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

Patrick Heagerty, PhD
Professor, Department of Biostatistics
Director, Center for Biomedical Statistics

NIH Health Systems Collaboratory Grand Rounds 5/29/2020
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Disclosures (Jarvik)

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- **Springer Publishing:** Royalties as a co-editor for *Evidence Based Neuroimaging Diagnosis and Treatment*
- **GE-AUR Radiology Research Academic Fellowship:** Travel reimbursement to academic advisory board meeting
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)
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:

- 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 Lavallee, 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

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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 ≥ 120 MED, benzodiazepine co-use, high utilizers [≥ 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

DeBar et al, Contemporary Clinical Trials, 2018;
DeBar et al, Translational Behavioral Medicine, 2012
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).

Panel Support Tool – it takes more than EPIC to prompt administration.
What it might really takes to collect PRO data in routine clinical care

Participants at 3 months
Eligible for PRO Collection n = 831

OVERALL: Total PROs Completed n = 718 (86%)

Window for PHR 7 days
Completed PRO via PHR: 149 (22% of total contacted)

PRO Outreach via Personal Health Record (PHR) n = 676

Step Skipped n = 155
Participant Does Not Have PHR Account (19% of study participants)

18% overall

Window for IVR 5 days
Completed PRO via IVR: 334 (52% of total contacted)

PRO Outreach via Interactive Voice Response (IVR) n = 647

40% overall

Window for Clinical Support Staff 5 days
Completed PRO with Clinical Support Staff: 235 (70% of total contacted)

PRO Outreach via Clinic Support Staff n = 335

28% overall

Owen-Smith et al, Journal of General Internal Medicine, 2018
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

• “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
• 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

Eligibility
Who is selected to participate in the trial?

Recruitment
How are participants recruited into the trial?

Setting
Where is the trial being done?

Organization
What expertise and resources are needed to deliver the intervention?

Flexibility: delivery
How should the intervention be delivered?

Flexibility: adherence
What measures are in place to make sure participants adhere to the intervention?

Follow-up
How closely are participants followed-up?

Primary outcome
How relevant is it to participants?

Primary analysis
To what extent are all data included?

PRO with adjudication

PRO Only (TSOS)

EDIE
Administrative data (accrues without PRO interview)
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

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Implementing PROVEN

PRagmatic Trial of Video Education in Nursing Homes

Susan L. Mitchell, MD, MPH
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
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
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