ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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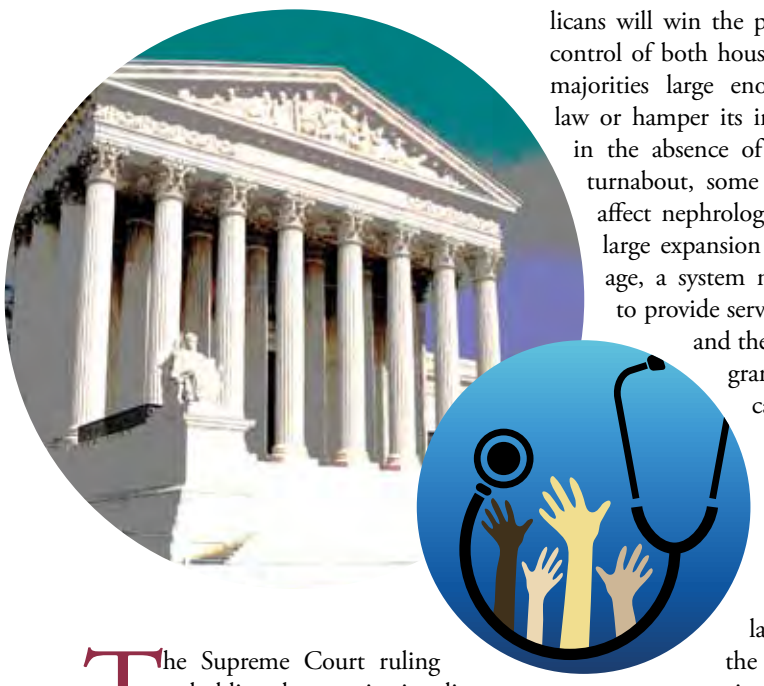
Supreme Court's Health Care Ruling Ushers in Host of Reforms Affecting Kidney Care

By Eric Seaborg



The Supreme Court ruling upholding the constitutionality of the Affordable Care Act (ACA) gave the green light to a host of reforms that will affect the practice of kidney care.

The possibility remains that Republicans will win the presidency as well as control of both houses of Congress with majorities large enough to repeal the law or hamper its implementation. But in the absence of that large political turnabout, some changes that could affect nephrology practice include a large expansion of insurance coverage, a system needing adjustments to provide services to more people, and the output of new programs for research on care quality.

The main goal of the ACA was to increase the number of Americans covered by health insurance, and the latest projections of the nonpartisan Congressional Budget Office are that an additional 30 to 33 million people will have health insurance by 2016, an increase from today's 82 percent to 92 percent of the population under Medicare age. One big driver of the growth in coverage is a planned expansion of Medicaid eligibility, but the portion of the court ruling that allows states to opt out of the expansion could have a big effect on these numbers (see sidebars). But in any scenario, millions more people should obtain coverage.

An underlying theme of the reform is that this increased coverage should translate into earlier and better care. "Increasing access to primary care can only be a good thing in terms of preventing and slowing the progression of kidney disease," said Rachel Shaffer, manager of policy and government affairs at the American Society of Nephrology.

Early treatment in the primary-care environment of two common causes of kidney failure, hypertension and diabetes, could prevent or delay the need for many patients to see a nephrologist, said Thomas Hostetter, MD, chair of ASN's public policy board: "If more people have coverage, we would not be in the position

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Delayed Graft Function: Increasingly Common, and Increasingly Expensive

Delayed graft function (DGF) is a growing problem in kidney donation, given that donor kidneys increasingly come from older and more health-compromised individuals. Among other effects, the impact is felt on the hospital's bottom line. The complex picture of DGF in renal transplantation was the focus of a discussion among experts in a "Transplantation in Depth" panel at the American Transplant Congress in Boston.

The gap between supply and demand for kidneys is growing, with 92,000 patients on the waiting list in the United States alone. The shortage of organs and the lengthening of wait times have led to considerable reliance on expanded-criteria donor (ECD) kidneys, defined as those from donors over age 60, or between 50 and 59 with either a history of hypertension, elevated creatinine, or death resulting from cerebrovascular disease. "These donors are associated with higher risk of DGF," said Norberto Perico, MD, of the Mario Negri Institute for Pharmacological Research in Bergamo, Italy, "and may account for the increase in DGF in the last 2 decades."

The incidence of DGF in ECD kidneys is between 5 percent and 50

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Health Care Ruling

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where we've often been, where people arrive with very advanced kidney disease having had little if any prior care."

Another reform provision that could prove relevant is that insurers will not be able to deny coverage based on preexisting conditions, making it easier for patients with incipient or more advanced kidney disease to obtain coverage. The ACA also eliminates annual and lifetime caps on covered expenses, which could help chronic kidney disease patients who do not progress to Medicare coverage or family members on their policy.

The expansion of coverage will be driven by incentives and subsidies for buying health insurance, penalties for not buying it, and an expansion of Medicaid and the Children's Health Insurance Program. Individuals and small employers will be provided easier access to health insurance through the establishment of health insurance exchanges set up in each state. So far, 17 states and the District of Columbia have taken the first steps toward establishing exchanges, which are scheduled to come on line in 2014. Some governors have said that their states will not participate in these exchanges, but residents of those states will have access to a multi-state exchange set up by the U.S. Department of Health and Human Services.

To be sold on the exchanges, policies will need to meet defined standards, including what the ACA calls "essential benefits packages." The packages will be defined mostly by the states where they are offered based largely on the customary policies already available, but they will also have to meet standards for deductibles and out-of-pocket costs. The federal government will also have a role in setting standards, and one of the key questions to be answered in coming months is what essential benefits packages will include in terms of kidney care.

These issues include the availability of immunosuppressive drug coverage for kidney transplant recipients, the interface between exchange-based insurance coverage and Medicare's end stage renal disease program, and the treatment of living organ donors, according to Dolph Chianchiano, JD, MBA, health policy adviser to the National Kidney Foundation. Chianchiano said that the U.S. Department of Health and Human Services (DHHS) is being slow to weigh in on some of these questions, perhaps to allow states the latitude to design their own programs.

Coverage of immunosuppressive drugs would obviously be critical to kidney transplant patients at the end of the three years of Medicare coverage. The National Kidney Foundation and groups like the American Medical Association have urged that the essential benefits package be modeled on Medicare Part D, which includes anti-rejection medications on its list of protected drug classes. DHHS has not yet given a specific response on whether kidney transplants and their follow-up care will have comprehensive coverage although it acknowledges that transplant benefits are typically provided in private insurance.

Another issue is whether patients who receive end stage renal disease treatment will have to enroll in Medicare, or whether they can stay on their private insurance for their care. In a Federal Register posting, DHHS said that individuals would not automatically lose their private coverage if they are eligible for Medicare coverage. In addition, new end stage renal disease patients can remain in their small group employer health insurance available through the exchanges, rather than transfer to Medicare, for the first 30 months of kidney replacement therapy, Chianchiano said.

Living kidney donors do not have a preexisting condition, "but insurance companies on occasion have acted as if they [do]," Chianchiano said. "One would assume that if you cannot discriminate against an individual because of a preexisting condition, an insurer cannot discriminate against someone because they have been a living organ donor." This protection has not been spelled out explicitly, however.

An influx of millions of new patients will pose a challenge to a health care system already facing physician shortages, said Atul Grover, MD, PhD, chief public policy officer of the Association of American Medical Colleges (AAMC), particularly the teaching hospitals that his organization represents.

A key concern of the AAMC is whether the Medicaid expansion will take place as planned. Hospitals are facing cuts in Medicare and disproportionate share payments written into the ACA, cuts they could accept based on the assumption that with more people being covered, more patients would be able to pay for the services they receive. If some governors make good on their threats to not expand Medicaid, that will throw a monkey wrench into the whole formula. Grover looked to the experience of Massachusetts, which passed its reform aimed at universal coverage in 2006, for clues about the future.

"They had a very small percent uninsured, 2 or 3 percent, [yet] a lot of those who remained uninsured ended up in our teaching hospitals, so they had to go back and tweak the formulas for how they appropriated some of the [disproportionate share] money in those cases," Grover said.

Looming physician shortages

The AAMC's other big concern is that it had been projecting looming shortages of physicians and other health care professionals even before the ACA passed. "If you add to that 32 million people potentially gaining new insurance, you are really accelerating those shortages because people are going to end up in the system where maybe they weren't going to be before," Grover said.

Grover noted that in Massachusetts patients have not experienced difficulty obtaining care: "In primary care in particular, they have figured out how to use other health care professionals, nurse practitioners and physician's assistants, to improve access." But demand has risen: a study by a Boston University School of Medicine professor found that inpatient procedures increased among lower- and medium-income Hispanics and whites after the health reform law went into effect. Hispanic patients underwent 22 percent more elective surgeries, including knee and hip replacements.

Grover questioned whether a system in which Medicare has not supported its share of the cost of training physicians at teaching hospitals could adjust to more patients nationwide: "We have advocated a modest expansion of residency training to try and close a third of the gap between now and 2020 or 2025, in hopes that some of the delivery system reforms, some of the focus on prevention, can actually slow down the increase in demands for physicians' care."

Patient outcome research

The kidney community also has its eyes on a pair of research centers established by the ACA. The Patient-Centered Outcomes Research Institute (PCORI) is a nonprofit organization governed by a board drawn from the public and private sectors and appointed by the head of the Government Accountability Office. Created to back comparative effectiveness research, particularly kinds that are difficult to find funding for, PCORI's research will extend to all disciplines, but could have particular benefits for nephology.

"We are the first to admit that there is insufficient hard data for lots of things that we do for patients," Hostetter said. "There are some things that we understand well for the general population, but we get different outcomes if we use that approach with people with end stage renal disease."

The Centers for Medicare and Medicaid Innovation is another new creation, within the Centers for Medicare and Medicaid Services, with a mission of finding new payment and delivery methods that improve care and health while lowering costs—including looking at ways to improve kidney care. As a part of this effort, DHHS has recognized 154 accountable care organizations (ACOs), groups of doctors and other providers who work together to coordinate care for Medicare recipients.

Hostetter said that ASN has weighed in with recommendations on future directions because kidney care is particularly well-suited for refinement in this sort of venue: "People with most kinds of early kidney disease can be cared for by primary-care providers, sometimes with consultation to a nephrologist. But there is a stage in chronic kidney disease where it's important that there be integrated care, then there is a stage where it's important that a nephrologist do essentially all of the care for the kidney portion of a person's illness." Research could certainly contribute to better integrating these states.

By upholding the Affordable Care Act, the Supreme Court allowed these kinds of efforts to continue. Many supporters of the ACA's goals in the health care community acknowledged that the law has its flaws, but echoed the hope of American College of Physicians president David L. Bronson, MD, that the debate could move away from whether or not to repeal the law in order to focus on "preserving all of the good things that it does while making needed improvements."

