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.

Jill Harrison, PhD:

Hello, everyone. I'm Jill Harrison, one of the executive directors at the NIA IMPACT Collaboratory. Welcome to today's podcast. I'm joined today by Dr. Ab Brody. He's the pilot core lead of the NIA IMPACT Collaboratory and faculty at the NYU Rory Meyers College of Nursing and NYU Grossman School of Medicine. Dr. Brody, welcome to the podcast.

Ab Brody, PhD, RN, FAAN:

Thank you so much, Dr. Harrison. It's wonderful to be here with you.

Jill Harrison, PhD:

Thank you. Thanks so much for being here. This is the companion podcast that accompanies a presentation you made last week at our monthly Grand Rounds on the topic of results and lessons learned from the Hospice Advanced Dementia Symptom Management and Quality of Life embedded pragmatic clinical trial. Can you please just give folks tuning in today a high level summary of the HAS-QOL trial and the lessons learned?

Ab Brody, PhD, RN, FAAN:

Of course. To start off, the HAS-QOL trial, as we came up with the fancy acronym, as we must all do, was a trial that we performed to examine how to improve the quality of care for behavioral symptoms and care partner support of persons living with dementia receiving hospice care. The overall design was a 25-site stepped wedge trial that was randomized in tranches, and I'll get into a little bit of why that was, and it was meant to start in January of 2020 with primary outcomes around persons living with dementia receiving care in private homes, and then secondary outcomes in other groups of persons living with dementia. So those with secondary diagnoses, those in nursing homes or assisted living, and the primary outcome was around anti-psychotic use that was not within the last seven days of life. Secondary outcomes were around transitions in care and permanent institutionalization.

The intervention for the trial was a multi-component intervention of Aliviado Dementia Care, which is a program that we've created here at the Hartford Institute for Geriatric Nursing at NYU. It is a quality assurance performance improvement program that consists of training, mentoring, a technical assistance center that is housed at NYU, as well as care plans, assessment instruments, caregiver education materials, and a QI program that all help to reinforce the training because we know that training alone does not change practice. So that was the overall vision of the trial. The trial was paused after the COVID-19 pandemic began in the United States to hit full force in the beginning of March. So we ended up cleaving off our first five hospices into a naturalistic experiment, and then the other 20 moved forward in the following March. We paused for a year trying to do a secondary stepped wedge trial.

Jill Harrison, PhD:

I really appreciate you sharing the story about the interruptions that you experienced related to COVID. Can you talk a little bit about how you maintained relationships during that pause and how you kept the trial afloat, maintained the momentum amongst all the various stakeholders that you had to partner and engage with during that time?

Ab Brody, PhD, RN, FAAN:

Well, a lot of tears to start off with, but then once we got over our initial shock of having to shut down a trial, what really we focused on was meeting hospices where they were. We realized right away that as this started to occur, there was going to be no meaningful continuation of the study in that first six to nine months at a minimum. So that was our initial pause plan, was at least six months. We did keep in touch with the hospices in a number of different ways. Our amazing operations team had monthly meeting with our hospices who had already started implementing, just to check in on them. We also conducted a survey with them to ask them how they were addressing care needs with the switch over to a lot of virtual care. And so we did have a paper come out about that on how hospices were providing support to care partners during the pandemic, and we also really focused on how we could be of assistance.

These folks were all scrambling. It was incredibly hard for hospices to receive PPE and to provide care. So if we learned of best practices that one hospice was doing, we shared them with others. We maintained a monthly newsletter for all the executive leadership and people who had started to go through the program, just to provide them ideas from what's going on elsewhere. So there were a lot of different ways that we touched base, even if we couldn't move the trial forward, and help to facilitate learning discussions as well, even if they weren't about dementia and implementation of our study, because this is a long-term relationship building, to do this type of research in a non-academic setting, in particular, where they hunger really for more evidence-based care, but academic researchers have really not spent a lot of time or focus going into hospices.

Jill Harrison, PhD:

Thank you so much for describing that. Many investigators interested in embedded pragmatic trials often underestimate how many resources need to be dedicated to stakeholders and building relationships not only in conceptualization but throughout the course of the project and evaluation. So appreciate the complexities there. You had mentioned the content and delivery of the Aliviado program. Could you just direct some of our listeners to where can they find more information about that program?

Ab Brody, PhD, RN, FAAN:

Just as a bit of background, we started developing the program back in the early 2010s. It was initially called the Dementia Symptom Management at Home Program, and the first iteration of it was geared at home health. So there was a Journal of Gerontologic Nursing paper that came out in, I believe, 2016 that covered the initial development. We then started to work on a home health R01 that was also interrupted by the pandemic. And while we were doing that, we also started to convert this for hospice. So there's a paper that the lead author is Tessa Jones who just completed her PhD at the Silver School of Social Work here at NYU about transitioning the training programs from home care to hospice social workers from home care, which has a more nursing, PT/OT-driven model, and also changing the other training elements to be more hospice specific.

