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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

IMPLEMENTATION SCIENCE
INTEGRATING SCIENCE, PRACTICE, AND POLICY

NCI Implementation Science
Team Vision

To achieve the rapid <u>integration</u> of scientific evidence, practice, and policy, with the ultimate goal of improving the <u>impact of research</u> on cancer outcomes and promoting health <u>across</u> individual, organizational and community <u>levels</u>.

http://cancercontrol.cancer.gov/IS/

Translational Research: A T0- T4 Model
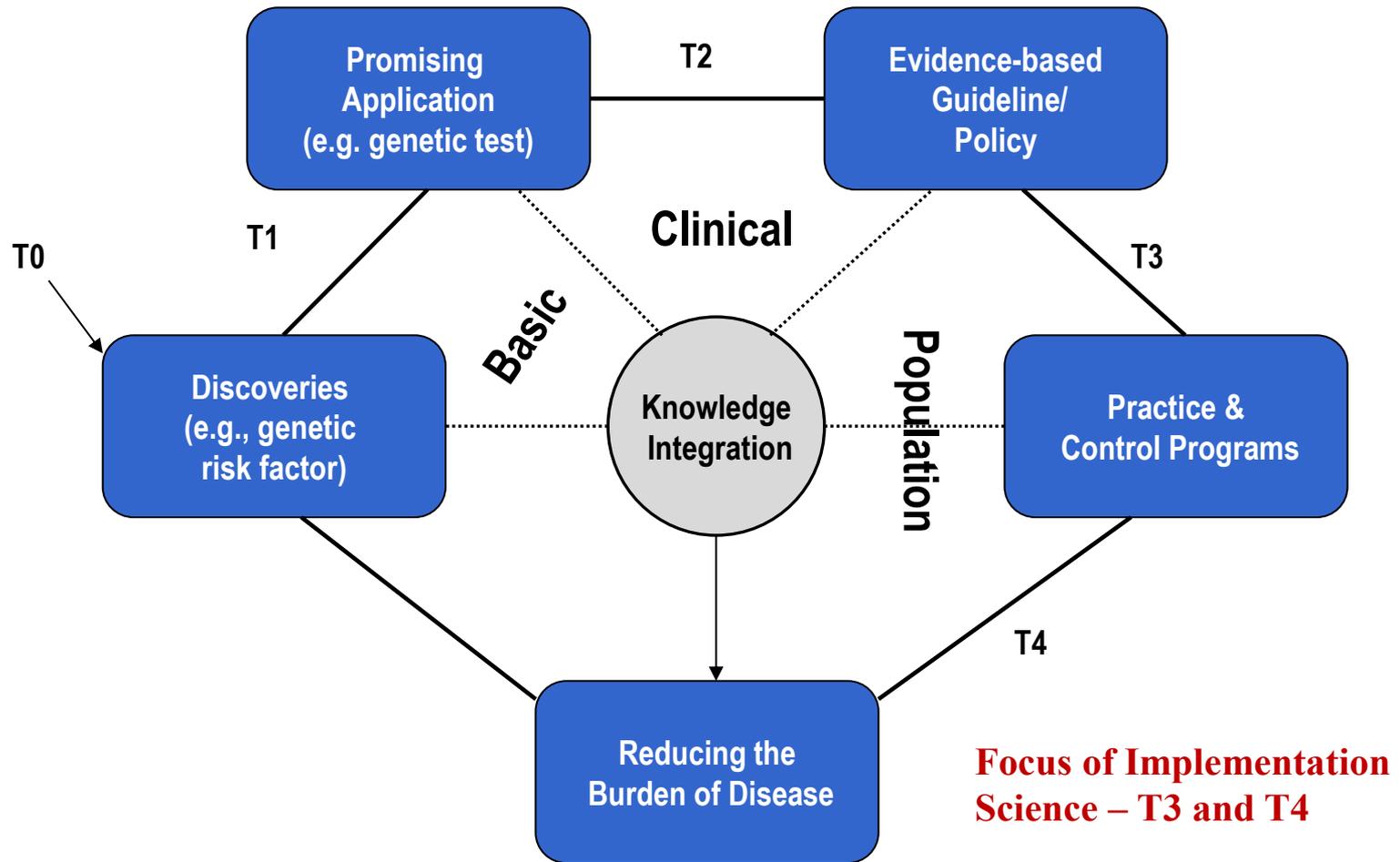
Modified from Khoury et al. *Genetics in Medicine* 2007;9(10):665-674

