

# Fundamentals of Implementation Science

## An introduction to implementation science frameworks and terminology

### Week 1 methods lecture

#### Case Example

In this lecture, we will provide an orientation to the field of implementation science and introduce you to some key vocabulary. Our goal is that, after this lecture, you will be able to distinguish implementation research from clinical efficacy and effectiveness research, and you will also be able to understand the value of models, theories, and frameworks in guiding implementation research. For our first lecture, let's dive right in with an exercise to help contextualize why implementation science is relevant in global health.



This is a picture of a baby receiving the rotavirus vaccine, RV5. Rotavirus is the most common cause of severe diarrheal disease in young children globally. The vaccine has been approved for use since 2006 and is given in three doses, one dose at two months, 4 months, and 6 months of age. Development of the vaccine has been taking place for decades, including a failed licensure of the vaccine in the late 1990s.

Image source: <https://www.defeatdd.org/resources/visual-media/rotavirus-vaccines-africa>

Thanks to Gavi's support over the past three years, the vaccine is now available in 40 countries with some of the highest risk of rotavirus associated morbidity and mortality, due to substandard water and sanitation access.

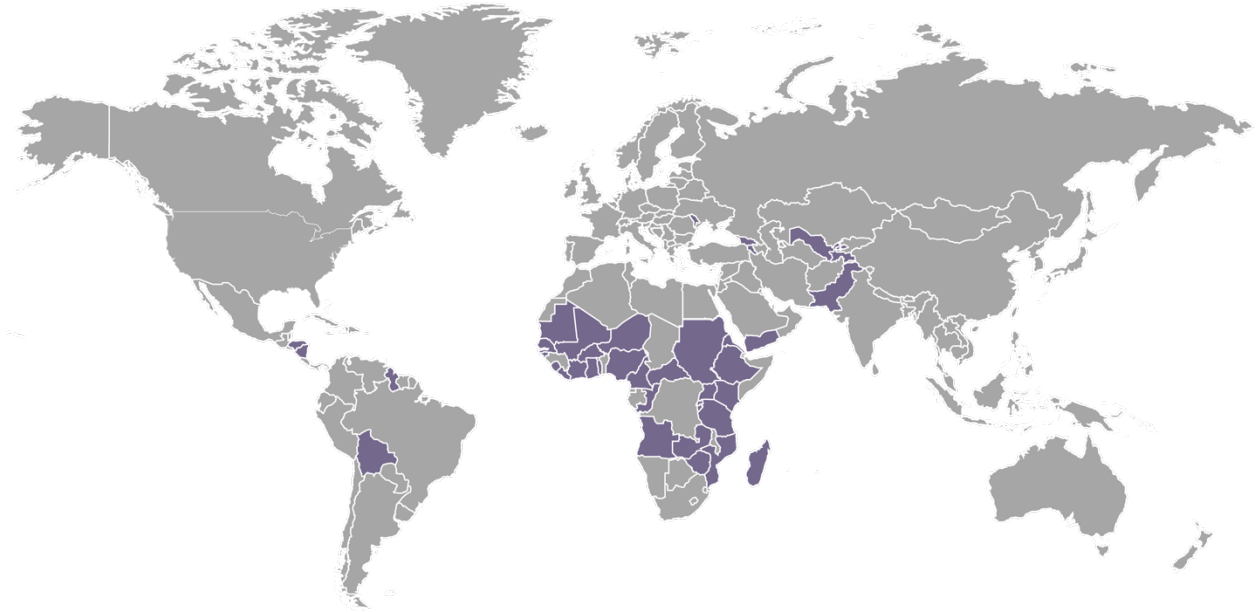


Image source: [www.gavi.org](http://www.gavi.org)

So, now that people have been working for decades to create the vaccine, license it, and then ensure that there are funders to support dissemination to low-and middle-income countries... shouldn't that be enough to ensure that all children in need have access to this important preventative health service?

Unfortunately, it is not. Do you have a guess for what proportion of children in need of the vaccine globally actually receive it? Only 28% of children in need of the vaccine have received it...part of that is certainly because some countries are still scaling their campaigns, but there is much more to it than that, delivering evidence-based health programs at scale is challenging, and THAT is where implementation science comes in.

So, let's pretend that we have a new vaccine that is 98% efficacious (and we'll revisit that term in a second), meaning that 98% of children who are fully vaccinated will be protected. Due to a variety of reasons, a fully efficacious vaccine is available 80% of the time – this might be due to stock outs at the health facility level, supply chain issues, including issues with keeping the vaccine at the appropriate temperature...or it could be an issue associated with providers forgetting to recommend the vaccine. Furthermore, only 75% of children in need of the vaccine in this setting receive the first dose, which is hugely disappointing, but, pretty normal. And, remember, that this is a multi-dose vaccine and due to participation fatigue, expensive travel costs, or lack of community member knowledge about well child appointments... only 46% of children receive the second dose, and 32% of children receive the third dose. This means, that this amazing vaccine that has the potential to protect 98% of people who had full access to it is now only fully protecting—in this example— 9% of targeted children in the community. This issue of implementation, including the supply of the technology, the demand for the technology, and the manner in which it is effectively implemented ultimately affects the impact

of an innovation such as a vaccine can have. And, obviously, this compromises child health in serious and urgent ways.

The purpose of implementation science is to use rigorous scientific approaches to bridge the gap between what we KNOW and what we DO to ensure that evidence-based practices reach everyone in need.

### **There is a “Know-Do” Gap in Global Health**

It is estimated that there are 10 million deaths annually from diseases that are preventable, including 6.6 million deaths of children under 5. About half of the deaths of children under five are caused by infectious diseases such as HIV, pneumonia, diarrhea, etc. Many of these diseases are readily preventable or treatable with proven, cost-effective interventions. In fact, it is estimated that if we could reach scale with evidence-based practices that we KNOW work, such as providing ARVs...or... providing high quality routine antenatal care we could cut the occurrence of these preventable deaths in half. But as you can see here, this gap between **availability of** evidence-based interventions **and** delivery of the interventions is quite stark.

Coverage estimate	Median (World)	Median (Low income)
Antenatal care coverage (>1 visit)	94%	72%
Births by skilled health personnel	96%	47%
Measles vaccination	93%	77%

For example, 47% of births are attended by skilled health personnel in low income countries, while the median worldwide is 96%.

New interventions can often be expensive, technically demanding, or just not customizable enough to be useful in the real world. Additionally, health delivery takes place in challenging environments. Often there are competing demands, limited resources, perverse incentives, and prevailing practices that are contrary to innovation. These barriers make it difficult to implement effective interventions or programs with fidelity. And, finally, the evidence that we generate is sometimes not completely relevant because it is produced in very controlled settings. The patients, organizations, and providers may not be representative of what we see in routine practice settings. So, this final barrier really highlights the difference between efficacy and effectiveness.

