



# Grand Rounds EHR Workshop Series - Advances at the Intersection of Digital Health, Electronic Health Records and Pragmatic Clinical Trials

## Experiences from the Collaboratory PCTs

**Guest Moderator:**

**Wendy Weber, ND, PhD, MPH**

National Center for Complementary and Integrative Health, NIH

**Panel:**

**Jeffrey (Jerry) G. Jarvik, MD, MPH**

LIRE Demonstration Project

**Lynn DeBar, PhD, MPH**

PPACT Demonstration Project

**Doug Zatzick, MD**

TSOS Demonstration Project

**Vince Mor, PhD**

PROVEN Demonstration Project

# Experiences from the Collaboratory PCTs: Lumbar Imaging with Reporting of Epidemiology (LIRE)

Jeffrey (Jerry) Jarvik, MD MPH

Departments of Radiology, Neurological Surgery, Health Services  
Comparative Effectiveness, Cost and Outcomes Research Center

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NIH Health Systems Collaboratory Grand Rounds 5/29/2020

# Acknowledgements

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## Disclosures (Jarvik)

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# Talk Outline

- Brief review of study goals/design
- Challenges
  - Intervention implementation
  - Outcome measurement from EHR



# Disc Degeneration in Asx



# Primary Hypothesis

- For patients referred from primary care, inserting prevalence benchmark data in lumbar spine imaging reports will reduce overall spine-related healthcare utilization as measured by spine-related relative value units (RVUs)



# Intervention Text

The following findings are so common in normal, pain-free volunteers, that while we report their presence, they must be interpreted with caution and in the context of the clinical situation. Among people between the age of 40 and 60 years, who do not have back pain, a plain film x-ray will find that about:

- 8 in 10 have disk degeneration
- 6 in 10 have disk height loss

Note that even 3 in 10 means that the finding is quite common in people without back pain.



# Intervention Implementation Challenges

- Technical
- Cultural





# Implementation Challenges- Technical: Different Deployment by Health Systems

- Radiology Information System (RIS) (during dictation) vs. EHR (after dictation)
- Different EHRs required different modes of insertion (dynamic pop-ups vs. static)
  - Pop-ups had potential to interfere with temporal randomization
- “Upgrade” of RIS broke implementation



# Technical Challenge Solutions

- Pilot at all health care systems working closely with site programmers who best know the systems
- Monitor implementation at regular intervals to check for breakage



# Implementation Challenges- Cultural

- Some of radiologists at one health system against intervention
- Some radiologists wanted to be able to remove it when they thought that it wasn't clinically relevant



