





# **Causal Pathway Diagrams**

TOOLKIT FOR SELECTING, DESIGNING, TAILORING, AND OPTIMIZING IMPLEMENTATION STRATEGIES

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### **GETTING STARTED**

#### What is a causal pathway diagram?

Causal pathway diagrams (**CPDs**) are a tool to help implementation scientists to develop, select, optimize, and evaluate implementation strategies, with a deliberate focus on context. They are graphical representations of the processes that connect implementation strategies with the outcomes they are intended to impact (**Figure 1**).

CPDs guide users to clarify their assumptions about

- · How implementation strategies work
- The circumstances under which they work
- · How they work in combination with other implementation strategies

These assumptions can be vetted and tested to ensure users are prioritizing strategies that are most likely to be effective. CPDs are a tool intended to aid the field's efforts to move beyond an "it sounded like a good idea at the time (ISLAGIATT)" approach to a precise and targeted approach to support implementation.





#### Who is this toolkit for?

This toolkit is designed for researchers with a background in implementation science. It is intended to support those who are developing, testing, or using implementation strategies to improve health care. While this toolkit is also applicable to implementation practitioners, such as quality improvement teams, this version of the toolkit is geared towards scientists who are conducting implementation research. Future iterations will incorporate a process adapted for implementation practitioners.

#### Why use causal pathway diagrams?

Implementation strategies do not directly impact health outcomes. Instead, they initiate a chain of events—such as organizational changes and changes in social norms—that can affect whether, how well, and for how long evidence-based interventions (**EBIs**) are used. Their ultimate success depends on the successful activation of each event in this chain. The complexity of implementation, and the interaction of strategies and local conditions, has historically led to low rates of implementation success.

We believe that a key reason for limited implementation success is that implementation initiatives do not pay sufficient attention to the process—the full chain of events—that connects implementation strategies to the intended implementation outcomes. CPDs provide a structure to think carefully about how implementation strategies will work best. CPDs have six core functions:

- 1. Selecting or designing an implementation strategy
- 2. Understanding the conditions under which an implementation strategy will work
- 3. Designing and optimizing multifaceted implementation strategies
- 4. Developing causal theories of how implementation strategies work
- 5. Measuring implementation strategy functioning
- 6. Diagnosing why an implementation strategy did not work as intended

#### When to use causal pathway diagrams?

We encourage the use of CPDs throughout the implementation process. They can be useful while planning and during implementation and after implementation is complete.

- 1. Planning for implementation: To guide you through selection and design of an implementation strategy
- 2. During implementation: To inform evaluation of an active implementation strategy and guide adaptive approaches to increasing effectiveness
- 3. After implementation: To clarify why a strategy did or did not work as planned

#### How to use this toolkit?

This toolkit is a one-stop shop for *nearly* everything you need to know about using CPDs. Instead of reading from beginning to end, navigate to the most relevant sections.

#### Section 1: An Introduction to Causal Pathway Diagrams

This section is the starting place if you are interested in learning about CPDs. It describes the structure of a CPD and introduces its elements.

#### Section 2: Principles and Practice of Developing Causal Pathway Diagrams

This section is for a deeper understanding of the process for developing a CPD, each element that makes up a diagram, and principles for their development.

#### Section 3: Functions of Causal Pathway Diagrams

This section provides in-depth guidance and examples illustrating how to develop a CPD for six different functions. You may find it most helpful to navigate to specific CPD functions of interest.

#### **Frequently Asked Questions**

This section addresses common questions that come up while developing a CPD. It is most useful if you have a basic understanding of CPDs and want guidance on more complex issues, such as how to operationalize an implementation strategy or how to select and define a mechanism.

#### Tools to Build Your Own Causal Pathway Diagram and Additional Resources

A <u>separate document</u> includes tools for developing a CPD such as a diagram template and questions to guide the CPD development process. It also has a section with links to resources on implementation science topics that may be helpful as you develop a CPD. The resources include implementation strategy compilations to identify possible strategies and links for identifying and prioritizing determinants.

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# SECTION 1: AN INTRODUCTION TO CAUSAL PATHWAY DIAGRAMS

CPDs are a tool for thinking through how implementation strategies work and under what conditions they will work best. They are box-and-arrow diagrams that describe the cause-and-effect process through which an implementation strategy is thought to influence the intended implementation outcomes.

These causal relationships can be graphically represented in various ways—such as directed acyclic graphs, causal loop diagrams, and logic models (Smith et al., 2020; Geng et al., 2022; Lipsky and Greenland, 2022).

This section is the starting place if you are interested in learning about CPDs. It gives you a sense of what CPDs are and how they can be used to support implementation research and practice.

### What's in this section?

- The basic structure of a CPD
- · Elements that make up a CPD
- A CPD in practice
- Functions of CPDs

#### The structure of the causal pathway diagram

CPDs include a set of elements that are considered the "stem" of the diagram and capture the causal logic of how a strategy works. The "leaves" capture elements that can affect whether and how well that strategy works.





Precondition: A factor that is necessary for change to occur between any 2 elements in the CPD stem.

#### Stem of the causal pathway diagram

The stem includes the elements for thinking through assumptions of how a specific implementation strategy works to achieve one or multiple distal implementation outcomes. Assumptions about how a strategy works are represented by the mechanism. At a minimum, this requires the following three factors (**Figure 2**).



Figure 2. A basic causal pathway diagram stem.

Implementation efforts often center on determinants, aiming to either resolve a barrier or harness a facilitator. In most cases, a series of causal events occur after a mechanism is activated and before the distal implementation outcome is achieved. These events can provide early signals of whether an implementation strategy is working. Therefore, the stem of a CPD most often includes a determinant that is being targeted and a proximal outcome to provide an early signal of strategy effectiveness. Note that the mechanism is now centered on how the strategy resolves or achieves the determinant (**Figure 3**).



Figure 3. An extended causal pathway diagram stem.

#### Leaves of the causal pathway diagram

Moderators are factors that strengthen or weaken the relationship between *any two elements* in the diagram. They strengthen or weaken the effect of an implementation strategy on the implementation outcome.

Preconditions represent factors that are necessary for a part of the causal process to take place. While similar to moderators, if preconditions are absent, they will completely inhibit a strategy from working. Their presence is necessary but does not guarantee that a strategy will be effective (**Figure 4**).



Context affects

whether and to

what extent an implementation

strategy works.

Figure 4. Causal pathway diagram leaves.

#### Flexibility in the elements included in a causal pathway diagram

CPDs have some inherent flexibility in the number and placement of their elements. We describe this flexibility below and illustrate it in the examples.

#### Adding or removing elements from the stem

The ordering of the elements in the stem represents the core causal logic and should not be modified. However, some elements may be omitted or added. When a strategy is not targeting a specific determinant, the determinant may be omitted. For instance, when developing a CPD that describes how a strategy works across diverse contexts, context-specific determinants may not be relevant.

CPDs may also include intermediate outcomes between the proximal and distal implementation outcome to capture intermediate signals of a strategy's continued effectiveness. Finally, CPDs may also include clinical or service outcomes added after the distal implementation outcome. The ultimate goal of implementation strategies is to improve clinical or service outcomes by achieving implementation outcomes (Proctor et al., 2011), so these additions can make that explicit in a CPD.

#### Placement of elements in the leaves

Both moderators and preconditions may be influential between any two factors along the causal chain of events. In the diagram above, moderators and preconditions are incorporated at two points in the causal process, but they can be present at different points in the chain (e.g., between a proximal and distal outcome) depending on the specifics of each implementation effort.

#### Elements of a causal pathway diagram

We describe the elements of the stem and leaves of the CPD as they occur along the diagram from left to right. The development of a CPD often does not follow this progression, however. For instance, a diagram commonly begins by defining the distal implementation outcome. The development order will depend on the function of the diagram and the questions it answers. Guidance on the ordering of articulating CPD elements is in Section 3: Functions of Causal Pathway Diagrams.

#### The stem

**Implementation strategy:** These are methods to improve the adoption, fidelity and sustained use of an evidence-based practice or an innovation (Powell et al., 2012). The simplest CPDs describe the functioning of a single, discrete implementation strategy. The strategy is at the left of the diagram, and the arrows to the right represent its causal influence.

While CPDs can be built to understand causal functioning of generally described strategies, such as reminders or audit and feedback, they typically describe the functioning of a specific *operationalization* of a strategy—how it will be deployed in a particular setting. This includes details such as who delivers the strategy and when or in what order it is delivered. We recommend using strategy-specification guidelines (Proctor et al., 2013; Presseau et al., 2019) because the way a strategy is operationalized often influences how it works. Guidelines for operationalizing a strategy are in the FAQ section.

**Mechanism:** This is the process through which a strategy is thought to impact the determinant it is intended to address. The mechanism describes how and why a strategy works. Implementation strategies may work through a single or multiple mechanisms.

**Determinant:** This is a barrier that impedes the desired implementation outcome or facilitator that enables implementation. A CPD typically centers on addressing a determinant or set of determinants thought to affect a distal outcome. While most settings have several implementation determinants, each CPD should include the determinant the strategy intends to address.

For strategies that resolve multiple determinants, we recommend creating CPDs that represent the causal paths through which each determinant might be addressed by that strategy. Each process may contain distinct preconditions or moderators.

**Proximal outcome:** These represent measurable impacts that, if the strategy operates as intended, occur before a more distal implementation outcome. Proximal outcomes are a sequence of observable effects through which the strategy impacts implementation outcomes. They enable assessing if the strategy works and identifying if and where the impact of an implementation strategy is stalling. A robust set of proximal outcomes supports development of a measurement battery to assess the process and success of an implementation initiative.

The number of proximal outcomes and their location in the causal process varies. Choose proximal outcomes that assess aspects of a strategy's operation about which you have the greatest uncertainty or that provide early signals of whether the strategy is working, to allow for adjustment.

**Distal implementation outcome:** This is the global intended effect of an implementation initiative, such as rate of depression screening for a clinic. A strategy's impact on a distal outcome is mediated by its proximal outcomes. Including distal implementation outcomes in a CPD ensures that each strategy being considered makes a plausible contribution to the desired implementation ends.

#### The leaves

CPD leaves represent contextual factors that facilitate or impede a strategy's operation. Two types of effect modifiers are preconditions and moderators.

**Preconditions:** These *must be present* for a part of the strategy's causal process to take place. If not present, preconditions block the strategy from having any effect. Preconditions can exert influence between any two linking elements in the CPD stem. Although an implementation strategy may have many preconditions, include only those that plausibly *might not be present* in the clinical setting. Identifying preconditions allows for devising activities or additional implementation strategies that ensure the preconditions are met.

**Moderators:** Moderators are factors that either strengthen or weaken the functioning of an implementation strategy. Like preconditions, moderators can operate at different points along the causal pathway.

