

March 2021

Implementation Blueprint for Community-Based Pilots for Supporting Decision Making



Institute for Research and Development on Inclusion and Society (IRIS), Oshawa.
© 2021 Institute for Research and Development on Inclusion and Society

IRIS claims copyright in this publication. You may copy, download, distribute, display, and otherwise deal freely with this publication, but only if you comply with the following conditions:

1. You must acknowledge the source of this publication;
2. You may not modify this publication or any portion of it;
3. You must not use this publication for any commercial purpose without the prior written permission of IRIS.

ISBN: 978-1-897292-38-9

Title: Implementation Blueprint for Community-Based Pilots for Supporting Decision Making

Author: Sobia Khan and Lauren Tessier, The Centre for Implementation

Project Director: Michael Bach, IRIS

Acknowledgments

The Institute for Research and Development on Inclusion and Society gratefully acknowledges the fruitful collaboration with Sobia Khan and Lauren Tessier of The Centre for Implementation (Toronto) who authored this resource, and the generous financial contributions of Employment and Social Development Canada to the 'solutions lab' hosted by Inclusion Canada, and of the Open Society Foundations, which helped to make it possible.

About IRIS

Informed by the systemic exclusion that people with intellectual disabilities and other marginalized groups face, IRIS' mission is to seed and support transformative social development. Guided by principles of full inclusion and human rights, we carry out research to identify issues and policy options. We foster social innovation to re- imagine inclusion and design new ways to meet unmet needs. Through capacity- building we strengthen leadership and constituencies for transformative change. For more information: visit us as at www.irisinstitute.ca or email contact@irisinstitute.ca.

Table of Contents

WHAT IS THE PURPOSE OF THIS BLUEPRINT?	1
PART 1: AN OVERVIEW OF THE COMMUNITY-BASED PILOTS FOR SUPPORTING DECISION MAKING (SDM PILOTS)	4
1.1 DESCRIBING THE CORE FUNCTIONS OF COMMUNITY-BASED SUPPORTS FOR DECISION MAKING	4
1.2 SELECTING CHANGE STRATEGIES.....	6
1.3 IMPLEMENTING THE INTERVENTION	7
1.3.1 <i>Context and adaptations</i>	7
1.3.2 <i>Roles in the system</i>	9
1.4 EVALUATING THE SDM PILOTS	10
1.5 SUSTAINING THE SDM PILOTS	11
PART 2: APPLYING IMPLEMENTATION SCIENCE TO THE SDM PILOTS	12
1 OVERVIEW OF IMPLEMENTATION SCIENCE	12
2 DEVELOPING THE INTERVENTION	15
2.1 <i>The Knowledge to Action Model</i>	15
2.2 <i>Defining your intervention: the WHAT and the HOW (KTA steps 4 and 6)</i>	16
<i>Why is this important?</i>	16
<i>What are the key constructs?</i>	16
<i>What is the intervention in the SDM pilots?</i>	18
<i>What are the common hurdles?</i>	19
2.3 <i>An in-depth look at the theory of change (KTA step 6)</i>	21
<i>What are the key constructs?</i>	22
<i>What are the common hurdles?</i>	27
2.4 <i>Strategies (KTA step 6)</i>	27
<i>What are the key constructs?</i>	28
<i>What are the common hurdles?</i>	33
3 IMPLEMENTING THE INTERVENTION (KTA STEP 7 & GTO STEPS 4-7).....	34
3.1 <i>Getting to Outcomes</i>	34
3.2 <i>Identifying local needs (GTO steps 1-3)</i>	34
<i>Why is this important?</i>	35
<i>What are the key constructs?</i>	35
<i>What are the common hurdles?</i>	36
3.3 <i>Adapting the intervention (GTO step 4)</i>	36
<i>Why is this important?</i>	36
<i>What are the common hurdles?</i>	38
3.4 <i>Roles in the system (GTO step 5)</i>	38
<i>Why is this important?</i>	39
<i>What are the common hurdles?</i>	42
4 EVALUATING THE INTERVENTION (KTA STEP 9 AND GTO STEPS 7-9)	43
<i>Why is this important?</i>	43
<i>What are they key constructs?</i>	44
4.1 <i>The RE-AIM framework</i>	44
4.2 <i>Process evaluation and implementation quality (GTO step 7)</i>	45
4.3 <i>Outcome evaluation (GTO step 8)</i>	46
4.4 <i>Continuous Quality Improvement (GTO step 9)</i>	46
<i>What are the common hurdles?</i>	47

5	SUSTAINABILITY (KTA STEP 10 AND GTO STEP 10)	49
	<i>Why is this important?</i>	49
	<i>What are the common hurdles?</i>	50
6	REFERENCES.....	51

What is the purpose of this Blueprint?

This “blueprint” sets out the different components of planning for community-based initiatives to implement Pilots for Supporting Decision Making (SDM pilots). It references two tools developed through the Inclusion Canada initiative, “Empowering the Most Excluded: Practical Solutions for Exercising Legal Capacity and Supported Decision Making.” The two tools are designed to assist community actors in designing and implementing pilot initiatives for supports for decision making. The tools are:

- *Community-led Initiatives for Supporting the Right to Decide: A Framework to Support Design and Implementation.* This resource describes the core functions in arranging and delivering community-based supports for decision making
- *Community-led Initiatives Supporting the Right to Decide – A Readiness Assessment Tool.* This resource guides community organizations in reviewing their capacity to deliver the core functions presented in the Framework resource guide.

Understanding implementation requires acknowledging the purpose of distinct components of the practice being implemented (SDM pilots in this case) and their interactions with one another. For this, we turn to a field called implementation science. Implementation science is the study of how to implement change (e.g., a policy, clinical intervention, program) effectively. The basis of implementation science is “the need for someone (usually more than one person or group), somewhere (from organisational leadership through to those on the frontlines of service delivery), to do something (usually more than one thing) differently (1).

In this blueprint, we outline the implementation science concepts underlying the key components of both designing an intervention for implementation and implementing an intervention. This blueprint is intended to be used by and is appropriate for all partners in the SDM pilots, including both individuals and organizations who are supporting the pilots and those actually delivering them. Overall, we lay out important considerations for the SDM pilots based on what we know from implementation science. Ultimately, we use this important field to craft recommendations to guide the design and implementation of the SDM pilots.

How to use this Blueprint

This blueprint is divided into two parts.

- Part 1 describes the recommended implementation process of the SDM pilots.
- Part 2 describes the theoretical and conceptual grounding of the SDM pilots in implementation science, using TMFAs from implementation science.

Part 1 can be used as a standalone summary document (or to inform a document of this type) that describes the SDM pilots to implementers and other stakeholders who do not require in depth knowledge of theoretical and conceptual underpinnings of the approach.

Part 2 can be used by the technical assistance team and researchers to better understand the theory and concepts behind the SDM pilots, and to use these descriptions to enhance their messaging about and evaluation of the approach.

PART 1: An Overview of the Community-Based Pilots for Supporting Decision Making (SDM pilots)

1.1 Describing the core functions of community-based supports for decision making

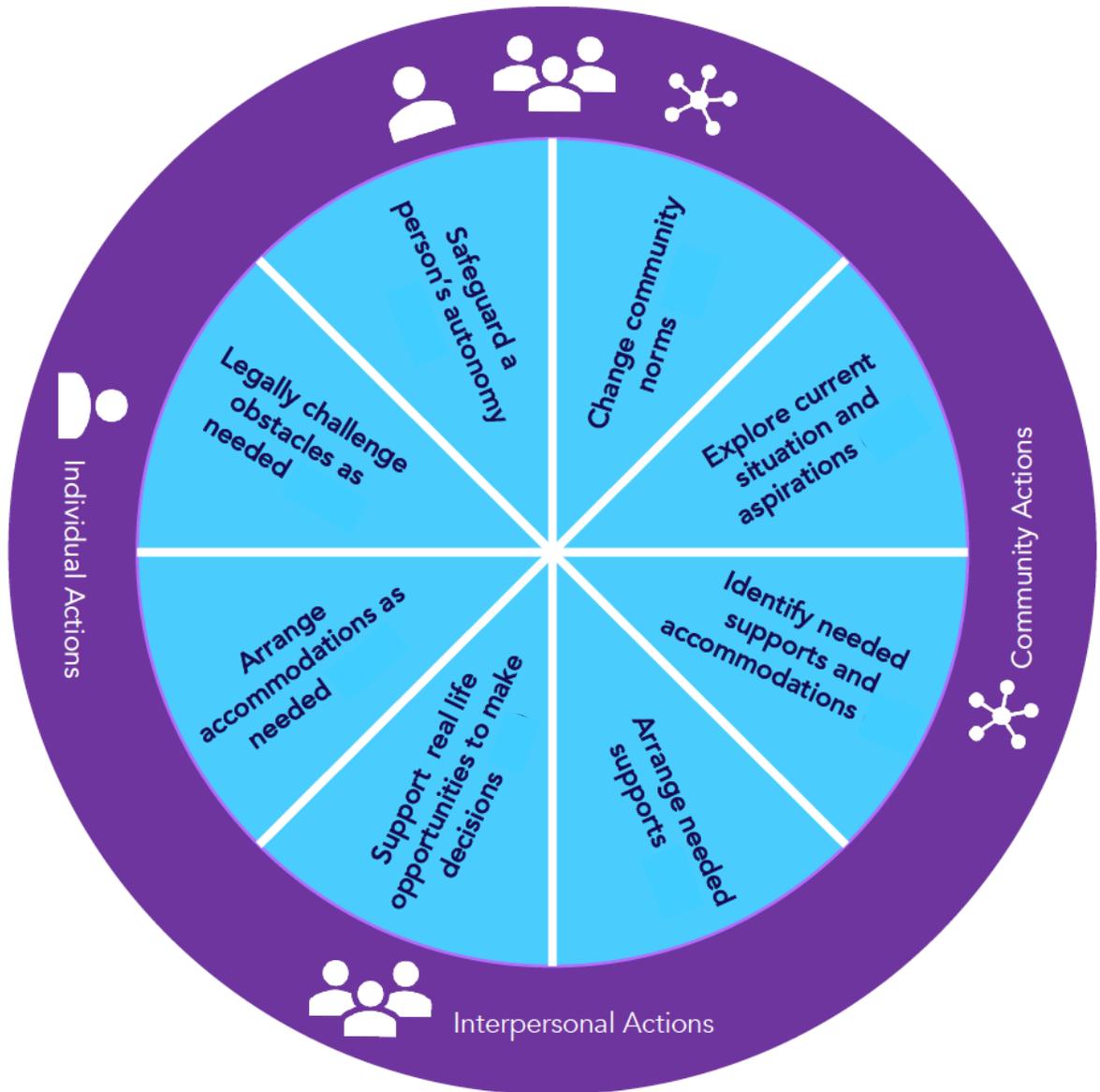
Every person has the capacity and right to participate in the decisions that govern their lives. However, for people with intellectual or cognitive disabilities, or living with mental health issues, the right to do so is often denied because their capacity is not seen or recognized. As a result, others take on or are given the right to make financial, health, personal care and all other decisions for that person. The person is left without a voice of their own.

Instead of resorting to substitute decision making, the overall aim of this initiative is to facilitate a community-wide shift towards supported decision making – i.e., enabling a person to make their own decisions with decision-making support. A supported approach to decision making ensures that:

- A person's expression of their will, preferences and contributions are acknowledged, noticed, recognized and respected.
- People have relationships of value and respect that enable their voice to be expressed and heard, and enable them to have choice, power and control in their lives.
- People have access to the range of decision-making supports they may need. These supports could include: communication assistance; independent advocacy; a trusted supported decision-making network of family, friends or other supporters; adapted decision-making processes; or assistance in planning for and making person-directed decisions, etc.

Based on research and experience in implementing community-based initiatives, a *Framework for Community-based Initiatives for Supporting Decision Making and the Equal Right to Decide* has been developed. This framework consists of eight core functions that have been identified as enabling the provision of decision-making supports. These core functions are the foundational activities that constitute best practices in supporting decision making for people who are traditionally stripped of this right. They are not steps or stages of a process, or a prescriptive guideline.

