TRANSLATING RESEARCH INTO PRACTICE: PRAGMATIC RESEARCH APPROACHES

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CONFLICTS OF INTEREST

- No conflicts of interest to disclose

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It takes an average of 17 years before 14% of research findings are translated into practice.


In many fields, RCT’s remain the gold standard for clinical research. However, RCT’s have numerous limitations including:

- Not perceived as relevant or realistic
- Slow
- Complex and costly
- Lack of generalizability or replicability
A DIFFERENT APPROACH: PRAGMATIC RESEARCH

Pragmatic trial: Real-world test in a real-world population

Explanatory trial: Specialized experiment in a specialized population

Pragmatic designs emphasize:

- Participation or reach
- Adoption by diverse settings
- Ease of Implementation
- Maintenance
- Generalizability

The 5 R’s: To Enhance Pragmatism and Likelihood of Translation

Research that is:

- Relevant
- Rapid and Recursive
- Redefines Rigor
- Reports Resources Required
- Replicable


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

Main reason practitioners do not use research: not perceived as relevant

How to address relevance:

- Involve stakeholders and end users from the beginning (and continuously)
- Ultimate use perspective
- Make sample, resources, and staff similar to those in applied settings
- Partner with and learn from other disciplines


RAPID AND RECURSIVE

- When possible, use routinely collected clinical data from sources such as EHRs, registries, databases or research networks
- Include iterative mini-assessments and interviews to guide adjustments
- Concept of ‘Adaptome’ (Chambers et al, 2016)
- Use adaptive research designs
- Disseminate research findings to those who can use them


Pragmatic does not mean less rigorous!

To include external validity (generalizability) and representativeness

Includes transparent reporting of recruitment of settings and participants, modifications made, nonsignificant results and unanticipated impacts

Use of ‘Extended’ CONSORT diagram
EXTENDED CONSORT DIAGRAM

1. Total number of potential settings (n)
   - Settings eligible (n, %)
   - Excluded by investigator (n, %, reasons)

2. Settings and agents who participate, (n, %)

3. Staff who participate, (n, %)

4. Total potential participants (n)
   - Individuals eligible (n, %)
   - Excluded by investigator (n, %)
   - Not contacted/Other (n, %)

5. Settings and agents who decline (n, %)

6. Staff who decline, (n, %)

7. Other (n, %)
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

REPLICABILITY (AND GENERALIZABILITY)

- Important to report conditions under which program was delivered
  - To what extent is the program replicable:
    - In similar settings?
    - In different settings?

- Goal – what intervention do you compare it to (real world alternative)?

- PICOT – Population, Intervention, Control, Outcome, Target of the trial

- Bottom Line and 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?”
Focus on enhancing:

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


## WHY IS THIS IMPORTANT?
### IMPACT LOSS AT EACH RE-AIM STEP

<table>
<thead>
<tr>
<th>Dissemination Step</th>
<th>Concept</th>
<th>% Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of clinics use intervention</td>
<td>Adoption</td>
<td>50.0%</td>
</tr>
<tr>
<td>50% of clinicians/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>
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<tr>
<td>50% benefit from the intervention</td>
<td>Effectiveness</td>
<td>3.2%</td>
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<tr>
<td>50% continue to benefit after 6 months</td>
<td>Maintenance</td>
<td>1.6%</td>
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</tbody>
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PRAGMATIC RESEARCH

- What is it?
- Planning tools
- Large recent investment by NIH and PCORI
  - NIH: Pragmatic Trials
    - URL: http://commonfund.nih.gov/hcscollaboratory/
  - PCORI: several large pragmatic trials announcements up to $10 million
How pragmatic is your study?

Tool to help in planning and reporting.


THE PRAGMATIC-EXPLANATORY CONTINUUM INDICATOR SUMMARY (PRECIS): HOW PRAGMATIC IS YOUR STUDY?

10 domains plotted on a “spoke-and-wheel” diagram:

1. Eligibility criteria
2. Intervention flexibility
3. Practitioner expertise (experimental)
4. Comparison intervention
5. Practitioner expertise (comparison)
6. Follow-up intensity
7. Primary outcome
8. Participant compliance
9. Practitioner adherence
10. Primary analyses

Need for an expanded focus to produce:

- More relevant results
- More pragmatic research
  - Does not mean less rigorous!
  - From stakeholder/decision maker perspective
  - Specifies conditions of study to aid replication and judgment of applicability

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QUESTIONS?
MORE INFORMATION

- Re-aim.org
- https://www.precis-2.org/
- Betterevaluation.org