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

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Slide 1-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

Slide 2-NCI Implementation Science Team Vision

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/

Slide 3-Translational Research: A T0- T4 Model

[Image] The framework for the continuum of multidisciplinary translation research builds on previous characterization efforts in genomics and other areas in health care and prevention. The continuum includes four phases of translation research that revolve around the development of evidence-based guidelines. "Discoveries (e.g. genetic risk factor)" is connected to "Promising Application (e.g. genetic test)" (T1 – Basic Science) which is, in turn, connected to "Evidence-Based Guideline/Policy (T2 – clinical Science) which is then connected to "Practice and Control Programs" (T3 – Population Science), which is connected to "*Reducing the Burden of Disease*" (T4 – Population Science). "*Reducing the Burden of Disease*" completes the circle and is connected to "Discoveries". At the center of the figure is a box titled "Knowledge Integration". The box is connected by bi-directional arrows to each of the phases (T0-T4) of the pentagon described above. [End Image]
The focus of Implementation science is T3 and T4.

Modified from Khoury et al. *Genetics in Medicine* 2007;9(10):665-674
Glasgow RE, et al. *Am J Public Health* 2012;Jul;102(7):1274-1281

Slide 4-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

Glasgow R & Steiner J. (2012). In *Dissemination and Implementation Research*. Brownson, R, Colditz, G, and Proctor, E (Eds.). Oxford University Press

Slide 5-Research usually goes bench to bookshelf

[Image] Researcher examining vial with arrow pointing to dusty bookshelf. [End Image]

Slide 6-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

Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med*. 2012 Sep; 43(3):337-50.
Pragmatic Perspective / World View

Slide 7- No title

"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

Slide 8-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

Slide 9-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
Kessler RS, et al. What Does It Mean to "Employ" the RE-AIM Model? *Eval Health Prof* 2012;Mar;36(1):44-46.

Slide 10-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.

Slide 11-Key Differences between Efficacy RCTs and Pragmatic Studies

[Table]

	A traditional RCT tests a hypothesis under ideal conditions	A PCT compares treatments under everyday clinical conditions
GOALS	To determine causes and effects of treatment	To improve practice and inform clinical & policy decisions
DESIGN	Tests the intervention against placebo using *rigid study protocols & minimal variation*	Tests two or more real-world treatments using *flexible protocols & local customization*
PARTICIPANTS	Highly defined & carefully selected	More representative because eligibility criteria are less strict
MEASURES	Require data collection outside routine clinical care	Brief and designed so data can be easily collected in clinical settings
RESULTS	Rarely relevant to everyday practice	Useful in everyday practice, especially clinical decision making

[End Table]

Slide 12-PCTs: Fewer Exclusions Allow for a Broader Subset of Settings, Staff, and Participants

[Figure] There are two sections to the figure. The first section is titled "Traditional RCT" and shows a funnel with a number of dots representing the eligible population at the top of the funnel, then at the bottom of the funnel (after exclusions and non-responses) you have only 3 dots remaining indicating you are only testing efficacy among a defined sub-set of the population. In the second part of the figure, titled "Pragmatic Control Trial (PCT)", there is a wide cylinder that has dots representing the eligible population at the top and then a near equal number of dots at the bottom indicating that, in a PCT, you are studying the effectiveness in a **broad** sub-set on the population since you have excluded fewer participants rather than a select few as in an RCT. [End Image]

Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research

Slide 13-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

Glasgow RE et al. Practical clinical trials…*Med Care* 2005;43(6):551-557

Slide 15-Take-Home Messages: Benefits of PCTs for Health Systems, Patients, and Providers

[Figure] Three boxes are displayed on a continuum. The first is labeled "Actionable" and states "Designed around application to practice, with an emphasis on successful implementation"; the second is labeled "Patient-Centered" and states "Research questions and goals are strongly

aligned with patient-centered research and care"; and the third is labeled "Relevant" and states "Transparent reporting of results that are focused on issues and data that are relevant for making decisions and taking action." [End Image]

