Innovation Center Announces Long-Awaited ESRD Care Model

By Rachel Shaffer

The government agency charged with developing new health care payment and service delivery models—CMS and its Center for Medicare and Medicaid Innovation (CMMI)—recently announced the Comprehensive ESRD Care Initiative. The announcement marks the end of months of speculation about when—and whether—the Innovation Center would announce a coordinated care model for kidney care. ASN, along with many other stakeholders in the kidney community, advocated in support of such a model. However, as of press time, numerous details about the Innovation Center’s vision for the program remained unclear to many in the kidney community.

CMS began accepting letters of intent for the Comprehensive ESRD Care Initiative in early February. The Innovation Center states that it anticipates that 10 to 15 so-called ESRD Seamless Care Organizations (ESCOs) will participate in the model. The first performance period for the model will begin in the fourth quarter of 2013, and interested participants must submit a letter of intent by March 15 and apply by May 1.

Yet it is unclear how many dialysis organizations, nephrology providers, and other health professionals will ultimately participate—and whether CMS will consider altering specifics of the program.

The Comprehensive ESRD Care Initiative is the first chronic disease-specific shared savings model that the Innovation Center has launched. While other fields of medicine—

Online Hemodiafiltration Prolongs Life Compared with Standard Hemodialysis

Results of Prospective Randomized Trial May Change Clinical Practice

H emodialysis is now a routine renal replacement therapy with guaranteed short-term safety, but long-term outcomes are far from ideal. Retrospective studies suggest that online hemodiafiltration (OL-HDF) may reduce kidney failure patients’ risk of premature death compared with standard hemodialysis, but the results of prospective studies have failed to confirm this finding.


“In view of this study’s results, OL-HDF may become the first-line option in hemodialysis patients,” said first author Francisco Maduell, MD, PhD, of the Hospital Clinic in Barcelona, Spain.

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The studies showed a 39 percent and 46 percent mortality risk reduction in patients receiving high convective volumes of greater than 22 and 20 liters per session, respectively,” he said. “These results provide evidence of the need to deliver high convective volumes to reduce all-cause mortality. To achieve this goal, high blood flow rates and long dialysis times are required.”

In the ESHOL study, the average blood flow rate was higher than in the CONTRAST and Turkish studies, whereas the average length of dialysis was longer than in the CONTRAST study and similar to that of the Turkish study. These factors led to a higher average delivered convective volume in the ESHOL study (23.7 L/session) than in the CONTRAST and Turkish studies (20.7 L).

“Our results indicate that the treatment modality could modify patient survival when a sufficient convective volume is reached,” said Maduell.

Others in the field agree. Richard Ward, PhD, a professor of medicine in the kidney disease program at the University of Louisville, noted that the study is important for two main reasons: it is the first to show an unequivocal survival benefit from OL-HDF, and it confirms post-hoc analyses from the previous two studies, suggesting that the realization of a survival benefit requires the delivery of a minimum convective volume of about 24 L.

“My hope is that this article will provide the final push to see the introduction of online hemodiafiltration in the United States,” Ward said. “The three randomized trials published in "The reduction in all-cause mortality associated with OL-HDF treatment observed in this trial was focused on cardiovascular and infectious diseases. Cardiovascular disease is the most common cause of mortality in chronic hemodialysis patients, and the mortality rate is still 10 times higher than in the general population,” said Maduell. “Also, end-stage renal disease patients have a significant risk of infectious complications, which represent the first cause of hospitalization and the second cause of death in hemodialysis patients.”

The risk reductions shown in the ESHOL study suggest that switching eight patients from hemodialysis to OL-HDF may prevent one annual death.

Differences from previous studies
Results of earlier studies on hemodiafiltration were disappointing.

Two recent prospective, randomized trials failed to demonstrate a survival advantage of OL-HDF over hemodialysis. In the Dutch Convective Transport (CONTRAST) study, 714 prevalent dialysis patients were randomized to low-flux hemodialysis or OL-HDF, with an average follow-up time of 3 years. No survival difference between the groups was observed at the end of the study, (Grooteman MPC, et al. J Am Soc Nephrol 2012; 23:1087–1096). In the Turkish Online Haemodiafiltration Study, 782 prevalent dialysis patients were randomized to high-flux hemodialysis or OL-HDF, and, again, all-cause mortality was not affected by treatment allocation during 2 years of follow-up (Ok E, et al. Nephrol Dial Transplant 2013; 28:192–202).

Convective volume seems to be an important issue, based on the results of the CONTRAST and Turkish studies, Maduell said.

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“My hope is that this article will provide the final push to see the introduction of online hemodiafiltration in the United States,” Ward said. “The three randomized trials published in
the last 12 months, together with everyday clinical experience from use of the therapy in many other countries, show that online hemodiafiltration can be performed safely. Moreover, with the blood flow rates commonly used in the United States, it should not be difficult to deliver the convective volumes associated with reduced mortality.”

Enric Vilar, MD, PhD, of the department of renal medicine at Lister Hospital in England, also noted that the study provides valuable clinically relevant data. “This is an important randomized control trial with a clear message for the dialysis community,” Vilar said. “The positive results confirm the findings from previous cohort studies and also the CONTRAST study, which demonstrated improved survival for the subgroup with high substitution volume hemodiafiltration.”

Despite the positive findings from this trial, Maduell stressed that hemodiafiltration is far from perfect. “The main limitation is the belief that the technique solves all problems of hemodialysis. Many other aspects need to be addressed to improve overall survival in the dialysis population—for example, getting a good vascular access, avoiding volume overload, and reducing cardiovascular risks,” he said.

Still, the study’s results indicate that widespread use of OL-HDF could have a considerable impact on dialysis patients’ health and longevity. “Mortality remains very high in dialysis patients, ranging from 15 percent to 25 percent annually. Any reduction of this mortality would be an important achievement,” Maduell said.

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atypical Hemolytic Uremic Syndrome (aHUS)
is a chronic, genetic, lifelong disease of systemic, complement-mediated thrombotic microangiopathy (TMA) with catastrophic consequences.1,4

• 33% to 40% of patients die or progress to end-stage renal disease (ESRD) with the first clinical manifestation3,6
• 65% of all patients die, require dialysis, or have permanent renal damage within the first year after diagnosis despite plasma exchange or plasma infusion6

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