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.

Vince Mor:

Jennifer, Ariel, thank you very much for this extra time. This was a wonderful, wonderful Grand Rounds. That was very exciting to hear from these two pilot projects as to where they stand. And I have a couple of questions to sort of help embellish the responses we got to the great questions from the audience. So let's start with you Jennifer, I have then some questions for Ariel, and then for both of you. So first Jennifer: you mentioned that you were trying to measure the fidelity of the intervention as implemented to the model as designed, relatively speaking. How hard was that to measure? Could it have been measured more pragmatically in a way that might have been more convincing? What do you think?

Jennifer Gabbard:

Yeah, that's a great question. Yeah, and thanks so much. I'm excited to be here today. So I think one of the things that we tried to do with this study which I think helped make it pragmatic and be able to really measure fidelity is that most of the materials we actually embedded directly into the electronic health record, and we made those materials also structured data elements. And so when you build something within the electronic health record you can kind of have it like kind of free text where you can't really pull it and analyze it and track it, or you can do it as structured.

Jennifer Gabbard:

And so what we did was we had the tool that the primary care providers had to use to conduct the visits to be all structured, and so they could press buttons depending on how the patient responded. And they could also click that they didn't cover it or the patient wasn't ready to answer it. So we were able to really measure what components they've actually covered during that visit, which components they didn't cover, and we were able to easily measure quality that way. And then they also kind of tracked if a care partner was with them and how the visit was conducted, if it was video or through telephone. So it really made it easy and pragmatic to be able to really know if they followed the model kind of how we designed it, if that makes sense.

Vince Mor:

Yeah. And the docs were okay with complying and doing this stuff?

Jennifer Gabbard:

Yeah, I mean, when we actually surveyed the providers and we actually did exit interviews, so we had site champions at each of the sites, and we got really good feedback. Some them of course learning to document that way was a little bit of a challenge versus most primary care providers are used to just free texting these discussions. But we had done qualitative interviews before and got what were the most common responses that patients would respond. So many of them found it really easy because the thing that the patient said they were able to click on, but we did have the option of other and free text

options that they could add additional information if something wasn't there that they really wanted to ensure was documented.

Vince Mor:

So you did a course correction and began allowing patients into the study who didn't have a caregiver. What are the implications of this for larger studies? Is it more difficult to do, and who would you get to decide whether a patient without a caregiver could participate? How did that work?

Jennifer Gabbard:

Yeah, it's a great question. I mean, I think the crux for this and why we didn't think it would be problematic is the patients did have to have capacity to participate in our study. Now measuring capacity pragmatic is very, very challenging, there isn't a really good way within the electronic health record to know if a patient has capacity to maybe consent to participate. So we did ask the primary care providers to let us know, so any patients that we felt would be eligible for the study we reached out to the PCPs and they confirmed capacity or not. So once we knew that they had capacity having that care partner essential didn't seem a needed requirement.

Jennifer Gabbard:

And we're actually glad we made that adaptation because 39% of our patients didn't have a care partner, but it's really important that we know their goals and values and what's important to them and future preferences, so we didn't want to exclude such a big component. And I think because we had such a large trajectory of patients who had mild cognitive impairment to dementia, many of those patients early stream don't have as much need for a care partner as they do as their disease progresses.

Vince Mor:

That's actually great. So it can be in that sense pragmatic because of the distribution of who wouldn't have a caregiver, a care partner, et cetera. So are you able to look at responses of the non-white study participants, and did they have a different experience? Have you done that?

Jennifer Gabbard:

Yeah, we have. We had the patients fill out a survey, and we used two kind of validated mechanisms that Whiner and Auld developed. One is measuring acceptability, which is called the AIM, and then the other one is kind of measuring appropriateness, which is IAM. And the nice thing is they're written at a fifth grade reading level. They're just four simple questions so there's not question fatigue on patients, and they've been tested in different ethnicities, which is why they're a great tool to kind of assess or do people find this acceptable and appropriate. And among whites for acceptability we found 94% found it acceptable and minorities it was 85%. And for appropriateness it was 85% for whites and 98% for minorities. So it was actually just slightly higher in minorities though it wasn't statistically significant. But yeah, we didn't find any differences which was great.

Vince Mor:

That's really encouraging, that's just terrific. Thank you very much. So Ariel, let's take a quick shift to you. The pharm D and your intervention needs to be embedded in the primary care practices or they serve sort of as a centralized resource to larger pools of practices. If you had to move forward and

propose a model as part of it, really a big embedded trial, is there one approach that is more workable do you think?

