EVALUATION FOR D&I: MODELS, PRAGMATISM, RELEVANCE, RE-AIM, RESOURCES, AND REPORTING

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CONFLICTS OF INTEREST

- No conflicts of interest to disclose
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OVERVIEW

- Evaluation- formative, iterative and summative
- Pragmatic Research and PRECIS Planning Model (exercise)
- Selecting an Evaluation Model - tips and options
  - RE-AIM
  - Concrete example (exercise)
- Resources Required
- Reporting and Replication (StaRI and ultimate use question)
- Discussion - Q and A
EVALUATION

- General: Evaluation is the systematic collection of information about the activities, characteristics, and results of programs to make judgments about the program, improve or further develop program effectiveness, inform decisions about future programming, and/or increase understanding.

- For D&I: This includes stakeholder-based assessment of multi-level and contextual influences on processes, and the outcomes related to producing broad, population-based impact, and understanding of how, why and under what conditions these results were obtained.
DEFINITION AND OPPORTUNITIES

- Formative* – more than focus groups; design for dissemination
- Iterative – merge/interface with QI; little done; new area for D&I
- Summative** – many models to guide evaluation
- It is never too early to begin evaluation, designing for dissemination, and considering ‘ultimate use’
ULTIMATE USE QUESTION - TAKE AWAY FROM THIS TALK

“What program/policy components are most effective for producing what outcomes for which populations/recipients when implemented by what type of persons under what conditions, with how many resources and how/why do these results come about?”

NOT possible to address all these issues in any one study.... BUT should consider each of them pragmatically and transparently; then select and report those most relevant.
A DIFFERENT APPROACH: PRAGMATIC RESEARCH

External Validity/Pragmatic Criteria - often ignored

- Participant Representativeness
- Setting Representativeness
- *Multi-level Context* and Setting
- Community/Setting Engagement
- Adaptation/Change in Intervention and Implementation Strategies
- Sustainability
- Costs/Feasibility of Treatment
- Comparison Conditions
THE 5 Rs
TO ENHANCE PRAGMATISM AND LIKELIHOOD OF TRANSLATION

Research that is:

- Relevant
- Rapid and recursive
- Redefines rigor
- Reports resources required
- Replicable


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

A. Einstein
ENHANCING PRAGMATIC RESEARCH

“If we want more evidence-based practice, we need more practice-based evidence.”

External Validity/ Pragmatic Criteria - often ignored

- Participant **Representativeness**
- Setting Representativeness
- **Multi-Level Context** and Setting
- Community/Setting Engagement
- **Adaptation/change**
- Sustainability
- **Costs, Feasibility** of Program or Policy
- Comparison Conditions
### Key Differences Between Traditional Randomized Control Trials (RCT) and Pragmatic Controlled Trials (PCT)

<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 <strong>determine causes</strong> and effects of treatment</td>
<td>To improve practice <strong>and inform clinical and policy decisions</strong></td>
</tr>
<tr>
<td><strong>DESIGN</strong></td>
<td>Tests the intervention against placebo using rigid study protocols and minimal variation</td>
<td>Tests two or more real-world treatments using flexible protocols and local customization</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>
THE PRAGMATIC-EXPLANATORY CONTINUUM INDICATOR SUMMARY (PRECIS-2) PLANNING TOOL

- How pragmatic (vs. explanatory or efficacy) is your study?
- Tool and graphic to help in planning and reporting. (see next slide)
- HANDOUT AND HOMEWORK: Complete next Figure


ELIGIBILITY
Who is selected to participate in the trial?

RECRUITMENT
How are participants recruited into the trial?

SETTING
Where is the trial being done?

ORGANISATION
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?

1
2
3
4
5
ACHIEVING THE 5 Rs: RE-AIM FRAMEWORK
WWW.RE-AIM.ORG
91 frameworks:
Most common at NIH: REAIM and DOI
Many commonalities across models and theories
ACHIEVING THE 5 Rs: RE-AIM FRAMEWORK
WWW.RE-AIM.ORG

Focus on enhancing:

- **Reach** – Participation rates and **representativeness**
- **Effectiveness** – Breadth (quality of life), **including negative or unintended effects**
- **Adoption** - Setting and staff participation rate and representativeness
- **Implementation** – Consistency, **adaptation and costs** of the program
- **Maintenance** – Extent to which program and effects are **sustained**


