Pa Patient Saf Advis 2018 Dec;15(4).

How Wet Is Your Patient's Bed? Blood, Urine, and Microbiological Contamination of Mattresses and Mattress Covers

Authors

Amanda Sivek, PhD

Senior Patient Safety Analyst

James Davis, MSN, RN, CCRN-K, CIC, HEM, FAPIC

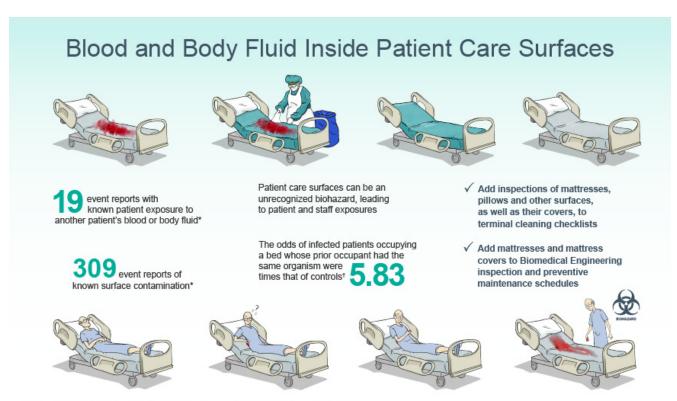
Senior Infection Prevention Analyst

Pennsylvania Patient Safety Authority

Corresponding Author

Amanda Sivek, PhD

Abstract



Pa Patient Saf Advis. 2018 Dec;15(4). http://patientsafety.pa.gov/ADVISORIES/Pages/201812_FluidIngress.aspx

†Cohen B, Liu J, Cohen AR, Larson E. Association between healthcare-associated infection and exposure to hospital roommates and previous bed occupants with the same organism. Infect Control Hosp Epidemiol. 2018 May;39(5):541-6.

HAI, Healthcare-associated infection



^{*} Pennsylvania Patient Safety Reporting System and FDA's Manufacturer and User Facility Device Experience databases, January 1, 2005, through March 31, 2018.

Body fluid and microbiological contamination can remain on, or within, bed and stretcher mattresses and mattress covers after cleaning. This puts subsequent patients and even staff at risk of exposure to infectious materials. Mattress and mattress cover contamination may go unrecognized and unreported, unless a patient experiences body fluid oozing from the mattress surface. To increase knowledge about the prevalence of patient safety events related to mattress and mattress cover contamination, Pennsylvania Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) and the U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) databases for reports of body fluid and microbiological contamination of bed and stretcher mattresses and covers submitted between January 1, 2005, and March 31, 2018 (PA-PSRS), and between January 1, 2008, and March 31, 2018 (MAUDE). Analysts identified 14 events reported through PA-PSRS of patient exposure to a previous patient's blood or urine when it oozed out of their support surface. In addition, analysts identified five reports in the MAUDE database of patient bloodborne pathogen exposure to a previous patient's blood when it seeped out of the support surface. Review of PA-PSRS and MAUDE event reports provides insight about how these events occur and adds depth to FDA's 2017 guidance and 2013 Safety Communication regarding the problem of body fluid ingress in hospital mattresses and covers. To reduce the risk of such contamination, a joint initiative with the infection prevention and control, environmental services, and clinical/biomedical engineering departments to address inadequate mattress cover reprocessing and deficient inspection of mattresses and mattress covers may be needed.

Introduction

Various factors make the care and maintenance of bed and stretcher support surfaces difficult for facilities, including dealing with support surface contamination. Each bed and stretcher support surface consists of a mattress and a mattress cover. Mattresses may be powered (air, air-foam hybrid) or unpowered (foam/gel, air-foam hybrid) and mattress covers may be removable or nonremovable. For facilities that own most of their bed and stretcher frames, it is common to buy support surfaces from vendors other than their primary bed- or stretcher-frame vendor. Bed and stretcher frames and support surface components have different expected service lives, disparate inspection intervals, and require diverse reprocessing materials and procedures.

If the integrity of a mattress cover is compromised, a mattress can become contaminated during patient care and remain contaminated for subsequent patients.^{1.4} The U.S. Food and Drug Administration (FDA) has published on the problem of body fluid ingress in bed support surfaces.¹ The agency first reported it had received 458 reports¹ between 2011 and 2013, and in a separate second report of data from 2011 through 2016, it reported receiving more than 700 reports in total⁴ of hospital bed mattress covers failing to prevent blood and other body fluids from leaking into mattresses.

