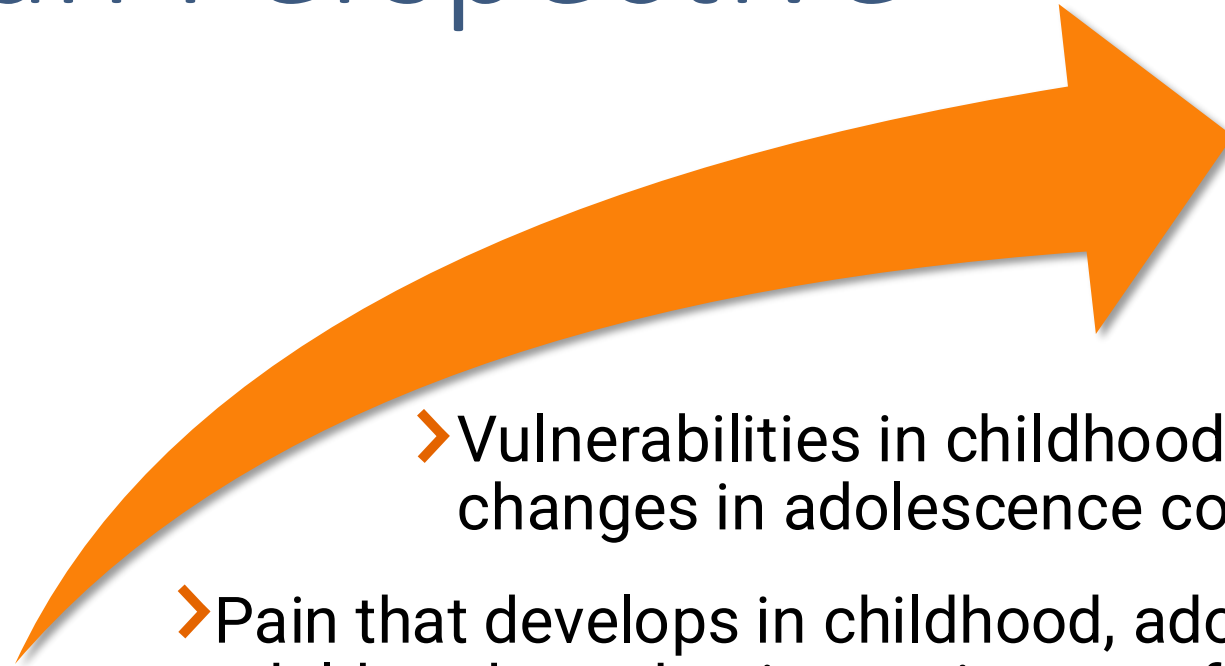
> Vulnerabilities in childhood and developmental changes in adolescence contribute to onset of pain

> Pain that develops in childhood, adolescence, and young adulthood may begin a trajectory of pain into adulthood

>> Childhood, adolescence and young adulthood are critical windows of risk and opportunity for prevention

Chambers, Taylor, Potenza. Developmental neurocircuitry of motivation in adolescence: a critical period of addiction vulnerability, Am J Psych, 2003
Rosenbloom, Rabbitts, Palermo, A developmental perspective on the impact of chronic pain in late adolescence and early adulthood, Pain, 2017
Palermo. Pain prevention and management must begin in childhood: the key role of psychological interventions. Pain, 2020.

Current Prevention Priorities

Pain Prevention:

- Optimize Public Health Strategies to Educate Patients on Managing Pain

- Evaluate Safety and Effectiveness of Management of Procedure-Associated Pain

- Optimize Post-Surgical Approaches for Acute Pain

- Evaluate Safety and Effectiveness of Early Interventions for Tertiary Prevention

Transition to Chronic Pain:

- Determine Acute Pain Management Strategies that Promote or Prevent Development of Chronic Pain

Current Landscape in Pain Prevention

- HEAL funded Clinical Pain Management Trials

HEAL Effectiveness Research Network	
Effectiveness of an mHealth psychosocial intervention to prevent transition from acute to chronic postsurgical pain in adolescents (SurgeryPal)	MPI: Jennifer Rabbitts, Tonya Palermo
Optimizing the use of ketamine to reduce chronic postsurgical pain	MPI: Jing Wang, Lisa Doan
Peer support for adolescents and emerging adults with sickle cell pain: promoting engagement in cognitive behavioral therapy (PRESENCE)	MPI: Charles Jonassaint, Cristin Murray-Krezan

https://heal.nih.gov/research/clinical-research

Current Landscape in Pain Prevention

- HEAL funded Clinical Pain Management Trials

Advancing Health Equity in Pain Management	
Latinx Children and Surgery	PI: Zeev Kain
PAINED: Project Addressing Inequities in the Emergency Department	*PI: Monika Goyal*

https://heal.nih.gov/research/clinical-research

Pediatric Chronic Pain

Partnering For Pain: a Priority Setting Partnership to identify patient-oriented research priorities for pediatric chronic pain in Canada

Kathryn A Birnie [1,✉], Katherine Dib [1], Carley Ouellette [1], Mary Anne Dib [1], Kimberly Nelson [1], Dolores Pahtayken [1], Krista Baerg [1], Jill Chorney [1], Paula Forgeron [1], Christine Lamontagne [1], Melanie Noel [1], Patricia Poulin [1], Jennifer Stinson [1]

Box 1: Top 10 patient-oriented research priorities in pediatric chronic pain in Canada, in order of importance.

1. What treatments or strategies effectively prevent acute pain from becoming chronic in children and adolescents?

Objective: Examine effectiveness of an mHealth CBT-based intervention to prevent transition from acute to chronic postsurgical pain after **adolescent spinal fusion**

