Jill Harrison (00:02):

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 (00:30):

Good afternoon or good morning wherever you are. My name is Vince Moore. On behalf of myself and co-director of the NIH IMPACT Collaboratory Dr. Susan Mitchell, I'd like to welcome everyone to our Grand Rounds now in it's six months. The admission of the IMPACT Collaboratory is to build the nation's capacity to conduct pragmatic clinical trials of interventions embedded in healthcare systems for persons living with dementia and their caregivers. These monthly Grand Rounds are meant to promote that mission through knowledge dissemination and fostering dialogue across the wider community of investigators and stakeholders.

Vince Mor (01:06):

Today's presentation is from doctors Eric Larson and Leah Hanson who direct the Healthcare Systems Core and two of their executive committee members, doctors David Reuben, and Jeff Williamson. They'll be doing a tag team on the topic, Breaking the Cycle, Health Care Systems Interactions for Impactful Results. Okay, so Eric, I'm going to turn it over to you for your beginning of your discussion.

Eric Larson (01:33):

Thanks Vince. This is Eric Larson out in Seattle, and I co-direct this Core with Leah Hanson from the Twin Cities in Minnesota. We believe that the upside of pragmatic trials in finding better ways to care for persons with dementia is extremely high. For decades really there's been a slurry of publications and knowledge generated from clinical research about how best to care for persons with dementia, but we're struck by the fact that the field hasn't really been populated with elements that you could say broadly, this really works, or this is ready for implementation and widespread dissemination.

Eric Larson (02:19):

And that was brought out by a recent evidence practice center reviewed, done for the National Academy of Medicine and the National Institute on Aging stating that there were very few studies that passed the evidence-based criteria for believable and implementable results in spite of the fact that there've been thousands of papers. So what this says to me is that we really need to succeed in the mission of the IMPACT Collaboratory, which is to develop the evidence base and the methods that will lead to better dissemination.

Eric Larson (02:56):

One of the things we've learned over the 10 or so years, thanks to Francis Collins and the director's office at NIH is that pragmatic clinical trials can be fielded and can be used to generate the kind of information that leads to implementation and ultimately improvement in care and health. And over the years, a team of us here at Kaiser in association with the team at Duke have been able to learn how to work within healthcare systems and create the partnerships that we need. So in my view, and I started in this field back when I was a very junior faculty and we didn't know what was right. The field is right for

exactly what the IMPACT Collaboratory is aiming to produce. Vince, I hope that answers your question about how we got started on this Grand Rounds.

Vince Mor (03:50):

Yeah. That's wonderful. Leah, do you want to sort of talk about how this relates to the broader healthcare systems research network that you and Eric had been part of along with Jeff and David for the last decade?

Leah Hanson (04:06):

Yes. I'd be happy to, Vince. Thank you. I'm from HealthPartners located in Minnesota and we collaborate with institutions across the nation part of this healthcare research network. And one of the great things about thinking about a pragmatic trial is a shared data model that we use across our systems, which we can hopefully leverage in conducting these trials. One of the things that I think came out of our discussion on the Grand Rounds was just thinking about the limitations in the data we collect for persons living with dementia and their caregivers, and how that could be a challenge in doing these types of studies. And I'm wondering specifically, since we have Jeff and David joining us, if they could address that issue of pragmatic data versus the data needed to be collected for research in order to answer these questions.

Vince Mor (05:10):

David, Jeff. Jeff, why don't you go ahead.

Jeff Williamson (05:14):

Yeah, thank you, Leah. That's a very important question and observation. I think most people will recognize immediately that I'm sort of I've been for most of my life a traditional clinical trial, just like most of us actually in this field. One of the reasons that the problem that Eric and you have already observed is that a lot of the outcomes that we're interested in, in the IMPACT Collaboratory may not even be in the electronic data sets, but a lot of the things that impact these outcomes are.

Jeff Williamson (05:46):

And so one of the things that I think will come out of this collaboratory is truly what the name of our group is. The Collaboratory that can leverage both pragmatic, but also occasionally have to use some traditional methods for obtaining some of those outcomes, like a physical function and cognitive function, which are often not very well characterized, at least in their subtleties in the electronic health record. And I hope that as we go along, we'll be able to advocate for better inclusion of these important outcomes in the electronic health record. Traditionally electronic health records have been graded, including cancer outcomes or cardiovascular disease-based outcomes. But many of the things we're interested here are care, provision, care reception, physical, and cognitive function outcomes. And those, the electronic health record needs some help in ascertaining.

