The goal of the ICD-Pieces trial is to evaluate a novel technology platform (Pieces) supported by practice facilitators to improve care for patients with chronic kidney disease, diabetes, and hypertension within primary care practices or community medical homes. The hypothesis is that patients who receive care with the collaborative model of primary care/subspecialty care will have fewer hospitalizations, emergency department admissions, cardiovascular events, and death. The trial is expected to enroll approximately 11,000 people in four health systems.

We sat down with Dr. Vazquez to discuss the status of his trial, challenges and surprises, and advice he has for new investigators. The implementation phase of ICD-Pieces was started in Spring 2016, and as of May 2017, the trial was busy recruiting with most of the clusters actively enrolling patients and the remaining sites expected to be online soon.

Dr. Vazquez is a professor of internal medicine and a specialist focusing on chronic kidney disease, end-stage renal disease, and kidney transplants at the University of Texas Southwestern Medical Center. He provided an update on the Improving Chronic Disease Management with Pieces (ICD-Pieces™) trial at the May 2017 Collaboratory Steering Committee Meeting (view slides).

Challenges

During the early enrollment period of the study, we had more resistance than expected from some of the practices due to a belief that there might be extra work. Our previous experience showed us that just having electronic tools was not enough, and we provided assistance through practice facilitators, who performed education, orientation, and onboarding visits. The facilitators spent time at the sites and were available in the early days for ongoing conversations so they could discuss what was working and what wasn’t in real time, and develop ways to solve problems and ensure that—although there was some extra work associated with the intervention—the additional burden of it would be as minimal as possible. Having a champion at the site also really helped with this process.

“Try to really learn from others who have conducted pragmatic trials—even if you are the first one doing your specific trial with your specific questions.”

– Vazquez
Help From a Core Group

We had a fundamental challenge with the statistical design because one of the healthcare systems had to change the distribution of clusters, and this would affect our sample size, power, and analysis. We discussed the problem with the Biostatistics and Study Design Core to develop a distribution with more heterogeneity of the clusters. This turned out to be a fortuitous change because in the end, it made the study better.

“Other Collaboratory projects had already faced some problems, and we were able to anticipate and develop solutions proactively.”

– Vazquez

Surprises During Pilot Phase

We originally planned the study to be more complex, and we needed to change the interventions to make them easier to use and to make the orientation packages more succinct. Also, dealing with turnover was a constant: we lost co-investigators, facilitators, information specialists, and managers of sites, etc. We addressed this turnover by turning to the leaders of the healthcare systems—who are also our partners in trial—and collaborating with them to cope with these and other challenges.

Advice to New Investigators

Try to really learn from others who have conducted pragmatic trials—even if you are the first one doing your specific trial with your specific questions. It was helpful for us to learn from the other Collaboratory projects; they had already faced some problems, and we were able to anticipate and develop solutions proactively.

Make sure to include the health system partners in planning the study from the very beginning. We took a bidirectional approach: we learned from the healthcare system, and they learned from us. Sometimes, when we thought we had the best way to do something, they had a better way. We were all working toward the same goal, and it helped to collaborate.

“Make sure to include the health system partners in planning the study from the very beginning.”

– Vazquez