The Individual Mandate

Perhaps the most controversial provision of the Affordable Care Act is the so-called individual mandate that individuals must either buy health insurance or pay a penalty. Chief Justice John Roberts led the Supreme Court in ruling that the mandate is constitutional because it is a tax.

The penalty is $95 or 1 percent of income in 2014, $325 or 2 percent of income in 2015, and $695 or 2.5 percent of income in 2016 (but no more than the cost of an average basic plan). These penalties are generally much less than the cost of insurance.

But the experience in Massachusetts—the ACA was largely modeled on that state's 2006 health care reform law—has been that the penalties do seem to be effective at getting people on the insurance rolls. That law has decreased the number of uninsured in the state from 10 percent to 2 percent of the population.

The Massachusetts law itself is viewed favorably—74 percent of residents want it to continue versus 9 percent favoring repeal. But the mandate is not nearly as popular, with 51 percent supporting it, a 2011 poll by the Harvard School of Public Health and *The Boston Globe* found.

To encourage people to buy insurance, federal tax credits tied to its cost compared with income level will be available to people with incomes up to 400 percent of the federal poverty line (about $88,000 for a family of four). Small businesses with fewer than 25 workers will receive tax credits for up to 50 percent of the premium cost. Employers with 50 or more full-time employees that do not offer coverage or offer coverage deemed unaffordable will incur penalties. And employers with more than 200 employees must automatically enroll new full-time employees in coverage.

The big bargain among stakeholders such as insurers, providers, pharmaceutical companies, and the government was that each could afford to give up something if enough people were covered with some form of insurance. For example, insurance companies could afford to waive preexisting conditions if they knew that a patient could not simply wait until a disorder appeared, then buy insurance. Similarly, hospitals could accept lower Medicaid reimbursement rates if they took less of a loss from treating uninsured patients who never paid.

Medicaid Ruling Could Have Far-Reaching Effects

The Supreme Court ruling making the Affordable Care Act's intended expansion of Medicaid optional for states is gaining attention as a sleeper issue that could destabilize some of the compromises struck to gain support for the law.

"The Roberts Court actually punched a big hole in the law, potentially reducing its historic coverage expansion by as much as a third," Jeff Goldsmith, PhD, wrote on The Health Care Blog. Goldsmith is a professor of public health sciences at the University of Virginia.

Several governors have said that they will not expand Medicaid, even though, on first look, it appears to be a sweet deal for states. The federal government pays about 60 percent of the costs of the current Medicaid program. In the expanded version, people with family incomes up to 133 percent of the federal poverty level would be eligible for Medicaid. The federal government will cover 100 percent of the cost for these newly eligible people in 2014 and 2015, then pay a declining share to 90 percent from 2020 on.

Even so, at least half a dozen Republican governors running cash-strapped states have said that they will not expand the program for both ideological and financial reasons. Medicaid spending is already a huge portion of state budgets, second only to education, taking 12 percent of state-generated revenues (those not including the federal contribution) in 2009. Some say that any expansion would come at the expense of taking money from education, public safety, and other priorities.

The Congressional Budget Office estimates that the expansions of Medicaid and the Children's Health Insurance Program would provide new coverage for some 16 to 17 million people, and providers were counting on receiving at least some payment for treating them. A lack of expansion could continue to leave millions without coverage.

"Hospitals are watching these developments with mounting alarm," Goldsmith wrote. "They gave up $155 billion in future Medicare payment reductions to gain 30 million new paying patients, and consented to the reduction of disproportionate share payments intended to compensate them for their bad debts and charity care. A cancelled Medicaid expansion would place the safety net hospitals in those states at serious economic risk."

Another worry for states is that the health care exchanges the ACA calls for could lead to their current programs becoming overloaded. In addition to offering insurance policies, the new exchanges are designed to lower the barriers to Medicaid enrollment. Many people could go to one intending to buy a policy, but find out they are eligible for Medicaid and enroll online, without the need for an in-person trip to a state office.

"In some states 5 to 8 percent of the entire population under age 65 are uninsured despite being Medicaid-eligible. Nationally, this 'woodwork effect' could draw out more than 9 million uninsured adults and children," write Benjamin J. Summers, MD, PhD, and Arnold M. Epstein, MD, both of the Harvard School of Public Health, in the *New England Journal of Medicine.* "Millions of low-income Americans are currently eligible for Medicaid but do not participate because of enrollment barriers, poor retention, or lack of information."

And if the new enrollees are eligible under the old Medicaid rules, the federal share of the payment is at the old level, leaving states to pay up to half their costs.

How Are Sates Dealing with Health Reform Fallout?

Waiting on November elections

Opponents continue to work toward a full repeal in Congress, and presidential candidate Mitt Romney has made repealing the Affordable Care Act (ACA) one of his primary campaign points. Arizona, Kansas, Nebraska, and South Dakota continue to hold still or move slowly in anticipation of the November election.

Opting out of state exchanges and Medicaid expansion

Governors in Florida, Louisiana, Mississippi, Texas, South Carolina, and Wisconsin have publicly stated that they will not move forward with state exchanges or the now optional Medicaid expansion. Proponents of the ACA in these states are expected to push back hard.

Consumers who need insurance in states that do not have their own exchange will be eligible for participation in the federal health exchange, and the Department of Health & Human Services (DHHS) Secretary Kathleen Sebelius has stated that any uninsured who would have been covered by the Medicaid expansion will not be penalized by the individual mandate, although details on how this will work remain limited.

Continuing to move along with state exchanges and Medicaid expansion

Even as some state governors and policymakers are opposed to the ACA, many state legislatures and health advocates continue to work on a basic infrastructure. Fifteen states and the District of Columbia have either passed legislation or had an executive order signed to establish exchanges, and 10 states and the District of Columbia have already begun or are currently working on Medicaid expansion programs. Both Massachusetts and Utah already have exchanges up and running, and Massachusetts has already broadened its pool for Medicaid eligibility. Utah has not yet decided on Medicaid expansion.

Weighing options

In over 20 states, governors and legislators in both political parties continue to weigh their options between a federal or state exchange and are waiting for more federal regulations before making any decisions. Many states that have not yet created exchanges are already out of session for the year, and only one (Michigan) has a bill currently in session.

States are also scrambling to understand exactly how the Medicaid expansion could help or hurt their tenuous budgets. Although the federal government will pay 100 percent of the expansion for the first three years with a gradual decrease to a 90 percent share, even adding a small percentage of costs could be a heavy burden.

Democratic and Republican governors have voiced concern over the fine print, and both the National Governors Association and the Republican Governors Association have formally asked President Obama and DHHS to clarify the nuts and bolts of how the expansion will work.

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Delayed Graft Function

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percent, depending on the study and also on the exact definition of DGF, which in most cases is taken to mean the need for dialysis within 7 days of transplantation.

DGF does have important consequences for the success of the graft, Perico said. A recent metaanalysis of 21 outcome studies suggested that the risk of graft loss is 41 percent higher in patients with DGF than in patients not experiencing DGF.

"But not all expanded-criteria donor kidneys are equal," Perico said. The age is important, but it is far from the only indicator of organ quality. Another factor at work is the duration of cold ischemia time. In a 2011 study of more than 9000 donor kidneys, an increase in cold ischemia time increased the risk of DGF after multiple other characteristics were controlled for. But in this case, there was no difference in graft survival at 96 months, highlighting the complexity of the impact of DGF on outcomes.

In any event, Perico said, "We need to look for strategies to maximize chances of success with ECD kidneys." He suggested that one strategy may be to use biopsy to match donors with patients for "nephron dose," to better accommodate differences in metabolism among patients. "An increased use of older kidneys, evaluated with biopsy, would permit a successful expansion of the donor pool for older patients, and would safely shorten the waiting list."

"Every transplant saves lives, and the same can be said for costs," said David Axelrod, MD, assistant professor of surgery at Dartmouth Medical School in Hanover, New Hampshire, who spoke about the economics of transplants with and without DGF.

Transplants are more expensive than dialysis in the short run, he said, but after a mean of 2.3 years for a living donor, or 3.6 years for a deceased donor, the cost curves cross because the recipient of a transplant requires fewer medical services than does the patient receiving dialysis. "The overall cost of transplanting is less than the cost of maintaining that same patient on dialysis. As a society, we benefit from kidney transplantation."

But an aging recipient population, and an increased use of ECD organs, is taking a toll on the economics of transplantation for the hospital. "Reimbursement costs have not kept pace with operation costs," he said. And neither is reimbursement tied to the quality of the kidney. As a result, "Delayed graft function largely determines the overall margin for the hospital," Axelrod said.

Patients experiencing DGF have an increase of about 50 percent in overall length of stay, not only for dialysis but often also for cardiac care in the intensive care unit, Axelrod said. His analysis shows that DGF is a major driver of Medicare payments, increasing the average reimbursement by about $13,000. However, he said, the hospital still lost about $5000 per patient because of the effects of DGF, which increased to almost $11,000 with the combination of ECD and DGF.

The indirect impact is also high, with an increased risk for decreased renal function and return to dialysis, and overall higher payments for chronic kidney disease care. "The cost of returning to dialysis is significant," he said.

So how can the risk of DGF be reduced? Mechanical perfusion—pumping—is one strategy, Axelrod said. "The benefit of pumping is going to be on graft survival," but not necessarily on cost, according to his analysis. "There is not much effect on cost at 3 years. At worst, you could say pumping is cost neutral." Induction therapy, designed to induce tolerance for the new organ, is another option to decrease the risk of acute rejection after DGF. "We use induction therapy quite liberally," Axelrod said, "but these agents are not cheap."

Other options were reviewed by Douglas Hanto, MD, PhD, from Beth Israel Deaconess Medical Center in Boston. Dopamine, levothyroxine, steroids, and vasopressin have all been used. A new option may be carbon monoxide, which, although toxic in high doses, is released naturally within the body at very low doses during hemoglobin catabolism and acts as a cytoprotective and anti-inflammatory agent through its ability to induce stress response pathways.

Carbon monoxide can be delivered as a gas. It has been shown to reduce lung injury from hyperoxia and to improve renal transplant outcomes in animals when delivered to the recipient intraoperatively. There are no side effects until the dose reaches twice the effective dose, Hanto said. The clinical development of carbon monoxide as an adjunct for transplantation is currently stalled because the company developing the delivery system is changing hands. "We think donor treatment is probably also a good idea, but that can be challenging," because it involves a tradeoff between taking the time for treatment and reducing the delay between removal of the donor kidney and transplantation.

Further research, all agreed, was needed to better define the risk factors for DGF, the best ways to reduce its incidence, and the optimal treatment strategies for patients who experience it.

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Findings: American Transplant Congress

How Can the Kidney Be Protected During Liver Transplantation?

Kidneys are at risk during and after liver transplantation. How can they be better protected? The prescription for intraoperative care is simple to state, if difficult to achieve.

