PACT
Pain
Program for Active
Coping & Training

Conducting Multifaceted Behavioral Pragmatic Trials Within Integrated Health Care Systems

Pragmatic Clinical Trial Sponsored by:
National Institutes of Health Common Fund
National Institute of Neurological Diseases and Stroke
National Institute of Drug Abuse
Administered by National Center for Complementary and Alternative Medicine
Pilot project funded by: Patient Centered Outcomes Research Institute

Lynn DeBar, PhD, MPH, Kaiser Permanente Center for Health Research

Center for Health Research

Agenda – Lessons Learned

- Comparing/contrasting Pragmatic Trials with traditional RCTs
- Partnering to Identify the Critical Central Study Question
  - Brief overview of PPACT study context and design
  - The potential underbelly of the timely clinical research question
- Qualitative Work Critical but Methods Driven by PCT Framework
  - Bi-directional learning, understanding your stakeholders, rapid assessment process/use of field notes
- Critical Issues for Quantitative Data Collection
  - Pragmatically driven assessment / centrality of the Electronic Health Record
  - PRO specific considerations
- Intervention – what is different?
  - The influence of patients, primary/specialty/ancillary health care providers, as well as broader (regulatory) system in shaping the intervention
- Summary of Lessons Learned

COMPARING AND CONTRASTING PRAGMATIC TRIALS WITH TRADITIONAL RCTS

Explanatory versus Pragmatic Trials

- An explanatory (or efficacy) trial seeks to answer the question, “Does a intervention work under *ideal* conditions?”
  - A “positive explanatory trial is not proof that its intervention will work in real world settings, or context different than those in which it was conducted
- A pragmatic (or practical) trial seeks to answer the question, “Does an intervention work under *usual* conditions?”
  - Needed to demonstrate that the intervention can work in real world settings

Why are Pragmatic Trials Needed?

We are:

- Not reaching patients with complex, comorbid problems and those most in need
- Not testing in settings and with staff that are typical to most clinical situations
- Not addressing issues important to clinicians, policy makers, and patients
- Many 'evidence-based' treatments not feasible in most real world settings
- Bottom Line- Research not seen as RELEVANT

Key Characteristics of Pragmatic Trials

- Focused on questions from and important to stakeholders
- Conducted in everyday clinical practice environment (multiple and varied settings) rather than in "parallel research universe"
- Intervention tailored to needs of setting, intended for sustained real-world practice, and compared to real world alternatives
- Representative populations / few exclusion criteria – enrolled patients are those health care providers/health plan identify as having greatest need
- Multiple outcomes important to decision and policy makers
  - Evaluation often based on clinical and administrative data that are highly relevant for clinicians and the health plan (e.g., patient reported outcomes already clinically collected, pattern of health service utilization including medication use, and health care costs)

	Pragmatic Trial	Traditional Clinical Efficacy Trial
Stakeholder Involvement	Engaged in all study phases (design, data collection, interpreting results, disseminating findings)	Limited engagement; often in response to investigator ideas or study subjects
Research Design	Includes internal & external validity, design fidelity, local adaptations, real life settings, contextual assessments, cluster randomized designs common	Focus on limiting threats to internal validity, typically uses RCT, participants and settings homogenous
Outcomes	Reach, effectiveness, adoption, implementation, sustainability	Efficacy, mechanism identification, component analysis
Measures	Brief, valid, actionable with rapid clinical utility, feasible in low resource settings	Validated measures that minimize bias, focus on internal consistency / theory rather than clinical relevance
Costs	Assessments include intervention and replication costs in relation to outcome	Often not collected or reported
Data Source	Existing data (EHR, administrative data) and brief patient reports	Data generation and collection part of clinical trial
Analyses	Process and outcome analyses relevant to stakeholders and from different perspectives	Specified a priori and typically restricted to investigator hypotheses
Availability of Findings	Rapid learning and implementation	Delay between trial completion and analytic availability

PARTNERING TO IDENTIFY THE CRITICAL CENTRAL STUDY QUESTION

Overall Study Aim from our Behavioral Pragmatic Intervention

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

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

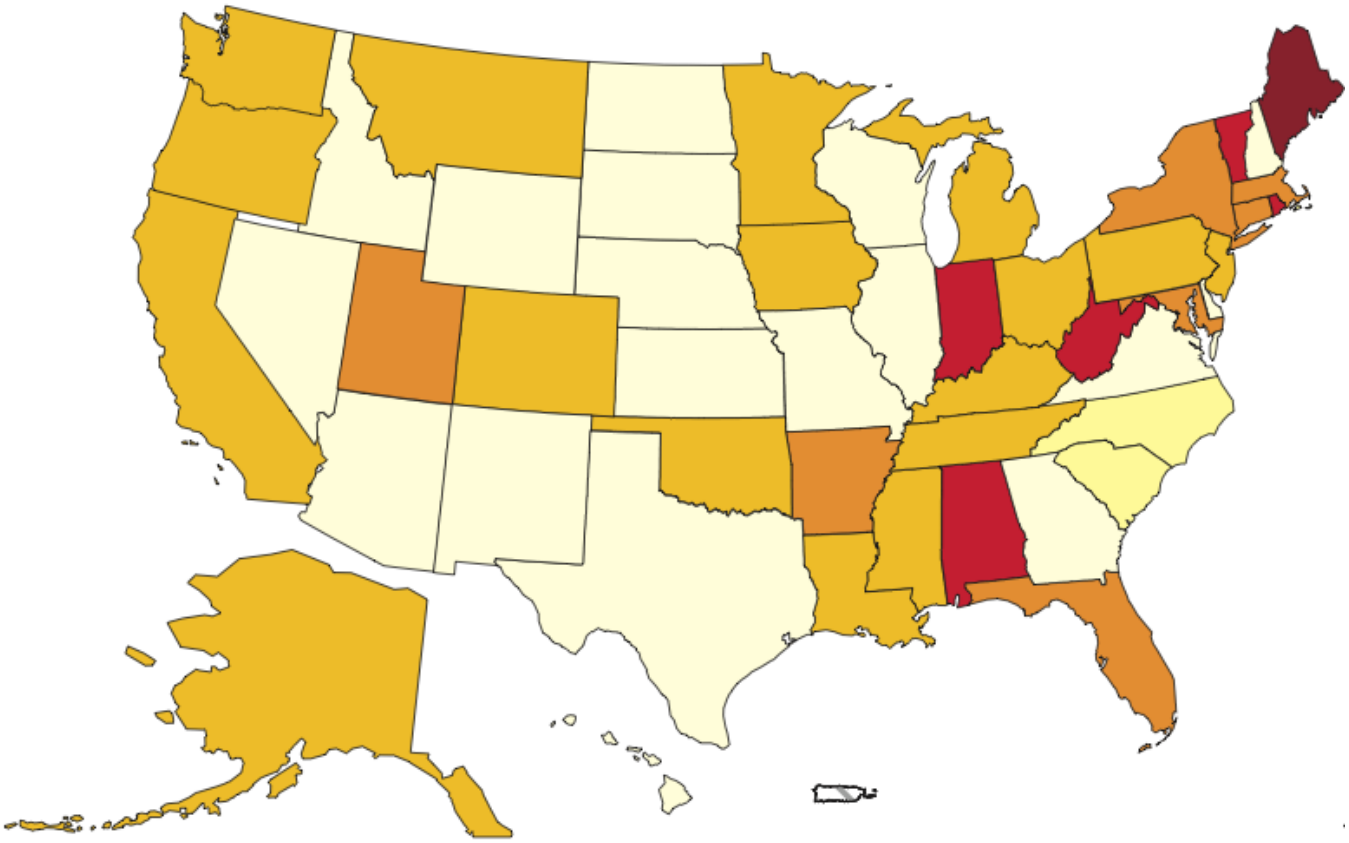
Optimal management relies on patient self-care

- 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

Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)



1999

(range 1 - 50)

< 8	15 - 18	45 or more
8 - 14	19 - 44	Incomplete data

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.

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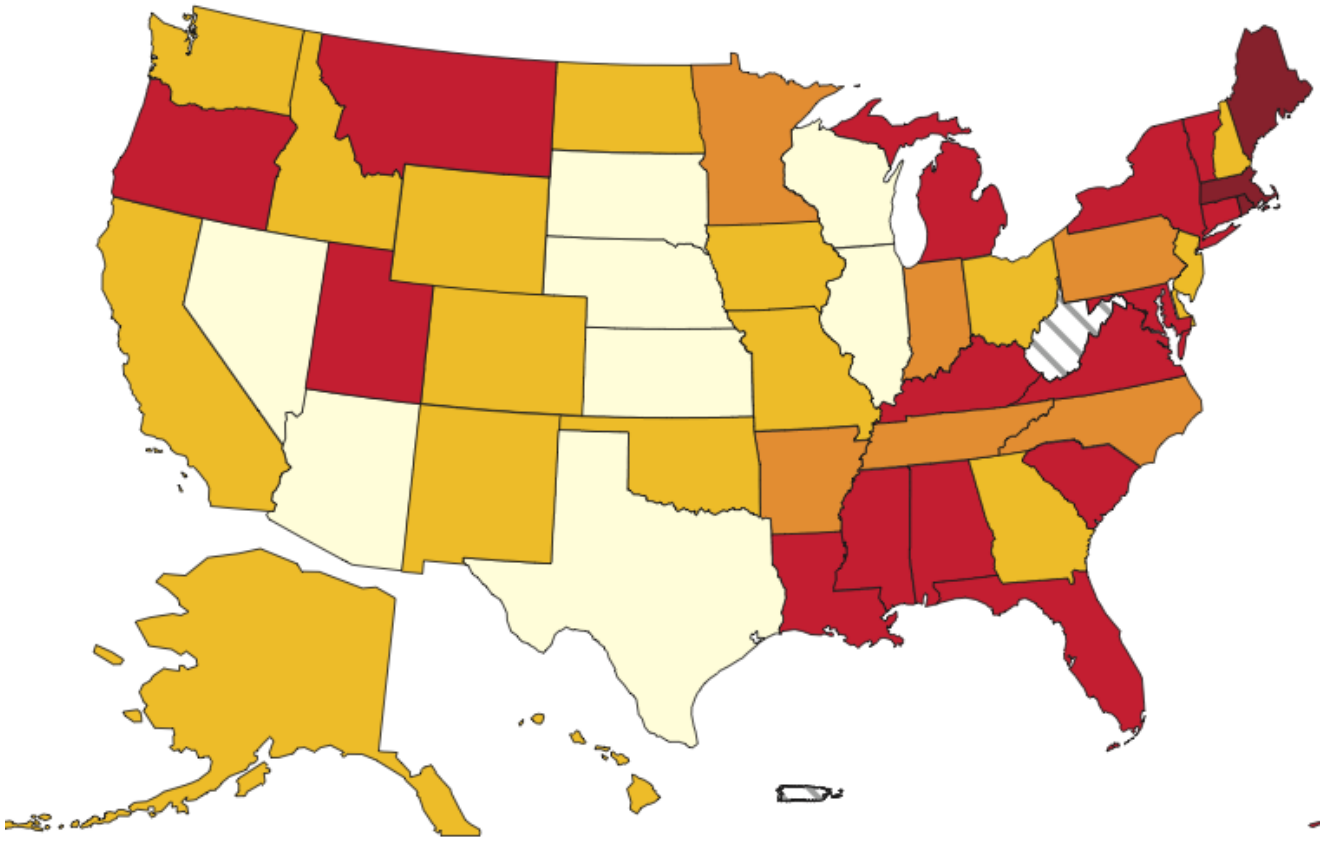

2001

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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.

