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Interim strategies for peritoneal dialysis (PD) solution use for prevalent patients undergoing PD

Situation: Baxter's primary manufacturing site for intravenous and peritoneal dialysis (PD) solutions in the United States is closed at this time due to flooding from Hurricane Helene. Healthcare providers, such as dialysis organizations and hospitals, are not receiving full allocations of these solutions.

Background: Baxter's North Cove production site, the largest manufacturer of these solutions in the United States, was affected by flooding due to the storm and is currently closed for production. The company is working around the clock in close coordination with local, state and federal officials to assess the extent of the damage and implement a plan to bring the plant back online as quickly as possible to help mitigate supply disruption to patients.

Assessment: Dialysis organizations and other PD solution users (such as hospitals) may experience shortages of PD solutions depending on their existing inventory, if any, and length of time that these solutions are in limited supply. The dialysis organization community in concert with the American Society of Nephrology (ASN), the International Society of Peritoneal Dialysis (ISPD), the American Society of Pediatric Nephrology (ASPN) and others are working together to provide interim strategies to appropriately conserve PD solutions. Much of this effort depends on operational adjustments at the facility and organizational level. This document aims to highlight patient-level changes that can be considered immediately to extend PD solution supply.

Strategies:

Please review and consider the following conservation approaches.

Overall approaches should prioritize bag-sparing, rather than solution-sparing

- For routine prescription changes that would customarily add a PD solution bag, consider holding temporarily, using other approaches, such as change in dwell times. Clinical judgment should be used foremost for any modification in patient care.
- Use of a PD prescription calculator, such as the AREP (Tools – Advanced Renal Education Program) calculator or Sharesource Adequest, may be useful to model changes to provide adequate therapy and decreased bag use.
- If using two different concentrations of PD solution for APD, prioritize higher concentration solution as final fill, leading to improved ultrafiltration
- Ensure optimal catheter function and flow to maximize ultrafiltration and solute exchange (constipation, malposition, etc…).
- In time, PD solution may originate from outside the U.S, after approval by FDA with potential unfamiliar packaging and nomenclature. Please review specifications of imported solutions and provide patient and interdisciplinary team appropriate education. Note that 5L APD solution bags will likely become more available than 6L bags for APD. Coordination with Baxter customer service regarding prescription changes from 6L to 5L should prioritize exhausting the current supply of 6L bags prior to using 5L bags. Prescription modifications should take this into account, see suggestions below.

Dietary Recommendations

Restrict sodium intake to < 3grams/day.

Residual Kidney Function

Adjustments to the PD prescription is dependent on the degree of a patient's residual kidney function. Suggestions for prescription adjustments that are described below depend on the contribution of residual kidney function, which includes 24 hour urine output and residual solute clearances, measured commonly as residual Kt/V. If there is uncertainty about the patient's current 24-hour urine output or residual Kt/V, please work with your home dialysis team and the patient to update that information. Consider routine monitoring of urine output (e.g. more frequently than every 3 months) if bag-sparing regimens were implemented based on residual kidney function.

Medications

- Loop diuretics should be continued in patients with residual kidney function to maintain euvolemia and BP control. Higher doses are required to achieve adequate diuresis (e.g. furosemide in doses of 120-240 mg orally twice a day, +/- metolazone 10mg a day).
- Assess utilization of ACE inhibitors or ARBs to support preservation of residual function.
- Start K binders to prevent hyperkalemia if needed.

Peritoneal Dialysis Prescription Adjustment

Initial step: for APD & NIPD, understand quantity of PD solution remaining in last bag used with respect to consideration for decreasing total PD solution use. (Goal: bag-sparing rather than solution sparing).

1. For patients with substantial residual kidney function (e.g. >750 mL/day of urine output, or residual Kt/V >1.0):

- Consider adjusting PD treatment frequency to 5 or 6 days per week.
    - This approach is consistent with incremental PD, as is commonly practiced in patients with newly diagnosed End-stage kidney disease (ESKD).
- Alternatively:
    - consider elimination of daytime dwell for APD patients, if this results in bag-sparing.
    - consider 10-20% decreased dwell volumes for APD patients if this results in bag sparing.

2. For patients with moderate residual kidney function (e.g. 250-750 mL/day of urine output, or residual Kt/V ≥0.3 and <1.0), if clinically appropriate:

- Consider elimination of day dwell in APD if being used
- If total Kt/V ≥2.0, consider decreased PD fluid dwell volumes per day by ~10-20%, if this results in bag-sparing.
- If total Kt/V is ≥1.8 and <2.0, consider decreased PD fluid dwell volumes by ~5-10%, if this results in bag sparing.

