Christine Kowalski (SP): And I would like to thank everyone for joining our Implementation Research Group Cyber Seminar today. My name is Christine Kowalski and I am an Implementation Scientist and the Director of the Implementation Research Group. That group is a learning collaborative set up for sharing best practices and lessons learned in *Implementation Science*. We have over 500 members in the group and the session today is part of our monthly catalog of events.

If you just happened to join this session today, and you're not part of the IRG, and you would like to join the group, you can send an email to IRG@va.gov. And in just a moment I'll put that email address in the chat too. Sometimes we get questions about that.

But now I'd like to thank our presenter for his work in preparing for the session today. Dr. Christopher Miller is a Clinical Psychologist and Investigator at the VA-Boston Healthcare System Center for Healthcare, Organization and Implementation Research—known as CHOIR.

He also has an appointment as an Assistant Professor of Psychology in the Harvard Medical School Department of Psychiatry and he is a co-PI of the VA Behavioral Health Query.

His research focuses primarily on the implementation of team-based outpatient mental health care. And in the field of Implementation Science and within Query, we have lately been focusing a lot on implementation strategies. And as we all know, those strategies are used to enhance the uptake of evidence-based practices and routine clinical care.

And like the practices themselves, implementations strategies are frequently modified. And so, in this session, Dr. Miller will be presenting the Frame IS which is a framework that can be used for documenting modifications to implementation strategies.

So, thank you all again for joining. Please enjoy this session. And now, I will turn things over to Dr. Miller.

Dr. Christopher Miller: Thank you for that wonderful introduction, Christine. Am I coming through okay on the audio?

Christine Kowalski: Yes you are. We can hear you great.

Dr. Christopher Miller: Okay.

Christine Kowalski: Thank you.

Dr. Christopher Miller: Great! Well, I will dive right in then. Thanks, everybody for being here.

So, as was mentioned before, the primary focus here is on this framework—the Frame IS. But let me just make sure I can advance the slides effectively. There we go.

So, here's an outline of what I'll be talking about today. I will start--as with many VA talks—with acknowledgements and disclaimers. I'll set the stage with some definitions, as well as why we think this field of study's important.

I'll talk a little bit about the development of the Frame IS and the components of the Frame IS. We'll also briefly talk through an example of how the Frame IS has been used to kind of document modifications to implementation strategies in the past. And then, we'll talk about future directions and wrap-up.

So, first, in terms of acknowledgements, the views that we're presenting today are our own. We don't have any conflicts of interest to declare. As a lot of us feel, I think if we wanted to make a lot of money off of our research, then probably the nitty gritty details of the implementation frameworks probably wouldn't be where we should've gone.

If you have one takeaway from this session today, hopefully it's to check out the associated paper which is at *Implementation Science*. It is available open access.

I want to really thank the co-authors on this and other words who we've done kind of in this field. And also, some details follow on those who weighed in to really lead us to the final version of the Frame IS including many people from the Implementation Research Group.

In terms of funding support, we've got a lot here. I won't belabor the specific funding details except probably to shout out the Implementation Research Institute or IRI. All of us co-authors have been involved with the IRI in one way, shape or form over the last decade. So again, here's the screenshot of the front kind of title piece of the manuscript, again, in *Implementation Science*.

So, with that out of the way, why don't we talk about just a few brief definitions here. I think a lot of folks on this call are probably familiar with these. But really, this is a part of the field where there are many kind of competing definitions or different use of verbiage throughout.

So, for our purposes today I'll be using EBP or Evidence-Based Practice, refer to clinical intervention that we've got some evidence is effective in some way, shape or form. A lot of different examples listed here.

For those of you who've read Jeff Curran's (SP) piece on kind of oversimplifying Implementation Science principles, the EBP is the thing. The thing that we want to get people to use more frequently.

In contrast, "implementation strategies"—which we'll be focusing on today—are "the methods or techniques used to enhance the uptake or increase the use of a given EBP", right? So again, in Jeff Curran's words, "These implementation strategies is stuff we do to try to help people or places do the thing", all right?

Now we know in practice that oftentimes there are blurred lines between EBP's and implementation strategies used to get them into practice. For example, it's with a psychotherapy manual that includes some components about how to make sure people are using it effectively. But for our purposes, we want to keep this distinction in mind and some citations on the bottom for further details as well.

Other definitions—we're going to use the term "modification" to refer to "any changes be they proactive or reactive made to an intervention or program". That is the term "modification" here can refer to EBP's or the implementation strategies used to get them into practice. And we use the term "adaptation" to refer to the subset of modifications that are made in a planned or a proactive manner, right?

So, somebody may, for example, modify their delivery of an evidence-based psychotherapy if a patient shows up 30 minutes late to a 45 minute appointment. That would be considered likely an unplanned modification.

In contrast, if you developed a version of that psychotherapy manual that's meant to be delivered in 15 minute bytes, then that would be an adaptation or a planned change. Even though the content of those two things would be the same, what differentiates these is the level of planfulness or kind of unfrontedness that goes into the modification itself. So, with that in mind, let's talk about why we care about this stuff, right?

So, when you think about modifications—and some of you may have seen this slide before in other versions of these kind of talks that we've given. But, you know, the traditional clinical trials view of modifications—especially the evidence-based practices—is that you really want to avoid them because they threaten the internal validity of your study, right?