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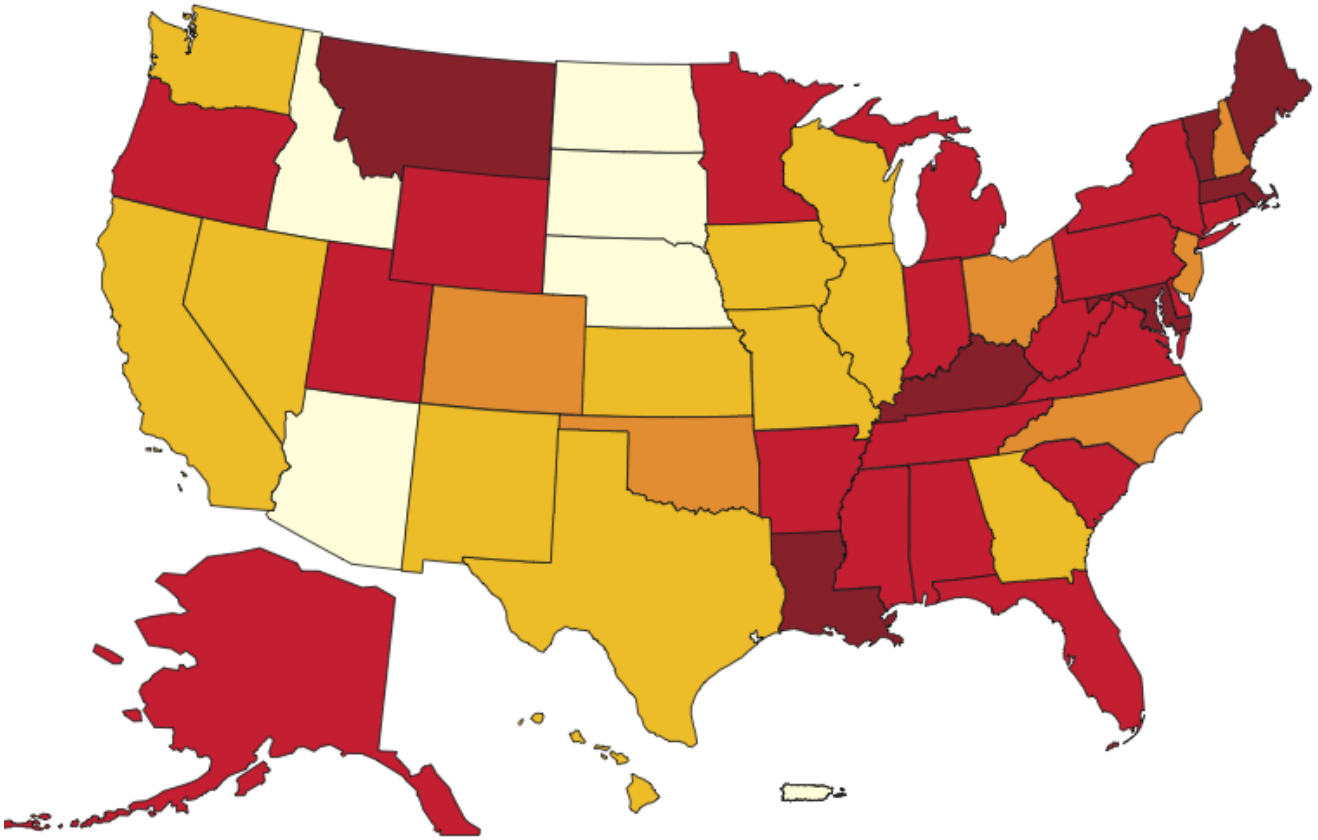

2003

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8 - 14	19 - 44	Incomplete data

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.

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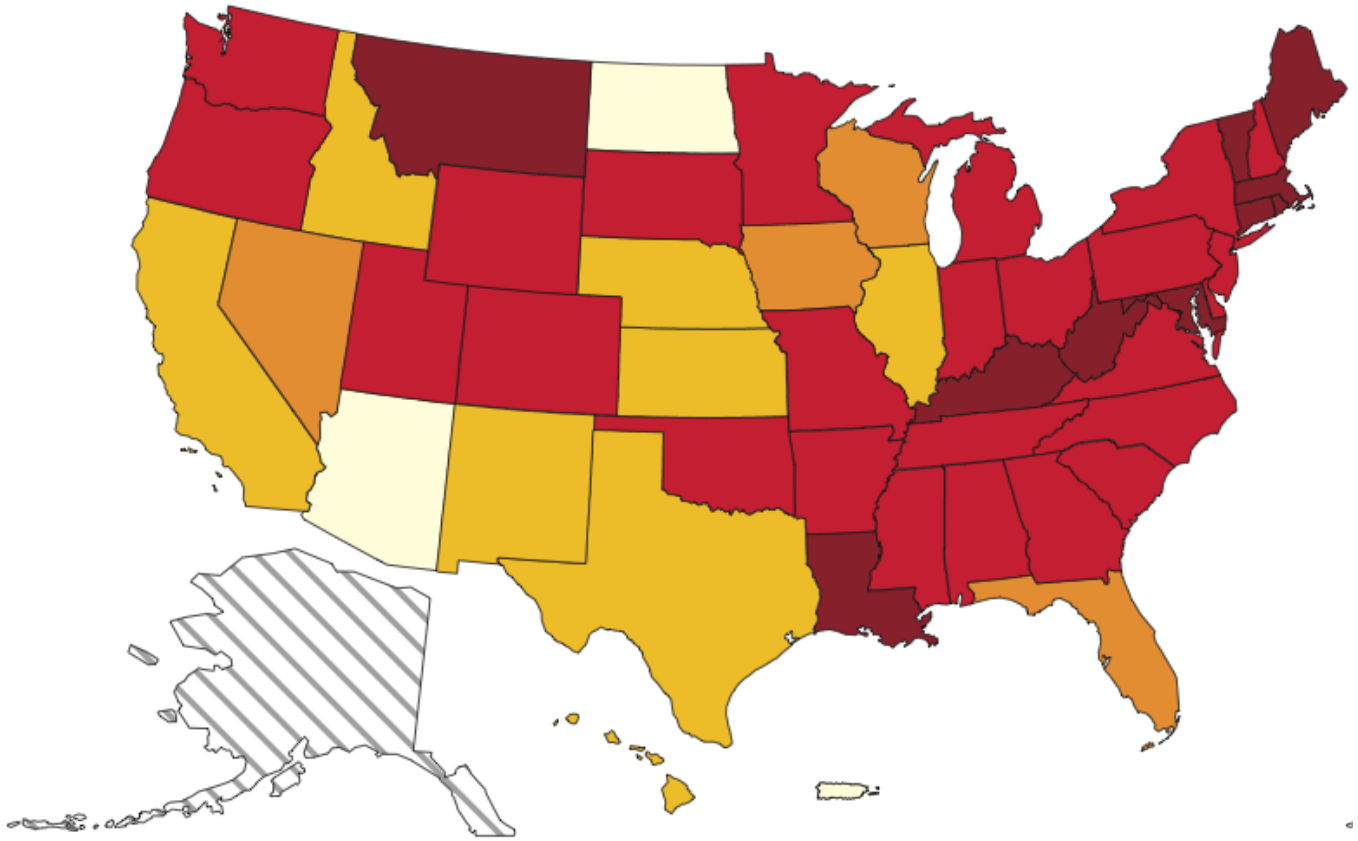

2005

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8 - 14	19 - 44	Incomplete data

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.