Ariel Green:

Yeah. So first of all, thank you so much for having me, it's really a pleasure to be here. So what we learned is most important is that there's a preexisting relationship between the pharmacists and the primary care providers. So we've interviewed pharmacists and primary care participants, and they all universally stress the importance of that. So the PCPs told us that they're much more likely to accept the pharmacist recommendations if they have that established trust beforehand as opposed to hearing from someone who is a stranger to them. And so we found that can actually be achieved through either a centralized model as at Kaiser Permanente where we piloted in Colorado, or when the pharmacist is physically embedded in the practices as at Johns Hopkins Community Physicians where we piloted in Baltimore, and the intervention was well received in both settings. So I think it is workable in either model as long as there is that established relationship.

Vince Mor:

So that means that for instance if you were working with a CVS or a Walgreens in primary care practices in a particular part of the country, if that relationship were there it might be better but know it might be something that a primary care group and a local pharmacy might actually undertake together.

Ariel Green:

Yeah. So I think... I mean, that is a model I think it would be great to explore how you could develop that trust between the PCPs and the pharmacists in something like a CVS beforehand. I think we've all gotten those... All of us who practice in primary care have gotten those letters from unknown entities, whether it be someone in an insurance company or a pharmacy program, and I think those are challenging to respond favorably to when you don't know who's writing to you. So I think if there were a way to develop a relationship beforehand I think it could definitely work.

Vince Mor:

Great. So in your study you had a lot of potentially eligible patients and caregivers who declined to participate, that doesn't really bode well for large scale implementation. Do you know much about how they declined and why they declined?

Ariel Green:

Yeah, so that's of course a very important question. So most of those who declined told us that they didn't feel they needed to participate in a medication management program like this one, or that they were just not interested. And so I think that raises the question of how we can best describe this intervention to patients and families ahead of time, or better target it to people who are interested in de-prescribing. So just like any health behavior change, people have to be ready to de-prescribe and so I think maybe targeting is necessary or maybe tweaking the brochure that we mailed to patients and families ahead of time. So I think that's something for us to explore further.

Ariel Green:

Another reason that we heard from people who declined to participate was that they did not have a care partner. Or less often, this was in infrequent, but that they declined to identify their care partner

and so that actually made them ineligible. And so I think the issue of not having a care partner is also something we should look into. For example, this was something that Jennifer raised, were we with our algorithm, were we misidentifying people who didn't truly have dementia? And so that's why they didn't have a care partner? Was it something about our language, the terminology of care partner, was that confusing to people or was it something else?

Ariel Green:

And then lastly a few of them said that they didn't have enough time, either the patient or the care partner, or sometimes the patient was hospitalized when we reached out to them, or they were in a skilled nursing facility for example. And we do still plan to, at Hopkins at least, to review some of the charts of people who declined, or this is something we could do, to explore whether there were differences. Like were they less sick or was their dementia less advanced for example.

Vince Mor:

Yeah. I think the issue of how advanced the dementia is, how long they've had some kind of diagnosis, and that might help a lot in the whole notion of whether it's targeting or sort of interest in general.

Ariel Green:

Right.

Vince Mor:

Yeah. Good, good. You talked briefly about a measure of medication regimen complexity. How is it characterized, and was it related to getting folks to reduce their medications or not? That is the complexity of any individual patient's regimen of medications.

Ariel Green:

Yeah, so that's a great question. So our primary outcome measure that we were interested in testing the feasibility of was the medication regimen complexity index, or the MRCI. And so that is a measure of medication regimen complexity that takes into account the number of different dosage forms and routes that a patient has in their regimen, as well as the frequency during the day, and any additional instructions for use, so things like whether a medication has to be taken with food or at a specific time of day. And so we were interested in this measure because it may better capture the patient and care partner experience as opposed to a simple medication count, and so it may better capture their experience of medication related burden.

Ariel Green:

So we are still digging into our data, so it's a little early to say. What we are learning so far is that it was easier for the pharmacist to de-prescribe things such as statins or Metformin in patients who had a hemoglobin A1C of 6%, for example. So medications that have a questionable benefit as someone's dementia is progressing and may no longer be goal aligned. So those medications may not impact the MRCI that much because they're just often taken once a day, but those may have been easier to de-prescribe.

Ariel Green:

And then another really important point that we're learning is that the pharmacist told us that the care partners were in many cases very anxious about stopping medicines that were being used to treat the dementia, like cholinesterase inhibitors, or medicines for behavioral and psychological symptoms, so some of the potentially inappropriate medicines like sedative hypnotics. And so they would say to the pharmacist during the goals alignment visit "please don't stop those medicines," and so there was this tension between de-prescribing, which was one goal of our intervention, and trying to align medicines with goals of care, which was the other goal. And so I think that, as I mentioned we're still sort of looking into our data, but I think that speaks to the challenge of measuring outcomes in de-prescribing trials. So the MRCI was the measure we chose but that may not actually be the best measure of whether people feel that their medicines are aligned with their goals, and I think measuring that especially pragmatically is really challenging.

