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.
Ellen McCarthy:	00:31	Welcome, everyone, and thank you for listening. My name is Ellen McCarthy, and I'm the Executive Director of the NIA IMPACT Collaboratory at Hebrew SeniorLife. We have with us today Dr. Enola Proctor, the Shanti K. Khindka Distinguished Professor and professor emeritus at the Brown School at Washington University in St. Louis. Dr. Proctor has graciously joined us to answer some of the questions that we were unable to get to following her Grand Rounds implementation outcomes and their role in treatment success. Welcome, Dr. Proctor.
Dr. Enola Proct...:	01:03	Thank you.
Ellen McCarthy:	01:05	I'd like to start by asking you to share a little bit about yourself and how you came to the field of implementation science research.
Dr. Enola Proct...:	01:12	Sure. I think that's an important question because many people [crossover 00:01:17] And how we can improve access and the quality of behavioral health care in those settings, although I've also done work in medical settings and in mental health specialty settings. I was directing an NIMH funded mental health services research center for about 20 years. And over the course of our work together, we started with questions of access. How do we ensure that more people have access to mental health services, because we have very huge and disturbing problems and lack of access. Both our own research and research in the field showed that sometimes just getting people to services didn't really help improve their functioning or their mental health symptoms or their quality of life. So like the rest of the field, we became focused in addition on improving the quality of those services. Our school of social work even made a commitment to training our students in evidence-based practices.

And I had a very influential conversation with a field instructor at the time we were rolling out this evidence-based curriculum. And he said, "I think delivering evidence-based services is really important, but how do I, as an executive director, make sure that I can reduce my delivery, our agency's delivery of ineffective services and increase our delivery of more evidence-based intervention?" So that conversation along with my growing concern about quality of services really brought me squarely into the field of implementation research.

And my focus has been on what are the strategies to deliver evidence-based interventions and how do we evaluate our success in doing so.

Ellen McCarthy: 03:58 That's great. Thank you. It's important because you began your Grand Rounds by reminding us about the research pipeline and the typically long process for timely integration of scientific evidence or effective interventions into our daily patient care practices. It takes about 17 years to close this gap and to move evidence into clinical practice. Implementation science research tackles two related objectives to both accelerate and increase the use of scientific discovery into practice, while also decreasing the use of ineffective and even harmful practices.

Could you tell us about some of the greatest challenges to implementation science research as it relates to integrating an evidence-based intervention into a healthcare system?

Dr. Enola Proct...: 04:47 Yeah, they're myriad. How long do we have? As everybody who tries to tackle this discovers, I think it's important to ground our thoughts about those challenges in context. And one of the tensions in implementation science is that between our focus on local improvements that we can see and the people we serve can experience local, but intention with developing generalizable knowledge. And I think this is one of the ways in which quality improvement initiatives are complimentary, but slightly different from implementation science.

In quality improvement, we're usually driven by specific challenges often in a particular subset of organizations or a particular division of a hospital or a clinic. That's really, really important and it's highly motivating. But in implementation science, we're trying to develop an evidence about how to improve the quality of service delivery, so that what is learned in one place can be shared, applied, and can be successful in other places. This tension between, is it local, is it generalizable, is one tension and the contextual factors come into play here.

We know that interventions that are delivered are a function of the frontline providers. They're a function of the team. They're a function of the organization. There are community influences, and there are policy influences. And as we like to say, when we consider this multilevel context, we quickly run out of N at the top. We know it is challenging to improve care in a particular clinic, but that's an N of one.

It's all the more challenging to improve care in a health system or a hospital, and yet that is an N of one when we think on a national perspective or a global perspective. The challenges include finding comparison groups. It involves structuring rigorous comparison conditions. It involves some degree of control, and by definition, it involves moving contexts and moving targets. I like to think and I believe that healthcare systems, delivery systems are constantly changing, and that's good.

They're learning from experience. But how we work within a given healthcare system and isolate the most influential factors in context and how we can construct ways of drawing comparisons that are robust enough to know that we can have confidence that what we're doing is successful, those are some of the challenges. Finally, it's like building the airplane while we're flying it. We have to deliver care. Most service delivery systems have an internal conflict in resources and time.