T1: Baseline — 4-8 weeks pre-surgery
Pre-surgery intervention phase — Surgery
T2: acute outcomes — 3 weeks post-surgery
Post-surgery intervention phase
T3: Chronic outcomes — 3-months post-surgery
T4: Final follow-up — 6-months post-surgery
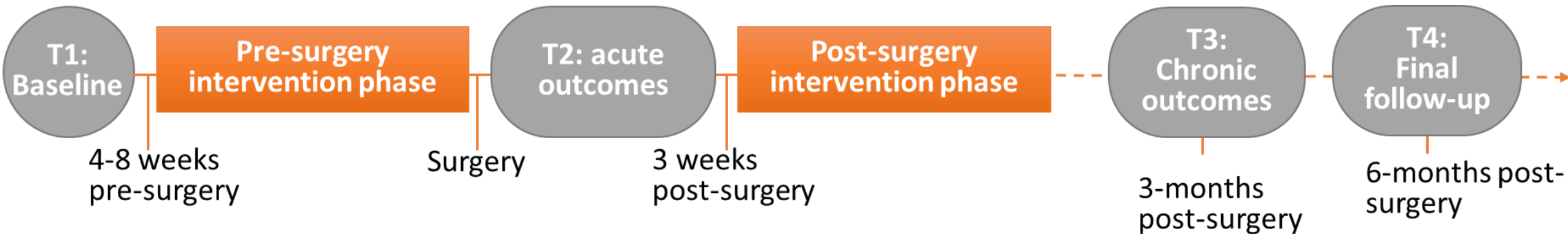
- N=433 adolescents (12-18 years) and parent/caregiver
- Cognitive Behavioral Therapy (**CBT**) based pre- and post- surgery intervention
- Patient reported pain and health outcomes at 3- and 6-months

Design and Randomization

Group	Pre-operative	Post-operative
1	ED	ED
2	CBT	ED
3	ED	CBT
4	CBT	CBT

- Factorial design
  - Cognitive behavioral therapy (**CBT**) *vs.* Internet-based education (**ED**)
  - 2 phases of intervention (pre-op, post-op)

Prevention and Early Intervention

Surgery

Pre-Surgery Phase	Post-Surgery Phase

Module 1

Preparing for Surgery

Module 2

Coping with worry before surgery

Module 3

Getting ready for hospital and recovery

Module 4

Coping at home after surgery

Module 5

Getting back to activities

Module 6

Long-term recovery

Pre-Surgery Phase
(4 weeks before surgery)

Post-Surgery Phase
(weeks 3-7 following surgery)
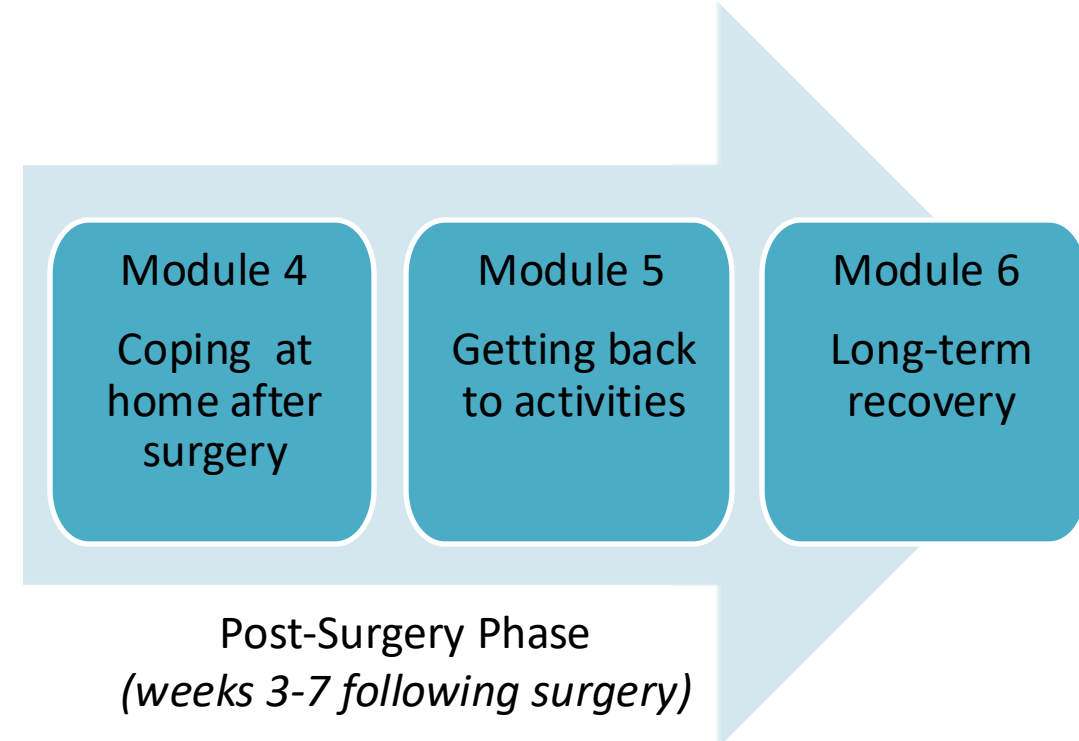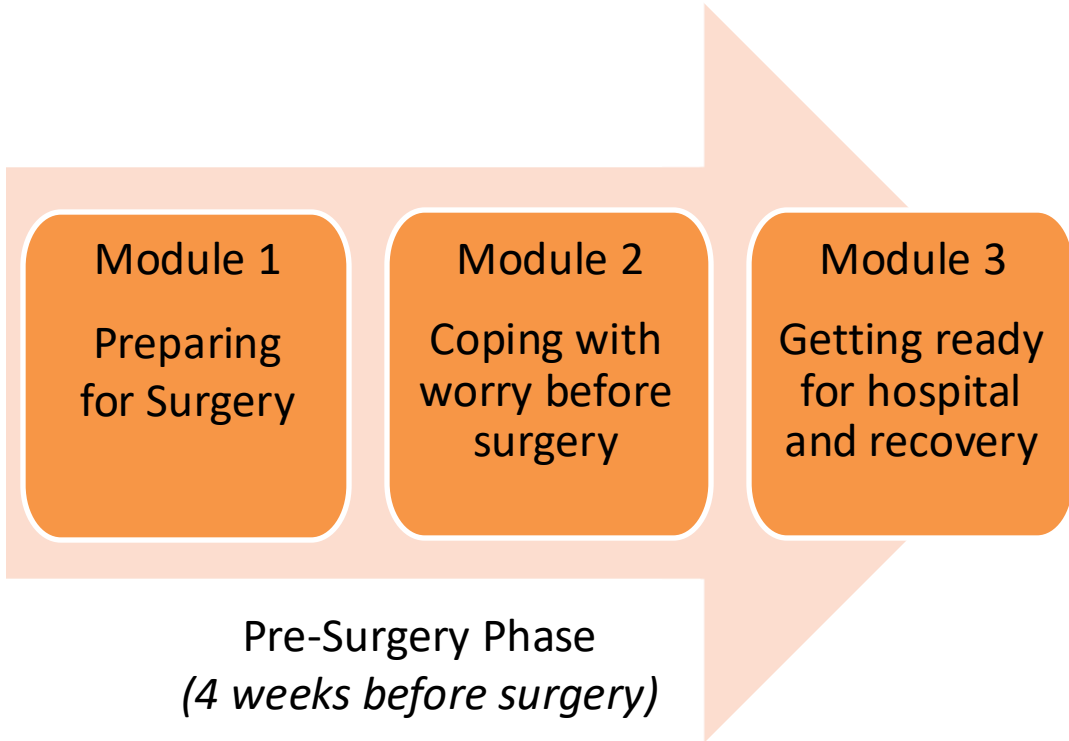
Primary prevention targeting key risk factors:
-Anxiety/distress, Sleep disturbance, Pain.
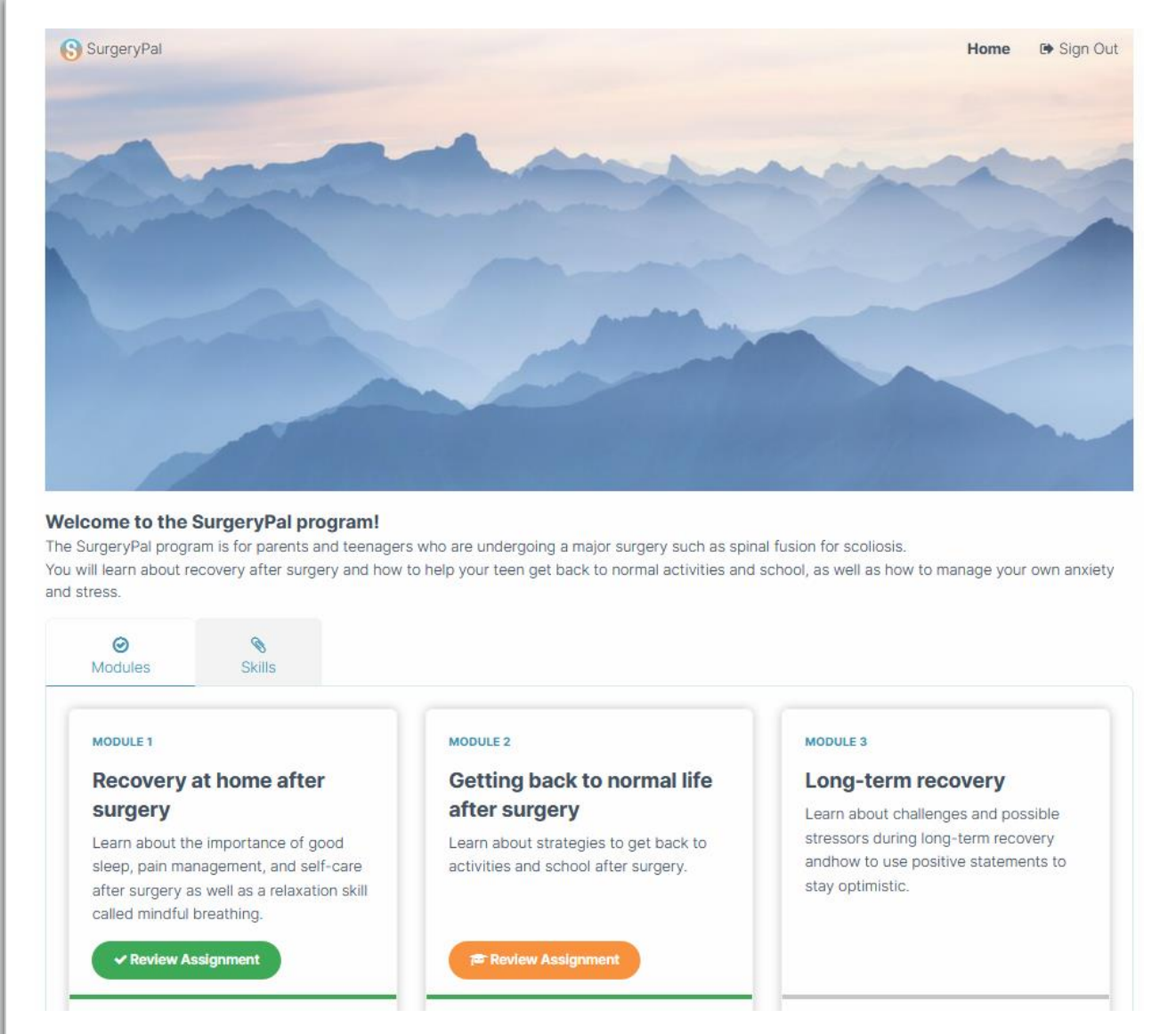
Secondary prevention to prevent progression to chronic pain:
- Anxiety/distress, Sleep, Pain, Physical Activity.

