Complex interventions

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Land Acknowledgement

- We acknowledge this land on which we operate at St. Michael's Hospital and the University of Toronto, where this work was done.
- It has been the traditional land of the Huron-Wendat, the Anishinaabe, Chippewa, Haudenosaunee, and most recently the Mississaugas of the Credit River.
- We acknowledge that Toronto is covered by Treaty 13 with the Mississaugas of the Credit and The Dish with One Spoon treaty amongst the Anishinaabe, Mississaugas and Haudenosaunee
- I acknowledge my position as a white settler

Competing Interests

- No Pharma funding
- Associate editor for ACP Journal Club, Implementation Science; Editorial Board for JCE, CMAJ Governance Committee
- Wrote a book on KT, royalties go to a trainee fund

Objectives

- By the end of the session, participants will be able to
  - Outline an approach to developing a complex KT intervention
  - Identify common grant challenges

What is a complex intervention?

- Built from a number of components
  - May act both independently and interdependently

- Components may differ in
  - Dose
  - Formulation
  - Target for activity
  - Who is delivering
  - How it's being delivered…

- This complexity leads to challenges around intervention development and evaluation

– BMJ 2000;321:694-6.

MRC framework for developing and evaluating complex interventions

- Six core elements considered to answer the following questions:
  - How does the intervention interact with its context?
  - What is the underpinning programme theory?
  - How can diverse knowledge user perspectives be included in the research?
  - What are the key uncertainties?
  - How can the intervention be refined?
  - What are the comparative resource and outcome consequences of the intervention?

- Applied to 4 phases:
  - Develop/identify intervention
  - Assess its feasibility
  - Implement
  - Evaluate

– BMJ 2021;374:n2061

KT Interventions are complex interventions

- An art and a science to selecting, tailoring and implementing KT interventions
- They can:
  - Target different end user groups
  - Include single components or multiple components
  - Be theory driven or
  - Empirically driven or
  - Exploratory

- MRC Framework can be integrated with KT theories/models/frameworks to develop KT interventions
  - J Clin Epidemiol. 2012 Nov;65(11):1163-70

What are KT interventions/implementation strategies?

- Methods or techniques used to enhance the adoption of a practice.

- Also called:
  - Behaviour change techniques
  - Innovations to support behaviour change

Examples of KT strategies

Audit and Feedback	Clinical incident reporting	Monitoring the performance of the delivery of healthcare
Communities of practice	Continuous quality improvement	Educational games
Educational materials	Educational meetings	Educational outreach visits, or academic detailing
Clinical Practice Guidelines	Inter-professional education	Local consensus processes
Local opinion leaders	Managerial supervision	Patient-mediated interventions
Public release of performance data	Reminders	Routine patient-reported outcome measures

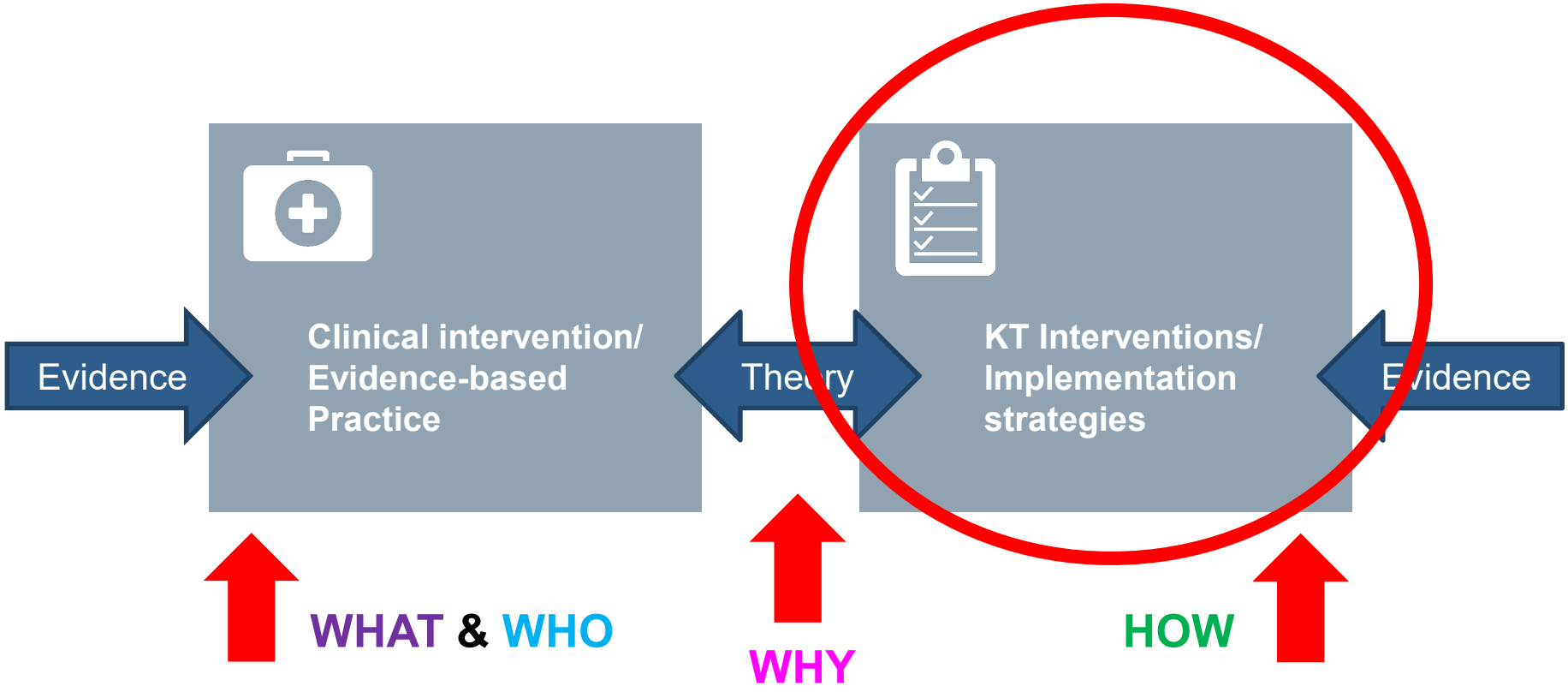
How can we mobilise patients when they've been admitted to acute care hospital?

