

Patient Safety Alert

Veterans Health Administration Warning System
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Item: Increased risk of metabolic alkalosis with acetate-containing dialysis acid concentrates that can cause cardiac arrest, arrhythmias and low blood pressure in dialysis patients

Specific Incident: The FDA issued a Safety Communication regarding dialysate concentrates and alkali dosing errors with hemodialysis. The communication reminds nephrologists, dialysis nurses and technicians about acetate, acetic acid and/or citrate levels in dialysate concentrates and the need to consider the impact of these substances when ordering or administering the patient's dialysate prescription (see Reference).

When metabolized, these sources of alkali can contribute to elevated bicarbonate levels in patients undergoing hemodialysis. This can lead to metabolic alkalosis (pre-dialysis serum bicarbonate levels greater than or equal to 27 mEq/L), which is a significant risk factor associated with cardiopulmonary arrest, low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia. In addition, metabolic alkalosis has also been associated with a higher risk of death in hemodialysis patients.

General Information: Dialysis acid concentrates may contain acetic acid, acetate, citrate and/or citric acid, which contribute to the total dialysate buffer. Because these components are rapidly converted into bicarbonate by the liver, the bicarbonate prescription entered into the dialysis machine may underestimate the total buffer that the patient receives from the dialysate. Not accounting for this additional buffer can lead to a high dialysate total buffer concentration and metabolic alkalosis.

- Actions:**
1. By Close of Business (COB) November 19, 2012, the **Medical Center Director (or designee)** shall ensure the facility's Dialysis Unit Director (or Chief Nephrologist where there is no Dialysis Unit) is made aware of this Patient Safety Alert and that it has been shared with all dialysis staff (physicians, nurses, technicians, pharmacists, etc.).
 2. By COB December 12, 2012, **Dialysis Unit Directors (or Chief Nephrologist where there is no Dialysis Unit)** shall:
 - a) Determine if the dialysis acid concentrates in use at your facility have a contribution to the total buffer greater than 4 mEq/L. (See Attachment

2 for some products commonly used in VHA settings that have already been identified as having a contribution of 4 mEq/L or higher.)

Note: If you are using, an acid concentrate with a contribution to the buffer of 4 mEq/L or less, proceed to Action 2c.

b) Begin replacing identified acid concentrates with a contribution to the total buffer greater than 4 mEq/L with an acid concentrate which has a contribution to the total buffer of 4 mEq/L or less.

c) Institute a procedure to assure that future acid concentrates will not be purchased if their contribution to the total buffer is greater than 4 mEq/L. The procedure shall be reviewed by your Purchasing contact and the individual who orders supplies in your unit.

d) Train appropriate staff on how to adjust the bicarbonate level on dialysis machines used at the facility to compensate for the contribution of acid concentrates to the total buffer. Consult your dialysis machine's operator manual or contact the supplier for more information.

e) Verify that a pre-dialysis checklist or standard operating procedure assures that a pre-dialysis serum bicarbonate analysis is performed before the patient's first dialysis session and at least monthly thereafter on each patient receiving dialysis treatments at your facility.

3. By COB February 22, 2013, the **Dialysis Unit Directors (or Chief Nephrologist where there is no Dialysis Unit)** at VA medical centers that use contracted or fee basis dialysis services shall share this Patient Safety Alert with the fee basis providers and verify that they are in compliance with contract language regarding safety notices. Facilities should also ensure that future contracts for dialysis care reflect actions in this alert.
4. By COB February 28, 2013, the **Patient Safety Manager** must document on the VHA Hazard Alerts and Recalls Web site that medical center leadership has reviewed and implemented these actions or that individual actions are not applicable to your facility (e.g., no dialysis is performed at or contracted out by your facility).

Source: Food and Drug Administration (FDA)

Reference: FDA Safety Communication: Dialysate Concentrates and Alkali Dosing Errors with Hemodialysis
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm305477.htm>

Contacts: Alerts and Advisory Team at the National Center for Safety (734) 930-5890