David Reuben (06:47):

And if I could echo that, Jeff is absolutely right here. I think where the electronic health record is currently limited, and this doesn't need to be the future of the electronic healthcare record is really in collecting data that mattered to people, clinical symptoms, quality of life, wellbeing. These are not elements that are routinely collected in clinical care. Where it's exceptionally valuable are things like

utilization, testing, maybe even pharmacologic therapy, those kinds of things, but subjective, personal goal-oriented types of care just are not collected right now.

Jeff Williamson (07:31):

If I could just add one other things to this. Traditional clinical trials are not very good at this either. Probably the last decade or two decades of my career, I've been so to speak on the battlefield, trying to include cognitive outcomes and functional outcomes in traditional clinical trials, which have also mainly focused on disease-based outcomes or death. And so it's not that traditional clinical trials are doing it well either versus pragmatic trials. So I just wanted to make that point.

Vince Mor (08:07):

So that's a really great point. I want to just ask. So when you, in a pragmatic trial, you want to try to embed the intervention and all of its complexity, as much as possible into the infrastructure that's inherent or that exists in the healthcare system already. And one key part of that is identifying who is a candidate for the participation in the study. And so the question is this, is the electronic medical record appropriate or is it good enough to identify the people with dementia in many healthcare systems? And then secondly, Jeff and David, maybe you can respond or Leah and Eric as well, the extent to which that is also applicable to the caregiver and whether that person can be identified in any reasonable way from the electronic medical record.

Eric Larson (09:13):

This is Eric, and I'd be happy to start answering the question. The electronic health record can be used to find people who have dementia based on codes and other things, but by and large, it is lacking in sensitivity because so many persons in whatever electronic health record you're looking at are not identified well in that. More importantly, though, the challenge in caring for persons with dementia or pragmatic trials and case finding if you will, in dementia, is that people with living with dementia, typically go from system to system, to system.

Eric Larson (09:54):

So in an integrated system like Kaiser, we may have very good tracking of the same person over many years, and that can be a rich way to identify people albeit not by any means perfect, but if you're out in other systems and even in Kaiser where people go to adult family homes or other places which may be under contract with the healthcare system, there may not be anything that even resembles an electronic health record. And again, you ended up using claims and claims are okay, but they probably are not nearly as good as the data that would be in an electronic healthcare record.

David Reuben (10:39):

I can say a little bit more about that. We have used electronic health record to identify people. We've done it with ICD codes. We've done it with medications, we've done it with natural language processing and you can do it. You can do it. It is not perfect. There are errors and it may not be sufficient if you're trying to recruit for a clinical trial, say that you may need additional efforts to do so with. With respect to your second question, which I think is exceptionally interesting about the caregiver that in no health system that I have seen is that readily identifiable. Even if you were to do manual review of charts, that information frequently is not readily identifiable. So those are the caregivers basically in our electronic health records and many of the ones I've seen are absolutely invisible.

Jeff Williamson (11:39):

Yeah. Just to add on ratifying everything that's been said, an excellent editorial, by the way, in the Annals of Internal Medicine this week, talking about some of the deficiencies in the current generation of the electronic record. It is disease-centered and billing-centered, but not patient-centered for the most part now. And so we're losing the story and the story of human beings is really, what's really important for much of the work we're doing. And so that doesn't mean it can't be that, but again, I hope the collaboratory will begin to highlight there's a different kind of data that needs to be collected to help us with these very important caregiver outcomes and patient-centered outcomes that have not traditionally been included thus far.

Vince Mor (12:27):

That's a really good point because this is actually a real challenge for, there are actually some of the work that actually did moderately pass muster in the AHRQ systematic review that was done for the evidence-based group. There were some caregiver interventions that were helpful in jet by and large reducing stress and strain and helping the caregiver cope with a patient with advanced disease. And yet if we can't find them in the healthcare system, or they're not routinely there, the process for recruiting them becomes very complicated. And that means that it's going to be less pragmatic. And the question is, would a healthcare system, for instance, like Kaiser take on the problem? Let's say we were able to say that yes, a caregiver intervention really worked and it really made a difference in the lives of the caregiver plus the lives of the patient. But that in order to do that, you have to spend a lot of time reaching out and having supplemental information for the caregiver. Would Kaiser or Partners actually say, yes, well, let's do that. This is important. Eric, Leah, what do you think?

Eric Larson (13:53):

This is Eric. I think the answer is yes. And part of the reason for the answer is we know that the person living with dementia and the caregiver are a dyadic unit and some of our own research has demonstrated that the challenges of people who become demented without a caregiver without living alone, for example, and I think through research integrated delivery systems are beginning to learn that things like legal, next of kin, other ways of recording information will eventually allow the recognition of a caregiver. But I'm not disagreeing with David or Jeff that the electronic health record as currently written makes that easy. It has to be a policy decision. And I think that clearly when people in a system like Kaiser and probably HealthPartners are identified as demented, the standard of practice is really to make people aware of who the caregiver is. Now, I can't tell you that it's systematically recorded in a box that you can immediately pull up without NLP or something like that. But I think over time, that's going to become the standard of practice.

