The PPACT Study: Delivery Collaborative Care for Pain in Primary Care

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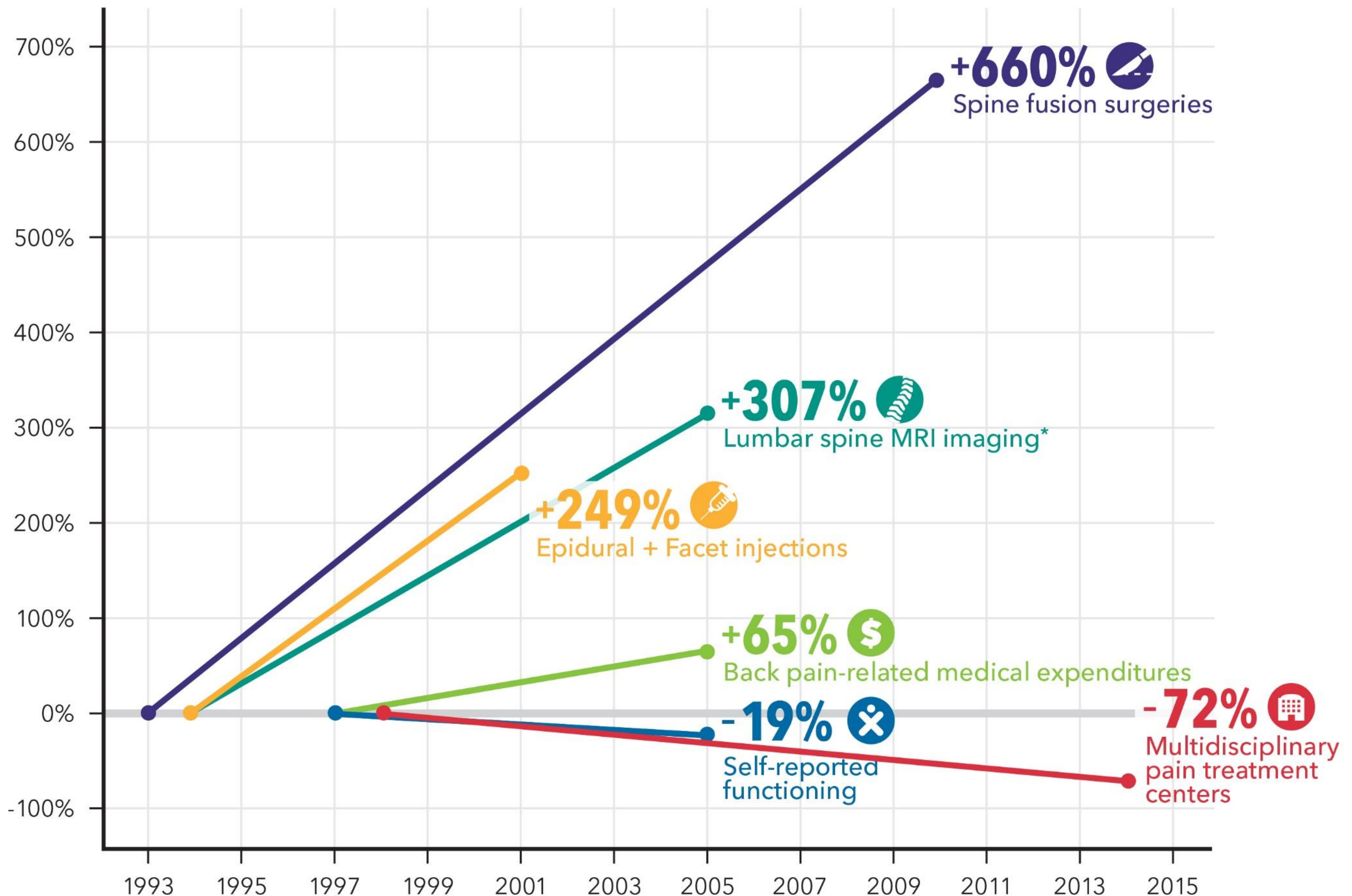
Supported by NIH Common Fund and by NINDS through cooperative agreement (with NIDA scientific advisory support) (UH3NW0088731)

The Road Map

- Context
- Pragmatic trials and PPACT (key features / early learnings)
- Where we’re falling short and how to address
- Overall conclusions

CONTEXT

An acute care treatment model for a chronic condition?



Deyo et al. J Am Board Fam Med 2009; 22: 62-8, AHRQ 2014 Literature Synthesis; Friedly, Chan, & Deyo. Spine 2007; 32: 1754; Martin et al. JAMA 2008; 299: 656-64; Gatchel et al. Am Psychol 2014; 69:119-130.

Policies/guidelines

NCQA, State Medical Boards, DEA opioid prescription mandates

Changes in expectations

Shifting marijuana laws & policies

Brief visits

Complicated patients

Gaps in coordination with specialty care

Measurement and alert fatigue

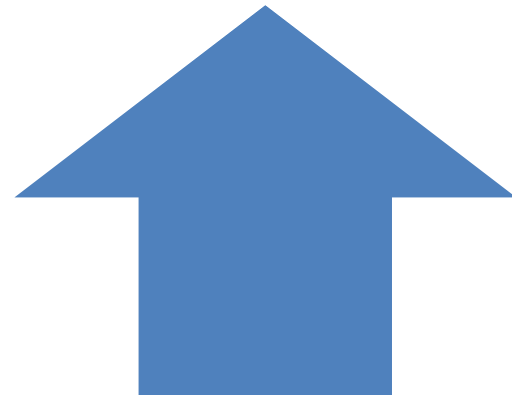
Limited pain treatment options

adapted with permission from Rollin Gallagher

The Paradox of Primary Care Based Pain Services

Primary care most logical setting for treating medically complex chronic pain patients

Structure, process, and staffing of primary care make implementation of best-practice interventions extremely challenging



How is Kaiser Permanente (KP) similar to / different from National Health Care Landscape?

- Integrated delivery system / care and insurance
- PCP-Specialty care: model of care increasingly emulated
  - Physicians salaried; reimbursement not RVU-based
  - Shared responsibility for defined population
  - Complex patients managed within primary care as much as possible
- Semi-autonomous regions / different structures

PPACT: Our Pragmatic Trial Approach

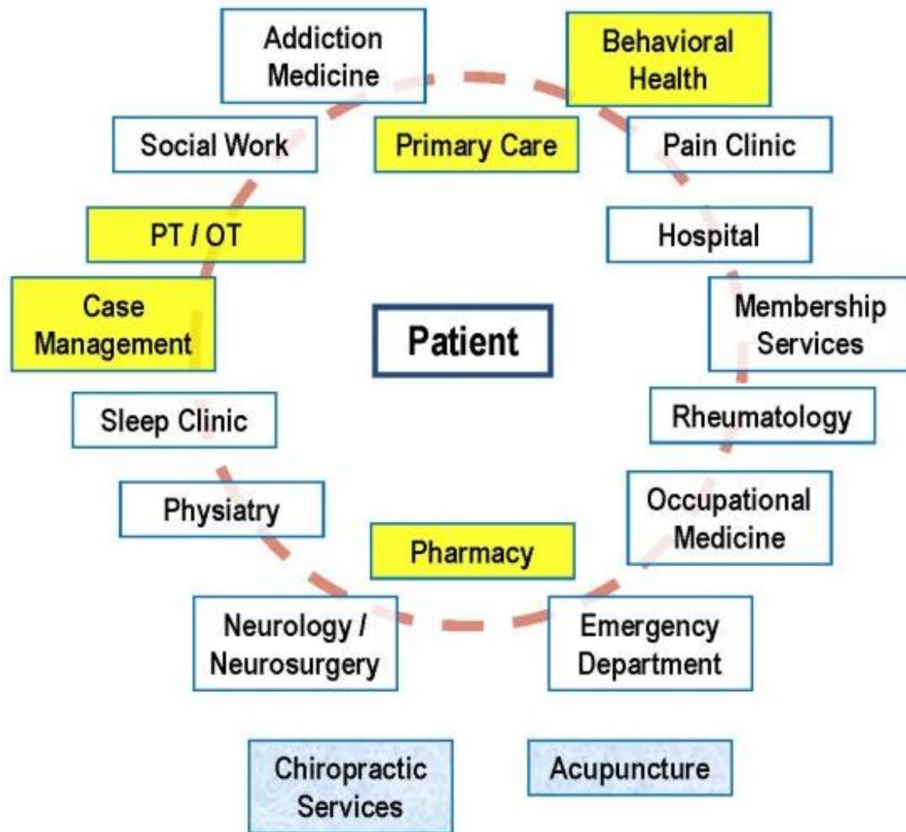
The “ask” from clinical and health plan leadership…