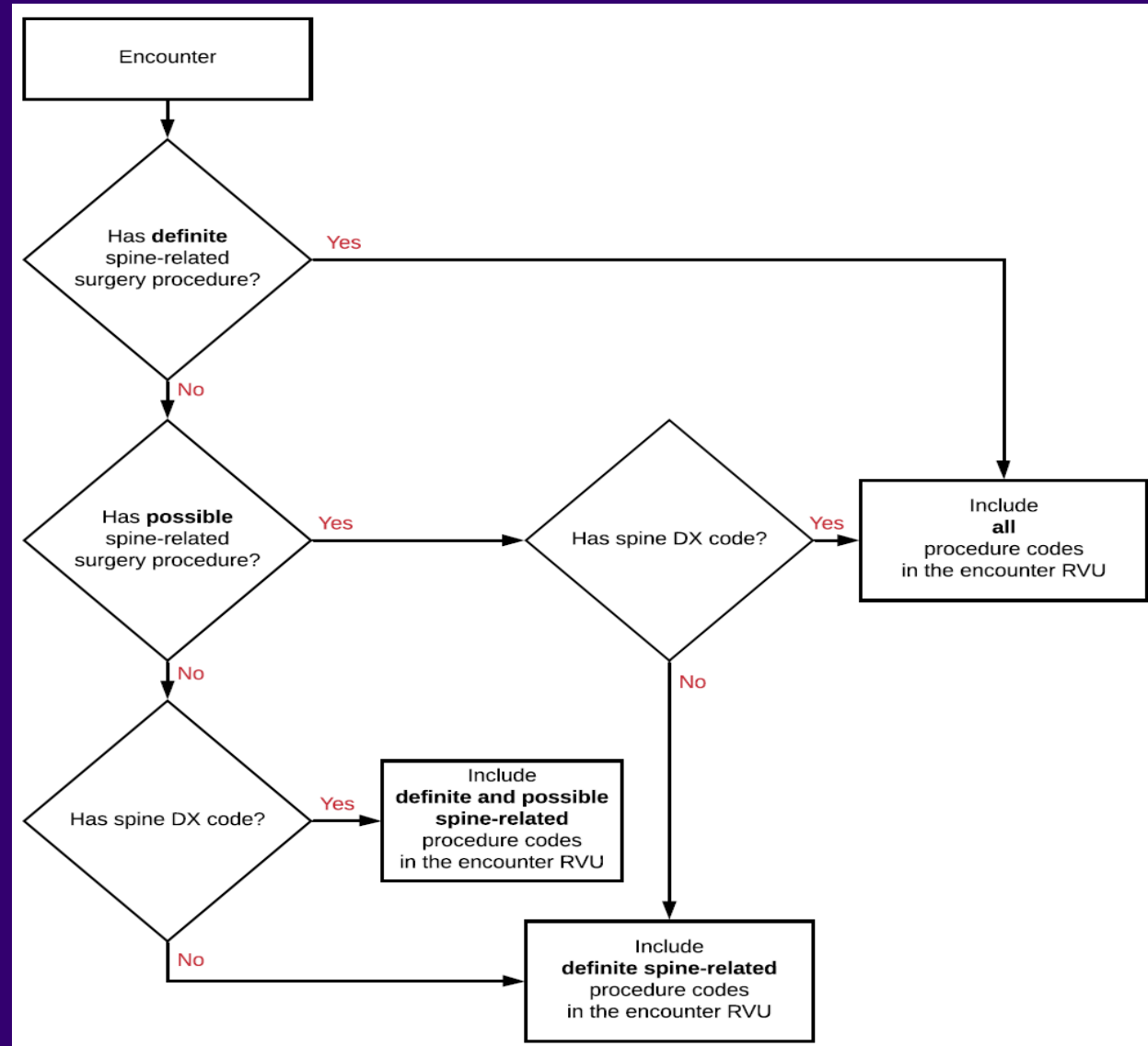
# Cultural Implementation Solutions

- Worked closely with health system leadership to gain their buy-in
- Site PI with site leadership able to convince site docs to cooperate



# Outcome Measurement Challenge: Spine-related RVU

- Diagnosis codes
  - ICD-9
  - ICD-10
- Procedure codes
  - CPT
  - ICD 9/10
- Need to account for annual changes in codes



# Outcome Measurement

## Challenge: Decoding the Codes

- People assigning the codes at health systems make decisions/judgements
- Practices vary regarding what is coded how
  - Specificity may vary- # of levels may not be included
  - Approach (anterior vs. posterior vs. combined) may not be specified
  - Sometimes used CPT vs. ICD-PC vs both



# Some Key Lessons Learned

- Keep intervention as simple as possible
- Keep outcomes as simple as possible
- Minimize burden on system partners
- Understanding complexities of EHR coding is iterative process that takes time



# Key People

- Katie James, PA, MPH, Director
- Brian Bresnahan, PhD- Health Econ
- Bryan Comstock, MS- Biostats
- Janna Friedly, MD- Rehab
- Laurie Gold, PhD- Radiology
- Patrick Heagerty, PhD- Biostats
- Larry Kessler, PhD- HSR
- Danielle Lavalley, Pharm D, PhD
- Eric Meier, MS- Biostats
- Nancy Organ, BA- Statistics
- Kari Stephens, PhD- Informatics
- Judy Turner, PhD- Psychol/Psych
- Sean Rundell, DPT, PhD
- Zachary Marcum, PharmD, PhD
- Katherine Tan, PhD Candidate, Biostats
- Rick Deyo, MD, MPH- OHSU
- Dan Cherkin, PhD- KPWA
- Karen Sherman, PhD- KPWA
- Heidi Berthoud, KPWA
- Brent Griffith, MD- HFHS
- Dave Nerenz, PhD- HFHS
- Dave Kallmes, MD- Mayo
- Patrick Luetmer, MD- Mayo
- Andy Avins, MD, MPH- KPNC





