TRANSLATING RESEARCH INTO PRACTICE: PRAGMATIC RESEARCH APPROACHES

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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


ENHANCING PRAGMATIC RESEARCH

“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


**REDEFINES RIGOR**

- *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
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/recipients 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>
</tr>
<tr>
<td>50% continue to benefit after 6 months</td>
<td>Maintenance</td>
<td>1.6%</td>
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Re-aim.org
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
THE PRAGMATIC-EXPLANATORY CONTINUUM INDICATOR SUMMARY (PRECIS) PLANNING TOOL

- 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

SUMMARY: THE 5 R’S TO INCREASE USEFULNESS

- 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


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