Implementing New Care Pathways for Low Back Pain in Academic Healthcare Systems: Early Lessons from IMPACt-LBP

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Leadership Team & Funding Sources

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Funding Sources

National Center For Complementary & Integrative Health (NCCIH, Primary)

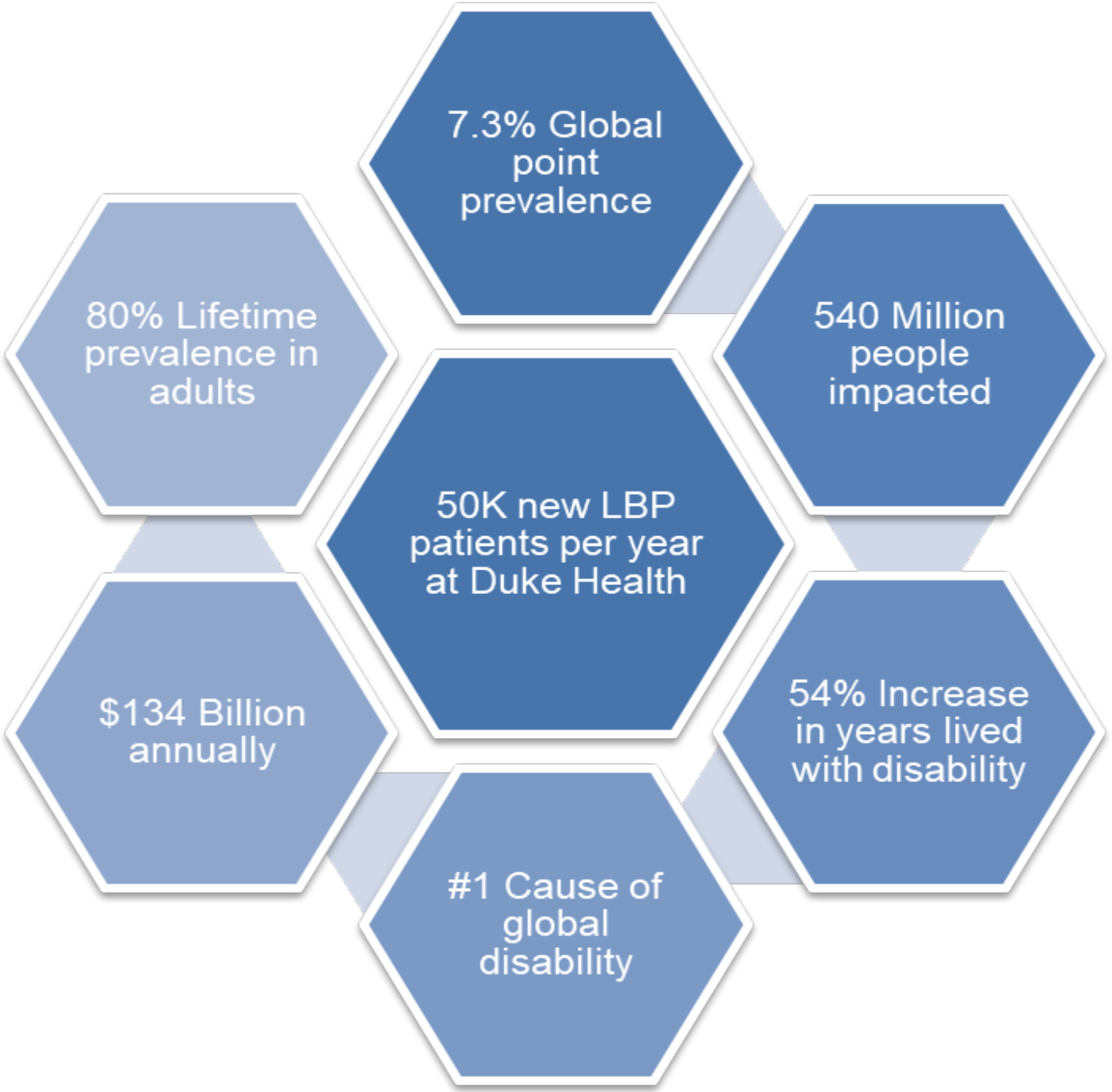
Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD, Secondary)

National Institute Of Arthritis And Musculoskeletal And Skin Diseases (NIAMS, Secondary)

Overarching Project Goal

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 aged 18 and older suffering from LBP.