# Collecting and Sharing Patient Reported Outcomes (PROs) in Pragmatic Trials: Lessons learned from the PPACT trial

**Lynn DeBar, PhD, MPH**

Kaiser Permanente Washington Health Research Institute

Seattle, Washington

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

## PPACT Overview

**AIM:** Integrate interdisciplinary services into primary care to help patients adopt self-management skills to:

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

*Focus on feasibility and sustainability*

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

**ELIGIBILITY:** Chronic pain, long-term opioid tx (prioritizing  $\geq 120$  MED, benzodiazepine co-use, high utilizers [ $\geq 12$  visits in 3 months])

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

**OUTCOMES:** Pain (3-item PEG), opioid MED, pain-related health services, and cost

# 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)

**PST - PATIENT**

Print Preview

DM	CVD	CHF	HTN
Y			
CKD	Asth		Gap
	Y		8

Consider Dx refrest: 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.  
X2 205 01 ACUTE MYELOID LEUKEMIA IN REMISSION Source: KPCH 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 Pnuemo: 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)

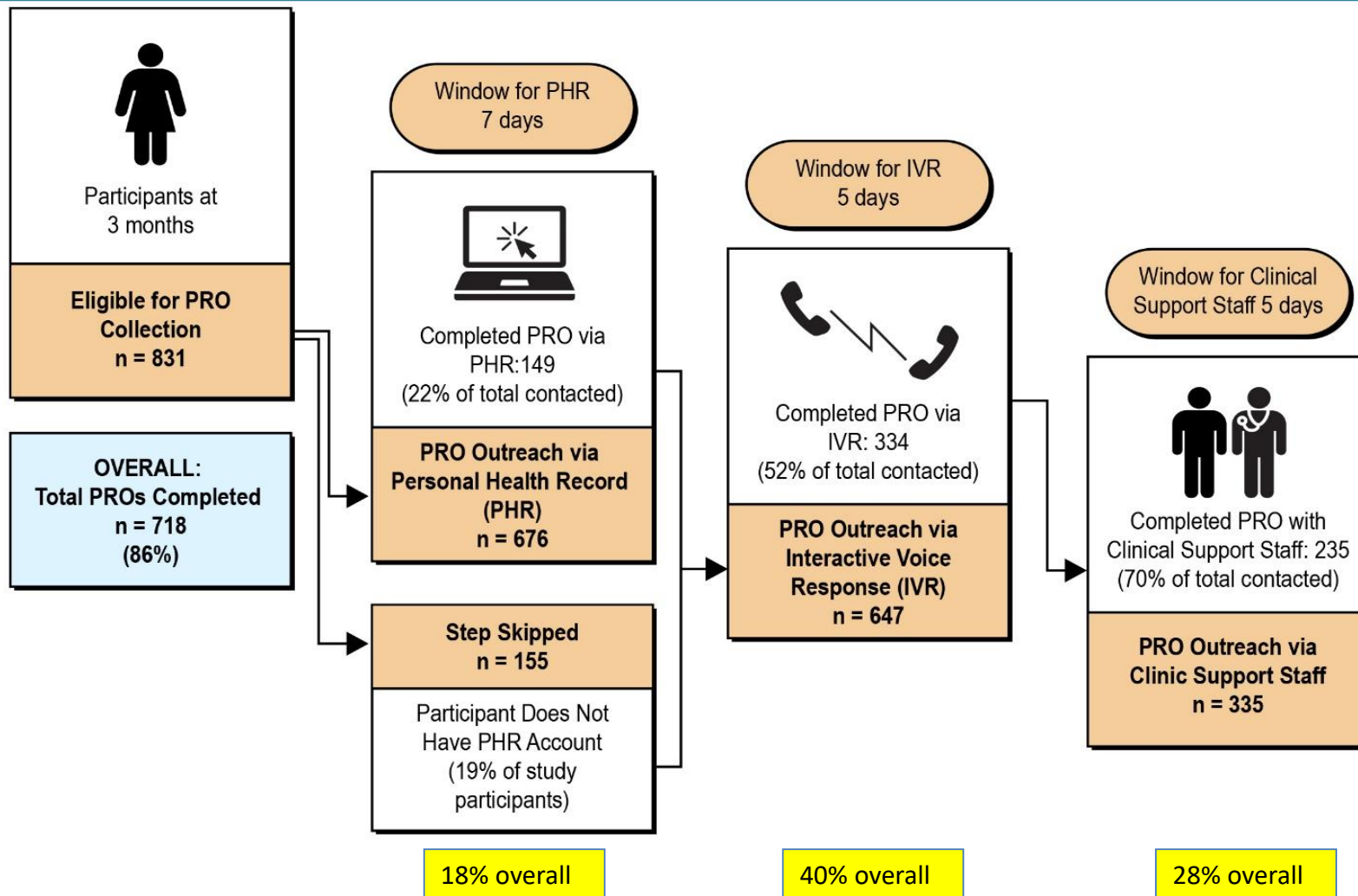
** LDL	224	11/24/10
HDL	56.0	11/24/10
TRI	212	5/6/08
CHOL	297	11/24/10
** A1C	7.1	4/5/11
FBG	71	4/23/10
ALT	28	4/23/10
** CRE	0.8	4/5/11
BUN	19	4/5/11
** GFR	98.0	4/5/11
** ALB/CRE	24	10/8/10
** PRO/CRE		
HGB	13.6	9/29/10
HCT	41.5	9/29/10
NA	139.0	4/5/11
K	4.1	4/5/11
TSH	2.94	8/29/11
** PSA		