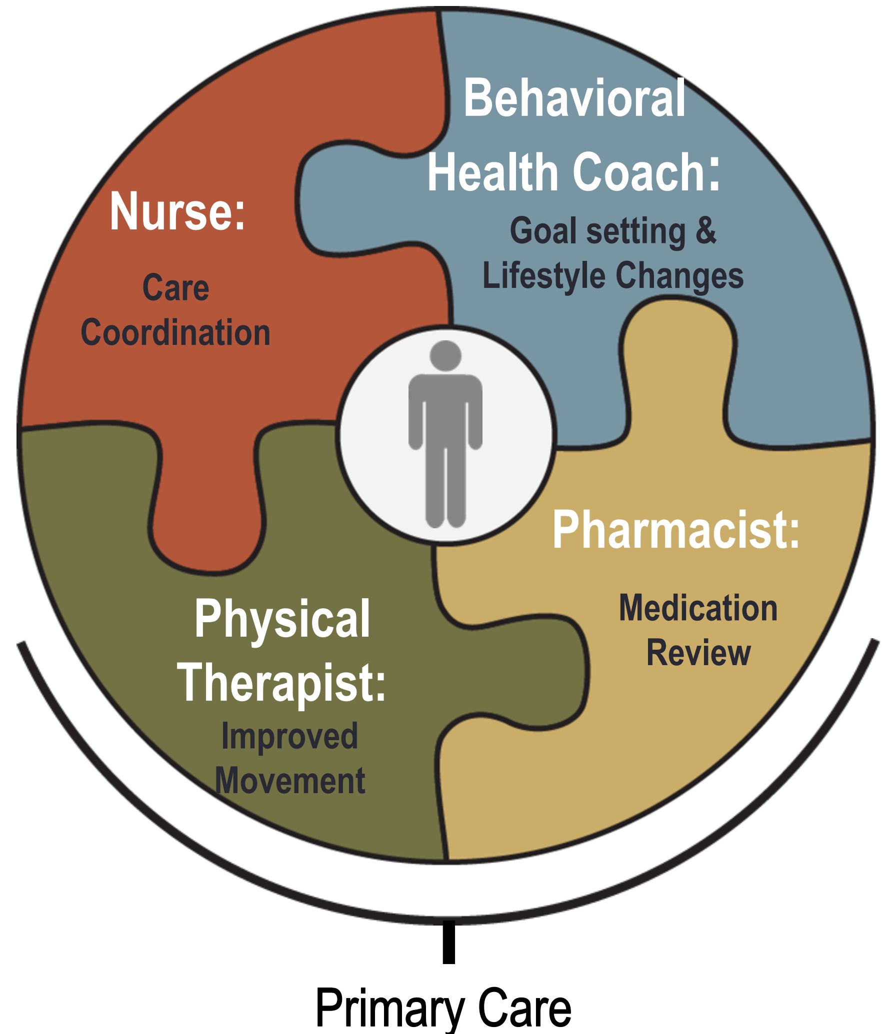
How do we keep our primary care providers from burning out and leaving the health care system?

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

Pain Management in Usual Care

Interdisciplinary Pain Management Embedded in Primary Care





Pragmatic clinical trials: Responsive to real-world needs

- Target population with greatest need (few exclusions)
- Tailor intervention to what is practical and sustainable
- Embed deeply in everyday clinical practice **not** orbiting in "parallel research universe"
- Questions and outcomes of highest priority to clinicians, policy makers, and patients
    - Health service use and cost / return on investment (from EHR)
    - Patient-reported outcomes (pragmatic & scalable collection)

NIH Health Care Systems Research Collaboratory Program

Demonstration Projects

The Research Collaboratory is designed in part to support the design and rapid execution of several Pragmatic Clinical Trial Demonstration Projects. These projects address questions of major public health importance that engage health care delivery systems in research partnerships. The data, tools, and resources produced by the Demonstration Projects will be made available to the greater research community to facilitate a broadened base of partnerships with health care systems. A UH2 is a cooperative agreement that supports the development of exploratory or innovative research activities, and a UH3 award provides support for the second phase of research activities initiated with the UH2.

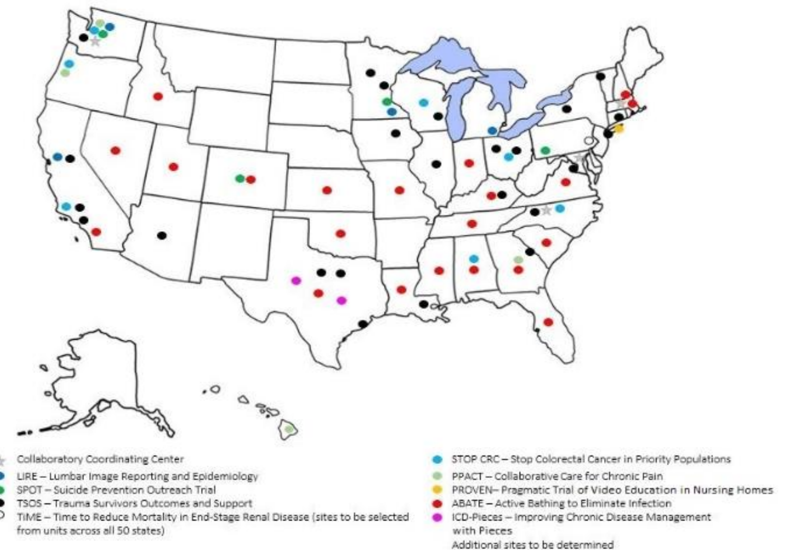
Projects

Title	Investigator	Collaboratory Affiliation	Name
UH3 Project: Time to Reduce Mortality in End-Stage Renal Disease (TiME)	Dember, Laura	University of Pennsylvania	TiME
UH3 Project: Suicide Prevention Outreach Trial (SPOT)	Simon, Gregory	Group Health Cooperative; Group Health Research Institute	SPOT
UH3 Project: Strategies and Opportunities to Stop Colorectal Cancer (STOP CRC)	Coronado, Gloria	Kaiser Foundation Research Institute	STOP CRC
UH3 Project: Pragmatic Trial of Video Education in Nursing Homes (PROVEN)	Mor, Vincent; Volandes, Angelo; Mitchell, Susan	Brown University School of Medicine	PROVEN
UH3 Project: Lumbar Imaging with Reporting of Epidemiology (LIRE)	Jarvik, Jeffrey	University of Washington	LIRE
UH3 Project: Improving Chronic Disease Management with Pieces (ICD-Pieces)	Vazquez, Miguel	UT Southwestern Medical Center	ICD-Pieces
UH3 Project: Collaborative Care for Chronic Pain in Primary Care (PPACT)	DeBar, Lynn	Kaiser Foundation	PPACT
UH3 Project: Active Bathing to Eliminate (ABATE) Infection	Huang, Susan	University of California, Irvine	ABATE
UH3 Project: A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support [TSOS])	Zatzick, Douglas	University of Washington	TSOS
UH2 Project: A Blood Pressure Medication Timing Study (BPMedTime)	Rosenthal, Gary	University of Iowa	BPMedTime

