Jill Harrison, PhD:

Hi, this is Jill Harrison, Executive Director of the National Institute on Aging IMPACT Collaboratory at Brown University. Welcome to the IMPACT Collaboratory Grand Rounds podcast. We're here to give you some extra time with our speakers and ask them the interesting questions that you want to hear most. If you haven't already, we hope you'll watch the full Grand Rounds webinar recording to learn more. All of the companion Grand Rounds content can be found at impactcollaboratory.org. Thanks for joining.

Susan Mitchell, MD, MPH:

Hi, I'm Susan Mitchell, one of the PIs of the IMPACT Collaboratory, and today I have the pleasure of hosting a podcast with Dr. Shannon Wiltsey Stirman, who's an Associate Professor in the Department of Psychiatry and Behavioral Sciences at Stanford University, and recently gave a Grand Rounds at IMPACT entitled Adaptation of Behavioral Interventions and FRAME. I really enjoyed your Grand Rounds.

Shannon Wiltsey Stirman, PhD:

Thank you. Yeah, it was fun to do. It was really a nice group to talk with and hear a little bit about what people are working on and what they're trying to adapt and use FRAME for.

Susan Mitchell, MD, MPH:

Yeah, we use it all the time in IMPACT. As I mentioned at the Grand Rounds, it's actually one of the key guidance materials that we give to our pilot applications because so many of them include some form of adaptation of their interventions that they're proposing to pilot tests for a pragmatic trial. Actually one thing that comes up over and over again, and you definitely touched on this in your talk, but maybe we can just chat about it a little bit more, is that, the question is how much adaptation is too much adaptation in the sense that we're all familiar with the NIA stage model and we at IMPACT are looking at pilot studies and demonstration projects for stage four effectiveness trials or pragmatic trials.

And, as I mentioned, a lot of these studies are coming to us with some level of adaptation. We talk a lot with our NIA Project Scientist, Dr. Lisa Onken, about how much is adaptation that we can live with for the funding mechanisms or how much is it so adapted that really the best course of action for the investigator is go back to more of a stage one or two work to see if their adaptations are efficacious. Any guideposts at all for us about how much adaptation is too much adaptation and how much could we live with within this paradigm?

Shannon Wiltsey Stirman, PhD:

Yeah. I mean it's a good question and you're touching on exactly what the challenges are with it. I think that some of what can be useful to help guide decisions around that is thinking about the form versus function distinction. If you have a fidelity measure and you have what are thought to be the unique and essential items or elements of the intervention, it can be good to check in with your adapted form and see if you are still hitting all of those elements, if not in the exact form, then in terms of the function. A really simple example I give is around providing education, and that can be done in lots of different ways. Maybe in the original protocols it was done through a discussion between the provider and the patient or the patient's family, but you might need to move it to something where maybe a different provider does it, maybe it's done by watching a video together and discussing, or it's a pamphlet that people read and then they're just asked if they have any questions.

But if the key element is accomplished in some way, then we would say that that fits. I think it gets a little bit trickier if the form starts moving so far away that people wouldn't recognize that it's actually performing that function, if that makes sense. So the form and function distinction I think can be helpful

in terms of thinking about are these key elements represented in some way and at a reasonable enough intensity that people would recognize it's happening. Using the fidelity tools and guidance that you have, but considering whether different elements might need to take a different form can be really helpful. And then if all of the elements are represented at a dose that approximates what was in the original intervention or if you have a strong rationale for having more or less of it, but it's there, you can consider that.

But I also think that it's really important to measure and document what's happening with the fidelity when you're actually doing it and look at your outcomes. Because in some ways, even if we a priori say, "We don't think this has gone too far. We still recognize it as the intervention," if it's not effective when you do it, you're of course going to look at is it because it was too heavily adapted, because it's not a good fit with this population, because there's something else that we haven't measured or identified going on. But leading up to getting your outcomes, I think we have to be thinking about fidelity at least to the key functions to guide us in whether we're going too far or not.

Susan Mitchell, MD, MPH:

So maybe I'll get a concrete example of something we typically get. We do get a lot of applications wanting to evaluate deprescribing interventions, and often these deprescribing interventions were initially tested in older patients, a sort of mixed population of older patients, and now they want to try the deprescribing intervention specifically among people living with dementia. So we're going from a general population of older people to people living with dementia. They'll modify it, some materials. They may actually modify who gets the intervention. It could be directed this time to the care partner instead of the patient themselves. So the function's the same, but it's actually implemented quite a bit differently in the population with dementia because now you're giving it to the care partners. How would you think about that example?

Shannon Wiltsey Stirman, PhD:

I mean, it sounds like at least the way we categorize in the FRAME, the recipient population would be somewhat different, so you might need to adapt how you talk about it, how you provide the rationale. It would help to know some of the steps involved in doing that, but yeah, you might need to adapt because your population's different. They might be younger, they might have other considerations and questions and concerns. But I think if the function is the same and if in some ways you're providing the rationale, you're taking the steps, but you're doing it with someone different, then it's an adapted form of the intervention and you'd probably want to represent that in the way you talked about it. You wouldn't want to just say, "We implemented the blank intervention for a deprescribing." You'd want to say, "And it was adapted for caregivers," and describe it well enough so people could understand how it was adapted.

