Transcript: Lessons Learned From Implementing a Pragmatic Trial Using EHR and Other Real-World Data

We'll be talking a little bit about the experience of the ICD-Pieces trial in three domains, eligibility of patients for enrollment, delivering interventions, and then systematic outcomes assertion using EHR tools.

The challenge for clinical trials in general and pragmatic clinical trials specifically is how to accomplish those aims using the data that's generated in routine care processes. And so the benefit was that so much clinical care is being delivered with the steps being captured in the EHR, but there's not much traction in turning that into real world evidence.

We proposed the ICD-Pieces trial where we would use a standard set of EHR data to identify patients with chronic kidney disease as well as type 2 diabetes and hypertension. And these multi-comorbid patients are the type of patients that are frequently excluded from standard trials. And so use the real world care for those patients to strengthen the level of evidence for guidelines to get a geographic and diverse population so that the evidence generated by this trial to be as widely applicable as possible.

Part of our pragmatic clinical trial network was designed to include multiple different healthcare locations, and so that included a trial site that a community county public safety net hospital, a VA healthcare system hospital also in North Texas, as well as a private practice clinical network. And then we also included an outpatient practice network in Connecticut to give both an additional demographic variability and care location context.

In that sense, the evidence generated will hopefully be as widely applicable as possible, but that created a host of IT challenges and highlight I think some of the design choices the trialists have to make in the care that they want to deliver.

So we sort of dodged a bullet of workflow intervention standardization, which is probably the most challenging aspect of the trial. And we did that by allowing the local healthcare systems to figure out the implementation. And so that was a compromise on our part, but we think that, that, again, in the principle of beginning with the end in mind, allowed us to get the most diversity across diverse EHRs.

This led to potentially certain problems that the EHRs that were different and they had to be solved to different ways. I think the idea of having ready-made collaborations where the data harmonization is already in place would certainly avoid some of these challenges. But I think the benefit of these ad hoc collaborations is that they do allow you to inject a different amount of variability.

The experience we had to the VA integrating with the VistA Healthcare System, the largest integrated healthcare system that's providing care for CKD patients and renal replacement services in the nation. And so it's a very important provider of CKD care. And so I think our trial is very strengthened.

The other challenge to work in the VA is they have quite severe PHI restrictions on moving data out of their systems, which made us change some of our strategy of implementing a shared clinical decision support software across all of the sites. But the trade-off was that they had excellent adherence to standards, so they had the best support of the standards we used in our patient selection algorithm and made it very easy to harmonize with our outcome ascertation with value set authority sets.

One of our biggest challenges is that we had a lot of turnover over the course of the time, and by not having an embedded VA analyst sort of built into the trial, that was a big hurdle for us. Our site in Connecticut, ProHealth has a great benefit where injected geographic and demographic representation from a different sort of network than we see in North Texas. And we had several interesting things.

As a private practice organization, they had to change in their partner organizational structure where they became affiliated with MELP during the middle of the trial. That led to some changes in the way that their data warehouse was laid out and extracted. So a lot of our initial queries and things had to be redesigned.

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We were integrating data from EHRs from three different electronic health records, including an Epic's system on an Allscripts outpatient environment and the VA VistA environment that provides care to our veterans. To then get a standard set of outcomes, we were getting hospitalization data from claims that would come from both hospital claims data, commercial claims data, and Medicare claims data from the ResDAC, as well as from the National Death Index for a standardized death ascertation at the end of trial.

The challenges of that is we are trading off the scalability where you have several networks all in the same EHR to get sort of a diversity. So if our outcomes are successful, they would be widely applicable, but we had to overcome the data harmonization challenges.

We solved some of these problems by sticking to standard parts of the EHR data, what I consider the shallow and the pool for the patient selection algorithm. Sticking to areas which are better harmonized already across diversity EHRs and that included lab data, the ICD-10 CS or PCS data that's used for billing and claims, as well as standard date or encounter information. That made it easier to harmonize as data into a final data set to use for algorithm selection.

And by focusing then on data that's generated for the claims process for hospitalizations, that led to a final standard data set for our outcome ascertation of primary and secondary outcomes from hospital claims data. So I think the trials that occur over several years, you potentially have to deal with these organizational changes as they happen and be flexible to be able to handle them.

We had to have some budget changes over the course of the trial to adapt to these IT changes. Our data structure was originally based on queries that were designed at the outset of the trial. Several of those had to be revisited over the course of the trial, especially after EHR upgrade cycles, which turned out to be much more of a headache than we had anticipated, just because small changes can lead to fields being deprecated.

Integration challenges as you try to implement decision support, we sort of went for a minimum necessary approach because of the pragmatic aspect of getting provider network buy-in so that they didn't have to learn new tools. And that meant the challenge of maintaining the testing validation and setting up guardrails to make sure though that our integration endpoints stayed up and active over the course of the trial.

We had a lot of changes in the workflow in terms of personnel, just because our trial occurring over several years. The transition between analysts was a big challenge. I think good documentation was a big help, but our handoffs, or you don't have a complete knowledge transfer even though you have a complete code transfer. And even within our EHR partners, you get different analysts helping you at different time over the course of a trial, and that level of documentation is good for those types of handoffs as well.