NIH Implementation Team

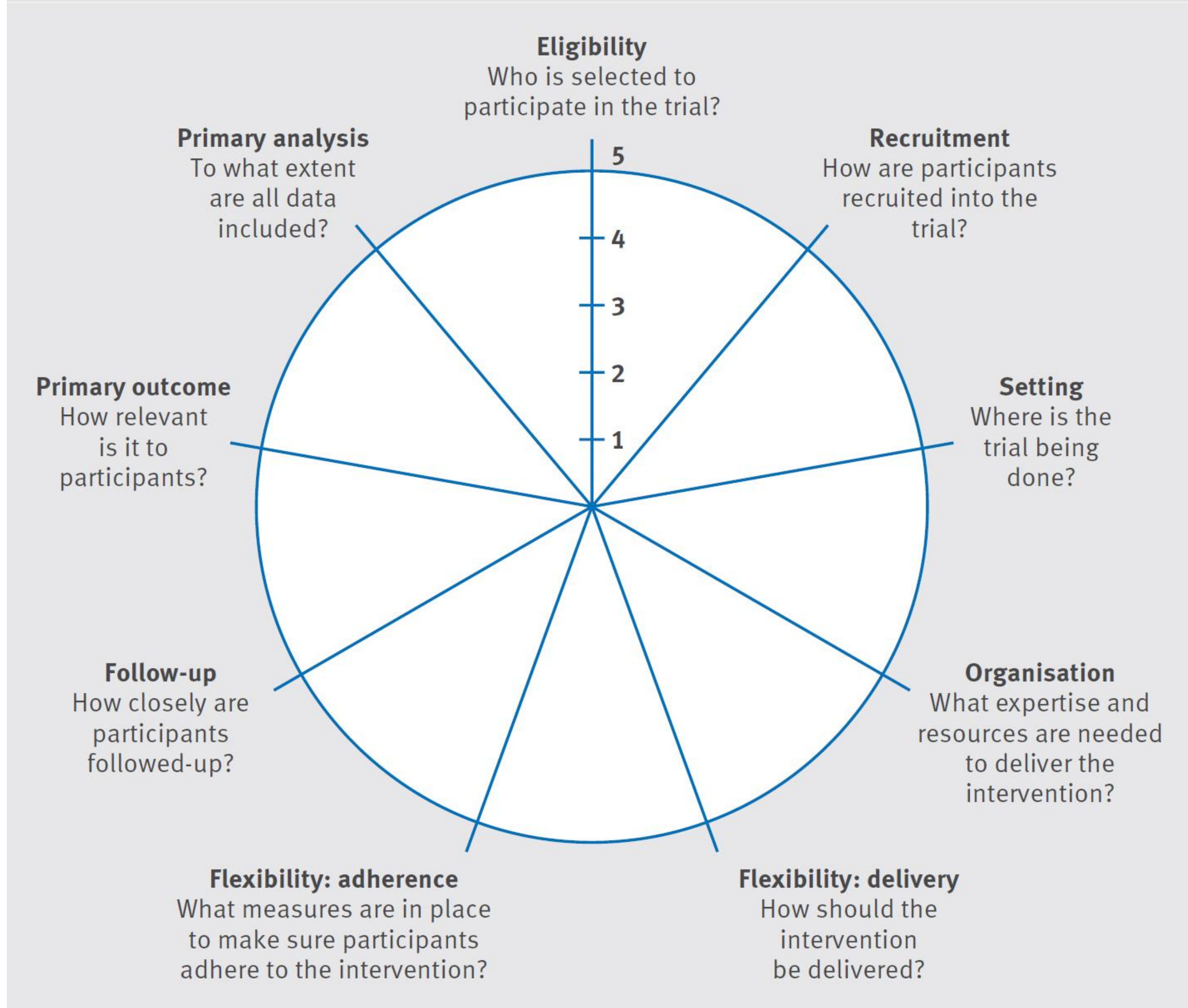
Team Co-Chairs: Drs. Josephine Briggs (NCCIH) and Michael Lauer (NIH)

Clayton Huntley / Gregory Deye (NIAID)
Stephen Taplin / Jerry Suls (NCI)
Matthew Rudorfer / Jane Pearson (NIMH)
Linda Porter (NINDS) / Sarah Duffy (NIDA)



Upcoming NIH-VA-DoD NonPharmacological Pain Management Collaboratory

https://www.nihcollaboratory.org



The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

RESEARCH Open Access

Trials

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

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

ABATE Infection

Eligibility, Recruitment, Setting, Organization, Delivery, Adherence, FollowUp, Outcome, Analysis (scale 1–5)

PPACT

Eligibility, Recruitment, Setting, Organization, Delivery, Adherence, FollowUp, Outcome, Analysis (scale 1–5)

LIRE

Eligibility, Recruitment, Setting, Organization, Delivery, Adherence, FollowUp, Outcome, Analysis (scale 1–5)

STOP CRC

Eligibility, Recruitment, Setting, Organization, Delivery, Adherence, FollowUp, Outcome, Analysis (scale 1–5)

TiME

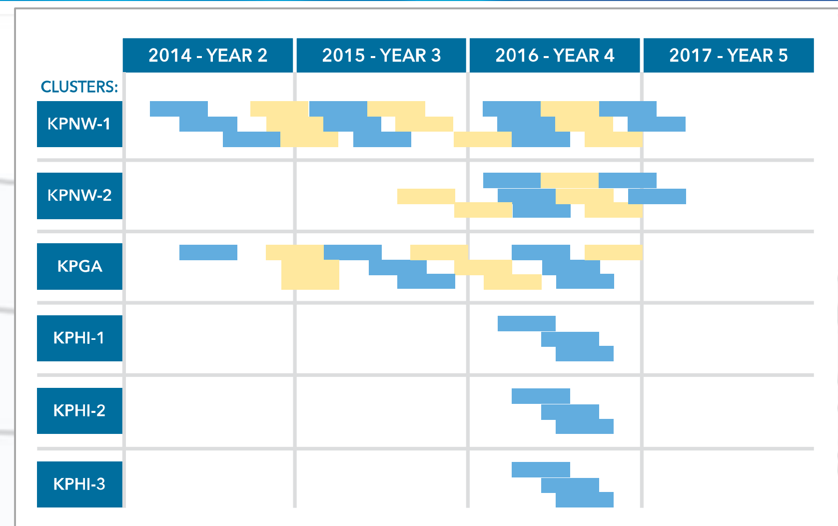
Eligibility, Recruitment, Setting, Organization, Delivery, Adherence, FollowUp, Outcome, Analysis (scale 1–5)

- - - Planning phase

— Implementation phase

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

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



PPACT Overview

AIM: Coordinate and integrate services feasible/sustainable in primary care for helping patients adopt self-management skills to:

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

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

ELIGIBILITY: Chronic pain, long term opioid tx *(prioritizing high utilizers of primary care, ≥120 MEQ benzodiazepine use)*

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

OUTCOMES: Pain (3[4]-item PEG), opioids, pain-related health services, and cost

Intervention Description

Patient Identification / Referral

Comprehensive Intake Evaluation by Care Manager Team (CMT), Including Nurse, Behavioral Specialist, & Physical Therapist, & Pharmacy Consultant