Leah Hanson (15:05):

And Vince, I think this gets really to one of the priorities of our Core is that when we conduct research within healthcare settings, we really have to know that the values align because doing something like that requires extra effort on part of the clinical care team or the operations. And while I think, yes, it's definitely thought to be important and a priority. You also have to weigh that against all of the other priorities in primary care and in the memory clinic and all of the other chronic diseases that are being managed. So I think that's the issue we're really trying to, in our Core plan to bring together the groups that have this as a priority and bring together care settings, like the learning health systems, integrated care delivery, like Kaiser and HealthPartners and figure out how can we best do that? How can we do

that in a way that works within workflow, doesn't add burden and really have that value proposition for the institution.

Vince Mor (16:14):

So David, if I'm going to shift to you, you presented a wonderful trial. That was collective lots of really important data about both the family member, the caregiver, as well as the patient in terms of their outcomes that presumably would matter to them, but there were a lot of them. When you were actually designing that or thinking about how to put that package together with this large consortium group that you have, how did you actually balance this issue of how much is pragmatic and how much is all this data collection going and how would you then ultimately say to capture what's important out of this for the future. And would you suggest to a healthcare system, your own healthcare system that they try to embed some of these kinds of elements in the electronic medical record?

David Reuben (17:09):

Yes, that's a great question. So as much as possible, we tried to rely on what was already there, but we found that as we mentioned earlier, there was a lot that wasn't there. And I think that as healthcare systems begin to address dementia and dementia care systematically, there is great opportunity to make the electronic health care record much more robust in terms of the data. That will take time. That will definitely take time. In terms of deciding what measures to collect in addition, this was an interesting process. We came in with a relatively minimal set of measures that we knew were responsive to the interventions that we were launching. And then as we opened it up to stakeholders and our study advisory committee and additional investigators, everybody had another thing they wanted to measure. And then when we submitted the grant to the National Institute on Aging, they had additional things they wanted to measure.

David Reuben (18:24):

And one of the critiques said, "With all this effort, why aren't you collecting more data?" So it's tough. It is a tight rope that you walk between three things. One is what you're able to collect easily from like the electronic health record and claims data. Two, what you think is important to be measured, what really matters. And three is respondent burden because the more you burden your respondents, the less likely you are to get comprehensive and complete data. So it is a tight rope and you have to make some decisions yes to some and no to others.

Vince Mor (19:09):

So Eric, you have been leading the Health Care Systems Core for the NIH Collaboratory for a number of years now. And so had a particularly insight to a variety of different, large pragmatic trials that have been done under the auspices of the NIH Collaboratory. What is your experience with this kind of balancing act that David described between lots of primary data collection versus less primary data collection in the context of pragmatic trials? How have those debates and discussions gone from your perspective?

Eric Larson (19:46):

It's a really good question. And one of the goals of the common fund collaboratory has been to create generalizable knowledge. And I think we're beginning to have some of that knowledge with regard to fielding pragmatic clinical trials. First, well, first of many, really that I can think of is relationship building. And as Leah mentioned earlier, finding a shared values that says you're asking a question, looking for an

answer that's a value to the research team and will be a value to the delivery system. And it's real clear to me that the trials in the original pragmatic trials, the healthcare systems collaboratory, that had the easiest run either had a prior relationship or developed a really strong relationship with their partners on the clinical side.

Eric Larson (20:38):

Another piece that we learned is that healthcare systems are dynamic. They're changing a mile a minute some of the times, to respond to, for example, the pandemic and suddenly something is very important that may crowd out the interest of the team doing the trial. And the key there is to have a strong relationship and to expect the unexpected, if you will. And that unexpected can range from a change in the electronic medical record, where suddenly a data element has changed and you don't know about it, unless you have on the ground kind of partnership. And also leadership changes are common as well as policy changes and challenges there.

Eric Larson (21:25):

And then the point that David made in talking about data, one of our investigators, Greg Simon likes the phrase that researchers are not the dog wag the tail and tail doesn't wag the dog. And so for pragmatic trials to operate in a way that that doesn't add to burden is absolutely critical. And granted there almost always will be some added burden, but the whole goal is to make them as efficient and seamless as possible. And the point that I learned over the years is that the researcher generally would like to do exactly what they want. And sometimes, and I think the dementia field has this trait. We would like as researchers to just somehow sit outside the system and do our study, and then tell people what we found.

