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Dissemination and Implementation Studies: The Statistician/ Methodologist's Role and Responsibilities

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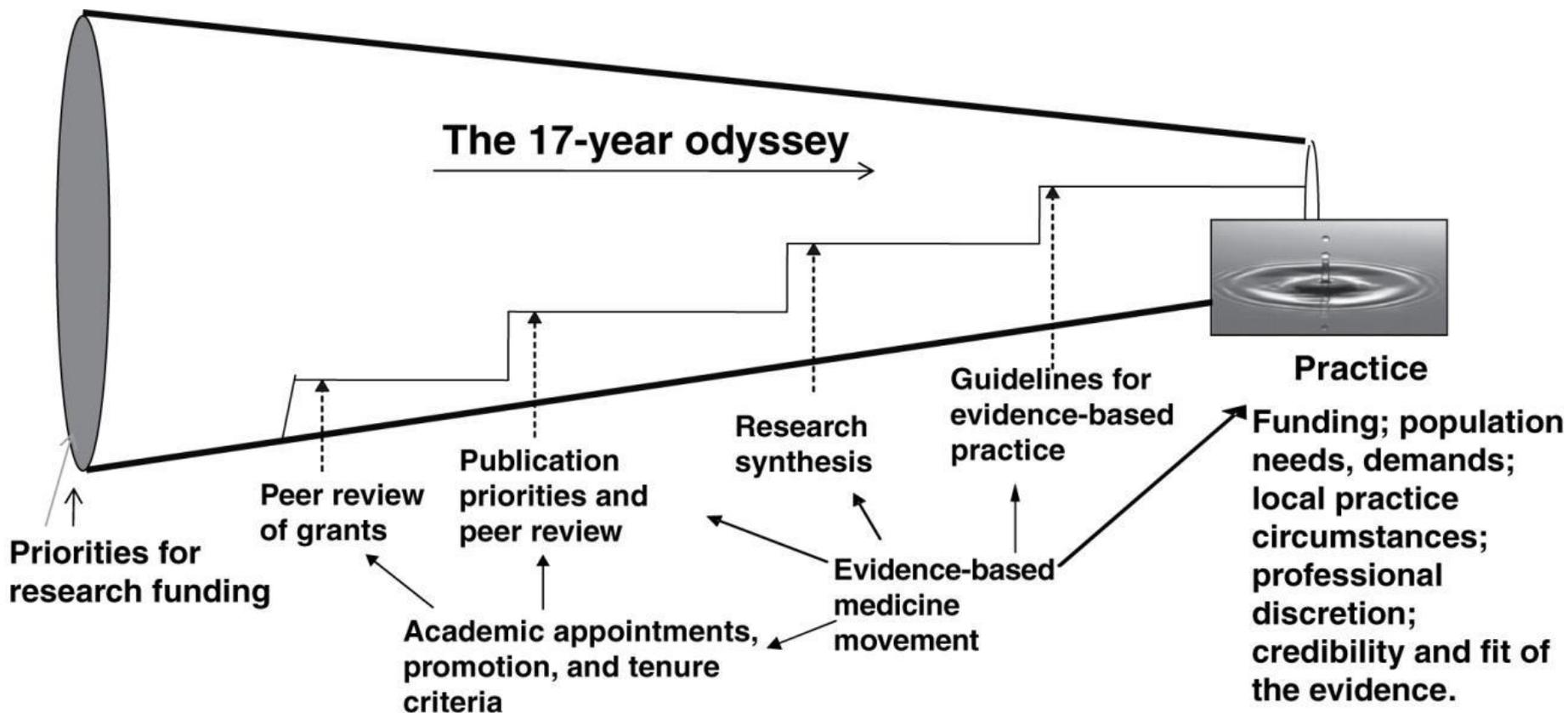
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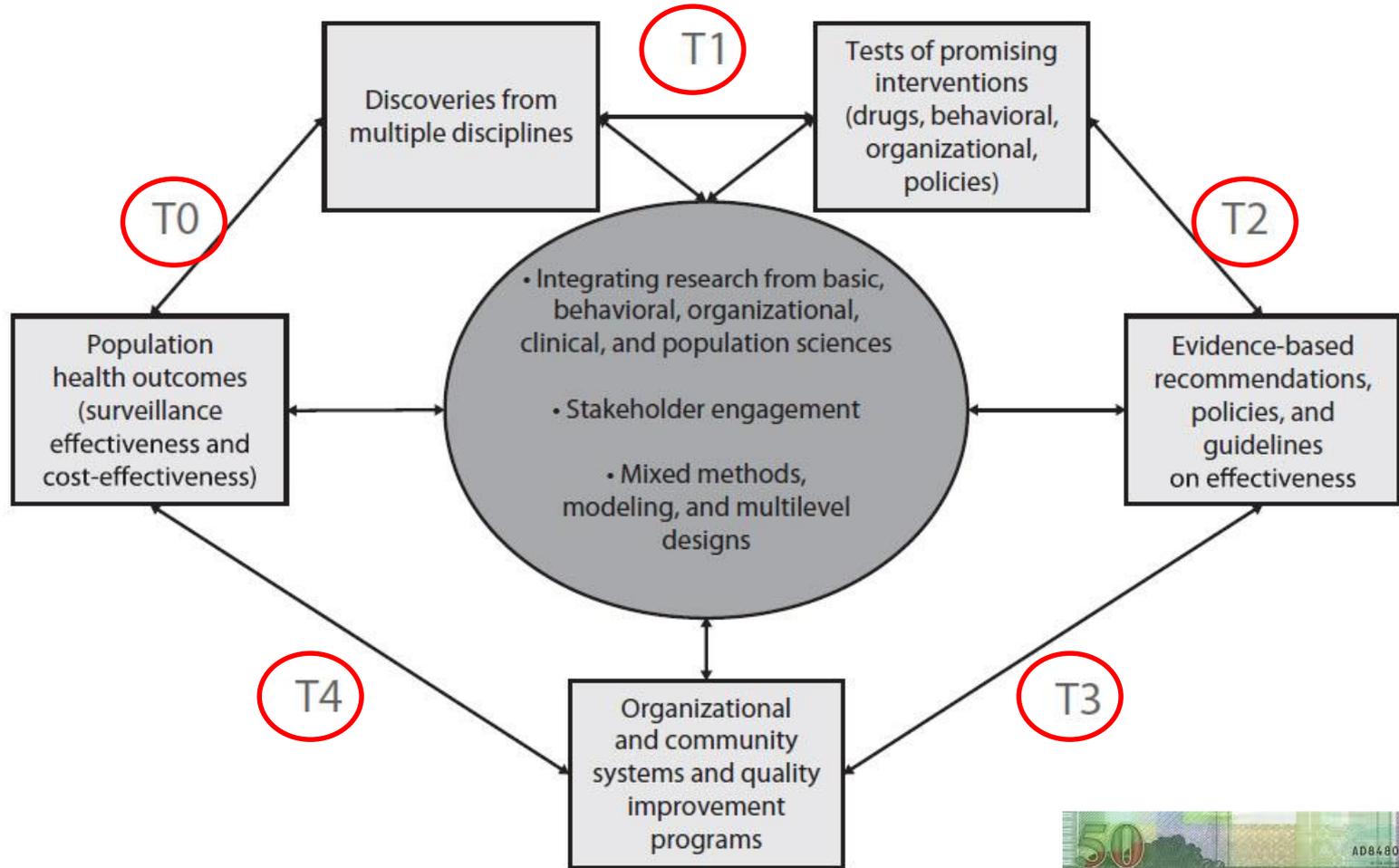