Framework for Community-based Initiatives for Supporting Decision Making and the Equal Right to Decide. These core functions are actioned at the individual (person making decision), interpersonal (planning facilitator and supporters), and community levels.



The core functions that each partner organization adopts as part of the SDM pilots and the way they perform that function might vary depending on the person involved and the community context. However, they are core functions because the purpose of doing these activities in each community remains the same, even if the activities look slightly different.

Note: these core functions are WHAT you are implementing. They describe the change you are trying to make. To know more about how to define the WHAT of your intervention from an implementation science perspective, refer to Part 2, section 2.2.

Many community-based organizations are already performing these core functions, at least to some extent. In this work, the process of piloting community-based initiatives to support decision making begins with partners:

- Understanding which core functions are already being used in practice
- Identifying which additional core functions may/will be adopted
- Exploring what it looks like to perform each of these core functions in their community

As part of designing community-based initiatives, change strategies will be identified (the HOW of your intervention - e.g., tools, resources, trainings, champions and opinion leaders, etc.) which can be used to help facilitate the adoption and uptake of the core functions for supporting decision making and the equal right to decide.

The long-term vision of supporting decision making in all communities is that supports will become less formalized and professionalized; and that supports and arrangements will become widely known, respected, valued and legally recognized.

Action step: use the community profile template to document which core functions you are already doing, which ones you hope to implement, and what these look like in practice within your agency.

1.2 Selecting change strategies

Change strategies are the ‘how to’ of implementation: they describe how the intervention will support people to change their behaviour. Without realizing it, we tend to employ these in many aspects of our work and lives, though they often remain unnamed, with a tendency to operate on implicit assumptions about how they work. For example, training is a common change strategy used across all initiatives. We rarely call it a change strategy in practice, but the assumption is that people don’t have the knowledge and skills to do something, and if they did, they would be able to make that change. In this example, we have identified barriers (knowledge and skills), a theory (that increased knowledge and skills will improve behaviour), and a change strategy linked to those pieces (training is provided to improve knowledge and skills). Therefore, picking change strategies requires you go through the following process:

- Step 1: Conduct a barriers and facilitators assessment (see Part 2, section 2.3)

- Step 2: Use a theory/framework to categorize your barriers/facilitators (see Part 2, section 2.3)
- Step 3: Select change strategies that help overcome barriers and leverage facilitators (see Part 2, section 2.4).

The WHAT and the HOW together make up your intervention that you will implement in your community/agency. In their current state, the SDM pilots have a WHAT. As already noted, certain core functions are already being performed, at least to some extent, and so there are likely accompanying HOWs that are already being performed. However, it is anticipated that the pilot sites will want to adopt additional core functions and so will need to select additional change strategies, in which case the above steps can be followed to do so.

Action step: Assess barriers and facilitators, and use the processes described in Part 2, sections 2.3 and 2.4 to understand how your existing change strategies map to barriers and facilitators, and which additional change strategies should be selected.

1.3 Implementing the intervention

There are multiple considerations when actually implementing the intervention (the WHAT and the HOW). These are:

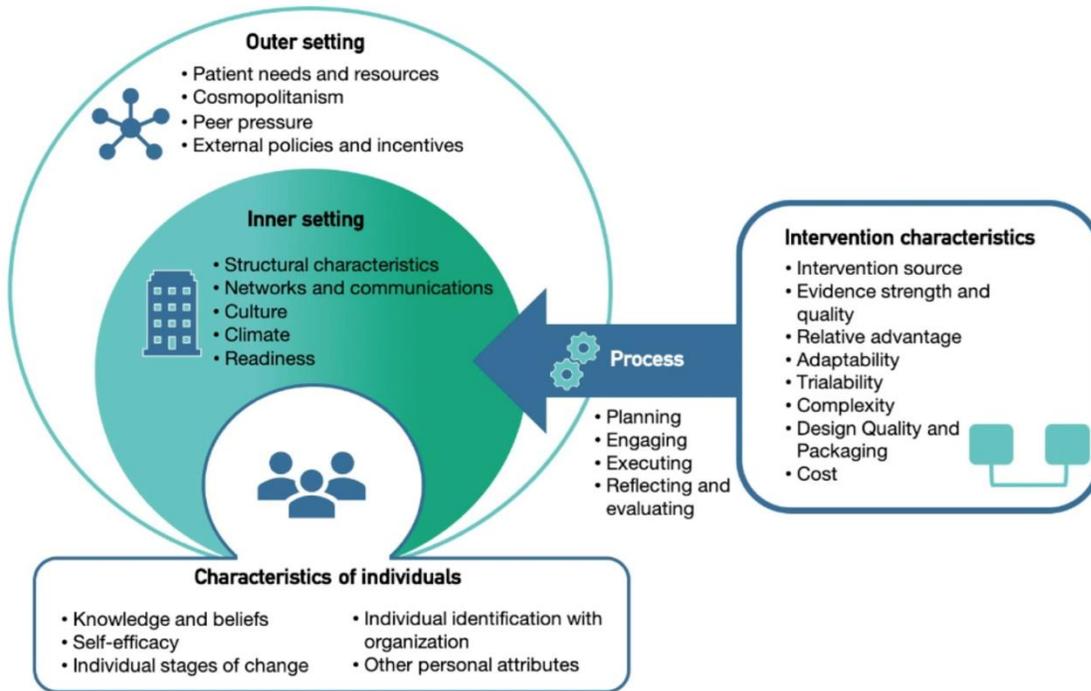
- Context and adaptations
- Roles in the implementation system

1.3.1 Context and adaptations

As you are implementing the SDM pilots, you might find that context might affect how you implement the WHAT and the HOW, and that you might have to make adaptations to both of these.

There are different ways you can assess context. The Consolidated Framework for Implementation Research (CFIR; Part 2, section 2.3, Figure 7 and pictured below) is a common framework that outlines contextual factors in the “inner setting” and “outer setting” domains. You can do a formal context assessment or an informal one, by either conducting interviews/surveys/focus groups using the CFIR as a question guide, or by having informal discussions with people and categorizing their responses to the relevant CFIR domains so that you know which contextual factors are emerging as the most important.

The Consolidated Framework for Implementation Research



Next, you can plan for adaptations. Planning for adaptations means understanding your context, and thinking through the processes of how the WHATs and the HOWs can be altered to better suit your context. Proactive planning for adaptations has been shown to result in better outcomes than reactive planning (which is usually how adaptations are made). Part 2, section 3.3 describes this process in depth.

It is never too early to start thinking about adaptations, as they make up a key component of the sustainability of any intervention. As the pilots select change strategies and move forward with implementation, it will be important to start having conversations early and often about how implementation conditions will change over time and the implications of this for the intervention and what adaptations may need to be made to meet those evolving conditions. For example, you may start by thinking about what adaptations might need to be made to the WHAT (i.e., the core functions). Do they stay the same over time or can any changes be anticipated? The same is true of the HOW (i.e., the change strategies). As noted earlier, many sites likely already perform certain HOWs. Do these need to be adapted and how so? Can you proactively plan for adaptations for additional HOWs you may select?

Action step: Consider using the Consolidated Framework for Implementation Research to understand characteristics of context (the “inner setting” and “outer setting” domains) that might impact your

implementation. Create a proactive plan for adaptations that might be made to the WHAT and HOW.

1.3.2. Roles in the system

It is important to delineate your implementation infrastructure – i.e., who will occupy what role during implementation, and who will support who to do it (and how). There are important considerations for who is in the boundary of the SDM pilots within each community (see Part 2, section 3.4) and what roles people can fulfill in each community.

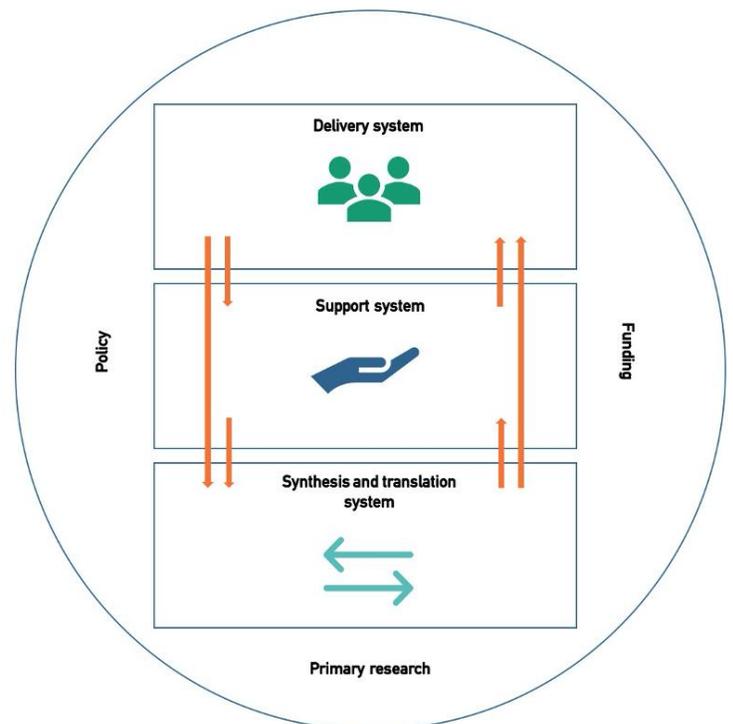
The Interactive System Framework (ISF; Part 2, section 3.4, Figure 10) and pictured below outlines the implementation system/infrastructure nicely. As the SDM pilots move toward implementation, it will be critical to establish further understanding of the pilots on several fronts:

- Who is actually doing the core functions? I.e., who is making the core functions happen in practice with clients?
- Who is going to support people/organizations to do the core functions? How will they support them (e.g., are there support mechanisms or tools available)?
- What level of change is each implementation support trying to impact (individual, interpersonal, community)?
- Is there an implementation team (i.e., a group of people who are responsible for enacting the implementation process, to ensure the people are doing the WHAT, and to make sure the HOWs are being developed and used)?

The implementation team can play multiple roles (can be doing the core functions, can be supporting implementation, etc.).

Part 2, section 3.4 describes these considerations in greater detail.

Action step: Think about who makes up the implementation team within each community-based pilot, and whether there are actors in the support system (i.e., people supporting implementation). It is important to understand who will be providing support to which teams and what that support will look like.



The Interactive Systems Framework

1.4 Evaluating the SDM pilots

It is essential that evaluations (particularly process evaluations) form a consistent part of implementation practice. A comprehensive evaluation of implementation will include variations of the following questions:

1. A) Did we do what we intended to do? [a process evaluation question]
B) Why or why not? [a process evaluation question]
2. What change(s) did we make in outcomes? [an outcomes evaluation question]

When we are thinking about process evaluation, we are looking at the process of both the WHAT and the HOW. There are specific types of indicators that can be used to understand the process of the WHAT and the HOW – these are dose (how much of something was delivered), reach (to whom was it delivered), participant satisfaction (were the people who participated engaged in the process), and quality of delivery (did the person delivering the WHAT or the HOW do a good job). These indicators can be used to measure the delivery of the core functions, as well as any change strategies (e.g., training) that were selected. A final indicator is adaptations/fidelity – i.e., did you implement what you planned to do; why or why not? It is important to document changes to your plan so you know why certain adaptations needed to be made if they occurred.

When thinking about outcomes, we think about the short-, medium- and long-term outcomes we hope all of these actions (implementing the WHAT and the HOW) will make.

Part 2, section 4 provides a more in-depth description of different types of evaluations as well as indicators and considerations for each. While the intention of the SDM pilots is to evaluate supporting decision making in the community and that evaluation plan will be created by researchers, it might be helpful for those who are the implementer to know how to evaluate implementation efforts and how to set up the resources, processes, and data collection methods you will need for evaluation from the beginning. Usually, once an intervention is more fully fleshed out (i.e., change strategies have been selected and operationalized), implementing sites can begin to think through and specify important process and outcome indicators and their plans for measuring these. Role clarity is also critical when thinking about evaluation. It will need to be determined who will be responsible for evaluation at each site and who will be responsible for collecting the necessary data.

Action step: For the SDM pilots, understand how each implementation partner is contributing to the overall evaluation. In general, become familiar with how implementation can be evaluated from a process and outcomes perspective.

