What Can Researchers Do to Address Health Inequities? Pragmatic Models, Methods and Measures

Russell E. Glasgow, PhD
Research Professor, Department of Family Medicine
Director, ACCORDS Dissemination and Implementation Science Program

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About Me

• Trained as behavioral scientist
• Experience working in academic, health research (managed care and VA), and government (NCI Implementation Science) settings
• Focus on health equity at levels of recruitment, implementation, sustainability and dissemination stages of research and evaluation
• Primary focus on pragmatic research*
• Content experience in research on behavior change (organizational, staff and patient/family levels), chronic illness prevention and management, and cancer prevention and control
• Work with community health centers, tribal communities, diverse worksites, community initiatives, and primary care settings
• .......and an old, white male

Collaborative learning partnerships to translate research into practice more quickly and successfully

Local consultation on D&I related research to increase funding and publication success

Interactive on-line resources and support for patients, medical and public health students, trainees and faculty researchers

Frequently updated information on D&I related conferences, articles, grant opportunities, events, webinars, talks, and training

Cutting edge research on: pragmatic research and measures, adaptation of interventions, designing for dissemination, shared decision making, planning for and evaluation of reach, implementation and sustainability

www.ucdenver.edu/accords/implementation
Problems Applying Evidence-Based Research to Health Equity

• Lack of information on inclusion criteria and participation for settings and patients creates questions about relevance

• Lack of focus on reducing rather than documenting inequities

• Not assessing or considering impact of social determinants of health or context*

• Focus on average outcomes rather than different subgroups

Opportunities to Address Health Inequities

• Problem Identification and Question Specification

• Planning and Design (PRECIS pragmatic methods*)

• Implementation

• Analyses

• Interpretation and Dissemination

THE IDEALIST VS. THE PRAGMATIST

DUUDE, I HAVE SOOO MANY IDEAS THAT WOULD REVOLUTIONIZE LIFE ON EARTH AND BRING AWESOMENESS TO MANKIND.

HOW 'BOUT YOU JUST TAKE OUT THE GARBAGE AND DO THE DISHES FOR ONCE??
Problem Identification and Question Specification

- Select a problem where there are important health inequities (not just what is easy to study or you have researched before)

- Consider studying or at least including policies and context

- Study interventions to reduce health inequities, not just more documentation

- Ask more sophisticated questions than just overall effects- e.g., what effects for which subgroups on which outcomes under what conditions over what time period?

Planning and Design

• Purposively include low-resources settings in sample

• Diversity and variation are good; not to be controlled or minimized

• Research occurs in a multi-level context*

• Specify eligibility, recruitment, and participation at several levels:
  – Setting (worksite, community, clinic)
  – Staff or intervention agent (physician, lay health worker, nurse)
  – Patient and family
  – Choose a Pragmatic Design

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 Trial

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

Fig. provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research
<table>
<thead>
<tr>
<th>Contextual Data and Participation Rates</th>
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</thead>
<tbody>
<tr>
<td><strong>Total Number Potential Settings</strong></td>
</tr>
<tr>
<td>1. Settings Eligible (n and %)</td>
</tr>
<tr>
<td>2. Settings that Participate (n and %)</td>
</tr>
<tr>
<td>3. Agents or Staff Eligible (n and %)</td>
</tr>
<tr>
<td>4. Agents or Staff that Participate (n and %)</td>
</tr>
<tr>
<td>5. Total Potential Participants (n)</td>
</tr>
<tr>
<td>6. Individuals Eligible (n and %)</td>
</tr>
<tr>
<td>7. Individuals Randomized to Intervention or Control (n and %)</td>
</tr>
<tr>
<td>8. Treatment Present at Follow-up (n and %)</td>
</tr>
<tr>
<td>9. Treated Individuals Analyzed (n and %)</td>
</tr>
<tr>
<td>10. Settings in which Program Continued/Modified (n and %)</td>
</tr>
<tr>
<td><strong>Key Differences</strong></td>
</tr>
<tr>
<td><strong>Participants vs. Non-Participants</strong></td>
</tr>
<tr>
<td>Key Differences of Adopters vs. Non-Adopters (or none significant)</td>
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<tr>
<td>Key Differences of Staff Participants vs. Decliners (or none significant)</td>
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<tr>
<td>Key Differences of Participants vs. Decliners (or none significant)</td>
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<tr>
<td>Key Differences of Present vs. Lost (or none significant)</td>
</tr>
<tr>
<td>Key Differences of Analyzed vs. Excluded (or none significant)</td>
</tr>
<tr>
<td>Key Differences of Settings that Continue vs. Do Not (or none significant)</td>
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</tbody>
</table>
Implementation

