Kaiser Permanente
Research

Using Integrated Health Plan EMR Data to Evaluate Outcomes Associated with Clinical Services for the Treatment of Non-Malignant Chronic Pain

Lynn L DeBar, PhD MPH

Kaiser Permanente Center for Health Research

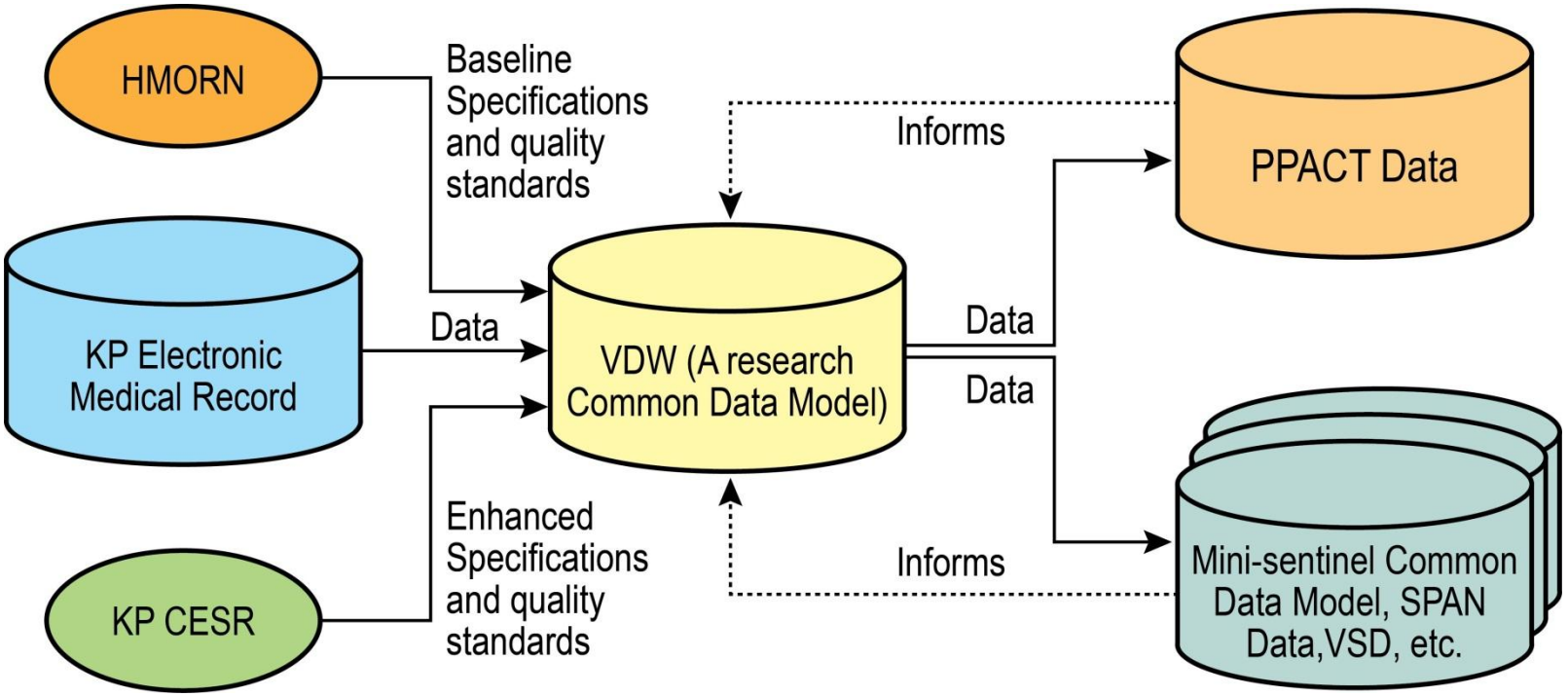
Agenda

- Utilizing EMR Data for Clinical Research
  - Types of data / variables available
  - Ascertaining data quality and comparability across health care systems: the role of the HMORN Virtual Data Warehouse
- The Opioid Use Improvement Project at KP-Northwest: an approach to enhance responsible prescribing and clinical care
  - Instituting the Regional Opioid Treatment Plan
  - Centrality of the Panel Support Tool
- PPACT – using health plan tools to conduct a pragmatic trial
  - Study design and use of EMR and related clinical tools
  - The special case of Patient Reported Outcomes
- Summary of Additional EMR-based Opioid Studies Underway

EMR Data from Integrated Health Plans: Advantages for Clinical Research

Kaiser Permanente
Research

- Practice based (not just claims data but details of care)
- Defined populations (known denominator)
- Integrated health care systems: Most medical care is obtained within our systems
- Automated case identification (facilitates recruitment)
- Diverse provider base (enables studies of relationships between provider behaviors and outcomes)
- Same EMR system across all Kaiser sites yet system differences (facilitates natural experiments and internal replication)