Identifying moderators is important for two reasons. First, it enables incorporating additional strategies to potentiate (for facilitating moderators) or weaken (for impeding moderators) the influence of those moderators. Moreover, identifying moderators can inform how strategies should be sequenced. Second, identification of moderators can inform how to measure them to understand variation in a strategy's effectiveness.

#### Causal pathway diagrams in practice

Now that we have reviewed the structure and elements of a CPD, we explore how they can be used in practice, with an example of increasing depression screening in primary care.

**The context:** A team of implementation scientists is working to increase the rate of depression screening in a primary care clinic. Through a needs assessment, they find that the primary barrier to clinicians consistently administering depression screening is that their attention is divided during patient encounters due to competing demands. The scientists consider using electronic health record (**EHR**)-based decision-support prompts to remind clinicians to administer depression screeners when they access patient records at the start of visits. The literature suggests this may

be a promising strategy. The primary question is how to operationalize this strategy to maximize the chances it will work in their setting. A CPD can help answer that question.



Figure 5. Causal pathway diagram for electronic health record prompts for depression screening

#### Using a causal pathway diagram to match strategies to determinants

**Figure 5** shows that EHR decision-support prompts (implementation strategy) would primarily work through the mechanism of enhancing the salience of the need to screen for depression. Enhancing salience is intended to overcome the barrier of clinicians' divided attention due to competing demands during a clinic visit. If the mechanism is activated, the most direct behavioral outcome of a single such prompt (proximal outcome) is that the clinician administers the depression screener with the patient. If this happens repeatedly for most clinicians in the clinic, the overall screening rate (distal outcome) increases.

However, this chain of events can be affected—and potentially derailed—by a range of factors: First, some factors must be in place for the strategy to work. For the mechanism to be activated, the clinician must notice the prompt (precondition). If the prompt window is covered by other prompts or not particularly noticeable, the strategy will not work. Even if the clinician sees the prompts and intends to administer the screener, a lack of screener forms in the exam room (another precondition), prevents screening.

Second, some factors may make the operation of this strategy work more or less well. For instance, if clinicians are bombarded by prompts when they open a patient record, they will stop paying attention to them (habituation), reducing the prompts' effectiveness (moderator). Similarly, if the clinic visits are short (moderator), clinicians may not feel they have time to screen for depression, and are less likely to respond to the prompt.

What have we learned? Creating this CPD helps articulate the mechanism through which the EHR prompts should work (enhancing the salience of the need to screen). This, in turn, allows for identifying factors such as noticeability and habituation that may interfere with the activation of the mechanism, leading to project failure. By identifying these factors early, you can design prompts and their timing to avoid these risks and maximize the likelihood that the prompts are noticed and the strategy works.

In addition, the diagram allows for identifying larger organizational factors, such as visit length, that could interfere with screening even if the prompts are well designed. This understanding enables considering other strategies that may be needed to increase the likelihood of implementation success. In other words, the CPD informs the design of the decision-support prompt strategy or the employment of additional, supportive implementation strategies.

#### Key functions of causal pathway diagrams

CPDs can be used to achieve six key functions that contribute to decisions about designing, selecting, optimizing, and evaluating implementation strategies. Section 3 of this toolkit provides illustrations and recommendations for using CPDs for each function.

- 1. Select or design an implementation strategy that is likely to work: Ensure that an implementation strategy aligns with the determinant and outcome it intends to change
- 2. Understand the conditions under which an implementation strategy works: Identify preconditions for an implementation strategy to work and moderators that may strengthen or weaken how well it works
- 3. **Design and optimize multifaceted implementation strategies:** Understand how multiple implementation strategies will work together
- 4. Develop causal theories of how implementation strategies work: Create generalizable accounts of how an implementation strategy is expected to work and under what conditions it will work
- 5. **Measure implementation strategy functioning:** Identify early signals of whether a strategy is working and select instruments to measure strategy functioning
- 6. **Diagnose why an implementation strategy did not work as intended:** Retrospectively explore implementation strategy functioning to pinpoint where in the causal chain of events it stopped working

### SECTION 2: PRINCIPLES AND PRACTICE OF DEVELOPING CAUSAL PATHWAY DIAGRAMS

This section provides a deep dive into the process of developing a CPD. It is for users who are ready to develop a diagram.

### What's in this section?

- Where do I begin when developing a CPD?
- · What sources of information should I use to develop my CPD?
- What principles should inform my approach to developing a CPD?

#### Developing a causal pathway diagram

The process for developing a CPD depends on the questions of interest and the information available. The process of developing a diagram can have different starting points and elements to focus on. Section 3 discusses how the function of the CPD informs these decisions. This section has common approaches to developing CPDs.

#### Where to begin?

A common way to begin is with the distal implementation outcome you want to impact and the determinant, either a barrier or facilitator, that must be addressed to achieve the implementation outcome. From here, most people add implementation strategies to the stem of the CPD to vet which strategy, or set of strategies, plausibly addresses the determinant (**Figure 6**).



Figure 6. Beginning a causal pathway diagram with the outcome.

A second common starting point is with an implementation strategy. For instance, if developing a causal theory of how an implementation strategy works, you may begin with a strategy and build your diagram by focusing on the outcomes the strategy can bring about (**Figure 7**).



What outcomes can this strategy address and how does it work?

#### Figure 7. Beginning a causal pathway diagram with the implementation strategy.

Another common beginning is with an implementation strategy in mind, using a CPD as a plausibility check to ensure a strategy will work as planned (**Figure 8**).



Will this strategy work as intended?

## Figure 8. Beginning a causal pathway diagram with the implementation strategy and outcome.

Another common beginning is with an implementation strategy in mind, using a CPD as a plausibility check to ensure a strategy will work as planned (**Figure 8**).

#### Which elements of the causal pathway diagram to include?

Each element of the CPD serves a different purpose, and its utility depends on the questions of interest. For instance, if you are interested in a brief plausibility check of whether an implementation strategy can change an outcome, you might focus on the elements of the stem in **Figure 9**. If you are interested in measuring early indicators of implementation strategy functioning, add a proximal outcome.



Can this implementation strategy plausibly bring about change in the implementation outcome?

#### Figure 9. Selecting elements for a causal pathway diagram, part 1.

If you are interested in understanding the conditions in which a strategy would work, you would benefit from including both the stem and leaves of the CPD in **Figure 10**.



How and under what conditions can the implementation strategy plausibly bring about change in the implementation outcome?



#### Steps for developing a causal pathway diagram

The Tools to Build Your Own Causal Pathway Diagram document that provides a step-by-step example of how to develop a CPD. This process can be adapted, depending on your questions of interest. Below, we present questions that will guide you through the steps of describing how, and under what conditions, an implementation strategy can bring about change in an implementation outcome.

#### Questions to develop the stem of the causal pathway diagram

- 1. **Distal implementation outcome:** What implementation outcome are you hoping to change through this effort?
- 2. **Determinant:** What is the barrier that is obstructing that change or the facilitator needed to enable that change?
- 3. Implementation strategy: What strategy might overcome the barrier or achieve the facilitator?
- 4. Operationalization of the strategy: How would this strategy be carried out?
- 5. Mechanism: How or why would this strategy lead to change in the barrier or facilitator?
- 6. **Proximal outcomes:** What would be an early, observable sign indicating the strategy is working to address the barrier or facilitator?
- 7. **Intermediate outcomes:** Are there important, observable signs that the strategy is continuing to work, that follow the proximal outcome?
- 8. **Reflection:** How convincing is the pathway between the implementation strategy and distal implementation outcome?

**Figure 11** shows one common process for developing the CPD stem. It shows the core cause-andeffect steps that describe how an implementation strategy is expected to work. This is a good point in the development process to pause and assess how convinced you are that the strategy is likely to address the determinant and achieve the implementation outcome.



Figure 11: Core cause-and-effect steps in developing a causal pathway diagram stem

#### Evaluating the stem of the causal pathway diagram

We recommend the questions and actions in **Table 1** for evaluating alignment of an implementation strategy and a determinant, as a plausibility check. The approach and rigor of the check will depend on your needs. In fast-paced environments where decisions must be made quickly, use this as a "gut-check" of whether a strategy is likely to work. You may rely on logic to assess plausibility.

If you are designing an implementation strategy to be empirically tested, we encourage you to maximize rigor by drawing on empirical studies and theoretical literature when developing and assessing the plausibility of the CPD stem. Repeat this process with multiple implementation strategies until you are convinced that the strategy under consideration has the potential to enact the intended change in the determinant and improve implementation outcomes.

Possible solutions if you respond "no"
Change details of the strategy to make it more likely to activate the mechanism.
Consider replacing the strategy with a different strategy you think would lead to a stronger change.
Change details of the strategy (e.g., the dose) to lead to stronger change.
Consider replacing the strategy with a different strategy you think would lead to a stronger change.
Consider adding an additional strategy that combines with the current one to produce a stronger change.

Table 1: Evaluating the causal pathway diagram stem

Once the implementation strategy has a plausible stem, add the leaves (**Figure 12**). At each place in the diagram where two steps are linked, ask these questions:



Figure 12. Adding leaves.

### 1. What, if anything, must be in place for this step to be possible, but might not be present?

The answer points to preconditions for the strategy to work. Preconditions can exert their influence between any two elements in the stem.

For instance, in the decision-support prompt example in Section 1, for the prompt (implementation strategy) to enhance the salience of the need to screen for depression (mechanism), the prompt must be noticeable. Noticeability is a precondition for the implementation strategy to activate the mechanism.

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preconditions that are essential for the strategy to work and *might not be present* should be listed.

#### 2. What, if anything, might strengthen or weaken the relationship between these elements?

The answer surfaces potential moderators of how well the implementation strategy will work. Like preconditions, moderators can also influence the relationship between any two links in the CPD. The **Table 2** questions inform whether to include a moderator in a CPD.

Questions	Actions
How much variation in this moderator are you likely to see?	If minimal variation is expected (e.g., in layout of exam rooms), the moderator is probably not worth tracking.
How much of an influence would this moderator likely have?	Focus on moderators that likely have sufficient impact on the strategy's functioning.
Can you measure it?	Some moderators may be important and variable (e.g., clinician stress level over a day), but may not be measurable at an informative frequency. If so, note this moderator and revisit it later.

#### Table 2. Questions about including moderators.

If a moderator likely varies over the course of an initiative, is expected to be influential, and is measurable, add it to the diagram where it will exert its influence.

**Reflect on strategy feasibility:** Once the full diagram is developed, pause and reflect on the feasibility of the strategy using questions in **Table 3**.

Questions	Possible solutions if you respond "yes"
Does the strategy seem less appealing given the preconditions that must be in place for it to work?	Consider an additional strategy to make sure a precondition is met or moderator is addressed.
Do you think it is likely that the moderators will significantly weaken the impact of the strategy?	Consider changing how a strategy is carried out to eliminate the precondition or moderator. Consider a different strategy that is less likely to be affected by the preconditions or moderators.