FDA's Manufacturer and User Facility Device Experience (MAUDE) reports do not encompass of all of the reports that FDA receives. In addition, MAUDE data may not be comprehensive; report completeness depends on reporters and their descriptions of reported adverse events.

Support surface contamination can occur for myriad reasons. Using incompatible reprocessing materials or procedures could cause immediate damage or degradation of mattress cover materials, which could allow mattresses to become contaminated during subsequent patient use. Inadequate disinfection of mattress covers can occur if manufacturers or rental companies do not recommend effective reprocessing materials for common contaminants on mattress covers, such as bacterial spores. Deficient support surface inspection—both by environmental services

(EVS) staff during terminal room cleaning and clinical/biomedical engineering staff during inspection and preventive maintenance (IPM) procedures—can be part of the problem. Finally, using bed and stretcher mattress covers beyond their expected service life can further contribute to support surface contamination.

Support surfaces have been reported as an environmental source of microorganisms^{2,3,5} and have contributed to patient healthcare-associated infections (HAIs) with extended-spectrum β -lactamase (ESBL)–producing *Enterobactercloacae*.⁶ ESBL-producing organisms are resistant to a broad range of extended spectrum β -lactam antibiotics. However, the risk of patients acquiring an HAI from other pathogens on or within a support surface and the frequency of contaminated support surface usage is difficult to determine.

A recent study by Cohen et al. examined whether there is an association between patient HAIs and previous bed use by infected or colonized patients.⁷ The authors analyzed 10,289 HAIs collected over seven years from four inpatient acute care hospitals and reported "a multivariable analysis controlling for both exposures and patient characteristics, the odds of cases having been exposed to a prior bed occupant with the same organism were 5.83 times that of controls (95% confidence interval [CI], 3.62–9.39), and the odds of cases having been exposed to a roommate with the same organism were 4.82 times that of controls (95% CI, 3.67–6.34)."⁷

These observations show that if a mattress or mattress cover is contaminated with a patient's pathogens, blood, or body fluids, there may be an increased risk of subsequent patients developing an HAI.

Authority analysts found that adverse outcomes related to contaminated support surfaces may go undiscovered unless the contamination becomes obvious during patient use, such as absorbed body fluid oozing out of a support surface onto a patient. In addition, if a patient is exposed to body fluids within a contaminated support surface, reporters may specify the incident as an accidental exposure and omit that a support surface was the source of patient body fluid exposure. Consequently, patient exposure to contaminated support surfaces is likely an underreported issue.

Methods

Pennsylvania Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for acute care events associated with body fluid and microbiological contamination of bed and stretcher support surfaces, pillows, props, and wedges reported from January 1, 2005, through March 31, 2018. The search was designed to retrieve qualitative narrative data, not quantitative data.

Analysts performed a key word search in the narratives for bed, mattress, stretcher, gurney, gown, and linens—including word trunks and misspellings—and in the equipment manufacturer field for major manufacturers as identified through ECRI Institute's Sourcebase and Healthcare Product Comparison systems. Events containing the narrative or manufacturer keywords in combination with the terms urine, fluid, wet, soiled, absorb, or puddle were analyzed.

Analysts also queried FDA's MAUDE database for reports of mattress and mattress cover contamination. MAUDE data represents reports of adverse events involving medical devices, consisting of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.8

To retrieve available MAUDE data associated with support surface body fluid and microbiological contamination, FDA product codes for bed and stretcher mattresses and covers were used in searches. Product codes FMW (mattress cover for medical purposes); IKY (non-powered flotation therapy mattress); FNM (alternating pressure air flotation

mattress); FPO (wheeled stretcher); INK (powered wheeled stretcher); and FOH (temperature regulated water mattress) were each searched in MAUDE for the period from January 1, 2008, through March 31, 2018. System restraints limit the maximum number of reports that can be returned for any MAUDE search to 500.

To cast a wider net, additional searches of those specific product codes were performed using the same time frame and each of the following MAUDE-defined product problems: bacterial contamination of device; blood pooling; clean, failure to; contamination during use; defective item; device contamination with biological material; device contamination with blood or blood product; device disinfection or sterilization issue; disinfection, inadequate/improper; failure to disinfect; strikethrough; and unknown (for use when the device problem is not known).

