PACT
Pain
Program for Active
Coping & Training

Successes Evolving From Constraints: Lessons Learned about Embedding Complex Pragmatic Trials in Delivery Systems

Collaborative Care for Chronic Pain

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Center for Health Research

Agenda

1. Study Background
2. Successes Evolving from Constraints:
   - Achieving the Robust Implementation of PROs
   - Innovative Qualitative Methods Driven by PCT Framework
   - Integrating Behaviorally Intensive Interventions into Primary Care Clinics…a Work in Progress
3. Wrap up – Q&A

Overall Study Aim and Approach

Coordinate and integrate services for helping patients adopt self-management skills for managing chronic pain, limit use of opioid medications, and identify exacerbating factors amenable to treatment that is feasible and sustainable within the primary care setting

- Implemented across KPNW, KP-Georgia, and KP-Hawaii regions
- Targeting patients with chronic pain from diverse conditions on long-term opioid therapy
- Prioritized recruitment based on operationally identified need:
  - Morphine equivalent dose (MEQ) ≥ 120mg
  - Concurrent opioid and benzodiazepine use
  - High utilization of primary care services (> 12 outpatient contacts / 3 months)
  - Other primary care provider (PCP) nominated patients

PPACT Pain Program for Active Coping & Training

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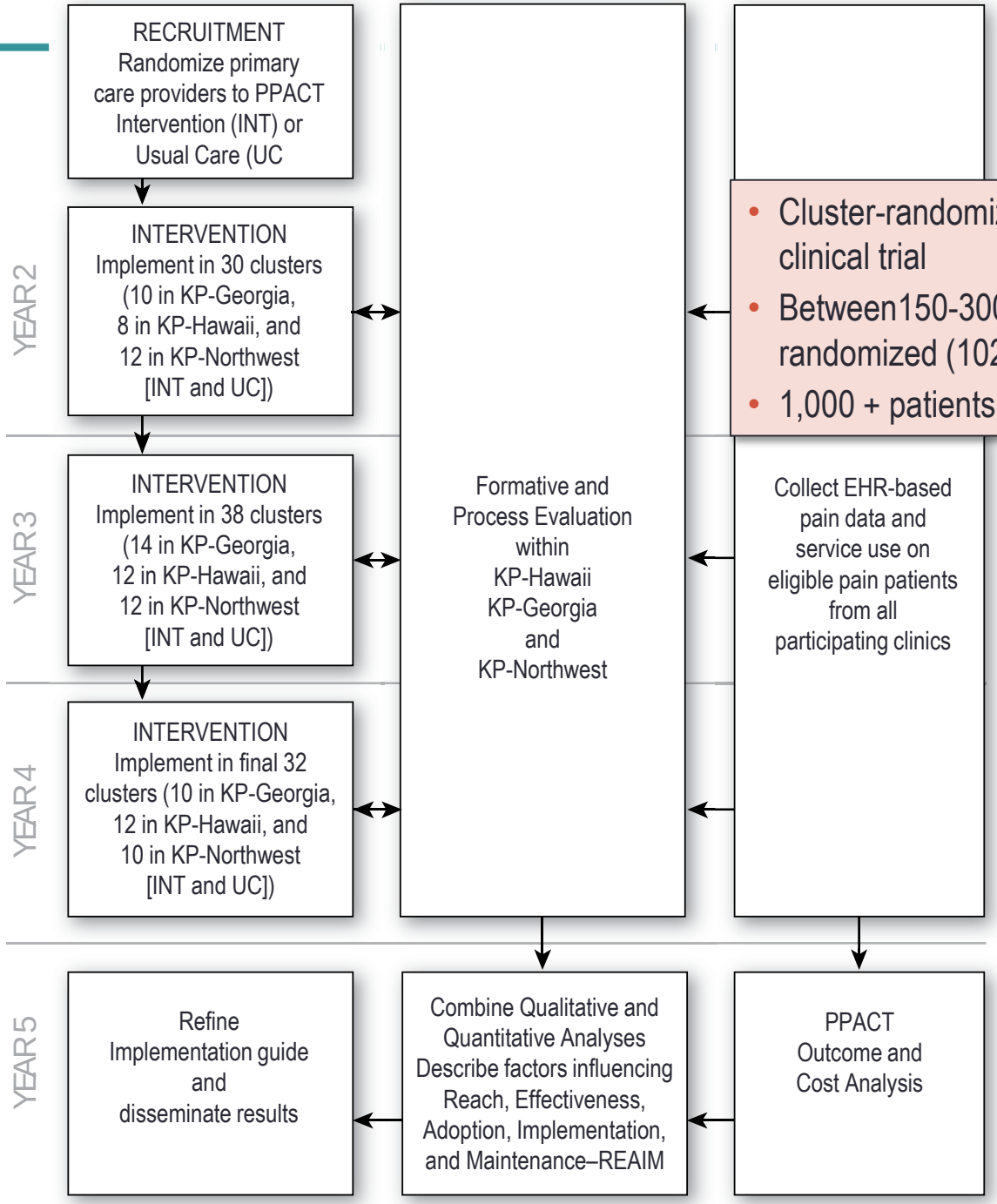
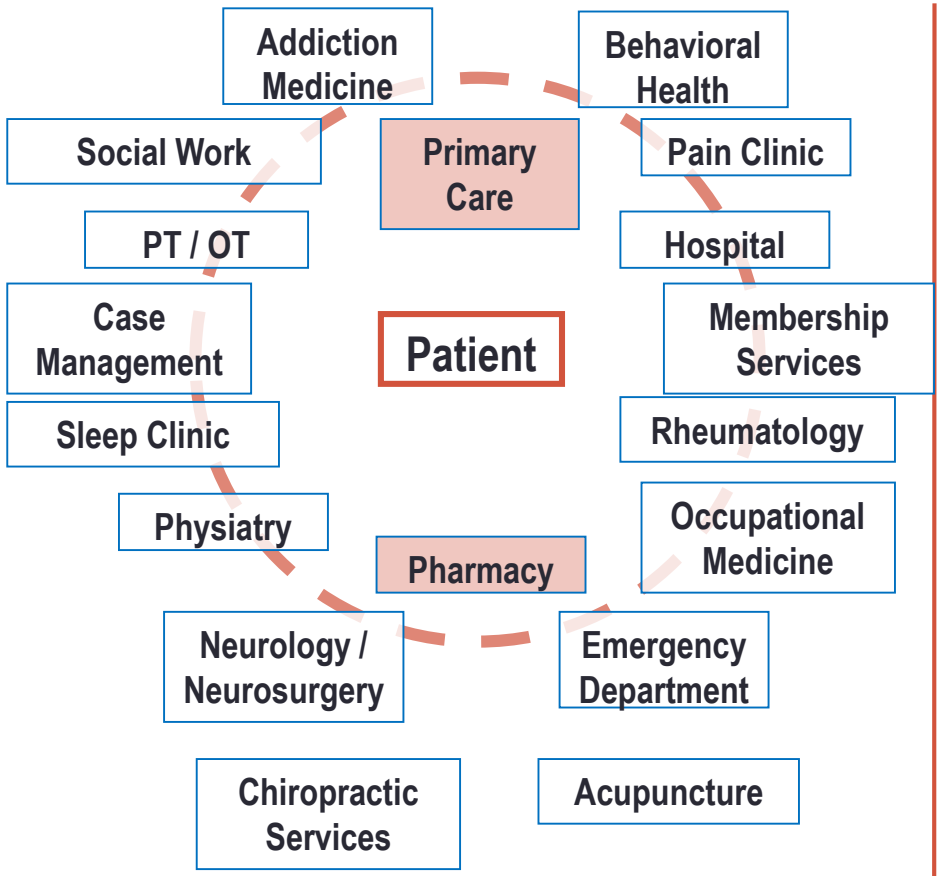
Trial Design