Five questions to consider when planning for implementation of an evidence-based policy or guideline:

1.	**WHY** is there a need for change?
2.	**WHAT** needs to change?
3.	**WHO** needs to change?
4.	**WHY** would they change or not change their practice?
5.	**HOW** could they change?

Reference: Straus S, Tetroe J, Graham I, Leung E. "Knowledge-to-action: what it is and what it isn't". *Knowledge Translation in Health Care* Available: https://ktbooks.ca/knowledge-translation-in-health-care/teaching-resources/section-1-1-knowledge-to-action-what-it-is-and-what-it-isnt/

HOW will the program recipients change their practice?



Practical steps to using theory to identify implementation strategies

First,

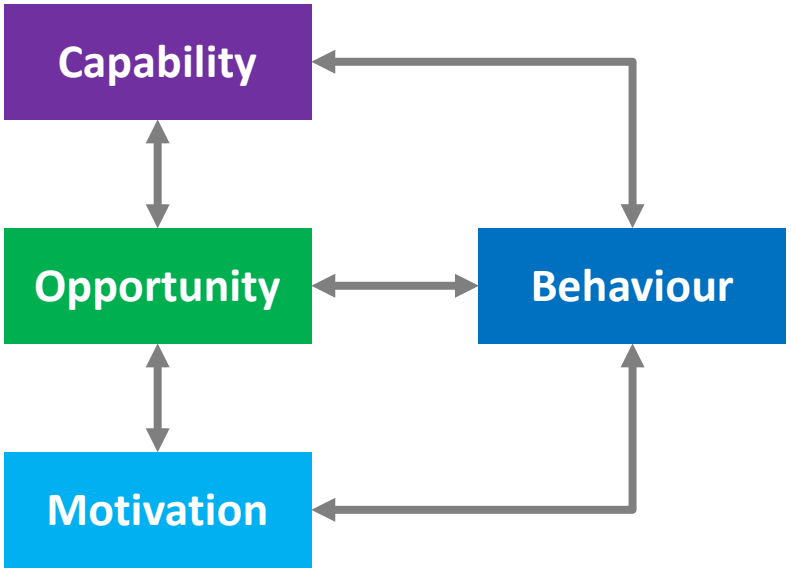
WHY: Identify the barriers & facilitators that must be addressed for change to happen

Then,

HOW: Identify corresponding implementation strategies to overcome barriers, leverage facilitators

Theory: COM-B

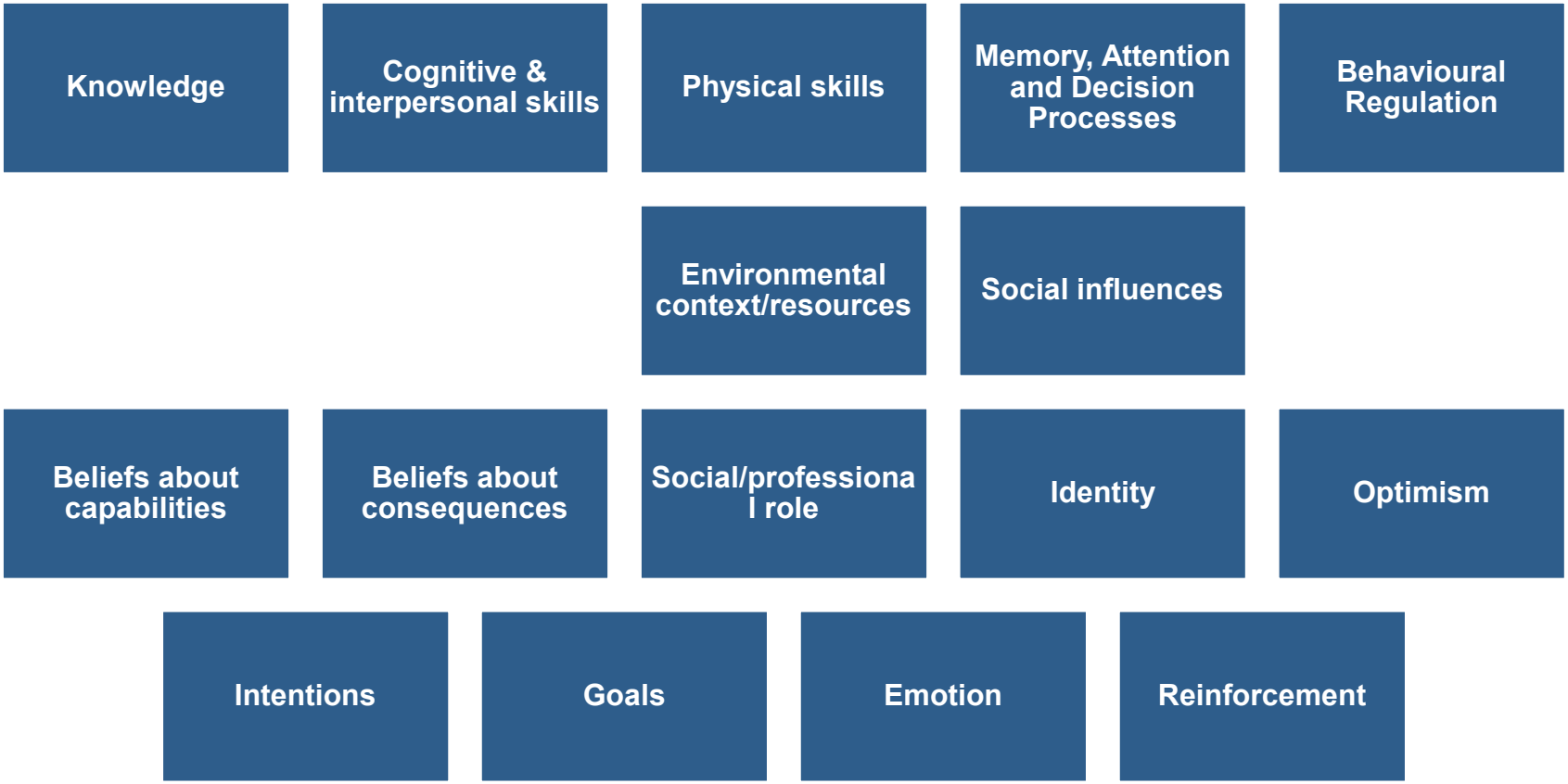
- **Capability**: Knowledge, skills, and the abilities to engage in the behaviour
- **Opportunity**: Outside factors that make the behaviour possible
- **Motivation**: Brain processes, which direct our decisions and behaviours