1.5 Sustaining the SDM Pilots

Planning for sustainability from the start of implementation is just as critical as planning for actual implementation. Often, implementation projects are treated as if they have a defined start and end rather than as something that is going to continue, which undermines sustainability. Sustainability considerations are covered in-depth in Part 2, section 5.

As the pilots move forward with selecting change strategies and with implementation, it will be important to start having conversations early and often about sustainability. It is important to remember that sustainability doesn't just happen; it requires time and effort. It is helpful to change how you think about implementation (i.e., as ongoing, rather than having a defined start and end) and to embed sustainability into the process. There are a number of tools available to help in assessing sustainability factors such as: the [NHS Sustainability Model](#); the [Long-Term Success Tool](#); and the [Program Sustainability Assessment Tool](#).

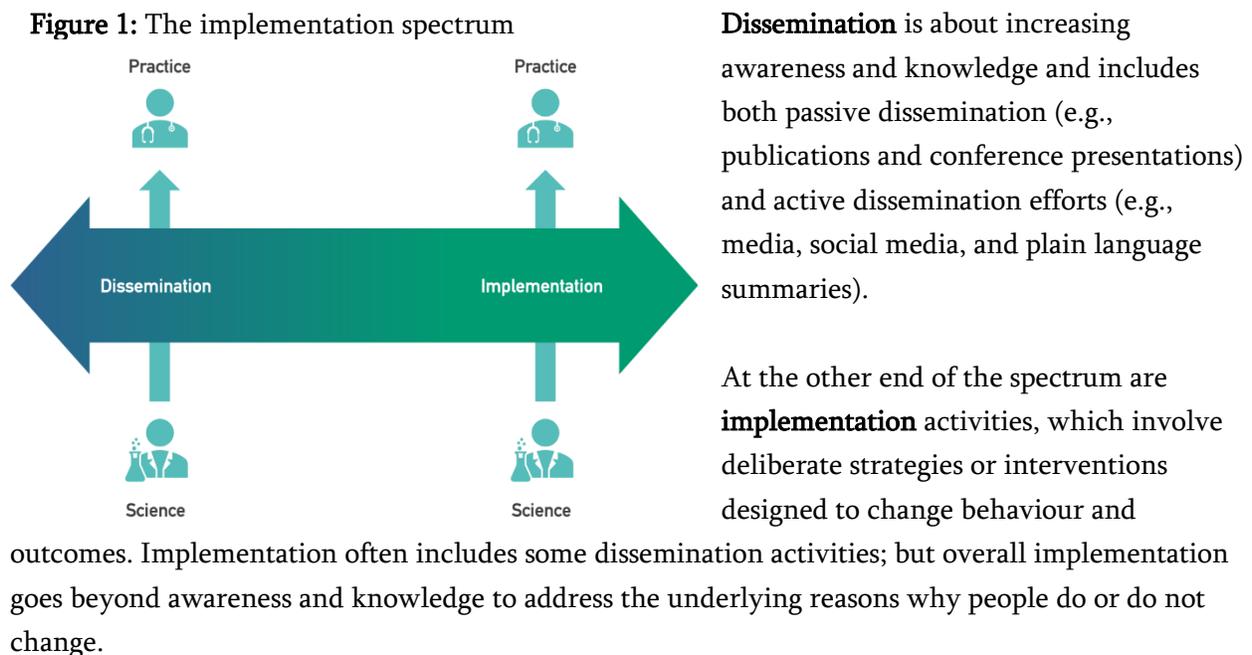
Action step: Use one of the suggested tools to help you plan for sustainability of your efforts.

PART 2: Applying implementation science to the SDM pilots

1 Overview of implementation science

Researchers have found that it can take 17 years for evidence to be used in practice (2). There are many reasons for this “leaky pipeline” from evidence to practice. One of them is the reality that most implementation and scale up efforts are not implemented well. Optimal implementation is guided by evidence from implementation science – a field that assesses how to effectively implement interventions. Using implementation science to guide practice can both decrease the time required to adopt these interventions and improve implementation fidelity. To understand how implementation science can support change efforts, it is important to become familiar with a few key constructs, outlined below.

Actions that can be taken to bridge the evidence-to-practice gap reside on a spectrum, with dissemination being situated at one end of a spectrum, and implementation at the other end.



The practice of dissemination and implementation is informed by science. **Dissemination science** aims to determine the most effective ways to disseminate information specific to different contexts and different audiences. **Implementation science** is the study of identifying the best ways to put research evidence into practice. It draws from multiple fields to address the complexity of change, including psychology, healthcare, mental health, program evaluation, epidemiology, and organizational change,

and tackles questions of “how” and “why” innovations work under different conditions. Examples of implementation science questions include:

- How and why did the change occur?
- How can changes be scaled up?
- How can improvements be sustained?
- What contextual factors affect whether change will happen or not?

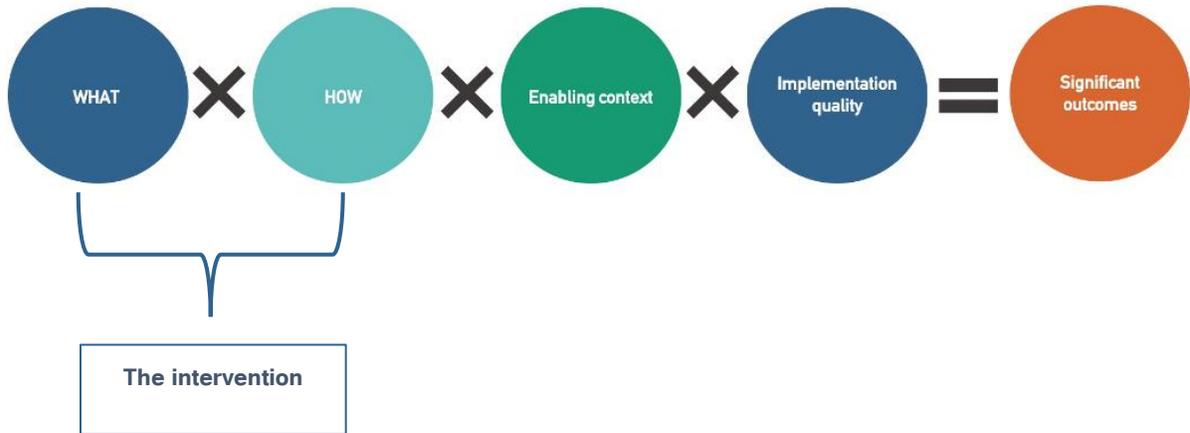
This guide focuses on **applying implementation science** to inform implementation practice. It is important to note that implementation science can guide two very broad categories of implementation activities: 1) developing the intervention and 2) implementing, evaluating, and sustaining the intervention. There are different activities related to each of these broad categories that use different **theories, models, frameworks and approaches (TMFAs)** to guide these activities.

Implementation science provides TMFAs, developed from large bodies of research, that serve as the basis for how implementation science can be used in practice. TMFAs help people design interventions, plan for implementation, and implement and evaluate more strategically and with evidence-based guidance.

- **Theories** describe and predict causal mechanisms of behaviour. They tell us about how individuals, organizations, systems and communities change.
- **Models** (also referred to as **process models**) outline the steps or stages in implementing something. There are two different kinds of process models: ones that guide the design of interventions for implementation, and ones that guide implementation, spread, and scale. Note, the stages outlined within process models do not need to be linear. In fact, they often involve an iterative, back-and-forth process.
- **Frameworks** explain different factors that may impact implementation outcomes.
- **Approaches** is a catch-all term that refers to the tools and strategies you can use to help you through the implementation process.

Theories, models, frameworks and approaches are used collectively to effectively carry out implementation. No one theory, model, framework or approach describes the complexity of implementation from start to finish, therefore multiple TMFAs are needed. In fact, implementation is similar to a set of cogs and gears produced separately but working together to help the intervention operate smoothly. In order to successfully achieve intended outcomes, there are interactions between the intervention, implementation, and the context (**Figure 2**). If any of these components are missing, you will not produce the outcomes you are looking for.

Figure 2: The implementation equation



In this blueprint we will describe important considerations in developing and implementing the Community-Based Pilots for Supporting Decision Making (SDM pilots) based on implementation science concepts, specifically TMFAs. We will provide an overview of TMFAs that can be used for developing the SDM pilots and for implementing the SDM pilots.

2 Developing the intervention

In this section, we describe key considerations in developing the SDM pilot intervention (recognizing that the “intervention” will not look exactly the same in every community). Because the SDM pilots are still a “work in progress” and not an established, evidence-based program or practice, there are no off-the-shelf solutions that can be implemented. This means that an intervention needs to be developed from scratch.

2.1 The Knowledge to Action Model

When applying implementation science, choosing a process model is the best place to begin as they are actionable and provide concrete guidance in the form of stages or steps to follow. There are two different types of implementation process models:

- 1) process models used to design interventions for implementation;
- 2) process models used to support implementation, spread, and scale up.

At this stage of the SDM pilots, we are focused on process models for designing interventions for

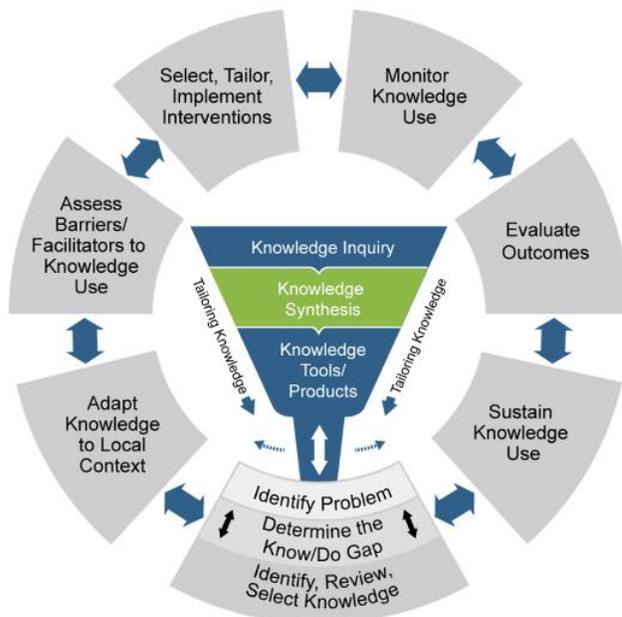


Figure 3: The Knowledge to Action

implementation. Specifically, we recommend the Knowledge to Action (KTA) as the foundational process model for the pilots for two reasons: 1) the KTA is based on a review of over 30 planned action theories and; 2) the KTA begins by assessing evidence (3). The goal of implementation is to use evidence in practice to produce sustainable outcomes and we wanted a process model that considers evidence as the first step. Examples of alternate process models for designing for implementation include Intervention Mapping (4). The KTA consists of ten stages grouped into two distinct parts: 1) a knowledge generation funnel, through which primary research is conducted and synthesized and key messages are distilled into usable knowledge products and tools; and 2) an action cycle, through which the knowledge products and tools are implemented.

implementation. Specifically, we recommend the Knowledge to Action (KTA) as the foundational process model for the pilots for two reasons: 1) the KTA is based on a review of over 30 planned action theories and; 2) the KTA begins by assessing evidence (3). The goal of implementation is to use evidence in practice to produce sustainable outcomes and we wanted a process model that considers evidence as the first step. Examples of alternate process models for designing for implementation include Intervention Mapping (4). The KTA consists of ten stages grouped into two distinct parts: 1) a knowledge generation funnel, through which primary research is conducted and synthesized and key messages are distilled

The early stages of the KTA involve identifying the problem, determining the gaps between research and practice, and selecting appropriate evidence. Next you adapt knowledge to local contexts, understand barriers and facilitators to change, and then select implementation strategies that facilitate change.

In this roadmap, we take you through these early steps of the KTA to describe key considerations in developing the SDM pilots. We then introduce a second process model, **Getting to Outcomes**, to describe key considerations in implementing the SDM pilots. This second process model fits into Step 7 of the KTA, *select, tailor, and implement interventions*. Implementation is a complex process, though reflects only one KTA step, hence why a second process model is required.

2.2 Defining your intervention: the WHAT and the HOW (KTA steps 4 and 6)

What is the purpose of this section?