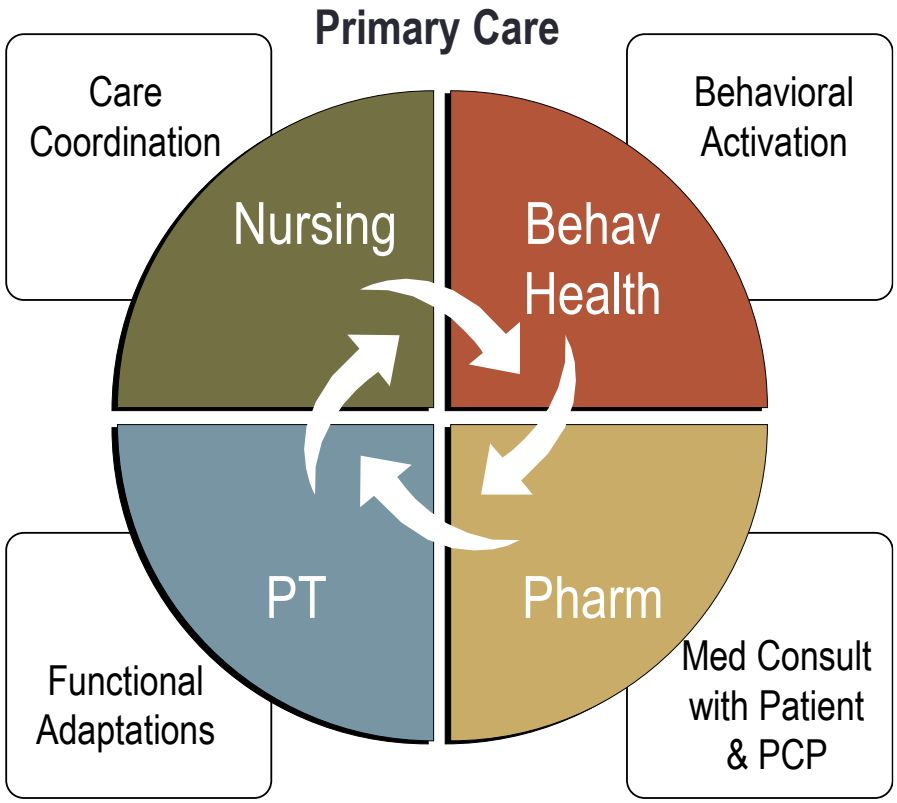


- Cluster-randomized pragmatic clinical trial
- Between150-300 PCPs will be randomized (102 clusters)
- 1,000 + patients

Pain Management: Usual Care



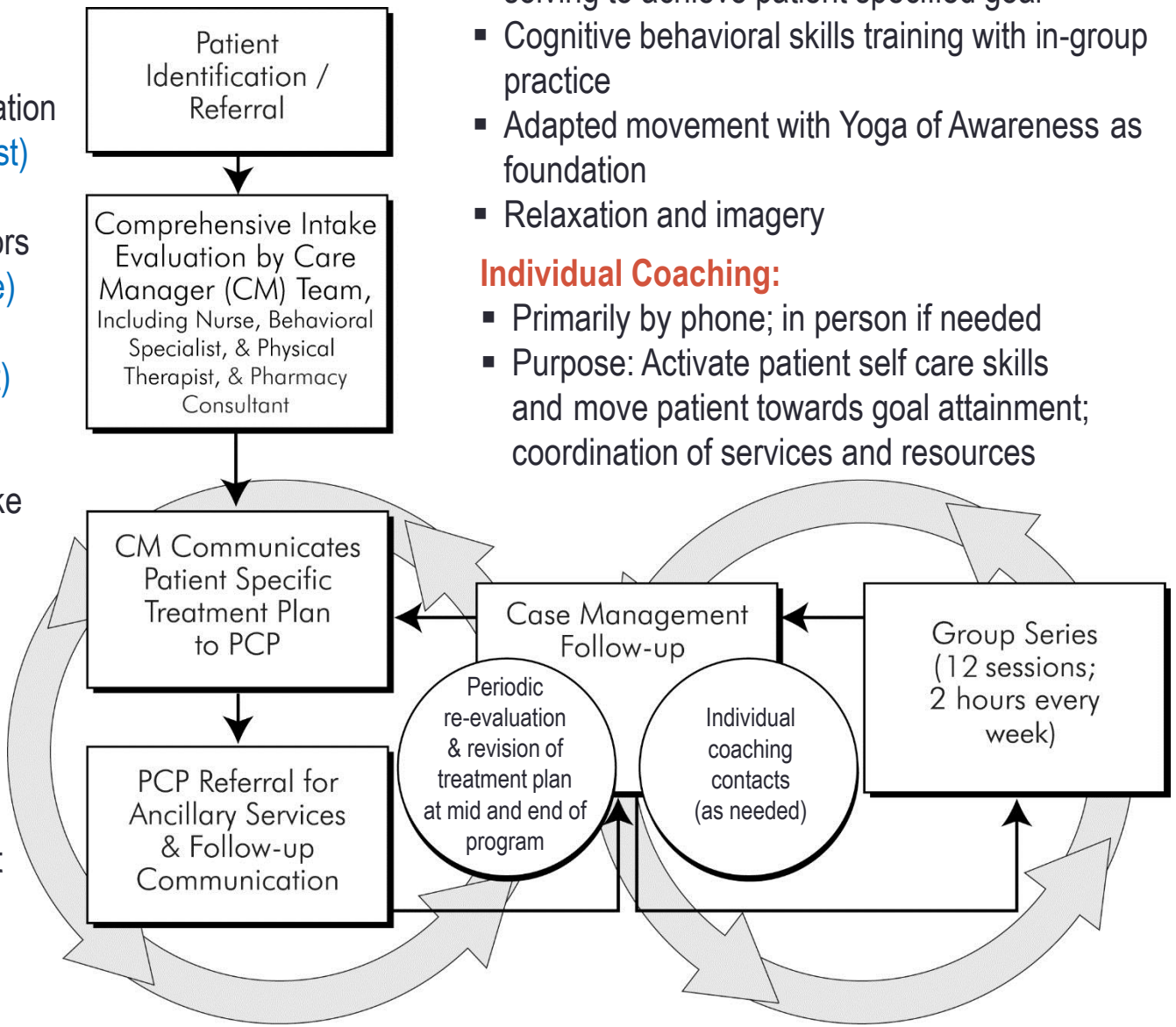
Interdisciplinary Management Embedded in Primary Care



About the Intervention

Comprehensive Intake:
- Functional and physical adaptation assessment (Physical Therapist)
- Behavioral assessment of biopsychosocial and contributors (Behavioral Specialist or Nurse)
- Medication review and recommendations (Pharmacist)

Communication with PCP:
- Brief, 1 page summary of intake assessment to PCP
- Dashboard of all assessment info documented in chart (linked from problem list)
- Template to guide PCP communication with patient
- Weekly progress notes from PPACT interaction with patient



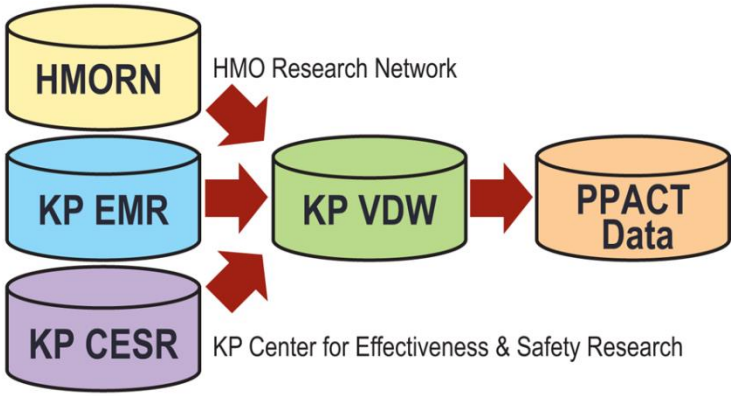
Group Session Components:
- Goal setting, barrier identification, problem solving to achieve patient specified goal
- Cognitive behavioral skills training with in-group practice
- Adapted movement with Yoga of Awareness as foundation
- Relaxation and imagery

Individual Coaching:
- Primarily by phone; in person if needed
- Purpose: Activate patient self care skills and move patient towards goal attainment; coordination of services and resources

Outcome Variables

Variable	Analytic Purpose
Brief Pain Inventory (BPI) **(Severity & Interference)**	Primary Outcome
Opioids Dispensed (in morphine equivalents)	Secondary Outcome
Pain related treatment or diagnostic procedures	Secondary Outcome
Use of emergency / urgent care services	Secondary Outcome
Use of primary care services	Secondary Outcome
Use of specialty care services	Secondary Outcome
Total health service use & cost	Secondary Outcome
Comorbidities (Depression, anxiety, obesity/BMI, chronic disease burden, sleep difficulties)	Covariates
Patient satisfaction	Secondary Outcome
Exercise as Vital Sign (EVS)	Secondary Outcome

