Types of Evidence

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What level of evidence do you draw on for your implementation study?

Key Questions:

Define study types that inform your intervention choice.

- What level of evidence does this represent?
- What setting does this arise from?
- What is your target intervention population?
- How does your definition of “evidence-based” fit with that from NIH?

A backdrop

- NIH calls for:
- "…invite research grant applications for research that will identify, develop, and refine effective and efficient methods, systems, infrastructures, and strategies to disseminate and implement evidence-based health behavior change interventions, prevention, early detection, diagnostic, treatment, symptom management, and quality of life improvement interventions, clinical guidelines, policies, and data monitoring and surveillance reporting tools into public health and clinical practice settings."

From: NIH PAR 13-055: Dissemination and Implementation Research in Health (R01)

A backdrop

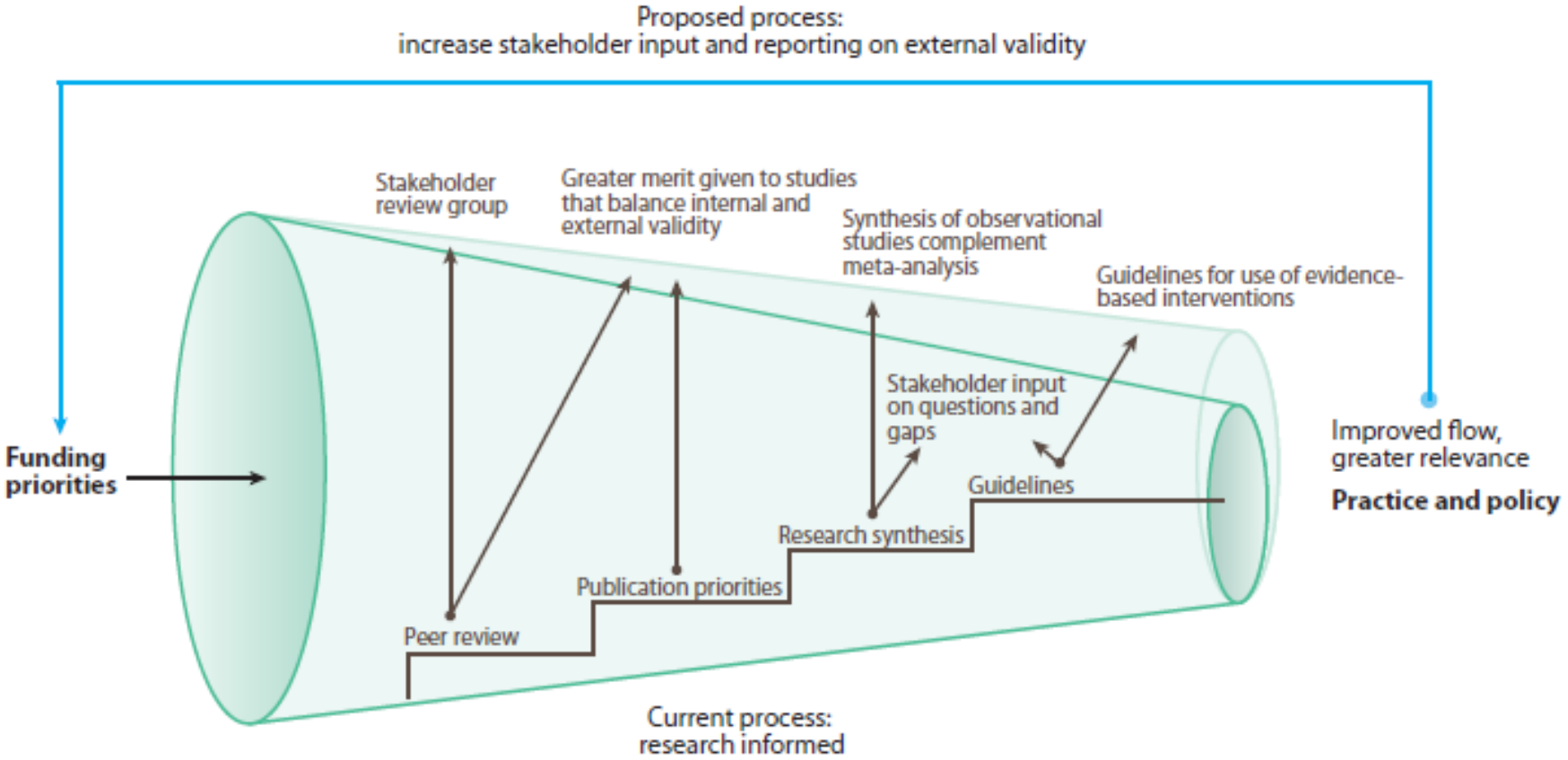
- Frequently calls for uptake of:
- Evidence-based interventions (not defined in PAR)
  - **Evidence-based intervention:** The objects of dissemination and implementation are interventions with proven efficacy and effectiveness.
- PAR refers to IOM, Community Guide, USPSTF
- To some degree “evidence” is in the eye of the beholder

