Jill Harrison: 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: Thanks everyone for joining. I'm Susan Mitchell, one of the Impact Collaboratory principal investigators and I'm happy to be hosting this podcast. It's a followup to our Grand Rounds, which happened last week and that was called Implementation in ongoing ADRD ePCTS or pragmatic trials in different healthcare settings using real examples. And the Grand Rounds really got into the nitty gritty of implementation challenges in these types of trials. And I'm joined today by four the presenters of that Grand Rounds. Ab Brody, Jessica Colburn, Ellen McCreedy, and Brian Mittman. And at the Grand Rounds, Ab and Jessica and Ellen presented their implementations experiences for an actual EPCT that they're leading for people living with dementia and Brian provided some extra expert commentary. Let's dive a little deeper into these issues. Hi everybody, glad you're with us. My first question's for Jessica.

Jessica, one of the unique challenges we're becoming very aware of in our supportive trials for dementia populations is the dyadic nature of the participants, namely the person living with dementia and their care partners. And this challenge really impacts every aspect of a pragmatic trial design from recruitment to analysis, but it's especially pertinent for implementation challenges and especially for advanced care planning interventions, because we have to consider how and when to involve just the patient, just the care partner or both. Can you speak to how you approach this implementation challenge in your trial?

Jessica Colburn: Sure. Happy to comment on that. The trial that I discussed last week is our trial on advanced care planning in primary care, working with older adults with and without cognitive impairment and their care partners. And in the pilot, we actually only enrolled older adults who had care partners to participate because we wanted to test the feasibility of how well that would work. And we found actually that both our participants and their care partners really appreciated the opportunity to discuss these important issues. And in fact, we had good uptake in the trial. Even for people with cognitive impairment, of the 12 people who we thought had cognitive impairment, 10 of them ended up participating.

We are now in the process of rolling out the pragmatic trial. And in the trial, we will enroll people whether or not they have a care partner, though the encouragement is going to be to involve the care partner for several parts of the intervention. One, for the advanced care planning conversation, but also for the agenda setting checklist which we use to help older adults and their care partner plan for a visit and how each of them will be involved and how they

each have different concerns or questions for the provider. And also the proxy access to the medical record. We found in the pilot that because of those different pieces of the involvement that that really helped the care partners see that advanced care planning is one part of the continuum of being involved in helping someone with their care.

Susan Mitchell: When you thought about who you were going to send the information about advanced care planning, et cetera, was there much consideration or complications relating to deciding whether a certain patient with dementia was able to understand and receive that information?

Jessica Colburn: We did have some information with that related to training of our facilitators. Helping the facilitators become comfortable with assessing when they were talking to a participant, whether they had capacity to understand the conversation and involvement of the care partner there, as well as what to do if the participant themselves, the older adult themselves could participate quite a bit in the conversation versus not very much in the conversation. How to kind of do that back and forth with the dyads, since they each have their own concerns. And even in early stages of dementia or especially in early stages, many older adults can participate themselves in the conversation. And so also there was training for the facilitators as part of the original respecting choices curriculum we use as to what to do if there are differences in opinion and what to do if the differences in opinion or thought seemed to relate in part to the patient not fully understanding the conversation. And then any of those nuances often go back to the provider, the physician or nurse practitioner to help sort out the capacity piece for the older adult.

Susan Mitchell: That's great. I've seen a few applications come in through Impact that are trying to evaluate advanced care planning interventions like yours in different settings. And I think don't underestimate the challenges you've overcame. And so there might be some learning that you can give to the community about how you approach this dyadic issue in your implementation.

Jessica Colburn: Well, thank you for saying so. I think one of the things we're most excited about with this is the involvement of thinking of them in a dyad and thinking of that dyad partnership across the continuum of assisting with care. The advanced care planning, but also as part of working towards advanced care planning, that it isn't only end of life care that the care partner is helping with. And so how to make decisions all along that way and how to help primary care teams partner better with care partners in that way.

Susan Mitchell: Great, thanks. I'm going to turn the next question to Brian. At Impact, we've really been struggling with the question of what types of interventions we feel are ready for funding through our pilot program. And one of the main concerns has been the challenge associated with assuring a proposed complex or multi-component intervention can be implemented with fidelity. In fact, one solution suggested to us was that we really just focus and select interventions that are

not complex, but rather simple in preventions like nudge type intervention. Can you comment with this? And is this a reasonable approach? Or is dementia care so complex it has to be addressed with complex solutions and interventions?

