



Health Care Systems Research Collaboratory Grand Rounds:

Collaborative care for Chronic Pain in primary care:
Systematizing our approach for ensuring PRO data quality and stakeholder engagement

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The Collaboratory



Health Care Systems Research Collaboratory Grand Rounds:

General Instructions for our viewers during today's call:

- To enhance audio quality, all attendees are muted.
- Address your questions for our speakers to “everyone” using the chat pod. Your questions will be answered by the speaker at the end of the presentation.
- Address technical support questions to Sandi McDanel as a private chat using the chat pod.

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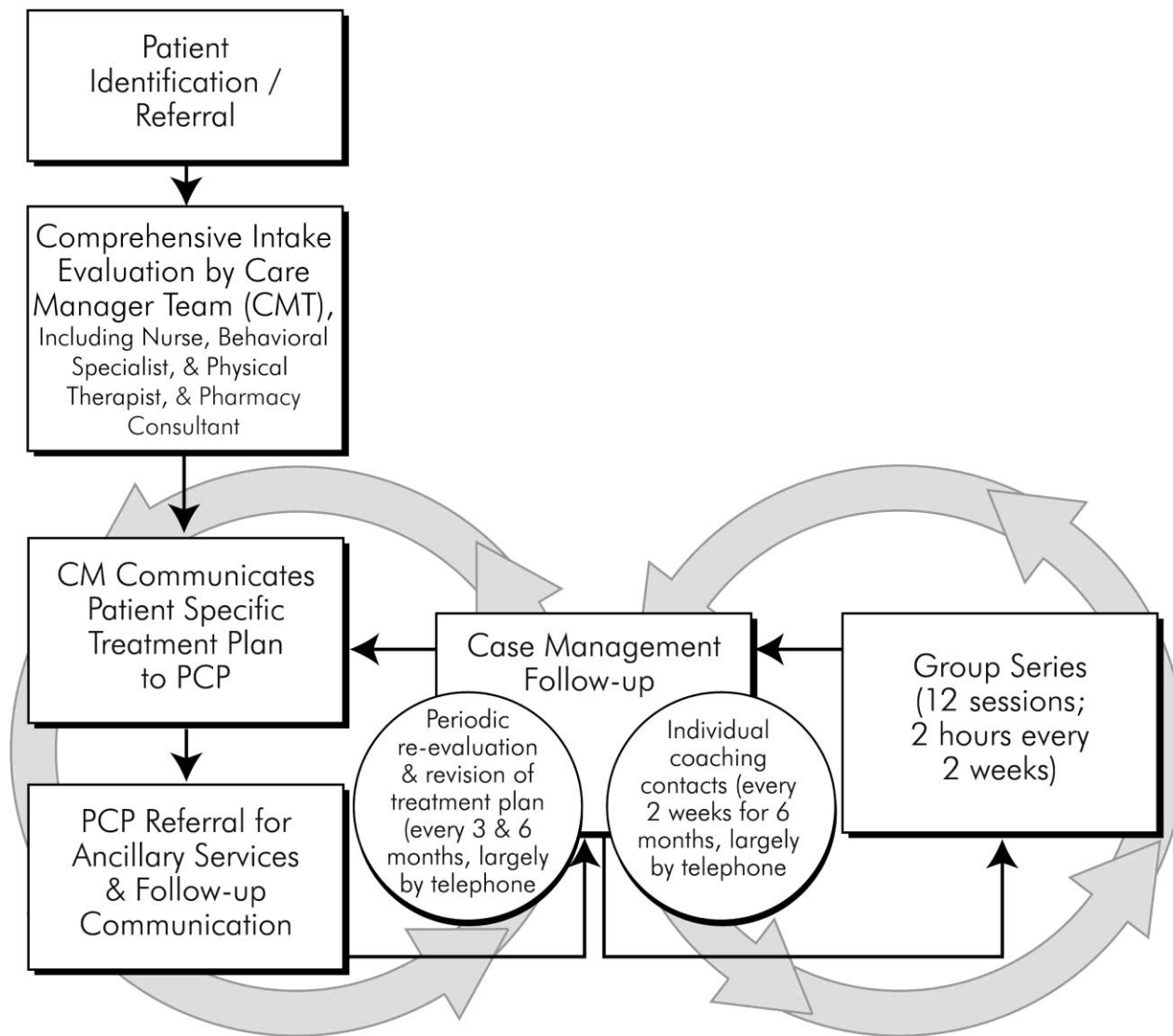
Agenda

- Background
 - Summary of Study Design
 - Key Contextual Factors (safety concerns, utilization and cost, clinical complexity)
- Measurement / Data challenges: Ensuring PRO adequacy
 - Understanding heterogeneity across health settings
 - Study process for quantitative and qualitative review of PRO data
 - Steps to enhance PRO collection and build transferable products
- Engaging Key Stakeholders: novel methods and approach
 - Organizational structure and the identification of key stakeholders
 - Adapted qualitative methods: rapid assessment and the adoption of Kaiser Permanente's business model for organizational change
- Summary of Key Points

Overall Study Aim

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

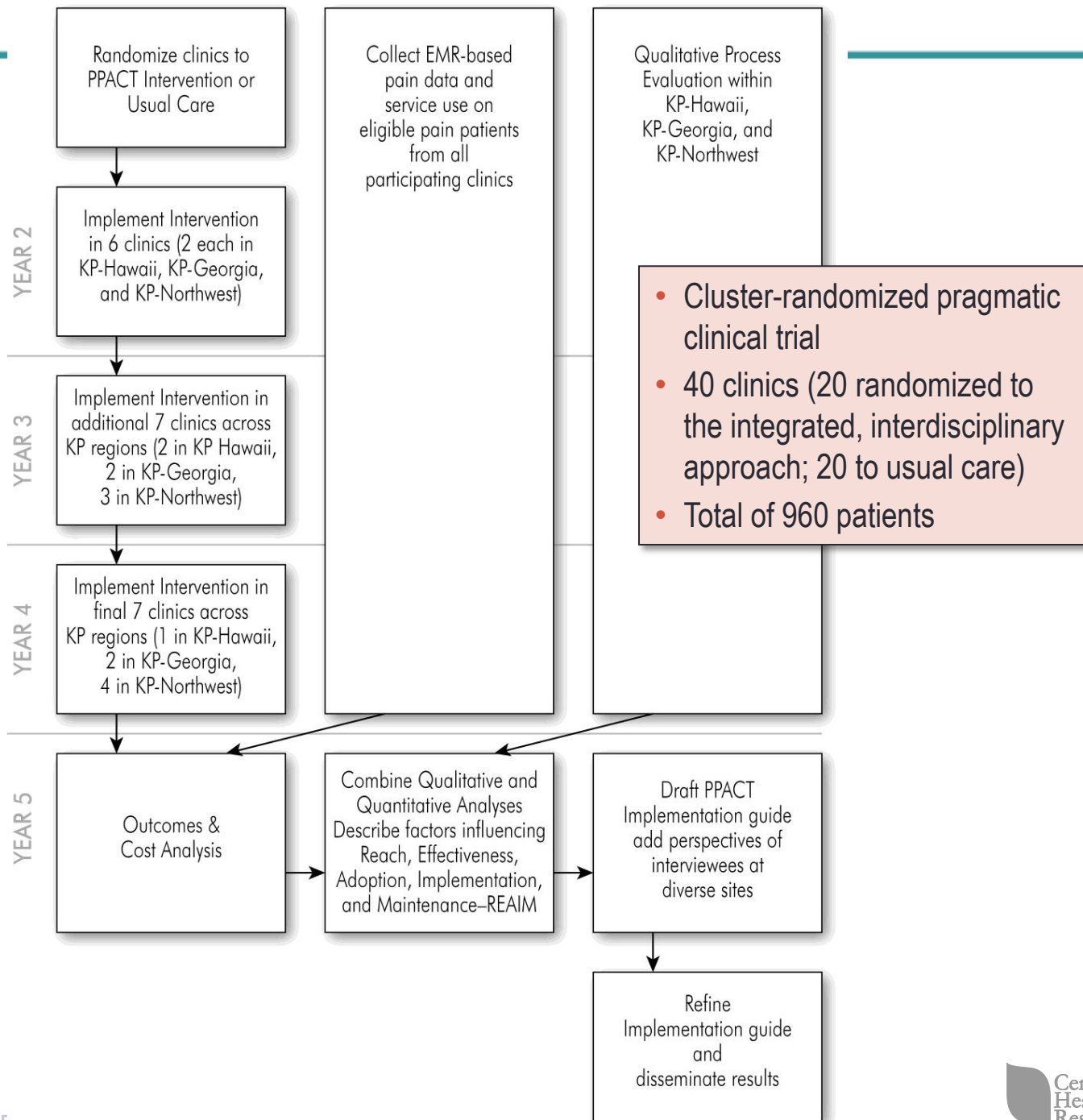
Intervention Description



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, myofascial pain, neuropathies, migraine, tension headache, temporomandibular joint disorder, carpal tunnel syndrome, nonspecific chronic pain, abdominal pain, pelvic pain

Trial Design



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

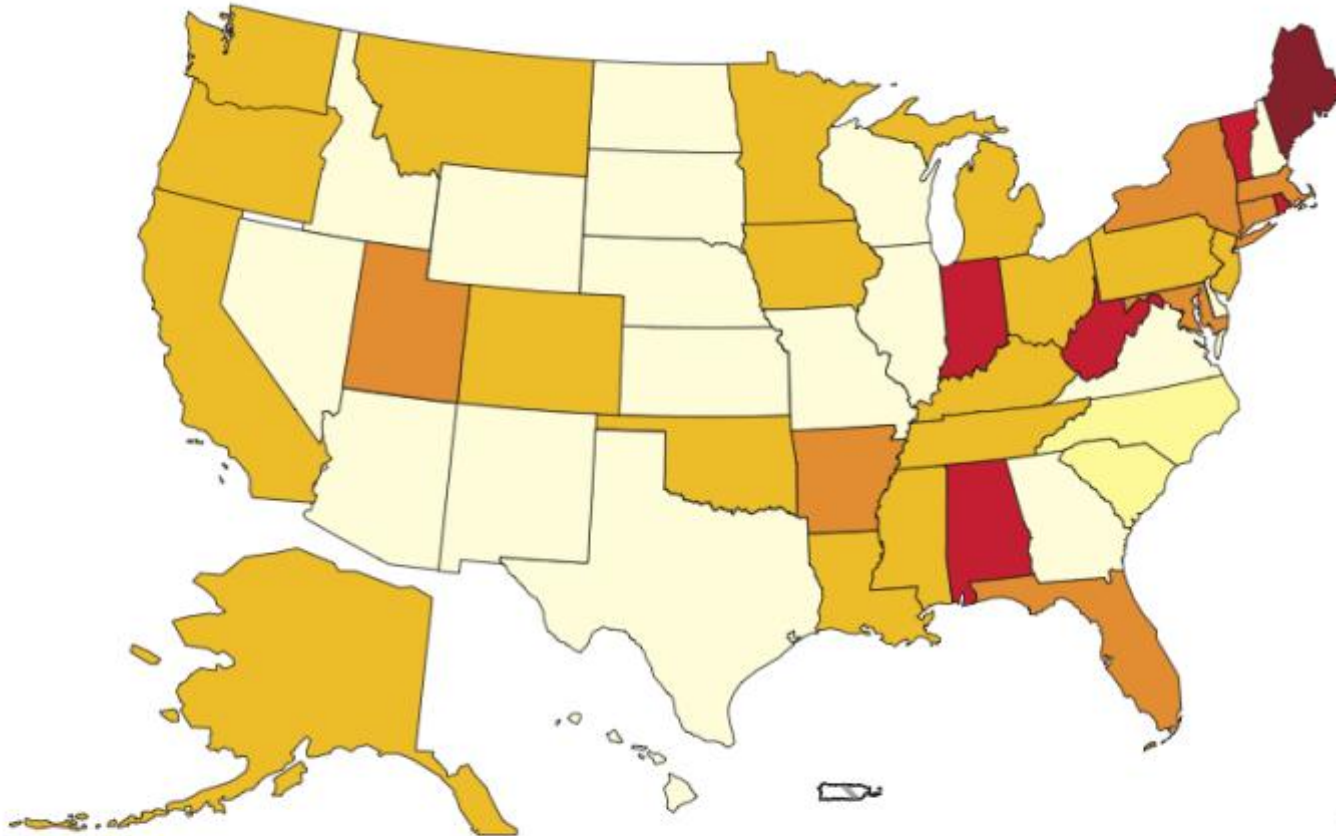
- Chronic illness management necessitates an activated patient
- Provider-directed treatments not practical nor sustainable