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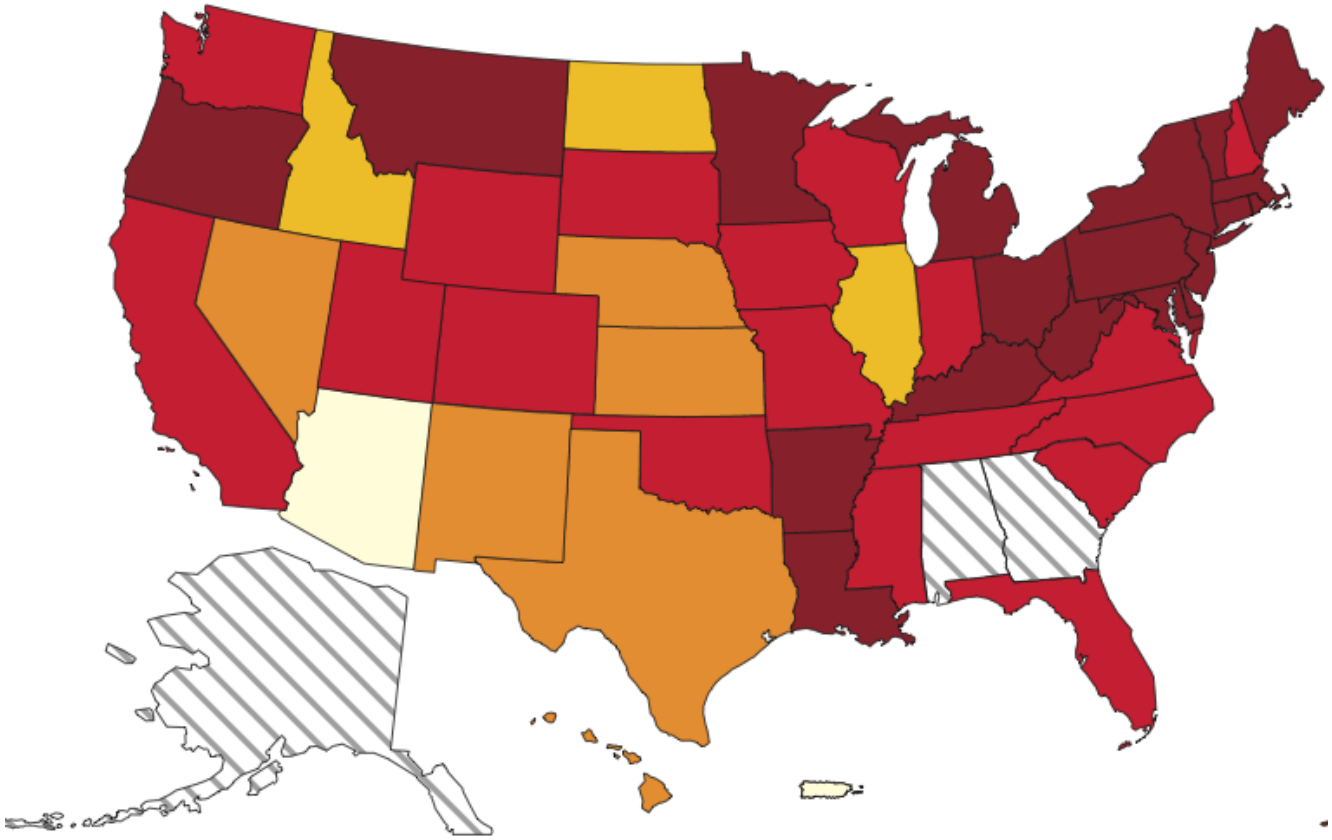

2007

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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.

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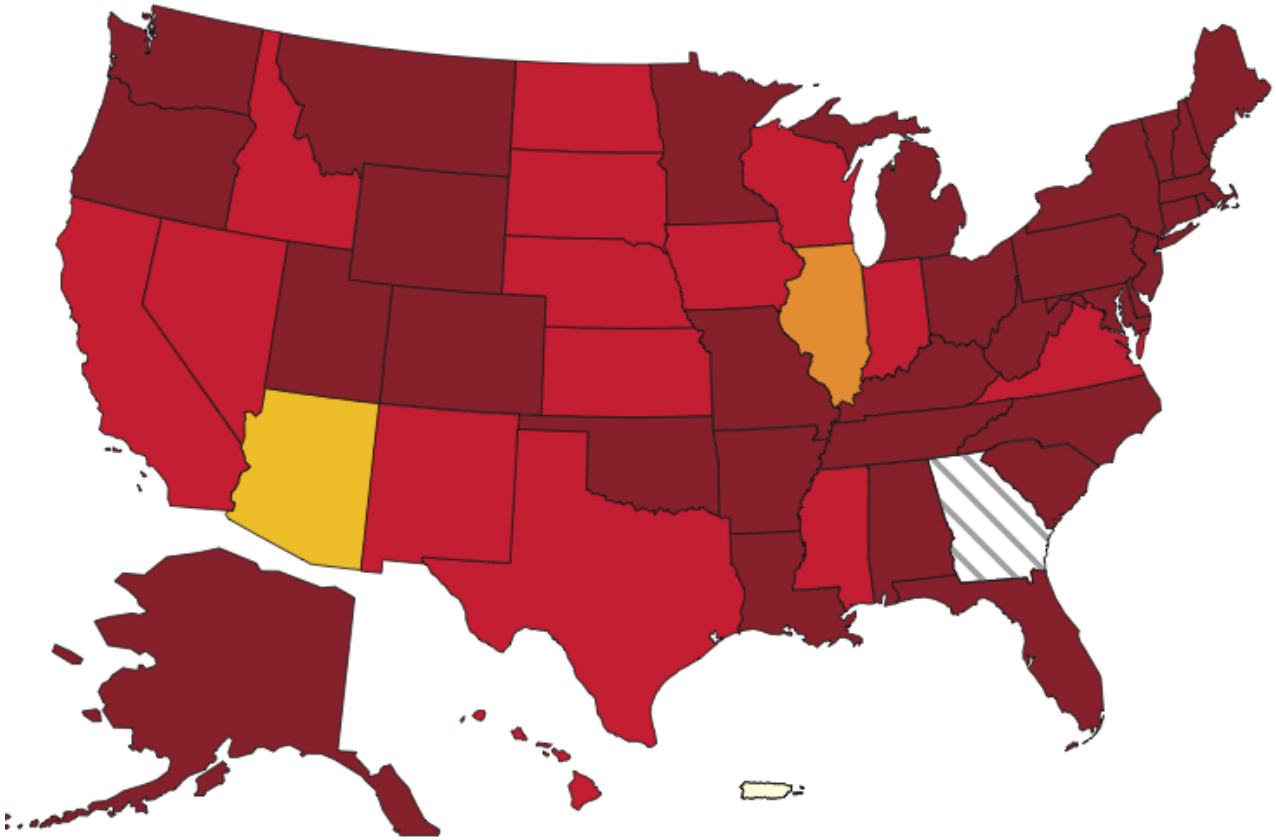


2009

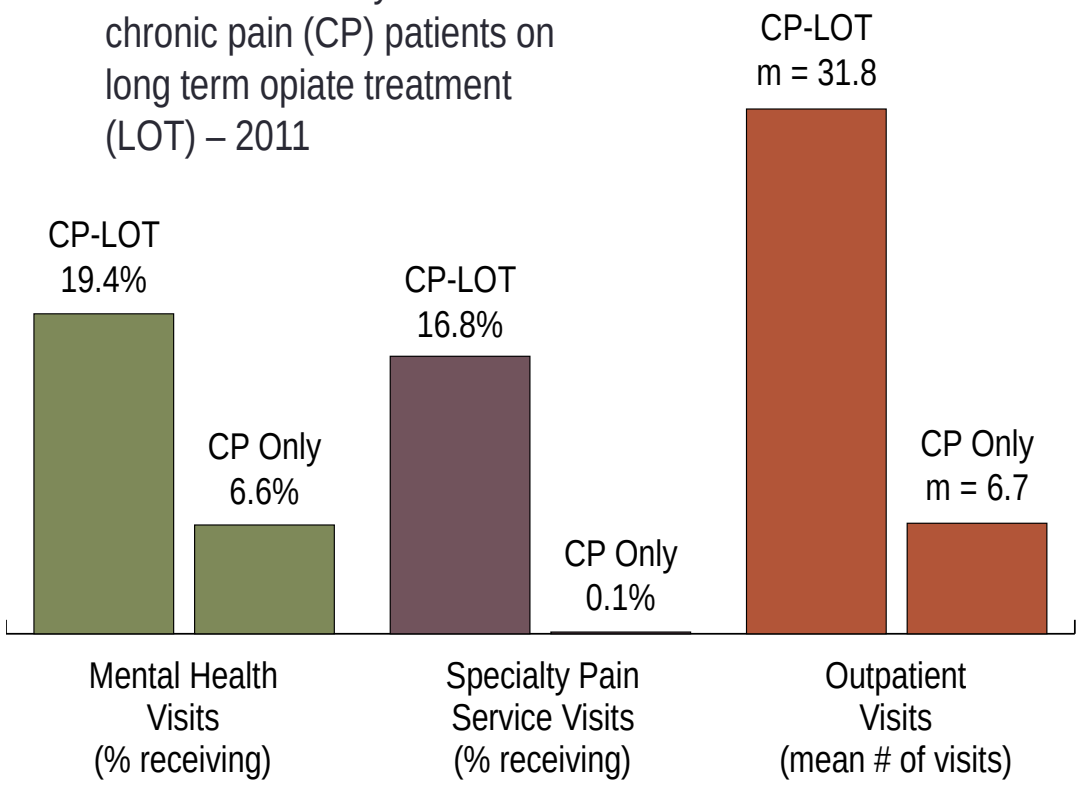
(range 1 – 379)

< 8	15 - 18	45 or more
8 - 14	19 - 44	Incomplete data

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.

Utilization Associated with Opioid Use

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

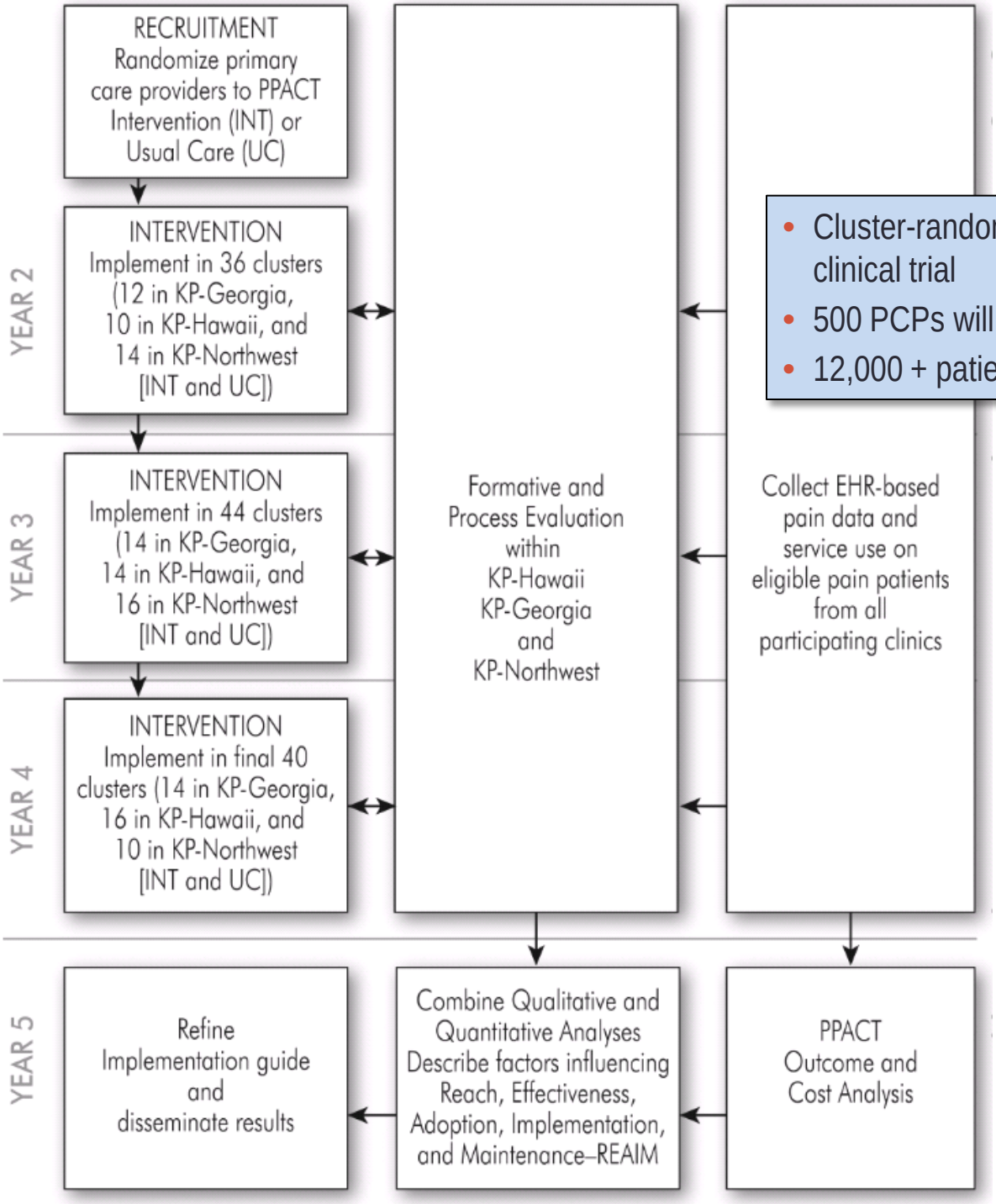


Opiate users are more likely to:

- Use mental health services
- Use specialty pain services
- Be hospitalized
- Have increased outpatient visits

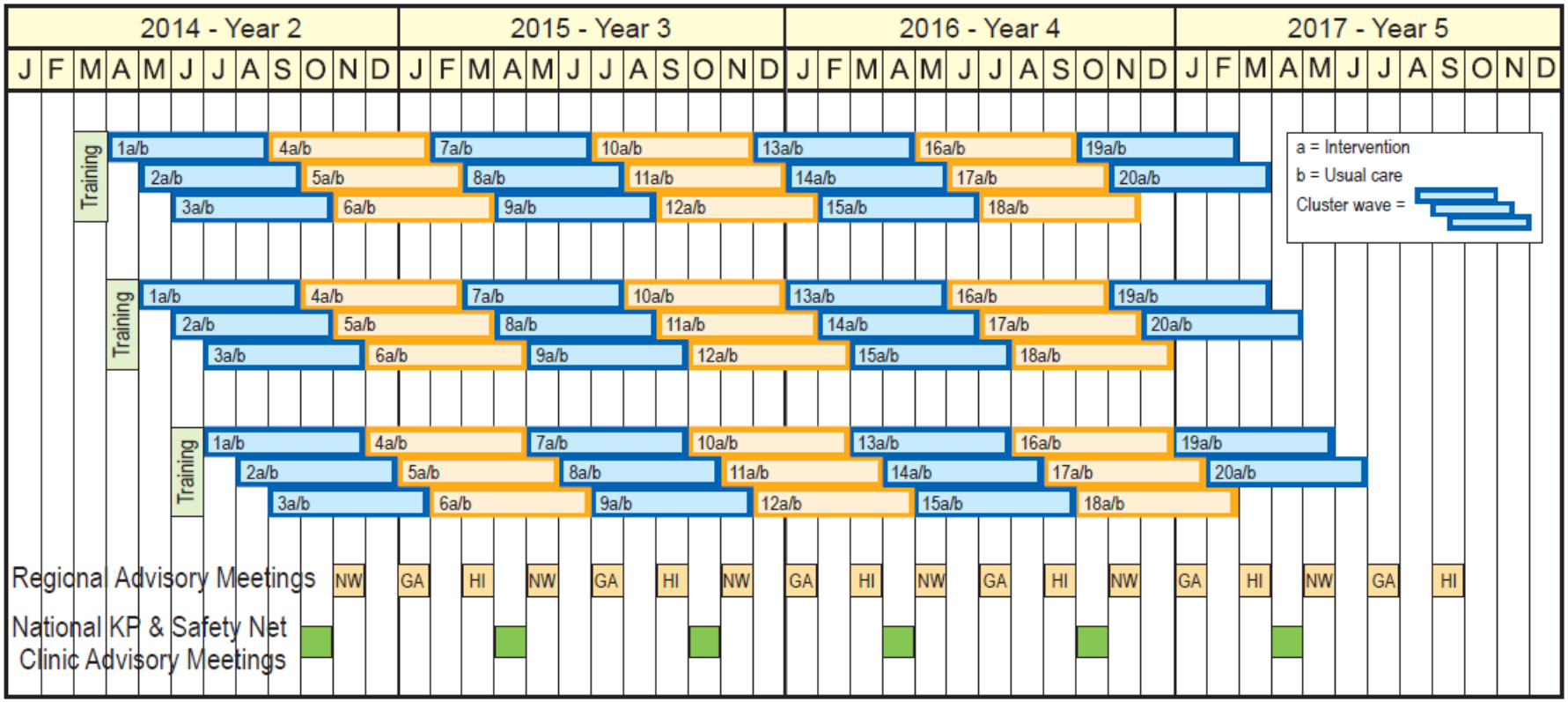
Patients with chronic pain (CP) using long term opiate treatment (LOT) have increased utilization across the system and are associated with a larger treatment burden.

Trial Design



- Cluster-randomized pragmatic clinical trial
- 500 PCPs will be randomized
- 12,000 + patients

Flowchart of Cluster Implementation



Characteristics of Cluster Randomized Trials

- Unit of assignment is an identifiable group (e.g., medical center, primary care clinics)
- Different groups are allocated to each condition (groups are nested within treatment)
- Unit of observation can be at group level (e.g., proportion screened) or at the level of individuals within groups
- The number of groups is often small, even though total sample size may be very large

Impact of "Clustering" on the Design and Analysis

- Limited opportunity for randomization to distribute potential sources of bias evenly
  - Implies need for careful attention to how randomization is carried out
- Greater potential for bias in Group or Cluster Randomized Trials than in most traditional RCTs
- Observations within a group (cluster) are often less variable than observations between groups
  - This may severely limit "effective" sample size
  - More smaller groups preferable to fewer large groups
- Analyses that ignore clustering will have inflated type 1 error rates
- Power generally less than for conventional RCT with same total number of individuals

The Potential Underbelly of the Timely Clinical Research Question

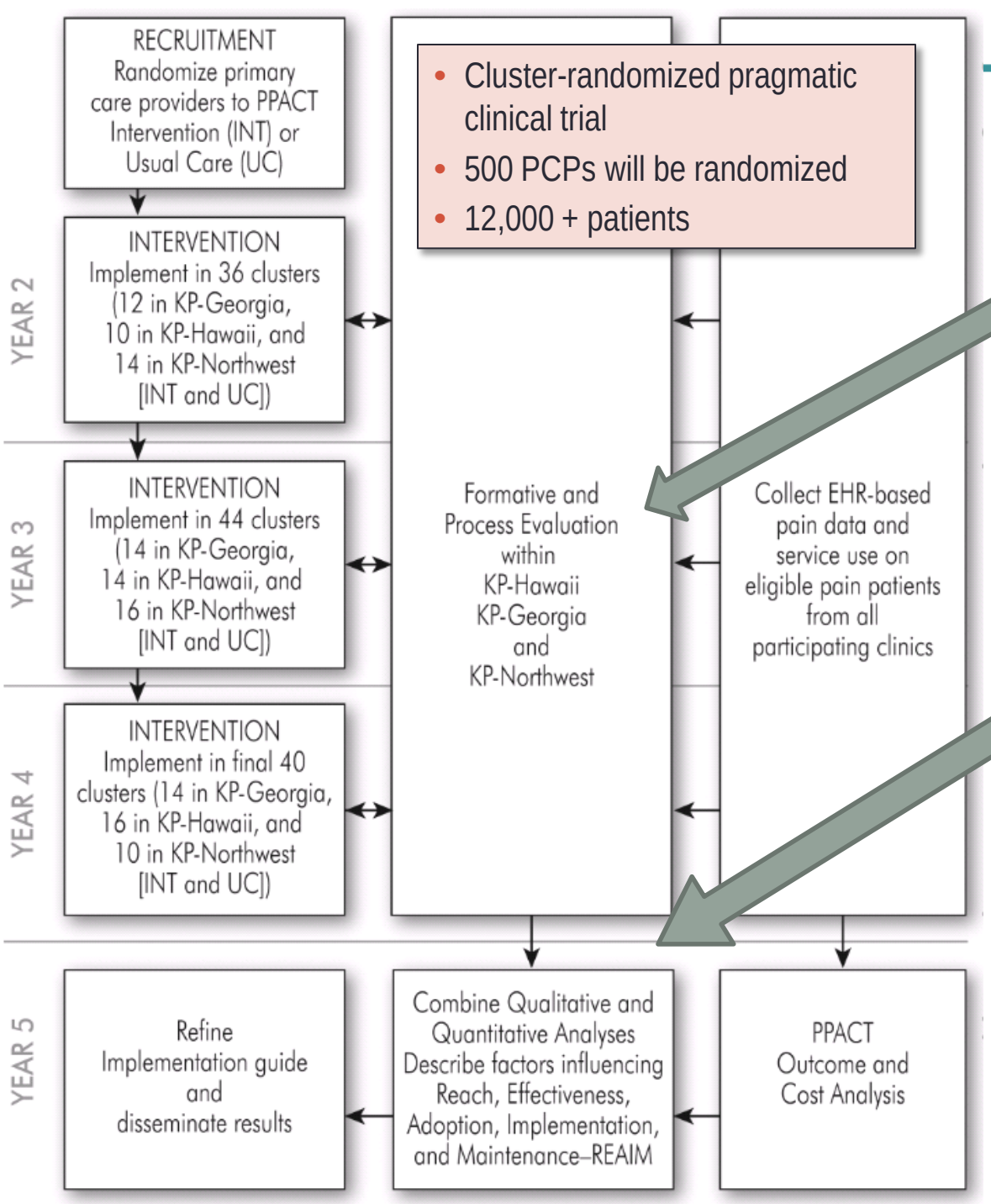
- Expect usual care practices to be dynamic if the issue is critical to operational and clinical leaders in participating health plans
- What makes this a “timely clinical research question” to health plan stakeholders portends likely challenges in implementation (i.e., underperformance vs. lack of function)
- Delicate balance between meeting a clinical need with commitment to rigorous evaluation with building sustainability
- Know that perception of “research” to clinical stakeholders (e.g., untested) can impact buy-in and stakeholder actions during trial role-out