#### Table 3. Feasibility questions.

**Repeating the process:** Creating CPDs often requires repeating all the steps to (1) continue considering alternative strategies until you are satisfied the strategy is feasible, and (2) make sure you assessed each outcome and associated barriers or facilitators.

Below are some instances when repeating the steps will probably help. This list is not exhaustive, so be flexible and repeat as often as is helpful to clarify your thinking.

- 1. When you have additional outcomes from question 1 and associated barriers or facilitators from question 2 that need to be addressed.
- 2. If you are designing more than one implementation strategy, repeat the process for each strategy to ensure its unique outcomes and associated barriers or facilitators are addressed.
- 3. If you are not convinced by the current form of an implementation strategy, consider changing how it will be delivered, such as the dose, who will deliver it, and the timing.
- 4. If you identify challenging preconditions or moderators, repeat the steps to select strategies to resolve them.

At the end, you will probably have several CPDs to compare and contrast as you decide which implementation strategies are most likely to be effective and feasible.

#### A deep dive into each element of the causal pathway diagram

In this section, we dig into how to specify each CPD element (defined in Section 1) and the sources of information for thinking through each element. The order in which these elements are articulated in a CPD depends on the function of the diagram and the questions being answered. Guidance on the ordering of each element is in Section 3: Functions of Causal Pathway Diagrams.

#### Implementation strategies

Three key points determine how implementation strategies should be specified in a CPD:

#### 1. Each basic diagram should center on a single discrete implementation strategy.

Even if an initiative deploys several strategies, the first step is *creating a single CPD for each discrete implementation strategy*. The reasons for this are:

*Focusing on one discrete implementation strategy at a time helps manage complexity.* Discrete implementation strategies, which involve one action or process, are the most basic form of a strategy (Powell et al., 2012). Common discrete implementation strategies include reminders or educational meetings.

Often, implementers combine multiple discrete strategies to form a multifaceted implementation strategy (e.g., training and technical assistance) (Powell et al., 2015), sometimes called blended strategies. A CPD for a multifaceted implementation strategy can easily become too complex to be useful. Rather than diagramming all discrete strategies together, we recommend beginning with a single CPD for each discrete strategy in a multifaceted implementation strategy.

*Focusing on strategies separately ensures that each uniquely contributes to addressing the determinant(s).* The package of implementation strategies used in an initiative should be comprehensive enough to bring about the intended change, but parsimonious enough to avoid wasting time and resources. If you cannot articulate a plausible way that a particular strategy would work, it is unlikely to be helpful and should probably be left out.

Once independent CPDs are created, you can layer them to assess whether they interact and how they might be sequenced. Section 3 illustrates this process.

### 2. Each implementation strategy should have a concrete operationalization before developing the diagram.

Most implementation strategies can be deployed in several ways. How a strategy is operationalized can impact how well it works, what might get in its way, and what might make it work better or worse.

In the example of the decision-support prompt for depression screening (**Figure 5**), a prompt could be a simple post-it note on the side of a monitor, a poster in examination rooms that lists required screenings, a desktop background that clinicians see on exam-room computers, or an EHR prompt. While these reminder variations all function to remind the clinician to administer a depression screening during a patient visit, they have different forms, and their potential effectiveness will be influenced by different factors. The aim of a CPD is to help you think through these considerations for a particular version of the strategy. The more specifically the strategy is defined, the more helpful the CPD will be in uncovering key factors that diminish or augment its effectiveness.

### 3. Each diagram should focus on a clearly defined "dose" of an implementation strategy that is expected to be effective.

Just as treatments and interventions can vary in dose, implementation strategies also vary in dosage or intensity (Proctor et al., 2013). For implementation strategies, dose refers to the frequency, and duration that a strategy will be applied. Examples of dose include the amount of time spent with a practice facilitator, the time and intensity of training, or the frequency of audit and feedback.

As with treatments, the anticipated effects of implementation strategies may depend on the dose. A strategy's dose can also dictate its preconditions (e.g., resources or time availability) and moderators. Therefore, we encourage clearly defining the strategy dose when developing a CPD. Specifying an implementation strategy template concretely defines the details and dose of each diagrammed implementation strategy.

Deploying implementation strategies at the smallest dose believed to be effective can be advantageous. Larger doses (e.g., higher frequency, longer duration) may place higher demands on the setting of implementation, so minimizing the dose can support feasibility. But this must be balanced with the dose believed to be effective for the circumstances.

For instance, a training and consultation strategy for experienced providers might involve a 16-hour training over 2 days with monthly 60-minute group consultation over 3 months. For community health workers without formal clinical training, the minimal effective dose might be 80 hours of training over 2 weeks, with 6 months of biweekly consultation. Defining minimum dosage help develop parsimonious implementation strategies that are not unnecessarily burdensome. You can then leverage different types of optimization studies (e.g., factorial experiments or sequential multiple assignment randomized trials [SMART]) to empirically test the optimal dose.

Sources of information for selecting implementation strategies to center in a causal pathway diagram: CPDs can be used when the implementation strategy is known, such as when developing a causal theory of how an implementation strategy works. Implementers also often explore alternative strategies to address a determinant. The Additional Resources document has links to a selection of resources, such as the ERIC compilation, to help identify implementation strategy options. Once strategy options have been selected, constructing CPDs for them can help in comparing their likely effectiveness and feasibility.

#### Mechanism

Articulating mechanisms has two main purposes. First, it allows you to check your assumptions about how a strategy is intended to work. Checking assumptions serves as a decision-making tool for determining how plausible it is that the strategy can address the identified determinant. Second, it allows testing putative mechanisms to advance the field's understanding of how implementation strategies work. Empirically establishing mechanisms can help you choose strategies based on how they work, ultimately improving implementation effectiveness. Use the following recommendations to help you identify mechanisms.

#### 1. Mechanisms should describe the change process within the target of the implementation strategy.

Implementation strategies can be directed at different targets. For example, training targets frontline providers while task-shifting targets the organization.

Mechanisms should describe the change process that the strategy initiates within the target of the implementation strategy. Mechanisms should not describe actions by the person delivering the implementation strategy. Take training, for example. Articulating one of the mechanisms as "providing didactic instruction" would describe what the instructor does. Articulating the mechanisms as "engaging in experiential learning" describes the process of change that occurs within the target, the frontline provider.

#### 2. The precision and granularity of mechanisms depends on why they are being articulated.

When mechanisms are used as a decision-making tool to evaluate whether a strategy can plausibly address a determinant, the primary goal is a convincing explanation of how the strategy works. Mechanisms used for this purpose will likely be described with less precision and granularity.

Again considering training, a general mechanism might be that training works by improving an individual's knowledge. If mechanisms are used to empirically establish how a strategy works, these mechanisms require a higher degree of precision and granularity to allow for careful operationalization and measurement of the mechanism. For this purpose, we might articulate the mechanisms of training as improving declarative and procedural knowledge (e.g., know what, know how). This level of granularity allows precise measurement of whether this mechanism was activated.

**Sources of information for articulating mechanisms:** Research on the mechanisms of implementation strategies is growing, but evidence in this area is still limited (Lewis et al., 2020). The Additional Resources document includes resources for identifying mechanisms.

Theory and reasoning can inform the articulation of mechanisms. For instance, you may draw on theories and models such as the Theory of Planned Behavior (Ajzen, 1991) or the Capability, Opportunity, Motivation, and Behavior (COM-B) model (Michie et al., 2014) to inform mechanisms. Conceptual implementation literature can often suggest possible mechanisms of implementation strategies. For instance, Diffusion of Innovations (Rogers, 2003) points to attitude formation as a potential mechanism of opinion leaders.

The literature on mechanisms is often imprecise or nonexistent. You may need to infer plausible mechanisms from conceptual literature. You may also need to engage in novel theorizing to reason through how an implementation strategy is likely to work. The sources used for articulating mechanisms will depend on the purpose of the CPD. When the CPD is used as a decision-making tool to assess plausibility, you may primarily rely on reasoning, whereas when used to empirically test mechanisms, you will benefit from drawing heavily on theory and research when available.

#### **Determinants**

Implementation strategies often aim to address an implementation determinant (barrier or facilitator) that influences the desired implementation outcome. Because of the centrality of determinants, CPDs tend to begin by identifying the determinant(s) that influence the desired implementation outcome. Beginning with determinants helps to ensure that strategies align with the context-specific determinants that influence implementation.

When an implementation strategy is not targeting a specific determinant, such as when exploring

how an implementation strategy works outside a specific context, a CPD may not include a determinant. However, in most cases, centering determinants in a CPD is useful.

#### 1. Focus on a single determinant at a time.

In a specific setting such as a hospital or community, many determinants typically affect a desired implementation outcome. Implementation efforts commonly prioritize a smaller set of determinants that are believed to have the greatest influence on implementation.

Once determinants are prioritized, each strategy should initially be matched to a *single determinant*. This ensures that each determinant is addressed, and that each strategy makes a meaningful contribution. As the strategy-determinant matching process evolves through constructing independent CPDs, you may find that a single strategy can address multiple existing determinants, or conversely, that multiple strategies are necessary to adequately address a single determinant. The case illustration below of matching strategies to determinants shows how strategies can target multiple determinants and how CPDs in the later stage of development can represent those relationships.

## 2. The specificity of the determinant will depend on the function of a causal pathway diagram.

The scope of implementation efforts can vary widely. Sometimes implementation strategies are deployed in similar contexts and determinants can be clearly and narrowly defined. Other times, implementation efforts are targeting broad, diverse settings, such as hospitals in sub-Saharan Africa, and determinants may be shared but their form may vary.

For instance, while all sites may experience organizational staffing issues, in some sites this may stem from poor staff retention due to a negative working environment while others may have difficulty recruiting to their rural location. Different strategies could be selected to address each of these determinant forms, or the same strategy might be operationalized differently to address the determinant.

Generally, determinants should be defined with enough specificity to inform what strategy is selected and how it is operationalized. When deploying an implementation strategy across diverse settings, determinants may be defined with less specificity to enhance their generalizability. This tradeoff should be carefully considered during the diagram development process.

**Sources of information for identifying determinants:** Methods for identifying and prioritizing determinants are outside of scope of this toolkit, but the Additional Resources document has resources to support this process.

#### **Proximal outcomes**

Implementation efforts often wait until the end of an initiative, which can be years, to determine if a strategy had its intended impact on the implementation outcome. Proximal outcomes provide earlier signals of whether the implementation strategy is working as intended. Identifying and measuring proximal outcomes—as well as subsequent *intermediate outcomes* along the causal chain—determines if a strategy is likely to work. If there is no or minimal change in the proximal outcomes, you may decide to do something differently, or use the information to diagnose where the implementation process broke down.

### 1. Proximal outcomes should be *concrete, measurable* actions and other impacts that a strategy is intended to bring about.