"The bottom line is that if we avoid hypertension, avoid severe blood loss, and avoid reperfusion injury, the kidney will be fine," said Michael Ramsay, MD, chief of service for the department of anesthesiology and pain management at Baylor University Medical Center in Dallas, in a forum held in Boston at the American Transplant Congress. "But the question is, how do you do that?"

To give a sense of the scope of the problem, Ramsay said that at his own center, acute renal dysfunction occurs in as many as 78 percent of patients intraoperatively. "So it happens, and it happens because of all the rigors we have to put the patients through during transplantation." Factors that increase the risk of renal injury include preexisting renal impairment, hemodynamic instability, perioperative bleeding, inflammation, and abdominal compartment syndrome.

Changes in operative technique may or may not have helped. The "piggyback" technique is typically used to preserve the patient's own vena cava while controlling blood flow during transplantation, and it has largely supplanted the older technique of venovenous bypass. The latter technique "is controversial, and is used less these days," Ramsay said. He noted that a recent analysis of clinical trials in one center where these options were used concluded that piggyback alone resulted in less transfusion, shorter stay in the intensive care unit, and less acute renal failure. However, that analysis compared sequential, not concurrent, outcomes, and a Cochrane review concluded that there was no evidence to support or refute venovenous bypass.

"It may be that once we get good biomarkers, that in those patients with significant hepatorenal dysfunction, some form of bypass may be better for them, but until we get that onsite, immediate marker, I think it is going to be hard to show," he said.

Reperfusion syndrome can be a major problem during surgery as well, increasing the risk of renal failure. "Severe hypotension, arrhythmia, cardiac arrest, acidosis, fibrinolysis: this is a result of all those bad things that are inside that liver graft," which accumulate during its explantation, hitting the heart when flow is restored through the implanted liver. It occurs in about 25 percent of liver transplant recipients. The risk can be reduced by flushing the graft out with saline before restoring flow to the heart, and also by the prophylactic use of vasopressors, Ramsay recommended.

Choice of immune suppression therapy matters

Immune suppression can also lead to kidney injury, and the choice of agents may have a big effect, said James Trotter, MD, medical director of liver transplantation at Baylor University Medical Center in Dallas.

"By any measure, a substantial number of patients come into liver transplant with renal dysfunction, and 30 percent have renal insufficiency," meaning that many patients are already at risk for posttransplant renal complications. Twenty-eight percent of liver recipients experience renal failure within 10 years of transplantation, and one quarter of those, he noted, do so within the first year. This "front-loaded effect implicates the possibility of immunosuppression as a potential cause," he said.

Calcineurin inhibitors (CNIs), including cyclosporine and tacrolimus, are probably the most important nephrotoxic agents used. Cyclosporine can cause ischemia, scarring, and fibrosis. As a result, "We've had an evolution of how we handle immunosuppression over the past 20 years," he said. "To a large extent, avoidance of CNIs" is a mainstay of protecting the kidney in the context of liver transplantation.

Trotter noted that it is important to distinguish between immunosuppression in the induction phase, or the first few weeks after transplantation, and the maintenance phase, many months to years afterward.

The field is now moving toward biologic agents for induction, with such agents as daclizumab and alemtuzumab, and today about a quarter of patients receive these. There is also a movement toward using mycophenolates as CNI-sparing agents, he said.

"Right now, the most common immunosuppressive regimen at the time of discharge is mycophenolate plus CNIs," he said, accounting for 70 percent of patients, rather than using a CNI as monotherapy. Although the number of patients never receiving a CNI is still small, that number is growing as well.

"Liver transplant patients undergo multiple hits to the kidney, on top of likely having underlying kidney dysfunction," which often ultimately leads to chronic kidney disease, explained Josh Levitsky, MD, of Northwestern University in Illinois.

"It would be extremely valuable to have a biomarker that could identify who is at increased risk of posttransplant kidney disease," he said, in order to tailor therapy to that risk. But such a biomarker has been slow in coming.

He noted the important distinction between diagnostic and predictive biomarkers. "Creatinine is not a good biomarker because injury has already occurred," he said, and the same goes for epidermal growth factor receptor and proteinuria. "These are diagnostic, but the goal is to push it ahead to prediction." A good biomarker, he said, should improve with successful intervention to prevent progressive kidney injury. "That would be a slam dunk."

For acute kidney injury, the most promising markers are neutrophil gelatinase–associated lipocalin, interleukin-18, renal liver-type fatty acid binding protein, cystatin C, and kidney injury molecule-1. "But none provide a clear advantage beyond traditional clinical serum creatine," according to a recent review, he said.

And for predicting chronic kidney disease, "There is actually less data, and at the present time, none are ready for use."

In the search for such a predictive marker, Levitsky and colleagues are first looking retrospectively using serial collections of plasma, and comparing those who experience chronic kidney disease after transplantation with those whose long-term renal function is stable. Ultimately, he said, this might help determine whether a liver transplant patient would be better off with a simultaneous liver-kidney transplant.

Regulation or Autonomy in Transplantation: A Debate

Transplant surgeons are among the most innovative of physicians, and they have to be: placing an organ from one person into another is risky, even under the best of conditions, and the shortage of organs has meant that surgery is often performed with less-than-ideal organs. Although that willingness to take risks has led to life-saving operations for many patients, not every outcome has been ideal, and not every transplant program matches the best centers in the level of patient care it provides.

Given the tension between the benefits of innovation and the costs of poor outcomes, what is the proper role of regulation? That was the topic of debate between Thomas Hamilton, director of survey and certification for the U.S. Center for Medicare and Medicaid Services (CMS), and Dorry Segev, MD, PhD, associate professor of surgery at Johns Hopkins University, speaking at the American Transplant Congress held in Boston in June.

"When there is a high level of complexity, and a high degree of trust is required, these are environments that make regulation useful. That is true of the banking industry, and it is also true of organ transplantation," Hamilton said.

Segev countered, "If the system for identifying consequences is not good, but the consequences are severe, then risk-averse behavior will undoubtedly ensue."

The CMS has regulated transplant centers since 2007, stepping in after many years of a hands-off policy because of "a number of headline articles" involving either questionable ethical practices or poor outcomes, Hamilton said. "The problem is there are always a certain number of outliers. That's what the regulations are designed to address. And this is not just in the public interest. CMS is the primary purchaser of organ transplantation services in the world," and the regulations are the means for insisting on a certain basic level of outcome to get the most value for public resources.

"There are bad regulations and there are good regulations. At CMS, we are talented in both directions," Hamilton said. "Smart regulations tend to be outcome focused, rather than dictating every single step, and they recognize unique circumstances, and they promote self-governance and learning." Those, he said, are the kind of regulations CMS uses to improve programs. A center can be "flagged" for outcomes below the expected range, after consideration of the many factors involved, including patient and organ characteristics. But flagging doesn't close a center. "We provide the time for programs to improve." A "mitigating factors" provision "allows a program to come forward, and demonstrate how it has turned the ship around," Hamilton noted.

Some centers, he said, "are unacquainted with their own data," and once they understand the data better, they improve. "Ninety percent of programs [which have been flagged] have improved," some dramatically so. "Ten percent, we invited to voluntarily withdraw."

The result, he said, is that "for every organ type, since 2007, we've seen a continued overall increase in survival. "So despite acceptance of riskier organs and recipients," which has been a national trend, "the survival is going up. That is absolutely tremendous."

Making the case for autonomy, Segev stressed a distinction that is often lost when outcomes between centers are compared. "A transplant candidate is someone who does better with a transplant than without one, not someone who does better than someone else," he said. "The question is,

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Chronic Kidney Disease:

- **In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.**
- **No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.**
- **Use the lowest OMONTYS dose sufficient to reduce the need for red blood cell (RBC) transfusions.**

Contraindications

OMONTYS is contraindicated in patients with uncontrolled hypertension.

Warnings and Precautions

Increased mortality, myocardial infarction, stroke, and thromboembolism:

- Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit. Use caution in patients with coexistent cardiovascular disease and stroke. Patients with CKD and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular reactions and mortality than other patients. A rate of hemoglobin rise of >1 g/dL over 2 weeks may contribute to these risks
- In controlled clinical trials of ESAs in patients with cancer, increased risk for death and serious adverse cardiovascular reactions was observed. These adverse reactions included myocardial infarction and stroke
- In controlled clinical trials of ESAs, ESAs increased the risk of death in patients undergoing coronary artery bypass graft surgery (CABG) and deep venous thrombosis (DVT) in patients undergoing orthopedic procedures
- In 2 trials of OMONTYS, patients with CKD not on dialysis experienced increased specific cardiovascular events

Increased mortality and/or increased risk of tumor progression or recurrence in patients with cancer: The safety and efficacy of OMONTYS have not been established for use in patients with anemia due to cancer chemotherapy. OMONTYS is not indicated in patients with cancer receiving chemotherapy.

Hypertension: OMONTYS is contraindicated in patients with uncontrolled hypertension. Appropriately control hypertension prior to initiation of and during treatment with OMONTYS. Reduce or withhold OMONTYS if blood pressure becomes difficult to control. Advise patients of the importance of compliance with antihypertensive therapy and dietary restrictions.

Lack or loss of response to OMONTYS: For lack or loss of hemoglobin response to OMONTYS, initiate a search for causative factors. If typical causes of lack or loss of hemoglobin response are excluded, evaluate for antibodies to peginesatide.

Dialysis management: Patients receiving OMONTYS may require increased anticoagulation with heparin to prevent clotting of the extracorporeal circuit during hemodialysis.

Laboratory monitoring: Evaluate transferrin saturation and serum ferritin prior to and during OMONTYS treatment. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%.

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The most common adverse reactions in clinical studies in patients with CKD on dialysis treated with OMONTYS were dyspnea, diarrhea, nausea, cough, and arteriovenous fistula site complication.

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Debate

Continued from page 7

will this patient benefit from this procedure?"

Pressure to improve, he said, can and does come from multiple other sources besides the CMS, including one's self, one's fellow workers, and one's colleagues in the field. "This field has been doing this for 50-some years, without a tremendous amount of regulatory pressure, and outcomes have become better every single year." Segev said. And the system of regulation, he said, may not be very effective at identifying which centers are doing well and which are not. There are certainly centers that perform below par and are flagged. Even in these cases, Segev said, the consequence could be that fewer patients benefit from transplants. Remember the definition of a transplant candidate, he said: someone who does better with an organ than without one. Studies have shown that the effect of flagging is to reduce transplant volumes at the institution, reducing the number of patients who benefit.

More troubling is that the model used to flag institutions is imperfect and will inevitably lead to flagging centers that are performing at the norm. This, he said, is a statistical artefact of the model. What happens when an artefact makes it seem as if there is a problem when there isn't? "What happens when we try to improve outcomes that don't need improving? The answer is we become more restrictive, because we don't know what else to do."