LOW BACK PAIN IS VERY COMMON



CLINICAL GUIDELINES | 4 APRIL 2017

Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians FREE

*Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians **

Article, Author, and Disclosure Information

Eligible for CME Point of Care *Learn More*

Abstract

Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain.

Methods: Using the ACP grading system, the committee based these recommendations on a systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and nonpharmacologic treatments for low back pain. Updated searches were performed through November 2016. Clinical outcomes evaluated included reduction or

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"Physicians and patients should treat acute, sub-acute and chronic low back pain with non-drug therapies."

Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain.

Methods: Using the ACP grading system, the committee based these recommendations on a systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and nonpharmacologic treatments for low back pain. Updated searches were performed through November 2016. Clinical outcomes evaluated included reduction or

Recommendation	ACP	CCGPP	ICSI	NASS	TOP	VADoD
Pharmacological						
Acetaminophen	✓	--	✓	IE	✓	X
Epidural Spinal Injection	--	DNE	✓*	IE	X	X
NSAIDs	✓	DNE	✓	✓	✓	✓
Opioids	IE	DNE	X	X	X	X
Skeletal Muscle Relaxants	✓	DNE	✓	DNE	✓*	✓
Systemic Corticosteroids	NE	DNE	NE	NE	X	IE
Non-Pharmacological						
Acupuncture	✓	✓*	✓	✓*	✓*	IE
Cognitive Based Therapy or other psychological treatment	IE	✓*	--	✓	✓*	✓
Exercise (General)	✓	✓	✓	✓	✓	✓
Exercise (Motor Control)	IE	DNE	DNE	NE	DNE	✓
High Value Care	✓	✓	✓	✓	✓	✓
Patient Education	✓	✓	✓	✓	✓	✓
Pilates and Tai Chi	IE	✓*	IE	NE	DNE	✓
Spinal Manipulation	✓	✓	✓	✓	NE	✓
Superficial Heat/Cold	✓*	DNE	✓*	✓	✓	✓
Traction	IE	DNE	X	X	X	IE
Transcutaneous Electrical Nerve Stimulation	IE	X	DNE	--	X	IE
Yoga	IE	✓*	IE	✓	IE	✓

Key
Guidelines: ACP = American College of Physicians (2017)[5], CCGPP = Council on Chiropractic Guidelines and Practice Parameters (2016)[6], ICSI = Institute for Clinical Systems Improvement (2018)[7], NASS = North American Spine Society (2020)[8], TOP = Toward Optimized Practice Low Back Pain Working Group (2017)[9], VADoD = Veterans Affairs/Department of Defense Collaboration Office (2017)[10]
Identifiers: ✓ = Supported, X = Not Supported, -- = Conflicting Evidence, IE = Insufficient Evidence, DNE = Did not evaluate, ✓* = Use with other treatments, but not alone, NE = No Effect
Strength of Recommendation: Strong Evidence, Moderate Evidence, Weak Evidence, Consensus

IMPACt LBP

The SPINE JOURNAL NASS ADVANCING GLOBAL SPINE CARE

DISCUSSION | VOLUME 17, ISSUE 10, P1570-1574, OCTOBER 01, 2017

A proposal to improve health-care value in spine care delivery: the primary spine practitioner

Christine M. Goertz, DC, PhD • William B. Weeks, MD, PhD, MBA • Brian Justice, DC • Scott Haldeman, MD, PhD, DC

Published: June 20, 2017 • DOI: https://doi.org/10.1016/j.spinee.2017.06.013 •

Back pain is the leading cause of disability in the world, with global prevalence and burden increasing with age [[1]]. In the

References

Primary Spine Provider (PSP)

- Multi-disciplinary collaborative care that includes doctors of chiropractic (DC) and physical therapists (PT) as first line care for LBP.