Multidisciplinary, multimodal treatment shows promise

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

Opioid treatment for chronic pain: safety concerns

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

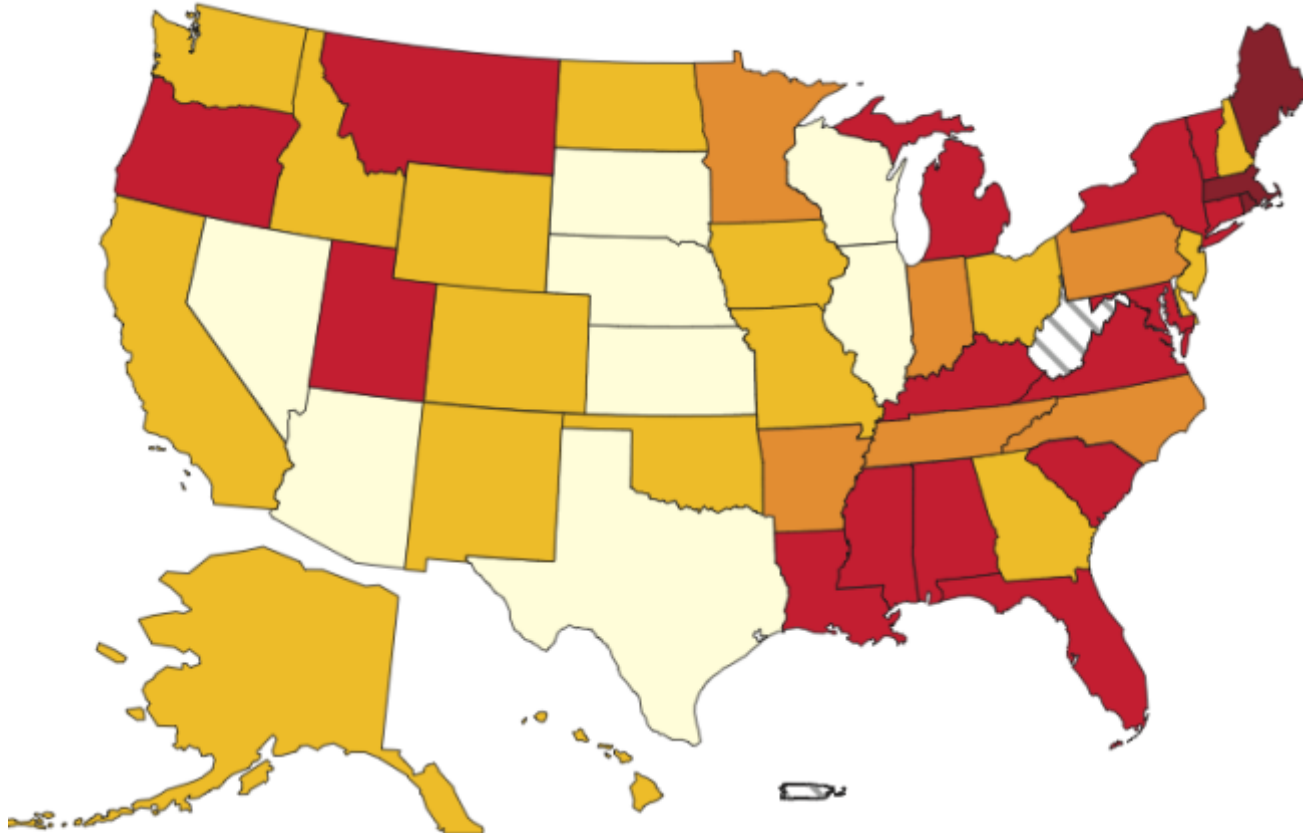


1999
(range 1 - 50)



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)

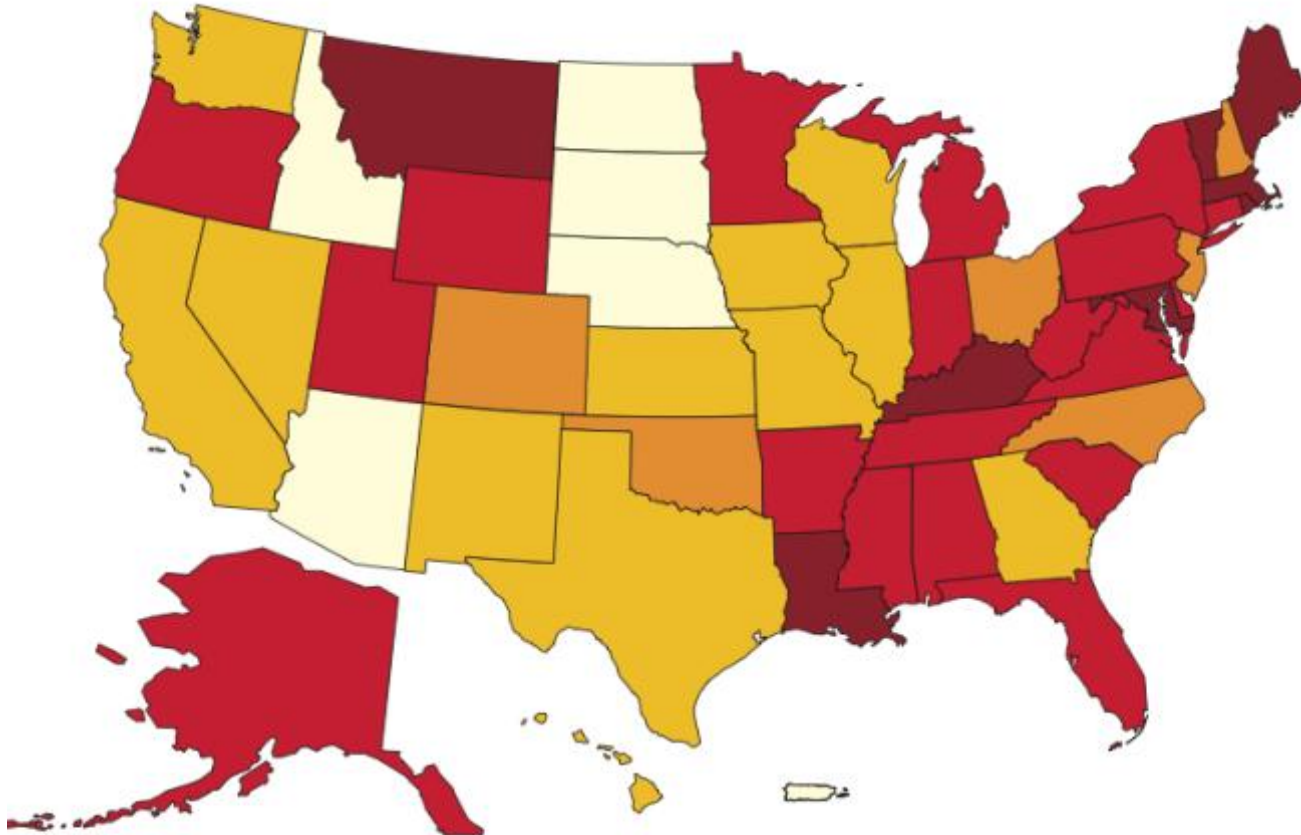


2001
(range 1 – 71)



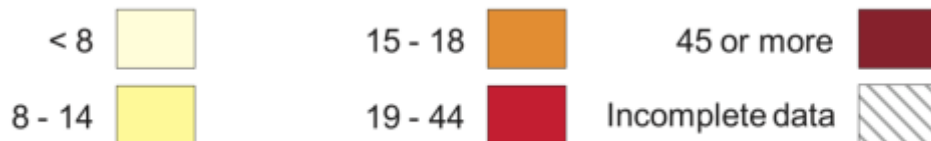
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



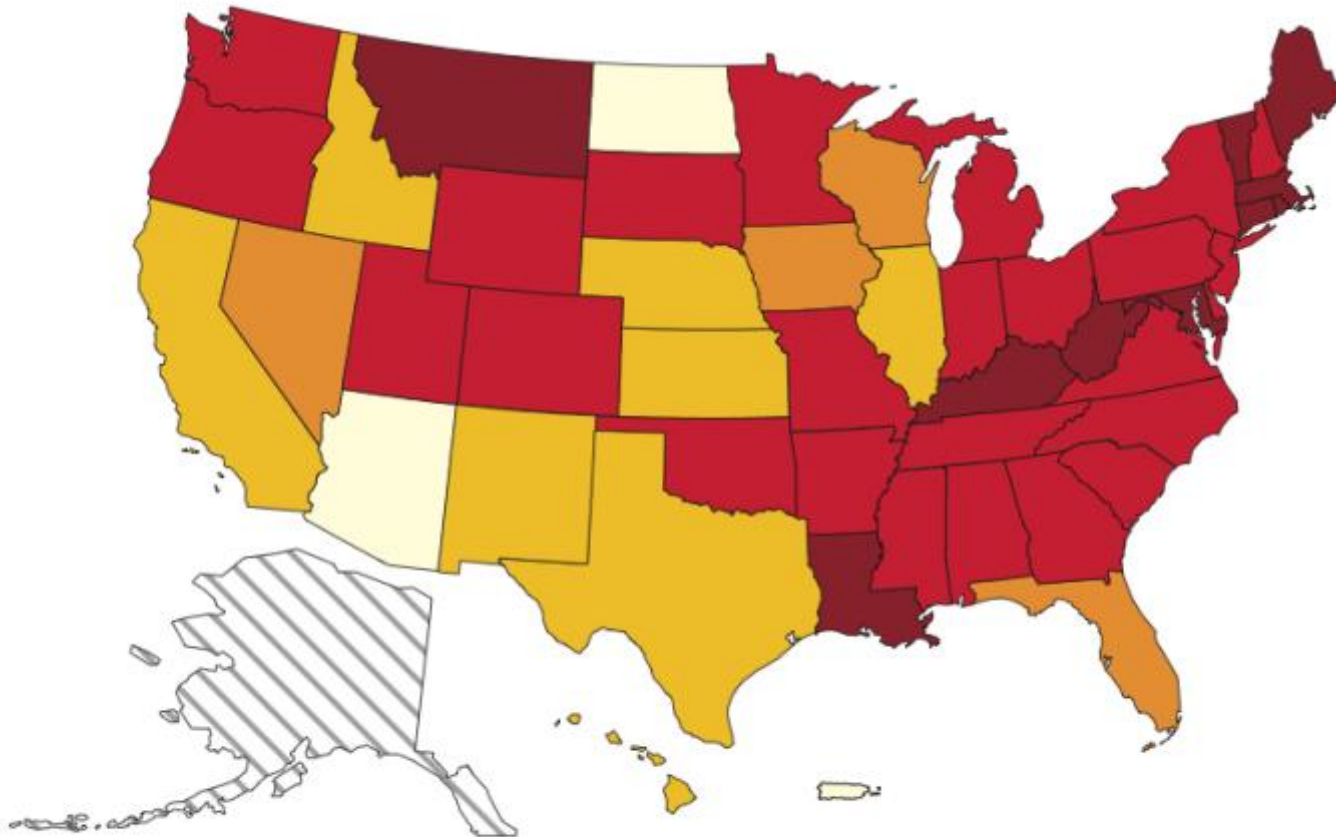
2003

(range 2 – 139)



