Implementation Research: From Gaps to Strategies to Outcomes

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Disclosures

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<th>Entity</th>
<th>Type(s) of relationship(s)</th>
<th>Product name(s)</th>
<th>Relevant disease(s) or condition(s)</th>
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K01TW009218  
R01HL125487  
U01HL114200  
U01HL138636  
U01HL142099  
R01MH118075  
R21HL140474  
14SFRN20490315
Implementation research

- Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and public health.

- It includes the study of influences on healthcare professional and organizational behaviour.

- (Eccles/Mittman, 2006)
Knowledge-Practice (Know-Do) Gap

STROKE 8%

MYOCARDIAL INFARCTION 14%
Implementation pipeline- Mittman & Curran 2012

- Efficacy studies
  - Clinical
  - Health Behavior
  - Health Services

- Observational studies
  - Effectiveness Studies
  - Document and diagnose quality gaps
  - Implementation Practice
  - Implementation Trials
  - Improved Health Processes, Outcomes

Hybrid – Type 1
Test intervention, gather information on implementation

Hybrid – Type 2
Test intervention, Test implementation strategy

Hybrid – Type 3
Test implementation strategy, gather effectiveness data
Theories, Models, Frameworks—Why?

1. Describe/guide the process of conducting implementation research

2. Understand and leverage mechanisms of change
   - Individual
   - Community
   - Organizational

3. Guide comprehensive evaluation
Implementation Research Frameworks—CFIR

Damschroder (2009) Imp Sci
Implementation Research Frameworks—RE-AIM

- **REACH**
  How do I reach the targeted population?

- **EFFECTIVENESS**
  How do I know my intervention is effective?

- **ADOPTION**
  How do I develop the institutional support to deliver my intervention?

- **MAINTENANCE**
  How do I incorporate the intervention so it is delivered over the long term?

- **IMPLEMENTATION**
  How do I ensure the intervention is delivered properly?

**RE-AIM**
Translating Research into Action
re-aim.org
Implementation Research Frameworks—PRISM

Feldstein and Glasgow (2008) Joint Com J Qual Pat Safety
Implementation Research Frameworks—i-PARIHS

Harvey and Kitson (2016) Imp Sci
Health Equity Implementation Framework

- Societal Influence
  - Context
  - Recipients: Patient Factors
  - Recipients: Provider Factors
  - Clinical Encounter
  - Characteristics of the Innovation
- Physical Structures
  - Inner: Organizational Level
  - Outer: Healthcare System
- Economies
  - Inner: Local Level + Facilitation
- Successful Implementation
- Improvements in Health Equity

Woodward (2019) Imp Sci
Implementation Research Frameworks—PRECEDE-PROCEED

**PRECEDE-PROCEED Framework**

- **Phase 1**: Social Assessment
- **Phase 2**: Epidemiologic Assessment
- **Phase 3**: Behavioral & Environmental Assessment
- **Phase 4**: Educational & Ecological Assessment
- **Phase 5**: Administrative Policy Assessment
- **Phase 6**: Implementation
- **Phase 7**: Process Evaluation
- **Phase 8**: Impact Evaluation
- **Phase 9**: Outcome Evaluation

**HEALTH PROMOTION**
- Health Education
- Policy, Regulation, Organization

**Predisposing factors**
- Behavior & lifestyle
- Environment
- Health

**Reinforcing factors**
- Enabling factors

**Enabling factors**
- Quality of life

Green and Kreuter (1999)
When theories fail: Example of lifestyle change

Medical model / expert script:

Symptom(s) or problem  →  Diagnosis  →  Treatment / Solution  →  Successful Condition cured / problem solved

Unsuccessful

Alternative model: Teetering

Wake up!  →  WTH? Do I need to do something?  →  Trying things  →  Maintenance  →  Relapse?

Co-occurrence  →  Opportunity  →  Action  →  Feeling  →  Experience

©Absetz & Patja, 2007, 2017
Suggested criteria for a good theory:

1. Clarity of theoretical concepts
2. Clarity of relationships between constructs
3. Measurability
4. Testability
5. Being explanatory (statistically or logically)
6. Describing causality
7. Achieving parsimony
8. Generalisability
9. Having an evidence base

Implementation Research

Vedanthan (2011) MSJM
Problem Analysis—Flow Chart

[Flow Chart Image]
Problem Analysis—Pareto Chart

Pareto Chart - Types of Medication Errors (n=430)

- **Vital Few**
  - Once missed: 92
  - Wrong time: 83
  - Wrong drug: 76
  - Over dose: 59
  - Wrong patient: 53
  - Wrong route: 27
  - Wrong calculation: 16
  - Duplicated drugs: 9
  - Under dose: 7
  - Wrong IV rate: 4
  - Technique error: 3
  - Unauthorised drug: 1

- **Trivial Many**

80% Cut off (80:20 Rule)

Clinical Excellence Commission (Aus)
Problem Analysis—Fishbone/Ishikawa Diagram
Problem Analysis—Fishbone/Ishikawa Diagram
Analyze Determinants

- Context, Agency, Structure
Determinants

- Behavior

Michie (2011) Imp Sci
Behavior Change Wheel

Michie (2011) Imp Sci
Other examples... (there are MANY)
Modified HBM: LARK

Implementation Research

Vedanthan (2011) MSJM
Intervention Selection

- Patient-focused
- Provider-focused
- Education
- Feedback/Reminders
- Patient safety
- Organizational change
- Economic strategies
- Policy/Regulation
- Multifaceted
DESIGN THINKING

Designer's **sensibility** and **methods** to match:

- **Desirability** (people’s needs)
- **Feasibility** (social, political, technological, cultural)
- **Viability** (economic, sustainable, scalable)
Designer’s Triad

- Desirability
- Viability
- Feasibility
Designer’s Sensibility: Integrative Thinking

ANALYTICAL THINKING

Deductive reasoning

Inductive reasoning

INTUITIVE + IMAGINATIVE THINKING

Abductive reasoning

INTEGRATIVE THINKING
Please do not pee everywhere. Keep the bathroom clean for next use.

Thanks,
Bayanihan Management
Reduces spillage by over 80%!
How can we get more people to use stairs?
Designer’s Method: Three Spaces

1. Inspiration
2. Ideation
3. Implementation
Bridging Income Generation with Group Integrated Care

PI (USA): Rajesh Vedanthan, MD MPH
PI (Kenya): Jemima H. Kamano, MMed
Leung, et al, forthcoming
Aim 1.1: Prototype
The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel

- **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?
- **Follow-up**: How closely are participants followed-up?
- **Primary Analysis**: To what extent are all data included?
- **Primary Outcome**: How relevant is it to participants?
- **Flexibility: adherence**: What measures are in place to make sure participants adhere to the intervention?
- **Flexibility: delivery**: How should the intervention be delivered?

Kirsty Loudon et al. BMJ 2015;350:bmj.h2147
Pragmatic vs. Explanatory

Eligibility - Who is selected to participate in the trial?

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 - What measures are in place to make sure participants adhere to the intervention?

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?

Flexibility - How should the intervention be delivered?
## Pragmatic vs. Traditional

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<th>Pragmatic</th>
<th>Traditional</th>
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<tbody>
<tr>
<td>Stakeholder Engagement</td>
<td>Engaged in all phases</td>
<td>Limited engagement</td>
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<tr>
<td>Research Design</td>
<td>Internal and external validity; design fidelity; local adaptation; real-life settings; context</td>
<td>Limiting threats to internal validity; usually RCT; homogenous participants</td>
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<tr>
<td>Outcomes</td>
<td>Reach, effectiveness, adoption, implementation, comparative effectiveness, sustainability</td>
<td>Efficacy, mechanism, component analysis</td>
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<tr>
<td>Measures</td>
<td>Brief, valid, actionable, rapid utility, feasible</td>
<td>Validated measures that minimize bias; internal consistency/theory vs. clinical relevance</td>
</tr>
<tr>
<td>Data Source</td>
<td>Existing data, health records, admin data, patient reports</td>
<td>Data generation and collection part of clinical trial</td>
</tr>
<tr>
<td>Availability of Findings</td>
<td>Rapid learning and implementation</td>
<td>Delay between trial completion and analytic availability</td>
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# Pragmatic vs. Traditional

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<td>Few exclusion criteria; higher external validity</td>
<td>More exclusion criteria; lower external validity</td>
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<tr>
<td>Wide range of patients, providers, and settings</td>
<td>Limited range of patients, providers, and settings</td>
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<tr>
<td>Active comparators</td>
<td>Mostly placebo-controlled</td>
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<tr>
<td>Patient-centered outcome measures</td>
<td>Clinical or physiological outcome measures</td>
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<tr>
<td>Longer follow-up with less intensity</td>
<td>Shorter follow-up with more intensity</td>
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<tr>
<td>Often not blinded</td>
<td>Often double-blinded</td>
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<tr>
<td>Often cluster-randomized</td>
<td>Often individual-randomized</td>
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Stepped-Wedge Design

Adaptome

- "Positive Deviance"
- "Program Drift"

