



TRANSLATING RESEARCH INTO PRACTICE: PRAGMATIC RESEARCH APPROACHES

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CONFLICTS OF INTEREST

No conflicts of interest to disclose

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CHALLENGES TO TRADITIONAL OUTCOMES RESEARCH

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



Balas, E. Managing clinical knowledge for health care improvement. Yearbook of Medical Informatics. Stuttgart, Germany: Schattauer; 2000.

Green, L.W. (2006). Public health asks of systems science: to advance our evidence-based practice, can you help us get more practicebased evidence?. American journal of public health, 96(3), 406-409.

CHALLENGES TO TRADITIONAL OUTCOMES RESEARCH

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:

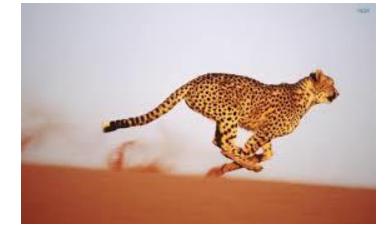
- Participation or reach
- Adoption by diverse settings
- Ease of Implementation
- Maintenance
- Generalizability

Maclure, M. (2009). Explaining pragmatic trials to pragmatic policy-makers. Canadian Medical Association Journal, 180(10), 1001-1003.

THE 5 R'S TO ENHANCE PRAGMATISM AND LIKELIHOOD OF TRANSLATION

Research that is:

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



Peek, C. J., et al. (2014). The 5 R's: An Emerging Bold Standard for Conducting Relevant Research in a Changing World. Annals Of Family Medicine, 12(5), 447-455. doi:10.1370/afm.1688

deGruy, F.V., et al. (2015). A plan for useful and timely family medicine and primary care research. Family medicine, 47(8), 636-42.

ENHANCING PRAGMATIC RESEARCH

"If we want more evidence-based practice, we need more practice-based evidence."

Green, L.W. (2006). Public health asks of systems science: to advance our evidence-based practice, can you help us get more practice-based evidence?. *American journal of public health*, 96(3), 406-409.

RELEVANCE

- 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

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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

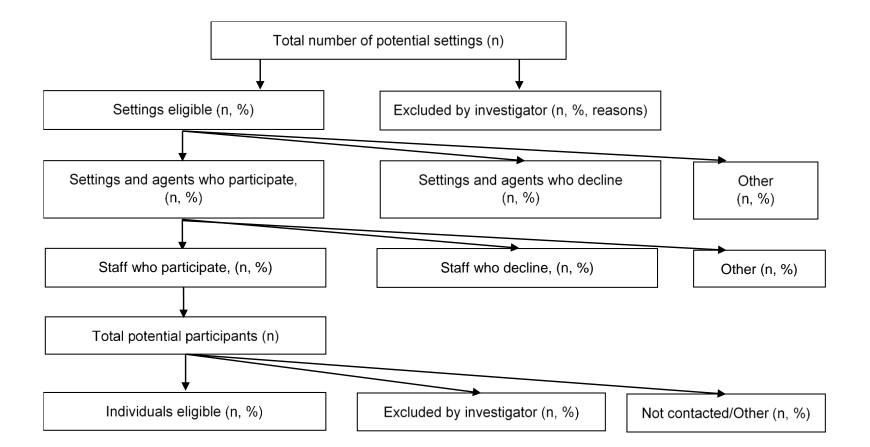
Glasgow, R. E., et al. (2014). Conducting rapid, relevant research: lessons learned from the My Own Health Report project. American journal of preventive medicine, 47(2), 212-219.

Chambers, D.A., et al. (2016). The Adaptome: Advancing the Science of Intervention Adaptation. American Journal of Preventive Medicine.

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

EXTENDED CONSORT DIAGRAM



re-aim.org: https://www.re-aim.hnfe.vt.edu/resources_and_tools/figures_and_tables/consort.pdf

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

Ritzwoller, D. P., et al. (2009). Costing behavioral interventions: a practical guide to enhance translation. Annals of Behavioral Medicine, 37(2), 218-227.

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?"