Proximal outcomes include things like attitudes, changes in the physical environment, and changes in behavior. Making proximal outcomes measurable allows them to serve as a preliminary test of whether an implementation strategy is working. Proximal outcomes may assess early signs that a mechanism was activated, a barrier was changed, or a factor that precedes the desired implementation outcome has been achieved. A strategy can achieve its proximal outcome, but go awry downstream, resulting in nonachievement of the distal outcome.

#### 2. Sources of information for identifying proximal outcomes:

When determining what proximal outcomes to measure, consider these questions:

- (a) What early signs would indicate that the mechanism through which a determinant is addressed is activated?
- (b) What is the earliest sign that addressing the determinant is having the intended effect?
- (c) What can I feasibly measure given existing instruments and resources?
- (d) What are early indicators that the strategy is improving outcomes earlier in the chain of events to the distal outcome?

The answers to these questions can inform the selection of *early* indicators of whether the strategy is working and assist in additional strategy selection, dose changes, and strategy reconsideration.

#### **Distal implementation outcome**

A distal outcome is the ultimate outcome that an implementation effort aims to achieve through an implementation strategy. Distal implementation outcomes are usually measured by the rate of use or quality of delivery of an EBI in the target clinical setting over a time window (Proctor et al., 2011). CPDs thus typically stay at the level of implementation.

### 1. Distal implementation outcomes should include only outcomes that, under ideal conditions, can be brought about by an implementation strategy.

Implementation strategies often fail to bring about meaningful changes in the target outcomes. One reason may be that the strategies were never equipped to bring about the intended change. When developing a CPD, *think critically about the distal outcome that can be brought about by the implementation strategy being diagrammed*.

**Figure 13** shows how the strategy "provide financial rewards for the delivery of evidence-based actions" may achieve adoption of an EBI. But the dotted lines demonstrate how, without additional strategies, incentives cannot ensure fidelity based on their current operationalization.

To achieve fidelity, the strategy would either need to require delivery of evidence-based actions *with fidelity* to receive the incentive, or an additional strategy such as clinical supervision or use of quality monitoring system. When strategies are unlikely to bring about the intended outcome on their own, depicting those outcomes in dotted lines can help you think critically about what else would be needed to achieve those outcomes.



Figure 13. A causal pathway diagram depicting an unachieved outcome.

### 2. Clinical and service outcomes can be included in a causal pathway diagram, but the impact of the implementation strategy should be carefully considered.

Implementation efforts target implementation outcomes in service of improving clinical or patient outcomes. A CPD can include clinical or service outcomes. They should typically be after the implementation outcome, as many implementation outcomes are prerequisites for clinical and service outcomes. However, implementation strategies are typically not sufficient to ensure good clinical or service outcomes. To reflect this insufficiency, we depict those outcomes in dotted lines, as with implementation outcomes that were not directly achieved. This is to encourage you to think critically about what else is needed to bring about those ultimate outcomes.

**Sources of information for identifying distal implementation outcomes:** Resources for selecting, measuring, and reporting implementation outcomes are in the Additional Resources document.

#### **Preconditions and moderators**

The elements discussed so far constitute the stem of the CPD and describe how an implementation strategy works. Preconditions and moderators constitute the leaves of a CPD and describe the conditions that dictate whether and how well an implementation strategy works. Both are effect modifiers, meaning they influence the impact of an implementation strategy, although in slightly different ways.

Preconditions are akin to a light switch. The switch determines whether the light is on or off, but it has no influence on its strength. Moderators are like a light with a dimmer. The strength of the light depends on the dimmer position. Preconditions have an all-or-nothing relationship with a strategy, while moderators have a dose-response relationship.

To distinguish between preconditions and moderators, ask the following questions:

- Is this *critical* for the implementation strategy to work? Critical or necessary elements point to preconditions. As in the decision-support prompt example in Section 1, a decision-support prompt *must* be noticeable to work.
- Will the implementation strategy work *more or less well* depending on the intensity, degree, or amount of this factor? These features point to moderators. In our earlier example, decision-support prompts more consistently lead to improved rates of depression screening when clinic visits are longer, but have less effect with shorter clinic visits.

#### 1. Capture only preconditions that may not be present.

Many actions have preconditions that are always present regardless of the context. There is little value in representing these preconditions in a CPD since nothing needs to be done about them. For instance, an EHR system must be in place for a decision-support prompt to be possible. However, since this strategy is used only in hospitals with EHRs, this precondition is not useful.

If a precondition is never present, the causal path toward the implementation outcomes is unlikely to work, and you need to rethink the strategy selection. <u>Preconditions that are worth</u> <u>documenting are possible to achieve but may need action to ensure they are consistently</u> <u>present</u> (such as availability of depression screening forms). Ensuring the presence of preconditions becomes part of what the implementation team must accomplish to ensure success.

Some preconditions must be present for a strategy to be deployed at all. For instance, providing financial rewards for performance requires funding for incentives and a data system for monitoring performance. Using electronic clinical reminders requires an EHR. Preconditions that precede the use of an implementation strategy can be thought of as boundary conditions. Whereas preconditions describe conditions necessary for a strategy to exert its influence, boundary conditions reflect conditions necessary for a strategy to be deployed. Boundary conditions will often take the form of resources.

### 2. Distinguish between preconditions and moderators to inform the actions of an implementation initiative.

The utility in distinguishing between preconditions and moderators is their distinct implications for implementation.

- (a) Preconditions must be addressed: Because only preconditions that may not be present are documented, preconditions must be addressed. They can be addressed in two ways. First, details of the implementation strategy may be changed to ensure the precondition is always met. For instance, a clinical reminder could be designed to meet the precondition of being noticeable, perhaps by popping up in a conspicuous location. Second, additional actions or implementation strategies can be added to ensure the precondition is met.
- (b) If a precondition cannot be addressed, a different implementation strategy should be chosen. In some cases, it isn't possible to ensure a precondition is met. For instance, a financial reward strategy requires funding that in some settings isn't available. A utility of articulating preconditions is they push you toward strategies with fewer or feasible preconditions.

(c) **Moderators** *may* be addressed. Preconditions *require action*. Moderators may *encourage action* but do not necessitate it. Moderators strengthen or weaken the impact of a strategy, but their degree of influence varies. If a moderator could greatly weaken the impact of a strategy, it should be addressed, if possible. As with preconditions, moderators can be addressed by modifying the strategy or by adding strategies that directly target the moderator.

For instance, when using audit and feedback, the clarity of the feedback message (e.g., its interpretability and understandability) can moderate how much the strategy activates the mechanism of highlighting performance discrepancies. Feedback message clarity could be addressed by modifying the design of the feedback report (i.e., modifying the strategy). Goal setting and action planning strategies could be added to strengthen the intention-behavioral link, thus improving the impact of audit and feedback.

(d) Moderators may be tracked to assess their influence. In other cases, moderators may reflect factors over which you have little control. For example, the length of clinic visits is determined by high-level organizational policies and the specifics of individual patient cases. Both are likely to be outside the scope of an implementation project on depression screening. In such cases, the reason to include a moderator in a CPD is that measuring it helps you understand why a strategy worked better or worse than expected.

Being explicit in advance about key factors that could influence the effectiveness of a strategy allows devising ways to measure those factors. Measurement can lead to a deeper understanding of why and how a strategy succeeded or failed and how organizational policies might be adapted to improve future rates of implementation success.

(e) **Numerous or high-impact moderators may indicate that you need a different implementation strategy.** In some cases, the cumulative threat of moderators or a particularly influential moderator may push you to consider alternative strategies with fewer threatening moderators.

#### 3. Know that contextual determinants can act as preconditions or moderators.

Some determinants directly influence implementation outcomes. These determinants are centered in the stem of CPDs. Other determinants influence whether or how well implementation strategies work. Causal pathways often include contextual determinants such as leadership, available resources, knowledge, or self-efficacy, as factors that influence whether or how well a strategy works.

**Sources of information for identifying preconditions and moderators:** Context-specific determinants may point to potential moderators and preconditions. In some cases, those determinants are directly targeted with implementation strategies, but sometimes they are contextual factors that influence whether or how well a strategy works. Similar to mechanisms, moderators and preconditions can be identified through implementation theory, classic theory, and conceptual papers that theorize about how an implementation strategy works. Because the exploration of effect modifiers of implementation strategies is limited, these are often inferred from conceptual literature and through reasoning.

#### Principles for constructing causal pathway diagrams

**Causal pathway diagrams are tools for thinking; they should be quick to create and easy to discard:** CPDs are process representations created to facilitate thinking through an implementation effort. Put only as much effort into creating CPDs as needed to further your thinking. For this reason, you should create many diagrams quickly, to efficiently unearth all factors that must be considered during planning. If a diagram is not producing helpful information, move on; if creating additional diagrams is not yielding additional insights, stop.

**Start with the information you currently have or understand:** CPDs do not have to be developed linearly. The process may begin with a barrier surfaced during needs assessment; CPDs can then be used to identify promising strategies to remove that barrier. Other reasonable places to begin include the distal implementation outcome.

When available, theory should be central to the CPD development process. Existing theories are informative in understanding elements of how an implementation strategy will function, such as its mechanisms or moderators. However, they often articulate the theory of the problem (e.g., determinants that impede implementation) rather than the solution (e.g., how a strategy can address determinants). CPDs may require you to draw on existing evidence or stakeholder experiences, or collect new evidence to articulate how a strategy will work.

**Keep it simple; add complexity only when it is helpful:** Implementation initiatives are anything but simple. For instance, change in distal implementation outcomes typically occurs from the combined influence of all implementation strategies used, rather than a single one. Conversely, a single implementation strategy can influence multiple outcomes. However, much of the value of CPDs for supporting thinking comes from parsimonious diagrams (**Figure 5**). We recommend starting with diagrams that show basic functioning of each strategy, or a set of CPDs that cover each prioritized barrier well. Add complexity only when more complex representations answer questions that simpler representations cannot answer.

**Center CPDs on specific questions:** Each CPD should answer an important question, such as: What are promising strategies to address barrier X? Which strategy is a better match for barrier Y? What measure would assess the earliest signal that strategy X is working?

The complexity and focus of a CPD should be a function of your question. Starting with clear questions will help you decide what elements to include. Developing a CPD may surface new questions to center in additional CPDs. This often occurs when a precondition or moderator surfaces in a CPD. The next central question becomes, "What additional strategy might ensure this precondition is met?" In this way, a precondition in one CPD becomes a targeted determinant in another.

**Work together:** CPDs facilitate collaboration. They are easy to draw on a whiteboard or collaborative tool such as Miro (Miro, 2023) and allow contributions from multiple people. We include common language questions in the Tools to Build Your Own Causal Pathway Diagram document to model how CPD elements can be discussed with nonexpert collaborators. As shared representations, CPDs promote productive team thinking and dialogue. This may be a CPD's secret sauce: a structure for efficiently, collaboratively thinking about complex causal processes.