Eric Larson (22:22):

The nature of a pragmatic trial is that it's embedded in the system. So you, in doing a pragmatic trial are inevitably going to rub shoulders and have a relationship and an effect on the system as you do the trial. And that is sort of got to be uppermost in your mind, I think as a researcher. The work that we're doing is very important, but it's not the goal of the delivery systems. The goal of the delivery systems is to take care of their patients and to do so in a way that is fiscally responsible. So that's some of the things that we've learned. I probably could talk on forever, Vince, if you wanted me to, but I think others have ideas too.

Vince Mor (23:03):

Leah, could you comment on that from your experience at both at Partners as well as in the broader ACSRM?

Leah Hanson (23:10):

Yeah. Maybe I'll share one example I had of working with our medical group and trying to add data collection point. And so when Medicare Annual Wellness Visits were started, our Center for Memory and Aging team worked with leadership to lobby to get them to include a standardized assessment for cognitive function versus the question is how is your memory or are you worried about your memory or anyone in your family? And so it was a complex process that actually took us 18 months of conversations, but we were successful in being able to influence the test that was used and to have a discrete data field, which meant we could pull it directly from the medical record.

Leah Hanson (23:58):

Once that happened, we were really excited, but the adoption of the wellness visit in our system was really low. So we were disappointed in the number of people that were being screened because they weren't doing this visit. And it wasn't until the payer, until Medicare changed reimbursement policies that really leveraged our leaderships to say, if we do this visit and if we're doing the annual physical, we're able to get higher reimbursement on care. So it really, I think, points to the fact that policy or a quality measure or finances in terms of the payers hold a lot of influence over the amount of work that the healthcare system is willing to do or to add data elements.

Vince Mor (24:48):

That's great. So David or Jeff, anything else you'd like to comment on that with regard to this question?

David Reuben (24:56):

I would just say a word about embedded pragmatic clinical trials. And I think there are two components to that. The first is about embedding the intervention, including identifying persons for the intervention into clinical practice. The second is about embedding outcomes into already collected data. And they're really separate issues. I think that we are much closer to the former about really being able to put changes into clinical practice than we are with the latter about being able to extract outcomes. But that said, healthcare systems are really looking for better ways of doing things. And Jeff talks about the win, win, win. Better ways of doing things means both saving time, becoming more efficient, and also as Leah referred to is perhaps increasing revenue.

Vince Mor (26:10):

Jeff, you want to give us an example for that?

Jeff Williamson (26:14):

Sure. Even before the example, maybe Vince, what I'll just say is, is it for young people, investigators listening to this podcast I hope that none of this dissuades you. I think of the science of pragmatic trials, sort of like I think of how Watson and Crick must've felt back 55, 60 years ago or more. We're at the very beginning now. And so there's a lot of groundwork and the slow progress of science in this area is going to happen. And sometimes I think those of us involved in clinical care were impatient to see the whole genome sequence at one time, but it's not going to happen like that. So that's why this committee, this Core is so important to help investigators understand where the science is and how they can make important incremental contributions while at the same time, still changing patient care.

Jeff Williamson (27:12):

And that sort of leads to that win, win, win. I think at all times, you, as an investigator, your team and the leadership who are sponsoring your project need to understand, what's a win for the patient, what's a win for science and what's a win for the healthcare system. And that when may be different now, just like it was for the DNA sequencing way back, that was a different kind of win, but the win and the win, win, win will change as time goes on. And this should, I hope that people are very excited to be in on the ground floor of this kind of work that we're doing. And we're talking about today.

Vince Mor (27:51):

Great. Thank you very much. Eric, any last comments before we turn it over to Aaron?

Eric Larson (27:58):

I really would like to endorse what Jeff just said. We're at the beginning of a new phase, I think in clinical research in general, the pragmatic clinical trial becoming more acquainted the realm than it has ever been in the past, but for our field, for the dementia care field, tremendous, tremendous opportunities to contribute to knowledge and the kind of knowledge that will make a difference in the long haul. I think that's what draws most people to research in the medical field, which is how can we make a difference. And I really believe that in the next five to 10 years, the IMPACT Collaboratory by working with healthcare systems is going to make a huge difference in the lives of others.

Vince Mor (28:43):

Thank you very much. I want to thank all four of you for your great effort at putting your talks together and for this time and the question and answer period. Eric, Leah, Jeff, David, thank you very much for your time.

Leah Hanson (28:58):

Thank you, Vince.

David Reuben (28:58):

Thank you.

Jill Harrison (29:02):

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.