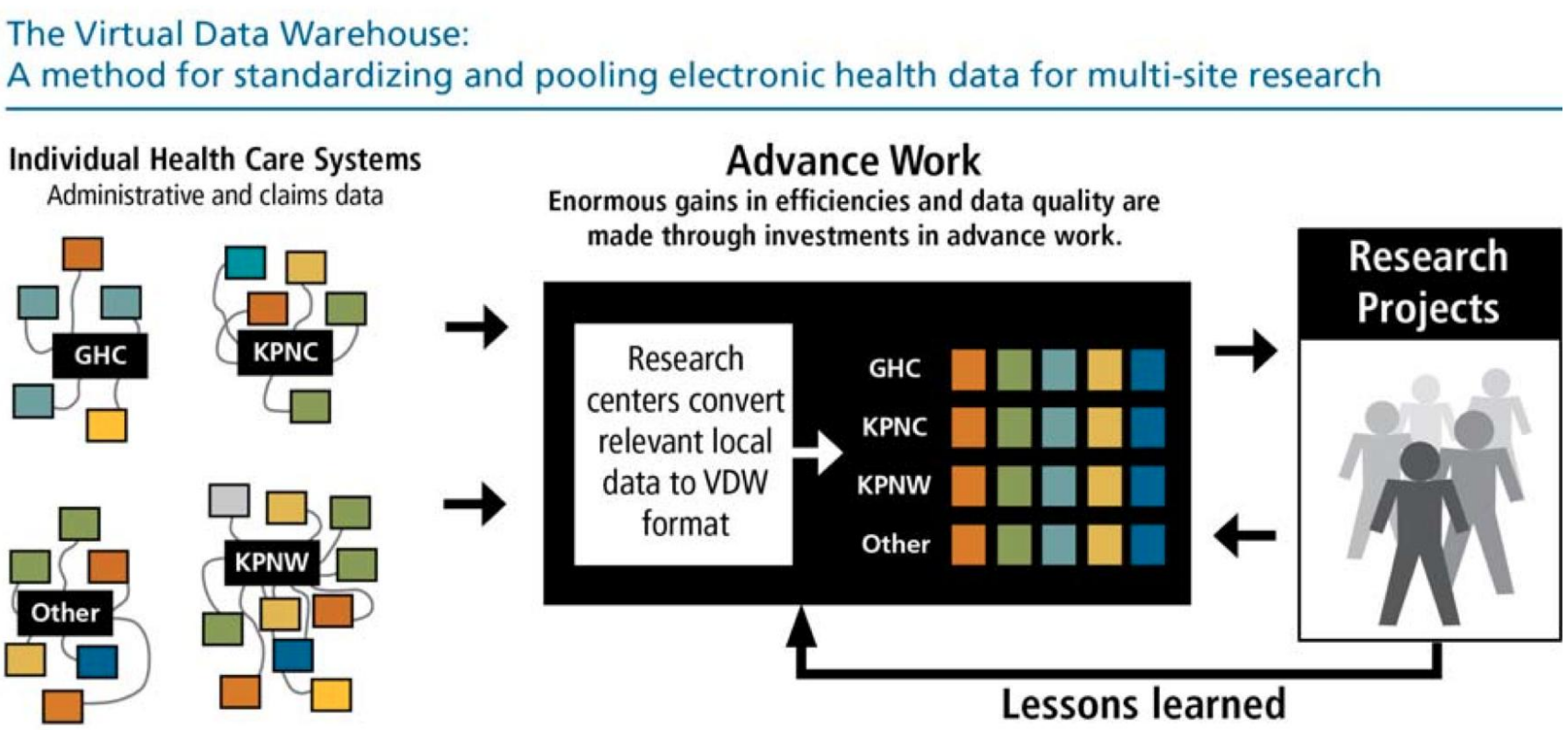
Kaiser Permanente
Research

Data Resources:
Virtual Data Warehouse (VDW)

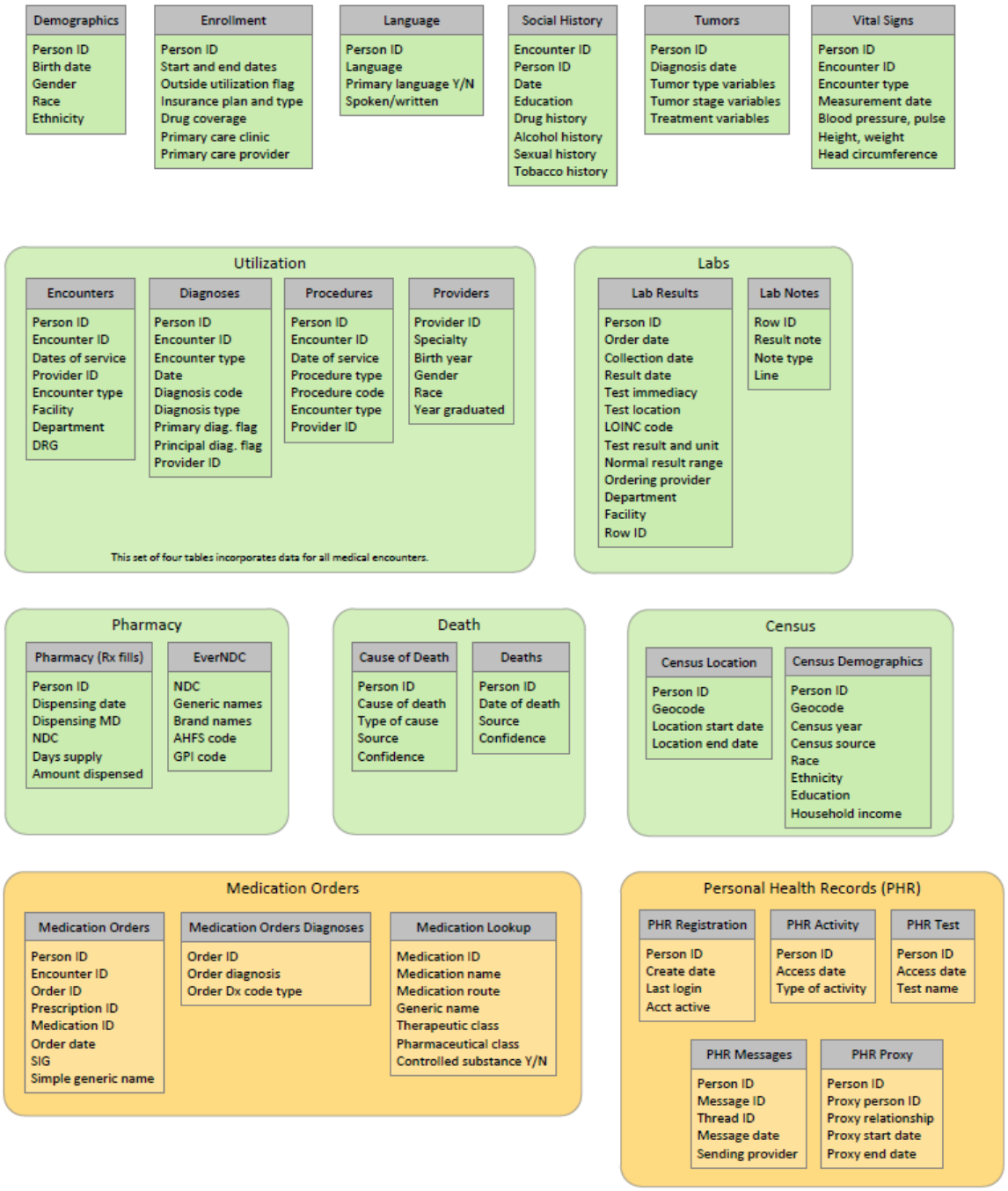
- Set of Common Data Standards: Variable names, definitions, formats, data structures
- "Virtual" = data are maintained at each participating site*; "Distributed" may be an equally appropriate description
- Source data (EMRs, other clinical and administrative databases) may differ from Site to Site
- SAS and Oracle databases

* Kaiser Permanente Research Centers in Northwest, Hawaii, Northern California, Southern California, Colorado, Georgia, and MidAtlantic), Group Health Cooperative, Health Partners, Harvard Pilgrim, Geisinger, Henry Ford, Maccabi Institute (Israel), Marshfield, Essentia Institute of Rural Health, Meyers Primary Care Institute, Scott and White Research, Palo Alto Medical Foundaiton Research Institute

The VDW: How It Works



Kaiser Permanente
Research



Kaiser Permanente
Research

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

Identification of high risk patients

- High daily MEQ
- Suicide Attempts
- Pharmacy Concerns (multiple and/or early refills)
- Substance Abuse
- Dose Escalations