We then published two papers from the R61 phase of this trial, that's the developmental phase. One is in The Gerontologist with Shih-Yin Lin as the lead author, and then one is in the Journal of Pain and Symptom Management, and the author of that was Catherine Schneider that goes through how the hospice program improved knowledge, confidence, and attitudes in staff. And so those were from our initial pilot. So we took a really iterative approach where we engaged our stakeholders, and Dr. Lin's paper really does bring out some of that development process. And so even our algorithms changed. We added a mobile health application. There were a lot of things that changed because the executive leadership, the folks up on the front lines of care were telling us things that needed to be changed to make this an even more applicable program to them.

Jill Harrison, PhD:

Wonderful. You mentioned algorithms just now, and we like to use these podcasts to get to questions that we didn't have time for during your Grand Rounds presentation. And so I'd like to do that now. This question was posted in the chat, "Very impressive presentation and study. You mentioned that the algorithms were evidence-based and created and designed by the group. Were these created during the pilot? Has there been any publications on these algorithms?"

Ab Brody, PhD, RN, FAAN:

So we have not published our algorithm. The algorithm really was developed in the home health program first. And what we did initially was we reviewed all the literature out there on non-pharmacologic interventions. We pulled out all of the systematic reviews that have been done, the Cochrane reviews, et cetera, and pulled them into what works for each of these seven main behavioral and psychological symptoms of dementia. So agitation and aggression, delusions and hallucinations, sleep disturbances, et cetera, that are the major symptoms that persons living with dementia affects their quality of life and that care partners and caregivers really find concerning. They do align with the 13 symptoms that are in the NPI-Q, which is one of our assessment instruments. And so what we did was we went through all of that. We started with what happens if there's a new symptom, and think delirium, versus an old symptom that's either slowly worsening, and thinking more on the chronic side and a behavioral and psychological symptom of dementia.

And then the next piece of this, the key was: Is this concerning? Because oftentimes, we treat things, even though they're not really big problems. So for instance, someone might have a hallucination or a delusion, let's say that they're Miss America, as one of my former patients used to believe she was Miss America, and she was going to go out on a date with Fred Astaire, and it was great. She was happy. Every day in the afternoon, she would be primping and getting prepared for her date with Fred, and it would work really well. And then what would happen is it wasn't concerning. However, we see many cases like this where patient is automatically put on an antipsychotic because the family member is concerned about the fact that she's seeing or believing something that's not there. And this is a normal part of dementia where we see in many of our persons living with dementia that this occurs.

And so we use this kind of framework around, "Well, if it's not concerning and not a danger to self for others, then nothing should really be done other than reinforcing the fact that this is, not a normal part of aging, but a normal symptom that we might see, and if it's not concerning that the best approach is to allow it to play out." Now, on the flip side, let's say that symptom turns concerning, that creates a different need within the algorithm to actually treat. So for instance, in the case of Miss America, when Fred would not show up every night, she would get really angry and start throwing her cane into the wall and it became a significant problem for safety. Oftentimes, we're thinking about what are the challenges that are being created? And oftentimes, that would end up with an antipsychotic being given.

But there's this wonderful program that was created in Canada called PIECES, which we've integrated into our program. It stands for physical, intellectual, emotional capabilities, social, environmental. So PIECES, P-I-E-C-E-S. And the idea behind it is that you're looking for the underlying cause of the behavior. And so before we move to anywhere else within our algorithm, we're training our clinicians in this evidence-based model of care. So again, it comes back to evidence-based. I didn't know PIECES existed before we did our evidentiary scan, and now, it's been developed much further along, and they have a wonderful website with resources and training all of their own, but we integrated that.

So for Miss America, the issue was she had this delusion. It fit into the social because she believed she was going to go out and be this social butterfly and have this date with Fred, and how could we ameliorate that? And so in that particular case, we created an intervention each day that was dealing with this through the social aspect of a letter that came that said Fred wasn't going to be able to make it tonight, but looked forward to seeing her in the future. It's not untrue, depending on your notion of the afterlife that they could meet in a future life or post-death. And so you try and find the methods that are both ethical and are going to be the least restrictive. And in this case, we use the PIECES method, and then we flowed down into non-pharmacologic and pharmacologic interventions, and again, went by the evidence. And we've updated it.

