PACT

Pain
Program for Active
Coping & Training

Primary-care Based Collaborative Care for Chronic Pain: Overcoming Patient, Provider, Data, and System Challenges in Implementing the Pragmatic Trial

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Agenda

- Summary of the Specific Features of PPACT that Invite Implementation Challenges
  - Summary of study design
  - Framework for care
- Specific Barriers and Potential Solutions
  - Engagement of Patients, Clinicians and Health Care Systems
  - Data collection – building robust PRO collection into the HCS
  - Regulatory issues – heterogeneity across "sibling" HC Systems
  - (In)Stability of Usual Care – "may a thousand flowers bloom"
- "If We Knew Then What We Know Now"…Advice for UH2 Projects

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

- Implementing in three regions of Kaiser Permanente (Northwest, Georgia, and Hawaii)
- 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

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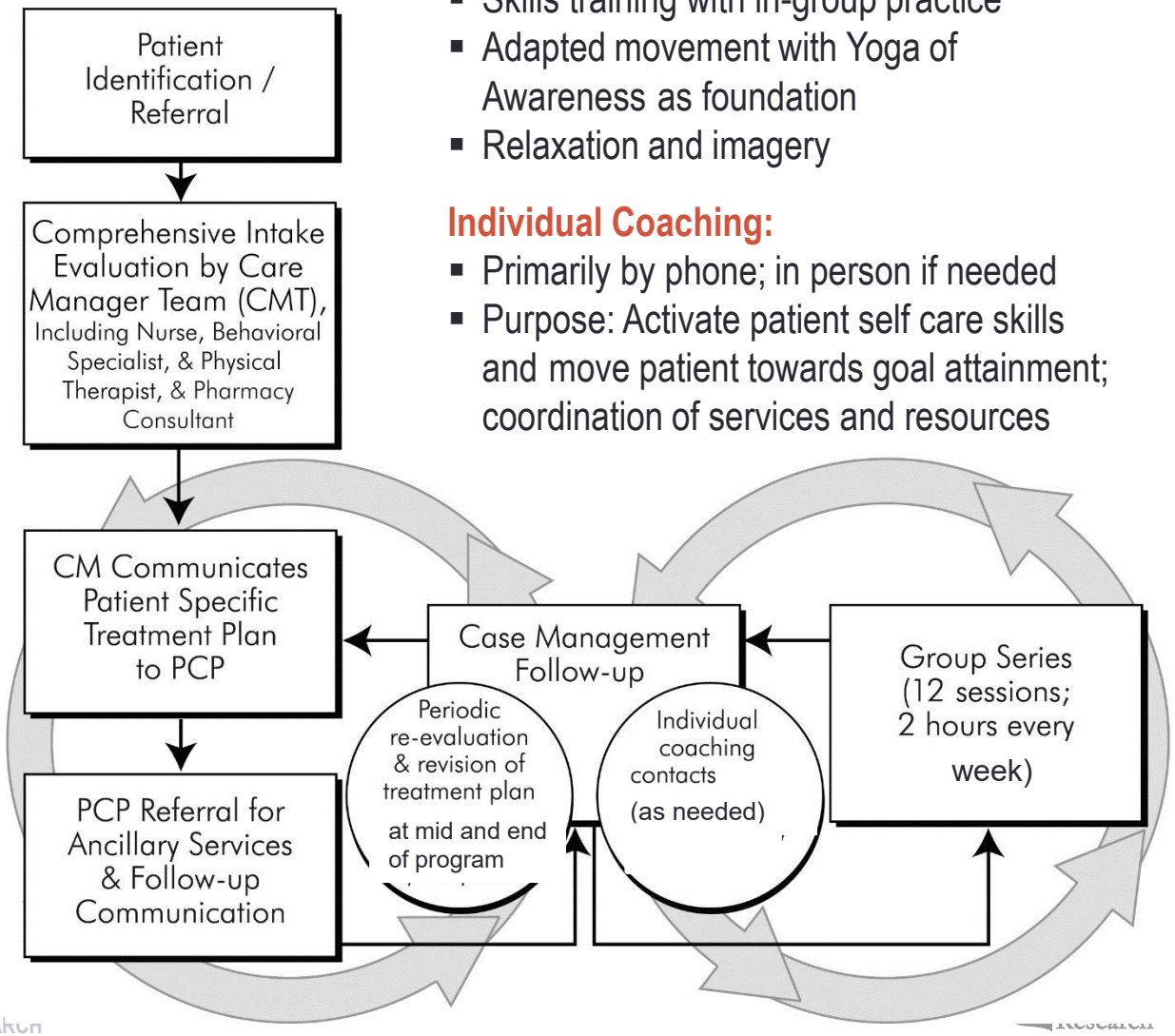
About the Intervention