- Treatment approaches include non-pharmacological approaches recommended by the ACP LBP guideline, including spinal manipulation and exercise.

IMPACt-LBP Study Design

- Pragmatic multi-site two-arm cluster-randomized trial with the unit of randomization at the primary care clinic level.

- 22 Family Medicine, Primary Care and General Internal Medicine Clinics.

- A total of 1,800 patients >18 years with a primary complaint of LBP who contact a participating primary care clinic to make an appointment with a primary care provider.

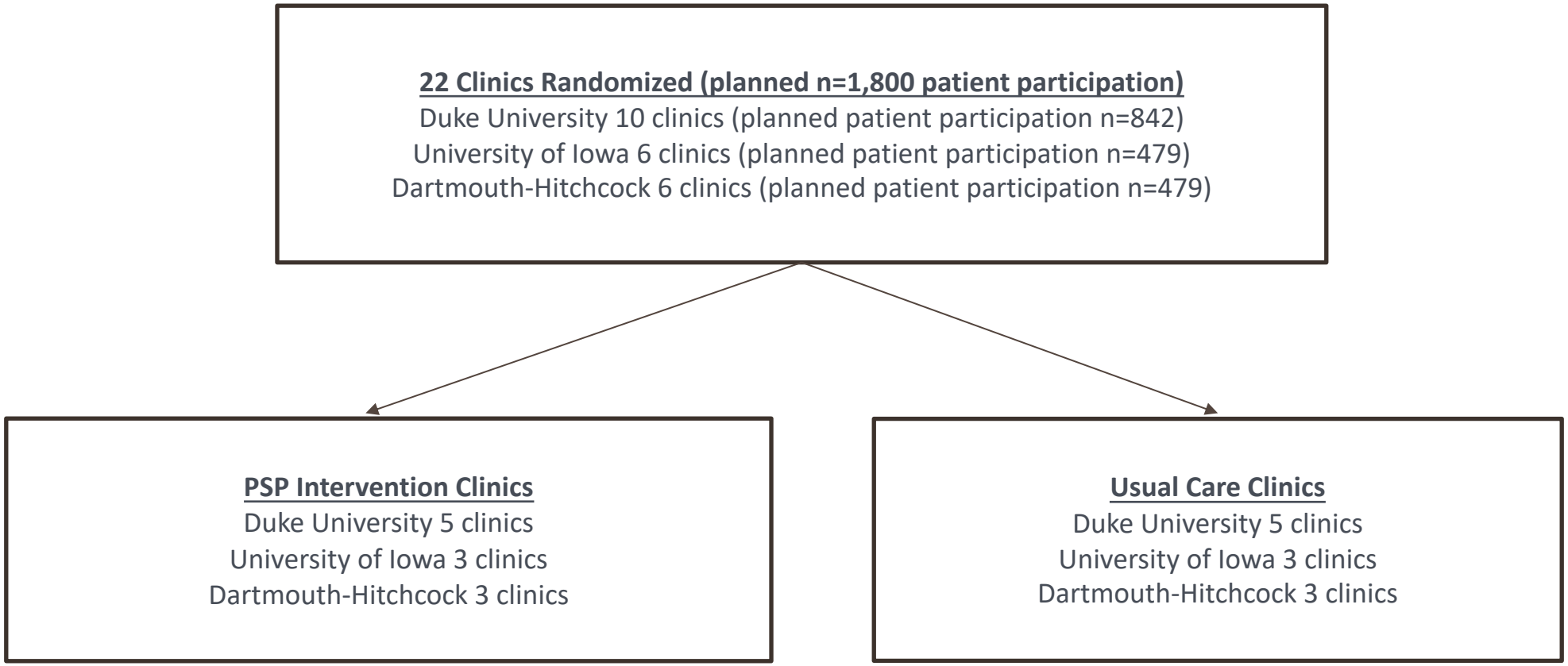
PCP Clinic Eligibility

- Affiliated with one of the 3 participating academic HCS;
- Designated as primary care, family medicine or general internal medicine;
- Willing to participate in the PSP model;
- Provide a signed site participation agreement; and
- Had at least n=250 unique patient visits with LBP assessed in UG3 planning year.