To explore the risks of this scenario, Segev, who has a master's degree in biostatistics, set up a simulation model. His model included the same number of transplant centers as there are in the United States, with the same size distribution, and gave every center the nationally expected outcomes. "Everybody did OK in this simulation," he said. "Then we ran the [Program Specific Report] methodology to see who gets flagged."

"When everybody is doing OK, when nobody is working outside of the window we want them to work in, there is an 11 percent chance that a center will be flagged by the methodology at least once," with higher-volume centers far more likely to be flagged than low-volume centers, even if they are performing exactly the same.

In another simulation, he programmed some centers to have higher risk, with enough poor outcomes to trigger flagging, but he found they were not being consistently flagged. "When there are centers with worse outcomes, there is a16 percent sensitivity for identifying those centers." And if a center was flagged, there was less than a one-in-four chance that it was in fact one of the poorly performing ones.

Finally, he said, the appropriate level of risk may not be captured, leading the center to appear to have worse outcomes than it actually does, given the risks. "Our ability to predict outcomes in transplantation, based on the data we've collected, is just not very good at all." but barely better than a coin toss, he said.

Will We Ever Know the Long-Term Consequences for a Living Kidney Donor?

A family member, a loved one, or just a Good Samaritan who contemplates donating a kidney naturally wants to know what the effect may be on his or her own long-term health. Although many studies have attempted to address this pressing question, there are few first-rate data, according to researchers speaking at the American Transplant Congress in Boston. And although several new studies are under way to address the deficiencies of the past, even these studies are rife with problems, and definitive results may not be available for years, if ever. "We need better information in this area," according to Amit Garg, MD, PhD, of London Health Sciences Center in Ontario, "but there are many challenges to getting it."

"It is only in the last 10 years that there has been enough activity to support large, long-term studies," he said. Even still, most studies have been of questionable utility. Single-center studies tend to have uniform data but are too small to enable meaningful conclusions to be drawn. Multicenter surveys tend to suffer from a high degree of variability in practices between centers, especially across international borders. Retrospective studies have the potential for selection bias, whereas prospective studies,

as others have detailed, have been hampered by the ability to recruit and retain control participants for very-long-term follow-up.

Didier Mandelbrot, MD, medical director of the living kidney donor program at Beth Israel Deaconess Medical Center in Boston, noted that the need for living donors arises from the huge disparity between the need for kidneys and the supply. In addition, living donation has several benefits for recipients, including minimal waiting time (versus an average of 3–5 years for a kidney from a deceased donor), reduced need for dialysis, longer survival of the graft, and longer survival of the patient. Of the 15,000 kidney transplants in the United States every year, about 6000 are from living donors; more than 90,000 living donor transplantation procedures have been performed over the past 20 years.

A 2009 study in the *New England Journal of Medicine* indicated that the long-term survival of donors was no different from that of matched control individuals, but some questions have remained about the adequacy of the control in this study.

A critical unanswered question, Mandelbrot said, is who is an acceptable living donor? Should the decision hinge on kidney-specific factors, such as creatinine clearance? What else must be considered? "I think it is fair to say there are no long-term data to guide us," he said. The effects of donation are better known for the most typical donors—young, healthy, white persons—"but what are the long-term outcomes in more borderline patients?"

One potential source for information might be follow-up data kept by the United Network for Organ Sharing, the organization that manages donations in the United States. But there is a steep dropoff in the percentage of donors seen postoperatively over time, with fewer than half returning at 1 year and only 7 percent at 5 years.

An attempt to overcome this lack of information is under way with the Kidney Donor Outcomes Cohort (KDOC) study (www.kdocstudy.com). KDOC is a prospective study that will assess living donors for psychological, social, functional, surgical, and medical outcomes. As of May 2012, the study has enrolled 74 of a planned 280 donors. Enrolling healthy control individuals has been more of a challenge, Mandelbrot said.

Other studies have faced different challenges. Alan Leichtman, MD, of the University of Michigan, described the Renal and Lung Living Donors Evaluation (RELIVE) study, a joint effort among several national kidney transplant centers. Earlier iterations of the study were retrospective or cross-sectional, whereas the current one is prospective. The goal is to assess outcomes in almost 9000 donors over time, combining information from multiple datasets, including transplant center records, Medicare and Medicaid records, the National Death Index, and, for control individuals, the National Health and Nutrition Examination Survey (NHANES).

Much of the work has been resolving discrepancies among the sets. "It is an enormous amount of work," Leichtman said. The payoff is that the comprehensiveness of the approach "should allow a high probability of accurately estimating the frequency of common postdonation events."

Bertram Kasiske, MD, professor of medicine and head of transplant nephrology at the University of Minnesota, reported on the Assessing Long-term Outcomes after Living Kidney Donation (ALTOLD) study. This prospective trial, at eight sites in the eastern and central United States, aimed to enroll 200 donors plus paired control individuals, with a 36-month follow-up. "We were perhaps a bit naïve. We wanted to look at living unrelated donors, and find controls through siblings," but that proved too challenging. "We gave up being purists," he said. The researchers expanded their enrollment to include any living donors and nonsibling control individuals.

After 6 months, their original 204 donors had dropped to 198. Currently, they have 80 percent of the original cohort out to 24 months.

Given the enormous challenges, expense, and difficulties of conducting such long-term studies, one audience member suggested, "Perhaps we are trying to achieve something we can never achieve." Instead, perhaps the focus should be on teaching donors to understand that any increase in risk is likely to be quite small and to help them find healthy ways of dealing with the inevitable uncertainty after their generous gift.

Mandelbrot offered some support to that idea. "We may have to accept the fact that we will never know what we want to know," he concluded—that is, how donors do over the very long term. "We may have to accept there will always be uncertainty."

Leichtman countered that there was no reason to accept the fatalism of that view. "It would be a shame if, 50 years from now, we were still bemoaning that we didn't have the data," he said.

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Peritoneal Dialysis

Trends in Outcomes of Peritoneal Dialysis Patients in the United States

By Rajnish Mehrotra

In the 1960s, peritoneal dialysis for the treatment of uremia was performed intermittently. Patients would come in to receive treatment for 10 to 24 hours or more at a time, two to four times weekly. It was soon recognized that intermittent peritoneal dialysis did not provide adequate control of uremia and this approach was abandoned in favor of thrice-weekly hemodialysis. This changed in 1975 with the successful treatment of one patient with peritoneal dialysis performed continuously, rather than intermittently, while living at home, rather than in a healthcare setting.

The delivery of continuous peritoneal dialysis has substantially improved over the last three decades. It is estimated that about 15 percent of the dialysis population worldwide uses the therapy now. The proportion of dialysis patients in the United States treated with peritoneal dialysis is about 7 percent.

As more patients with ESRD began treatment with peritoneal dialysis, the question of whether patients do as well when treated with this form of dialysis compared to in-center hemodialysis gained importance. Most studies have examined patient survival, and the discussion herein will be limited to this issue.

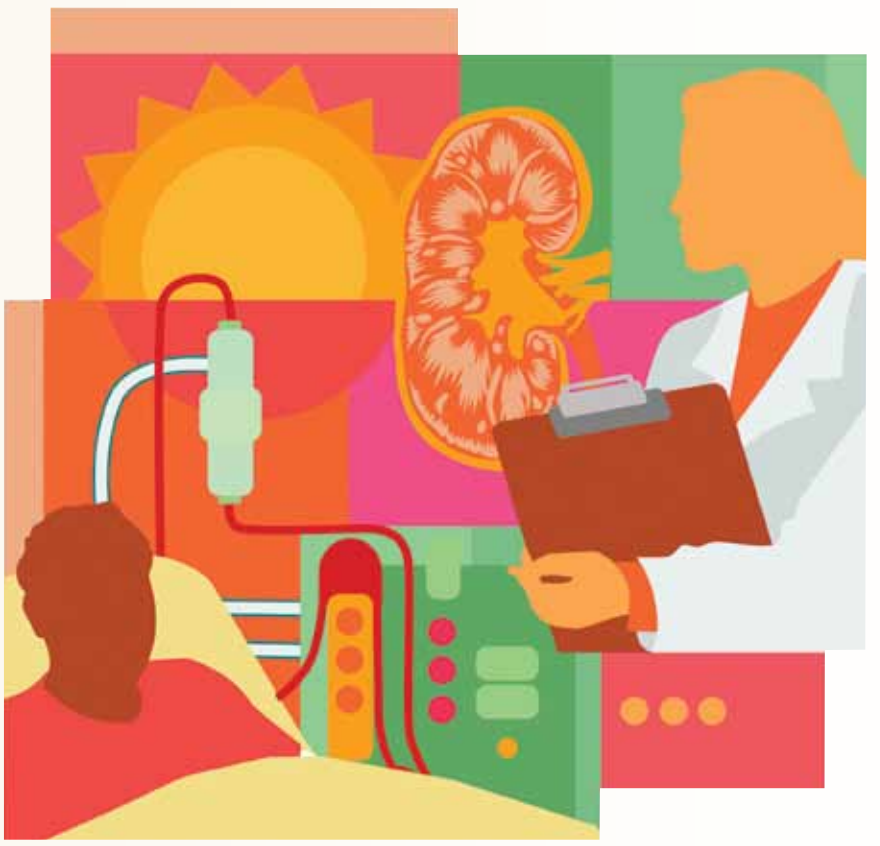
Initial studies were small, often from a single center. Since the 1990s, a large number of studies have used information from all ESRD patients in any given country from different parts of the world. The studies from the 1990s showed that patients who started treatment with peritoneal dialysis had a lower chance of dying in the first 2 to 3 years of starting dialysis compared to those who started treatment with hemodialysis. The apparent "benefit" of treatment with peritoneal dialysis was greatest for the youngest and healthiest patients and least for the oldest and sickest patients. However, the long-term death risk was seemingly greater for peritoneal dialysis patients compared to those treated with hemodialysis. These studies showing an apparent change in death risk over time were interpreted as reflecting the advantages and disadvantages of each individual dialysis therapy. This interpretation has led to the widespread perception that peritoneal dialysis is a good therapy for some, but not all patients. Moreover, it is believed that peritoneal dialysis can be used for only a short period of time, generally for only as long as patients with ESRD make at least some urine.

Over the past decade, the survival of patients who start treatment with peritoneal dialysis has improved significantly more than that of in-center hemodialysis patients. Greater improvements in survival of peritoneal dialysis than of hemodialysis patients have been reported from North America (United States and Canada), Europe (France and Denmark), Asia (Taiwan), and Oceania (Australia and New Zealand).

Studies of patients who have started treatment with dialysis therapies in the 21st century show that the 4-, 5-, and 10-year survival of peritoneal dialysis and hemodialysis patients in the contemporary era are virtually identical (1–3). This equivalency in outcomes with peritoneal dialysis and hemodialysis has been reported from North and South America, Europe, Asia, and Oceania (4–7). These studies challenge the traditional paradigm of which patient with ESRD should be treated with peritoneal dialysis and for how long (8). It would seem that there are no meaningful differences in patient survival with peritoneal dialysis and hemodialysis. Thus patient survival should not be a consideration when patients are counseled about the different renal replacement therapies.