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



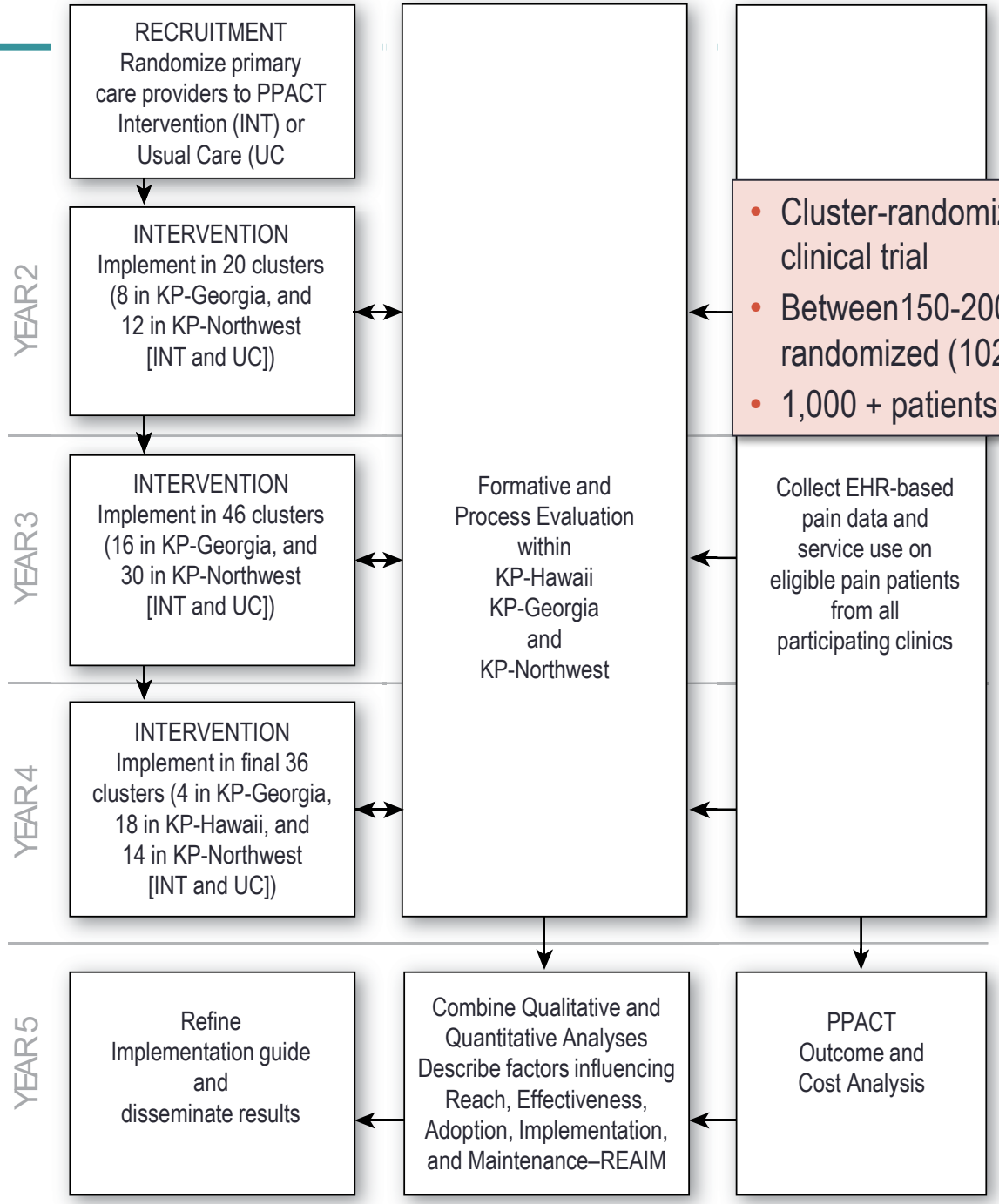
Group Session Components:

- Goal setting, barrier identification, problem solving to achieve patient specified goal
- 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