Also see Rabin chapter in Oxford D&I text

The Challenges & Opportunities

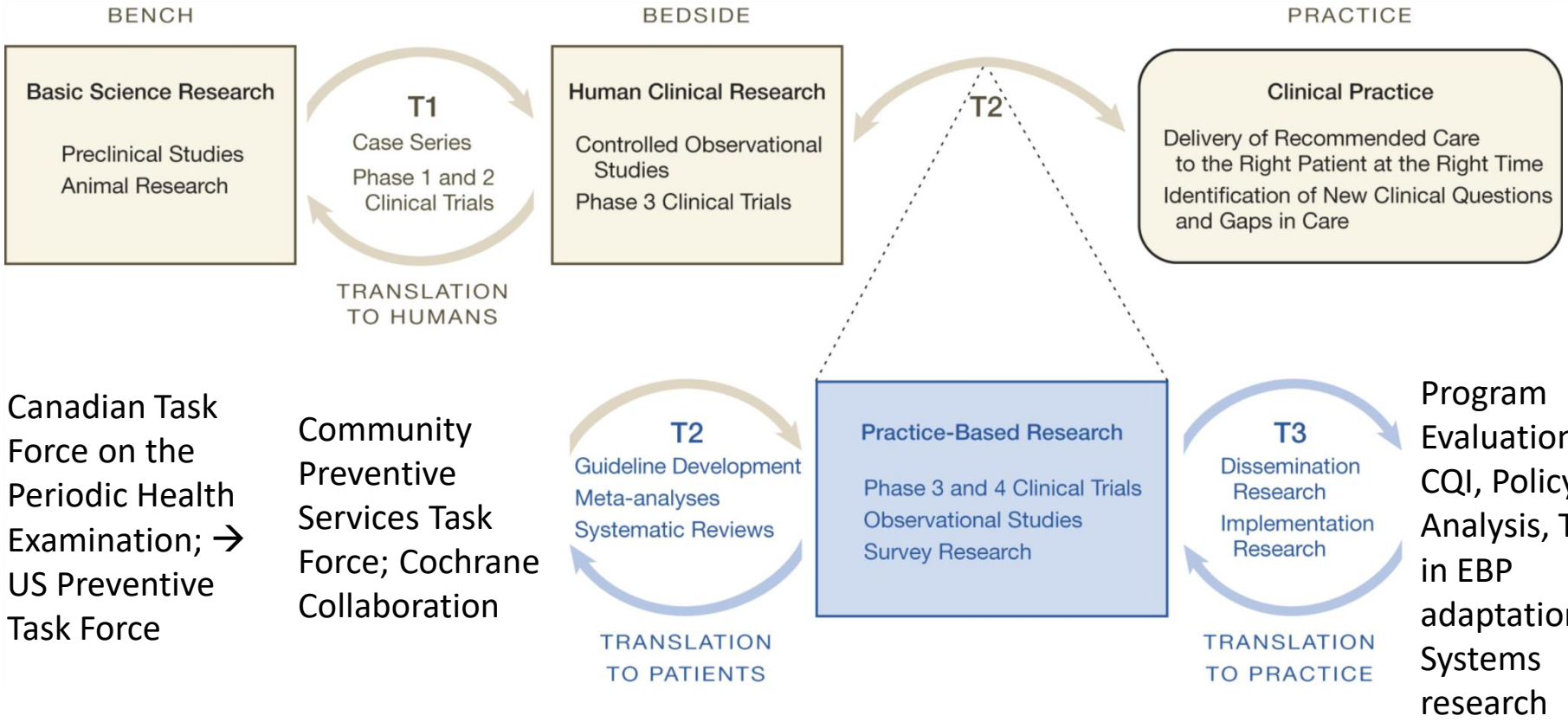
- The three biggest challenges:
  - To close the gap between the evidence for implementation that policy makers, program planners, practitioners and communities need, and what they are getting from our research
  - To make the case for an evidence-based intervention
  - Reform some peer review and editorial tendencies
- The biggest opportunities:
  - Extend participatory research principles to work with policy makers, program planners, and practitioners in use of natural experiments- e.g., surveillance, evaluation, and continuous quality improvement methods
  - Combine PR with multi-site RCT methods to expand the external validity of the results
  - Redesign incorporating design for implementation

