Implementation Science: How It Can Complement, Extend, and Challenge How You Do Science (and increase your success)

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Dissemination and Implementation Science Program, and Shared Decision Making Core
Adult and Child Consortium for Outcomes Research and Delivery Science
Conflicts of Interest

FINANCIAL DISCLOSURE:

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UNLABELED/UNAPPROVED USES DISCLOSURE:

None
Need for Implementation Science
How is Implementation Science Different?
Examples
Tools and Resources
Conclusions, Discussion; Q & A
Overview

- Need for Implementation Science
- How is Implementation Science Different?
- Examples
- Tools and Resources
- Conclusions, Discussion; Q & A
### Need for Implementation Science?

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1497</td>
<td>Capt James Lancaster sails with 4 ships: crew on Ship #1 given 3 tsp of lemon juice daily; 0% mortality. 40% of crew on other 3 ships perish.</td>
</tr>
<tr>
<td>1601</td>
<td>James Lind, British Navy physician conducts random trial of 6 treatments for scorbutic sailors on HMS Salisbury: citrus again proves effective against scurvy</td>
</tr>
<tr>
<td>1795</td>
<td>British Navy orders that citrus fruits become the diet on all navy ships.</td>
</tr>
<tr>
<td>1865</td>
<td>British Board of Trade adopts the innovation, ordering proper diets on merchant vessels.</td>
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Total elapsed time from Lancaster to adoption: 264 years
Bench to Bookshelf
Need for Implementation Science?

- SLOW
  - Traditional RCTs are slow and expensive
  - Rarely produce findings that are easily put into practice

It takes an average of 17 years before 14% of research findings lead to widespread changes in care.
Research to Practice Pipeline

Need for IS

How Different

Examples

Tools

Conclusions

The 17-year odyssey

Priorities for research funding

Peer review of grants

Publication priorities and peer review

Research synthesis

Guidelines for evidence-based practice

Practice

Funding; population needs, demands; local practice circumstances; professional discretion; credibility and fit of the evidence.

Academic appointments, promotion, and tenure criteria

Evidence-based medicine movement

Green, LW et al. Diffusion theory and knowledge dissemination... Annu Rev Public Health 2009;30:151-74
Need for Implementation Science

- Traditional RCTs study the effectiveness of treatments delivered to carefully selected populations under ideal conditions.

- Even when we do implement a tested intervention into everyday clinical practice, we often see a “voltage drop”—a dramatic decrease in effectiveness.

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

Green LW. Am J Pub Health 2006

Science

- knowledge or a system of knowledge covering general truths or the operation of general laws especially as obtained and tested through scientific method.
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Science

- knowledge or a system of **knowledge** covering **general truths** or the operation of **general laws** especially as obtained and tested through scientific method.
Implementation Science

- Implementation science is the *study of methods* to promote the integration of research findings and evidence into healthcare policy and practice.

- Dissemination science is the *study of methods* of distribution of information and intervention materials to a specific public health or clinical practice audience.
When are you ready to study Implementation Science?
When are you ready to study D&I?

Adapted from Figure 11.1 Implementation and dissemination of Prevention Programs (2009)
Effectiveness/Implementation hybrids

- Clinical Effectiveness Research
- Implementation Research

Hybrid Type 1: Test clinical intervention, observe/gather information on implementation
Hybrid Type 2: Test clinical intervention, test implementation intervention
Hybrid Type 3: Test implementation intervention, observe/gather information on clinical intervention and outcomes

Curran et al. Medical Care. 2012
Overview

• Need for Implementation Science
• **How is Implementation Science Different?**
• Examples
• Tools and Resources
• Conclusions, Discussion; Q & A
“The significant problems we face cannot be solved by the same level of thinking that created them.”

