Research Use of PRO data from EHRs

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Professor of Surgery
Chair, myQuest Steering Committee, D-H
Physician Lead, Patient Reported Measures, TDI
The Spine Center at Dartmouth-Hitchcock 1998
Many Programs See Value in PRMs

<table>
<thead>
<tr>
<th>Department</th>
<th>Condition/Population</th>
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<tr>
<td>Ortho</td>
<td>Hip/Knee/Shoulder</td>
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<tr>
<td>Plastics</td>
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<tr>
<td>Spine Clinic</td>
<td>Spine Diagnoses</td>
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<td>Pain Clinic</td>
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<td>Neurology</td>
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<td>Surgery/Anesth</td>
<td>Pre-Admission Testing</td>
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<tr>
<td>Vascular</td>
<td>Aneurysm, Carotid Disease, Varicose Veins</td>
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Dartmouth-Hitchcock
Practical Issues
GET ALL THE INFORMATION YOU CAN, WE'LL THINK OF A USE FOR IT LATER.
Selecting the right questions requires broad consensus from providers and patients.

- 1–2 local champions does not result in high quality, evidence-based Q with a high degree of buy in.
- Consider respondent burden.
### Common Tests for Heart Failure

To determine whether you have heart failure, procedures.

- Physical examination
- Blood Tests
- Chest X-Rays
- Electrocardiogram (abbreviated: ECG)
- Echocardiography (abbreviated: ECHO)
- Exercise Stress Test
- Radionuclide Ventriculography or Nuclear Cardiac Imaging Scanning (abbreviated: VQ)
- Cardiac Catheterization

**Where is the patient reported measure?**
Envision seamless integration of PROs into practice
Questionnaire Completion Rates: Process Measure
Exit Survey

Did you fill out an electronic health questionnaire for your visit today?

[ ] Yes  [ ] No

(if you check "No" you do not need to answer any other questions.)

Did anyone thank you for filling out the questionnaire during your visit?

[ ] Yes  [ ] No

Did anyone show you or talk to you about the results from the electronic questionnaire during your visit?

[ ] Yes  [ ] No
Incorporation into the clinical encounter

Building
Queuing/Ordering
Patient Interfaces
Clinical Team Use
Built it and they will use it

...not

simple

complex

Dartmouth-Hitchcock Medical Center
Questionnaire Queuing in EPIC

- Initiated with Appointment
- Sent as Secure Patient Message
- Added on-the-fly as Kiosk Questionnaire
- *Order as a pre-defined series (future)*

![Table Example]

**Kiosk Code** | **Qttr Details** | **Questionnaire**
---|---|---
26610320 | Unanswered | Q - PAIN SURVEY

![Email Icon]

![Kiosk Questions Icon]
Patients need multiple options for Q completion.
Example of Multimedia

To help you to make an informed decision about colon cancer screening, please choose one of the following radio buttons:

- Link to detailed written information on my computer now
- Watch a 30 minute video streaming on my computer now
- No, thanks- I already know enough to make the decision
- No, thanks- prefer my doctor makes this decision for me, or not interested

Colon Cancer Screening: Deciding What's Right For You

Fred A.
Had more than one test including colonoscopy
Engaging patients in co-design improves usability

- Volunteers testing design interface
- Capture and track recommendations
Frontline Team needs Training

1 Pt
All patients in half day session
Patients for more providers
Meet weekly to review completion rates and workflow issues

Debrief and improve
Debrief and improve
Debrief and improve
Debrief and improve
Patient Data Displays?
Research Use of PRO data from EHRs

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My Own Health Report (MOHR) Project

Russell E. Glasgow, PhD.
University of Colorado School of Medicine

...on Behalf of the MOHR Investigator Group

Funded by NCI, AHRQ, and OBSSR
Purpose

To test the feasibility of assessing and providing feedback on 10 key health behavior, mental health risk, and substance abuse factors in diverse primary care settings.

