Health Care Systems Research Collaboratory Grand Rounds:

Collaborative care for Chronic Pain in primary care: Systematizing our approach for ensuring PRO data quality and stakeholder engagement

Lynn DeBar
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The Collaboratory
Health Care Systems Research Collaboratory Grand Rounds:

General Instructions for our viewers during today’s call:

• To enhance audio quality, all attendees are muted.

• Address your questions for our speakers to “everyone” using the chat pod. Your questions will be answered by the speaker at the end of the presentation.

• Address technical support questions to Sandi McDanel as a private chat using the chat pod.
Collaborative care for Chronic Pain in primary care:

Systematizing our approach for ensuring PRO data quality and stakeholder engagement

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KAISER PERMANENTE NORTHWEST
Agenda

• Background
  • Summary of Study Design
  • Key Contextual Factors (safety concerns, utilization and cost, clinical complexity)

• Measurement / Data challenges: Ensuring PRO adequacy
  • Understanding heterogeneity across health settings
  • Study process for quantitative and qualitative review of PRO data
  • Steps to enhance PRO collection and build transferable products

• Engaging Key Stakeholders: novel methods and approach
  • Organizational structure and the identification of key stakeholders
  • Adapted qualitative methods: rapid assessment and the adoption of Kaiser Permanente’s business model for organizational change

• Summary of Key Points
Overall Study Aim

Adopt an integrative rehabilitation approach for helping patients adopt self-management skills for managing chronic pain, limiting use of opioid medications, and identifying exacerbating factors amenable to treatment (e.g., depression, sleep problems) that is feasible and sustainable within the primary care setting.
Intervention Description

Patient Identification / Referral

Comprehensive Intake Evaluation by Care Manager Team (CMT), Including Nurse, Behavioral Specialist, & Physical Therapist, & Pharmacy Consultant

CM Communicates Patient Specific Treatment Plan to PCP

PCP Referral for Ancillary Services & Follow-up Communication

Case Management Follow-up
- Periodic re-evaluation & revision of treatment plan (every 3 & 6 months, largely by telephone)
- Individual coaching contacts (every 2 weeks for 6 months, largely by telephone)

Group Series (12 sessions; 2 hours every 2 weeks)
Participant Eligibility Criteria

• Current adult KP member (18 years or older)

• Within the last 180 days either:
  • 90 day supply of short acting opioid spanning at least 120 days
  • 2 or more long acting opioid dispenses

• Pain diagnostic ICD-9 code within the past 180 days
  • Diagnostic categories include but are not limited to:
    Back pain, neck pain, fibromyalgia, arthritis, myofascial pain, neuropathies, migraine, tension headache, tempromandibular joint disorder, carpal tunnel syndrome, nonspecific chronic pain, abdominal pain, pelvic pain
Trial Design

YEAR 2
- Randomize clinics to PPACT Intervention or Usual Care
- Implement Intervention in 6 clinics (2 each in KP-Hawaii, KP-Georgia, and KP-Northwest)

YEAR 3
- Collect EMR-based pain data and service use on eligible pain patients from all participating clinics
- Implement Intervention in additional 7 clinics across KP regions (2 in KP Hawaii, 2 in KP-Georgia, 3 in KP-Northwest)

YEAR 4
- Qualitative Process Evaluation within KP-Hawaii, KP-Georgia, and KP-Northwest
- Implement Intervention in final 7 clinics across KP regions (1 in KP-Hawaii, 2 in KP-Georgia, 4 in KP-Northwest)

YEAR 5
- Outcomes & Cost Analysis
- Combine Qualitative and Quantitative Analyses
  - Describe factors influencing Reach, Effectiveness, Adoption, Implementation, and Maintenance–REAIM
- Draft PPACT Implementation guide
  - Add perspectives of interviewees at diverse sites
- Refine Implementation guide and disseminate results

- Cluster-randomized pragmatic clinical trial
- 40 clinics (20 randomized to the integrated, interdisciplinary approach; 20 to usual care)
- Total of 960 patients
Rising prevalence of chronic pain
- 1/3 of the US pop. has chronic pain
- Annual US cost of $560-600 billion in health care costs and lost productivity

Primary care plays a central role in managing CNMP
- Primary care oversees & coordinates care
- Primary care providers (PCP) are faced with a paucity of systematic resources and support
- This gap leads to a reliance on opioids as a monotherapy