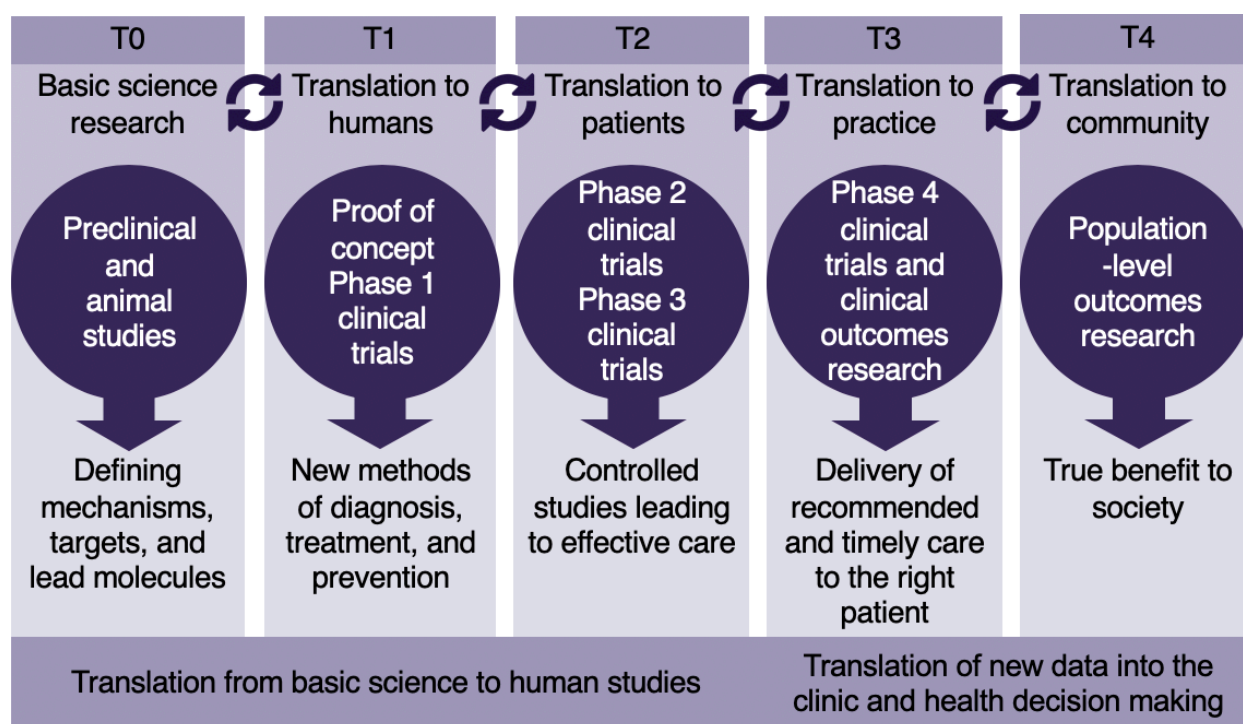
### **Efficacy does not equal effectiveness.**

Are you familiar with the term's *efficacy* and *effectiveness*? Let's take a moment to refresh our knowledge of these terms.

The difference between *efficacy* and *effectiveness* is very important in implementation science. *Efficacy* is defined as performance of an intervention under ideal and controlled circumstances

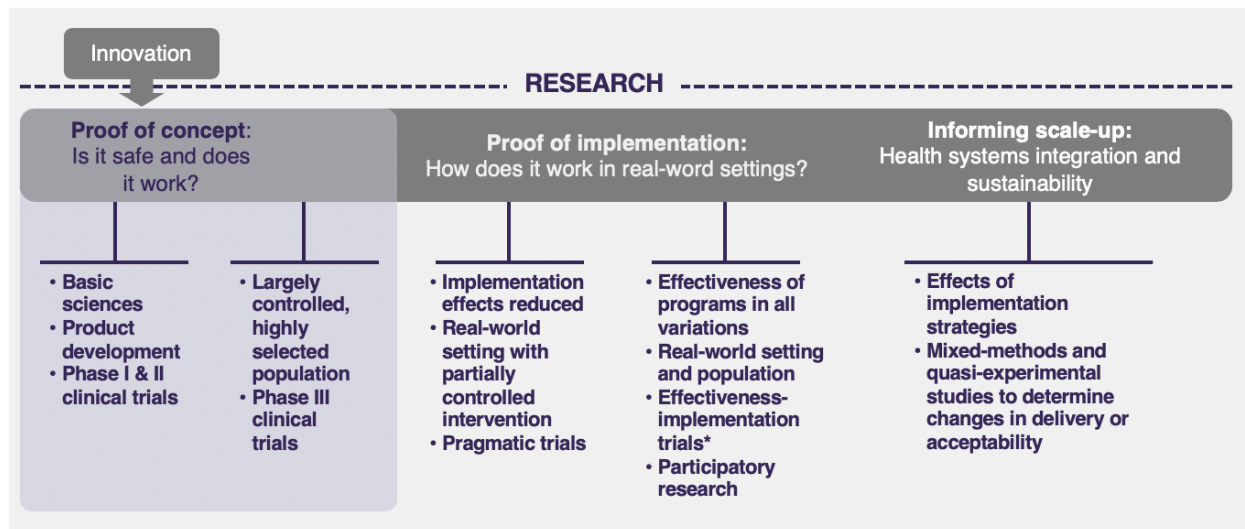
so usually when we do individually randomized clinical trials, these are very often efficacy studies. *Effectiveness* on the other hand examines the performance of an intervention under “real-word” conditions. Thus, efficacy and effectiveness inherently answer two different questions and fulfill two very different purposes. For example, efficacy research maximizes the likelihood of observing an intervention effect if one exists. Whereas, effectiveness research accounts for external patient, provider, and systems-level factors that may *moderate an intervention’s effect*. So, the two concepts are extremely different but highly linked, and both forms of research are vital in public health. This distinction is important because the presence of an evidence-based practice, such as the existence of a rotavirus vaccine, does NOT equal health impact, because efficacy does NOT equal effectiveness.