From Research to Practice



Knowledge Integration Process



Khoury MJ, et al (2010). The emergence of translational epidemiology: from scientific discovery to population health impact. *Am J Epidemiology*. (5):517---524.



Importance of Models and Frameworks

- ✓ To guide the planning, development and evaluation of D&I studies
- ✓ Enhance effectiveness of interventions by helping to focus interventions on the essential processes of behavioral change, which can be quite complex
- ✓ Enhance interpretability of study findings
- ✓ Ensure that essential implementation strategies are included





Rigor and Relevance

Traditional RCTs focused on efficacy and effectiveness have advantages

- Internal validity and testing under optimal conditions

Less Beneficial

- External validity

- Relevance to many complex health care questions

- Time

Alternative research designs and approaches should be considered

Key Opportunities

Studies focused on diverse, low-resource settings

Recognition of the importance of alternative research designs—simulation modeling, pragmatic trials, rapid learning studies, and systematic studies combined with environmental and community data—to address important public health challenges

Efficiency and Speed

Key Opportunities

Limited funding for large-scale, multisite randomized controlled trials
requires a shift to research designs that access existing and expanding
data sets

Growth in the availability of electronic health record data under new
meaningful use guidelines

Rapid learning health care systems and organizations





Collaboration

Key Opportunities

Team science

Community/clinical partnerships through community-based participatory research

Clinical and Translational Science Awards

Improved Capacity

Key Opportunities

Clinical and Translational Science Awards

Training Institute for Dissemination and Implementation Research in Health

E-learning

Web 2.0 social networking





Cumulative Knowledge

Key Opportunities

Emerging textbooks to consolidate knowledge

Source materials in diverse fields



RE-AIM Evaluation Framework

The **Reach**,
Effectiveness,
Adoption,
Implementation and
Maintenance (RE-AIM) framework offers a comprehensive approach to considering five dimensions important for evaluating the potential public health impact of an intervention



RE-AIM Evaluation Framework

Address the barriers in the knowledge transformation process

Guide researchers through a systematic process of communicating findings that will be relevant to:

- Ongoing research about mechanisms and interventions;

- Clinical and community provider practice in real world settings;

- Patient and caregiver decision-making and health behaviors in every day life; and

- Related health care policies

Accelerate knowledge transfer





Purposes of the RE-AIM Framework

Focus on impact of research efforts

Broaden the criteria used to evaluate programs to include external validity

Evaluate issues relevant to program adoption, implementation, and sustainability

Help close the gap between research studies and practice by

- Informing design of interventions
- Providing guides for adoptees
- Suggesting standard reporting criteria



What is “REACH”?

- **Reach** is the extent to which a program attracts its intended audience;
- The participation rate among the target audience and the representativeness of those participants.

Why is “REACH” important?

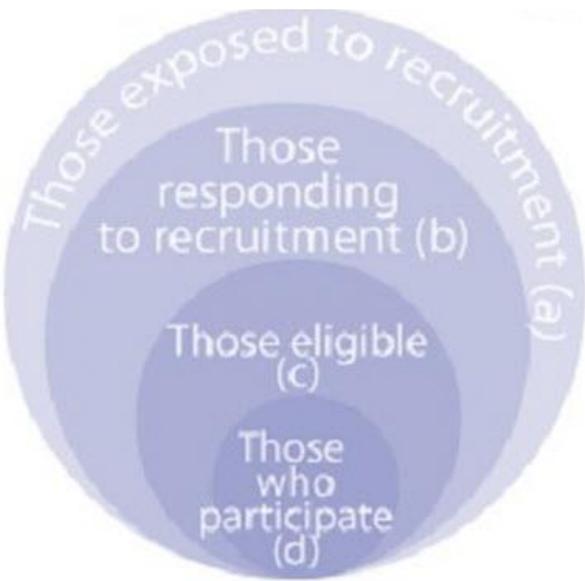
- Focuses on “Representativeness”
- Am I reaching the right population?
 - What are their characteristics that are important to know about them (income, education, ethnic group, etc)?





Calculating REACH

- 1) Estimated number exposed to recruitment [a]
- 2) Actual number who respond to recruitment [b]
- 3) Actual number who are eligible [c]
- 4) Actual number who participate [d]



- % of target who respond to recruitment
- % of eligible who participate
- % of REACH into target population
- % excluded from study
- % participation among eligible

What is “EFFECTIVENESS” and why is it important?

- **Effectiveness** is the extent to which program outcomes are achieved.
- Defined as the impact on health and disease, as well as broader outcomes such as quality of life. It also captures any adverse consequences that may occur as a result of the program, and emphasizes impact among vulnerable subgroups of the overall target population.
- Focuses on impact
 - Am I providing individual-level health benefits related to behaviors, attitudes and/or improving quality of life?
 - Am I improving practice or policies?
 - Am I unintentionally causing negative consequences/harm?
 - What are the costs?



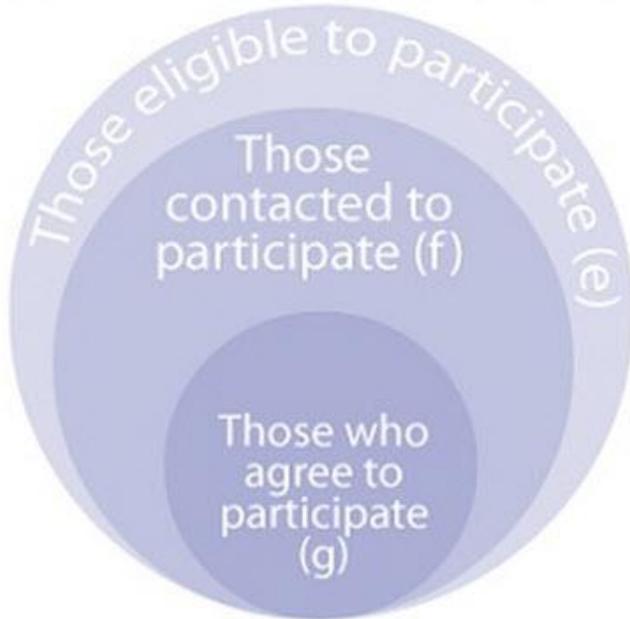


What is ADOPTION & why is it important?

