Amy: And I'm very excited. And apologies for being a little bit late, but I am thrilled to have Dr. J.D. Smith present to the group today. He is Associate Professor in Department of Population Health Sciences at the University of Utah-School of Medicine and is a national leader in Implementation Science.

On a personal level, I know J.D. in particular from some work that we are co-leading in the NHLBI Decipher Disparities Elimination work to basically help understand what implementation strategies help reduce disparities in cardiovascular disease in community based settings.

But in this particular talk, he is going to be describing some of the innovative and groundbreaking tools he's created to prove (SP) the rigor of implementation research. This was a talk that when I've talked with Christine Polanski and others from Cider (SP) about having people present their cutting edge implementation research, I definitely wanted J.D. to present to us in part because I think the next generation of implementation research and implementation science will basically focus on this need to better describe with rigor the types of implementation strategies that are being used in order to understand the mechanisms by which we basically facilitate the uptake of evidence-based practices.

But I'm sure he will describe this in a much more exciting way than I just did, so I will stop now and let him take it from here. Thank you so much.

Dr. J.D. Smith: Thanks, Amy. It's a pleasure to be invited to talk to this group and to be able to share some of this new work. I'm going to jump right into it.

So, I have my customary many, many acknowledgements. There was a lot of folks who had a hand in developing and having input on the two different tools that I'll present today including a number of obviously, funded grants from the NIH, from CDC and others.

So, I will say that this presentation is relatively truncated given the time constraints as well as the need to present to different tools. But at least the beginning portion here—the Implementation and Research Logic Model or the IRLM—there is a published paper that came out I think it was in September of 2020. So, it's relatively new still that was published in *Implementation Science*. And I'll also have a link to our website at the end which also has a lot of the same materials and additional things to help people understand how to use this.

So, everyone always asks, you know, is another model needed? Those of you who do implementation research know that our field is flooded with different models, theories, frameworks, etc.

And we do think that there is a need for a implementation research specific logic model for a number of reasons. One of which is that the integration of necessary consensual elements of implementation research necessarily involves multiple

models, frameworks and theories. And this is an ongoing challenge especially for folks new to the field, but even for those of us who have done it for a long time. Every project presents unique challenges. And actually picking and integrating frameworks and models can always be a bit of a challenge both in conceptualization as well as execution of projects.

As Amy kind of alluded to, there's also I think going to be a push within the field of Implementation Science for better transparency, better rigor, and of course this kind of dovetails with kind of the open science and specification issues that have been put forth in the field of Healthcare Research in general.

So, one of the things that we said about the Implementation Research Logic Model is that it's intended to improve the specification of the phenomenon that we study in Implementation Research. And this is really a necessary component to understanding particularly how implementation strategies work and getting more specificity about the specific context of the for whom and under what determinant conditions.

And then, of course, we know that there is kind of interrelated nature of implementation outcomes. And also, we do target those. We want to know exactly how these strategies work on specific outcomes both clinical and implementation.

Everyone probably knows what "rigor" is, but it's defined here as "the strict application of scientific method to ensure robust and unbiased experimental designs, methodology, analysis, interpretation and reporting. And anyone who, you know, reads metanalyses and some of these big conceptual papers about implementation knows that this is something that we could use some improvement.

In general, a logic model is going to help us provide a testable way of explaining phenomenon by specifying the relationships among critical variables as well as different elements in Implementation Research. And what this is supposed to do in kind of I think aspirational ways in some ways is to help us enable the prediction of outcomes. Not just like describing what happened, but actually getting it from the beginning that, you know, the logic model will actually help us select the appropriate implementation strategies to make sure our implementation achieves what we think it will.

So, the theory and elements of the IRLM, most of these are going to sound very familiar to folks. But I think it's worth, you know, kind of setting the stage here.

So, in our paper, we presented a generalized theory of Implementation Research that kind of underpins the entirety of the IRLM. This is not our theory. This is really kind of pulling from many other sources. But again, I think it's worth rehashing this a little bit.

So, some of the kind of key elements of this generalized theory is that we assume or we understand that implementation strategies are selected for a given evidence-based practice or intervention. And those strategies are related to both the implementation determinants as well as the intervention itself. So, there's, you know, content specific

varies with facilitators that we're attempting either to address and overcome or to leverage to help our implementation.

We also positively assume that strategies work through specific mechanisms of action to change the context or the behaviors of those within the context to achieve implementation outcomes. And we assume that these implementation outcomes are the proximal impact of the strategy working through those specified mechanisms which then relate to the downstream clinical outcomes of the evidence-based practice on more typically individual level symptomatology functioning, etc. for the patient or participant.

So, the IRLM is really attempting to help us gain the specifications and relationship between each of these foundational elements of an Implementation Research study. Thinking about it in very simplistic linear terms, you know, we really see that determinants help us understand or help us pick what implementation strategy we're using. Those again, work through the mechanisms of action to achieve outcomes.

I borrowed this slide here from Byron Powell. This has been presented. I've seen David Chambers present a very similar slide as well and others that really do kind of lay out this causal pathway kind of perspective of how these four pieces sort of relate to each other.

In practice, we know this is not a completely linear process. In some ways there's some non-linearity particularly around the Implementation Strategy mechanism is often some kind of change of the actual determinant or the barrier.