### The translational research highway spans efficacy to effectiveness

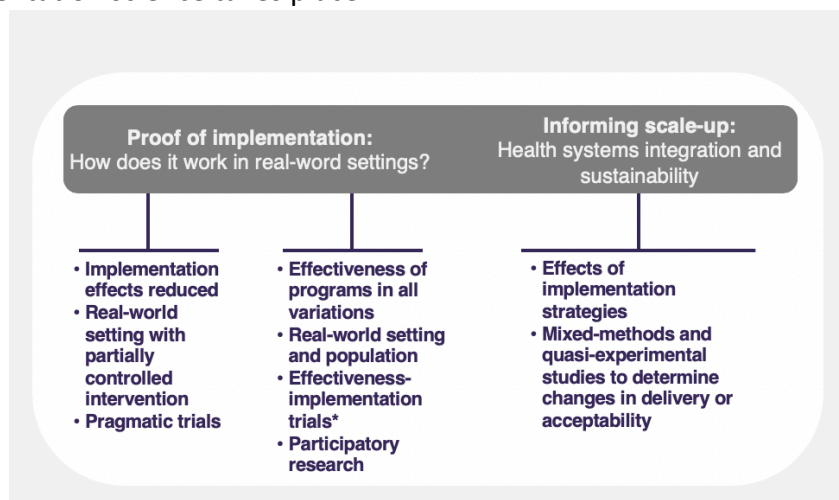


Source: Blumberg R. S., B. Dittel, D. Hafler, M. von Herrath, and F. O. Nestle. 2012. Unraveling the autoimmune translational research process layer by layer. *Nature Medicine* 18(1):35-41.

The translational research pipeline outlines the process from efficacy research to effectiveness research, which is typically called T0 to T4, by the National Institutes of Health in the United States. T0 through T2 encompass translation of basic science to human studies. While T3 and T4 encompass translation of new data into clinical and health decision making.



Another way of thinking about this is that you start with an innovation, a proof of concept, such as a new rotavirus vaccine. And you are really focused on conducting basic science research, usually in clinical trials, to answer the question is it safe and does it work? After demonstrating EFFICACY of your intervention, you would want to understand how intervention delivery affects public health in real-world settings, and provide proof of implementation. You might have a partially controlled environment, such as through the design of a cluster randomized trial in which you randomize health catchment areas or other logical administrative boundary areas. Or you might have hybrid effectiveness-implementation studies, in which you merge classical clinical effectiveness and implementation research studies. During this phase you also want to highly engage with community members to ensure that the intervention is delivered as intended. Lastly, after demonstrating that the intervention works, you want to scale it up and integrate it into the health system to ensure sustainability. This often requires using implementation strategies, which we will discuss in a moment, and mixed-methods designs to evaluate programs before they scale, as they scale, and after scaling. Let's focus on the right side of this Figure for a moment, proof of implementation and informing scale-up, as THIS is where implementation science takes place.

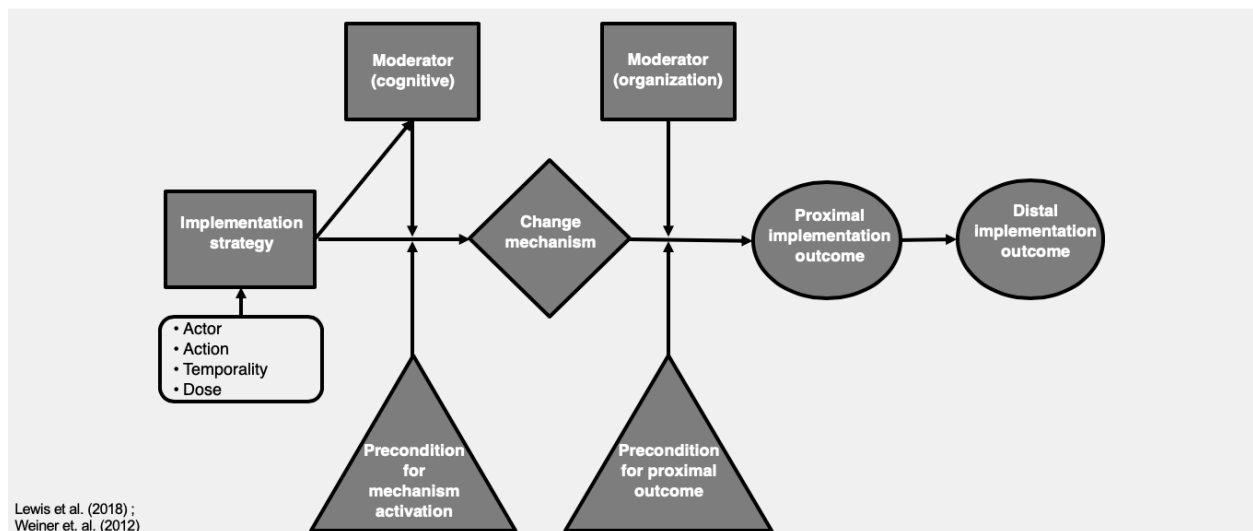


## Implementation science (IS) asks and answers the fundamental question

This brings us to an overarching definition of implementation science. Implementation science asks and answers the fundamental question: How do we get what works to people with greater quality, speed, fidelity, efficiency, and relevant coverage? To do so, we use a scientific approach to understanding the many determinants of successful implementation.

## IS requires studying mechanisms of implementation

Some of you might have taken an epidemiology course before, and this might look to you like a familiar directed acyclic graph, or DAG. Here, what we are looking at is a way to characterize the implementation of an evidence-based intervention to understand if the intervention has the desired effect on our outcomes. Using a model like this can help you think through an implementation science research question and clearly define each component of the research question at hand. On the left you have the implementation strategy, and you can track the many determinants of implementation that influence if and how the implementation strategy affects the targeted outcomes of interest. Let's break this down piece by piece.



Let's start with what an implementation strategy means. An implementation strategy is different than the evidence-based practice that is being implemented. This cannot be highlighted enough, and what largely distinguishes implementation science from standard clinical or epidemiological research. For example, full and timely vaccination with the rotavirus vaccine is an evidence-based practice...the implementation strategy would be a specific strategy used to increase coverage, acceptability, or other relevant outcomes. For example, perhaps a new sensitization campaign is launched to ensure parents know about the new vaccine, to generate demand. Implementation strategies can be complex and characterized by four features, (1) Actors, or the individuals carrying out the intervention and relevant group characteristics of the individuals, (2) Actions, or the specific activities that will be implemented as part of the intervention, and (4) Dose and temporality, including the timing, frequency, and intensity of the activities that will take place as part of the implementation strategy.



## Implementation strategies used to optimize HIV treatment in LMICs (N=34)

<b>Service delivery</b>	<ul style="list-style-type: none"><li>• Outreach</li><li>• Mobile testing</li><li>• Point of care</li><li>• DOT</li><li>• Navigator</li></ul>	<b>Social/behavioral</b>	<ul style="list-style-type: none"><li>• Social support</li><li>• Peer support</li><li>• Community support</li><li>• Male involvement</li></ul>
<b>Infrastructure management</b>	<ul style="list-style-type: none"><li>• Task shifting</li><li>• Guidelines</li><li>• Training</li><li>• QI</li></ul>	<b>Technology</b>	<ul style="list-style-type: none"><li>• Reminder</li><li>• mHealth</li></ul>
<b>Counseling</b>	<ul style="list-style-type: none"><li>• Counseling</li><li>• Patient skill development</li></ul>	<b>Demand creation</b>	<ul style="list-style-type: none"><li>• Incentives</li><li>• Community mobilization</li><li>• Food supplementation</li></ul>

Source: Hickey (2017) *Implementation Science*

There are many different implementation strategies that can be used and tested in implementation science. A systematic review of implementation strategies used to optimize HIV treatment in low- and middle-income countries specifically found that the strategies could be organized into 6 different categories, including strategies related to service delivery, infrastructure management, counseling, social/behavioral change, technology, and demand creation. The specific implementation strategies used include training, social support, mHealth, incentives and many more. Again, all of these strategies are intended to improve delivery, adoption, or sustainability of evidence-based practices.

