Peritoneal Dialysis Fluid Shortage Disrupted Growth of Popular Therapy

By Eric Seaborg

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 Andason, 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...
Vessel Calcification

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the University College London Medical School in the UK and the Shaare Zedek Medical Center in Israel.

Approximately 10% of men and 7% of women develop kidney stones or nephrolithiasis. Although the mecha-
nisms involved in the potential link between nephrolithiasis and increased cardiovascular risks are unknown, Shavit and her colleagues suspected that abnormal
deposition of calcium in the blood ves-
sels may play a role. Such vascular calci-
fication is considered a strong risk factor
for heart-related disease and death.

In a 111-participant study that in-
cluded 57 recurrent kidney stone formers
and 54 healthy controls, the researchers
used computed tomography (CT) scans to
evaluate the severity of abnormal cal-
dium deposition in the abdominal aorta,
one of the largest blood vessels in the hu-
man body.

Individuals with kidney stones had
more calcification in the abdominal aor-
ta, which could explain their increased
risk for heart disease. They also had less
dense bones and more prominent bone
demineralization compared with individ-
uals who did not develop kidney stones.

Average vertebral bone mineral density
was 159 Hounsfield Units in stone form-
ners vs. 194 in controls. Previous studies
have shown that vascular calcification often occurs alongside bone loss, suggest-
ing a relationship between osteoporosis and atherosclerosis.

“Our findings raise several important
questions that may be relevant to the care
of patients with kidney stones,” Shavit
said. “Existing CT can be a useful tool
for assessment of aortic calcification and
osteoporosis, along with kidney stone
number and distribution. Moreover, pre-
liminary experimental and clinical evi-
dence suggests that therapeutic strategies
aimed to treat osteoporosis may have a
favorable effect on vascular calcification.”

According to the authors, CT tech-
nology for both aortic and spine meas-
urements provides clear benefits over
conventional radiographs, which are less
precise and do not permit clinicians to
obtain graded quantifications.

“This interesting study confirms one
previous observation of my group that
in calcium renal stone formers, arteries
are rigid and calcified,” said Giovanni
Gambaro, MD, PhD, who was not in-
volved with the study and is head of the
Division of Nephrology and Dialysis at
Columbus-Gemelli University Hospital,
in Rome. “We advanced that in neph-
rolithiasis, a liaison exists between bone
and vessels. This is probably a general
phenomenon since it has been observed in
osteoporosis, in hypertension, and in
chronic kidney disease.”

While the study cannot prove direct
causality, it provides controlled evidence
for a possible role of vessel calcification,
and associated osteoporosis, in cardio-
vascular morbidity among kidney stone
formers, and it suggests that prospec-
tive trials are warranted to explore the
potential benefits of targeting the bones
and cardiovascular system to help protect
kidney stone formers’ heart health.

In an accompanying editorial, Eric
Taylor, MD, MSc, of the Maine Medi-
cal Center and Brigham and Women’s
Hospital, noted that the study has several
strengths, including its systematic pro-
cess to generate abdominal calcification
scores and its use of existing imaging data
obtained for other indications. However,
he also pointed to several limitations,
such as the presence of certain factors in-
cluding race and body size that may con-
found the observed associations. Also, it
is unclear whether the greater severity of
calcification in stone formers was inde-
pendent of differences in bone mineral
density between patients and controls.

Taylor noted that the study raises a
number of important unanswered ques-
tions: “The nexus between calcium kid-
ney stone formation, bone deminerali-
ization, and atherosclerosis should be an
active area of investigation pursued by
the clinical investigator and basic scien-
tist alike,” he wrote. “Future studies will
require careful assessment of calcium-
phosphorus regulatory hormones and
inhibitors of tissue calcification hypoth-
esized to play important roles in the
complex pathophysiology of all 3 disease
states.”

For now, while it is too early to in-
corporate a history of calcium nephro-
lithiasis into screening guidelines for os-
teoporosis or cardiovascular risk factors,
the findings suggest that addressing heart
disease risk factors may also help prevent
kidney stones and bone fractures.

Disclosure: Robert Unwin is currently
on secondment as a chief scientist with
AstraZeneca Cardiovascular & Meta-
bolic Diseases Innovative Medicines
and Early Development Science Unit
(Mölndal, Sweden).

The article is entitled “Vascular Calci-
fication and Bone Mineral Density in Recur-
rent Kidney Stone Formers.”