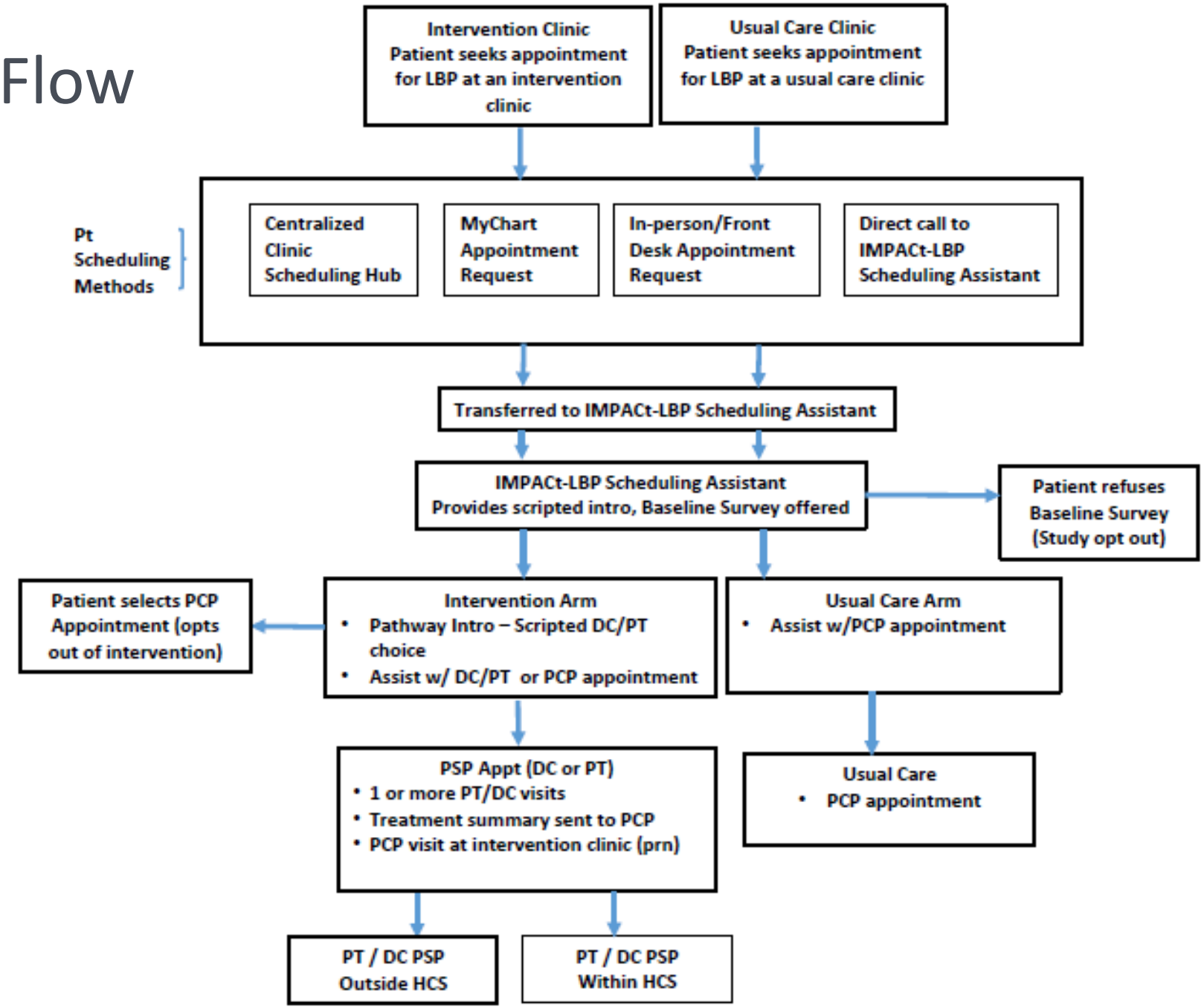
Patient Eligibility

- Aged >18 years old;
- Initiating an outpatient visit for LBP at a participating PCP clinic; and
- Agree to participate and complete baseline questionnaire.