### IS requires studying mechanisms of implementation

Consider an intervention aimed at increasing HIV testing amongst adolescents, compared to just standard facility based self-referral programs. The implementation strategy might be to take an evidence-based intervention, HIV testing, and deliver it via mobile home-based HIV testing. In doing so, your action is to change the site of health service delivery, and decentralize it outside of the health facility. You are engaging lay health workers, such as community health workers, who are your actors. The temporality might be to conduct mobile testing twice per year, targeting individuals 15 years of age or older. If you changed any of these components of the implementation strategy, it would be a similar but entirely different strategy. Thus, it is important to clearly define your implementation strategy from the onset.

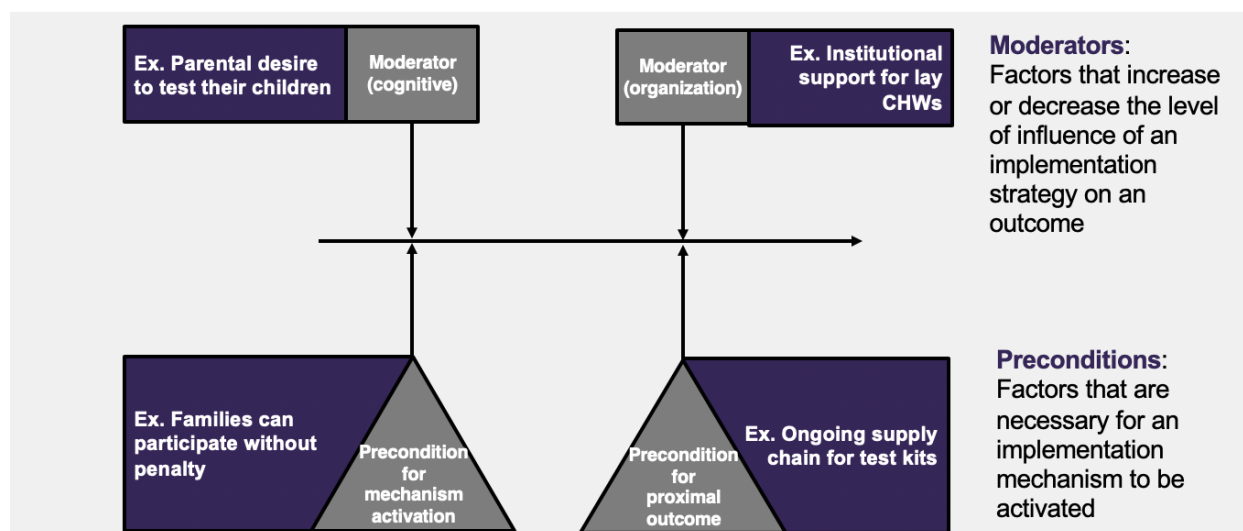
The change mechanism is the process or event(s) through which an implementation strategy affects the desired implementation outcomes. Returning to our example, what might be the change mechanism through which community-based HIV testing has an impact? Any ideas? Well, transitions to community-based care may increase participation in HIV testing by making the intervention more acceptable to community-members in HIV endemic areas and thus

influencing their individual decision processes regarding whether or not they will participate in the service. But keep in mind, there are a number of potential change mechanisms here,

Now let's talk about outcomes for implementation science studies. Typically, implementation science studies focus on implementation outcomes, such as the 8 listed here. They include acceptability, adoption, appropriateness, cost, feasibility, fidelity, penetration, and sustainability. Implementation outcomes can be proximal, meaning they are the product of the implementation strategy's specific mechanism of action. They are the most immediate, observable outcome in the causal pathway. Implementation outcomes can also be distal. These are the outcomes that the implementation processes are ultimately intended to achieve, not the most immediate outcome in the causal pathway. In the [Appendix](#) of this slide deck, you will find a table outlining and defining each of these outcomes in more detail.

Back to our example, of the community-based HIV testing intervention → What outcome do you think it might be targeting? Perhaps the outcome of acceptability (*proximal implementation outcome*).

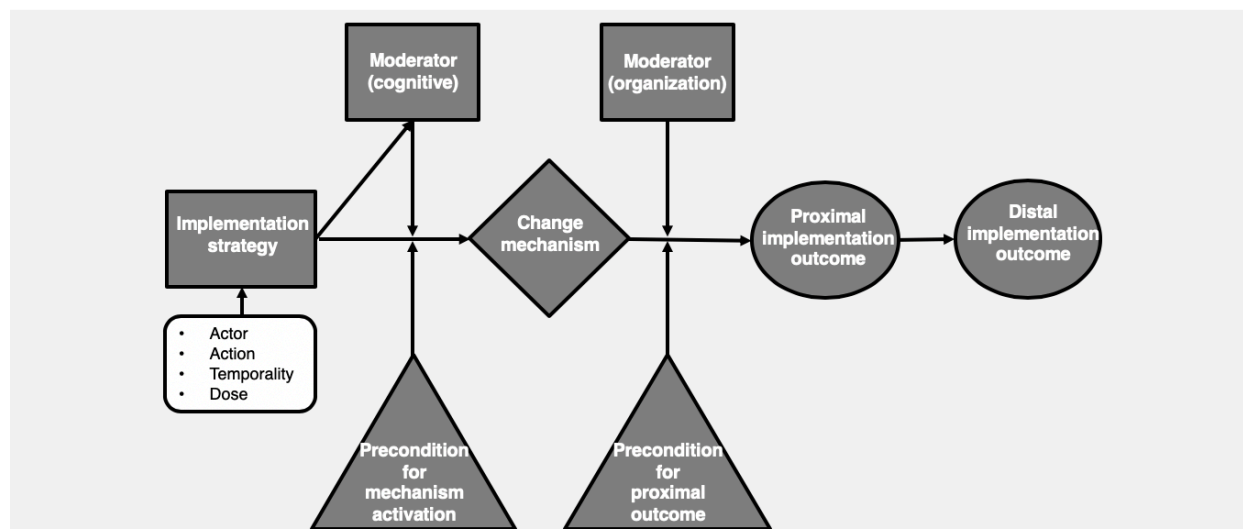
This approach also calls for us to identify other important covariates that may have confounding, moderating, or modifying effects—meaning that the influence of these variables affects the way in which our implementation strategy of interest.... affects our outcome of interest. These include moderators, which increase or decrease the level of influence that an implementation strategy has on our targeted outcome. It also includes preconditions, or factors that are necessary for an implementation mechanism to be activated.