If the EBP is delivered in a different way by every clinician in your trial, then it's hard to tell at the end of the day which version of that EBP was absolutely the effective one even if you find overall good results from that study.

Perhaps a more realist view acknowledges that modifications are basically inevitable. So, we might as well document them just so we know what's going on.

But really the view that we take here is that modifications—be they to EBP's or the implementation strategies—are essential to maximize EBP success and to reduce health disparities. Especially in a situation where they kind of unmodified EBP, for

example, might be really geared toward populations that are not the underserved populations who may be most in need of help, right?

So, I want to acknowledge here some work by Dr. Bowman and Leo Cabalsa. (SP). Really, we think that developing the science of adaptations may be seen as one of the five key elements to really address inequities or help disparities.

I apologize for the coloring here. But for those of you who have the slide set separate from this presentation mode, hopefully you can click on that link to go right to the article, all right?

So, we don't just think that modifications or adaptations are common—although they are. We think that they are essential in many situations, right? But without measurement, there is no study and without study there is no improvement, right?

So, answering questions like when, where, how, why and by whom should modifications be made at the very least to address this, you need to engage in some documentation, so we know what's happened. The screenshot here is of a prior well-known article for this group. But David Chambers and Lynn Norton's Adaptone (SP) basically acknowledging that what we really would like to do—the Holy Grail for the adaptation literature—is to develop some kind of compendium where we carefully note what kind of adaptations have been made in what settings and use that to guide future adaptations.

But the example we sometimes use for this is that let's say you have some kind of implementation trial where you find not so great results, right? Unless you have a clear sense though of what modifications were made to the EBP, what modifications were made to the implementation strategy, it's hard to tell whether your less than stellar results are due to the EBP not being a great fit in the first place, the modifications for the EBP being misguided, whether the implementation strategy wasn't a great fit in this setting, whether the implementation strategy was modified in a way to make it less effective. Again, these are hard questions and answering them at the very least requires understanding what adaptations or modifications have been made.

So, this is kind of where we're coming from. And so, to start to build this literature going back to 2013, Shannon Leslie Sternham (SP) developed the first framework around kind of documenting modifications to EBP's. And then, we published an updated version in 2019 in *Implementation Science*.

Credit to Dr. Leslie Sternham for being fantastic with acronyms. I believe it was she who came up with the framework for reporting adaptations and modifications to evidence-based interventions or again, in the terminology we're using today to evidence-based practices.

However, both of those frameworks, right? And a lot of other work conducted by other fabulous researchers is really as I mentioned, oriented around documenting

modifications to EBP's, right? But what about the implementation strategies used to get those EBP's into practice, right?

It's not simply a matter of taking the frame and completing it for an implementation strategy because implementation strategies are fundamentally different from the EBP's that are meant to get them into practice, right?

And so, therefore, we set out to develop essentially a modified version of the frame specifically oriented around implementation strategies or the Frame IS. So, that's the apple and orange here just to show kind of the apples and oranges—difference—between modifications to EBP's and modifications to the implementation strategies we used to get people to use those EBP's.

So, moving on then. How did we develop the Frame IS? How did we take the frame and turn it into this version that's really oriented around implementation strategies? For those of you who have access to the manuscript—again, which I believe went out with distribution of this and people can link because it is available open access—we basically tried to go through as rigorous as possible a multi-step process to develop the Frame IS to be as applicable and useful as possible.

I'm not going to go through these steps in detail, but I did want to really acknowledge this fifth step here, so "Listening and integrating stakeholder feedback". Thanks to folks from this group, as well as the wonder group, as well as some people who worked with us for one-on-one think aloud's basically to help us take the initial version of the Think IS—the official draft that kind of we had developed just amongst us co-authors and really turn it into the final version.

So, some of the feedback that we had received is kind of really pretty strongly the initial version was way too long and had too many items that really didn't seem very applicable or useful, right? So, a nurse thought that we really did want to try to shrink down and kind of cut out the fat so to speak—kind of cut out the extraneous pieces of the draft Frame IS.

People also really desired a modular format with guidance around what should be considered core modules of the Frame IS that most people would want to complete for their implementation project versus optional modules that might be nice in some settings, but aren't really core or central to getting useful data out of the Frame IS. So, we really tried to take these pieces to heart in developing the final version.

So, now I'm going to shift and talk about the components of the Frame IS. I'm going to try not to go into too much detail on each of these both because I think going painstakingly step-by-step through a model as complicated as the Frame IS would probably put everybody to sleep. But also, this isn't really a great format for learning those pieces. Again, I direct people to the manuscript if they want to see kind of the whole thing in the components and detail.

But long story short, the first of the four core modules—the ones that we pretty much recommend completing—for most people who are going to use the Frame IS to

document modifications to implementation strategies, Module I really is just kind of a summary module, right?

Laying out in just a real plain language, hopefully in just a few words each, "Well, what's the EBP that we're trying to get people to use?" "What's the implementation strategy that may be modified through the course of our project?" "Why are we making modifications that we have in mind and why are those modifications made?", right?

So, Module I really is just meant to give an overall summary of what modifications we're talking about. And we thought this was important because oftentimes people will be making multiple different types of modifications to a given implementation strategy. And we wanted to make sure that in completing the rest of the Frame IS, it's easy to keep clear in your mind what modification are we talking about at any given point.

So, the second core module, "What is modified?" This is really meant to capture just in broad strokes. Well, are we modifying the content of the implementation strategy? Kind of the details of really what we're trying to do to get people to use an EBT? Are we modifying the way that the implementation strategy is evaluated that second check box? Are we modifying the way that implementors are trained?

