Lessons Learned about Embedding Complex Pragmatic Trials in Delivery Systems: Collaborative Care for Chronic Pain

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PPACT Study Design & Rationale

The “ask” from clinical and health plan leadership…

How do we keep our primary care providers from burning out and leaving the health care system?

What do we do with the patients with complex pain who “belong to everyone and no one?”

Policies/guidelines

NCQA, State Medical Boards, DEA opioid prescription mandates

Changes in expectations

Shifting marijuana laws & policies

Brief visits

Complicated patients

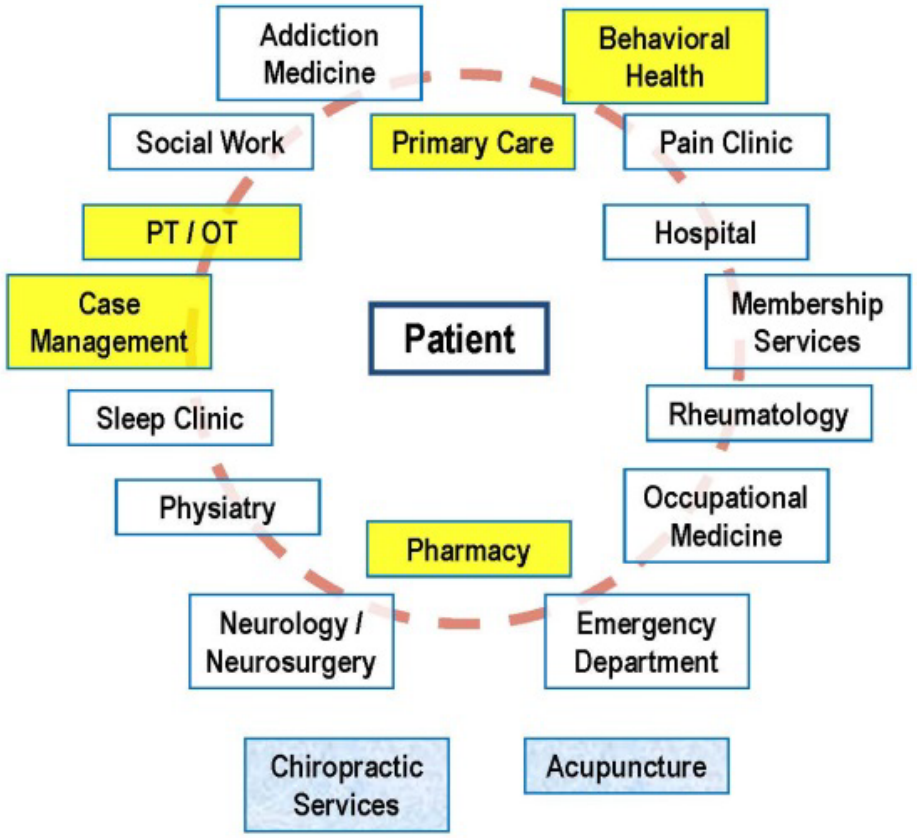
Gaps in coordination with specialty care