- 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



Key Contextual Issues

PROBLEMS

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

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

REALITY

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

SOLUTIONS

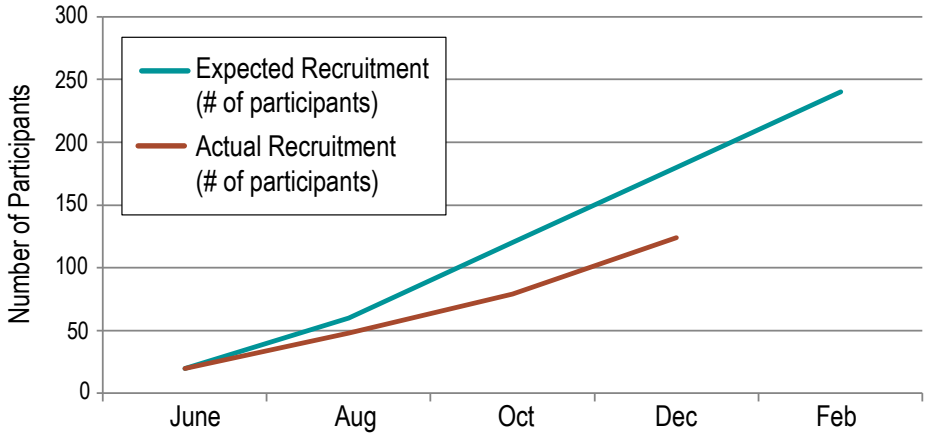
Optimal management relies on patient self-care

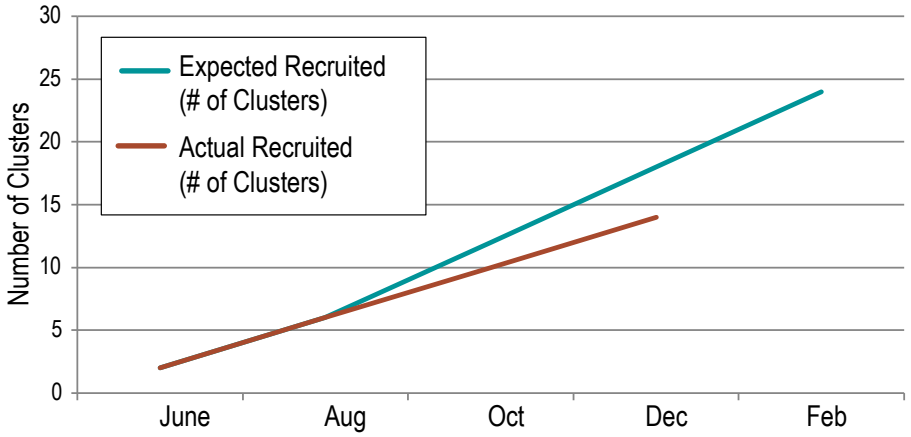
- Chronic illness management necessitates an activated patient
- Provider-directed treatments not practical nor sustainable

Multidisciplinary, multimodal treatment shows promise

- Synthesizes expertise from diverse medical professionals
- Combines multiple modalities targets multitude of factors that influence pain

Progress to Date





69% recruitment yield to date

Challenges: Training, staffing, and recruitment in outer regions

Solutions: local touch critical for recruitment, more structure in supporting regional staffing and training

ACHIEVING ROBUST IMPLEMENTATION of PROs

Clinical Context: KPNW Operational Response to Opioid Use

- Motivating factors for systematic clinical response
  (safety & efficacy concerns)
  - High dose opioid prescribing
  - Primary care in need of assistance
- Opioid Use Improvement Project (OUI)

Objectives:

- Improve patient safety
- Improve provider and team support
- Improve outcomes with chronic pain management

Opportunity for implementation of pain-related PRO

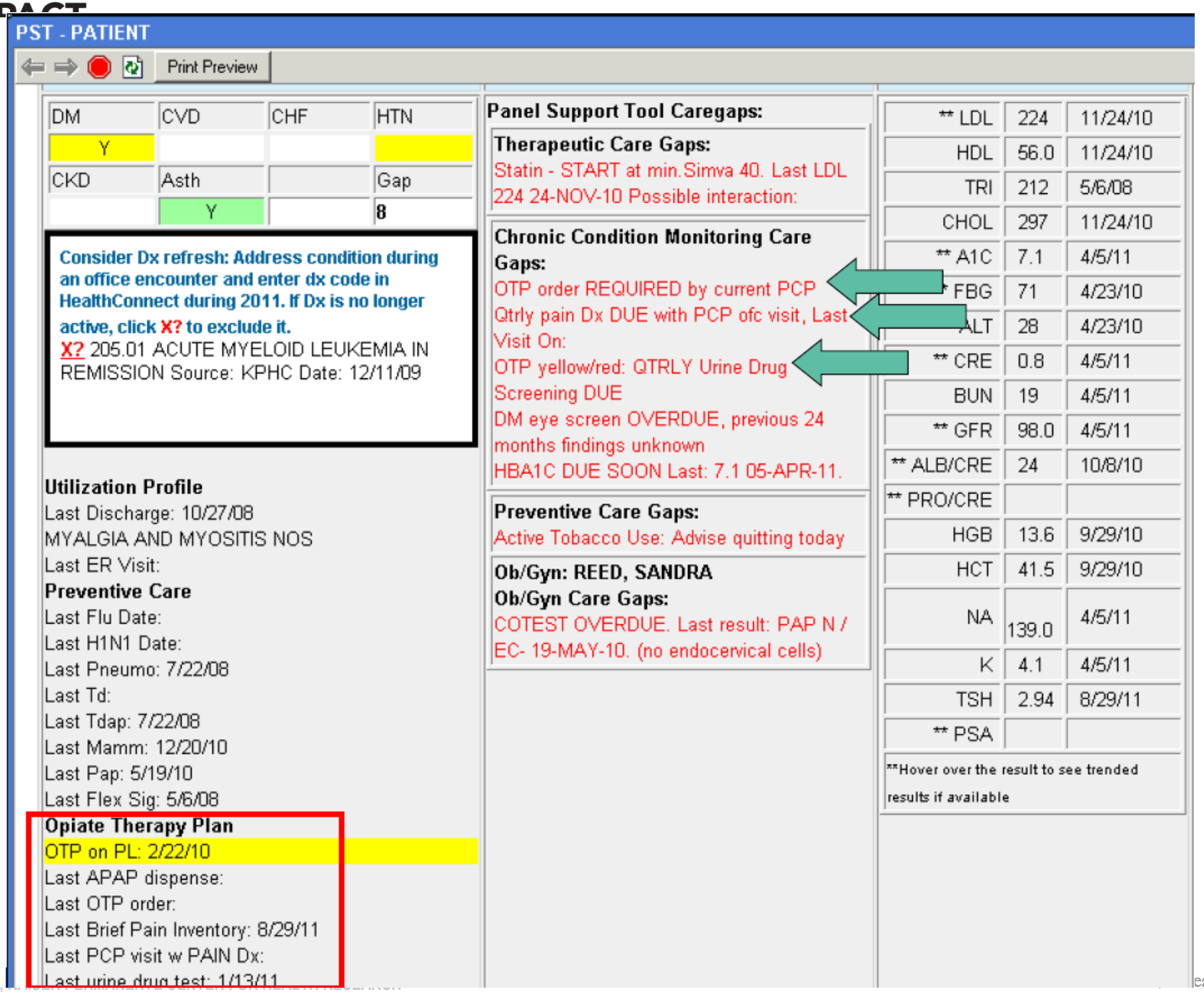
Opioid Therapy Plan (OTP) Operational Criteria

PATIENT CRITERIA	BASIC GREEN	COMPLEX YELLOW	COMPLEX RED
Follows plan reliably	X		
No history of opioid abuse	X		
No history of other substance abuse within past 2 years	X		
No current behaviors indicating drug misuse	X		
Current behaviors raise questions about the ability to follow the OTP		X	
History of opioid abuse		X	
History of other substance abuse within past 2 years		X	
Calculated overall opioid dosing level at 180mg morphine equivalent or higher		X	
Have demonstrated repeated problems following the OTP (e.g. unexpected UDS)			X
Active substance abuse			X
Have current behaviors which raise concerns about possibility of diversion			X