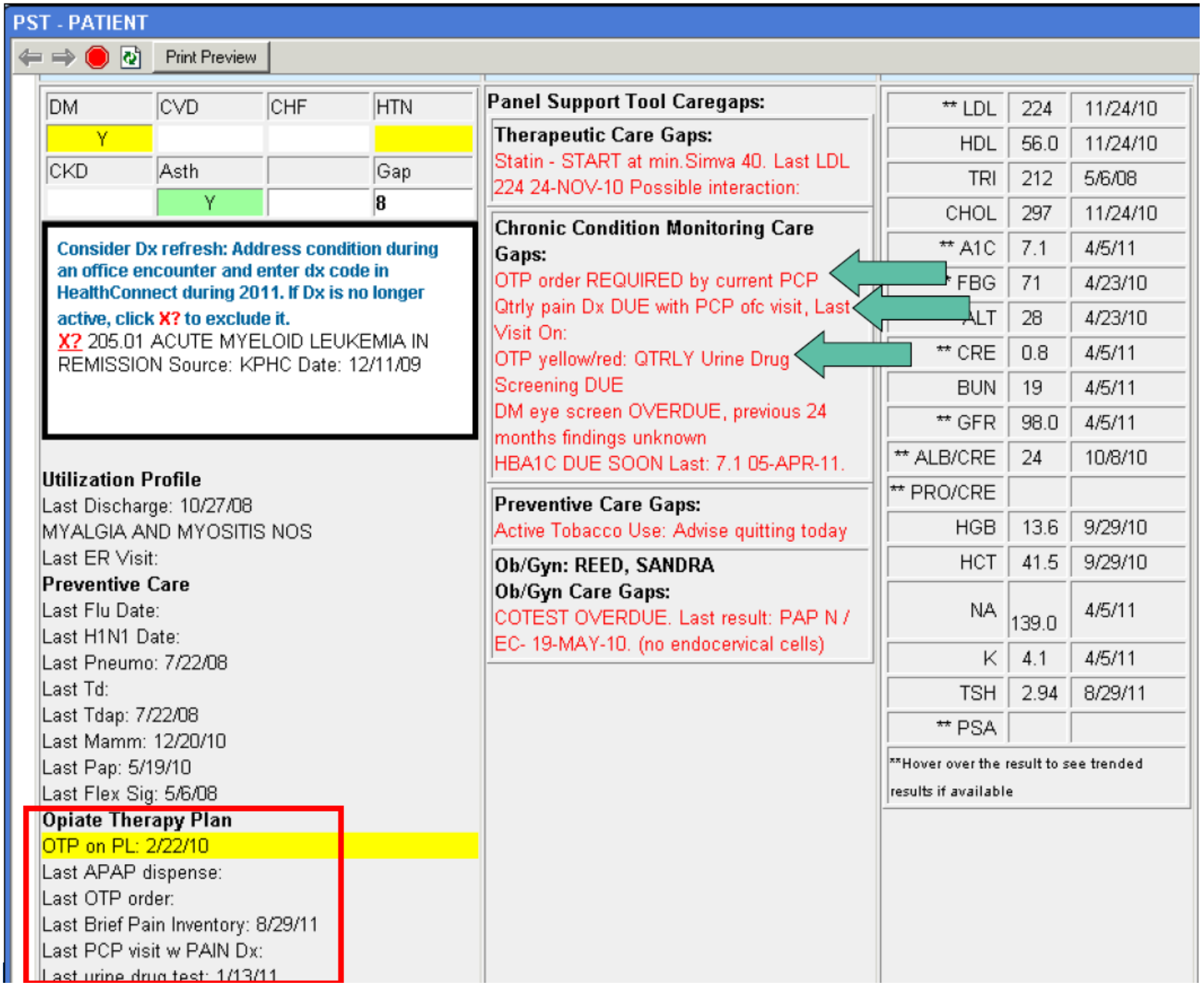
Care Management Tools

- Opioid Therapy Plans (OTP)
- Care flags added to Patient Support Tool (PST)
- Brief Pain Inventory (BPI)
  - Back office staff trained to enter data
  - Clinicians trained to track functional improvements
- Best Practices Alerts (BPA)

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

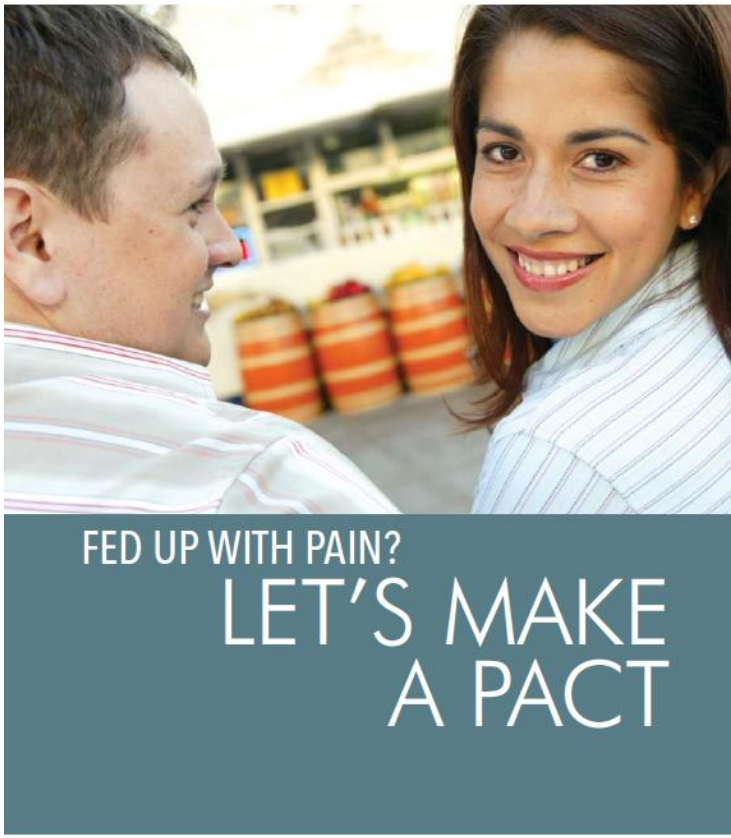
PPACT: Building Upon Regional Actions & Data Capabilities

Kaiser Permanente
Research

PAIN PROGRAM FOR ACTIVE COPING & TRAINING

- Principle Investigator: Lynn DeBar, PhD MPH Kaiser Permanente NW Center for Health Research
- Sites: KP Northwest, KP Southeast, KP Hawaii
- Pragmatic Clinical Trial Sponsored by:
  - National Institutes of Health Common Fund
  - National Institute of Neurological Diseases and Stroke
  - National Institute of Drug Abuse
  - Administrated by the National Center for Complementary and Alternative Medicine

