Adrian H: [00:00:04] 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 Rethinkingclinicaltrials.org. Thanks for joining.

Lesley C: [00:00:28] Today we're here with Dr. Michelle Mellow, who will be reflecting on clinical trial data sharing, perspectives from participants and PCORI. So maybe let's begin for our listeners by having you tell them a little bit about your study.

Michelle M: [00:00:43] Sure. We were funded by the Greenwall Foundation to do, what I think is the first study of how clinical trial participants think about the prospect of having their participant level clinical trial data widely shared. So as distinct from sharing trial results, the actual underlying data de-identified, of course, but potentially posted on a website where it might be available to a variety of types of people.

Lesley C: [00:01:08] Great. And what did you find?

Michelle M: [00:01:11] We found that the majority of trial participants, indeed a very strong majority, had little or no concerns about the potential downside risks of data sharing. And were very broadly supportive of the idea of data sharing in general, and having their own data shared in particular. So we presented them with a list of about 15 different potential risks that might be associated with sharing their data, as well as a comparable number of benefits that might accrue from data sharing. Asked them to talk a little bit about each of those with us, and then at the end of the survey, asked them about their overall attitude towards data sharing, having considered all of that information. And on that overall question, about 82% felt that the positives of data sharing outweigh the negatives, with about half giving the strongest possible positive response. 10% considered the benefits and negatives about equal, and only 8% had a negative view.

Lesley C: [00:02:08] Michelle, those results are really fascinating to me, and I suspect to many others, given that we're certainly hearing in the lay press a lot of concern about privacy, data privacy, and data sharing. Were you surprised, and what do you make of those responses?

Michelle M: [00:02:33] I was surprised that support was quite as high as it was. I hypothesized that actually it would be higher than one would expect if one just sort of participated in discussions about data sharing that go on at academic and policy meetings, where we hear a lot of concern expressed about privacy and informed consent. That concern is generally actually expressed not by patients or patient representatives, but by pharmaceutical companies, or academic investigators who are purporting to speak for their participants. I suspected that may have, actually, an exaggerated impression of the importance of these issues to participants. And that proved to be right. But I was still surprised at how strong positive valence was. Particularly given what we know about low trust in the pharmaceutical industry, and broad concerns about privacy.

Lesley C: [00:03:22] Yeah. And, you touch on, in your response, you touched on, I think an important issue that oftentimes in those conversations some stakeholders speak on behalf of patients, but we may not be hearing directly from patients or patient groups themselves. That's an important point.

Michelle M: [00:03:46] Yeah, that's right. And I think it's important to remember that most patient groups were created and organized to get cures. They are organizations of patients who want to see science progress, and address their disease. And that desire really came through loud and clear in the survey responses that we received. These are individuals who have chosen to donate their time and body to scientific research, and they strongly desire to have that contribution to science maximized through data sharing.

Lesley C: [00:04:14] Now, we know that a communicating clearly risks to patients, especially, I think, risks associated with data sharing and privacy is challenging. Can you talk a little bit about, maybe, the development work you did in the study to make sure that you were effectively communicating risks and that the participants understood the questions that were being asked of them?

Michelle M: [00:04:43] Yeah, that was a big concern of ours. Because these are complicated concepts. So, we did a number of things in pilot work to try to ensure that the concepts were coming across, starting with convening focus groups of people who have been involved in clinical trials here at Stanford, from a variety of socioeconomic and racial and ethnic groups, to talk with us generally about the concepts on the survey. And proceeding then to formal piloting and pretesting of the survey in a series of debriefing interviews with people who had taken the survey, to talk with us about what was on their mind when they were answering the question. And we learned a couple of important things. One is that most people don't intuitively understand what data sharing is all about. It needs to be explained to them. The second is that the word de-identified doesn't really have a lot of meaning to people. The word anonymous does. But of course anonymous and de-identified or not quite the same thing. So we had to be careful about that. And then the third is that when people think about data sharing, their natural inclination is to think about sharing of results, i.e., through publication. So we had to constantly remind people of exactly what it was that we were asking about.