Use of opioids to treat CNMP rising
- Opioid prescriptions for CNMP doubled since 1980
- Opioid related morbidity and mortality have increased in past 2 decades
- Opioids are associated with significant efficacy-limiting side effects

Optimal management relies on patient self-care
- Chronic illness management necessitates an activated patient
- Provider-directed treatments not practical nor sustainable

Multidisciplinary, multimodal treatment shows promise
- Synthesizes expertise from diverse medical professionals
- Combines multiple modalities targets multitude of factors that influence pain
Opioid treatment for chronic pain:
safety concerns
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

1999 (range 1 - 50)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroine opioid admission rates, by State (per 100,000 population aged 12 and over)

2001
(range 1 – 71)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2003
(range 2 – 139)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2005
(range 0 – 214)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2007
(range 1 – 340)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)

2009
(range 1 – 379)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Unintentional overdose deaths involving opioid analgesics parallel per capita sales of opioid analgesics in morphine equivalents by year, US, 1997-2007

Source: National Vital Statistics System, multiple cause of death dataset, and DEA ARCOS

*2007 opioid sales figure is preliminary
### Opioid Therapy Plan (OTP) Operational Criteria

#### Patient Criteria

<table>
<thead>
<tr>
<th>Patient Criteria</th>
<th>Basic Green</th>
<th>Complex Yellow</th>
<th>Complex Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follows plan reliably</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No history of opioid abuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No history of other substance abuse within past 2 years</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No current behaviors indicating drug misuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current behaviors raise questions about the ability to follow the OTP</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>History of opioid abuse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of other substance abuse within past 2 years</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Calculated overall opioid dosing level at 180mg morphine equivalent or higher</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have demonstrated repeated problems following the OTP (e.g. unexpected UDS)</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Active substance abuse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have current behaviors which raise concerns about possibility of diversion</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

#### PCP Requirements

<table>
<thead>
<tr>
<th>PCP Requirements</th>
<th>Basic Green</th>
<th>Complex Yellow</th>
<th>Complex Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office visit frequency (minimum)</td>
<td>Semi-annually (1 may be TAV)</td>
<td>Quarterly (2 may be TAVs)</td>
<td>Quarterly (no TAVs)</td>
</tr>
<tr>
<td>Office visit required for any dosing changes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Brief Pain Inventory (BPI) completed (minimum)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>[Recommended to be administered at every office visit]</td>
<td>Semi-annually</td>
<td>Quarterly</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Refresh pain diagnosis on problem list</td>
<td>Yearly</td>
<td>Yearly</td>
<td>Yearly</td>
</tr>
<tr>
<td>Verify current dosing level is reflected on OTP on the problem list</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Discuss with the patient their use of opioid, non-opioid and non-pharmacological modalities to control pain</td>
<td>Each visit</td>
<td>Each visit</td>
<td>Each visit</td>
</tr>
<tr>
<td>UDS ordered and resulted (minimum)</td>
<td>Yearly</td>
<td>Quarterly</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Confirm random pill counts completed</td>
<td>PRN</td>
<td>2x/Year &amp; PRN</td>
<td>2x/Year &amp; PRN</td>
</tr>
<tr>
<td>Create AVS or send letter with patient’s dosing and instructions after dosing change</td>
<td>Yes</td>
<td>Yes – AVS only</td>
<td>Yes – AVS only</td>
</tr>
<tr>
<td>Create separate monthly opioid prescriptions, no refills and no mail order</td>
<td>No</td>
<td>Yes*</td>
<td>Yes</td>
</tr>
<tr>
<td>Early refills for travel</td>
<td>Yes</td>
<td>Yes</td>
<td>Up to 2/year</td>
</tr>
<tr>
<td>May refill prescriptions early for lost or stolen reasons (Police report needed before receiving refill of stolen medications)</td>
<td>Yes</td>
<td>Limited supply only</td>
<td>No</td>
</tr>
<tr>
<td>New OTP required when prescriber changes or OTP color changes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Opioid treatment for chronic pain: cost and utilization
## Total Sales & Prescriptions for OxyContin (1996-2002)