CM Communicates Patient Specific Treatment Plan to PCP

PCP Referral for Ancillary Services & Follow-up Communication

Case Management Follow-up

Periodic re-evaluation & revision of treatment plan at mid and end of program

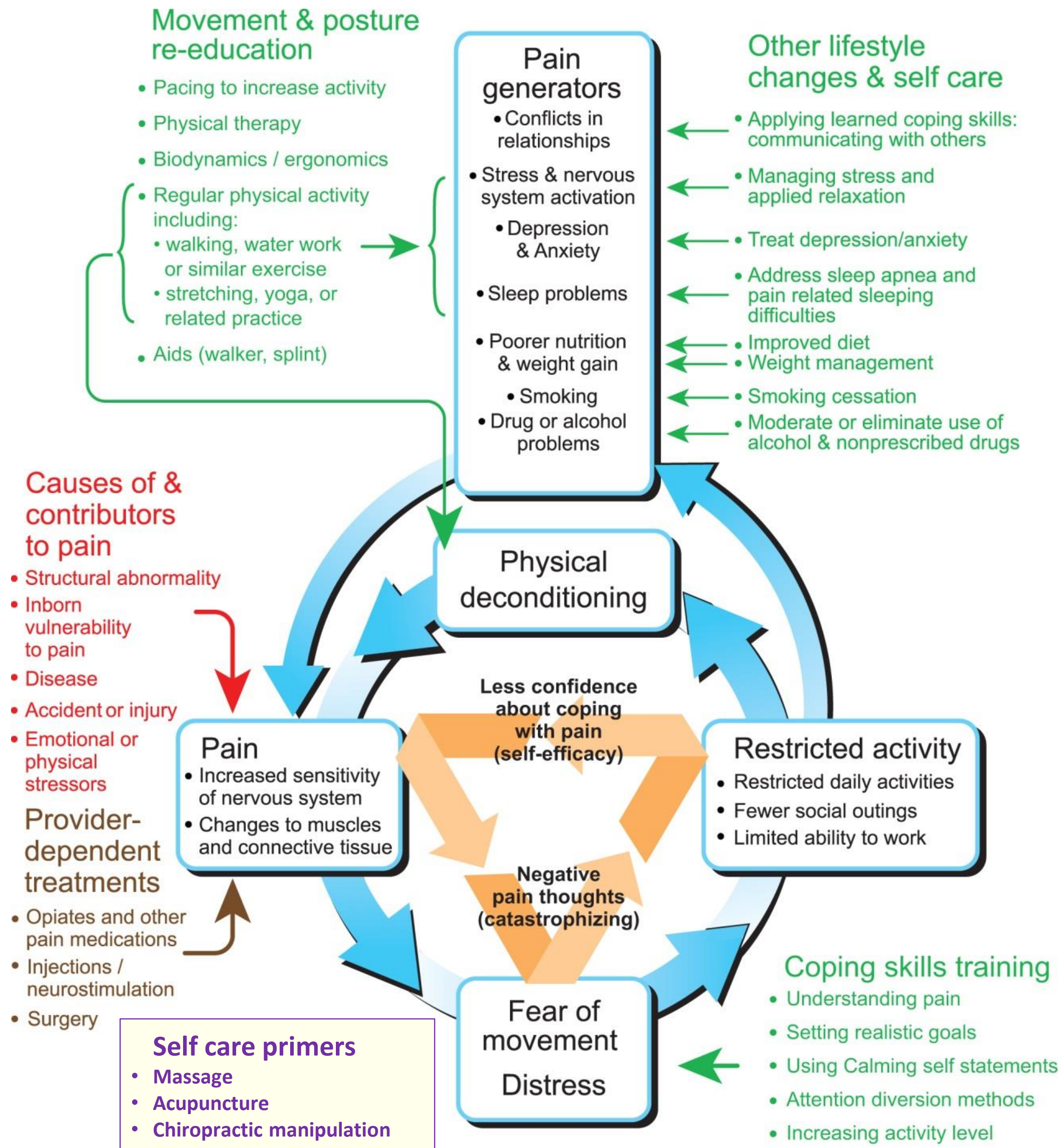
Individual coaching contacts (as needed)

Group Series (12 sessions; 2 hours every week)

PCP Component:

- Brief, 1 page summary of intake & discharge assessment provided to and discussed with PCP
- Dashboard of all assessment info documented in chart (linked from problem list)
- Weekly progress notes from PPACT interaction with patient
- **PCP expected to make outreach call to patients at program onset (template to guide PCP communication with patient)**

Intervention ~4 months in duration



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

Collecting Patient Reported Outcomes (PROs) in pragmatic trials

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

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

Opioid Therapy Plan (OTP) Operational Criteria

PATIENT CRITERIA	BASIC GREEN	COMPLEX YELLOW	COMPLEX RED
Follows plan reliably	X		
No history of opioid abuse	X		
No history of other substance abuse within past 2 years	X		
No current behaviors indicating drug misuse	X		
Current behaviors raise questions about the ability to follow the OTP		X	
History of opioid abuse		X	
History of other substance abuse within past 2 years		X	
Calculated overall opioid dosing level at 180mg morphine equivalent or higher		X	
Have demonstrated repeated problems following the OTP (e.g. unexpected UDS)			X
Active substance abuse			X
Have current behaviors which raise concerns about possibility of diversion			X

PCP REQUIREMENTS	BASIC GREEN	COMPLEX YELLOW	COMPLEX RED
Office visit frequency (minimum)	Semi-annually (1 may be TAV)	Quarterly (2 may be TAVs)	Quarterly (no TAVs)
~~Office visit required for any dosing changes~~	~~No~~	~~Yes~~	~~Yes~~
Brief Pain Inventory (BPI) completed (minimum) ***[Recommended to be administered at every office visit]***	Semi-annually	Quarterly	Quarterly
~~Refresh pain diagnosis on problem list~~	~~Yearly~~	~~Yearly~~	~~Yearly~~
Verify current dosing level is reflected on OTP on the problem list	Yes	Yes	Yes
Discuss with the patient their use of opioid, non-opioid and non-pharmacological modalities to control pain	Each visit	Each visit	Each visit
UDS ordered and resulted (minimum)	Yearly	Quarterly	Quarterly
Confirm random pill counts completed	PRN	2x/Year & PRN	2x/Year & PRN
Create AVS or send letter with patient's dosing and instructions after dosing change	Yes	Yes – AVS only	Yes – AVS only
Create separate monthly opioid prescriptions, no refills and no mail order	No	Yes*	Yes
Early refills for travel	Yes	Yes	Up to 2/year
May refill prescriptions early for lost or stolen reasons (Police report needed before receiving refill of stolen medications)	Yes	Limited supply only	No
New OTP required when prescriber changes or OTP color changes	Yes	Yes	Yes

PST - PATIENT

Print Preview

DM	CVD	CHF	HTN
Y			
CKD	Asth		Gap
	Y		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.

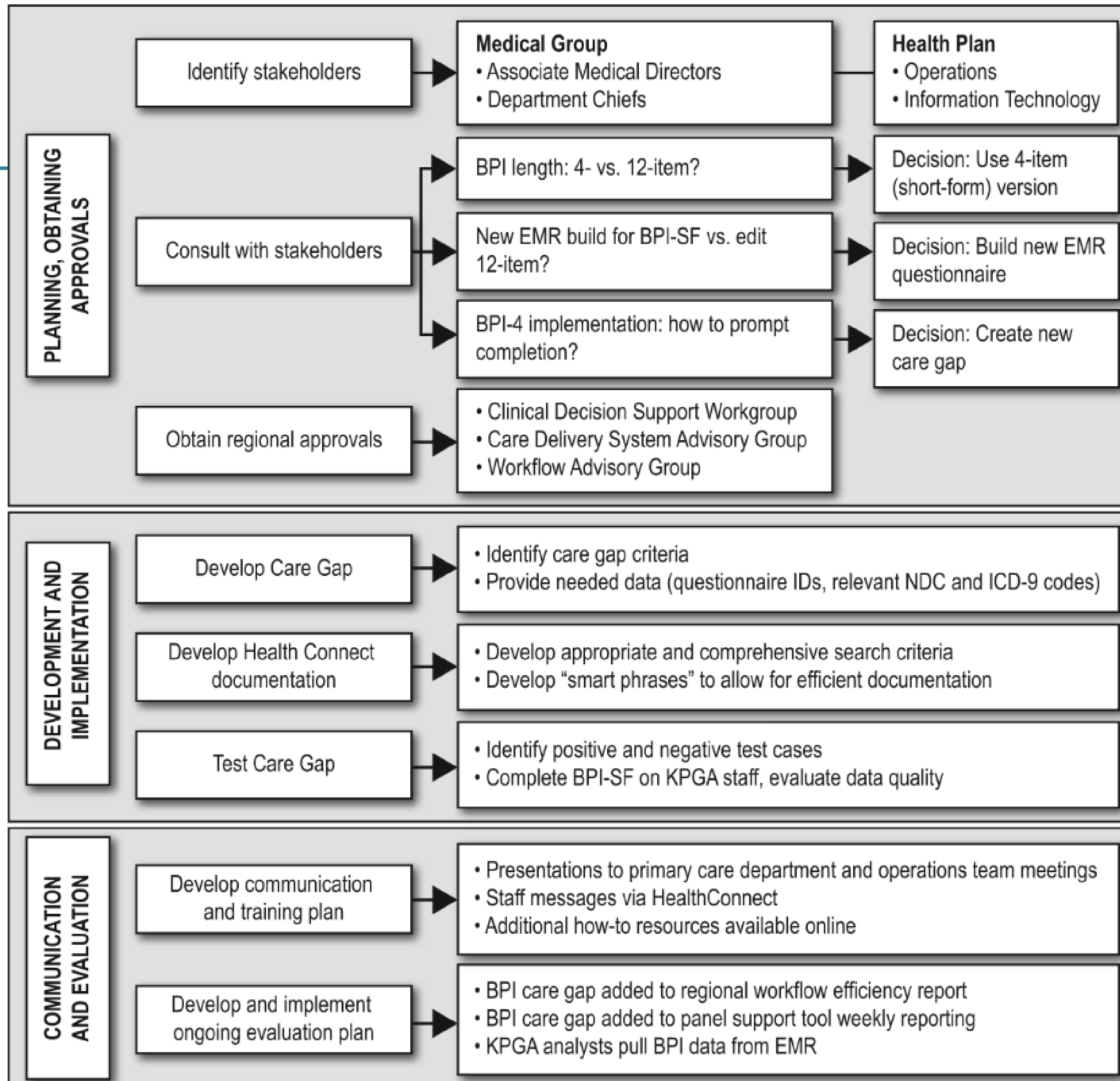
Preventive Care Gaps:
Active Tobacco Use: Advise quitting today