PPACT



KAISER PERMANENTE®

Kaiser Permanente
Research

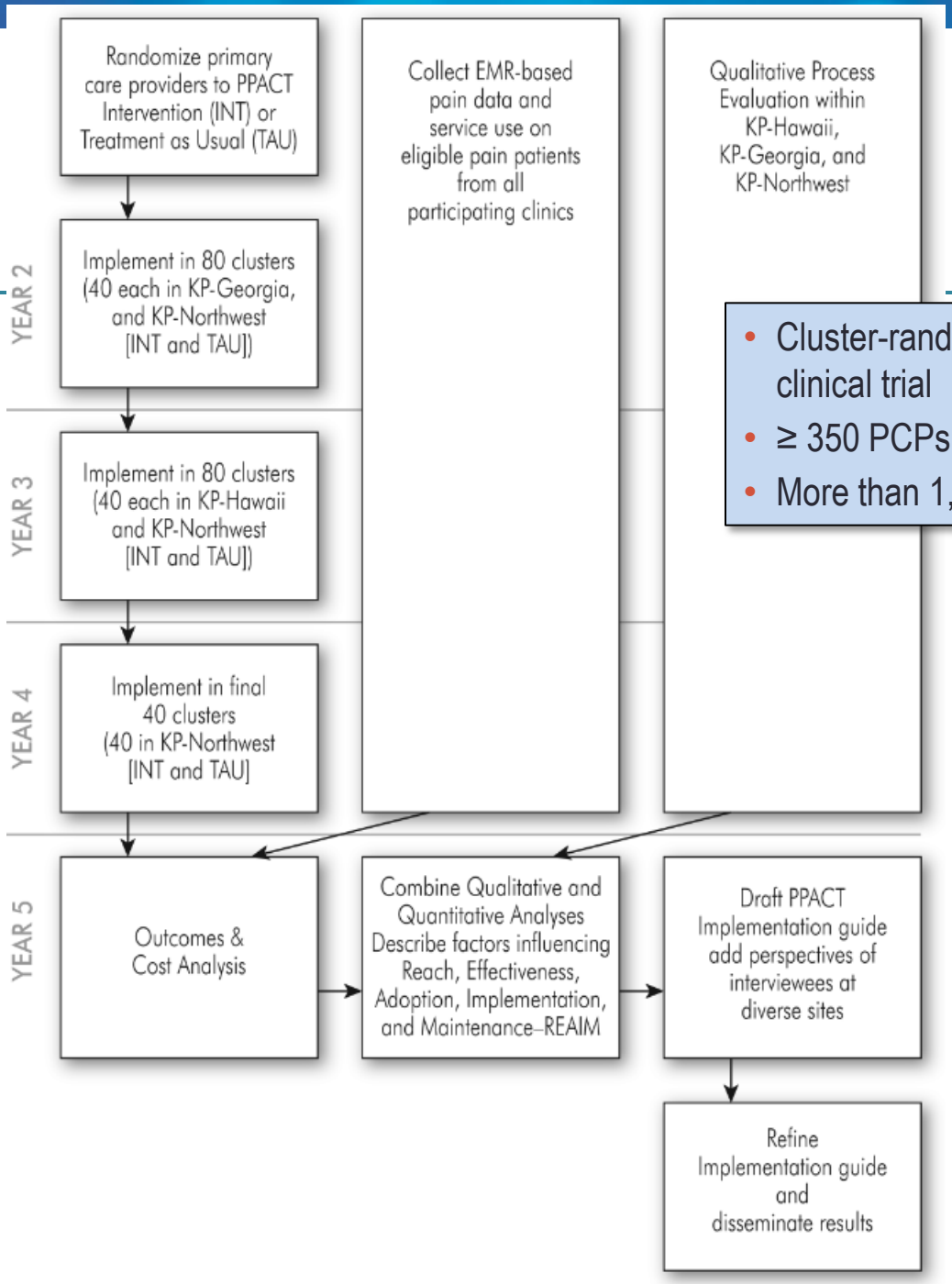
PPACT: Building Upon Regional Actions & Data Capabilities

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
- Involves 1,200–2,000 patients with chronic pain on opioids (600–1,000 receiving study-supported active care)
- Prioritized recruitment based on operationally identified need:
  - MEQ ≥ 120mg
  - Concurrent opioid and benzodiazepine use
  - High utilization of primary care services

PPACT
Pain Program for Active Coping & Training

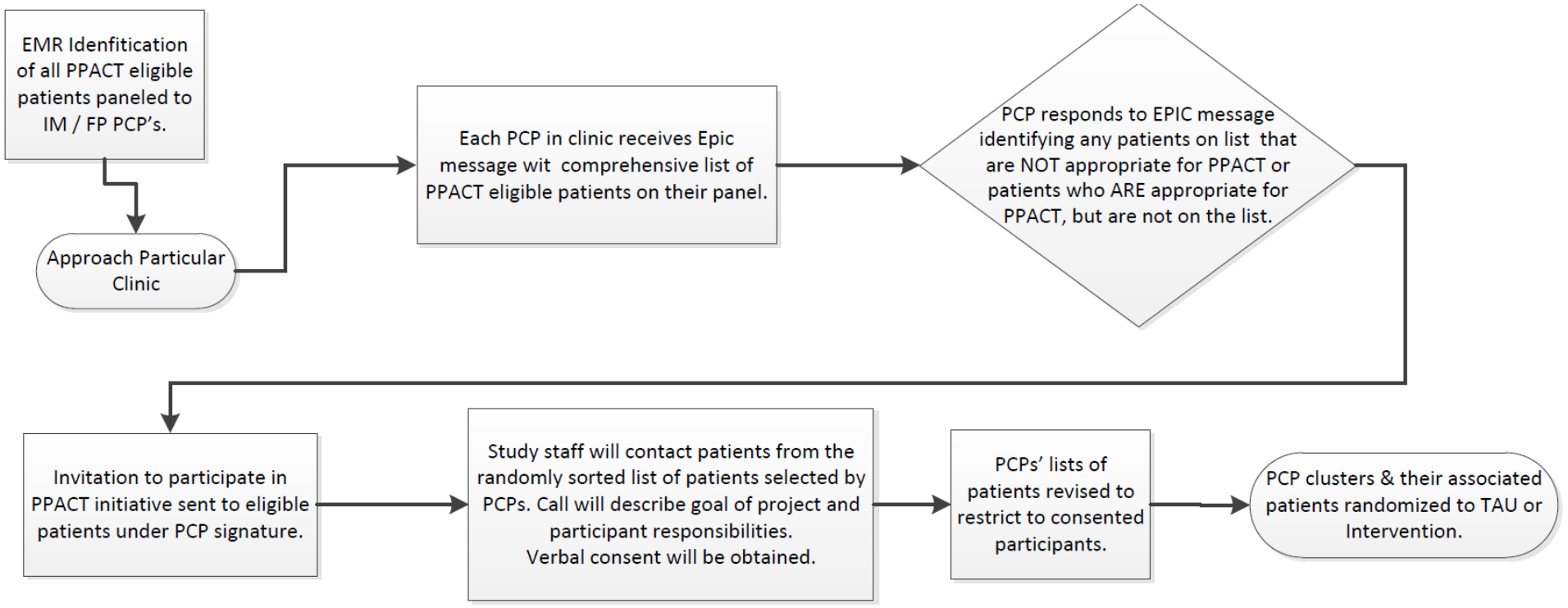
Trial Design



- Cluster-randomized pragmatic clinical trial
- ≥ 350 PCPs will be randomized
- More than 1,000 patients

Kaiser Permanente
Research

PPACT Recruitment & Randomization



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

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)	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

Kaiser Permanente
Research

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

Kaiser Permanente
Research

Current EHR Primary Outcome Data: Analytic Challenges & Interpretative Concerns

- Administration of BPI linked to Opioid Prescription
  - Frequency of PRO administration linked to opioid dose (morphine equivalent level)
  - Potential loss of follow-up data for those tapering off opioids

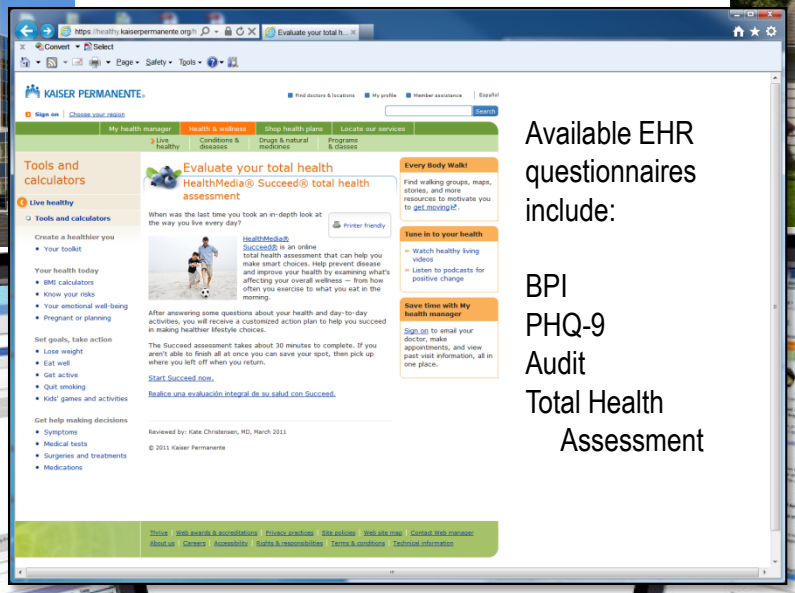
- Timing and Amount of Data Variable
  - Heterogeneity across health care providers
  - Potential for more frequent collection of PRO among patients with higher rates of health care utilization (potential bias by medical complexity or pain severity)