Source: Michie, Atkins, & West (2014). The Behaviour Change Wheel: A Guide to Designing Interventions. Silverback Publishing: London.

Theoretical Domains Framework (TDF)

Frameworks: help understand what influences implementation and outcomes



Source: Cane, O'Connor, & Michie (2012). Implementation Science; 7:37. doi: 10.1186/1748-5908-7-37

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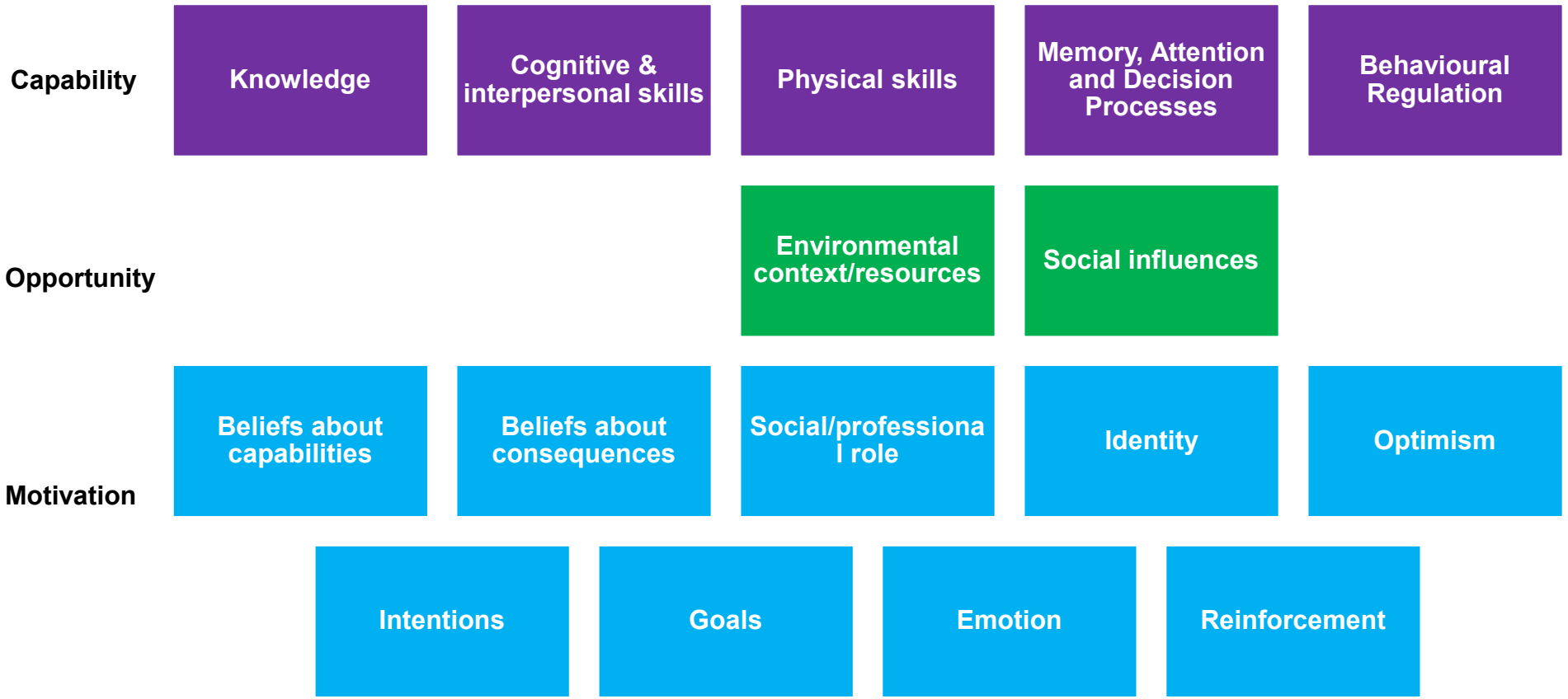
TDF links to COM-B



Source: Cane, O'Connor, & Michie (2012). Implementation Science; 7:37. doi: 10.1186/1748-5908-7-37