How do we take time to study something versus how do we keep on delivering services and meeting the immediate need? So just a few of the challenges.

Ellen McCarthy: 08:18 Thank you. The importance of N value of context is something that you also really highlighted in your Grand Rounds. Over the next four to five years, the IMPACT Collaboratory plans to fund about 40 pilot studies for stage four effectiveness trials of non-pharmacological interventions for people living with dementia and their care partners.

How do you think about using implementation science research to strengthen the process of scaling up your intervention from a pilot test of an intervention in a few healthcare systems to a full scale pragmatic trial embedded in several healthcare systems?

Dr. Enola Proct...: 08:59 What an exciting project and how terrific for you and for the field that you have the resources to do that. That's exactly the kind of broad thinking that we need in constructing research projects and in a way that we can apply findings from one study

to another. I think I would, first of all, think in terms of kind of two principles. And I'll name them so I don't forget them, and then I'll expand on them a little bit. One is to leverage every project to try to extract, to learn what we need to inform the next. In this regard, I'll talk a little bit about hybrid trials.

And the other issue I would encourage you to pay very close attention to is variation. What variation can be controlled and what variation do you want to bring into this program of research? First, back to the applicability of hybrid trials, as I said in my talk, and I referred to Jeff Curran's a terrific paper on hybrid trials, while pilots are being conducted and as you move to test of efficacy, I think it's really opportune and critical to use that opportunity to capture systematically and from a variety of perspectives an understanding of what it would take to deliver that.

Who would deliver it? What training would they need? What resources are needed? How long does it take to get the expected response? And how do a variety of stakeholders perceive and respond to that? We call this a hybrid one, so that the focus is on developing an intervention and testing an intervention, but using that opportunity to gain an understanding of the implications for implementation.

That puts us much farther ahead and lets you begin thinking at the get-go about what it will take to implement and also what adaptations might be needed, what variations might be needed for the array of settings that intervention could be deployed in in a full scale up, leveraging every opportunity. And I love that you've got this vision of where you're going, why you're constructing these studies. And that's really the benefit of conducting research within the context of a center to have a long range game plan, a research agenda, and to be very purposeful with each study.

Not only for its own sake, but to inform and guide you in the overall research agenda. The second point is thinking about context and what needs to be varied and what needs to be held constant. You have a perfect opportunity, for instance, to hold constant to some degree the intervention, but vary the contextual settings. And that will tell you how transferable or how generalizable something is at the outset. The other way to think about that is to hold a setting constant and test out variations or potential adaptations of an intervention in one setting.

When I'm teaching research methods, I think the heart and soul of research is variation and figuring out what variation do you want and what variation do you need to control for robust comparisons. I think attending to those two issues will give you a good platform to think about how you can leverage fully the opportunities in each individual study to inform your long-term research agenda and your long-term care improvement objective, which is to scale up across a variety of settings.

Ellen McCarthy: 13:15 Thank you. This issue of variation actually sort of brings us to the next question that was asked by one of our listeners. When you're integrating an intervention into a usual clinical workflow, you inevitably make some changes to adapt the intervention to that healthcare system. The question is, how do you strike a balance between fidelity and fit, particularly when adoptions need to be made? And along those lines, how do you know that you've retained all the key components, the secret sauce, so to speak?

And then I guess a related question would be, is all fidelity drift bad?

Dr. Enola Proct...: 13:57 Yeah, I know your center is really going to teach us all a lot about fidelity in the context of implementation research. That will be very, very welcome. I think we're coming to understand that adaptation happens. As one of my slides indicated way back in the day, we thought that any adaptation was bad. And now I think we view it as inevitable and often helpful, and yet we can't answer the question of how much fidelity is good and how much is bad without knowing what are the consequences of adaptation or drift?

I think that this is kind of a push-pull conundrum for the field. Treatment developers, intervention developers, usually they're pushing out something and they want it to stay true to the blueprint. But those who are pulling for interventions are saying, "Bring it here and make it fit, because it may not work unless we make it fit." We have both phenomenon going on, and I view adaptation a... Well, I used to say it's neither good nor bad.