Defining the WHAT involves defining all key the stakeholders involved in a change and clearly describing what they are being asked to do differently to address a need or gap and achieve a goal or outcome. Defining the HOW involves describing the strategies that are going to be used to support these stakeholders in changing their behaviour. This section will provide an overview of the key elements of this step.

Why is this important?

Irrespective of the level at which an intervention operates, change occurs when individuals change their behaviour (i.e., do something differently). Defining **the WHAT** amounts to understanding and defining what exactly the individuals targeted by the intervention (**the WHO**) need to do differently. Clearly specifying such behaviour is a key but often overlooked first step in designing and implementing interventions. If you cannot tell someone what it looks like to be successful, they cannot be expected to succeed. Effective definition of the practice change can be thought of as allowing for the delineation of ‘who does what; to, for or with whom; when; where?’ (1). Defining **the HOW** amounts to clearly describing the strategies that will be used to support **the WHO** to do **the WHAT** (i.e., to change their behaviour). It is critical that the WHO, the WHAT, and the HOW be clearly linked to intervention outcomes.

What are the key constructs?

When we are trying to stimulate change in a system, we are essentially attempting to do something differently than the status quo. This is what we refer to very broadly as our “**WHAT**” – what it is that

we are trying to change. The “what” is ideally based in evidence, and can come in several forms, called the 7Ps (5):

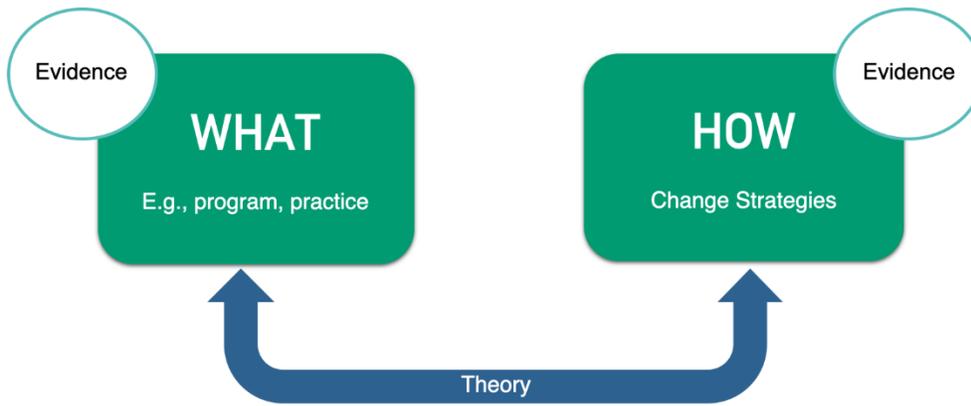
1. **Policies** (legislative/regulatory decisions made to ensure that specific actions can be taken within a legal/regulatory framework)
2. **Practices** (the application of an idea or belief, e.g., a guideline recommendation)
3. **Programs** (a set of coordinated activities to accomplish a specific goal)
4. **Procedures** (a set of instructions or sequential activities that help guide a specific action)
5. **Principles** (beliefs/philosophies that guide action)
6. **Products** (tools or resources that guide people in accomplishing activities/goals)
7. **Pills** (refers broadly to any drugs that might be used to improve outcomes)

When defining the **WHO**, it is important to identify *all* key stakeholders who will need to change. As most interventions involve complex behaviour change, it is most often the case that the **WHAT** is not limited to one group of stakeholders or one of the 7Ps:

- You may have multiple **WHATs** (e.g., a change in practice as well as policy)
- You may have multiple **WHOs** (e.g., people with cognitive disabilities, supporters, agency staff, policy makers)
- There may be a complex network of **WHOs** and **WHATs** (agency staff have to make changes to their practice so that people with cognitive disabilities have support to make changes needed to make decisions, and this is all supported by policy makers making changes to policy to facilitate this.)
- If you find that this is the case, then mapping out the **WHOs** and **WHATs**, and interactions between these, can help you highlight where and how these stakeholders and the changes they need to make interact.

Finally, there is also a set of strategies we use to facilitate the change described by the **WHAT**. We refer to these broadly as **change strategies**; in other words, **HOW** we will get people to change. In the implementation science literature, they are also referred to as implementation strategies, or integration strategies (6). Change strategies exist to enable people to overcome barriers and leverage facilitators to making a change. For example, a common change strategy is training. We offer training because we believe that people lack knowledge and skills to do the **WHAT**. This demonstrates a clear link between the **WHAT** and the **HOW**. Essentially, the **HOW** makes it easier for people to do the

Figure 4: The WHAT and the HOW linked through theory



WHAT.
It is critical that the WHAT and the HOW be linked through theory because the way we plan

to make a change is based on what we think the mechanisms (or levers, or pressure points) of change are (**Figure 4**). Together, your *WHAT* and your *HOW* make up your intervention.

What is the intervention in the SDM pilots?

As noted above, an intervention is comprised both of a WHAT and a HOW (a set of change strategies) that are linked through theory. The WHAT of the SDM pilots is the *Framework for Community-based Initiatives for Supporting Decision Making and the Equal Right to Decide* (“the Framework”). This framework consists of eight core functions that have been identified as enabling the provision of decision-making supports. These core functions are not steps or stages of a process, or a prescriptive guideline. Rather, they are the foundational activities that constitute best practices in supporting decision making for people who are traditionally stripped of this right.

The core functions that each partner organization adopts and the way they perform that function might vary depending on the person involved and the community context. However, they are core functions because the purpose of doing these activities in each community remains the same, even if the activities look slightly different.

Many community-based organizations are already performing these core functions, at least to some extent. In the context of the SDM pilots, the process of piloting community-based initiatives to support decision making begins with partners:

- Understanding which core functions are already being used in practice
- Identifying which additional core functions may/will be adopted
- Exploring what it looks like to perform each of these core functions in their community

The Framework, and more specifically the core functions, can be understood as the WHAT of the SDM pilots. The next step for each community-based pilot is to identify specific change strategies (the HOW) that can be used to help facilitate the adoption and uptake of the core functions of interest for supporting decision making and the equal right to decide. As noted, many community-based organizations are already performing the core functions, at least to some extent. As well, within the communities, certain change strategies may already be in place. What remains to be determined is whether these existing change strategies can be linked to the Framework through theory. Again, it is critical that the WHAT and the HOW be linked through theory because the way we plan to make a change is based on what we think the mechanisms of change are. A common example of failing to link the WHAT and the HOW through theory is the selection of education as a change strategy. Education is commonly used because the underlying assumption of an education strategy is that people do not know something and by educating them and increasing their knowledge of that thing, they will then change their behaviour to reflect this new knowledge. However, there may be other reasons that people are not able to change their practice/behaviour/etc., and so we see that education strategies on their own do not elicit behaviour change. This highlights the importance of linking the WHAT and the HOW through theory. It should be noted that even if communities' existing change strategies can be linked to the Framework, it is likely that additional strategies will need to be implemented as part of the SDM pilots.

What are the common hurdles?

While this step of intervention design can seem both obvious and intuitive, it is often overlooked. Skipping this step or not allocating enough time for it can lead to confusion about the core of the intervention – WHO needs to do WHAT differently – which can unravel other intervention design

and implementation efforts. Moreover, if not enough time is taken for this step, the WHO might be too narrowly defined; in other words, not all relevant stakeholder groups are identified.

2.3 An in-depth look at the theory of change (KTA step 6)

What is the purpose of this section?

The purpose of this section is to outline the steps involved in identifying and categorizing barriers and facilitators to behaviour change (the WHAT) for each of the stakeholder groups that needs to change (the WHO). This process is critical to the selection of appropriate change strategies (the HOW). The important role of theory in this process is also discussed.

Why is this important?

Remember that the key to applying implementation science involves using theories, models, frameworks and approaches (TMFAs). Using TMFAs to guide implementation activities sets us up for the best chance of success.

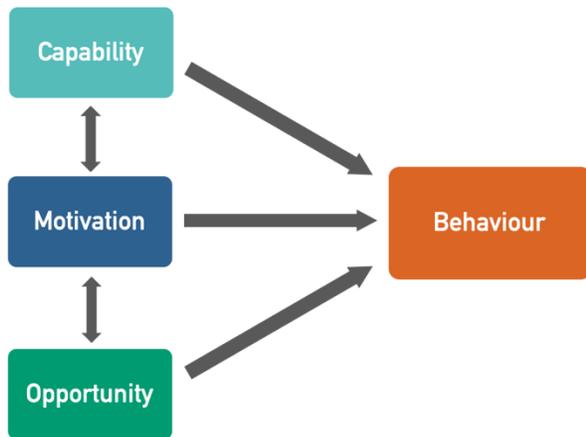
Theories are the most integral component to implementation science. Behaviour change theories aim to predict and understand the causal mechanisms of behaviour change. They explain why your intended behaviour change (your WHAT) leads to the ultimate outcomes you are targeting. Further, they explain how your selected change strategies (your HOW) will lead your stakeholders (your WHO) to change their behaviour (the WHAT).

All interventions and programs rely on a theory, whether it is stated or not, because all of the activities that occur as part of the intervention or program are anticipated to impact change in some way – sometimes the theory is explicit, other times we make assumptions about how our intervention works that are implicit. When the theory is explicit, it is easy to test these assumptions and link change strategies (HOW) to the targeted behaviour change (the WHAT).

The process of linking change strategies to the targeted behaviour change occurs through a barriers and facilitators assessment (described in greater detail below). Overall, it is essential that we know the barriers and facilitators to change, because this tells us which change strategies will be required. The barriers and facilitators tap into mechanisms of change (or how we think change will happen), which are elaborated by known theories of change. For example, if we provide training as a strategy, part of our theory of change is that there is a lack of knowledge and skills to do the WHAT, which is why we provide training as a HOW. However, if knowledge and skills are not the problems, and other more important barriers and facilitators are prevalent, then training is no longer an effective change strategy. It may be that there are attitudes or beliefs that are prevalent that are causing reluctance to do the WHAT, or that people don't think it's their professional role to do the WHAT. In this case, other change strategies will be required, such as opinion leaders or mentors.

What are the key constructs?

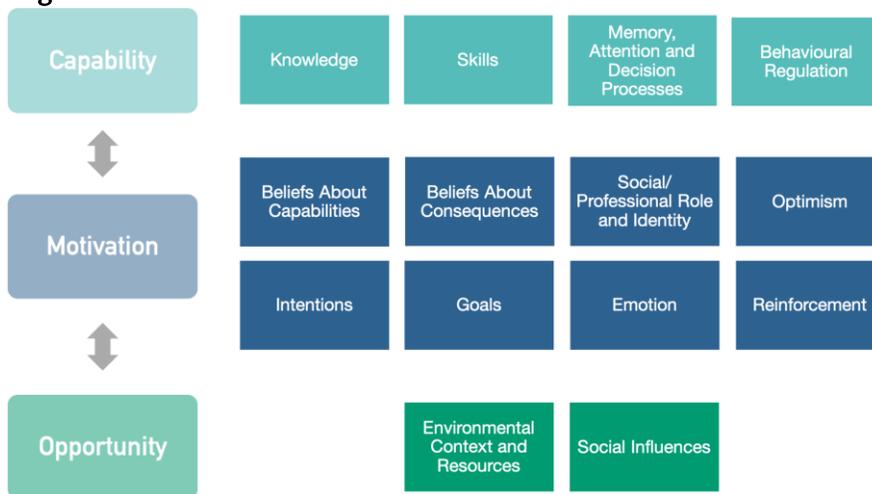
Barriers and facilitators operate at the individual, contextual (e.g., organization or community), and/or wider system levels. **Individual-level** barriers and facilitators hinder and facilitate, respectively, behaviour change in an individual or group of individuals. These types of barriers can be mapped onto the **capability-opportunity-motivation behaviour (COM-B) theory**, which is widely used in implementation and is simple to understand.



The **COM-B** (7) states that in order for people to change, they must be capable of change, they must have the opportunity to change, and they must be motivated to change. The COM-B is accompanied by a framework called the **Theoretical Domains Framework (TDF)** (8,9), which further breaks down what is underlying individual-level barriers and facilitators to change. The COM-B and TDF are commonly used together to categorize these types of barriers (**Figure 6**).

