Implementing a Pragmatic Trial in Low Back Pain

TARGETTRIAL

PANTHER Rehab Rounds

October 17, 2018

Patient-Centered Outcomes Research Institute (PCORI) Award PCS-1402-10867

NATIONAL MULTI-SITE TRIAL

Serving patients in Maryland, Massachusetts, Pennsylvania, South Carolina, and Utah.

Pragmatic research…

Implementing pragmatic research

Issues to discuss

1. Background and Overview of TARGET
2. Recruitment in Primary Care: Implementation
3. Progress to date

Key payer stakeholder: OPTUM

- Optum is a health information technology and services firm that is part of UnitedHealth Group. It provides technological, operational and consulting solutions and services to individuals, healthcare organizations, pharmaceutical companies as well as the federal and state governments.

Top cost driver

- Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. J Bone Joint Surg Am. 2006 Apr;88 Suppl 2:21-4
- Dieleman JL, et al MI. US Spending on Personal Health Care and Public Health, 1996-2013. JAMA. 2016;316(24):2627–2646. doi:10.1001/jama.2016.16885

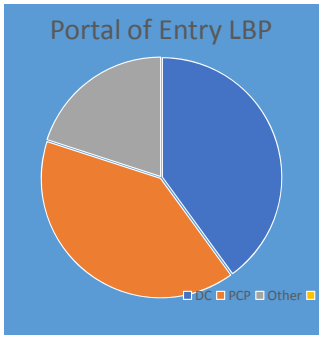
Top non-cancer reason for opioid prescription

- Hudson, T. J., Edlund, M. J., Steffick, D. E., Tripathi, S. P. & Sullivan, M. D. Epidemiology of regular prescribed opioid use: results from a national, population-based survey. J. Pain Symptom Manage. 36, 280–288 (2008
- Kea, B., Fu, R., Lowe, R. A. & Sun, B. C. Interpreting the National Hospital Ambulatory Medical Care Survey: United States Emergency Department Opioid Prescribing, 2006-2010. Acad. Emerg. Med. Off. J. Soc. Acad. Emerg. Med. 23, 159–165 (2016).

Guidelines recommend non-pharm mgmnt 1st

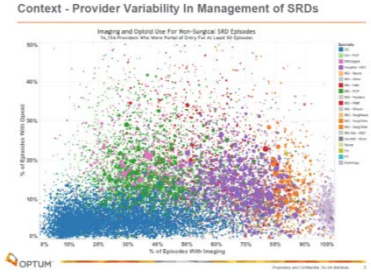
- Qaseem A et al. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2017. 10.7326/M16-2367
- Chou R et al. Nonpharmacologic therapies for low back pain: a systematic review for an American College of Physicians clinical practice guideline. Ann Intern Med 2017] doi: 10.7326/M16-245

Are people with LBP getting care consistent with guidelines?



Why should our "target" be Primary Care?

Context - Provider Variability In Management of SRDs

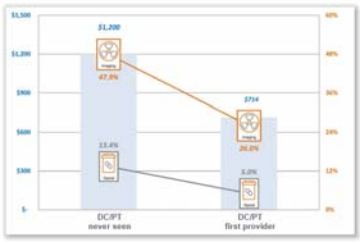


Current practice

Non-surgical spine attributes by DC/PT Involvement

n=4,148,996 complete episodes

Our data does demonstrate benefits of early conservative care for low back pain



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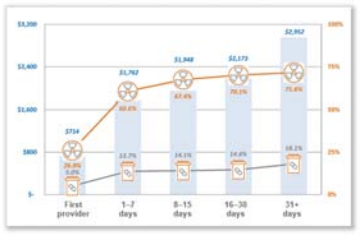
Current practice

Non-surgical spine attributes by DC/PT Involvement

n=4,148,996 complete episodes

Benefits of conservative care are lost the longer it takes a patient to see a PT or DC