Glasgow RE, et al. *Am J Public Health* 2012;Jul;102(7):1274-1281

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

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Bench to Bookshelf
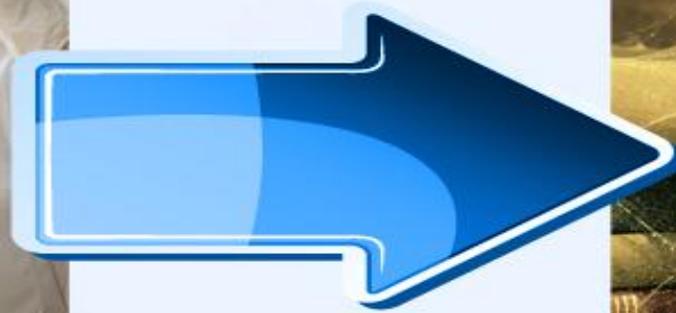
Implementation Science Models
Key Common Points

- 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

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

"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

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

	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

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
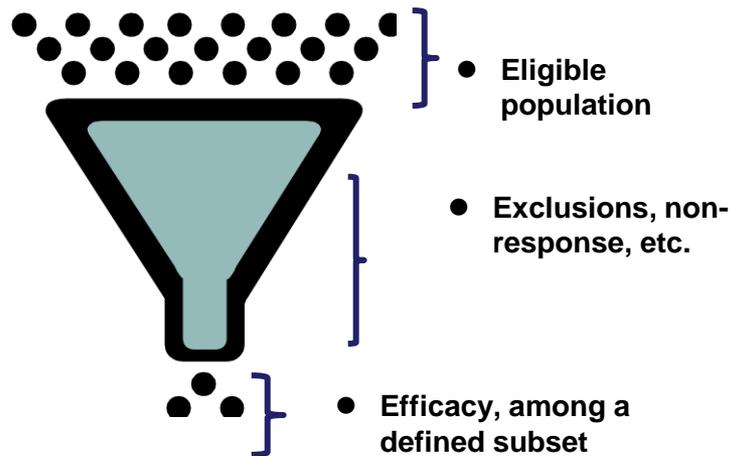
Pragmatic Control Trial

- Eligible population
- Exclusions, non-response, etc.
- Effectiveness, in a broad subset
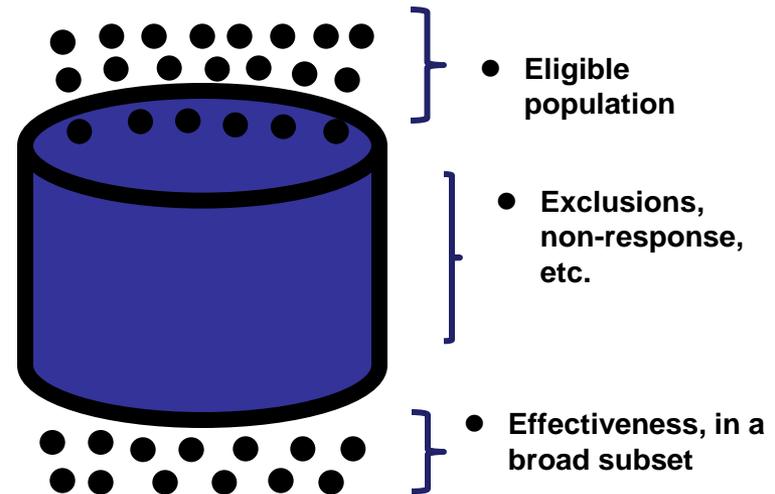
Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research

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

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

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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)

Intervention Program/Policy
(Prevention or Treatment)
(e.g., key components; principles; guidebook; internal & external validity)

Feedback

Feedback

Evidence

Stakeholders

Participatory Implementation Process
(e.g., stakeholder engagement; CBPR; team-based science; patient centered)

Feedback

Practical Progress Measures
(e.g., actionable & longitudinal measures)
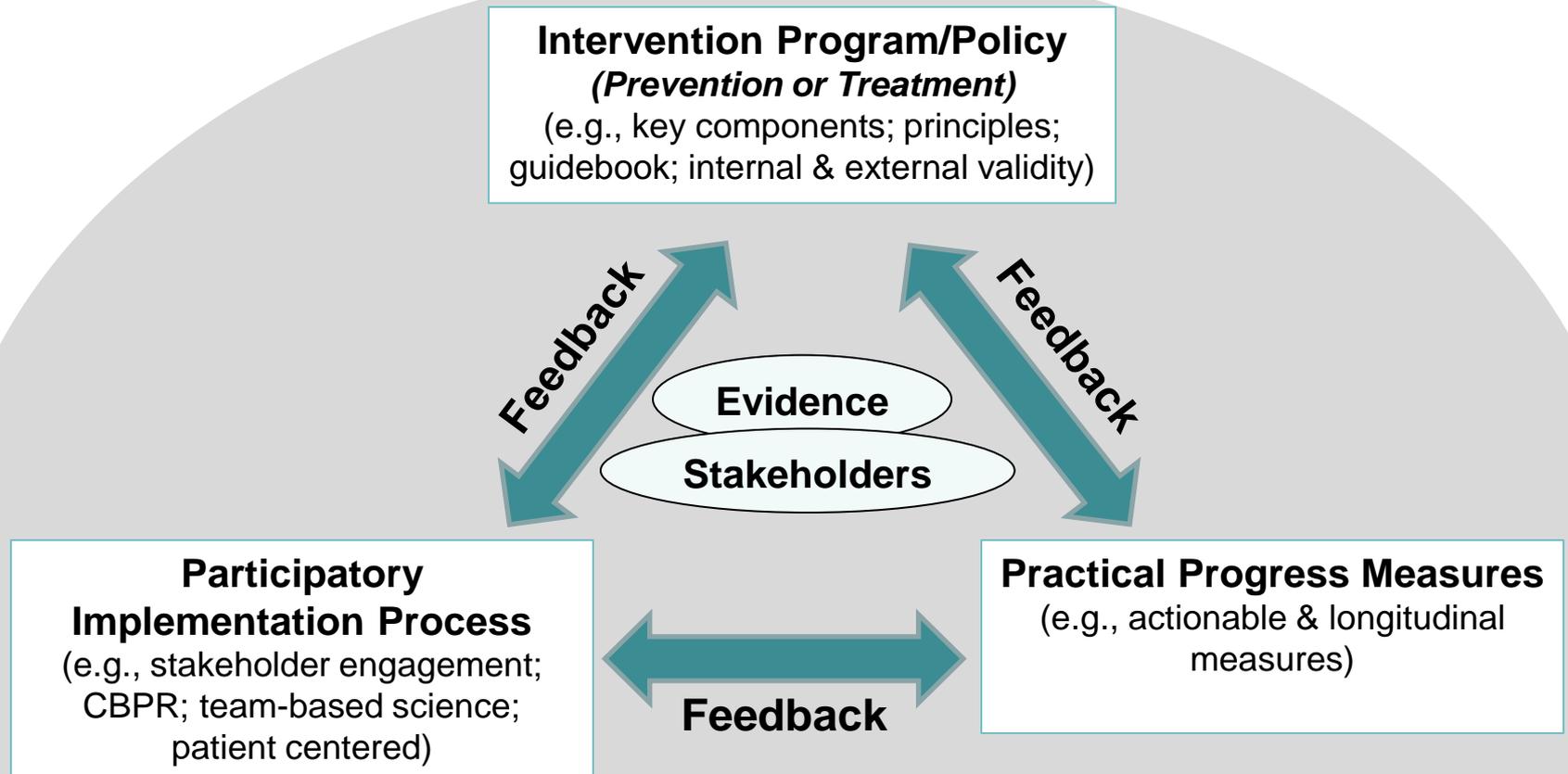
Multi-Level Context

- Intrapersonal/Biological
- Interpersonal/Family
- Organizational
- Policy
- Community/Economic
- Social/Environment/History

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

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

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

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

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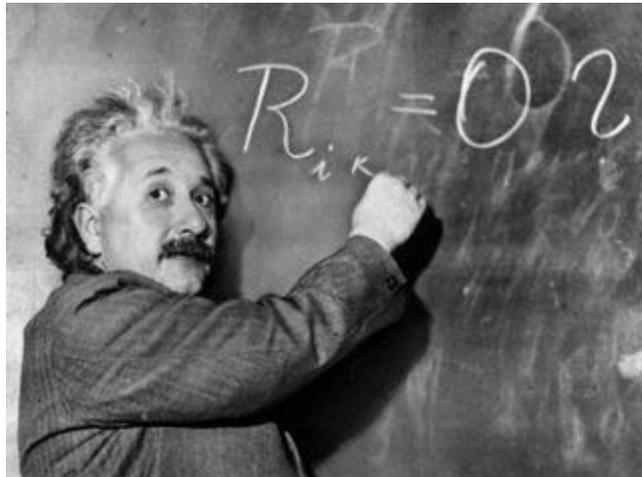
~A. Einstein

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*

Feedback

Feedback

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

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

Feedback

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

Multi-Level Context

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

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

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: <u>Patient-Reported Measures</u>

- *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.