I'm coming to think of it more as good because I think it helps the puzzle piece fit in the new setting of the new position much better. How we know whether we've gone too far is really continuing to assess the clinical outcomes. I think we can stretch, adapt, modify an intervention as far as we need, as long as it's still effective. And that's where a hybrid three research

design focuses on issues of fit, implementation outcomes, such as appropriateness, acceptability, sustainability, feasibility.

And yet it continues to monitor the clinical outcomes that that intervention is targeted toward so that we will know whether or not we've done harm to the intervention and we're no longer seeing the improvement that we expect. I kind of think of it as the old limbo game. How low can we go? How far can we adapt and still get the successful service system and clinical outcomes that we're striving for?

Ellen McCarthy: 16:34 So one of the things that our pilot studies have been struggling with is this issue of fidelity and particularly with more complex multi-component interventions. What recommendations do you have for investigators to ensure that the intervention is delivered with fidelity, particularly when they scale up given the highly variable context that you mentioned earlier?

Dr. Enola Proct...: 17:01 Well, there are a variety of approaches to measuring fidelity, and I think the current tension in the field, and I would call everyone's attention to a recent special issue in Administration and Policy in Mental Health Services research on fidelity, what measures are portable, what measures themselves are feasible to use in a variety of settings. I was trained clinically in an era where there were videotape recordings of every session to determine fidelity.

We know that that's feasible in a laboratory training session, perhaps in a research setting, but it's not sustainable and feasible or cost realistic in complex service delivery settings. I encourage those who have the strongest interest in the integrity of a particular intervention to continue to work on pragmatic measures of fidelity, checklists, sometimes brief questionnaires even of our clients or patients, did the session address X, Y, and Z, spot checks. There are a variety of ways of constructing feasible measures of fidelity.

I think we've all learned that drift regression to the mean, those are normative. Periodic coaching, we see physicians using pocket checklists to make sure that certain things happen. I think we could be aided if our clinical records functioned more as a quality control for ourselves, for providers. We're a long way from having nuanced procedure codes. And if procedure codes were nuanced, to ensure that they captured critical ingredients of an intervention.

We could very efficiently use the clinical record as a check, as a reminder, as a prompt, either as services being delivered or after a service has been delivered. We see a lot of advances here in medical healthcare. And yes, there are challenges with providers reacting strongly and negatively to pop up reminders to, you can't go on, you can't close out this record until you've told us X, Y, and Z.

And yet the evidence is that the electronic health record can be a tremendous boon in both ensuring that care is delivered and in monitoring for research purposes so that we can know who got what in service and we can link that to outcomes and be in a much stronger position to have nuanced knowledge about what care was actually delivered. I don't know whether your center investigators are considering leveraging technology, those kinds of prompts, checklists.

I'd think that your settings would lend themselves to that and the field could certainly use what you learned to help us have a stronger sense of what kind of... These are implementation strategies, so here we're talking about constructing fidelity checks and continued coaching through some infrastructure or technology supported implementation strategies.

Ellen McCarthy: 20:39 That's really helpful. And I do know that some of our pilots are working with the electronic medical record in sort of the clinical workflow of the delivery system to try to make sure that checks are in place with regard to fidelity. This is very helpful.

Dr. Enola Proct...: 20:56 That's really exciting, and also dashboards.

Ellen McCarthy: 20:58 Really good point. One of our Grand Rounds listeners asked if you could address what the relationship is between implementation science research and change management. Are they complimentary, similar, or different?

Dr. Enola Proct...: 21:15 Well, I'll quote one of my most influential colleagues and I would characterize him as a mentor because I've learned so much, David Chambers at NCI, who has a slide. I didn't use it in my presentation, but I'm sure you can find it. It's called The Big Tent of Implementation Science, and it shows overlapping circles of depicting the contribution of various allied fields to what we're calling implementation science. And I certainly would put change management as he positions quality improvement science.

It depends on whether the change management is really change management science, or it is the practice, much as Dr. Chambers shows quality improvement itself as not overlapping with implementation science, but quality improvement science as overlapping. I think the strength of all change science approaches, including management science, is they focus us on a piece of the action and clearly leadership, organizational management, the organizational context.