Figure 5: The COM-B

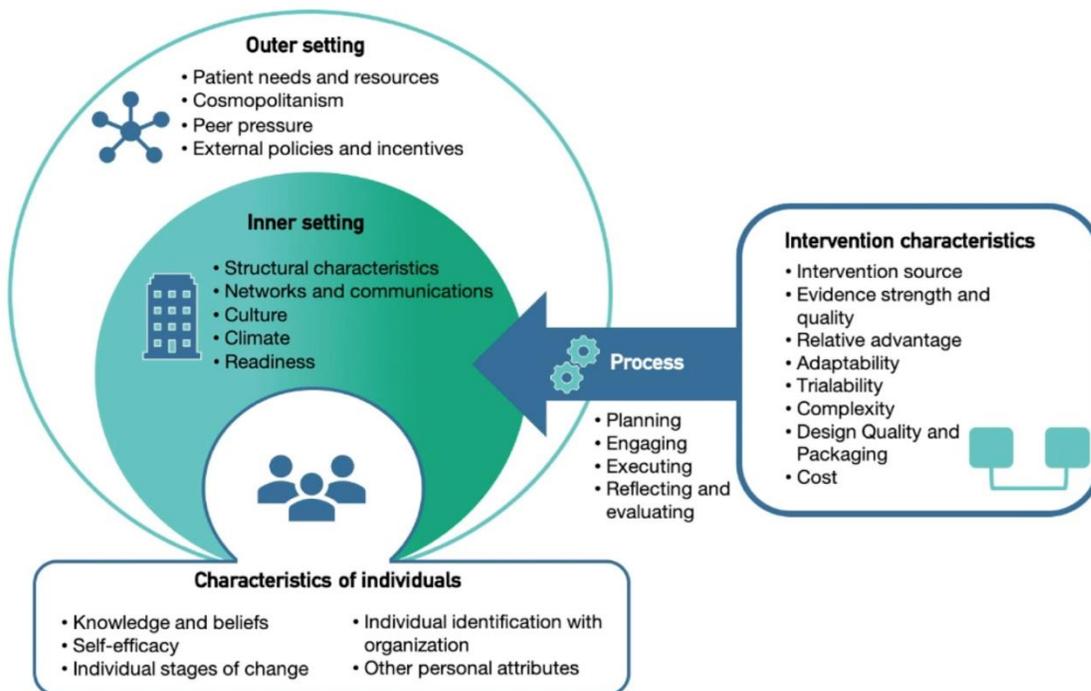
Figure 6: The Theoretical Domains Framework linked to the COM-B



As mentioned, there can also be barriers and facilitators at the organizational, community and system levels. For this, we need a different way of understanding and describing the barriers and facilitators

to change than what is provided by the COM-B and TDF. Here we can use a framework like the **Consolidated Framework for Implementation Research (CFIR)** (10), which is not a theory, but can help you make sense of the types of barriers and facilitators being faced at these levels. Specifically, the CFIR is a great tool for understanding considerations that need to be made with respect to the implementation context. In implementation, context is relative and depends on the level at which you are implementing (e.g., within an organization, within a community, or at the system level). The CFIR breaks down factors related to both a context's inner setting and outer setting that affect implementation success. The inner setting can be thought of as the implementation setting, while the outer setting consists of high-level elements outside of the implementation setting that affect implementation nonetheless, such as peer pressure or external policies and incentives. The CFIR can be thought of as an expansion of the 'environmental context and resources' domain of the TDF.

Figure 7: The Consolidated Framework for Implementation Research



In addition to operating at different levels, barriers and facilitators affect one of two main components of an intervention: the WHAT or the HOW. Remember, your WHAT is the behaviour change you are targeting and your HOW refers to the set of change strategies you employ to change the targeted behaviour. Making this distinction is important as different activities ensue from it. **Barriers and facilitators to the behaviour change (the WHAT)** ultimately aid in the selection of **change strategies**. Conversely, **barriers and facilitators to the change strategies (the HOW)** ultimately

aid in the selection of **implementation supports**. Implementation supports help implementation teams (i.e., the individuals actually delivering an intervention) to deliver the intervention effectively through the provision of tools, training, technical assistance and quality assurance.

Collecting barriers and facilitators data

Collecting and categorizing barriers and facilitators data is foundational to understanding which change strategies are most likely to result in change. This step requires quality sources of barriers and facilitators data as well as evidence of linking or mapping the collected barriers and facilitators to theory. Note that linking the barriers and facilitators to theory often occurs through the use of a framework (e.g., linking to the COM-B through the TDF).

The discussion that follows focuses on both barriers and facilitators. It should be noted that in practice, people tend to focus more on collecting and categorizing barriers to change rather than facilitators. However, gathering data on facilitators is just as critical, as they can be leveraged to inform change strategy selection.

Under most circumstances, implementation occurs in a time- and resource-limited setting. Fortunately, there are very practical, inexpensive, and relatively quick ways to assess barriers and facilitators.

The literature is often the easiest and fastest way to get information about barriers and facilitators. There are many published studies assessing barriers and facilitators to change on a wide range of topics. While you may not be able to find a study that specifically looks at the barriers and facilitators to your exact practice change, chances are you can find things that are conceptually similar. It is important to consult literature that looks at the same target population and/or the same or similar practice change. However, some of the more generic literature on barriers and facilitators will also be helpful.

Another simple yet effective method of collecting barriers and facilitators data is through informal conversations with key stakeholders. An interview guide with predetermined questions during these discussions can be used, but it does not need to be formal. When doing this, it is important to understand the type of information you wish to collect and how this information will be used.

A related method to these informal conversations is sitting in on existing meetings, particularly if the proposed practice change is discussed in those meetings, to learn about potential barriers and facilitators through what is said, what is not said, and the reactions people have.

Mapping barriers and facilitators data

Once barriers and facilitators data have been collected, they are mapped to an implementation theory or framework (or both). Mapping can be thought of as the process of categorizing or coding – taking large pieces of information and distilling them to a central category, code or theme that reflects what that large piece of information is trying to convey. Doing this makes the information more meaningful and manageable to work with.

When mapping barriers and facilitators, start first by selecting an appropriate framework (or multiple frameworks). As already noted, the TDF is a good fit for your projects when mapping individual-level barriers and facilitators. If you are mapping contextual level barriers and facilitators, you might use the CFIR. *Remember that contextual level barriers and facilitators (e.g., those mapped to the CFIR) do not provide the information necessary to select change strategies (the HOW).*

If barriers and facilitators have been collected through qualitative means (this method is strongly suggested, even if the approach is informal), it is very helpful to use direct quotes from your conversations with key stakeholders and map these directly onto your framework. If using the TDF and linking it to the COM-B, barriers and facilitators will ultimately be grouped into one of three categories:

- Barriers/facilitators to capability – do they have the knowledge and skills?
- Barriers/facilitators to opportunity – does the environment support the change?
- Barriers/facilitators to motivation – do they want to change?

You may discover that some data does not fit cleanly into your selected framework domains and/or may require some interpretation to understand important themes. Being interpretive is okay if there are sufficient amounts of data to support the interpretation and if working with people who are interpreting the information in the same way. It cannot be assumed that these interpretations are correct, but they can be used as a starting place to collect more information and probe more deeply about certain topics or barriers.

When collecting and mapping barriers and facilitators data, it is also important to be mindful of what people do not say. A common example is leadership support. If people do not report that leadership supports the change, the lack of information on leadership support may indicate that leadership is not very supportive. However, just as noted above, do not make that assumption either, instead collect more data (formally or informally) to explore hypothesized barriers and facilitators.

Remember to collect barriers and facilitators from the people being asked to change – WHO needs to do WHAT differently. We often default to thinking about those affected by the intervention rather than the people implementing the intervention. To select change strategies, you need the barriers and facilitators to the WHO that is being asked to change (e.g., professionals asked to do their jobs differently).

Relevance to the SDM pilots

As noted earlier, in their current state, the SDM pilots have a WHAT. The next step in developing the intervention is to select a set of change strategies (the HOW). In order to do this, there are a series of steps each community-based pilot will need to follow, depending on whether they have already adopted certain core functions.

If certain core functions have already been adopted, the pilot will need to:

- Engage in **backmapping**. Ideally, change strategies are selected based on identified barriers and facilitators. If change strategies have been implemented without a prior barriers and facilitators assessment, backmapping allows you to work backwards to understand which barriers and facilitators any strategies already being performed address. This allows you to determine if you can address additional barriers and facilitators or if you need additional change strategies to address the remaining barriers and facilitators.

As already noted, most of the core functions are already being performed to a certain extent. It is therefore likely that all of the community pilots will need to engage in backmapping. It is also likely that the pilots will want to adopt additional core functions as part of the pilots and that they will need to select additional change strategies, for which the following steps can be followed:

- Identify which of the core functions they are interested in adopting as part of the SDM pilots
- Ascertain what it means to “do” the core function(s) of interest; in other words, they will need to describe either which new activities will take place or which activities will need to change (and how they will need to change), as well as who is responsible for carrying out these activities
- Once the communities have identified WHAT needs to change and WHO needs to change, it will then be possible to conduct barriers and facilitators assessments within each community/sub-pilot to guide the selection of change strategies to address the adoption of the core functions within each community. Ideally, each site will have its own implementation team, who will be responsible for the implementation of the core functions within their site/community. It is the responsibility of the implementation team to conduct a barriers and facilitators assessment.

What are the common hurdles?

The role and value of theory in improvement work is underrecognized. Many professionals, including improvement practitioners, are overwhelmed by theory and consequently avoid using it explicitly in their work; however, even in those situations they are using implicit theories because they have made assumptions about how they think change will happen. They just don't realize they have made those assumptions. Relatedly, theory use can also be superficial.

In other words, a theory may be selected but not used to appropriately guide change strategy selection or data collection, for example. Finally, it is also very common that a theory is applied at the wrong level. For example, the COM-B is a theory of individual-level behaviour change. Therefore, it cannot be used to understand change at other levels (organizational or system).

When collecting barriers and facilitators data, common challenges include: failing to assess barriers and facilitators or not allowing enough time to collect the information; only collecting data from one source; focusing exclusively on knowledge barriers; focusing on external barriers while not considering internal barriers (e.g., participants stating that all barriers are external to themselves); failing to consider barriers at multiple levels (i.e., individual, organizational, system); not consulting the literature; and failing to collect information on facilitators. Finally, it is also common that only themes are mapped rather than direct quotes from stakeholders. This presents challenges because once barriers and facilitators get grouped into themes, the level of detail needed to map them to certain frameworks can disappear.

2.4 Strategies (KTA step 6)

What is the purpose of this section?

The purpose of this section is to provide an overview of the process of selecting and operationalizing change strategies to address barriers and facilitators to your targeted behaviour change (the WHAT) for each group of stakeholders required the change (the WHO).

Why is this important?

Change strategies are the 'how to' of implementation: they describe how the intervention will support people to change their behaviour. Without realizing it, we tend to employ these in many aspects of our work and lives, though they often remain unnamed, with a tendency to operate on implicit assumptions about how they work. For example, training is a common change strategy used across all initiatives. We rarely call it a change strategy in practice, but the assumption is that people don't have the knowledge and skills to do something, and if they did, they would be able to make that change. In this example, we have identified barriers (knowledge and skills), a theory (that

increased knowledge and skills will improve behaviour), and a change strategy linked to those pieces (training is provided to improve knowledge and skills).

However, issues arise when developing an intervention and attempting to rely on intuition and assumptions to target explicit behaviour change. If change strategies are selected without an explicit method and reasoning, then they might not be effective and/or may fail to address the underlying barriers and facilitators to change.

Ideally, change strategies are selected using a combination of theory and evidence – the theory assures the strategies address people’s underlying barriers and facilitators to change, while evidence of the effectiveness of the different change strategies can be used to guide strategy selection. This process involves a combination of art and science. As a result, this can be the most challenging component of implementation.

What are the key constructs?

Linking change strategies to theory

Change strategies are selected to overcome the identified barriers and leverage the identified facilitators to change. Theory is the bridge between your barriers and facilitators and your change strategies. This is because theory can help us identify what the underlying determinants of change are, and also what can impact those determinants of change (strategies). While there is no exact formula available to identify which specific behaviour change strategies directly address specific underlying barriers and facilitators, there are helpful approaches available. In the case of the SDM pilots, mapping individual-level barriers and facilitators to the TDF and then linking to the COM-B theory has been identified as a good fit. The benefit of this approach is that the TDF and COM-B can be linked to **intervention functions** (Figure 8).