Improving the flow and relevance of research evidence for implementation



R Lobb, GA Colditz. Implementation science and its application to population health. *Annu Rev Public Health*. 2013;34:235–251

“Blue Highways” on the NIH Roadmap



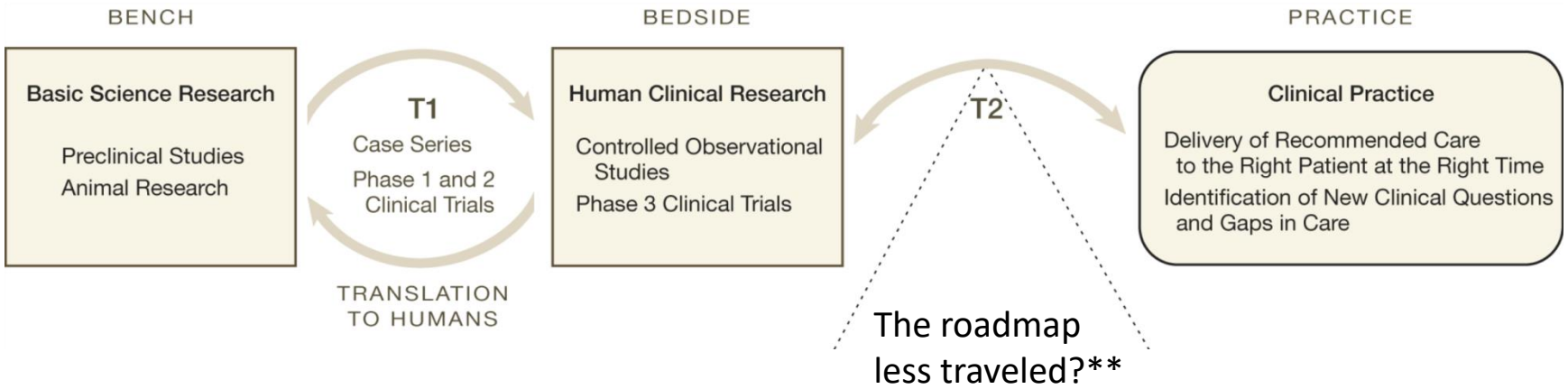
Canadian Task Force on the Periodic Health Examination; → US Preventive Task Force

Community Preventive Services Task Force; Cochrane Collaboration

Program Evaluation, CQI, Policy Analysis, TA in EBP adaptation. Systems research

Adapted from Westfall, J.M. et al. Practice-based research—”Blue Highways” on the NIH roadmap. *JAMA* 2007; 297:403-406