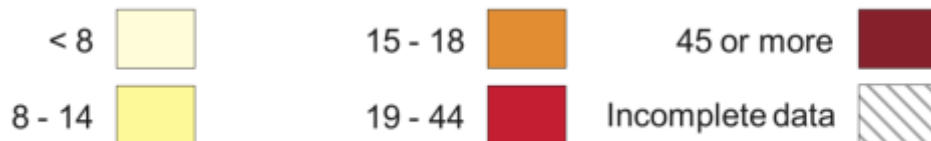
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



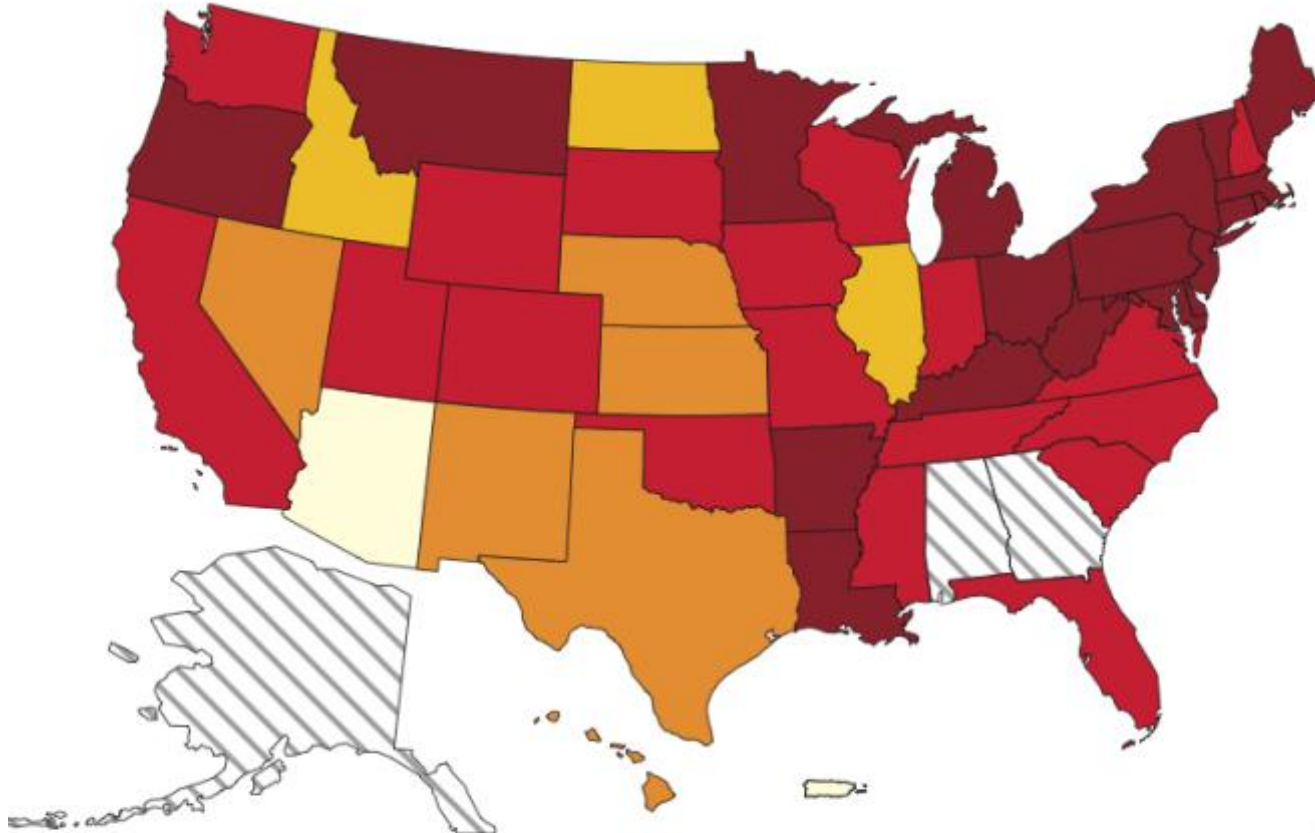
2005

(range 0 – 214)



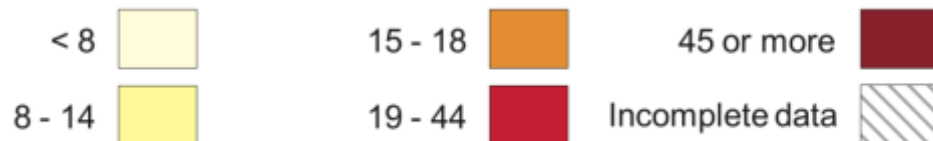
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

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



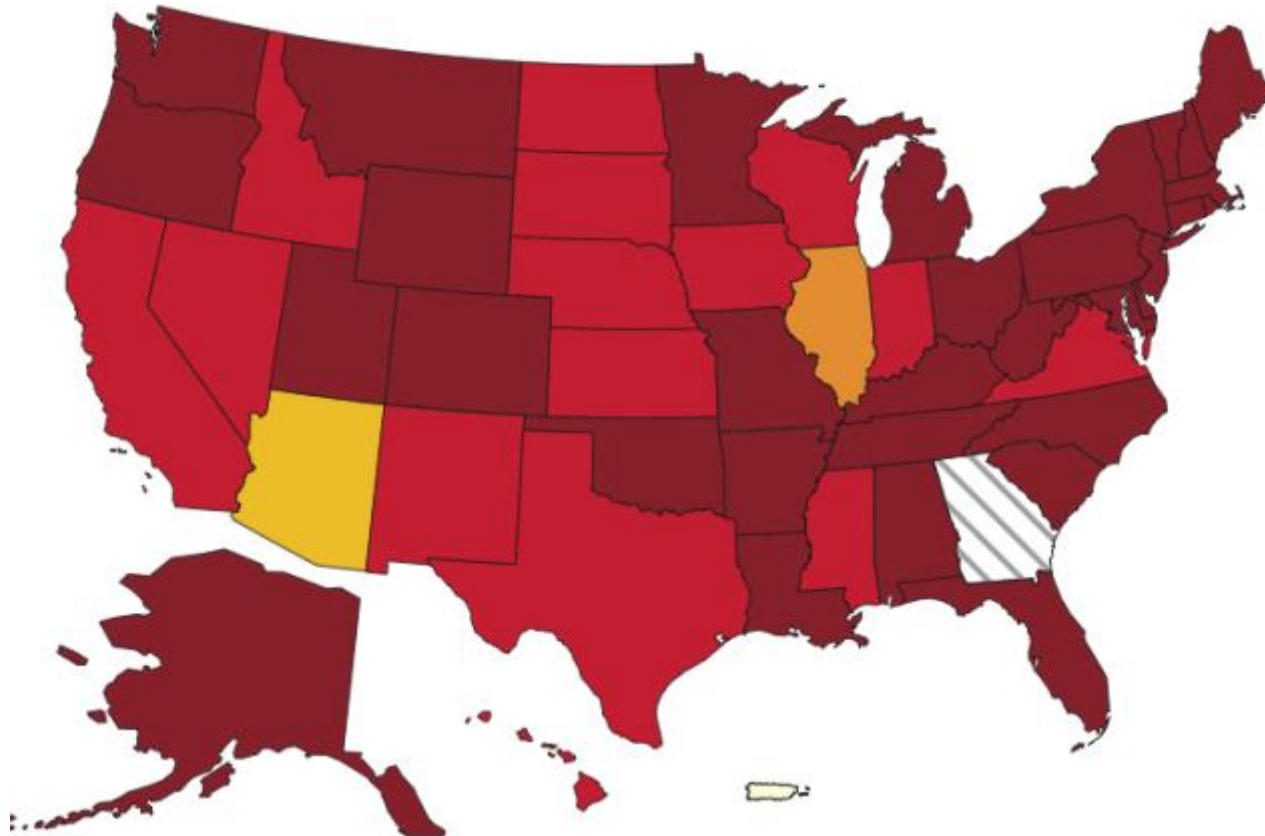
2007

(range 1 – 340)



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)

8



15 - 18



19 - 44



45 or more



Incomplete data

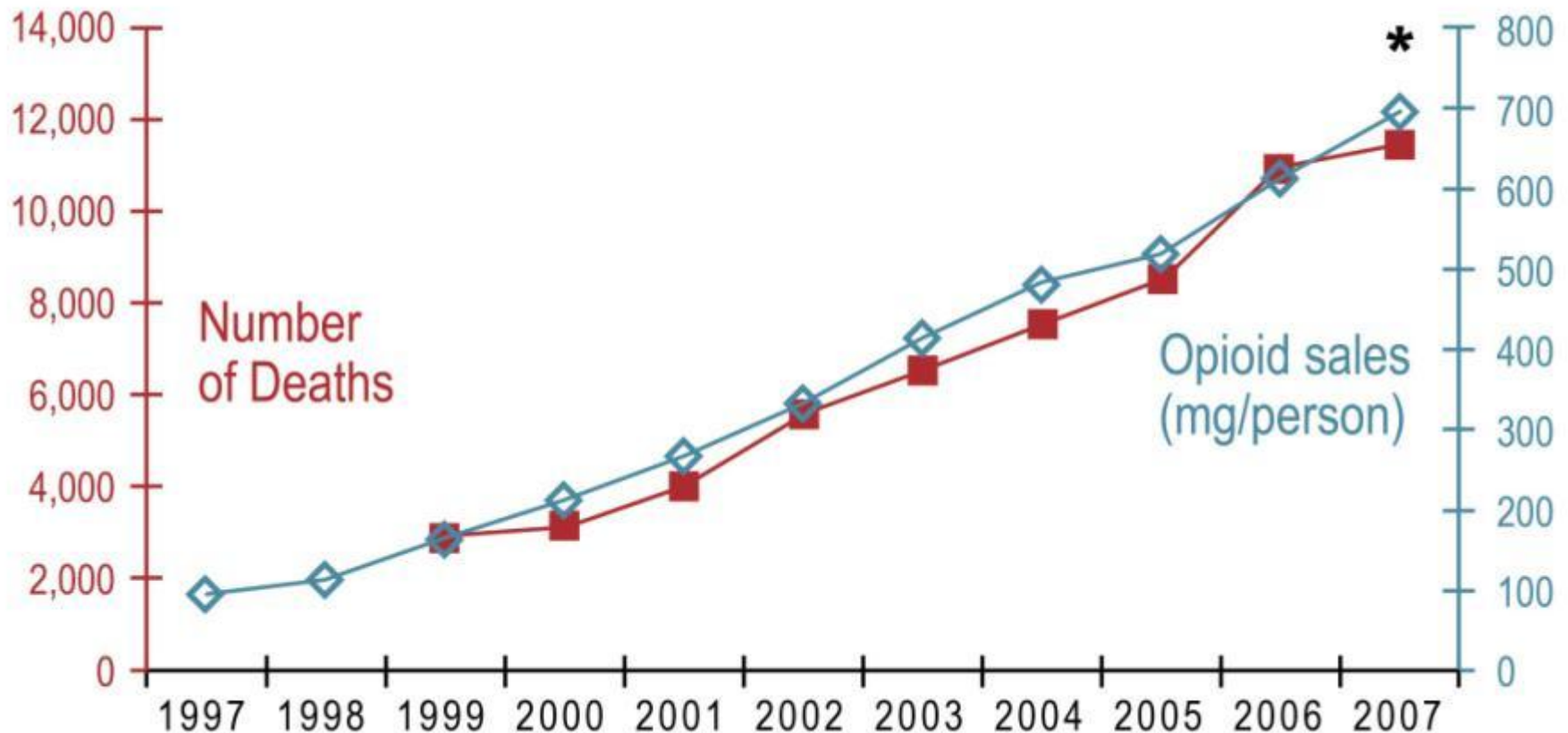


8 - 14



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

| 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) <i>[Recommended to be administered at every office visit]</i> | 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 |