Murray et al. (2022), Canadian Journal of Pain 6(1):12-23
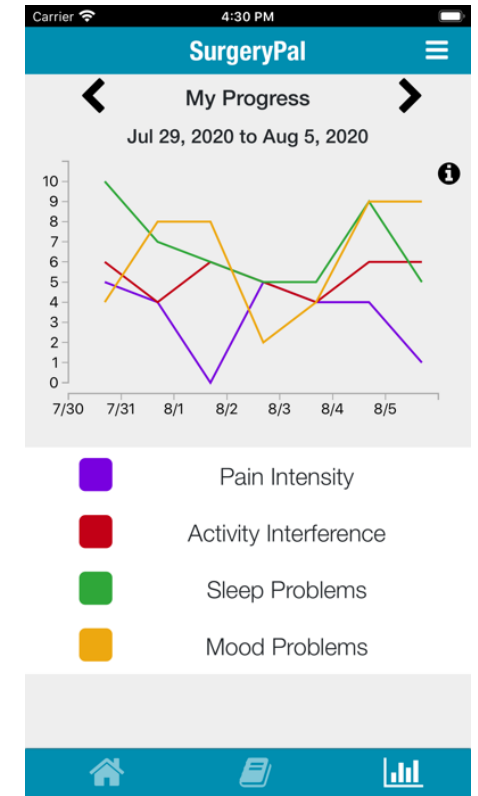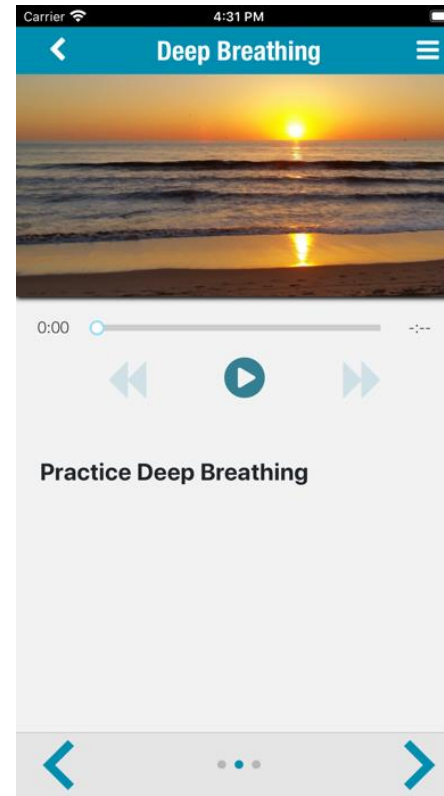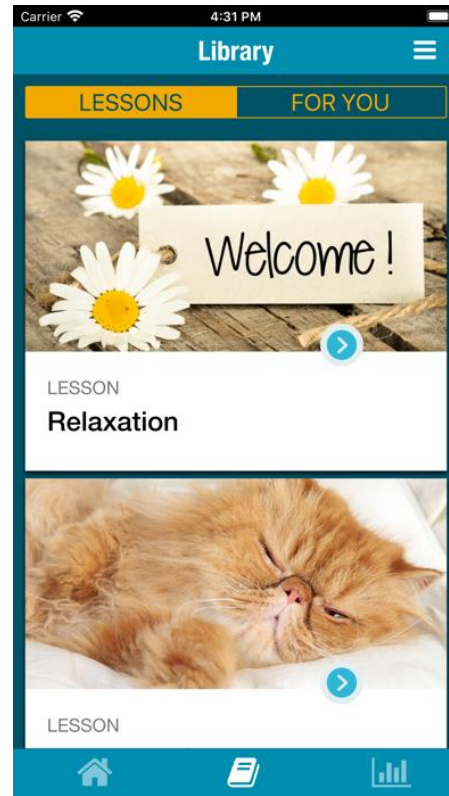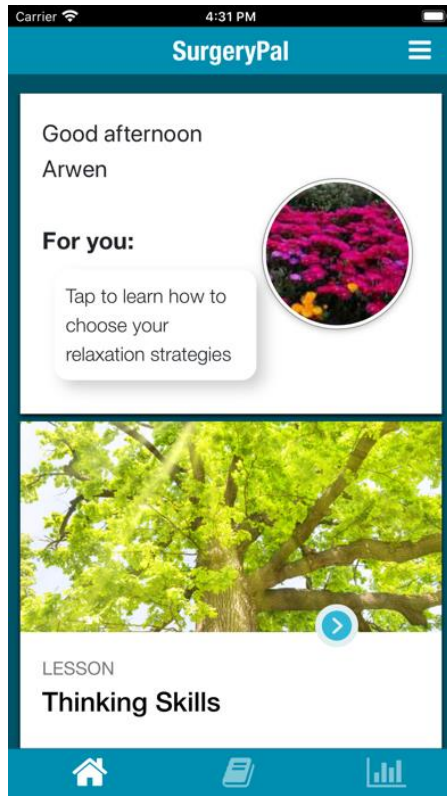
- **Cognitive strategies:** e.g., replacing worries
- **Behavioral:** Sleep hygiene, activity pacing
- **Relaxation skills:** e.g., deep breathing, imagery, mindfulness
- **Validation** through hearing experiences from teens who underwent spine surgery