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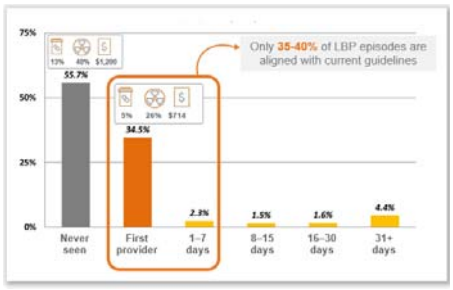
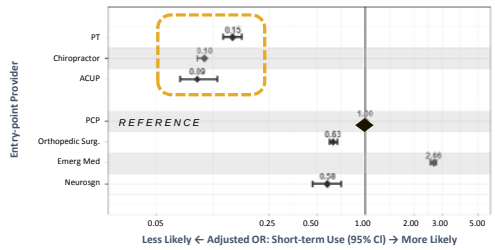
Where's the opportunity for PT?

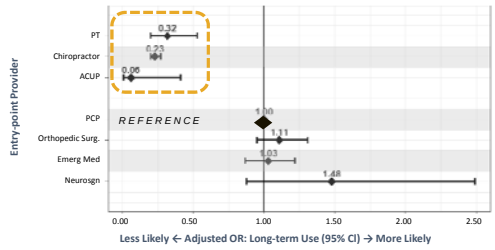


Likelihood of early opioid use



Unpublished data from OptumLabs Data Warehouse. Kazis et al.

Likelihood of late opioid use



Unpublished data from OptumLabs Data Warehouse. Kazis et al.

Our Main Research Question

*Can chronic LBP be prevented by prompt referral of **high-risk patients** with acute LBP to psychologically informed physical therapy?*

Aims for RCT

For patients with acute LBP deemed "high risk", compare PCP guideline-based care + PIPT vs. PCP guideline-based care only. Primary outcomes:

- PA1: Proportion of high risk acute patients that transition to chronic LBP during the initial 6-month follow-up period
- PA2: Back-related function at 6 months using the Oswestry Disability Index
- SA1: LBP-related medical utilization (12 mos)

Secondary Aims (Observational Cohort)

Follow patients with acute LBP who are deemed "low to medium risk"

Determine

- the proportion that transitions to chronic LBP
- functional ability at 6 months
- LBP-related medical utilization through 12 months

Stratified Approach to LBP

Effect of Stratified Care for Low Back Pain in Family Practice (IMPaCT Back): A Prospective Population-Based Sequential Comparison

Foster NE, Mullis R, Hill JC, Lewis M, Whitehurst DGT, Doyle C, Konstantinou K, Main C, Somerville S, Sowden G, Wathall S, Young J, Hay EM, IMPaCT Back Study team

Ann Fam Med 2014;102-111. doi: 10.1370/afm.1625.

CONCLUSIONS Stratified care for back pain implemented in family practice leads to significant improvements in patient disability outcomes and a halving in time off work, without increasing health care costs. Wider implementation is recommended.

STarT Back Screening Tool

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and it's **never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

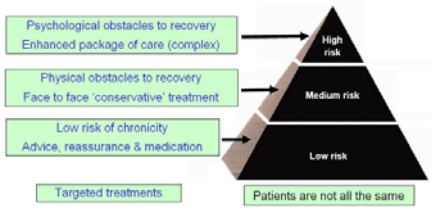
9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐ 0	☐ 0	☐ 0	☐ 1	☐ 1

Total score (all 9): _____ **Sub Score (Q5-9):**_____

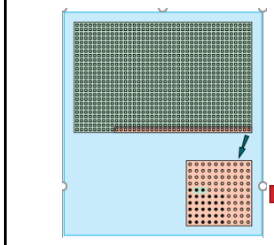
STarT Back Screening Tool

Concept of subgroup & targeting for primary care low back pain

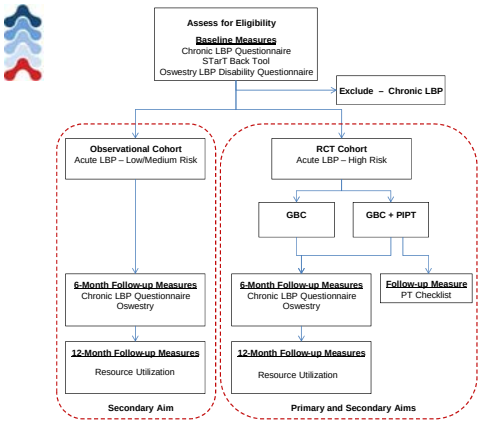


Psychologically Informed Physical Therapy (PIPT)