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

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

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

Domain	Final Measure (Source)
1. Overall Health Status	1 item: BRFSS Questionnaire
2. 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]
3. Physical Activity	2 items: The Exercise Vital Sign [Sallis R. *Br J Sports Med* 2011;45(6):473-474]
4. Stress	1 item: Distress Thermometer [Roth AJ, et al. *Cancer* 1998;15(82):1904-1908]
5. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. *Psychosomatics* 2009;50(6):613-621]
6. Sleep	2 items: a. Adapted from BRFSS b. Neuro-QOL [Item PQSLP04]
7. Smoking/Tobacco Use	2 items: Tobacco Use Screener [Adapted from YRBSS Questionnaire]
8. Risky Drinking	1 item: Alcohol Use Screener [Smith et al. *J Gen Int Med* 2009;24(7):783-788]
9. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. *Arch Int Med* 2010;170(13):1155-1160]
10. 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)*

MyOwnHealthReport

Developing *M*y *O*wn *H*ealth *R*eport

- 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

Database of text messages and triggers

Summary display and printout for patient

Action Plan printout

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

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

Context Assessment
(Both EIS & DIS)

Context
Update- EIS

Contextual
Changes
Update- EIS & DIS

Pilot in
EIS

Intervention EIS

Cost of
Intervention
Collection-
EIS

Cost of
Intervention
Collection- EIS

Long-term
Implementation &
Adaptation
Check - EIS

Implementation Data Collected-EIS

IRB Approval

Patient Experience
Survey—EIS &DIS

Post-Intervention
Staff Interview—EIS

Optional MOHR Patient Reported Outcomes
Follow-up--EIS

Intervention--DIS

Implementation Data Collected-
DIS

Post –Intervention Staff
Interviews—DIS

Pre-Implementation   1   2   3   4   5   6   7   8   9   After 9/30/13

←————————————   Months   ————————————→

*EIS=Early Interventions Site   DIS=Later Intervention Sites   MOHR= My Own Health Report

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, variation across sites and implementation models, lessons learned

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**

MyOwnHealthReport

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

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

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NCIdccpsISteam@mail.nih.gov

TIME FOR QUESTIONS
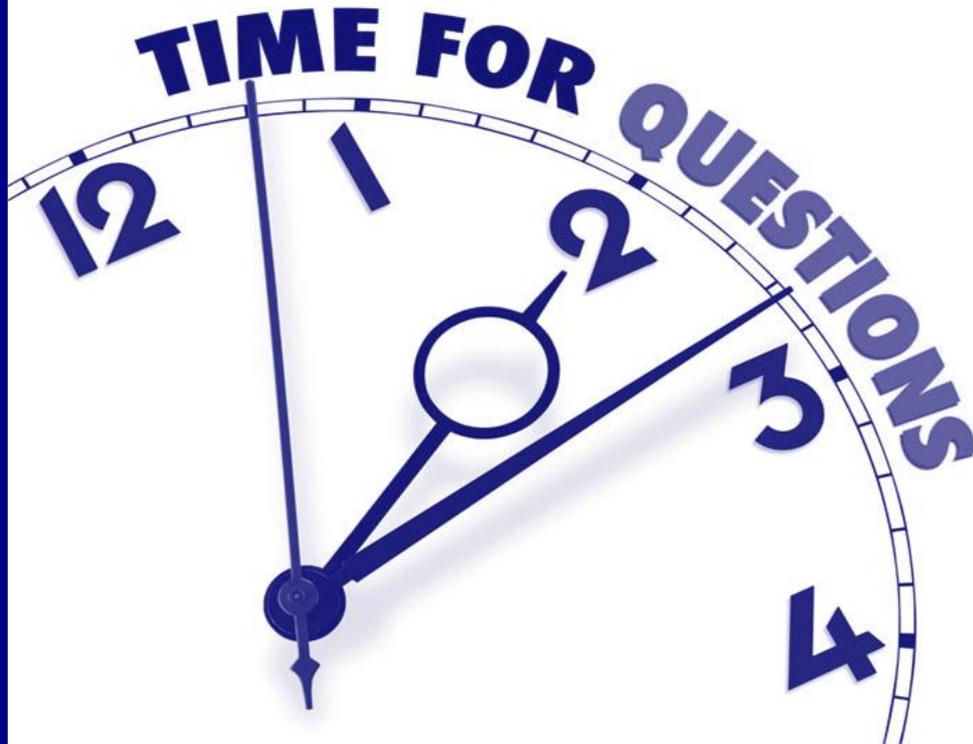
Why Not Just Use PROMIS Measures?

- 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

"**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

![MyOwnHealthReport] **Patient Health Summary Report**

Date of Birth: 1/1/1970

Visit Date	Height	Weight	BMI
1/30/2013	6 ft. 1 in.	210 pounds	27.7

YOUR Health Behaviors and Mental Health

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

⭐ = Most important to you

Keep up the GOOD Work!
- You are meeting or exceeding the physical activity recommendations for health.
- You said there are few days you feel nervous, anxious, on edge or unable to stop or control worrying.
- You said there are few days you feel down, depressed, hopeless or have little interest or pleasure.
- You never drink too much alcohol.
- You do not use illegal drugs or prescription medications for non-prescribed reasons.

Recommendations to Improve Your Health

Medium Priority
- Excess weight can lead to a number of health problems. Increase physical activity and/or limit the unhealthy food you eat to reduce your weight.
- Decrease your fast food meals or snacks to less than one per week.
- Decrease the number of soda 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.

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