Measurement and alert fatigue

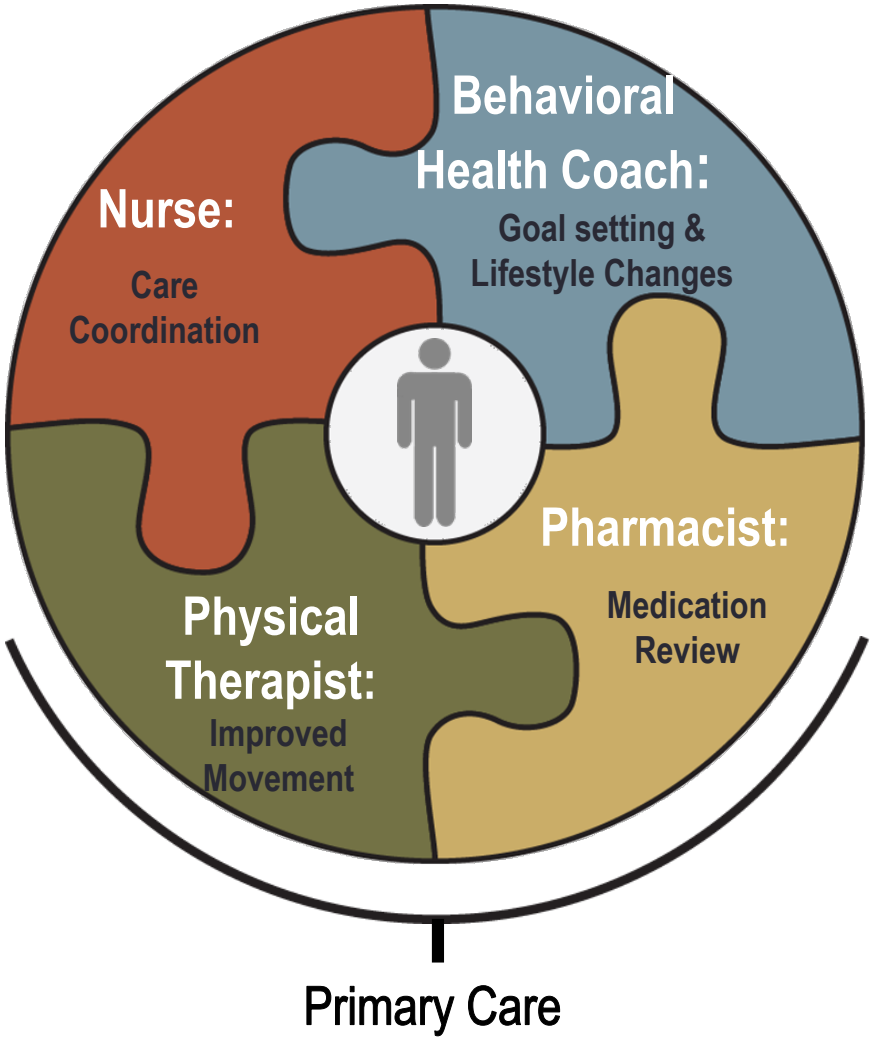
Limited pain treatment options

adapted with permission from Rollin Gallagher

Pain Management in Usual Care



Interdisciplinary Pain Management Embedded in Primary Care



DeBar et al, Contemporary Clinical Trials, 2018;
DeBar et al, Translational Behavioral Medicine, 2012

PPACT Overview

AIM: Integrate interdisciplinary services into primary care to help patients adopt self-management skills to:

- Manage chronic pain (decrease pain severity / improve functioning)
  - Limit use of opioid medication
  - Identify exacerbating factors amenable to treatment

Focus on feasibility and sustainability

DESIGN: Cluster (PCP)-randomized PCT *(106 clusters, 273 PCPs, 851 patients)*

ELIGIBILITY: Chronic pain, long-term opioid tx (prioritizing ≥ 120 MED, benzodiazepine co-use, high utilizers [≥ 12 visits in 3 months])

INTERVENTION: Behavioral specialist, nurse case manager, PT, and pharmacist team; 12 week core CBT + adapted movement groups

OUTCOMES: Pain (3-item PEG), opioid MED, pain-related health services, and cost

Outcome Variables

Table 1. PPACT Outcome Variables

Measure		Source	Schedule of Assessment					
			Up to 12 months preceding patient enrollment	Study Month				
				0	3	6	9	12
Patient-Reported Outcomes								
PEG	Primary outcome	Study survey		✓	✓	✓	✓	✓
Roland Morris Disability Questionnaire	Secondary outcome	Study survey		✓	✓	✓	✓	✓
Patient Satisfaction Survey	Secondary outcome	Study survey		✓		✓		
Medication-Related Outcomes								
Opioids dispensed	Secondary outcome	EHR						
% of patients with morphine equivalents ≥ 90 and morphine equivalents ≥ 50	Secondary outcome	EHR						
Benzodiazepines dispensed	Secondary outcome	EHR						
Health Service Utilization								
Primary care utilization (outpatient visits, emails, telephone contacts and total)	Secondary outcome	EHR						
Emergency and urgent care services	Secondary outcome	EHR						
Use of specialty pain services (physiatry, pain clinic, physical and occupational therapy)	Secondary outcome	EHR						
Overall outpatient service utilization	Secondary outcome	EHR						
Inpatient services related to pain condition	Secondary outcome	EHR						

Unique Features of Complex Behavioral PCTs? PRECIS footprint / cluster randomization downside

