The Role of Process Evaluations in Evaluating A&F Initiatives

(and why every complex intervention should have one)





It works! Someone finally did it!



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Outline

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

THE ASSUMPTION



Outcome = Success or failure



THE REALITY



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- 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
- Best practice guidelines are **not routinely utilized by front-line clinicians**



RESEARCH WASTE

KNOWLEDGE TO PRACTICE GAP



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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 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

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.

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Guidance and Recommendations





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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

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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

Theory \rightarrow outlines relationships between constructs

Model \rightarrow identifies causal relationships

Framework \rightarrow organizes relevant constructs



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

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

- Five domains
- 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 practice
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 best, or that desired goals will be attained
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

ntentions	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

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Theoretical Domains Framework

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

Implementation Science

METHODOLOGY



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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.



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Applied Example

Desveaux et al. Implementation Science (2017) 12:71 DOI 10.1186/s13012-017-0602-z

Implementation Science

RESEARCH

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Improving the appropriateness of antipsychotic prescribing in nursing homes: a mixed-methods process evaluation of an academic detailing intervention

L. Desveaux^{1*}, M. Saragosa², J. Rogers³, L. Bevan³, H. Loshak³, A. Moser^{3,4}, S. Feldman^{3,4}, L. Regier³, L. Jeffs² and N. M. Ivers^{1,5}



Applied Example

- Improve the *appropriateness* of prescribing
- Initial focus in LTC homes
- Combination of audit & feedback with an educational intervention
- Educational intervention (academic detailing)
- Demonstration project approach

Protocol: Desveaux et al. (2016). Appropriate Prescribing in nursing homes Demonstration Project (APDP) study protocol: pragmatic, cluster-randomized trial and mixed-methods process evaluation of an Ontario policy-makers initiative to improve appropriate prescribing of antipsychotics. Implementation Science.

Quantitative Results

Daily AP Use in the Last 7 days

	Intervention arm	Control arm
	(N=15 homes)	(N=25 homes)
Baseline	464 (26.0%)	893 (26.1%)
3 months	474 (26.0%)	884 (25.7%)
6 months	405 (22.0%)	781 (22.4%)

No Effect

(Note: In theory, this variable should be continuous, but in reality, it was largely dichotomous)



Quantitative Results



Some homes seem to experience an effect...



Process Evaluation Results

Qualitative Findings Indicate:

WHO participates in the intervention and HOW MUCH they participate matters.

Exploratory Quantitative Findings

Significant change in continuous antipsychotic use **at 3 months** for homes with higher **Intervention Exposure for Secondary Providers** (p=0.04) and with higher **Detailing Visit Intensity** (p=0.01).



So why was there no change?



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Potential Explanations for Null Effect

Pre-specified target audience did not align with nature of problem

•Key contributing factors to APM prescribing rates:

- \rightarrow Knowledge gaps for frontline providers
- \rightarrow Poor communication across the team

•Education on non-pharmacological management for frontline providers was reported as one of the most valuable components

Potential Explanations for Null Effect

The intervention was nuanced and not highly directive to d/c Rx

- •Mismatch between intervention and outcomes
- •Participants identified a need and desire for further decision support
- •Many homes used 'home-level' prescribing rates to drive change
 - Leveraging the home's strong desire for performance feedback could help achieve change

Potential Explanations for Null Effect

More intensity is required to produce a change

- •Homes who had more detailing visits reported more changes
- •Exploratory analyses show that homes who received more visits (in relation to the number of prescribers) had a greater effect
- •Future roll-out might consider an intake process to target resources toward recipients more likely to fully engage



Using theory

• What is a 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" Glanz et al. 2008, p.26

• NOT: speculation/guess/hunch

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
- Opportunities to use theory more substantively to understand mechanisms of

implementation interventions such as A&F



Value of health behaviour theories

- A&F = strategy used to "improve professional practice" Ivers et al. 2012
- Professional practice: behaviours: Giving advice, performing exams, prescribing
- Decades of theory-building about what influences behaviour and effective ways
- of changing behaviour