Behavioral and mental health issues account for large share of preventable deaths, disability, and health care costs

Patient report and health behaviors are not routinely assessed or part of the medical record

Logically impossible to be patient centered if do not assess and respond to patient reports and preferences

Practices need help and structure to do this—that does not interfere with their other goals
In primary care—need to address many things

PR items asked had to be actionable and broadly applicable (as well as valid, reliable, and exceedingly brief)

Intent was to use items for both clinical (individual and panel) and research purposes

Needed to provide immediate summary feedback to patient/family and primary care team

myownhealthreport.org in public domain
Evidence Integration Triangle (EIT)—A Patient-centered Care Example

**Intervention Program/Policy**
Evidence-based decision aids to provide feedback to both patients and health care teams for action planning and **health behavior counseling**

**Evidence:**
US Preventive Services Task Force recommendations for health behavior change counseling; goal setting & shared decision making

**Stakeholders:**
Primary care (PC) staff, patients and consumer groups; health care system decision makers; groups involved in meaningful use of EHRs

**Practical Progress Measures**
Brief, tested, **standard patient-reported data items** on health behaviors & psychosocial issues—actionable and administered longitudinally to assess progress

**Participatory Implementation Process**
Iterative, **wiki activities** to engage stakeholder community, measurement experts and diverse perspectives

**Multi-Level Context**
- Dramatic increase in use of EHR
- Primary Care Medical Home
- CMS funding for annual wellness exams
- Meaningful use of EHR requirements

<table>
<thead>
<tr>
<th>Domain</th>
<th>Final Measure (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Overall Health Status</td>
<td>1 item: BRFSS Questionnaire</td>
</tr>
<tr>
<td>7. Smoking/Tobacco Use</td>
<td>2 items: Tobacco Use Screener [Adapted from YRBSS Questionnaire]</td>
</tr>
<tr>
<td>10. Demographics</td>
<td>9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran’s status. Multiple sources including: Census Bureau, IOM, and National Health Interview Survey (NHIS)</td>
</tr>
</tbody>
</table>
My Own Health Report (MOHR) Web-based Assessment and Feedback Tool

Patient Health Update
Check the box next to your answer.

Q1. Over the past 7 days:
   a. How many times did you eat fast food meals or snacks?
      - less than 1 time
      - 1-3 times
      - 4 or more times
   b. How many servings of fruits/vegetables did you eat each day?
      - 5 or more
      - 3-4 servings
      - 2 or less
   c. How many soda and sugar sweetened drinks (regular, not diet) did you drink each day?
      - Less than 1
      - 1-2 drinks
      - 3 or more

MRN: ____________________________

- Database of text messages and triggers
- Action Plan printout
- Summary display and printout for patient and family
- Summary display and printout for health care team
- Report data stored in database
- Research analysis

Krist A, et al. Designing a valid pragmatic primary care implementation trial...Implement Sci, 2013, 8:73
Cluster randomized trial of 9 clinic pairs, staggered early and late intervention

Approximately half of clinics community health centers, others AHRQ-type PBRN clinics

Designing for flexibility and adoption—e.g., varying levels of clinic integration of EHRs, different levels and modalities of decision aids

**WHAT is delivered**—e.g., automated assessment tool, feedback, goal setting materials, follow-up are **STANDARD**

**HOW this is delivered is customized** to setting

Study goal = Sustainable, routine use of intervention
MOHR Key Outcomes

Primary Outcome = Percent and representativeness of patients who have a personalized action plan set (‘meaningful use’)

Secondary Outcomes = Percent who receive follow-up contacts; improvement on health behaviors and mental health issues; costs and resources required; adaptations made

Note: At this point not integrated into the diverse EHRs
MOHR: Current Status

- Completing intervention phase
- Different cultures in PBRNs and community health (safety net providers for low income and uninsured) centers
- This trial will be fast, inexpensive, implementation informative…and not definitive

**Key focus is implementation:** reach, equity and ‘fit’ in diverse settings are central.
MOHR: Lessons Learned to Date

- Each clinic, population, and IRB is different
- Key to pragmatic study success is balancing fidelity (to evidence-based principles not static protocol) with context-sensitive adaptation
- Context Changes—and needs repeated, multi-method assessment
- Patients have multiple needs—average of over 6 areas
- Cost, resource, and time issues are central
- Importance of flexibility for researchers and clinics—e.g., to fit local flow, priorities, modality and timing preferences
For More Information on MOHR
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Russ Glasgow, University of Colorado
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For info on training, materials, etc.:
healthpolicy.ucla.edu/mohr
Other Data Collected in MOHR