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		

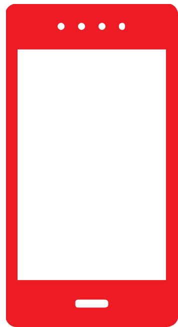
**Hover over the result to see trended results if available

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

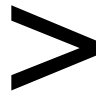


Establishing Routine BPI Administration in Clinical Workflow

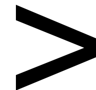
What it really takes to collect PRO data in routine clinical care



Personal Health Record (kp.org)



Interactive Voice Response (KP Messaging Center)



Live Call by Medical Assistant

Health Care Delivery System PROs: Lessons Learned

- Routine PRO collection likely to be variable and biased
- Supporting evaluation and improving clinical utility: Simplify assessment and build enhanced infrastructure
- IT / medical informatics partnerships critical

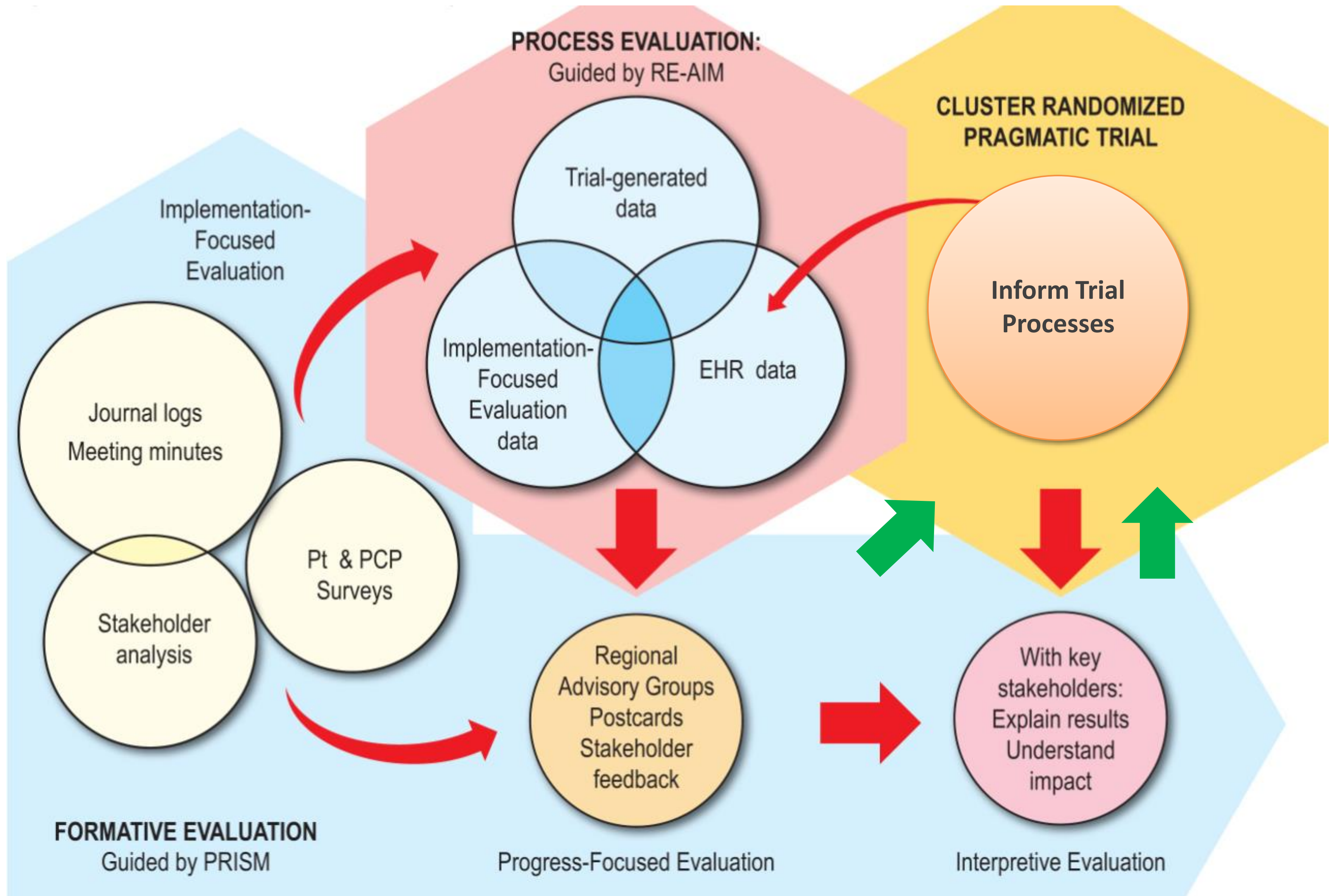
Online
or paper
collection

EMR Provider
Summary
Report

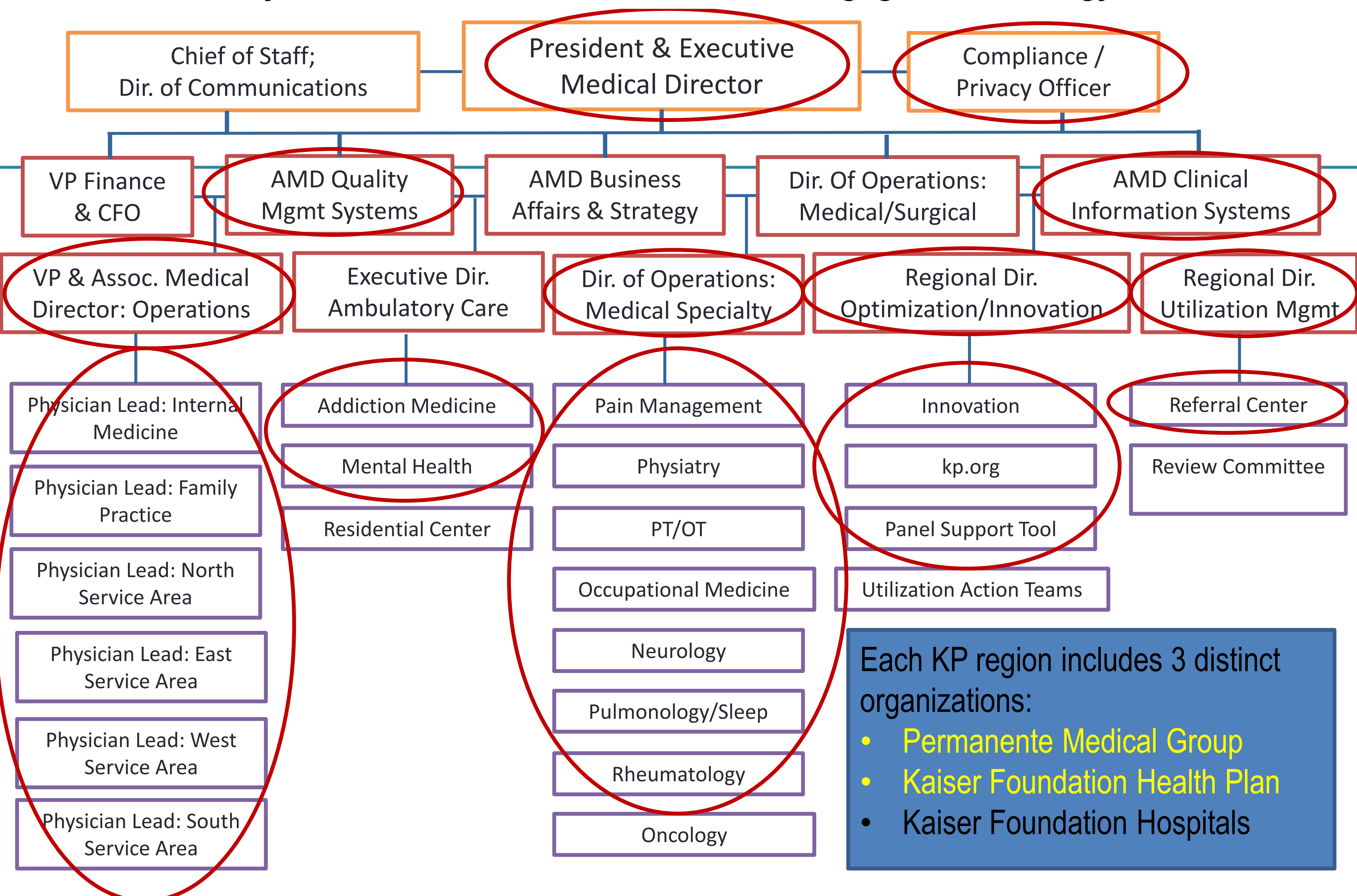
Scoring or
compilation
of relevant
assessments

Is a different approach to process evaluation warranted?