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

Opioid Therapy Plan (OTP) Operational Criteria	BASIC GREEN	COMPLEX YELLOW	COMPLEX RED
<b>PATIENT CRITERIA</b>			
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
<b>PCP REQUIREMENTS</b>			
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)	Semi-annually	Quarterly	Quarterly
<b>[Recommended to be administered at every office visit]</b>			
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

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

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



# There is no obvious best way to communicate with PCPs about individual patients within the EMR

- EMR-based PPACT pre/post summaries not as effective as hoped
- PCP workload/workflow attentional constraints
- Emailing/messaging providers about specific actionable concerns works well, but does not provide the “big picture” required for co-management

*“Unless we were specifically alerted to look in this place... there’s way too much noise in the chart”*

– PCP, about reviewing a PPACT report



# Enhancing PRO use in routine clinical care: Lessons learned

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- “Pulling” PROs from EHR (data availability / quality)
  - Most PRO adoption “stick” rather than “carrot” driven
  - EHR IT enhancements (pop mgmt) critical for routine PRO collection
  - Frequency and amount of “routinely” collected PRO data often confounded with patient’s clinical severity
- “Pushing” PROs into EHR (enhancing clinical utility)
  - Multimodality support for enhanced collection may be needed
  - PRO EHR display may limit clinical utility (esp for complex conditions)
  - HCS technology often lags, untethered systems may be most feasible

**SHOULD WE UNCOUPLE [some types of] PRO DATA COLLECTION  
FROM ROUTINE CLINICAL CARE?**



# Using EHR Innovation to Enhance Pragmatic Trial Follow-up Approaches for Trauma Care Systems

Douglas Zatzick, MD

Principal Investigator

Trauma Survivors Outcomes & Support (TSOS) Study

Professor Department of Psychiatry

Harborview Level I Trauma Center

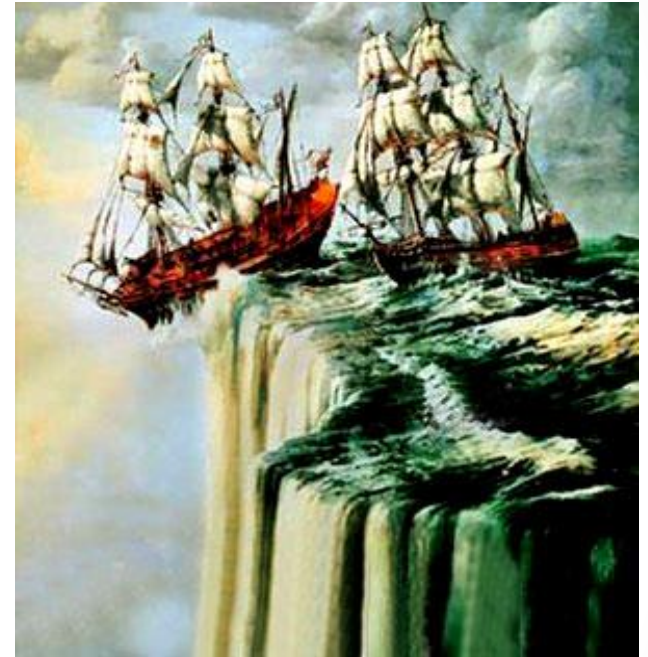
University of Washington School of Medicine Seattle

