Summary of today’s discussion

HEAL Multidisciplinary Working Group

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Enhancing Pain Management

Improving Treatments for Misuse and Addiction

- Enhance Treatments for Infants with NAS/NOWS
- Optimize Effective Treatments
- Develop New and Improved Prevention & Treatment Strategies
- Expand Therapeutic Options
- Advance effective treatments for pain through clinical research
- Accelerate discovery and development of pain treatments

HEAL Initiative Research
Federal Partners
HEAL Federal Working Group
Working group of HHS and other federal partners focused on coordinating efforts across HEAL research projects

NIH Leadership
NIH HEAL Executive Committee
DECISION MAKING

Councills and External Experts
HEAL Multi-Disciplinary Working Group
Specialized working group of NINDS/NIDA and other IC councils provide input to prioritize HEAL research projects

Trans-NIH Scientific Teams
RESEARCH IMPLEMENTATION
Senior NIH scientific staff leading individual HEAL projects align efforts and build cohesion in programs
Optimal Length of Treatment for MOUD

- Questions to be answered by the CTN trial in two phases
  - How to enhance retention-in-treatment?
  - How to safely discontinue medication?
- Design seeks creative approaches in a challenging clinical circumstance
- Now need to convert straw model to a detailed protocol
- Consider cluster randomization for standard f/u vs. relapse prevention
- Will there be sufficient individuals in the centers who have already been stabilized on MOUD for 2 years and can start immediately in the discontinuation phase?
• Keep in mind that a large percentage of people with OUD also have pain - a major reason for relapse of treatment
• Strong support for inclusion of these projects in HEAL
• Focus on retention of participation in behavioral research intervention should be included
• What about “second generation” of mind-body interventions?
• Overarching goal is enhancing self-care
Preclinical research in pain treatments

• Discover new targets, and then validate - de-risk for clinical development
• Pain models are critical, but are they any good for chronic pain?
  • Depends on the type of pain
  • What is central pain anyway?
  • Needs to assess spontaneous activity too
  • What can be learned about animal models from failed industry projects?
• Potential role of cannabinoids?
• Need to be sure potential compounds are non-addictive
EPPIC-Net

• Looking for early wins - compounds ready for Phase 2
• But can compounds be considered for EPPIC-net that still need phase 1? If so, add other measures that shed light on mechanism
• What happens if there are lots of compounds that look promising but are still in the pre-clinical phase? Take advantage of Blueprint platform. NCATS can do ADME-tox (and more).
• Need to prepare for rapid enrollment of trials for multiple different pain syndromes
• Importance of precise phenotyping. Genotyping?
• Regulatory review process will be crucial - how to streamline?
  • Partnership with FDA essential
• Including biomarkers? What is valid? What will be the primary outcome? Going beyond VAS is crucial.
• MDWG will be critical in achieving balance of the Pain ERN trials
• Seek ways to accelerate achievement of results
• Seek ways to learn from metadata in trials in advance of completed data set - without compromising rigor
• Collect biospecimens even if you aren’t sure what you will want to do with them
General Issues

• Keep health equity issues in mind in all projects
• Reimbursement will be critical - need evidence to convince CMS
• Workforce training needed
• OUD needs both treatment and support for recovery
• Data sharing is crucial!
• Seek opportunities for overlap between OUD and pain research projects
• Sex as a biological variable - even in cells

THANK YOU FOR A GREAT MEETING!