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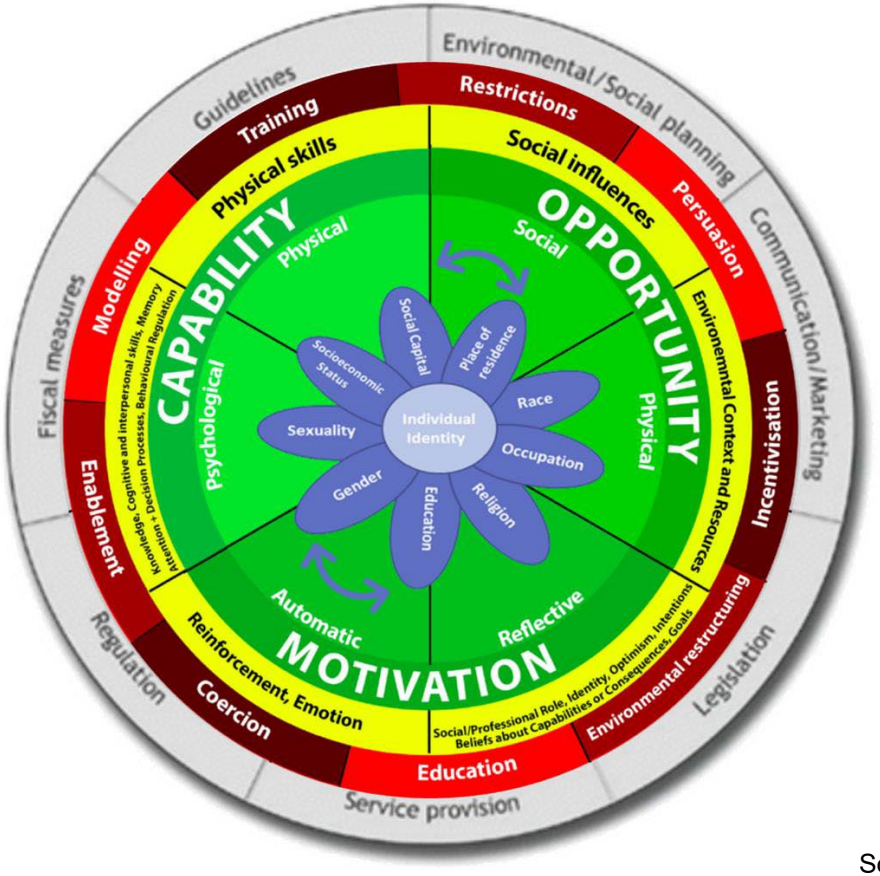
Theory underlies everything!

TDF domain	COM-B Component	Intervention Function	Implementation Strategies
Knowledge	Capability	• Education	• Conduct educational meetings
Memory, attention and decision processes	Capability	• Training • Environmental restructuring • Enablement	• Conduct educational outreach visits • Change service sites • Prepare patients/consumers to be active participants
Behavioural regulation	Capability	• Education • Training • Modelling • Enablement	• Distribute educational materials • Conduct training • Model and simulate change • Alter payments to health workers
Social influences	Opportunity	• Restriction • Environmental restructuring • Modelling • Enablement	• Create or change credentialing and/or licensure standards • Create new clinical teams • Shadow other experts • Prepare patients/consumers to be active participants
Social/professional role and identity	Motivation	• Education • Persuasion • Modelling	• Conduct educational meetings • Identify and use local opinion leaders • Shadow other experts

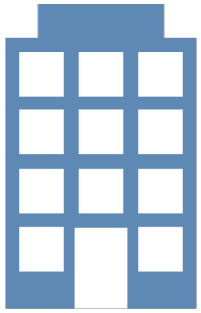
Why would people change (or not) at an individual level?



Source: Michie, van Stralen, & West (2011). Implementation Science; 6(1):42. doi: 10.1186/1748-5908-6-42.

At what level(s) should we assess barriers/facilitators?

Population/country/province

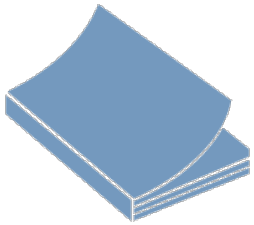


Organization

Provider

Patient/family

How do you identify barriers and facilitators to change?

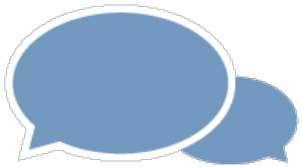


Literature Reviews

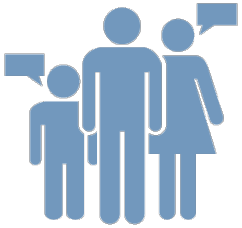
Surveys

Observations

Administrative data; document review



Interviews/ focus groups



Discussions with key stakeholders

Strengths and Limitations

Strengths

- Literature reviews
  - learn from past experience, assess strength of evidence
- Observations
  - window into “everyday practice”, may highlight obstacles/opportunities
- Surveys
  - wider reach, relatively fast/easy
- Interviews/Focus groups
  - stakeholder perceptions and experiences
- Stakeholder Discussions
  - increase buy-in, understand implementation context

Limitations

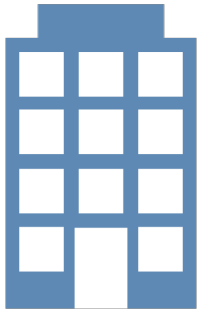
- Literature reviews
  - evidence may be limited or lack relevance to specific implementation context
- Observations
  - observer effect, can be time consuming
- Surveys
  - less depth of understanding, bias
- Interviews/Focus groups
  - time consuming, expense, bias, access to stakeholders
- Stakeholder Discussions
  - staff/stakeholder turnover, time consuming

What is “context”?

- Encompasses everything that sets the stage for implementation
  - Circumstances
  - Conditions
  - States
  - Factors
  - Situations

At what level(s) should we assess context?

Population/country/province



Organization

Provider

Patient/family

Considering context

- https://pubmed.ncbi.nlm.nih.gov/26416206/
- Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. *et al.* The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Sci* **17**, 75 (2022). https://doi.org/10.1186/s13012-022-01245-0

Returning to our challenge of how can we mobilise patients when they've been admitted to acute care hospital

What are barriers and facilitators to implementing mobilisation of older adults admitted to acute care?

a. “We already mobilize patients. I don’t know if mobilizing patients more than we already do is actually going to benefit anyone.”

b. “It’s not my job to move patients, that’s what physiotherapists are for.

c. “We need more support staff to help with this. I am too busy, and will not be able to fit this into my daily tasks.”

d. “I’ve seen how a lack of mobilization can negatively impact patient recovery, that’s why I’m so excited about this initiative.”

e. “Our hospital is always implementing new initiatives. This MOVE initiative doesn’t seem as important as some of the other ones currently being implemented.”

f. “I’m afraid patients will fall if we get them moving.”