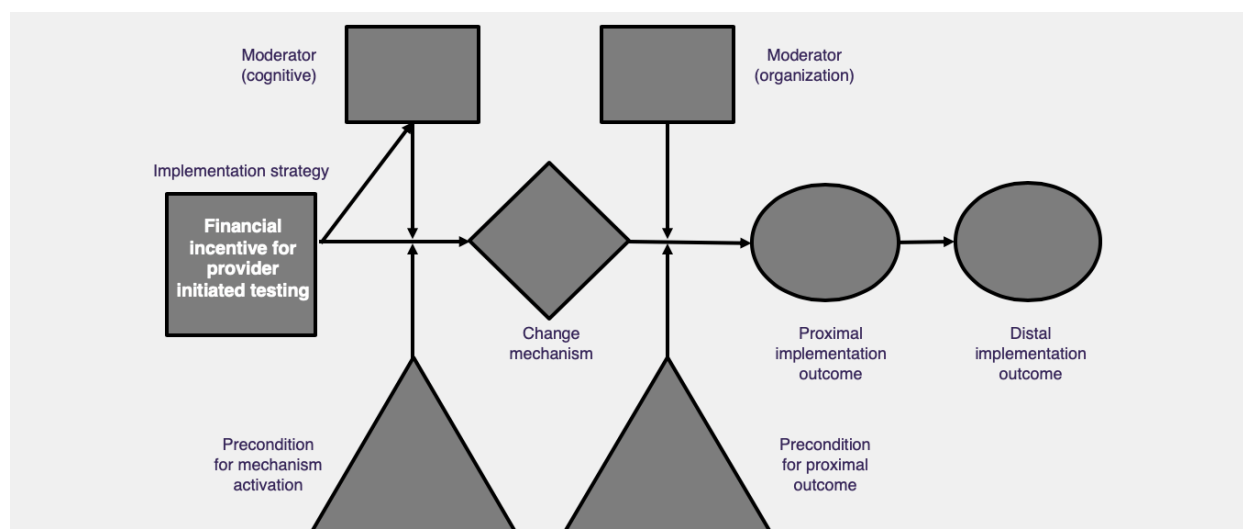
Thinking back to the mobile testing example...moderators might include parental desire to test their children or institutional support for lay health workers to sustain service activities. Preconditions might include whether or not families can actually participate in the program with social or economic penalties, and whether or not there are ongoing resources available for



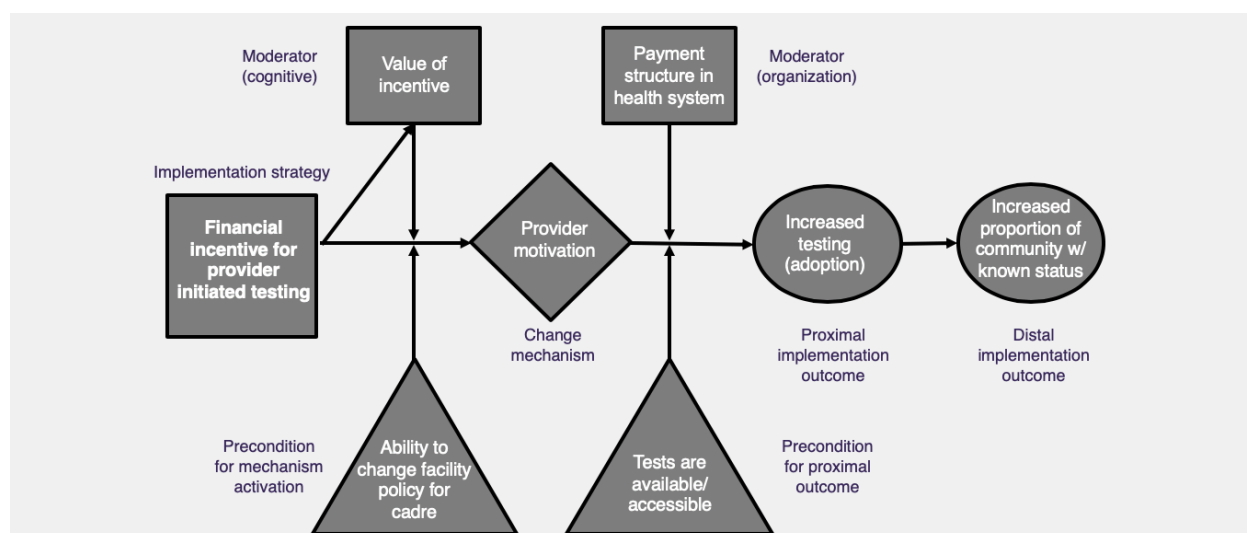
the program, including test kits, fuel for the vehicle, and so forth. So, as you can see, these implementation determinants are very contextual and setting specific.



Together, all of these considerations need to be accounted for and if possible measured, as part of implementation science to understand how to improve healthcare delivery, demand, and sustainability. Let's take a moment to practice.



Let's consider an evidence-based intervention centered around provider-initiated HIV testing in health facilities. Perhaps you choose to introduce financial incentives for provider-initiated testing, because you have learned through formative work that providers do not feel motivated to initiate testing. Take a few minutes to brainstorm how you might complete the rest of this model. And remember – there are No right answers.



Here are a few examples of possible answers. Financial incentives to increase provider-initiated HIV testing might affect testing rates by influencing provider motivation to offer counseling and testing to clients during routine care. In other words, this would be the change mechanism. The most immediate targeted outcome of a change in motivation might be increased adoption of the evidence-based practice, meaning there is increased provider-initiated testing. A more distal outcome might be the proportion of the community that knows their status. However, there are a number of implementation determinants that may affect this process. First, if and how health workers value the incentive will inherently influence whether or not the incentive is sufficiently motivating to them. Second, the engrained payment structure of the health system may make it more or less feasible for health workers to receive their financial incentives, thus influencing sustainability of the program over time. Pre-conditions that might affect delivery also include the ability for the health facility to change their policy for a specific cadre. Perhaps the facility can change the policy for physicians but not for nurses, which would certainly affect health worker motivation. Lastly, at an organizational level, simply the availability of HIV tests can influence whether or not the provider's change in motivation can actually directly lead into an increase in HIV testing.

### Review of IS vocab: A cheat sheet!

Nice job working through the graph! Here is a short cheat sheet of some of the vocabulary that we just covered.

