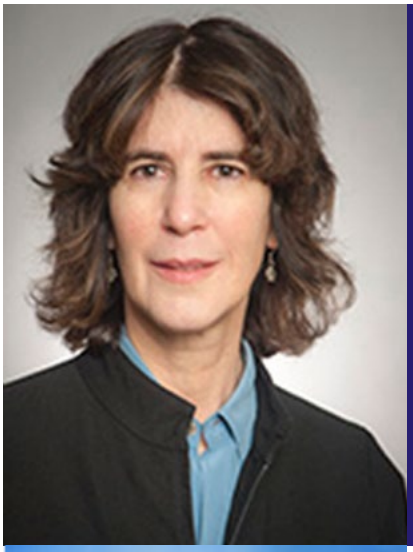
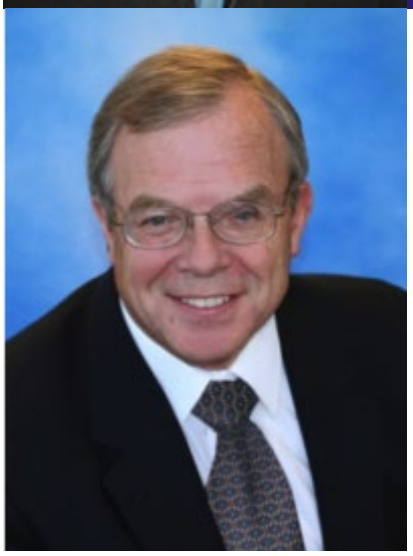


AN INTERVIEW WITH LAURA DEMBER AND ERIC LARSON

Lessons Learned from TiME: Time to Reduce Mortality in End-Stage Renal Disease

CONDUCTED:
April 20, 2015



At the April 2015 NIH Collaboratory Steering Committee Meeting, Drs. Dember and Larson discussed the challenges and lessons learned in the TiME trial's UH3 activities (PDF slides). TiME is a pragmatic, cluster-randomized clinical trial testing a simple intervention to improve survival and quality of life for patients with kidney failure who require chronic treatment with dialysis.

The study evaluates a minimum hemodialysis session duration of 4.25 hours compared with usual care for patients with end-stage renal disease who are initiating treatment with thrice-weekly maintenance hemodialysis. TiME is conducted through a partnership between academic investigators and two large dialysis provider organizations and expects to enroll patients at approximately 400 dialysis facilities in the United States.

Collaboration and Engagement Are Key

Dr. Dember, PI of the TiME trial, said early engagement with stakeholders has been critical. During the UH2 phase it was recognized that the trial would require comprehensive support across the enterprise. The study design was developed through a collaborative effort among research teams at the dialysis provider organizations and academic investigators. Some of the many decisions made together include the specifics of the intervention, methods for informing potential participants, approaches to enrolling and training facilities, which data elements to collect, and how to transfer the data.

Dr. Larson, PI of Group Health Research Institute and co-PI of the NIH Collaboratory Coordinating Center, says that the best way to create engagement is for partners to commit to it at the outset so that they learn to trust each other and address problems collaboratively. But engagement is not automatic—it must be mindfully established. Such collaborations are the key to solving the unforeseen and inevitable challenges of conducting clinical trials in large health care systems. Changing the duration of dialysis sessions for some of the patients at a dialysis unit, for example, can affect operations and personnel facility-wide. While not everything about an implementation approach works as initially planned, seemingly insurmountable problems usually have solutions.

> For everything we do, we need to have the health care systems on board—from the central leadership to the personnel at the individual dialysis facilities.

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During the UH3 phase, buy-in continues to be essential from all stakeholders in the TiME trial—not only from health system corporate leadership but also from regional operations groups, administrators, dialysis facility nephrologists, nurses, patient care technicians, dieticians, social workers, and patients. Even a highly developed and centralized health care delivery infrastructure does not remove the need for coordination at the local level and with individual practitioners and administrators.

While the TiME intervention itself is simple—the admission order set is 4.25 hours of dialysis—its implementation is complex. Clinicians need to agree that it is appropriate for individual patients, and patients need to be willing to accept the intervention. Secular changes also create challenges: nationally, dialysis session duration is increasing in response to the general view that longer is better. Overall, the TiME trial is addressing these important questions: Do longer dialysis sessions provide important benefits to patients? How can pragmatic clinical trials be conducted successfully in the dialysis setting? Ultimately, it is expected that the pragmatic nature of the TiME trial, the use of multiple electronic health record systems for trial implementation, and the partnership between academia and industry will establish a framework for conducting research within health care delivery systems that will be relevant to a broad range of diseases and research questions.

For more information on the TiME trial, visit the Collaboratory website.

> What we view as a small change to work flow or the IT system is often viewed as a large change by health system personnel

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