Opioid treatment for chronic pain: cost and utilization

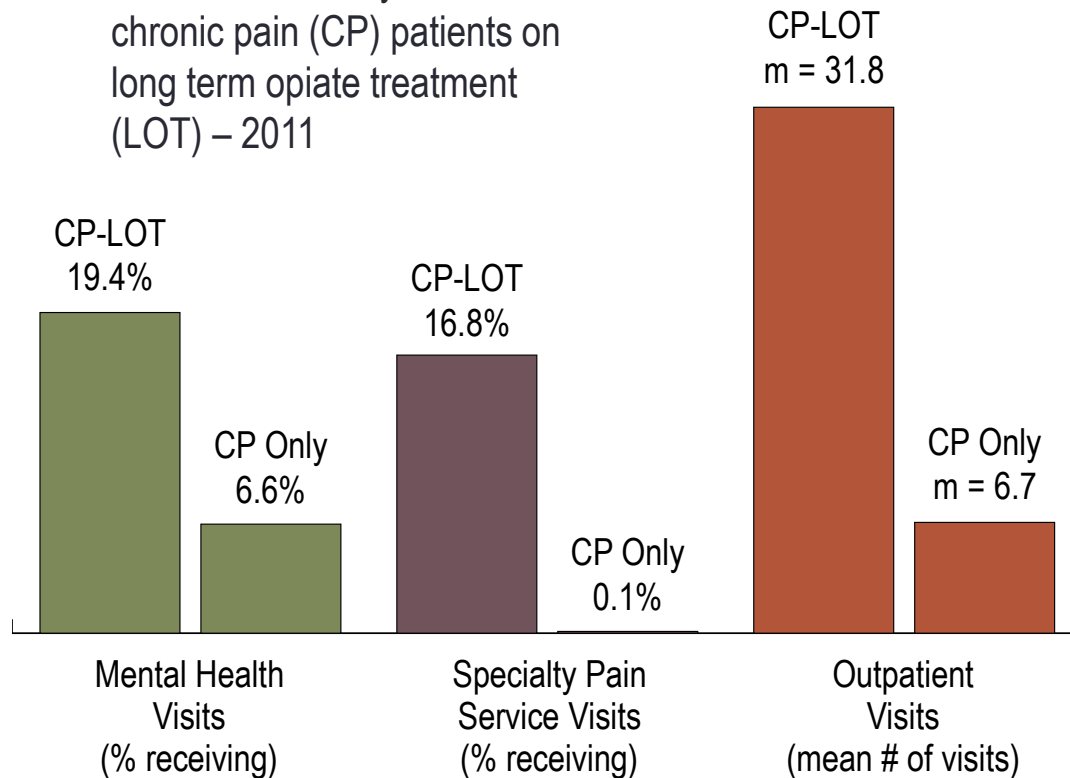
Total Sales & Prescriptions for OxyContin (1996-2002)

| 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."

Utilization Associated with Opioid Use

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

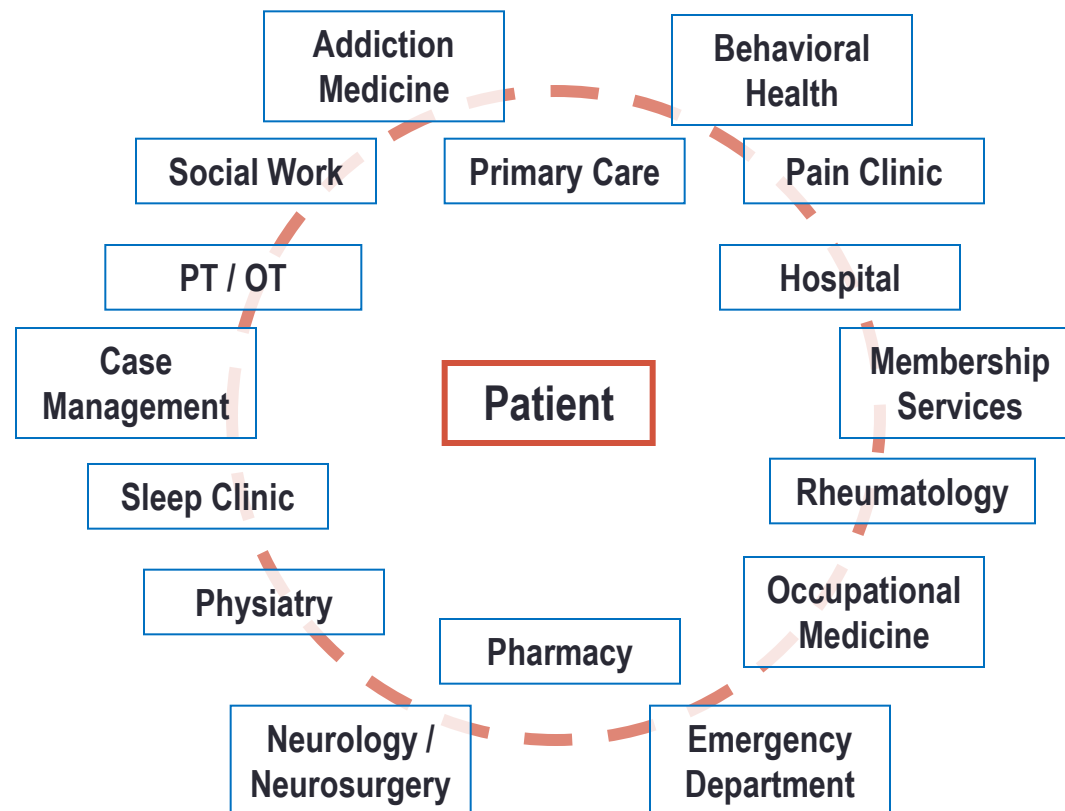


Opiate users are more likely to:

- 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.

Opioid treatment for chronic pain:
clinical complexity of the patients



Patient Characteristics

| Pain Characteristics | KP Northwest |
|---|-----------------|
| Total members (18 and older) with chronic non-malignant pain (CNMP) | 164,693 (36.8%) |
| Back and neck pain | 12,659 (63%) |
| Joint pain (including osteoarthritis) | 13,336 (67%) |
| Non-specific and other pain | 11,876 (59%) |
| Two or more CNMP diagnoses | 14,988 (75%) |
| Three or more CNMP diagnoses | 8,361 (42%) |
| Comorbid Medical Conditions | |
| Diabetes | 4,264 (21%) |
| Cardiovascular disorders | 11,084 (55%) |
| Psychiatric disorders | 7,053 (35%) |
| Diagnosed sleep problems | 4,261 (21%) |

Measurement / Data Challenges: Ensuring PRO adequacy

Study process for quantitative and qualitative review of PRO data and processes for addressing identified problems



Outcome Variables

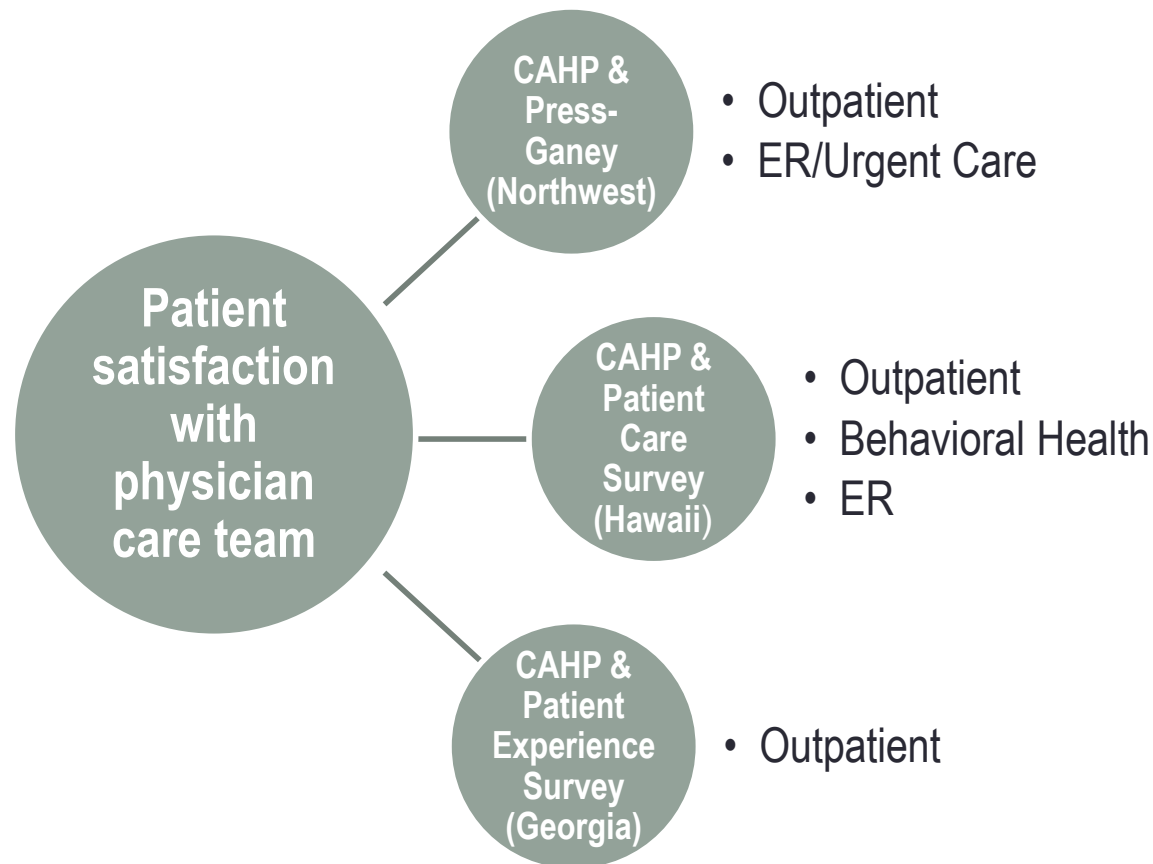
| Variable | Analytic Purpose |
|---|-------------------|
| Brief Pain Inventory (BPI) (Severity & Interference) | Primary Outcome |
| Opioids Dispensed (in morphine equivalents) | Secondary Outcome |
| Pain related treatment or diagnostic procedures | Secondary Outcome |
| Use of emergency / urgent 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

Heterogeneity Across our Health Plans

- The three Kaiser health systems have a common EMR
- However...
 - Work flows for administering PRO differ by site
 - Data sources for the same PRO vary across sites
 - Implementation Modality varies across sites and within a site
 - Paper pre-visit
 - Asked by health plan staff during visit
 - Online

Instruments for a similar PRO may vary across sites



CAHP = Consumer Assessment of Healthcare Providers and Systems

Systematically test and validate PRO data: Cross-Site Assessment

- Instrument and how it's presented by site
- Instrument versions and implementation dates
- Implementation modalities used (paper, asked by health plan staff, online)
- Data accessibility (e.g., privacy concerns around some PROs such as patient satisfaction, data refresh frequency)

Table 1: PRO Summary by Site (Instrument, version, Implementation Date, Implementation Modality)

| | KP Hawaii | KP Northwest | KP Georgia |
|-----------------------------------|---|---|---|
| Brief Pain Inventory (BPI) | BPI Version: Implementation Date: Implementation Modality: Data Refresh Frequency: Other: | BPI Version: Implementation Date: Implementation Modality: Data Refresh Frequency: Other: | BPI Version: Implementation Date: Implementation Modality: Data Refresh Frequency: Other: |

Systematically test and validate PRO data: Compare availability and density of the PRO data across sites

- Total record counts by year and site, subset for the population of interest
- Proportion of the population with PRO records
- Median and mean # of PRO records per person