A. Einstein
PCTs: Fewer Exclusions Allow for a Broader Subset of Settings, Staff, and Participants

**Traditional RCT**
- Eligible population
- Exclusions, non-response, etc.
- Efficacy, among a defined subset

**PCT**
- Eligible population
- Exclusions, non-response, etc.
- Effectiveness, in a broad subset

*Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research*
External Validity/ Pragmatic Criteria—Often Ignored

- Participant Representativeness
- Setting Representativeness
- Context and Setting
- Community/Setting Engagement
- Adaptation/change
- Sustainability
- Costs/Feasibility of Tx
- Comparison Conditions
A Different Approach: Pragmatic Research

Explanatory trial: Specialized experiment in a specialized population
Pragmatic trial: Real-world test in a real-world population

Pragmatic designs emphasize:
- Participation or reach
- Adoption by diverse settings
- Ease of Implementation
- Maintenance

### Key differences between Traditional Randomized Control Trials (RCT) and Pragmatic Controlled Trials (PCT)

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<tr>
<td><strong>GOALS</strong></td>
<td>To determine causes and effects of treatment</td>
<td>To improve practice and inform clinical &amp; policy decisions</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DESIGN</strong></td>
<td>Tests the intervention against placebo using rigid study protocols &amp; minimal variation</td>
<td>Tests two or more real-world treatments using flexible protocols &amp; local customization</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PARTICIPANTS</strong></td>
<td>Highly defined &amp; carefully selected</td>
<td>More representative because eligibility criteria are less strict</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MEASURES</strong></td>
<td>Require data collection outside routine clinical care</td>
<td>Brief and designed so data can be easily collected in clinical settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
<td>Rarely relevant to everyday practice</td>
<td>Useful in everyday practice, especially clinical decision making</td>
<td></td>
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</table>
Other models

- 91 frameworks: http://dissemination-implementation.org/index.aspx
- Most Common at NIH: REAIM and DOI
- Many commonalities across models and theories
Readiness for Translation? RE-AIM

• Internal validity perspective
  ▪ The *magnitude of effect* as the key indicator of readiness for translation and adheres to the principles of *evidence rating* for determining efficacy

• External validity perspective
  ▪ Attention to intervention features that can be *adopted* and delivered broadly, have the ability for *sustained* and consistent *implementation* at a reasonable cost, *reach* large numbers of people, especially those who can most benefit, and produce *replicable* and *long-lasting effects*

### RE-AIM Precision (Personalized) Medicine Questions

**Determine**
- What percent and types of patients are **Reached**;
- For whom among them is the intervention **Effective**, in improving what outcomes, with what unanticipated consequences;
- In what percent and types of settings and staff is this approach ** Adopted**;
- How consistently are different parts of it **Implemented** at what cost to different parties;
- And how well are the intervention components and their effects **Maintained**?

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<tr>
<th>RE-AIM Dimension</th>
<th>Key pragmatic questions to consider and answer</th>
</tr>
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<tbody>
<tr>
<td>Reach</td>
<td>WHO is (was) intended to benefit and who actually participates or is exposed to the intervention?</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>WHAT is (was) the most important benefits you are trying to achieve and what is (was) the likelihood of negative outcomes?</td>
</tr>
<tr>
<td>Adoption</td>
<td>WHERE is (was) the program or policy applied and WHO applied it?</td>
</tr>
<tr>
<td>Implementation</td>
<td>HOW consistently is (was) the program or policy delivered, HOW will (was) it be adapted, OWHOW HOW much will (did) it cost, and WHY will (did) the results come about?</td>
</tr>
<tr>
<td>Maintenance</td>
<td>WHEN will (was) the initiative become operational; how long will (was) it be sustained (Setting level); and how long are the results sustained (Individual level)?</td>
</tr>
</tbody>
</table>
Why is this important? impact Loss at each RE-AIM step

<table>
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<tr>
<th>Dissemination Step</th>
<th>Concept</th>
<th>% Impact</th>
</tr>
</thead>
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<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>
</tr>
<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>
</tr>
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### Ultimate Impact of a Weight Management Program

