Transcript

Adrian Hernandez

Welcome to the NIH Pragmatic Trials Collaboratory Podcast, where we discuss the latest knowledge and best practices in pragmatic clinical trials. I'm Adrian Hernandez, Co-PI for the NIH Collaboratory, and one of the moderators for this series. You can find a full list of episodes at rethinkingclinicaltrials.org/podcasts. Thanks for joining.

Hi, I'm Adrian Hernandez, and today we're here with James and Angelo, who will be discussing a recent Grand Rounds session on a cluster-randomized, stepped-wedge pragmatic trial to enhance goals of care communication for older adults with cancer. A really important problem and what they've done together with their team, is really to not only address an important question, but also how to so-called reinvent clinical trials.

So James and Angelo, thanks for taking time to spend with us going behind the scenes of your trial. Tell us a little bit about the background of the study. What was the important problem it was aiming to solve?

Angelo Volandes

So I'll I'll start. James is always kind to let me go first. You know, Adrian, over the last 30 years, a lot of us in the field have been trying to encourage patients to have conversations with their clinicians, especially patients who have an advanced serious illness like cancer. And despite a lot of these efforts, most patients still aren't having these conversations with their clinicians. Especially patients who are 65 and over and especially patients with advanced cancer.

So our goal in the ACP PEACE trial was to try to change that. And if you look at one person who has really focused on oncology patients over the last 30 years, it really has been James Tulsky and his team, and so even though he's right down the block from where I was for the last couple of decades, we called each other up and said, you know, you do a lot of work, James, in training clinicians on how to have these conversations with communication skills through the VitalTalk Program. And James has known for years that I've been trying to create these video decision aids to encourage patients to know a little bit more about their options for medical care and to encourage them to have these conversations. So, we thought the dynamic duo would be an intervention that addresses

both the clinicians but also patients and families. And that's what we did, and I'll let James describe the ACP PEACE trial.

Adrian Hernandez

And James, before you do that, I want to get a little bit of an understanding of why is it a problem? Why is it hard? Is it just because most patients with cancer, they're coming in with a cure and then we're not really thinking about the downstream or long-term problems that they may face?

James Tulsky

Yeah, I think it's hard for lots of reasons. First of all, it's hard because most clinicians haven't been well trained to actually have these conversations. These are not easy conversations. This is not your average walk in the, in the door, talk to your patient, describe the treatment, go through some options and so forth. It really requires a delicate understanding of how to deliver sort of serious news, how to discuss prognosis. Prognostic awareness is hugely important to these kinds of conversations. And how to present options and and really elicit patients preferences in a way that's going to make sense for what you're trying to talk about treatments. So that's one reason it's hard, is people haven't been trained to do it and the conversations are tough.

The other reason it's hard is because patients bring so much to it, and there are a lot of people don't want to talk about it. There are a lot of people for whom it's very scary. You have to be able to sort of address the affect in the room and how people sort of get through that piece of it.

Another reason it's hard is because of the tremendous uncertainty. And I think that's what oncologists today are probably struggling with most. In the time that I've been doing this work, the changes in cancer care, the changes in outcomes are dramatic, and so diseases that used to just be death sentences in a year are now having people living longer and longer. And there are new clinical trials all the time. So confronted at that level of uncertainty, I think both the oncology teams as well as the patients really struggle with, how do I know where to be making decisions about reducing aggressiveness of intervention. So for all those reasons, I think it's tough.

Adrian Hernandez

What was the design of the study?

James Tulsky

What we did was a stepped-wedge, cluster randomized, pragmatic trial of these two interventions combined, and I'll explain the intervention in a little more detail. In three different health systems; they're geographically separate, they are different in lots of ways.

And what we did was at each of these sites, we trained the oncology teams in communication skills using the VitalTalk approach, which in this case was a full day or half day training in communication skills that are particularly useful for discussing goals of care. And there's a way we have about going about doing that. It's highly interactive. It involves practice, observation and feedback. So all the oncology clinicians were given the opportunity.

And then we also introduced the ACP Decisions videos, which have been developed by Angelo and his team over many years and have lots and lots of study behind them. Which show patients what possibilities are in the future, they describe what advanced care planning is about. They describe things like what is hospice. They help people understand more clearly what really the options look like and help them engage with the material before they might have a conversation with their clinician.

The idea was, if the clinicians are trained to have better conversations, the patients are prompted to be more willing to have the conversations and to have a little better education prior to the conversations. This would help stimulate more advanced care planning. And then what we did was we looked at outcomes among cancer patients over the age of 65 with advanced disease across these health systems.

And the outcome that we were looking at was advanced care planning documentation. And it could be any one of several things, it could be discussions of goals of care written in the medical record. It could also be referrals to hospice, referrals to palliative care. It was introduced, and I mentioned it was a stepped-wedge, at each of the sites it was introduced serially to more and more clinics, and before those clinics had the training and and received the videos, we collected baseline data and then we compared after they had been trained to prior.