Table 2: PRO Available Data by Site

| | KP Hawaii | KP Northwest | KP Georgia |
|-----------------------------------|--|--|--|
| # Eligible Patients | # | # | # |
| Brief Pain Inventory (BPI) | Total Record Count: Total Completed Rec Count: PPACT Rec Count: PPACT Completed Rec Count: Proportion of PPACT with Records: Median # Recs per member: Mean # Recs per member: | Total Record Count: Total Completed Rec Count: PPACT Rec Count: PPACT Completed Rec Count: Proportion of PPACT with Records: Median # Recs per member: Mean # Recs per member: | Total Record Count: Total Completed Rec Count: PPACT Rec Count: PPACT Completed Rec Count: Proportion of PPACT with Records: Median # Recs per member: Mean # Recs per member: |

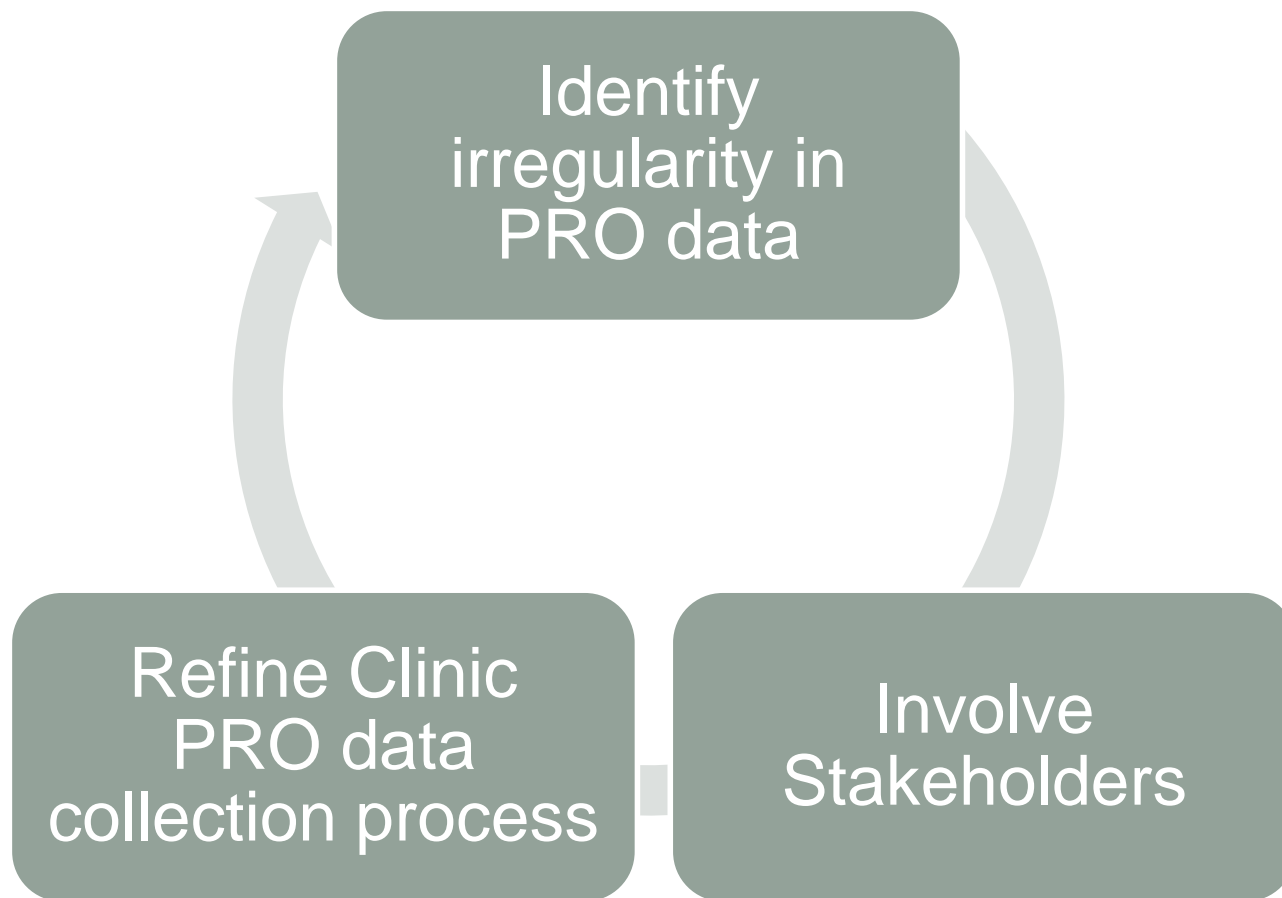
Systematically test and validate PRO data: Validate that data extract matches the EMR presentation

- Confirm the back end data sources are correct and complete
- Check narrative strings for alternative placement of PRO data in the EMR (e.g. progress notes)

Table 3: PRO Summary by Site

| | KP Hawaii | KP Northwest | KP Georgia |
|-----------------------------------|--|--|--|
| Brief Pain Inventory (BPI) | Sample of extracted records match presentation in EMR: | Sample of extracted records match presentation in EMR: | Sample of extracted records match presentation in EMR: |

Influencing Health Systems



Influencing Health Systems Use of PROs

- Health plan systems can adopt PROs quickly

Total Exercise as Vital Sign (EVS) Questionnaires per Year

| | KP Northwest | KP Georgia |
|------|--------------|------------|
| 2011 | 4,977 | 0 |
| 2012 | 927,312 | 9,003 |

KP Georgia implemented use of EVS in the final few months of 2012

Increased patient health record adoption provides additional opportunities to collect PROs

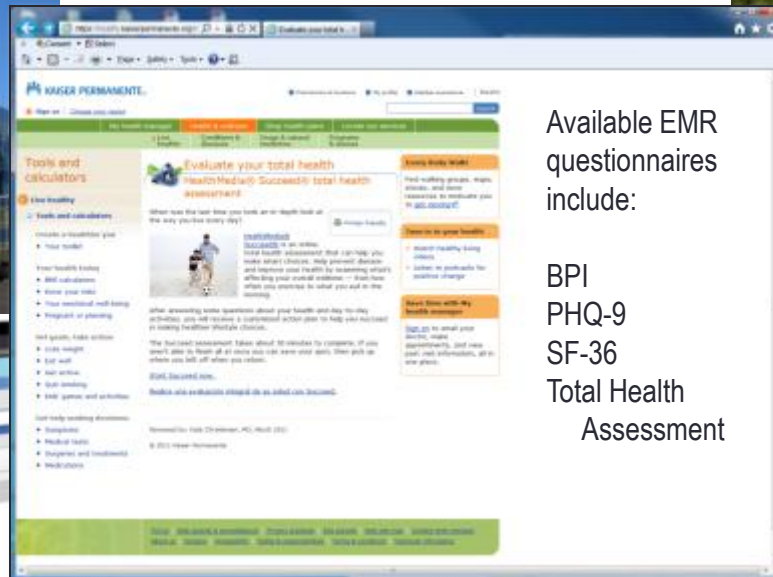
| | Change between 2008 and 2011 |
|--|--|
| Total visits to kp.org | 220% increase (Over 100 million visits in 2011) |
| Members registered for secure features | 140% increase |
| Total online prescription refill orders | 290% increase |
| Total online appointment requests | 200% increase |
| Total e-mails sent to doctors & other care team members | 200% increase |
| Total lab-test results view online | 180% increase |
| Total healthy lifestyle program questionnaires submitted | 200% increase |

Kaiser Permanente's Personal Health Record

Kaiser Permanente

www.KP.org

Patient Home



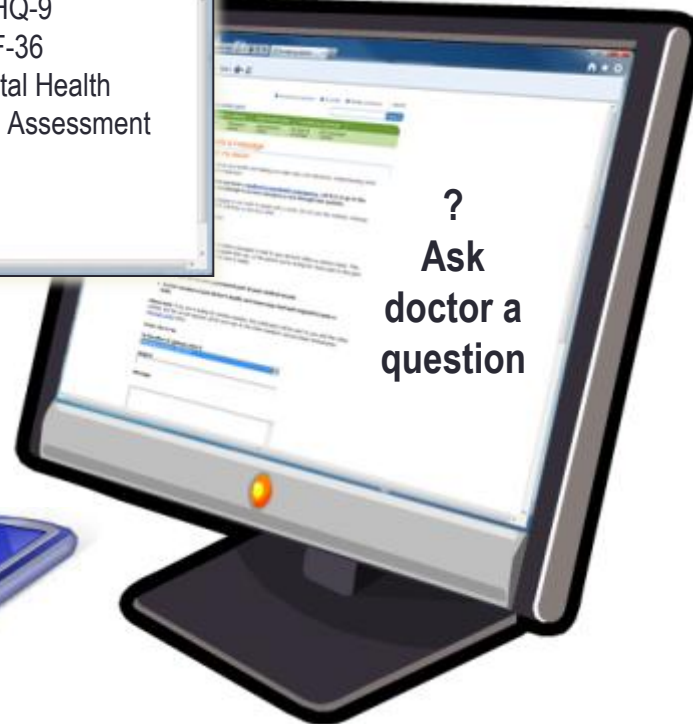
Available EMR
questionnaires
include:

