



NIH Pragmatic Trials Collaboratory Steering Committee Meeting

May 16-17, 2023

Bethesda, MD

Brief Overview

- To implement the American College of Physicians Low Back Pain Guideline by evaluating the impact of the Primary Spine Practitioner (PSP) model in 3 academic Health Care Systems (HCS) and then evaluating its effectiveness by comparing it to usual medical care alone in patients age 18 and older suffering from LBP.

Current Status

- Recruitment and enrollment initiated
 - Duke – February 28, 2023
 - Dartmouth – April 13, 2023
 - University of Iowa – February 22, 2023
- Enrollment Status – current as of April 26, 2023
 - Screened
 - Duke - 59*
 - Dartmouth - 26*
 - University of Iowa - 27*
 - Enrolled
 - Duke - 21*
 - Dartmouth - 5*
 - University of Iowa - 16*

Barrier Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects					X
Engagement of clinicians and health systems		X			
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)			X		
Stability of control intervention		X			
Implementing/delivering intervention across healthcare organizations					X

Top Challenges

- Administrative Challenges
 - Hiring challenges related to current job market and institutional policies during fiscal challenge (hiring freeze requiring extra layers of administrative approvals for all hires).
- Regulatory Challenges
 - A sIRB does not eliminate requirements of the local IRBs. Site teams had to work with their local IRBs to explain the regulatory strategy including justification for a waiver of consent (longitudinal cohort) and waiver of documentation of consent (enrolled cohort).
- Patient-specific Challenges
 - Some patients don't want to be approached or discuss research during an acute pain episode.
 - Concerns about co-pays to see PT/DC.
 - Multiple reasons for PCP visit (not just LBP); some patients would rather see their PCP instead of adding a visit to the PT/DC.
 - Patients may be frustrated by going through the HCS phone triage system before getting to us.
 - Fewer patients wanting to see a chiropractor at the site with no DC on staff.

Top Challenges

- Scheduling Challenges
 - Although consults may not technically be required for physical therapy, some insurance companies require a signed doctor's order for prior authorization and/or reimbursement.
 - Getting appointments scheduled within a reasonable timeframe. This has been more of an issue with scheduling patients in usual care and obviously not a challenge specific to this study.
- Data Collection Challenges
 - Using two REDCap systems, one for screening at each site with patient names and addresses, and one centrally at the DCRI, increases the potential for data entry errors.
- Coordinating Center Challenges
 - Aligning information across the CCC, DCC, multiple Committees, Collaboratory, DSMB, and NIH whose information needs are not always coordinated.

Recent Generalizable Lessons Learned

- Change is hard
 - Working with health system schedulers
 - Changing HCS “habits” when it comes to PT referrals
- Insurance coverage is a barrier to delivering guideline concordant care for LBP.
- Providers want to know who they are working with and be kept up to date on study progress, but in ways that don’t take a lot of time.

Current Data Sharing Plan

- Limited dataset (Enrolled Cohort):
 - Require Data Use Agreement and IRB approval*
 - Custom dataset created to include just the subset of data needed*
- De-identified dataset (Longitudinal Cohort):
 - Not subject to HIPAA's minimum necessary standards*
 - Not required: Data Use Agreement and IRB approval*

Current Data Sharing Plan Obstacles

- Create limited datasets after the trial ends
- Funding to maintain data sharing after the trial ends



Questions?