### Example of Translation of Interventions into Practice

<table>
<thead>
<tr>
<th>Dissemination Step</th>
<th>RE-AIM Concept</th>
<th>% Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of settings use intervention</td>
<td>Adoption</td>
<td>50.0%</td>
</tr>
<tr>
<td>50% of staff take part</td>
<td>Adoption</td>
<td>25.0%</td>
</tr>
<tr>
<td>50% of patients identified, accept</td>
<td>Reach</td>
<td>12.5%</td>
</tr>
<tr>
<td>50% follow regimen correctly</td>
<td>Implementation</td>
<td>6.2%</td>
</tr>
<tr>
<td>50% benefit from the intervention</td>
<td>Effectiveness</td>
<td>3.2%</td>
</tr>
<tr>
<td>50% continue to benefit after six months</td>
<td>Maintenance</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

Re-aim.org
What is the moral of this story?
EXAMPLE: MY OWN HEALTH REPORT (MOHR) STUDY

Cluster randomized pragmatic trial of web-based brief health behavior and mental health assessment and intervention in 9 diverse pairs of primary care practices to test whether they could implement My Own Health Report (MOHR). Outcomes included:

- **Reach** of the MOHR program across patients
- Whether practices would **adopt** MOHR
- How practices would **implement** MOHR
- **Effectiveness** of the MOHR program
### Patient Health Summary Report

**Date of Birth:** 1/11/1970

<table>
<thead>
<tr>
<th>Visit Date</th>
<th>Height</th>
<th>Weight</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/30/2013</td>
<td>6 ft 1 in</td>
<td>210 pounds</td>
<td>27.7</td>
</tr>
</tbody>
</table>

### 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><strong>Overall Health Rating</strong></td>
<td>Good to Excellent</td>
<td>Poor</td>
<td>A Lot</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Body Mass Index</strong></td>
<td>20-25</td>
<td>27.7</td>
<td>Some</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Health Behaviors

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>Your Performance</th>
<th>Level of Concern</th>
<th>Ready to Change?</th>
<th>Want to Discuss?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruits/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>None</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sodium/Sugary Beverage Intake</td>
<td>Less than 1/day</td>
<td>1 to 2/day</td>
<td>Some</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>
</tbody>
</table>

#### Mental Health

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>Your Performance</th>
<th>Level of Concern</th>
<th>Ready to Change?</th>
<th>Want to Discuss?</th>
</tr>
</thead>
<tbody>
<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
OVERALL REACH
1768 OF 3591 PATIENTS (49.2%)

Mailed (patient complete)
Site 1: 100 of 344 (29.1%)
Site 3: 11 of 420 (2.6%)
Site 4: 138 of 444 (31.3%)
Site 5: 115 of 248 (46.4%)

Phone (nurse complete)
Site 3: 291 of 453 (64.2%)

Lobby (patient + MD complete)
Site 2: 192 of 437 (43.9%)

Lobby (MA or coordinator)
Site 6: 265 of 287 (92.3%)
Site 7: 211 of 306 (69.0%)
Site 8: 247 of 323 (76.5%)
Site 9: 198 of 329 (60.2%)
WEEKLY MOHR REACH

Graph showing the number of patients completing MOHR across different sites over study weeks.
ADOPTION

18 practices agreed to adopt MOHR

- 30 practices approached (adoption 60%)
- 7 of 9 sites recruited first practices approached
  - decliners participating in other studies, worried about workload or doing HRAs
- Participating practices represented a diverse spectrum of primary care (see Table 1)
IMPLEMENTATION

Practices used one or more of **four main implementation strategies**

- Web at home (n=3), called patients (n=1), completed in office on paper (n=1), or electronically in office (n=4)
- 4 had patients and 5 had staff complete MOHR with patients
- 8 needed research team or health system help
- 8 had clinicians counsel patients, 4 had some follow-up, 1 had no counseling or follow-up
- Delivering MOHR took ~28 minutes (16-31) including assessment and feedback
NUMBER OF HEALTH RISK FACTORS BY SITE

$p < 0.0001$
### DID ANYONE HELP YOU SET A GOAL?

<table>
<thead>
<tr>
<th>Topics</th>
<th>% Yes</th>
<th></th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Eating/Diet</td>
<td>51.7</td>
<td>34.1</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Physical Activity/Exercise</td>
<td>49.5</td>
<td>37.9</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Tobacco/Smoking</td>
<td>22.6</td>
<td>19.7</td>
<td>0.0769</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>17.1</td>
<td>13.1</td>
<td>0.0055</td>
</tr>
<tr>
<td>Drug Use</td>
<td>13.5</td>
<td>11.4</td>
<td>0.1012</td>
</tr>
<tr>
<td>Stress Level</td>
<td>31.2</td>
<td>22.2</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Anxiety/Depression</td>
<td>32.1</td>
<td>23.1</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Sleep</td>
<td>29.6</td>
<td>24.4</td>
<td>0.003</td>
</tr>
</tbody>
</table>
### HAVE YOU MADE ANY POSITIVE CHANGES?