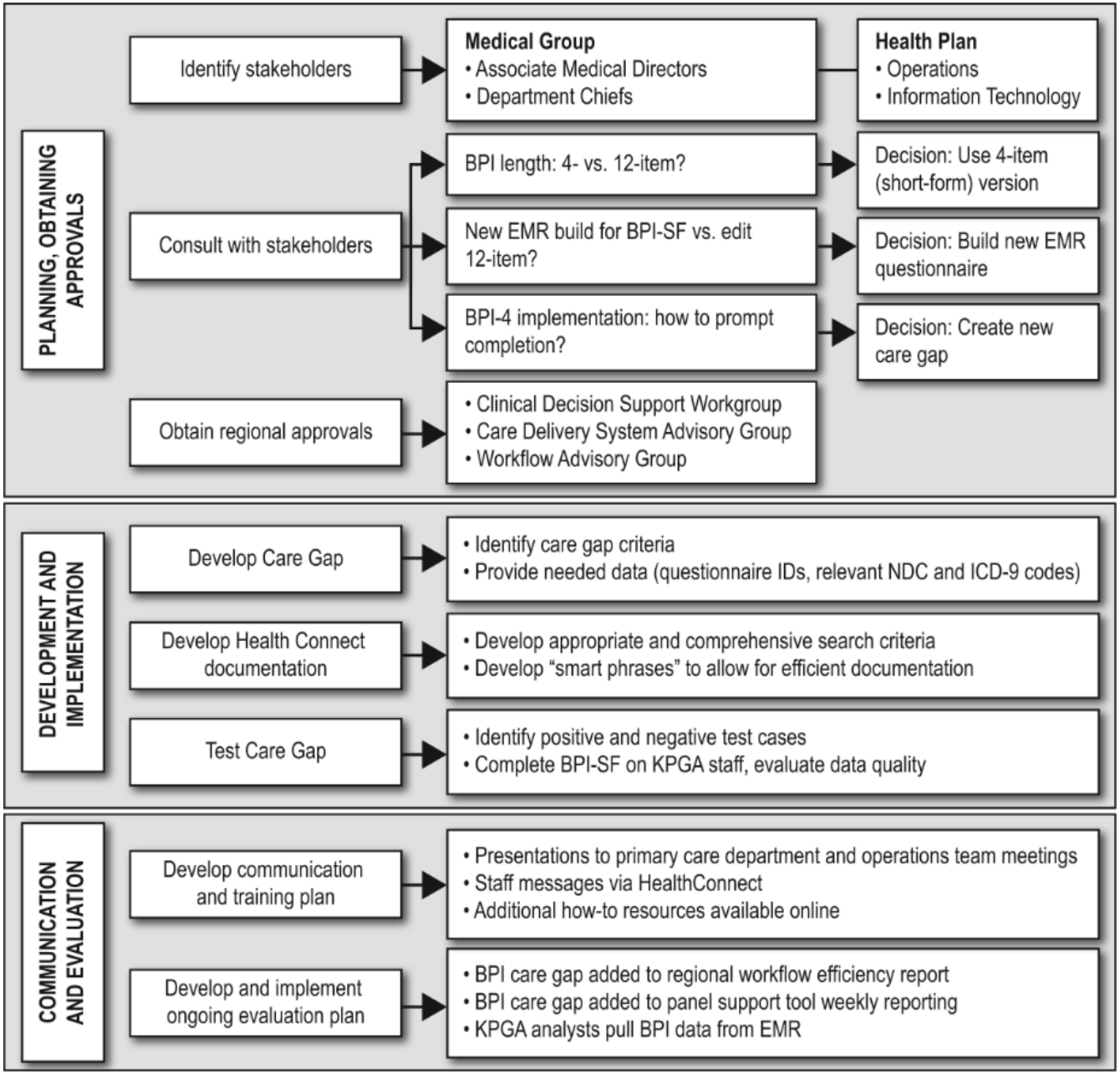
PCP REQUIREMENTS	BASIC GREEN	COMPLEX YELLOW	COMPLEX RED
Office visit frequency (minimum)	Semi-annually (1 may be TAV)	Quarterly (2 may be TAVs)	Quarterly (no TAVs)
Office visit required for any dosing changes	No	Yes	Yes
Brief Pain Inventory (BPI) completed (minimum)			
[Recommended to be administered at every office visit]	Semi-annually	Quarterly	Quarterly
Refresh pain diagnosis on problem list	Yearly	Yearly	Yearly
Verify current dosing level is reflected on OTP on the problem list	Yes	Yes	Yes
Discuss with the patient their use of opioid, non-opioid and non-pharmacological modalities to control pain	Each visit	Each visit	Each visit
UDS ordered and resulted (minimum)	Yearly	Quarterly	Quarterly
Confirm random pill counts completed	PRN	2x/Year & PRN	2x/Year & PRN
Create AVS or send letter with patient's dosing and instructions after dosing change	Yes	Yes – AVS only	Yes – AVS only
Create separate monthly opioid prescriptions, no refills and no mail order	No	Yes*	Yes
Early refills for travel	Yes	Yes	Up to 2/year
May refill prescriptions early for lost or stolen reasons (Police report needed before receiving refill of stolen medications)	Yes	Limited supply only	No
New OTP required when prescriber changes or OTP color changes	Yes	Yes	Yes

Kaiser Permanente's Panel Support Tool

- Web-based software extracts information from KP HealthConnect EMR (Epic) to help physicians improve and manage patient care
- Highlights "gaps" between delivered care and guidelines for chronic disease management and preventive care.
- Includes "gaps" associated with OTP (regular administration of Brief Pain Inventory)
- Specifies actions a primary care team must take to resolve these gaps both for individual patients and across PCP panel


PST - PATIENT
Print Preview
DM
CVD
CHF
HTN
Y
CKD
Asth
Gap
Y
8
Consider Dx refresh: Address condition during an office encounter and enter dx code in HealthConnect during 2011. If Dx is no longer active, click X? to exclude it.
X? 205.01 ACUTE MYELOID LEUKEMIA IN REMISSION Source: KPHC Date: 12/11/09
Utilization Profile
Last Discharge: 10/27/08
MYALGIA AND MYOSITIS NOS
Last ER Visit:
Preventive Care
Last Flu Date:
Last H1N1 Date:
Last Pneumo: 7/22/08
Last Td:
Last Tdap: 7/22/08
Last Mamm: 12/20/10
Last Pap: 5/19/10
Last Flex Sig: 5/6/08
Opiate Therapy Plan
OTP on PL: 2/22/10
Last APAP dispense:
Last OTP order:
Last Brief Pain Inventory: 8/29/11
Last PCP visit w PAIN Dx:
Last urine drug test: 1/13/11
Panel Support Tool Caregaps:
Therapeutic Care Gaps:
Statin - START at min.Simva 40. Last LDL 224 24-NOV-10 Possible interaction:
Chronic Condition Monitoring Care Gaps:
OTP order REQUIRED by current PCP
Qtrly pain Dx DUE with PCP ofc visit, Last Visit On:
OTP yellow/red: QTRLY Urine Drug Screening DUE
DM eye screen OVERDUE, previous 24 months findings unknown
HBA1C DUE SOON Last: 7.1 05-APR-11.
Preventive Care Gaps:
Active Tobacco Use: Advise quitting today
Ob/Gyn: REED, SANDRA
Ob/Gyn Care Gaps:
COTEST OVERDUE. Last result: PAP N / EC- 19-MAY-10. (no endocervical cells)
** LDL 224 11/24/10
HDL 56.0 11/24/10
TRI 212 5/6/08
CHOL 297 11/24/10
** A1C 7.1 4/5/11
* FBG 71 4/23/10
ALT 28 4/23/10
** CRE 0.8 4/5/11
BUN 19 4/5/11
** GFR 98.0 4/5/11
** ALB/CRE 24 10/8/10
** PRO/CRE
HGB 13.6 9/29/10
HCT 41.5 9/29/10
NA 139.0 4/5/11
K 4.1 4/5/11
TSH 2.94 8/29/11
** PSA
**Hover over the result to see trended results if available

Establishing Routine BPI Administration in Clinical Workflow



Reality: PRO Data Collected in Everyday Clinical Work…

- Timing and amount of data variable
  - Heterogeneity across health care providers
  - More frequent PRO collection among patients with higher rates of health care use
  - Less routine collection among patients showing improvement
- Need to support "enhanced" PRO collection for evaluation and improved clinical utility
  - Low burden modes of collection critical to encourage more frequent PRO collection (e.g., Personal Health Record / e-mail, IVR)
  - Piloting suggested that shorter (4- vs 12-item BPI) and more targeted scale (emphasis on functioning) improved work flow and clinical utility
- IT/medical informatics partnerships have been critical for successful PRO integration into clinical care workflow and "enhanced" collection process

Process for "Automated" Enhanced PRO* Collection

Personal Health Record / email (www.kp.org)

* 4-item BPI using all modalities, treatment satisfaction collected by telephone

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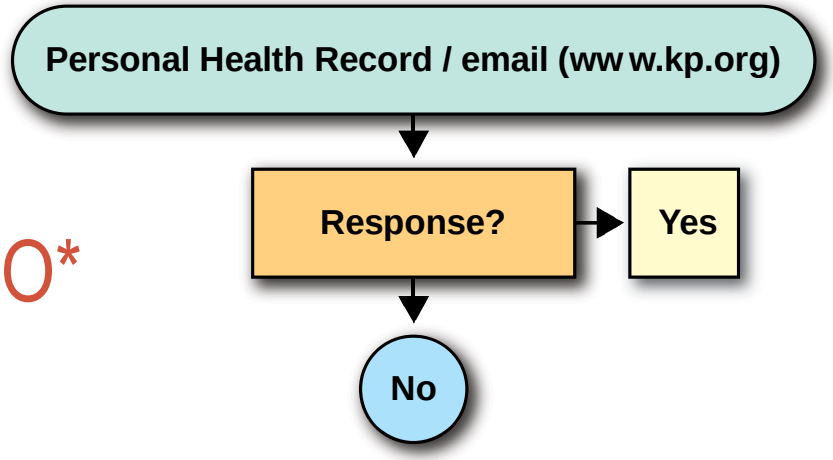

