Medical Bed Mattresses: FDA Safety Communication - Damaged or Worn Covers Pose Risk of Contamination and Infection

AUDIENCE: Biomedical Engineering, Infectious Disease, Nursing, Risk Managers

ISSUE: From January 2011 to January 2013, the FDA received 458 reports associated with medical bed mattress covers failing to prevent blood and body fluids from leaking into the mattress (fluid ingress). Fluid ingress may occur if mattress covers become worn or damaged from small holes or rips in the fabric or from incorrect cleaning, disinfecting and laundering procedures. The zipper on the cover may also allow fluid to penetrate the mattress. Some reports indicate that if blood and body fluids from one patient penetrate a mattress, they can later leak out from the mattress when another patient is placed on the bed. Patients are at risk for infection if they come into contact with blood and body fluids from other patients.

Medical literature shows that damaged and wet (soiled) mattresses can be a source of contamination during infection outbreaks. The FDA is concerned that fluid ingress from worn or damaged medical bed mattress covers may be widespread and largely under-recognized by health care providers, health care facility staff, and caregivers. The FDA will continue to monitor this issue and keep the public informed if new information becomes available.

BACKGROUND: A medical bed mattress cover provides outer protection to a medical bed mattress by preventing blood and body fluids from entering the inside (inner core) of the mattress. Medical bed mattress covers, whether water-resistant, water-proof, or water-repellent, may lose their effectiveness over time. The duration of time that a medical bed mattress cover is expected to last (expected life) varies from manufacturer to manufacturer. In addition, the expected life of a medical bed cover may differ from that of the mattress itself.

RECOMMENDATION: The Safety Communication lists several recommendations for inspection and maintenance including:

- Regularly check each medical bed mattress cover for any visible signs of damage or wear such as cuts, tears, cracks, pinholes, snags or stains.
- Routinely remove the medical bed mattress cover and check its inside surface. Once the mattress cover is removed, inspect the mattress for wet spots, staining, or signs of damage or wear. Check all sides and the bottom of the mattress.
- Immediately replace any medical bed mattress cover with visible signs of damage or wear to reduce the risk of infection to patients.
- DO NOT stick needles into a medical bed mattress through the mattress cover.

Refer to the Safety Communication for the complete list of recommendations.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the Recall Notice, at: