PACT

Pain
Program for Active
Coping & Training

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

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Portland, Oregon

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Agenda

- Background
  - Summary of Study Design
  - Key Contextual Factors (safety concerns, utilization and cost, clinical complexity)
  - The potential underbelly of the timely clinical research question
- Lessons learned:

1. Innovative Qualitative Methods Driven by PCT Framework
   - Bi-directional learning, understanding your stakeholders, rapid assessment process/use of field notes
2. Collecting PROs in Pragmatic Trials
   - Pragmatically driven assessment / centrality of the Electronic Health Record
   - Patient Reported Outcomes (PROs) specific considerations
3. Implementing Behaviorally Intensive Interventions
   - New processes for everyone
   - Complex and urgent clinical focus presents unique challenges and opportunities

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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 on long-term opioid therapy
- Prioritized recruitment based on operationally identified need:
  - MEQ ≥ 120mg
  - Concurrent opioid and benzodiazepine use
  - High utilization of primary care services

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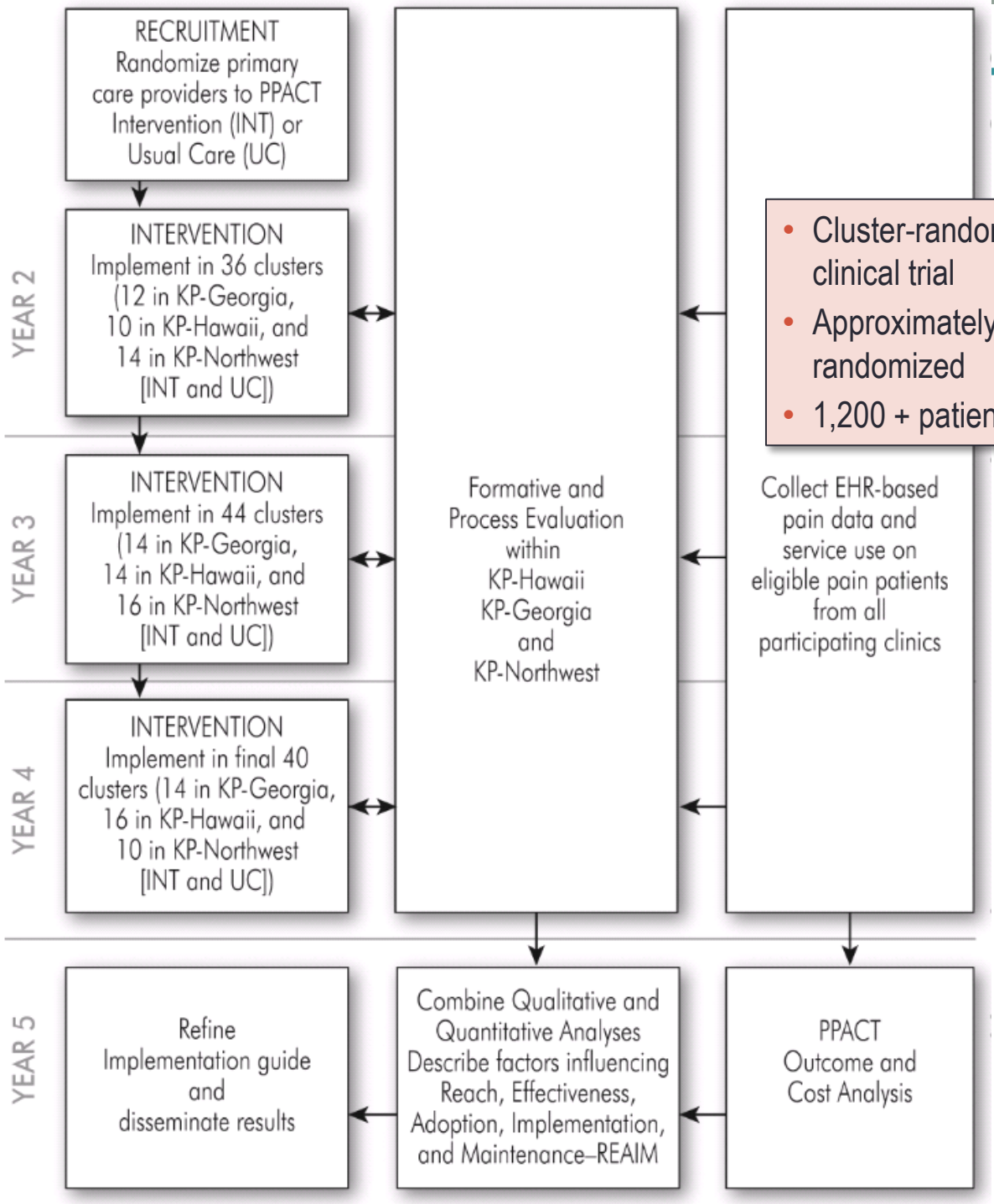
Trial Design



- Cluster-randomized pragmatic clinical trial
- Approximately 500 PCPs will be randomized
- 1,200 + patients

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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, myofsacial pain, neuropathies, migraine, tension headache, tempromandibular joint disorder, carpal tunnel syndrome, nonspecific chronic pain, abdominal pain, pelvic pain

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Patient Characteristics

Pain Characteristics	KP Northwest	KP Georgia	KP Hawaii
Total members (18 and older) with chronic non-malignant pain using long term opioid therapy	12,579 (Remaining numbers subset of this N)	1,473 (Remaining numbers subset of this N)	1,560 (Remaining numbers subset of this N)
Back and neck pain	4,595 (37%)	985 (67%)	866 (56%)
Joint pain (including osteoarthritis)	2,748 (22%)	439 (30%)	432 (28%)
Non-specific and other pain	3,910 (31%)	233 (16%)	530 (34%)
Two or more CNMP diagnoses	2,625 (21%)	359 (24%)	434 (28%)
Comorbid Medical Conditions			
Diabetes	2,444 (19%)	314 (21%)	354 (23%)
Cardiovascular disorders	4,267 (34%)	852 (58%)	652 (42%)
Two or more chronic medical conditions (Diabetes, CV, Respiratory)	1,990 (16%)	364(25%)	302 (19%)
Psychiatric disorders	3,005 (24%)	550 (37%)	347 (22%)

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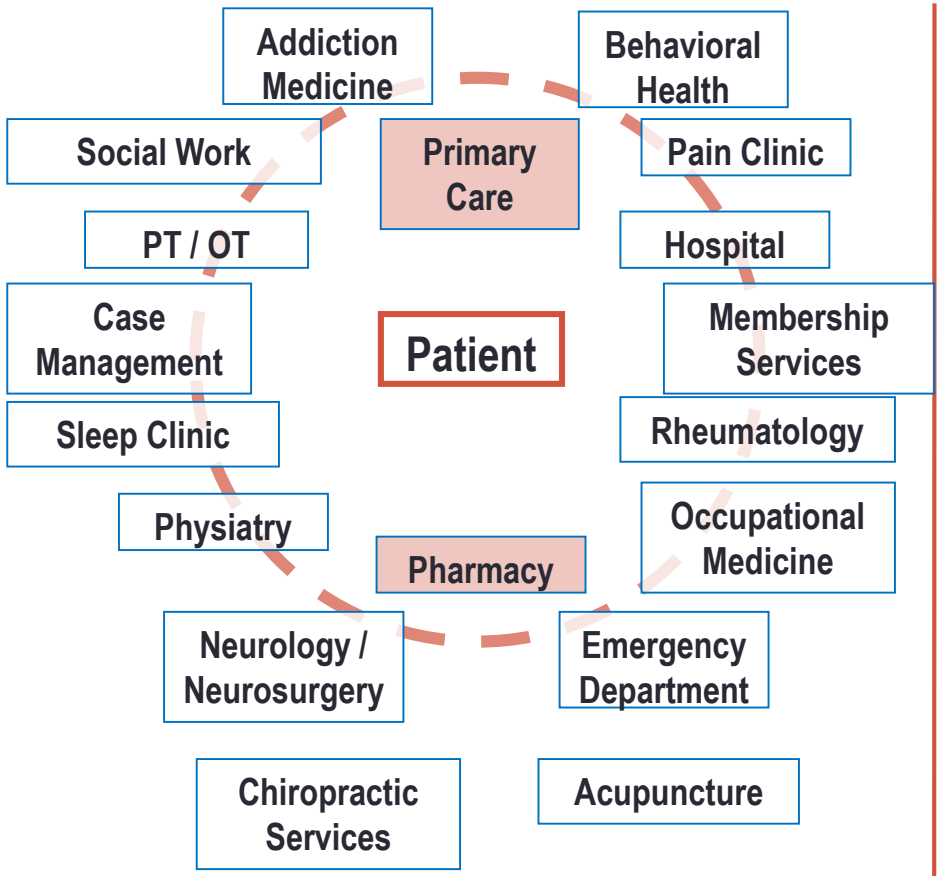
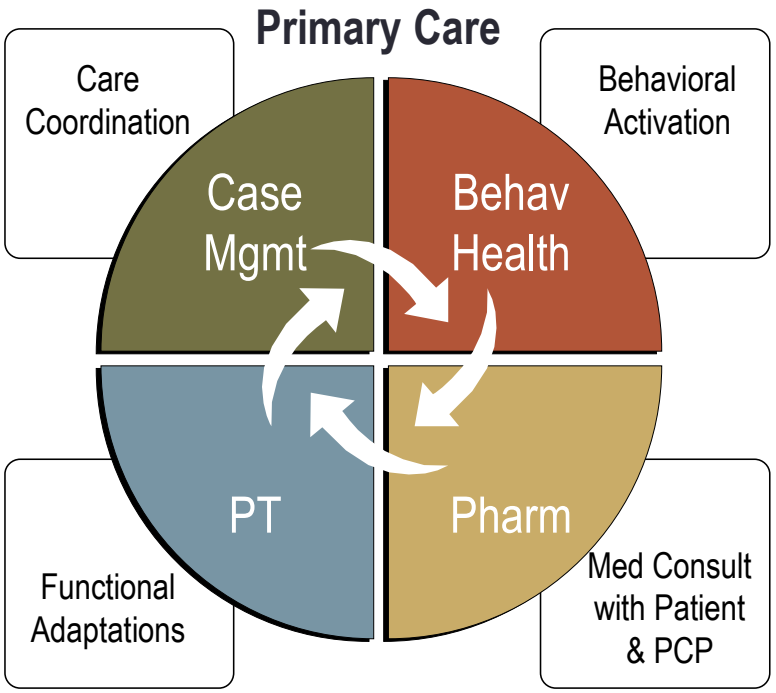
Pain Management: Usual Care



Interdisciplinary Management Embedded in Primary Care



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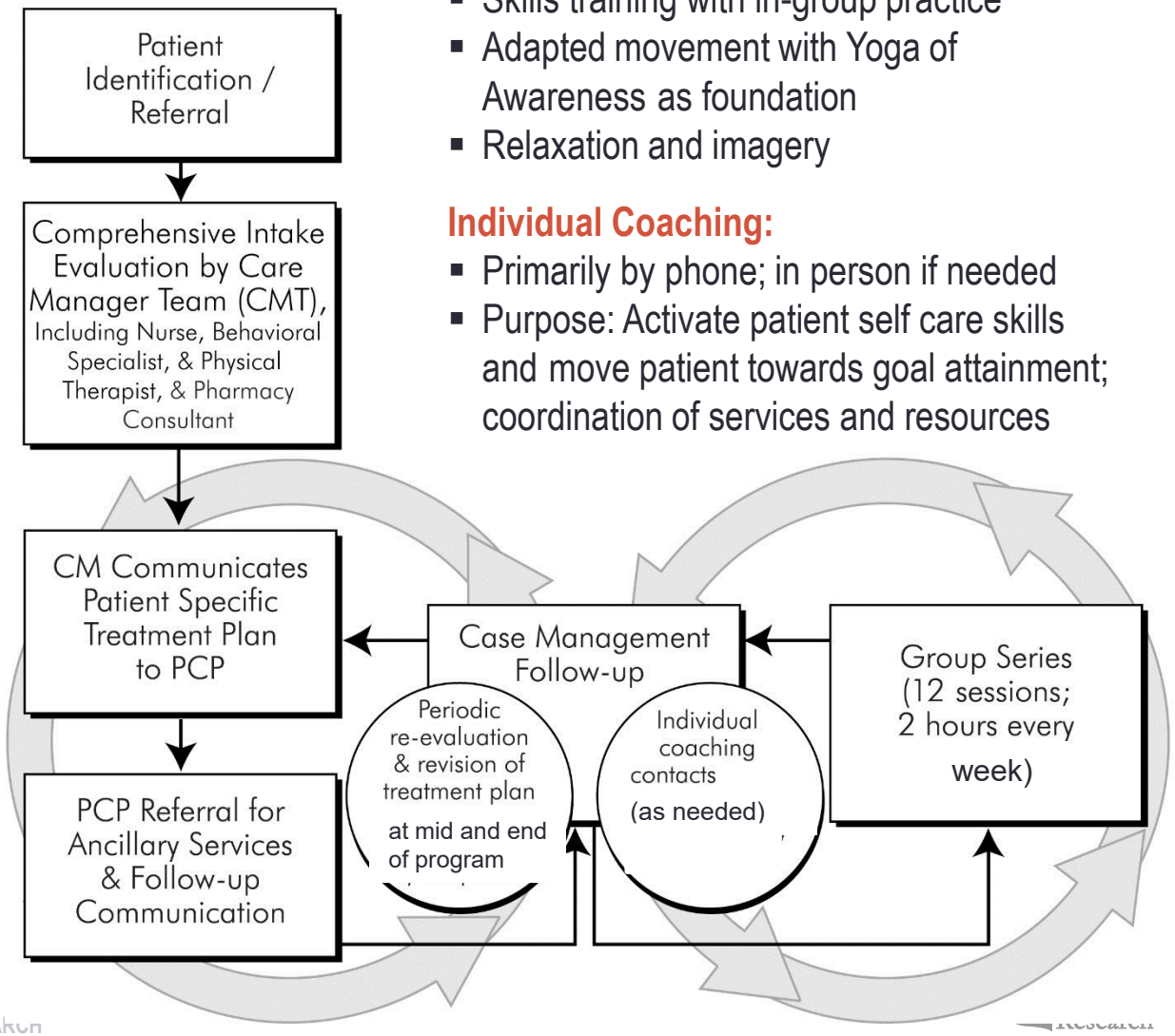
About the Intervention

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

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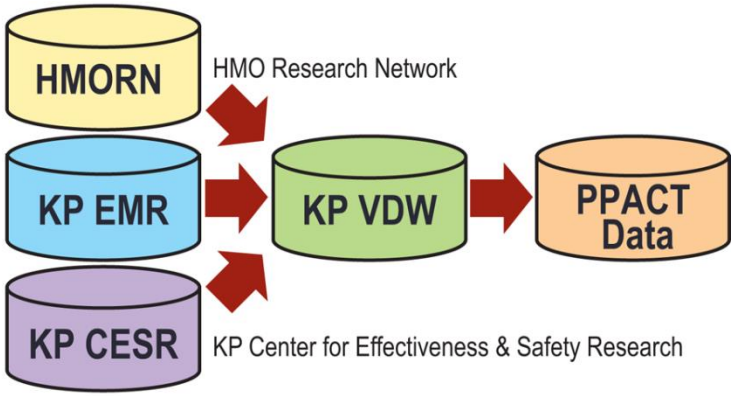
Outcome Variables

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



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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

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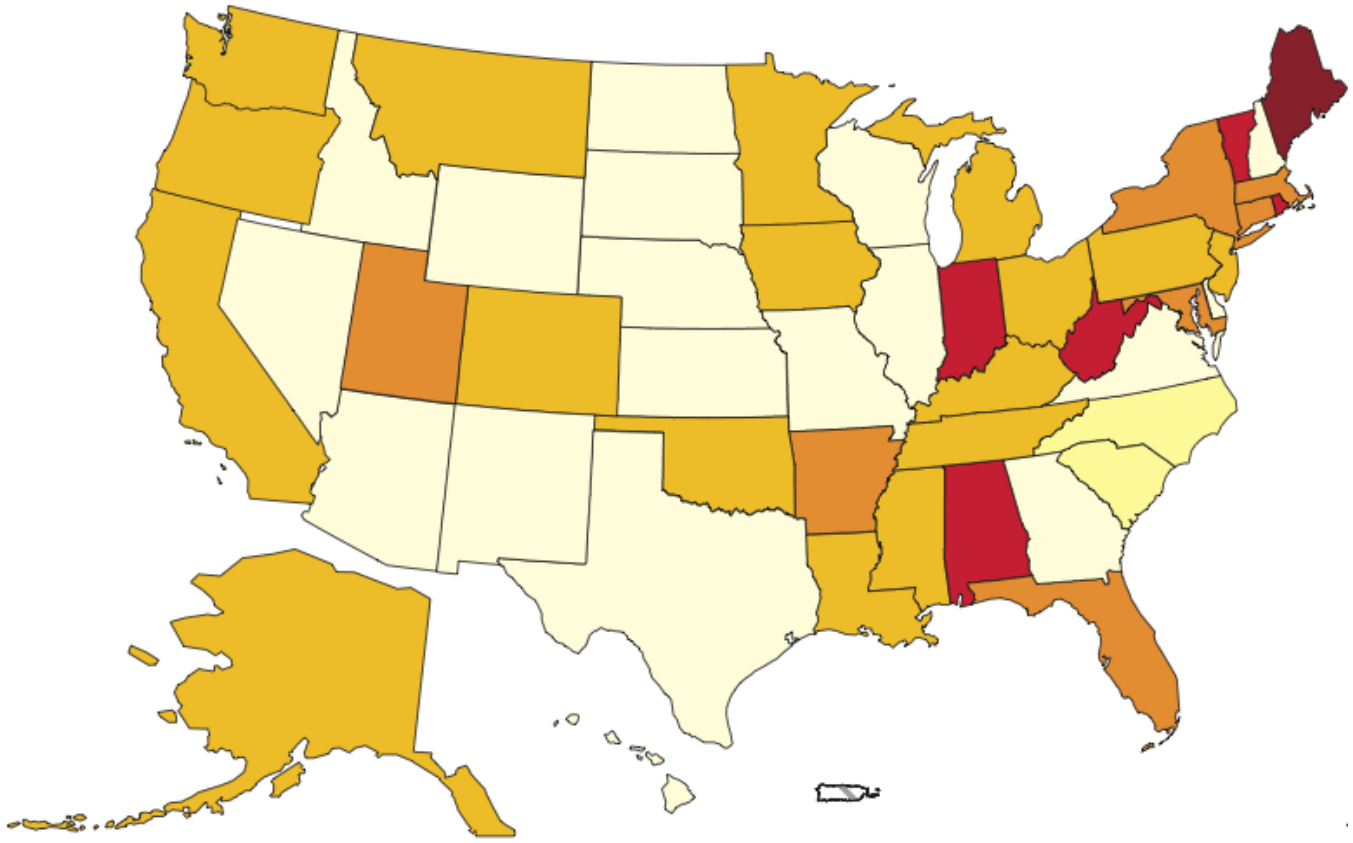
Primary non-heroin opioid admission rates, by State (per 100,000 population aged 12 and over)



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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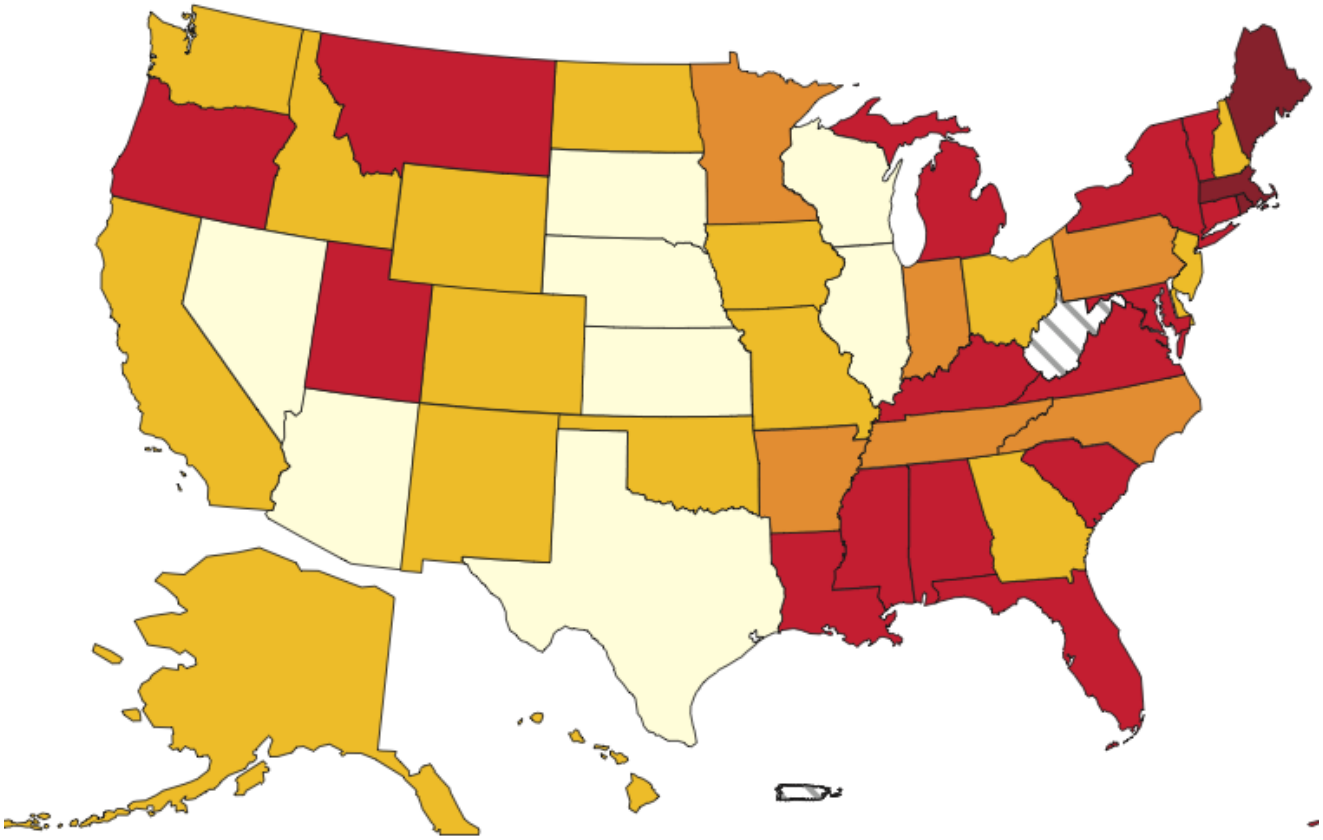

2001

(range 1 – 71)

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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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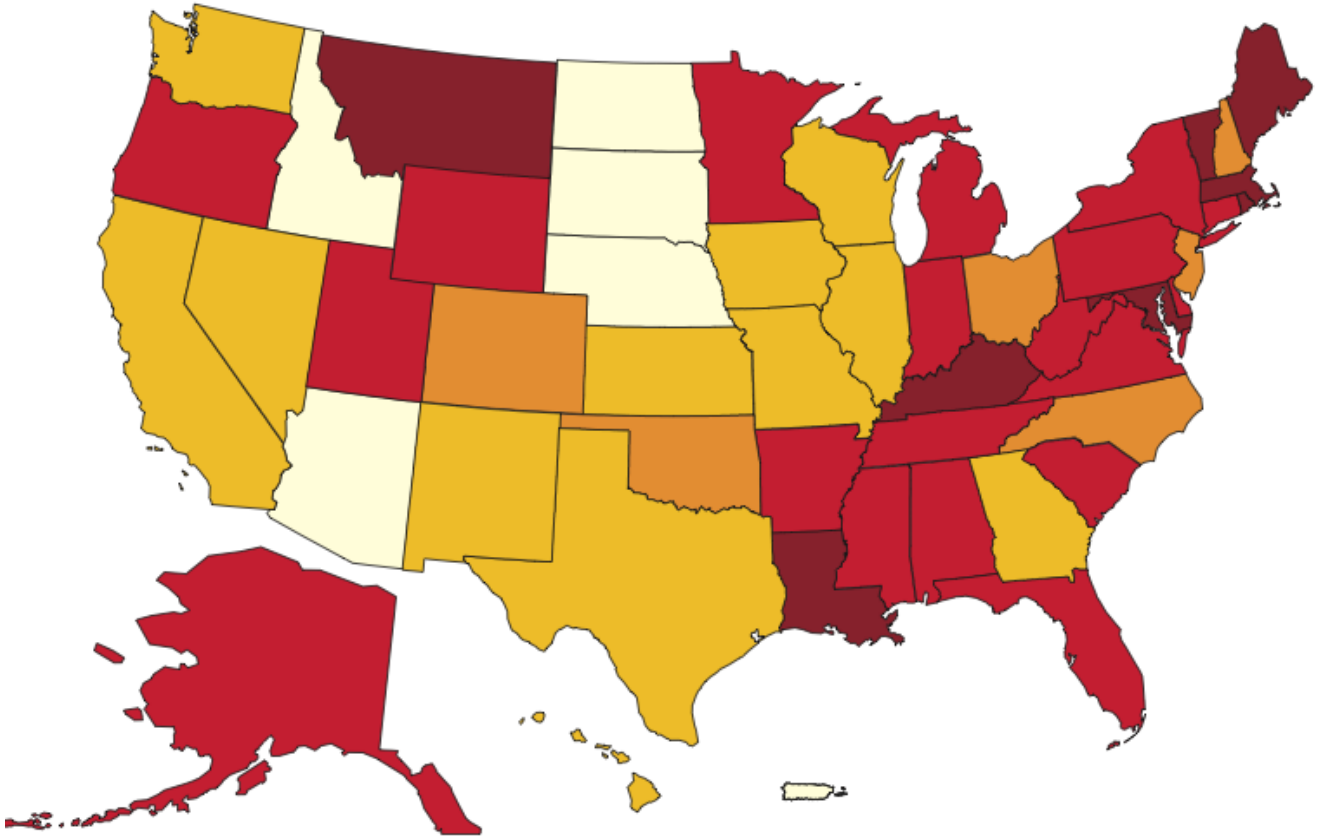

2003

(range 2 – 139)

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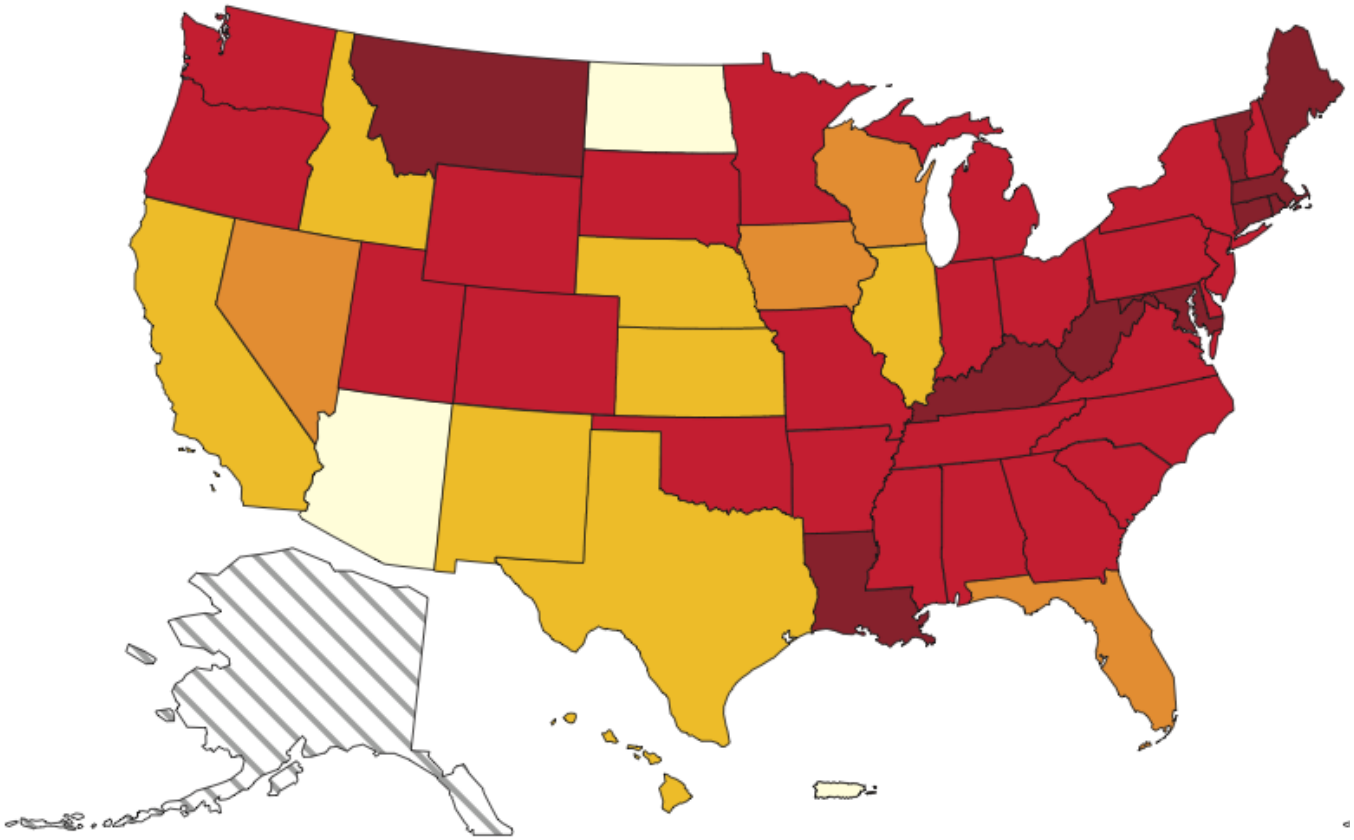
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



2005

(range 0 – 214)

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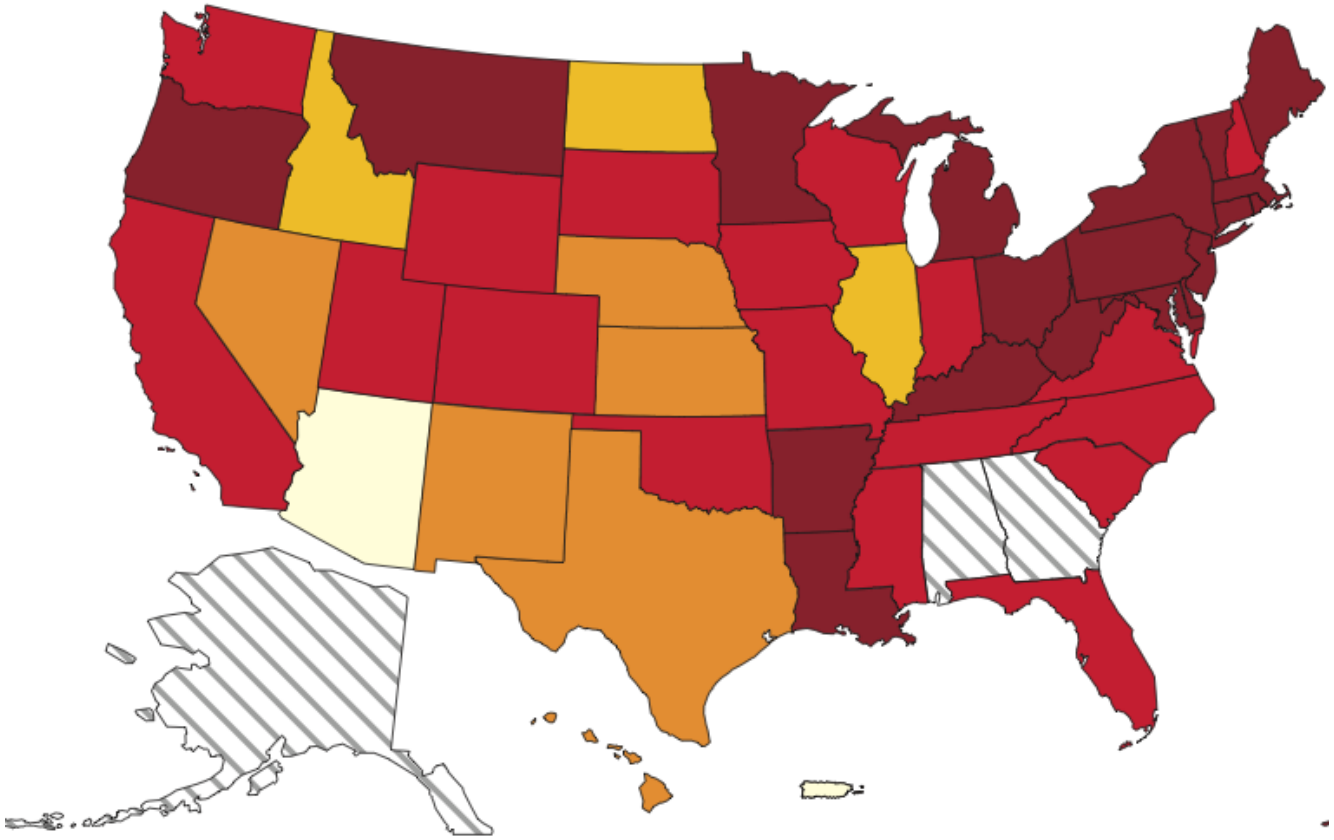
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



2007

(range 1 – 340)

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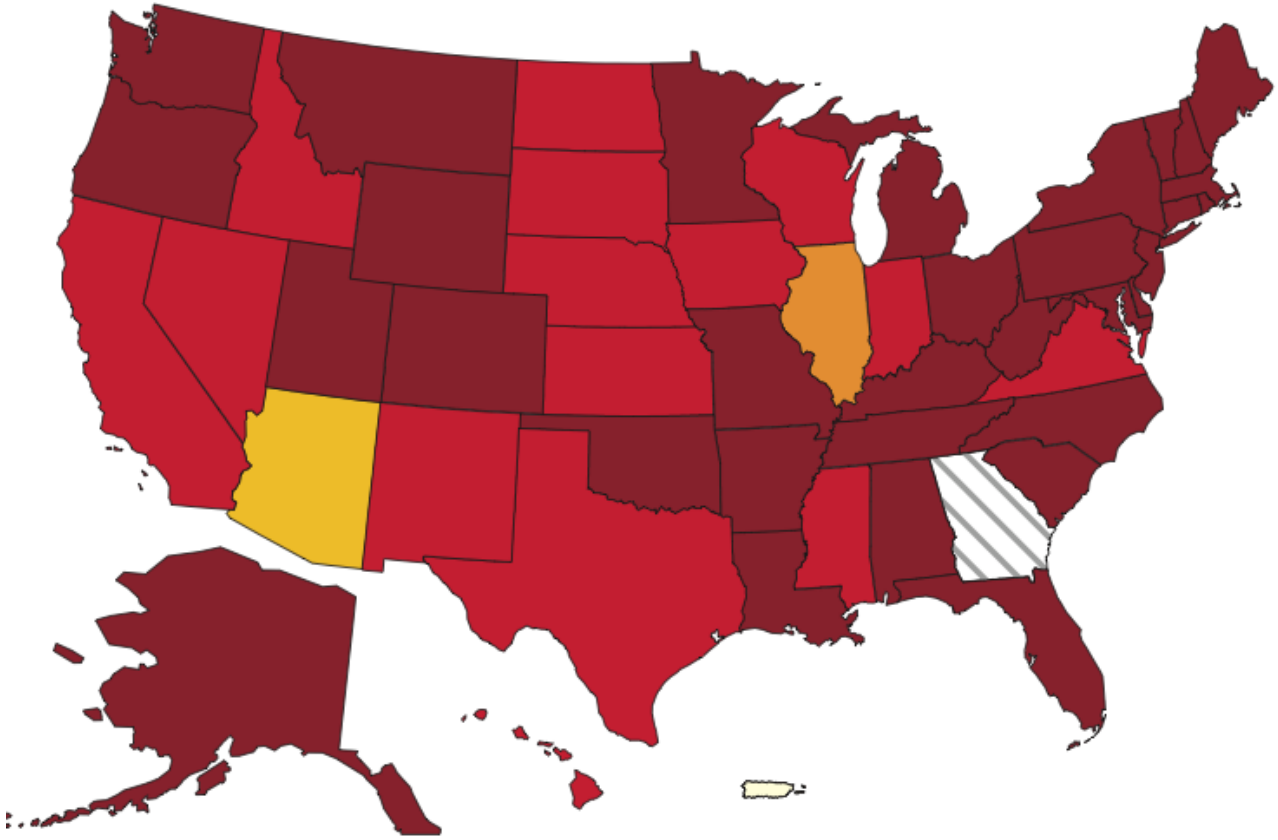
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



2009

(range 1 – 379)

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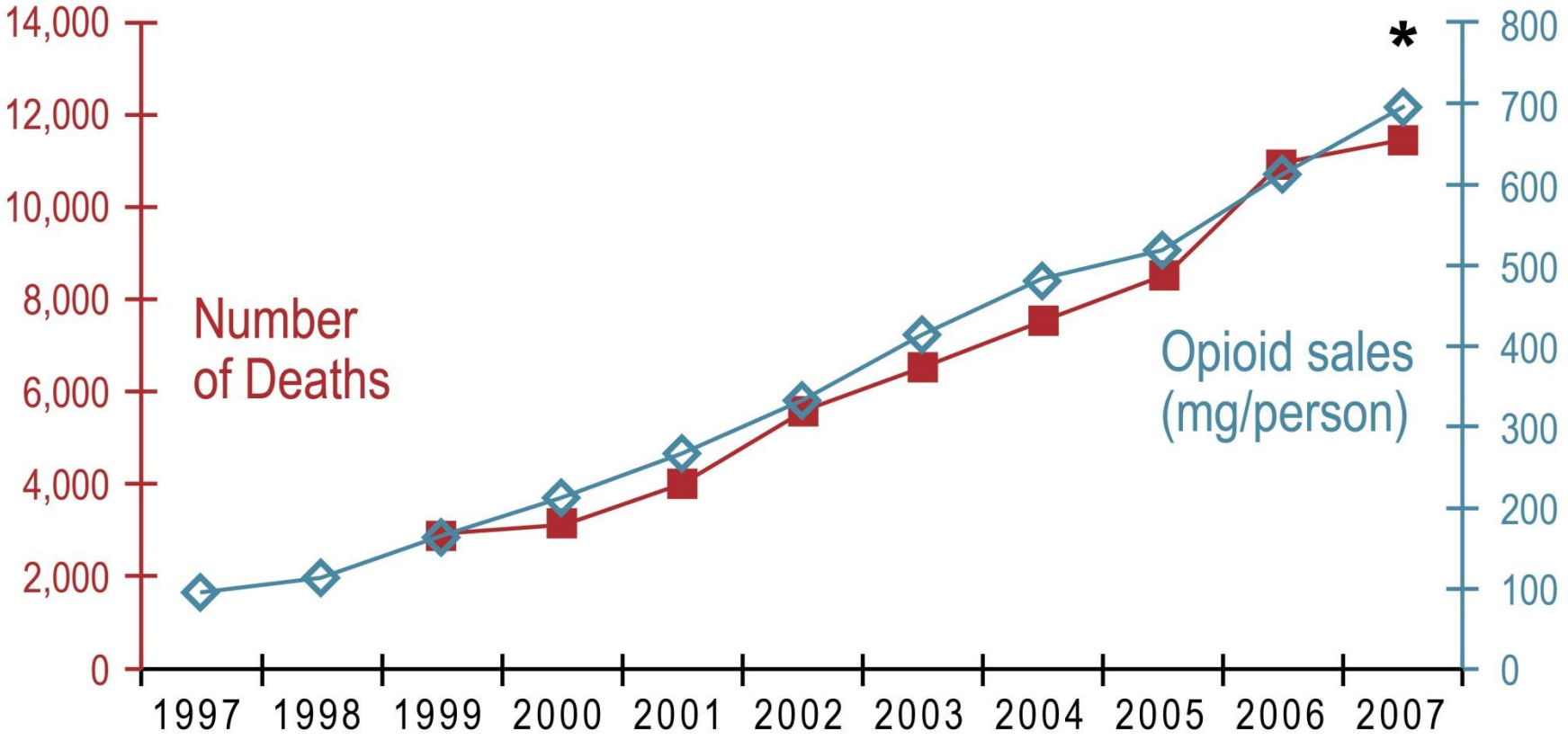
8 - 14	19 - 44	Incomplete data

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.

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

Total Sales & Prescriptions for OxyContin (1996-2002)

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

Source: United States General Accounting Office: Dec. 2003, “OxyContin Abuse and Diversion and Efforts to Address the Problem.”

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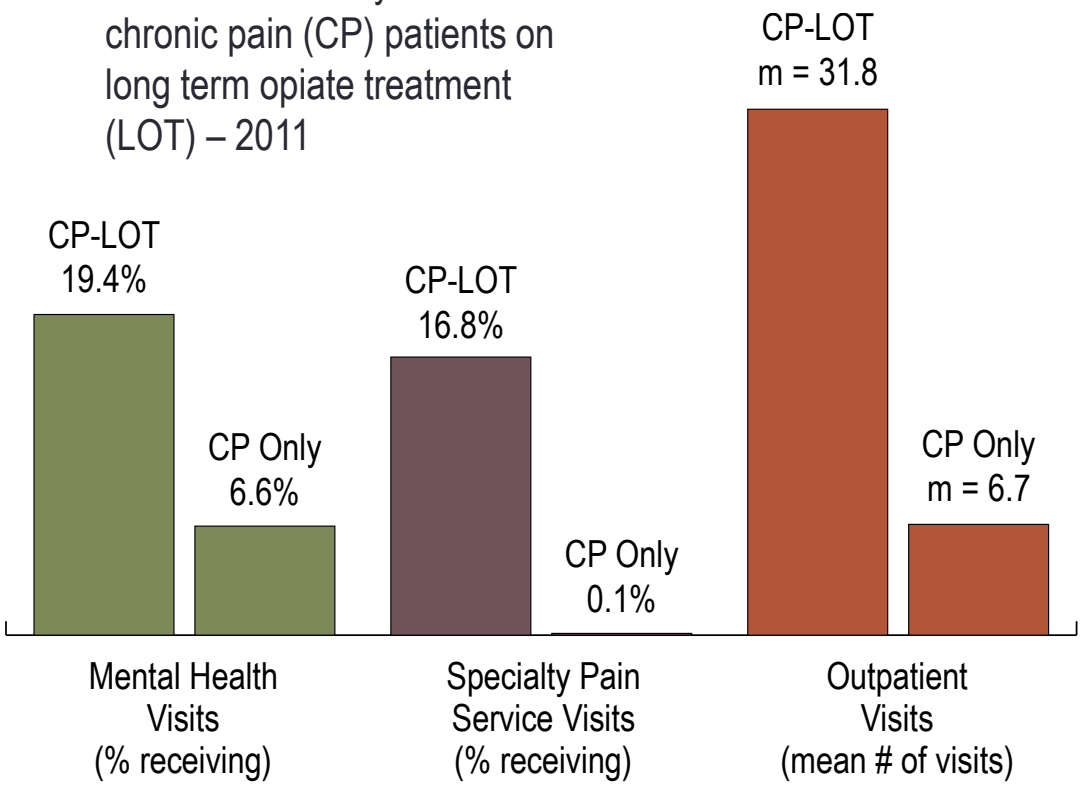
Utilization Associated with Opioid Use

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.

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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 your healthcare setting(s)
- What makes this a “timely clinical research question” to health care 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

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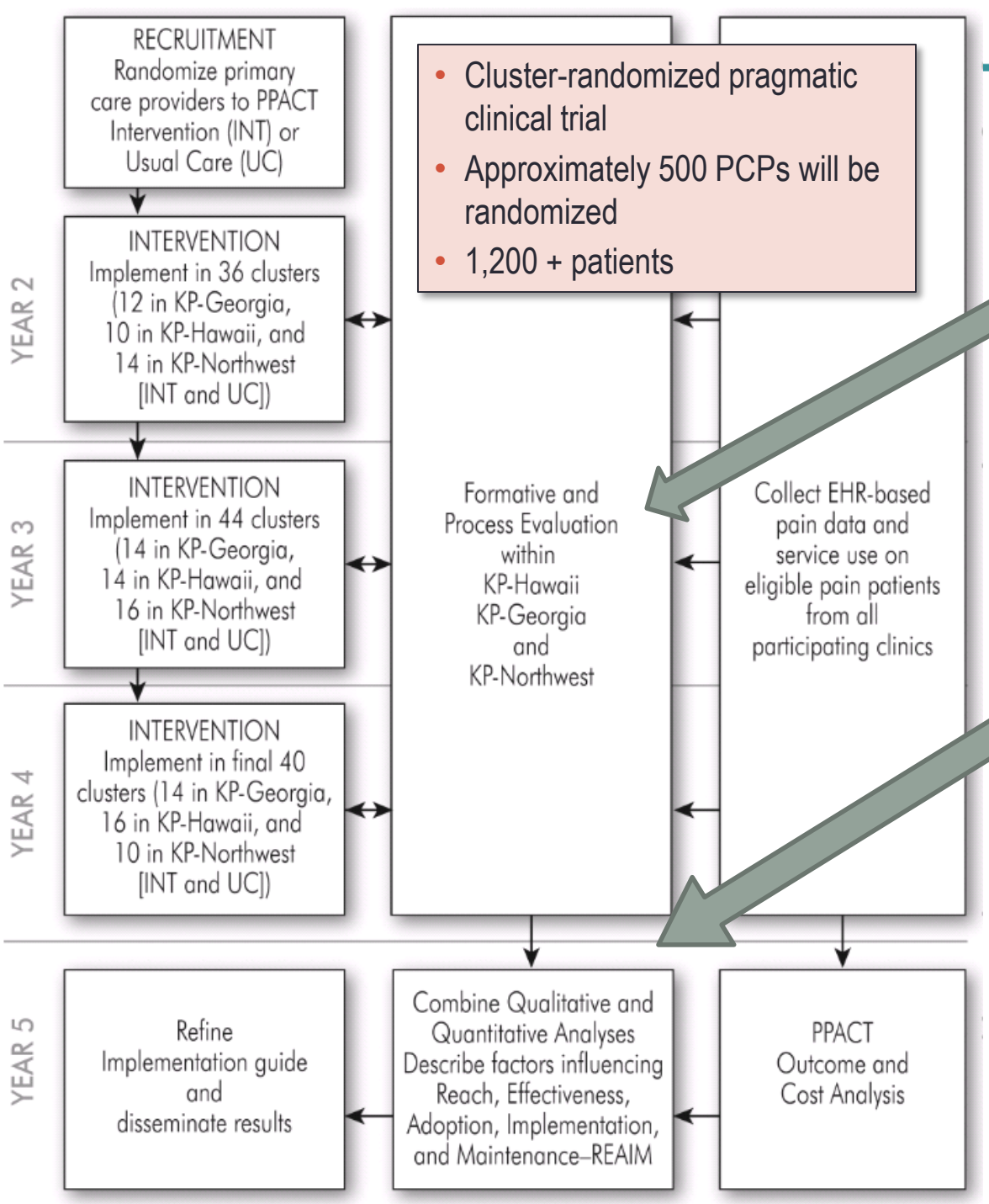
QUALITATIVE WORK CRITICAL BUT METHODS DRIVEN BY PCT FRAMEWORK

Adapted Qualitative Methods



- Cluster-randomized pragmatic clinical trial
- Approximately 500 PCPs will be randomized
- 1,200 + patients

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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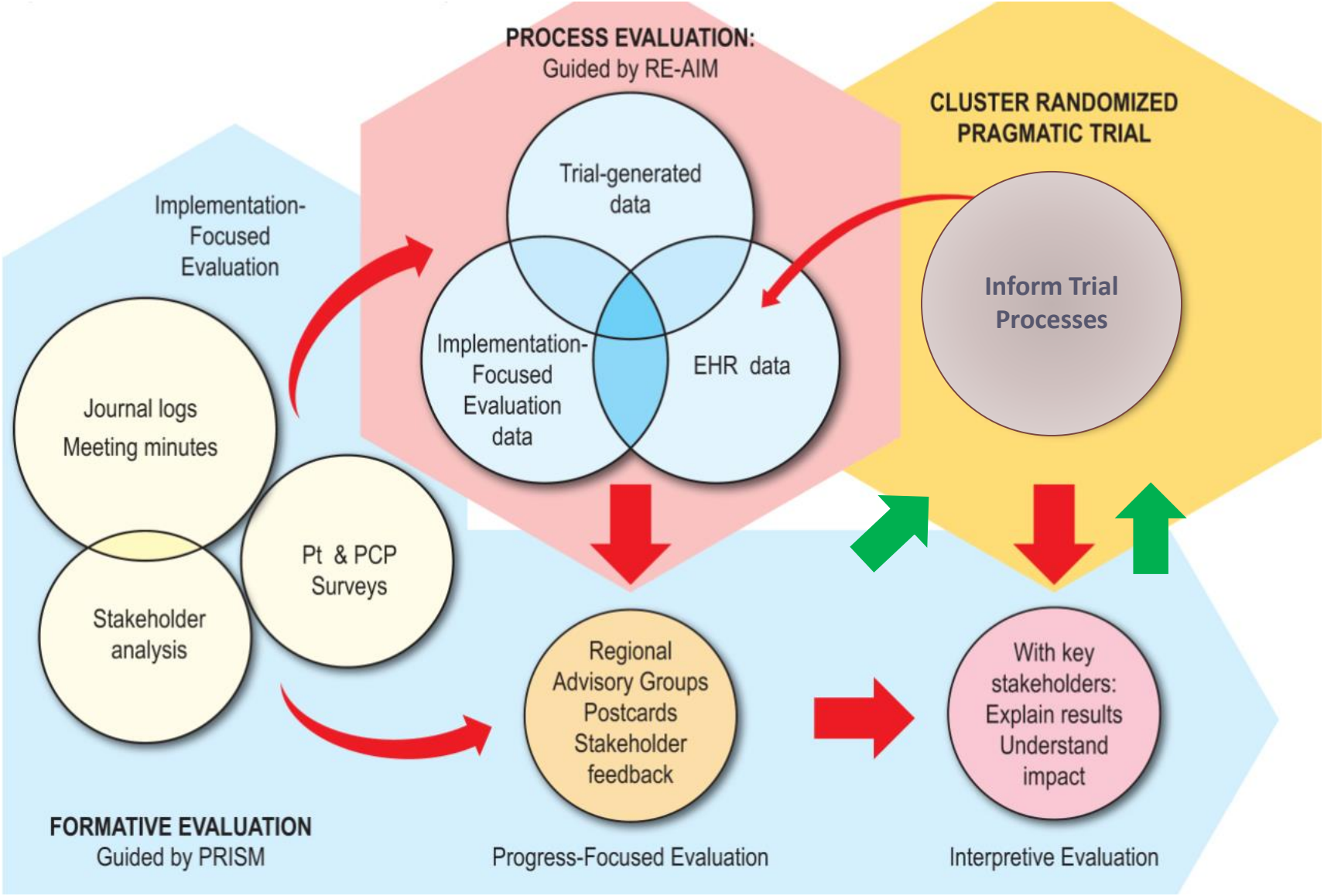
Importance of Two-way Flow of Information / Education



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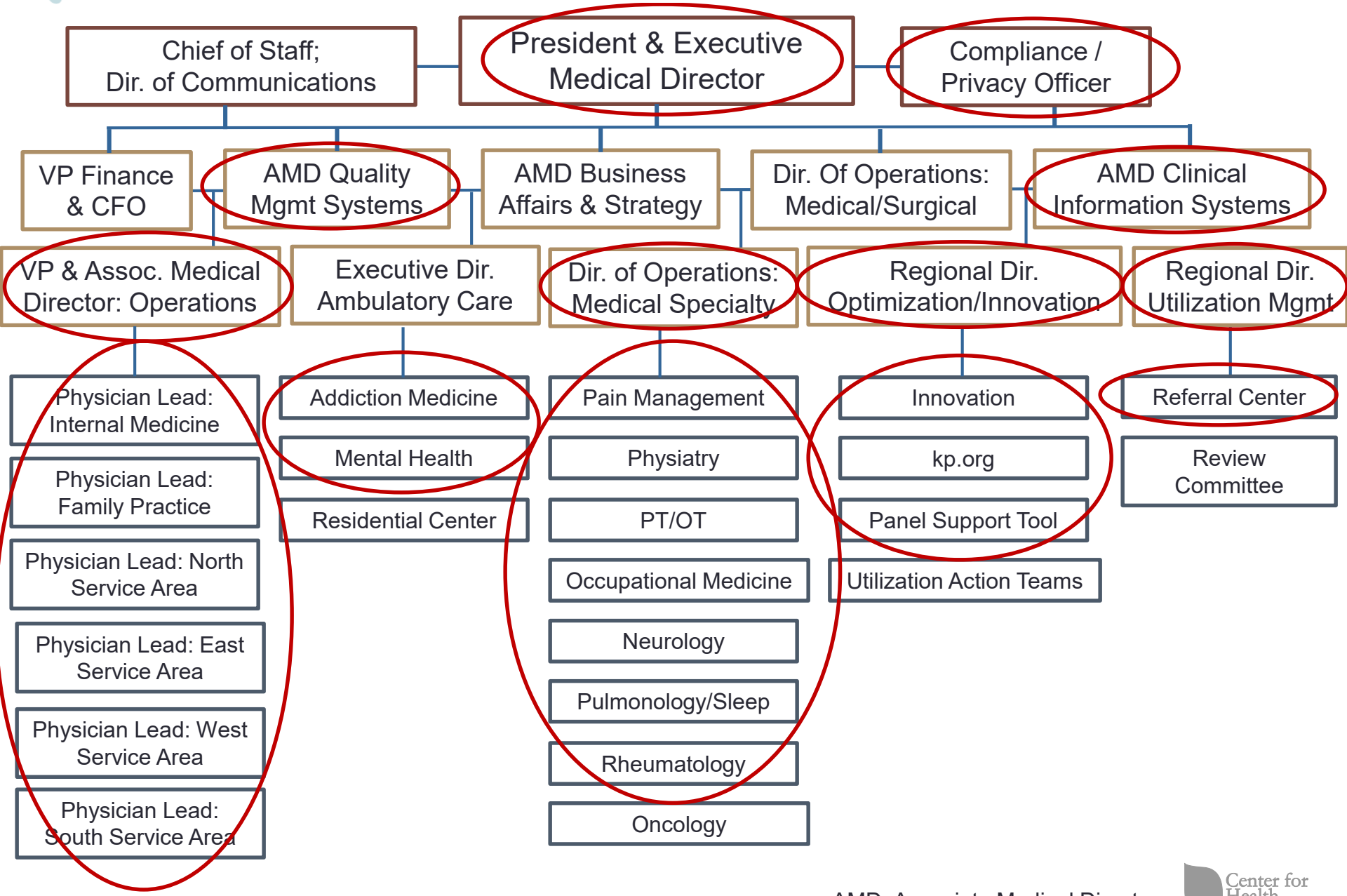
Many stakeholders no one size fits all engagement strategy…



AMD: Associate Medical Director

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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

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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Other Critical Issues for Formative Evaluation of Pragmatic Trials

- Most valuable information is not 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)

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COLLECTING PATIENT REPORTED OUTCOMES (PROs) IN PRAGMATIC TRIALS

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

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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

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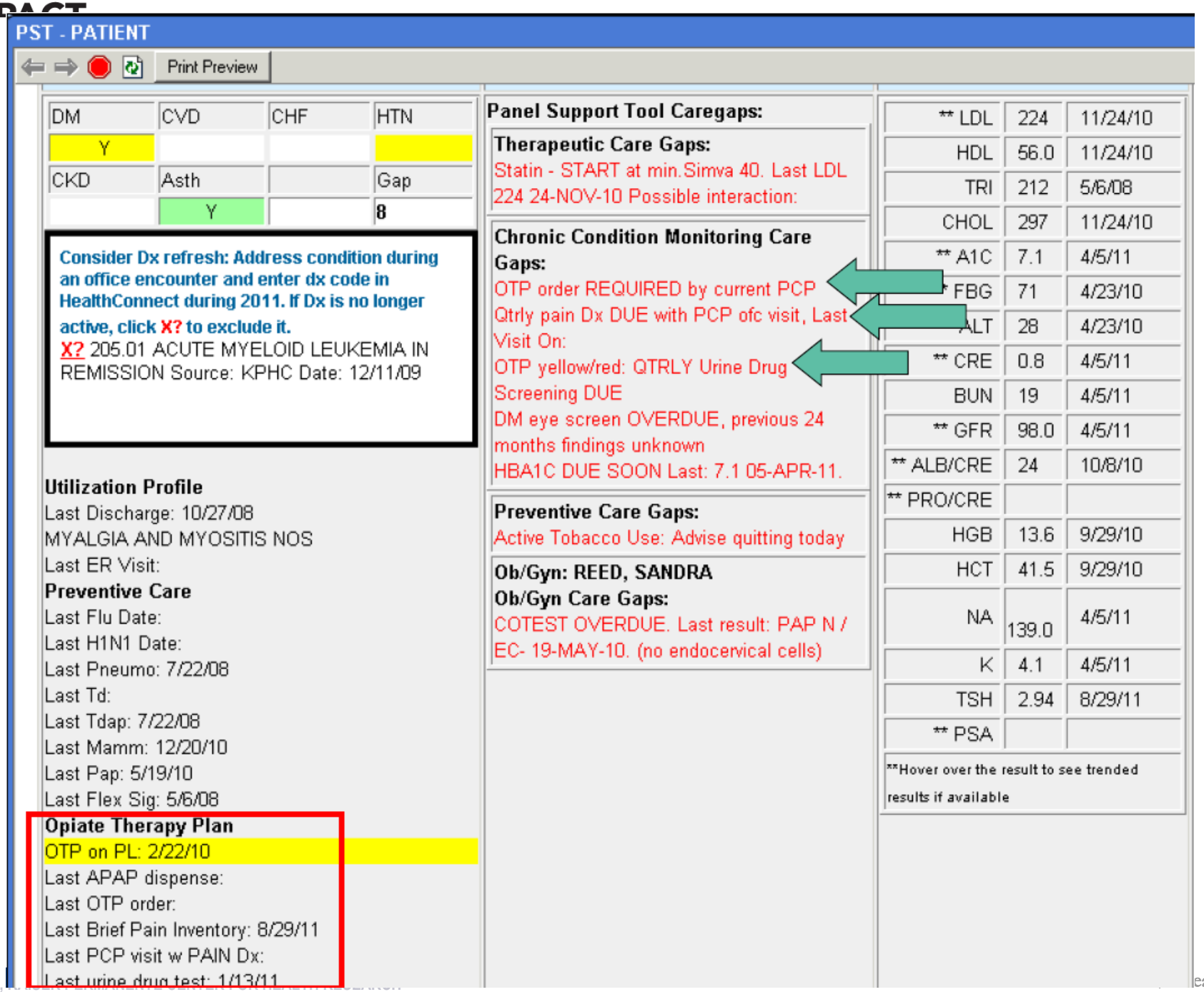
PST - PATIENT
Print Preview
DM
CVD
CHF
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CKD
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8
Consider Dx refresh: Address condition during an office encounter and enter dx code in HealthConnect during 2011. If Dx is no longer active, click X? 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