ACHIEVING THE 5 R'S: RE-AIM FRAMEWORK WWW.RE-AIM.ORG

Focus on <u>enhancing</u>:

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

Gaglio B, et al. The RE-AIM Framework: A Systematic Review of Use over Time. (2013). <u>Am J Public Health</u> Jun;103(6):e38-46. Kessler RS, et al.. (2012) What Does It Mean to "Employ" the RE-AIM Model? <u>Eval Health Prof</u> Mar; 36(1):44-66.

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

Example of Translation of Interventions into Practice		
Dissemination Step	Concept	% Impact
50% of clinics use intervention	Adoption	50.0%
50% of clinicians/staff take part	Adoption	25.0%
50% of patients identified accept	Reach	12.5%
50% follow regimen correctly	Implementation	6.2%
50% benefit from the intervention	Effectiveness	3.2%
50% continue to benefit after 6 months	Maintenance	1.6%

PRAGMATIC RESEARCH

- What is it?
- Planning tools
- Large recent investment by NIH and PCORI
 - NIH: Pragmatic Trials
 - URL: <u>http://commonfund.nih.gov/hcscollaboratory/</u>
 - PCORI: several large pragmatic trials announcements up to \$10 million
 - URL: <u>http://www.pcori.org/funding-opportunities/announcement/pragmatic-clinical-studies-</u> <u>Cycle-2-2016</u>

THE PRAGMATIC-EXPLANATORY CONTINUUM INDICATOR SUMMARY (PRECIS) PLANNING TOOL

- How pragmatic is your study?
- Tool to help in planning and reporting.

Gaglio, B., et al. (2014). How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research. *Implementation Science*, 9(1), 1.

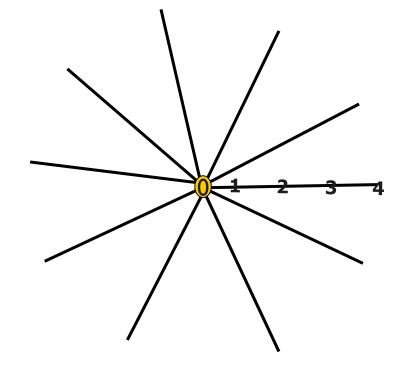
Thorpe KE, et al. A pragmatic-explanatory continuum indicator summary (PRECIS)...CMAJ 2009;180(10):E47-E57.

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

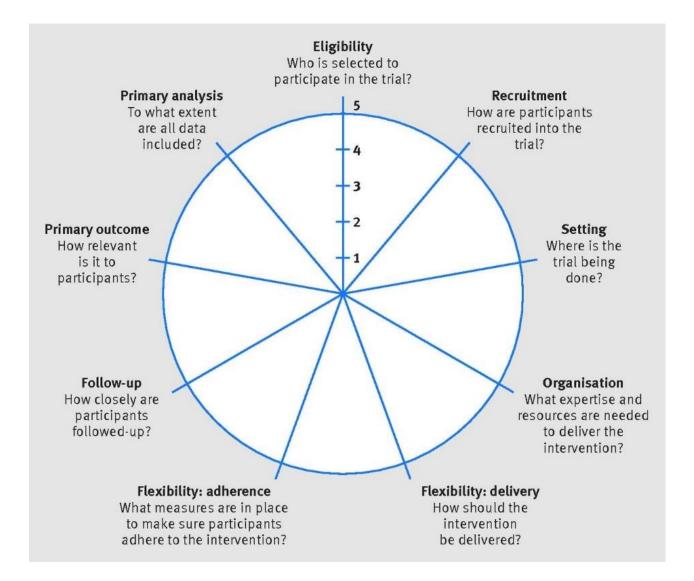
10 domains plotted on a "spoke-and-wheel" diagram:

- I. 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



Thorpe KE, et al. A pragmatic-explanatory continuum indicator summary (PRECIS)...CMAJ 2009;180(10):E47-E57.



Loudon, K., et al. "The PRECIS-2 tool: designing trials that are fit for purpose." BMJ 2015: h2147.

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

RELEVANT – RAPID – RIGOR – RESOURCES – REPLICABLE

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QUESTIONS?



MORE INFORMATION

- Re-aim.org
- https://www.precis-2.org/
- Brownson, R. C., Colditz, G.A., & Proctor, E. K. (2012). Dissemination and implementation research in health: translating science to practice. Oxford University Press.
- Betterevaluation.org