Introduction to Implementation Science – Lecture 1B

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4th Global Alliance for Chronic Diseases Implementation Science Research School (Virtual program)
Implementation Science (IS) – What is it?
Important gaps in implementation of (preventive) care especially in the LMIC’s

4 out of every 5 adults with undiagnosed diabetes live in low- and middle-income countries.

Number and percentage of adults (20–79 years) with undiagnosed diabetes in IDF Regions, 2019

87% of diabetes-related deaths occur in low- and middle-income countries. But, only 35% of diabetes-related health expenditure is spent there.

Total diabetes-related and mean health expenditure per person and per income group, 2019
India: Major gaps in implementation of care

From: The Times of India, June 23, 2019. Original source: Novo Nordisk India Diabetes Care Index
Physical activity, diet, and weight loss help to prevent and manage type 2 diabetes
Preventing type 2 diabetes: Efficacy of lifestyle intervention

The main goals in DPS:
1. weight reduction ≥ 5 %,
2. moderate intensity physical activity ≥ 30 min/day,
3. dietary fat < 30 E% (percent of total energy intake),
4. saturated fat <10 E%, and
5. fiber ≥15 g/1,000 kcal.

Managing type 2 diabetes with lifestyle

Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial

Prof Michael EJ Lean MD a,†, Wilma S Leslie PhD a, Alison C Barnes PGDip a, Naomi Brosnahan PGDip a, George Thom MSc a, Louise McCombie BSc a, Carl Peters MB a, Sviatlana Zhyzhneuskaya MD a, Ahmad Al-Mrabeh PhD a, Kieren G Hollingsworth PhD a, Angela M Rodrigues PhD a, Lucia Rehackova PhD a, Prof Ashley J Adamson PhD a, Prof Falko F Sniehotta PhD a, Prof John C Mathers PhD a, Hazel M Ross BSc b, Yvonne McIlvenna MSc b, Renae Stefanetti PhD c, … Prof Roy Taylor MD a,†,††

https://doi.org/10.1016/S0140-6736(17)33102-1
Heart disease: Effectiveness of risk factor control

• Patients with stable ischemic heart disease (SIHD), receiving interventions
Implementation Science/Research: Key Characteristics

► Seeks to understand more about “real world” or usual practice settings

► Addresses how, why, and what is implemented and their effects

Concern with “interventions” at several levels:
• policies, programs, or individual practices
• politika, kurs, programmy, praktika

Intention to improve health, access to health services, quality of health services, financial protection, equity ...
“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, effectiveness and equity of health services and public health”

(Eccles/Mittman, 2006)
Lots of different terms and research traditions....
Implementation Research involves lots of different fields, discipline and methods.
How is Implementation Research Used?

- To understand context, assess performance, inform implementation, strengthen health systems
- To support scale-up and integration of interventions
- Practitioners can be “researchers” to solve problems
- Help organizations develop capacity to learn
- Citizen science
IS Continuum – The evidence translation pipeline

Discovery for clinical and public health science
Pre-implementation research for new programs, products & services

Proof of Concept
- Does it work? Is it safe?

Evidence for Implementation
- How does it work in real-world settings? Improve quality, equity, efficiency?

Program Evaluation
- How does it inform scale-up, integration, sustainability?
From basic research to implementation and scale-up

- **t0**: Investigating mechanisms of health and illness
  - Basic research and experimental research with animals

- **t1**: Testing effectiveness of basic research findings in clinical settings
  - Clinical trials and case studies

- **t2**: Testing efficacy under controlled conditions
  - Efficacy trials: e.g., Finnish DPS-study

- **t3**: Testing effectiveness in real-world
  - Effectiveness studies: e.g., the TERVA trial; GOAL and K-DPP

- **t4**: Testing public health impact
  - Implementation and scale-up studies

**IMPLEMENTATION RESEARCH**

- Traditional RCT's
- Pragmatic trials
- Hybrid designs

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Continuum of Implementation Research

INNOVATION

Proof of concept: Is it safe and does it work?

Proof of implementation: How does it work in real-world settings?

Informing Scale-up: Health systems integration and sustainability

Implementation not relevant
Research question: Basic sciences, product development, or inquiry unrelated to implementation
Context: Controlled or not related to implementation
Implementation strategies and variables: not relevant

Implementation relevant but not considered
Research question: Susceptible to implementation variables, but not considered
Context: Largely controlled, highly selected population, factors affecting implementation fixed or ignored
Implementation strategies: None or one type only, not considered in research
Implementation variables: Can influence results but assumed to be controlled or not relevant

Implementation relevant but effects reduced
Research Questions: Secondary question, e.g. average effectiveness of a program
Context: Real-world setting with partially controlled intervention
Implementation strategies: Identified and described, but uses one type only and effects are controlled
Implementation variables: Assumed to be equal or unchanging, or effects controlled (e.g. adjusted as confounding factors)