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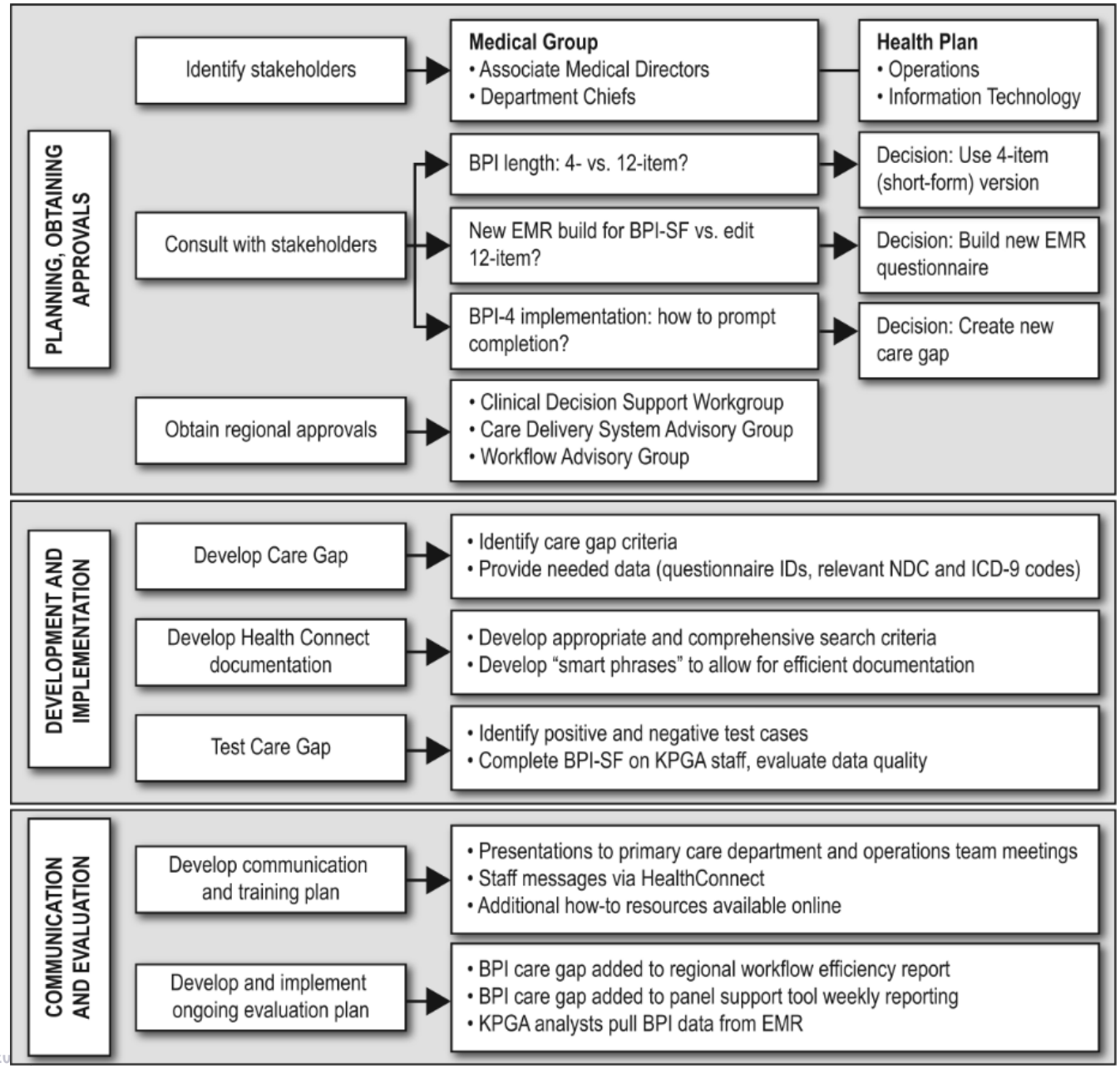

Establishing Routine BPI Administration in Clinical Workflow

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Using the Personal Health Record to Collect PROs

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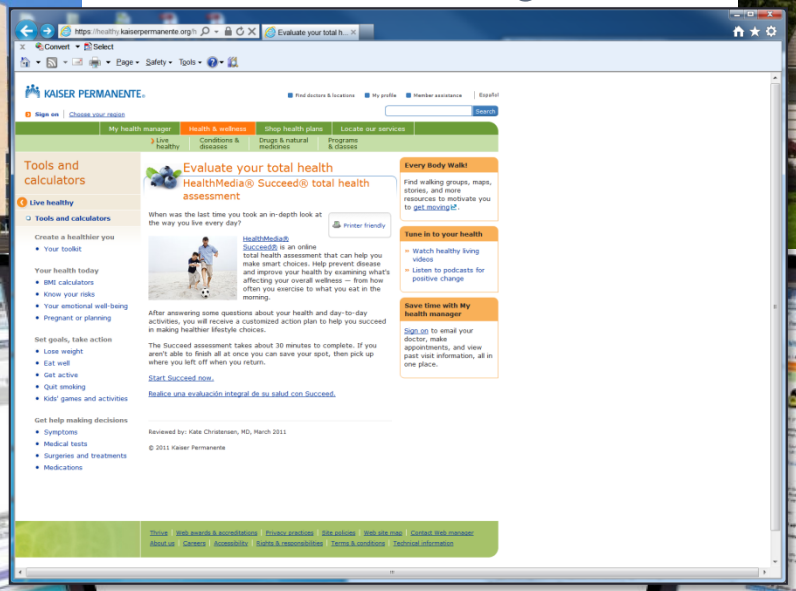
Patient Home

www.KP.org



EPIC Terminal

Personal Digital Devices

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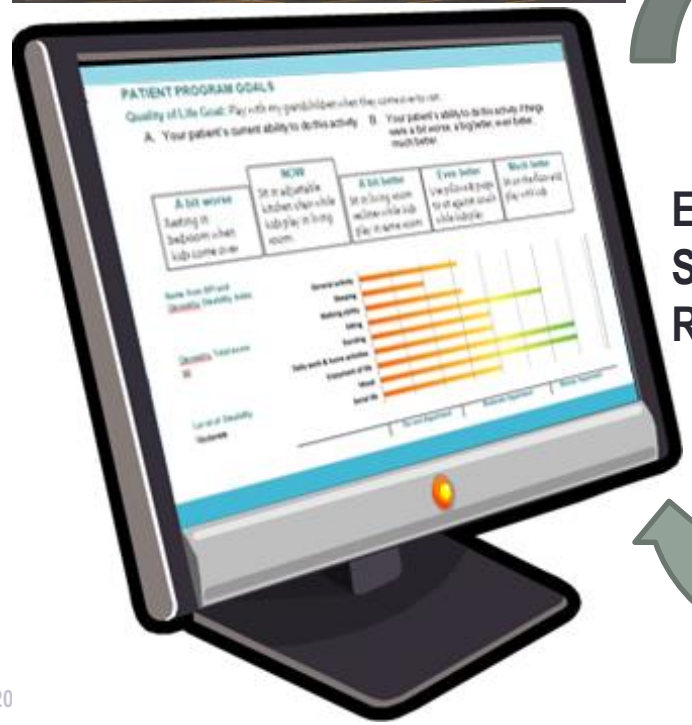
Online
or paper
collection



EMR Provider
Summary
Report

Scoring or
compilation
of relevant
assessments

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Health Care Delivery System PROs: Lessons Learned

- Timing and amount of data likely to be 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
- May need to support "enhanced" PRO collection for evaluation needs and improved clinical utility
  - Low burden modes of collection critical to encourage more frequent PRO collection (e.g., Personal Health Record / e-mail, IVR)
  - Shorter (4- vs 12-item BPI) and more targeted scale improves work flow and clinical utility
- IT/medical informatics partnerships are critical for successful PRO assessment as part of regular clinical care workflow

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ADDITIONAL ISSUES IN IMPLEMENTING INTEGRATED AND BEHAVIORALLY INTENSIVE PRIMARY CARE BASED INTERVENNTIONS

Intervention – Lessons Learned

- Anticipate roadblocks and organizational change needs if the intervention is not culturally consistent with current system. (In our case, behavioral change may not be optimally/consistently supported)
- Scope of practice and financial compliance/billing issues 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)

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Broader Study Challenges: What is New

- Everyone* doing things/creating partnerships never done before:
  - Redeploying/hiring clinical staff for intervention roles not well aligned with existing health plan structure or traditional scope of practice
  - Expanding use of EHR (real time pulling-out / pushing-in data utilizing clinically actionable formats)
  - Creating scalable staff training model with attention to fidelity and cost/resources
  - Sharing costs (building infrastructure processes) – NIH/health plan, patient/CMS
  - IRBs unfamiliar with pragmatic trials and uneasy relinquishing tight research constraints (low risk intervention but among patients and focused on clinical care issue contentious and fraught with risk)

* Operational/clinical leaders; health plans' finance, billing and compliance departments; HR; IT; front line clinical staff; IRBs; study investigators and broader research staff

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Broader Study Challenges: What is Complex

- Complex and urgent clinical focus presents unique challenges and opportunities
  - Politics tricky – many stakeholders who see challenges/needs differently
  - Usual care practices dynamic – researchers need to understand usual care *and* get a seat at the table in discussions regarding overlapping initiatives, changes in practice
  - Tension between availability of care for high needs patients and rigorous design/evaluation

  (All of the above requires regular and systematic feedback to stakeholders)
- Simple constrained interventions have been unsuccessful
  - Patients have "failed" multiple treatments and PCPs/specialists have "failed" the patients making the behavioral intervention particularly challenging and adequate dose and intervention quality important
  - Enhanced training of / communications to PCPs critical to support patients in culture not optimally/consistently supporting behavior change

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Closing Thoughts on Conducting Multifaceted Behavioral Pragmatic Trials…

- Rewarding but more complicated and potentially expensive (at least now) than traditional randomized clinical trials
- Organizational change framework of change, communication and stakeholder engagement strategies as well as data collection tools and reporting should be native to health care system
- Know that perception of "research" to clinical and operational stakeholders (e.g., untested) can impact buy-in and stakeholder actions during trial roll-out
- More to "carry" (patients, context of care) with behavioral change intervention than in traditional/non-embedded trials
- Many of the challenges in this type of trial (e.g., PCP level paneling, continued health plan leadership support, integration into primary care clinics) never substantively "settle down" as would be expected for most RCTs

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