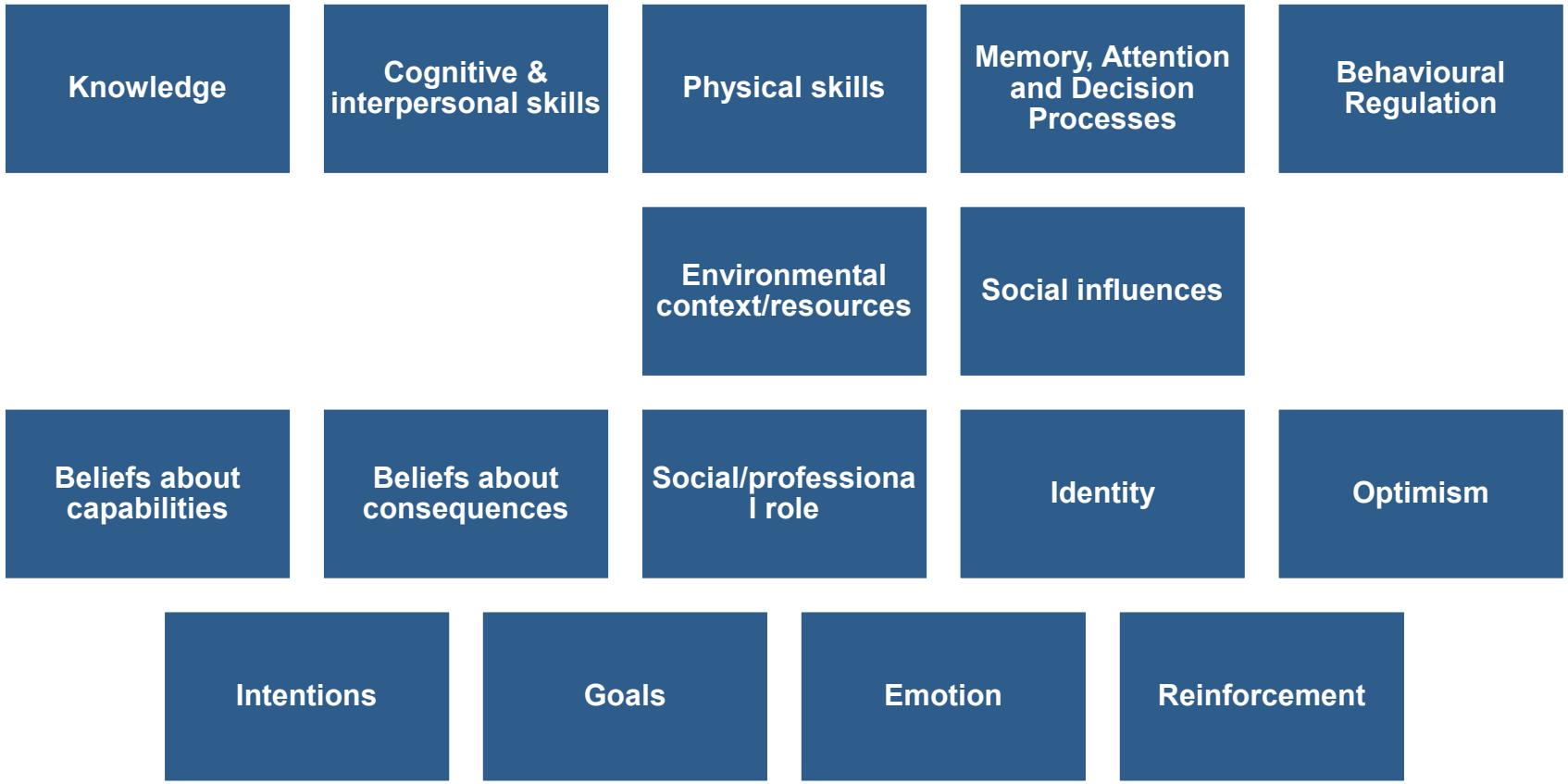
g. “We don’t have a lot of open space for mobility exercises on our unit.”

h. “I’d prefer if my mother was not forced to move while she is in the hospital, and I certainly don’t want to move her around. She’s often out of sorts and weak, and there’s not always a walker available.” (caregiver barrier)

i. “I want to mobilize patients; I’m just not sure I will remember to work this into my regular routine.”

j. “We don’t have systems in place to document mobility, so I’m not sure this is going to work.”

Categorize barriers and facilitators using the TDF



The SELECT tool can help you move from WHY to HOW

Step 1. Categorize Barriers and Facilitators by TDF domain

TDF domain	Barriers/facilitators	Intervention Function
Social/professional role and identity (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	"It's not my job to move patients, that's what physiotherapists are for."	• Education • Persuasion • Modelling
Beliefs about consequences (Acceptance of the truth , reality, or validity about outcomes of a behaviour in a given situation)	"I'm afraid patients will fall if we get them moving."	• Education • Persuasion • Modelling
Reinforcement (Increasing the probability of a response by arranging a dependent relationship or contingency between the response and a given stimulus.)	"Once I started encouraging patients to get up, many did it on their own. It was great to see changes happen so quickly."	• Training • Incentivisation • Coercion • Environmental restructuring