Brian Mittman: But it's an important question. And I would lean in the direction of the latter that we do need complex interventions often multilevel. And obviously there's a trade off as you've suggested. And sometimes I'll view this as akin to the story of the drunk looking for his or her keys under the lamppost. They were not lost there. We know that that's not the right place to look, but there's light so it's easy. And that's akin to this situation because we know how to both design, deploy and more importantly, evaluate in a rigorous manner, simple single component interventions. And so we have a bias towards trying to find those solutions, but in my view, both in dementia, as well as many other clinical domains, those interventions are simply too little too late. They don't address the full spectrum of barriers and constraints and influences on the desired practices and therefore they're not likely to achieve the change that we desire.

In my view, we're sort of stuck with the need to both design and deploy and again, evaluate multi-level, multi-component complex interventions that are adaptable and to do so in a way that sort of redefines the way that we think about fidelity, rather than thinking about fidelity to a manualized intervention with the details laid out in a very highly detailed manner. We need to step back a bit and think about the core functions or the purposes of each component of the intervention and think about the kinds of adaptations or local tailoring that might be permitted so that for example, a patient education activity that might be scripted in a typical manualized intervention, we may want to think about alternative ways of achieving those educational goals and allowing for more flexibility or more tailoring to provide written forms of education or physician interventions, nurse educational interventions, in some cases, peer interventions and others.

Identifying the core functions and the purpose in trying to achieve fidelity to those core functions, while allowing for the local tailoring, may be a way of essentially having it both ways. There may be rare instances where a simple intervention might be sufficient and might address the dominant barrier or barriers or constraints. But again, as I indicated, generally speaking, these problems are sufficiently complex that we need to deploy interventions that address patient and caregiver considerations, staff considerations, organizational, oftentimes community, regulatory fiscal and we're sort of forced to grapple with the complexities of the complex interventions.

Susan Mitchell: Great, thanks. It's a very interesting dilemma in some ways. I had a conversation with a colleague who knows a lot about EPCTs and we were commenting about how so many of them turn out negative. And in fact, this person's view on that is that some of them are so light touch that they really don't get at the issue. I guess just turning to very simple interventions, doesn't really sound like a solution. Thank you, Brian.

Dr. Brody. Your trial's very interesting because it's one of the very few EPTs I know about that takes place in a community hospice healthcare system. A lot of them more have been done in nursing homes or hospital settings. What do you consider some of the unique implementation challenges in this particular setting for pragmatic trials?

Ab Brody: I think when you move out into community based settings, I have one in hospice and one in home care, but I think you could probably say the same for a lot of disseminated primary care practices for instance, is that the entire organizational infrastructure is different. The healthcare clinicians and others within those organizations are all disseminated so you can't necessarily use the same sort of methods of peer to peer contact that you would expect. And then it varies even within those groups. For instance, hospices, by the nature of what they do, have for the most part weekly or bi-weekly interdisciplinary team meetings, which is a pretty good intervention and inflection point. And home care doesn't really have that same infrastructure nor do primary care clinics. And so I think this idea of how you work with a disseminated group of clinicians or staff that are not going to be in contact with each other frequently, plays a huge role because there's less mentorship that can be provided or touch points for reminders or modeling. And I think that becomes a huge issue.

And then once you move out of academia, I think the other issue is you run into organizations that are not necessarily used to doing research and that can be a good thing because they can be very energetic and engaged and excited to be participating in something different. But there's also certain lack of understanding that can occur or lack of capacity to carry out certain portions. And so I think there are some really great pros in terms of this is where a lot of people are, but at the same time, there are some infrastructure and experience issues that do need to be overcome that aren't necessarily the same as academic medical centers or nursing homes where there are a lot of people congregated in one place.

Susan Mitchell: Well, I would assume that since you're doing groundbreaking work in this area, you are setting up the field for doing these types of integrated studies in hospice systems in the community and will be a great service for those who continue to do research in that area.

Ab Brody: Yeah. There've been a few others, not many in Alzheimer's disease and related dementias, but there are so many opportunities, especially as we move towards more home based and community based care options to get out of the academic medical center. And it also helps with issues of diversity and equity, because you can reach populations that may not be involved at academic medical centers or being seen at academic medical centers. And so I think there's a huge opportunity to reach people where they are, which can have huge influence on the system. And it's just figuring out how to do it the best way within those settings.