So, there's not a pure linear nature. But this really does help us understand and specify our underlying theory in why we're doing what we're doing in our Implementation Research Studies.

So, these are some examples here of what this looks like. I think one of the most common ones of the top two, you know, most of our implementation studies we're going to be looking at trying to improve the knowledge and self-efficacy as well as skills of the implementers. And so, we choose strategies like education or training.

These work through, you know, increasing awareness, building knowledge or skills that lead to refinement and mastery of delivery. And we can imagine that the most proximal implementation outcomes could different slightly between those. But we're mostly looking at potentially improving fidelity to the evidence-based practice or demonstrating that there's feasibility, acceptability, and appropriateness of the intervention that leads to adoption.

So, that's just kind of a, you know, a general way of thinking. I don't think this is probably new to anyone. But it's important for this talk.

So, there's a number of different Implementation Research Logic Model formats. I'm only going to actually present the one that I think is most relatable and also the one that is most generalizable. In the paper itself—as well as on our website—there's

a number of variants of the IRLM that are really specific to different study designs and different kinds of contextual situations that you might encounter like working in two different multi-sectoral contexts that you'd have to specify different determinants for. But this one is kind of the general model.

So, we originally actually started with an IRLM that did not include the clinical intervention. It just included the four major elements that I just mentioned. But we found that it's often really helpful for both people completing the model, but for people understanding the IRLM to actually specify the clinical intervention.

So, we integrated that. In this particular case, you can use the example of the seven peas which was put forth by Hendrix (SP) Brown and colleagues. This is, you know, your evidence-based programs, pills, practices, principles, products, policies and procedures. And I have some examples here from the field of HIV.

We then have a box on the far left which specifies our determinants. We use the consolidated framework for implementation research largely because it's very well-known and a pretty comprehensive framework. But we are not necessarily endorsing it as the only one.

If you're more familiar with Prism, or with the Theoretical Domains Framework, or want to use the terminology and the determinants from the ethics (SP) model, for model. Totally appropriate to change this from the language there for your project.

So, we then showed that the implementation strategies are in some ways conceptually related to those determinants and also to the clinical intervention. Of course, there has to be a logical or empirical reason to pick what you pick.

Again, those strategies work through mechanisms of action that lead to different approximal implementation outcomes that hopefully should lead to different service outcomes as well as our final downstream clinical patient outcomes. And you can see there's also a little kind of slightly faded arrow that of course, there is a direct relationship between clinical intervention and patient outcomes.

But when we're looking at this from a population impact perspective, it really has to go through the full pathway with implementation and service outcomes leading to clinical patient outcomes given that we know that relationship between reach, fidelity, etc. and the overall impact of an intervention's implementation.

So again, you can kind of overlay existing models and frameworks onto the IRLM. So, here we have the consolidated framework implementation research. We have Byron Powell and colleagues, you know, naming conventions and taxonomy for implementation strategies if you wanted to use those.

No one has a good mechanisms thing yet, so I just have these fun cogs to show that there's something happening here. And then, for those who are familiar with the proctor at all, implementation outcomes taxonomy. This is really that taxonomy kind of laid on its side or flipped, you know, 90 degrees.

So again, we really were trying to actually pull from existing models and frameworks that people are both familiar with, but also those that are sort of expected in Implementation Research and put them into something that helps to integrate and show the conceptual connections between all of them.

So, the other thing that we did. Again, this is kind of going back also to my earlier comment about the different formats of the IRLM. That is really flexible. I wasn't able to show the alternative formats. But one thing I want to really say is that it's a very flexible model. We don't intend for it to be used in a rural governed manner in any way, shape or form other than to follow these guiding principles.

So, these principles are, you know, really I want to say kind of aspirational to some extent. But there's still three major principles to try to abide by when using the Implementation Research Logic Model.

So, Principal 1) is to strive for comprehensiveness. This means listing all determinants that are relevant, listing all strategies, not just those that are introduced for your particular implementation project. As you know, going into any healthcare system or community delivery system, there's already going to be strategies in place or those that are going to be used regardless if you are introducing them or positing them as an independent variable in your experimental study design.

So, understanding that entirely this is almost a context kind of variable. But to some extent it also is just relevant to include in your implementation strategies, so you know how those are interacting.

And then, of course, all of the relevant outcomes, you know. We have always specified primary outcomes. But if there's other things that are going to be measured or there's others that are relevant for your project, those should also be listed within the IRLM as well, so they can be conceptually connected to different strategies and determinants.

Principle 2) is to indicate in some way the key conceptual relationships. And I'll give an example of this in a completed hypothetical IRLM on the next slide. But typically what we have found is that notations—typically superscripts and colors sometimes when color is useful—are the best way to indicate the relationships between elements and the alignment with a specific theory of change.

So, if you're using an organizational theory of change, an individual level of kind of a behavior change model, you could actually specify in some ways consistent with that theory within the elements of the IRLM as well.

Principle #3) is to study pretty critical study design elements. This is sort of a when applicable to some extent. There are certain things that are always applicable and what is the primary outcome?

But then there are others that are a bit more again, when applicable to specific kinds of experimental or non-experimental designs where you may have to specify different conditions of implementation strategies. You may have to again, somehow delineate those that are introduced and kind of considered part of the independent variable so to speak of the implementation strategies condition.