Vince Mor:

Yeah, that would make sense to have this medication complexity. So I would imagine that another hold independent of cholesterol inhibitors or independent of even other drugs that might be problematic for persons with dementia, just sort of saying somebody might only need to take drugs sort of twice a day as opposed to maybe four times a day with different combinations doing it, etcetera, sort of having them aligned in some particular way that's possible to simplify matters, that might be more desirable by the family members because they're the ones who have to set this up and do it.

Ariel Green:

Right, exactly. And so I think the pharmacists were trying to do that as well. And so part of what they were trying to do is identify which medications are particularly burdensome to the patient or the family and which medicines they feel are particularly helpful. And so I just think maybe what we found is we're trying to achieve multiple things that may not always be able to achieve simultaneously.

Vince Mor:

That actually brings me right to the next question for both of you. So how viable do you think given what you've learned and are still learning that your interventions are now ready for full-fledged ePCT, are you ready to write your RO1 grants?

Ariel Green:

Yeah, so I mean, I'll jump in. So I think first of all so we have been interviewing care partners, pharmacists, and PCPs as I mentioned who participated in the pilot, and so we're learning that it was highly acceptable across the board. And so there's a lot of enthusiasm for PCPs and families working with clinical pharmacists on de-prescribing and on aligning medicines with goals of care. The pharmacists are highly trusted and can really help people make sense of these complicated information and complicated clinical scenarios involved in de-prescribing, so that's a positive.

Ariel Green:

I think we have a few things to figure out before a full fledged RCT. So I think the biggest challenge for us is that, although this was designed to be a pragmatic trial, the process of goals alignment was very complex. And so as I mentioned in the Grand Rounds most of these intervention visits took at least 30 minutes. There were multiple contacts between the pharmacists and the care partners and the PCPs. And so I think one thing we need to do, and we're currently talking to stakeholders to try to figure out opportunities to streamline the intervention. So for example as I alluded to a minute ago, so focusing

either on de-prescribing of potentially inappropriate medicines or on aligning with patient and care partner goals, and maybe also streamlining the classes of medicines that we focus on rather than looking at the entire medication regimen. So I think that's one thing.

Ariel Green:

I think we are finding that identifying care partners took a lot of time and resources on the part of research staff. And so we actually have another ongoing project as I mentioned during the Grand Rounds to try to identify a way to an approach to systematically identifying care partners.

Ariel Green:

And then lastly we are sort of a secondary or exploratory outcome measure for us that we were interested in was a care partner reported outcome measure. Again, trying to get at whether medications are more goal aligned or whether people feel that the medications are less burdensome, but that was challenging to collect pragmatically, especially at three months. And so I think pragmatically we need to learn more about how to pragmatically collect patient or care partner reported outcome measures.

Vince Mor:

It's particularly when you learn how to identify care partners you're going to have a lot of people beating down, getting advice at your door, because that's a challenge many people are having. How about you Jen?

Jennifer Gabbard:

Yeah, like Ariel I think we definitely have some other things that we definitely need to think through before we move kind of full-fledged. As I talked about, I think if we could come up with a way to pragmatically identify capacity it would be really essential just because reaching out to the primary care providers took a lot of times three or four outreaches before they would get back to us. And sometimes we would have to reach out to them by different venues, either email or telephone or portal to get responses. So on a larger scale that would be very, very challenging.

Jennifer Gabbard:

We used multiple mechanisms to identify our eligible patients, we use ICD10 codes but we didn't want to solely rely on ICD10 codes because we know that they're highly underutilized, especially in outpatient primary care. So we did us Barnes & Auld radar to get patients who likely have cognitive impairment just don't have the formal diagnostic code on their problem list, but that does require a substantial informatics build. And so that is something we would have to think about too if we want to scale this up is how do we do that? And it would have to be in systems that have that infrastructure which can limit, or is there a way that we can use more of a simple lot five mechanism to identify eligible patients or not?

Vince Mor:

Yeah. So it's interesting, both of you are in a position where you're offering an intervention and a program to people who are not a hundred percent sure they one know what it is or two, know whether they want it. And so how to do that is a challenge altogether without sort of asking for volunteers, which is really the height of un-pragmatic. So interesting.

Jennifer Gabbard:

One thing that we found that... Because we did involve the PCPs from the beginning but when we reached out to patients and said your primary care provider wants you to do this intervention, we had much higher buy in I think because of that-- many patients saying they really trusted their primary care provider and if they felt they needed to do it they would do it. So I think that can help, just that rapport that's already there.

Vince Mor:

No, that's a great point. That's a really, really excellent point. So I want to thank you both very much for your time. This podcast will be then joined together with the Grand Round session that's available, so this will be one of many that are going to be up and available on our website. So I thank you very much for gracing us with your company and your experience as one of the early finishers in the pilot race as it were. So thanks very much and to the audience please enjoy the others in the pool. Thank you very much.

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.