Few treatments impact so many aspects of an individual's life as dialysis therapy does. Given the overall equivalency of patient survival with the two therapies, the overwhelming majority of patients can and should choose which dialysis therapy they will use, on the basis of lifestyle considerations with active support and guidance from the healthcare staff.

Rajnish Mehrotra, MD, is section head of nephrology with the Harborview Medical Center at the University of Washington in Seattle, WA.



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Organization and Structure of a Successful Peritoneal Dialysis Program

By Fredric O. Finkelstein

One important reason for the limited use of peritoneal dialysis in the United States involves problems with the organization of peritoneal dialysis facilities. The basic structure and function of peritoneal dialysis facilities needs to be quite different from that of in-center hemodialysis facilities. Four key elements need to be addressed in organizing a peritoneal dialysis facility:

- Adequate chronic kidney disease (CKD) education program
- Adequate size and structure of peritoneal dialysis centers
- Development of appropriate support systems: a team approach
- Development of appropriate continuous quality improvement (CQI) programs to monitor a variety of domains

CKD education

The importance of developing and implementing adequate CKD education programs cannot be overemphasized. The vast majority of CKD patients do not have contraindications to receiving peritoneal dialysis. The majority of patients approaching ESRD have surprisingly little knowledge about treatment options. This occurs even if patients have been referred to nephrologists, indicating that the process of providing education for CKD patients needs to be reexamined. Funds should be allocated to support education programs and train educators and to incorporate CKD education into the routine fabric of care.

Center size

Several studies have documented the impact of center size on the outcome in patients receiving peritoneal dialysis. In terms of peritonitis rates, technique failure, and mortality rates, smaller units tend to have worse outcomes. The reasons likely relate to the experience of nurses and physicians, the ability to develop a support team, and the development of effective CQI programs. It has been suggested that the growth of peritoneal dialysis programs in the United States has been limited by the attempts to grow small peritoneal dialysis programs rather than the consolidation of small peritoneal dialysis programs into larger centers. Certainly, the experience in the Far East suggests that large programs may be extremely successful. Many programs in China, Taiwan, and Hong Kong care for more than 300 peritoneal dialysis patients and report excellent results of this therapy, with low rates of peritonitis and technique failure.

Appropriate support systems: a team approach

The peritoneal dialysis unit needs to use a team approach to treating the patient. Nurses are the backbone of the program. Nurses who are dedicated to the peritoneal dialysis program, have sufficient experience, and are readily available to patients 24 hours a day are critically important to program success. Social work and dietary input are also crucial ingredients for a successful program. Psychosocial assessments and interventions are particularly important for patients receiving maintenance therapy at home because various psychosocial factors can have an adverse impact on outcomes, including depression and anxiety in patients and stress in caregivers. Attention to dietary input is also essential. The importance of sodium restriction in terms of controlling blood pressure and limiting the dextrose exposure required to maintain fluid balance with peritoneal dialysis needs to be emphasized. Limitations of phosphate clearance with peritoneal dialysis require that careful attention be paid to restriction of dietary phosphate and compliance with the administration of phosphorus binders.

CQI programs

CQI programs are critical to the success of a peritoneal dialysis program, as has been discussed in the KDOQI guidelines. A modification of the domains suggested in the KDOQI guidelines for CQI is summarized in Table 1. Successful peritoneal dialysis programs need to track their outcomes and address the important areas that affect the outcomes in peritoneal dialysis patients. Difficulties in managing a peritoneal dialysis unit vary from facility to facility, and each facility must identify and deal with the problem areas that are unique to its program.

Fredric O. Finkelstein, MD, is affiliated with the Hospital of St. Raphael, Yale University, New Haven, CT.

Table 1. Continuous quality improvement domains

1.	Peritonitis rates
2.	Exit site infection rates
3.	Technique failure rates
4.	Patient satisfaction
5.	Health-related quality of life
6.	Catheter-related problems and catheter survival rates
7.	Adequacy of dialysis
8.	Anemia management
9.	Calcium and phosphorus metabolism
10.	Blood pressure and volume control
11.	Lipid control
12.	Weight management
13.	Dextrose use

Dr. Gregory Braden interviews Gayle Gray, peritoneal dialysis patient for three years

Dr. Braden Gayle, I know you just received a kidney transplant and are doing great with it, but how long were you on peritoneal dialysis?

Gayle Gray I was on peritoneal dialysis for three years.

Dr. Braden Why did you choose peritoneal dialysis instead of in-center hemodialysis or home hemodialysis?

Gayle Gray I chose peritoneal dialysis because I didn't want to have the ups and downs of both fluid and toxin removal, which I did not think would be good for my body since I have had type 1 diabetes for the last 35 years.

Dr. Braden Why did you choose continuous ambulatory peritoneal dialysis (CAPD) over CCPD (continuous cycling peritoneal dialysis)?

Gayle Gray I did not have enough room in my bedroom to store all the supplies and the machine for CCPD. In addition, I have to get up at night to go to the bathroom often and I did not want to have to use a bedside commode.

Dr. Braden What do you feel were the greatest benefits of performing home peritoneal dialysis?

Gayle Gray I enjoyed doing home peritoneal dialysis because I was playing an active role in my care. I have to watch my diabetes carefully, and although the sugar in the fluid caused me to use more insulin, with peritoneal dialysis I thought I was in charge of my health.

Dr. Braden Do you have any regrets about your decision to perform home peritoneal dialysis?

Gayle Gray As I look back on my three years of dialysis I really have no regrets. I know that I live in an old house and I live with my older parents and I even had at times to do the exchanges in the bathroom with the door closed so there was no air moving, but overall I am glad I did it. It would have been nice if my house was larger, but it just wasn't. Also when I look at my body after peritoneal dialysis I did have some abdominal skin stretching and weakened abdominal muscles from the 2 liters of abdominal fluid with each exchange.

Gregory Braden, MD, is fellowship director and chief of the nephrology division at Baystate Medical Center/Tufts University School of Medicine in Springfield, MA.

Physician Education in Care of Peritoneal Dialysis Patients During Fellowship and Beyond: Opportunities and Challenges

By Joni H. Hansson

The use of peritoneal dialysis for treatment of ESRD in the United States has remained low (approximately 7 percent) despite an expanding number of patients reaching ESRD. It has been suggested that limited fellowship training in peritoneal dialysis may be one of the factors contributing to this decline, because this can result in provider inexperience and bias against peritoneal dialysis as a modality for treating ESRD.

The Accreditation Council for Graduate Medical Education program requirements for graduate medical education in nephrology state: "Fellows must have formal instruction, specialized clinical experience and demonstrate competence in dialysis," which includes peritoneal dialysis. Over the past decade, several surveys have examined dialysis training from the perspective of program directors and graduates. In general, it is thought that fellowship training in peritoneal dialysis is inadequate and needs to be improved. Less time is spent with didactic teaching and direct care of peritoneal dialysis patients in comparison with hemodialysis. In fact, fellows in most training programs follow up five or fewer peritoneal dialysis patients in the ambulatory setting during their fellowship.

To address the concerns of fellowship education in peritoneal dialysis, several educational initiatives have been developed (Table 1). Several educational courses are now available for peritoneal dialysis. The Peritoneal Dialysis University, developed in 1999 and now known as Home Dialysis University, is a 2.5-day course offered four to five times a year. Many training programs use these courses to supplement their curriculum for their fellows.

Unfortunately, not all fellows (or nephrologists wishing to expand their knowledge of peritoneal dialysis) can attend one of these conferences. This led to a collaborative effort of the training program directors, the ASN Dialysis Advisory Group and the North American Chapter (NAC) of the International Society of Peritoneal Dialysis (ISPD) to develop a comprehensive curriculum in peritoneal dialysis that is available online for all to use. This curriculum contains 20 presentations with references and questions to test learning. It includes peritoneal dialysis basics, management and complications of peritoneal dialysis, educational resources, and special topics. The ASN Dialysis Advisory Group has developed the ASN Virtual Mentor Dialysis Curriculum, which is also freely accessible online and covers all aspects of dialysis, including peritoneal dialysis. These educational resources offer wonderful opportunities for fellows, nephrologists, and other health care providers to learn all aspects of peritoneal dialysis.

Our greatest educational challenge is ensuring an adequate patient care experience in peritoneal dialysis. Many fellowship programs have limited exposure to the care of patients receiving peritoneal dialysis, either because of a small number of peritoneal dialysis patients at that institution or because of scheduling conflicts with other fellowship requirements. Fellowship programs must ensure that time is built into the fellow's schedule for an ambulatory peritoneal dialysis experience, and they should consider using local offsite clinics within or outside the institution.

Future educational initiatives should focus on novel programs to provide a meaningful experience with ambulatory peritoneal dialysis so that fellows can learn how to treat patients receiving peritoneal dialysis and understand how to develop and structure a peritoneal dialysis program. For example, training sites could be developed in large successful peritoneal dialysis units across the country that have a standardized experiential curriculum for the care of peritoneal dialysis patients. Programs with limited peritoneal dialysis patients could send their fellows to such a program for 1 week. A precedent for such a program exists through initiatives in Toronto and New Haven. Another example is faculty development ("train the trainer") in peritoneal dialysis, so that faculty will embrace and grow peritoneal dialysis programs at their institutions. This could be accomplished by developing a resource/mentoring programs for nephrologists interested in expanding peritoneal dialysis in their practices. All these initiatives, it is hoped, will enhance the educational experience that fellows will have in caring for patients receiving peritoneal dialysis.

Fellowship training in peritoneal dialysis is quite variable and needs to be improved. This has led to the development of multiple educational resources in the care of patients receiving peritoneal dialysis. However, in the future we need to focus on how to enhance and ensure a direct patient care experience in peritoneal dialysis. Knowledge and experience will result in the growth of peritoneal dialysis as a modality for ESRD and also will improve fellowship training and patient outcomes.

Joni H. Hansson, MD, is nephrology fellowship program director at the Hospital of Saint Raphael and assistant clinical professor at Yale University School of Medicine in New Haven, CT.

