Jill Harrison: 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.

Vince Mor: Welcome to our podcast from the IMPACT Collaboratory. I'm delighted to be your host today. This is Vince Mor, and I'm one of the principal investigators of the NIA-funded IMPACT Collaboratory. And I have the pleasure of interviewing two wonderful friends, colleagues of longstanding, Dr. Joan Teno and Dr. Debra Saliba. They gave a wonderful Grand Rounds last week, talking about the advantages and pitfalls of using existing data to building your pragmatic trial, how to measure patient outcomes and patient conditions using existing data as part of a pragmatic trial.

Vince Mor: So it was a delightful talk. Dr. Saliba is a senior scientist at RAND Corporation in California, in Los Angeles. And Dr. Teno is a professor at the Health Science University of Oregon. And so I'm going to actually begin. There were a number of questions asked from the audience, but I'd like Dr. Teno to expand on a point that she made in her talk, regarding what's the right unit of randomization when you're actually doing a pragmatic trial using identifiable information from something like an MDS?

Dr. Joan Teno: So I think the right unit of analysis all depends on what your experimental design is. So, for example, if you're intervening in nursing homes, the unit of analysis would be the nursing home. I think the really important consideration is to look at how balanced your randomization is on the characteristics of the nursing homes, and whether some of those characteristics influence your outcome variables.

Dr. Joan Teno: So, for example, it's well known within the Medicare billing data that the South has a tendency to document more diagnoses than in the Northern states. At least that was a known journal article that was written several years ago by my colleagues at Dartmouth. So I think those are things you really need to think through as you do these pragmatic, clustered, randomized control trials.

Vince Mor: Great, thank you very much. So another related question, actually to the South, North and otherwise, is given the huge variation across the country in things like billing practices, or even the mix of residents or the performance of some of the healthcare systems, [how do you think about] when you want to use these kinds of data? How do you think about making sure that you've adequately selected a good nationally representative sample? Or that you are representing, even if it's not perfectly represented, that you're representing broad swaths of the country, so that a finding from your study might be broadly generalizable?
Dr. Joan Teno: So, what really is nice about administrative data is that you can use information from previous years to analyze and to look at how that organization, be it a hospital or how that nursing home is behaving. And so that will give you some ideas on the degree to which your randomization is balanced or not, depending on your clusters. So, that's one question that maybe is not directly getting at the point you make.

Dr. Joan Teno: Then the second question is when you think about selecting facilities, you want to think about the generalizability of those facilities, and how it relates to the type of nursing homes or acute care hospitals out there. And the one thing nice about administrative data is you can start looking at the data to understand the institutions you're enrolling, and what the bias is of those institutions and how they compare to the rest of the population.

Vince Mor: So, might you want to recommend to somebody pulling a study together like this that they might want to have representation in both the experimentals and controls in different parts of the country, or alongside one or two parameters of interest, like the prevalence of a particular condition or otherwise?

Dr. Joan Teno: Yeah, I think it all really depends on the research question that you're answering. And the one thing that is important is that you want to make sure that you have equity, in terms of including minorities and different populations, to make sure that the intervention that you're testing is applicable to all populations out there.

Vince Mor: Yeah. Very good. Thank you. Dr. Saliba, for those of you who didn't hear the talk, is the originator or the designer, the coordinator of the creation of the current Minimum Data Set version 3.0, and has been responsible for many of the elements within that instrument and its use in various ways, as quality measures and outcome measures, et cetera.

Vince Mor: So Dr. Saliba, one of our listeners wanted to know whether you could comment on the ability of the MDS to track fluctuations or changes in some of these outcome measures of interest over time? How sensitive are those measures, and do they vary?

Dr. Debra Saliba: The MDS measures, the outcome measures are sensitive to change over time. We see when we track them, for example. The implementation of measures in the five-star system, we will see improvements in those over time. Some of which may be related to improved documentation. Some of which may be related to improved performance. But we have seen that they are sensitive to change.

Dr. Debra Saliba: Other work that we've done has shown that nursing facilities do pay attention to their outcome metrics, and they do try to implement performance improvement. Some do that at a very basic level of just, again, improving
documentation. Others, however, do try to implement quality improvement activities in response to those. And we do see some sensitivity.

Dr. Debra Saliba: Additionally, some of the measures were selected, because in other settings, they do show sensitivity to performance improvement and to change. So, for example, with the PHQ-9, the severity scale within PHQ-9 has been shown to be sensitive to improvements, including treatment and management of mood disorder.

Vince Mor: Very good. So, the other related question that person also asks, somebody who's obviously quite familiar with the data, is there's a practice that has been characterized, that some nurses from one assessment to the other, from one quarterly assessment to the other, might merely just carry over the last quarter's scores.

Vince Mor: Do you have any suggestions for people working with these data to say, or using them as an outcome measure for a pragmatic trial, to say, are there tricks to the trade to find out which homes tend to do that more? How can you identify that in the data?

Dr. Debra Saliba: That's a great question. And a fundamental issue, I think, with all data, particularly as we see the electronic health record, is specifically designed to auto-populate and carry forward data. It's felt to be a way of improving efficiency within practice, and decreasing provider burden. So, this is something we're going to have to figure out how to address.

Dr. Debra Saliba: Within the MDS data, there are ways to do some internal validity checks, to look at whether there are consistent pictures of the residents that are coming out of that data set, to try to better understand whether that data is accurate. And then additionally, some of the items, if facilities are doing them correctly, then by going to the resident and actually asking the questions of the resident, we really are trying to avoid some of those biases that are in electronic health records and in administrative data, where things are just carried forward.

