will be safe in ESRD patients, whose kidneys are compromised. There was also discussion about behavioral or other therapies that might be helpful. For example, Wilkie suggested that cognitive behavioral therapy or exercise might ease symptoms such as cramping and fatigue that might be to adjust dialysis itself, noted St. Peter. She explained that rapid removal of fluids and shifts in electrolyte levels during traditional in-center dialysis, which is usually delivered three times a week for 4 hours, might contribute to cramps or fatigue. Slowing the process or using more frequent home dialysis might help, but more study is needed.

"Patients who are getting daily dialysis or longer dialysis often times feel better overall," St. Peter said. "These therapies haven’t been investigated yet for symptoms such as cramping or fatigue, so those are really important considerations."

To help drive such research and the development of new therapies, KHI held a workshop with patients, clinicians, industry representatives, and the FDA in January 2018 to develop plans for each of the top-rated symptoms. Those plans will be published later this year. Weisbord cautioned that the process of translating the findings of the KHI project into practice will be challenging and may take a long time.

In the meantime, Flythe hopes the KHI project will help raise awareness among physicians about the importance of symptoms to patients’ quality of life. A study by Weisbord and colleagues found that physicians often weren’t aware of their patients’ symptoms. Weisbord attributed this in part to a focus by nephrologists on adjusting medications or dialysis prescriptions, along with potential discomfort or unfamiliality with treating conditions like pain or depression.

"When you have a limited time to talk to a patient, ofentimes conversations get focused on numbers," Flythe said. "But it is important for physicians to ask, Flythe and Weisbord said.

"We need to be very cognizant of patients’ symptoms and what is very important to each patient," St. Peter said. They want to feel their care providers are listening to them, that if they’re having symptoms they are taken seriously. Wilkie also urged patients to speak up and share their symptoms with their physicians.

"It helps, even if there’s nothing that can be done; it helps for your doctors to know what you’re going through," Wilkie said.


Measuring Fatigue Is Key to Knowing How to Manage It

By Bridget M. Kuehn

Fatigue is one of the most common symptoms reported by patients on dialysis, but there is little data to guide clinicians about how to manage it. A new initiative aims to change that by helping researchers routinely and consistently measure fatigue in their studies of dialysis-related care.

The Standardized Outcomes in Nephrology–Hemodialysis (SONG-HD) project was created to establish a standard set of measures that should be used in all studies enrolling patients receiving dialysis. Having such a standard set of measures used across clinical trials makes it easier to compare the results of different studies, explained Angela Ju, BSc, of the University of Sydney in Australia. To identify which measures were most important to patients and clinicians, SONG-HD did a rigorous, three-round online survey of patients and clinicians.

"Fatigue was the top patient-reported outcome that health professionals and patients both picked," said Ju, who is the project coordinator of the SONG-HD fatigue project. So, Ju and her colleagues began assessing how fatigue is currently measured in clinical trials, with the hope of identifying an existing questionnaire they could recommend for use across trials. Their results were published in a review that found many different measures were being used ranging from 20 questions to only 4 questions. Ju noted. Some questions ask only about physical fatigue while other questions address other dimensions of fatigue, for example, how it affects mental capacity.

"There’s a whole lot out there, but it became clear that it wasn’t really standardized," Ju said.

Shared values

To assess what is most important to patients and other stakeholders when measuring fatigue, Mark Unruh, MD, professor of medicine at the University of New Mexico and chair of the SONG-HD fatigue project, led a workshop in Chicago in November 2016. The workshop brought together 15 patients or caregivers and 42 other stakeholders, including clinicians, researchers, policymakers, and industry representatives.

The participants confirmed that fatigue is seen as a key measure that should be measured consistently across studies.

"The patients and stakeholders felt that fatigue was important enough to include as a measure in basically every trial looking at dialysis outcomes," Unruh said.

For patients, the most important aspect of dialysis-related fatigue was how it affected their day-to-day life. One patient participant said: “When I got off [dialysis] I was wasted. I couldn’t do anything. It was hard to walk a block to get to my car.”

Researchers on the project also expressed a need for short, meaningful questionnaires that can fit into the workload of research teams.

A better measure

The workshop and surveys by the SONG-HD team revealed three key dimensions of fatigue that should be measured: fatigue’s impact on the patient’s life, patient’s energy level, and their degree of tiredness. None of the existing measures Ju and her colleagues identified in her review looked at all three of these dimensions.

"There wasn’t one measure that maps out these dimensions that we could just take and validate," Ju said.

So, they created a short questionnaire of their own that addresses these three dimensions, and they have already begun the process of validating it.

Once that process is complete, Unruh said he hopes this new measure will become a tool that is used routinely in studies in the same way that estimated glomerular filtration rate is used as a routine measure of kidney function. This will allow researchers to track how the treatments they are studying affect fatigue, even if reducing fatigue is not the primary goal of the treatment being studied.

Weisbord explained.

"We all kind of know what fatigue is, but being able to measure it and reproduce it is what has been missing because everybody kind of chooses their own fatigue questionnaires," Unruh said. "Measuring fatigue in a careful way and being able to reproduce that I think would be helpful toward improving that outcome."