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales</th>
<th>Percentage Increase</th>
<th>Number of Prescriptions</th>
<th>Percentage Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>$44,790,000</td>
<td>N/A</td>
<td>316,786</td>
<td>N/A</td>
</tr>
<tr>
<td>1997</td>
<td>125,464,000</td>
<td>180</td>
<td>924,375</td>
<td>192</td>
</tr>
<tr>
<td>1998</td>
<td>286,486,000</td>
<td>128</td>
<td>1,910,944</td>
<td>107</td>
</tr>
<tr>
<td>1999</td>
<td>555,239,000</td>
<td>94</td>
<td>3,504,827</td>
<td>83</td>
</tr>
<tr>
<td>2000</td>
<td>981,643,000</td>
<td>77</td>
<td>5,932,981</td>
<td>69</td>
</tr>
<tr>
<td>2001</td>
<td>1,354,717,000</td>
<td>38</td>
<td>7,183,327</td>
<td>21</td>
</tr>
<tr>
<td>2002</td>
<td>1,536,816,000</td>
<td>13</td>
<td>7,234,204</td>
<td>7</td>
</tr>
</tbody>
</table>

Utilization Associated with Opioid Use

Use of services by KPNW chronic pain (CP) patients on long term opiate treatment (LOT) – 2011

- CP-LOT: 19.4%
- CP Only: 6.6%
- CP-LOT: 16.8%
- CP Only: 0.1%
- CP Only: m = 6.7
- CP-LOT: m = 31.8

Opiate users are more likely to:
- Use mental health services
- Use specialty pain services
- Be hospitalized
- Have increased outpatient visits

Patients with chronic pain (CP) using long term opiate treatment (LOT) have increased utilization across the system and are associated with a larger treatment burden.
Opioid treatment for chronic pain:
clinical complexity of the patients
### Patient Characteristics

<table>
<thead>
<tr>
<th>Pain Characteristics</th>
<th>KP Northwest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total members (18 and older) with chronic non-malignant pain (CNMP)</td>
<td>164,693 (36.8%)</td>
</tr>
<tr>
<td>Back and neck pain</td>
<td>12,659 (63%)</td>
</tr>
<tr>
<td>Joint pain (including osteoarthritis)</td>
<td>13,336 (67%)</td>
</tr>
<tr>
<td>Non-specific and other pain</td>
<td>11,876 (59%)</td>
</tr>
<tr>
<td>Two or more CNMP diagnoses</td>
<td>14,988 (75%)</td>
</tr>
<tr>
<td>Three or more CNMP diagnoses</td>
<td>8,361 (42%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbid Medical Conditions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>4,264 (21%)</td>
</tr>
<tr>
<td>Cardiovascular disorders</td>
<td>11,084 (55%)</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>7,053 (35%)</td>
</tr>
<tr>
<td>Diagnosed sleep problems</td>
<td>4,261 (21%)</td>
</tr>
</tbody>
</table>
Measurement / Data Challenges: Ensuring PRO adequacy

Study process for quantitative and qualitative review of PRO data and processes for addressing identified problems
### Outcome Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Analytic Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Pain Inventory (BPI)</strong>&lt;br&gt;(Severity &amp; Interference)</td>
<td>Primary Outcome</td>
</tr>
<tr>
<td><strong>Opioids Dispensed</strong>&lt;br&gt;(in morphine equivalents)</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Pain related treatment or diagnostic procedures</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of emergency / urgent care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of primary care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of specialty care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Total health service use &amp; cost</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Comorbidities <em>(Depression, anxiety, disability, chronic disease burden, sleep difficulties, kinesiophobia)</em></td>
<td>Covariates</td>
</tr>
<tr>
<td><strong>Patient satisfaction</strong></td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td><strong>Exercise as Vital Sign (EVS)</strong></td>
<td>Secondary Outcome</td>
</tr>
</tbody>
</table>

- All data collected in routine clinical care
- Data pulled from electronic medical record (EMR) and administrative data systems
- KP Virtual Data Warehouse provides common EMR to ensure standardization across 3 regions
- BPI completion for patients using opioids: Recommended at every visit, required quarterly to semi-annually
Heterogeneity Across our Health Plans

- The three Kaiser health systems have a common EMR
- However...
  - Work flows for administering PRO differ by site
  - Data sources for the same PRO vary across sites
  - Implementation Modality varies across sites and within a site
    - Paper pre-visit
    - Asked by health plan staff during visit
    - Online
Instruments for a similar PRO may vary across sites

- CAHP & Press-Ganey (Northwest)
  - Outpatient
  - ER/Urgent Care

- CAHP & Patient Care Survey (Hawaii)
  - Outpatient
  - Behavioral Health
  - ER

- CAHP & Patient Experience Survey (Georgia)
  - Outpatient

CAHP = Consumer Assessment of Healthcare Providers and Systems
Systematically test and validate PRO data: Cross-Site Assessment