- Improve physical function through tailored stretching, strengthening, and aerobic exercises
- Address psychosocial obstacles to recovery through education, coaching, graded exercise
  - Fear-avoidance behaviors and beliefs
  - Catastrophizing

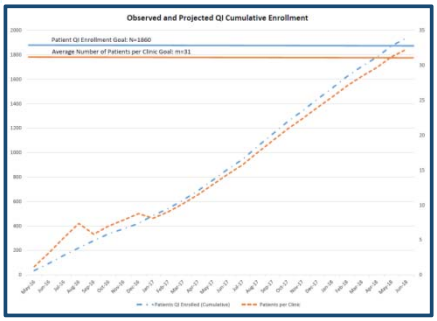


Risk Stratification



PROGRESS TO DATE

Enrollment for High Risk



Through August 2018: Enrollment and Follow Up by Site

Summary of Target Trial Cumulative QI Enrollment, 6-month Assessments

Report Date: 8/31/2018
Time Range: May 2016 - August 31st 2018 (for UPMC, IMH, BMC and JHU)

	UPMC		Inter-mountain		Boston Med Ctr		Johns Hopkins†		MUSC*		Total	
QI Baseline Enrolled	**5026**		**2122**		**989**		**674**		**126**		**8811**	
HR Enrolled	1152		496		331		170		26		2149	
LMR Enrolled	3874		1626		658		504		100		6662	
6-Month Assessment HR												
Expected	**943**		**383**		**237**		**101**		**11**		**1664**	
Completed	564	60%	284	74%	143	60%	80	79%	4	36%	1071	64%
Unable to complete	379	40%	99	26%	94	40%	21	21%	7	64%	593	36%
6-Month Assessment LMR												
Expected	**3177**		**1214**		**412**		**318**		**31**		**5121**	
Completed	1828	58%	884	73%	217	53%	248	78%	19	61%	3177	62%
Unable to complete	1349	42%	330	27%	195	47%	70	22%	12	39%	1944	38%

*MUSC data is through April 30th 2018 and is not included in the Total
†Johns Hopkins numbers include only those that were consented at baseline
HR: High Risk (RCT Cohort)
LMR: Low-Medium Risk (Observational Cohort)

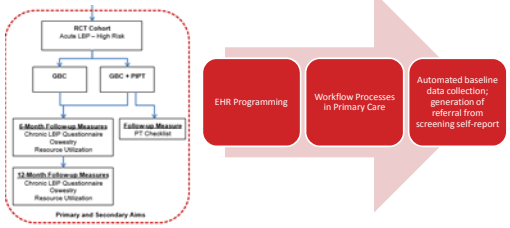
Aug 2018: Enrollment and F/U by Site with Average per Clinic