Intervention functions describe the underlying *function* a change strategy would serve. They are not to be confused with change strategies themselves. Intervention functions can be linked to the COM-B and are a validated, well-respected and frequently used approach. For example, the goal of education is to educate, and this can be linked to the capability and motivation domains of the COM-B as well as to many TDF domains, including knowledge. If social influences are identified as a barrier to behaviour change, then appropriate change strategies would serve the following intervention functions: to enable the behaviour change, provide models of the behaviour change, restructure the implementation environment to favour the behaviour change, or restrict feasible behaviour to the desired behaviour change. The table below illustrates how the COM-B and TDF are linked to intervention functions. This linking was conducted by psychologists (7).

Figure 8: Intervention functions linked to the TDF and COM-B

		Intervention Functions									
	TDF Domain	Education	Training	Environmental restructuring	Enablement	Modelling	Persuasion	Incentivization	Restriction	Coercion	
COM-B Domain	Capability	Knowledge	✓								
		Skills		✓							
		Memory, attention and decision processes		✓	✓	✓					
		Behavioral regulation	✓	✓		✓	✓				
	Opportunity	Environmental context and resources		✓	✓	✓				✓	
		Social influences			✓	✓	✓			✓	
	Motivation	Social/professional role and identity	✓				✓	✓			
		Beliefs about capabilities	✓			✓	✓	✓			
		Optimism	✓			✓	✓	✓			
		Intentions	✓				✓	✓	✓		✓
		Goals	✓			✓	✓	✓	✓		✓
		Beliefs about consequences	✓				✓	✓			
		Reinforcement		✓	✓				✓		✓
Emotion					✓	✓	✓	✓		✓	

**Note that change strategies with coercive functions may have unintended consequences and should be used with caution.*

Defining change strategies

Once an understanding of the underlying functions of the change strategies has been established, the actual change strategies to be used can be selected. Strategies are available from a few key sources, including the **Expert Recommendations for Implementing Change (ERIC)** list (Table 1) (11). This list is perhaps the most widely used resource in the field of implementation science. The ERIC list originally contained 73 strategies that were broadly defined and that serve multiple purposes along the implementation pathway. The authors are refining the list, but we have taken the liberty of using the original list as a starting point to identify specific change strategies that facilitate behaviour change and that align with intervention functions. This list is not exhaustive but provides a starting

point once people have identified the relevant intervention functions to address identified barriers and facilitators.

Table 1: ERIC strategies linked to intervention functions

Intervention function	Strategies
Education	<ul style="list-style-type: none"> • Educational materials • Educational meetings • Knowledge broker • Mass media • CoP/learning collaborative • Audit and feedback • Capture and share local knowledge
Training	<ul style="list-style-type: none"> • Educational materials • Educational meetings • Educational outreach visit • Local opinion leaders • Train-the-trainer • Work with educational institutions • Provide supervision
Environmental restructuring	<ul style="list-style-type: none"> • Reminders • Revise professional roles • Record systems • Service sites • Prompts/cues • Change the physical environment

<p>Enablement</p>	<ul style="list-style-type: none"> • Champions • CoP • Opinion leaders • Patients as active participants • Allocation of funds • Payment schemes • Build a coalition/network • Data sharing • Leaders • Involve executive boards • Social support • Goal setting • Restructuring the environment • Problem solving • Action planning • Self-monitoring of behavior
<p>Modelling</p>	<ul style="list-style-type: none"> • Model and simulate change • Visit other sites • Shadow other experts • Provide supervision
<p>Persuasion</p>	<ul style="list-style-type: none"> • Opinion leaders • Mass media • Champions • Local consensus process • Facilitation • Identify early adopters • Patient/consumers to enhance uptake • Leaders
<p>Incentivization</p>	<ul style="list-style-type: none"> • Accreditation • Allocations of funds • Payment schemes • Audit and feedback
<p>Coercion (there are potential negative ramifications to using coercion; therefore, it should be used judiciously)</p>	<ul style="list-style-type: none"> • Mandate change • Develop disincentives • Audit and feedback • Change liability laws

Despite its limitations, the ERIC list is nonetheless valuable for selecting and designing change strategies.

Operationalizing change strategies

Once the change strategies that best fit the implementation goals have been selected, it is necessary to operationalize them (keeping in mind your underlying barriers and facilitators). This amounts to providing a full description of their components and how they should be used. This step is often missed following the process of choosing strategies using evidence and theory but is critical to enable measurement and reproducibility. Once the implementation strategies have been operationalized, it is good practice to review the underlying barriers and facilitators to behaviour change once again to ensure that the strategies will effectively address them.

Guidelines exist for operationalizing change strategies. You can adequately operationalize your change strategies by thinking about the details of your strategies across the following seven dimensions (12):

1. *The actor* – defining the stakeholder who actually delivers the implementation strategies.
2. *The action* – defining how the strategy is executed. Implementation strategies require dynamic verb statements that indicate actions, steps or processes, and sequences of behavior. Ideally, these actions are behaviourally defined a priori to allow comparison with what was actually done during the implementation process.
3. *Action target* – defining where implementation strategies are directed or the conceptual targets they attempt to impact; in other words, defining who the strategy is targeted to. For example, ‘training’, as an implementation strategy, would target the intervention recipients.
4. *Temporality* – in cases where multiple implementation strategies are required, specifying the order or sequence of strategy use, if the order is important.
5. *Dose* – defining how much or how often the strategy is delivered, how much time needs to be spent doing the strategy (i.e., intensity of the strategy), etc. These details should be designated and described a priori. For example: we plan to deliver 4 training sessions at 1-hour each over a 2-month period.
6. *The implementation outcome affected* – specifying the link between the strategy and the hypothesized outcome.
7. *The justification* – providing justification or rationale for the strategies used to implement a given intervention. This justification acts as the link between the change strategies and the

barriers/facilitators and the program theory. Such justifications may be based on prospective assessments of practice, or may be identified using theory, research literature, or more informal approaches such as brainstorming.

Relevance to the SDM pilots

Once the implementation team at each implementation site has conducted a barriers and facilitators assessment, the next step for each team will be to go through the process of selecting change strategies. Specifically, they will need to link identified individual-level barriers and facilitators to change to the COM-B and TDF and then to intervention functions. Once linked to intervention functions, they will then need to select and operationalize the change strategies that will be used in their setting to support relevant stakeholders in changing their behaviour and performing the desired core functions.

What are the common hurdles?

Despite the importance of selecting and tailoring change strategies, there is a limited amount of literature available to support these steps. As a result, it is not always easy to find the evidence you need to support change strategy selection. Relatedly, another challenging aspect of this step in the implementation process is that it is not strictly a science; there is an art to it as well. Appropriately selecting and tailoring strategies does not amount to following a checklist. It also requires a thorough knowledge of the implementation setting and a felt understanding of the strategies that will fit (and those that will not fit) the context.

3 Implementing the intervention (KTA step 7 & GTO steps 4-7)

Once we have developed an intervention, we can come up with a plan for implementing it.

3.1 Getting to Outcomes

As mentioned, there are process models to guide the process of designing interventions for implementation and process models to guide the implementation, spread, and scale-up of interventions. Therefore, once the SDM pilots have been fully developed, it will be necessary to select a process model that will guide their implementation. We have identified **Getting to Outcomes (GTO)** as being a good fit for the SDM pilots.

Figure 9: Getting to Outcomes



Getting to Outcomes (Figure 9) is a 10-step process model to help plan, implement and evaluate the impact of programs and community initiatives. It is designed to help organizations run programs well and get desired outcomes. The GTO process is supported by training, technical assistance, and guides in several content areas, which offer tools and instructions to help users complete the ten GTO steps. In the discussion that follows, we provide an overview of the GTO steps most relevant to the SDM pilots. While we do not review every step in-depth, remember that it is nonetheless critical to go through each step when planning for implementation.

3.2 Identifying local needs (GTO steps 1-3)

What is the purpose of this section?

This section outlines key considerations to be made during the first three steps of the GTO process, as well as their relevance to the SDM pilots.

Why is this important?

When developing an intervention, it is critical that you assess the gap between the current practice and the ideal practice, and identify whether that particular intervention is needed to address the gap. Even with the strongest evidence of effectiveness, if an intervention is not needed or does not address a gap, it is not a good use of resources and time to invest in implementing that intervention. Ascertaining needs and gaps also helps you identify the goals and outcomes you are hoping to achieve through implementation.

What are the key constructs?

Intervention development is most often spurred by an identified gap in outcomes. Once such a gap has been established, it is important to first set out to understand why that gap exists and what needs to be done to fill it. In the context of the SDM pilots, this has already been accomplished and has resulted in the development of the Framework and its component eight core functions. However, because the Framework will be adopted in different communities and with different community partners, it is important to dedicate time to understanding how these differences come into play and affect which core functions communities decide to adopt and how they adopt them. This is what is meant by “identifying local needs and context.”

When thinking about needs, we can distinguish between **apparent needs** and **expressed needs**.

Apparent needs are those needs that are identified through quantitative data analysis, for example, through a comparison of performance on a specific metric between departments within an organization.

Expressed needs are those actually identified by the group of people you want your intervention to target.

The difference between apparent needs and expressed needs highlights the importance of soliciting the opinions and values of people in the implementation setting. When multiple gaps in practice are identified, a prioritization exercise is required to help you understand which gaps to tackle, and it is important that such an exercise also incorporate the values and opinions of those individuals that will

be affected by implementation. When deciding which gaps to tackle, it is important to consider multiple elements that can affect implementation, such as implementation capacity and context. The **Contextual Framework for Implementation Research** can also be used at this stage to help to guide conversations about, and understand, each community's context and how this will affect which core functions they decide to adopt.

Relevance to the SDM pilots

The Framework and its core functions, which reflect best practices for providing supports for decision making (GTO step 3), can be understood as having been developed based on system needs and gaps (GTO step 1). Based on these needs and gaps, the desired outcomes for the pilots has been established, including that supports will become less formalized and professionalized and that supports and arrangements will become widely known, respected, valued and legally recognized (GTO step 2).

In the next steps of the SDM pilots, each community pilot will need to select which core functions they will adopt, ideally based on their own local needs and gaps. The core functions they adopt and the change strategies they utilize will ultimately serve to address those gaps.

What are the common hurdles?

At this stage of intervention development, a common misstep is not assessing needs and gaps. When these are assessed, other hurdles include: not adequately exploring why these needs and gaps exist; capturing only one type of need, and failing to use local data in order to identify local needs.

3.3 Adapting the intervention (GTO step 4)

What is the purpose of this section?

The purpose of this section is to outline the steps involved in adapting the targeted behaviour change (the WHAT) and its change strategies (the HOW).

Why is this important?

Historically, tension has existed between the concepts of fidelity and adaptation. Implementation scientists used to believe that fidelity was necessary to achieve outcomes, but since fidelity is not a reality in practice we need to consider how adaptations can help or hinder outcomes rather than force people into maintaining fidelity.

Because adaptations will happen whether you intend for them or not, *it is better to be proactive about them and think about them critically as you plan for implementation*. Failing to plan for adaptations can be risky and potentially detrimental if unintended changes are made to the mechanisms or underlying theory for the WHAT or the HOW.

What are they key constructs?

There are six key questions that can guide you to better plan for and address adaptations.

1. *Who are your key stakeholders?*

It is important that decisions about adaptations be made collaboratively, specifically with those who will be affected by the adaptations. Engage key stakeholders in the adaptation planning process.

2. *Are you adapting the WHAT or the HOW?*

The two main components of any intervention are the behaviour change you want to target (the WHAT) and the change strategies you will use to get people to change their behaviour (the HOW). When discussing adaptations, it is important to distinguish whether they relate to the WHAT or the HOW.

3. *Why are you adapting/what is the reason for the adaptation?*

Common reasons to adapt include implementing in a new setting or with a new population. No matter the reason, it is good to ask the question and make sure that everyone involved understands why you are making adaptations.

