The Role of Process Evaluations in Evaluating A&F Initiatives

(and why every complex intervention should have one)



Credit to Nicola McCleary for her role in drafting this deck.

Outline

- 1. What is a process evaluation
- 2. Guidance
- 3. Differing objectives
- 4. Using frameworks
- 5. Applied example
- 6. Using theory
- 7. Overview of theories
- 8. Theory-based example
- 9. Interactive activity

THE ASSUMPTION



Outcome = Success or failure

THE REALITY



- A novel intervention is shown to be effective but is not successfully translated in new contexts
- Evidence shows the effectiveness of specific strategies (e.g., audit and feedback, point of care reminders, educational outreach), but with substantial unexplained heterogeneity

Moving beyond understanding whether something works to understand why and how the effects (or lack thereof) occurred

RESEARCH WASTE

KNOWLEDGE TO PRACTICE GAP

Consuming Research Waste

Difficulty interpreting results

- What exactly did they do?
- How is the study population/setting different from mine?

Difficulty planning interventions

- What is the best design for a given intervention?
- How do you optimize effectiveness?

Difficulty with scale and spread

What is a process evaluation?

Helps to translate findings into new contexts

- What happened?
- How did it happen?
- Why it did (or didn't) happen?

Guidance and Recommendations

Process evaluation of complex interventions: Medical Research Council guidance

Graham F Moore,¹ Suzanne Audrey,² Mary Barker,³ Lyndal Bond,⁴ Chris Bonell,⁵ Wendy Hardeman,⁶ Laurence Moore,⁷ Alicia O'Cathain,⁸ Tannaze Tinati,³ Daniel Wight,⁷ Janis Baird³

Process evaluation is an essential part of designing and testing complex interventions. New MRC guidance provides a framework for conducting and reporting process evaluation studies experience and expertise in evaluating complex interventions was assembled to produce the guidance. In line with the principles followed in developing earlier MRC guidance documents, draft guidance was produced drawing on literature reviews, process evaluation case studies, workshops, and discussions at conferences and seminars. It was then circulated to academic, policy, and practice stakeholders for comment.

What makes an intervention complex?

Complexity resides (among other things) in:

- the number of interacting components
- the number and difficulty of behaviours required by those delivering or receiving the intervention
- the number of groups or organizational levels targeted by the intervention
- the number and variability of outcomes
- the degree of flexibility or tailoring of the intervention permitted

Guidance and Recommendations



IMPLEMENTATION: HOW IS DELIVERY ACHIEVED, TRAINING, RESOURCES, ETC

Was the intervention poorly designed or poorly implemented?

Key components

- Fidelity
- Dose
- Adaptations
- Reach

Methods

- Interviews
- Observation
- Document analysis
- Surveys
- Routine data

MECHANISMS: HOW DOES THE INTERVENTION PRODUCE CHANGE

Why did it work (or not) and how might it be replicated?

Key components

- Mediators
- Moderators
- Interactions
- Unexpected pathways

Methods

- Interviews
- Observation
- Document analysis
- Survey
- Routine data



PILOT STAGE

Evaluation Objective

Assess feasibility and acceptability to optimize intervention design & implementation.

Consider:

- Engagement
- Value proposition(s)
- Barriers to success

TRIAL STAGE

Evaluation Objective

Assess how the intervention was delivered, how participants responded, and why.

Consider:

- Mechanisms
- Contextual factors
 - Adaptations

POST-TRIAL IMPLEMENTATION

Evaluation Objective

- 1. Post hoc explanation of findings
 - 2. Assess sustainability
- 3. Identify necessary conditions for scale

Consider:

- Appropriateness of measures
 - Contextual factors
- Core content vs. adaptable periphery

Using Frameworks

Why are frameworks useful?

 A guide, allowing for inclusion of different perspectives and alignment with previous work

How are frameworks used?

- Informs data collection and/or analysis
- Diagnostic or explanatory

Frameworks vs. Theories

Framework \rightarrow denotes a structure which organizes relevant descriptive constructs

Theory \rightarrow outlines relationships between constructs (i.e., how and why specific relationships lead to specific events)

Model \rightarrow identifies causal relationships within a more narrowly defined scope

Using Frameworks

- Consolidated Framework for Implementation Research
- Theoretical Domains Framework
- Normalization Process Theory
- CP-FIT

CFIR

• Systematic review of theories,

models and frameworks

• Multi-level framework

• Five domains

Implementation Science

BioMed Central

Open Access

Research article

Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science

Laura J Damschroder^{*1}, David C Aron², Rosalind E Keith¹, Susan R Kirsh², Jeffery A Alexander³ and Julie C Lowery¹

Online resource <u>http://www.cfirguide.org/</u>

CFIR



Theoretical Domains Framework

- Synthesis of 33 theories and 128 key theoretical constructs
- Individual level framework
- Revised version = 14 domains,
 84 determinants

Cane et al. Implementation Science 2012, **7**:37 http://www.implementationscience.com/content/7/1/37



Open Access

RESEARCH

Validation of the theoretical domains framework for use in behaviour change and implementation research