So, an example here might be if your implementation strategies implementation facilitation. I know that we've got folks in VA, right? During Kirk and Cathy Dollar's (SP)S group who have the Implementation?/Facilitation Training Hub, right?

It might be different delivering implementation facilitation trained by that group versus a different type of training for implementation facilitation. So, if the training for implementors has changed, you might want to be checking that training box to a modification to your implementation strategy.

And finally, here especially relevant for Covid times, other modifications to implementation strategies really might be about the context, right? This is the way the implementation strategy is delivered.

So, for example, when we think about the format here, right? Are we delivering the implementation strategy in a group versus an individual format? For instance, a good example might be if your implementation strategy is provider training for a particular EBP, if you're changing the format in which the clinicians are being trained, right? That might be a contextual modification changing the format, right?

So again, I'm not going to go into a ton of detail here. But these are the kinds of things to think about for Module II. Are we changing the content? Are we changing details of the evaluation or training for the implementation strategy, or are we changing the context in which the implementation strategy is delivered.

Moving on to the third core module. Note that this is really only delivered or applicable for content evaluation for training modifications. The reason for that being if we go back to Slide 15, for content modifications we include the additional checkboxes here for format, setting, personnel, population or other.

But for content, evaluation or training modifications, we want to basically then document, "Well, what specifically is being modified about the implementation strategy?", right?

So, you can see that these can range from relatively small like tailoring, tweaking or refining at the very top to relatively more fundamental, right? Things like integrating another implementation strategy into the primary implementation strategy we're using.

So, for example, if your implementation strategy again is implementation facilitation, but you're building in a very robust audit and feedback component that is kind of separate from, or independent of, or built on top of implementation facilitation, then that might be considered a modification that is integrating another strategy, right?

So, another one I want to mention too here is the second to last one "Drift from the implementation strategy without returning", right? We certainly want to acknowledge that in some of our implementation projects things fall by the wayside, right? And so, we may want to be able to document that especially if we can document when the modification occurred as we'll talk about later.

Another thing I want to acknowledge here from Module III, right? There's an optional addendum over on the right-hand side of the slides here, right?

Now you may also want to—excuse me—can you folks still hear me?

Christine Kowalski: Yes, we can.

Dr. Christopher Miller: Okay. Sorry about that. I had a call coming in. I apologize for that disruption.

But for this optional component for Module III "The Relations of True Fidelity or Core Elements", right? Certainly when it comes to evidence-based practices, a lot of emphasis has been placed on maintain fidelity to the core components or core functions of an EBP, right?

The idea being that you don't want to change those core elements or functions. But some of the adaptable periphery, some of the kind of other things about the EBP may be more amenable to modification, right?

Now in this case, we acknowledge that for implementation strategies, it may not be really clear what exactly those core components or functions are. So, you may not want to use this optional addendum to Module III.

But on the other hand, it may be useful to document, "Do we think this modification was consistent with kind of the core sense of the implementation strategy or do we think that this was a more radical departure?"

The idea being that by tracking this we may be able to then reflect on whether in fact the things we thought were core functions actually are core functions. If we had an implementation project where the core functions are modified and yet the implementation strategy was really successful, then maybe we should rethink whether those are in fact core functions of the implementation strategy.

So, this is kind of Module III. It's really about kind of the details of what was changed and whether we think that what was changed is still consistent with kind of the core design, core elements or core functions of the implementation strategy that we're using.

I'm going to pause here just to get some water.

Moving on then to the last of the core modules—Module IV. We really want to have a sense of what the goal is for the change to the implementation strategy.

So, you can see a bunch of these things listed. I'm not going to go through them in detail. But since we wanted to acknowledge that on the left-hand side here, we basically derive these things from the re-aim framework, as well as proctor's dimensions with an additional item about increasing health equity or decreasing disparities in EBP delivery.

Certainly, some people might fold health equity or decreasing health disparities into the reach dimension of re-aim. But we really wanted to have this be a separate thing, right?

And we acknowledge that if you're doing and documenting an implementation project's modifications using the Frame IS, there are certainly changes or modifications for which multiple of these boxes might be applicable. But the goal here is to get at kind of what is the goal of this modification to the implementation strategy?

Again, the idea being that if people use this frequently enough, we may be able to determine whether certain goals are better served in terms of making modifications to our implementation strategies.

Part II is kind of the level of the rationale for the modification. And they're basically different levels here ranging from a very broad level, you know. We're making a change based on broad national mandates, right?

Which would probably apply across a full range of different implementation strategies to relatively more specific, right? Are we modifying the implementation

strategy specifically to meet the needs of an individual patient, an individual clinician, or an individual implementor, or implementation facilitator, right?

So, this is kind of the end of the core module. So, just to summarize what we've talked about so far. The core of the Frame IS are these four modules—an overall summary module about kind of what we're talking about, what modifications, implementation strategies we're referring to.

A Module II is really about overall what was modified.

Module III's about the nature of certain types of modifications.

And Module IV's about the goal or rationale for the modifications that are being made to implementation strategy.

We now move on to the three optional modules. You can decide whether it make sense to administer these or kind of use these to track modifications in your own implementation project, right?

Part I is "The modification initiated, right?" Now we talk about when the modification is initiative rather than when it's made because we acknowledge that many modifications to implementation strategies are going to be made throughout the entire course of the implementation, right?