RESEARCH Open Access

Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory

Trials

Karin E. Johnson[1†], Gila Neta[2*†], Laura M. Dember[3], Gloria D. Coronado[4], Jerry Suls[2], David A. Chambers[2], Sean Rundell[5], David H. Smith[4], Benmei Liu[2], Stephen Taplin[2], Catherine M. Stoney[6], Margaret M. Farrell[2] and Russell E. Glasgow[7]

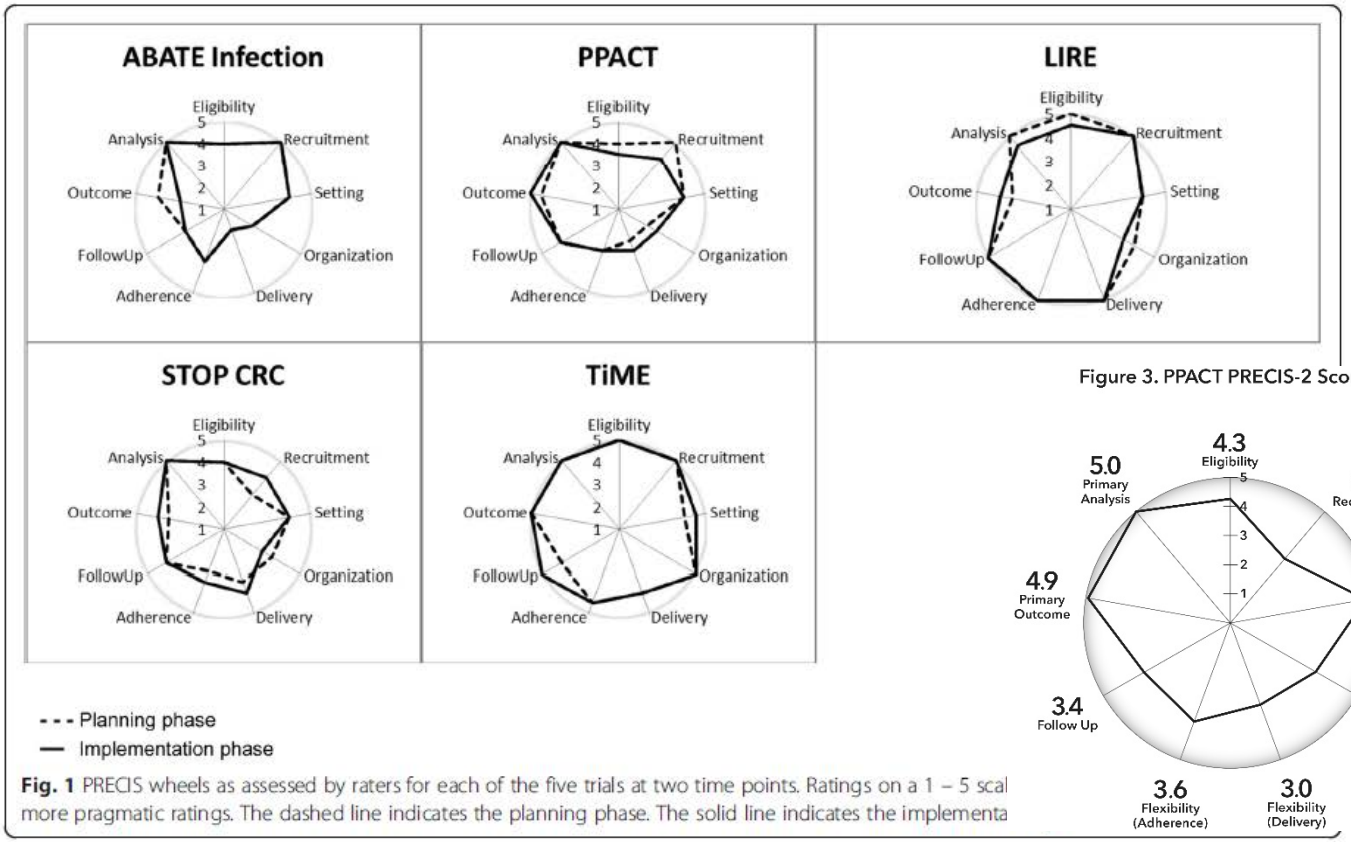
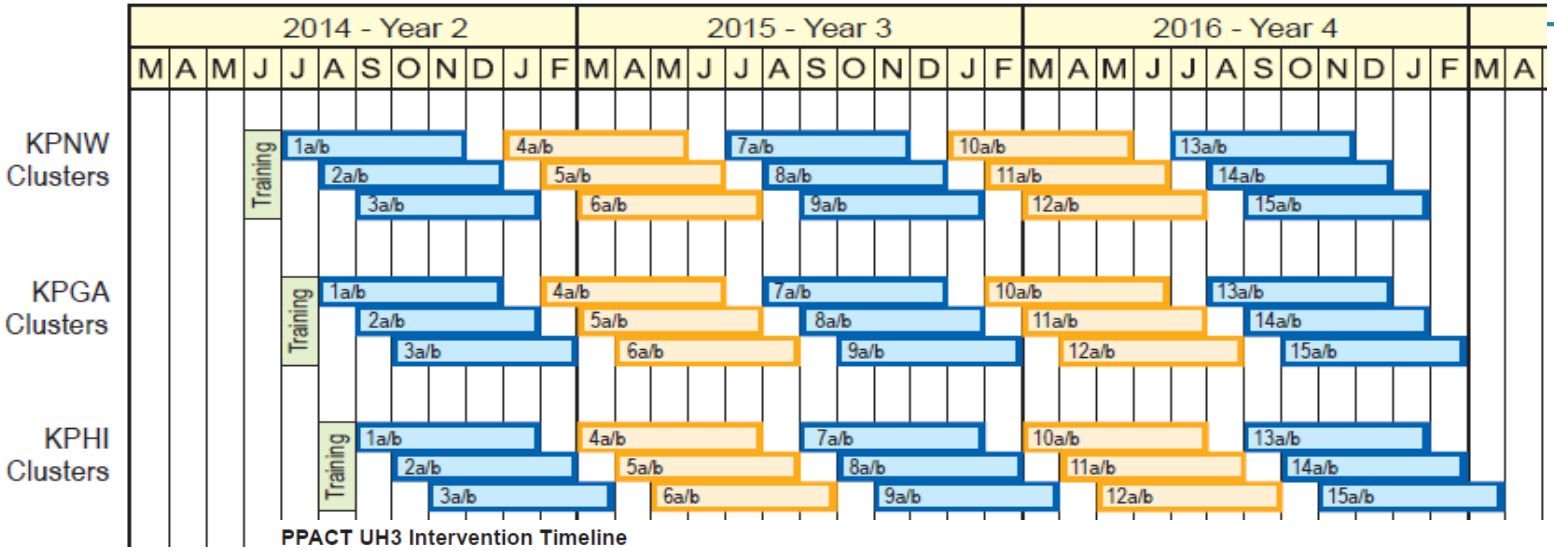