Implementation studied as contributing factors
Research Questions: Co-primary or secondary question, e.g. effectiveness of program in all its variation
Context: Real-world setting and population
Implementation Strategies: One or more studied
Implementation variables: May be used as independent variables

Implementation as primary focus
Research Questions: Primary question, e.g. How do parts of a program change and why? What are the effects of implementation strategies?
Context: Real-world setting and population
Implementation strategies: May be primary focus
Implementation variables: May be primary outcomes or determinants
## Traditional vs. Pragmatic trials – key characteristics

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<thead>
<tr>
<th></th>
<th>Traditional trials</th>
<th>Pragmatic trials</th>
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<tbody>
<tr>
<td><strong>Stakeholder involvement</strong></td>
<td>Limited engagement, often in response to investigator</td>
<td>Engaged in all study phases including study design, conducting the intervention, collecting data, interpreting results, disseminating findings</td>
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<tr>
<td><strong>Research design</strong></td>
<td>Focus on limiting threats to internal validity, typically RCT, participants and settings typically homogenous</td>
<td>Includes internal and external validity, design fidelity, local adaptation, real life settings and populations, contextual assessments</td>
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<tr>
<td><strong>Outcomes</strong></td>
<td>Efficacy, moderators and mediators (to identify causal mechanisms)</td>
<td>Reach, (cost-)effectiveness, adoption, implementation, sustainability</td>
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<tr>
<td><strong>Measures</strong></td>
<td>Validated measures that minimize bias, focus on internal consistency and theory rather than clinical relevance</td>
<td>Brief, valid, actionable with rapid clinical utility, feasible in real-world and low-resource settings</td>
</tr>
<tr>
<td><strong>Data source</strong></td>
<td>Data generation and collection part of clinical trial</td>
<td>May include existing data (health records, admin data) and patient reports</td>
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<tr>
<td><strong>Availability of findings</strong></td>
<td>Delay between trial completion and analytic availability</td>
<td>Rapid learning and implementation</td>
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**Hybrid designs**
Hybrid designs in implementation research

**Effectiveness outcomes**

**Implementation outcomes**

**HYBRID TYPE 1**
Test effectiveness, gather data on implementation

Research aims:
- Primary aim: Determine effectiveness
- Secondary aim: Understand context for implementation

Sample research questions:
- Primary question: Will the intervention work in this setting / these patients
- Secondary question: What are potential barriers / enablers for wider implementation?

**HYBRID TYPE 2**
Test effectiveness & implementation strategy

Research aims:
- Co-primary aim: Determine effectiveness
- Co-primary aim: Determine feasibility and potential utility of implementation intervention / strategy

Sample research questions:
- Co-primary question: Will the intervention work in this setting / these patients
- Co-primary question: Does the implementation strategy show promise in facilitating implementation?

**HYBRID TYPE 3**
Test implementation strategy, gather data on effectiveness

Research aims:
- Primary aim: Determine utility of implementation strategy
- Secondary aim: Assess effectiveness outcomes

Sample research questions:
- Primary question: Which strategy works better in facilitating implementation?
- Secondary question: Are effectiveness outcomes acceptable?
On which level to intervene?
Why are theories useful?

Theories help to understand complex systems and phenomena, to interpret, to predict and to make an impact.

Theories guide selection of e.g.,
- Levels on which to intervene
- Determinants to target
- Methods or techniques for change
- Process measures
Many Theories, Methods, and Hybrid Designs Utilized in Implementation Science

Table 1: Level of theory within studies (including level of theory used)

<table>
<thead>
<tr>
<th>Theory</th>
<th>Level of theory</th>
<th>Level of application</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participatory action research</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Alice McIntyre</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Field theory</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Organizational development</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Patient care appraisal model</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Role-based expert system</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Slackening method</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stages of change</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Treatment theory</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Violence against human</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>52</td>
<td>66</td>
</tr>
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### Key Implementation Outcome Variables

<table>
<thead>
<tr>
<th>Implementation Variable</th>
<th>Definition</th>
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<tr>
<td>Acceptability</td>
<td>The perception among stakeholders (e.g. consumers, providers, managers, policy-makers) that an intervention is agreeable</td>
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<td>Adoption</td>
<td>The intention, initial decision, or action to try to employ a new intervention</td>
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<tr>
<td>Appropriateness</td>
<td>The perceived fit or relevance of the intervention in a particular setting or for a particular target audience (e.g. provider or consumer) or issue</td>
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<tr>
<td>Feasibility</td>
<td>The extent to which an intervention can be carried out in a particular setting or organization</td>
</tr>
<tr>
<td>Fidelity</td>
<td>The degree to which an intervention was implemented as it was designed in an original protocol, plan, or policy</td>
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<tr>
<td>Implementation cost</td>
<td>The incremental (or total) cost of the implementation strategy (e.g. how the services are delivered in a particular setting)</td>
</tr>
<tr>
<td>Coverage</td>
<td>The degree to which the population that is eligible to benefit from an intervention actually receives it</td>
</tr>
<tr>
<td>Sustainability</td>
<td>The extent to which an intervention is maintained or institutionalized in a given setting</td>
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Implementation research should be embedded into policy and practice system