Kaiser Permanente
Research

KP workflow process of PRO email collection

Kaiser Permanente

www.KP.org



Available EHR questionnaires include:

BPI
PHQ-9
Audit
Total Health Assessment

Patient Home

? Ask doctor a question

Personal Digital Devices

EPIC Terminal

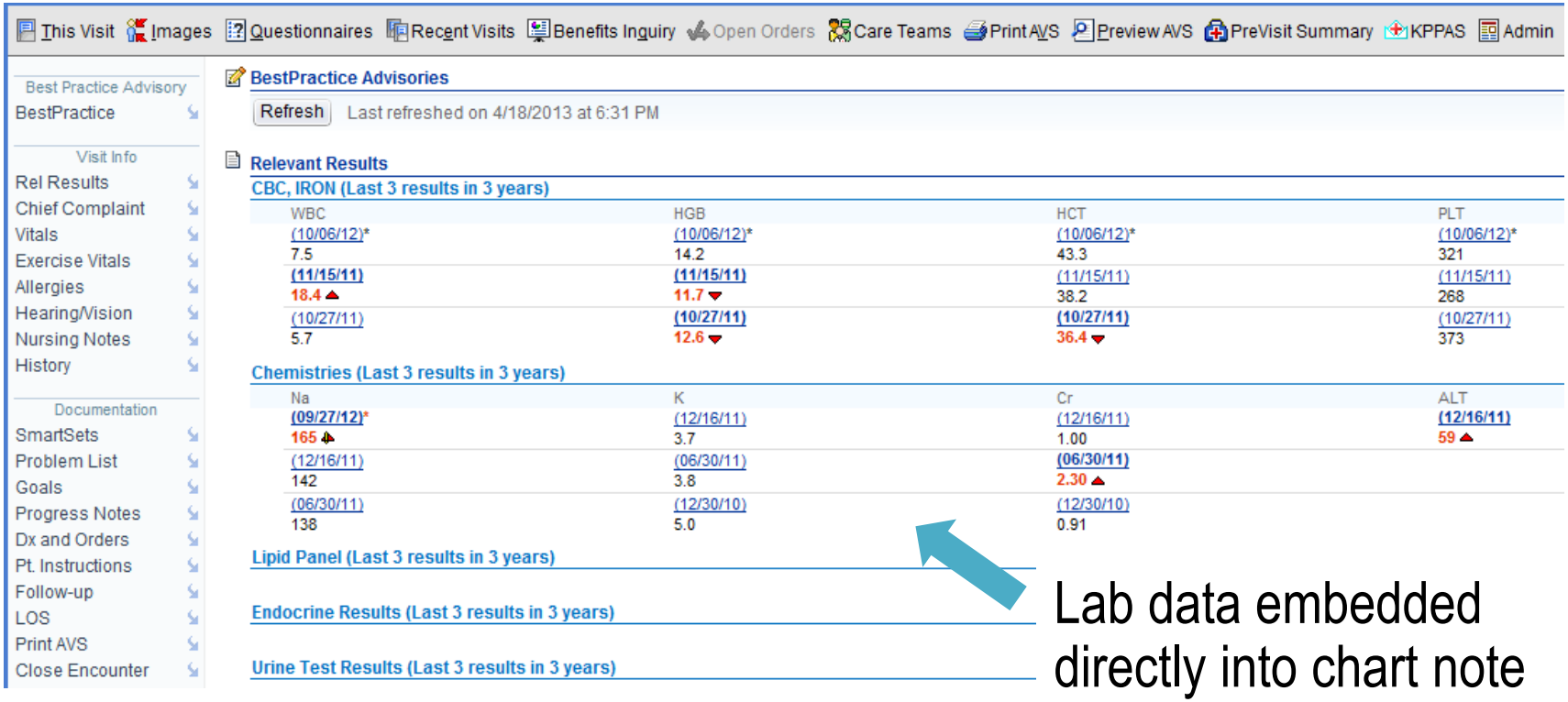
Increased patient health record adoption provides additional opportunities to collect PROs

	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

Why is the Clinical Use of PROs Limited?

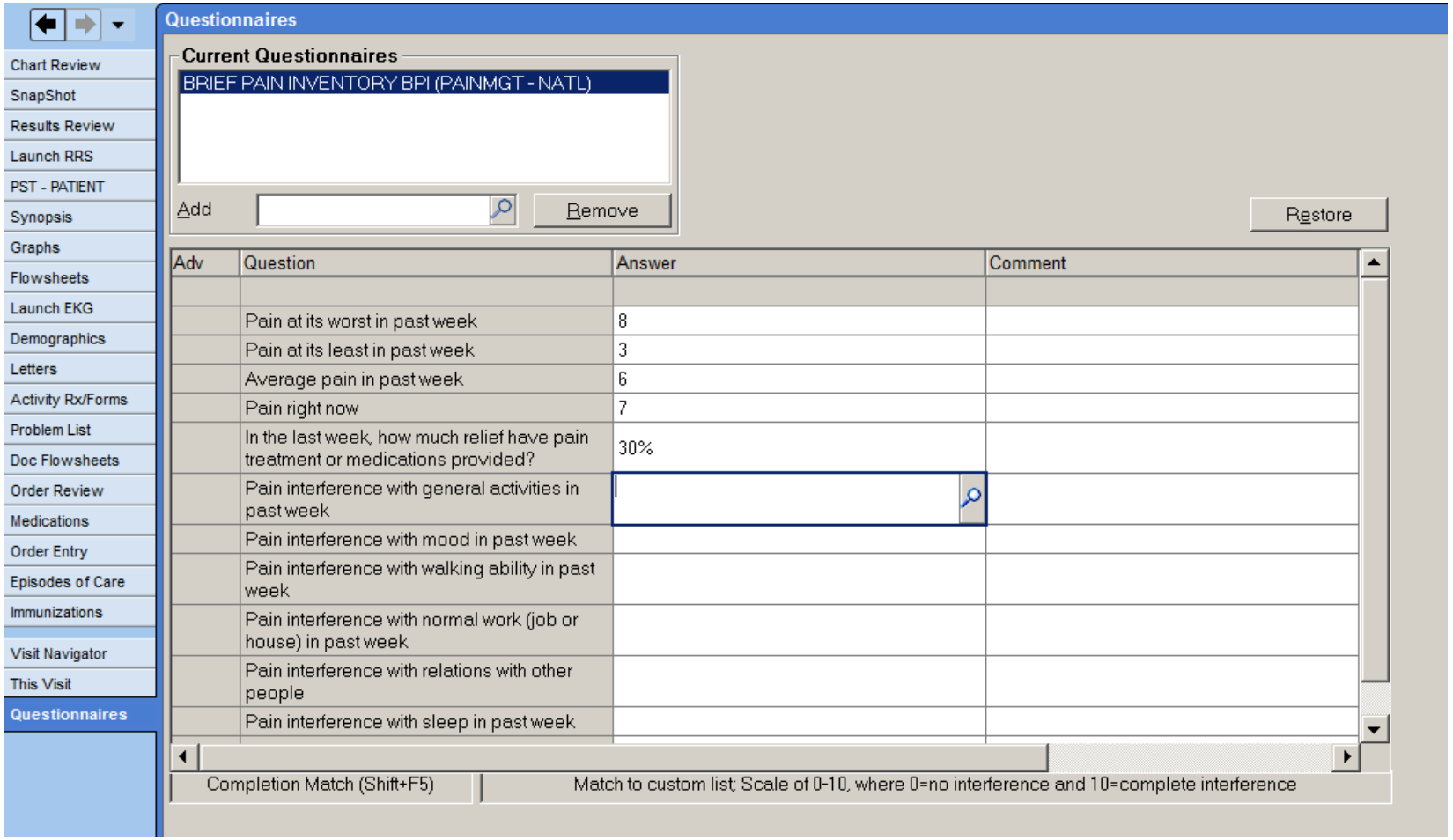
- Adoption largely driven by “stick” (regulation or safety concerns) rather than “carrot” (clinical utility)
- PRO instruments need to fully meet both clinical and evaluation needs
- Administration not hardwired into work flow so that change over time can be tracked (more frequent use as screening measure or single point in time evaluation)
- Available technology often only partially implemented due to health plan or patient resource constraints and compliance/privacy concerns
- Placement in Clinical Record not convenient/ accessible