If we're going to really believe that it's all about context, then we welcome and need to figure out how to harness the synergy between fields such as this and implementation science. And yet, it's probably not the full picture. It may not address... So I would say it's necessary, but not probably sufficient because there are external policy factors, there's reimbursement factors, there's demand factors from advocates, from consumers of our services. There are additional influences on implementation that we need to harness for implementation science in addition.

But attending to the internal context of the organization and leadership, Gregory Aarons at university of California, San Diego does some of the strongest research on the role of transformational leadership, Charles Glistens, decades of work on organizational context and climate, the work of Laura Damschroder in helping us understand the complexities of the organizational context through the CFIR model, all of those are in close with what I understand as being the key principles of change management.

Ellen McCarthy: 23:51 Great. Finally, we received a lot of questions around the level of evidence in the research pipeline. And you noted that we're fortunate that evidence is always evolving and that we will always know more tomorrow than we do today. And you've talked a little bit here today about hybrid interventions and their utility.

Could you talk about how they can help inform questions of the effectiveness of the underlying intervention while you're gathering information relevant to implementation, particularly I think as it would pertain for the IMPACT Collaboratory to pilot studies for stage four ePCT?

Dr. Enola Proct...: 24:34 Yeah. Well, again, we're seeing this in our public discourse how much evidence is enough for us to have confidence in a COVID vaccine, how much evidence is enough. Now the general public even knows things about different phases of trials, which is maybe that's a little science education going on at the same

time, fueled by our eagerness to get back to a more normal, whatever that's going to be, routine. So the evidence that we derived from small pilot studies is that, it's small and it's pilot, and it's preliminary, and that needs to inform moving on.

I think when I think about the sufficiency of evidence, let's go back to the larger point. The larger point is to improve care. And therefore, we know that we don't want to be working to spread, to disseminate, to implement interventions that don't work. I think that's what has given rise in the implementation science community to a caution around enthusiasm to move forward with implementation or scale up when the evidence remains shaky. And yet, as I said, the real world has to deliver care now, so we're always striving to improve that.

I think the hybrid designs offer us the best way to leverage this. As I suggested earlier, trying to understand the implications for implementation, even in small scale pilot studies where the purpose is and kind of the you're going to get a red light, a green light, or a yellow light to move forward on the basis of a pilot trial. And then making sure that even once we're concerned with implementation and our focus is on implementation outcomes and service system outcomes, we don't want to take our eye off the clinical outcomes.

It is a challenge. How much evidence is enough? When can we move forward? That's always going to be subjective, although grant reviewers are going to have and bring to their evaluation of our proposals their standards. But also my experience with the real world, I remember when I was working on an implementation initiative for depression care for older adults in the senior services arena, gerontological services.

And the director of a very large statewide organization said to me, "Well, this sounds good. The evidence looks good, but how much is it going to cost? And how much havoc is it going to reek?" And I think she was asking me, "Is the evidence worth the disruption it's going to take to implement this?" Questions of, is the evidence good enough, are not just reviewers whom we have to convince or get by. It's a question that all of us who are committed to improving care have to really have our eye on because change is disruptive.

Change is costly. I come down on the side of, is taking this step to improve care, do we believe that yes, it is worth it? So that's a more nuanced and a less calculable ratio to come up with, but

I think we need to think about evidence in terms of, again, the broader context of implementation.

Ellen McCarthy: 28:28 It is really important, particularly given the state of dementia care evidence at this time. Well, Dr. Proctor, I'm grateful for the time you spent with me this morning and for your Grand Rounds. It's certainly been terrific for me and our listeners to learn more about implementation outcomes and implementation science research. Your work is foundational and has really shaped all of our understanding of the field.

We are grateful for IRI, your Implementation Research Institute, for its work to train the first generation of implementation science researchers, as well as its knowledge resources. Thank you so much for joining me today. We have this podcast and Grand Rounds available on our website, as well as a new knowledge repository that I would encourage folks to check out. And we'd also like to invite our listeners to follow us on Twitter and LinkedIn. Thank you again so much for your time today. It was really a pleasure speaking with you.

Jill Harrison: 29:26 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.