Trial Design



- Cluster-randomized pragmatic clinical trial
- Between150-200 PCPs will be randomized (102+ clusters)
- 1,000 + patients

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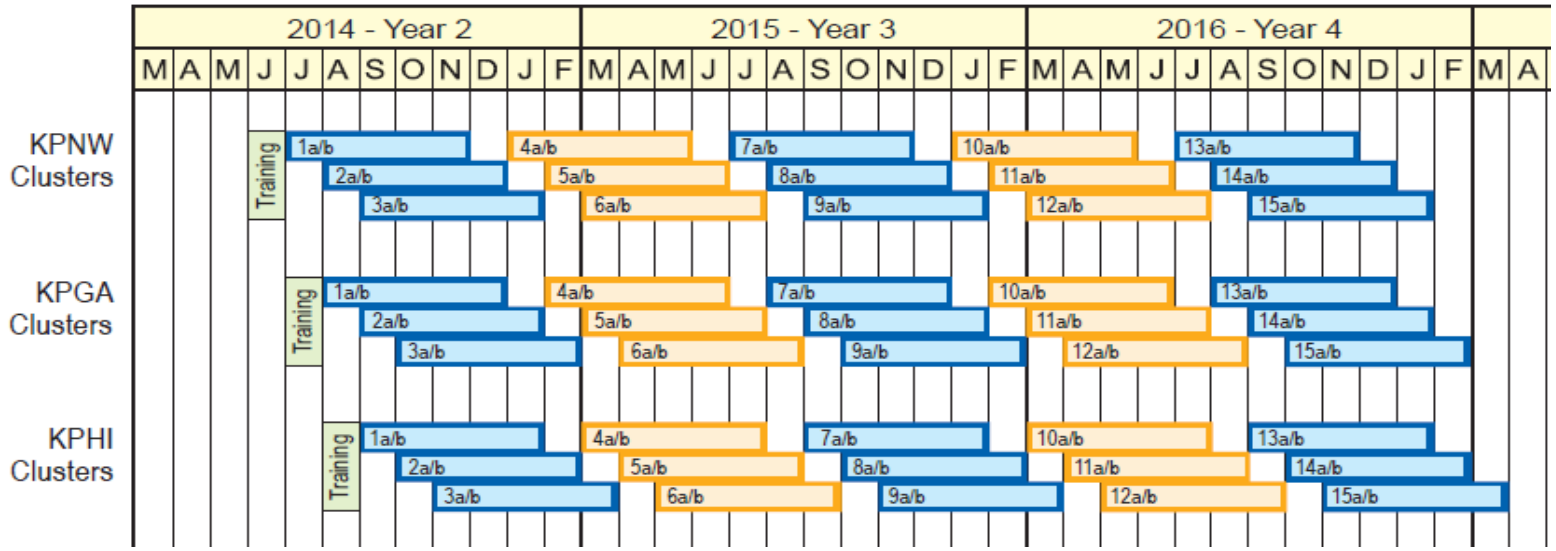
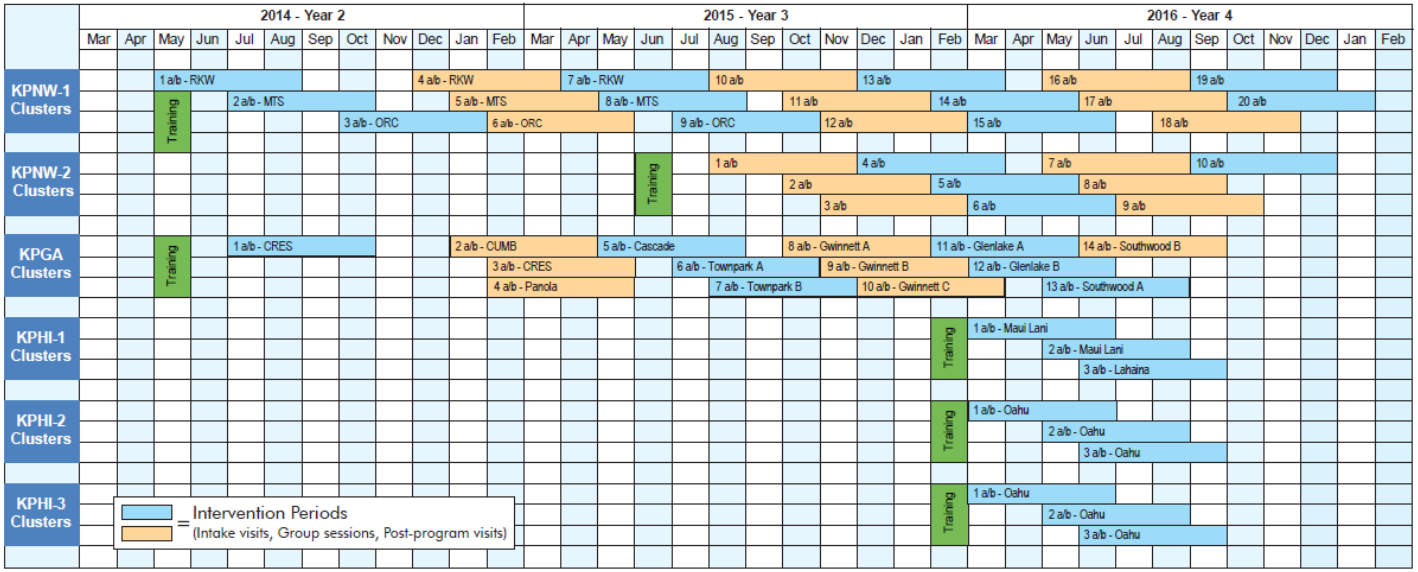