SurgeryPal

CBT for Adolescents

Parent Web-based CBT program

Prevention of Pediatric Pain

Priority Statement

Advance pain prevention by evaluating primary and secondary strategies to reduce pain and prevent transition from acute to chronic pain across the lifespan. Integrating lived experience to assess preventive approaches and implement safe and effective early treatments for novel cohorts, high-risk populations, and the whole population.

- **Pediatric cohorts/ populations:** primary care, education systems (school nurse), sport programs, community centers, parent programs, maternal health, emergency room, sports medicine, ortho, surgery.

- **Interventions:** Pain self-management, psychological, physical pre- or rehabilitation, complementary and integrative therapies, pharmacological interventions, interdisciplinary interventions.

Pain Prevention

Jennifer Rabbitts, MD
Professor of Anesthesiology, Perioperative and Pain Medicine,
Stanford University

John Farrar, MD, PhD
Professor of Epidemiology, Neurology, and Anesthesia,
University of Pennsylvania

Joletta Belton, MSc
Lived Experience Partner

NIH HEAL INITIATIVE

- Prevention Priority Statement
- Where does prevention fit into HEAL
- Current Prevention Priorities and HEAL Research
- Prevention in Pediatric Pain
- **Prevention in Adult Pain**
- Discussion of Priority Areas

Primary Prevention: Avoid the Development of Disease and Remove Risk Factors

- Addressing basic issues in public health will also often address the development of pain.
- Focus on good general habits starting as a child with continuing into adulthood
  - Need for regular exercise
  - Need for good nutrition – avoidance of obesity
  - Teaching principles of dealing with life's normal pain issues – (examples)
    - Teach resilience – limit expression of anxiety about minor pain episodes
      - Childhood - From parents and caregivers
      - Adulthood – From friends, partners, and healthcare providers
    - Involve patients in planning the management of any pain-related care
    - Encouragement of self-help processes for patients to deal with issues as they come up
- Prevention of pain related illness – (examples)
  - Vaccine for varicella-zoster as both a child and older adult to prevent shingles
  - Vaccine for covid to potentially limit development of long-covid symptoms
  - Improved diabetes control to limit development of painful neuropathy
- Attention to psychosocial issues that might increase the experience of pain- (examples)
  - Adequate treatment of severe or prolonged depression and anxiety beyond the normal range
  - Reduce catastrophizing - identify such behaviors and work to reduce concerns

Secondary Prevention:
Early Detection and Treatment to Prevent Progression

- Studies of what promotes pain resilience and self-management capabilities
- Dealing with Initial Pain Episodes – (examples)
  - Use of back screening tools to predict the potential for transition and target appropriate therapy
  - Nutritional and life-style approaches to reduce headache pain
  - Exposure to a physical therapy, massage, or chiropractic therapy session in Emergency Room visits for pain with appropriate scheduled follow-up
- Dealing with post-operative pain – (examples)
  - Appropriate plans for post-operative care developed with patients
  - Concept of tolerable pain rather than complete pain relief
  - Methods to achieve appropriate pain level expectations and realistic treatment benefits
  - Develop appropriate expectations of likely limitations and solutions
  - Teach clear and appropriate self-help programs with defined goals for achievement
  - Appropriate close follow-up to encourage patient active participation in the process