<table>
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<tr>
<th>Dissemination Step</th>
<th>Concept</th>
<th>Percent Impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.8% of Weight Management sites participated</td>
<td>Adoption</td>
<td>8.80%</td>
</tr>
<tr>
<td>5.9% of members participated</td>
<td>Reach</td>
<td>0.52%</td>
</tr>
<tr>
<td>91.4% program components implemented</td>
<td>Implementation</td>
<td>0.47%</td>
</tr>
<tr>
<td>43.8% of participants showed weight loss</td>
<td>Effectiveness</td>
<td>0.21%</td>
</tr>
<tr>
<td>21.2% individuals maintained benefit (individual)</td>
<td>Maintenance</td>
<td>0.04%</td>
</tr>
</tbody>
</table>

Abildso CG, Zizzi SJ, Reger-Nash B. *Prev Chronic Dis* 2010 May;7(3):A46
Comparison of Two Different Types of Programs

Glasgow et al. AJPH, September 1999, Vol. 89, No. 9
Extended CONSORT Diagram

Total number of potential settings (n)

Settings eligible (n, %)

Settings and agents who participate, (n, %)

Staff who participate, (n, %)

Total potential participants (n)

Individuals eligible (n, %)

Excluded by investigator (n, %)

Not contacted/Other (n, %)

Excluded by investigator (n, %, reasons)

Settings and agents who decline (n, %)

Staff who decline, (n, %)

Other (n, %)

Other (n, %)
What are unique considerations about this framework?

- Intended to facilitate translation of research to practice
- Internal and external validity and emphasizes representativeness
- Individual and organizational factors
- Public health impact depends on all elements (reach x effectiveness, etc)
- Resource materials for researchers and community leaders (www.re-aim.org)
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**Overview**

- Need for Implementation Science
- How is Implementation Science Different?
- **Examples**
- Tools and Resources
- Conclusions, Discussion; Q & A
Planned Parenthood Smoking Cessation Example

- Patient randomized study (n = 1154) in low income Planned Parenthood clinics
- Eligible and target population = women smokers coming into clinic for contraception, wellness, or non-pregnancy follow-up
- INT= 9-minute tailored video, clinician advice to quit, brief behavioral counseling, follow-up phone calls
- Control = Advice to Quit and Stop Smoking brochure

Glasgow R et al. A brief smoking cessation intervention. AJPH, 2000, 90: 786-789
Planned Parenthood Smoking Cessation Results

- **Reach:** 99% had smoking identified, 76% of smokers approached participated, no differences on demographics for participants vs. decliners

- **Effectiveness:** 10.2% quit INT vs. 6.9% CON at 6-week follow-up, p<.05

- **Adoption:** Approached 4 clinics in lowest SES neighborhoods in area (most below 125% poverty level), also most diverse clinics—all participated
Results (cont.)

- **Implementation:**
  - Excellent (>85%) on all components except phone calls, which were problematic—only 43% successfully contacted

- **Maintenance:**
  - Individual level: Higher, but NS different levels cessation (18.3 vs. 14.9%, p=.09) in INT condition at 6-month follow-up
  - Setting level: Not reported
DECIDE – LVAD trial

A Multicenter Trial of a Shared Decision Support Intervention for Patients and their Caregivers Offered Destination Therapy for End-Stage Heart Failure

Principal Investigator
Larry A. Allen, MD, MS

Organization
University of Colorado Denver

State
Colorado

Year Awarded
2014

Funding Announcement
Communication and Dissemination Research

Project Budget
$2,052,964

Project Period
3 Years
**DECIDE-LVAD Trial**

**Objective:** Understand the **effectiveness** and **implementation** of a shared decision support intervention for advanced heart failure patients considering DT LVAD.
Key Considerations:
1. Desire to evaluate implementation in multiple real-world settings
2. Specific small population (DT LVAD 25-50 per site/year)
3. Max 5-6 sites due to budget constraints ($2M)
4. Randomization needed to assess effectiveness
5. Intervention involves both patients and clinicians/program
Study Design Options for DECIDE-LVAD Trial