PPACT UH3 Intervention Timeline

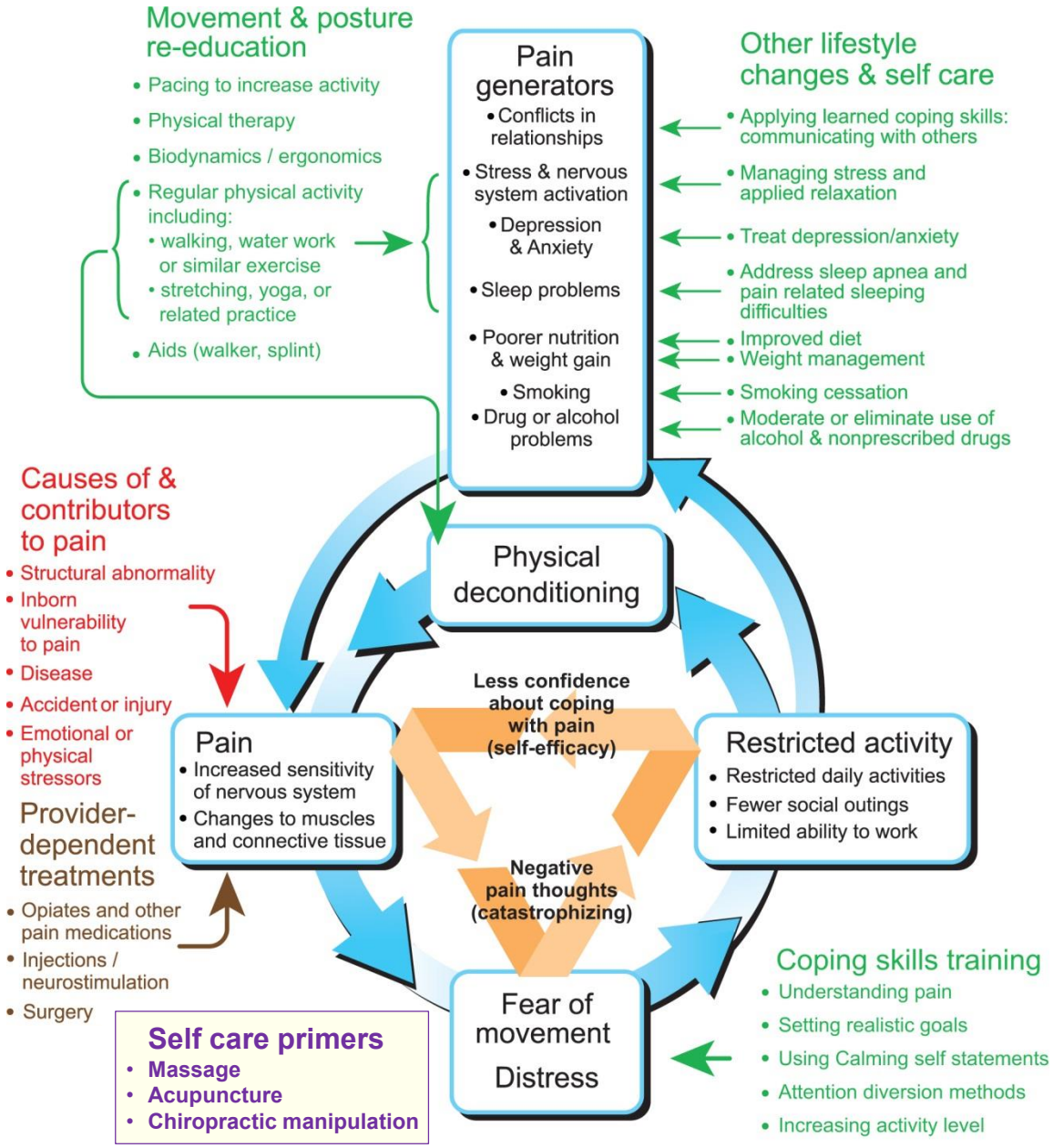


Barriers Scorecard

Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects				X*	
Engagement of clinicians and Health Systems					X
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)		X			
Stability of control intervention			X*		

1 = little difficulty
5 = extreme difficulty

* Expected in advance



Persistent Pain Cycle

- Framework to guide understanding of patient's condition and care planning