And this is also the place where you can use the design specific IRLM formats. And we have a number of those for again, like kind of comparative implementation studies. We've done it for optimization studies like factorials, and most designs, and smart designs. And we also—as I mentioned previously—have ones where we are kind of in multi-context meaning that you'll have to split the determinants box between the two different contexts and likely also have to split the implementation strategies accordingly given that the determinants and context are going to dictate a different strategy likely.

So, here is a completed hypothetical Implementation Research Logic Model. This is actually related to two or three studies that I've been involved in. But it's a conglomeration of those more for illustrative purposes than anything else.

So, this is an implementation of an obesity management intervention in community call centers. And so, in this one, we have it's a Behavior Obesity Management Program. So, not a medication or surgery based.

So, in this particular case we specify kind of the critical elements of the intervention program itself. It involves both individual and group visits, is delivered by a multi-disciplinary team that is kind of exemplified by centralized case management and also designation of a clinical champion.

You're starting to see that some of these are getting into implementation strategies. But nonetheless this was part of kind of, you know, the package or the implementation protocol. Then you can see a number of other kind of pieces of the intervention program as well that are kind of critical to its success.

I should mention too that our guidance around completing the IRLM is to typically start with what is known. In most situations, the piece that is the simplest is you know what your intervention is. So, you can usually complete this part of the IRLM pretty rapidly. And you also know what kind of outcomes you'd like to achieve.

The other thing that people usually know is which implementation context they will be trying to implement in. And then, that means that you can fill in the implementation determinants relatively easily as well. And so, we call that the bookending approach.

So, in this particular case, we do specify here our outcomes. And you can see that we have a number of super scripts as well as some other notations in ways that helping the reader understand what this is primarily by bolding our primary outcomes.

So, in this particular case, we had kind of three primary outcomes. We had adoption, acceptability and feasibility. And you can see we specified acceptability and feasibility of both the program itself, but also implementation strategies because that will be directly related to how we plan to actually do our measurement approach as we will separately evaluate each of the perspective of those.

We then bookend it again with completing the determinants. In this particular case, we used Lord Dan (SP) Schroeder's multi-valiant coding scale to be able to indicate something is a significant facilitator, or something that's going to help us with our implementation, or something that is a minor or moderate barrier which are indicated by the negatives, or there's a couple of situations where we know that there is some variation depending on the clinic that we're involved in, or there's kind of an in-between rating.

So, we were able to show which of these are actually barriers/facilitators. In this case too, we also used Seefer (SP) terminology rather than something that is more study specific. This was done really to just help others understand exactly what we were evaluating.

The paper, or the proposal, or whatever is going to accompany this. We get into specifics and I'll, "What do you actually mean by adaptability?" "Why is it given a -1?" But the IRLM is really the snapshot of the overall context and elements of the implementation project.

So, in this particular case, so we knew our context was community health centers. We knew we wanted to improve obesity-related outcomes. We knew that the way to do that was through an evidence-based Behavioral Obesity Management Program, and actually getting that adopted, and demonstrating acceptability, and feasibility.

So, what we need now is to figure out what are our implementation strategies. So, in this case, we had a fairly, you know, comprehensive multi-component implementation strategy package that would be used. It involved training, community resource engagement, obviously engagement of leadership, external state level organizations and national organizations, fidelity monitoring, etc.

And so, you know, a lot of really common implementation strategies for working in healthcare systems. We then posited what we thought might be the mechanisms of action.

So, there's a couple of things here in the notation that I want to point out to help understand exactly how to interpret and make use of this model. So, the one thing that we did is in our super scripting, we started by actually labeling the implementation strategies.

There's a good reason for doing this and I think anyone who completes an IRLM will understand why we do this. And we started our labeling our ABCDE all the way through L at our discreet strategy level. It's because we were able to go backwards

and actually say, "Well, what?" Hypothetically, "Why are we using this particular strategy?"

Well, in this case, we're using training modules and learning collaboratives to hopefully address these minor barriers or these -1 barriers of adaptability and complexity of the intervention. And you can see that that plays out throughout all of these where you can actually backtrack to which multiple barriers.

So, again, this should not be necessarily a one-to-one relationship. But which of the barriers and facilitators are being addressed or are related to each of the different implementation strategies?

You can then—and actually you can see here too—that we also think that doing training and learning collaboratives is going to address a number of facilitators in this case, but determinants nonetheless within our characteristics of individuals bucket of the consolidated framework for implementation research. I already mentioned that part of it.

So, the other thing you can kind of basically kind of take this forward as well and this goes back to that earlier table that I showed of kind of the causal pathway perspective of things. But if we are able to actually successfully train and use these learning collaboratives effectively, what should happen is we should improve self-efficacy among the clinic staff, deliver the intervention.

We should certainly, you know, basically show they've increased their knowledge and skillset of the clinic staff around obesity management. And that would be indicative of improvements in reach, higher adoption rates, higher acceptability of the program as well as maybe the strategies themselves. And we could actually test this in a causal pathway type approach.

We also in this case actually extended our pathway all the way down to which of the implementation strategies we felt was going to actually improve the clinical outcomes. So, this would get at some mediation type models or some hypotheses related to the relationship between implementation strategies and the clinical effects that they produce.