Adrian Hernandez

Oftentimes theory is different than actually evidence. And you all conducted this study to generate the evidence. So what were the results, Angelo, what did you guys find?

Angelo Volandes

Yeah. So what we found was that patients that were seen by clinicians during the intervention phase, who had used the video decision aids and had clinicians who had undergone the VitalTalk training were much more likely to have a conversation documented in their EHR.

So to be a little bit more specific about the results, we had about 30,000 patient visits and we saw that there was a 7% increase in documentation for those patient visits that were during the intervention phase. So, not only a statistically significant difference, but also a clinically important difference as well.

So what we saw was that patients were using the decision aids, they were thinking about these things, they were more informed about their decisions. And then when they saw their clinician in the clinic or on telehealth, they were more likely to raise the discussion and to have the clinician document that into the electronic health record.

Adrian Hernandez

So James, were you surprised by any of the findings?

James Tulsky

I wasn't really surprised. I was grateful, but I wasn't surprised. I mean, I think that there have been a lot of interventions in the past that have been able to show in a variety of ways that you can increase documentation of advanced care planning. And so I think the fact that we were able to do it with this focus intervention, I think what was nice was that this was very large, much larger than most other studies. This was a pragmatic trial. This was extremely real life.

The part that was maybe a little bit surprising and maybe a little bit disappointing actually was that, all the change that we saw was driven by increasing documentation of goals of care in the record, but there was not a significant difference in referrals to palliative care. There was not a significant difference in referrals to hospice, and there was not a significant difference in limitation of life sustaining treatments. That's the part where how

much of a difference it's going to make, we don't know. In the long run, we know we can shift this piece of it.

Adrian Hernandez

There's, you know, certainly scale here that you showed and it shows like parts are more amenable to movement, but they're part of other things that need to be done that's more intense. Maybe this goes into your next design for a pragmatic trial.

Angelo, let me ask you this. Given the results for this, how easy will it be to scale this across multiple health systems? Indeed, that's part of that premise of doing pragmatic trials. Is this a scalable set of solutions now?

Angelo Volandes

Well, I think that's the really key important part of the trial is that both of these interventions -- so this is a what we call a complex intervention because it has multiple parts, are extremely scalable. The big surprise was the pandemic. We had to rapidly transition from what we initially were going to do in person. So the VitalTalk training was a full day, in-person, for all of our clinicians and the video decision aids were going to be in clinic on an iPad and then all of a sudden everything stopped. And so we had to immediately transitioned to an even more scalable process where we really leveraged technology.

James was immediately able to transition the VitalTalk program from in-person to over Zoom. Which is really complicated. Just, you know, go back to the spring of 2020. I think if you asked me, "Can you train a clinician to do anything over Zoom?" And I would say, "Heck no." And yet today that's the standard of care. And then for the videos, we did not have a process of sending links or sharing off of telehealth. Five years later, standard of care.

So we had to really leverage technology and I think one of the silver linings of the pandemic is now we have 2 interventions that can be immediately scaled across the country, rapidly, and at minimum cost. I mean, if you think about it, what we were planning initially when James and I sat down over a drink to to write this grant, was everything was going to be in person or using iPads and that was not scalable. And yet, post-pandemic, we now have an intervention that can be easily and cheaply scaled to every healthcare system in America, which is both of our ambitions.

Adrian Hernandez

Terrific. Well, I know you all learned a lot from this trial and one of the goals for the Collaboratory trials is to generalize understandings that can improve the research ecosystem, so-called Rethinking Trials. And one of the things I remember from your Grand Rounds was, you guys had some terrific ideas. So, I want to give you both magic wands to how you would change the world to make clinical trials easier, more efficient and more effective.

James Tulsky

I'd love to use that magic wand in so many ways. One of the things we didn't mention that was a surprise and was an issue for us was how different the intervention played out in the 3 different health systems. And it turned out that it was kind of like the three bears.

At one health system, it really just -- there was very little uptake. For a lot of reasons that were very unique to that institution. And as a result, the findings were actually negative for that particular health system. At the other two health systems with varying degrees, the uptake was considerably better. One of them was much better. And there was a lot more buy in locally. All the positive results for the study really they came from those 2 places. Which actually meant that the intervention had even a greater effect in the places where it actually worked and where there was actually uptake.

So one of the things that I would do from a trials perspective, looking back on this is... We started this in 2017, 2018, whenever it was. And there was just a very long period of time between the first part of the UG3, part of the grant, where we were just getting it all in place and doing the pilot. And then when we started the trial. And then of course we had COVID that derailed us, but even if we hadn't had COVID derail us, it was still going to take a tremendous amount of time before we were going to figure out what was really going on and we were already stuck with the 3 places we were working with, and we were learning a lot about them in the process.