BPI
PHQ-9
SF-36
Total Health
Assessment



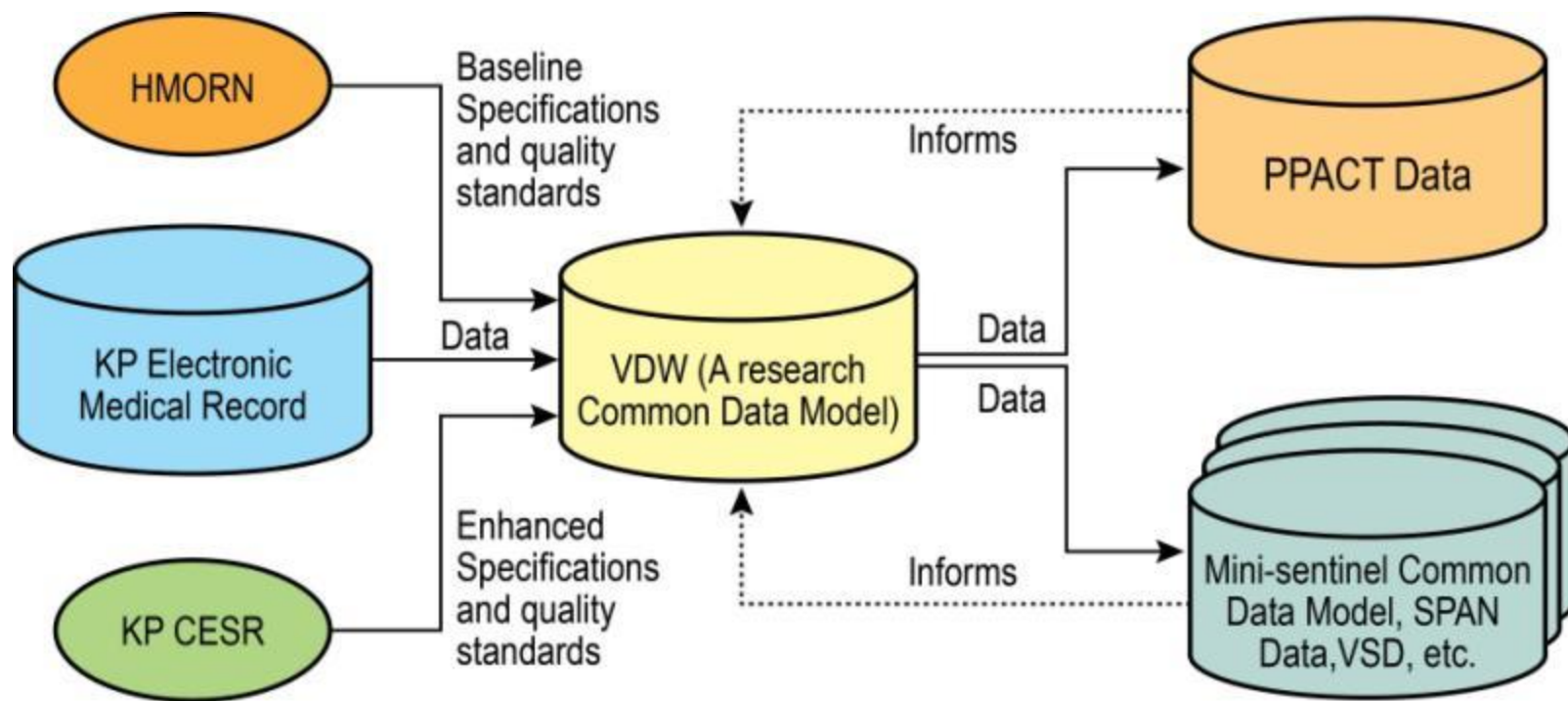
EPIC
Terminal

Personal
Digital
Devices

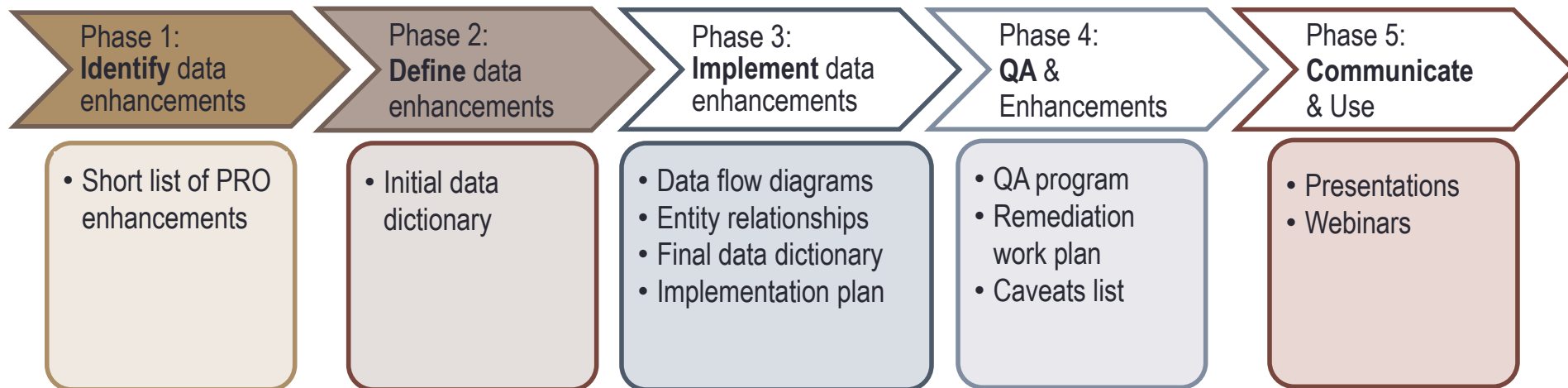


?
Ask
doctor a
question

Leveraging what is learned about PRO data to enhance broader research data systems



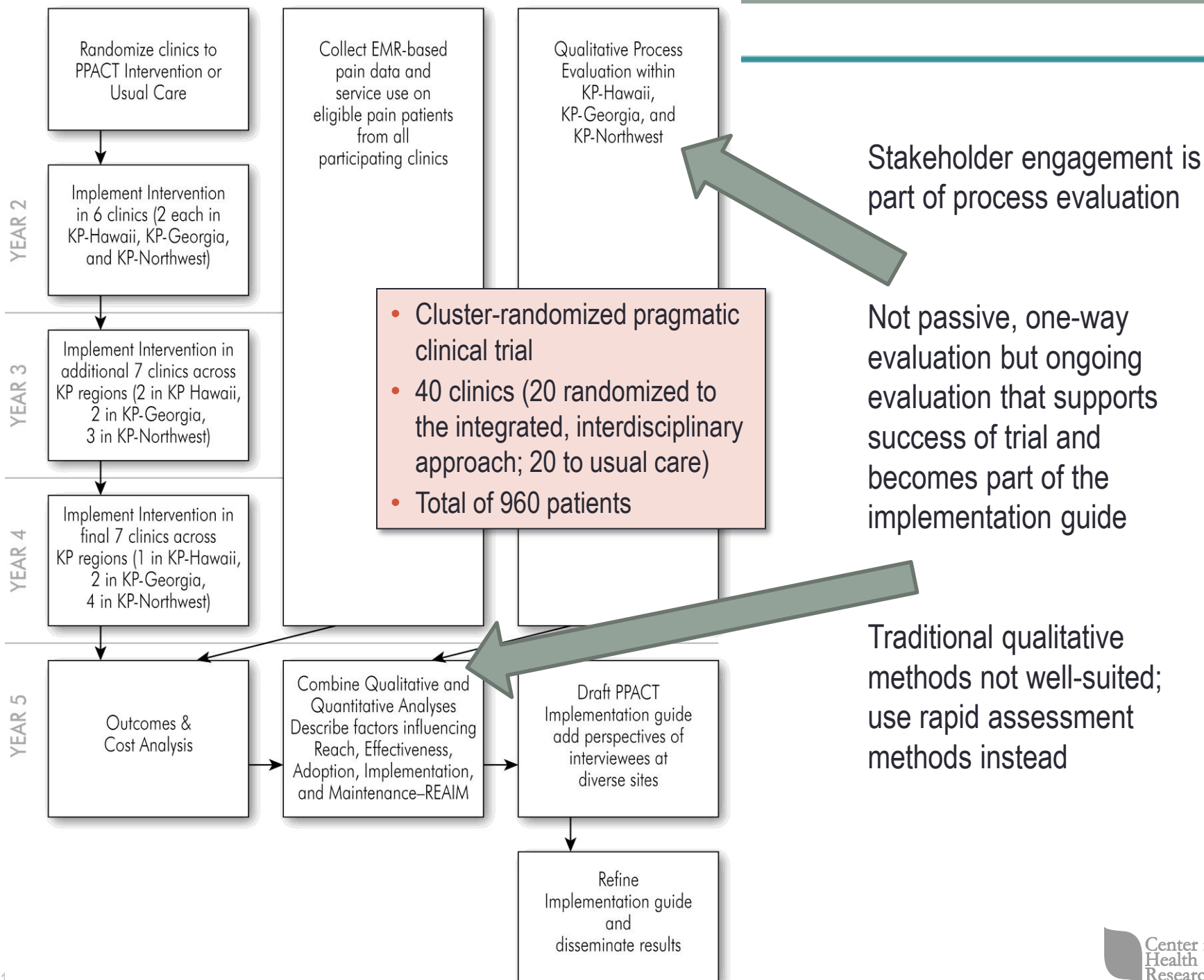
Leveraging what is learned about PRO data



Systematic stakeholder engagement

The first step of rapid assessment for successful implementation



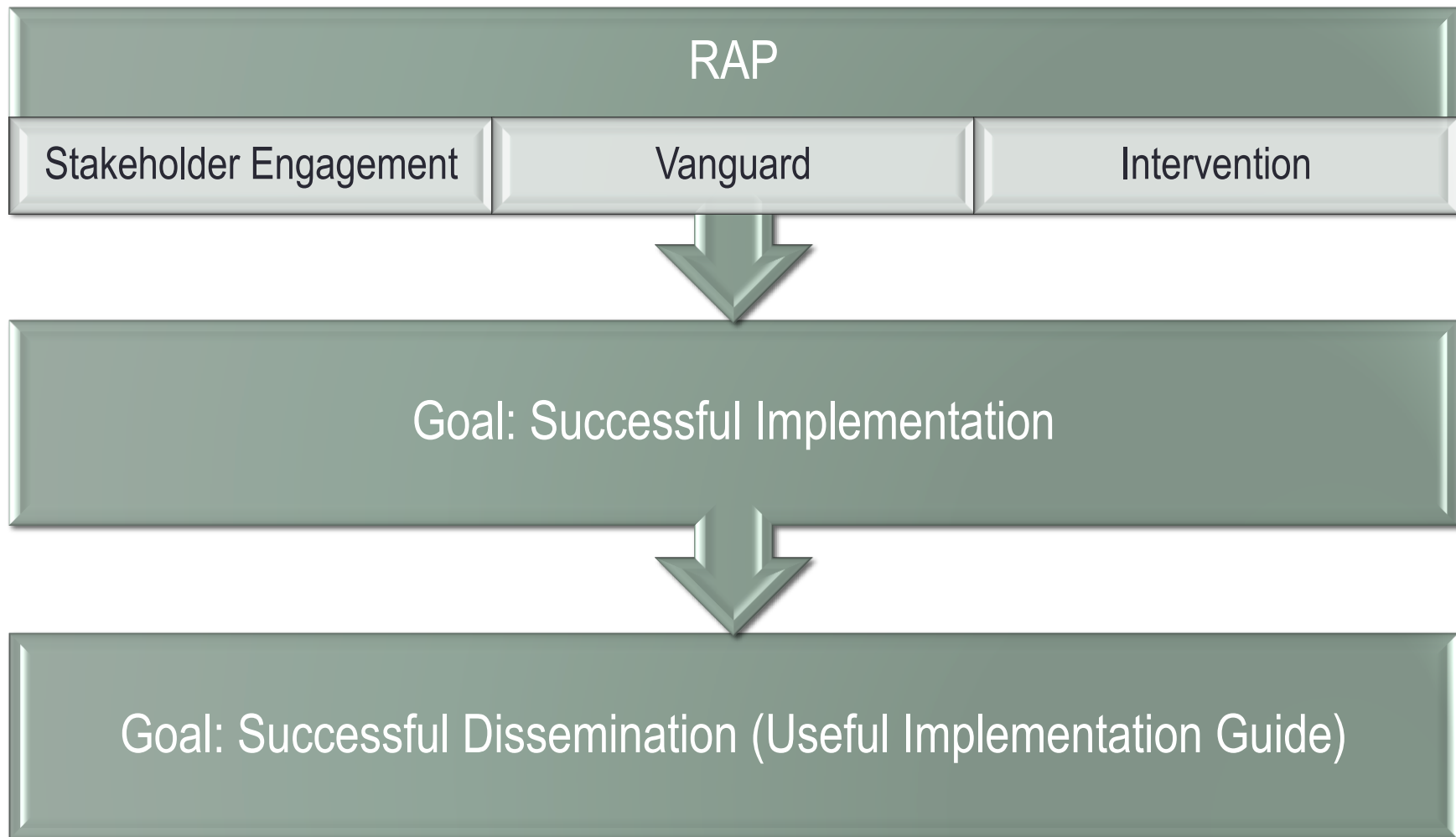


Rapid Assessment Process (RAP)

- 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.

RAP is our qualitative process evaluation



Our RAP Toolkit:

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

PPACT STUDY – Weekly Implementation Journal

Date: _____ Name: _____

Please include anything you think might help us understand barriers and facilitators to PPACT implementation.

Reminders:

- Goal is to reveal the stories and ongoing processes of implementation.
- Please be specific and include details (how, who, what & when) whenever possible.
- Note the feedback source (i.e. nurse, clinic administrator, clinician, etc).
- Use square brackets when sharing your insights and interpretations
- Use quotation marks for verbatim quotes.

Potential topics for your feedback log:

- ✓ Implementation (day-to-day logistics)
- ✓ Stakeholder engagement
- ✓ Communication (formal and informal)
- ✓ Tools (BPI, Intervention materials, scheduling tools)

✓ Surprises, challenges, solutions

✓ Unresolved or ongoing issues

✓ Other feedback that you think is relevant



We are still moving and shaking!

The past two weeks we hosted our second Deep Dive— one at Rockwood Medical Office Building in the Northwest and one for Terrace Medical Office Building in SCAL. For each of the sessions, we had providers, staff, and regional team members join us for a day of learning the innovation process and ideating around Project Move.