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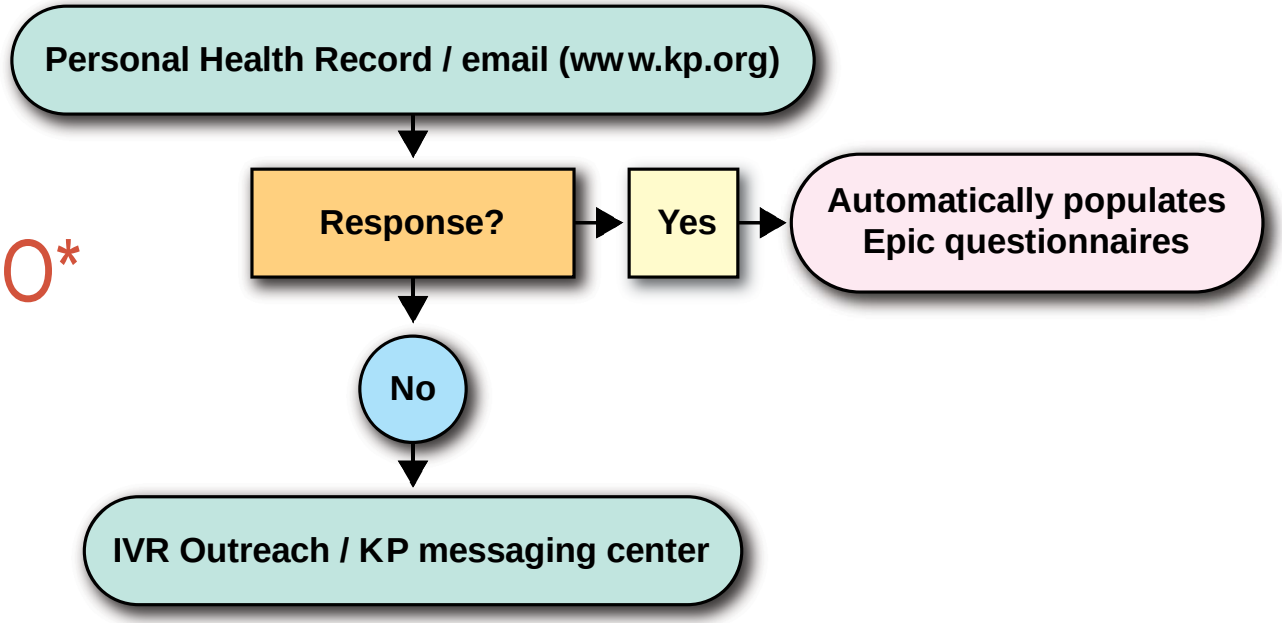

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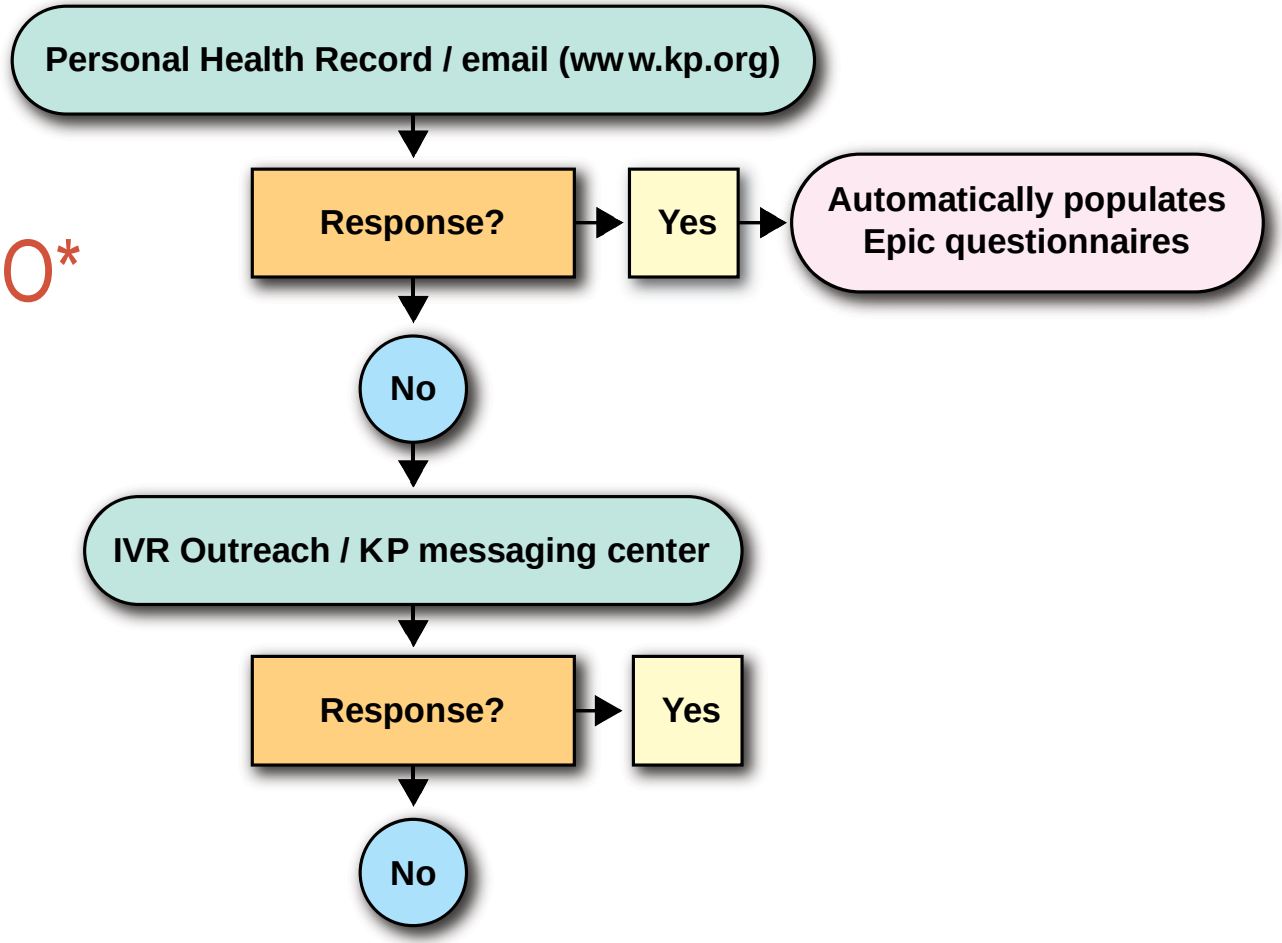