- Instrument and how it’s presented by site
- Instrument versions and implementation dates
- Implementation modalities used (paper, asked by health plan staff, online)
- Data accessibility (e.g., privacy concerns around some PROs such as patient satisfaction, data refresh frequency)

Table 1: PRO Summary by Site (Instrument, version, Implementation Date, Implementation Modality)

<table>
<thead>
<tr>
<th>Instrument</th>
<th>KP Hawaii</th>
<th>KP Northwest</th>
<th>KP Georgia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Pain Inventory (BPI)</td>
<td>BPI</td>
<td>BPI</td>
<td>BPI</td>
</tr>
<tr>
<td>Version:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation Modality:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Refresh Frequency:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
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</tbody>
</table>
Systematically test and validate PRO data: Compare availability and density of the PRO data across sites

- Total record counts by year and site, subset for the population of interest
- Proportion of the population with PRO records
- Median and mean # of PRO records per person

<table>
<thead>
<tr>
<th>Table 2: PRO Available Data by Site</th>
</tr>
</thead>
<tbody>
<tr>
<td># Eligible Patients</td>
</tr>
<tr>
<td>Brief Pain Inventory (BPI)</td>
</tr>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>
Systematically test and validate PRO data: Validate that data extract matches the EMR presentation

- Confirm the back end data sources are correct and complete
- Check narrative strings for alternative placement of PRO data in the EMR (e.g. progress notes)

Table 3: PRO Summary by Site

<table>
<thead>
<tr>
<th></th>
<th>KP Hawaii</th>
<th>KP Northwest</th>
<th>KP Georgia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Pain Inventory</td>
<td>Sample of extracted records match presentation in EMR:</td>
<td>Sample of extracted records match presentation in EMR:</td>
<td>Sample of extracted records match presentation in EMR:</td>
</tr>
<tr>
<td>(BPI)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Influencing Health Systems

- Identify irregularity in PRO data
- Refine Clinic PRO data collection process
- Involve Stakeholders
Influencing Health Systems Use of PROs

- Health plan systems can adopt PROs quickly

<table>
<thead>
<tr>
<th>Year</th>
<th>KP Northwest</th>
<th>KP Georgia</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>4,977</td>
<td>0</td>
</tr>
<tr>
<td>2012</td>
<td>927,312</td>
<td>9,003</td>
</tr>
</tbody>
</table>

KP Georgia implemented use of EVS in the final few months of 2012.
Increased patient health record adoption provides additional opportunities to collect PROs

<table>
<thead>
<tr>
<th></th>
<th>Change between 2008 and 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total visits to kp.org</td>
<td>220% increase (Over 100 million visits in 2011)</td>
</tr>
<tr>
<td>Members registered for secure features</td>
<td>140% increase</td>
</tr>
<tr>
<td>Total online prescription refill orders</td>
<td>290% increase</td>
</tr>
<tr>
<td>Total online appointment requests</td>
<td>200% increase</td>
</tr>
<tr>
<td>Total e-mails sent to doctors &amp; other care team members</td>
<td>200% increase</td>
</tr>
<tr>
<td>Total lab-test results view online</td>
<td>180% increase</td>
</tr>
<tr>
<td>Total healthy lifestyle program questionnaires submitted</td>
<td>200% increase</td>
</tr>
</tbody>
</table>
Kaiser Permanente’s Personal Health Record

Available EMR questionnaires include:
- BPI
- PHQ-9
- SF-36
- Total Health Assessment

www.KP.org
Leveraging what is learned about PRO data to enhance broader research data systems
Leveraging what is learned about PRO data

Phase 1: **Identify** data enhancements
- Short list of PRO enhancements

Phase 2: **Define** data enhancements
- Initial data dictionary

Phase 3: **Implement** data enhancements
- Data flow diagrams
- Entity relationships
- Final data dictionary
- Implementation plan

Phase 4: QA & Enhancements
- QA program
- Remediation work plan
- Caveats list

Phase 5: Communicate & Use
- Presentations
- Webinars

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Systematic stakeholder engagement

The first step of rapid assessment for successful implementation
Stakeholder engagement is part of process evaluation

Not passive, one-way evaluation but ongoing evaluation that supports success of trial and becomes part of the implementation guide

Traditional qualitative methods not well-suited; use rapid assessment methods instead
Rapid Assessment Process (RAP)