Tertiary Prevention:
Reduce Complications of Established Disease

- Develop standardized approaches to individualized pain care to achieve tolerable pain and acceptable level of function
  - Develop evidence-based sequence of providing therapy to patients that must:
    - Be based on the clinically relevant presentation of applicable efficacy and side effect data
    - Be adaptable to patient-stated pain component that is important and known comorbidities
    - Be adaptable to individualized responses, given the wide variability in response to all known treatments
    - Be adaptable to patient preferences and likelihood persistence with therapies
    - Include healthcare providers trained to deal with the complexity of the individual needs
    - Have planned timing for the initiation and use of multidisciplinary approaches
    - Target individualized levels of tolerable pain and function goals
    - Target individual preferences for tolerable risk and side effects

- Design individualized patient care as a collaboration between providers and patients, with both understanding the best available evidence to achieve reasonable goals for the therapy

Some References

1) Hill, J. C., Dunn, K. M., Lewis, M., Mullis, R., Main, C. J., Foster, N. E., & Hay, E. M. (2008). A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Care & Research: Official Journal of the American College of Rheumatology*, *59*(5), 632-641.

2) Beneciuk, J. M., Bishop, M. D., Fritz, J. M., Robinson, M. E., Asal, N. R., Nisenzon, A. N., & George, S. Z. (2013). The STarT back screening tool and individual psychological measures: evaluation of prognostic capabilities for low back pain clinical outcomes in outpatient physical therapy settings. *Physical therapy*, *93*(3), 321-333.

3) Sakamoto, J. T., Ward, H. B., Vissoci, J. R. N., & Eucker, S. A. (2018). Are nonpharmacologic pain interventions effective at reducing pain in adult patients visiting the emergency department? A systematic review and meta-analysis. *Academic Emergency Medicine*, *25*(8), 940-957.

4) Schuster, N. M., & Rapoport, A. M. (2016). New strategies for the treatment and prevention of primary headache disorders. *Nature Reviews Neurology*, *12*(11), 635-650.

Pain Prevention

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- Prevention Priority Statement
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- Prevention in Adult Pain
- **Discussion of Priority Areas**

Prevention of Pain

Advance **pain prevention** by evaluating **primary and secondary** strategies to reduce pain and prevent transition from acute to chronic pain across the **lifespan**. Integrating **lived experience** to assess **preventive approaches** and implement **safe and effective early treatments** for **novel cohorts, high-risk populations, and the whole population.**

Priority Area 1:

Evaluate interventions for the **whole population**, at individual (e.g., coping skills training), interpersonal (e.g., parent, caregiver intervention), and systems level (e.g., pain neuroscience education) to prevent onset and persistence of pain across the lifespan.

- Intervention settings may include community centers, education systems, parent programs, youth sports.

Prevention of Pain

Advance **pain prevention** by evaluating **primary and secondary** strategies to reduce pain and prevent transition from acute to chronic pain across the **lifespan**. Integrating **lived experience** to assess **preventive approaches** and implement **safe and effective early treatments** for **novel cohorts, high-risk populations, and the whole population.**

Priority Area 2:

Evaluate effectiveness of strategies targeting risk factors and early intervention in **novel cohorts and high-risk populations** to prevent transition from acute to chronic pain across the lifespan.

- Test safe preventive and early treatments ranging from complementary and integrative therapies, physical pre- or rehabilitation, psychological, pharmacological, and interdisciplinary interventions.

- Settings may include primary care, urgent/emergency care, sports medicine/orthopedics, surgery, trauma.

Prevention of Pain

Advance **pain prevention** by evaluating **primary and secondary** strategies to reduce pain and prevent transition from acute to chronic pain across the **lifespan**. Integrating **lived experience** to assess **preventive approaches** and implement **safe and effective early treatments** for **novel cohorts, high-risk populations, and the whole population.**

Priority Area 3:

Sleep deficiency is a key health issue across the lifespan contributing to development and progression of chronic pain.

Evaluate effectiveness of complementary, psychological, pharmacologic, and multi-modal interventions targeting sleep in at-risk populations to prevent onset and persistence of pain.

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Clinical Pain Research Postdoctoral Fellowship

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Developing HEAL Pain Strategic Research Priorities: Optimizing Interventions to Improve Pain Management
Mini workshop

Research priority: Optimization and Adaptation

Benedict Alter, **Jennifer** Gewandter, David White

Rationale

- Pain is often driven by multiple mechanisms.
- Most treatments provide, at best, modest improvements.
- It is generally accepted that comprehensive multimodal care is best; however, evidence to support optimal combinations of treatments for various pain conditions is limited.
- Traditional multimodal care carries financial and time burden.
- Available drugs target a limited number of mechanistic pathways.

Overall goal

To address gaps in pain treatment by:

- Providing evidence for optimal combinations of treatments

- Increasing engagement in multimodal care by identifying barriers to engagement and adherence in these treatments and strategies to mitigate these barriers

- Adapting current therapies from related conditions or adapting current pain therapies to different populations to increase available components for future multimodal care.

Advance evidence for optimal therapy combinations.

Advance evidence-based pain management by identifying optimal therapy combinations, developing self-management programs tailored for diverse populations, and identifying methods to optimize integrating psychological, medical, and interventional approaches in care models.

Relevant contexts:
- Acute pain
- Chronic pain
- Acute-to-chronic pain transition
- Co-morbidities associated with pain (e.g., psychological, cognitive, physical function)

Advance evidence for optimal therapy combinations.

Examples:

- A Sequenced Strategy for Improving Outcomes in People With Knee Osteoarthritis Pain (SKOAP) trial (NCT04504812).

- SYNergizing Negative Affect & Pain Treatment In Chronic pain (SYNNAPTIC) trial (NCT04747314).

- Optimal pathway for treatIng neuropathic pain in diabetes mellitus (OPTION-DM) trial (ISRCTN17545443),

Factorial designs, SMART designs, Hybrid designs

Optimize engagement and adherence

Identify methods to optimize patient engagement with and adherence to different treatment modalities.

Example:

Targeted Interventions to Prevent Chronic Low Back Pain in High-Risk Patients (TARGET) Trial (NCT02647658).

- Adapts traditional PT to psychologically-informed PT
  - Among other benefits, psychological component could help increase engagement in the physical component.

Patient-centered treatment planning

Develop patient-centered, treatment planning methods for multimodal care for immediate and profound impact on pain management.

Example:

HOPE Consortium Trial to Reduce Pain and Opioid Use in Hemodialysis (HOPE) (NCT04571619).