Importance of Two-way Flow of Information / Education



Many stakeholders; no "one size fits all" engagement strategy…



Rethink your process evaluation toolkit

- Informal stakeholder conversations
- Mapping (organizational relationships, processes)
- Weekly journaling by study staff
- "Postcards" to inform stakeholders and prompt dialogue
- Rapid Assessment approach
- 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

Journal entry:

PPACT Postcard #2, June 2013

We've started testing the PPACT intervention in one KPNW clinic. Together with PCPs in the Mt. Scott clinic, we identified patients who would benefit from this program. Comprehensive evaluations were conducted by a psychologist, clinical nurse specialist, physical therapist, and pharmacist.

This series of evaluations culminates in an individualized care plan that will guide the patient and PPACT team throughout the 3-month program. Patients say they appreciate care plans that speak to their individual situation and needs. They like the process because it identifies their unique strengths, validates their previous efforts to manage pain, and sets targets for improved function that reflect their priorities.

PPACT brings together multi-disciplinary teams to create patient-centered pain management plans–and so far, patients tell us they like it.

Lynn DeBar, PhD & the PPACT team at
The Center for Health Research
(Hawaii, Georgia, Northwest)

PPACT Team
Kaiser Permanente
USA

51380 6/13 CHR

We assess patients' health & medication use.

Together, we plan
for 3 months of active coping & training.

The underbelly of the urgent clinical question…

2013

Q1

Q2

Q3

Q4

2014

Q1

Chief champion (VP for Quality) retires; position split

Q2

Primary care champion steps down

Q3

Q4

Behavioral health director retires; addiction medicine reshuffled

2015

Q1

Pain medicine chief resigns; addiction medicine/behavioral medicine chief steps down

Q2

Q3

Mental health leadership change (Perm + HP)

Q4

Regionally assigned advisory group reshuffled

2016

Q1

Q2

Q3

Internal medicine chief steps down

Q4

17

Q1

Pain medicine leadership change (chief + HP)

2013

Q1

Q2

Q3

Q4

2014

Q1

Q2

Opioid pill limit

Q3

Q4

2015

Q1

Q2

Q3

Q4

2016

Q1

Opioid taper initiative (<120 MED)

Q2

Q3

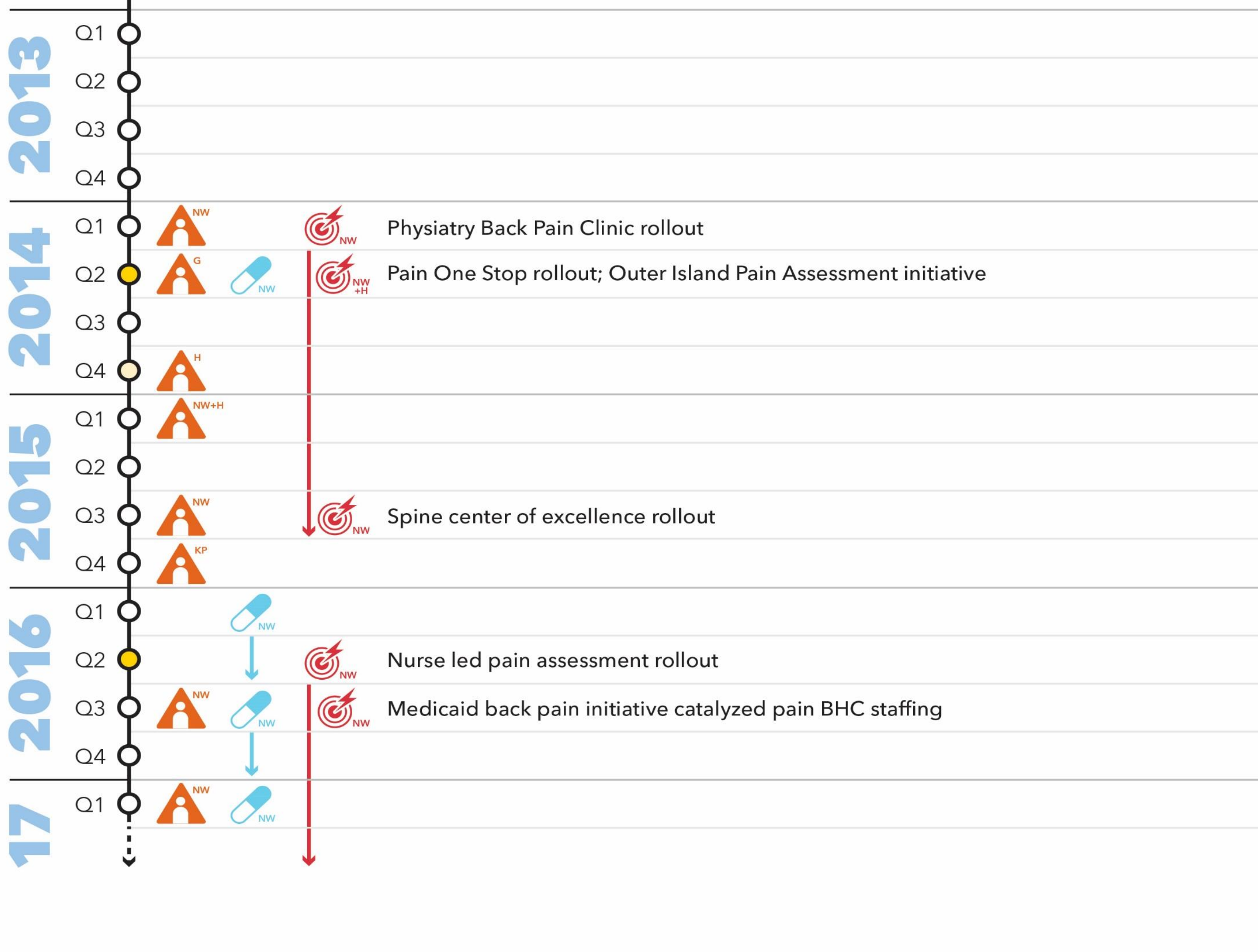
Opioid taper initiative (<90 MED)