Cost
- Collected 2x in early intervention sites

Clinic Context
- Collected 3x pre-, mid-, post-intervention, qualitative template

Project Context
- Collected once, end of project, open-ended survey of key project stakeholders (e.g., researchers, funders)

Post-Implementation Interview
- Group interview, clinic staff
Future Pragmatic Needs and Opportunities: Keys to Advance Translation in MOHR and in General

- Health equity impacts—along multiple dimensions of RE-AIM
- Context—key factors that may moderate results, measurement
- Scalability—potential to impact large numbers
- Sustainability
- Patient / citizen / consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice
PRO, EMR and research: the Cleveland Clinic experience

Ajit A. Krishnaney, M.D., FAANS
Center for Spine Health
Department of Neurosurgery
Cleveland Clinic

November 20, 2013
Knowledge Program

Background

- Originated 2007 as a collaboration between Neurological Institute, Imaging Institute and Information Technology Division at Cleveland Clinic
- Disease Outcome Integration

Neurological Institute:

- 15 disease based Centers of Specialty
- Clinics Main Campus & 15 Ambulatory Health Centers
- 154,944 ambulatory visits 2010
Need patient centered outcomes
Need efficient data entry
Need efficient workflow
  high volume center, multiple providers at multiple locations
What health status measures do we use?
  Faculty polled and …
  MOS-36, ODI, NDI, Euroqol, VAS, PHQ-9, PDI

2007 -- Spine Center and KP – New strategy needed
What happened?

Forms not completed – too long

Forms not completed – slowed down clinic too much

Forms not completed – not available at remote locations
Spine Center and KP -- where are we now?

Changed strategy for outcome measures

- Broke with tradition – MOS-36 / ODI / NDI/ PDI dumped
- Rational design of outcome measures to cover multiple domains
  - EuroQol
  - Patient Disability Questionnaire
  - PHQ-9
  - VAS
  - Work status
  - Personality inventory
  - (JOA)
You are being asked to complete this questionnaire as part of your care. You may be asked to complete this at future visits so we can see how things may have changed over time. This information will provide a better understanding of how you are feeling and will allow us to better care for you.

Instructions: Click a numbered button below each entry area to add that number to the end of the entry.

MRN or SSN: xxxxxxxx (8 or 9 digits)

1 2 3 4 5 6 7 8 9 0 Erase

Date of Birth: mm dd yyyy

1 2 3 4 5 6 7 8 9 0 Erase

Register
Section 1: Mobility

Select one of the following responses:

- I have no problems in walking about.
- I have some problems in walking about.
- I am confined to bed.

How would you best describe your CURRENT level of head/face pain?

Please select the number on the scale (by clicking on the number) which best describes your response.

0 1 2 3 4 5 6 7 8 9 10

No Pain

Worst Pain Imaginable

Does your pain interfere with your normal work inside and outside the home?

(Please answer every question by clicking on the line to show how much your pain problem affects you (from having no problems at all to having the most severe problem you can imagine).)

Work normally

Unable to work at all
Physician workflow

European Quality of Life (EQ-5D): Index = 0.778 (range: -0.109 to 1.0, a higher score indicates a better quality of life)
- Mobility: (2) I have some problems in walking about.
- Self-Care: (1) I have no problems with self-care.
- Usual Activities: (2) I have some problems with performing my usual activities.
- Pain / Discomfort: (2) I have moderate pain or discomfort.
- Anxiety / Depression: (1) I am not anxious or depressed.