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# SECTION 3: FUNCTIONS OF CAUSAL PATHWAY DIAGRAMS

The previous sections presented the basic structure of CPDs, recommendations for the elements that make up the diagram and a description of a common process for developing a CPD. This section is an overview of key CPD functions with case illustrations of CPDs in practice.

The functions capture common ways in which CPDs are used to facilitate selecting, designing, and evaluating implementation strategies. The functions are described separately to demonstrate how CPDs can answer different questions and how these questions inform which CPD elements are relevant. The functions are not mutually exclusive and can complement one another. For instance, a CPD can be used to develop a causal theory of how a strategy works (function 1) and also inform what to measure to assess strategy functioning (function 2).

### What's in this section?

- 1. Selecting or designing an implementation strategy that is likely to work: Ensure that an implementation strategy aligns with the determinant and outcome it is intended to change.
- 2. Understanding the conditions under which an implementation strategy works: Identify preconditions for a strategy to work and moderators that may strengthen or weaken how well it works.
- 3. **Designing and optimizing multifaceted implementation strategies**: Understand how multiple implementation strategies work together.
- 4. **Developing causal theories of how implementation strategies work**: Create generalizable accounts of how and under what conditions an implementation strategy is expected to work.
- 5. **Measuring implementation strategy functioning:** Identify early signals of whether a strategy is working and select instruments to measure its function.
- 6. **Diagnosing why an implementation strategy did not work as intended**: Retrospectively explore implementation strategy functioning to pinpoint where in the causal chain of events it stopped working.

# Function 1: Selecting or designing an implementation strategy that is likely to work

Implementation efforts often begin by identifying determinants, in the form of barriers or facilitators that influence implementation success. Efforts can surface dozens of determinants. After prioritizing determinants to target, implementers have the challenging task of selecting from the 70+ implementation strategies to target those determinants and operationalizing them to be effective, or designing new implementation strategies.

Resources and methods for matching strategies to determinants exist, such as the Consolidated Framework for Implementation Research (CFIR)-matching tool (Waltz et al., 2019), Theory and Techniques Tool (Theory and Technique Tool, 2023), and intervention mapping. These methods either lack specificity, primarily focus on individual behavior change techniques, or require technical expertise. Using the stem of the CPD to articulate how a strategy can plausibly address determinants and change outcomes can help implementers select or design effective implementation strategies.

#### Key guiding questions

Two questions guide the use of a CPD to select or design an implementation strategy.

- **1. Can a compelling mechanism explain how this strategy would address the determinant?** Articulating the mechanism, that is, stating how or why the implementation strategy addresses the determinant, helps you evaluate the alignment of the strategy to the determinant. If a compelling mechanism cannot be identified, consider alternative strategies.
- 2. If a plausible mechanism can be articulated, would its activation result in meaningful change in the determinant?

Even if activated by a strategy, a mechanism may not change a determinant enough to improve the downstream outcomes. If you are not convinced that the magnitude of change will be sufficient, consider if the strategy might operate through additional mechanisms—and if its combined mechanisms will produce sufficient change—or look for alternative or additional strategies that ensure that intended outcomes are achieved.

Accurately gauging how well a mechanism is likely to work is difficult given the lack of empirical literature on strategy mechanisms. Clinical experience and judgement may be sufficient to identify mechanisms that are highly unlikely to work and help you move to a more appropriate strategy.

#### Case illustration: Increasing youth engagement with digital mental health care

**The context:** Appa Health is a digital mental health tool for adolescents. The treatment model is (1) digital mental health tools based on evidence-based practices such as cognitive behavioral therapy (**CBT**), delivered in short-form video content from "influencers" with >1 million followers on TikTok; and (2) near-peer lay mentors with relatable lived experience providing supportive accountability, via text and video chat, in learning and using the evidence-based strategies and therapeutic skills. An Appa study found good youth engagement with mentoring, but low use of CBT-informed tools and videos. While 80% of teens communicated with mentors weekly, only 50% viewed the video content. Appa used CPDs to select strategies to address the determinants of youth engagement with the video content.

**Using CPDs to select an implementation strategy**: Appa Health partnered with implementation scientists to identify key determinants of adolescent engagement with their digital mental health content, prioritize determinants, and use CPDs to select strategies to address these determinants.

#### Causal pathway diagramming process:

#### Identifying and prioritizing determinants

Based on the Appa Health study, the distal outcome to address was low youth engagement with the video content. To understand what got in the way this outcome, the team conducted a rapid evidence review and focus group with Appa Health users, resulting in a list of key determinants. Representatives from Appa Health and the Center to Optimize Evidence-Based Practice Implementation for Clinical Impact (IMPACT) participated in four 90-minute sessions over 4 weeks to develop CPDs to evaluate alternative strategies to address key determinants. Before CPD development, the team used the Miro Board "Lean Coffee" template (Miro, 2023), combined with Nominal Group Technique (Harvey and Holmes, 2012), to prioritize key barriers to target with CPDs (**Figure 14**).



#### Figure 14. Prioritized determinants of youth engagement in digital mental health content.

Developing the CPD stem: What strategies plausibly address the determinants of adolescent engagement with the EBI content?

CPD development began by focusing on the main causal process through which candidate strategies would work. The team articulated the distal outcome, adolescent engagement with digital mental health content, and the proximal outcome that precedes adolescent engagement. For each CPD stem, they focused on a single barrier, beginning with "numerous steps to access content" (**Figure 15**).



Figure 15. Target proximal and distal outcomes.

The team brainstormed strategies to address the barrier and voted on a subset to compare using diagramming. Each strategy was clearly operationalized with enough detail to identify a mechanism, describing how the strategy would work. A resource for operationalizing an implementation strategy is in the Tools to Build Your Own Causal Pathway Diagram document. With a set of operationalized candidate strategies, the team began articulating the mechanism for each strategy.

Strategies were eliminated if a compelling mechanism could not be articulated. **Figure 16** shows this resulted in a stem for each implementation strategy. The team reflected on the plausibility of the stems by asking:

Are we convinced that the strategy, in its current form:

- 1. Will activate the mechanism that explains how change will happen?
- 2. Leads to enough change in the determinant to have a large enough impact?



Figure 16. A causal pathway diagram stem for targeting engagement with digital mental health content.

The team eliminated several strategies because of poor plausibility that they could address the determinant and intended outcomes.

#### Developing the CPD leaves: Under what conditions would those strategies work best?

For strategies deemed to plausibly address the barrier, the team added leaves to the diagram. First, preconditions were added to stems to compare conditions necessary for each strategy to work (e.g., teens must have access to a phone). If preconditions could not be met, strategies were eliminated. Second, they added moderators to assess if factors interfered with or enhanced how well the strategy worked (e.g., mentors providing accountability support). **Figure 17** is the final CPD for the implementation strategy selected to address the steps required for youth to access digital mental health content.



### Figure 17. A complete causal pathway diagram for targeting engagement with digital mental health content. SMS, short messaging service (text messaging).

*Repeating the process.* This process was repeated, centering each prioritized barrier. The team ultimately identified two strategies to plausibly address five unique barriers (**Figure 18**). Some strategies addressed multiple barriers, aiding the team in selecting a high-impact, parsimonious strategy package. This process retained only those strategies with the most compelling rationale for effectiveness in increasing youth engagement with digital mental health content.



Figure 18. Combined causal pathway diagrams for targeting prioritized determinants of engagement with digital mental health content.

**What did they learn?** The team identified two strategies to address the five prioritized determinants. During the process, they eliminated strategies without a compelling mechanism, with unfeasible preconditions, or with moderators they could not address. This left several potential strategies that could work and they selected two, the fewest number that covered the most determinants.

### Function 2: Understanding the conditions under which an implementation strategy will work

The purpose of aligning implementation strategies with determinants is to ensure that, under ideal circumstances, a strategy brings about change. But contexts of implementation are complex and circumstances are rarely ideal. Identifying circumstances that affect whether (i.e., preconditions) and how well (i.e., moderators) a strategy will work can inform whether a strategy will work in your setting and what may be required to ensure it works as intended.

**Preconditions:** Things that need to be in place for a strategy to work

**Moderators:** Things that can strengthen or weaken how well a strategy works

For instance, training (implementation strategy) is aligned with addressing knowledge gaps (determinant) that interfere with practice adoption (implementation outcome), but for many reasons, training might not improve adoption or bring about only limited changes. If a trainee does not attend to the training information, their knowledge (precondition) will not improve. Training may have a larger impact on providers whose work mirrors the conditions under which a practice was taught in training. Providers whose clinical population or clinic visits substantially differ from the training conditions may see only modest changes (moderator). The goal of articulating moderators and preconditions is to improve the fit and effectiveness of implementation strategies with conditions in which they are deployed.

The preconditions and moderators section discusses how distinguishing between preconditions and moderators informs practical decisions about implementation. The flowcharts (**Figures 19, 20**) show examples of strategy selection, design and evaluation decisions informed by preconditions and moderators.

Identifying a precondition triggers two questions. First, can the precondition be met? If not, the strategy is unlikely to work and should be replaced. For instance, when preconditions such as resources or leadership support required for an implementation strategy, cannot be met, you might abandon the strategy. Second, if preconditions can be met, what is required to meet that precondition? This question informs the feasibility of addressing preconditions. Preconditions may require additional activities or implementation strategies to be met. For instance, a setting may need to reallocate resources to ensure a resource precondition.

Moderators can inform the selection, design, and evaluation of an implementation strategy. Under ideal circumstances, conditions favor a moderator that enhances the strategy. For instance, if leadership support is a strong moderator of how well creating a learning collaborative works, then a setting with highly supportive leadership would facilitate the leadership effect. But conditions for a

moderator may not be favorable or conditions may vary across settings.

For instance, leadership support may be strong in some clinics in a learning collaborative and lacking in others. In such cases, you might add a strategy such as educational meetings to improve leader support. You can also measure a moderator to understand its influence in a strategy's success. If conditions for an influential moderator are not favorable (e.g., most clinics do not have supportive leadership), you may decide to abandon a strategy (**Figure 20**). The purpose of identifying preconditions and moderators is to point to strategies that work in your conditions.



## Figure 19. A decision-making flowchart for preconditions.



#### Key guiding questions

1. Might aspects of the context—preconditions or moderators—influence whether or how well the implementation strategy functions?

Identifying preconditions and moderators allows assessing whether a strategy will work under your conditions and what is required to support its effectiveness.

2. What can be done to make the conditions of implementation supportive or favorable? The identified preconditions or moderators inform making the conditions, such as the context, more favorable for a strategy. This might be by assuring preconditions are present, harnessing facilitators, or addressing barriers.