A couple of other things that are unique about this model are not so unique, but things that are maybe potentially a little bit helpful. We also used—especially in the Mechanisms box—these parentheses.

So, the parentheses were indicative of primary and secondary. So, primary was in the bold outside of parentheses. What we thought maybe secondarily effecting this mechanism were these other strategies that are placed here in the parentheses and not bolded.

So, you can see this can get pretty complex pretty quickly. But that's not necessarily a bad thing. I think, you know, these are complex systems. These are multi-component implementation strategies as well as sometimes complex interventions.

And so, a degree of specificity is going to be needed that sometimes does get complex.

As you probably have already had thoughts, the Implementation Research Logic Model does not do everything. And there will be a need for additional supporting text and resources to help people understand what the context of the project is and exactly how things will be done.

And so, we just put together this little table about, you know, kind of how you might supplement the IRLM with data regarding how you collected the determinants, how you determined whether they were a barrier/facilitator. You can do that in a number of ways describing your actual measure in typically text or tables.

The way that you'd specify your strategies would probably be done through text and table as well since the IRLM would not provide sufficient space to go through all of those necessary elements of the proctor Powell & McMillan. And you can see how this goes down the LIST there.

So, there's a number of different ways you can use the Implementation Research Logic Model. This is really kind of by different stages and different kind of, you know, maturation of implementation research.

And this is where it's been used the most so far is in planning implementation projects. As I already mentioned, this kind of begins with the known parameters of the study doing this bookending approach. Not surprisingly, most people find trying to hypothesize mechanisms to be very challenging.

It's in part because it is challenging. But the other part is that it's a kind of newer area of Implementation Science. And so, I think over the next, you know, 5-10 years that will become much easier as more research is out there about the mechanistic actions of implementation strategies that we use.

We also really recommend that you work with community partners and organizational stakeholders to fill in the implementation strategies given their knowledge of what's working and what might not work within the organization that you plan to implement in.

You can also use the IRLM to execute projects. So, a completed IRLM can actually serve as your protocol in many ways for actually doing your implementation project. It can also form the basis for ongoing tracking of what is occurring, potentially what is altered, added, or any protocol deviations as well. And so, it can be used in sort of an irritative way across the life of a project.

At the completion of a project or if you wanted to apply this retrospectively to a project that's already done which we have done in a number of cases, you can use it to actually report what happened during the study. And so, this is actually reporting hypothesized relationships or those that were actually found empirically to be related to each other. And it can really help facilitate the communication of findings.

There's a _____[00:26:27] under review that I'm aware of that use the IRLM essentially as a figure to show either the planned project and part of a protocol paper or as part of a completed study.

And then, the last place is really to potentially synthesize a number of studies that have similar EDP's done in particular context to really start to say, "Here's, you know, the implementation strategies that have been shown to be effective and for specific kind of constellations of determinants."

This has not been done yet at least not in a very formal way. But I'm aware of a couple of groups that are trying it.

So, again, I mentioned there's a number of resources for using the IRLM. We have a quick reference guide that kind of gives definitions and some resources to point folks to where they might look for additional detail about strategies, determinants, what mechanisms are, how to think about them. This is literally a one-pager especially for stakeholders and folks who may be less knowledgeable about this terminology that we use for the IRLM.

We also have a number of worksheets that kind of get into more detail about the primary elements of the logic model. So, we have a multi-page determinant one. We have one for implementation strategies and we have one for outcomes.

Again, this does use the Seefer model, the expert recommendations for implementing change or ERIC Taxonomy, and then the re-aim and proctor. So, we again tend to use things that people would be familiar with which are no way tied to those specifically to be kind of, you know, using maybe IRLM with fidelity so to speak.

And I mentioned too that the Center for Prevention Implementation Methodology at Northwestern University houses our current Implementation Research Logic Model website which has all of these resources available. They're also available as additional files within the publication. And we do intend to provide additional examples of completed logic models as well as have a running reference LIST of papers that have published with logic models actually in them as those come out.

So, now I'm going to shift gears a little bit to a second tool that actually in some ways complements the Implementation Research Logic Model, but can be used completely independently. And it is intended for a different purpose.

So, let's just kind of go into that even though I know this is a bit of an abrupt transition which is sort of necessitated by the format today. So, what I'd like to talk about here is a method for reporting strategy use and their modifications over time. And we co-authors Wynne Norton from NCI, Lisa DiMartino from RTI, as well as a number of members of the Impact Consortiums Implementation Science Working Groups that I chair.

We came up with this fun acronym because everyone loves a good acronym. It's the Longitudinal Implementation Strategies Tracking System or LISTS. And I do need to acknowledge this was supported by the NCI under what's called the Impact Research Consortium.

So, a little bit of background to give you a sense of how we came up with this and why this was even kind of created within the consortium in the way that it was. So, Impact consist of three resource centers as well as the coordinating center. And of course, we work cooperatively with NCI because it was a u-mechanism (SP).

The research centers are all using and effecting this implementation hybrid designs. They're all also using some kind of a rollout or modified step wedge design which is also relevant to the LIST's tool. And they're all testing routine surveillance and integration of symptom management interventions in Ambulatory Oncology Care settings. So, the same kind of evidence-based intervention.

So, within and across the research, there was a need to comprehensively track and report the many implementation strategies that were being used. I mentioned already these are all using some kind of cluster randomized rollout design.