- **Classic patient-level randomization**
  - Intervention is patient AND program-based; not at individual-level
  - Diffusion among participants at each site is probable

- **Cluster randomization**
  - Concerns about statistical power with only 6 total sites
    - 3 sites intervention, 3 sites control
    - Homogeneity of intervention participants and control participants

- **Stepped wedge cluster randomization**
## DECIDE-LVAD Trial

### Figure 5. Stepped wedge randomization scheme.

<table>
<thead>
<tr>
<th>Site</th>
<th>Pre 4 months</th>
<th>Phase 1 4 months</th>
<th>Phase 2 4 months</th>
<th>Phase 3 4 months</th>
<th>Phase 4 4 months</th>
<th>Post 4 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinating Site</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Random Sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Random Sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Random Site</td>
<td></td>
<td></td>
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</table>

- Control Period
- Roll-Out
- Intervention Period
**Stepped Wedge Design Ideal When...**

- **Diffusion** of intervention to control participants is likely
- **Implementation** is a focus
  - Iterative adjustment possible at each phase
  - All clusters go through implementation (not half)
- **Staggered** rollout provides *logistical*, practical, or financial advantages
- **All sites** wish to receive the intervention
- Randomization itself can be a reason sites don’t participate
Evaluation Procedures

- **Reach & Effectiveness:**
  - Patients and caregivers
  - Surveys:
    - Baseline
    - 1 month
    - 6 months

- **Adoption, Implementation & Maintenance**
  - Qualitative interviews:
    - Baseline
    - Post-intervention implementation
    - Post-study completion
  - Checklist of education materials/procedures for each patient
## Implementation Intervention

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- **Pre-implementation:**
  - Planning, identifying key people

- **Implementation visit**
  - 1 hour: Grand rounds presentation (large audience)
  - 1 hour: Communication Training (heart failure team)
  - 1 hour: Discuss new process
    - Already a delivery process “plug and play”

- **Post-implementation**
  - Ongoing site support
  - Follow-up visit
Communication Training

Four key communication concepts

1. How to introduce the LVAD
2. How to frame the options:
3. How to respond to emotions:
4. How to provide recommendations

“Bad”

“Good”
RE-AIM Summary Points

- RE-AIM is an outcomes framework that can be used for planning and evaluation
- Each dimension is an opportunity for intervention
- RE-AIM can be used for efficacy, effectiveness, and implementation science projects
- All dimensions can be addressed within a given study (though likely not all intervened upon)
- Methods exist to combine and summarize RE-AIM outcomes
Overview

- Need for Implementation Science
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- **Tools and Resources**
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The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) Planning Tool

- How pragmatic is your study?

- Tool to help in planning and reporting. (see next slide)


Eligibility
Who is selected to participate in the trial?

Recruitment
How are participants recruited into the trial?

Setting
Where is the trial being done?

Organisation
What expertise and resources are needed to deliver the intervention?

Primary analysis
To what extent are all data included?

Primary outcome
How relevant is it to participants?

Follow-up
How closely are participants followed-up?

Flexibility: adherence
What measures are in place to make sure participants adhere to the intervention?

Flexibility: delivery
How should the intervention be delivered?
Overview

- Need for Implementation Science
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Evolution of RE-AIM

Reviews documenting use over time
- Applicability to many different content areas
- Used for both planning and evaluation

Underreporting of key components
- Setting level factors reported much less often (e.g., adoption)
- Maintenance (sustainability) reported least often

Focus on Context!

NEW AREAS

Health Policy
Multilevel community interventions
Built environment
Patient centered outcomes research

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)?
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)?

- 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?*”
Resources (SEE YOUR HANDOUT)

- Re-aim.org
- https://www.precis-2.org/
- www.ucdenver.edu/accords/implementation
- www.Dissemination-Implementation.org
Questions?

We’re all ears!
Common questions?

- How does ‘adaptation’ fit with fidelity to protocol?
- How do I plan or design for dissemination’?