Table 1. Educational resources for training in peritoneal dialysis

NAC-ISPD Comprehensive Peritoneal Dialysis Curriculum
http://ispd.org/NAC/education/pd-curriculum/

ASN Virtual Mentor Dialysis Curriculum
http://www.asn-online.org/education_and_meetings/distancelearning/curricula/dialysis/

Home Dialysis University
http://www.hdufellows.com/
https://secure.lenos.com/lenos/northpointe/HDUPhysiciansPage/

Enhancing Nursing and Allied Staff Peritoneal Dialysis Education in a Chronic Kidney Disease Program

By Beth Piraino and Judith Bernardini

The option of peritoneal dialysis for management of advanced chronic kidney disease (CKD) is best introduced while the patient is being followed up in the CKD clinic. Educational approaches to patients with CKD include classes, instruction one-on-one by a nurse educator or other allied health care professional, and information provided by the physician. A team approach is often used in peritoneal dialysis education as part of a well-run CKD program. Therefore, all members of the team should be fully informed and up to date about peritoneal dialysis. The CKD team may include medical assistants, physician assistants, nurse practitioners, dieticians, nurses, and renal fellows as well as nephrologists. Education about peritoneal dialysis should be provided to these important team members.

Educating allied health care professionals about peritoneal dialysis, a modality with which many are unfamiliar, ensures that all speak with informed voices and avoid giving incorrect information about peritoneal dialysis. It is rather common for those with little knowledge about peritoneal dialysis to tell patients that the procedure is associated with a high risk of infection, thus discouraging patients from home peritoneal dialysis. Patients may also have obtained information about renal replacement therapy from the Internet (1). Although some websites have factually, clearly presented information, others are inaccurate and may be self-serving. It is quite possible that allied health care professionals have likewise been exposed to incorrect information about peritoneal dialysis, and this may unfortunately reinforce a patient's wrong perceptions. Therefore, a structured approach to educating staff members of the CKD clinic about peritoneal dialysis seems desirable.

CKD patients with GFR levels of 20 mL/min or lower who are aware that dialysis will be likely needed in their future often have major depression (25 percent) or subthreshold depression (20 percent) according to structured psychiatric interviews (2). The team approach for these patients provides support and correct information in a longitudinal fashion. Many CKD clinics do not have the services of a social worker, so other allied health care professionals must provide such support and psychological insight. Sequential measures of depression, loneliness, and isolation might be useful in this setting. Some patients use avoidance, which results in faster progression of CKD (3). Patients facing dialysis who have greater psychological stress levels related to CKD as measured by the Chronic Kidney Disease Stress Inventory are more likely to start dialysis with in-center hemodialysis than with peritoneal dialysis (4). It seems probable that support by a well-educated CKD team will diminish stress in this setting.

Table 1 shows resources for teaching health care professionals about peritoneal dialysis. Most of the information would be suitable for physician assistants, nurse practitioners, nurses, and social workers who work in the CKD clinic. The best approach to training these allied health care professionals is not known, but it might include attendance at one of the meetings listed, regular reading of the journal *Peritoneal Dialysis International*, and a review of the free slide set put together by expert members of the International Society for Peritoneal Dialysis North American Chapter (ISPD NAC) available at the ISPD website (http://ispd.org/NAC/education/pd-curriculum). A peritoneal dialysis expert in the program could present the slide sets to the health care professionals working in the CKD program.

To summarize, little is known about the level of knowledge regarding peritoneal dialysis among allied health care professionals who work in CKD clinics. It appears probable that knowledge of peritoneal dialysis is variable and often lacking. A well informed approach to educating the allied health care professionals in the CKD clinic about peritoneal dialysis as an option for patients should enable the entire team to support the patient to make informed choices. This is a fertile area for further research.

Beth Piraino, MD, is professor of medicine at the University of Pittsburgh School of Medicine and Judith Bernardini, RN, is adjunct assistant professor at the University of Pittsburgh School of Nursing and Medical School.

Table 1. Peritoneal dialysis training tools for allied health care professionals

Meetings with peritoneal dialysis courses available for allied health care professionals:

International Society for Peritoneal Dialysis North American Chapter meeting every other year
National Kidney Foundation spring meeting every year
ASN pre-meeting course
Annual Dialysis Conference

Online peritoneal dialysis course: freely available at ispd.org (http://ispd.org/NAC/education/pd-curriculum/)

Journal: Peritoneal Dialysis International: free online after first year, free to members of the ISPD.

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Maximizing Success with Peritoneal Dialysis: Best Demonstrated Practices

By Seth B. Furgeson and Isaac Teitelbaum

Peritoneal dialysis offers unique advantages for patients with ESRD. Peritoneal dialysis offers the convenience of home dialysis, allows continuous solute and fluid removal, and, for the incident dialysis patient, appears to be less harmful to residual kidney function (RKF). Many peritoneal dialysis patients have successfully used the therapy for a decade or longer without significant problems. To maximize success with peritoneal dialysis, providers must carefully attend to its many components. Preserving RKF, maintaining peritoneal membrane function, preventing cardiovascular disease, and avoiding infectious complications are all crucial components of therapy.

Preserving residual kidney function

It has long been recognized that peritoneal dialysis is associated with a slower decline in RKF than hemodialysis. Studies have also demonstrated that preservation of RKF correlates with improved survival. RKF allows for increased volume removal as well as improved phosphorus and middle molecule clearance. To preserve RKF, providers need to minimize nephrotoxic medications (e.g., intravenous contrast medium, nonsteroidal anti-inflammatory drugs), avoid rapid fluid shifts and hypovolemia, and, whenever possible, treat with blockers of the renin-angiotensin system. Two small randomized trials have shown that angiotensin converting enzyme inhibitors and angiotensin receptor blockers can minimize the loss in RKF (1,2). It is therefore recommended that patients with RKF receive either of these agents, assuming there are no contraindications.

Maintaining peritoneal membrane function

For peritoneal dialysis to be successful, adequate ultrafiltration is essential. However, in many peritoneal dialysis patients, anatomical changes in the peritoneal membrane affect ultrafiltration. Currently, a leading hypothesis posits that prolonged exposure over time to bioincompatible peritoneal solutions (high glucose, high glucose degradation products, low pH) damages mesothelial cells lining the peritoneum and increases vascularity of the peritoneum.

Consequently, over time, many patients will have more rapid solute transport, quicker dissipation of the glucose-induced osmotic gradient, and less ultrafiltration. Given the available data, it seems prudent to minimize glucose exposure during dwells. Furthermore, salt restriction and judicious use of diuretics can reduce the need for hypertonic solutions. Recently, more biocompatible solutions (normal pH or low glucose degradation products) have been studied in small trials. To date, however, these trials have not conclusively determined whether biocompatible solutions preserve peritoneal membrane function, and their routine use cannot yet be recommended. Further data are necessary.

Preventing cardiovascular disease

As is true of patients receiving hemodialysis, cardiovascular disease is the primary cause of death in peritoneal dialysis patients. The majority of patients beginning dialysis have evidence of left ventricular hypertrophy (LVH) that correlates with an increased risk of sudden cardiac death. Hypertension and chronic volume overload likely contribute to LVH. Randomized controlled trials comparing a daily icodextrin dwell with a dextrose dwell have shown improved ultrafiltration and LVH. Peritoneal dialysis providers must use a comprehensive care plan to help patients remain euvolemic. Dietary sodium restriction, diuretics, and icodextrin (in appropriate patients) are all components of this care plan.

In some patients, atherosclerotic coronary disease contributes to the increased risk of cardiac death. The SHARP study, a trial comparing ezetimibe/simvastatin with placebo in chronic kidney disease and dialysis patients, enrolled 496 patients in peritoneal dialysis. Although there was a trend toward reduced atherosclerotic events in the treatment group, it was not statistically significant (3). By contrast, observational U.S. Renal Data System data from Dialysis Morbidity and Mortality Study wave 2 do indicate a significant decrease in both all-cause and cardiovascular mortality in peritoneal dialysis patients using lipid-lowering therapy (4). We routinely treat our peritoneal dialysis patients with lipid-lowering therapy targeting low-density lipoprotein <100 mg/dL.

Avoiding infectious complications

Both peritonitis and refractory infections of the exit site or tunnel are associated with significant morbidity. Catheter loss, ultrafiltration failure, and death are all associated with peritonitis. To minimize the risk for peritonitis, proper patient training and sterile technique are essential. Controlled trials have also shown that local antibiotic prophylaxis at exit sites, such as gentamicin cream or mupirocin, can reduce the risk of peritonitis and should therefore be routinely used.

In conclusion, peritoneal dialysis is a well-tolerated treatment for ESRD patients. Paying attention to these aspects of therapy will maximize the chances of successful peritoneal dialysis.

Seth B. Furgeson and Isaac Teitelbaum are with the division of renal diseases and hypertension at the University of Colorado Anschutz Medical Campus in Aurora, CO, and Seth Furgeson is with the renal division at Denver Health Hospital.

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Getting the Right Care at the Right Time: Empowering Patients with Effective CKD Modality Education

By Leanna B. Tyshler and Mary Dooley

Most new dialysis patients start dialysis without permanent access and unaware of home therapies. Making informed decisions and starting with a permanent access are strongly associated with patients getting the right care at the right time. Northwest Kidney Centers, a nonprofit dialysis provider, has made a significant commitment to predialysis modality education. We educate about 300 patients per year, plus their families and friends. About 30 percent of our incident dialysis patients have attended our classes before starting renal replacement therapy. The focus is simple: help patients consider home therapies and renal transplantation, and start dialysis with a permanent access.

These are some elements essential to effective education:

1. The primary responsibility of program educators is education about chronic kidney disease (CKD). We have a dedicated CKD nurse and a social worker who are knowledgeable and passionate about modality education.

2. Program structure is flexible, is widely available, and provides the right amount of information. Scheduling and location should not be barriers for patients. We offer Choices, a 2.5-hour class that gives an overview of treatment options, four times a month, each at a different location in our service area. We see patients individually when education is needed urgently, if an interpreter is required, or if concerns need to be discussed privately. We use a phased model for education because every patient needs to know the basics, but some may need more information. After attending the Choices overview class, a patient can attend "graduate school"—shorter classes focused on one modality (peritoneal dialysis, home hemodialysis, or transplantation). These "next step" classes provide more in-depth information and emphasize treatment planning.

3. The right curriculum is key. We have developed a curriculum that is understandable, is relatable, and facilitates informed consent based on three principles:
   - Health literacy: The CKD population and the low health literacy population overlap. We use standardized PowerPoint materials with minimal words, many pictures, and stories. All handouts are written at a 5th to 6th grade reading level.
   - Patient-centered: The choice of a dialysis modality is a psychosocial one, made in the context of personal goals and lifestyle. To make education relevant, we try to understand the patient's personal situation rather than simply present information.
   - Evidence-based: Educating for informed consent means presenting understandable and compelling facts on survival, risks, and benefits.

4. CKD patients must be reached at the right time. The KDOQI guidelines state that every patient with stage 4 disease should receive modality education. Dialysis providers have access to CKD patients only through nephrologists' referrals. Marketing to nephrologists is essential to create a culture in which referral to modality education is routine and expected. We emphasize the value to the nephrologist of having an educated patient—better patient compliance, better outcomes, and time saved in the office. We provide literature and posters in offices, reminders in our publications directed to nephrologists, reminders at meetings, and informal contacts from our staff and from the highest level in the organization. We look for a nephrologist "champion" in every group, and we partner with office staff to facilitate the referral process. After we receive referrals from nephrologists, we make several attempts to reach patients and to track those who refuse treatment or are unreachable. With aggressive follow-up on all referrals, 80 to 90 percent of referred patients attend our classes.