Dr. Debra Saliba: But this has been something that has plagued medicine for a long time. For example, diagnoses lists. We know they rarely get updated and maintained in terms of accuracy. That's just an example of something that we need to figure out how to do better at the clinician level, in addition to doing these internal validity checks as data analysts.

Vince Mor: This is great. I will now ask you one more question, as you raise this, is that one of the great advantages and leaps forward of MDS 3.0 was to actually hear the voice of the patient, to direct staff to actually ask questions of the patient, which is a really wonderful innovation in that sense. Not so much an innovation, but a regulatory change.
Vince Mor: But one of the questions was whether you could provide any guidance about how to integrate the staff observation information and the resident responses, particularly for when there are people who have dementia or otherwise? How can you bring those two together? Should they be correlated? Should they not be correlated? Under what circumstances would you want to bring them together as one measure?

Dr. Debra Saliba: It varies by measure, depending on what you're looking at. Certainly for certain items, the instructions that are there encourage the individual assessor to integrate that information themselves, to look at what's documented in the medical record, talk to staff across multiple shifts, observe and talk to the resident. That has been left to the skills of the assessor, which really is how medicine works, is taking these multiple sources of information and integrating them.

Dr. Debra Saliba: But I think the question specifically is referring to those sections of the MDS, where there are, for those persons who are able to make themselves understood at least some of the time, specific questions that should be asked of that individual. And then for those who cannot, the observational protocols. And I think, again, that varies by section in terms of the best way to try to match those.

Dr. Debra Saliba: We know and recognize that observation is not going to be as sensitive as the patient's self-report will be. I think it's very important to realize that even people with some levels of cognitive impairment can answer questions about how they feel and their recent experience, so that those folks are not excluded and are not shifted over to observational approaches.

Dr. Debra Saliba: Standardizing the observational approach, having some specific parameters that you're going to implement, to collect observational data, can make a difference in being sure that you are going to be more sensitive and pick up information. For example, making sure you talk to caregivers across multiple shifts.

Dr. Debra Saliba: The extent to which you improve the quality of your observational data, it makes it more likely to align with self-report. But when we compare them, even in patients who can self-report, and we look at the comparison of observational data to self-report data, they don't typically directly align.

Vince Mor: Thank you very much. So, I'm going to ask each of you one last question. So, I know both of you are at the forefront of not just analyses of these existing sources of secondary data, but also in the development of new data sources that are available for, ultimately, future secondary data sources.

Vince Mor: So Dr. Teno, what's coming down the pike? What are you working on? What's next that might be available for future researchers to look at?
Dr. Joan Teno: So rather than talk about what I'm working on, I want to highlight what CMS is working on. And CMS is now working on claims-based measures to examine the quality of care. And so they're looking at specific practices that raises a concern with the quality of care, and they're aggregating them to use it potentially in star ratings. So, I think there needs to be a word of caution on the degree to which you can infer quality from claims-based indicators.

Dr. Joan Teno: The one example that I always use, when I talk about this, is not all hospice admissions in the last three days of life are preventable. Not everybody can have a hospice length stay longer than three days. So, while many people will say a hospice admission less than three days is associated with poor quality care, it's not always possible for a clinician to change that disease trajectory, because people do have catastrophic events.

Dr. Joan Teno: So, I think we need to be very careful when thinking about inferring quality from these claims-based indicators. I understand that CMS wants to do this, to make it easier on the providers and to decrease costs. But you've got to be careful that you're really fairly measuring the quality of care across these providers, when it comes to public reporting.

Vince Mor: Thank you. Dr. Saliba, what do you see coming down the pike?

Dr. Debra Saliba: Well, we know that the standardization of data elements across different post-acute care settings is going to be implemented in the next few years. That's part of the IMPACT Act that was a bipartisan piece of legislation aimed to improve the ability to compare outcomes across all of the post-acute care settings. Then through the regulatory process, and the plan was to implement the standardized data elements, that was put on hold because of the public health emergency.

Dr. Debra Saliba: However, once we're through this public health emergency, CMS remains committed to implementing those standardized data elements. They've now said that it will be two years after the end of the public health emergency to implement those changes across all of the post-acute care settings. And by that, we mean in nursing homes, in home health, in inpatient rehab facilities, and in long-term care hospitals.

Dr. Debra Saliba: And there may be, hopefully at some point, some standardization of some of these data elements into other settings as well, so that we can really get a picture as people are moving across settings about what's going on with them. And really be able to understand the trajectory of some of our patients because we know patients move back and forth a lot across these different settings. And that each one, as Joan referred to earlier, and you mentioned, have different incentives for how they document in their data sets, who have different even approaches to how they organize clinical care.
Dr. Debra Saliba: So to the extent that we can come up with some data elements that are not as affected by some of those financial motivations, that people can employ in assessing residents, I think it'll give us a much better way of both tracking from an administrative data perspective what's going on with patients, as well as from a clinical perspective, to really get a good picture of what's going on with that individual over time.

Vince Mor: Great. Thank you very much. It's a great vision of being able to see the same kind of data elements about people, as they go through this transitions from one setting to the other, through characterizing the movements in their lives. That's wonderful. It's an interesting vision.

Vince Mor: I want to thank you both very, very much for your time, and your great insights into how we use secondary data for doing analysis and understanding people's experience in the healthcare system. Thank you very much again. For those of you who are outside listening, please tune in at our next Grand Rounds, which I think the next one is in September. And I believe that's me who's actually going to be doing the next Grand Rounds on September 22nd. Thank you very much. We're having a summer break. I want to thank you all very much again, and we'll sign off here. Thank you. Bye-bye.

Jill Harrison: 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.