US NIH "Roadmap Initiative" "—translating discoveries into health"*



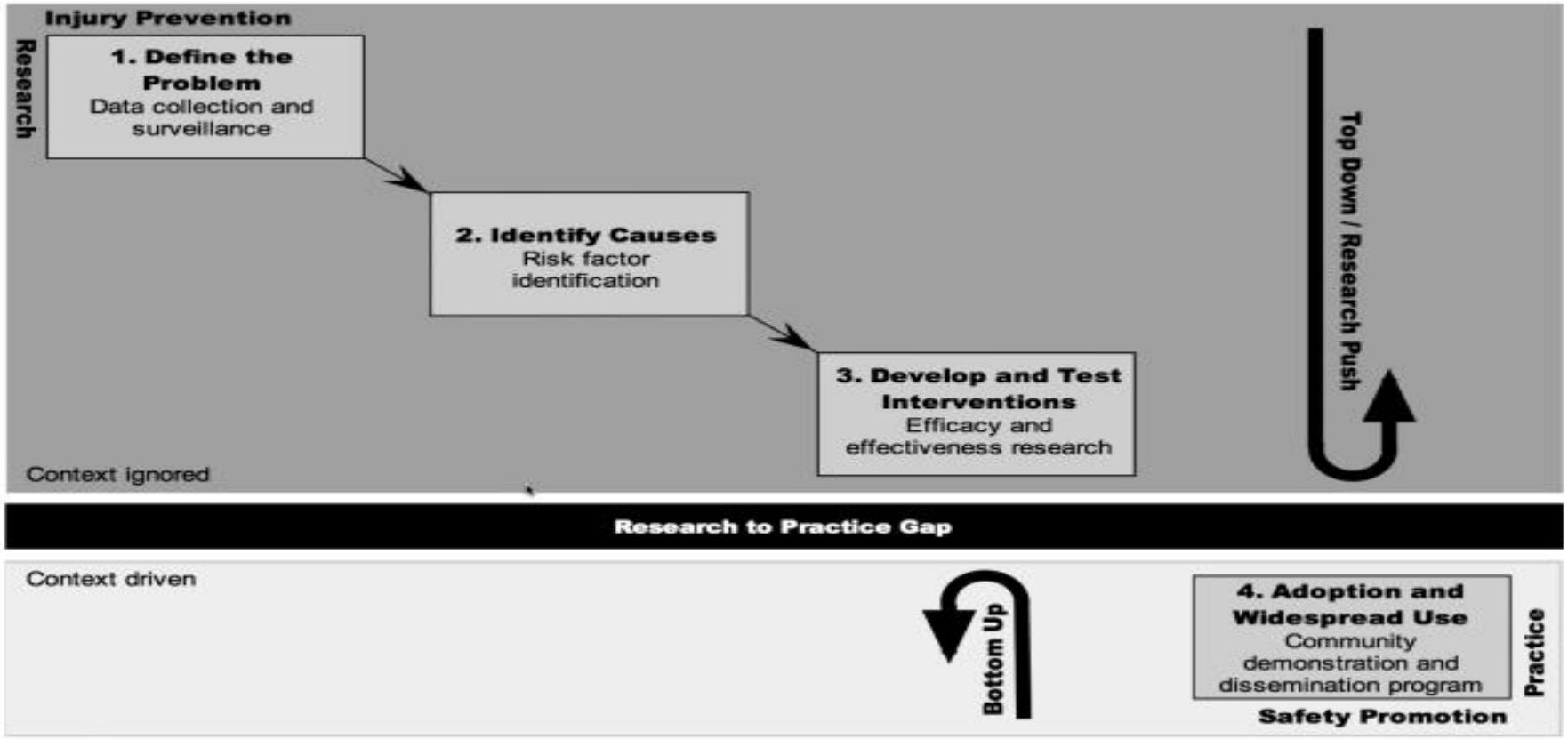
Alberts et al PNAS – Too much emphasis on translation and application – stifling discovery

Vs: the road map identifies most compelling opportunities in 3 arenas: new pathways to discovery; research teams of the future; reengineering the clinical research enterprise

*Zerhouni E., *Science* 2003, Oct 3:302(5642):63-72.