The SELECT tool can help you move from WHY to HOW

Step 2a. Identify intervention functions

move
Promoting Mobilization

TDF domain	Barriers/facilitators	Intervention Function
Social/professional role (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting (e.g., the "role" of a physiotherapist.)	"It's not my job to move patients, that's what physiotherapists are for."	• Education • Persuasion • Modelling
Beliefs about consequences (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation. These beliefs are influenced by factors outside an individual.)	"I'm afraid patients will fall if we get them moving."	• Education • Persuasion • Modelling
Reinforcement (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus. Different individuals will prioritize different rewards/reinforcements over others.)	"Once I started encouraging patients to get up, many did it on their own. It was great to see changes happen so quickly."	• Training • Incentivisation • Coercion • Environmental restructuring

The SELECT tool can help you move from WHY to HOW

move
Promoting Mobilization

Step 2b. Prioritize Intervention Functions

TDF Domain	*Coercion*	*Education*	*Enablement*	*Environmental restructuring*	*Incentivisation*	*Modelling*	*Persuasion*	*Restriction*	*Training*
Knowledge									
Skills									
Memory, attention and decision processes									
Behavioural regulation									
Social influences									
Social/professional role and identity		X				X	X		
Beliefs about capabilities									
Optimism									
Intentions									
Goals									
Beliefs about consequences		X				X	X		
Reinforcement	X			X	X				X
Emotion									
Environmental context and resources									
Total selected:	1	2		1	1	2	2		1

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Intervention functions vs Implementation strategies

- **Intervention functions** refer to 9 umbrella category strategies that can be used to facilitate change
  - They include: coercion, education, enablement, environmental restructuring, incentivisation, modelling, persuasion, restriction, and training
  - For instance,
    - Coercion: creating expectation of punishment or cost (e.g., raising the financial cost to reduce excessive alcohol use)
    - Modelling: providing an example for people to aspire to or imitate (e.g., inviting a visiting surgeon to demonstrate a procedure in the OR)
- We will link the intervention functions to **implementation strategies**, which are specific, pragmatic interventions
  - For instance, if the function of 'education' (intervention function) is selected, you can
    - Conduct educational meetings (implementation strategy)
    - Distribute educational materials (implementation strategy)

Step 3. Identify Implementation Strategies

move
Promoting Mobilization

Intervention Function	Implementation Strategies	Definition	Level	Use Strategy (Yes/No?)	Target Audience 1: _____	Target Audience 2: _____
Modelling	Model and simulate change	Have experts/leaders/respected colleagues model or simulate the ideal practice	Organization, Provider	Y		
Modelling	Visit other sites	Visit sites that have been successful in implementing the ideal practice	Provider	Y		
Modelling	Shadow other experts	Provide ways for designated individuals from the target stakeholders group(s) to directly observe other experienced people perform the ideal practice	Provider	Y		
Education	Conduct educational meetings	Hold meetings involving program targets (e.g., providers, administrators, other organizational stakeholders, and community, patient/consumer, and family stakeholders) to improve knowledge about the ideal practice	Patient, Provider	Y		
Education	Distribute educational materials	Distribute educational materials (e.g., guidelines, manuals, and toolkits) in person, by mail, and/or electronically to improve knowledge about the ideal practice	Patient, Provider	Y		

