Practical, Patient Report Measures for Primary Care: Progress on the My Own Health Report (MOHR) Project to Date

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Overview

• Rationale and Need for Practical Patient Report Measures
• Implementation Science and Translational Perspective
• Selecting Practical, Actionable Measures and Pragmatic Design for MOHR
• MOHR Development, Current Status, Lessons Learned
• Future Directions and Discussion
To achieve the rapid integration of scientific evidence, practice, and policy, with the ultimate goal of improving the impact of research on cancer outcomes and promoting health across individual, organizational and community levels.

http://cancercontrol.cancer.gov/IS/
Translational Research: A T0- T4 Model

Modified from Khoury et al. Genetics in Medicine 2007;9(10):665-674
Key Issues in Integrating Research into Policy and Practice

- Contextual
- Complex
- Multi-component programs and policies
- Non-linear
- Transdisciplinary
- Multi-level
- Addresses “wicked”, messy, important problems

Bench to Bookshelf
Implementation Science Models

Key Common Points

• Context is critical

• Begin with stakeholders—take their perspective

• Design for dissemination—from beginning—cannot wait until the end

• Need balance between fidelity to evidence-based program and adaptation to local setting

Pragmatic Perspective / World View

“The importance of an idea or action lies in whether it makes a difference in everyday life. Ideas or actions that correspond to attractive explanations (e.g., metaphysical theories), but make no difference to outcomes, are problematic.”

~Charles Pierce
Basic Idea

- A pragmatic trial is a real-world test in a real-world population, whereas an explanatory trial is a specialized experiment in a specialized population and often optimal setting*

- Pragmatic does not mean being less rigorous

*Maclure, 2009 CMAJ
Designing a Pragmatic Trial: Consider the RE-AIM Framework

- **Reach:** percent and representativeness of participants—getting those most in need?
- **Adoption:** Settings and staff who can deliver
- **Effectiveness:** for which groups on which outcomes; unanticipated results
- **Implementation:** costs, fidelity and adaptation
- **Maintenance and sustainability**

www.re-aim.org

Challenge: Clinical Research is Slow, Expensive, and Often Does Not Translate

- To most people, randomized controlled trials (RCTs) are the mainstay of clinical research.
- But traditional RCTs are slow and expensive—and rarely produce findings that are easily put into practice.
- In fact, it takes an average of 17 years before 14% of research findings lead to widespread changes in care.
# Key Differences between Efficacy RCTs and Pragmatic Studies

<table>
<thead>
<tr>
<th></th>
<th>A traditional RCT tests a hypothesis under ideal conditions</th>
<th>A PCT compares treatments under everyday clinical conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GOALS</strong></td>
<td>To determine causes and effects of treatment</td>
<td>To improve practice and inform clinical &amp; policy decisions</td>
</tr>
<tr>
<td><strong>DESIGN</strong></td>
<td>Tests the intervention against placebo using <em>rigid study protocols &amp; minimal variation</em></td>
<td>Tests two or more real-world treatments using <em>flexible protocols &amp; local customization</em></td>
</tr>
<tr>
<td><strong>PARTICIPANTS</strong></td>
<td>Highly defined &amp; carefully selected</td>
<td>More representative because eligibility criteria are less strict</td>
</tr>
<tr>
<td><strong>MEASURES</strong></td>
<td>Require data collection outside routine clinical care</td>
<td>Brief and designed so data can be easily collected in clinical settings</td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
<td>Rarely relevant to everyday practice</td>
<td>Useful in everyday practice, especially clinical decision making</td>
</tr>
</tbody>
</table>
PCTs: Fewer Exclusions Allow for a Broader Subset of Settings, Staff, and Participants

Traditional RCT

- Eligible population
- Exclusions, non-response, etc.
- Efficacy, among a defined subset

Pragmatic Control Trial

- Eligible population
- Exclusions, non-response, etc.
- Effectiveness, in a broad subset

Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research
Pragmatic Study Methods: Key Characteristics

• Questions from and important to stakeholders
• Multiple, heterogeneous settings
• Diverse populations
• Comparison conditions are real-world alternatives
• Multiple outcomes important to decision and policy makers

Thorpe KE et al., Can Med Assoc J, 2009;180:E47-57
Tunis SR et al. Practical clinical trials…JAMA 2003;290:1624-1632
Take-Home Messages: Benefits of PCTs for Health Systems, Patients, and Providers

**Actionable**
- Designed around application to practice, with an emphasis on successful implementation.

**Patient Centered**
- Research questions and goals are strongly aligned with patient-centered research and care.

**Relevant**
- Transparent reporting of results that are focused on issues and data that are relevant for making decisions and taking action.
Evidence Integration Triangle (EIT)

- **Participatory Implementation Process** (e.g., stakeholder engagement; CBPR; team-based science; patient centered)
- **Intervention Program/Policy** *(Prevention or Treatment)*
  - (e.g., key components; principles; guidebook; internal & external validity)
- **Practical Progress Measures**
  - (e.g., actionable & longitudinal measures)
- **Multi-Level Context**
  - Intrapersonal/Biological
  - Interpersonal/Family
  - Organizational
  - Policy
  - Community/Economic
  - Social/Environment/History