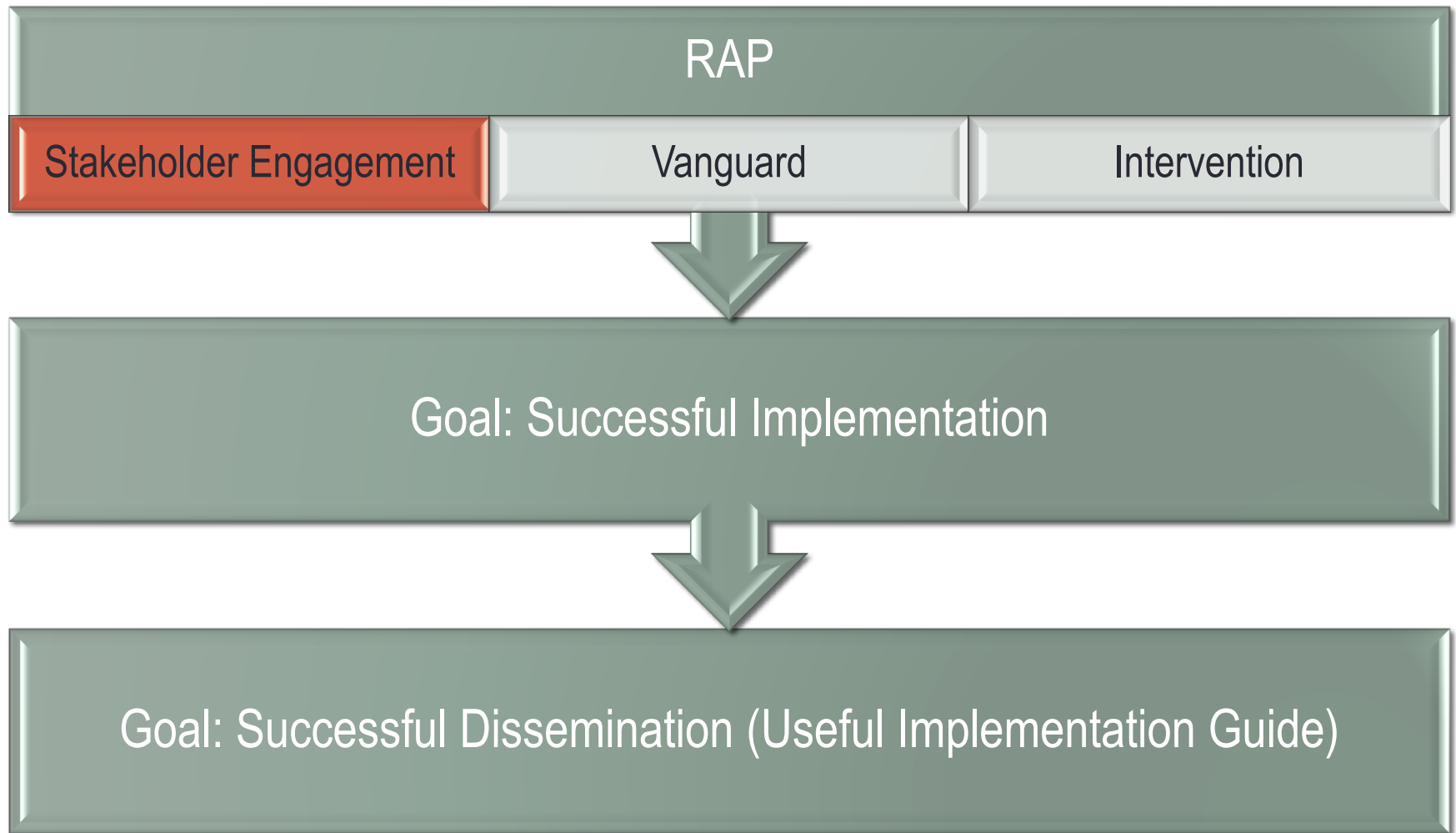
In both the NW and SCAL, we spent the following morning testing some of the ideas at the clinic. We learned a lot, and we are looking forward to learning more in the next couple of weeks.

Until next time,
Chris, Dana, Mary, Katherine, and Scott

 innovation consultancy
Kaiser Permanente

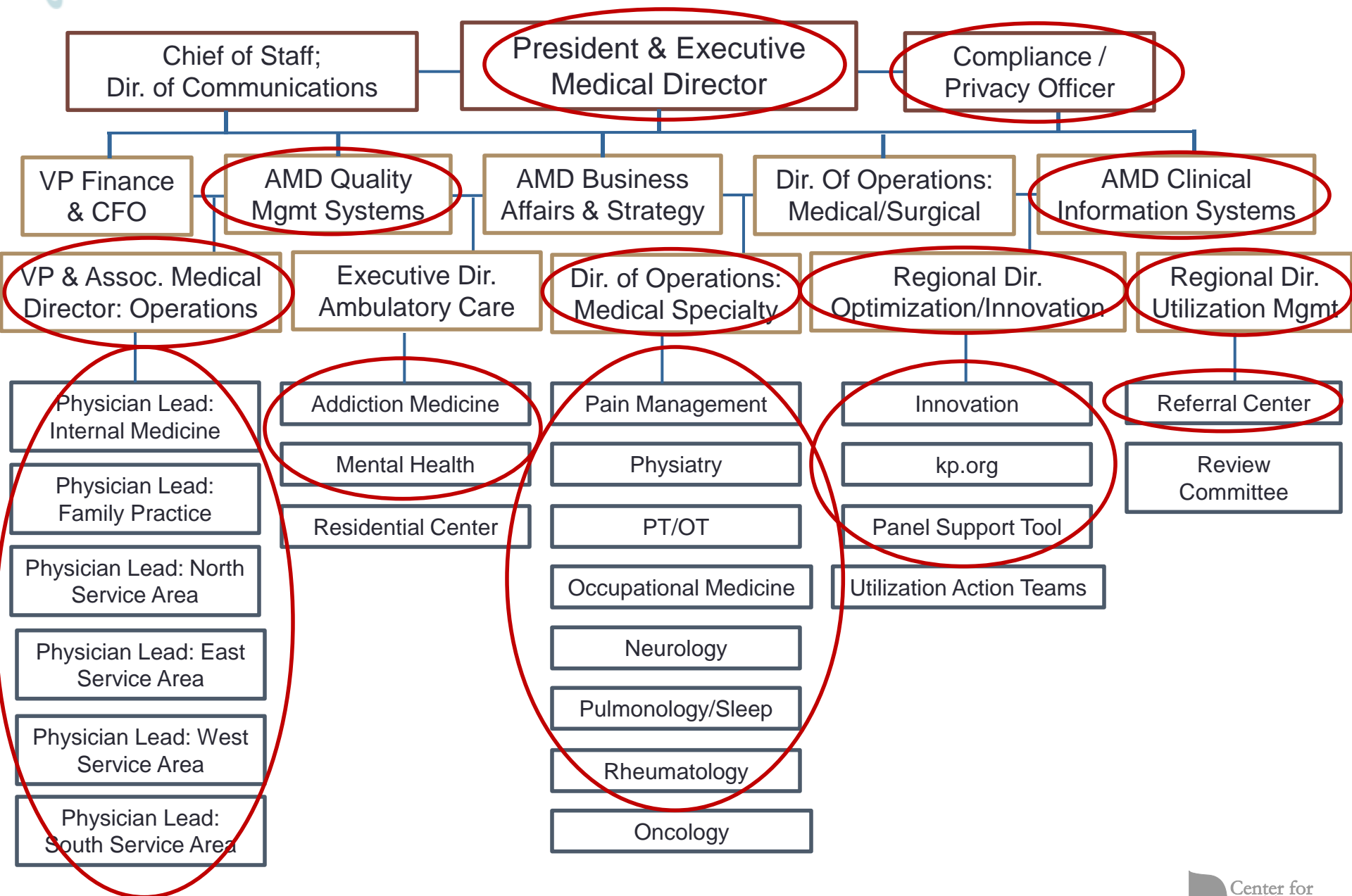
Project Move Team
Kaiser Permanente

RAP is our qualitative process evaluation



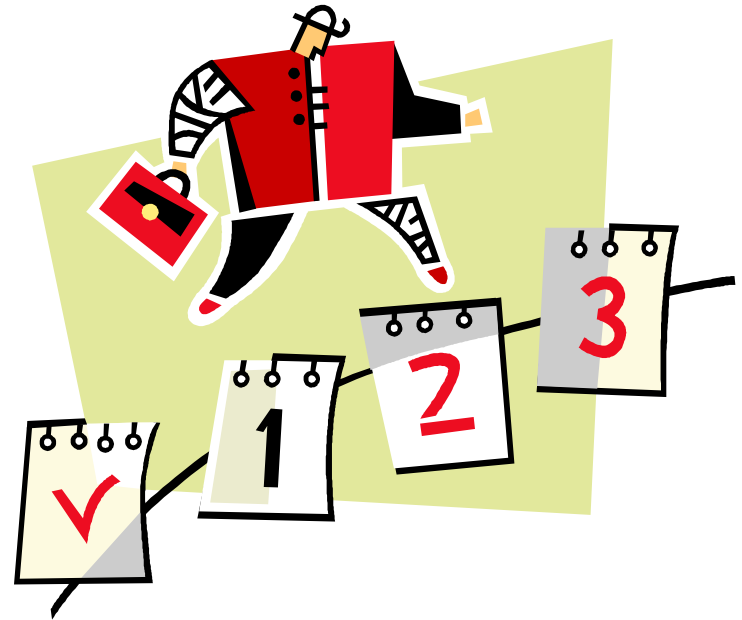
Where do we start?

- Each KP region is a complex system
- Our intervention is complex
- Implementation requires many approvals and process changes
- Researchers can learn from organizational effectiveness/process improvement
- How does our own organization deal with change management?
- Research requires systematic approach
- Pragmatic trial will benefit from a locally-acceptable approach (suited to the culture of KP)



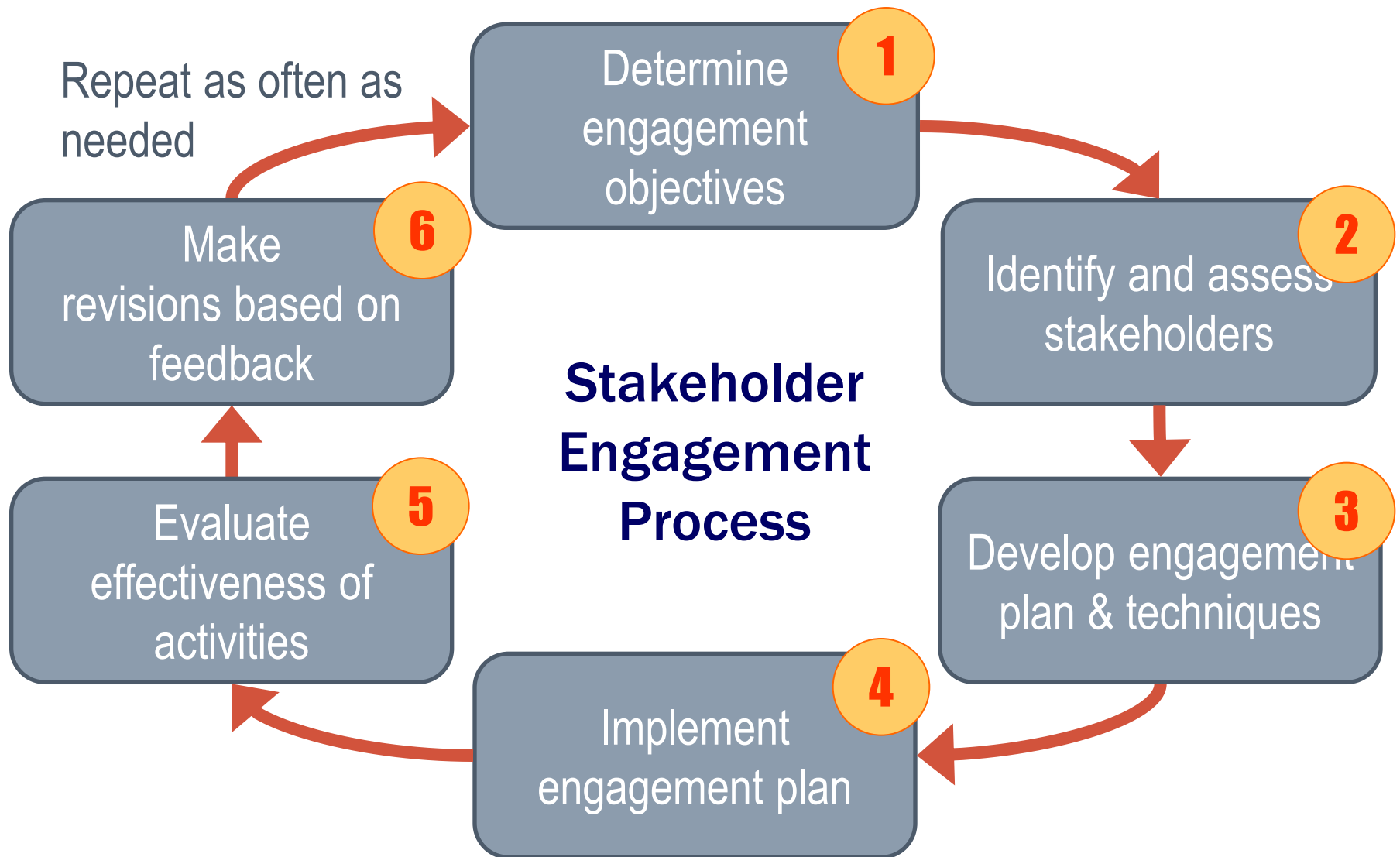
Adopting an In-House Stakeholder Engagement Approach