## Case illustration: Examining how and under what conditions educational brochures work to increase the reach of HPV testing

**The context:** The US Preventive Services Task Force updated cervical cancer screening guidelines to include human papillomavirus (**HPV**) infection testing alone as a newly recommended strategy for women aged 30-65 years. Home-based screening is a new option for HPV tests on self-collected samples. A National Cancer Institute-funded pragmatic trial found that mailing HPV self-sampling kits to women overdue for HPV screening increased screening by 50% versus usual care. Despite this, screening remained low. The trial data highlighted barriers to screening—patient understanding of HPV testing and perceived efficacy of self-sampling—that could be addressed by outreach materials before widespread implementation.

**Using CPDs to design an implementation strategy with maximal effectiveness:** The Patient-Centered Approach to Tailoring HPV Self-Sampling for Cervical Cancer Screening (**PATH**) study aimed to increase the reach of HPV testing by addressing barriers identified in the initial trial: knowledge, perceived risk, self-efficacy, and test-efficacy. Given the clinical setting, the PATH team decided on educational brochures as the implementation medium for encouraging cervical cancer screening. The team used CPDs to (1) ensure that educational brochures aligned with addressing these barriers, and (2) identify conditions under which educational brochures work best to inform the most effective design of a brochure to improve the reach of HPV testing.

**Evaluating the alignment between educational brochures and determinants of HPV testing:** Drawing on the process in function 1, the team used CPDs to ensure that the intended content of the educational brochures, which was the implementation strategy under consideration, aligned with the determinants most relevant for reach. They completed this in two phases.

#### Phase 1: Can educational brochures address the barriers to HPV screening?

The team assessed whether the brochure content, which was based on the team's formative work and previous research, addressed the prioritized determinants. They constructed CPDs to depict strategy-mechanism-determinant linkages to evaluate whether they could articulate a plausible mechanism for the content that targeted each of the four determinants. This plausibility check convinced the team that the drafted content was reasonably aligned with the targeted determinants.



Figure 21. Strategy-determinant linkages.

*Phase 2: Is the educational brochure content operationalized in a way that activates the intended mechanisms?* 

In focus groups, the team engaged stakeholders in participatory design to further develop brochure content. The design process focused on the form and framing of messaging to address the 4 key educational needs, and testing barriers identified in the original trial. This process produced brochure sections that addressed the 4 barriers (knowledge, perceived risk, self-efficacy, and test-efficacy).

CPDs were used again to ensure that the revised content still activated the mechanisms. For instance, personalizing risk information in the educational brochures was believed to be an effective method to increase screening rates. To evaluate this reasoning, the team developed more detailed CPDs to clarify how personalization would improve screening rates (**Figure 22**). They reasoned that connecting new information (e.g., that HPV vaccine does not eliminate HPV contracted prior to vaccination) to patients' situations (e.g., vaccinated at 20, with sexual contact at an earlier age) could address patients' lack of perceived cervical cancer risk. The barrier was assumed to be addressed by improving individuals' perception that HPV risk information is relevant to them (mechanism).



Figure 22. Using CPDs to evaluate the effectiveness of strategy content.

## Using moderators and preconditions to improve whether and how well educational brochures work: Moderators and preconditions were then identified to answer two questions:

- What conditions must be present, but might not be, for the brochures to work as planned?
- What characteristics of educational brochure content or brochure recipients might make them work better or worse?

The answers were used to further refine features of the educational brochures and determine whether the content needed tailoring to fit recipients' characteristics. As shown in **Figure 23**, a key precondition for improving risk-perception accuracy using personalized risk information is that the prevalence and personalized risk information *must be understood by the patient*. By making this point explicit, the diagram informed user-centered design testing to ensure that risk information was presented in an accessible, understandable way.

The team also identified moderators, including age and vaccine status, that could make the presentation of personalized risk information work better or worse. For instance, in brochures targeting individuals older than 45, risk information referred to situations in which the individual was in a monogamous long-term relationship or was not sexually active. The content made clear why cervical cancer could be a risk even for people not engaged in sexual activities that would result in new HPV infections. The identification of these patient-specific moderators led to the development of several versions of brochure content tailored to patients that are being tested in an optimization trial.



Figure 23. Moderators and preconditions of strategy effectiveness.

### Function 3. Designing and optimizing a multifaceted and multicomponent implementation strategy

CPDs also have an important role in projects that design or refine a set of implementation strategies used in combination. Implementers often design and deploy packages of strategies to address a set of determinants. These implementation strategies may be multifaceted, meaning they consist of more than one discrete implementation strategy. For instance, practice facilitation is a multifaceted implementation strategy that helps practices develop capacity for sustained implementation of quality improvement interventions (Taylor et al., 2013; Liddy et al., 2014). Practice facilitation can be made up of discrete strategies such as workflow mapping, review of performance data, and educational meetings (Walunas et al., 2021). Multicomponent implementation strategy: A discrete implementation strategy made of multiple activities.

#### Multifaceted strategy: An implementation strategy made of two or more discrete implementation strategies.

Discrete strategies may be multicomponent strategies, meaning they consist of several actions. For example, clinical supervision can include components such as fidelity assessment, review of practice, and didactic instruction (Dorsey et al., 2018). Without a clear understanding of how each discrete strategy or component works, you risk developing effective but overly complex strategies or strategies that cannot sufficiently address the full range of determinants.

Discrete implementation strategies involve a single process or action

#### Key guiding questions

Broadly speaking, when used to design or optimize multifaceted or multicomponent implementation strategies (referred to as multifaceted), CPDs can help answer the following questions:

#### 1. Is each implementation strategy making a meaningful contribution?

This question ensures parsimony when designing or refining a multifaceted strategy. The CPD stem can be used to evaluate whether each strategy or component contributes to addressing key determinants and outcomes. Consider eliminating strategies or components for which you cannot articulate a plausible mechanism, that do not contribute to a key determinant, or that are redundant with other strategies that sufficiently address the same determinant.

#### 2. Is each key determinant being sufficiently addressed?

This question speaks to an implementation strategy's comprehensiveness. Developing CPDs for each discrete strategy or component facilitates evaluation of whether a multifaceted implementation strategy is comprehensive enough to address all key determinants. If key determinants remain unaddressed after developing CPDs for each strategy or component, you may need additional strategy identification.

#### 3. Can the multifaceted implementation strategy be feasibly deployed?

Even if a multifaceted implementation strategy can work, the required conditions may be too burdensome or costly to allow effective program scaling. CPDs for each strategy or component, assessed for cumulative preconditions, can inform the feasibility of the full strategy package. When preconditions may not be feasible, consider more resource-efficient versions of the strategy. CPDs can help think through whether a more resource-efficient strategy serves the same function as a burdensome strategy.

#### **Process**

Optimizing multifaceted strategies draws on the processes in functions 1-3, but the order of steps is flexible and depends on the starting information and the questions of interest.

**Designing an optimized multifaceted strategy:** When designing a multifaceted implementation strategy, begin developing a CPD by identifying determinants and outcomes that are the intended targets. Centering these targets, you can use CPDs to brainstorm the set of strategies that can be used together to address them.

**Optimizing an existing multifaceted implementation strategy:** To optimize an existing multifaceted implementation strategy, begin the CPD by defining each discrete implementation

strategy or component (see function 1) and articulating how each strategy is believed to work.

**Assessing how causal pathway diagrams fit together:** An important consideration when developing CPDs for multifaceted implementation strategies is how the strategies function together. Develop independent diagrams for each strategy and look across those diagrams to answer questions such as: Is each strategy making a meaningful contribution? Is each key determinant sufficiently addressed?

In some cases, like when two implementation strategies are dependent on one another to work effectively, diagramming them together to represent those dependencies can be helpful (**Figure 24**). However, this can also be done by simply noting these dependencies. Ideally, keep the diagramming process as simple as possible, as diagrams quickly become overly complex and challenging to understand.



Figure 24. Causal pathway diagram of two strategies that have dependencies with one another. EBT, evidence-based treatment; BR, behavioral rehearsal.

**Figure 24** shows how two strategies that work together can be layered onto one diagram. The diagram depicts how clinicians' attitudes towards evidence-based treatments moderate how well behavioral rehearsal, a supervision component, improves clinician's fidelity. To improve the effectiveness of behavioral rehearsal, you could add a hiring strategy to recruit and hire clinicians with positive attitudes about evidence-based treatment.

# Function 4: Developing causal theories of how implementation strategies work

A significant body of theoretical literature describes what influences implementation (Nilsen, 2015), but few theoretical accounts exist of how and under what circumstances implementation strategies work. Generalizable causal theories of implementation strategies aid the field in testing and clarifying what implementation strategies work, for which outcomes, and under what circumstances.

These narrow-scope, context-agnostic, theories (i.e., microtheories) of implementation strategy functioning benefit both implementation science and practice. For science, microtheories guide the field in testing and accumulating evidence of how implementation strategies work. Microtheories also offer practical guidance for selecting strategies that are theoretically well-aligned with the targeted problems. CPDs are an efficient way to represent evidence and hypotheses about a strategy's functioning.

#### Process

The process for developing a CPD to understand how a strategy works begins with the implementation strategy. The process can proceed with various elements. The questions below demonstrate a common order for developing the diagram.

- 1. **Implementation strategy**: What is the implementation strategy of interest and what are the core activities that comprise this strategy?
- 2. **Determinant(s)**: What determinants do the evidence and literature suggest this strategy can address?
- 3. Distal implementation outcome: What implementation outcomes do the determinants affect?
- 4. Mechanism: How would this strategy address this determinant?
- 5. Proximal outcomes: If the strategy works as planned, what are the earliest signs of change?
- 6. Preconditions: What conditions must be met for this strategy to work?
- 7. Moderators: What factors can strengthen or weaken the impact of this strategy?

#### Key guiding question

### How does this implementation strategy work, irrespective of the context in which it is deployed?

This application of CPDs centers on a particular implementation strategy, and at a high level of abstraction, to produce a *generalizable account of how an implementation strategy works*. This higher level of abstraction is most notable in the operationalization of the implementation strategy and articulating determinant(s) the strategy is equipped to address.

While contextual factors that can strengthen, weaken, or obstruct strategy functioning are captured in preconditions and moderators, the strategy itself is not operationalized within a CPDs can produce a generalizable account of how an implementation strategy works.

particular setting. Instead, it is defined in terms of its core components. Those components may not be immediately clear due to the lack of empirical evidence about components that are core to an implementation strategy's effectiveness. In the absence of evidence, a key part of theorizing is identifying components that are both common (i.e., found across different operationalizations of a strategy) and believed to be responsible for the strategy's function.

#### Case illustration: A microtheory of how audit and feedback works

**The context:** Audit and feedback provides clinicians or leaders a summary of clinical performance compared to a benchmark. It is typically used in clinical settings to support adherence to evidence-based guidelines. Audit and feedback is among the most widely used and tested implementation strategies, with over 140 clinical trials (Ivers et al., 2012). Despite widespread use and establishment of meta-laboratories to optimize it (Grimshaw et al., 2019), no empirical studies or conceptual papers have established mechanisms that explain how audit and feedback works.