If you're changing something about how your implementation strategy is delivered, that may apply across a broad timeframe. What we're most interested in here is when did you decide to make the change, right?

And then, Part II is "Was it planned, right? Is this a planned or proactive modification which we call adaptation? Was it planned, but in some sense reactive?" In which case it might be considered a reactive adaptation or was it a true modification in a sense that it was unplanned and reactive, made almost completely on the fly, right?

Again, the idea here is that if we track this, we can learn a bit more about when it might be appropriate to make unplanned modifications and when it might make sense to stay the course in delivering your implementation strategy, all right?

So again, an optional module, but one that might be important for your implementation projects.

The next optional module, "Who participated in the decision to modify?" Again, the idea here is that you could use multiple checkmarks to show how broad the coalition was. It settled on this modification with an optional piece at the bottom to indicate who made the ultimate decision.

Again, this could be useful for determining whether in fact, broad based modifications—ones that got buy-in from a larger group of people—are in fact more

effective or there are certain circumstances where even if just one person or one group makes the decision to modify, that could still be an effective modification.

And finally, the last of the optional modules, "How widespread is the modification?" That is for whom or what is the modification made. This is really just getting at the scope question, right?

So, it could be again, for more individuals, for groups or for broader organizations, or clinics, or even network system level. So, this is really similar to kind of the Module IV in getting at the rationale which can occur at multiple levels.
But we also want to acknowledge that in this case we want to get a sense of the scope of the modification that was made to our implementation strategy.

So, that takes us through the core and optional modules of the Frame IS, right? So, going through somewhere between 4-7 of these would allow completion of the Frame IS for your implementation process.

But I know that probably up to this point, this feels pretty kind of 50,000 foot view. So, I wanted to talk a little bit about example completion of the Frame IS, right?

So, in this case—and thanks to Dr. Maya Barnett for providing this example for the manuscript that we wrote and for the slides here. But our EBP—Parent/Child Interaction Therapy or PCIT, right?

As you can see here, it's an evidence-based parenting program for young children with disruptive behavior disorders. It's typically delivered by a cast sharing model where you've got professional clinicians partnering with lay health workers. And the lay health workers are really working directly with the families to promote kind of adherence to the protocol and helping them improve skill acquisition.

So, in this case—the case for example—the implementation strategy in question was a training program for the lay health workers, right? So, in this case, part of the reason that—as you'll see—there was a modification potentially needed is because the implementation strategy—the training program specifically the lay health worker training program—was originally developed for a Hispanic population in Miami, but was now being rolled out in California, right?

So, these are the core modules of the Frame IS as it pertains to this particular modification to the implementation strategy of the lay health worker training. And as you can see, even though the Frame IS is pretty expansive, we really just boiled this down to a few kind of bullet points hopefully clearly describing how the implementation strategy was modified in this case, right?

So, you see Module I there is just making sure that we know what we're talking about as we're going through this, right? EBP is PCIT. The implementation strategy is this training program for the lay health workers. In this case, right? There is some tailor in the training content—specifically language—to fit the kind of local

population differences acknowledging that the Hispanic population in Miami is fundamentally different in some ways from the Hispanic population in California.

Also, worth noting that there was removal of a behavioral coding component of the training. Specifically, again to better fit the needs of the population. And the reason that these changes were made was to improve the appropriateness and feasibility of this modified implementation strategy—this modified training program for the lay health workers.

So, you can see that these qualified as content and context modifications to the implementation strategy. Specifically, the modifying language that's considered a tailoring change to this implementation strategy. And the removal of the behavioral coding component is considered removing or skipping elements of that implementation strategy.

We wanted to acknowledge that we aren't really sure whether these should be considered core components of the training program of the implementation strategy. And the goal again, in a little bit more detail is about increasing acceptability, appropriateness, and feasibility of the implementation at first.

And this is basically done at the practitioner and patient level. Again, to address some differences here in the population of predominantly Mexican decent in California.

So, long story short. So, there's one takeaway from this slide. It's that this is an example completion of the core modules of how this implementation strategy was modified based on the Frame IS for documentation.

So, our hope is that this gives a relatively easy to digest kind of version that easily communicates what was changed for this implementation strategy for this particular project.

Go through a bit more briefly for the optional modules. These changes were made in the pre-implementation or planning phase. These are considered planned or proactive. Like before rolling these out in California is when these changes were made to this implementation strategy.

While a lot of different people did participate in the decision to modify, ultimately it was researchers who kind of settled on the final version and made these changes. And how widespread was the modification?

Well, it applied to the entire California rollout. So, that's the kind of scope or widespreadness of this modification or really adaptation of this implementation strategy of the lay health worker training program. So, I hope that that reasonably communicates kind of how this could be completed for an example.

Moving on then in terms of future directions, right? There's still a bunch of unknowns here, right? We don't want to pretend like this is settled law, right?

This is a new implementation strategy modification documentation framework that has started to be used, but there are a lot of questions to answer, right? "How frequently should this be completed?" "Can we simply look back at the end of the implementation project and complete the Frame IS for all modifications that were made throughout?"

Well, we don't really know yet. I think my gut reaction would be that it's a really long implementation project. You might want to look at the Frame IS periodically and just see whether their new modification's kind of coming online.

We're also not really clear exactly who should be completing this or how best to limit the documentation burden. Again, we tried to make it relatively digestible by having this modular format and kind of sliding what we considered to be the core modules.