Slide 16-Evidence Integration Triangle (EIT)

[Image] Intervention (Program/Policy) (e.g. design; key components; principles guidebook; internal and external validity) has a bi-directional connection to "Practical Progress Measures (e.g. actionable & longitudinal measures)". "Practical Progress Measures" has bi-directional connection to "Participatory Implementation Process" (e.g. stakeholder engagement; team-based science; CBPR; patient centered care). "Implementation Process" has a bi-directional connection to "Intervention (Program/Policy)". Each bi-directional arrow displays the word "Feedback" above it. This completes the circular connection from "Intervention (Program/Policy)" to "Practical Progress Measures" to "Implementation Process" back to "Intervention (Program/Policy)". Two ovals with the words, "Evidence and Stakeholders" are in the middle of the triangle. A circle encompasses the whole triangle and lists the six Multi-level contexts: (1) Intrapersonal/biological; (2) Interpersonal/Family; (3) Organizational; (4) Policy; (5) Community/Economic; (6) Social/Environment/History.[End Image]

Glasgow RE, Green LW, Taylor MV, Stange KC. AJ Prev Med 2012;42(6):646-654

Slide 17-EIT Conclusions

- 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

Slide 18-Practical Measures Criteria—For Use in Real-World Settings and Pragmatic Research

1. Required Criteria
   a. Important to stakeholders
   b. Burden is low to moderate
   c. Sensitive to change
   d. Actionable
2. Additional Criteria
   a. Broadly applicable, has norms to interpret
   b. Low probability of harm
   c. Addresses public health goal(s)
   d. Related to theory or model
   e. "Maps" to "gold standard" metric or measure

Glasgow, R. E. & Riley, W. T. Pragmatic measures… *Am J Prev Med 2013*.

Slide 19- No Title

"The significant problems we face cannot be solved by the same level of thinking that created them."
~A. Einstein

Slide 20-Pragmatic Example:
Using Practical Measures Based on a Pragmatic Model in a Pragmatic Trial—The *M*y *O*wn *H*ealth *R*eport* (MOHR Project)
* For general, adult primary care patients with or without disease(s)

Slide 21-Evidence Integration Triangle (EIT)—A Patient-Centered Care Example
[Image] Intervention Program/Policy (Evidence-based decision aids to provide feedback to both patients and health care teams for action planning and health behavior counseling) has a bi-directional connection to "Practical Progress Measures (Brief, standard patient reported data items on health behaviors & psychosocial issues -- actionable and administered longitudinally to assess progress)". "Practical Progress Measures" has bi-directional connection to "Participatory Implementation Process" (Iterative, wiki activities to engage stakeholder community, measurement experts and diverse perspectives). "Implementation Process" has a bi-directional connection to "Intervention (Program/Policy)". Each bi-directional arrow displays the word "Feedback" above it. This completes the circular connection from "Intervention (Program/Policy)" to "Practical Progress Measures" to "Implementation Process" back to "Intervention (Program/Policy)". Two ovals appear in the center of the triangle: (1) Evidence: US Preventive Services Task Force recs. for health behavior change counseling; evidence on goal setting & shared decision making; and (2) Stakeholders: Primary care (PC) staff, patients and consumer groups; PC associations; groups involved in meaningful use of EHRs, EHR vendors. A circle encompasses the whole triangle and lists the multi-level context for this example: Dramatic increase in use of HER; Primary Care Medical Home; CMS funding for annual wellness exams; Meaningful use of EHR requirements.[End Image]

Glasgow RE, Green LW, Taylor MV, Stange KC. AJ Prev Med 2012;42(6):646-654

Slide 22-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

Estabrooks PA, et al. Harmonized patient-reported data elements…*J Am Med Inform Assoc* 2012 Jul-Aug;19(4):575-82.

Slide 23-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

Slide 24-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

Estabrooks PA, et al. Harmonized patient-reported data elements…*J Am Med Inform Assoc* 2012 Jul-Aug;19(4):575-82.