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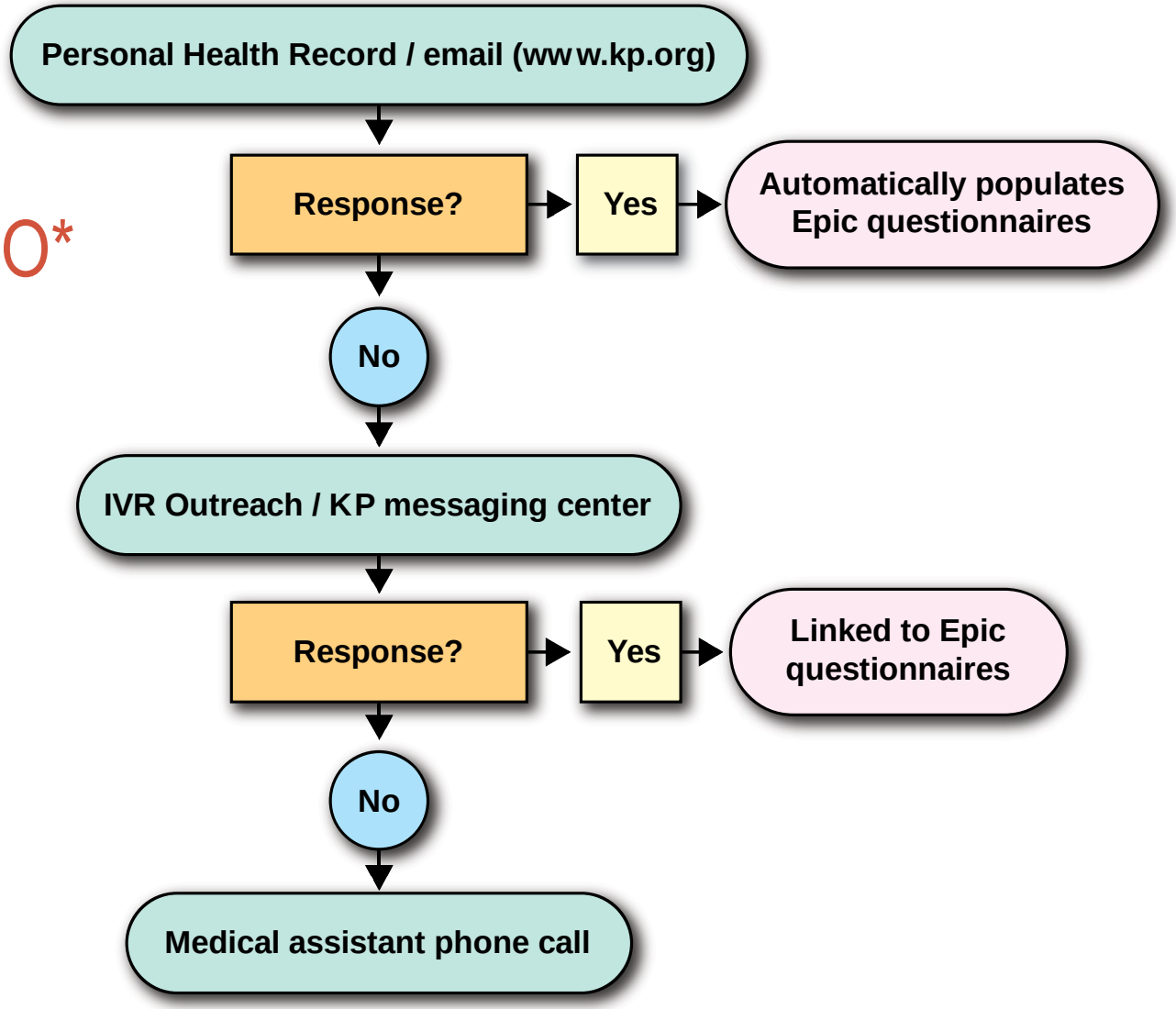

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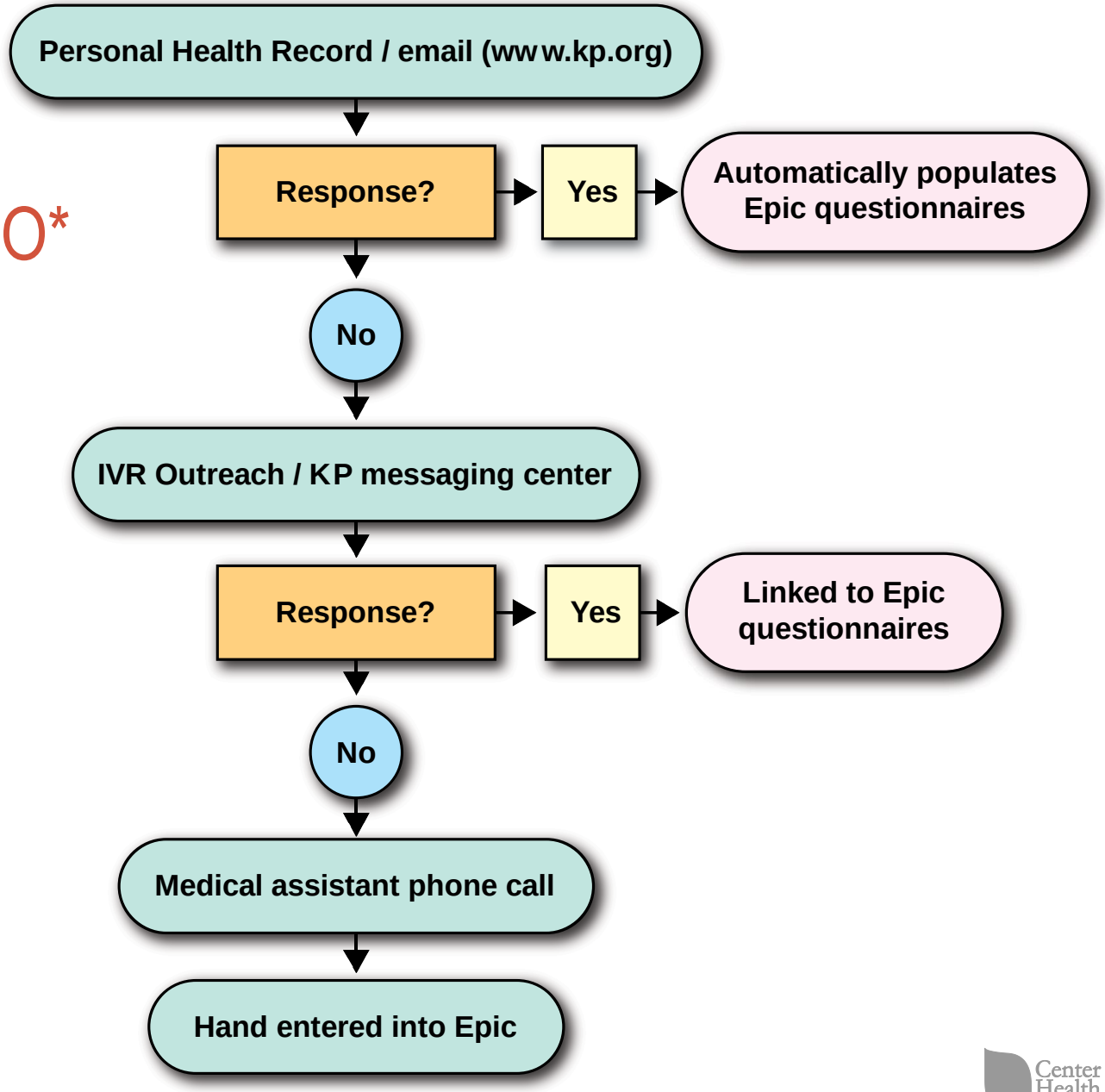

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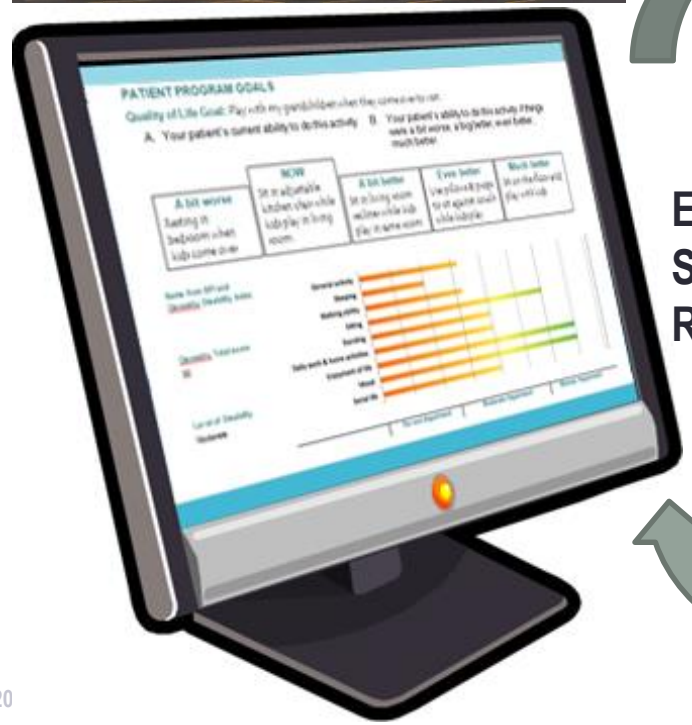
Using Untethered Systems to Build EMR Embedded Actionable Reports