Relevant Service Characteristics of Participating Kaiser Permanente Regions

Service	KP Northwest	KP Georgia	KP Hawaii
Mental Health	Standard	Standard	Standard
Behavioral Health co-located with primary care	Limited	Mature	+Developing
Physical therapy internally located within clinics	Standard	- *Absent* -	Standard
Addiction medicine services as benefited service	Standard	Standard	Standard
Specialty pain service	Mature	Limited	+Developing
Pharmacy consult with PCPs re: opioid treatment	Mature	- *Absent* -	- *Absent* -

QUALITATIVE WORK CRITICAL BUT METHODS DRIVEN BY PCT FRAMEWORK

Adapted Qualitative Methods



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

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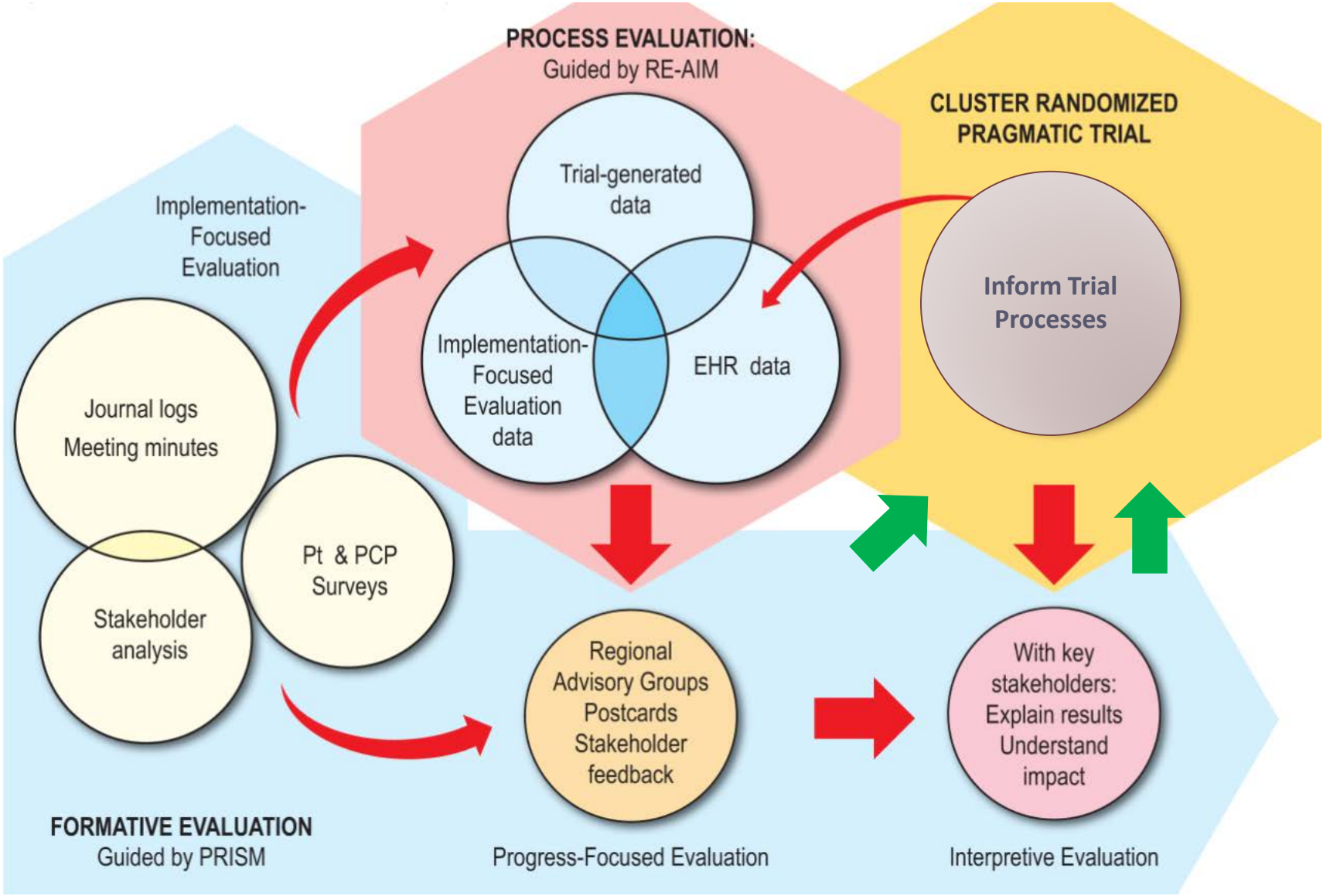
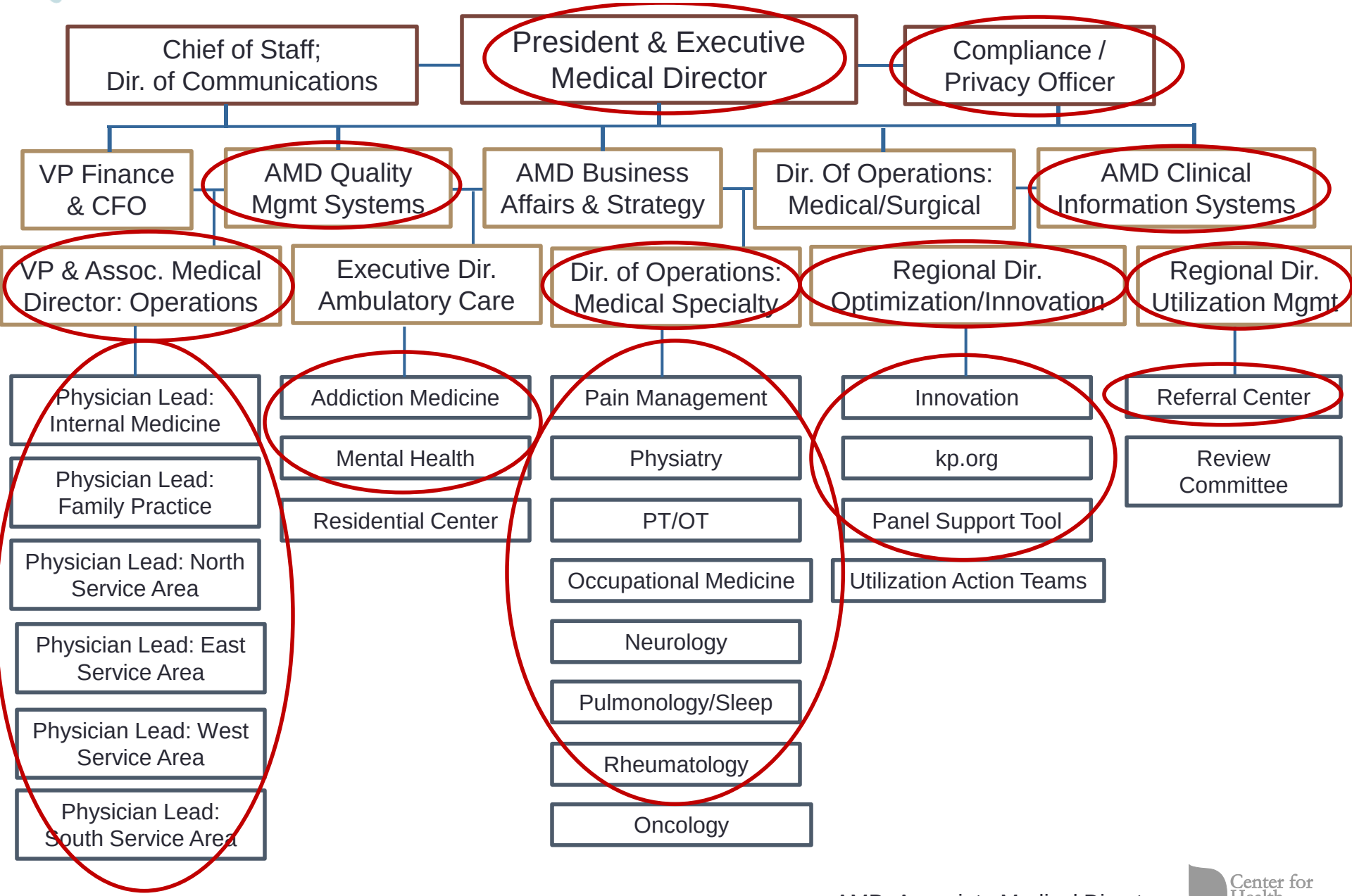
Importance of Two-way Flow of Information / Education



Many stakeholders but not all created equal…



AMD: Associate Medical Director

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

Other Critical Issues for Qualitative Component of Pragmatic Trials

- What the researchers most need to know less attainable using traditional interviews and focus groups
  - Need for fast turn around, recognize may learn more "off the record", observing routine interactions/meetings often more helpful than formal feedback
  - Use of rapid assessment process and field notes helpful approach
- More congruent with PCORI focus on inclusion of patients/clinical stakeholders as partners rather than primarily as study participants
- Regular feedback to stakeholders critical
  - Multiple modalities helpful (advisory groups, postcards, video ethnographies)
  - Emphasize illustrative stories/case histories rather than emphasis on quantitative interim results (easily misinterpreted with small numbers)

Rapid Assessment Process (RAP)

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

Beebe "Rapid Assessment Process" (2001) Altamira Press.

