Aiming to Coordinate Care, ACO Proposed Rule Falls Short
By Rachel Shaffer and Daniel Kochis

In January 2012, the Centers for Medicare and Medicaid Services (CMS) will launch a new congressionally mandated initiative designed to help improve the quality of patient care. In the initiative currently proposed, accountable care organizations (ACOs) may not be well positioned to appropriately care for patients on dialysis or who have a recent kidney transplant. Despite this concern, the ASN ACO task force believes that ACOs may offer significant benefits to the chronic kidney disease patient population; however, significant modifications to the existing proposal would be necessary.

ACOs are envisioned by Congress as a new, coordinated approach to care delivery and reimbursement that will drive down costs while ensuring quality. While ACOs were mandated by the Affordable Care Act (ACA) of 2010, CMS must issue regulations that specify how ACOs will function. In March, CMS issued an ACO Proposed Rule outlining its vision for the program and solicited public comment. The ASN ACO Task Force, chaired by Lee Hamm, MD, conducted a comprehensive review of the 427-page proposed rule and drafted a comment letter to CMS detailing ASN’s recommendations and concerns. According to Hann, “Overall, while the Task Force recognized the potential ACOs hold for advancing care and driving down costs, we were very concerned that the proposal, as written, could do more harm than good for patients on dialysis or with a recent kidney transplant.” (See Q and A on p. 2).

According to the ACA, an ACO is a network of providers, hospitals, and other health care organizations that agree to assume responsibility for providing care to

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Catheter Use, Health Differences Influence Morbidity in Hemodialysis vs. Peritoneal Dialysis
By Doug Kaufman

End stage renal disease (ESRD) patients receiving peritoneal dialysis (PD) usually have lower morbidity than hemodialysis (HD) patients, but other factors play a role as well. The difference in morbidity could be partly due to the higher risk of early death among patients undergoing HD with central venous catheters (CVCs), according to a study in the June Journal of the American Society of Nephrology. In addition, “it may reflect the patients selected more than the
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In the 7-year study, 63 percent of the patients started HD with a central catheter inserted into one of the large veins. Another 17 percent began HD with an arteriovenous fistula (AVF) or arteriovenous graft (AVG). The remaining 19 percent started with PD at home, with education in advance about treatment options.

In the first year of the study, the risk of death for patients starting HD with a CVC was 80 percent higher than for patients who began with PD. The first-year death risk for patients with an AVF or AVG was similar to that in the PD group. In the 5 years after dialysis was begun, the death risk was still 20 percent greater in the patients receiving HD with a CVC compared with the PD group. The survival rate for patients receiving HD with an AVF or AVG remained similar to that in the PD patients.

“All the previous studies tried to compare hemodialysis versus peritoneal dialysis in terms of patient survival,” Perl said. “Ideally, the best way to study this question of which therapy is associated with better survival is to do a randomized controlled trial. That’s not going to be feasible when so much of why patients choose one therapy over another is lifestyle-based. It’s really difficult to do studies that are randomized controlled trials in this area.”

The next best thing researchers can do is to look at very large databases that have tracked the outcomes in patients who have chosen HD versus patients receiving PD, and examine the outcomes in those patients after accounting for things like diabetes, age, and comorbidities that may make comparison more difficult.

“Those studies have traditionally demon-strated that peritoneal dialysis was associated with better outcomes in the first 1 to 2 years compared to hemodialysis,” Perl said. The main criticism of such studies is that the average PD patient tends to be younger, with fewer comorbidities, and generally healthier enough to handle the home therapy. “The results of those studies may speak more toward the type of patient selected for peritoneal versus home, rather than the actual effect of the therapy itself,” Perl said.

In designing this study, Perl said he hoped to delineate an HD patient who chose HD, was able to start electively, and had predialysis care—just like a PD patient. One indication would be if a patient on HD had a surgical access—a planned way of creating a connection between the artery and the vein—which can take months to establish.

