• Introductions Dr. S. Katz
• BACPAC Program Overview Dr. R. Carter and S. Sztein
• Q1
• Q2
• Q3
• Q4
• Q5
• Other
• Closing remarks

Webinar Agenda
HEAL Research Priorities

Improve Treatments for Opioid Misuse and Addiction

Enhance Pain Management

Back Pain Consortium (BACPAC) Research Priorities

Expand the number of therapeutic options to improve pain and function

Understand the mechanisms of low back pain

• *Use novel technologies to identify new druggable disease mechanisms*
• *Develop precise diagnostic and treatment algorithms*
• *Tailor therapies to individual patients*
• *Test new therapies*
Expected Outcomes

Integrated model of LBP through improved understanding of mechanisms, leading to new therapies

Clinical trials, integrating new therapies into multimodal interventions, combined with deep phenotyping and patient-reported symptoms and outcomes

Algorithms to match patients to best treatments based on phenotype
Components

Systems Level Data Analysis

Data, Algorithm and Research Program Management Center

Technology Sites

Mechanistic Research Centers
Clinical Cohorts

Clinical Data Standardization/Integration/Analysis

Collaborative Adaptive Multimodal Clinical Study

EPPIC

Phase 2 Trials

NIH BACPAC Research Program
Clinical Cohorts / Clinical Adaptive Protocols

Clinical Cohorts
• be existing and ongoing with a minimum of 100 consented patients
• include current and proposed methods for deep clinical phenotyping
• includes PROs and patient reported preferences and values related to treatments, healthcare states, and outcomes
• be available for studies in other centers

Collaborative Clinical Adaptive Study
• subjects prospectively assigned to one or more interventions to evaluate the effects on health-related biomedical or behavioral outcomes.
• use multimodal therapy approaches
• emphasize innovation in trial design (SMART, adaptive design, T2T, etc.)
• carried out collaboratively

What are the existing back pain cohorts and what type of infrastructure is needed to carry out multimodal clinical trials for chronic low back pain?

What are the challenges for developing standards for dx definition, minimum dataset and common outcomes?
BACPAC Phase 2 Trials

- Phased cooperative agreement to plan and implement Phase 2 efficacy trials in chronic low back pain
- Test new drugs, devices, biologics, CAM
- May use traditional RCT or novel design
- Will use EPPIC-Net Hubs, CCC and DCC
- Led by trial PI
- Under EPPIC-Net Governance/Standards

- Are there drugs, devices, biologics and complementary medicines approaches with a strong biologic or clinical premise ready to be tested in Phase 2 Clinical trials?
BACPAC Technology Research

Develop, test and deploy novel analytic tools, technologies and/or methods that will improve our understanding of mechanisms of cLBP

(I) Exploratory Research for Technology Development: High risk leads to proof-of-concept.
(II) Focused Technology Research and Development: Innovative research to address technical challenges.
(III) Iterative Technology Research and Development: Close coupling of technology development and biomedical projects.
(IV) Research and Development for Technology Optimization: Development of transferable technologies for biomedical impact.

Potential technologies include:

• Wearable devices
• Noninvasive devices to image and assess precise location of structures and pathways involved in pain
• Devices to measure and quantify markers of pain mechanisms/intensity

• What are the opportunities for interrogation of structures, organs, tissues, cells and pathways involved in chronic low back pain and what infrastructure is needed to support that effort?
• How can the results of these studies be used to generate integrated, 4D models of the role of abnormalities in different tissues (structures, organs, tissues, cells and pathways)?
BACPAC Mechanistic Research

- Address either a **scientific theme** or a **scientific challenge** in low back pain (LBP)

- Designed to
  - Improve understanding of the mechanism of action of the intervention or pathogenesis of the disease
  - Address fundamental questions about back pain

- **Use analytics** (assays, instruments, tests, methods, etc.) to generate data that
  - 1. improve understanding of LBP
  - 2. improve phenotyping of LBP patients
  - 3. can be used in the generation, modification and refinement of algorithms that help match patient phenotypes with best available or new therapies

- Must be linked to either a clinical prospective BP observational cohort and/or a clinical trial

- Data are shared with other centers, and systems level data analysis is conducted to produce an integrated model of LBP
  - What technologies can be developed and ready for deployment in the clinical setting for accurate diagnosis and for evaluation of chronic low back pain and for delivery of therapies within the next five years?
Supports all aspects of clinical research carried out by the BACPAC

Supports the BACPAC Collaborative Adaptive Clinical Study

Interfaces with EPPIC Net CCC and DCC in support of BACPAC Phase 2 trials.

Conducts Clinical Data Integration and Systems Level Analysis Develops algorithms

What computational tools are needed to integrate broad-based datasets, develop multiscale models, and carry out systems-level analyses of such data leading to the development of patient-based algorithms?