Repurposing clinically-available treatments

Explore the potential of repurposing clinically-available therapies with promising analgesic potential and their potential to become part of multimodal treatment.

Example:

NHS recommendations for neuropathic pain (pharmacologic):
- Amitriptyline
- Duloxetine
- Pregabalin
- Gabapentin
- Capsaicin (topical)
- Tramadol

https://www.nhs.uk/conditions/peripheral-neuropathy/treatment/

Cross-Cutting Values

Joletta Belton, Jeff Dusek, and Adam Hirsh

Our Approach

Overall topic: Optimizing interventions to improve pain management

What is cross-cutting? Themes that intersect and are relevant to all aspects of the overall topic

What is complementary to other workgroups and subgroups? (next slide)

Other Cross-Cutting Topics

- **From other workgroups:**
  - Intersection of pain and substance use (Dec 2)
  - Health equity and pain across the life course (Dec 6)

- **From the current workgroup:**
  - Lifespan perspective
  - Individualized and flexible care
  - Adaptable to patient preference / treatment response / comorbidities
  - Innovative care delivery models (e.g., digital, telemedicine, hybrid)

Emphases from our research and discussions

1. <u>Values</u>: guiding principles, ways of being and doing

2. <u>Partnerships</u>: multidisciplinary, co-equals, meaningful (contra tokenism), full spectrum

3. <u>Integration</u>: Multi-modal, conventional + complementary, synergy

3 Sub-topics

1. Long-Term Perspective

2. Collaborative Research

3. Integrative Perspective

Subtopic 1: Long-Term Perspective

- Emphasize meaningful change over a meaningful time frame, defined collaboratively with people with relevant lived experience.

- Evaluate the long-term effectiveness of treatments, emphasizing sustained improvements in quality of life, improvements in functional ability, and reductions in pain-related disability.

- Cohen et al. (2021). Chronic pain: an update on burden, best practices, and new advances. The Lancet, 397(10289), 2082-2097.
- HHS (2019). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations.

NIH · Helping to End Addiction Long-term®

Federal Pain Research Strategy

Advance Knowledge of the Relationship between Socioeconomic Status and Pain.

Social determinants play a key role in a variety of health statuses. Some argue that lifestyle, environmental, and economic factors are more important than biological factors in the etiology of health and disability. Others argue that the patterning of effects over time may implicate social and economic factors, occupational risks, and low educational attainment as fundamental causes of poor health. Others suggest that environmental exposures play a direct role in causing unhealthy conditions, which in turn influence health outcomes. The lack of socioeconomic and related resources, is clearly related to help-seeking and access to care and may influence treatments for physical and mental health conditions related to pain. This is especially true for high impact chronic pain. It has been more difficult to explicate whether social and environmental resource factors play a direct role in the experience of pain. Integrative research adopting a biopsychosocial perspective is needed to: (a) elucidate the associations of SES with psychological and physical mechanisms and progression of pain and treatment response, (b) clarify the contribution of SES to ethnic differences in pain, and (c) understand the potential etiologic role that lack of long term access to social and economic resources plays in the psychological and physical experiences of pain. Recent advances in research have provided innovative tools for understanding the biological underpinnings of lower SES. These tools will allow for analyses of gene-by-gene and gene-by-environment interactions as well as epigenetic and transcriptional changes (e.g. the conserved transcriptional response to adversity) that may serve as pathways whereby social, economic, and environmental resource factors influence the experience of pain.

Subtopic 2: Collaborative Research

- Develop and sustain collaborative, community-based partnerships across the research spectrum – from priority setting, to study design, to analysis and interpretation, to implementation and evaluation.

- These partnerships are multidisciplinary and include scientists, clinicians, people with lived experience, and other community members (e.g., non-profits, local allies and leaders), with a particular focus on under-resourced areas.

- IASP 2022 Fact Sheet: Partnering with People with Lived Experience in Pain Research.
- ENTRUST-PE project. Patient and Public Involvement and Engagement.

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Home / Resources / Patient and Community Eng…

Patient and Community Engagement Resources

Pain and addiction are conditions shaped by biology, psychology, and social determinants of health. People who have lived and living experience (PWLE) with these conditions bring an important perspective to virtually all aspects of research. Their contributions can improve the relevance of the study to the community and the impact of the research on public health.

HEAL seeks effective engagement of people with lived experience in research. Effective engagement 🔗 **pdf 213.44 kb** can help achieve health equity by building trust and respecting cultural traditions. It can also facilitate people's interest in research, help encourage participation, recruitment, and retention, and improve outcomes for the people and communities the research serves.

Effective engagement can benefit the people with lived experience who participate in the research. It can provide them with new skills, opportunities to connect with others with shared experience, and greater awareness of cutting-edge research on their condition.

[Read more on the value of Patient and Community Engagement]

"Something that's really important for all of us as basic researchers is including patients early on in the process."