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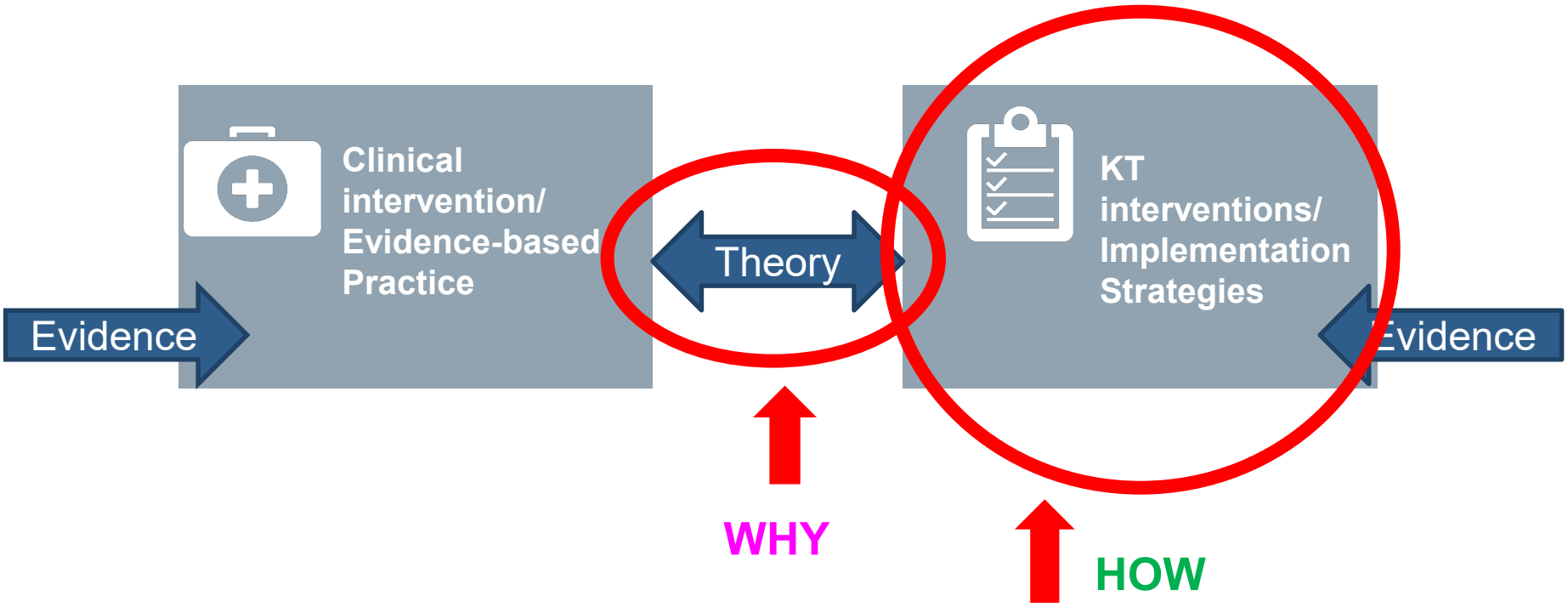
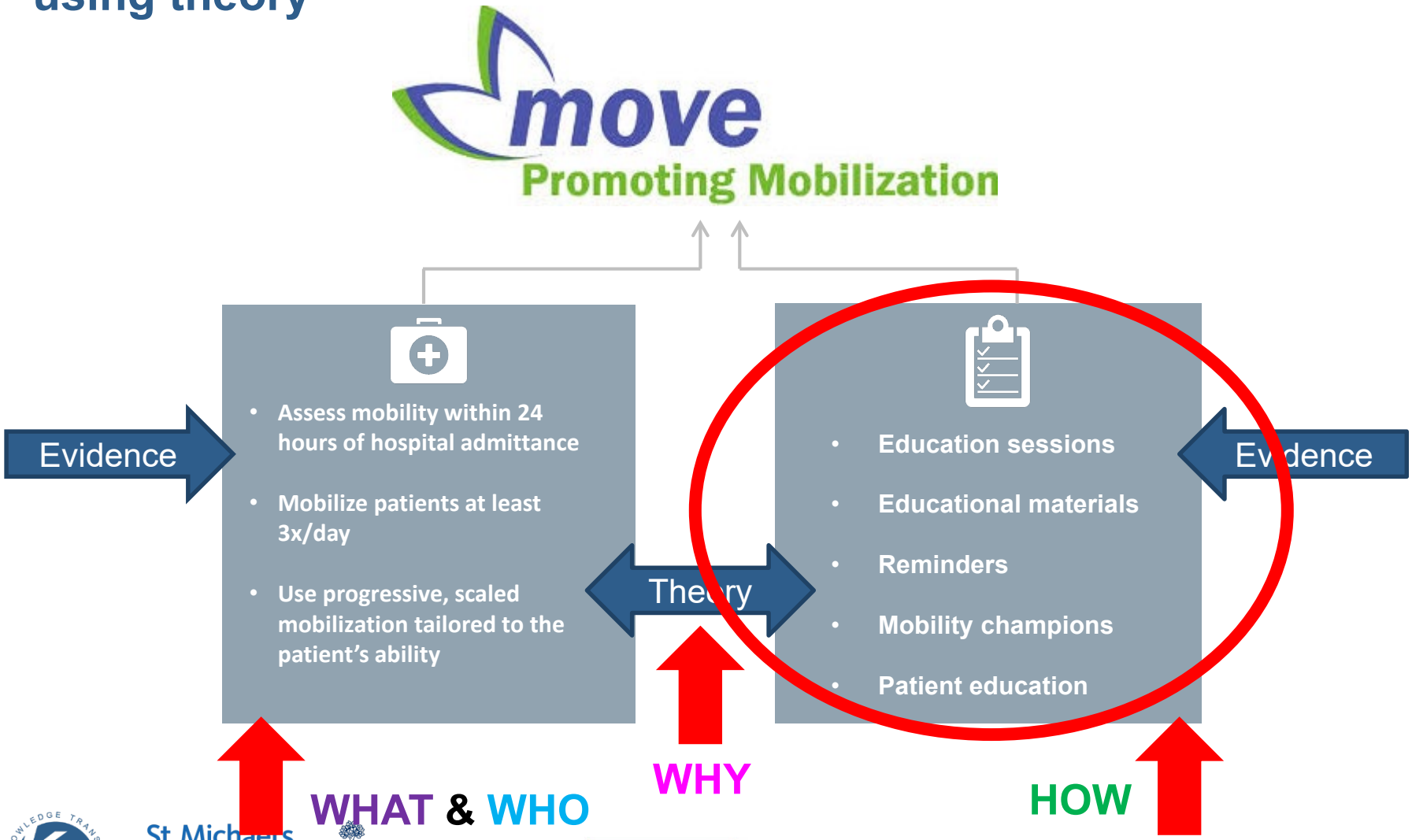
Using this process, we can use the WHY to identify the HOW



MOVE Program has 5 KT interventions that were selected using theory



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- https://cfirguide.org/choosing-strategies/
- **https://knowledgetranslation.net/the-select-tool/**

Consolidated Framework for Implementation Research

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Strategy

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Welcome to the CFIR-ERIC Barrier Buster Tool V0.53

- A full description of CFIR constructs can be found at https://doi.org/10.1186/1748-5908-4-5 and www.cfirguide.org
- A full description of the ERIC implementation strategy compilation can be found at https://doi.org/10.1186/s13012-015-0209-1
- Please see below for important Disclaimer.
- CFIR constructs were framed as barriers for the purpose of this work. This Tool is provided based on endorsements from n=169 respondents who selected and ranked "up to 7 strategies that would best address" each CFIR barrier.

How to use this workbook:

1) The "Summary" worksheet provides the results of the rank task where ERIC strategies are considered endorsed if they were ranked by a panelist for a specific CFIR-related barrier. Percentages reflect the proportion of panelists endorsing a strategy as being a "top seven" strategy for that barrier.

2) The "CFIR" worksheet allows a user to indicate specific barriers of interest, and then initiate a query by clicking the "Query" button at the bottom of the worksheet. The output of the query is posted to the "Output" worksheet. If multiple barriers were selected, then a cumulative percentage column will appear next to the strategies and the strategies will be

For more information on intervention functions & implementation strategies

Michie *et al. Implementation Science* 2011, **6**:42
http://www.implementationscience.com/content/6/1/42

IMPLEMENTATION SCIENCE

RESEARCH Open Access

The behaviour change wheel: A new method for characterising and designing behaviour change interventions

Susan Michie[1*], Maartje M van Stralen[2] and Robert West[3]

Abstract

Background: Improving the design and implementation of evidence-based practice depends on successful behaviour change interventions. This requires an appropriate method for characterising interventions and linking them to an analysis of the targeted behaviour. There exists a plethora of frameworks of behaviour change interventions, but it is not clear how well they serve this purpose. This paper evaluates these frameworks, and develops and evaluates a new framework aimed at overcoming their limitations.

