After several months of a sudden, unforeseen shortage, the supply of peritoneal dialysis (PD) fluid is expected to return to normal by the end of March, when Baxter Healthcare says it will have more production capacity on line. The supply disruption came as a surprise in August 2015, when Baxter sent dialysis clinics and patients letters informing them that “several factors, including limited manufacturing capacity, along with increased overall demand for sterile solutions, have resulted in temporary supply constraints … expected to last for the next six months.”

Home PD has grown tremendously in recent years, particularly since the Centers for Medicare and Medicaid Services changed payments in 2011 in ways designed to encourage its use. Demand grew 30% in the past three years alone. Baxter said that it was committed to supplying patients currently on PD, but restricted expansion to new patients. The shortage disrupted provider operations and patient care in many important ways.

PD providers were given allocations for how many new PD patients they could accept based on the providers’ history of growth during the first six months of 2014. For example, Northwest Kidney Centers (NKC), the largest dialysis provider in the Puget Sound area of Washington, had been training seven or eight new patients a month. Their allocation was set at two new patients per month. Dialysis Clinic, Inc. (DCI), a nonprofit based in Nashville, Tenn., that operates 235 clinics in 28 states, was starting about 69 new patients per month with Baxter fluid. Its allocation was set at 17 or 18 new patients a month.

“Even as current PD patients predictably dropped off the rolls due to death or a switch to hemodialysis, NKC was not allowed to replace them with new patients,” said Connie Anderson, vice president of clinical operations at NKC. As a result, NKC’s PD patient count decreased from 200 to 192 in September, and has only slowly begun climbing back up. Patient referrals decreased at both NKC and DCI, apparently because as word of the shortage spread, physicians...

The development of kidney stones is a common problem that has traditionally been recognized as no more than an isolated and painful condition. Yet epidemiological studies have revealed links between nephrolithiasis and conditions such as the metabolic syndrome, hypertension, chronic kidney disease, and cardiovascular disease. In support of the concept that nephrolithiasis is a systemic disease, a new study published in the Clinical Journal of the American Society of Nephrology shows that blood vessel calcification in recurrent kidney stone formers may put patients at increased risk of heart disease, and kidney stones’ effects on the bones may increase osteoporosis risks.

“This is the first study to our knowledge to provide controlled evidence for a possible role of vessel calcification and associated osteoporosis in cardiovascular morbidity among kidney stone formers,” said lead author Linda Shavit, MD, of...

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did not refer patients for a therapy they could not receive.

The shortage eased somewhat by November. The Food and Drug Administration fast-tracked approval for Baxter to import PD fluid from its plant in Ireland. And Baxter bought a large amount of PD fluid from Fresenius Medical Care to distribute to its own customers. Baxter’s allocations for new patients slowly rose from the starting level of 25% of historic usage to 35% and then to 60% in December.

Anderson said that the supply was not so great, however, that Baxter would not receive for Baxter’s customers. The Fresenius product, clinics were limited to offering new patients continuous ambulatory PD, and they are still not able to offer automated PD, Anderson said. Patients already on PD received the fluid they needed, but their routine often involved stressful disruptions for a patient relying on a life-or-death treatment. Patients accustomed to receiving a monthly shipment from a Baxter delivery person who would bring it into the house and help them with it often had a two-week supply left on the doorstep by a commercial carrier. Baxter might then need to send an employee to the residence to help.

“Baxter … did a lot of workarounds to try to make up for the issues that the shortage caused,” said Joan Thomas of Kidney Community Emergency Response, based in New York State. Thomas coordinated regular conference calls that brought together officials from CMS, FDA, other government agencies, medical suppliers, renal clinics, and many other stakeholders who shared information, discussed problems, looked for solutions, and provided the main source of information for the clinics having to cope with the shortage.”

Doug Johnson, MD, vice chair of the board at DCI, said that his company has been focusing on increasing home dialysis, which more patients are choosing when they understand the options: “What was so difficult for us was that we had a therapy that we saw as ideal for a patient on dialysis, and we knew that we were going to have to limit access to that therapy.”

With a colleague, Johnson personally reviewed patient cases to determine who could be started on PD and who could be deferred, and he was impressed by the way that everyone worked together to cope with the constraints. The cooperation even extended to some patients’ employers, who offered the flexibility to allow the patient to keep working and get in-center treatment while waiting to switch to home dialysis. Johnson said that Baxter also had a medical justification form, and “if there was a person with a clear medical need for PD, it was approved.”

The cause of the sudden shortage remains unclear. Baxter received several letters from the FDA citing quality improvement problems in its plants and voluntarily recalled two lots of PD solution in August, but Baxter representative William Rader said that those issues did not contribute to the supply constraints. He cited the following July 2015 letter to Baxter that those issues did not contribute to the supply constraints. He cited the fact that Baxter received several letters from the FDA citing quality improvement problems in its plants and voluntarily recalled two lots of PD solution in August, Baxter representative William Rader said that those issues did not contribute to the supply constraints. He cited the following July 2015 letter to Baxter that those issues did not contribute to the supply constraints. He cited the fact that Baxter received several letters from the FDA citing quality improvement problems in its plants and voluntarily recalled two lots of PD solution in August, Baxter representative William Rader said that those issues did not contribute to the supply constraints. He cited the following July 2015 letter to Baxter that those issues did not contribute to the supply constraints. He cited the fact that Baxter received several letters from the FDA citing quality improvement problems in its plants and voluntarily recalled two lots of PD solution in August, Baxter representative William Rader said that those issues did not contribute to the supply constraints. He cited the following July 2015 letter to Baxter that those issues did not contribute to the supply constraints. He cited the
clinics could simply switch large numbers of patients over to it. The shortage’s long-term implications for the spread of PD remain to be seen, but it is likely to be only a temporary glitch. “It has been a long-stated goal of CMS to expand the proportion of patients with end stage renal disease that are dialyzed at home. When people are aware of their options, a lot more people choose to dialyze at home, and so the growth of patients on PD in the United States has happened at an unprecedented rate,” said Raj Mehrotra, MD, professor of medicine at the University of Washington and chair of the dialysis advisory group of the American Society of Nephrology. “I think the shortage teaches us that we need to have some redundancy in the system, whether it is with regards to the number of manufacturers, or number of plants a single manufacturer has, which would have ensured the availability of solution to patients.”

As the supply returns to levels to meet the growing demand, Johnson said that the shortage could actually lead to greater use of home PD in the future because of the attention it brought to the treatment. Johnson’s involvement in the allocation process made a great impression: “I now know even more than I did before how valuable it is to be able to dialyze at home, and the way it can change a person’s life. I was already a very strong advocate for home dialysis, but I am a stronger advocate today than I was before the shortage.

ASN invites the kidney community to participate in the 2015 ASN Innovations in Kidney Education Contest to develop innovative tools to teach medical students and residents aspects of kidney physiology, including how it relates to human health, disease diagnosis, and a disease state.

Contest Goals

- Develop and share tools to enhance teaching kidney physiology using nondidactic, interactive teaching instruments
- Generate excitement among medical students and residents about the field of nephrology
- Engender interactions between medical students, residents, graduate students, nephrology fellows, post-doc trainees, faculty, practicing nephrologists, and researchers
- Engage learners in ASN activities
- Create novel ideas for additional curricula development for medical and graduate students in the field of nephrology

What Is the Contest?

There are two parts to the contest.

Part 1: Idea Submission
Submission of ideas for an innovative teaching tool that will help teach kidney physiology

Part 2: Teaching Tool Submission
Development and submission of the new teaching tool

More information, including the contest rules and FAQs is available at www.asn-online.org/contest