- Isabella Romano, University of New Mexico (UNM), Health Sciences Center

Featured Resources

The Patient and Community Engagement Tip Sheets and accompanying worksheets are designed to equip researchers with tools to engage with PWLE and community members effectively. Download the tip sheets to learn how to plan for patient and community engagement, best practices for fostering genuine relationships, and how to disseminate
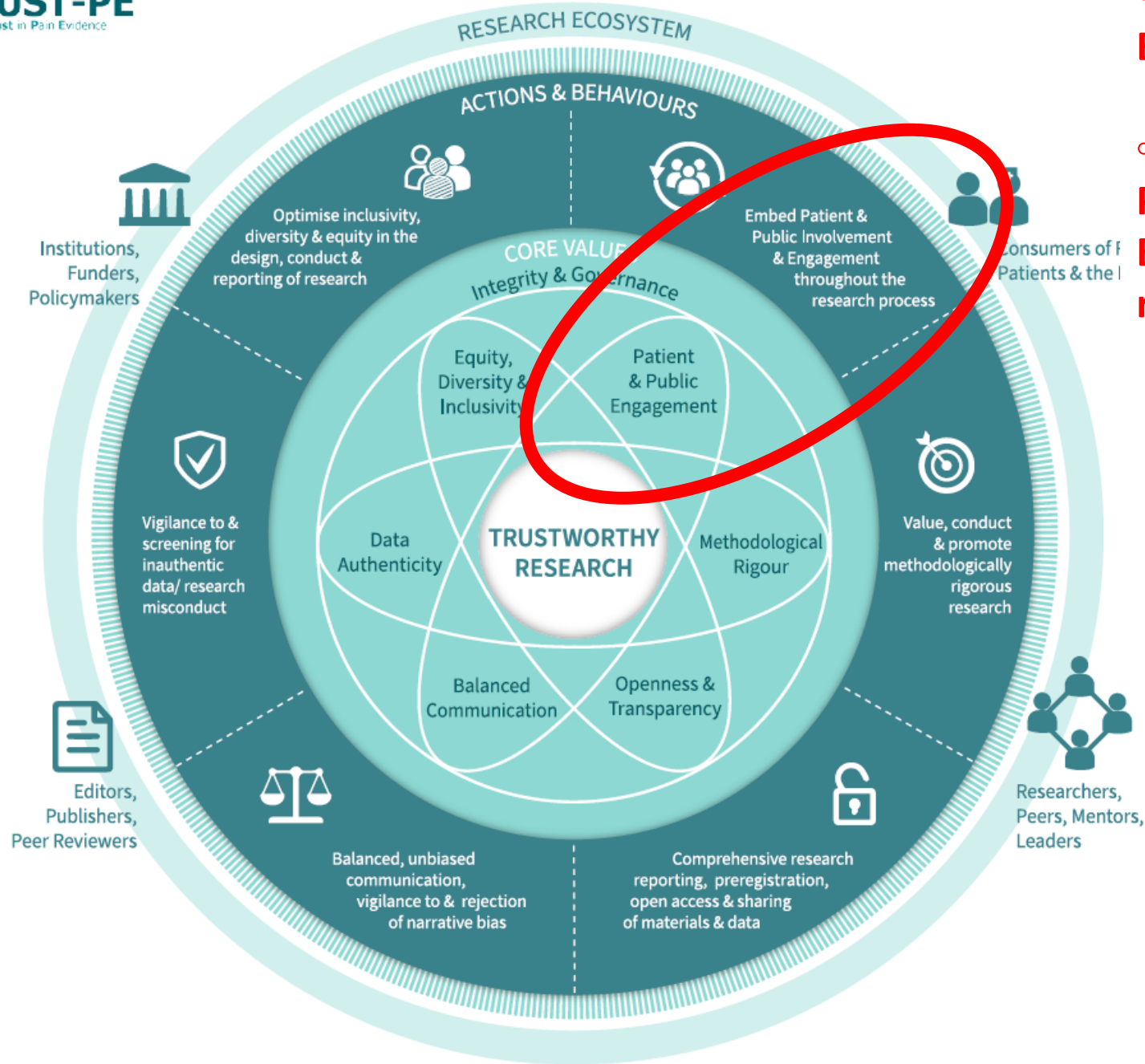
◦ **Value**: Patient & Public Engagement

◦ **Behavior**: Embed Patient & Public Involvement & Engagement throughout the research process

Subtopic 3: Integrative Perspective

- Prioritize the integration of self-management, non-pharmacological (e.g., complementary and integrative health), and/or medication-based approaches to improving pain care and patient reported outcomes.

- International Association for the Study of Pain (IASP). 2023 Global Year for Integrative Pain Care
- NCCIH Strategic Plan FY 2021–2025: Mapping the Pathway to Research on Whole Person Health.

Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR)

Treatment Challenge

OUD
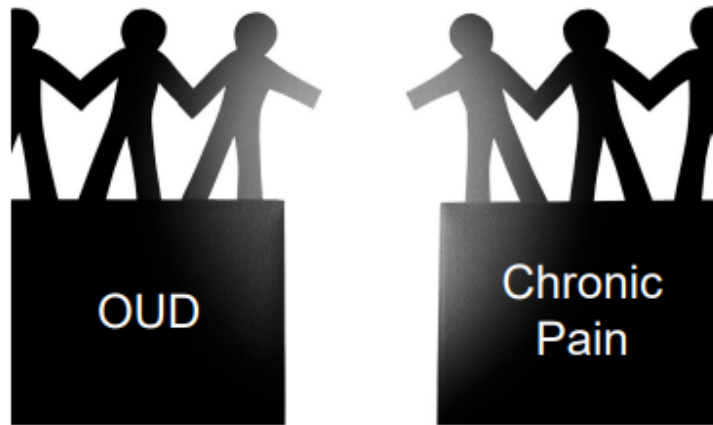
Chronic Pain

- 40-60% of individuals with OUD experience chronic pain (CP), which impacts OUD recovery
- Lack of evidence-based integrated treatments for treating both OUD & CP
- Service provision for patients with both CP and OUD is fragmented
- Limited resources, expertise, and communication leave patients behind

IMPOWR Vision

Generate evidence-based, patient-centered solutions for integrated management of co-occurring CP and OUD and rapidly disseminate knowledge to stakeholders to impact population health.

IMPOWR Goals

1. Maximize generalizability of developed interventions
2. Focus on the *Whole Patient* (co-occurring conditions, stigma/discrimination)
3. Emphasis on health inequities
4. Public/Private Partner involvement
5. Strengthen the next generation of scientists

References

Subtopic 1: Long-Term Perspective

- Cohen SP, Vase L, Hooten WM. (2021). Chronic pain: an update on burden, best practices, and new advances. *The Lancet, 397*(10289), 2082-2097
- U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations

Subtopic 2: Collaborative Research

- International Association for the Study of Pain (IASP). 2022 Fact Sheet: Partnering with People with Lived Experience in Pain Research
- ENTRUST-PE project. Patient and Public Involvement and Engagement

Subtopic 3: Integrative Perspective

- International Association for the Study of Pain (IASP). 2023 Global Year for Integrative Pain Care
- National Center for Complementary and Integrative Health (NCCIH). Complementary and Integrative Management of Pain