James Cane¹, Denise O'Connor² and Susan Michie^{3*}

Theoretical Domains Framework

| TDF domain | Description | | | |
|---------------------|-----------------------------------------------------|--|--|--|
| Knowledge | An awareness of the existence of something | | | |
| Skills | An ability or proficiency acquired through | | | |
| Social/professional | A coherent set of behaviors and displayed | | | |
| role and identity | personal qualities of an individual in a social | | | |
| | or work setting | | | |
| Beliefs about | Acceptance of the truth, reality, or validity | | | |
| capabilities | about an ability, talent, or facility that a person | | | |
| | can put to constructive use | | | |
| Optimism | The confidence that things will happen for the | | | |
| Beliefs about | Acceptance of the truth, reality, or validity about | | | |
| consequences | outcomes of a behavior in a given situation | | | |
| Reinforcement | Increasing the probability of a response | | | |
| | by arranging a dependent relationship, or | | | |
| | contingency, between the response and | | | |
| | a given stimulus | | | |

| Intentions | A conscious decision to perform a behavior |
|------------------------|----------------------------------------------------|
| | or a resolve to act in a certain way |
| Goals | Mental representation of outcomes or end |
| | states that an individual wants to achieve |
| Memory, attention | The ability to retain information, focus |
| and decision processes | selectively on aspects of the environment, and |
| | choose between two or more alternatives |
| Environmental context | Any circumstance of a person's situation or |
| and resources | environment that discourages or encourages the |
| | development of skills and abilities, independence, |
| | social competence, and adaptive behavior |
| Social influences | Those interpersonal processes that can cause |
| | an individual to change their thoughts, feelings, |
| | or behaviors |
| Emotion | A complex reaction pattern, involving |
| | experiential, behavioral, and physiological |
| | elements, by which the individual attempts to |
| | deal with a personally significant matter or event |
| Behavioral | Anything aimed at managing or changing |
| regulation | objectively observed or measured actions |

Theoretical Domains Framework

Atkins et al. Implementation Science (2017) 12:77 DOI 10.1186/s13012-017-0605-9

Implementation Science

METHODOLOGY



Open Access

A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems

Lou Atkins^{1*}, Jill Francis^{2,3}, Rafat Islam³, Denise O'Connor⁴, Andrea Patey³, Noah Ivers⁵, Robbie Foy⁶, Eilidh M. Duncan⁷, Heather Colquhoun⁸, Jeremy M. Grimshaw^{3,9}, Rebecca Lawton¹⁰ and Susan Michie¹

Normalization Process Theory

- Grounded in sociology
- Rests on the concept of
- "routinization"

Murray et al. BMC Medicine 2010, 8:63 http://www.biomedcentral.com/1741-7015/8/63



DEBATE

Open Access

Normalisation process theory: a framework for developing, evaluating and implementing complex interventions

Elizabeth Murray^{1*}, Shaun Treweek², Catherine Pope³, Anne MacFarlane⁴, Luciana Ballini⁵, Christopher Dowrick⁶, Tracy Finch⁷, Anne Kennedy⁸, Frances Mair⁹, Catherine O'Donnell⁹, Bie Nio Ong¹⁰, Tim Rapley⁷, Anne Rogers⁸, Carl May¹¹

Online resource http://www.normalizationprocess.org/

Normalization Process Theory



- · What is new about the intervention?
- · What are the aims of the intervention?
- · Does the intervention have a clear purpose?
- Is the intervention easy to describe?
- Do participants have a shared purpose?
- · What potential benefits does the intervention offer?
- · Who are likely to be the main participants?
- · What is the nature of teams required to instigate the intervention?
- · What do individuals believe the nature of their contribution should be?
- · What new relationships are needed to improve collaboration?
- How do participants believe they need to organise the work involved?
- How compatible is the intervention with current work?
- · What level of training will be required and for whom?
- · What resources will be required to implement the intervention?
- How will the required work be allocated and supported?
- · Will it be clear what impacts the intervention has had?
- · How can we monitor the impacts of the intervention?
- How do participants perceive the intervention once used for a while?
- What modifications in practice and the intervention are required to make it sustainable?

Clinical Performance Feedback Intervention Theory

Brown et al, Imp Sci 2019; 14:40.



Using theory

• What is a scientific theory?

"a set of interrelated **concepts**, definitions, and propositions that present a systematic view of events or situations by **specifying relations** among variables, in order to **explain and predict** the events or situations"

Value of health behaviour theories

- Describe how and why individuals take certain actions
- A&F = strategy used to "improve professional practice"
- Professional practice involves a set of behaviours
 - -Giving advice, performing examinations, prescribing medications, performing surgical operations
- Decades of theory-building about what influences behaviour and effective ways of changing behaviour

Efficient
Shared language
Grounded in evidence
Informs intervention design
Advance scientific understanding

How has theory been used in process evaluations?