Intervention and Usual Care Clinics



Patient Flow



Patient Screening

- IMPACt-LBP Scheduling Assistant
  - Screens for cauda equina syndrome
  - Provides an overview of the study/offers participation
  - If the patient is interested:
    - An appropriate appointment is made (with PCP, DC or PT)
    - A consent form and baseline questionnaire are sent to the patient

Patient Interventions

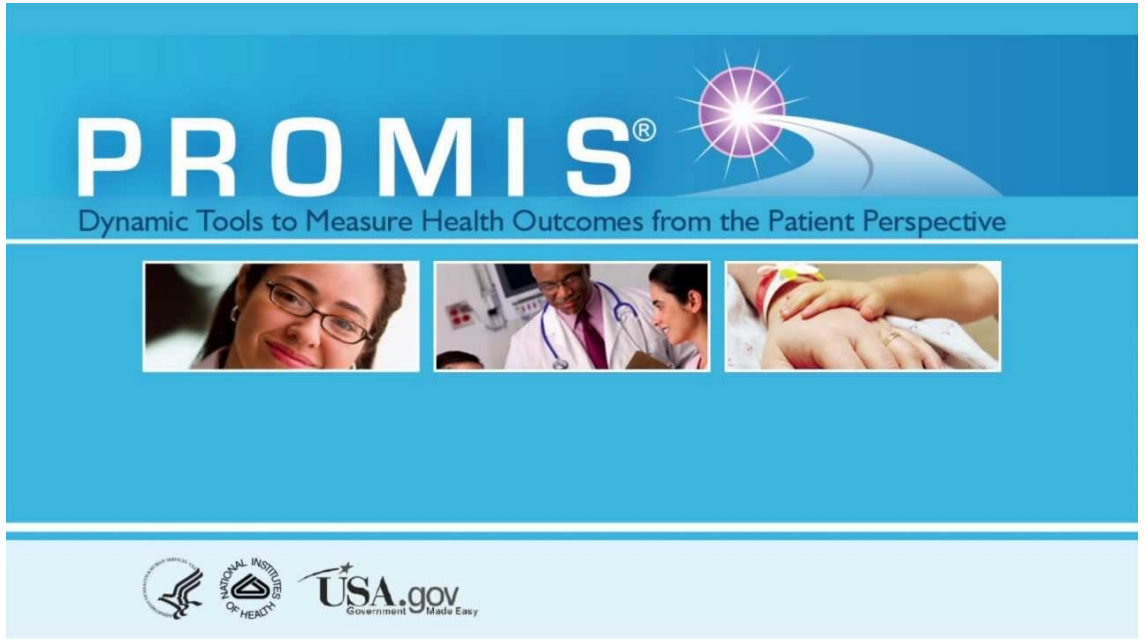
- Patients seeking care at intervention clinics will be given the option of seeing either a DC or a PT as their first contact clinician for an initial trial of PSP care.
- Each participating PCP clinic will have a preferred set of PTs/DCs to which patients will be offered referral.
- PTs/DCs will be identified by study investigators and approved by the site PIs, and
  - agree to receive educational materials (which may include the use of existing clinical care pathways, evidence-based treatment approaches, and a standardized diagnostic classification system)

Usual Care

- Usual care is defined as any care designated by a PCP.
- In most cases this care will be a combination of treatments or referrals that could consist of
  - 1) education and counseling,
  - 2) systemic medications (e.g., NSAIDS, muscle relaxants, opioids, etc.),
  - 3) referrals for non- pharmacological interventions such as PT, DC, or massage, or
  - 4) specialty care for invasive procedures such as nerve blocks, spinal injections, or surgery.