Funded by Grant UH3 MH106338



# Trauma Center Care Transitions

- Patients “sail off of a flat earth” after trauma center care
- Transition across multiple service delivery sectors
- Paucity of “routine” follow-up





# From NIH Collaboratory ePCT Training: Choosing Endpoints in PCTS (Richesson & Curtis 2/18)

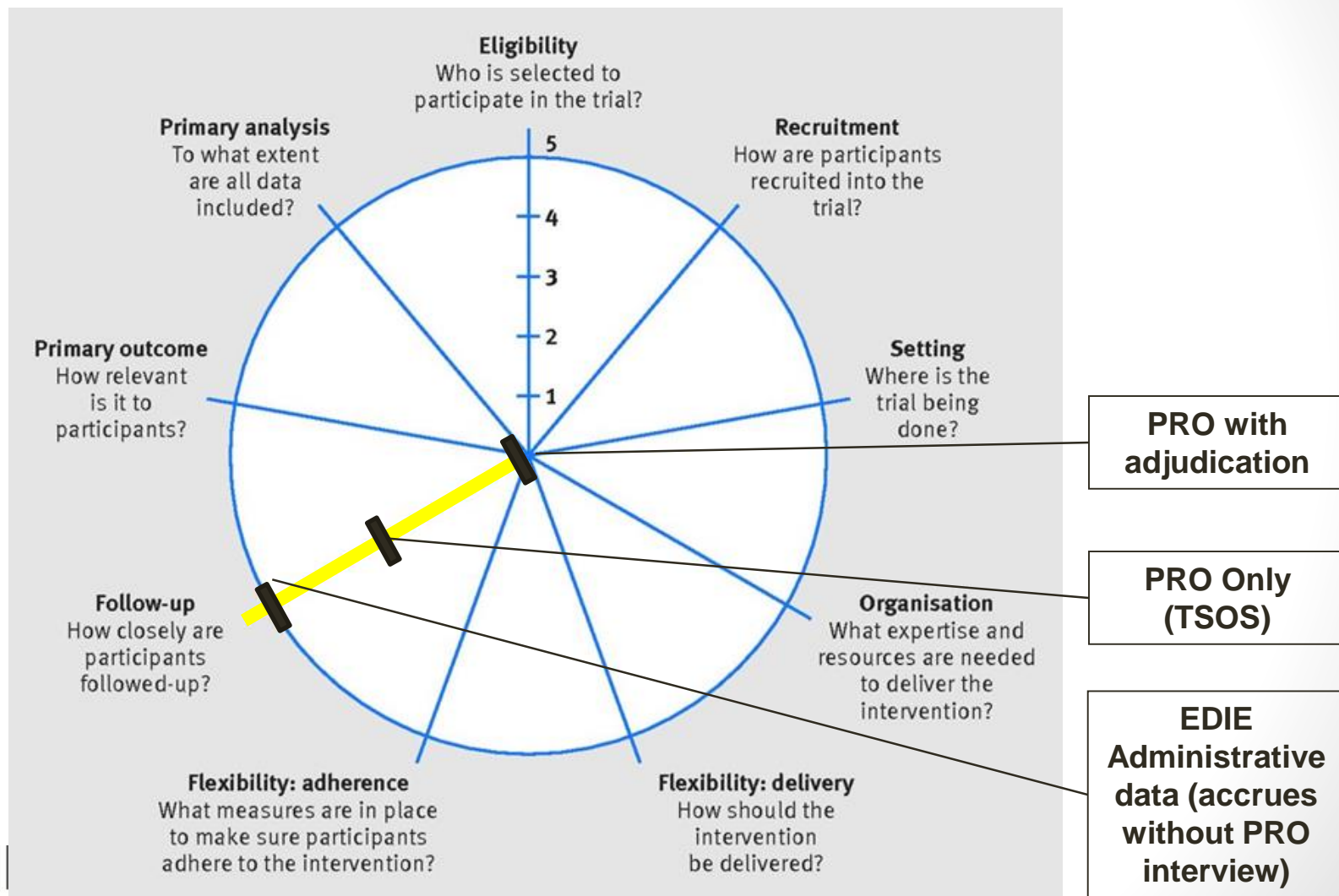
- More pragmatic endpoints...
  - Matter to providers and patients
  - Are captured reliably as part of routine clinical care
  - Do not require central adjudication
  - Are shorter-term in nature

