The PROVEN trial is a pragmatic, cluster-randomized trial of an advance care planning video intervention in nursing home patients with advanced comorbid conditions in two nursing home healthcare systems. Advance care planning is a process of communication that aims to align patient care with preferences, and may lead to advanced directives, such as do not resuscitate (DNR), do not hospitalize (DNH), or no feeding tubes. Better planning is associated with better outcomes, but this type of planning is suboptimal in nursing homes, where advance directive completion rates are low, and there are regional and ethnic disparities. The intervention is a suite of five advanced care planning videos (goals of care, advanced dementia, hospitalization, hospice, and advanced care planning for healthy people) to be offered to patients as part of the admission (or readmission) process and as part of regular updates to patient’s care plan. The control nursing homes do not receive the trial-based video intervention.

Dr. Mor is the is the Florence Pirce Grant Professor of Community Health in the Brown University School of Public Health and a Research Health Scientist at the Providence VA Medical Center. The other co-principal investigators of the PROVEN trial are Susan Mitchell MD, MPH, who is a Senior Scientist and Director of Palliative Care Research, Institute for Aging Research Professor of Medicine at Harvard Medical School, and Angelo Volandes, MD, MPH, who practices internal medicine at Massachusetts General Hospital in Boston and is on faculty at Harvard Medical School. Dr. Mor provided an update on the PROVEN Demonstration Project at the May 2017 Collaboratory Steering Committee Meeting (view slides).

We sat down with Dr. Mor to discuss the status of his trial, challenges and surprises, and advice he has for new investigators. As of May 2017, the PROVEN investigators have been enrolling patients for 14 months.

Challenges: Defining Compliance

To document whether the trial intervention was given to a participant, a video status report was programmed in the electronic health record of the health system partners. The staff would check a box every time the video was offered to a patient or family member, and in the early stages of the trial, the nursing homes that offered the most videos were celebrated for having good compliance to the intervention. However, offering a video is quite different than actually showing it, and we found that people weren’t actually viewing the video, and we weren’t meeting our anticipated proportion of eligible residents actually exposed to the video. We changed the way we graded compliance by tying it how many times the video was actually shown.
Help from a Core group

Investigators were originally slated to stop enrollment in November 2017 (at 20 months); however, patients were not shown the video as often as was needed in the early stages of the trial. We consulted with Lesley Curtis, David Murray, and the Biostatistics and Study Design Core, and with their input and help, decided to extend the enrollment period for 6 more months.

Surprises During Pilot Phase

Our biggest surprise from our pilot phase of the study was that our partners wanted to make sure that we offered the video to everybody who walked in the door of the nursing home—not just our target population—so we redesigned our approach to implementing the intervention.

Another surprise was the non-responsiveness of some of the facilities. Prior to randomly assigning the facilities of our two healthcare system partners, we gave them an opportunity to exclude facilities which were challenged operationally, had recent turnover in facility leadership, or that had performed poorly on a recent quality inspection. Each chain excluded a handful of such facilities, so we assumed that the rest would be fully engaged in adopting the video-assisted advanced care planning intervention. For the pilot, we chose sites that were eager to participate. Given the selection process, we didn’t anticipate that, out of 120 facilities, there would be 10 to 15 that would not participate in implementing the video although they had allowed their staff to be trained.

Advice to New Investigators

It is very important to work with a corporate partner who is willing to engage in the intervention. Furthermore, there must be an aligned interest. That is, the health care system must agree that the outcome your intervention is seeking to achieve is consistent with their mission. Your outcome goal should be something they care about. Finally, they need to trust you that you respect them as providers and understand the world from their point of view. At the same time, researchers must accept the fact that there will be real-world events that might occur, such as regulatory or financing changes that will become of paramount importance, and the health care system’s response to these events will draw most executive time and attention away from the intervention to which the company made a commitment.

“The health care system must agree that the outcome your intervention is seeking to achieve is consistent with their mission. Your outcome goal should be something they care about.”

– Mor

Other Lessons Learned

Nursing homes are very complex systems, and the patients themselves may be medically complex with advanced, comorbid illnesses. Implementation in these systems is challenging and particularly difficult in nursing homes because of the high rate of turnover across the system at all levels—from leadership to clinical staff. We know that the facilities with more turnover have lower rates of offering and showing the video, and we try to reach out and give them information regarding viewing rates at the sites along with reminders to show the videos.

You have to work carefully with leaders to embed an intervention; if you can make the intervention part of the standard operating procedures—make it part of someone’s job description—then it will be easier to test because it will be implemented more consistently. In addition, we are generating lists of patients who have not yet seen the video, and engaging sites to encourage participation. When the trial is complete, to support our corporate partners and help implement the intervention (if it is found to be successful), we will continue to work with them and offer suggestions about how to modify job descriptions and generate reports regarding who has seen the video.