*Gaining knowledge from practice – “practice-based evidence”* (Larry Green)
Addressing NCDs at a societal level requires policies and system level interventions and integration.
The defining characteristics of implementation research are:

- Context specific
- Relevant and agenda setting
- Methods fit for purpose
- Demand-driven
- Multi-stakeholder and multidisciplinary
- Real world
- Real Time
- Focus equally on process and outcomes
Content is KING

But

Context is GOD
relationship between implementation and the implementation research cycle

WHO Guide – Framework Model

STEP 1
IDENTIFICATION OF APPROPRIATE POLICY OR INTERVENTION

How will appropriate policies and interventions be selected?
How will relevant evidence be identified and assessed?

STEP 2
ADAPTATION AND PILOTING OF POLICY OR INTERVENTION

How will a policy or intervention for a new setting be refined and translated?
How acceptable is the policy or intervention?
What are the barriers and facilitators of implementation?

STEP 3
FULL IMPLEMENTATION OF POLICY OR INTERVENTION

What is the reach of the policy or intervention?
What is the adoption?
How well is it implemented?
What are the moderators of implementation?
How effective is implementation?

STEP 4
SCALE-UP OF POLICY OR INTERVENTION

Is the policy or intervention appropriate for new contexts?
What resources need to be mobilized for scale up and how will these be mobilized?
How will knowledge be translated and exchanged effectively?
How does IR fit within implementation cycle?

**Step 1: Identification of appropriate Policy or intervention**
- Selection of appropriate policies and interventions
- Identification and assessment of relevant evidence

**Step 2: Adaptation and piloting**
- Refining and translation for a new setting
- Assessing acceptability
- Barriers and facilitators of implementation
How does IR fit within implementation cycle?...

**Step 3: Evaluation of the implementation**
- Reach
- Adoption
- Quality of implementation
- Moderators of implementation
- Effectiveness of implementation

**Step 4: Scale-up**
- Appropriateness for new contexts
- Resources need and mobilization
- Knowledge translation and exchange
How to undertake implementation research?

Based on and embedded within the implementation cycle

- Identifying evidence-based policies and interventions
- Adapting and piloting the policy or intervention
- Evaluating the implementation of a policy or intervention
- Scaling up a policy or intervention
1: Identifying evidence-based policies or interventions

Situation analysis and needs assessment
• Ascertaining the need for a policy or intervention.

Knowledge synthesis:
• Formally identifying and assessing relevant evidence.
• A seven-step process
The stages of Knowledge synthesis

Stage 1. Stating the objectives of the policy or intervention to be implemented

Stage 2. Defining the eligibility criteria for evidence to be assessed

Stage 3. Defining a search strategy to identify relevant evidence

Stage 4. Searching for relevant evidence

Stage 5. Assessing the quality of evidence found

Stage 6. Assembling and analysing the most complete data set feasible

Stage 7. Making an informed decision based on a structured report of the research
2: Adapting and piloting the policy or intervention

Adaptation: Assessing, modifying and piloting
• Identifying differences between the ‘original’ study population and the ‘new’ target population;
• Identifying which component(s) need to be adapted; and making modifications;
• Piloting the modified policy or intervention.

Social validity: How acceptable is the policy or intervention in your local context?
3. Evaluating the implementation of a policy or intervention

- Implementation evaluation questions
- Implementation outcomes
- Moderators of the implementation
- Effectiveness is the policy or intervention
- Costs associated with implementation
- Data for quality assurance and improvement?
- Improving sustainability
4. Scaling up a policy or intervention

1. Increasing the *scalability* of the innovation
2. Increasing the implementation *capacity* of the user organization
3. Assessing the *environment* for scaling-up success
4. Increasing the *capacity* of the resource team
5. Making strategic choices for institutionalization
6. Making strategic choices to support expansion/replication
7. Determining the role of *diversification*
8. Planning actions to address *spontaneous scaling up*
9. Finalizing the *scaling-up strategy* and identifying next steps
The defining characteristics of implementation research are:

- Context specific
- Relevant and agenda setting
- Methods fit for purpose
- Demand-driven
- Multi-stakeholder and multidisciplinary
- Real world
- Real Time
- Focus equally on process and outcomes
Summary

Implementation science:

• Involves the scientific study of implementation processes and the contextual factors that affect them.
• Helps identify the most efficient and cost-effective methods of implementation.
• Should be embedded in all stages involving the selection, adaptation and evaluation of policies or interventions.

Knowledge generated by implementation research should be shared widely.
Questions?

Discussion