4. *What is the purpose of adapting/what is the goal of making an adaptation?*

Adaptations are made with a host of goals in mind, for example to increase recruitment or retention. It is important that the goal of an adaptation(s) be established and understood by everyone involved.

5. *What is the nature of the adaptation? Provide a clear description of the adaptation and how it is different than the original intervention.*

If adapting the WHAT, then this amounts to redefining the WHAT using the 7Ps. If adapting the HOW, then this amounts to understanding the local barriers and facilitators and selecting or adapting the change strategies to reflect these.

6. *What is the potential impact of the adaptation? Will it change the effectiveness of the intervention?*

Although we do not know the impact of adaptations until we evaluate them, if we truly understand the underlying mechanism of change/the theory of change, we can hypothesize the potential impact of different adaptations. Ideally, we should be making adaptations that do not change the underlying function/mechanism of change of the interaction.

Relevance to the SDM pilots

It is never too early to start thinking about adaptations, as they make up a key component of the sustainability of any intervention. As the pilots select change strategies and move forward with implementation, it will be important to start having conversations early and often about how implementation conditions will change over time and the implications of this for the intervention and what adaptations may need to be made to meet those evolving conditions. For example, you may start by thinking about what adaptations might need to be made to the WHAT (i.e., the core functions). Do they stay the same over time or can any changes be anticipated? The same is true of the HOW (i.e., the change strategies). As noted earlier, many sites likely already perform certain HOWs. Do these need to be adapted and how so? Can you proactively plan for adaptations for additional HOWs you may select?

What are the common hurdles?

Despite the fact that adaptations are inevitable in the implementation process, many adaptations are not planned. This is potentially detrimental, as planned adaptations are less likely to negatively impact outcomes. Further, with unplanned adaptations, it is common that these are not documented. When adaptations are being planned for, other common challenges include: failing to engage key stakeholders; not differentiating between adaptations of the WHAT or the HOW; failing to consider the potential impact of the adaptations on outcomes; and failing to revisit barriers and facilitators. It is important to note that even planned adaptations can be detrimental if you do not go back to barriers and facilitators when making those adaptations, as failing to do so increases the likelihood that you will stray from the theory underlying your WHAT or your HOW.

3.4 Roles in the system (GTO step 5)

What is the purpose of this section?

The purpose of this section is to highlight the importance of establishing role clarity at the beginning of implementation and to provide guidance on how to delineate your implementation system.

Why is this important?

It is important to understand who is doing what in your implementation system. Despite this, one of the biggest challenges in change efforts is defining who is in your implementation system, and the roles of actors in this system. Establishing early on who needs to do what to make implementation happen is key to success.

What are they key constructs?

There are two key aspects of systems that are important to keep in mind when thinking about implementing in a system.

The first is that even though systems are big and connected, we have to impose boundaries on our **implementation system**. We have to understand **who is in the system** and **who is out of the system** in order to make implementation more manageable.



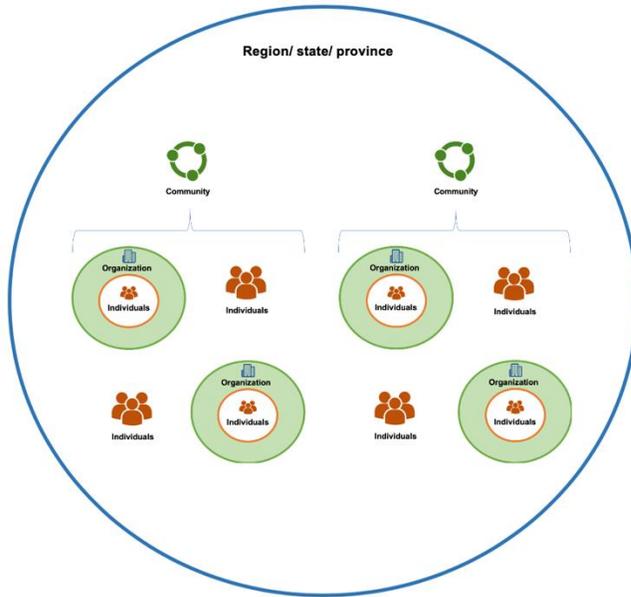
The second is that of **connectedness**; in other words, how are the different system components connected to one another?

As the definition of a system is so broad, it's important to set boundaries about what is included in your system.

These boundaries may seem artificial, but setting boundaries is important to manage action and the change you are trying to make.

When you are **setting system boundaries**, think about who you are trying to impact. In other words, who has to do what differently? Within the implementation system, we often try to target groups of individuals to do something differently, so individuals will almost always have to be a part of your system, no matter what level of the system you work at. There are other people, organizations, and

structures at play at different levels that support individuals to make the change you're targeting. When we draw boundaries, often we are drawing boundaries that determine what level of the system we are trying to directly impact with our initiative.



When implementing at higher levels in the system, as is the case in the SDM pilots, things can get a bit more complicated as more groups of individuals and organizations are involved and involved in different ways. Here, it is important to discern between who has direct involvement, indirect involvement, and no involvement at all, in order to draw boundaries. When setting system boundaries, it is important to beware of our tendency to boundary creep. We tend to want to keep pushing the system boundary and be more inclusive of who's

in the system. This is okay to do if you have the time and resources to accommodate this, but will make things challenging if you do not.

The other thing we have to consider when working within systems is how connected the different components of the system are and how they work with one another. The **Interactive Systems Framework (ISF)** (13) can help you think through this. It describes different roles, and how these roles are connected to one another in the implementation system.

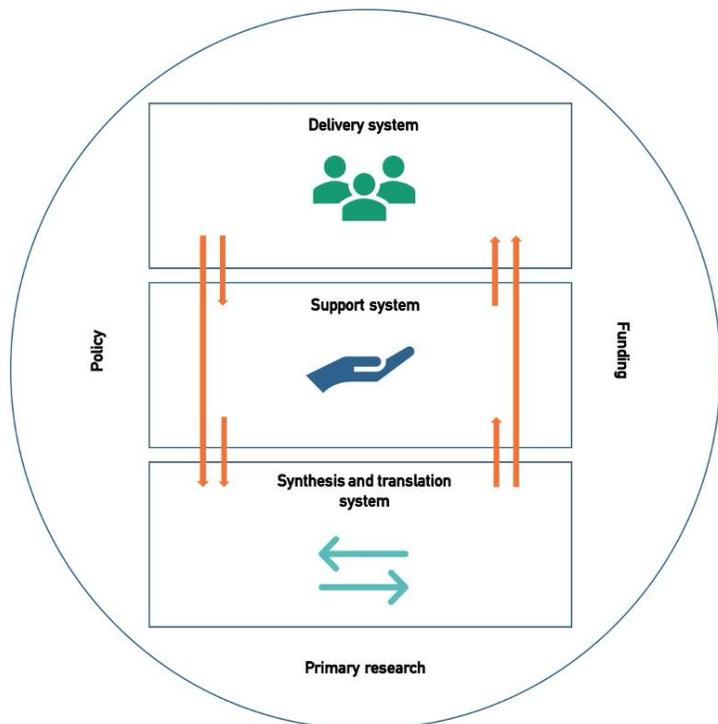


Figure 10: The Interactive Systems Framework

The idea behind the ISF is that there are different people who help make implementation happen, and all of those people, or groups of people, have different roles. One of the things that can make implementation challenging is that we don't always clarify people's roles and how they are contributing to implementation. The ISF helps us to clarify different roles in a systematic way.

Individuals in the **delivery system** are those responsible for actually delivering the intervention (sometimes referred to as the implementation team). Who this is and what their jobs are can vary depending on the setting you're

working in. Ultimately, we need these people to have knowledge and expertise in the intervention they're delivering. They also need to know about implementation, which often requires some capacity building.

In order for people in the delivery system to have something to deliver, we need to have people who **synthesize and translate research evidence**. Sometimes the delivery system and the synthesis and translation system interact directly. But often times, there is an intermediary between the two, termed the support system.

The **support system** is a person or a group of people who support implementation. They help the delivery system implement and they help the synthesis and translation system understand what's happening on the front lines and communicate the most helpful evidence to the delivery system.

The ISF also highlights high-level roles that nonetheless affect implementation, such as primary research, policy, and funding.

Roles in the context of the SDM pilots

As the SDM pilots move toward implementation, it will be critical to establish further understanding of the pilots on several fronts:

- Determine who is actually doing the core functions, who is going to support people/organizations to do the core functions, and how they will support them
- Determine what level of change each support is trying to impact
- Determine what the implementation team looks like at each level. One of the key next steps will be to establish an implementation team within each community-based pilot and to determine which actors in the support system will be providing support to which teams and what that support will look like.

What are the common hurdles?

As noted, one of the biggest challenges in change efforts is defining who is in your implementation system, and the roles of actors in this system. This ultimately undermines both the efficiency and success of implementation efforts. For interventions that target change at multiple levels of a system, such as the SDM pilots, it is critical to spend time clearly delineating the system and the roles of different actors and how and to whom they are providing support. It is equally important that this is widely understood and communicated so that every person involved in implementation is on the same page.

4 Evaluating the intervention (KTA step 9 and GTO steps 7-9)

What is the purpose of this section?

The purpose of this section is to provide an overview of different types of evaluations for implementation efforts as well as key considerations when planning for evaluation.

Why is this important?

When spreading and scaling up any intervention, it is critical to maintain rigorous monitoring of its impact and outcomes. There is a tendency to conduct comprehensive evaluations during the initial implementation cycles of a program or intervention but to subsequently discontinue this high degree of evaluation as it is scaled up or spread (e.g., to new locations). It is only appropriate to conduct less thorough outcome and impact evaluations once there is clear evidence that an intervention is consistently effective at achieving the anticipated results. After this stability has been established, the assumption is that an intervention implemented with high quality will continue to produce the outcomes that have previously been demonstrated through evaluation. Unfortunately, when interventions are implemented in real world settings, for various reasons they are rarely executed with the necessary quality. Therefore, it is essential that evaluations (particularly process evaluations) form a consistent part of implementation practice.

Evaluating implementation aligns with realist evaluation approaches that ask the questions *what works, for whom, under what conditions* and in which processes are a key focus and context is emphasized (14).

A comprehensive evaluation of implementation will include variations of the following questions:

3. A) Did we do what we intended to do? [a process evaluation question]
B) Why or why not? [a process evaluation question]
4. What change(s) did we make in outcomes? [an outcomes evaluation question]

What are they key constructs?

4.1 The RE-AIM framework

The RE-AIM framework was conceptualized over two decades ago and is one of the most frequently applied implementation frameworks. While RE-AIM has been applied most often in public health and health behaviour change research, it is increasingly being applied in more diverse content areas and within clinical, community and corporate settings. It was originally developed as a framework for consistent reporting of research results and later used to organize reviews of the existing literature on health promotion and disease management in different settings. Its goal now is to encourage program planners, evaluators, readers of journal articles, funders, and policy makers to pay greater attention to essential program elements that can improve the sustainable adoption and implementation of effective, generalizable, evidence-based interventions.

RE-AIM consists of five elements: 1) reach; 2) effectiveness; 3) adoption; 4) implementation; and 5) maintenance (15).

- **Reach** is defined as the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program, and reasons why or why not.
- **Effectiveness** is defined as the impact of an intervention on important individual outcomes, including potential negative effects, and broader impact including quality of life and economic outcomes. It is recommended that variability across subgroups, if applicable, also be considered when assessing effectiveness (i.e., generalizability or heterogeneity of effects).
- **Adoption** is defined as the absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program, and why. Note, adoption can have many (nested) levels, e.g., staff under a supervisor under a clinic or school, under a system, under a community.
- **Implementation** refers to intervention agents' fidelity to the various elements of an intervention's key functions or components, including consistency of delivery as intended and the time and cost of the intervention. Importantly, it also includes adaptations made to interventions and implementation strategies. Implementation is also referred to as implementation quality. Within implementation quality, common indicators include:
 - Dose (e.g., how many reminders were posted? How many sessions were delivered?)
 - Reach (e.g., what proportion of staff participated? What were the professions of staff that participated?)
 - Adaptation/fidelity (i.e., what was changed? What remained the same?)
 - Participant responsiveness (e.g., how invested were education session participants in the session content?)