MAUDE reports were reviewed and relevant findings were grouped into four categories: patient exposure to bloodborne pathogens (BBPs) or other body fluids from contaminated mattresses; mattresses with microbiological contamination without known patient exposure; mattress cover degradation without fluid ingress; and mattress and mattress cover fluid ingress without known patient BBP or other pathogen exposure.

Results

PA-PSRS Search

Analysts identified 14 events reported through PA-PSRS of patient exposure to a previous patient's blood or urine when it oozed out of their support surface. No reports were identified in which the source was from pillows, props, or wedges. The following five narratives are examples of adverse events due to support surface contamination in a clinical setting:*

When patient sat down, mattress was found to be soaked with urine from previous patient.

Patient reported to staff that stretcher smelled bad and, when back of stretcher was raised, [the patient's pants were dampened by] urine that seeped out of the mattress onto her pants.

Patient sat on bed, and pants became wet. Staff noted crack in mattress. Previous patient had urinated on bed. Bed had been cleaned by Environmental Services. Patient removed pants and was given hospital pants to wear.

Patient placed on stretcher that was cleaned by housekeeping from the previous patient with gastrointestinal bleeding. After lying on the stretcher, the patient felt something wet underneath. When [the patient] felt around to ascertain the source, the patient's hand became wet with blood. When assessed, the blood was noted to be seeping through the stretcher mattress that had small cracks and tears. The patient was moved to a clean stretcher. Infectious Disease was consulted and appropriate screening was done on the source patient and the exposed patient.

Bed was cleaned by housekeeping staff. Significant bleeding was noted from previous patient. The next patient to be treated sat on the bed, felt wetness under his buttocks, then stood and discovered he was sitting on a blood-soaked sheet.

The analysts' search found an additional three events of support surface fluid ingress without known patient BBP or other pathogen exposure.

FDA MAUDE Search

Analysts identified five MAUDE reports of patient BBP exposure to a previous patient's blood when it seeped out of their support surface. The following event descriptions from MAUDE reports are additional examples of adverse consequences of clinical support surface contamination:

12/19/2018

Patient placed on stretcher in room. The stretcher mattress appeared visually intact and clean. When she rose from the stretcher, patient noted to be covered with blood on her back. Blood had seeped from the mattress through the mattress cover and sheet. Patient exposed to blood from another patient.9

Emergency department patient placed on stretcher. When patient laid down on stretcher, nurse noted blood on the sheet. Patient assessed and found to have no areas of bleeding. Patient immediately moved to another stretcher. Bloody stretcher then examined and found to have blood ooze from the mattress when weight placed on it. Mattress cover removed and underlying mattress foam found to be soaked with blood from previous patients. Stretcher/mattress had been cleaned per protocol in between patients.¹⁰

Male patient was in the emergency department for abdominal pain. Physician noted patient's gown had blood soaked spot (quarter-sized). Patient assessed and noted to have no open wounds. It was determined that the mattress cover was cracked and mattress soaked with blood. Previous patient had a vaginal hemorrhage.¹¹

The analysts' search found 4 additional reports of support surface microbiological contamination (fungi¹²⁻¹⁴ and unspecified bacteria¹⁵); 30 other reports of mattress cover degradation; and 306 reports of support surface fluid ingress without known patient BBP or other pathogen exposure.

Discussion

The 19 combined PA-PSRS and MAUDE events of patient exposure to another patient's blood or urine within their support surface is of great concern for patient safety and affects facility endeavors to decrease HAIs.

To reduce the risks of body fluid and microbiological contamination of a healthcare facility's mattresses and covers, address three key areas:

- · Mattress cover cleaning and disinfection
- EVS staff training and room cleaning checklists
- · Mattress and mattress cover inspection and service lives

It may be necessary to implement a joint initiative with the infection prevention and control, environmental services, and clinical/biomedical engineering departments to address these key areas.

To ensure adequate mattress cover reprocessing, confirm that the facility's mattress covers can be disinfected using at least one antimicrobial product specified as being effective against *mycobacterium tuberculosis*, human HIV-1, and hepatitis B virus (found on the U.S. Environmental Protection Agency's [EPA] List E¹⁶). Confirm also that covers can be disinfected using at least one product specified as being effective against *Clostridium* (now *Clostridioides*) *difficile* spores (found on EPA's List K¹⁷).