- **Intervention/evidence-based practice:** The seven “Ps” (programs, practices, principles, procedures, products, pills, or policies) intended to improve health. Can have a *clinical* intervention or an *implementation* intervention.
- **Implementation strategy:** Methods to enhance the adoption, implementation, sustainment, and scale-up of an intervention/EBP (ex. provider incentives)
- **Implementation determinant:** Also, commonly referred to as “barriers” and “facilitators,” a factor that enables or hinders the implementation strategy from eliciting the desired effect (ex. perceived self-efficacy to enact change)

- **Implementation mechanism:** Process or event through which an implementation strategy operates to affect desired implementation outcomes (ex. provider motivation). Note: mechanism not typically measured
- **Implementation outcome:** “How will I know if this implementation strategy had an effect *via* the mechanism that I think it is activating?” (proximal outcomes) and acceptability, feasibility, appropriateness, adoption, penetration, fidelity, cost, and sustainability (distal outcomes)

Please refer back to this as you continue thinking through this theoretical foundation for implementation science, and as you start to craft some of your own implementation research questions. So, how exactly is implementation science research conducted?

### Implementation Science Methods/Tools



As we have discussed, implementation science is designed to improve health delivery systems during implementation and scale-up. So relevant methods that can be used to study this process, include:

- Surveillance and data system evaluation and improvement.
- Systems analysis and improvement tools are used to perform quality improvements of an intervention or program.
- Economic evaluation, which can be used for evaluating costs, including financial and economic costs. It can also be used to determine the cost-effectiveness of your intervention or program as compared to an appropriate comparator, typically the standard of care.
- Qualitative research methods, are used to understand *why* programs do or do not work, and to identify opportunities from the perspective of diverse stakeholders (such as program beneficiaries) to improve the delivery of interventions or programs.
- Operational research methods, including applied mathematical modeling, provide an opportunity to simulate delivery systems to identify opportunities to optimize the delivery of an intervention or test different delivery strategies and see how they perform in a modeled environment.
- Stakeholder and policy analysis tools can be used when a policy is needed to deliver, sustain, or scale an evidence-based intervention. This toolset requires understanding the different interests of stakeholder groups as well as strategies for framing your program within the policy environment.

- Organizational assessment can be used to obtain valid information about the performance of an organization and the factors that affect performance, such as the influence, adoption, implementation, and sustainment of evidence-based interventions.
- Impact evaluation methods, which can be used to link your intervention or program to targeted outcomes or impacts in order to understand if your strategy is effective in achieving targeted objectives.
- Dissemination research methods can be used to systematically identify opportunities to sustain or scale-up interventions. Using dissemination methods, the diffusion of new interventions can be systematically tracked by public health researchers
- Lastly, social marketing methods can be used to ensure that target populations are engaged in new interventions once available. This requires a unique set of tools, drawing from business and marketing to communicate with target populations in such a way that they are inspired to seek care or practice a health behavior.

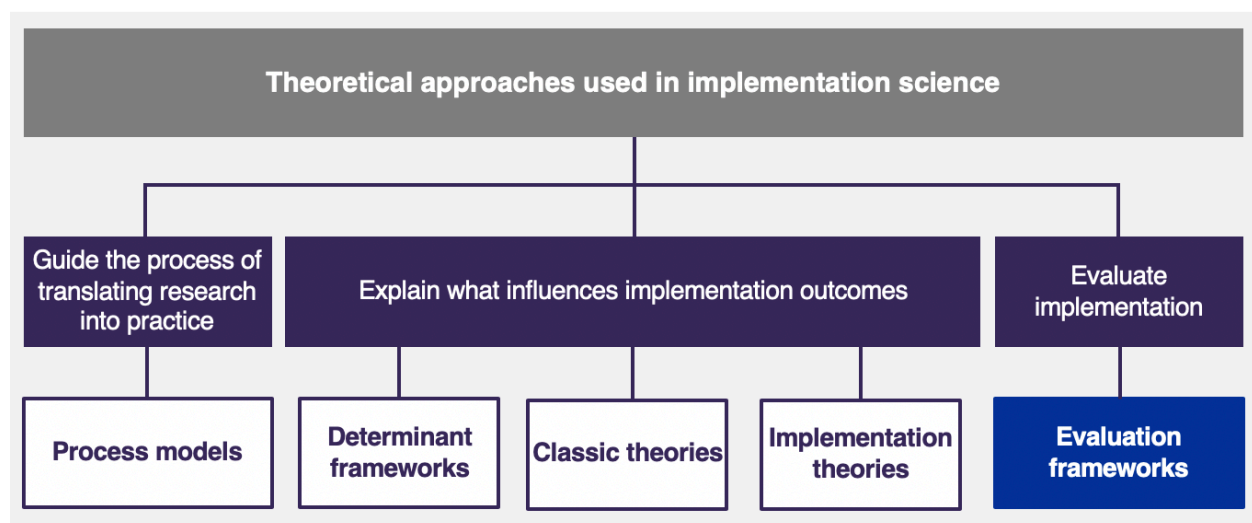
Together, these methods provide somewhat of an implementation science starter toolkit. You can choose from this toolkit - to utilize methods that are most fit for purpose – when you are identifying ways to bridge the know-do gap and ensure that evidence-based interventions are identified, evaluated, improved, or delivered at scale.

### **Implementation science frameworks guide standardized research**

For the last few minutes of this lecture, we are going to focus on how can you communicate or organize your approach to implementation science research. Theories, models, and frameworks are helpful in this regard because they can be used to guide implementation.

- Help select implementation strategies
- Frame study questions and anchor the background literature
- Clarify the constructs that need to be measures
- Illustrate the relationships to be evaluated or tested
- And contextualize study results within the wider implementation science literature, which augments the rigor and generalizability of the study findings. However, frameworks are rarely used. A review of over 200 implementation studies found that less than 25% of the studies employed theory in any way This is not for lack of theories. Another review identified over 60 implementation theories and frameworks available for implementation science practitioners.