And so, even for internal validity of each of these studies, there needs to be some demonstration that strategies were similar if that was the intention or in what ways did they differ if that was a part of the research design.

But then, of course, because this is part of a research consortium, there's a desire to try to have common data elements, and do data integration, and synthesis to create better generizeable (SP) knowledge coming out of the consortium. And so, that was kind of across the RC's. We needed a way to actually say, "Well, which of these strategies are actually effective and why?"

So, I want to acknowledge that this is not the first or only systematic approach for tracking and reporting implementation strategies. It has been relatively understudied to date. And even the papers that I have here that are all published have pretty significant limitations in different ways.

So, the Alicia Bungers papers used activity logs to track strategy use. It was kind of low structure. Boyd, Powell, Endicott and Lewis, they coded existing meeting transcripts. So, again, kind of made use of, you know, unobtrusively collected data. But again, there were some challenges here around specification and specificity because it was not structured to necessarily gather all of the necessary pieces to specify implementation strategies.

Russ Glasgow and colleagues used a kind of re-aim-based approach that involves semi-structured interviews implementing groups. This involved two meetings at six month intervals and the semi-structured interviews were coded according again, to re-aim kind of terminology around how did things change over the course of the project.

Callie Walsh-Bailey has a paper that came out actually very recently in 2021 on implementation, research and practice that compared three different types of methods for actually tracking. But these kind of differed by the level of detail and structure that was involved.

So, they have brainstorming which was relatively unstructured. They used activity logs which had a little bit more structure, and they used these detailed tracking logs which were a bit more comprehensive and structured. Their finding was that the kind of activity logs were the most acceptable to participants

No one probably needs to know this reminder, but here's the definition of "implementation strategies". They're "the methods or techniques that we use to enhance adoption". And there's kind of two different kinds that often get mentioned.

So, there's discreet strategies which are really like these single actions or processes. And then, we have these multifaceted which go by other names as well like multi-component, implementation interventions, etc. That is a combination of multiple discreet strategies. And some of which are actually protocolized and branded such as Erin's Low Sci (SP) Intervention, and Charles Grissom's (SP) Arc (SP). And there are others. Getting to outcomes is another example as well.

So, this is where I think in some ways a comprehensive strategy tracking system is most useful is when you do have these multifaceted, multi-component, interrelated, you know, kind of implementation strategies, they can be broken down into their discreet strategies to figure out exactly why certain things work or don't work. But that's often not done.

So, the goals were to develop a system that would allow us to capture the dynamic changes as well as the actual specification according to kind of best available guidelines currently. And these dynamic changes would include planned and unplanned strategy modifications, as well as additions in continued and discontinuations of implementation strategies all together.

We wanted to produce data that could be compared and synthesized. And that's why the, you know, kind of background on this being within a kind of research consortium was important. But this was certainly something that would help the field more generally is well is to have a method that could be synthesized.

And we wanted to be pragmatic to minimize response burden while also, you know, keeping true to the overall goal of being comprehensive enough to have the granularity of detail needed to understand process and mechanism.

So, today I'm going to describe LIST as well as the proposed administrative procedures, a little bit of data by it's usability, and then show you very briefly the Electronic Data Capture Interface that we developed that is pretty darn sophisticated.

So, in the actual development of LIST—not it's use, but in the actual development—it was created using an reiterative process among researchers and practitioners. It

included feedback on the initial set of kind of questions or dimensions, the response options that would be available, the frequency at which we needed to actually complete lists, the data captured interface as well as the reporting method within each of the research centers.

We started out with a fairly open. It was guided. I shouldn't say it was totally unstructured or anything. We had a guided administration procedure that did allow for some flexibility because we knew this was kind of the initial attempt and wanted to allow people to kind of, you know, change the way they did things and find something that worked for them, so that we could revise.

So, the research team members and local implementers would complete the tool at variable intervals. And we said this needed to be at minimum quarterly and probably at most monthly where there would be kind of formal meetings to go through and complete the LIST tool. And we would use a timeline follow back procedure.

So, that's why this kind of variable interval happening monthly to quarterly is important is you want it to minimize retrospection error that we know is common for any kind of, you know, modifications and changes. But we also didn't want to have something that required kind of real-time data since that would be really onerous and not really a pragmatic approach.

And we created this data capture tool using Red Cap not surprisingly. That's pretty common obviously these days. One of the things that's important about Red Cap is that there is a one of the very first things that you do is you specify your study units. And it could be done at multiple levels.

So, if you had multiple healthcare systems, you could have the healthcare system level. If you have a rollout design or some of the kind of cluster randomized design, you may specify the cluster level. If you think that clusters may have different implementation strategies or you could actually be all the way down to the clinic level to get at really kind of granular data about how clinics are actually differing even within clusters and systems. And every project would have its own course, you know, specification of those units.

So, here is just a snapshot of the Red Cap tool itself, you know. The first question here is, "What implementation outcome are the secondary targets of the strategy?" The previous question is, "What's the primary targets of your implementation strategy?" And you can choose all that apply. And of course, we have kind of our usual suspects here of acceptability, adoption, appropriateness, etc.

We ask whether or not the strategy that's being reported here was a prospective meaning was it planned to be used in the study during preparation. And if no, we ask questions about, "If it wasn't prospective, why was it introduced?"