Fig. 1 PRECIS wheels as assessed by raters for each of the five trials at two time points. Ratings on a 1 – 5 scal more pragmatic ratings. The dashed line indicates the planning phase. The solid line indicates the implementa

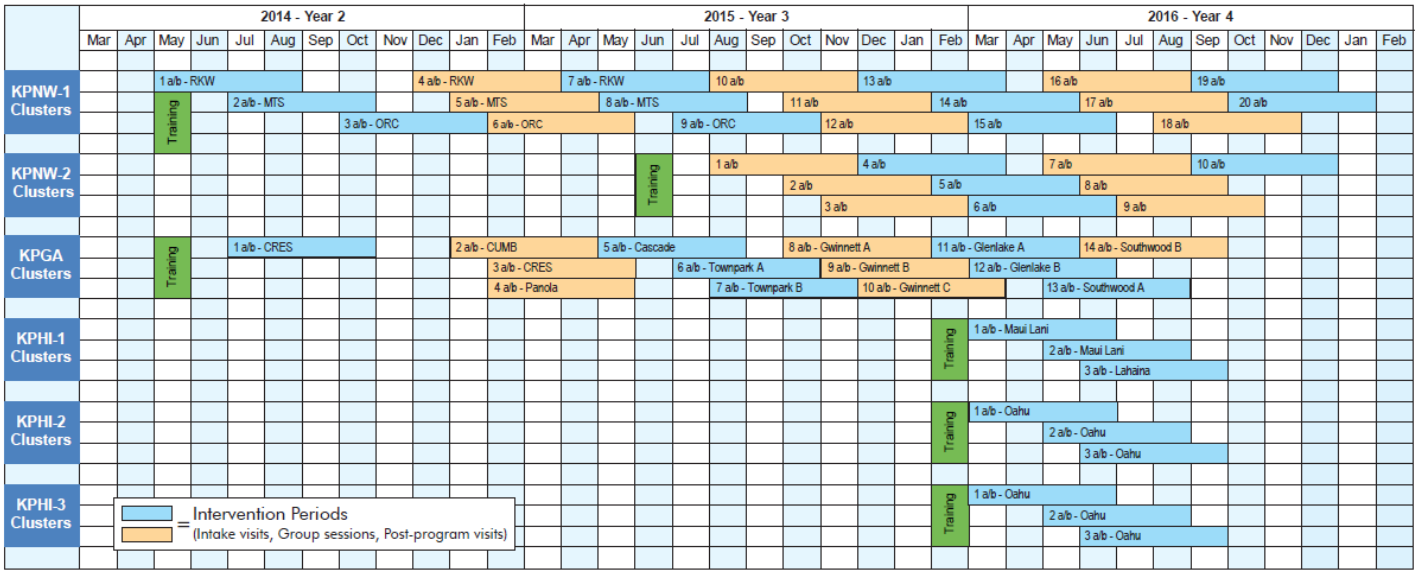
Figure 3. PPACT PRECIS-2 Scoring

Johnson *et al. Trials* (2016) 17:32
DOI 10.1186/s13063-016-1158-y

The plan, the reality, & consequences of our PCP cluster randomized approach



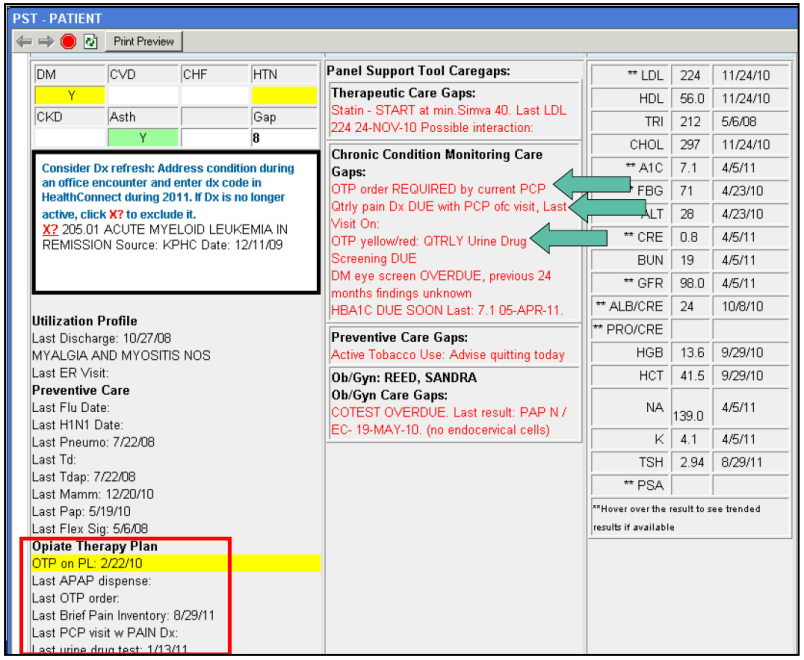
PPACT UH3 Intervention Timeline



Collect and Sharing Patient Reported Outcomes (PROs) in Pragmatic Trials

What does it take to collect PRO data in routine clinical care?

- Opioid therapy plans required for all patients on long-term opioids and included “regular” BPI administration
- 12-item BPI resisted by clinicians (too long, focused on pain intensity)
- Shifted national KP EHR-embedded standard to PEG(S) (Pain, Enjoyment of Life, General Activity, Sleep)