I think that a few things I would take away from this. First of all, the time on this is just too long. It's just way too long to try to implement change, see what happens, and, in the process of trying to do that, we learned so much early on. I mean we could have known early on that we might have been able to have shed an institution. Or try to go to a different kind of place that would have been better. Also, I think we learned a lot more about what buy in really looks like and what it means that we didn't kind of understand. We picked our

institutions more based on who our collaborators were than we did based on what the institutions looked like. And afterwards I think we would think differently about that.

So, I think what I would want to do would be to have a lot more iterative processes. I would want to have faster turnaround on trial. I would want to pick institutions and probably continue to work in places over and over that actually have buy in for these kinds of things.

One other little magic wand piece, which is what I would change as far as the interventions themselves, or I should say, perhaps, where I hope to see this work go. Which is everything needs to have a much better feedback loop and reporting and engagement of the clinicians that are involved with ongoing support. So, for example, what I would do now with the VitalTalk part of it -- like we did, we gave it a half-day training and then we sort of said like, go off and do good stuff. And I would now do a lot more feedback. I would try to get them feedback on their own conversations over time. I would give refreshers over time. I think the dosing was too low on that end. I think we did a better job of that on the videos with kind of ongoing intervention.

And then I think, the other thing is I think clinicians need to know how they are doing. And they need to get feedback on that. So for example, if you're not having any of these conversations, that needs to be fed back to you. And that needs to be very apparent. And I think with AI and other methods we have coming along, I think we're able to do a lot of this much better.

Adrian Hernandez

Terrific. Alright Angelo, what are you going to do with your magic wand?

Angelo Volandes

So first, I couldn't agree more with what James just mentioned. And I think it's important, the context that, this is the 32nd trial of the Collaboratory. And both James and I have been privileged to be part of the Collaboratory for so many years. So, we are making these suggestions in the spirit of having the Collaboratory remain the premier Collaboratory for pragmatic clinical trials.

So first, it's got to be done faster. You know, Wendy Weber has been saying this for years. Even though we do have 5 years, you don't need to take the 5 years. These should be 2-year trials, because healthcare changes rapidly. If you're doing a trial longer than 2 years, it's

probably outdated by the time you find the results, and that's not being good stewards of our limited resources.

The other thoughts that I had was, cost savings. There's no better way to get a decision maker at a healthcare system than to show cost savings. The sweet spot is your intervention leads to outcomes that are great for patients, great for the health system and our cost savings. And so that should be something that is required, I feel, in some pragmatic clinical trials. For us, you know, there -- we didn't have CMS' VRDC, the Virtual Research Data Center, which was developed after we started the trial. But what a great idea to not only look at documentation, but to look at what happened at the end of life for deceased patients and looking at costs.

The other aspect that I think should be required are interim analysis, which is something that James was alluding to and something that Lesley Curtis has been talking about. We need to check in with trials earlier and more often either fail fast or succeed fast. And I think that's critically important.

And the last thing that I'll say is, how we select our trials. You know, I've been privileged to be on the study section that's selected the trials over the years and I think we do need to give a competitive edge to investigators that are willing to do trials faster, to have cost savings, to have interim analyses.

And the other thing that I believe this wonderful doctor, Dr. Hernandez, mentioned, was: If you finish your trial earlier, we will give you that balance of money, which is so critically important today. But I would even say let's bonus it. Let's double it. Whatever savings you have at the end, we'll double it. And we'll let you have another trial.

So those are the things, if I had my magic wand, I'd love for the Collaboratory to consider. After our Grand Rounds, when James and I mentioned this, someone came up to me actually through an e-mail and said, “Well, what does that do for the junior people who want to get into this?” And, and I thought that's a fair point. You know, James and I are pretty senior. We're both endowed professors. And so maybe having a requirement where senior investigators have to partner with a junior investigator to lead these trials so that we have the next generation of pragmatic clinical trialists out there. I thought that might be something to also throw in the mix.

Adrian Hernandez

Well, I certainly love it. Certainly aligning incentives so those teams that are answering important questions, doing so efficiently and effectively, get rewarded for doing so and so

see that hopefully on the horizon as everyone is really rethinking how to do clinical trials in a better way. Angelo and James, thanks for a terrific discussion. It was great to hear what you all did and how that has general implications for how we do clinical trials. And I hope everyone enjoyed this podcast. If you're interested in hearing more first-hand perspectives on pragmatic clinical trials, join us next month for another episode of the NIH Collaboratory Podcast.

Thanks for tuning in to this episode of the NIH Pragmatic Trials Collaboratory Podcast. You can find other resources related to conducting a pragmatic clinical trial on our website, rethinkingclinicaltrials.org. We look forward to seeing you next time on the NIH Collaboratory podcast.