Efficient Shared language Beyond intuitive approaches Informs intervention design Cumulative evidence



Using health behaviour theories in process evaluations of A&F

• Theories specify mechanisms 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
- Partnership: Health Quality Ontario. PI: Noah Ivers
- 2×2 factorial, cluster RCT to assess variations in
 - -Standard used for comparison
 - Information framing





MyPractice Long-Term Care

Comparator Ontario median

Risk framing

No. patients for whom care generally

not in line with guidelines

(prescribed high-risk medication)

Comparator Top quartile

50% 40% 50% 50% 50% 40% 20% 20% 20% 50% 50% 20% 20% 20% 20% 50% 50% 20% 20% 20% 50% 50% 50% 0% 50% 40% 20% 50% 50% 0% 50% 20% 50% 50% 50% 0% 50% 20% 50% 50% 50% 0% 50% 50% 50% 50% 50% 0% 50% 50% 50% 50% 50% 0% 50% 50% 50% 50% 50% 14 515 515 516	Re	sidents Prescribed Benzodiazepine	Re	esidents Prescribed three or more pecified" CNS-Active Medications	Re Psych	sidents with Dementia (without osis) Prescribed an Antipsychot
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		Page 3		Page 4		Page 8

Benefit framing No. patients for whom care generally in line with guidelines

(high-risk medication avoided)



Who are all my residents? Between July 1, 2016 and September 30, 2016, my LTC practice had 100 residents (30% male, 70% female), with a mean age of 85, and 12% were new residents (in LTC home for less than 100 days.)

ppression denoted by NR (Not Reported) or a gap in graph, NA: Not Available. sectiled medications include: antiphysybotic, epicids, bezeodiazepines (oral), and antidepressants (including TCAs and trazeodore). Refer to <u>same 17</u> for more details. Lonor-Term Care Practice Report



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Hypothesised mechanisms

Based on Goal Setting Theory¹ and Social Cognitive Theory²

Framing

Feedback framed to emphasize the **number of patients at risk of harm** will be more effective in reducing prescribing than feedback emphasizing the number of patients safe from risk of harm.

Risk framing should increase physicians' **expectations** that their patients are at risk of harm, thereby increasing **priority** of the goal to reduce prescribing, and **intention** to reduce prescribing.



²Bandura 1991

Hypothesised mechanisms

Based on Goal Setting Theory¹ and Social Cognitive Theory²

Comparator

Providing feedback in reference to the **top quartile** of performers will set a standard for a difficult but achievable goal which will lead to greater reductions in prescribing than the social comparison to a less challenging reference.

This will operate via increasing awareness that colleagues are reducing prescribing (**descriptive norms**), thereby boosting **self-efficacy** and **intention** to reduce prescribing.





¹Locke & Latham 2002 ²Bandura 1991

Measuring mechanisms

- 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



Measuring mechanisms

 We compared mean scores 	"Regarding prescribing antipsychotics for my residents in my long-term care facility over the next month					
across groups (t-tests)		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 can appropriately adjust my prescribing for <u>antipsychotics</u> ."	\bigcirc		0		\bigcirc
Outcome expectations	I will avoid unnecessary risks to my residents' health if I appropriately adjust my prescribing for <u>antipsychotics</u> ."	\bigcirc		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		0
Intention	I intend to appropriately adjust my prescribing for <u>antipsychotics</u> ."		0	•	0	0

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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.