# From NIH Collaboratory ePCT Training: Choosing Endpoints in PCTS (Richesson & Curtis 2/18)

- More pragmatic endpoints...
  - Matter to providers and patients
  - Are captured reliably as part of routine clinical care
  - Do not require central adjudication
  - Are shorter-term in nature

Choosing an endpoint that is not captured reliably as part of routine clinical care or impedes the clinical workflow is not pragmatic!

# PRECIS-2 & Injury Follow-up Methods

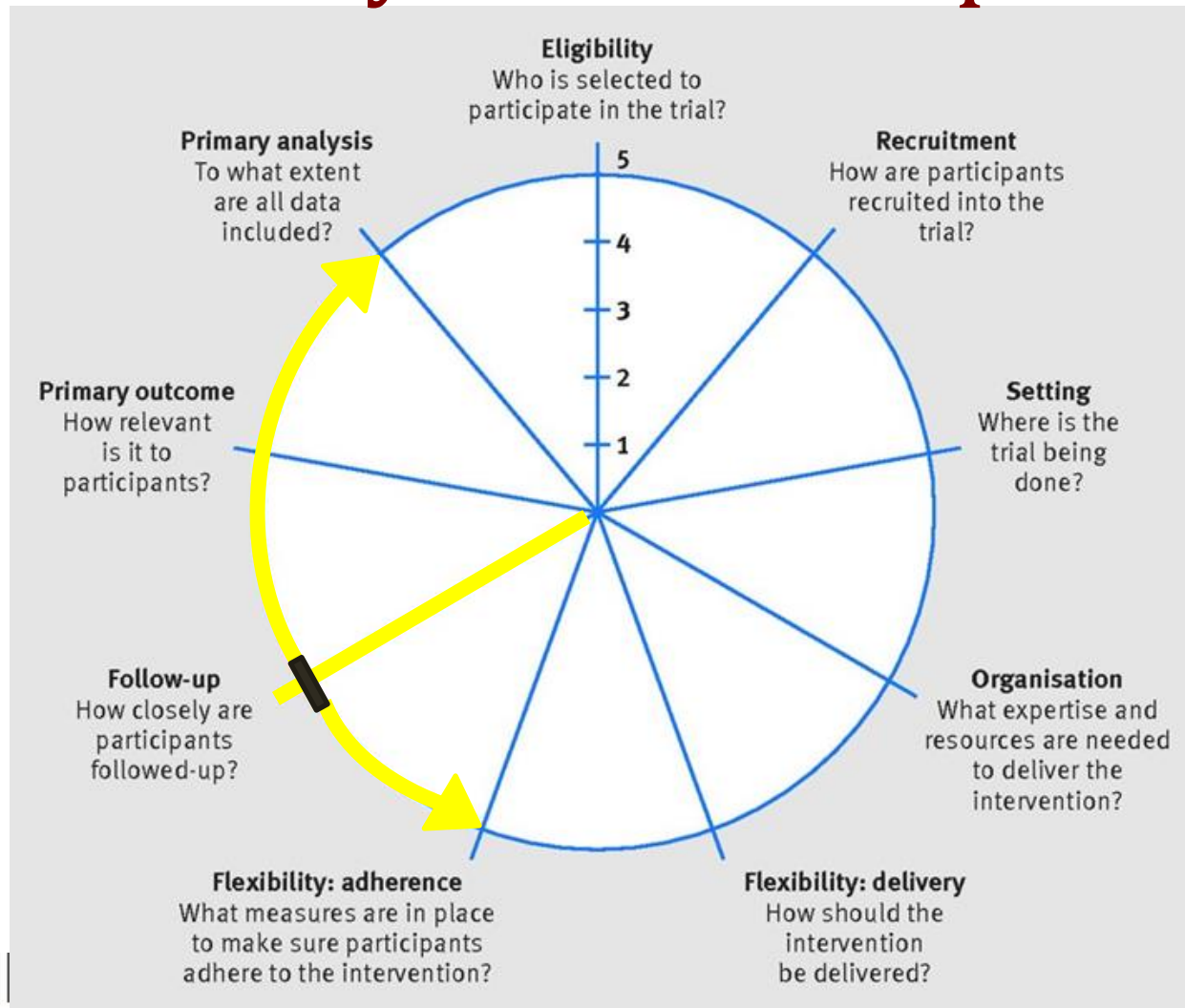




# EHR Innovation - Population Level Administrative Data for Acute Care Follow-up: Emergency Department Information Exchanges (EDIE)