It's more useful for certain implementation strategies than others, right? I've referenced implementation facilitation as an example of an implementation strategy that can certainly be modified.

Now one of the challenges for that is that by its very nature, implementation facilitation is meant to be adaptable. It's meant to not be delivered in the same exact way in two different projects.

It remains to be seen whether the Frame IS is going to be useful, or more, or less useful for there's more complex adaptable modular implementation strategies as opposed to kind of more clearly defined and encapsulated implementation strategies. And most importantly, the patterns and implementation outcomes emerge, right?

Again, our underlying assumption is that tracking this stuff will be helpful for hopefully unlocking the black box about which implementation projects really work really well versus crash and burn, right?

We think that tracking this will help hopefully differentiate which modifications are most useful to enhance overall outcomes of our implementation projects. But that's an empirical question.

And we also want to acknowledge that the Frame IS is currently being piloted in a relatively robust study here thanks to Cathy Goodner (SP)—one of the co-authors—for kind of helping incorporate the Frame IS into this ongoing project.
So, hopefully as that project wraps up, we'll have some additional information relevant to these other questions regarding the applicability and utility of the Frame IS.

Having said that, in terms of wrap-up and summary here, right? There is broad agreement in the field that modifications both to EBT's and to the implementation strategies we use to get them into use are important for healthcare innovations to stick in real world clinical practice.

We think that there's a need for careful documentation of those modifications because without that documentation, it'll be hard to kind of exactly get the mechanisms by which these implementation strategies are working. The Frame IS is designed to do exactly that. It's designed to track these modifications that we think may be useful.

And again, our overall goal here is not just to develop a cool model or framework. But we hope it helps us really understand how we can maximize health outcomes and address inequities or help disparities in our implementation work and ultimately in the healthcare that we deliver.

So, I wanted to thank everybody for your time and attention. I do, again have the link to articles in the slide set. There's also a link here to Dr. Leslie Sternham's Facts (SP) Lab. The Resources section of that website has a ton of information and detail.

And if you'd like to use the Frame IS for an upcoming project I mean, we'd love that, right? So, I've got my email address linked here as well as my Twitter handle.

And I believe that takes me through the presentation. So, thank you, everybody. And I'm happy to hopefully address some questions here. I can't see the chat right now. Christine, I don't know if you want me to leave my slides up or if I should stop sharing? What makes sense—

Heidi Lynchburg: Why don't we leave—

Dr. Christopher Miller: --to you?

Heidi Lynchburg: Why don't we leave the slides up? Sometimes we get questions that you want to refer back to a slide. You'll have that available for that.

Dr. Christopher Miller: Sounds good.

Heidi Lynchburg: Okay.

Dr. Christopher Miller: Thank you, Heidi Lynchburg (SP).

Heidi Lynchburg: We do have a few pending questions here. For the audience, if you do have a question, we have plenty of time for questions. If you do have a question, please send those in using the Q & A screen.

The first question that we have here, "There seems to be an underlying assumption perhaps that only one implementation strategy would be utilized to facilitate the implementation of an intervention. Is this true? And do you have an opinion about an effective number of implementation strategies to use for an EBP?

Dr. Christopher Miller: Yes, that's a great question. And, you know, I don't have a hard and fast answer. I mean, I think as we want to acknowledge here, oftentimes implementation strategies do get added on top of others, right?

So, if your situation is simply that you are going in from the outset, combining multiple different implementation strategies, then you may just want to define that, you know, right there in Module I, right? That our baseline implementation strategy is actually a combination of two. And then, we'll document modifications beyond that.

In contrast, it may make more sense to frame this as we're starting with a baseline implementation strategy. And then, one modification we are making is integrating components from other implementation strategies as a modification.

My gut tells me that which of those two views you take will depend on whether one is really considered the primary to which you're adding versus if they're really kind of co-equal implementation strategies from which you're starting.

Either way, I think the most important thing is clearly communicate that as you're writing things up. Again, I think sometimes it's going to take more than one implementation strategy and that's fine. When it comes to the use of the Frame IS, I think it comes down to just clearly delineating how you're viewing that, so you don't end up confusing yourself or your reader about what's a modification to that two implementation strategy package versus whether one of those is really modifying the other.

Heidi Lynchburg: Great, thank you. The person sent in additionally, "This seems to assume discreet implementation strategies being used rather than comprehensive implementation strategies. Is this a correct assumption?"

Dr. Christopher Miller: Yes, that's a great question. And I wouldn't say that that assumption is kind of fully settled, right? We suspect that this may be more useful for relatively more discreet implementation strategies.

Having said that, you can use the Frame IS even for relatively complex multi-component implementation strategies. For example, you know, if you've got a very complex one like implementation facilitation, but you're switching from kind of face-to-face implementation to something remote for Covid-19, you could still document that using the Frame IS as a context modification of implementation facilitation.

But having said that, I think a fundamental assumption of this is that you're starting with something that at least is clearly defined because documenting modifications to something that's so fluid that every modification can be subsumed under it would be a bit of a hard sell.

So, I think honestly, we don't necessarily know yet exactly how applicable this is to the complete universe of implementation strategies that are out there. And certainly, we want to acknowledge that documentation is going to be harder for some than for others.

Heidi Lynchburg: Great, thank you. The next question here, "Can this be used ass a retrospective set of activities rather than prospective activities?"