Feedback loop:
- Evidence
- Stakeholders

The evidence-based movement is a good start, but only gets us so far.
To make greater progress, two other elements also need attention:
  - Practical MEASURES to track progress and
  - Implementation PROCESSES that use partnership principles
  - These 3 legs of the “EIT” are each necessary but not sufficient by themselves

http://cancercontrol-dev.cancer.gov/IS/presentations
Practical Measures Criteria—For Use in Real-World Settings and Pragmatic Research

1. **Required Criteria**
   - Important to stakeholders
   - Burden is low to moderate
   - Sensitive to change
   - Actionable

2. **Additional Criteria**
   - Broadly applicable, has norms to interpret
   - Low probability of harm
   - Addresses public health goal(s)
   - Related to theory or model
   - “Maps” to “gold standard” metric or measure

“The significant problems we face cannot be solved by the same level of thinking that created them.”

~A. Einstein
Pragmatic Example:

Using Practical Measures Based on a Pragmatic Model in a Pragmatic Trial—The *My Own Health Report* *(MOHR Project)*

* For general, adult primary care patients with or without disease(s)
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

EHR Measures for Adult Primary Care

- Advent of patient-centered medical home, CMS annual wellness exams, “meaningful use” of EHRs

- In the billions of dollars spent on EHRs in last several years, one thing is missing: Patient-Reported Measures

- *Impossible to provide patient-centered care if no patient measures, goals, preferences, concerns collected*

- With recent advances in measurement, meaningful use incentives, time is right

Vision for “Big Data”
A Comprehensive Big Database to be Maximally Useful Should Contain:

• Diagnostic and health care utilization data
• Genomic and biomarker data
• Patient-reported information, preferences, and patient-centered goals
• Geospatial and social/physical/environmental data on fundamental determinants of health
MOHR Background, Phases 1 & 2

- SBM content experts identify 2-3 candidate measures in each of 13 key domains

- Widespread web-based wiki activity: www.gem.beta.org

- “Town Hall” Meeting at NIH: Day 1 town hall followed by Day 2 invited stakeholder decision makers

- Post-Meeting and Beyond: Pilot study of “Patient Health Update” 2011-2012

Identifying Patient-Report Measures
Pre-MOHR Project Phase 1, 2

- SBM content experts identify 2-3 candidate measures in each of 13 key domains

- Widespread web-based wiki activity: www.gem.beta.org (go to “EHR Initiative”)

- “Town Hall” Meeting at NIH: Day 1, town hall followed by Day 2, invited stakeholder decision makers

- Post-Meeting and Beyond: Pilot study of “Patient Health Update” 2011-2012
# EHR Measures for Primary Care

<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>
Developing *My Own Health Report*

- MOHR (patient-reported data tool) developed by a process of iterative crowd-sourcing:
  - Small group developed initial model for MOHR based on the *Patient Health Update* (included NIDA and SAMSHA reps)
  - Reviewed with changes recommended by all partners
    - Clinic stakeholders involved in process
    - Small group made recommended changes
  - Process repeated every 2-3 weeks over several months, Fall 2012
My Own Health Report (MOHR)
Automated Assessment Tool

Patient Fills Out 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

Report data stored in database

Database of text messages and triggers

Summary display and printout for patient
Action Plan printout
Summary display and printout for health care team
Research analysis

Krist A, et al. Designing a valid pragmatic primary care implementation trial...Implement Sci, 2013, 8:73
The MOHR Research Group

• **Funders:**
  – National Cancer Institute
  – Office of Behavioral and Social Science Research
  – Agency for Health Research and Quality

• **Collaborating Research Teams**
  – Texas A & M
  – University of California, Los Angeles
  – University of North Carolina, Chapel Hill
  – University of Vermont
  – University of Texas, Houston
  – Virginia Tech

• **Coordinating Center**
  – Virginia Commonwealth University
MOHR Project—Key Points

- 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

www.myownhealthreport.org
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, sustainability discussion**
  - Group interview, clinic staff
Key Outcomes in MOHR

- **Primary**
  - Percent of patients who worked with provider to set an action plan for one or more health areas

- **Other**
  - Reach: percent and representativeness of patients completing and benefitting from MOHR intervention
*EIS=Early Interventions Site  
DIS=Later Intervention Sites  
MOHR= My Own Health Report
## Pragmatic Features of MOHR

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant</td>
<td>Diverse, real-world primary care settings; and staff who do all the intervention</td>
</tr>
<tr>
<td>Rigorous</td>
<td>Cluster randomized, delayed intervention design</td>
</tr>
<tr>
<td>Rapid</td>
<td>One year from concept, planning, and execution, low cost, and cost informative</td>
</tr>
<tr>
<td>Resource</td>
<td>Low cost; studying costs and cost-effectiveness under different delivery conditions</td>
</tr>
<tr>
<td>Informative</td>
<td>Report on adaptations, failures, variation across sites and implementation models, lessons learned</td>
</tr>
</tbody>
</table>
Transparent Reporting on.....

