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| 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. |
| Dr. Weinfurt: | 00:27 | Hi, this is Kevin Weinfurt from Duke University, and today we're here with Sascha Dublin and Gaia Pocobelli, who will be reflecting on "A Learning Health System Story: Perinatal Outcomes Associated with a Major Change in Gestational Diabetes Screening." Welcome, Sascha and Gaia. Could you just give us a quick summary of the work you did and what you found? |
| Dr. Dublin: | 00:49 | Sure. Thank you for inviting us to participate. I'm Sascha Dublin, and I'm from Kaiser Permanente Washington, where in 2011 we made a major change to our approach to screening women for gestational diabetes. We switched from the traditional and accepted two-step screening strategy to a one-step screening strategy in which more women got a full-blown diagnostic test, and as a result, the rate of gestational diabetes was expected to increase. So, we studied the impact of that change on both some process outcomes, measures of how well the guideline was taken up, and what kind of care women received. We also studied maternal outcomes and neonatal outcomes, and what we found overall was that this new testing strategy was very rapidly and dramatically adopted in our system. |
| Dr. Dublin: | 01:37 | We were also able to compare what happened to women who were enrolled in Kaiser, but got their care from external providers, a group we call the network. That group of women didn't get affected by the guidelines, so we're able to prove that sort of in the surrounding community, clinical practice didn't change much in people who didn't get exposed to the new guideline. We were really able to compare the changes in our system where we saw dramatic uptake of the new screening test, and along with that we saw a lot more women got put on insulin. Then we looked at the maternal and neonatal outcomes. We were able to say that there was no change in some of the major outcomes where we'd hoped to see benefit. So, we didn't see a reduced risk of caesarean delivery. We didn't see a reduction in babies been born large for gestational age, but we did see a large increase in the prevalence of gestational diabetes. That was expected, and we saw increases in some other things too. |

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| Dr. Dublin: | 02:34 | We saw higher rates of induction of labor. We saw that more babies got diagnosed with neonatal hypoglycemia, and we saw that more non-stress tests were being done. This was all an analysis that accounted for trends in the general area, trends in these outcomes that were time trends in our region unrelated to the guideline change. So, we were able to say that with this guideline change, we saw some outcomes that are undesirable. More inductions, more hypoglycemia, and we didn't see the benefits that people had really been hoping for. When we brought these findings back to our healthcare system, they took them very seriously. They were very thoughtful. They were seriously considering going back to the old testing strategy, and they did this through a formal mechanism of a guideline review and evidence review, and they ultimately decided to go back to the old way of doing things because the new way just hadn't panned out and hadn't proven to be any better. |
| Dr. Weinfurt: | 03:34 | That's great, and clearly this had a lot of value for health system leadership. I'm wondering, Sascha, could you tell us a little bit about the experience of this from the perspective of the patients and the providers in the system? |
| Dr. Dublin: | 03:46 | Sure. We know that when a woman's diagnosed with gestational diabetes, it really has a big impact on her life. It can affect her sense of self. It brings with it a lot of new, kind of, burdensome things she needs to do. She'll need to poke her fingers to check her sugar, and she may need to take insulin. We had, earlier, actually done a qualitative study of women in our delivery system and heard from them that their experience of gestational diabetes was sort of painful and stressful. It led to a lot of changes in their care. Women told us about being induced early or being induced when they wanted to have a vaginal delivery, and about really stressful experiences using insulin. We also heard from our providers. |
| Dr. Dublin: | 04:27 | They felt they were just spending so much of their time working with women on blood sugars, and that it just seemed to be really taking over their experience of pregnancy care, but at the same time we heard from providers who were pretty excited about the new guidelines, and anecdotally thought that maybe they were making things better, and so they were so eager to get a real formal analysis with rigorous methods that gave them some real data on what was going on for thousands of women in our system. They were very receptive to what we found, which was that overall there weren't any real benefits realized, and there may have been some harms, at least in terms of care that women don't really always want to get, like induction of labor or non-stress tests, or the hypoglycemia in the babies. |

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| Dr. Weinfurt: | 05:14 | Well, that's great. You were in a situation where you were able to conduct a fairly elegant study in the trenches, so to speak, and support some fairly strong inferences about what was going on. I remember one of the things you had mentioned was that the decision to systematically evaluate this was made after the policy change was instituted. I'm just wondering, if the research team had been brought in from the beginning, what are some things you might have done differently to make this an even more powerful study? Anything you would've done differently if you'd come in in the beginning? Let's start with you, Gaia. |
| Dr. Pocobelli: | 05:55 | Sure. If we had been brought in at the beginning an ideal study, which would have been a relatively expensive study and a somewhat burdensome study to women, would be to give each woman both tests. So, both the traditionally used two-step approach and then the new one-step approach. Then we would have been able to identify the sub group of women who would be diagnosed by the more sensitive one-step approach, but not by the other approach. And then, in those women we could randomize them to either receive treatment or not, and then we could follow them for outcomes and to see whether treatment of women identified only by the one-step approach results in better outcomes compared to not treating them. But there are other designs we couldn't do which are perhaps more feasible, and I think Sascha has some ideas on that. |
| Dr. Dublin: | 06:55 | Sure. I think one thing I would say is just that the time lag... Probably the biggest effect, if we had been asked early on to participate in designing an evaluation, I think we could have just done the study a couple of years earlier. If you think about the fact that the guideline change happened in 2011, it was really 2015 when circumstances brought me together with our women's health leaders and we started planning a proposal, and then it was 2018 when we got the results. That's a relatively long time to wait to find out if a practice change worked. It would be really nice if you're going to back up and undo a practice change to do it sooner. So, I think that's one issue. |
| Dr. Dublin: | 07:38 | The other issue is that the reason we were able to do our evaluation was that I was already working in the area of pregnancy research. We had obtained state birth certificates. We had done mom/baby linkage. That was all funded by NIH-funded grants, and so a health care system may need to invest some resources up front in getting the data ready over the first year or so of an initiative while it's rolling out, and then you could really jump on the evaluation with the data in hand. We were really fortunate that I had external funding to build the |

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| | | data that were needed, but those weren't just easily extractable from the EMR. |
| Dr. Dublin: | 08:12 | My third thought in this area would just be that, I don't know if it's the best design for this case, but for many healthcare system interventions, something like a stepped wedge design where you roll the intervention out one at a time in smaller units, such as one or two clinics at a time. That can be a really powerful design. I think in our system, where we really wanted to switch over entire panels of test orders in Epic, and just make it like automatic for providers to do the right thing, you wouldn't really want to roll out new Epic smart sets in one clinic at a time, but I think for lots of interventions where you're training staff at a clinic level, or you're changing care at a clinic level, people should consider that design as a way to add rigor when you're changing care across the health care system. |
| Dr. Weinfurt: | 09:01 | Well, that's really helpful. You guys certainly were able to pull off a really impressive evaluation that had a lot of value to the health systems leadership, and we're really grateful that you've spent a little additional time talking with us today. Please join us for our next podcast as we continue to highlight fascinating and informative changes in the research world. |
| Adrian H.: | 09:23 | 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. |