- Washington & 21 other states
- Population level ED data
- Accrues on Intent-to-treat sample
- No additional clinical follow-up required
- EDIE technology innovation ongoing
  - Care plans
  - 24/7 Alerts

# Extending EHR Pragmatic Innovation Beyond Follow-up



# Implementing PROVEN

PRagmatic Trial of Video Education in Nursing Homes

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Vincent Mor, PhD

Angelo Volandes, MD, MPH

UH3AG049619

Grand Rounds: Advances at the Intersection of Digital Health, Electronic Health Records and Pragmatic Clinical Trials: Experiences from the Collaboratory PCTs

Friday, May 29, 2020 — 1-2 p.m. Eastern Time



**BROWN**  
School of Public Health



Institute for  
Aging Research  
Hebrew SeniorLife



# PROVEN: Objective

- To conduct a pragmatic cluster RCT of an Advance Care Planning video intervention in NH patients with advanced comorbid conditions in two NH healthcare systems

# Background: Nursing Homes

- NHs are complex health care systems
  - 3 million patients admitted annually
  - Rapidly growing % post-acute care
- Patients medically complex with advanced comorbid illness
- NHs charged with guiding patient decisions by default



# Background: ACP

- Advance care planning (ACP)
  - *Process* of communication
  - Align care with preferences
  - Leads to advance directives (e.g., DNR, DNH)
- Better ACP associated with improved outcomes
- ACP suboptimal in NHs
  - Not standardized
  - Low advance directive completion rates
  - Not reimbursed
  - Regional and racial/ethnic disparities