Recap
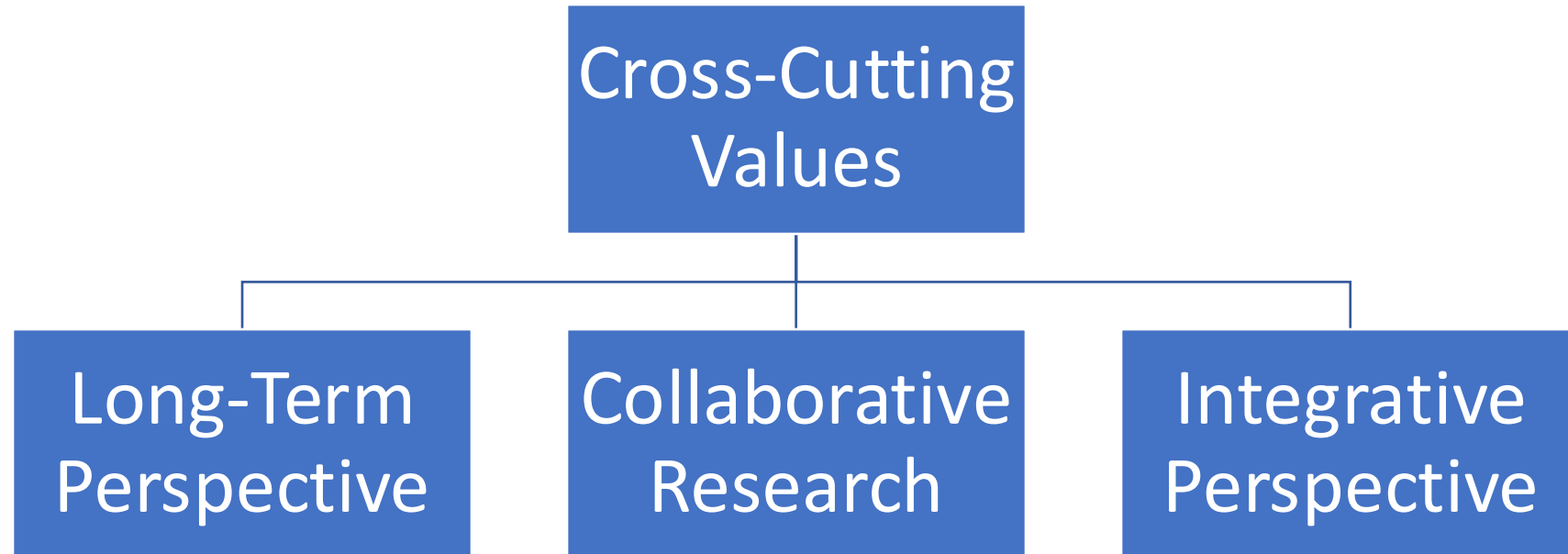
Discussion

Long-Term Perspective

- Emphasize meaningful change over a meaningful time frame, defined collaboratively with people with relevant lived experience.
- Evaluate the long-term effectiveness of treatments, emphasizing sustained improvements in quality of life, improvements in functional ability, and reductions in pain-related disability.

Collaborative Research

- Develop and sustain collaborative, community-based partnerships across the research spectrum – from priority setting, to study design, to analysis and interpretation, to implementation and evaluation.
- These partnerships are multidisciplinary and include scientists, clinicians, people with lived experience, and other community members (e.g., non-profits, local allies and leaders), with a particular focus on under-resourced areas.

Integrative Perspective

- Prioritize the integration of self-management, non-pharmacological (e.g., complementary and integrative health), and/or medication-based approaches to improving pain care and patient reported outcomes.

Priority Areas

Personalized Pain Management Priorities

1: Develop and validate comprehensive models that integrate biological (biometrics, genomics), psychological (self-report), functional (wearables), and social determinants of health to guide personalized pain management shared decision-making

2: Create flexible, feasible, and meaningful assessment frameworks for capturing individual patient characteristics that guide treatment decisions and optimize treatment response.

3: Support methodological studies and mixed-methods research aimed at transitioning from a managed care to implementation of a personalized pain management approaches in diverse healthcare settings

4: Develop and test culturally appropriate personalized interventions for underserved and vulnerable populations, including pediatric, elderly, and rural people.

Prevention Across the Lifespan

1. Evaluate interventions for the whole population, at individual (e.g., coping skills training), interpersonal (e.g., parent, caregiver intervention), and systems level (e.g., pain neuroscience education) to prevent onset and persistence of pain across the lifespan. Example intervention settings may include community centers, education systems, parent programs, youth sports.

2. Evaluate effectiveness of strategies targeting risk factors and early intervention in novel cohorts and high-risk populations to prevent transition from acute to chronic pain across the lifespan. Test safe preventive and early treatments ranging from complementary and integrative therapies, physical pre- or rehabilitation, psychological, pharmacological, and interdisciplinary interventions. Settings may include primary care, urgent/emergency care, sports medicine/orthopedics, surgery, trauma.

3. Sleep deficiency is a key health issue across the lifespan contributing to development and progression of chronic pain. Evaluate effectiveness of complementary, psychological, pharmacologic, and multi-modal interventions targeting sleep in at risk populations to prevent onset and persistence of pain.

Treatment Combinations and Adaptation

1. Advance evidence-based pain management by identifying optimal therapy combinations (including pharmacologic, interventional, surgical, and non-pharmacologic treatments), developing self-management programs tailored for diverse populations, and identifying methods to optimize integrating psychological, medical, and interventional approaches in care models. There should be a focus on acute and chronic pain, reducing the risk of acute-to-chronic pain transition, and improving co-morbidities associated with pain (e.g., psychological, cognitive, physical function).

2. Identify methods to optimize patient engagement with and adherence to different treatment modalities.

3. Develop patient-centered, treatment planning methods for multimodal care for immediate and profound impact on pain management.

4. Explore the potential of repurposing clinically-available therapies with promising analgesic potential and their potential to become part of multimodal treatment.

Cross-Cutting Values

1. <u>Long-term perspective</u> - Emphasize meaningful change over a meaningful time frame, defined collaboratively with people with relevant lived experience. Evaluate the long-term effectiveness of treatments, emphasizing sustained improvements in quality of life, improvements in functional ability, and reductions in pain-related disability.

2. <u>Collaborative Research</u> - Develop and sustain collaborative, community-based partnerships across the research spectrum, from priority setting, to study design, to analysis and interpretation, to implementation and evaluation. These partnerships include scientists, clinicians, people with lived experience, and other community members (e.g., non-profits, local allies and leaders), with a particular focus on under-resourced areas.

3. <u>Integrative Perspective</u> - Prioritize the integration of self-management, non-pharmacological (e.g., complementary and intergrative health), and/or medication-based approaches to improving pain care and patient reported outcomes.

Parking Lot –
Lower Priority or Handled by Another Group

- Improving current treatments
  - Identify and isolate the most effective component and increase it's effect
  - Tailor existing treatment components to the individual

- Optimizing methods
  - Altering the order of bundled treatments
  - *Implementation*
  - Using AI in creative ways
  - Reducing placebo effects and enriching population samples
  - Personalized outcomes/specific to patient goals

- Adding suggestion
  - Exploiting placebo response
  - Strategically reinforcing certain expectations
  - Improving the therapeutic context