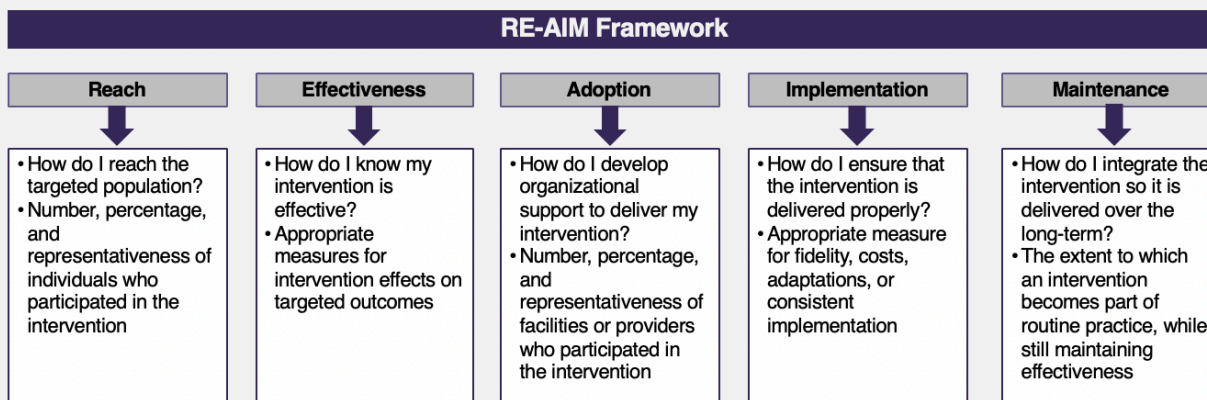
There is a difference between implementation theories, frameworks, and models. In implementation science, theories attempt to PREDICT or explain the causal mechanisms of implementation. For example, a theory could be used to understand the extent to which a health care practitioners' beliefs about a clinical guideline, actually predict their adherence to this guideline. Frameworks do not provide explanations; instead they try to provide a guide for **describing** and **understanding** factors that influence implementation outcomes. Models are a deliberate simplification of real life. Models don't predict or analyze what factor x influence implementation outcomes... they are used to describe and **guide** the process of translating research into practice... so they are more practice oriented as opposed to research oriented.



These theories, models, and frameworks can be categorized as follows: **Process models** specify the steps of translating research into practice (so, again) this is more implementation practice, than implementation research. **Determinants frameworks** describe barriers and facilitators that influence use of evidence-based health interventions and other implementation outcomes. So, unlike process models, which describe steps of implementation, determinants frameworks identify factors that hinder or facilitate implementation. Determinants frameworks are useful for guiding the selection of implementation strategies that either overcome barriers or take advantage of enablers. Determinants frameworks are also useful for explaining implementation fidelity or variations in fidelity across settings. Less comprehensive than determinants frameworks are classic theories and implementation theories, which help you make predictions about how or why implementation strategies work to achieve outcomes. A well-known example of an implementation theory, is organizational readiness for change, which will be discussed during a subsequent course module. Lastly, evaluation frameworks identify specific aspects of implementation that could be evaluated to determine implementation success. Perhaps the most well-known example of an evaluation framework is the RE-AIM framework. As a more concrete example of what a framework looks like, let's take a closer look at RE-AIM.

## Example of an implementation framework

**The RE-AIM Framework conceptualizes and describes intervention impact as the product of five factors:**

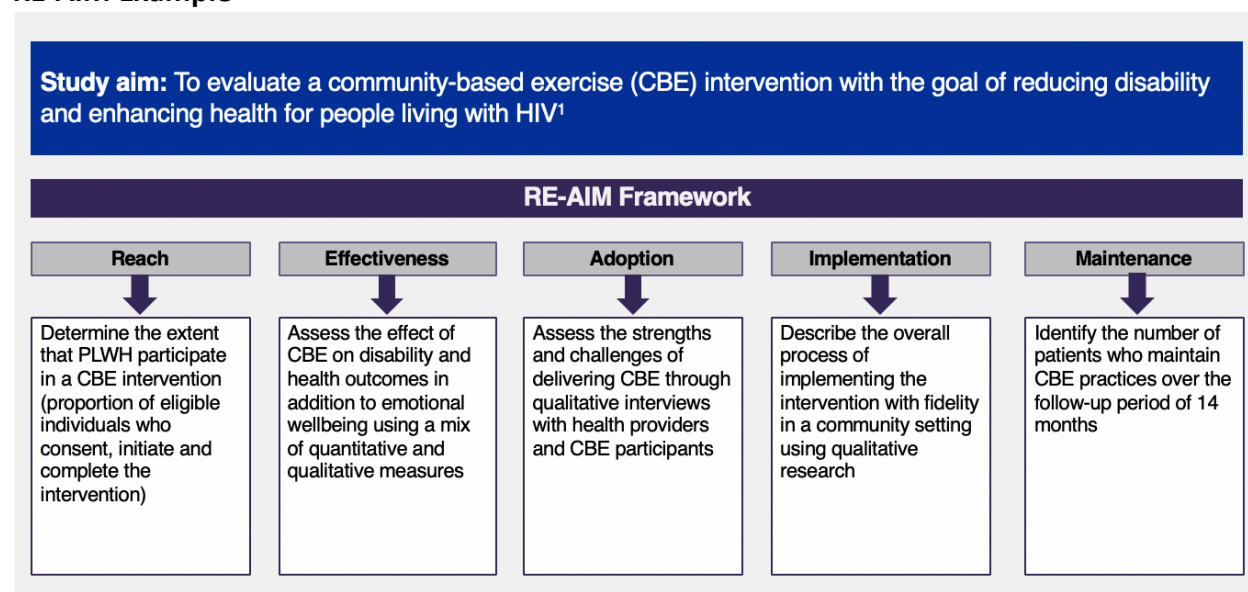


Source: Glasgow RE, Eckstein ET, Elzarrad MK. Implementation science perspectives and opportunities for HIV/AIDS research: integrating science, practice, and policy. *J Acquir Immune Defic Syndr* 2013;63(Suppl 1):S26–31

The RE-AIM Framework conceptualizes and describes intervention impact as the product of five factors: reach, effectiveness, adoption, implementation and maintenance. The goals of using the RE-AIM is to anticipate...or prepare...for translating research programs into real world applications. Let's start with Reach, which asks the question, "how do I reach the targeted population. Here you would look at the number, percentage, and representativeness of individuals who participated in the intervention. Effectiveness asks the question, "how do I know my intervention is effective?". Here you would identify appropriate measures for targeted outcomes. Adoption asks the question, "how do I develop organizational support to deliver my intervention." Here you would want to document the number, percentage, and representativeness of facilities or health workers who participate in the intervention. Implementation asks the question, "how do I ensure that the intervention is delivered properly?". Are you will want to document and identify measures intervention fidelity, costs, or adaptability. Maintenance can be a tricky one: it is the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. Here you ask the question, "how do I integrate the intervention so it is delivered over the long-term"? Here you are focused on measuring penetration, sustainability, or buy-in into the program. So, the RE-AIM framework is considered more operational than many implementation science frameworks, in part because it includes both dissemination and implementation issues, ranging from effectiveness to longer-term maintenance.