Target Trial Study
Data: 5/1/2016 - 8/31/2018

GBC+PIPT Clinics	46
GBC Clinics	42
Total Clinics	88

	Mean HR QI enrolled/clinic	Mean HR QI enrolled/clinic/month	Mean HR 6-mo completed /clinic	Mean HR 6-mo completed /clinic/month	Number of Clinics	QI Enrollment Months	6-month Follow-up Months
	#	#	#	#			
Intervention Group (GBC+PIPT)							
University of Pittsburgh/UPMC	36.6	1.3	18	0.9	17	28	20
Intermountain Health Care	21.5	0.9	11	0.8	11	23	15
Boston Medical Center	29.0	1.5	14	1.2	6	20	12
Johns Hopkins	34.5	1.8	8	0.8	6	19	11
Med University of South Carolina	3.0	0.2	0	0.0	6	15	7
SUBTOTAL GBC+PIPT							
Control Group (GBC)							
University of Pittsburgh/UPMC	33.1	1.2	17	0.9	16	28	20
Intermountain Health Care	28.9	1.3	18	1.2	9	23	15
Boston Medical Center	26.0	1.3	11	0.9	6	20	12
Johns Hopkins	27.0	1.4	6	0.5	6	19	11
Med University of South Carolina	1.0	0.1	0	0.1	5	15	7
SUBTOTAL GBC							
Intervention + Control Group							
University of Pittsburgh/UPMC	34.9	1.2	18	0.9	33	28	20
Intermountain Health Care	24.8	1.1	14	1.0	20	23	15
Boston Medical Center	27.5	1.4	13	1.1	12	20	12
Johns Hopkins	30.8	1.8	7	0.6	12	19	11
Med University of South Carolina	2.4	0.2	0	0.1	11	15	7
TOTAL							

TARGET Trial: a Type I Effectiveness/ Implementation Design



Enrollment Strategy

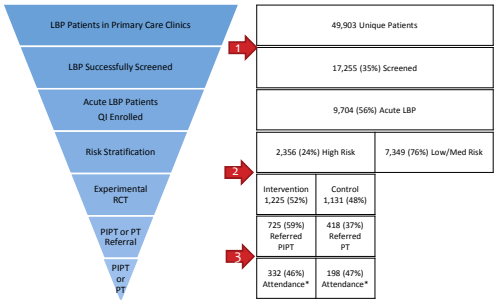
Two-part interdependent process

1. Quality improvement (QI) enrollment
   - Clinic personnel identifies LBP patients
   - Baseline data collection
   - High-risk patients receive immediate PIPT referral in the intervention clinics
2. Informed consent
   - Web, paper, telephonic (at 6 mo.) or point-of-care
3. Follow-up assessments
   - Web, paper & telephonic follow-up at 6

Data Capture at Point-of-Care

- Responsibility of each study site
- Develop mechanism to collect patient-reported information
  - Tablet, electronic health record, patient portal, patient navigator
- Integrate baseline data into the electronic medical record
- Trigger an automatic PIPT referral for high risk patients in intervention clinics

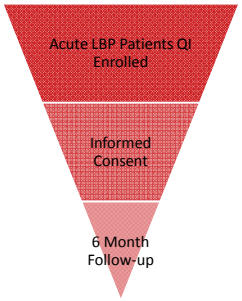
Pathway to PT: ***Leakage***



*Estimated

Implementing pragmatic research

Consent & Six Month Follow-up

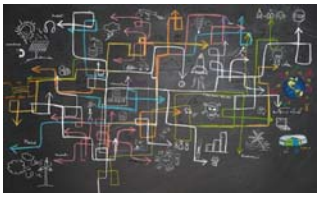


2,356 High Risk	7,349 Low/Med Risk
1,424 (60%)	4,260 (58%)
1,388 (97%)	4,149 (97%)

Implementing pragmatic research

Implementation Science: Moving Research into Real World Practice Settings

Providers Must Make it Work in Their Own Environment



Implementation Research

- The scientific study of techniques & strategies to promote the *uptake and sustained use* of evidence based practices into routine practice[1]
- The scientific study of techniques & strategies to *abandon ineffective or harmful interventions* that do not provide optimal care to patients in the settings in which they are delivered[2]
- Seeks to understand the *behavior* of healthcare professionals and other stakeholders as a *key variable* in implementation of evidence-based practices[3]

[1] Eccles MP, Mittman BS. Welcome to implementation science. Implement Sci. 2006
[2] Prasad V, Ioannidis JP. Evidence-based de-implementation for contradicted, unproven, and aspiring healthcare practices. Implement Sci. 2014
[3] Fogarty International Center. https://www.fic.nih.gov/researchtopics/pages/implementationscience.aspx