**Green LW, *Am J Prev Med*, 2007; 33(2);137-138

CDC's Blend of Top-Down Academic Evidence Push with Bottom-Up Practice Based Evidence



CDC, National Center for Injury Prevention & Control, as adapted by Hanson DW, et al. Closing the gap between injury prevention research and community safety promotion practice: Revising the public health model. *Public Health Reports* 2012;127(2), p. 147.

Threats to External Validity in the RCT Prevailing Standard of Evidence

- Intervention tested by comparison with a control condition
  - Interventions are highly standardized, reduced to simplistic form, and do not allow for any discretion by interventionists
  - All other factors are held constant
  - Clients are randomized and have no choice
- Change in outcome variables measured and compared between experimental and control groups
  - Comparison between experimental and control is based on average change for each group
  - Subgroup analysis is discouraged
  - Dropouts often discounted and ignored
  - Cut-off date for outcomes often too soon for change to occur

What's Good for Scientists Not Necessarily Good for Science

- Leveraging chance by running many low-powered studies, rather than a few high-powered ones (Ioannidis, 2005)
- Uncritically dismissing "failed" studies as pilot tests or because of methodological flaws, but uncritically accepting "successful" studies as methodologically sound (Bastardi et al., 2001; Lord et al., 1979)

Nosek et al., Scientific utopia: restructuring incentives and practice to promote truth over publishability. *Perspectives on Psychological Science*. 2012; 7:615.

Scientists vs Science vs Practice (cont'd)

- Selectively reporting studies with positive results and not studies with negative results[a] or selectively reporting "clean" results[b]
- Stopping data collection as soon as intended effect is obtained[c]
- Resting on internal validity without much concern for external validity[d]

[a]Greenwald, 1975; John et al., 2012; Rosenthal, 1979
[b]Begley & Ellis, 2012; Giner-Scrolla, 2012
[c]John et al., 2012; Simmons et al., 2011; Green et al., 2010
[d]Glasgow et al., 2006; Green & Glasgow, 2006; Green, 2006; Green et al., 2008

Problems Identified by IOM Report

- Narrow focus: Lack of attention to larger systems context
- Lacking details of implementation process
- Lack of relevance to real world
- Many studies focus on one intervention, but obesity may require a combination of interventions; in fact, some things appear not to work when tested alone, but are essential ingredients in a more comprehensive program (www.nap.edu)