- Health state: 57 (0 - 100, a higher score indicates a better perceived health state)

Pain Disability Questionnaire
   - Functional Status Component: 40
   - Psychosocial Component: 21
Real Patient – s/p TLIF 12/12/11
Knowledge Program Outcomes

Distress/Depression

Global Assessment of Health (EQ-5D)

Change in Physical Ability

Lumbar Herniated Disc
Change in General Health Status Measures

- Change in PHQ-9 Score
- Change in EQ-5D Index
- Change in PDQ Total

N = 65  N = 74  N = 90

- Stable and Worsened
- Slightly Improved (0 - 20%)
- Improved (20% +)
Knowledge Program Outcomes

Stenosis with Fusion
Change In General Health Status Measures

- Change in PHQ-9 Score
- Change in EQ-5D Index
- Change in Physical Ability

N = 89  N = 82  N = 94

- Stable and Worsened
- Slightly Improved (0 - 20%)
- Improved (20% +)

Global Assessment of Health (EQ-5D)

- Pre-Op: 0.54
- Post-Op: 0.82

Distress/Depression

- Pre-Op: 10.97
- N=62: 5.92
- Post-Op: 5.92
Current Studies:

Comparative effectiveness of TLIF vs PLF in degenerative spondylolisthesis

Comparative effectiveness of ACDF vs cervical foraminotomy

Does improvement in mJOA scores after surgery for cervical myelopathy correlate with improvement in quality of life scores?

Does obesity have an effect on outcomes in patients undergoing spinal fusion for degenerative spondylolisthesis
  • Fellow: Dhaliwal

Cost of surgery vs outcome
  • Resident: Rosenbaum

Cell salvage vs blood transfusion – effects on cost and outcomes
  • Resident: Rosenbaum

Effect of microdiscectomy on depression scores in patients with radiculopathy
  • Fellow: Anderson
What have we learned?

KP extremely powerful tool for research
Important to have a well designed battery of outcomes instruments
Need to keep questionnaires as short as possible
Frustrations:

- Incomplete data sets!
  - Sub-optimal completion rate
  - Inconsistent follow-up
  - Length of follow-up
- Efficiency of data extraction / searches
- No “gold standard” for outcomes measures / cost analysis
  - Commonly used spine measures are long
  - Up hill battle to change “standard” measures
- Difficulty obtaining long term follow-up (financial pressures)
Future?

Decouple PRO from clinical encounter

Standardize follow-up across practice

Refine measures (PROMIS)?
Acknowledgements:

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THANK YOU
PCORI: PRO Infrastructure Workshop

Research and Clinical Uses of EMRs and PROs

November 2013

Marc L. Berger, M.D.
Vice President
RW DnA

Enhancing Real World Insights Together
Current Landscape

Data Source Explosion
- EMR
- laboratory
- surveys
- claims
- PHR
- social

Technology Evolution
- cloud
- massively large databases
- SaaS
- PaaS
- advances in distributed computing

Advanced Analytics Techniques
- machine learning
- SVM
- NLP
- geo-spatial predictive modeling
- neural networks

Expanding Applications
- patient mining
- hospital productivity
- clinical data analysis
- drug-drug interaction
- drug value

93% US HCPs using EMR
78% US HCPs enter patient notes into EMR
65% US HCPs using e-Rx

PROs

What is Real World Data?

Real World Data is healthcare data used for decision making that is not collected in conventional randomized controlled trials (RCTs).

Sources of Real World Data:

- **Databases**
  - Cross-sectional and longitudinal databases which essentially provide retrospective data but increasingly offer the opportunity to have prospective add-ins.

- **Surveys**
  - Primarily for epidemiological information.

- **Pt Reported Measurements**
  - Used to reflect particular insights in patient management.

- **EMRs**
  - What most people would understand by real life studies.

- **Cohort studies**

- **Pragmatic clinical trials**
  - Simple experimental trials, where efforts are however made to mimic a real life situation as much as possible.

- **Registries**
  - Analyzing all patients treated at a particular center for a particular condition on a continuous basis.

Real World Data is Big Data

## Typical RW Studies and Analyses

### Research & Analysis
- Natural Hx of Disease
- Treatment Patterns
- Burden of Illness
- Response to Treatment
- Adherence/Persistence
- Comparative Effectiveness
  - Individual Treatments
  - Systems of Care
- Health Care Resource Use
- Cost-Effectiveness
- Predictive Modeling
  - Tx Choice, Brand Choice
  - Disease Progression – Pt Heterogeneity
  - Response to Therapy – Pt Heterogeneity

### Clinical Care
- Assess Quality of Care
  - Support Quality Improvement Efforts
  - Compare outcomes among providers & centers
- Assess Cost of Care
  - Manage HC expenditures
  - Compare costs among providers & centers
- Identify patients for specific interventions
  - Disease / Care Management
    - Patient Heterogeneity
  - Screening
- Risk Estimation and Management
  - Benefit Design, Contracting
Who Can Respond to Treatment?  