PRO data entered in separate charting area

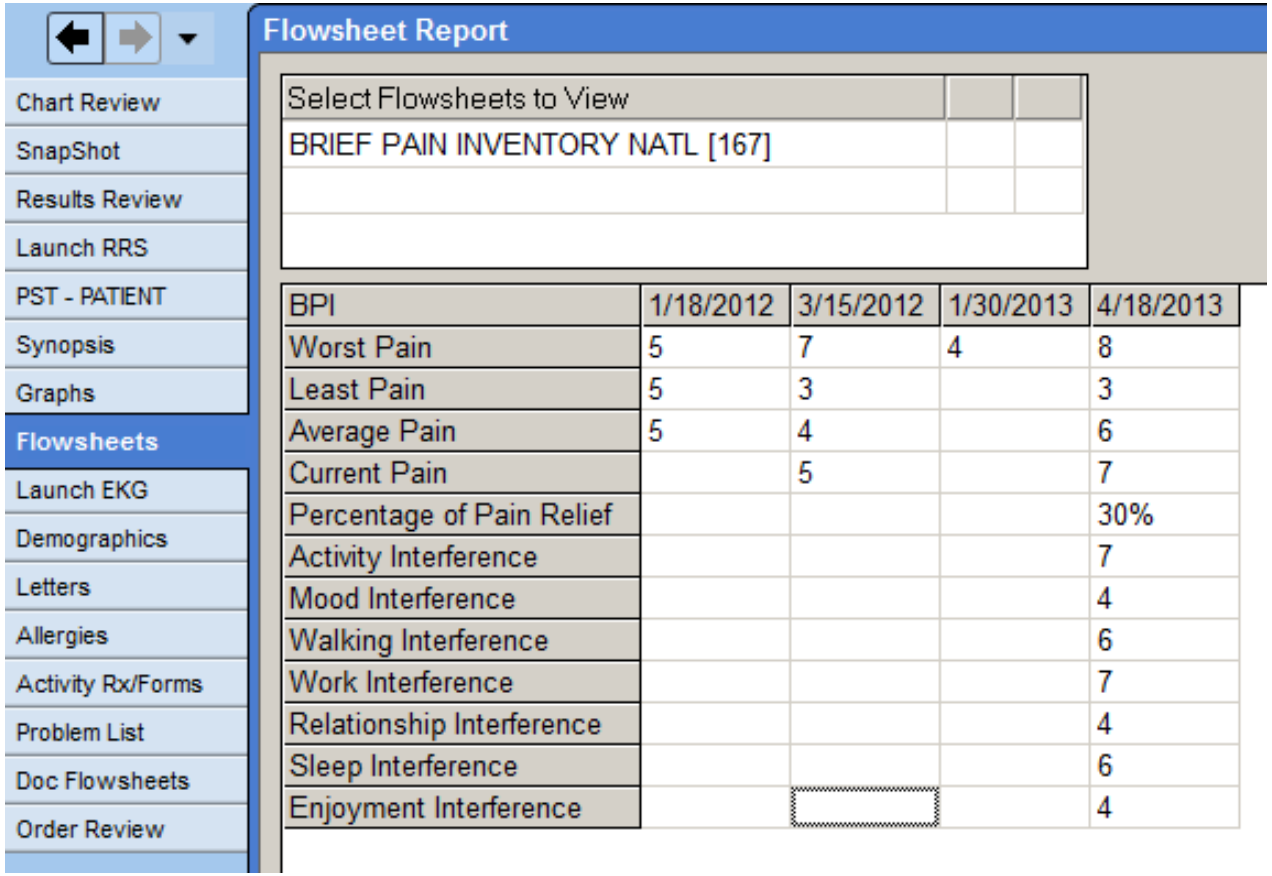


Lab data embedded directly into chart note

- Less than ideal interface and data entry



- Variable collection of PROs



BPI	1/18/2012	3/15/2012	1/30/2013	4/18/2013
Worst Pain	5	7	4	8
Least Pain	5	3		3
Average Pain	5	4		6
Current Pain		5		7
Percentage of Pain Relief				30%
Activity Interference				7
Mood Interference				4
Walking Interference				6
Work Interference				7
Relationship Interference				4
Sleep Interference				6
Enjoyment Interference				4