Q4

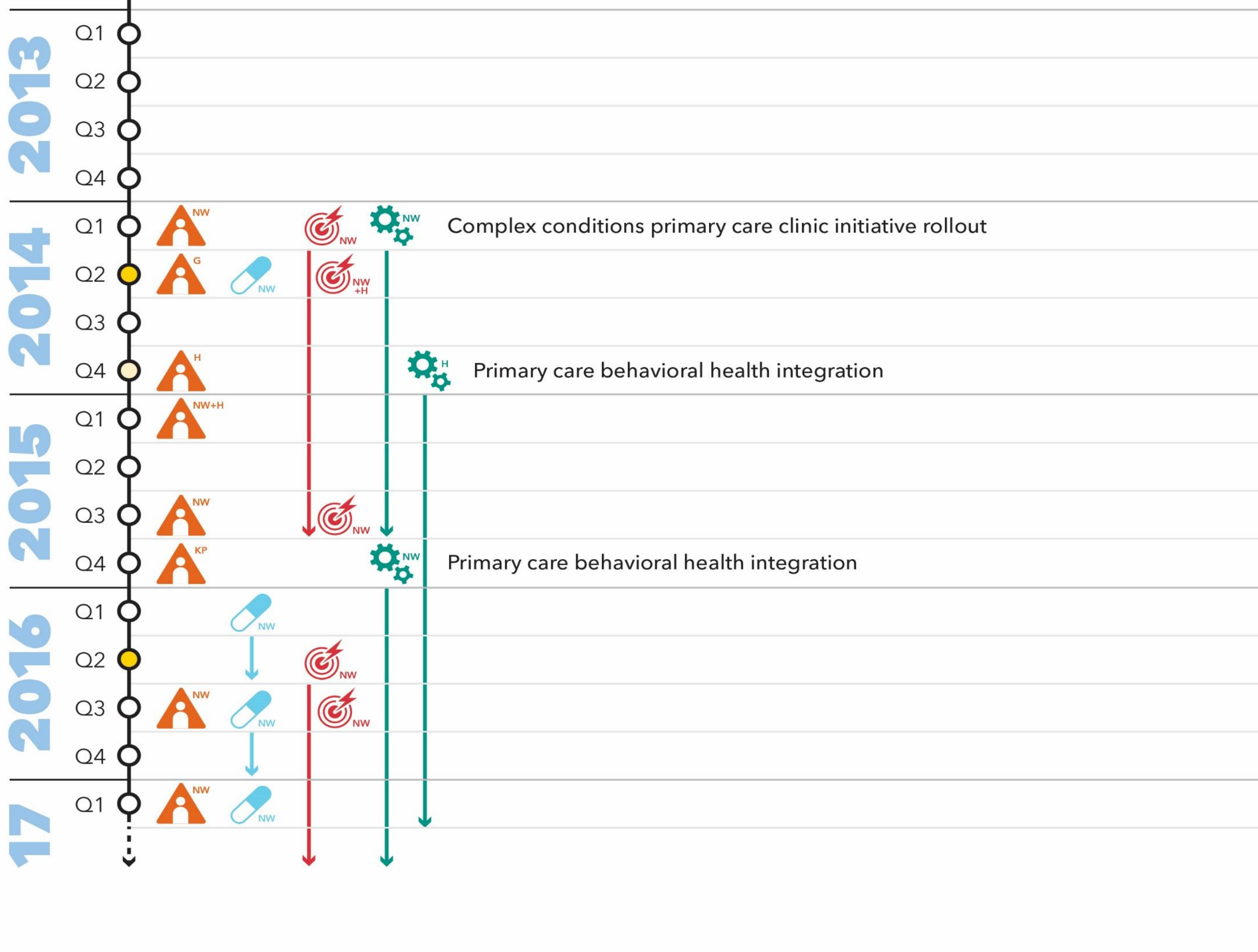
17

Q1

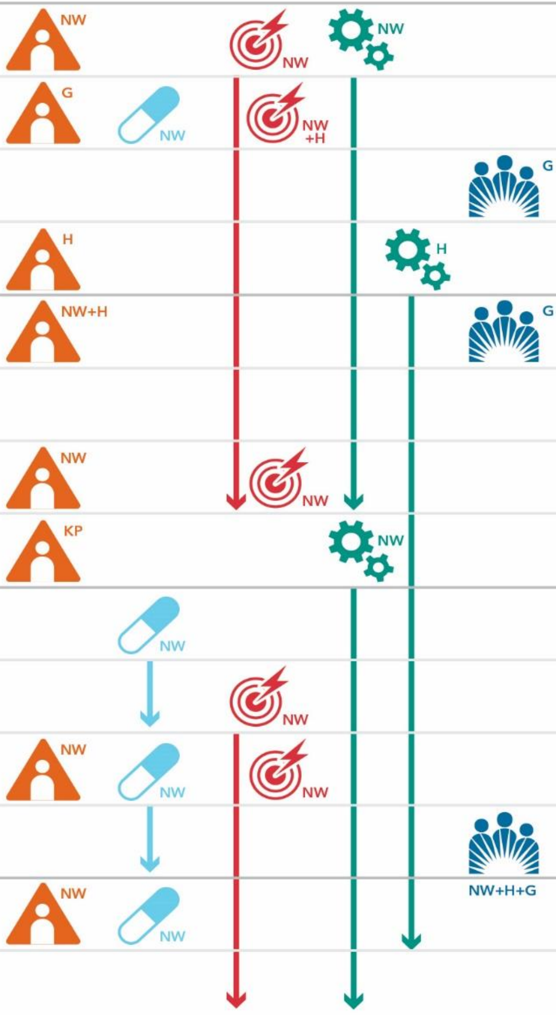
Benzodiazepine reduction initiative for COT patients

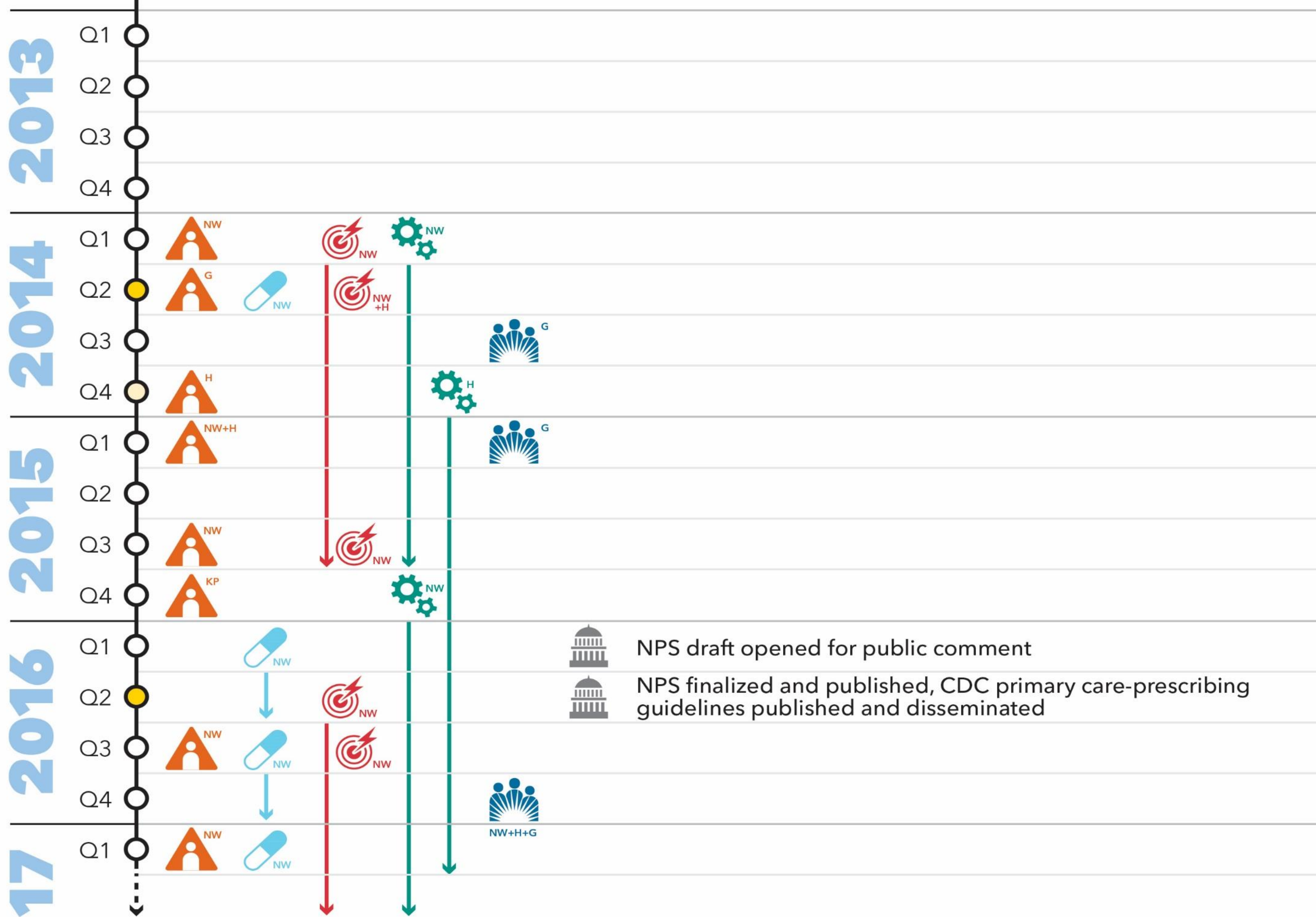


2013
Q1
Q2
Q3
Q4
2014
Q1
NW
NW
Physiatry Back Pain Clinic rollout
Q2
G
NW
NW +H
Pain One Stop rollout; Outer Island Pain Assessment initiative
Q3
Q4
H
2015
Q1
NW+H
Q2
Q3
NW
NW
Spine center of excellence rollout
Q4
KP
2016
Q1
NW
Q2
NW
Nurse led pain assessment rollout
Q3
NW
NW
NW
Medicaid back pain initiative catalyzed pain BHC staffing
Q4
17
Q1
NW
NW