Susan Mitchell: Yeah. Well, thank you. And lastly, I'll ask Dr. McCreedy a question. I think Ellen, you're probably among the group, probably the furthest along, or pretty far along in your trial, the music and memory trial. And so I'm going to ask you that extremely painful question. In hindsight, if you could redesign or adapt your implementation strategy now, what would you do differently? And I know Brian's a big proponent of learning and adapting, so with that in mind.

Ellen McCreedy: Yeah, we have plenty of lessons learned already. We've completed the first parallel trial and we're to complete the second later this year. Some of the biggest learnings are really related to the implementation strategy and the engagement of nursing staff, which came up during the Q and A after the talk, after the Grand Rounds. And this is a challenge, this is a really tough nut to crack and really it's that frontline nursing staff and nursing staff in general are not taught to use these non-pharmaceutical interventions. They're not trained to think about music and art and sensory interventions as alternatives to using medications with patients. And so it's how do you really find those champions within an organization? And how do you engage them? And how do you give back the proper training all the way down to frontline staff to start thinking, noticing early signs of agitation differently and reacting differently?

I think that what we would have done differently is really have this be more focused on CNA training as an intervention. There's some CNA specialization coming out, CNA, certified nursing assistant, are the frontline staff in nursing homes. There's some certifications coming out that really focus on dementia care, noticing symptoms of dementia and these non-pharmaceutical interventions. I think we would kind of set that as the incentive to participate is to really be, that the CNAs would receive some additional dementia training and then have the intervention kind of fold over on that and say, "This is one intervention in a suite of interventions that are in this non-pharmaceutical group. And after you complete the training and become certified, you would start to use it with residents as appropriate."

I think we would focus more on the nursing frontline education and then fold in the intervention as one example of a non-pharmaceutical treatment. Because I think that's where most of these studies are really lacking is there's an education gap and we're kind of throwing it on top and expecting there to be this shift without really addressing the core issue. I think we would probably realign the incentives and focus of the intervention that way.

Susan Mitchell: Thanks. That's an interesting point about incentives. And I guess maybe I'll ask Brian this, I think in a pragmatic trial, you want to make sure that whatever incentives are there, whether it's a certification or something else, that it's reasonable to assume that that incentive would be present in real clinical care and not introducing some sort of research only intervention incentive. We often get questions, can we provide incentives during a pragmatic trial? And again, I think you have to think about after the pragmatic trial, if that incentive is

something that could happen in the real world. Do you want to comment on incentives for implementation within pragmatic trials, Brian?

Brian Mittman: Sure. No, it's an important point. And it's an even broader point, I think, which is that all elements of the intervention need to be a sustainable. That when we think about an efficacy trial, very early stage, we essentially stack the deck in favor of a finding of effectiveness. We often will recruit so called healthy white males from high SES populations. We will provide not only incentives to patients, often to the clinicians, other staff, the systems. We will use grant funds to in some cases, hire staff or supervise staff, provide them onsite technical assistance. All of those elements that allow us to get an estimate of under best case scenario circumstances, whether this is likely to be efficacious. When we think about the efficacy phase, thinking about each of those elements and exactly as you said, whether they can be sustained, whether they can be replicated.

That's not to say that we shouldn't be trying ideas that may not be compatible with current infrastructure. There may be certain services that currently are not reimbursed, but if we find that they're highly effective, the kinds of regulatory and policy and reimbursement policy changes that would be needed might be attainable in the future. As with many other issues, there are trade offs. But I think the key point though is to consider each element of the intervention and to think about whether it is realistic, whether the external validity is present, whether it can be sustained after the study ends. And if not, what does that say about limitations in the external validity of the study and obviously at minimum disclosing those when we report the results is important. But ideally there would be a clear explicit path to facilitate sustainment and facilitate the ongoing continuation of those. And sometimes artificial supports and factors that allow the intervention to be maintained and allow it to be effective.

Susan Mitchell: Great. Thank you. Well, thank you all. This has been a great discussion. I think as Impact continues to evolve, we will also continue to learn from our experiences and challenges related to implementation in these types of pragmatic trials for people living with dementia and their care partner. I look forward to an ongoing discussion and ongoing learning and want to thank you all for your time and experience.

Jill Harrison: 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.