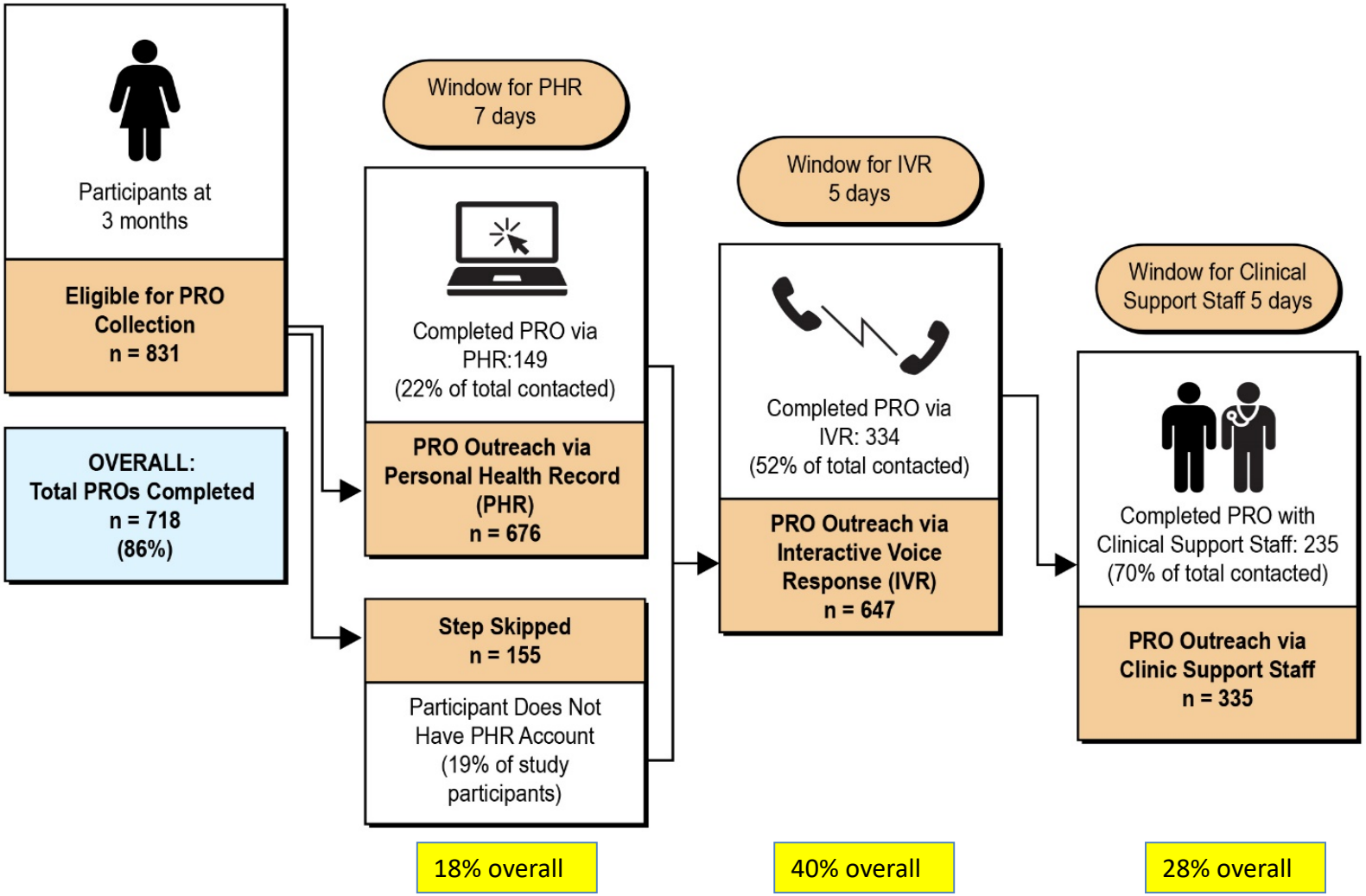
Opioid Therapy Plan (OTP) Operational Criteria

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

Panel Support Tool – it takes more than EPIC to prompt administration

What it might really takes to collect PRO data in routine clinical care



Owen-Smith et al, Journal of General Internal Medicine, 2018

There is no obvious best way to communicate with PCPs about individual patients within the EMR

- EMR-based PPACT pre/post summaries not as effective as hoped
- PCP workload/workflow attentional constraints
- Emailing/messaging providers about specific actionable concerns works well, but does not provide the "big picture" required for co-management

"Unless we were specifically alerted to look in this place… there's way too much noise in the chart"
– PCP, about reviewing a PPACT report

Enhancing PRO use in routine clinical care: Lessons learned

- "Pulling" PROs from EHR (data availability / quality)
  - Most PRO adoption "stick" rather than "carrot" driven
  - EMR IT enhancements critical for routine PRO collection
  - Frequency and amount of PRO data often confounded with patient's clinical severity
- "Pushing" PROs into EHR (enhancing clinical utility)
  - Multimodality support for enhanced collection may be needed
  - PRO EHR display may limit clinical utility (esp for complex conditions)
  - HCS technology often lags, untethered systems may be most feasible