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Intro: [00:00:01] Hey this is Adrian Hernandez and welcome to the NIH Collaboratory Grand Rounds podcast. We're here to give you some extra time with our speaker and ask them the tough and interesting questions you want to hear most. If you haven't are ready, we hope you'll watch the full Grand Rounds webinar recording to learn more. All of our Grand Rounds content can be found at rethinkingclinicaltrials.org. Thanks for joining.

Adrian Hernandez: [00:00:24] Hi there, I'm Adrian Hernandez with the NIH Collaboratory. I want to welcome you to today's podcast with Kevin Weinfurt, and we're going to reflect on the Collaboratory highlights for the past and also consider what's coming up next. So Kevin welcome and it's good to do this with you.

Kevin Weinfurt: [00:00:43] Hello. Yeah, excellent to chat about this.

Adrian Hernandez: [00:00:46] So Kevin, what really makes you excited for the next year, what's going to be the thing we see coming out the Collaboratory that will have an impact over the next year?

Kevin Weinfurt: [00:00:56] Well I think the first thing is going to be the results from these demonstration projects. You know these were pretty impactful trials and it's really going to be interesting to see how the results are received by the various stakeholders who have an interest in these, and I really enjoy listening to a workshop where Greg Simon was was doing sort of a mock presentation of the SPOT trial findings to health care leadership and we're going to get a chance to see how this goes in reality now.

Adrian Hernandez: [00:01:29] Yeah it's actually amazing when you go back and look and consider the bold ideas that people are taking on. I mean the SPOT trial's a great example. I mean who would imagine doing a trial within a health system to try to prevent suicide. And when you consider that the suite of trials, they all are tackling big problems and seeing the results come out as I think that's going to be tremendous. I'm curious how do you think the health system leaders will react as they see results?

Kevin Weinfurt: [00:02:03] It's a great question, it's something that I think we're try to learn from. I would hope that especially with the health systems that were involved with these Collaboratory trials that over the years now we've developed maybe a greater sophistication and appreciation for this kind of research and the potential for it among health care leadership. So I think it will be interesting to see what parts of it resonate with them, what parts are they still sort of stuck on. It will help us to retool as we're providing guidance to people about planning these types of studies in the future.

Adrian Hernandez: [00:02:37] Another thing that has me really interested in is how the research community will receive these. People have often talked about pragmatic trials but these are really pragmatic trials done in health systems and seeing how that the research and clinical community will take these up and what their reactions will be.

Kevin Weinfurt: [00:02:57] I think it's a great point. People have sort of a template for how they listen to and think about traditional trials, maybe even older pragmatic trials. But you're right, this is kind of pushing people to bit, and so some education is needed there too I think to help people figure out how to process these and evaluate the quality of these types of studies.

Adrian Hernandez: [00:03:20] The other thing I'm excited about is actually the new wave of

pragmatic trials with the Collaboratory, so it sounds like we'll see something coming out sometime in the next year in terms of what's the next wave of Collaboratory very pragmatic trials. Any predictions on what those may look like?

Kevin Weinfurt: [00:03:40] You know one benefit that these folks will have is that they've had an opportunity to really study these 10 trials that began the first round of the Collaboratory and nine that were executed and to learn from them. So I think it's going to be really interesting to see the plans that people come in with and how those plans may be different in sort of maturity compared to the plans from five years ago. And I would hope we get a chance to learn something about how to do A versus B comparison studies.

Adrian Hernandez: [00:04:14] You know the other thing I'm excited about is now seeing what's possible in applying the Living Textbook. So that was built from the current experience the Collaboratory, but as you said how that actually may help get incorporated and hopefully help with this next wave of trials. Let me turn to another topic here. What's the next big challenge you think that the Collaboratory should take on in the next year for embedded health system pragmatic trials?

Kevin Weinfurt: [00:04:44] Well I think the challenge that we're going to be forced to take on is trying to understand what the revised common rule means for the new studies that we'll be trying to mount in this next round of the Collaboratory. Most of the provisions go into place in January and so these trials will be done under those revisions and you know the broader ethics and regulatory community are still digesting these and trying to figure out how best to implement them and what exactly they mean. So we're going to have to do that for these studies specifically and I think we're going to learn a lot, it will be challenging but we're going to generate some helpful information about how to do these studies consistent with the revised regulations.

Adrian Hernandez: [00:05:29] I guess when you think about it at the beginning of the Collaboratory that was one of the areas that was known quickly as needing attention and needing a pathway for how to do these trials and the body of work that has come out of that to help others is tremendous, so I think you're right. That's going to be a very interesting and important area especially as we want to scale these studies to be more every day. Now that we're going to have results, we spent some time this past year on implementation or de-implementation depending on the result. I think that will be another thing that we may be able to focus on as well is how does that actually work, and any other challenges with that. There's been so much attention towards the front end of these trials, I think on the back end how data comes together for the answer that people need. How that process works. And are there opportunities to learn from that and hopefully make it better. It's another challenge that I can see the Collaboratory taking on.

Kevin Weinfurt: [00:06:36] Absolutely.

Adrian Hernandez: [00:06:38] You know it's that time of year where people start making predictions of the future. Where do you think embedded pragmatic trials with health systems will be in five years?

Kevin Weinfurt: [00:06:52] Well I think one thing we can expect is greater sophistication among the research community and among health systems leadership about these types of studies and their potential and I think if you think between now and a couple of years from now we'll have nine major trial results reported and processed within the community. You know we're starting an education program in the laboratory and hopefully we'll be replicating that in different venues and in increasing the knowledge base among clinical researchers about how to do this work, so I hope and maybe it's a prediction is that we're going to have a much more knowledgeable community of scholars and leaders who can do these types of studies and then know what to do with the results.

Adrian Hernandez: [00:07:42] And one thing that's been striking especially this past year is changes in the health care environment. And you know over the last five years that's really been consolidation of hospitals and health systems, outpatient practices and in-patient with our health system. But now this past year is seeing changes with health plans and health systems coming together and also perhaps very new disruptors. So when you see the likes of Amazon starting to engage in health care it makes you wonder in five years whether the data and the approaches that are used for learning health systems will be a combination of different data streams and whether they'll be hopefully more embedded pragmatic trials taking advantage of that new healthcare ecosystem and we'll have to see how that plays out because certainly all those players will be highly interested in trying to improve the value of healthcare delivery.

Kevin Weinfurt: [00:08:54] Yeah that's a great point and piggybacking on that you know the new sources of data that are more readily available and they're cheaper these days from wearables and other passive measurements being incorporated into the EHR could really mean a greater potential for pretty impactful research down the road. I mean that would be my hope is that this health care systems are set up in such a way that they're culling all of these data from multiple sources. Now we've got a much richer data set that we can use to examine outcomes.

Adrian Hernandez: [00:09:30] Lots to see and I imagine that things will continue to rapidly evolve and we'll have to see what's next. Well this has been great to spend some time talking about what's next for the Collaboratory. Kevin it's always fun hearing your insights and thinking about the future. So I just want to thank everyone for listening to today's podcast. Our next podcast will be with Greg Simon and Susan Ellenberg on data and safety monitoring and pragmatic clinical trials. That's a very important area and actually one of the things that people have not paid as much attention to in the past.

Closing: [00:10:10] Thanks for joining today's NIH Collaboratory Grand Rounds podcast. Let us know what you think by rating this interview on our website. And we hope to see you again on our next Grand Rounds Fridays at 1:00 p.m. Eastern Time.