5. Continuing communication with nephrologists is a must. We keep the referring nephrologists in the loop at every step. We report whether a patient attends, summarize the patient's modality preference, and discuss any barriers. Feedback underscores the credibility and effectiveness of our program. We give nephrologists "report cards" that show how many of their patients attended class, how many new patients started peritoneal dialysis, and how many started hemodialysis with permanent access. Every report reiterates outcomes data that support the efficacy of our program: Attendees are 2.5 times more likely to choose peritoneal dialysis and 44 percent more likely to start hemodialysis with a permanent access in place and in use.

6. The immediate goal of education is not education—it is action. Patients may leave class planning on peritoneal dialysis but then start later with in-center hemodialysis. To address this, we retooled the Choices curriculum to focus on coach-

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CKD Modality Education

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ing patients to take the next step, priming patients to go back to their nephrologist with specific questions ("Am I a candidate for peritoneal dialysis?" "When should I get a peritoneal dialysis access?") and to actively plan (e.g., plan for peritoneal dialysis at work and figure out home supply storage).

We are also piloting a patient navigation program for Choices attendees who are interested in home dialysis that includes routine telephone contacts with the CKD nurse educator, who provides guidance toward treatment goals.

The right care at the right time benefits patients, nephrologists, and dialysis providers. Timely and effective modality education empowers patients to take actions that improve their health and quality of life. But it takes significant and thoughtful institutional commitment to make a program successful. We believe that the impact on the long-term quality outcomes of our organization makes it a worthwhile investment.

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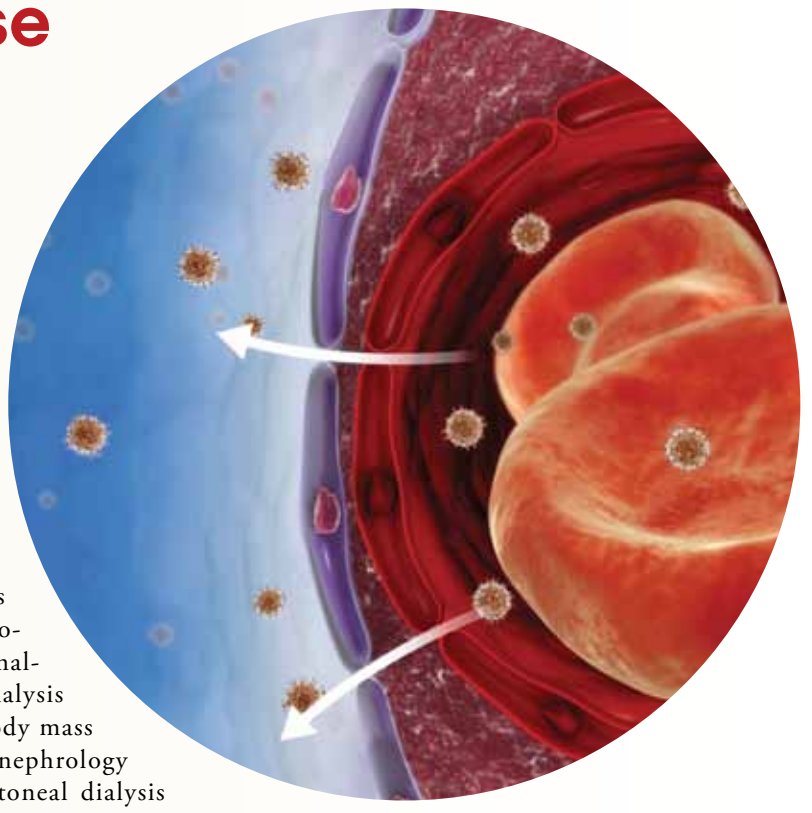
Historical Reasons for Underuse of Peritoneal Dialysis in the United States

By Gregory L. Braden



Improvements in the delivery of peritoneal dialysis in the 1980s using plastic dialysate bags rather than bottles, Y-sets for continuous ambulatory peritoneal dialysis, improved catheter design, and the development of easy-to-use automated peritoneal dialysis cyclers have made peritoneal dialysis an effective option to treat patients with ESRD. In addition, the peritoneal membrane removed toxic "middle molecules" better than earlier-generation hemodialysis filters made with cupraphan. In the 1980s, in our center and in some dialysis centers in the United States, up to 35 percent of all ESRD patients were receiving peritoneal dialysis, but this percentage has recently dropped to under 10 percent. The use of peritoneal dialysis in the United States lags far behind that of other countries. Several reasons may explain the underuse of peritoneal dialysis in the United States.

Over the past two decades, U.S. physicians have developed a bias against and lack of enthusiasm for peritoneal dialysis. Early studies suggested that the mortality of peritoneal dialysis patients was greater than that of similar patients receiving hemodialysis, and even recent studies suggest that the mortality of peritoneal dialysis patients older than 45 years may be greater than that in similar patients on hemodialysis. These studies may have biased some nephrologists against offering peritoneal dialysis to their patients. However, newer registry and epidemiologic studies in the United States, Canada, and Denmark have shown that mortality is lower with peritoneal dialysis in the early years of therapy compared with similar patients receiving hemodialysis. When these data are taken together, there is no clear evidence that survival is better in ESRD patients with hemodialysis than in those receiving peritoneal dialysis. Thus, any apparent survival difference is not great enough between modalities to warrant physicians offering either method over the other for patients approaching ESRD. Rather, psychosocial issues, complex medical problems, and patient choice should determine who can successfully perform peritoneal dialysis.

Physicians' bias favoring hemodialysis over peritoneal dialysis may also be due to recent improvements in biocompatible hemodialyzers, which now have better middle molecule clearance. In addition, the rise of interventional radiologists placing temporary or longer-term dialysis catheters allows easier management of the initial uremic state with hemodialysis. Annually, approximately 15 percent of patients receiving peritoneal dialysis transfer to hemodialysis because of severe peritonitis, peritoneal membrane failure, or catheter malfunction. Difficulty in achieving dialysis adequacy in patients with a large body mass index and insufficient training of nephrology fellows in the management of peritoneal dialysis patients are additional reasons why nephrologists have shifted away from peritoneal dialysis as an important therapy for ESRD.

In the past two decades, most academic centers that train nephrology fellows no longer provide peritoneal dialysis education and training in their hospital-owned peritoneal dialysis programs. Rather, hospitals have divested their nonprofitable dialysis units to one of several national dialysis companies that primarily focus on hemodialysis patients, with few resources or champions devoted to peritoneal dialysis. However, the new bundled payment schedule for ESRD patients offered by the Centers for Medicare and Medicaid Services financially favors the use of peritoneal dialysis and should help increase the numbers of ESRD patients receiving it. The ease and focus on hemodialysis rather than on peritoneal dialysis has diminished the use of the latter. However, developing the expertise of physicians and nurses could enhance the use of peritoneal dialysis as an effective therapy for ESRD.

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Implications of Regulatory and Reimbursement Changes for the Future Success of Peritoneal Dialysis

By Suzanne Watnick

Patients with ESRD constitute less than 1 percent of the total Medicare population but account for nearly 7 percent of dollars spent. Recognizing powerful financial incentives for the overuse of certain separately billable items, Congress mandated that the Centers for Medicare and Medicaid Services implement a per-dialysis-session expanded bundled payment in 2008. This bundled payment aims to reduce costs, attempting to pay no more than dialysis providers require to offer high-quality care. Any change in profit margin would be recognized by the dialysis provider; thus, the drive to do less as opposed to more might be incentivized by such a payment system. Also, dialysis modalities that cost less than others would be encouraged. The costs of peritoneal dialysis, not including payments to physicians, are estimated to be approximately $20,000 lower than the costs of hemodialysis, with similar outcomes noted between modalities over the first several years of therapy.

A major implication of these regulatory and reimbursement changes is the expansion of peritoneal dialysis use, reversing the trend over the past 20 years. The use of peritoneal dialysis in the United States peaked at 16 percent in 1985 and started to decline around 1994 to the current prevalence rate of 7 to 8 percent. Data showing a possible reversal of the downward trend will be forthcoming in a General Accounting Office report due in March 2013. U.S. Renal Data System data for 2011 have not yet been released, and the full impact of these changes may not be understood until well after 2012.

If the use of peritoneal dialysis grows, peritoneal dialysis units may receive additional resources, which may drive additional growth. Economies of scale may decrease costs even further. With a more comprehensive bundled payment system, dialysis providers have already shifted some of their resources to promote peritoneal dialysis as an underused modality. Even before the reimbursement changes, large dialysis organizations recognized the benefit of having an expanded home dialysis program.

Another relevant regulatory change was the addition of the Medicare education benefit in January 2010. Providers are now reimbursed for up to six sessions to educate patients with stage 4 chronic kidney disease about dialysis options, which may drive an increased use of peritoneal dialysis. In one study of 1600 ESRD patients surveyed, of the 61 percent who were counseled about all dialysis options, 11 percent started peritoneal dialysis. Of the 39 percent not counseled, only 1.6 percent started peritoneal dialysis.

With further resources and more education benefits, providers may have a greater percentage of their patients begin with peritoneal dialysis rather than with hemodialysis. More patients who are less fit as candidates for peritoneal dialysis may be swayed to start it. Interestingly, this may increase the expense of peritoneal dialysis and narrow the gap between the expenses of one dialysis modality versus another.

Last, with these regulatory and reimbursement changes and the potential increase in use of peritoneal dialysis, the workforce needs to be prepared to care for these patients. Better provider education may expand the use of peritoneal dialysis. Studies have shown that nephrology fellowship trainees have much less exposure than their Canadian counterparts and than historical control individuals, given the decreased use of peritoneal dialysis in this country. Groups such as the International Society of Peritoneal Dialysis and the American Society of Nephrology have recognized this and have made concerted efforts to create and sponsor additional educational experiences, such as a peritoneal dialysis curriculum and focus groups among the directors of nephrology fellowship training programs.

In this changing practice environment, many opportunities exist to expand peritoneal dialysis. As a community we should promote these changes in the most thoughtful way to provide care for our patients, who cannot always advocate for themselves. Through active education of patients and providers, close communication with policy makers and dialysis providers, and conscientious monitoring of the effects of these changes, we can encourage the optimal provision of peritoneal dialysis in this country.

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Policy Update

CMS Proposes Revisions to ESRD Payment System, Additions to Quality Incentive Program

By Rachel Shaffer

The Centers for Medicare and Medicaid Services (CMS) released a proposed rule on July 2, 2012, that addresses dialysis care. The ASN Quality Metrics Task Force is analyzing the proposed rule and, with the ASN Public Policy Board, will provide input to CMS on behalf of ASN members.