Identifying Patient Characteristics Related to Heterogeneity of Treatment Effects

Sherrie H. Kaplan, PhD, MPH, John Billimek, PhD, Dara H. Sorkin, PhD, Quyen Ngo-Metzger, MD, MPH, and Sheldon Greenfield, MD

**Background:** Interest in comparative effectiveness research and the rising number of negative or "small effect" trials have stimulated research into differential response to treatment among subgroups of patients.

**Objective:** To develop and test the Potential for Benefit Scale (PBS), a composite measure to identify subgroups of patients with differential potential for response to treatment, using diabetes as a model.

**Design:** Cross-sectional and longitudinal cohort study.

**Subjects and Setting:** Type 2 diabetes patients (n = 1361) were identified from 7 outpatient clinics serving a diverse population. Of these, 611 completed a 1-year follow-up.

**Measures:** To represent patients' health status, we used the Total Illness Burden Index, the Physical Function Index of the SF-36, the Center for Epidemiologic Studies Depression Scale, and the Diabetes Burden Scale. To represent personality characteristics related to health, we used the Provider-Dependent Health Care Orientation scale. We assessed the contribution of these measures to a composite scale of patients' potential for treatment response in terms of self-reported medication adherence and glycemic control.

**Key Words:** heterogeneity of treatment effects, comorbidity, diabetes

*(Med Care 2010;48: S9–S16)*

*If it were not for the great variability among individuals, medicine might as well be a science and not an art.*

—Sir William Osler, *The Principles and Practice of Medicine* 1892

Called "heterogeneity of treatment effects," the recognition that patients vary in response to treatment is not a new concept, as illustrated by the quote from Sir William Osler from 1892. However, the recent re-emergence of this concept in the clinical and statistical literature is a reflection of its sustained importance for clinical practice, clinical guidelines, and most importantly, for the design and conduct of clinical trials. The need to understand and respond to patient variation in treatment response has been fueled by the occurrence of 3 phenomena: (1) the size in
Patient Reported Measurements and Other RWD may assist in assessing Patient Heterogeneity

Potential Data Sources

- Claims, Lab
- HRA, HSA, TIBI, PROs
- Pt Surveys
- Claims, HSA, HRA
- Survey, EHR
- Survey, HSA

Other RWD

- Purchasing Habits
- Internet Search
- FICO Data
- Travel Patterns

Modified from Kaplan et al Medical Care
179 The Total Illness Burden Index

S. Greenfield · J. Billimek · S. H. Kaplan

Log-rank test, p-value < 0.0001

* N = 135 deaths unrelated to prostate cancer
RW Research → Moving up in Value

Types of Analytics | Questions Addressed
---|---
**Stochastic optimization** | How can we achieve the best outcome given variability?
**Optimization** | How can we achieve best outcome?
**Predictive modeling** | What will happen next if?
**Forecasting** | What if these trends continue?
**Simulation** | What could happen?
**Alerts** | What actions are needed?
**Query/drill down** | What exactly is the problem?
**Ad hoc reporting** | How many, how often, where?
**Standard reporting** | What happened?

Adapted from IBM IT Enabled Healthcare

BIG DATA

Data Mash-ups

Advanced Analytics

Complexity

Descriptive

Predictive

Prescriptive
Challenges

• Current EMRs are not designed to support research
  • Structured and Unstructured Data
  • Ease of data extraction to create analyzable data sets

• Use of Natural Language Processing to extract Patient Reported Measures from Unstructured Notes
  • Missing Data is a big problem
  • Loss of information as data is structured

• Embedding standardized Patient Reported Measures into Clinical Practice
  • Cleveland Clinic experience → Must make Clinician’s job easier
    • 5 clicks for rehab

• Patient confidentiality, data ownership, and the opportunity for data integration / data mash-ups
  • Potential role of patient as true data owner