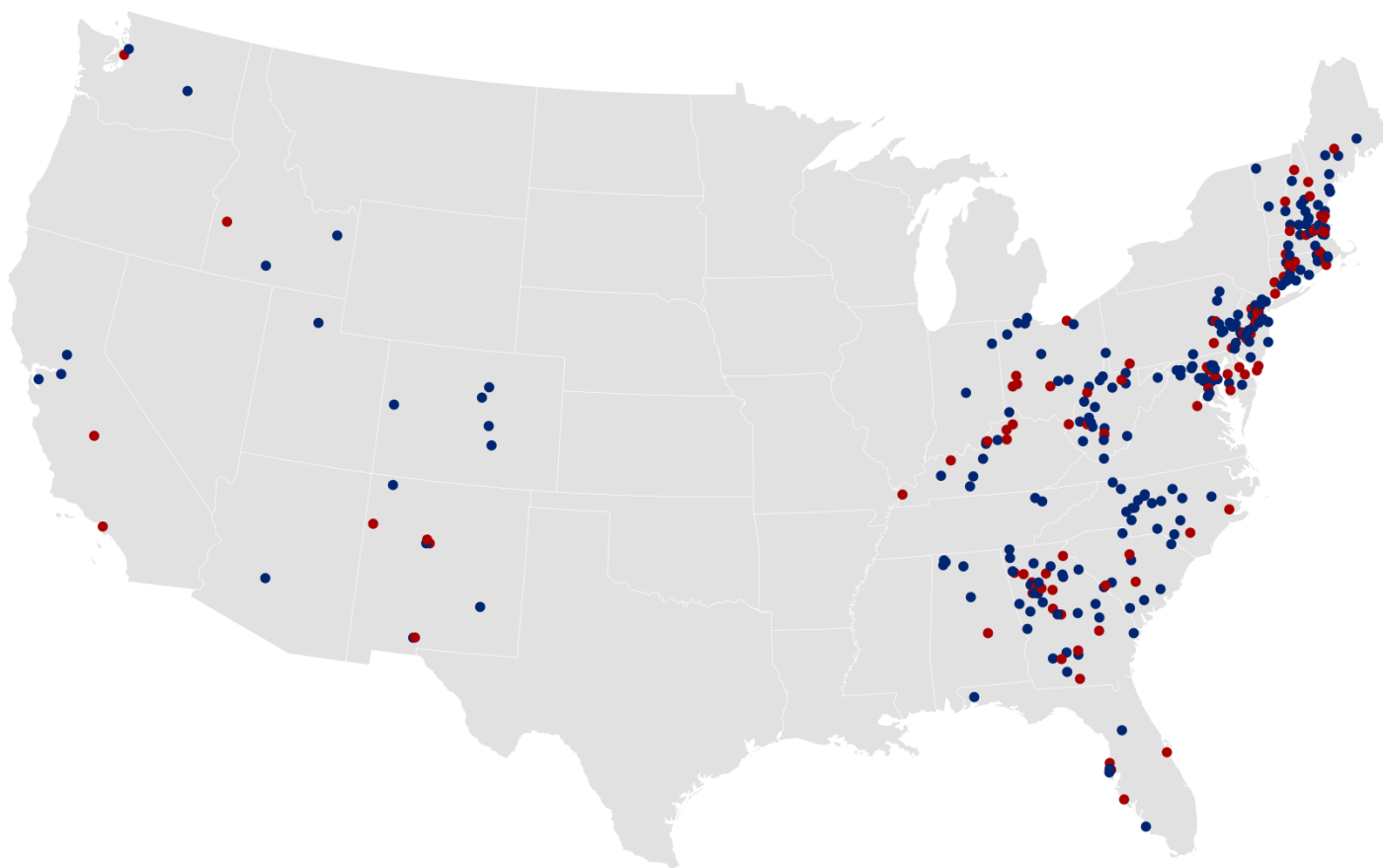
# PROVEN: Intervention NHs

- 18 month intervention period
- Suite of 5 ACP videos
  - Goals of Care, Advanced Dementia, Hospitalization, Hospice, ACP for Healthy Patients
- Offered facility-wide
  - All new admits, care-planning meetings for long-stay, readmission
- Flexible (who, how, which video)
- Tablet devices, internet via URL and password
- Training: corporate level, webinars, toolkit

# PROVEN: Control NHs

- Usual ACP practices
- Recognize programs may be going on in background (i.e., *INTERACT*)

# Distribution of PROVEN NHs



PROVEN centers  
(as of 2/16/2017)

- Intervention
- Control

# PROVEN: Primary Outcome

- **Primary Outcome Target Cohort:** Number of hospitalizations/person-days alive among patients  $\geq 65$  years old who are in a NH  $\geq 90$  days (“long-stay”) and who have EITHER advanced dementia or advanced congestive heart failure/chronic obstructive lung disease

# Assuring Completeness of Primary Outcome Data

- Reasons for Incomplete Data
  - Nursing home residents are hospitalized and may not return to originating NHs
  - NHs may not know if their hospitalized patients die
  - NHs may transfer patients to another facility
- Solution: Match NH EMR to Medicare Claims using Virtual Research Data Center

# Data infrastructure in PROVEN

These have been essential to implementing and monitoring PROVEN:

1. Integrated a Video Status Report (VSR) into the healthcare systems' EMRs to document delivery of the ACP Video Program
2. Data transfers between healthcare systems and Brown (Minimum Data Set, VSR, Physician orders)
3. Generated monthly compliance reports for the healthcare systems
4. Uploading data to the CMS Virtual Research Data Center (VRDC) to create finder files to match all Medicare claims, particularly hospitalization
5. Used CMS "Workbench" for immediate access to claims

# Implications of Using CMS VRDC

- Medicare hospital claims available within one month; ED and Obs day claims w/in 2 months
- Last day of study followup 5/30/19; last EMR data update 6/30/19; Final analyses began 10/15/19
- BUT
- 25% - 30% of patients are Medicare Advantage
- MA encounter data 4 years out of date; Hospital claims for MA 2 years late



# Summary

- Health services and mortality outcomes for Medicare Beneficiaries readily accessible
- Rapidity of outcome ascertainment in large pragmatic trials is a “game changer”
- Cost and technical challenges complicate things
- BUT, running large cluster RCTs relying on EMR for case identification allows uploading of data for case matching on CMS with no losses