- Informs team's communication with PCP and patient
- Promotes importance of active coping and self care to interrupt cycle
- Highlights multiple areas to target for improved pain and function

- **Green domains:** Reinforce multitude of active strategies
- **Brown domain:** Limit patient reliance on provider dependent treatments
- **Red domain:** Reframe patient mindset away from focusing on cause towards management

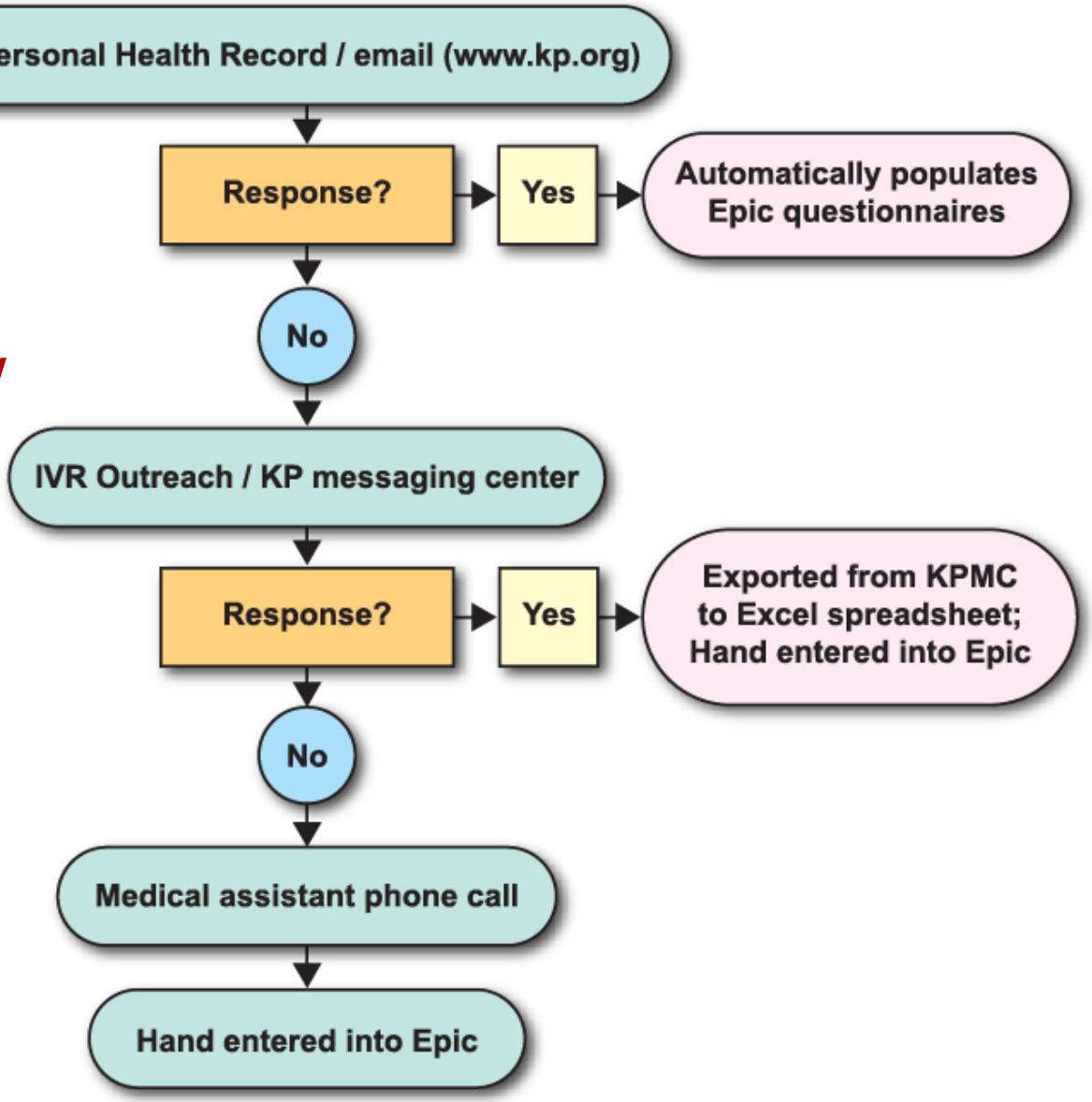
Challenges: Engagement of Patients, Clinicians, and Health Care Systems