Impact

Time and Setting

+ 

ITV

ITV_a

ITV_b

ITV_c

ITV_d

ITV_e

ITV_f

ITV_g
Adaptome

Sources of Intervention Adaptation

- INTERVENTION
  - SERVICE SETTING ADAPTATIONS
  - TARGET AUDIENCE ADAPTATIONS
  - MODE OF DELIVERY ADAPTATIONS
  - CULTURAL ADAPTATIONS
  - CORE COMPONENTS

Adaptation Examples
- Who delivers the intervention; fit with other interventions; financing source
- Age-appropriateness; health literacy; responsive to individual needs; comorbid conditions
- Number of sessions; dose; technological format; session length
- Cultural sensitivity; imagery used; consistency with belief system
- Core components of intervention identified through testing; mechanisms of action
Adaptome
FRAME—Framework for Adaptations and Modifications

[Diagram of FRAME framework with detailed categories and boxes for when, what, who, and reasons of adaptation and modification.]

Implementation Research

Vedanthan (2011) MSJM
Differences between hybrid designs 1, 2 and 3

Clinical Effectiveness Research

Hybrid Type 1
TEST CLINICAL INTERVENTION
Gather implementation data

Hybrid Type 2
TEST CLINICAL INTERVENTION & TEST IMPLEMENTATION STRATEGY

Hybrid Type 3
TEST IMPLEMENTATION STRATEGY
Gather data on clinical intervention effectiveness

Implementation Research
Hybrid Type 1

• Research Aim:
  – Primary: Effectiveness of intervention
  – Secondary: Better understand context for implementation

• Sample Research Question
  – Primary: Will treatment work in this setting/with these patients
  – Secondary: What are potential barriers/facilitators to widespread implementation
Differences between hybrid designs 1, 2 and 3

Clinical Effectiveness Research

Hybrid Type 1
TEST CLINICAL INTERVENTION
Gather implementation data

Hybrid Type 2
TEST CLINICAL INTERVENTION & TEST IMPLEMENTATION STRATEGY

Hybrid Type 3
TEST IMPLEMENTATION STRATEGY
Gather data on clinical intervention effectiveness

Implementation Research
Hybrid Type 2

• Research Aim:
  – Co-Primary (“clinical”): Effectiveness of intervention
  – Co-Primary (“implementation”): Feasibility and potential utility of an implementation strategy

• Sample Research Question
  – Co-Primary: Will treatment work in this setting/with these patients
  – Co-Primary: Does the implementation method show promise in facilitating implementation of the clinical treatment
BIGPIC—Type 2

MICROFINANCE GROUPS
- Health savings
- Increased income
- Financial literacy
- Self-confidence
- Decision-making agency
- Social Support

GROUP MEDICAL VISTS
- Efficiency of care delivery
- Improved quality of care
- Clinician-patient trust
- Increased self-efficacy
- Shared experiences
- Peer support

Changes in Social Network Characteristics

INTERMEDIATE FACTORS
- Healthy Diet
- Physical Activity
- Medication Adherence
- Retention in Care

CVD Risk Reduction

Differences between hybrid designs 1, 2 and 3

Clinical Effectiveness Research

Implementation Research

- Hybrid Type 1: Test clinical intervention
  Gather implementation data

- Hybrid Type 2: Test clinical intervention & test implementation strategy

- Hybrid Type 3: Test implementation strategy
  Gather data on clinical intervention effectiveness
Hybrid Type 3

• Research Aim:
  – Primary: Determine utility of an implementation strategy
  – Secondary: Assess clinical outcomes associated with implementation trial

• Sample Research Question
  – Primary: Which method works better in facilitating implementation of a clinical treatment
  – Secondary: Are clinical outcomes acceptable?
BIGPIC Global—Type 3
Process evaluation

Process evaluation of complex interventions: Medical Research Council guidance

BMJ 2015;350 doi:https://doi.org/10.1136/bmj.h1258 (Published 19 March 2015)
Cite this as: BMJ 2015;350:h1258
Process Evaluation
The Saunders Framework

Components of Process Evaluation

1. Fidelity (Quality)
2. Dose Delivered
3. Dose Received (Exposure)
4. Dose Received (Satisfaction)
5. Recruitment
6. Reach (Participation Rate)
7. Context
Implementation Research

IDENTIFY problem
ANALYZE determinants
DEVELOP solutions
IMPLEMENT interventions
EVALUATE outcomes

Community-based Participatory Research
Qualitative Methods
Biostatistics
Outcomes and Impact Evaluation
Cost Effectiveness Research
Modeling Techniques
Management Sciences
Operations Research
Supply Chain Logistics
Information & Communication Technology
Human Performance Engineering
THANK YOU