- Rapid but not rushed. Iterative but not haphazard
- Quickly understand the insider’s perspective on a situation or an intervention
- Guides decisions about interventions and to evaluate their implementation
- Intensive, team-based ethnographic inquiry using triangulation and iterative data analysis and additional data collection to quickly develop a preliminary understanding of a situation from the insider’s perspective

RAP is our qualitative process evaluation

Goal: Successful Implementation

Goal: Successful Dissemination (Useful Implementation Guide)
Our RAP Toolkit:

- Informal stakeholder conversations
- Mapping (organizational relationships, processes)
- Weekly journaling by study staff
- “Postcards” to inform stakeholders and prompt dialogue
- Along with more traditional qualitative techniques: Interviews, naturalistic observation (fieldwork), brief surveys, focus groups
RAP is our qualitative process evaluation

Goal: Successful Implementation

Goal: Successful Dissemination (Useful Implementation Guide)
Where do we start?

- Each KP region is a complex system
- Our intervention is complex
- Implementation requires many approvals and process changes
- Researchers can learn from organizational effectiveness/process improvement
- How does our own organization deal with change management?
- Research requires systematic approach
- Pragmatic trial will benefit from a locally-acceptable approach (suited to the culture of KP)
Adopting an In-House Stakeholder Engagement Approach

- KP National Organizational Effectiveness Team
- Stepwise approach for change management
- We are using RAP to answer these questions and to monitor our stakeholders’ engagement with our intervention

Thanks to… Briana Cornwell, Briana.K.Cornwell@KP.Org
Senior Organizational Effectiveness Consultant
**What is the process?**

1. Determine engagement objectives
2. Identify and assess stakeholders
3. Develop engagement plan & techniques
4. Implement engagement plan
5. Evaluate effectiveness of activities
6. Make revisions based on feedback

Repeat as often as needed
Who is a stakeholder?

Anyone who has a “stake” in the change being proposed or who can most influence the outcomes

<table>
<thead>
<tr>
<th>Stakeholder Engagement</th>
<th>Communications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic operations &amp; support staff (RN, LPN, MA, Clinic Directors)</td>
<td>Give people a chance to influence the process and ensure they are ready, willing and able to make the change</td>
</tr>
<tr>
<td>Physicians &amp; other providers in various departments (primary care, addition medicine, mental health, etc.)</td>
<td>Seek to issue a message or to influence groups to agree with a decision that is already made</td>
</tr>
<tr>
<td>Billing and compliance partners</td>
<td></td>
</tr>
<tr>
<td>Managers / Supervisors</td>
<td></td>
</tr>
<tr>
<td>Sponsors (VPs, Directors)</td>
<td></td>
</tr>
<tr>
<td>Information Technology</td>
<td></td>
</tr>
<tr>
<td>Project managers</td>
<td></td>
</tr>
</tbody>
</table>
Why engage people?

People need time to analyze, think about, and adjust to the new ideas – if we leave them behind, we increase the likelihood of misunderstanding, resistance, and exclusion.

- Increase their confidence
- Increase transparency
- To learn how to make the change easier
- Generate new ideas
- Gain higher levels of trust
- Show people we care about them
- Surface risks

People want to know how they fit in, the role they will play, and what help they can offer.
Determine engagement objectives

Before we engage people, we need to know:
- why we want to engage stakeholders
- who will count as a stakeholder
- what will result from stakeholder engagement
- the risks of not doing it.

Stakeholders are meaningfully engaged when their influence makes a difference, whether directly or indirectly.
Stakeholder engagement outcomes – PACT Yr 1:

• **Strategic objective:**
  - Lay groundwork for PACT trial in 3 KP regions.
  - Thoroughly identify stakeholders now, so we can effectively engage them throughout trial.

• **What will be different as a result of engagement?**
  - Permission/sponsorship from high levels of organization
  - Operational support for trial
  - Learn about existing processes to conduct trial with least amount of disruption needed to deliver intervention
  - Obtain PROs and other clinical data to conduct and evaluate trial

• **What level of engagement do we need?**
  - Variable. Early efforts will focus on stakeholders who require highest level of engagement in order to launch the trial.
Identifying stakeholders

Determining who should be included is hardest part of stakeholder engagement

- Who will be affected by any decisions on the final design and implementation of the trial? Who will be impacted directly or ‘down stream’?
- What do they care about?
- Who is influential?
- Who can obstruct a decision if not involved?
- Who has been involved in this issue in the past?