The translational stage is a good question. I think you'd still say it was further out along the spectrum because you already had data, you're just turning it in a little bit of a different place. You do still have to see if it works in that context, but I think if you could recognize that it was basically the same set of steps and basically the same functions, just involving the caregivers more, you could say that that was, well, "The same intervention adapted for a somewhat different population."

Susan Mitchell, MD, MPH:

I have the hat on to say, "You need to go back." You go back to stage two and see if this could work, efficacy-wise, in care partners. And then if it does, come back and think about a pragmatic trial.

Shannon Wiltsey Stirman, PhD:

It makes perfect sense why you want to do the earlier stages, but when you have some sense that something can work and you don't want to delay, and ultimately it's going to be deployed in these more uncontrolled contexts, testing it under the best of circumstances with a two-year delay, it asks the question of, great, if we know we can do it under these best of circumstances now, we still have to take it out into the less ideal circumstances, the more challenging set of circumstances.

Susan Mitchell, MD, MPH:

That's super interesting, and we wrestle with this question all the time. My next question, similar but different, we are very focused on health equity at IMPACT, and again, not infrequently we get pilot studies that are adapting an intervention that perhaps was used in a cohort of people living with dementia and now they want to use a particular intervention in let's say a Latino population or some other minoritized population, and so again, we're talking about adaptations. Can you just give us some thoughts about adapting along health equity lines and really do we just think about it the same way or are there some special ways we should be thinking about it?

Shannon Wiltsey Stirman, PhD:

I think in some ways you think about it in the same way, but I think that what becomes really important is to make sure... Anytime we adapt, we don't want to just assume that we're going to have to adapt because it's going somewhere new or to a different population. We want to have some understanding of what would make us need to adapt, which means that you need to have involvement of the community, of representative recipients, family members, et cetera, so that you can really understand what wouldn't work here the way it was originally designed. What would we need to change and why? Having that input I think is really essential. So we don't make a lot of assumptions so we get it right. That's really true I think in any context that you work, but I think it's also really important because the people that you're working with, it's important that they understand that really was designed with and for them in this new iteration and not something that's just being dropped.

That process of understanding becomes really important I think, in making sure that people don't dismiss it out of hand, making sure that people understand that it really is and is intended for them, and that they were heard in terms of what might be important to adapt in terms of fitting better with the culture, with the context, with their needs, with constraints so that they're not being asked to do things that are unrealistic or things that just run counter to the way things are typically done in their community.

Susan Mitchell, MD, MPH:

That makes a lot of sense. My last question really is getting a little bit away from the specific science, but talking about your investigators should think about their research team. Any recommendations, or again, guideposts or thoughts about when do you involve implementation scientist experts such as yourself on the research team or when is it enough to just go to the literature? I mean, do you think an implementation scientist expert should be on any ePCT that's testing an intervention in the real world, particularly if there's adaptations?

Shannon Wiltsey Stirman, PhD:

Some of it will depend on the questions that the grant is asking. I think there are times when actually someone with a lot of experience implementing who has some background in implementation science, but I mean I think there's value in having an implementation practitioner, so to speak, available even if

they haven't been on lots and lots of grants. They've got a deep set of experiences and have an understanding of implementation in the literature. If what you're trying to do is implement something and look at effectiveness, if you're doing a study where implementation science outcomes aren't critical outcomes, you might be okay. I think that designing and piloting with some input from someone who has some expertise in implementation can be really important so that you can hopefully head off some of the challenges that you might run into later, like making your fidelity assessment strategy too burdensome or doing something that just couldn't possibly work within the constraints of the healthcare system.

But in that context, you also need your partners' input. So sometimes the implementation scientist can be helping you think about the questions you need to be asking or what you need to be doing in your needs assessment. It depends, the extent of involvement or whether you need involvement at all, probably has more to do with the questions you're asking in your research, but if you're ever intending to get it out into routine care settings or to the community, I think it can be a good idea so that you can make sure that you're designing your research and designing the intervention and your implementation assessments in a way that'll be feasible and likely to not need lots of adaptation down the road.

Susan Mitchell, MD, MPH:

I've really come to appreciate the expertise I receive from my implementation science colleagues, and we are fortunate to have a great group of implementation scientists in IMPACT. We really appreciate everything and we really also appreciate your contributions to the field, which I think has helped make our IMPACT projects better and also helped us be able to guide our investigators in a more thoughtful, rigorous way around implementation, implementation, adaptation. So thank you very much.

Shannon Wiltsey Stirman, PhD:

Thank you. And thank you all for the work that you're doing. It's fantastic to see the work that's coming out and the work that everyone's focusing on. It's a super important area, so thanks for the work you all do as well.

Jill Harrison, PhD:

Thank you for listening to today's IMPACT Collaboratory Grand Rounds podcast. Please be on the lookout for our next Grand Rounds and podcast next month.