McMullen et al. Methods of Information in Medicine 2011; 50(4):299-307.

Our RAP 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

CRITICAL ISSUES FOR QUANTITATIVE DATA COLLECTION IN PRAGMATIC TRIALS

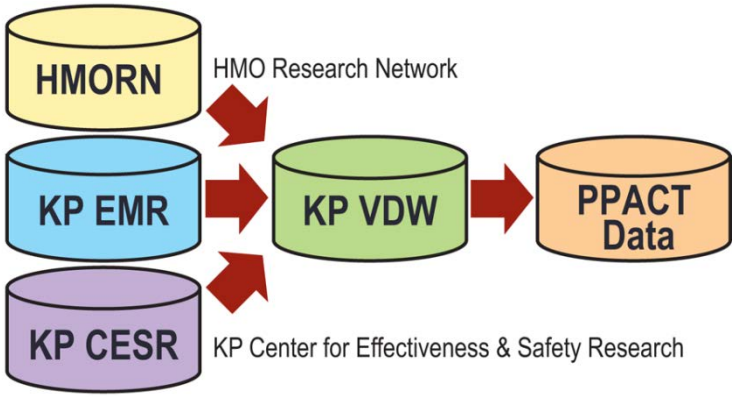
Critical Issues for Quantitative Data Collection

- (Funders) expect that trial data extracted from what is collected for clinical care
  - Clinical/functional measures, health care utilization, cost (potential moderator and mediator variables likely limited)
  - Need to adapt what is already used rather than imposing alternative scale (prioritizing brevity, face validity, discrete response options, and meaningful clinical cut-offs)
  - Return On Investment (ROI) critical for operational leaders in maintaining intervention
- Assessments that also addresses operational/regulatory need enhance uptake and sustainability (e.g., opioid monitoring for state medical boards / FDA REMS)

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, disability, chronic disease burden, sleep difficulties, kinesiophobia)	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



Opioid Therapy Plan (OTP) Operational Criteria

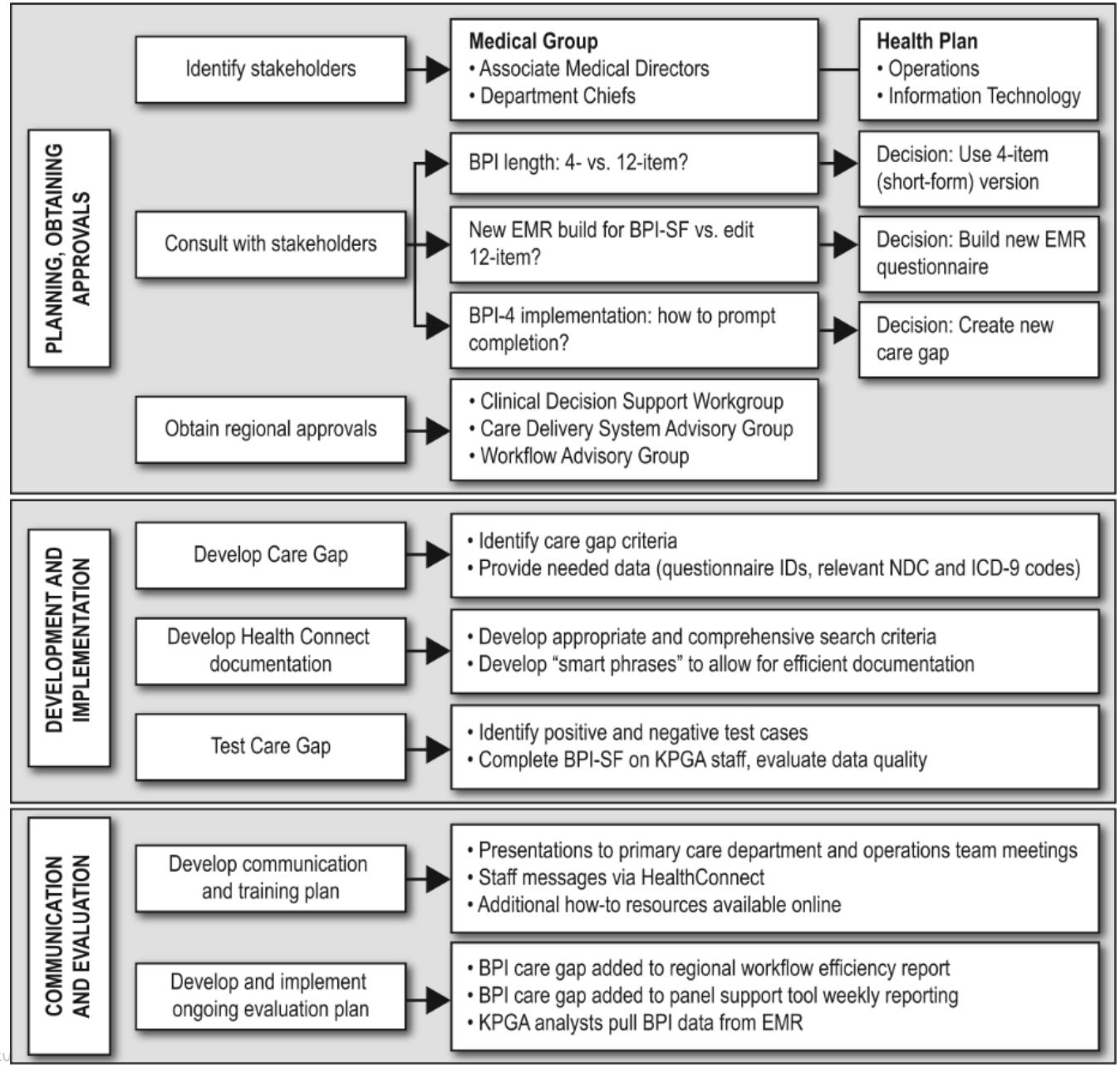
PATIENT CRITERIA	BASIC GREEN	COMPLEX YELLOW	COMPLEX RED
Follows plan reliably	X		
No history of opioid abuse	X		
No history of other substance abuse within past 2 years	X		
No current behaviors indicating drug misuse	X		
Current behaviors raise questions about the ability to follow the OTP		X	
History 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

Ensuring Adequacy of Primary Outcome Data

	KP Northwest	KP Georgia	KP Hawaii
Routine BPI collection	Established	Developing	Champion Driven
Currently established collection methods	- Panel Support Tool Care Gap - Nursing workflow - E-mail (kp.org)	- PCP training	- Panel Support Tool Care Gap (not maximally utilized)
Active work with region to establish additional methods	- Ongoing PCP training	- Panel Support Tool Care Gap - Pre-visit documentation - Nursing workflow - E-mail (kp.org)	- Pharmacy collection at point of refill - Nursing workflow - E-mail (kp.org)

BPI: Brief Pain Inventory



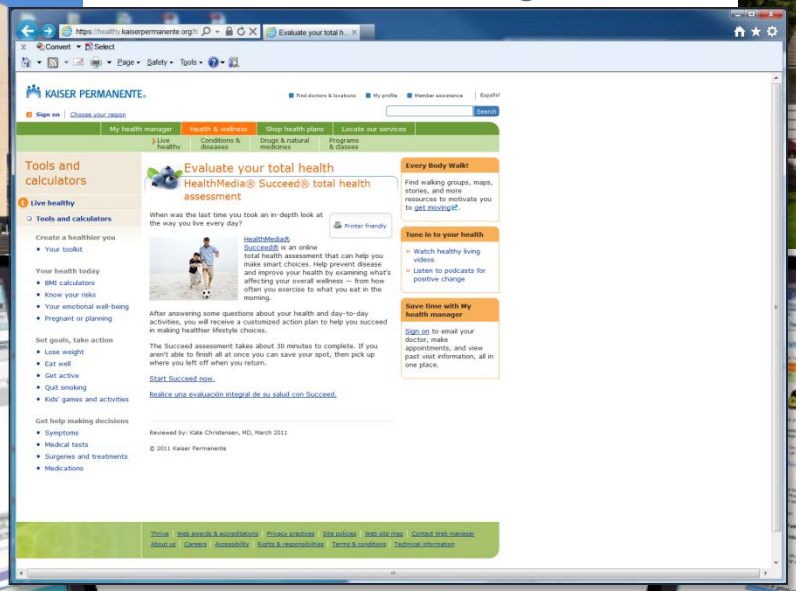
Establishing Routine BPI Administration in Clinical Workflow

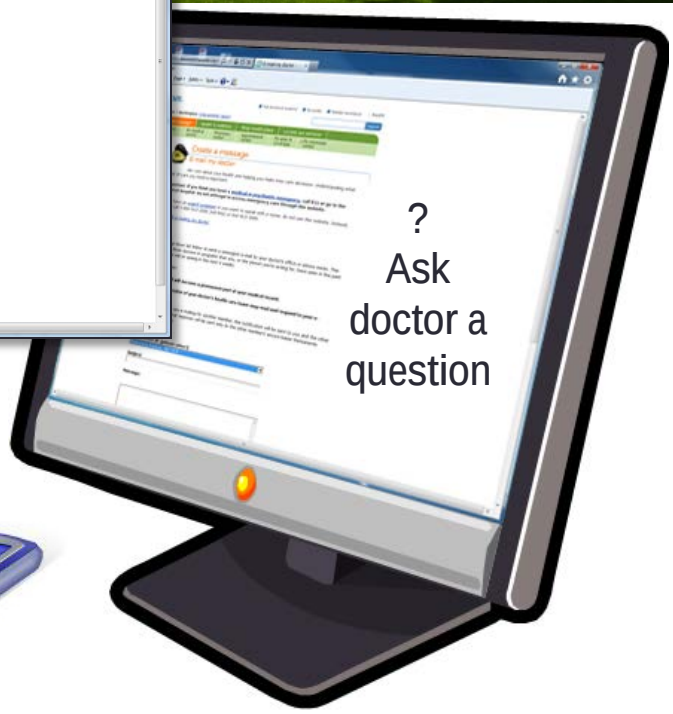
Using the Personal Health Record to Collect PROs

