

Adrian H.: [00:04] 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 already, 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 H.: 00:27 Hi there. This is Adrian Hernandez from the NIH Collaboratory and today we're here with Renee Mitchell, Terri Reed, and Roseanne White who'll be reflecting on MDEpiNet RAPID and SPEED Projects. These are projects leveraging real world evidence to get better, faster, cheaper, medical devices for physicians and patients with the answers that they need. So Renee, Terry, Roseanne, thanks for joining us.

Renee M.: 00:52 You're welcome.

Terri R.: 00:52 Thank you.

Adrian H.: 00:53 So Renee, let me start with you. Can you tell us a little bit about the concept of why MDEpiNet developed these projects? What was the problem you're trying to solve?

Renee M.: 01:04 Well I think today we all know that healthcare costs are rising. We also know that patients and physicians have a gap in getting new technologies to the bedside in a timely manner. So one of our goals again, the title of the webinar is we are trying to get better, faster, and cheaper medical devices for physicians and patients. We really believe that this is an innovative approach and we're looking for support across a wide range of healthcare academia, FDA, as well as global.

Adrian H.: 01:39 Right. And Terri, you worked across a number of different groups before. Can you speak to a little bit about the structure and collaborative nature that has been developed here?

Terri R.: 01:50 Yeah so my specific focus is on UDI adoption, unique device identification, and in this group, in RAPID, we worked specifically on the informatics side, not just looking at UDI, but also common data elements. And it ended up that we worked so collaboratively together, that the informatics group and the UDI adoption group actually formed one single group and what was really nice about this project is that from leadership on down, people listened to each other. They respect the expertise of those who have expertise in informatics versus the clinical versus statistics. And I think it's really made for what we like to

refer to as a rapid, speedy project. We use those terms often, as Renee mentioned.

- Adrian H.: 02:51 That's great and Roseanne, can you tell us a little more details about the RAPID and SPEED projects? What are they about?
- Roseanne W.: 02:58 So for the RAPID, it's changing the way we collect information. Instead of necessarily creating a separate case report form and having separate people write down information that you have to check. What we're trying to do is get closer to the source of the information. And where we're getting as close as possible to the medical records and then extract that information. So there is less work all around. You don't have to have multiple people entering the same information in several different places. It only happens once at a hospital.
- Roseanne W.: 03:38 We are able to collect more information than maybe we would have for the same amount of time and another important part of this is the sort of minimum core data set. We have an agreement about what everybody will collect and so that again, makes it easier to set up standardized programming, standardized analyses, etc. so that we can get data faster, better, and cheaper and get medical devices to patients.
- Adrian H.: 04:16 Now Roseanne you've had a lot of experience working across industry and academia on these types of projects and often finding the common denominator can be quite a challenge. Not all the information that people care about regarding devices are part of the routine healthcare record. How do you see that issue being addressed over time?
- Roseanne W.: 04:38 Well I think it's kind of a staged approach. Right now, we're working with entering information into registries. For example, the vascular quality initiative has a registry where they're collecting at several hundred hospitals information about all the vascular procedures. That will allow us, as we work with each one of these registries, to get everybody used to certain types of data that we're going to need.
- Roseanne W.: 05:07 Like I said, since we're trying to get it to a point where they only have to enter it in once, eventually, that'll trickle down to people's every day, what are they recording into the medical record. So it will evolve over time. It's a step-by-step approach. But one of the things that the project did, which I think is so remarkable, is they went and they looked at all the articles in this area plus case report forms from I think 20 or 30 different places and they found that there was maybe a 100 variables that were common across and also they were the most used.

Roseanne W.:	05:48	Many people collect information that is never used later on and so it was a lot easier than we thought to come to a common core minimum data set. Actually getting it to reflect in the medical records will evolve over time.
Adrian H.:	06:04	Wow, that's very impressive. Now Renee from your experience often there is this "what if" scenario that you have to be prepared for in industry. Do you see that being a barrier here or will people be comfortable with the, "Hey, we can be parsimonious. We can be focused and not have every ornament on the data tree."
Renee M.:	06:25	So I think that the adoption of this process has definitely been productive. I'm finding that from the regulatory side, we really have had great support from FDA. I think that's really important. We've done a great job of also coming back to our business partners in industry. And we are at the stage, we are looking for demonstration projects, which is really exciting. So I think that once we have some demonstration projects that have become successful, that we will have increased adoption. As with any other project that kicks off, until we can see some concrete output,
Renee M.:	07:04	for example, approving an additional indication for a device using this real world evidence, I think that will be really exciting and give us some additional momentum.
Adrian H.:	07:18	Great. And Terri, since you've been spending so much time focusing on UDI, how critical is that for success as we go forward for real evidence?
Terri R.:	07:27	Well we think it's foundational at FDA that the UDI be captured in all registries that are looking to support the National Evaluation System. And what I can say on this project in particular, is that because we had representation not only from FDA but from ONC and bringing expertise around infrastructure development, around interoperability and we could pass that along to the clinicians, and they could better understand what we were trying to achieve from a government perspective we really got a lot done in terms of data quality improvement and access good ID, identifying where the gaps were, and where we should go in the next phase of this project.
Adrian H.:	08:18	Great. Roseanne, why is the time now perfect? You know, some of the issues raised on Grand Rounds and here, the need to have better evidence in a more efficient way, has been around for a while but why is the time now for actually doing this?

Roseanne W.: 08:40 With the aging healthcare population, there's been enormous pressure on the healthcare system and we are faced with challenges to be able to be more efficient, with our healthcare resources and getting devices and therapies to the clinicians in a faster, better, cheaper way is so much more important now than it ever has been.

Adrian H.: 09:06 So Terri, tell us a little more about the evolution here for these projects in phase three?

Terri R.: 09:12 So for in particular for the UDI data, we're going to use the lessons learned. One of the realizations that we had, we focused initially on registries and the entry of the data into the registries and then we recognized the healthcare systems that have to put that data in. So for phase three, we're gonna engage those healthcare systems more in that initial entry scanning of the UDI, entering those common data elements and having that flow through to the registry to get rid of that swivel idea of double entry, to actually engage the hospitals.

Terri R.: 09:49 And we're putting that together, a proposal was put together by Cook Medical to look into that workflow and have industry partner with the healthcare provider, partner with the regulatory staff and the academia and see how much more we can go with this project.

Adrian H.: 10:08 All right. Well great. So thanks for joining us on this podcast and special thanks to Renee, Terri, and Roseanne for reflecting on their Grand Rounds and the MDEpiNet and what it's doing there for the RAPID and SPEED projects. Our next Podcast will be with Tom Carden and Keith Marcello on data linkage within, across and beyond PCORnet. Thanks again for listening.

Adrian H.: 10:35 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.