Primary Endpoints

- Change in PROMIS Physical Function from baseline to 3 months.
- Change in PROMIS Pain Interference from baseline to 3 months.



Key Secondary Endpoints

Description	Baseline	3 Months	6 Months	12 Months	24 Months*
Pain Catastrophizing	X	X	X	X	X
PROMIS Global-10	X	X	X	X	X
Total Prescribed Opioid Dose	X	X	X	X	X
NIH LBP Questions	X			X	
Patient Satisfaction		X			
Perceived Improvement		X			
Patient Experience		X			

Participants are compensated for completing questionnaires at each time point up to a max of $100
*Participants enrolled in first 18 months of recruitment (or up until the time data collection stops) will be asked to complete 24 month questionnaires

Analysis

- Enrolled Cohort – patients that agree to complete PRO surveys for pain interference and functional status for primary analyses. This allows for detailed outcomes in a subset of patients who agree to enroll and complete questionnaires.

- Longitudinal Cohort – EHR data for all patients at participating PCP clinics to assess utilization and other broad outcomes in the full unselected population at the clinic to assess the clinic level impact.

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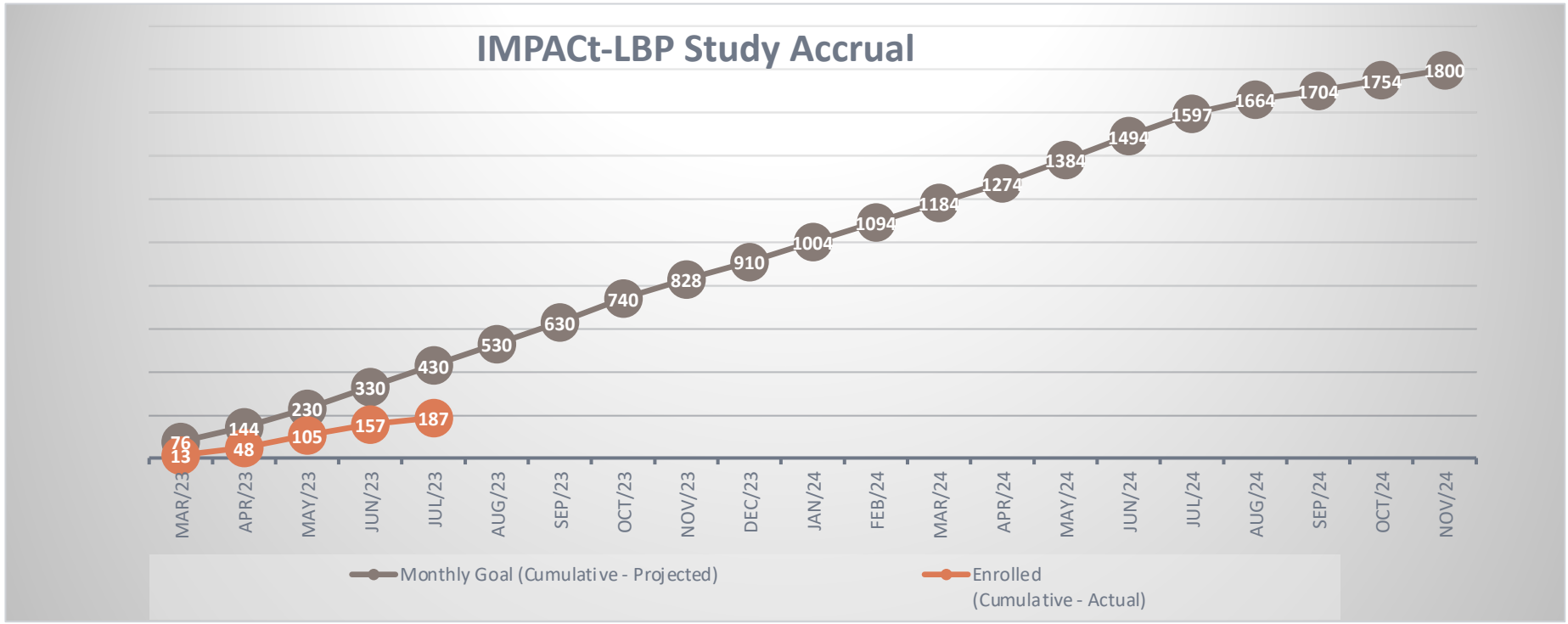
Current Status