So for instance, a couple years ago, Jacobo Mintzer came out with an article on use of methylphenidate in apathetic persons living with dementia that was really one of the first studies that actually showed this, even though some of us had been using it previously, without the studies, to similar effect. So we added that to our algorithm, for instance. So it's a living, breathing document, and we engage our clinical teams in this as well. So when we went to our hospices and were developing a new portion of the algorithm specifically focused on terminal restlessness and agitation, which occurs across the board in many people who are in that last dying phase where they'll have moments of lucidity and moments of agitation and restlessness, there's nothing really evidence-based about how to treat that.

And so for that, we used a more informal Delphi panel approach where we looked at how people were doing their care and what's worked for them. We addressed issues, for instance, that Haldol in this case, especially someone who has Lewy body or Parkinson's, is not a good medication. And so we thought through, "What's standard of practice, if there's no evidence base, and what are the things we have to look for specifically in persons living with dementia," and came to a consensus around that algorithm. So no, we haven't published because it's a living, breathing document that is continually changing. We have described it a little bit in some of our papers and now here, obviously, but it's really meant as a QI "what are the evidence-based practices that can be used?" It's not meant to sit in a dead set of electrons in a journal, and that's how we've approached it. So it morphs, it changes. As we work with hospices and learn more about how it works and doesn't work, we've gone back and fixed certain things about it or when new evidence comes in as well.

Jill Harrison, PhD:

Wow. That's extremely impressive. Certainly wishing the best for Miss America. And that case study there was very rich that you shared and just a great example of how much real-time customization and refinement that you spend with your team there on the algorithms. Very impressive.

Ab Brody, PhD, RN, FAAN:

Thank you.

Jill Harrison, PhD:

The NIA IMPACT Collaboratory is really focused on being a national resource for training and knowledge building for investigators that are interested in embedded pragmatic clinical trials. So, for investigators that are interested in these ePCTs, and specifically in hospice, where should they start? What training and resources do you recommend? Where do they go next?

Ab Brody, PhD, RN, FAAN:

It's a great question. So, there are not a ton of resources out there in terms of folks that are doing this work in hospice. There are some things that are a little bit more on the stage three side in hospice, but are implementation in nature. Most stuff in hospice is not these very tightly controlled studies. So I'd say you'd have to look along the span of what is included or not included within an embedded pragmatic clinical trial. There's been some work by George Demiris. They had a paper out on implementation in hospice. There's a new protocol that Dr. Jennifer Tjia has that is out there, but there's not a lot of interventional research period, let alone pragmatic trials in hospice. To go back, you have to really look at Jean Kutner, Dr. Kutner's POPCORN Network from back in the early 2000s, and she was a co-investigator on this HAS-QOL trial.

I think some of the things really are to reach out to the people who have done research in hospice, because there are not a ton of us, because there's a ton of lessons learned from everything from, "Oh, most hospices do not have an FWA." So if you're going to have them involved and engaged in research, in a multi-site trial, you have to help them get an FWA, a Federal Wide Assurance number, so that they can then sign on to a single IRB, to questions of how to engage in these limited resource environments in places that don't do a lot of research quite frequently. So I think there are some huge benefits to doing work in hospice. You can certainly look at the papers that we've written around doing our trial, and there will be more coming out about implementation benefits and challenges. Hospice is great at doing hospice, and they know how to implement new things because hospice does implement new things, but it's usually more along the QI spectrum.

So how do we help them to think of this from a research spectrum and go through the various issues that are raised? I think some of the other things are around setting expectations early. For instance, we had a randomized trial, and we learned very quickly that if we randomized everyone all at once in the beginning, we knew that some hospices were going to fall out, and then it was going to mess with the randomization process. And we learned that in our pilots. When we were in our pilot stage we learned from our hospices that were going to be in the next stage that setting a randomization date a year in advance was not going to work. And so we had to set tranches up, which does affect some of the internal validity of the study, but you have to do this in ways that can also be implemented.

So you really need to think about some of the implementation challenges that could occur. I think the other resource that exists for hospices is really reaching out to the organizations that work in hospice every day. So there's the HPNA and HPM, which both are professional organizations and have lots of our hospice leadership members are there, as well as I partnered with the National Partnership for Hospice Innovation, for instance, and some of their hospices, as well as a large for-profit hospice and working with their leadership. So I think it's about developing relationships, and then working together on what is feasible within the setting, because it's going to be very different than what you might be able to do in most academic settings. And that's not a bad thing. We're reaching people where they are, but you have to think a little bit differently around how you do this research because it's not a research-intensive setting.

Jill Harrison, PhD:

Dr. Ab Brody, thank you so much for sharing your work with us and all you do to improve the lives of people living with dementia. Thank you so much for your time today.

Ab Brody, PhD, RN, FAAN:

It's been my pleasure. Thanks for having me along.

Jill Harrison, PhD:

Of course. Have a wonderful day, and thank you again to all of our podcast listeners. 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.