The proposed rule updates Medicare's dialysis payment system administered through the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS). The Prospective Payment System pays a predetermined, fixed amount for all services related to each dialysis treatment. This is also known as a "bundled" payment system.

The Quality Incentive Program (QIP) is the first-ever mandatory value-based purchasing program within the Medicare system. Under the QIP, facilities that do not meet or exceed performance standards on quality measures receive a reduction in their payment rates. The QIP operates concurrently with the ESRD PPS.

After Congress mandated the ESRD PPS and QIP in 2008, approximately 90 percent of dialysis providers elected to begin receiving all payments under the new, bundled payment system from year one.

The proposed changes released for public comment on July 2 would affect dialysis treatments provided during calendar year 2013, while changes to the ESRD QIP would affect payments to providers in 2015 and beyond. Payment reductions would be calculated based on data from dialysis treatments provided beginning in 2013. In addition, the proposed rule describes a proposal to implement changes to bad debt reimbursement to eligible Medicare providers.

How would the proposed rule change the ESRD PPS?

The ESRD PPS base rate set for 2012 was $234.81; CMS proposes to increases this rate to $240.88 per dialysis treatment in calendar year 2013. On the basis of price factors and a projected increase in Medicare dialysis beneficiary enrollment, CMS estimates that dialysis facilities in 2013 will collect approximately $8.7 billion for treatments in 2013, a 3.1 percent overall increase. CMS notes that this increased payment to dialysis facilities means beneficiaries will also likely see a 3.1 percent increase in their co-payment responsibility.

Providers who opted to receive transitional "blended payments" will collect reimbursement that is 25 percent based on the previous composite payment system, and 75 percent based on the new PPS payment system.

Jonathan Blum, CMS deputy administrator and director of the agency's Center for Medicare, believes "that the policies and rate changes proposed today will continue to help ensure that beneficiaries diagnosed with ESRD continue to get the care they need."

QIP measures under consideration by CMS

1. Standardized Hospitalization Ratio (NQF #1463)
2. Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (NQF # 0369)
3. 30-Day Hospitalization Readmission Measure related to care coordination
4. Efficiency measure (though CMS states it is not aware of an efficiency measure appropriate for the ESRD population)
5. Population/community health measure (CMS requests comments on developing such a measure)

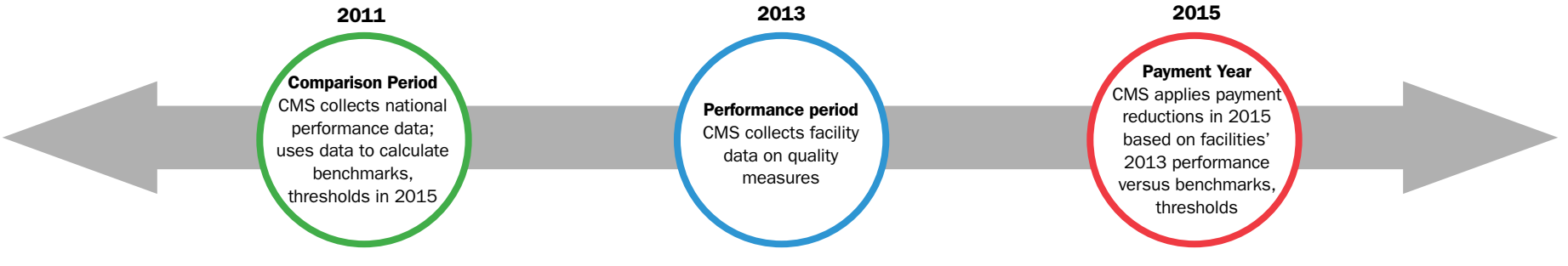
Table 1. Proposed criteria for considering removal or replacement of quality measures

1. Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.
2. Performance or improvement on a measure does not result in better or the intended patient outcomes.
3. A measure no longer aligns with current clinical guidelines or practice.
4. A more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available.
5. A measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.
6. A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.
7. Collection or public reporting of a measure leads to negative unintended consequences.

Table 2. Proposed 2015 clinical and reporting quality measures

Aspect of care evaluated	Measure	New Measure?
Anemia management	1. Percentage of Medicare patients with a hemoglobin >12 g/dL (clinical)	Existing
	2. Anemia Management: Report hemoglobin or hematocrit level and ESA dose, if applicable, for 98 percent of patients (reporting)	New
Dialysis adequacy	3. Kt/V measure for adult hemodialysis patients (clinical)	New (replace URR measure)
	4. Kt/V measure for adult hemodialysis patients (clinical)	
	5. Kt/V measure for pediatric hemodialysis patients (clinical)	
Vascular access type	6. Percentage of Medicare hemodialysis patients using an autogenous AV fistula with two needles during the last HD treatment of the month; and 7. Percentage of Medicare hemodialysis patients who have an intravenous catheter in place for 90 days or longer prior to the last hemodialysis session.	Existing
Bone mineral metabolism management	8. Hypercalcemia: Medicare patients with uncorrected serum calcium concentration >10.2 mg/dL (clinical)	New
	9. Mineral metabolism: Medicare patients serum calcium and serum phosphorus levels on monthly basis (reporting)	Existing (expanded)
Patient Safety	10. National Healthcare Safety Network (NHSN) Dialysis Event Reporting: Reports dialysis infection events to the Centers for Disease Control and Prevention on monthly basis (reporting)	Existing (expanded)
Patient Satisfaction	11. Patient Experience of Care Survey Usage: Surveys patients using in-center hemodialysis (ICH) consumer assessment of health care providers and systems (CAHPS) about experience of care	Existing

Table 3. Timeline of proposed comparison, performance, and payment periods 2011–2015



How would the proposed rule change the ESRD QIP?

The most significant proposed changes would apply to the ESRD QIP starting in 2015. CMS proposes adopting new clinical and reporting measures, as well as expanding the scope of two current reporting measures. These changes reflect a broader range of issues faced by patients who receive dialysis care.

CMS also puts forth criteria for removing or replacing quality measures. Finalized quality measures would remain part of the QIP program unless CMS alters or eliminates them through rulemaking or notification. However, if CMS believes a measure raises potential safety concerns, it proposes to immediately remove the measure from the QIP instead of waiting for the annual rulemaking cycle. The proposed criteria are summarized in Table 1.

Altogether, CMS recommends a total of 11 quality measures in 2015. These are summarized in Table 2. Among the new measures, CMS proposes to institute a reporting-only anemia management measure. Dialysis facilities would be required to report hemoglobin or hematocrit levels and erythropoiesis-stimulating agent (ESA) dose, if applicable, for 98 percent of patients. CMS "monitoring activities indicate that there has been a slight but noticeable increase in transfusions since the adoption of the ESRD PPS" and references a May 2012 United States Renal Data System analysis that found an increase in transfusions among ESRD patients concurrent with PPS implementation. Data collected from the proposed measure would facilitate development of future quality measures in an area "of critical significance to patient safety—anemia and transfusion" states CMS.

If the changes in the proposed rule are finalized, the 2015 QIP would apply new measures of dialysis adequacy to different patient populations—including adult peritoneal dialysis patients and pediatric hemodialysis patients. The proposed National Quality Forum (NQF)-endorsed measures would assess whether patients meet a modality-specific Kt/V threshold, and would replace the current urea reduction ratio measure of dialysis adequacy.

In addition, CMS proposes to add a clinical hypercalcemia measure (examining patient-months of Medicare patients with uncorrected serum calcium concentration >10.2 mg/dL) and expand the existing mineral metabolism measure by requiring facilities to report a serum calcium and serum phosphorus for every qualifying patient-month. The expanded reporting measure would allow CMS to develop mineral metabolism measures based on clinical data in the future.

Looking ahead, CMS is soliciting comments on measures it is considering adopting for future years of the QIP. These measures are summarized in the sidebar.

Proposed QIP scoring and evaluation

CMS proposes using the same scoring methodology for clinical measures in payment year 2015 as it used in payment year 2014 QIP, assessing providers on both "achievement" and "improvement" scales. As in 2014, CMS would score providers in payment year 2015 along an achievement scale ranging from an achievement threshold (set at the 15th percentile of the national facility performance in 2011) to the *benchmark* (set at the 90th percentile of the national facility performance in 2011).

The improvement scale would range from the *improvement threshold* (the providers' own performance on each measure in 2012) to the same benchmark. CMS would again calculate payments using whichever scale the facility scores better on, achievement or improvement.

CMS proposes to establish calendar year 2013 as the performance period for all of the payment year 2015 measures. To ensure time to calculate standards for payment year 2015, CMS proposes calendar year 2011 as the "comparison period" using national performance data from that time to calculate the achievement threshold and benchmarks in payment year 2015 (Table 3). However, CMS requests input on this issue since stakeholders might prefer standards based on more recent data, despite limitations, and requests input.

CMS is accepting public comment regarding the proposed rule until Friday, August 31, 2012. For a complete copy of the proposed rule as well as other resources, please visit the ASN public policy website at www.asn-online.org.

Industry Spotlight

DaVita Settles Federal Claim

DaVita recently settled a whistle-blower lawsuit from 2002 regarding its anemia management practices with a $55 million payment but no admission of wrongdoing by the company.

According to Zacks Financials, an online investment news website, Denver-based DaVita has adequate funds for the settlement, with cash and cash equivalents totaling $449 million as of March 31, 2012. The stock remained unaffected after the announcement, Zacks reported. However, the financial website did note that in October 2011 two law firms had begun investigating DaVita because of alleged over-billing of Medicare by the company, and if such charges were found to be valid they could weigh on the company's financials.

In DaVita's announcement of the settlement the company stated that "DaVita and its affiliated physicians did nothing wrong and stand by their anemia management practices, which were always consistent with their mission of providing the best possible care for each individual patient. As a result, the agreement contains no finding of wrongdoing or admission of liability by DaVita or its affiliated physicians."

To explain why the company decided to settle with the individual who sued, DaVita said that "agreements such as this one are sometimes in the best interest of shareholders."

The government investigated allegations raised by a sole individual in Texas regarding the company's Epogen practices over a 10-year period. During that time, DaVita stated "the government never intervened or filed any claims against DaVita. However, the individual was able to pursue the claims on his own."

In the fall of 2011 Amgen said it had set aside $780 million for potential settlements in whistle-blower lawsuits and investigations of its marketing practices for Epogen and its other anemia medications, according to October 2011 coverage in the Denver Post, which follows DaVita news in depth.

The Medicare ESRD prospective payment system—which pays a bundled sum for all services given to a patient rather than reimbursement for individual drug doses, for example—began January 1, 2011. This new system has reduced profits attached to individual orders of Epogen and other drugs.

"Critics of the Medicare payment system argued for years that paying dialysis providers for every unit of Epogen used encouraged overuse of the drug," the *Denver Post* reported.

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