- ***Adoption*** is the extent to which intended settings (such as community-based organizations and clinics) are involved in a program
- Both the participation rate and representativeness of delivery settings (and delivery staff) that take part in a program.

Calculating ADOPTION

Potential settings for ADOPTION



- 1) Number of eligible settings [e]
- 2) Number of settings asked to participate [f]
- 3) Number of settings that agree to participate [g]

% of eligible settings excluded from study

% of eligible sites contacted to participate

% participation among contacted settings





What is IMPLEMENTATION and why is it important?

The extent to which different components of a program are delivered as intended (intervention fidelity)

Includes the time and cost of program delivery.

- Concerned with the consistency of intervention delivery in different settings, by different staff members

It also examines the extent to which programs are adapted or modified over time /place

What is MAINTENANCE and why is it important?

The extent to which the program: 1) continues to be effective overtime for participants; and 2) is continued or modified by adopting settings.

- Applies to both the individual program participant & to the settings or organizations delivering the program.
- For the individual participant, maintenance is concerned with the long-term effects of the intervention on targeted outcomes.
- For delivery settings or organizations, maintenance refers to the program's institutionalization, or the extent to which a program or policy is sustained (or modified or discontinued) over time.





Why is “MAINTENANCE” important?

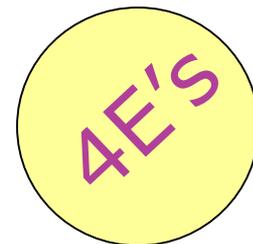
- Focuses on sustaining *individual-level benefits* participants (older adults, caregivers, clinicians) experience AND
- Focuses on sustaining the *program-level* innovation/intervention over the long-run
- Monitors *impact* on the health issue at the population level



Composite Indices

Concept	Calculation
RE (Individual Level Impact) measures	
RE (1)	Reach \times composite Intervention Effectiveness = (participation rate – median $ES_{\text{differential characteristics}}$) \times (median $ES_{\text{key outcomes}}$ – median $ES_{\text{negative outcomes}}$ – median $ES_{\text{differential impact}}$)
RE (2): Attributable Individual Level Impact	Problem prevalence \times RE (1) (see above)
RE (3): RE Efficiency	(Incremental cost of treatment – control)/ (incremental RE (1) of treatment – control)
AI (Setting Level Impact) measures	
AI (1)	(Setting adoption rate – median $ES_{\text{differential setting characteristics}}$) \times (staff adoption rate – median $ES_{\text{differential staff characteristics}}$) \times (median component implementation rate across staff and Tx components – median $ES_{\text{differential implementation}}$)
AI (2): Attributable Setting Level Impact	AI (1) \times number of target settings \times average no. of persons served per setting
RE-AIM profile	Graph using 0–100 scores of results on all RE-AIM dimensions
RE-AIM average	[Reach (as calculated above) + Effectiveness or Maintenance (see above) + Adoption (see above) + Implementation (see above)]/ 4

Dissemination/Utilization: For what aim?



- **Increase knowledge**
 - Provide *exposure* to new knowledge/innovation –
- **Increase knowledge and attitudes**
 - Provide *experiences* with new knowledge/innovation (e.g., new assessment tool)
- **Increase competence**
 - Develop *expertise* in application of new knowledge (e.g., building patient skills in symptom recognition and management),
- **Increase utilization over time**
 - *Embed* new knowledge into daily clinical practice or policy or patient behavior



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Other Frameworks

- Consolidated Framework for Implementation Research (CFIR)
- QUERI – Quality Enhancement Research Initiative

The ultimate goal of dissemination and implementation science is to ensure that advances in health science become standards for care in all populations and all health care settings.

Russell Glasgow



“To the individual who devotes his or her life to science, nothing can give more happiness than when results immediately find practical application. There are *not* two sciences. There is science and the application of science and these two are linked as the fruit is to the tree.”

Louis Pasteur



DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH

Translating Science to Practice



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