For, PACT stakeholders are:

- All who need to give permissions or who will contribute meaningfully toward trial’s implementation.
- Representatives of groups whose daily work will be impacted by it.

If your goal is to be inclusive, identify your initial stakeholders and then ask THEM who else should be involved.

Start with the stakeholders you have the best rapport with.
What is stakeholder’s level of influence?

1 = Little
2 = Some
3 = Moderate
4 = Major
5 = Significant
What is the change YOU need stakeholder to make? What is likely impact on the stakeholder?

• Top level permission
• Perceive the trial as an opportunity, not a risk
• Access to people, processes, data
• Spread the word
• Change daily practice…
Put yourself in stakeholder’s shoes and ask “What’s in it for me?”

- Gather the information you need to answer this question.
- Briefly describe what the benefit of the trial is to the stakeholder(s)
- How the research team and/or the organization working to make the change easier for them
- Make sure to think about what the stakeholder(s) would consider to be a benefit or what they care about
Determine what level of engagement you seek

Inform
- Provide the right information to help people understand what is happening and what the opportunities are

Consult
- Get targeted feedback on what is working well, what is needed, and what can be done differently

Involve
- Work directly with staff to ensure their concerns and ideas are understood and considered throughout the process

Collaborate
- Partner with impacted staff on the actual decision process, including identifying alternatives and solutions

Empower
- Place final decision-making in the hands of impacted staff
Keep track of:

• Likely issues/needs for each stakeholder
• Concerns stakeholder as raised
• Response to concerns
• Communication plan
Example 1:

**Chief of Primary Care**

- **DESIRED CHANGE** “Sponsor” of PPACT trial. Promoting trial as regional priority will be seen as leadership-level commitment to comprehensive, integrated pain management.

- **POSSIBLE IMPACTS** Credibility, Blame, Backlash

- **“WIIFM”** Amelioration of major clinical/cost problem, reputation

- **INFLUENCE** Significant

- **ENGAGEMENT LEVEL** Collaborate

- **ISSUES/NEEDS** Minimize PCP burden of participating in trial

- **METHOD/COMMUNICATION PLAN** Busy schedule necessitates regular, focused electronic communications supplemented by targeted in person meetings
Example 2:

Pain Clinic Medical Director

- DESIRED CHANGE Create a partnership that melds clinical, scientific, and evaluation expertise to create optimal opportunity for success among complex patients with pain and their primary care providers. Help identify levels of services and resources to meet complex patient needs.

- POSSIBLE IMPACTS Wide-ranging

- WIIFM Enhance pain management options for complex patients

- INFLUENCE Some

- ENGAGEMENT LEVEL Collaborate

- ISSUES/NEEDS Avoid overlap/duplication of services. PPACT should improve tracking of patient treatment/outcomes.

- METHOD/COMMUNICATION PLAN Team meetings aimed at system level problem solving
Implementing an engagement plan means knowing **who** is doing what **when**

- Who is responsible?
- Who is being engaged?
- What method is being used?
- When will it happen?
- How often?
- How will we know it was effective?
Evaluating effectiveness

Evaluating what happened tells us what we need to do differently next time

- Through weekly journals and reactions to “postcards” we will assess:
  - Did we achieve intended outcomes?
  - Do people feel good about their engagement level?
  - Was resistance managed appropriately?
  - Who needs follow up?
  - What tactics worked?
  - What would we do differently next time?
Making revisions

Engagement planning should be iterative and adaptable and last throughout the change implementation

- Engagement often happens in small spurts rather than large chunks
- Reflect on lessons learned before the next engagement cycle (vanguard, intervention roll out, post-intervention evaluation)
- A formal survey or focus groups can provide additional feedback
- Along the way, make sure to report concerns, recommended actions & successes to leadership/sponsors
Summary of Key Points

• Study Context: unusual window of opportunity for launch of intervention requiring disruptive change in primary care setting (impact and management of opioid tx for chronic pain)

• Measurement / Data challenges: Ensuring PRO adequacy
  • Expect heterogeneity of data across settings, active iterative process for ensuring adequate quality and comparability of data for study purposes
  • Increased adoption of patient health records provides potential opportunity for ancillary data collection

• Engaging Key Stakeholders: novel methods and approach
  • Identify range of important stakeholders and assess appropriate level of engagement for each
  • Consider adoption of organizational change processes familiar to those you are working with and well-vetted in these settings
Questions?