## RE-AIM Example



Source: 10'Brien, Kelly K., et al. "Evaluating a community-based exercise intervention with adults living with HIV: protocol for an interrupted time series study." *BMJ open* 6.10 (2016)

Let's look at a real-life example of how the RE-AIM framework has been applied to evaluate the impact and translation of an intervention. This study by O'Brien and colleagues aimed to evaluate a community-based exercise intervention, with the goal of reducing disability and enhancing health for people living with HIV. Within the dimension of reach, the researchers aimed to determine the extent to which people living with HIV participate in a community-based exercise program. So, for example, quantifying the number of people who successfully complete the intervention. For the effectiveness domain, they assessed the effect of the intervention on disability and health outcomes and emotional wellbeing, using a mixed-methods approach. Within the adoption domain, the evaluated strengths and challenges of delivering the intervention. Within the implementation domain, they describe the overall process of how to implement the intervention with fidelity in a community setting. And for maintenance, the researchers identified the number of patients who maintain the exercise practices over a follow-up period of 14 months.

## Implementation science frameworks guide standardized research

Research Focus			
Evaluating implementation barriers and facilitators	Designing implementation strategies	Evaluating implementation feasibility and effectiveness	Evaluating context
<ul style="list-style-type: none"> <li>• PARIHS</li> <li>• CFIR</li> <li>• Theoretical Domains Framework</li> <li>• Theory of Diffusion</li> <li>• Implementation Climate</li> <li>• Organizational Readiness</li> <li>• COM-B</li> <li>• Normalization Process Theory</li> </ul>	<ul style="list-style-type: none"> <li>• Theoretical Domains Framework</li> <li>• Intervention mapping</li> <li>• Six Sigma</li> <li>• EBQI</li> <li>• Continuous Quality Improvement</li> <li>• Facilitated Process Improvement</li> </ul>	<ul style="list-style-type: none"> <li>• RE-AIM</li> <li>• PRECEDE-PROCEED</li> </ul>	<ul style="list-style-type: none"> <li>• Theory of Diffusion</li> <li>• Implementation Climate</li> <li>• Absorptive Capacity</li> <li>• Organizational Readiness</li> <li>• Normalization Process Theory</li> <li>• PARIHS</li> <li>• CFIR</li> </ul>
Theories and Frameworks			

Here are a few examples of additional models, theories, and frameworks that may be relevant, depending upon your research focus. We won't discuss all of these in the course, however, as you start to craft implementation science research proposals and design implementation science projects, it is worth taking some time to consider first, if you are looking for a theory, framework, or model....and, second, what your overall research focus is in that regard. You may identify a theory, model, or framework that is helpful to you in informing your conceptual framework, study design, or analysis plan.

### A tool for selecting implementation frameworks

Before we wrap up, we would like to point you towards a helpful resource for learning about implementation science frameworks should you want to find one that might be compatible with your own research: <http://www.dissemination-implementation.org> This website (listed at the bottom of the screen) helps you sift through many of the available implementation frameworks by applying specific selection criteria. Here is an example of some of the criteria that you can search by, including level of implementation, as well as specific constructs.

### Search D&I Models

You can search for D&I Models by entering a keyword OR by selecting from the categories below.

Enter keyword for model search:  Submit Keyword Search

----- OR -----

Dissemination & Implementation Models can be searched using individually set criteria.

#### D And/Or I

☐ Dissemination Only  
☒ Implementation Only  
☐ Any

#### Socio-Ecological Levels

☐ Individual    ☐ Organization  
☐ Community    ☐ System  
☐ Policy    ☒ All

#### Constructs

☒ Acceptability/feasibility    ☐ Adaptation and evolution  
☐ Adopter/implementer/decision maker characteristics    ☐ Adoption  
☐ Awareness    ☐ Barriers and facilitators  
☐ Champion/field agent    ☐ Dose  
☐ Communication    ☐ Communication channels  
☐ Compatibility    ☐ Complexity  
☐ Context    ☐ Context - Inner setting

### **Key questions to assess IS research designs**

Finally, based upon this lecture, we want to leave you with a few key considerations as you start to increasingly read Implementation Science literature and think about implementation science within your own professional activities. Taking these questions into consideration will be very helpful in crafting your final project for this course. So, first, does the research clearly aim to answer a question concerning implementation? If the research is oriented towards purely assessing clinical efficacy, it is likely not an implementation research question. Does the research clearly identify the primary audience for the research, and how they would use the research? For example, is the research designed to inform policy? Or perhaps implementation within a specific health facility? Is there a clear description of what is being implemented? For example, is it clearly articulated what the evidence-based practice or policy of interest is? Does the research involve an implementation strategy? If so, is it fully described and examined? Is the research conducted in a “real world” setting? If so, is the context and sample population described in sufficient detail? This helps us understand generalizability, and the important influence on context as an implementation determinant. Does the research appropriately consider implementation outcome variables such as adaptability, cost, feasibility, sustainability, and others? Does the research appropriately consider context and other factors that influence implementation? Remember the causal models that we reviewed earlier in this lecture, and the important role that modifiers and pre-conditions can play. Does the research appropriately consider changes over time, and the levels of complexity in the system? In other words, does the research account for factors that influence current delivery, but also potential sustainability and scalability?

### **Summary**

Let's take a moment to summarize the information covered in this lecture. First, implementation science is focused on bridging the know-do gap, with a focus on delivering evidence-based interventions at scale and with high fidelity. Second, when planning an implementation intervention or evaluation, it is critical to consider the specific barriers being addressed, the evidence base of the implementation strategy, the mechanism through which the implementation strategy will address the barrier, and the appropriate implementation outcome. Third, remember that context is key. Implementation science is NOT one size fits all, but rather certain implementation strategies will be successful in some settings, but not others. Understanding what about an intervention is generalizable, and what is not, is important. And last, frameworks, theories, and models provide theoretical guidance for how to conceptualize determinants/barriers of implementation, plan interventions, or evaluate implementation. There are a large number to choose from, so consider the research focus before selecting.

Thank you for listening to this introductory lecture on implementation science and the know-do-gap. Have a wonderful day.

**Appendix:**

Outcome	Definition	Stage of use	Available measurement
Acceptability	Perception that a treatment, service, practice, or innovation is agreeable or satisfactory	Any	Survey Qualitative Administrative data
Adoption	Intention, initial decision, or action to try or employ an evidence-based practice, from the perspective of provider or organization	Early to mid	Administrative data Observation Qualitative data Survey
Appropriateness	Perceived fit, relevance, or compatibility of the evidence-based practice for a practice setting, provider, or consumer	Early (prior to adoption)	Survey Qualitative data
Costs	Depends upon the costs of the intervention, the implementation strategy used, and the location	Any	Administrative data
Feasibility	Extent to which an innovation can be successfully used or carried out	Early (during adoption)	Survey Administrative data
Fidelity	Degree to which an intervention was implemented as it was prescribed in the protocol or as it was intended by the developers	Early to mid	Observation Checklists Self-report
Penetration	Integration of a practice within a service setting and its subsystems	Mid to late	Case audit Checklists
Sustainability	Extent to which an innovation is maintained or institutionalized within a service setting's ongoing, stable operations	Late	Case audit Qualitative data Questionnaires Checklists