Dr. Christopher Miller: Yeah, I think probably the answer is yes. It can be done retrospectively. I think it remains to be seen whether that retrospective recall, you know, leaves something out. But certainly just thinking of the example that we talked about in the manuscript—the PCIP.

I believe that Dr. Barnett went through and essentially completed the Frame IS retrospectively. I don't think that this was something where she was documenting modifications throughout.

So, if I can scroll back here to PCIP right here, right? So, what was done here under Example Completion was done retrospectively.

Again, I think that that kind of retrospective completion is probably going to be more effective when you've got, you know, a really clearly delineated set of modifications that were made at a really discreet time, right?

Like the examples that were included here. If the modifications you're trying to track are the more kind of emergent modifications, the reactive modifications that may change from month-to-month or even week-to-week, that might require more periodic data collection throughout the implementation project rather than simply a retrospective lookback after three or six months of implementation.

So, I guess tying it all together remains to be seen. But I don't think that doing this retrospectively is necessarily a bad idea.

Heidi Lynchburg: Great, thank you. The next question here, "This is so interesting. Thank you. Two questions—1) If you do something to facilitate the implementation of a practice that is not evidence-based, but is obviously beneficial such as increase in communication among staff in an emergency department, would you count that as an implementation strategy?

And 2) Can you say more about a strategy such as audit and feedback as a standalone strategy versus integrated into another strategy such as facilitation?

Dr. Christopher Miller: Sure. Can you go back and read the first question again?

Heidi Lynchburg: Of course. "If you do something to facilitate the implementation of a practice that is not evidence-based, but is obviously beneficial such as increase in communication among staff in an emergency department, would you count that as an implementation strategy?"

Dr. Christopher Miller: That is a good question. I guess I think there are multiple ways to conceptualize that particular approach.

So, I guess from that perspective, you know, if the goal of the increased communication is to get the emergency department staff to do some kind of events-based practice more, then I guess I would consider that an implementation strategy.

So, in that case, communication training is implementation strategy with the ultimate goal of increasing uptake of some kind of evidence-based practice setting. I think you could conceptualize it that way, but don't quote me on that.

Again, I'm going to go back to Jeff Curran's work and just say that it's really important to kind of just clearly lay out to the extent possible what's the specific EBP you're trying to get into play and then what are the specific implementation strategies?

And then, if we accept that premise—if we accept the idea that some kind of communication training is an implementation strategy, then if you change the way you're training people to communicate, that might be considered a modification to that implementation strategy even if the implementation strategy itself—namely the communication training—doesn't have a robust set for evidence-base.

But again, I'd be happy to talk about that more offline too. That's a hard one to kind of really lay out. I'm kind of just verbally visualizing it in my mind.

And Heidi, what was the second question?

Heidi Lynchburg: The second question, "Can you say more about when a strategy—such as audit and feedback—is a standalone strategy versus integrated into another strategy such as facilitation?"

Dr. Christopher Miller: Yeah. I think the key to lineation there would just be is there another strategy going on at the same time. I mean, the way that at least I conceptualized it is that audit and

feedback is in and of itself an implementation strategy. I think it's one of the 73 ERIC strategies that's listed.

And so, if you're doing audit and feedback like that's the thing you're doing to get these providers to change their behavior, then I guess that would be standalone. If in contrast, the audit and feedback is being delivered alongside a bunch of other work from an implementation facilitator working with some kind of champion or internal facilitator at the site?

In addition to the audit and feedback that is if the audit and feedback is just one thing that's going on amongst a broader sweep of things being done to help get those providers to change their behavior, then I think that that could be considered a modification or an add-on.

But again, a lot of it depends on the timing, right? It's just that we're doing implementation facilitation. And then, we're building in a robust audit and feedback component or we're doing audit and feedback. And then, realizing that it's not working very well and we're adding on some additional facilitation support.

In the latter case, I would think that the modification would be adding some components of implementation facilitation to a baseline of audit and feedback rathe than the reverse. I hope that's helpful.

Heidi Lynchburg: Thank you. Next question here. "What are the principles to separate the core of an intervention from its adaptable periphery using Seefer (SP) terminology?"

Dr. Christopher Miller: Oh my goodness. I'm going to acknowledge that that is a really, really hard issue and that's one that other people have published a lot more stuff on than I have. I think about Brian Mitmin (SP) and his work alongside other really, really good researchers related to kind of core functions versus core elements.

I honestly don't have a clear sense for evidence-based practices. A lot of it really gets down to, "What do we think are the mechanisms by which this EBP is really improving clinical care/improving the outcomes of our patients?"

When it comes to implementation strategies, I think what's core is considered one of the things that are fundamental to actually getting providers to change their behavior or patients to change their behavior, so that this EBP is actually used kind of more basically.

So, I'm sorry. I kind of stumbled through that answer. But the short answer is that's a really tough question and I defer to other people in the field that have done a lot more research on that than I have.

For our purposes here, it's really left up to the person completing the Frame IS to determine whether it makes sense to try to delineate whether something was really

changing the essence of what the implementation strategy is versus kind of changing the kind of little pieces that are changing around that.

Heidi Lynchburg: All right, thank you. The next question here, "How would you ideally analyze this data that you receive on modifications using the Frame IS modules?

Dr. Christopher Miller: Yeah, that's a great question. I think one way to do it, if you have, you know, if you have let's say an implementation project that's a multi-side implementation project and you have kind of a robust picture of how implementation proceeded the site, something that might be useful to notice things like which modifications were made at the sites that did the best.