For those of you who are familiar with Shannon Sherman's (SP) frame or the new Frame IS, this is really consistent and we did actually borrow from the Frame IS to have these different dimensions and different elements that get reported.

So, conceptually, you know, in this case, we had, "Is this added to address a new or unknown barrier, to augment another strategy, to increase effectiveness, or was this a replacement of an ineffective strategy?

And then, you can specific which clinical units. Again, this is why it's important to have something that's customizable to your project is to specify exactly where this occurred as well.

This is again, just a snapshot. It's much larger, of course.

So, some of the procedures. This is actually what ended up happening in our research groups. So, this has been in use for almost an entire year now. I think 11 months. End of June will be our 12th month.

So, the process for population of lists—and we make this distinction of populating the LIST tool versus updating because we started kind of a year and a half into these projects. Meaning there was a lot of implementation strategies that had already been in use that needed to be recorded.

And so, the process for actually completing the population—and this might be true even still in the early phases of a planned project—is people in all of the research centers did these five things routinely. They reviewed the full LIST of ERIC discreet strategies to identify those that were used. This was kind of done as a prompt, so they wouldn't forget any.

They then entered strategies into an Excel spreadsheet, so that it could be checked and validated before entry into Red Cap.

People routinely confirmed the different LIST elements. And so, the time that it took, who actually did it. And they did this by consulting with other team members, looking at calendars, referring back to meeting notes kind of as needed by strategy.

There was also a process for once the Excel spreadsheet was completed for each strategy. It was signed off by a team, or unit, or Study Lead before it was then entered into Red Cap. And there was one point person for each research center that did the Red Cap entry just to make sure that there wasn't duplicate entry and that it was done accurately.

Once LIST was fully populated for least existing strategies, there were these routine meetings, of course, that were used to update strategies. So, there's routine check-ins that included implementers. So, I have in parentheses here the number of RC's that used this particular approach. All three had routine check-ins with implementers regarding changes as well as new strategies that have been introduced. And in those situations it would, of course, follow-up and get the needed information.

It involved routine review of entered strategies for any changes that had happened. Only two of the centers did this. And then, one each did periodic emails between

implementers and the Study Team, as well as kind of when each study unit rolled in, in their step-wedge design, they populated LIST accordingly. I think this was done in part because the monthly to quarterly meeting schedule for all of this was not necessarily always aligned with the roll-in. And so, they made a point of having it at that point as well.

Of course, the LIST dimensions as you probably already kind of surmise, we built on strategy reporting standards of proctor. And this had a, you know, a number of different elements and they're actually specified here in this nice figure that they created.

So, we had people name what the strategy was. They defined it. And then, there was all these different specification elements involving the actor or the action target, etc. So, all of those elements are in the LIST tool.

We also had them actually say what barriers you are addressing using again the Seefer domains. And also, what are the primary and secondary implementation outcomes. And again, we used rename and proctor to provide a comprehensive LIST.

We then used the number of the Frame IS prompts and kind of dimensions to help us understand the modifications that were done. So, there was, of course, as I showed already in the example, when discontinuation happens, give us the reasons and who made the decision, as well as what units it applied to, as well as when the unit had a new strategy that was not prospective, why was that done? And then, of course, specify it.

So, some preliminary results again of kind of the usability. We were able to achieve a system usability scale score of 67.5 which is essentially a C. It's good enough, but you could still improve. So, we plan to continue to intermittently make this LIST tool more useable.

I think not surprisingly, we found that people reported the most difficult elements to report where the frequency of strategy use as well as the dose. How long does it take to do the strategy each time?

And we asked about the difficulty of each of the elements. And here these two were the ones that rose to the top.

We're currently in the process of praising the interpretability of the data. We now have a year's worth of data. So, we can actually pull that and take a look at it. That will be part of an upcoming paper that we hope to submit in the next two months. And again, we will continue to interpretably define this.

So, some things that actually our users reported. These are direct quotes. Things they liked is that, you know, the tracking implementation strategies is compelling. And obviously, it could enhance the field.

People noted the Red Cap form was relatively complex, but very robust. And mentioned that it included functionalities that they didn't even realize were possible in Red Cap.

Another thing was that the tool forced the research groups to articulate all of their strategies as well as providing metadata in the spreadsheet which they found very relevant and valuable for their project.

Some things that they didn't like—that kind of terminology implementation strategies and determinants. And this is ERIC and Seefer. Groups have struggled to understand the definitions as well as the conceptual overlap. Not surprisingly, I think all three of the RC's relied heavily on implementation scientists for categorizing strategies and determining the barriers being addressed by each one.

This could be highly facilitated by having completed an Implementation Research Logic Model because that would already have been done to some extent. But it can also be back translated to where you can actually use the results of LIST to populate the logical model. So, that's kind of where there's a bit of an interface.

There was a mention that it may need to be updated or have some kind of modification to allow easier collection for multi-site predominantly like multi-healthcare system projects where it's difficult to have a centralized person. And then, of course, there was just the amount of effort involved and the potential for, you know, what was the actual value and usefulness of having this kind of granular microdata. So, that's something I think we'll be trying to demonstrate within the next few months and years.