Online
or paper
collection

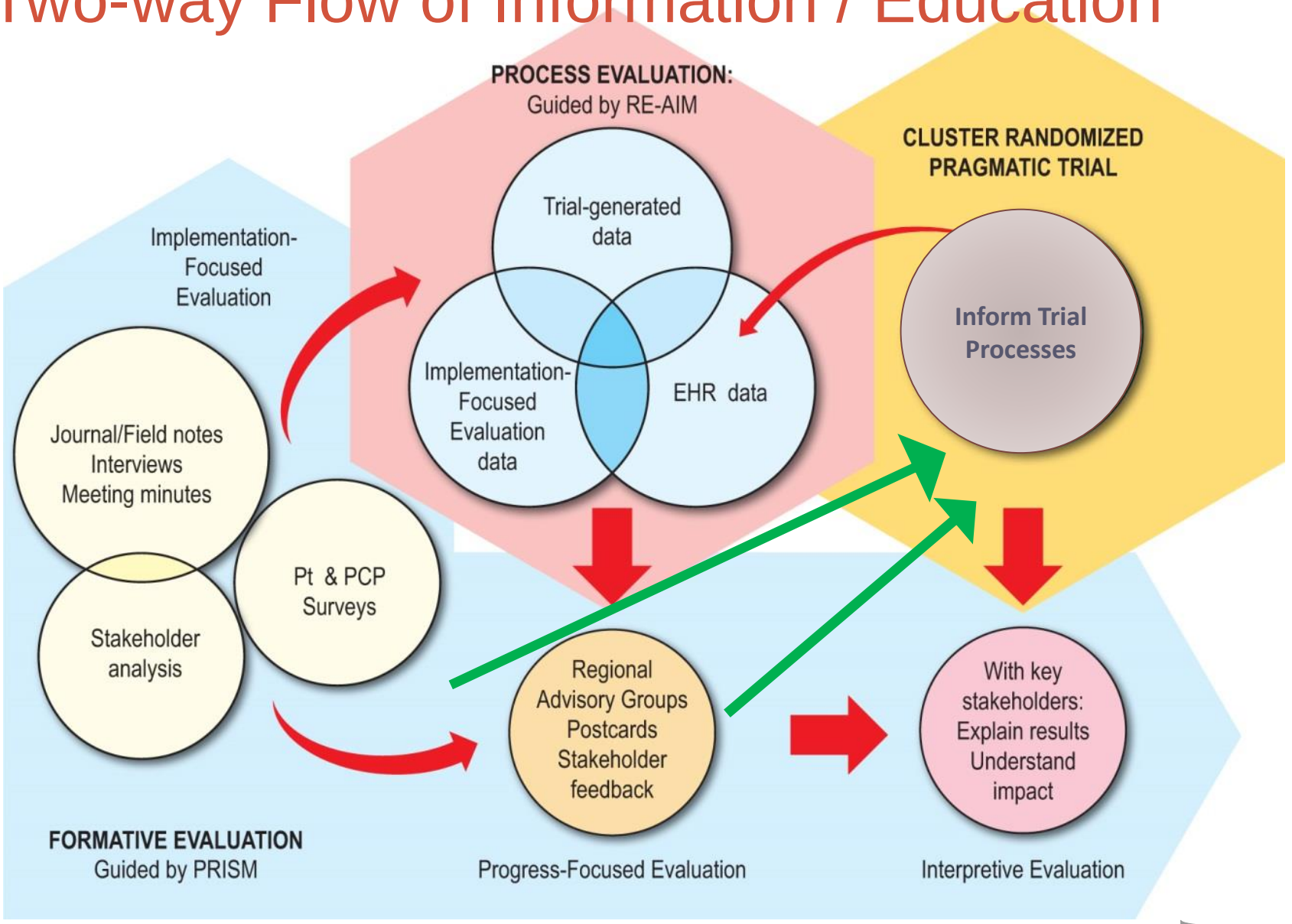


EMR Provider
Summary
Report

Scoring or
compilation
of relevant
assessments

INNOVATIVE QUALITATIVE METHODS DRIVEN BY PCT FRAMEWORK

Two-way Flow of Information / Education



Formative evaluation considerations:

- Need fast turn around
- Stakeholder engagement is happening all the time – why not take advantage of it?
- Learn a lot "off the record"
- Observing routine interactions/meetings often more helpful than formal feedback

Rapid Assessment Process (RAP)

- Rapid but not rushed. Iterative but not haphazard
- Quickly understand the insider's perspective on a situation and 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

Beebe "Rapid Assessment Process" (2001) Altamira Press.
McMullen et al. Methods of Information in Medicine 2011; 50(4):299-307
Bunce et al. BMC Health Services Research (forthcoming).

Our Rapid Assessment Process Toolkit:

- Informal stakeholder conversations
- Mapping (organizational relationships, processes)
- Weekly journaling by study staff
- "Postcards" to inform stake-holders and prompt dialogue
- Along with more traditional qualitative techniques: Interviews, naturalistic observation (fieldwork), brief surveys, focus groups

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PPACT

PPACT Postcard #5, May, 2014

With every step forward in science and medicine, lives are touched. Sometimes millions of them. And each one of those lives comes with a story.

The NIH Common Fund, the primary sponsor of PPACT, asked researchers from funded projects to create short videos that explain their studies in simple terms. In our video, you'll meet Katie, a PPACT participant at KP Northwest who says being involved in our trial has given her a new lease on life after decades of struggling with chronic pain. You'll also hear from her primary care provider, who reflects on the value of empowering patients to manage their chronic conditions.

Katie's story shows how conducting research in our delivery systems can have transformational effects–one patient and provider at a time.

Please take a moment to watch the video, and feel free to share it with your colleagues.

Until next time,

Lynn DeBar, PhD & the PPACT team at
The Center for Health Research
(Hawaii, Georgia, Northwest)

PPACT Team
Kaiser Permanente
USA

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paper for health research

Center for Health Research

What are providers saying about PACT ?

"From our end, it seemed seamless."

"The group setting is powerful."

"Patients are more motivated to talk."

"Workload on the physician end has been easy."

"It's a win-win."

"You see less burden on the system."

Center for Health Research

What are providers saying about PPACT ?

PPACT Postcard #6, June, 2014

In the early stages of PPACT, we checked in with several providers to ask about their firsthand experience with the project in their clinics. Here's a sampling of what we heard:

"[PPACT] gives us another avenue to help take care of probably the most difficult patients who cause providers the most stress."

"Chronic pain patients need a lot of visits, a lot of phone calls and emails, all that kind of stuff. I think this program could help [relieve] primary care physicians from some of that duty."

"The workload on the physician end has been very easy."

"The group setting is powerful."

"You're giving them more tools to deal with their pain. With that comes an improvement in mood–it's all tied together. You're giving them some life goals. Then you see less visits to the doctor, less phone calls, less burden on the system. It's a win-win."

We look forward to sharing more feedback with you in the months ahead.

Until next time,

Lynn DeBar, PhD & the PPACT team at
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Kaiser Permanente
USA