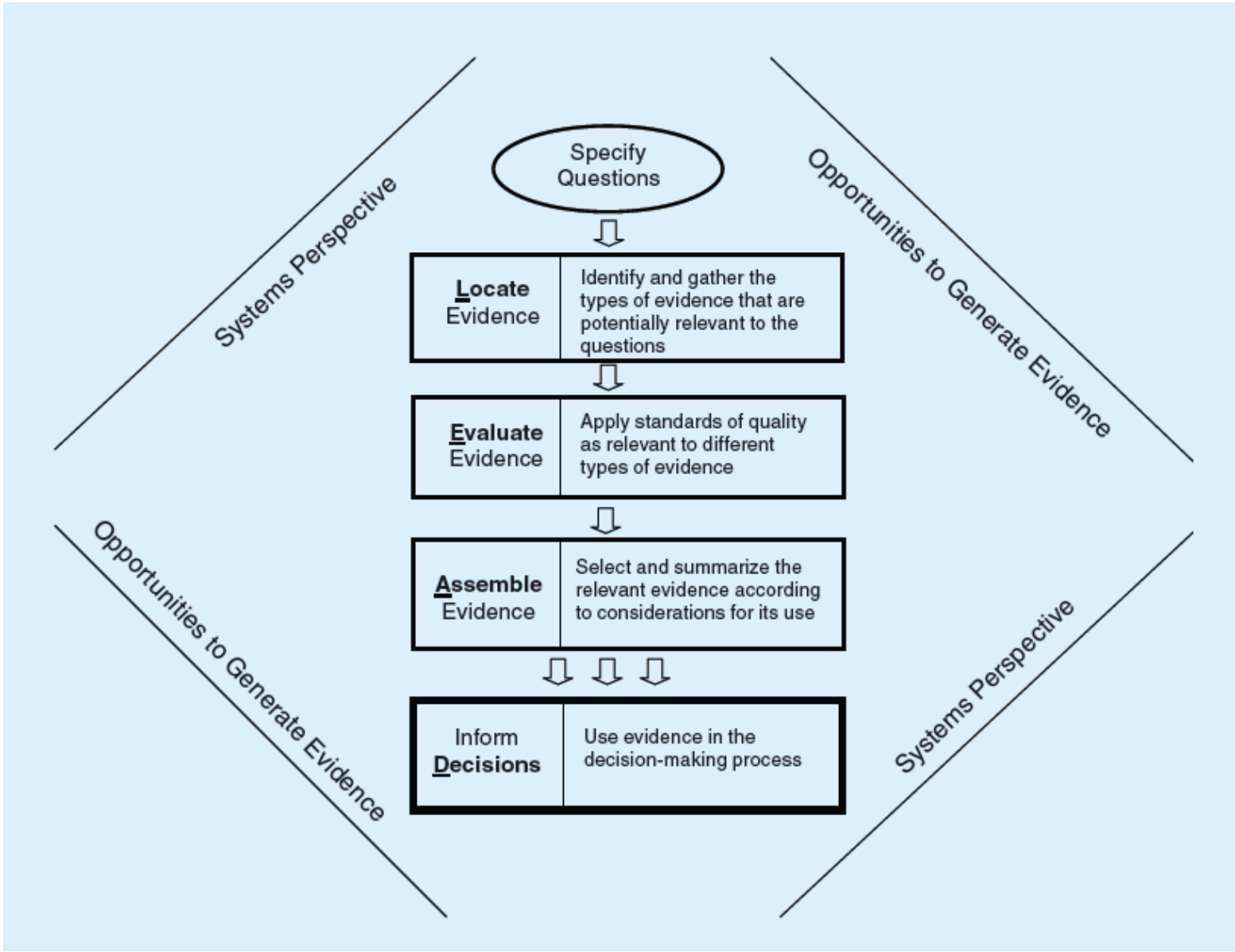
Institute of Medicine. *Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making*. Washington, DC: The National Academies Press, 2010.

IOM Conclusions about Status of Evidence

- The current evidence lacks the power to set a clear direction for obesity prevention across a range of target populations
- This lack of evidence for effectiveness seen as a lack of effectiveness
- It is difficult to fund, conduct, and publish research on community, environmental, and policy-based obesity prevention initiatives
- Assessing or reporting on generalizability of research results to other populations or settings has not been given priority

Institute of Medicine. *Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making*. Washington, DC: The National Academies Press, 2010.