In contrast, so there were modifications that were made at sites that didn't do so well. Now there may be a third variable problem there in that certainly one of the reasons people may modify their implementation strategies is because there are contextual challenges or other big barriers at the site that need to be overcome.

And so, just because a certain modification was made with a certain site. And that site's implementation didn't go so well. That doesn't mean you can necessarily attribute the lack of success to the modification.

But at the very least, if you have a multi-site trial and you're tracking modifications at each site individually, you can use that as data to reflect on maybe which modifications seem to be effective versus not. And you can then use that moving forward at other sites and implementation across those sites.

So, that's I think the big one. Again, that's the Holy Grail—the one where you use this to actually reflect on which modifications were most successful in which settings.

Heidi Lynchburg: Great. Thank you. The next question here, "Would you say more about your use of the term 'planning'? To me, 'planning' is forward looking. And so, the idea of reactive planning sounds like an oxymoron.

But I think it's meant to describe when modifications are made as part of a learning process that is in response to things that are learned in the process of implementation. Is that correct?"

Dr. Christopher Miller: Yeah. I like the latter half of that question so much I'm just going to say yes. I think that's a great example of a planned, but reactive modification, right?

So, it's some kind of issue that comes up in the middle of an implementation project. And it demands some kind of reaction. But even though the timeframe is tight, you know, the Implementation Team gets together and plans through, "Here is what we

want to do in response to this unforeseen challenge." I think that would be a good example of a reactive yet planned modification.

Heidi Lynchburg: Great, thank you. Next question here, "Is thee a simple Excel type template for Frame IS? If so, how can we get a hold of it?"

Dr. Christopher Miller: Yes, that's a great question. I think that on Shannon's end that may be in development. And I believe as well for the piloting of the Frame IS, Dr. Goodner as well may have an example of that.

So, if you want to email me or check out the Fast Lab website, we can certainly try to connect you to whatever resources we have to make this as completable as possible.

Heidi Lynchburg: Great, thank you. Just to interrupt questions for a second, I see we got a request in for a slide deck for today's presentation. The link to the slide deck was included in the reminder that was sent out this morning.

So, just refer back to that email. You should've received it 2-3 hours before the session. If you cannot find that reminder, we are recording today's call and we will send that link out as soon as that is posted. You will also be able to access the handouts from that link.

Okay. The next question here, "Do you have any recommendations on how to best collect adaptation information from providers or sites that is not too burdensome? For example, we are using Frame to ask site points of contact these questions at various timepoints."

Dr. Christopher Miller: I think that my gut reaction is that, you know, certainly in that case, if you're looking to minimize burden, I would probably not go with Modules V, VI and VII. It may be too much of a documentation burden.

Other options include, well, first I think thinking about who should be the one completing the Frame IS, right? If there is in fact, somebody external to the sites like an implementation facilitator or a trainer, it may be that they are well positioned to document the changes made to the implementation strategy or if the frontline clinicians may be better positioned to document changes to the EBP itself because that's what they're delivering.

So, I'd think carefully about whether there's somebody other than frontline staff who can document changes made to the implementation strategy itself. And it may very well be that you look at the core modules and you say, "You know what? We need to limit the number of check boxes. We think that these particular types of modifications to the implementation strategy just aren't very likely."

And so, maybe we don't include those in administering our modules. So, hopefully retaining some of the check boxes as originally intended in the Frame IS.

But again, a lot of this is really up to the field. A lot of this is really up to you folks as to what's useful about this. We aim to be comprehensive with the Frame IS. And of course, we'd love if it would be used as closely to its kind of distribution version. But we acknowledge that if the choices between overburdening people or kind of trimming down just to what you think is happening, then that may be better than nothing at all.

Heidi Lynchburg: Great, thank you. The next question here, "Do you believe that we really have enough descriptive information about the ERIC implementation strategies to know how to utilize these strategies?"

Dr. Christopher Miller: I guess I know that Eric, I mean, there are a lot of different strategies. My understanding is that kind of science of implementation _____[00:51:24]

Heidi Lynchburg: Chris, I think we've lost your audio a little bit.

Dr. Christopher Miller: Oh, I'm sorry. Can you hear me now?

Heidi Lynchburg: There we go, yep.

Dr. Christopher Miller: Sorry about that. That's what I get for walking around while I answer this. I was just saying that I think that in order to kind of bypass that really thorny challenge, that's why for the Frame IS we kind of start right with Module I as simply acknowledging, "Okay. What is the implementation strategy you're using?", right?

And whether that's something that's listed under ERIC or another implementation strategy that incorporates multiple of the ERIC components, that's kind of the view that we take for the Frame IS because we acknowledge that, you know, those ERIC strategies, there are a lot of them. And in many cases, multiple of those are being used even in context of one implementation project.

Heidi Lynchburg: Great, thank you. The next question here. "I'm curious about how you may go about establishing a reliability and validity of this tool within a given trial. I'm thinking about the different strategies we use to establish reliability to blinded outcomes/assessors for quantitative research and reliability of coding for qualitative research."

Dr. Christopher Miller: Yeah, that's a great question. And I think not to punt too much on that. But I think to a certain extent, that is really going to be dependent on future work, right?

Could you have for instance, each of two kind of implementation trainers or champions each independently complete the Frame IS based on the work that they kind of collaboratively did with the site? I would think that might be one way to really establish the reliability piece.