- Consider and assess costs- to whom, including time and opportunity costs
- Study variability in results-over time, across settings, staff, and subgroups
- Evaluate if tasks can be performed by less expensive staff (work on task shifting from LMICs)
- Study adaptation*- it always happens; need to understand it
- Issues discussed thus far can create IMPACT and population health inequities even if apparent effectiveness is not differential

## RE-AIM—Health Equity Implications

<table>
<thead>
<tr>
<th>RE-AIM Issue</th>
<th>Disparity</th>
<th>Overall Population Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH- patient/citizen participation.</td>
<td>30%</td>
<td>70% of benefit</td>
</tr>
<tr>
<td>Effectiveness- main outcome</td>
<td>0 (equal)</td>
<td>70% of benefit</td>
</tr>
<tr>
<td>ADOPTION- Setting participation</td>
<td>30%</td>
<td>49% of benefit</td>
</tr>
<tr>
<td>IMPLEMENTATION- delivery of program or policy</td>
<td>30%</td>
<td>34% of benefit</td>
</tr>
<tr>
<td>MAINTENANCE- long term sustainability</td>
<td>30%</td>
<td>24% of benefit</td>
</tr>
</tbody>
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IS Team Presentation on Health Inequities: [http://cancercontrol.gov/IS/presentations.html](http://cancercontrol.gov/IS/presentations.html)
Analyses

• Consider all levels above- settings, staff, patient/family subgroups when interpreting results and making conclusions

• How generalizable are results?

• Include social determinants of health (e.g., food scarcity, transportation, housing insecurity, violence, social isolation, etc.)
  – These can have main effects, interactions or both

• Analyze for robustness and specificity of effects- not just overall averages

• Power for and analyze specific subgroup effects
Interpretation and Dissemination

• “Design for Dissemination”*- from the outset- do NOT wait until end of study
  – Engage stakeholders- throughout and in ongoing, meaningful level
  – Report what it takes to implement the program- what resources by whom for how long
  – One size does not fit all- need for cultural and local adaptation
  – Provide guides to adaptation and customization to ones setting-cultural, resource, patient population, workflow, etc.

Crosscutting Issues

• Consider, study and report context
• Combine quantitative and qualitative methods to give voice to study results
• Consider all levels- broad setting and context, specific setting, delivery staff, patients
• Ask “who participates, who benefits (and who does not), who suffers and who profits?”*
• Most important is transparency- in selection, methods, results, and their application

It won’t always seem fair....
## Key Differences between Traditional RCTs and Pragmatic Controlled Trials (PCTs)

<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>
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<tr>
<td><strong>GOALS</strong></td>
<td>To determine causes and effects of treatment</td>
<td>To improve practice and inform clinical and policy decisions</td>
</tr>
<tr>
<td><strong>DESIGN</strong></td>
<td>Tests the intervention against placebo using rigid study protocols and minimal variation</td>
<td><em>Tests two or more real-world using flexible protocols &amp; local customization</em></td>
</tr>
<tr>
<td><strong>PARTICIPANTS</strong></td>
<td>Highly defined and 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>
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