- Less than ideal display when viewing multiple PROs

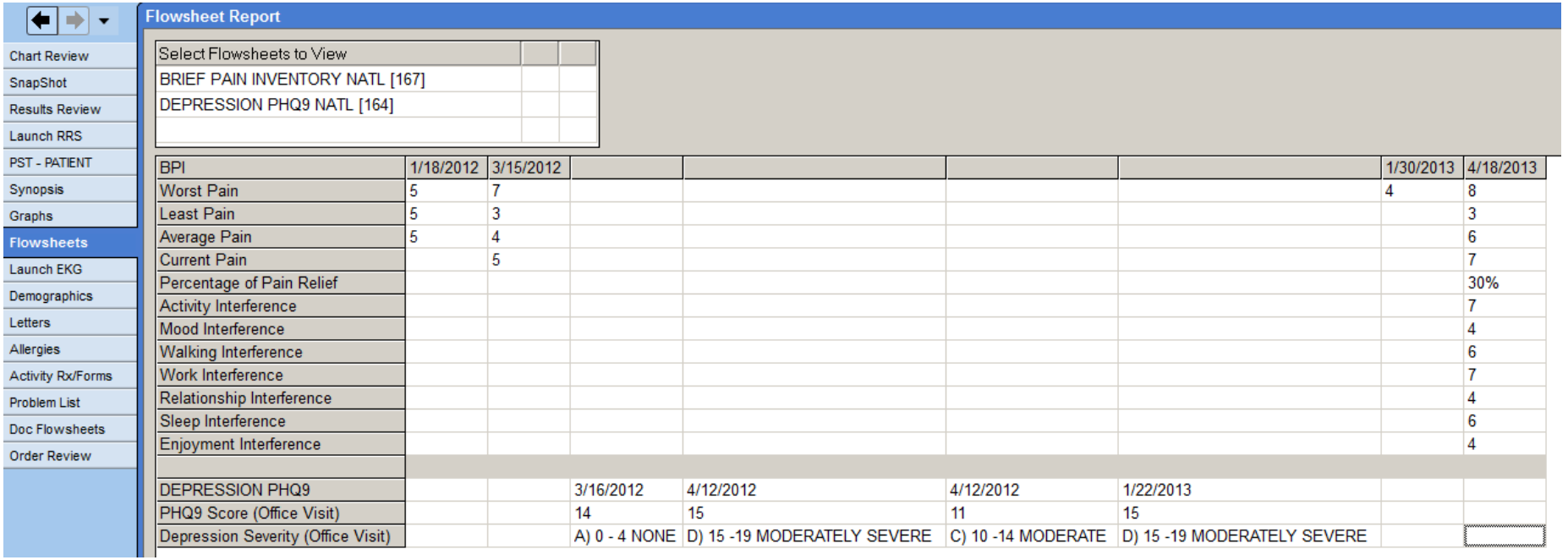
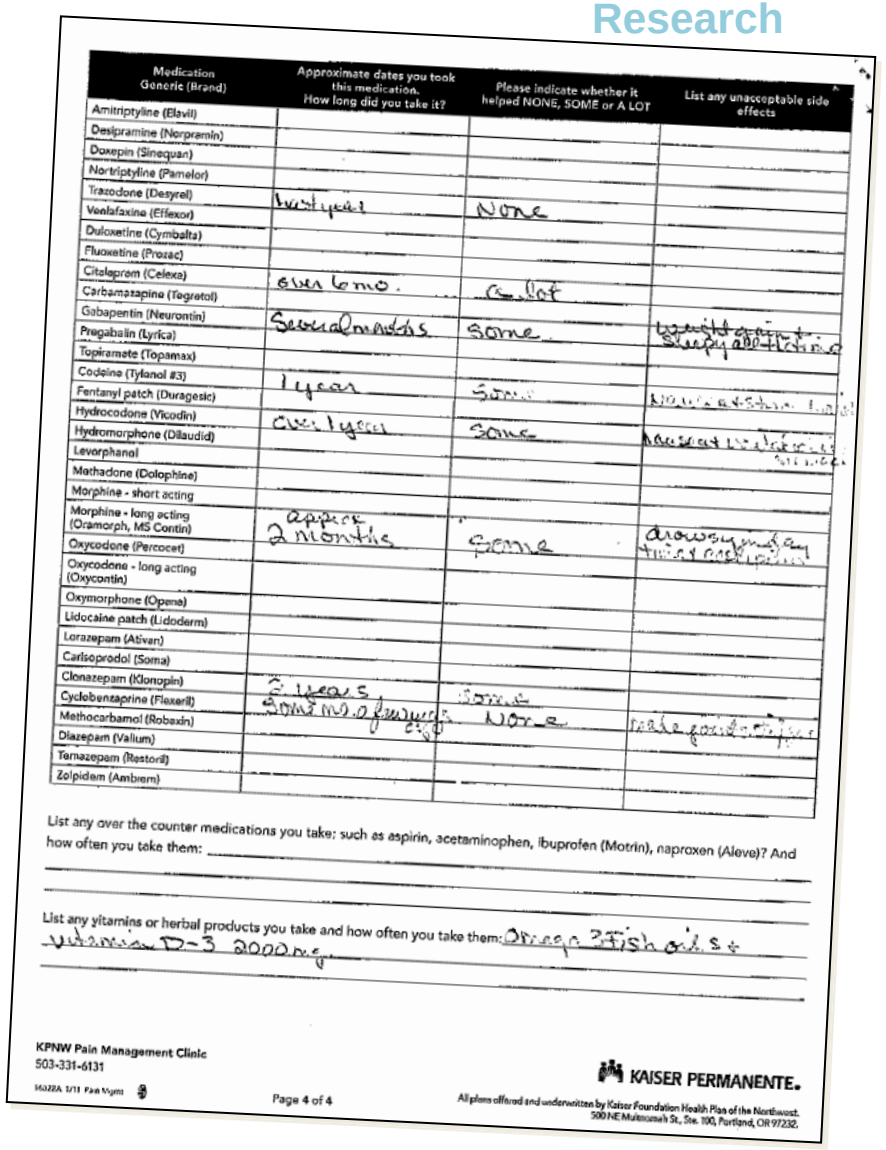


Chart Review
SnapShot
Results Review
Launch RRS
PST - PATIENT
Synopsis
Graphs
Flowsheets
Launch EKG
Demographics
Letters
Allergies
Activity Rx/Forms
Problem List
Doc Flowsheets
Order Review

Flowsheet Report

Select Flowsheets to View
BRIEF PAIN INVENTORY NATL [167]
DEPRESSION PHQ9 NATL [164]

BPI	1/18/2012	3/15/2012					1/30/2013	4/18/2013
Worst Pain	5	7					4	8
Least Pain	5	3						3
Average Pain	5	4						6
Current Pain		5						7
Percentage of Pain Relief								30%
Activity Interference								7
Mood Interference								4
Walking Interference								6
Work Interference								7
Relationship Interference								4
Sleep Interference								6
Enjoyment Interference								4
DEPRESSION PHQ9			3/16/2012	4/12/2012	4/12/2012	1/22/2013		
PHQ9 Score (Office Visit)			14	15	11	15		
Depression Severity (Office Visit)			A) 0 - 4 NONE	D) 15 -19 MODERATELY SEVERE	C) 10 -14 MODERATE	D) 15 -19 MODERATELY SEVERE		



Medication Generic (Brand)	Approximate dates you took this medication. How long did you take it?	Please indicate whether it helped NONE, SOME or A LOT	List any unacceptable side effects
Amitriptyline (Elavil)			
Desipramine (Norpramin)			
Doxepin (Sinequan)			
Nortriptyline (Pamelor)			
Trazodone (Desyrel)	[illegible]	NONE	
Venlafaxine (Effexor)			
Duloxetine (Cymbalta)			
Fluoxetine (Prozac)			
Citalopram (Celexa)	over 6 mo.	a lot	
Carbamazapine (Tegretol)			
Gabapentin (Neurontin)	several months	some	[illegible]
Pregabalin (Lyrica)			
Topiramate (Topamax)			
Codeine (Tylenol #3)			
Fentanyl patch (Duragesic)	1 year	some	
Hydrocodone (Vicodin)	over 1 year	some	
Hydromorphone (Dilaudid)			
Levorphanol			
Methadone (Dolophine)			
Morphine - short acting			
Morphine - long acting (Oramorph, MS Contin)	approx 2 months	some	
Oxycodone (Percocet)			
Oxycodone - long acting (Oxycontin)			
Oxymorphone (Opana)			
Lidocaine patch (Lidoderm)			
Lorazepam (Ativan)			
Carisoprodol (Soma)			
Clonazepam (Klonopin)	2 years	some	
Cyclobenzaprine (Flexeril)	some months	none	
Methocarbamol (Robaxin)			
Diazepam (Valium)			
Temazepam (Restoril)			
Zolpidem (Ambien)			

List any over the counter medications you take: such as aspirin, acetaminophen, Ibuprofen (Motrin), naproxen (Aleve)? And how often you take them:

List any vitamins or herbal products you take and how often you take them: Omega 3 Fish oils + Vitamin D-3 2000mg.

