NIH PRAGMATIC TRIALS COLLABORATORY

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IMPACt LBP
LOW BACK PAIN

Implementation of the American College of Physicians Guideline for Low Back Pain (IMPACt-LBP)

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ABSTRACT

Low back pain is the leading musculoskeletal pain condition and a key source of medical costs and disability. An estimated 20% of adults in the United States have low back pain; 50% to 80% report having a significant episode in their lifetime, and 23% experience disabling pain. Low back pain affects more than 31 million people in the United States at any given time, has increased threefold in prevalence in a 10-year period, and results in $100 billion to $200 billion per year in total healthcare costs. Low back pain is one of the leading causes of ambulatory care visits to physicians. These visits often result in treatments such as opioids that can lead to more harm than benefit. In 2017, the American College of Physicians (ACP) guideline for LBP recommended patients receive nonpharmacological interventions as a first-line treatment.

One solution that has been described in the literature but not yet tested is the primary spine practitioner (PSP) model. The PSP model involves multidisciplinary collaborative care that includes doctors of chiropractic and physical therapists—clinicians who have specific expertise in the treatment of musculoskeletal conditions—as first-line providers for low back pain. These clinicians routinely employ many of the nonpharmacological approaches recommended by the ACP guideline, including spinal manipulation and exercise.

IMPACt-LBP is a pragmatic, multisite, 2-arm cluster randomized trial that will evaluate the effect of first-contact patient referral to physical therapists and doctors of chiropractic. This study aims to determine if initial contact with these PSP clinicians will improve physical function, decrease pain, decrease opioid prescriptions, improve patient satisfaction, and decrease costs and utilization of health care services in patients with a primary complaint of low back pain, when compared with usual medical care.

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Several critical data elements, including patient-reported outcomes (PROs) and external PSP care, are not routinely captured within healthcare system electronic health records (EHRs).	The study team considered several alternative data collection strategies, ultimately opting to use electronic PRO survey data as the source of information about external PSP visits. Future study teams should carefully consider the availability of the data points of interest within the EHR; specifically, collaborate closely with each site, generate metrics for data availability for the population of interest, and engage in a realistic consideration of how that might or might not be extended.
The PROs used for this study (ie, PROMIS) are common but are not routinely captured in the EHRs used by the study's participating healthcare systems.	The study team developed a data capture system in REDcap to collect these measures, with use of the EHR as a backup source. The Cores helped greatly with the selection of secondary outcome measures. The study team sought consultation on outcome harmonization and participant burden. Future study teams should evaluate current PRO instruments within the EHR and, if possible, completion compliance rates. Consider a primary or backup data capture system for primary outcomes.

"We proactively worked with existing systems to design the protocol to fit into existing clinical workflows and avoid barriers. The study plan and protocol has been well received. However, we are not surprised that barriers did not appear during the planning phase, and we anticipate that new barriers will emerge as we move into implementation." — Dr. Christine Goertz

"Our original plan was to seek a full waiver of consent. However, after review with the Ethics and Regulatory Core, we shifted to a waiver of documentation of consent for data collection and a waiver of consent for deidentified EHR data extraction. These were approved without issue by the central IRB. Having adjusted our strategy prior to IRB submission based on input from the Core was likely a major reason the IRB review went so smoothly." — Dr. Christine Goertz

SELECTED PUBLICATIONS & PRESENTATIONS

- Video Interview: Update on the IMPACt-LBP Demonstration Project (2022)
- Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (2023)

Access the complete set of IMPACt-LBP resources.