2013
Q1
Q2
Q3
Q4
2014
Q1
NW
NW
NW
Complex conditions primary care clinic initiative rollout
Q2
G
NW
NW
+H
Q3
Q4
H
H
Primary care behavioral health integration
2015
Q1
NW+H
Q2
Q3
NW
NW
Q4
KP
NW
Primary care behavioral health integration
2016
Q1
NW
Q2
NW
Q3
NW
NW
NW
Q4
17
Q1
NW
NW

Year	Quarter	Event
2013	Q1	
	Q2	
	Q3	
	Q4	
2014	Q1	
	Q2	
	Q3	KPGA loses state contract PCMH nurse staffing reduced by 80%
	Q4	
2015	Q1	Health plan restructured under KPSC leadership
	Q2	
	Q3	
	Q4	
2016	Q1	
	Q2	
	Q3	
	Q4	Shift in retirement benefits causes large wave of retirements
17	Q1	




2013
Q1
Q2
Q3
Q4
2014
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NW
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Q2
G
NW
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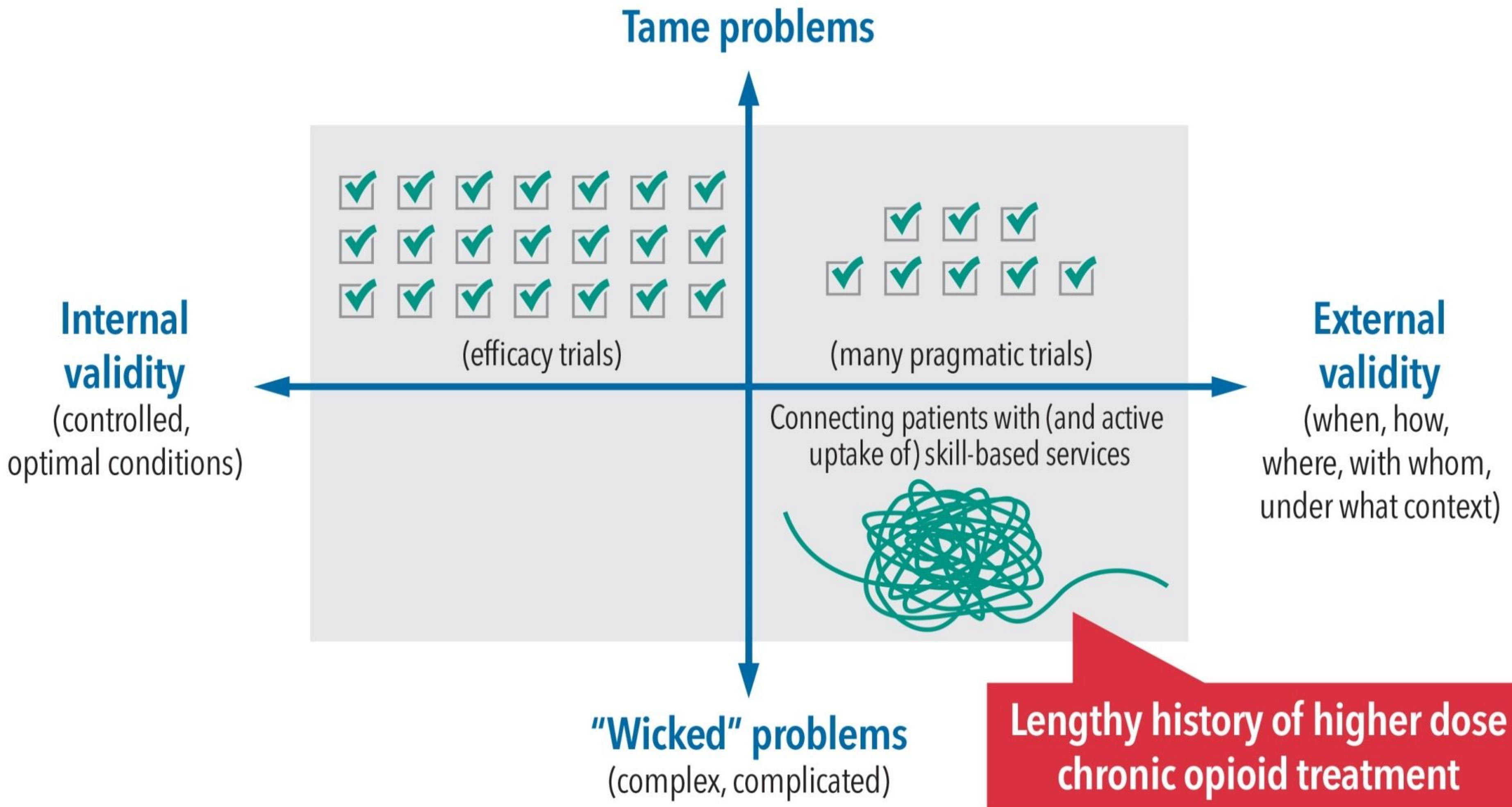
+H
Q3
G
Q4
H
H
2015
Q1
NW+H
G
Q2
Q3
NW
NW
Q4
KP
NW
2016
Q1
NW
NPS draft opened for public comment
Q2
NW
NPS finalized and published, CDC primary care-prescribing guidelines published and disseminated
Q3
NW
NW
NW
Q4
NW+H+G
17
Q1
NW
NW

Implications / Potential Actions?

- Consider comparing two active treatments if feasible (less perceived need to "innovate" on top of intervention of interest)
- Build in "Plan-Do-Study-Act" (PDSA) cycles to improve site-level tailoring and increase local staff buy-in
- Plan for constant surveillance / measurement of usual care
- Budget for one or more of the above approaches

WHERE WE’RE FALLING SHORT AND HOW TO ADDRESS…

Engaging highest need patients in pain self-management: How do we increase uptake?



COMPONENTS OF THE SOLUTION?

[FACT CONGRUENT]

STORIES

DESIGN TO OPTIMIZE "SPREAD"

Second generation technology-driven remote interventions

- Interactive voice response (IVR)-based self-management
- Mobile (Skype) delivery of pain coping skills
- Virtual reality (VR)-based pain treatments
  - Skill acquisition w/tailored multi-sensory tools
  - Enhance motivation (gaming approach)

Heapy et al, JAMA Internal Med, 2017; Somers et al Pain Research and Treatment, 2016; Keefe et al, Pain, 2012;153: 163-2166, Schroeder et al, IEEE Comput Graph Appl. 2013; 33: 82-89; Trost et al, Pain Manag. 2015; 5: 197-206.

Incorporating patient-driven models of support

- Existing approaches
  - Peer co-led self management group interventions
  - Individual peer coaching
  - ACPA peer-led support groups
- Peer-led adjunct to remote technology driven skills training?

Goal: Extend natural social networks, complement professional health services, provide emotional, [informational], and appraisal support in sustainable and cost-effective fashion

IN CONCLUSION?

Lessons learned so far…

- Challenging the status quo requires persistent and ***vertical*** health care system partnership
- Carefully consider "fit" of core intervention approach for frontline clinical staff and congruence with the organization's quality improvement approaches
- Health care systems need help for routine collection of Patient Reported Outcomes
- For chronic pain, mind/body split still deeply embedded in "behavior" of health care systems

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and research team…

KP Research Centers
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David Smith
Lindsay Benes
Bill Vollmer
Michael Leo

KP Operations / Clinicians
Charles Elder
Stacey Honda
Sharin Sakurai
Kelley DeGraffenreid

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Allison Bonifay
Meghan Mayhew

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Rick Deyo – OHSU
Bob Kerns – Yale
Michael Von Korff – KPWHRI
Patrick Finan – John Hopkins
Nicole Andrews – Royal Brisbane Hospital