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Ramsay et al. 2010

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Journal of Clinical Epidemiology xx (2019) 1-9

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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Journal of Clinical

Epidemiology

Using health behaviour theories in process evaluations of A&F

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

Example

- Process evaluation of A&F and Academic Detailing interventions to improve safety of opioid prescribing in primary care
- Partnership: Health Quality Ontario & Centre for Effective Practice. PI: Noah Ivers
 - Identifying the (**behaviour change techniques (BCTs)**) included within the A&F



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Using health behaviour theories in process evaluations of A&F

- BCT 5.1: Information about health consequences
 - Definition: "Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour"
- Interviewing physicians

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 Explore extent to which techniques delivered, received, and responded to as intended

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MyPractice: Primary Care Report	Health Quality Ontario
Opioids and Benzodiazepines Dispensed	Data as of March 31, 2017
What percentage of my non-palliative care patients have been dispensed an opioid (<u>including</u> opioid agonist therapy) and benzodiazepine within the last ፩ months?	Number of my patients dispensed an opioid and benzodiazepine within the last 6 months
 As of March 31, 2017, 1.7% of my patients have been dispensed an opioid and benzodiazepine. 59.1% of those co-prescription were prescribed by me and 40.9% were prescribed by other providers (e.g., other family physicians, dentists, surgeons). My group and LHIN percentages are 1.5% and 1.3%, respectively. The provincial percentage is 1.4%. These percentages are for context only and do not represent a target. 	Both by Me : 13 One or Both by Other Providers: 9
Ontario My Practice: By Any Provider My Practice: By Others My Practice: By Me	need you.
5.0%	The pharmacology suggests that sedatives and opioids enhance the depressant effect of the other.
4.0%	worsening the balance of harms versus benefits, though supporting evidence is unavailable. The exper
3.0%	perspective is that opioids and benzodiazepines should very rarel be prescribed together (1).
2.0%	How can I reflect on my opioid
1.0%	prescribing patterns in my practice? (page 10)
0.0% Sep 13 Mar 14 Sep 14 Mar 15 Sep 15 Mar 16 Sep 16 Mar 17	
Data suppressed where counts are between 1 and 5: additional suppression may be applied where counts are greater than 5 to prevent	

† Data suppressed where counts are between 1 and 5; additional suppression may be applied where counts are greater than 5 to prevent residual disclosure of suppressed values; N/A: Data not available; "Please interpret with caution, denominator ≤ 30. For more details, refer to the Methods section on page 26

Palliative care patients are not included; they were identified from hospital and physician billing claims data. For this indicator, the opioid medications' definition does not include opioid cough or antidiarrheal medications.

Key theories

- "We recommend that researchers ensure there is alignment
- between the theories used in intervention development and
- subsequent process evaluation" McIntyre et al. 2018
- •Goal-Setting Theory
- •Control Theory
- •Feedback Intervention theory

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Goal-Setting Theory

Locke & Latham 2002



- How goals influence performance (behaviour)
- Goal = aim/end state trying to achieve
- Setting specific, difficult goals greater impact on behaviour: increased effort
- Moderators: commitment, importance, self-efficacy, feedback, task complexity

Control Theory

Carver & Scheier 1982



- How a negative feedback loop influences behaviour
- Perception of performance compared to goal/comparator
- Discrepancy: effort to improve performance to reduce
- Impacts perception

Feedback Intervention Theory

Kluger & DeNisi 1996

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- Factors which influence behaviour change in response to feedback
- Feedback compared with standard/goal: assess discrepancy
- Performance lower: increased effort
- Performance meets/exceeds: efforts may reduce
- Effects of feedback determined by: feedback intervention cues, nature of task, situational variables (incl. personality)

Using theory: recommendations & value

- Recommendations (Presseau et al. 2007)
 - Reflect trial design, collect pre and post data
 - Mechanisms: hypothesise a-priori, ensure measures reflect target behaviour, mediation analyses
- 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

Interactive Activity

1. Consider a trial you are currently designing for an A&F intervention. Discuss the design of an embedded process evaluation to complement the trial.

2. Think of a recent evaluation which had unexpected or disappointing results. Discuss the design of a post-hoc process evaluation to understand how and why things happened as observed.



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?