“That would be a marker of someone who’s been exposed to nephrology care for a long period of time, and had to obviously get predialysis care and education, enough to have this access created and ready to use during their first treatment,” Perl said. HD patients who start with a fistula might be much more similar to a PD patient. By contrast HD patients who start with a catheter, which can be inserted within hours after the decision that a patient needs dialysis, generally need to begin dialysis more urgently.

“In the Peel study, the survival comparison was between those using a fistula or graft and those on peritoneal dialysis with exclusion of patients starting with a catheter. This removed some of the bias associated with starting dialysis with a catheter and compared a more homogeneous population, those who attended nephrolog-i-cal care, were able to make decisions and who were considered ‘eligible’ for PD and HD with a fistula or graft,” said coauthor Louise Moist, MD, of the University of Western Ontario. “This allows us to truly compare the dialysis modalities without as much influence from differences in the population that we are not able to control for. This study has addressed an important question. The two modalities, HD and PD, have similar outcomes once the playing field is leveled. Now the decisions should be based on patient preference and health-related quality of life.”

Said Perl: “When you separate the hemodialysis patients into those two groups, you realize that, really, it’s not that PD is associated with an early survival advantage; it’s that hemodialysis patients tend to be sicker, and those who start dialysis with a catheter actually have worse survival in the first 1 to 2 years. But those who start, optimally with a fistula or graft, have quite similar survival rates to peritoneal dialysis patients.”

Catheters have a greater risk of infection. “There’s no doubt about it. When you compare catheters to fistulas and grafts, there’s a higher rate of infection [with catheters], and there’s a higher rate of mortality,” Perl said. But the catheter does not necessarily cause all the problems. “It’s difficult to tease out how much of the impact of catheters is the effect of infection on mortality, and how much is based on...
the type of patient who uses a catheter," he said. "We're never going to randomize patients to a catheter or a fistula or graft. That would be unethical, based on the evidence we have right now; to suggest that catheters are associated with a much higher risk of death. But it's a difficult question."

The study's other "take-home point," Perl said, concerns the importance of planning and education. "To get a fistula or a graft takes quite a bit of time," he said. "You need to see patients months in advance.

Not all patients, even with the best intentions of the nephrologist and the treatment team, will be ideal candidates for a fistula or a graft. For patients who are diagnosed late, or who may be ineligible for a fistula or a graft, or who have a high likelihood of experiencing fistula or graft failure and having to start HD with a catheter, it would be good to have another option.

In spite of the risks, HD with a CVC may be the best option in some instances. "Every dialysis modality decision is a patient-by-patient analysis of the risks and benefits of each therapy," Perl said. "Not all patients are ideal candidates for peritoneal dialysis." It requires an intact abdominal cavity. "So, for example, if someone has had multiple surgeries on their abdomen, and bowel surgeries, they may not be an ideal candidate for peritoneal dialysis. Similarly, not all patients are candidates for fistula or graft. It requires relatively preserved blood vessels to facilitate being able to create, and then undergo a surgery to connect the artery to the vein."

So, while most nephrologists would consider HD with a CVC "the least favorable option," Perl said, "in many cases it is the only option." It can be the only option, for instance, in emergency situations where the kidney failure is identified in a hospital and dialysis must be started immediately. Also, some patients who have received predialysis care and education and are qualified candidates for fistula or graft or PD still make a conscious decision to have HD with a catheter. "This study couldn't really tease out those two types of patients. Getting around that would be very helpful," Perl said.

One of the study's shortcomings may be that comments about residual renal function and why the relative risk of PD versus HD changes over time may not be entirely correct said John Burkart, MD, professor of nephrology at Wake Forest Baptist Medical Center.

"The effect of residual kidney function (RKF) was not examined. One hypothesis based on these observations and the knowledge that RKF tends to decrease over time is that PD had an early survival advantage because of preservation of RKF or starting patients on PD who have F/U and RKF, I think disproved by this observation," Burkart said. "[For example], for the population as a whole HD starts out bad—due to CVC usage—however, we still do not know why. Relative risk changes over time and starts to favor HD. It may be that over time, as the RKF 'buffer' decreases, PD does not do as well because the MDs have typically not had the infrastructure or knowledge of how to adjust prescriptions and individualize the prescription. This is not shown or investigated in this data."