- Quality of delivery (e.g., were change strategies well designed? Were sessions delivered with high quality?)
- **Maintenance** – at the setting level, maintenance is defined as the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. Essentially, what processes, outcomes and impacts have been maintained, and which have changed over time?

Within the RE-AIM framework, certain elements are relevant to the implementation process (i.e., are process indicators) while others are relevant to implementation outcomes (i.e., are outcome indicators). Specifically, reach, adoption and implementation are process indicators, while effectiveness is comprised of outcome indicators. Maintenance should capture both process and outcomes. When specifying process measures for evaluation, it is important to think about both the WHAT and the HOW and clearly delineate between the process measures relevant to each component.

4.2 Process evaluation and implementation quality (GTO step 7)

Implementation is inherently process-oriented; as such, the evaluation of implementation efforts often takes the form of a process evaluation. It should be noted that the implementation outcomes discussed above can be captured by a process evaluation. Process evaluations ultimately aim to answer the following questions: Did we do what we intended to do? And why or why not? The Reach, Adoption and Implementation elements of the RE-AIM framework will all be helpful in guiding the evaluation of the SDM pilots.

Asking whether we “did what we intended to do” taps into a concept called *implementation quality*. This is less about checking things off of a list (i.e., were things done or not done), and more about how they were done. Knowing a great deal about processes tells us much about outcomes. For example, if a drug was prescribed to a patient but was not improving that patient’s health, we might be inclined to say that the drug does not work. However, a good clinician will know to ask that patient questions about how they are taking the drug. Are they even taking the drug in the first place or are we assuming that they are? Are they taking it when they are supposed to? Are they taking it how they are supposed to (e.g., with or without food)? Are they taking other medications that might counteract the effects of the drug? Is it possible that the dose isn’t correct? It could be that with adjustments to how the patient is taking the drug, the drug may actually become effective.

We find that the same is true in implementation. We often implement interventions without describing how it was implemented, and are then unable to explain what made the intervention

effective or ineffective. Good evaluation practice involves comprehensively understanding implementation quality of both the WHAT and the HOW.

Common indicators for implementation quality include (12):

- Dose (e.g., how many reminders were posted? How many training sessions were delivered?)
- Reach (e.g., what proportion of staff participated? What were the professions of staff that participated?)
- Adaptation/fidelity (i.e., what was changed? What remained the same?)
- Participant responsiveness (e.g., how invested were education session participants in the session content?)
- Quality of delivery (e.g., were change strategies well designed? Were sessions delivered with high quality?)

4.3 Outcome evaluation (GTO step 8)

In most cases, when planning for evaluation, it can be more intuitive to start by specifying indicators for outcome measures because it is a desired change in outcomes that generally spurs intervention development and implementation in the first place. A key consideration here is that, when talking about effectiveness (and maintenance), these are in reference to the effectiveness and maintenance of the *intervention*, which includes *both* the practice/policy change *and* the associated change strategies implemented to support the behaviour change targeted by the practice or policy or program. Despite there being two major pillars to any intervention, we rarely measure if a shift in the desired behaviour actually occurred. Instead, we assume that it did because we delivered the change strategy. A common example is delivering a training session. We often assume that people who attended a training session effectively learned what they needed to learn, but we do not know if their knowledge was actually improved if we do not measure it. The same can be said for other change strategies. This often represents a gap in our program logic, and without measuring the behavioural outcome of a strategy, we cannot effectively test our program's theory of change.

4.4 Continuous Quality Improvement (GTO step 9)

Continuous quality improvement involves monitoring program delivery and impact and using this information to enhance implementation quality. Providing guidance about continuous quality improvement is challenging, as what you should be doing with your data is highly dependent on what the data indicates. No matter what you find, there is always something that can be done to improve the program's implementation.

There are three steps to use your data for continuous quality improvement.

1. Based on the data you collected, determine which aspects of the program were well implemented and which ones could use improvement.
2. Explore areas that could use improvement. This might include getting feedback on barriers that prevent high quality implementation. You may also discover that the measures you used did not provide you with the information you needed. If so, when you deliver the program again, select different measures which better address these areas.
3. Use this information to improve implementation quality in the next round of program delivery.

It is helpful to think about how the process of change, the implementers and the participants can influence implementation quality. It is possible that changes to one or more of these aspects could enhance implementation quality. It is also important to ask yourself if you measured the most important things for understanding how your program is working; if not consider which measures you would use in the next implementation.

Relevance to the SDM pilots

It is important to plan for evaluation as you plan for implementation so that you can set up the resources, processes, and data collection methods you will need for evaluation from the beginning. At this stage, the SDM pilots will need to decide which type(s) of evaluation they will be conducting. Once the intervention is more fully fleshed out (i.e., change strategies have been selected and operationalized), sites can begin to think through and specify important process and outcome indicators and their plans for measuring these. Role clarity is also critical when thinking about evaluation. It will need to be determined who will be responsible for evaluation at each site and who will be responsible for collecting the necessary data.

What are the common hurdles?

A change in outcomes is often what spurs intervention development and implementation. And it is this change in outcomes that implementers are often most interested in capturing. While measuring implementation outcomes is important, it is critical that this not be done at the expense of measuring the implementation process, specifically aspects of implementation quality. Often, the need to measure implementation quality is overlooked, and this can have adverse effects, including leading to an unintentional change of the core components of the intervention (by not tracking adaptations). As noted above, implementation quality data is critical insofar as it can provide useful contextual

information. Without implementation quality data, if there are no positive program effects, then you cannot examine if this is the result of a flaw in the program theory or of poor implementation quality. Conversely, if positive outcomes are achieved, without implementation quality data, the components of the implementation process that are critical for successful replication cannot be captured or communicated. Measuring implementation quality enables you to think about how the implementation process produces certain outcomes; however, implementation quality is rarely included in evaluation plans.

What is the purpose of this section?

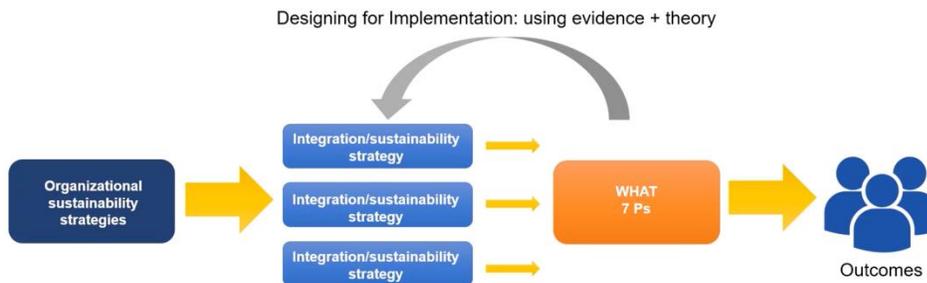
The purpose of this section is to provide an overview of sustainability and guidance on how to plan for sustainability.

Why is this important?

Just as adaptations should be planned for, sustainability should also be planned for. Planning for sustainability from the start of implementation is just as critical as planning for actual implementation. Often, implementation projects are treated as if they have a defined start and end rather than as something that is going to continue, which undermines sustainability.

What are they key constructs?

One of the challenges of planning for sustainability is that sustainability is not well defined. There are different components to sustainability and planning for sustainability.



The ultimate goal of sustainability and sustaining what it is we are implementing is to maintain the **outcomes** that are produced. In order for these outcomes to be sustained over time, behaviour change needs to be sustained. In other words,

individuals need to continue to do the **WHAT** as it is intended. Sustained behaviour change is itself contingent on sustaining the change strategies (the **HOW**). In order for change strategies to continue to be delivered over time, **organizational-level sustainability strategies** are required.

Picking sustainability strategies ultimately comes down to using a combination of evidence and theory. Your strategies should address the underlying barriers and facilitators to sustainability.

There are 5 steps involved in **planning for sustainability**:

1. Define who is involved in sustainability planning and execution (WHO)
2. Define what you are sustaining (WHAT)
3. Understand the context for sustainability (WHERE)
4. Select sustainability strategies (HOW)
5. Develop an ongoing monitoring and evaluation plan (EVALUATE)

Relevance to the SDM pilots

As the pilots move forward with selecting change strategies and with implementation, it will be important to start having conversations early and often about sustainability. It is important to remember that sustainability doesn't just happen; it requires time and effort. It is helpful to change how you think about implementation (i.e., as ongoing, rather than having a defined start and end) and to embed sustainability into the process. There are a number of tools available to help in assessing sustainability factors such as: the [NHS Sustainability Model](#); the [Long-Term Success Tool](#); and the [Program Sustainability Assessment Tool](#).

What are the common hurdles?

As mentioned, implementation projects are often treated as if they have a defined start and end rather than as something that is going to continue. The biggest hurdle when it comes to planning for sustainability is that it happens too late in the implementation process. It is important to plan for sustainability early on and think about it often.

6 References

1. Presseau J, McCleary N, Lorencatto F, Patey AM, Grimshaw JM, Francis JJ. Action, actor, context, target, time (AACTT): A framework for specifying behaviour. *Implement Sci* [Internet]. 2019 Dec 5 [cited 2020 Apr 6];14(1):102. Available from: <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-019-0951-x>
2. Balas EA, Boren SA. Managing Clinical Knowledge for Health Care Improvement. *Yearb Med Inf* [Internet]. 2000 [cited 2020 Jun 17];1:65–70. Available from: <https://pubmed.ncbi.nlm.nih.gov/27699347/>
3. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof*. 2006;26(1):13–24.
4. Fernandez ME, ten Hoor GA, van Lieshout S, Rodriguez SA, Beidas RS, Parcel G, et al. Implementation Mapping: Using Intervention Mapping to Develop Implementation Strategies. *Front Public Heal* [Internet]. 2019 Jun 18 [cited 2020 Sep 11];7(JUN):158. Available from: <https://www.frontiersin.org/article/10.3389/fpubh.2019.00158/full>
5. Brown CH, Curran G, Palinkas LA, Aarons GA, Wells KB, Jones L, et al. An Overview of Research and Evaluation Designs for Dissemination and Implementation. *Annu Rev Public Health*. 2017 Mar 20;38(1):1–22.
6. Leeman J, Birken SA, Powell BJ, Rohweder C, Shea CM. Beyond “implementation strategies”: Classifying the full range of strategies used in implementation science and practice. *Implement Sci* [Internet]. 2017 Nov 3 [cited 2020 Jul 1];12(1):1–9. Available from: <https://link.springer.com/articles/10.1186/s13012-017-0657-x>
7. Michie S, Atkins L, West R. *The Behaviour Change Wheel: A Guide to Designing Interventions*. London: Silverback Publishing; 2014.
8. Cane J, O’Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* [Internet]. 2012 Apr 24 [cited 2020 Jun 25];7(1):37. Available from: <http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-37>
9. Atkins L, Francis J, Islam R, O’Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implement Sci* [Internet]. 2017 Jun 21 [cited 2020 Jun 25];12(1):77. Available from: <http://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0605-9>
10. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implement Sci* [Internet]. 2009 Dec 7 [cited 2020 Jul 29];4(1):50. Available from: <http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-4-50>
11. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci* [Internet]. 2015 Feb 12 [cited 2020 Jul 1];10(1):21. Available from: <http://implementationscience.biomedcentral.com/articles/10.1186/s13012-015-0209-1>
12. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: Recommendations for

specifying and reporting. *Implement Sci* [Internet]. 2013 Dec 1 [cited 2020 Apr 6];8(1):139. Available from: <http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-139>

13. Wandersman A, Duffy J, Flaspohler P, Noonan R, Lubell K, Stillman L, et al. Bridging the gap between prevention research and practice: The interactive systems framework for dissemination and implementation. *Am J Community Psychol* [Internet]. 2008 Jun [cited 2020 Sep 9];41(3–4):171–81. Available from: <https://pubmed.ncbi.nlm.nih.gov/18302018/>
14. Pawson R, Tilley N. An Introduction to Scientific Realist Evaluation. In: *Evaluation for the 21st Century: A Handbook*. SAGE Publications Inc.; 1997.
15. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: Adapting to new science and practice with a 20-year review. *Front Public Heal* [Internet]. 2019 Mar 29 [cited 2020 Sep 14];7(MAR):64. Available from: www.frontiersin.org