The L.E.A.D. Framework for Obesity Prevention Decision Making



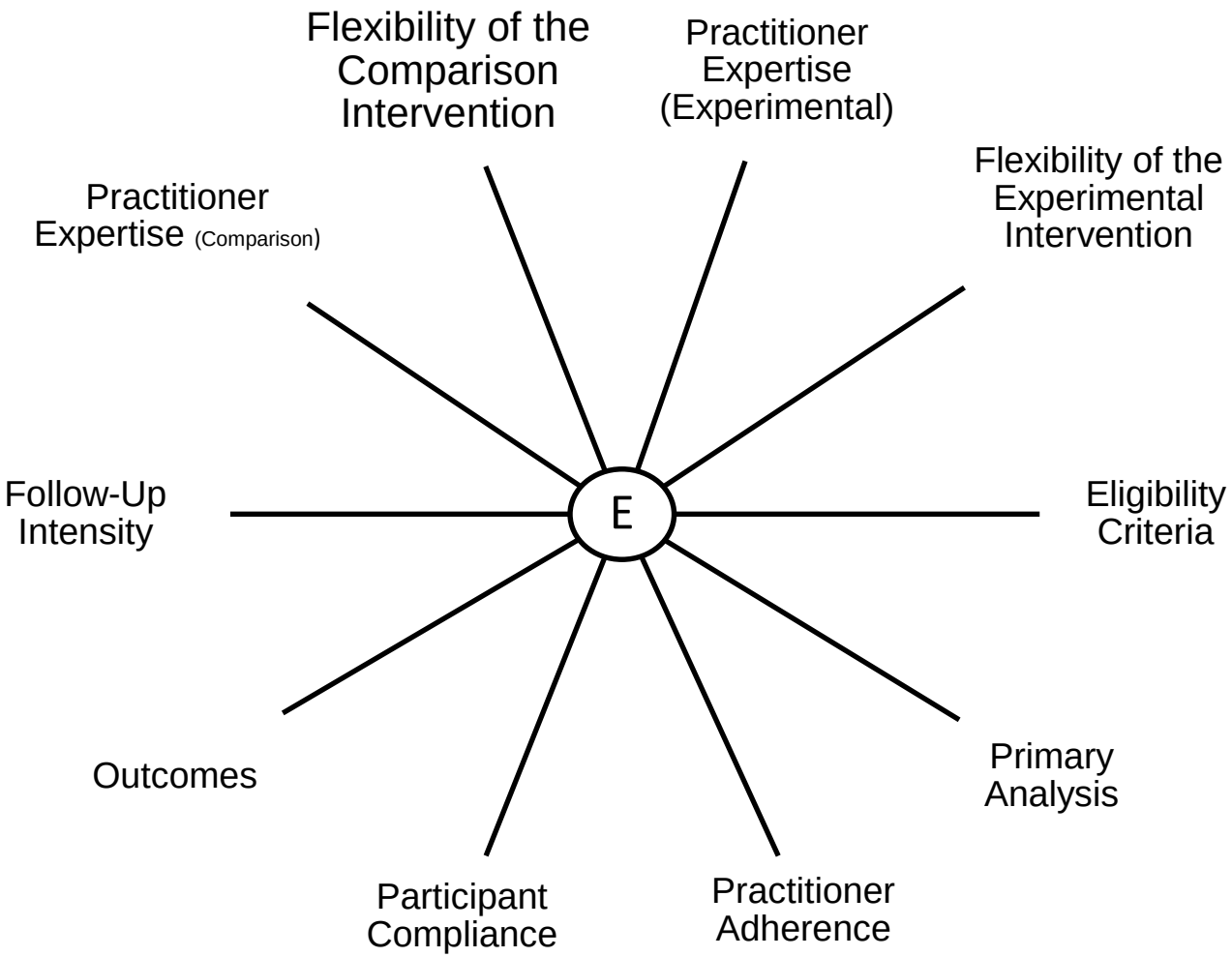
Institute of Medicine. *Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making*. Washington, DC: The National Academies Press, 2010.