- KP National Organizational Effectiveness Team
- Stepwise approach for change management
- We are using RAP to answer these questions and to monitor our stakeholders' engagement with our intervention



Thanks to... Briana Cornwell, Briana.K.Cornwell@KP.Org
Senior Organizational Effectiveness Consultant

What is the process?



Who is a stakeholder?

Anyone who has a “stake” in the change being proposed or who can most influence the outcomes

Clinic operations & support staff (RN, LPN, MA, Clinic Directors)

Physicians & other providers in various departments (primary care, addition medicine, mental health, etc.)

Billing and compliance partners

Managers / Supervisors

Sponsors (VPs, Directors)

Information Technology

Project managers

| | |
|------------------------|--|
| Stakeholder Engagement | Give people a chance to influence the process and ensure they are ready, willing and able to make the change |
| Communications | Seek to issue a message or to influence groups to agree with a decision that is already made |

Why engage people?

People need time to analyze, think about, and adjust to the new ideas – if we leave them behind, we increase the likelihood of misunderstanding, resistance, and exclusion

- Increase their confidence
- Increase transparency
- To learn how to make the change easier
- Generate new ideas
- Gain higher levels of trust
- Show people we care about them
- Surface risks

People want to know how they fit in, the role they will play, and what help they can offer

Determine engagement objectives

Before we engage people, we need to know:
why we want to engage stakeholders
who will count as a stakeholder
what will result from stakeholder engagement
the risks of not doing it.

Stakeholders are meaningfully engaged when their influence makes a difference, whether directly or indirectly

Stakeholder engagement outcomes – PACT Yr 1:

- **Strategic objective:**

- Lay groundwork for PACT trial in 3 KP regions.
- Thoroughly identify stakeholders now, so we can effectively engage them throughout trial.

- **What will be different as a result of engagement?**

- Permission/sponsorship from high levels of organization
- Operational support for trial
- Learn about existing processes to conduct trial with least amount of disruption needed to deliver intervention
- Obtain PROs and other clinical data to conduct and evaluate trial

- **What level of engagement do we need?**

- Variable. Early efforts will focus on stakeholders who require highest level of engagement in order to launch the trial.

Identifying stakeholders

Determining who should be included is hardest part of stakeholder engagement

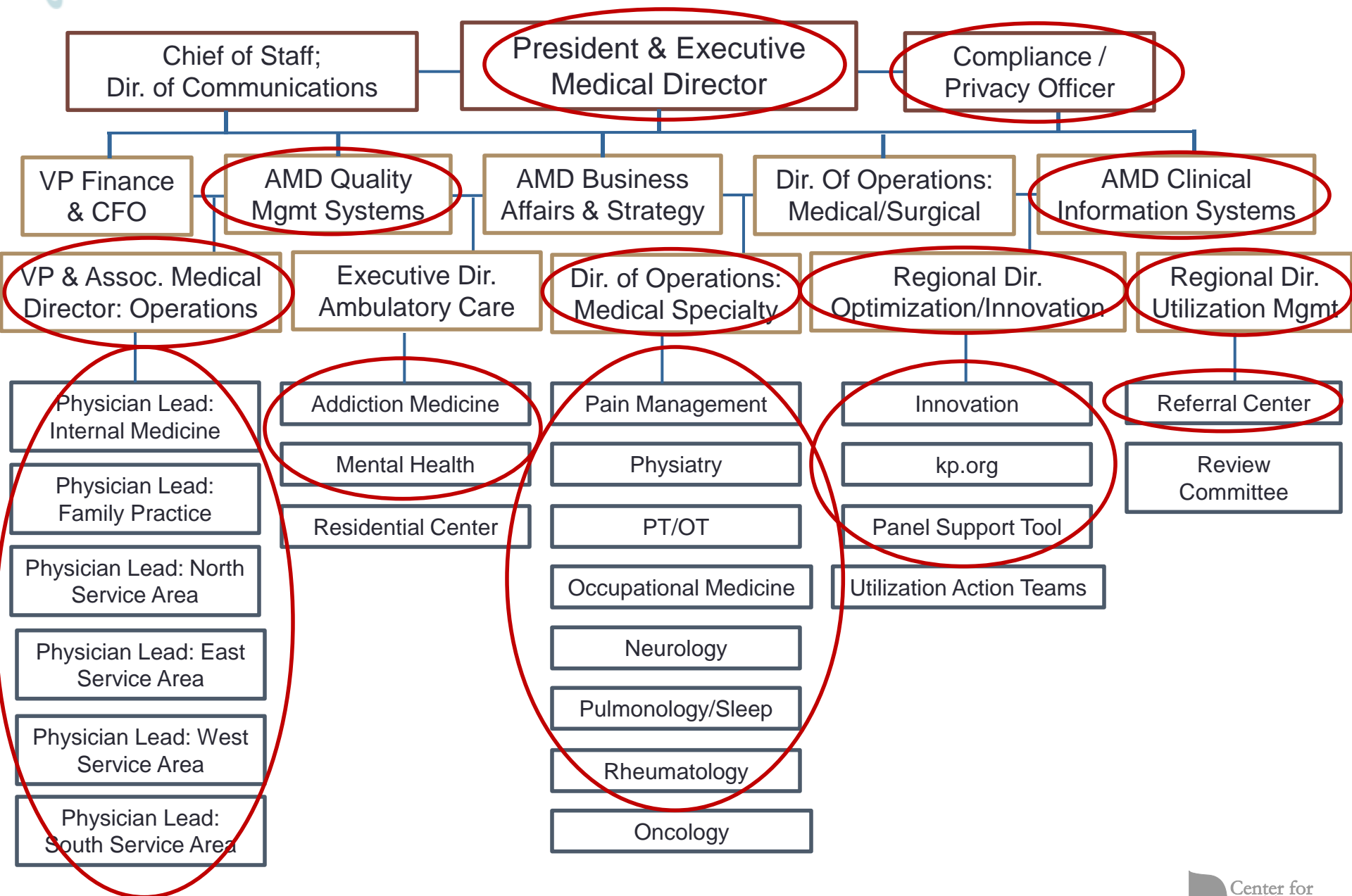
- Who will be affected by any decisions on the final design and implementation of the trial? Who will be impacted directly or 'down stream' ?
- What do they care about?
- Who is influential?
- Who can obstruct a decision if not involved?
- Who has been involved in this issue in the past?

If your goal is to be inclusive, identify your initial stakeholders and then ask THEM who else should be involved.

Start with the stakeholders you have the best rapport with.

For, PACT stakeholders are:

- *All who need to give permissions or who will contribute meaningfully toward trial's implementation.*
- *Representatives of groups whose daily work will be impacted by it.*



What is stakeholder's level of influence?

1 = Little

2 = Some

3 = Moderate

4 = Major

5 = Significant

What is the change YOU need stakeholder to make? What is likely impact on the stakeholder?



- Top level permission
- Perceive the trial as an opportunity, not a risk
- Access to people, processes, data
- Spread the word
- Change daily practice...

Put yourself in stakeholder's shoes and ask “What's in it for me?”



- Gather the information you need to answer this question.
- Briefly describe what the benefit of the trial is to the stakeholder(s)
- How the research team and/or the organization working to make the change easier for them
- Make sure to think about what the stakeholder(s) would consider to be a benefit or what they care about

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

Keep track of:

- Likely issues/needs for each stakeholder
- Concerns stakeholder as raised
- Response to concerns
- Communication plan



Example 1:

Chief of Primary Care

- **DESIRED CHANGE** “Sponsor” of PPACT trial. Promoting trial as regional priority will be seen as leadership-level commitment to comprehensive, integrated pain management.
- **POSSIBLE IMPACTS** Credibility, Blame, Backlash
- “WIIFM” Amelioration of major clinical/cost problem, reputation
- **INFLUENCE** Significant
- **ENGAGEMENT LEVEL** Collaborate
- **ISSUES/NEEDS** Minimize PCP burden of participating in trial
- **METHOD/COMMUNICATION PLAN** Busy schedule necessitates regular, focused electronic communications supplemented by targeted in person meetings

Example 2 :

Pain Clinic Medical Director

- **DESIRED CHANGE** Create a partnership that melds clinical, scientific, and evaluation expertise to create optimal opportunity for success among complex patients with pain and their primary care providers. Help identify levels of services and resources to meet complex patient needs.
- **POSSIBLE IMPACTS** Wide-ranging
- **WIIFM** Enhance pain management options for complex patients
- **INFLUENCE** Some
- **ENGAGEMENT LEVEL** Collaborate
- **ISSUES/NEEDS** Avoid overlap/duplication of services. PPACT should improve tracking of patient treatment/outcomes.
- **METHOD/COMMUNICATION PLAN** Team meetings aimed at system level problem solving

Implementing the plan

Implementing an engagement plan means knowing who is doing what when

- Who is responsible?
- Who is being engaged?
- What method is being used?
- When will it happen?
- How often?
- How will we know it was effective?

Evaluating effectiveness

Evaluating what happened tells us what we need to do differently next time

- Through weekly journals and reactions to “postcards” we will assess:
 - Did we achieve intended outcomes?
 - Do people feel good about their engagement level?
 - Was resistance managed appropriately?
 - Who needs follow up?
 - What tactics worked?
 - What would we do differently next time?

Making revisions

Engagement planning should be iterative and adaptable and last throughout the change implementation

- Engagement often happens in small spurts rather than large chunks
- Reflect on lessons learned before the next engagement cycle (vanguard, intervention roll out, post-intervention evaluation)
- A formal survey or focus groups can provide additional feedback
- Along the way, make sure to report concerns, recommended actions & successes to leadership/sponsors

Summary of Key Points

- Study Context: unusual window of opportunity for launch of intervention requiring disruptive change in primary care setting (impact and management of opioid tx for chronic pain)
- Measurement / Data challenges: Ensuring PRO adequacy
 - Expect heterogeneity of data across settings, active iterative process for ensuring adequate quality and comparability of data for study purposes
 - Increased adoption of patient health records provides potential opportunity for ancillary data collection
- Engaging Key Stakeholders: novel methods and approach
 - Identify range of important stakeholders and assess appropriate level of engagement for each
 - Consider adoption of organizational change processes familiar to those you are working with and well-vetted in these settings

Questions?