KPNW Pain Management Clinic
503-331-6131

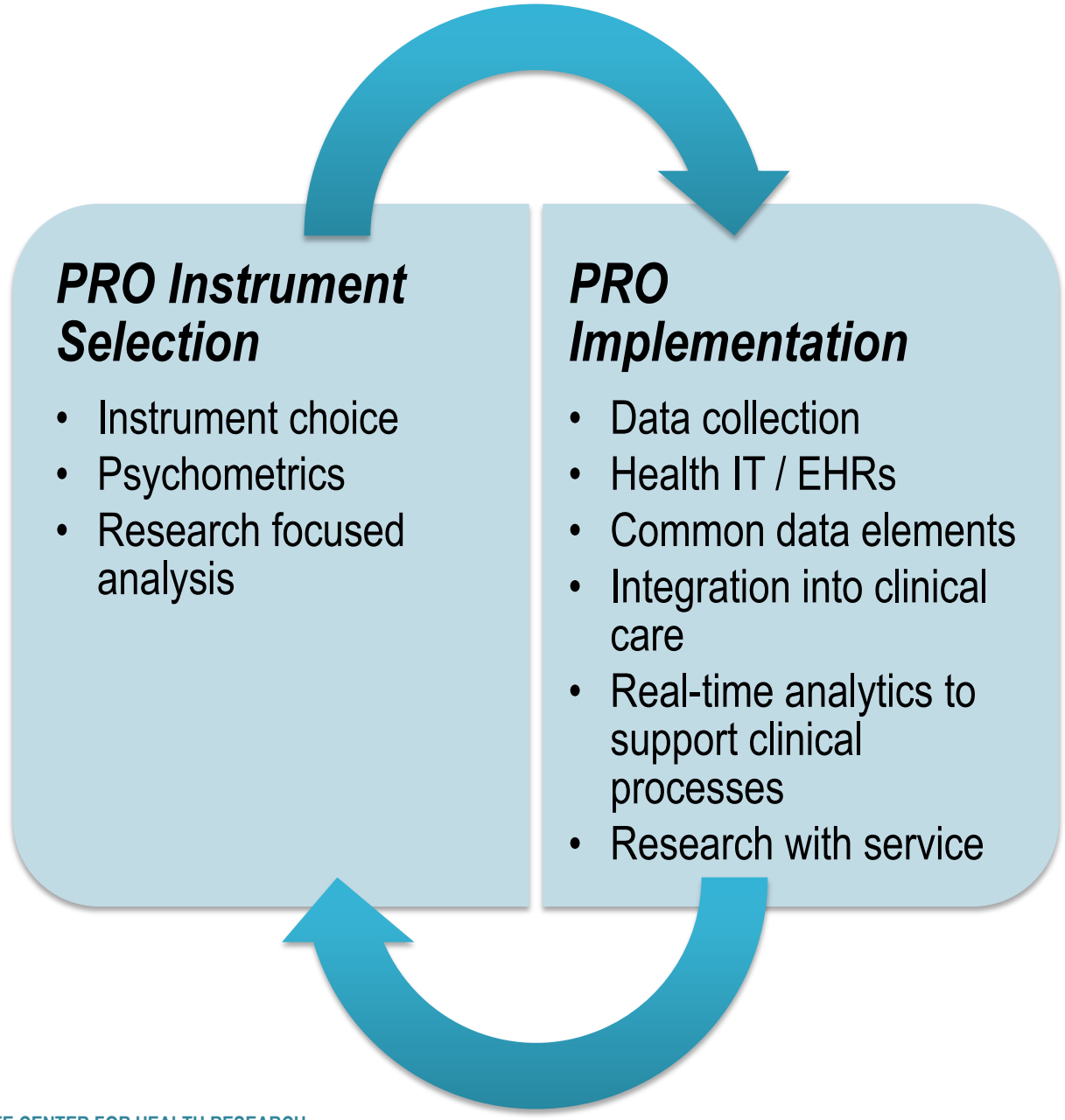
Page 4 of 4

KAISER PERMANENTE.

All plans offered and underwritten by Kaiser Foundation Health Plan of the Northwest. 500 NE Multnomah St., Ste. 100, Portland, OR 97232.

Select each page individually…

Highly variable quality…



Additional EMR-based Opioid Studies Underway…

Opioid Treatment Impact Study

- Funded by the National Institute on Drug Abuse
- Principal Investigator: Benjamin Morasco, PhD; Portland VA Medical Center and Oregon Health & Science University
- Sites: Portland VA & Kaiser Permanente Northwest

- Objectives:
  - to identify clinician- and patient-level factors that predict which patients will receive an increase in opioid dose
  - to evaluate clinical outcomes associated with opioid dose escalation
  - to assess factors associated with changes in pain intensity and pain-related function over time

Opioid Treatment Impact Study

- Participants from 2 clinical sites
  - Kaiser Permanente Northwest (n=333)
  - Portland VA Medical Center (n=167)
- Eligibility
  - musculoskeletal pain
  - receiving a stable dose of chronic opioid therapy for 90 consecutive days
- EMR data
  - used to identify eligible participants
  - checked weekly to identify dose increases of > 25% in morphine equivalents among participants
- Structured interviews at baseline, 6, 12, 18, and 24 months, & after dose increases
  - assess pain intensity, functioning, QOL, depression, anxiety, alcohol and substance use, prescription opioid misuse, sleep, sexual function, common side effects of opioids, overdoses

Study of Opioid Overdose & Poisoning Events

Funded by Purdue Pharma, LLP

Principal Investigators:

Carla A. Green, PhD, MPH & Nancy A. Perrin, PhD
Center for Health Research, Kaiser Permanente Northwest

- Objectives
  - To determine the best approaches for identifying opioid overdose and poisoning events (OOP events) using EMR data
  - To assess the effects of Oxycontin® reformulated with abuse deterrent properties on OOP events
  - To understand the circumstances surrounding OOP events, and any changes in circumstances following the introduction of the new formulation

Examines:

- The usefulness of different ICD-9 and ICD-10 codes, alone or in combination, for identifying OOP events
  - validated by chart audits
- Changes in rates of OOP events in the Kaiser Permanente Health System (KP Northwest & KP Northern California) using EMR-identified OOP events
  - Prior to and following the 2010 introduction of the tamper-resistant Oxycontin® formulation
    - Comparing different groups of opioids &
    - Evaluating morphine equivalents
- Changes in the circumstances surrounding OOP events
  - Using in-depth interviews with individuals and families of deceased individuals who experienced events
  - Using chart audits to identify route of opioid administration & how opioids were obtained

Summary

- EMR data improvement over claims data for clinical research but additional quality assurance necessary to ensure validity and usability
- Operational response to opioid-related efficacy and safety concerns can expand data available to study issues more broadly (e.g., pain-related PROs and PST elements)
- Clinical uptake of PRO's increasing but current data gaps
- Studies of opioid-related practice patterns must be augmented by ancillary data collection

Thanks to the following contributors:

- Lindsay Kindler, PhD, RN, CNS
- LouAnn Thorsness, RPH
- David H Smith, PhD
- Alan Bauck, BS
- Rick Deyo, MD
- Reesa Laws, MS
- Carla Green, PhD MPH
- Nancy Perrin, PhD
- Joan Holup, MS