- The patients most vexing to the health care system most difficult to engage (all [patients and PCPs alike] have been "fired" more than once)
- Requires different clinical skill set for participating providers (behavioral specialists, nurse case managers, physical therapists, pharmacists, and PCPs) than how they routinely deliver care.
- Primary or specialty care services – are our heath care systems really prepared to bridge the divide?
- Inherent tension between process needed for rigorous evaluation and building towards sustainability of the intervention

Challenges: Building Robust PRO Collection into the Health Care System

- 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
- Resource and staffing needs intensive for integrating PROs using our 3-tiered system (online, IVR, medical assistant calls)

Process for "Automated" Enhanced Quarterly PRO (BPI-SF) Collection



Challenges: Regulatory issues (heterogeneity across "sibling" HC systems)

- Kaiser Permanente regional IRBs unwilling to agree to centralized IRB process
  - Despite agreeing intervention low risk (reorganization of existing clinical services)
  - Despite broader encouragement by KP overall to streamline IRB processes and to work in closer partnership across regions
  - Sensitivity/concern about vulnerability of target patient population and controversies surrounding opioid treatment
  - Discomfort with "newness" of PCT model/design?
- Resulting heterogeneity in regional IRB requirements affecting elements of the study
  - KP-Georgia insistence on "research" language in patient materials may impact recruited sample / perception of embedded nature of the intervention
  - KP-Hawaii unwillingness to collect data from PCPs limits ability to evaluate intervention impact; unwillingness to share PHI requires additional data QA resources

Challenges: (In)stability of usual care ("may a thousand flowers bloom")

- Ongoing initiatives to launch patient-centered care / primary care medical home initiatives
  - KP-Northwest (aborted PCMH; complex conditions clinic; team-based care)
  - KP-Georgia (partial implementation of PCMH model)
  - KP-Hawaii (integrating behavioral health into primary care; "experiments" in nursing support)
- The continued dilemma of "feasible" alternatives to opioid pharmacotherapy for chronic non-malignant pain
  - KP-Northwest (partially overlapping initiatives: STORM, Global spine initiative, Opioid use initiative)
  - KP-Georgia (continued willingness to implement PPACT despite massive recent re-organization of delivery care system and leadership shifts)
  - KP-Hawaii (Maui consult pain pilot; PPACT at center of regional alternatives to opioid monotherapy)
  - KP-National Interregional Medication Adherence, Reconciliation and Safety (IMARS) group initiatives

"If We Knew Then What We Know Now"… Advice for UH2 Projects

- NOTHING is static / everything is new in "hybrid" system
  - Requires resilience and "can do" mind set of research and clinical staff alike for good fit
  - PPACT as counter-evidence for the "bigger, faster, cheaper" model for PCTs
- Adopt change processes "native" to health care delivery systems whenever possible
  - Language/procedures for internal quality improvement initiatives
  - Consider hiring HCS QI project managers as key partners in the process
- Optimize study infrastructures to enhance critical and ongoing communication across all "sectors" of the project
  - Everyone working at the top of their game and out at the end of a limb –> adjustments have repercussions but intensive work makes frequent meetings/communication challenging
- What makes this a "timely clinical research question" to health care stakeholders portends likely challenges in implementation
  - Underperformance vs. lack of pre-existing services

…but still the right thing to be doing!