<table>
<thead>
<tr>
<th>Topics</th>
<th>% Yes</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Eating/Diet</td>
<td>62.9</td>
<td>49.9</td>
</tr>
<tr>
<td>Physical Activity/Exercise</td>
<td>55.1</td>
<td>48.2</td>
</tr>
<tr>
<td>Tobacco/Smoking</td>
<td>17.3</td>
<td>16.6</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>15.2</td>
<td>14</td>
</tr>
<tr>
<td>Drug Use</td>
<td>11.5</td>
<td>11.2</td>
</tr>
<tr>
<td>Stress Level</td>
<td>31.2</td>
<td>25.1</td>
</tr>
<tr>
<td>Anxiety/Depression</td>
<td>29.2</td>
<td>24.6</td>
</tr>
<tr>
<td>Sleep</td>
<td>30.2</td>
<td>24.4</td>
</tr>
</tbody>
</table>
Moral of this example?
RE-AIM PRECISION (PERSONALIZED) MEDICINE QUESTIONS

Determine:

• What percent and types of patients are Reached;

• For whom among them is the intervention Effective, in improving what outcomes, with what unanticipated consequences;

• In what percent and types of settings and staff is this approach Adopted;

• How consistently are different parts of it Implemented at what cost to different parties;

• And how well are the intervention components and their effects Maintained?
EVOLUTION OF RE-AIM (ALL MODELS ARE WRONG)

Reviews documenting use over time

- Applicability to many different content areas
- Used for both planning and evaluation

Underreporting of key components

- Setting level factors reported much less often (e.g., adoption)
- Maintenance (sustainability) reported least often


NEW AREAS

- Health Policy
- Multilevel Community Interventions
- Built Environment
- Understanding Adaptations to Programs
- Mixed Methods

Focus on Context!
**HANDOUT AND HOMEWORK: Key translation and pragmatic questions to consider for the RE-AIM dimensions**

<table>
<thead>
<tr>
<th>RE-AIM Dimension</th>
<th>Key pragmatic questions to consider and answer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reach</strong></td>
<td>WHO is/was intended to benefit, and who actually participates or is exposed to the intervention?</td>
</tr>
<tr>
<td><strong>Effectiveness</strong></td>
<td>WHAT is/was the most important benefits you are trying to achieve and what is/was the likelihood of negative outcomes?</td>
</tr>
<tr>
<td><strong>Adoption</strong></td>
<td>WHERE is/was the program or policy applied, and WHO applied it?</td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>HOW consistently is/was the program or policy delivered, HOW will/was it be/ing adapted, HOW much will/did it cost, and HOW/WHY will/did the results come about?</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>WHEN will (was) the initiative become operational; how long will (was) it be sustained (Setting level); and how long are the results sustained (Individual level)?</td>
</tr>
</tbody>
</table>
REPORTING RESOURCES REQUIRED

- Reporting on cost and other resources in a standardized manner is useful in:
  - Demonstrating value
  - Promoting rigor, transparency and relevance to stakeholders
- Present from perspective of stakeholders and decision makers
- Simple is fine – sophisticated economic analyses are not needed
  - Report costs of conducting or replicating interventions
  - Beyond money, costs can include clinician and staff time, training, infrastructure, startup costs, opportunity costs

STANDARDS FOR REPORTING IMPLEMENTATION STUDIES (STARI)

27 reporting criteria identified by systematic review and international experts. INCLUDING:

- both implementation strategies and intervention effects
- related to, but expansion of CONSORT criteria
- reporting of context including SDOH and policy issues
- cost and economic outcomes
- fidelity and adaptations
- harms and unintended effects
- representativeness and estimated scalability

ULTIMATE USE QUESTION

- “What program/policy components are most effective for producing what outcomes for which populations/recipient when implemented by what type of persons under what conditions, with how many resources and how/why do these results come about?”

- NOT possible to address all these issues in any one study.... BUT should consider each or them pragmatically and transparently; then select and report those most relevant.
QUESTIONS? COMMENTS? I’M ALL EARS
RESOURCES (see handout)

- www.re-aim.org
- www.ucdenver.edu/accords/implementation
- www.Dissemination-Implementation.org