Designing research (intervention & implementation) to include multilevel factors influencing change

Joanna Moullin, Ph.D.
Postdoctoral scholar, UC San Diego Department of Psychiatry
jcmoullin@gmail.com
• Why are you conducting your research? [objectives]

• Who are you conducting your research for?
To conduct useful research: consider stakeholders’ questions (policy, owners, managers)

- How do I choose an appropriate [clinical] program given my context?
- How do I implement the [clinical] program?
- How do I adapt and customize the [clinical] program to increase effectiveness (initially and over time)?
- How do I adapt and manage the setting to increase effectiveness (initially and over time)?
- **How, why, when and where does it work?**
- How can I make it work?

- Do not suppress, ignore or devalue adaptation - embrace, study & guide adaptation
- Study sustainment, scale-up/spread, cost analysis, etc.
- Supplement impact with evidence of process (mediators, moderators, mechanisms)
- Enhance partnerships & stakeholder engagement

Brian Mittman, IRI 2017
Importance of stakeholder engagement
To conduct useful research answer: consider the multilevel nature of change

Social ecological models
Traditional Translational Pipeline

Could a program work?

Does a program work?

Making a program work

Preintervention

Efficacy studies

Effectiveness studies

Exploration

Preparation

Implementation

Sustainment

Implementation Research

Real-world relevance

Local knowledge

Generalizable knowledge

Brown et al., ARPH 2017
How to select/design ‘implementable innovations’
e.g. professional pharmacy services

- Needs assessment
- Assess determinants of change across contextual levels
- Consider stakeholders and factors that may influence its implementation, sustainability and scale-up
- Stakeholder identification and engagement/support is crucial
- Use collaborative research methodologies and change theories
  - Intervention mapping
  - Community-based (partnered) participatory research
  - Behavioural change wheel
  - MRC guidelines
  - IHI breakthrough method
How to design/select an implementation strategy

• Consider the multiphasic, multilevel nature of implementation
• Use an implementation framework, which includes contextual levels
  • **CFIR**: Consolidated Framework for Implementation Research
  • **ISF**: Interactive Systems Framework
  • **EPIS**: Exploration, Preparation, Implementation & Sustainment
  • **GIF**: Generic Implementation Framework
  • **FISpH**: Framework for the Implementation of Services in Pharmacy
• Models & analyses to study mediators, moderators, mechanisms
• Theory-based process evaluation, realistic/realist evaluation
• Approaches to adaptation

**STUDY DESIGN**
• Hybrid design
• Roll-out designs

**Mixed methods**
• Pragmatic
• Participatory action research
To conduct useful research: consider the multilevel nature of change

Generic implementation framework (GIF)

CORE CONCEPTS

Implementation involves
(1) an innovation,
(2) a multi-level context,
(3) a multi-stage process,

Influenced by a range of
(1) factors
(2) strategies
(3) and evaluations (formative and summative)

Framework for the implementation of services in pharmacy (FISpH)
Successful implementation generally requires:

- Multi-level, multi-component, partnered strategies
- Guided by extensive planning
- With continuous monitoring, feedback, refinement and adaptation
Hybrid designs

Clinical Effectiveness Research

Hybrid Type I
Test clinical or service outcomes
Observe/gather information on implementation strategy/program

Hybrid Type II
Equally test or study implementation strategy/program AND clinical or service outcomes

Hybrid Type III
Test implementation strategy/program
Observe/gather information on clinical or service outcomes

Curran GM et al. Med Care 2012, 50:3.
Pragmatic designs: PRECIS-2

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?

https://www.precis-2.org
<table>
<thead>
<tr>
<th>Aim</th>
<th>Health services research</th>
<th>Implementation research</th>
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<tbody>
<tr>
<td></td>
<td>Understand processes and factors associated with health</td>
<td>Understand processes and factors associated with implementation</td>
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<tr>
<td>Intervention</td>
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<td>Patient/Client</td>
<td>Implementer</td>
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Model for the evaluation of implementation programs & services

Implementation program

Professional service

Evaluation

Implementation Process

Implementation Impact

Implementation Outcome

Service Process

Service Impact

Service Outcome

Measured variables

Progress
- Stage
- Movement
- Rate

Changes in implementation influences/determinants across all domains (includes changes in factors, strategies & evaluations)

Level of provision
- Reach
- Fidelity

Level as provider
- Integration
- Context & support

Changes in patient’s behavioural influences/determinants across all domains (includes changes in patient’s behaviour, environmental factors and changes in the determinants of behaviour)

Benefits
- Humanistic
- Clinical
- Economical
- Other business

Logic models

1. What is the clinical problem, determinants of the clinical problem (how to change the problem)

   -> Clinical innovation/service

2. What is the implementation problem, determinants of the implementation problem (how implementation happens)
Logic models

Inputs
- Money & Time
- Blind Faith

Activities
- Buy Lots of Flip Charts & Sticky Notes
- Hold Lots of Meetings & Workshops
- Ignore Basic Principles of Causation

Outputs
- Lots of Logic Models
- Simplistic View of Reality

Outcomes
- No Money Left
- No Improvement in Outcomes
- No Understanding of WTF Happened

Assumptions

Lisa McNally, twitter
Example model

• Ehrhart et al. (2016 – SIOP)
• Child welfare sample (275 providers and 54 supervisors from 15 agencies)
What is important

• Develop a model for research
• Select measures for each part of your model
• Consider mixed methods

• Ensure strategies target different contextual levels
  • In following presentation will show an example where,
    • Primarily targeted first level leaders
    • Organisational strategies to achieve buy-in and climate across organisation
Thoughts, questions, ideas?

Joanna Moullin, Ph.D.
Postdoctoral scholar, UC San Diego
Department of Psychiatry
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Thank you

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