Lesley C: [00:05:51] Yeah, that is quite an involved and important process. Do you have a sense of the extent to which the participants in your study are generally representative of participants in clinical trials? What are your thoughts?

Michelle M: [00:06:09] I think they're fairly representative of participants in clinical trials. We had over 100 different trials represented in the sample, from three different academic medical centers in different parts of the country. When we looked at the nature of the trials, there was a strong representation of trials relating to diabetes, as well as nutrition, weight, vitamin supplementation. So on average, these may be a slightly healthier group than are participating in clinical trials nationally. We don't have a high representation of folks from cancer trials, only about 5%. So there may be some differences in terms of the topic of the trial and the health status of participants. But it was a fairly diverse group.

Lesley C: [00:06:51] And as you reflect on the results, I know you've had an opportunity to present them in a couple of places. What do you see as some of the major takeaways for ... Well, maybe we'll start ... Takeaways for people who are undertaking to do clinical trials?

Michelle M: [00:07:10] Well, I know there's been a lot of apprehension about data sharing, and not least because it involves a lot of personal costs for investigators to undertake the work of doing it. But I think one thing that they don't need to worry about his offending, or adversely impacting the interests of clinical trial participants. I think we get a strong message from this trial that overwhelmingly people would like to see this happen. And so, really the focus should be on how to communicate about it in a way that will be meaningful to subjects as well as how to set things up for data sharing systems in a manner that doesn't unduly burden investigators, or disadvantage them scientifically. In terms of specifics that researchers ought to keep in mind when designing consent forms, or talking with participants about this, again, we really heard the theme that people wish to maximize their scientific contribution.

Michelle M: [00:08:04] And so, explaining as part of consent processes why data sharing happens, what the benefits are to science, both in terms of accelerating the pace of discovery, and also serving as a check on improper practices in science. I think subjects will respond to that. It will be meaningful to them. And additionally, participants really need to know that steps are being taken to safeguard the security of their data, really much more than privacy, per se. They're interested in data security. The possibility of hacking, bad guys getting access to personal information. And so, part of the process of seeking permission for data sharing ought to be an explanation, as we would ordinarily do in a clinical trial, of the measures that we take to protect the security of data.

Lesley C: [00:08:50] I wonder if you might have a slightly different set of takeaways, or they might be the same, for sponsors, or for those, whether they be commercial or government sponsors of research. What could they do to really facilitate data sharing?

Michelle M: [00:09:11] Well, that's a good question. I think as far as NIH goes, they're already on board, of course, with this concept, and doing a great deal to accelerate the pace of data sharing. And so, I think these findings reinforce that mission, and the notion that it can be done in a manner that's consonant with protection of human subjects, and serving participants' interests. For trial sponsors, and pharmaceutical sponsors in particular, I guess to steal the phrase from the pharmaceutical industry's own lobbying group, go boldly here. I think they don't need to be afraid, again, about responses from participants. And the question is not whether to engage in data sharing, but how to do it in a responsible and expeditious manner.

Lesley C: [00:09:54] Yeah. Great. Really great takeaways for sponsors and researchers. Those are excellent. Michelle, I want to thank you again for joining us today and talking a little bit more about your research. Before we end, any other final points you'd like to make, or final comments?

Michelle M: [00:10:15] Well, I'll just throw in one other interesting tidbit. And that is that we saw really different levels of trust in universities and drug companies. Over 60% of the

sample have a lot of trust in universities. 15% have a lot of trust in drug companies. And it was really striking that not withstanding those differences, almost everybody was willing to share data, with both university researchers and private companies. And that really, I think, creates a very optimistic view of the future here, and the opportunities that private companies have to really accelerate science through data sharing.

Lesley C: [00:10:46] Ah, what a great note to end our discussion on. Thank you. Thank you, Michelle, and I hope that that others will join us for our next podcast as we continue to highlight fascinating and informative changes in the research world. Thanks again, Michelle.

Michelle M: [00:11:07] Thank you.

Adrian H: [00:00:09] 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 PM Eastern time.