But certainly, to a certain extent—at least the way that the Frame IS has been developed so far—that's an open question about kind of how reliable people are and how valid their ratings are given that people may for example, not want to admit that they've changed implementation strategy.

So, another thing might be to combine completion of the Frame IS with things like time tracking. I know for some of our implementation projects we have implementers kind of peering up to track the time we spend and on what activities. And it may very well be that that could be then put next to the Frame IS to look at whether there seems to be some kind of concordance between the kind of line-by-line of what people said they were doing and what overall kind of modifications they, you know, make into the implementation strategy. But I want to acknowledge that's kind of an open field at this point.

Heidi Lynchburg: Great, thank you. The next question here, "Can you provide an example of how to explicitly consider health equity in Module IV based on your PCIT example?"

Dr. Christopher Miller: Sure. So, going back to Module IV, we've got PCIT. Here we got. "What is the goal and what is the level of rational modification?"

So, I think in this case, right? Looking at the modification to Module IV to specifically kind of changing the language was increasing the kind of aim to increase in the appropriateness.

So, it may very well be that one could consider those modifications for the language as a way of increasing health equity or decreasing disparities in EVP delivery in the sense that perhaps the changed language in this lay health worker training is going to be a better fit for the population in question.

Also, thinking about removing the behavioral coding component, my understanding is that that was undertaken really just to be a better fit with the population even if it wasn't necessarily squarely aimed at kind of decreasing health disparities.

So, I do think that the modifications that we talked about in Module IV for the PCIT? I mean, I think the primary kind of goal was really to increase the acceptability, appropriateness, and feasibility. But it might very well be that another checkmark there should've gone into increasing health equity or just decreasing disparities in the

EBP delivery given just the population then being served ultimately with the basic population in California.

So, I don' know if that answers the question. But certainly acknowledge that it might well have been a good fit to kind of include an additional checkmark for that modification.

Heidi Lynchburg: Great, thank you. The next question here, "How important is it to track adaptations to the intervention being implemented in addition to adaptations to the implementation strategy? Seems that those could be very different from each other."

Dr. Christopher Miller: Yeah. I think my gut reaction is that it is a great point and I think it's very important to track those modifications as well, you know. The idea being that if you don't track modifications to the EVP, right?

Then you'll be uncertain at the end of the day. Well, is it that the implementation strategies was a bad fit? Is it that these modifications were a bad fit or is it that the frontline clinicians, or the administrators, or the clinical leaders were changing the EBP in a way that didn't necessarily lead to good outcomes, right?

So, when it comes to this kind of tracking, I think that is a great argument in favor of using the frame alongside the Frame IS, so that if you get good or bad outcomes, you kind of have a sense of what was going on and there's not kind of a gap in your understanding that might be responsible for those good or those bad outcomes.

Heidi Lynchburg: Great.

Dr. Christopher Miller: And maybe that's—

Heidi Lynchburg: Yep.

Dr. Christopher Miller: --technology. We're near the top of the hour. I know I have a patient at the top of the hour. So, maybe one more question if that's okay, Heidi?

Heidi Lynchburg: You know, actually we only have one more question. So, that works out really nicely.

Dr. Christopher Miller: All right.

Heidi

Lynchburg: Our question here, "The part in Module II in how implementors are trained can be confusing in practice. Many stakeholders think of implementers as for example, the clinicians doing the thing with or for patients rather than the people helping the clinicians do the thing.

The fact that training itself can be an implementation strategy may add to the confusion. Thoughts?"

Dr. Christopher Miller: _____[00:58:05]

Heidi Lynchburg: Chris, we're not able to hear you.

Dr. Christopher Miller: Hello? Can you hear me now?

Heidi Lynchburg: We can, yes.

Dr. Christopher Miller: Okay, sorry about that. Just my gut reaction is yes, that is a confusing distinction. We go into a bit more detail on the paper. And especially the supplemental material—the additional material from the paper—which has a little bit of extra detail for each module.

But yes, we certainly want to acknowledge that if the frontline clinicians delivering the EBP are also considered the ones kind of doing the implementation, that can create a lot of really hard distinctions to draw. And so, I think my overall feedback there is to make sure you're clearly delineating who's in what role.

And to the extent possible, really kind of making a clear distinction for those frontline staff. Are they really the implementors? Are they the people helping get the thing done or are they the people doing the thing if that makes sense?

Heidi Lynchburg: Makes sense. And that is all of our questions. We're at the top of the hour here. I know that you need to run to a patient. If you need to run, I'm just going to let Christine wrap things up and we will close the session out.

Dr. Christopher Miller: Okay.

Heidi Lynchburg: Thank you so much Dr. Miller.

Dr. Christopher

Miller: Thank you, everybody for your attention again. Do reach out if you have questions. And yeah, I'm going to sign off, but I really appreciate it.

Heidi Lynchburg: Thank you. Christine?

Christine Kowalski: Yes?

Heidi Lynchburg: Do you have any closing remarks?

Christine Kowalski: Just thank you so much, Heidi, and thank you to the audience for their wonderful questions. And of course, thank you to Dr. Miller. We'll be back.

There are no sessions in August, but we'll be back in September with a session with Dr. Russ Glasgow and Dr. Boris Levin (SP). So, please be sure to tune in for that.

And thank y'all so much. Have a good afternoon.

[End of Recording]