Types of Community-Engaged Evidence for Health Research

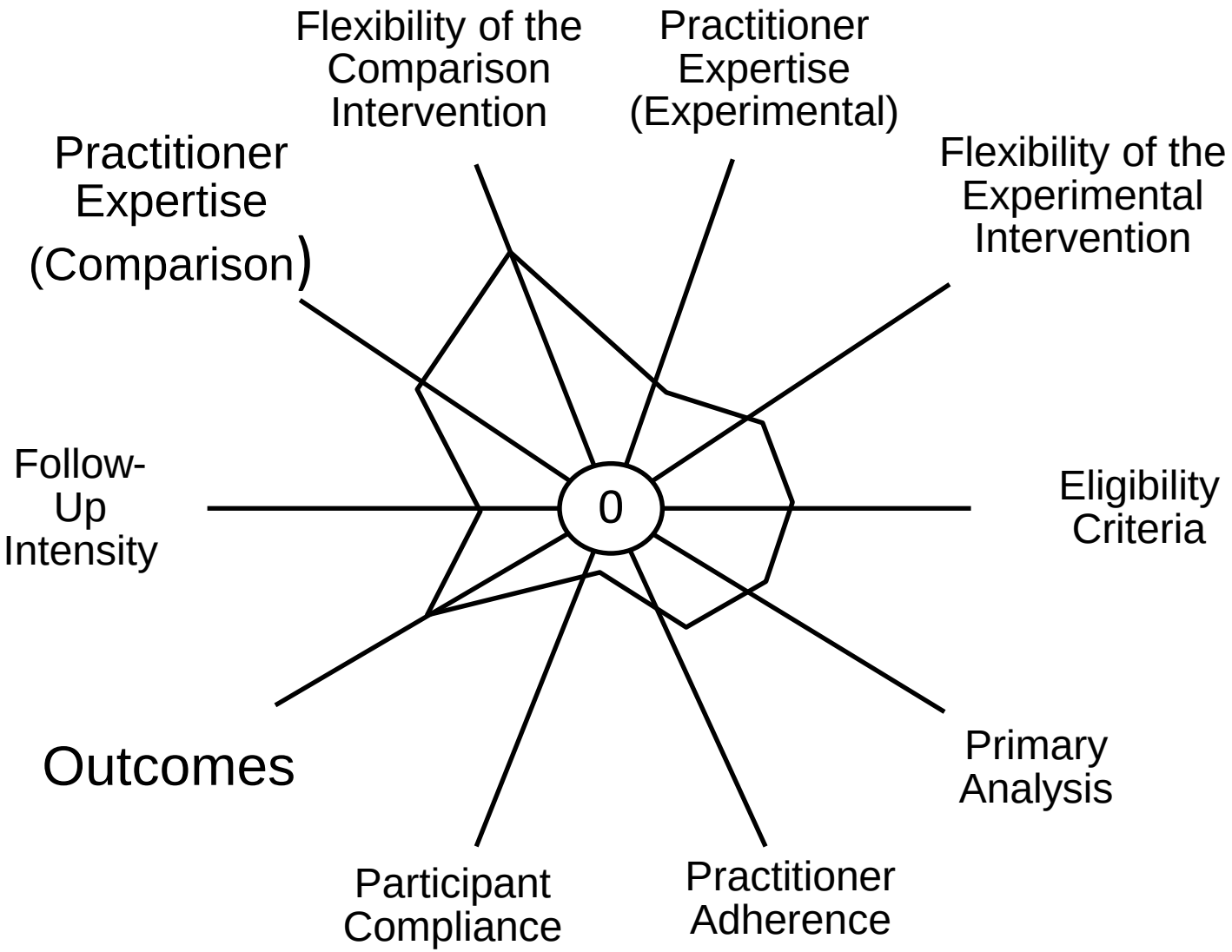
- Participatory research evidence
  - Community-Based Participatory Research (CBPR)
  - Practice-based or action research
- Surveillance evidence
- Population diagnostic evidence
- Program evaluation evidence
  - Multi-component; Continuous Quality Improvement
  - How context affects (moderates) outcomes

The Pragmatic-Explanatory Continuum Indicator Summary (*PRECIS*)

- Describes ten domains that affect the degree to which a trial is pragmatic or explanatory.
  1. Participant eligibility criteria
  2. Experimental intervention flexibility
  3. Practitioner expertise (experimental)
  4. Comparison intervention
  5. Practitioner expertise (comparison) outcome
  6. Follow-up intensity
  7. Primary trial outcome
  8. Participant compliance
  9. Practitioner adherence
  10. Analysis of primary


Flexibility of the Comparison Intervention
Practitioner Expertise (Experimental)
Flexibility of the Experimental Intervention
Practitioner Expertise (Comparison)
Follow-Up Intensity
E
Eligibility Criteria
Outcomes
Primary Analysis
Participant Compliance
Practitioner Adherence

PRECIS tool from the "POWER Hopkins" study



Glasgow,… Colditz, et al,. 2012 Health Serv Res "Applying the PRECIS criteria to describe three effectiveness trials of weight loss in obese patients with comorbid conditions."

Take home points

1. A single study unlikely to be source of evidence applicable in broader setting
2. Methods of meta-regression and similar synthesis strategies may be needed to move from individual studies to applicability
3. Engagement of stakeholders may add important aspects to evidence sources and applicability