So, this is the final slide here before starting discussion. Some implications in future directions. The tool and process represents what we view as an advancement in characterizing particular dynamic features of strategies over time. They're, you know, again, I mentioned there was other approaches. But I think there are things that are a little bit more advanced about this approach than others that are out there.

Clearly there is a need for having pretty high level of knowledge and familiarity with implementation science, theory and terminology. And improvements in strategy and determinant mainly in categorization and needed to aid in reporting.

And this is not the only context that I've heard, you know. People struggle with the ERIC compilation category use or struggle with the Seefer categories. And I know Laura and colleagues have a Seefer 2.0 that's going to be coming out that will address a number of those issues.

But I still think that the, you know, the overall issue of having a lot of knowledge around implementation's going to be needed. And of course, we need to demonstrate validity of this tool and to some extent usefulness of having this level of data.

So, I'm going to stop there. I'll leave this up in case anyone has questions via email that they would like to ask. And we'll start addressing some questions in the chat as long as we have time.

Unknown: We've got about 12 minutes. So, we are going to start moving through these questions. The first one we received is just a comment/feedback. "A wonderful, consolidated display format for IRLM. Reminds me of the A3 display in QI which is designed to provide a snapshot for the project. Lots of information packed into a distilled format.

Dr. J.D. Smith: Thank you.

Unknown: Okay. First question we have here, so it's a long one. Hold with me while I read through this. "This approach is really comprehensive. I'm wondering if you are mapping implementation strategies to elements of the management program. I am noting you're not using super scripts in the management program box and wondering why. Another way of posing this question is do you specify what a training covers? Is it on using text messages, recruitment, EHR, support, etc. or do you want an implementation strategy is supporting in terms of specific clinical program elements? Hope that makes sense."

Dr. J.D. Smith: Yeah, great question. That is certainly an option. For anytime you're using the IRLM and also specifying the different elements of the implementation of the program.

I think your question is most applicable to multi-component complex interventions rather than some of like the really simple things that we might do. I totally agree with you. I think that's another advancement. And I have seen people who have also super scripted the different intervention components.

So yeah, great suggestion, and really good for catching that, and pointing it out for us here.

Unknown: Next question here, "Great work on IRLM. Please say more about the executing application especially from the perspective from the implementation practitioner who is implementing an improvement as opposed to conducting IR."

Dr. J.D. Smith: Yeah. Great question, Kath (SP). I, you know, we've seen this mostly used with like Quality Improvement teams or, you know, kind of practice improvement champions where they kind of have this. They use it basically to keep in mind from a kind of a maybe a 5,000 foot view, not a 10,000, but a little bit closer to really keep a beat on what's happening.

They also use it to kind of make sure that all of these strategies continue to happen. They're checking in with the people who are involved.

So, there's a number of ways to do it. But I do think it's one of those things that's a little bit underdeveloped and people are using it kind of in multiple ways that I need to probably try to figure out how to synthesize and provide better guidance for.

But yeah, I think people find it useful in different was. But probably more from that, you know, one step up from the actual implementer and more to like the management than folks that potentially oversee that kind of stuff.

Unknown: Great, thank you. Next question here, "Wonderful presentation. Thank you. Was the LIST tool developed in the specific setting and practitioner type? Seems like healthcare. And if so, to what other settings or providers might it be most generalizable and which would need a good amount of adaptation?

Dr. J.D. Smith: Yeah. So, it was developed for healthcare settings. The way that we did it though is I don't think that's anything in there that is actually setting specific.

So, the one thing that might be is our response options for the actors. And so, we do have, you know, practitioners and other kinds of terms in there that maybe healthcare system specific.

The cool thing about this Red Cap data acquisition form is that it obviously can be customized. I mean, we have places that have to be customized like the study units or the unit of analysis, so you can specify where the strategy's being used and, of course, in which units the modifications are occurring.

The same thing is easily done for the practitioner type as well. And I think it really actually would not need much adaptation to be able to be applied in other ways. Really good question.

Unknown: Great, thank you. Next question here, "Thank you for the great ideas. It seems like the difference between IRLM's on the one hand and logic models in the program evaluation literature on the other is simply that the words you use in the IRLM for particular determinants, strategies and outcomes is determined by IR models and frameworks instead of by the specific context. Is that right?"

Dr. J.D. Smith: To some extent, yeah. So, I actually did a presentation. I did a half day workshop actually to the CDC at the request of their Evaluation Team and their Implementation Science Team. And I do actually have a slide where I did basically a crosswalk of the traditional pipeline logic model that the CDC uses and is most familiar with for program evaluation and the Implementation Research Logic Model.

And yes, I think there's a high degree of essentially the same elements are here. We're just putting them in different places and using, you know, slightly different terminology.

One of the actual impetuses—or I don't know what the plural of that is—for actually creating the IRLM in the first place is that myself and my colleague submitted two grants to the CDC and to the USDA Implementation Research Projects both of which required a logic model. And we, of course, completed it for the purposes of the grant.

But in looking back at those logic models they were completely useless. They were not helpful in any way to our project and we were putting things in there to complete a step that was required.

So, the actual translation of a Program Evaluation Logic Model to implementation research is not very good. But going backwards is potentially a little bit easier. And I do think that you're totally right. There is just a change of naming and potentially a different place that you would put certain elements in the IRLM compared to the traditional logic model.