- In patients who are currently undergoing nocturnal intermittent PD, any reduction in the volume of fluid per exchange can be compensated by increasing dwell time, particularly in patients with low and low-average transport status.
- Avoid changes to the last fill, if currently prescribed. The dwell time of the last fill is critical for middle molecule clearance and maintaining volume balance.

3. For patients with little (e.g. <250 mL/day of urine output, or residual Kt/V <0.3) or no residual kidney function:

- In general, patients with little or no residual kidney function are highly dependent on PD for both solute clearance and volume control. Small alterations to the prescriptions may have significant consequences to clinical status and patient well-being.
- If total Kt/V ≥2.2, consider reducing the total volume of PD fluid per day by ~5-10% if this results in bag-sparing.
- If total Kt/V <2.2, avoid changes to the prescription.
- Anuric patients may be currently prescribed a relatively large volume of PD fluid per day (e.g. >15 L/day). Ensure that these patients are fully using PD fluids shipped to the home. In consultation with your PD nurse, review prescription adherence and modify the treatment order, if needed. During this period of constrained supply, it is important that PD solutions shipped to the patient home is used as fully as possible.

4. Additional considerations for pediatric patients

- The overall goal, as with adults, is a bag-sparing approach. In small children with low fill volumes, consider adjustments to volumes, if appropriate, to avoid using a fraction of a bag. Instead of mixed dextrose prescriptions (1.5% and 2.5%) which is commonly done in children and which may result in waste, consider alternating between different dextrose concentrations nightly. After making any significant changes to prescriptions, increased lab frequency may be indicated for monitoring along with daily weight and BP tracking and frequent phone check-ins.

Responding to Kt/V <1.7

Total Kt/V <1.7 may constitute inadequate dialysis. Options for increasing Kt/V, including those that result in an increase in the total volume of PD fluid per day, can be considered. However, increased attention should be paid to discussing treatment adherence and catheter complications with patients, with the goal of avoiding excess PD fluid consumption. If PD patients are clinically stable with no other signs or symptoms of uremia or volume overload, clinicians could consider no prescription changes during this period of PD solution allocation.

Patients with high body mass index

In obese patients with very high body mass index (e.g. BMI >35 kg/m^2), the volume of TBW from typical equations (Watson's) may overestimate *V*, the volume of distribution of urea, due to adipose tissue. For this patient population, targeting total Kt/V of 1.7 may underestimate true clearance and could provide adequate therapy. As the physician, this decision is your judgement based on patient symptom control, electrolyte management and acid-base status. You may

consider reducing the total volume of PD fluid per day in obese patients with total Kt/V substantially greater than 1.7.

Use of Icodextrin

Allocation of icodextrin (Extraneal) may be lower than that of dextrose-based (Dianeal) solutions. If icodextrin is prescribed during the last fill and substitution with dextrose (Dianeal) is needed, ensure appropriate adjustment of dwell time to minimize glucose and fluid absorption, manage glycemic control in diabetic patients, optimize/start diuretic use as above, and re-emphasize fluid and sodium restriction < 3 grams/day. Alternately, can consider less frequent icodextrin use, e.g. every other day. Also consider switch to partially or completely dry periods, with appropriate alteration of prescription.

Continuous Ambulatory PD

Unlike in other countries, less than 10% of patients undergoing PD in the United States currently utilize continuous ambulatory PD (CAPD). However, CAPD is a highly effective therapy that efficiently maintains electrolyte and fluid balance (due to greater removal of sodium). Some patients who are currently using a cycler for PD may be good candidates for conversion to CAPD, if CAPD solutions are more available than APD (cycler) solutions, including:

- Patients who have difficulty sleeping while connected to a cycler, including those who experience drain complications
- Patients who are currently prescribed ≥12 hours of time on cycler
- Patients with uncontrolled hyperphosphatemia

One commonly used prescription of CAPD is 4 daily exchanges of 2 liters (pending appropriate assessment of patient well-being and physiologic needs).

Transitioning to HD

The goal is to avoid transition to HD if possible. If a patient has been struggling to maintain good health on PD—as evidenced by multiple hospitalizations, recurrent peritonitis, or decreased sense of well-being—or if PD has become incompatible with the patient's daily schedule, consider transitioning the patient to either home HD or in-center HD, rather than prolonging suboptimal therapy with PD. This approach is consistent with general standard practice.

Access to peritoneal dialysis for new patients

If considering prioritization for new PD starts, pediatric patients, those with exhausted vascular access, or those with urgent medical indications for PD may be considered high priority.