- Info needed to replicate or implement
- **Resources required**—costs for patients and delivery setting perspectives
- How were settings, clinicians, and patients selected—(*who was excluded and why*)
- **Adaptation**—changes made to protocol, to intervention, to recruitment, etc.
- Differences across settings
Current Status

- Completing Early Intervention Phase
- Different cultures in PBRNs and community health centers
- This trial will be fast, inexpensive, implementation informative…and not definitive
- Key focus is implementation; reach and equity are central
MOHR Lessons Learned to Date

- Each clinic, population, and IRB is different
- Key to pragmatic study success is balancing **fidelity** (to EB principles not static protocol) with context-sensitive **adaptation**
- Context Changes—and needs repeated, multi-method assessment
- Cost, resource, and time issues are central
- Importance of **flexibility** for researchers and clinics
The Future: Pragmatic Needs and Opportunities for 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 after official study period
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice
Take-Home Points

- There is a pressing need for a DIFFERENT type of research: PRAGMATIC models, measures, and methods—that translate more rapidly, and are more relevant to stakeholders.

- There is great opportunity to learn from the convergence of results from different study methods—clinical trials, pragmatic research, observational data, simulation modeling, patient-reported data.

- There are many opportunities for this type of research, especially among research networks and for coalitions to study context (e.g., the HCS Collaboratory; Ca Centers, VA centers, FQHCs, HMORN, extension, PBRNs, the Y, Livestrong Centers, MOHR, etc.)
All Models (and Methods) are Wrong…
….Some are useful.

“To every complex question,
there is a simple answer…
and it is wrong.”

~H. L. Mencken
Contact us: glasgowre@mail.nih.gov
sheurtin@mail.nih.gov

IS Team Website: http://dccps.cancer.gov/is/

IS Team Email: NCldccpsISteam@mail.nih.gov
Why Not Just Use PROMIS Measures?

- No measures for several behaviors and issues central to this project
- Most primary care, especially low-resource settings not using computer adaptive testing
- Many of the issues (e.g., healthy eating, substance use are not uni-dimensional)
- Short, fixed PROMIS measures generally too long
American Recovery and Reinvestment Act (ARRA)—2009 (included HITECH Act)

- Called for *meaningful use*:
  - Use of a certified EHR in a meaningful manner
  - Electronic exchange of health information to improve quality of health care
  - Use of certified EHR technology to submit clinical quality and other measures

- Centers for Medicare and Medicaid Services (CMS)
  - 2010 final rule to implement and use EHRs in a meaningful way to help improve the quality and safety of the U.S. healthcare system
 YOUR Health Behaviors and Mental Health

<table>
<thead>
<tr>
<th>Health Behaviors</th>
<th>Recommended Score</th>
<th>Your Score</th>
<th>Level of Concern</th>
<th>Ready to Change?</th>
<th>Want to Discuss?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Health Rating</td>
<td>Good to Excellent</td>
<td>Poor</td>
<td>A Lot</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Reason: I am working too hard at my job.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>20-25</td>
<td>27.7</td>
<td>Some</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Behaviors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit/Vegetable Intake</td>
<td>5+day</td>
<td>Less than 2/day</td>
<td>A Lot</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Fast Food Intake</td>
<td>Less than 1 time/week</td>
<td>1-3 times/week</td>
<td>Some</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Soda/Sugary Beverage Intake</td>
<td>Less than 1/day</td>
<td>1 to 2/day</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Activity Participation</td>
<td>150+ minutes/week</td>
<td>175 minutes/week</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep</td>
<td>Never/rarely sleepy</td>
<td>Often sleepy</td>
<td>Some</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Alcohol Intake</td>
<td>Never</td>
<td>Never</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobacco use</td>
<td>No</td>
<td>Yes</td>
<td>A Lot</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Illegal Drug/Prescription Use</td>
<td>Never misuse</td>
<td>Never misuse</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Health</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress</td>
<td>Less than 5</td>
<td>8</td>
<td>A Lot</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Anxiety/Worry</td>
<td>Not at all rarely</td>
<td>Not at all rarely</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>Not at all rarely</td>
<td>Not at all rarely</td>
<td>None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* = Most important to you

Basic patient and clinician goal advice (electronic) and goal setting (paper)

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**Recommended to Improve Your Health**

**Medium Priority**
- Excessive weight can lead to a number of health problems. Increase physical activity and/or limit the unhealthy foods you eat to reduce your weight.
- Decrease your fast food meals or snacks to less than one per week
- Decrease the number of sodas or sugary drinks you drink to less than 1 per day
- Try to get 7-8 hours of sleep each night

**High Priority**
- Increase fruits and vegetables to 5 or more servings per day
- You reported feeling stressed often
- Discuss ways to reduce your stress
- Discuss options for decreasing or quitting tobacco use.