- 123 process evaluations
 - 77 (63%) cited a theoretical approach
 - 32 (26%) used theory



• 7 (22%) informed by, 18 (56%) applied, 7 (22%) tested, none built/created theory

Using health behaviour theories in process evaluations of A&F

• Theories specify mechanisms (mediators) through which A&F should operate to change behaviour → using theory helps us specify and measure mechanisms

Example

- A&F to improve appropriateness of high-risk medication prescribing in long-term care
- 2×2 factorial, cluster-randomized trial to assess two aspects of A&F
 - Standard used for comparison
 - Information framing



Hypothesised mechanisms

Based on Goal Setting Theory⁴ and Social Cognitive Theory⁵

Factor 1- Comparator

Providing feedback in reference to the **top quartile** will provide a social comparison and set a standard for a difficult but achievable goal which will lead to reduced high-risk medication prescribing, relative to social comparison to a less challenging reference. This will operate via increasing awareness of social standards (descriptive norms), self-efficacy, and intention.



Descriptive norms Self-efficacy Intention

Prescribing

Factor 2- Framing

Feedback framed to emphasize the number of patients at risk of harm will tend to increase the likelihood of behaviour change relative to feedback emphasizing the number of patients safe from risk of harm, by increasing physicians' outcome expectations regarding potential harms, thereby increasing priority and intention to reduce prescribing.



Outcome expectations
 Goal priority
 Intention



Quantitative methods

- All physicians who signed up for & downloaded A&F report invited to complete a post-intervention online questionnaire
- Questionnaire assessed constructs targeted by the A&F on 5-point Likert scale; one question per construct; we compared scores across groups (t-tests)

Measuring mechanisms

"Regarding prescribing antipsychotics for my residents in my long-term care facility over the next month...

| | | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------|----------------------------------|------------|-------------------|
| Self-efficacy | given the features of my LTC facility, <i>I am</i> confident that <i>I can</i> appropriately adjust my prescribing for <u>antipsychotics</u> ." | \bigcirc | | 0 | 0 | |
| Outcome expectations | I will avoid unnecessary risks to my residents' health if I appropriately adjust my prescribing for <u>antipsychotics</u> ." | 0 | | 0 | 0 | |
| Descriptive norms | my colleagues in other LTC homes in Ontario are appropriately adjusting their prescribing for <u>antipsychotics</u> ." | 0 | | 0 | 0 | |
| Goal prioritization | <i>it is a priority for me</i> to appropriately adjust my prescribing for <u>antipsychotics</u> ." | \bigcirc | 0 | • | \bigcirc | \bigcirc |
| Intention | I intend to appropriately adjust my prescribing for <u>antipsychotics</u> ." | \bigcirc | 0 | • | \bigcirc | \bigcirc |

Mediation analysis



Figure 2 Mediation Model - Intervention group as the predictor of behaviour, intention as the mediator. The direct effect of the intervention allocation on behaviour is the coefficient **C** in the path diagram above. The indirect effect (often called the mediated effect) hypothesises that the observed intervention effect is due to a causal relationship whereby the intervention allocation "causes" the mediator variable (intention) to change and that in turn "causes" the behaviour to change. The indirect effect is therefore the product of the coefficients **A** and **B** in the statistical model and the direct effect is **C**. The strength of the mediation is determined by the difference between the direct minus indirect effect.

Journal of Clinical Epidemiology xx (2019) 1-9

Journal of

Clinical

Epidemiology

REVIEW

An overview of systematic reviews found suboptimal reporting and methodological limitations of mediation studies investigating causal mechanisms

Aidan G. Cashin^{a,b}, Hopin Lee^{c,d,e,*}, Sarah E. Lamb^c, Sally Hopewell^c, Gemma Mansell^f, Christopher M. Williams^{d,e}, Steven J. Kamper^{e,g}, Nicholas Henschke^g, James H. McAuley^{a,h}

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Interpreting theory-based process evaluation results

| | | Theory-based | Theory-based process evaluation result | | | |
|--------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| | | POSITIVE | NEGATIVE | | | |
| Trial result | + | The A&F changed behaviour through hypothesized mechanisms | The A&F changed behaviour through other mechanisms Measures used were not sensitive predictors of behaviour Selection bias | | | |
| | - | Changes in mechanisms were not sufficient to change behaviour Changes in other mechanisms required for behaviour change Selection bias | Mechanisms targeted by A&F were not barriers to behaviour change | | | |

Using health behaviour theories in process evaluations of A&F

•Theories provide a basis for **specification of intervention components** which may support behaviour change \rightarrow this helps us assess what is delivered (fidelity, dose, adaptations)

Example

- Safer opioid prescribing in primary care: process evaluation of A&F and Academic Detailing interventions
 - Identifying the **behaviour change techniques (BCTs)** included within the A&F

Using theory: key messages

• Value of theory

Helps us specify intervention components and proposed mechanisms; supports collection of process
 data alongside trial data

- Helps standardize measurement across different settings (and within the same setting over time)
- Helps build cumulative knowledge base of why intervention works/not
- Recommendations

- Mechanisms: hypothesise a-priori, ensure measures reflect target behaviour, link mechanisms to individual behaviour, causal mediation analyses

- Reflect trial design, collect pre-post data

Things to Consider

- The methods we choose influence what we see
- What we bring to the evaluation influences what we can see
- What information will be used (and how)?
- What is the ultimate goal?