**Using CPDs to develop a causal theory of how audit and feedback works:** To advance causal theories of how implementation strategies improve outcomes, implementation scientists are generating CPD representations of microtheories of how implementation strategies function, agnostic to context, for 30 commonly used strategies. This work is part of a National Cancer Institute-funded grant, "the Mechanics of Implementation Strategies and Measures." The team uses theory, empirical evidence, and subject matter experts to develop microtheories of how implementation strategies work. The first depicted how audit and feedback works.

**Causal pathway diagramming process:** To generate a general audit and feedback CPD, the team reviewed conceptual articles, systematic reviews, and practical articles on audit and feedback. While reviewing, the team gathered evidence and theoretical arguments related to these questions:

#### Operationalizing the strategy: What is audit and feedback?

Before theorizing about how audit and feedback works, the team developed a clear definition and operationalization of audit and feedback. They reviewed definitions and descriptions from the literature, noting variations in how the strategy was operationalized across research studies and implementation efforts. Since the purpose was a general theory of how and under what conditions audit and feedback works, the team operationalized the strategy in terms of core components—that

is, components that were commonly observed and considered essential features or activities of the strategy.

Audit and feedback was defined as the provision of clinical performance summaries to health care professionals or organizations (Brehaut and Eva, 2012). The strategy was operationalized in two core components: (1) health care professionals' practice or performance is assessed (i.e., audited) and compared to professional standards or targets; and (2) comparison results are fed back to the healthcare professionals, usually graphically with text.

#### Identifying determinants and outcomes: What is audit and feedback used for?

The team searched the literature to identify the purpose or goal of using audit and feedback. This was useful for identifying barriers that audit and feedback attempt to address and identifying outcomes that the strategy can address. Implementation literature may include theoretical accounts and empirical evidence for implementation outcomes that a strategy is intended to address, but the literature rarely clearly states determinants that a strategy is poised to address.

For audit and feedback, both theory and evidence pointed to plausible implementation outcomes, but determinants were inferred from the framing of the problem. Based on their interpretation of the literature, the team settled on unknown or inaccurate perception of performance as the key determinant that audit and feedback is intended to address. Similarly, clues about proximal and intermediate outcomes were used to develop plausible early signs to indicate if audit and feedback was working as intended.

#### Identifying mechanisms: How might audit and feedback address the determinant?

Theoretical and empirical literature that describes how implementation strategies work is a growing area of scholarship. Mechanistic accounts are rare and often drawn from conceptual literature and novel theorizing about how a strategy works. The team drew on conceptual literature, and experts' and their own reasoning to articulate how audit and feedback addresses the determinant (barrier) of unknown or inaccurate perception of performance. Specifically, the team concluded that audit and feedback works by *highlighting the discrepancy* between the clinician's performance and the desired standard.

## *Identifying moderators and preconditions: What impacts whether or how well audit and feedback works?*

For many implementation strategies, the literature describing or testing effect modifiers (i.e., preconditions and moderators) is sparse. Audit and feedback is a rare example of a well-studied implementation strategy, allowing the team to draw on empirically studied moderators and preconditions (e.g., data quality, baseline clinical performance, organizational support for quality improvement). Some are described in theoretical literature (e.g., clarity of the feedback message, behavioral control) and some derived from team theorizing (e.g., competing priorities).

#### Revising the causal pathway diagram

After reviewing the literature, the team drafted an initial CPD. They met with a team of implementation scientists to scrutinize the plausibility of each proposed linkage in the draft CPD. This collaborative approach to evaluating the diagram led to important refinements including modification of the proposed language and constructs in the pathway.



Figure 25. A microtheory of audit and feedback.

#### A microtheory of audit and feedback

This process resulted in a microtheory of the functioning of audit and feedback (**Figure 25**). This microtheory proposes specific hypotheses about how audit and feedback works that can be tested to determine if the theory is supported or requires modification. Such microtheories are a starting place for testing and iteration that pushes the field towards a clearer understanding of how implementation strategies work.

### Function 5. Measuring implementation strategy functioning

CPDs can guide the measurement approach for evaluating whether implementation strategies are working as planned. Measuring whether an implementation strategy impacted a distal implementation outcome is common. But focusing only on distal outcomes misses opportunities to get early signals of whether a strategy is working and if not, to diagnose why. CPDs help in developing a targeted measurement approach. When strategy functioning is measured during implementation, early signals can inform adjustments if strategies are not working as intended.

#### **Key guiding question**

#### Is the implementation strategy working as intended?

Measuring mechanisms or proximal or intermediate outcomes can provide an early indication of whether an implementation strategy is working and pinpoint where functioning broke down. Measuring moderators can help with understanding variability in an implementation strategy's effectiveness.

#### **Mechanisms**

Measurable mechanisms can indicate whether an implementation strategy has activated the causal process through which it is believed to work. They offer the earliest signs of whether a strategy is likely to have its intended effect on the distal outcome. In the decision-support prompt example (**Figure 5**), the mechanism, enhancing salience of the need to screen, could be measured by surveying providers after visits about their perceptions of whether a patient needed to be screened for depression. If there was no increase in the perceived need to screen, this would signal that the strategy is unlikely to improve depression screening rates.

#### Proximal outcomes

Proximal outcomes can also signal that the mechanism is activated and the distal outcome is addressed or reflect early changes necessary to achieve the outcome. In the cervical cancer-screening example (**Figure 23**), brief surveys of patients who received the educational brochure could assess if they can accurately articulate their own risk (proximal outcome), which is necessary to increase the screening rate (distal outcome). Proximal outcomes can be concrete actions that add up to the distal implementation outcomes. In **Figure 5**, these concrete actions include a clinician conducting depression screening after seeing the prompt. These actions, over time, improve the overall screening rate (distal outcome).

#### Measuring intermediate outcomes

Intermediate outcomes can be useful in detecting whether a strategy continues to have its intended effect and if not, pinpoint where that causal process is breaking down. In the cervical-cancer example (**Figure 23**), a survey of patients who received the brochure could assess their intention to screen. This outcome is further downstream than the change in knowledge and perception of risk, but not to the behavioral outcome of scheduling a screening.

Measuring intermediate outcomes can be useful for identifying additional moderators and determinants between the determinant that a strategy targets (e.g., lack of perceived risk) and the action it brings about (e.g., scheduling a screening appointment). If patients' intentions to screen are high after reading the brochure, but few schedule screening appointments, other barriers likely need to be addressed by additional strategies.

#### **Moderators**

Moderators can help diagnose variation in a strategy's effectiveness. Evidence for the effectiveness of common implementation strategies suggests their impact is often modest and varies widely (Powell et al., 2019). Exploring moderators can pinpoint why strategies vary in effectiveness and clarify targets for improving effectiveness.

#### **Process**

The process for developing a CPD to inform a measurement approach follows the processes described in the previous functions. When using a CPD to inform measurement, think through observable indicators to measure to assess change.

# Function 6. Diagnosing why an implementation strategy did not work as intended

Prospective use of CPDs to inform the design, selection, or evaluation of implementation strategies offers the most value in anticipating and avoiding threats to implementation success. CPDs can also be a diagnostic tool to understand why a strategy did not or is not working as intended. In this case, you would draw on evaluation data that was collected to understand how factors may have impacted implementation effectiveness. Rather than creating diagrams for all strategies in the initiative, you may want to create targeted diagrams centered around key evaluation findings from the evaluation.

#### Key guiding questions and processes

Questions and processes for diagnosing why a strategy did not work as planned depend on the problems. This section describes common questions you may encounter when a strategy is not working and shows how CPD elements can help diagnose the problem.

#### 1. Why isn't the barrier improving by using this implementation strategy?

A formative evaluation may reveal that an important barrier is not changing. To diagnose why, evaluators can construct CPDs centered around that barrier and the strategies meant to impact it. Potential issues that may emerge include:

- None of the strategies were well matched to the barrier
- The strategy was not sufficiently potent (e.g., low dosage, scattered effect)
- A precondition for change in the barrier is lacking in the clinical environment
- The ability of a strategy to target that barrier is strongly influenced by a factor (moderator) common in the clinical environment (e.g., notification fatigue for an EHR alert-based strategy)

In the latter two cases, you may need additional targeted evaluations to collect data to confirm or disconfirm these hypotheses.

### 2. A barrier is successfully altered, but why isn't this affecting behavioral and implementation outcomes?

In some cases, evaluation shows impact on an important barrier (e.g., perceived importance of an EBI increase) that does not translate into downstream outcomes (e.g., use of EBI). In such cases, you may develop CPDs that describe the causal process between the changed barrier and the distal outcome. Some questions to consider:

- · What are the preconditions for this process?
- What intermediate outcomes could be measured to diagnose where the process breaks?
- · What moderators may influence this part of the process?

Constructing diagrams that answer these questions can inform follow-up evaluations to uncover why removal of a barrier is not having desired downstream effects.

#### 3. Why isn't the implementation strategy being used as planned?

If an important strategy (e.g., professional learning community sessions) is not executed, diagramming the steps *before* its provision may be helpful. Specifically:

- What are the key preconditions for the strategy to occur? (Example: scheduling a learning community session).
- · What needs to happen for those preconditions to occur?
- What are the preconditions for those events?

You can go far back in such analyses, but even representing a few steps that lead to each precondition for strategy provision may be enough to identify a derailing factor. Information to test a hypothesis about where processes are breaking may be in collected data or could be collected in a brief evaluation follow-up.

## CONCLUSION

We hope that the examples illustrate the range of issues that CPDs can tackle. CPDs are explicitly designed to be quick to build and discard, so you can create them on the fly, whenever consulting a diagram would be useful. The illustrations in this toolkit are not an exhaustive list of ways to use CPDs. However, we hope that they give a flavor of the questions these diagrams can answer during preparation, conduct, and evaluation of implementation initiatives. We trust that you will find additional uses for your own projects.

Happy diagramming!

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### FREQUENTLY ASKED QUESTIONS

#### How do I know if an implementation strategy is being used as intended?

Uncertainty about whether a strategy was used as intended is a common challenge in determining the effectiveness of an implementation strategy. To avoid doubt and inconclusive results, define in advance how you will determine whether an implementation strategy is used as intended. Define details of each strategy (see the Tools to Build Your Own Causal Pathway Diagram document) to guide what the strategy concretely entails and how that can be measured.

Consider which features of the strategy are core to its integrity, and which are flexible. Capture this in the specification of the implementation strategy.

For elements core to the strategy, consider how you will know that the:

- (a) Necessary actors are involved
- (b) Actions have been completed
- (c) Actions are occurring at the intended time
- (d) Appropriate dose was achieved

When selecting method(s) to assess that a strategy is being used, consider the feasibility and importance of strategy integrity in the initiative. Methods may range from less-intensive self-report (e.g., email updates, surveys of strategy use) to highly intensive observation (e.g., record strategy delivery), depending on initiative needs.