If the facility's mattress cover supplier (i.e., the manufacturer or rental company) does not recommend at least one antimicrobial product from each of these lists, inquire as to how the facility can properly reprocess mattress covers that come in contact with body fluid or bacterial spores. Also, see that current EVS cleaning checklists include the recommended procedures and materials for cleaning and disinfecting your facility's mattress covers, which can be found in the support surface instructions for use (IFU), and be sure that both the instructional and the cleaning materials are readily available to staff. 18

^{*} The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Potential problems with mattress covers include the following:18

- · Exterior damage (cuts, tears, cracks, pinholes, snags, stains, or compromised zippers)
- · Material wear
- Shorter-than-normal cover drying times, because of increased absorption, which could indicate that fluid entered the mattress cover
- · Heavier support surfaces, which could indicate that the mattress has in fact absorbed fluid
- · Uneven support surfaces, which could allow fluids to pool at the lowest point on the surface
- Provide periodic training to EVS staff to recognize these problems and report identified problems to the facility's Clinical/Biomedical Engineering Department

To properly maintain support surfaces, add inspections of mattresses and mattress covers to EVS terminal cleaning checklists. EVS staff are to inspect the outside of covers (i.e., the cover top, bottom, and sides) during every terminal room cleaning. If a patient had a large volume of body fluid leakage on a support surface, EVS staff are to inspect the outside and inside of the mattress cover as well as the mattress surface during terminal room cleaning. Clinical/biomedical engineering staff can consider adding mattresses and covers to the IPM schedule if the facility has unique identifiers on each mattress and mattress cover. Finally, do not use bed and stretcher mattress covers beyond the expected service life identified in the support surface IFU.

Limitations

In this study, the analysts relied on the event descriptions in the MAUDE reports to ascertain relevance to the four categories defined in the Methods section. The analysts acknowledge that MAUDE reports do not represent all available information received by the agency. User reporting to the MAUDE database is voluntary; consequently, users may not report instances of patient exposure to contaminated support surfaces. In addition, MAUDE and PA-PSRS data may not be comprehensive; report completeness depends on reporters and their descriptions of reported adverse events. Although it is unlikely that the PA-PSRS and MAUDE reports overlap (e.g., involve the same incidents), this cannot be completely ruled out.

Conclusion

The 19 combined PA-PSRS and MAUDE events of patient exposure to another patient's blood or urine that oozed out of their support surface is of great concern, and it is likely these types of events are underreported. To reduce the potential risk of body fluid and microbiological contamination of a healthcare facility's mattresses and covers, three areas to initially focus on are mattress cover cleaning and disinfection; EVS staff training and room cleaning checklists; and mattress and mattress cover inspection and service lives. It may be necessary to implement a joint initiative with the infection prevention and control, environmental services, and clinical/biomedical engineering departments to address these key areas.

Acknowledgments

Edward Finley, BS, Data Analyst, Pennsylvania Patient Safety Authority, contributed to data acquisition for this article.

