Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL10-13 July 6, 2010

Item: **Redsense® Dialysis Alarm for Patients Undergoing Needle Access Procedures**

Specific Incident: VHA issued a Patient Safety Advisory, AD09-02, on October 21, 2008, and a Patient Safety Alert, AL10-05, on February 3, 2010, that addressed bleeding during dialysis. This Patient Safety Alert adds an additional control measure aimed at the early detection of blood loss due to venous needle dislodgement (VND) using the Redsense® Alarm. The prior documents are available at the NCPS website, www.patientsafety.gov.

The Redsense® alarm (www.redsensemedical.com) is an FDA approved device for the early detection of venous needle disconnections. Usability issues initially noted with this device by NCPS in 2008 have been resolved with manufacturer redesign.

General Information: The VA National Center for Patient Safety (NCPS) has analyzed forty nine (49) RCAs (Root Cause Analysis) and Patient Safety reports of bleeding during dialysis which occurred in VA dialysis units from March 1, 2002, through March 31, 2010. Forty two (42) of these events were serious bleeding episodes, Ten (10) incidents resulted from disconnection of the blood line at the dialysis catheter connection and thirty two (32) incidents resulted from VND. In the most severe bleeds, the dialysis machines did not alarm until significant blood loss had occurred or they did not alarm at all.

VA dialysis units performed more than 3.5 million chronic and acute dialysis treatments during the period of time reviewed. In addition to the review of RCAs and Safety Reports, the nurse managers of 65 VA dialysis units were interviewed by telephone as were some Patient Safety Managers.

Three major risk factors for bleeding during dialysis were found:

- 50% of the severe bleeds occurred outside of the dialysis unit (in the ICU or in dialysis isolation rooms) although only a small minority of patients received hemodialysis treatments in these locations.

- Approximately 75% of the most severe bleeds occurred in

patients who were restless, confused, agitated, or uncooperative.

- In 50% of the severe bleeds, the access site was reported as not visible at the time of the event, and in the remaining 50%, the visibility of the access site was not documented in the RCA.

Actions:

1**.** By close of Business (COB) July 9, 2010, the **Facility Director (or designee)** will ensure that all clinicians involved in the dialysis program are made aware of this Patient Safety Alert.

2. By COB November 1, 2010 the **Dialysis Director (or designee)** shall ensure that a Redsense® dialysis alarm is used on all patients with needle access undergoing hemodialysis outside of the dialysis units. Areas considered outside of the dialysis unit include in-hospital wards or ICUs where treatments are done at the bedside, and side rooms or isolation rooms in the hemodialysis unit that do not allow direct line-of-sight visualization of the patient and the dialysis machine during hemodialysis.

The Redsense® dialysis alarm may also be used on patients identified by dialysis staff at risk for VND. Risk factors may include confusion, agitation dementia, or uncooperative patients, those patients with difficult to secure needles, or other patients with risks which may be of concern to the dialysis team.

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3. By COB November 9, 2010, the **Patient Safety Manager** will document on the VHA Hazard Alerts and Recalls website that facility leadership has reviewed and implemented these actions.

Additional Info:

If another approved device that provides an equivalent or increased level of safety to the Redsense® alarm becomes available additional information will be distributed by NCPS.

References:

1. EDTMAERCA Poster: Prevent Venous Needle Dislodgement
http://www.edtnaerca.org/pdf/home/Edtna_poster_UK.pdf

2. Van Waeleghem JP, Chamney M. Lindley EJ, Pancirova J. Venous needle dislodgement: how to minimize the risks. J Ren
http://www.edtnaerca.org/pdf/home/VNDpaper.pdf

Source:

VA Medical Centers

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