Slide 25-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

Slide 26-EHR Measures for Primary Care

[Table]

Domain	Final Measure (Source)
1. Demographics	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)*
2. Overall Health Status	1 item: BRFSS Questionnaire
3. Eating Patterns	3 items: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al. *Am J Prev Med* 2011;40(1):67-71]
4. Physical Activity	2 items: The Exercise Vital Sign [Sallis R. *Br J Sports Med* 2011;45(6):473-474]
5. Stress	1 item: Distress Thermometer [Roth AJ, et al. *Cancer* 1998;15(82):1904-1908]
6. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. *Psychosomatics* 2009;50(6):613-621]
7. Sleep	2 items: a. Adapted from BRFSS b. Neuro-QOL (Item PQSLP04)
8. Smoking/Tobacco Use	2 items: Tobacco Use Screener (Adapted from YRBSS Questionnaire)
9. Risky Drinking	1 item: Alcohol Use Screener [Smith et al. *J Gen Int Med* 2009;24(7):783-788]

10. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. *Arch Int Med* 2010;170(13):1155-1160]

[End Table]

Slide 27-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

Slide 28-My Own Health Report (MOHR) Automated Assessment Tool

[Image] Showing an image of the checklist tool which the patient fills out this is connected by a uni-directional arrow which points to a box with the text "Database of text messages and triggers." The database is connected to two boxes (1) Summary display and printout for patient and (2) Summary display and printout for physician. These lead to a final box, "Action Plan printout." Additionally the first box showing the patient completing the form is connected to a separate box that says "Report Data stored in database" which is then connected through a uni-directional arrow to a box titled "Research Analysis."[End Image]

Krist A, et al. Designing a valid pragmatic primary care implementation trial…*Implement Sci* , 2013, 8:73

Slide 29-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

Slide 30-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

[Image] Map of US showing study sites in California, Oregon, Texas, North Carolina, Virginia, and Vermont [End Image]

www.myownhealthreport.org

Slide 31-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

Slide 32-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

Slide 33-MOHR Timeline

- Month 1-2:
  - IRB Approval
- Months 2-5:
  - Context Assessment (Both early intervention site and later intervention sites)
- Month 3:
  - Pilot in Early intervention site
- Months 3-7:
  - Intervention in Early Intervention Sites
  - Implementation of Data Collected in Early Intervention Sites
- Month 4:
  - Cost Intervention Collections in early intervention sites
- Months 4-8:
  - Patient Experience Survey for early intervention sites and later intervention sites.
- Months 6-7:
  - Cost intervention collection in early intervention sites
  - Context update in early intervention sites
- Months 7 to end (after September 2013):
  - Optional MOHR patient reported outcomes follow-up

- Months 8 to end (after September 2013):
  - Contextual changes update for early intervention sites and later sites
  - Post Intervention Staff Interviews – early intervention sites
  - Intervention – later intervention site
  - Implementation data collected – later intervention site
- Months 9 to end (after September 2013):
  - Long-term implementation and adaptation check – early intervention sites
  - Post intervention staff interviews – later intervention sites.

Slide 34-Pragmatic Features of MOHR

Relevant	Diverse, real-world primary care settings; and staff who do all the intervention
Rigorous	Cluster randomized, delayed intervention design
Rapid	One year from concept, planning, and execution, low cost, and cost informative
Resource Informative	Low cost; studying costs and cost-effectiveness under different delivery conditions
Transparent	Report on adaptations, failures, lessons learned

Slide 35-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

Slide 36-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

Slide 37-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

Slide 38-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

Slide 39-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.)

Slide 40-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

Slide 41-Contact us:

glasgowre@mail.nih.gov
sheurtin@mail.nih.gov
IS Team Website: http://dccps.cancer.gov/is/
IS Team Email: NCIdccpsISteam@mail.nih.gov

Slide 42-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

Slide 43- "Meaningful Use and EHRs"

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

Slide 44-Basic patient and clinician goal advice (electronic) and goal setting (paper)

[Image] Screenshot of My Own Health Report goal-setting page. [End Image]