Kaiser Permanente

Patient Home

www.KP.org





EPIC Terminal

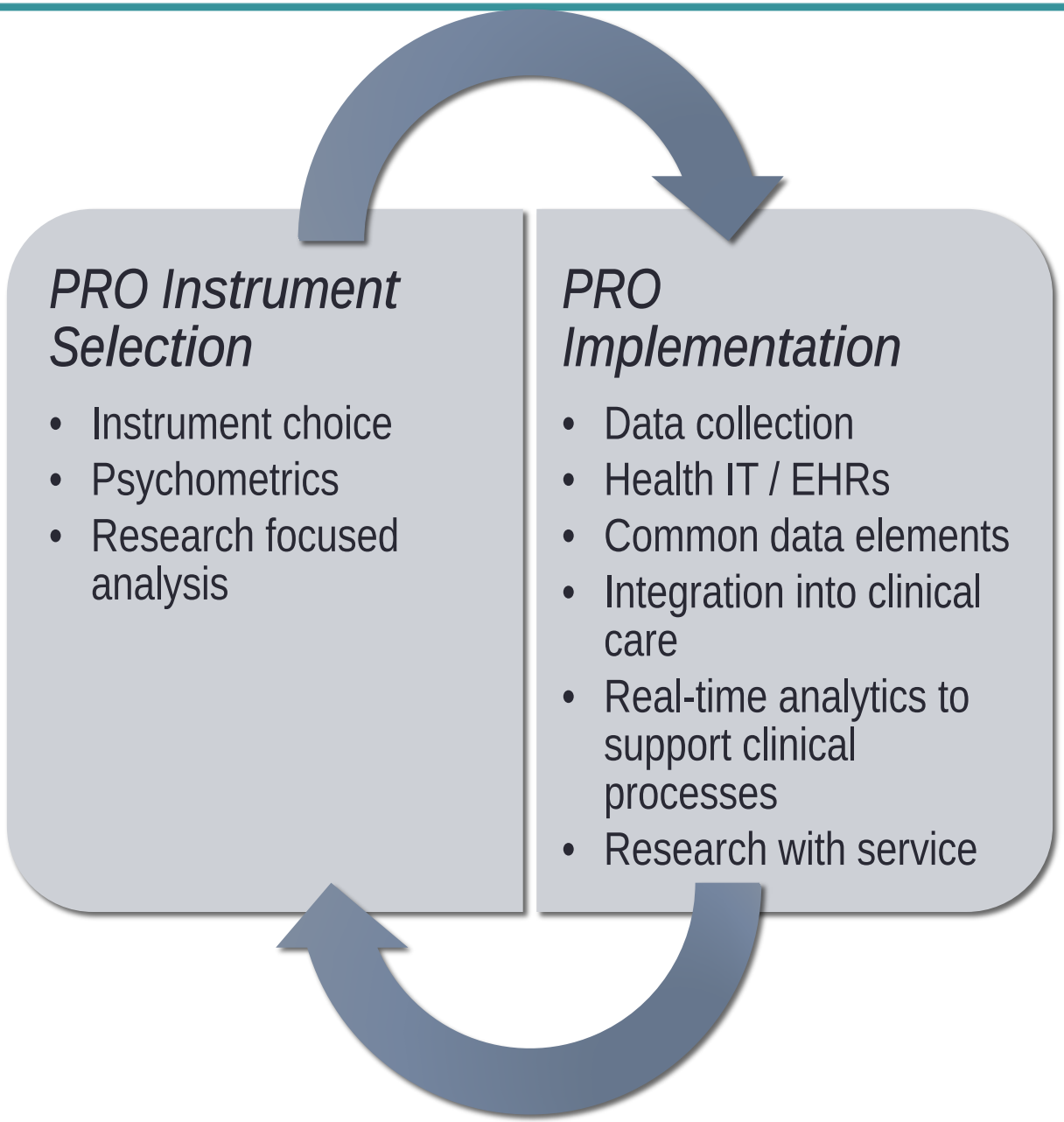
Personal Digital Devices

Important Characteristics of the PRO: Logistics of Administration and Potential Reactivity

- Logistics of Administration
  - Frequency of BPI administration linked to patient's OTP "risk" level -> need to support low burden modes of collection to encourage more frequent PRO collection (e.g., Personal Health Record / e-mail, IVR)
  - 4- versus 12-item scale improves work flow
- Consider context of PRO administration and potential reactivity
  - Patient belief: Pain severity linked to "need" for opioid medication
  - Reported PCP preference for abbreviated scale as "focuses the discussion on functioning and don't need to explain an arbitrary summary score"
  - Consider context of PRO administration and potential reactivity
- IT/Medical informatics partnerships critical for success in executing assessment through health care delivery systems

Potential Cautions for Research Use of Clinically Collected PROs

- Adoption can be largely driven by “stick” (regulation or safety concerns) rather than “carrot” (clinical utility)
- Example: Administration of BPI linked to Opioid Prescription
  - Frequency of PRO administration linked to opioid dose (morphine equivalent dose)
  - Potential loss of follow-up data for those tapering off opioids
- Timing and Amount of Data Variable
  - Heterogeneity across health care providers
  - Potential for more frequent collection of PRO among patients with higher rates of health care utilization (potential bias by medical complexity or pain severity)