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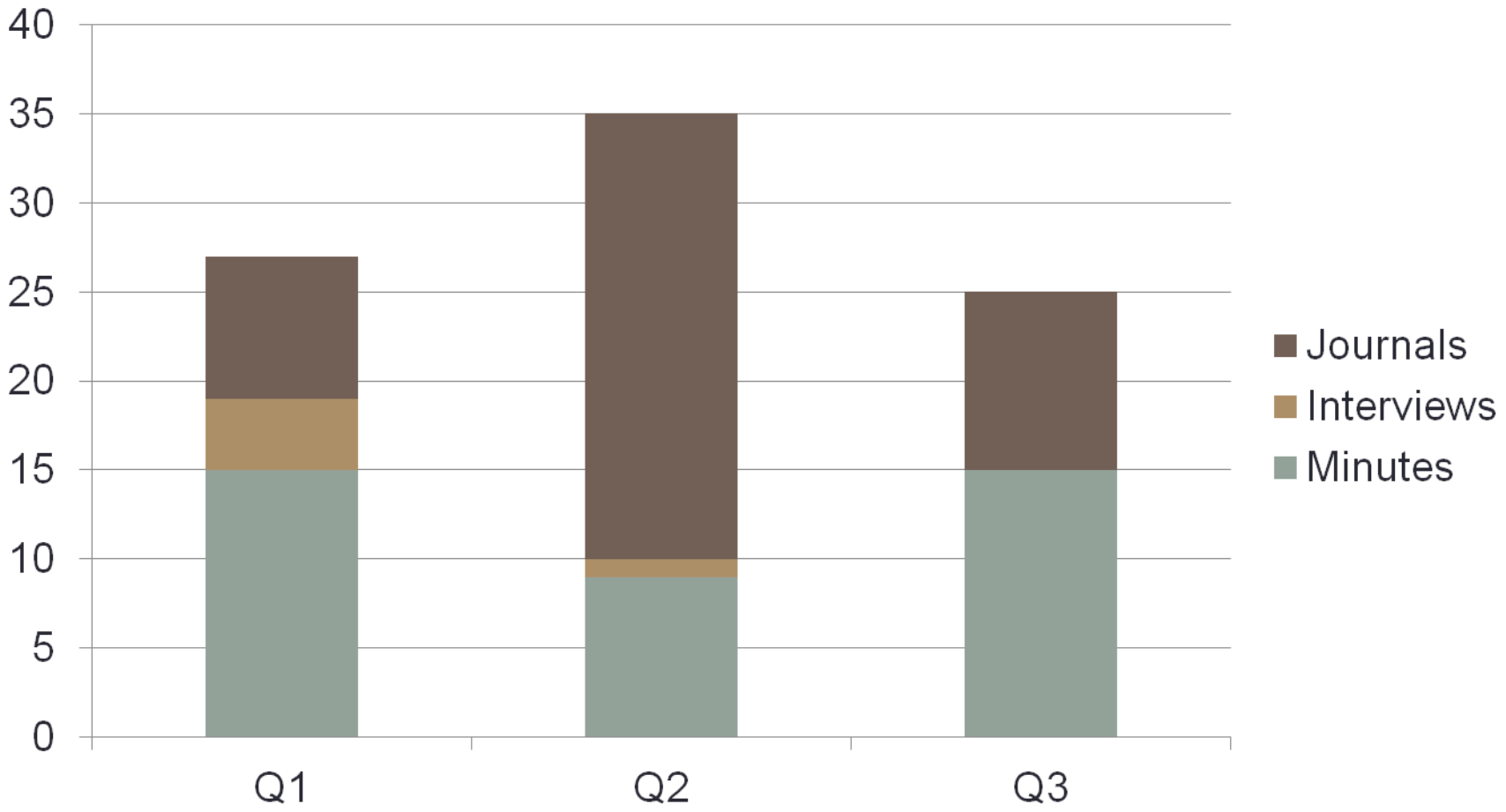
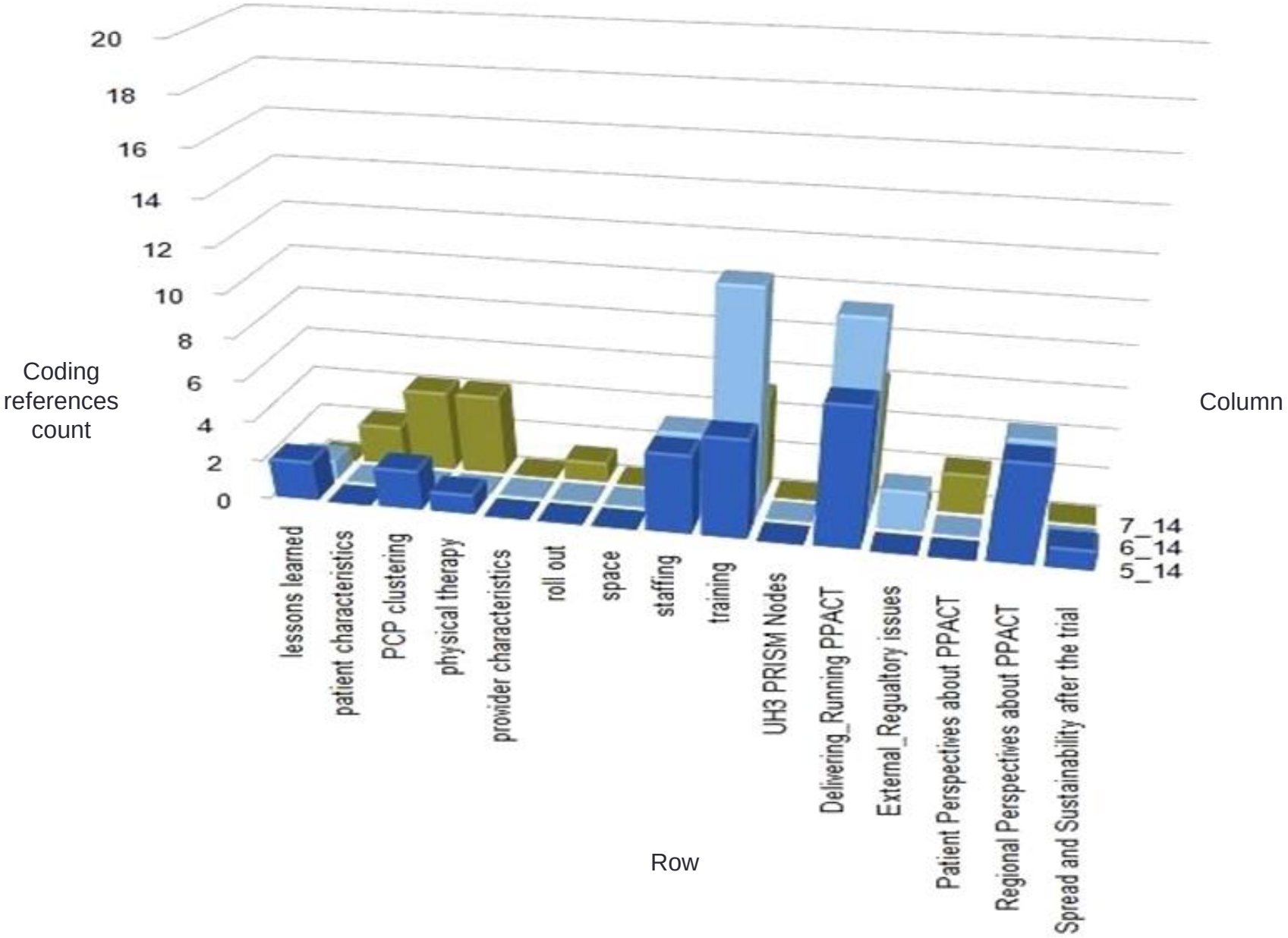
Formative Evaluation: Data sources



Rapid analysis creates “snapshots” of our trial

1. Code data elements (“big bucket” categories)
2. Review data in each category, by region
3. Synthesize main messages
4. “Member check” with study team
   - Validate findings
   - Identify areas for further data collection
   - Identify possible mid-course corrections, communication needs
5. Document changing understanding over time

What are people journaling about?



Stakeholder updates: translation in action

- Getting a seat at the table involves speaking the same language
- Avoid “code switching” to fit in
- Asked health system project managers: How do you give updates? To whom?

- Advisory Group Communication:
  - 1-page update (can be shared)
  - Case studies (in-depth discussion, learning)
  - Questions for advisory group (“We are your brain trust”)

Stakeholder updates: translation in action

Clinical/health system

- Who, among patients receiving pain services, is enrolling in the trial?
- Opioid reduction?
- How many ED visits are avoided?
- How much is PCP burden reduced?
- Case studies?

Clinical Trial

- Who is the denominator?
- Can't look at study outcomes
- Share some survey results
- Share case studies

Key Learnings: Formative Evaluation

- Getting a seat at the table is crucial, but takes persistence
- Shifts in leadership positions requires ongoing renegotiation
- Most valuable information is not attainable using traditional interviews and focus groups
- Different communication strategies for different stakeholders
- Regular feedback to stakeholders critical
  - Multiple modalities helpful (advisory groups, postcards, 1-page updates, 1-on-1)
  - Emphasize illustrative stories/case histories rather than quantitative interim results (easily misinterpreted with small numbers)
- In formative evaluation, keep asking “what don’t we know?” and adapt qualitative data collection to fill the gaps

INTEGRATING BEHAVIORALLY INTENSIVE INTERVENTIONS INTO PRIMARY CARE CLINICS … A WORK IN PROGRESS

Better Scaffolding Needed to Encourage Patient Activation

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  - Nurse and behaviorist intervention staff choice and training aimed at shifting frame of care

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  - Nurse and behaviorist intervention staff choice and training aimed at shifting frame of care
- Dominant health care system structure not culturally consistent with prioritization of lifestyle/behavioral management for chronic pain tx
  - Increase patients and PCPs understanding of neuroscience underlying physiological changes resulting from cognitive behavioral tx approaches

Unanticipated downsides to Cluster Randomized Design

- Shifted from clinic to primary care provider level clustering
- Increased power and opportunity for randomization, distributed potential sources of bias more evenly, but…

Unanticipated downsides to Cluster Randomized Design

- Shifted from clinic to primary care provider level clustering
- Increased power and opportunity for randomization, distributed potential sources of bias more evenly, but…

- Not a good reflection of how clinical care occurs for this condition
  - Clustering and "contamination" concerns limits PCPs ability to learn and enroll patients when they are ready
  - Intervention is somewhat artificial
  - Potential response: embedding experience of "like" providers/patients in process through the strategic use of video-storytelling/ethnography
- Tracking patients paneled to particular PCP at given time is very resource intensive

Lessons learned: Closing thoughts on conducting multi-faceted behavioral pragmatic trials

- General lessons:
  - Robust PRO collection and display through clinical delivery system and EMR likely requires additional support
  - Communication and stakeholder engagement strategies should be native to health care system, and customized to the audience
- Lessons specific to Behavioral and/or Complex interventions:
  - Consequences of enrolling “all comers” in evolving health care systems
  - Continue to expect the unexpected -- there is not a discrete “start up” phase
  - We need to do these behavioral pragmatic trials, but they are more complicated and expensive than traditional randomized clinical trials