Notes

- Damaged or worn covers for medical bed mattresses pose risk of contamination and patient infection: FDA
 Safety Communication. [internet archive]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2013
 Apr 19 [accessed 2018 Apr 10]. Available: https://wayback.archiveit.org/7993/20161022044101/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm348016.htm
 (https://wayback.archiveit.org/7993/20161022044101/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm348016.htm).
- Sehulster LM, Chinn RY, Arduino MJ, Carpenter J, Donlan R, Ashford D, Besser R, Fields B, McNeil MM, Whitney C, Wong S, Juranek D, Cleveland J. Guidelines for environmental infection control in health-care facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Chicago (IL): American Society for Healthcare Engineering/American Hospital Association;; 2004. 250 p. Also available: http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf (http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf).
- 3. Yu M, Cross K, Petrich A, Fish J. Crib Mattress Investigation: A quality improvement study to assess mattress cover permeability and bacterial growth in crib mattresses. Am J Infect Control. 2016 Jul 01;44(7):837-9. Also available: http://dx.doi.org/10.1016/j.ajic.2015.12.014 (http://dx.doi.org/10.1016/j.ajic.2015.12.014). PMID: 26856469
- 4. Covers for hospital bed mattresses: learn how to keep them safe. [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2017 Nov 20 [accessed 2018 Apr 10]. Available: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/ucm585737.htm (https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/ucm585737.htm).
- Viana Rel H, dos Santos SG, Oliveira AC. Recovery of resistant bacteria from mattresses of patients under contact precautions. Am J Infect Control. 2016 Apr 01;44(4):465-9. Also available: http://dx.doi.org/10.1016/j.ajic.2015.10.027 (http://dx.doi.org/10.1016/j.ajic.2015.10.027). PMID: 26739639
- Bousquet A, van der Mee-Marquet N, Dubost C, Bigaillon C, Larréché S, Bugier S, Surcouf C, Mérat S, Blanchard H, Mérens A. Outbreak of CTX-M-15-producing Enterobacter cloacae associated with therapeutic beds and syphons in an intensive care unit. Am J Infect Control. 2017 Oct 01;45(10):1160-4. Also available: http://dx.doi.org/10.1016/j.ajic.2017.04.010 (http://dx.doi.org/10.1016/j.ajic.2017.04.010). PMID: 28571981
- Cohen B, Liu J, Cohen AR, Larson E. Association between healthcare-associated infection and exposure to hospital roommates and previous bed occupants with the same organism. Infect Control Hosp Epidemiol. 2018 May;39(5):541-6. Also available: http://dx.doi.org/10.1017/ice.2018.22 (http://dx.doi.org/10.1017/ice.2018.22). PMID: 29486805
- 8. U.S. Food and Drug Administration (FDA). Manufacturer and User Facility Device Experience (MAUDE). [Web site]. Rockville (MD): U.S. Food and Drug Administration (FDA); Available:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm).
- MAUDE adverse event report number: MW5056020. In: MAUDE Manufacturer and User Facility Device
 Experience [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2015 Aug 26 [accessed
 2018 Apr 12]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?
 mdrfoi__id=5061665&pc=IKY (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?
 mdrfoi__id=5061665&pc=IKY).
- MAUDE adverse event report number: 4846824. In: MAUDE Manufacturer and User Facility Device
 Experience [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2015 May 26 [accessed
 2018 Apr 12]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?
 mdrfoi__id=4846824&pc=FPO (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?
 mdrfoi__id=4846824&pc=FPO).
- 11. MAUDE adverse event report number: 4619942. In: MAUDE Manufacturer and User Facility Device Experience [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2015 Feb 28 [accessed 2018 Apr 12]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=4619942&pc=FNM (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=4619942&pc=FNM).
- 12. MAUDE adverse event report number: MW5010967. In: MAUDE Manufacturer and User Facility Device Experience [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2009 Apr 30 [accessed 2018 Apr 12]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=1374500&pc=IKY (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=1374500&pc=IKY).
- 13. MAUDE adverse event report number: 2557908. In: MAUDE Manufacturer and User Facility Device Experience [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2012 Apr 24 [accessed 2018 Apr 12]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=2557908&pc=FMW (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=2557908&pc=FMW).
- 14. MAUDE adverse event report number: 2873545. In: MAUDE Manufacturer and User Facility Device Experience [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2012 Oct 15 [accessed 2018 Apr 12]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=2873545&pc=FMW (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=2873545&pc=FMW).
- 15. MAUDE adverse event report number: 1831750-2011-10368. In: MAUDE Manufacturer and User Facility Device Experience [internet]. Silver Spring (MD): U.S. Food and Drug Administration (FDA); 2011 Aug 26 [accessed 2018 Apr 12]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=2276978&pc=FNM (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm? mdrfoi__id=2276978&pc=FNM).
- 16. List E: EPA's Registered Antimicrobial Products Effective Against Mycobacterium tuberculosis, Human HIV-1 and Hepatitis B virus. Washington (DC): U.S. Environmental Protection Agency (EPA); 2018 Jan 5. 3 p. Also available: https://www.epa.gov/sites/production/files/2018-01/documents/2018.05.01.liste_.pdf (https://www.epa.gov/sites/production/files/2018-01/documents/2018.05.01.liste_.pdf).

- List K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores. Washington (DC): U.S. Environmental Protection Agency (EPA); 2018 Jan 10. 2 p. Also available: https://www.epa.gov/sites/production/files/2018-01/documents/2018.10.01.listk_.pdf (https://www.epa.gov/sites/production/files/2018-01/documents/2018.10.01.listk_.pdf).
- 18. "Clean" Mattresses Can Ooze Body Fluids onto Patients. Hazard #2 top 10 health technology hazards for 2019. Health Devices. 2018 Sept 26; Also available: http://www.ecri.org (http://www.ecri.org/).



The Pennsylvania Patient Safety Advisory may be reprinted and distributed without restriction, provided it is printed or distributed in its entirety and without alteration. Individual articles may be reprinted in their entirety and without alteration, provided the source is clearly attributed.

Current and previous issues are available online at http://patientsafety.pa.gov (http://patientsafety.pa.gov/).