INTERVENTION – LESSONS LEARNED

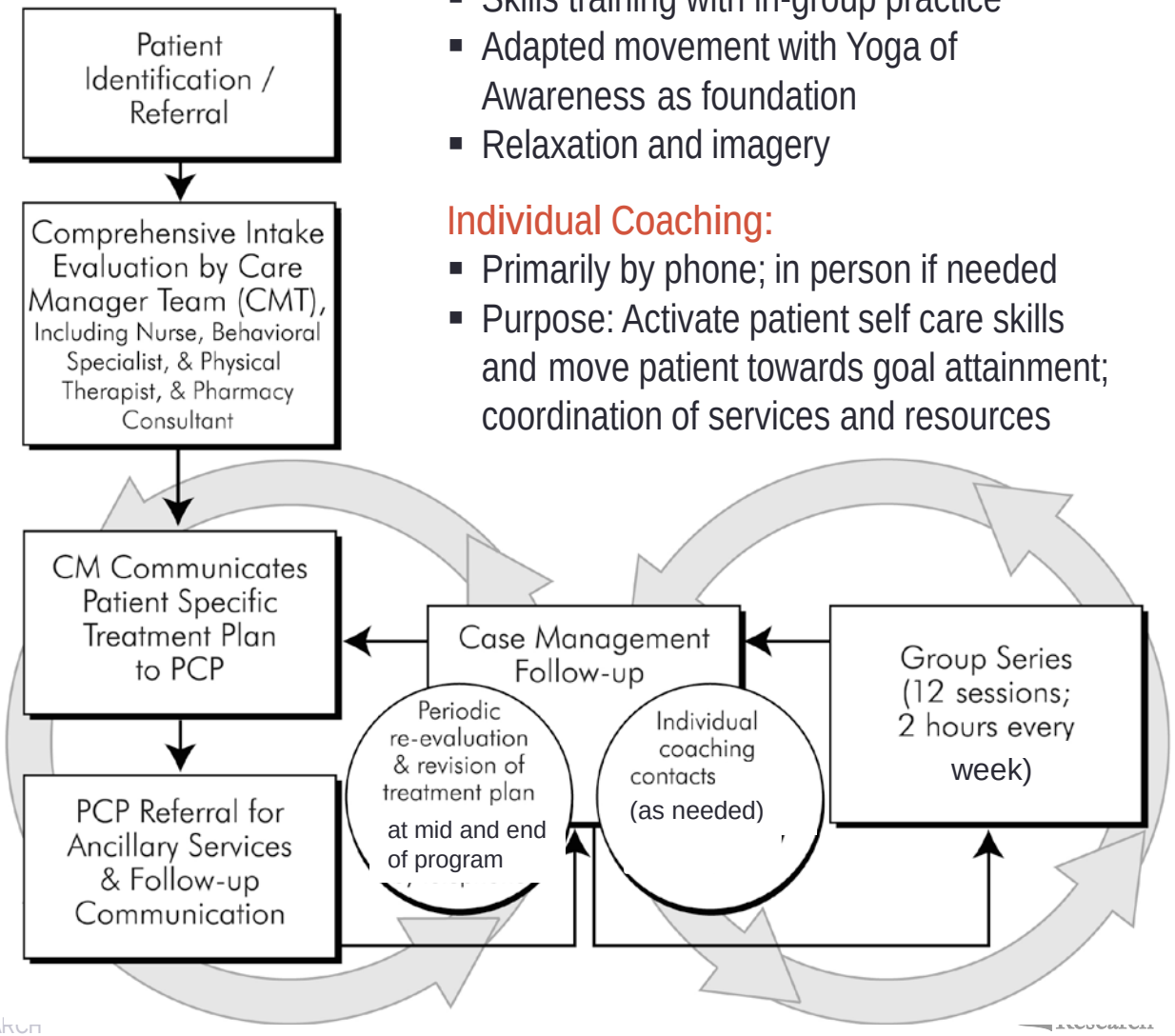
About the Intervention

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

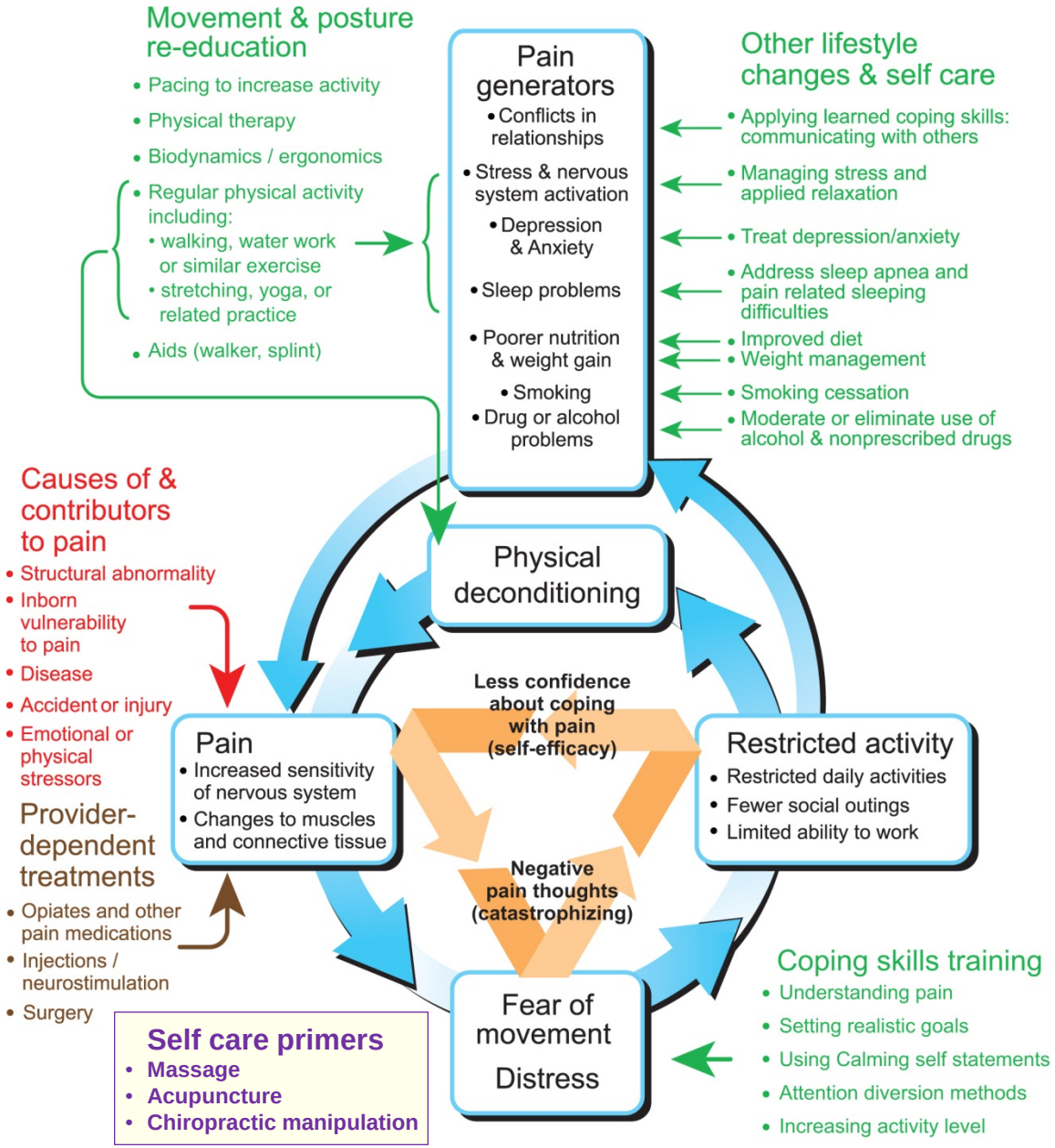


Group Session Components:

- 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



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 activate coping and self care to interrupt cycle
- Highlights multiple areas to target for improved pain and function

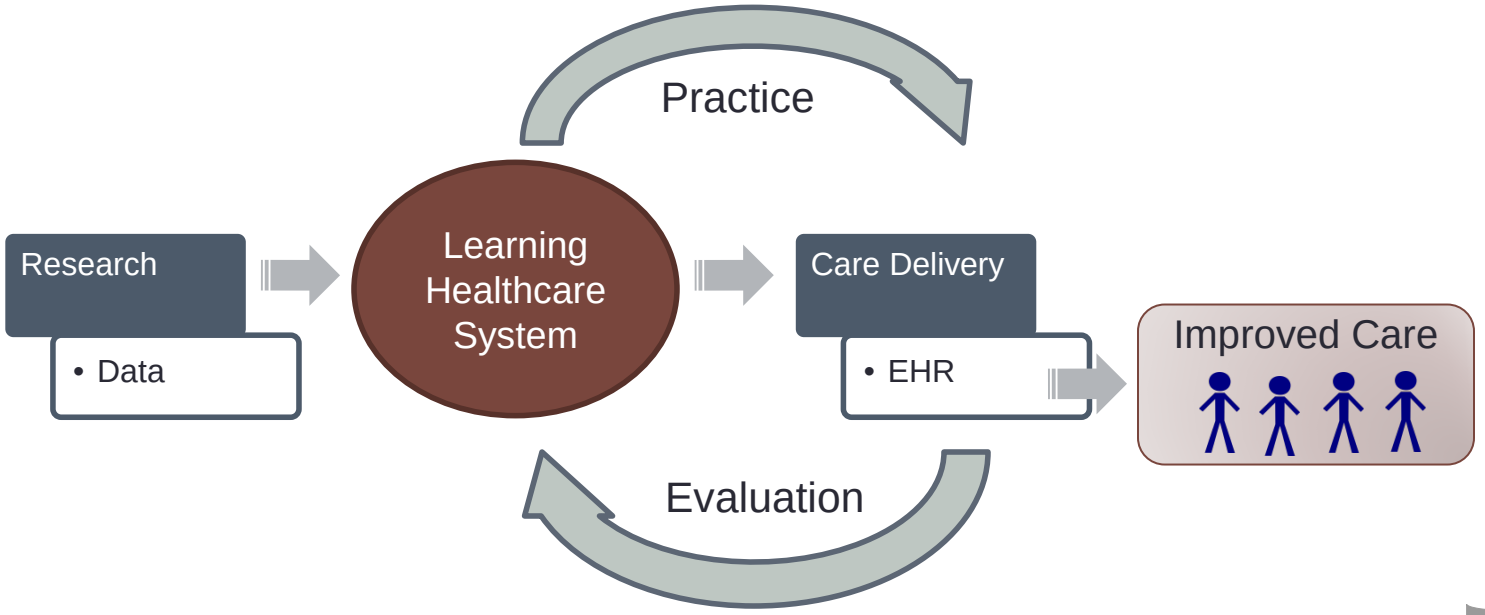
- Green domains: Reinforce multitude of active strategies
- Brown domain: Limit patient reliance on provider dependent treatments
- Red domain: Reframe patient mindset away from focusing on cause towards management

Intervention – Lessons Learned

- Embedding intervention into a *culture* in which behavioral change may not be optimally/consistently supported
- Disciplinary professional and financial compliance/billing may restrict elements of optimal intervention (e.g., physical therapy)
- Intervention (structure, training, and supervision/consultation) should be structured so that staffing can be realistically sustained in everyday clinical care
- Expect that there will be some evolution of the intervention structure across the course of the trial (accommodating fit with clinical work flow and clinical/operational stakeholder input)

Pragmatic Trial Embedded into Learning Healthcare System

- Potential to refine implementation as proceed and learn from stakeholder feedback
- Can evaluate sustainability of intervention and work to support in a gradated fashion
- May be more adaptable to budgetary and implementation constraints



Closing Thoughts on Conducting Multifaceted Behavioral Pragmatic Trials…

- Rewarding but more complicated and potentially expensive (at least now) than traditional RCTs
- Framework of change, communication language, choices for design and assessment should be native to health care system
- More to "carry" with behavioral change intervention than in traditional/non-embedded trials
  - Need to consider broader system, constraints on intervention dose and interventionist expertise/training, likely limits in setting/resource availability, more complex and often less motivated patients
- NIH Collaboratory/PCORnet may be helpful resources for conducting these types of trials (https://www.nihcollaboratory.org)

TBM

PRACTICE AND PUBLIC HEALTH POLICIES

A primary care-based interdisciplinary team approach to the treatment of chronic pain utilizing a pragmatic clinical trials framework

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ABSTRACT

Chronic pain affects at least 116 million adults in the USA and exacts a tremendous cost in suffering and lost productivity. While health systems offer specialized pain services, the primary care setting is where most patients seek and receive care for pain. Primary care-based treatment of chronic pain by interdisciplinary teams (including behavioral specialists, nurse case managers, physical therapists, and pharmacists) is one of the most effective approaches for improving outcomes and managing costs. To ensure robust integration of such services into sustainable health-care programs, evaluations must be conducted by researchers well versed in the methodologies of clinical trials, mixed methods and implementation research, bioinformatics, health services, and cost-effectiveness. Recent national health policy changes, in addition to the increasing recognition of the high prevalence and cost of chronic pain conditions, present a unique opportunity to shift the care paradigm for patients with chronic pain.

Implications

Practice: Treatment of chronic pain by interdisciplinary teams (including behavioral specialists, nurse case managers, physical therapists, and pharmacists) within the primary care setting best meets current health-care needs and promises one of the most effective approaches to care.

Policy: Recent health policy changes (increasing adoption of medical home model and electronic medical records) as well as the high prevalence and cost of chronic pain conditions may present a unique opportunity to shift the paradigm for care of chronic pain patients.

Research: Including researchers well versed in the methodologies of clinical trials, mixed methods and implementation research, bioinformatics, health services, and cost-effectiveness may best ensure robust integration of primary care-based interdisciplinary chronic pain treatment into sustainable health-care programs.

KEYWORDS

Chronic pain, Interdisciplinary/multidisciplinary teams, Primary care, Implementation, Research, Pragmatic clinical trials

It is becoming increasingly clear that pain is one of our most common and expensive public health problems [1]. Research shows that pain is the main reason patients seek medical care, and yet medical management of patients with chronic pain and complex problems remains fragmented, leading patients to seek a wide variety of primary and specialty care services in an effort to manage their pain and related conditions [1, 2]. Such fragmented care leads to poorer outcomes and significantly increases health-care costs as patients often receive unneeded diagnostic and medical procedures [2, 3].

Interdisciplinary pain management protocols, particularly those employing a biopsychosocial framework, have been among the most successful approaches in helping patients reduce symptoms and regain functioning [4–7]. Such protocols combine a variety of therapeutic modalities and rely on teams of physicians, behavioral specialists, nurse case managers, and physical therapists to help patients develop the skills to actively self-manage their condition [8–14]. However, while research has identified evidence-based interdisciplinary behavioral treatment approaches that are effective for patients with chronic pain, these interventions are rarely available in everyday practice settings [2] and will require a new care paradigm effected by changes in research, practice, and policy. Significantly, it is not enough to simply bring together treatment team members from different health-care disciplines. The treatment approach must be fully integrated across these disciplines to achieve the best results [15–17].

Finally, while interdisciplinary behavioral treatment programs have resulted in promising outcomes, they have generally not been conducted and evaluated in a manner to ensure robust integration into sustainable health-care programs. Specifically, this area of study

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