#### How do I know if my strategy is working?

A primary goal of CPDs is helping to determine if strategies are working—*early in the implementation process* rather than at project completion. In addition to measuring the distal implementation outcome, allow for early, continuous assessment of a strategy's effectiveness by defining and measuring:

**A proximal outcome that reflects the earliest detectable change in the barrier or facilitator.** Ask: "If the barrier or facilitator is impacted, what will the earliest sign of change be?"

Behavioral changes (e.g., administering the depression screener) often come to mind. However, psychological and cognitive changes (e.g., attitudes, beliefs, thoughts) often precede behavioral changes. An earlier indicator of change might be an intention to engage in a behavior (e.g., deliver the depression screener).

**Intermediate outcomes.** While proximal outcomes confirm a strategy has early intended effects, intermediate outcomes determine whether a strategy continues to impact outcomes along the causal chain of events to the distal outcome.

#### How do I operationalize an implementation strategy?

Defining a concrete, workable strategy is important for understanding how an operationalized strategy will work. Table 4 is an example adapted from Proctor et al. (2013) of concretely specifying an implementation strategy. We do not include specification of the implementation outcome or justification, because these are captured within the CPD.

When specifying a strategy, think through core elements that must be present to maintain strategy integrity or that are flexible. The example has inherent flexibility in the action target because several types of primary care clinicians can administer the depression screener. Other features such as the temporality and dose are fixed because this timing and dose are hypothesized as necessary to achieve the outcomes. The Tools to Build Your Own Causal Pathway Diagram document includes questions for concretely specifying each strategy.

Steps	Description	Example
Name it	Name the strategy using language consistent with the literature	Remind clinicians*
Define it	Define the implementation strategy and any discrete components conceptually	Develop a reminder system designed to help prompt clinicians to use a clinical innovation*
Specify it		
Actor	Identify who will enact the strategy	The implementation team will instruct software developers to program the prompt
Action	Specify the actions, steps, or processes that need to be enacted	Prompt reminding clinicians to deliver the depression screener displayed in EHR chart
Action target	Specify targets according to conceptual models of implementation	Primary care clinicians (e.g., medical assistant, nurse, doctor) Salience/awareness of the need to deliver the depression screener
Temporality	Specify when the strategy is used	Upon accessing the patient record during a clinic visit
Dose	Specify the dosage of the strategy	Every clinic visit; prompt displays until clinician closes prompt

#### Table 4. Specifying a strategy

\*Strategy name and definition from Powell et al., 2015

#### How do I select and define a mechanism for my causal pathway diagram?

Defining the mechanism by which a determinant can be addressed is one of the more challenging components of building a CPD. The priority is to evaluate and potentially adjust assumptions about how a strategy targets a determinant. The following guidelines can help in selecting useful mechanisms.

#### Mechanisms should:

**Be explanatory:** A mechanism should explain how a determinant is addressed (**Figure 26**). It is common to select mechanisms that name the absence of the determinant, without explaining the process by which a determinant is addressed. To check that a mechanism is explanatory, ask, "Does this mechanism clarify *why and how* the implementation strategy impacts the determinant?"



#### Figure 26. Nonexplanatory and explanatory mechanisms.

In this example, low leader support was a barrier to implementing a trauma-focused intervention in schools. Initially, the mechanism selected was "enhance leader support." This describes removal of the barrier but doesn't explain *how or why* leader support changed through educational meetings. In contrast, the mechanism "enhance perceived intervention value" describes how educational meetings with a principal impacts their support through changing their perceptions of the intervention's value.

**Be practical and actionable:** Mechanisms capture a causal *process* that results in change. A series of steps along that process can probably be described. For instance, in the example above, educational meetings may impact leader support by a process of attention, information processing, knowledge gain, value assessment, and enhanced perceived intervention value.

When naming a mechanism, the goal is a label that captures that causal process at a practical, actionable level. To be practical, mechanisms should be detectable and measurable. To be actionable, they can be feasibly changed given existing resources.

**Capture an active process:** Mechanisms describe *how* a strategy works. Therefore, they are often best captured using language that reflects that active process (e.g., learning to improve, increasing knowledge, personalizing risk).

A note of caution: When using language that reflects an action, avoid describing strategy actions as mechanisms. This can happen when describing strategies with a series of actions. For instance, conducting educational meetings may include activities such as (1) sharing evidence for the effectiveness of the intervention, and (2) aligning the evidence with the leader's values. These describe the active process of the strategy itself, not how those actions change leader support.

#### How do I differentiate between strategy components and mechanisms?

Strategy actions capture what will be done to address a determinant, whereas their mechanisms describe *how and why* those actions address the determinant. Distinguishing between implementation strategy actions and their mechanisms may appear straightforward but can be challenging in practice.

For instance, in a training implementation strategy, "modeling a skill" may mistakenly be identified as a mechanism by which training improves skill acquisition. Modeling a skill is one of many discrete actions that constitute the training strategy. A mechanism through which training may work is that the recipient of skill modeling will "learn through observation."

#### Takeaways

1. Mechanisms should capture the process of change within the *recipient* (e.g., individual, organization, system) of the implementation strategy. Use the following questions to evaluate a mechanism:

(a) Is this mechanism capturing a process that occurs within the target recipients of this implementation strategy?

(b) Does this mechanism explain why and how the discrete implementation strategy action impacts the determinant without merely stating that it has an effect?

2. A concrete, detailed definition of an implementation strategy can distinguish between strategy actions and mechanisms. This is particularly helpful when describing a broad meta strategy, such as practice facilitation or training with many discrete actions.

#### How do I select a proximal outcome?

Guidelines for selecting proximal outcomes are in the answer to "How do I know if my strategy is working?" To recap, the most useful proximal outcomes:

1. **Capture the earliest signs of change in the barrier or facilitator:** For individuals, the earliest proximal outcomes often reflect psychological or cognitive, rather than behavioral changes. For organizations or systems, earliest signs may be initial behavioral changes that are precursors to the distal outcome.

**Figure 27** shows three potential proximal outcomes of an audit and feedback strategy. Behavioral signs of performance improvement may be a proximal outcome (right circle), but earlier signs of change might be detected (left and middle circles).

#### **Proximal Outcomes**



Figure 27. Proximal outcomes.

- 2. **Capture detectible changes:** Some early changes may be challenging to detect, because they are subtle or unstable. Prioritize the earliest changes that can be reliably detected.
- 3. **Can be feasibly measured:** A lack of measures or burdensome methods to measure outcomes can interfere with feasibility. Prioritize proximal outcomes that can be practically measured.

#### Should I specify intermediate outcomes? How might specifying these be helpful?

Our examples focus on proximal and distal outcomes. Depending on the goals and characteristics of an implementation project, thinking through and measuring intermediate outcomes may be useful. Specifying intermediate outcomes can be useful for three reasons:

- 1. Outcomes of interest that occur between the proximal and distal outcomes may be important to your implementation project. Specifying them and considering their preconditions and moderators may be worthwhile.
- 2. Intermediate outcomes can confirm an implementation strategy is working as intended and likely to change the distal outcome. Some implementation projects may be interested in a single distal outcome. Measuring intermediate outcomes can be useful to assess whether a strategy has its intended effect, especially when the time to the distal outcome is long.
- 3. Intermediate outcomes can clarify why a strategy did not have the intended impact or only affected a subset of targets. By specifying intermediate outcomes and associated preconditions and moderators, you can find the point when the strategy failed to have its intended impact and the reasons for the block (preconditions) or weakening (moderators) of the impact.

## How can I use a causal pathway diagram to guide decision making during an implementation effort?

This toolkit presents examples of how a CPD informs decisions before, during, and after an implementation effort. **Table 5** summarizes decisions as "if, then" statements that are informed by a CPD. These decisions can be used (1) proactively before an implementation effort, (2) during implementation if the causal chain of events is disrupted (e.g., mechanism is not activated), or (3) when planning future modifications after diagnosing implementation challenges from a formative evaluation.

A CPD can identify decision points during implementation strategy rollout. **Table 5** demonstrates possible situations (if), and potential responses to them (then). This is not a complete list of anticipated decision points.

#### Table 5. If-then statement to guide decision making.

lf	Then
a precondition is not present	select an implementation strategy to target the precondition
a mechanism is not activated	adjust features of the implementation strategy (e.g., dose)
	select a different implementation strategy theorized to target the mechanism
a determinant is not addressed	consider additional mechanisms
	adjust features of the implementation strategy (e.g., dose)
	select a different implementation strategy theorized to target the mechanism
a moderator is modulating the impact of a strategy	select an implementation strategy to target the moderator (if modifiable)
	modify strategy design to address moderator
the intended magnitude of an outcome is not achieved	consider additional moderators
	consider additional preconditions

Our depression screening example (**Figure 28**) demonstrates incorporating decision points into CPDs to guide the adaptation of implementation strategies (DP1) and adding strategies to address moderators (DP2). The Tools to Build Your Own Causal Pathway Diagram document includes prompts for considering decision points to support the effectiveness of an implementation initiative.



Figure 28. Decision points, example. PHQ-9, Patient Health Questionnaire-9.

#### How do I know when my CPD is done?

Causal pathway diagramming is intended to be quick and iterative, without a concrete start or end point. This toolkit describes a series of steps that you should adjust based on your needs and context. The following questions can help you assess whether you have what you need from your CPD. No diagram will be flawless: The goal is utility, not perfection.

Has the CPD helped me clarify:

- 1. The concrete actions that constitute the implementation strategy?
- 2. My assumptions about how this strategy will work?
- 3. What must be in place for this strategy to work?
- 4. What strategy success looks like, at various points in implementation?
- 5. What might make this strategy work better or worse?
- 6. The points at which I might alter course if my implementation strategy is not working as intended?

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## GLOSSARY

**Determinant:** Commonly referred to as a barrier or facilitator, a factor that has an enabling or hindering influence on an implementation outcome. Determinants are often targets of implementation strategies.

**Discrete implementation strategy:** An implementation strategy with a single action or process.

**Distal implementation outcome:** The downstream implementation outcome that the implementation strategy intends to achieve.

**Implementation outcome:** The effects of deliberate, purposive actions to implement a new treatment, practice, and service.

**Implementation strategy:** Methods to improve the adoption, fidelity, or sustained use of an evidence-based treatment, practice or service.

**Intermediate outcome:** Observable outcome that occurs after a proximal outcome, but before a distal implementation outcome.

**Mechanism:** The process through which an implementation strategy affects an implementation outcome.

**Moderator:** A factor that strengthens or weakens the influence of an implementation strategy.

**Multicomponent implementation strategy:** A discrete implementation strategy made of multiple activities.

**Multifaceted implementation strategy:** An implementation strategy composed of multiple discrete implementation strategies.

**Precondition:** A factor that is necessary for an implementation strategy to exert its influence on an implementation outcome.

Proximal outcome: The most immediate, observable outcome of an implementation strategy.

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