Methods: A systematic search of electronic databases and consultation with behaviour change experts were used to identify frameworks of behaviour change interventions. These were evaluated according to three criteria: comprehensiveness, coherence, and a clear link to an overarching model of behaviour. A new framework was developed to meet these criteria. The reliability with which it could be applied was examined in two domains of behaviour change: tobacco control and obesity.

Results: Nineteen frameworks were identified covering nine intervention functions and seven policy categories that could enable those interventions. None of the frameworks reviewed covered the full range of intervention functions or policies, and only a minority met the criteria of coherence or linkage to a model of behaviour. At the centre of a proposed new framework is a 'behaviour system' involving three essential conditions: capability, opportunity, and motivation (what we term the 'COM-B system'). This forms the hub of a 'behaviour change wheel' (BCW) around which are positioned the nine intervention functions aimed at addressing deficits in one or more of these conditions; around this are placed seven categories of policy that could enable those interventions to occur. The BCW was used reliably to characterise interventions within the English Department of Health's 2010 tobacco control strategy and the National Institute of Health and Clinical Excellence's guidance on reducing obesity.

Conclusions: Interventions and policies to change behaviour can be usefully characterised by means of a BCW comprising: a 'behaviour system' at the hub, encircled by intervention functions and then by policy categories. Research is needed to establish how far the BCW can lead to more efficient design of effective interventions.

Michie S, van Stralen MM, West R. The behavior change wheel: A new method for characterizing and designing behavior change interventions. 2011. Implementation Science*;* 6:42. doi: 10.1186/1748-5908-6-42

For more information on implementation strategies …

DEBATE Open Access

Beyond "implementation strategies": classifying the full range of strategies used in implementation science and practice

Jennifer Leeman[1*], Sarah A. Birken[2], Byron J. Powell[2], Catherine Rohweder[3] and Christopher M. Shea[2]

Abstract

Background: Strategies are central to the National Institutes of Health's definition of implementation research as "the study of strategies to integrate evidence-based interventions into specific settings." Multiple scholars have proposed lists of the strategies used in implementation research and practice, which they increasingly are classifying under the single term "implementation strategies." We contend that classifying all strategies under a single term leads to confusion, impedes synthesis across studies, and limits advancement of the full range of strategies of importance to implementation. To address this concern, we offer a system for classifying implementation strategies that builds on Proctor and colleagues' (2013) reporting guidelines, which recommend that authors not only name and define their implementation strategies but also specify who enacted the strategy (i.e., the actor) and the level and determinants that were targeted (i.e., the action targets).

Main body: We build on Wandersman and colleagues' Interactive Systems Framework to distinguish strategies based on whether they are enacted by actors functioning as part of a Delivery, Support, or Synthesis and Translation System. We build on Damschroder and colleague's Consolidated Framework for Implementation Research to distinguish the levels that strategies target (intervention, inner setting, outer setting, individual, and process). We then draw on numerous resources to identify determinants, which are conceptualized as modifiable factors that prevent or enable the adoption and implementation of evidence-based interventions. Identifying actors and targets resulted in five conceptually distinct classes of implementation strategies: dissemination, implementation process, integration, capacity-building, and scale-up. In our descriptions of each class, we identify the level of the Interactive System Framework at which the strategy is enacted (actors), level and determinants targeted (action targets), and outcomes used to assess strategy effectiveness. We illustrate how each class would apply to efforts to improve colorectal cancer screening rates in Federally Qualified Health Centers.

Conclusions: Structuring strategies into classes will aid reporting of implementation research findings, alignment of strategies with relevant theories, synthesis of findings across studies, and identification of potential gaps in current strategy listings. Organizing strategies into classes also will assist users in locating the strategies that best match their needs.

Keywords: Implementation strategies, Dissemination, Scale-up, Interactive Systems Framework, Capacity-building

Leeman, Birken, Powell, Rohweder, & Shea. (2017). *Beyond "implementation strategies": classifying the full range of strategies used in implementation science and practice.* Implementation Science; 12:125. doi: 10.1186/s13012-017-0657-x

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Avoid common grant pitfalls in process evaluation studies

- Ensure research objectives include process evaluation objective
- Integrate evaluation framework throughout
- Optimise KU engagement in co-creation of the process evaluation including selection of outcomes, feasibility of outcome measures…
- Demonstrate understanding of what a process evaluation is, how it is different from effectiveness study etc
- Integrate systematic reviews of process evaluations
- Provide strong, clear rationale for and purpose of process evaluation
  - Is the purpose to understand mechanism of change, context, fidelity…
  - Explore mechanisms of the complex intervention such as understanding the 'active ingredient', dose, formulation…
- Understand what the strengths/limitations of study designs are
- Ensure clarity of evaluation of implementation intervention versus clinical intervention

Avoid common grant pitfalls in process evaluation studies

- Ensure feasibility of proposed methods (e.g. budget, timelines)
- Provide detail on recruitment capacity, especially when this is part of a larger proposal/study
- Ensure team has relevant expertise in qual, quant, mixed methods
- Consider what politics might need to be considered – context!!
- Avoid creating a new conceptual framework – pick one of the many that already exists
- Outline what is next, how does this process evaluation fit into the larger context or research agenda
- Consider that some reviewers will have expertise in process evaluations and others won't
- Ensure clarity of evaluation of implementation intervention versus clinical intervention

Acknowledgements

- With thanks to the following people who provided input on common pitfalls to avoid:
  - Melissa Brouwers
  - Tina Fahim
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