Unknown: Great, thank you. The next question here, "Is the end goal of LISTs to provide a metanalytic evaluation specific implementation strategies?"

Dr. J.D. Smith: No, I think that, you know, metanalysis would require actual data on the outcome itself to be able to have, you know, a demonstration. I would think of it a little bit more of hypothesis generating and being able to start to help people understand where they would focus and how they might do a form of metanalysis that's based on empirical data.

Currently, LIST does not actually have a place to add data itself. So, you could say that this implementation strategy is attempting to address acceptability. But there isn't actually a place to put in, you know, mean scores, or change scores in acceptability.

I think in some ways it's more about trying to get to a place where we can compare apples to apples or we can compare, you know, a Fuji with a MacIntosh Apple rather than what's currently seen in the field which is really like people say I'm doing audit and feedback. But when you look at metanalyses of audit and feedback, the specification is so poor or the actual operationalization of audit and feedback is so diverse that it's really hard to actually say, "This is actually even the same thing."

So, it was more about addressing that issue of naming operationalization specification and being able to compare than it was to actually getting to metanalysis directly. I think it could inform it indirectly though.

Unknown: Great, thank you. Our next question here, "What comments would you suggest for products that are not research that applied action-oriented projects conducted in real life?"

Dr. J.D.

Smith: Yeah. That's a good one. I mean, honestly when we actually introduced the Implementation Research Logic Model kind of to the world so to speak was actually at the end of the HIV epidemic funded training summit essentially.

So, there were 65 planning projects. And the requirement was that the research grantee had to have a community partner. It had to be their implementing. And they came to that workshop as well.

The IRLM served as kind of our kind of overarching structure of the entire two-day process. And then, we did our evaluation on both the research participant as well as the implementing partner.

The implementing partners, there was no significant differences between those two roles. I think that, you know, getting a little bit deeper into why they found it important or why they would find it useful may be helpful.

But even at the individual item level, they seemed to see the same positive things as the researchers did. So, I think it can be useful in a non-research context as well.

Unknown: Great, thank you. This isn't a question, but a comment that I just want to let you respond to. "This approach seems to lack a theoretical framework that informs the development of the strategies. The mechanisms reflect this, but you do not appear to inform the development."

Dr. J.D. Smith: Yeah. I think what we said in the IRLM paper is that really a theory would guide the entire thing. It would guide the selection. It would guide the actual operationalism and potential modification of strategies that are used.

We didn't want to impose a specific theory. That's why we had the generalized theory of Implementation Research which was more about the connection between the necessary elements than getting into the theory of a specific strategy or the specific use of a strategy.

But we do encourage people to actually do that when they're, you know, completing the logic model and, of course, when they're interpreting what it means.

Unknown: Great, thank you. Next question here, "Is there any thought in integrating cost matched with proctor dose, frequency specifications into the model?"

Dr. J.D. Smith: Yes. So, we actually specifically did the specification of actors, and dose, and temporality or duration like basically how in a project's life was this actual implementation strategy being used. We did that in a way that it could be converted into dollars.

So, it's very similar to an activity driven, time-based costing approach. It's not currently being done. But we made sure that the necessary elements were there, so that someone could do that pretty easily.

Unknown: Great, thank you. We're just about at the top of the hour. Here I'm going to try to sneak in one more question. "I thought that often for these outcomes that are mediated by underlying psychological processes that theoretical link between the changed technique and the outcomes seem arbitrary or underexplained. What are your recommendations to address this issue?

Dr. J.D. Smith: Yeah, that's a million dollar question. I think there's a lot of attention being given right now to that within the field. But partially--I kind of eluded to this with my little gears in part of the mechanisms--is we don't know a lot about that. And I think that you're certainly pointing out that there is a lack of underexplaining this issue or just not knowing.

I think part of it, you know, looking at some systematic reviews that have been done around mechanisms in mediation, there's just very little formal research being done on this. And I think one of the things that have been pointed out by other folks that are smarter than me is that people aren't even measuring them.

So, there's a, you know, there's a bit of this black box phenomenon of, you know, we see these outcomes. Here's the strategies we use, but there's something happening in between that we really don't know for sure. And there's a lot of theorization and hypotheses about it.

In good cases, people do that. In most situations there's no data, no hypothesis. But maybe at best there's speculation. So, that's a place that the field definitely needs to grow.

Unknown: Great, thank you. We do have some questions that we were not able to get into. J.D.'s contact information is on the screen if you would like to reach out or I will also pass these questions along to him.

But we are just past the top of the hour, so we need to wrap things up. Christine? Amy? Just wanted to check if you had any closing comments you'd like to make?

Amy: No, thanks again. Thanks, everyone, for participating. Thank you, J.D. for your talk and Christine for making it happen as well as Cider. So, I'm really excited about this work.

Christine: Yeah. Thank you, Amy. Thank you, J.D. This is Christine. This is one of the presentations I have to say that I am most excited that we've had in probably several years.

So, I'm sure that in Implementation Research we'll be talking about these topics much more. So, thank you so much, J.D. Thank you for everyone who joined. And

please stay on for the survey that you get because we do like to get your feedback about the sessions and what you'd like to see in the future.

Dr. J.D. Smith: Yeah, thank you for having me. I really appreciate it.

[End of Recording]