Recruitment

- A total of 187 participants have been enrolled; 36 at Duke, 72 at Iowa, and 79 at Dartmouth.



Team

- Highly supportive leadership at all 3 sites
- Productive operational committees
- Highly effective project management
- Engaged sites

Administrative Supplement

- NOT-AT-22-010 Administrative Supplements for Complementary Health Practitioner Research Experience (Admin Supplements) from the National Center for Complementary and Integrative Health (NCCIH)
- Romeo Perfecto, DC, MS, CCSP
  - Operational assistance
  - Site-level PSP provider coordination
  - Masters in Clinical Research
  - Mentoring

Close working relationship between CCC & DCC

- The data management team continues to work with the HCS sites to assess data collection challenges, and to develop revisions to REDCap and REDCap reports to improve workflow.
- PCORNet queries were released for testing. 2 sites (Iowa and Duke) use the PCORNet CDM, but Dartmouth does not. OMOP to PCORnet mapping is underway.
- Initial operational reports were rolled out to the study team, and reports have been revised to reflect feedback from the study team.

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Lessons Learned

Administrative/Regulatory Lessons Learned

- Change is hard
  - Integration of PT/DC at the forefront of the patient experience
- Administrative
  - 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
  - Original plan was waiver of consent for all participants. Waiver of documentation of consent granted for enrolled participants.
  - 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).
  - Aligning information across multiple Committees, Collaboratory, DSMB, and NIH whose information needs are not always coordinated.

Scheduling Lessons Learned

- Changing HCS “habits” when it comes to PT referrals
  - Physician order for prior authorization and/or reimbursement for PT.
- Scheduling appointments
  - Reasonable times
  - But after the patient completes baseline questionnaires
  - Need to work closely with health system schedulers
- Insurance coverage is a barrier to delivering guideline-concordant care for LBP.
  - This challenge is not specific to this study.
- Need for dedicated research staff at the scheduling hub to ensure adequate recruitment was not part of original research plan.
- Not all patients enter the health system the same way

Lessons Learned

- Screening
  - Differences in Cauda Equina screening by site
  - Protocol amendment - Main change is wording of cauda equina exclusion criteria as sites were over screening for cauda equina. Additional patient-facing materials are part of this amendment and are expected to help improve enrollment.
- Data Collection
  - Original plan was EHR-only abstraction, however PRO outcomes not yet integrated into clinical practice to a sufficient degree
  - Using two REDCap systems, one for screening at each site with patient names and addresses, and one centrally at the DCRI for PRO collection, increases the potential for data entry errors.

Lessons Learned

- Clinic Issues
  - Original plan was to engage PSP clinics as research sites.
  - 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.
  - More difficult than originally thought to engage with community PSPs
- Patient-specific
  - 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.

“When it comes to back pain, we have kind of done everything wrong.”

Francis Collins MD, PhD
Former Director, National Institutes of Health
NCCIH/NIH National Advisory Committee Meeting , October 6, 2017

IMPACt-LBP Team!

The University of Iowa

University of Iowa Carver College of Medicine
University of Iowa Health Care

PALMER College of Chiropractic

Dartmouth Geisel School of Medicine

Dartmouth-Hitchcock

NIH National Center for Complementary and Integrative Health

Duke Clinical Research Institute

Duke Orthopaedic Surgery

Duke Clinical & Translational Science Institute
Primary Care Research Consortium

Duke Health
Department of Physical Therapy & Occupational Therapy

Thank You!

Questions?

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