



PENNSYLVANIA PATIENT SAFETY ADVISORY

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About the Pennsylvania Patient Safety Advisory

OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS), especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

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Leadership Series: Is Your Institution Leaving Patient Safety Information at the Bedside?



John R. Clarke, MD

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The purpose of collecting reports of near misses in a patient safety reporting system is to identify weaknesses in a healthcare delivery system before a patient is harmed. The analysis of near-miss reports, roughly comparable to “Incidents” in the Pennsylvania Patient Safety Reporting System (PA-PSRS), can be as valuable, or more valuable, than analyses of adverse events, or “Serious Events,” that harm patients. A single near-miss report involving delay in cardiopulmonary resuscitation based on a misinterpretation of the meaning of a colored wristband has led to an international campaign to standardize the meaning of wristband colors.¹ Near-miss reports provide useful information not present in adverse-event reports—namely, the action that prevented a medical error from harming the patient. Comparisons of the root-cause analyses of wrong-site surgery and near misses in which the potential wrong-site error was corrected before the patient was harmed has revealed processes that catch errors before they reach the patient (see the article “Quarterly Update on the Preventing Wrong-Site Surgery Project” in this Advisory issue).

If your institution is not collecting and analyzing reports of near misses, or “Incidents” under Pennsylvania Mcare Act 13, you are missing valuable information that could make your healthcare system safer. Your competitors may not be missing this opportunity to deliver quality care more reliably. If you are a chief executive or board member of a healthcare facility, an intelligent question to ask your patient safety officer, risk manager, and legal counsel is “What is the number of near-miss (or Incident) reports in our facility per 1,000 patient days?”

PA-PSRS clinical staff reviewed all patient safety reports submitted for the calendar year 2007. We calculated the number of Incident reports per 1,000 patient days to compare hospitals. We then grouped the hospitals by types: acute care hospitals, behavioral health hospitals, children’s hospitals, critical access community hospitals, long-term acute care hospitals, and rehabilitation hospitals. We identified the average number of Incident reports per 1,000 patient days for each hospital group (see Table).

Table. Hospital Incident (Near-Miss) Reports per 1,000 Patient Days, 2007

HOSPITAL TYPE	AVERAGE INCIDENT (NEAR-MISS) REPORTS/ 1,000 PATIENT DAYS
Acute Care	27
Behavioral Health	2
Children’s	22
Critical Access Community	60
Long-Term Acute Care	51
Rehabilitation	21

We noticed that some hospitals reported fewer than 10% of the average for their group. This means the average hospitals in their group gets 10 times the information about weaknesses in their systems as these low-reporting hospitals.

- Of the 150 acute care hospitals, 13 had fewer than 2.7 Incident reports per 1,000 patient days, with 4 of them reporting fewer than 0.27 (1% of the average for the others) and another 2 reporting none.
- Of the 11 behavioral health hospitals, 1 reported fewer than 10% of the average for the others.
- Of the 7 children’s hospitals, 2 reported fewer than 5% of the average for the others.
- Of the 13 critical access community hospitals, 3 reported fewer than 1% of the average for the others.
- Of the 21 long-term acute care hospitals, 1 submitted less than 10% of the average for the others.
- Of the 16 rehabilitation hospitals, 1 reported fewer than 1% of the average of the others.

Hospitals that are not capturing near-miss, or Incident, events are hurting their ability to identify and correct problems before they harm patients. Hospitals with 10, 20, and 100 times more information are going to learn ways to improve their systems much faster. A wise leader will ask: “What information about patient safety are we not collecting?” If the answer is that the average hospital of your type is collecting many more reports than you are, you need to improve your collection of near-miss reports.

Note

1. Pennsylvania Patient Safety Reporting System. Use of color-coded patient wristbands creates unnecessary risk. Pa Patient Saf Advis [online]. 2005 Dec 14 [cited 2008 Nov 24]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/v2_s2_sup__advisory_dec_14_2005.pdf.

Letter to the Editor

Electrical Accidents in the Operating Room

Patient and personnel safety in the operating room (OR) is an ever-present concern for healthcare administrators, clinical staff, and engineering support personnel. A decades-old debate has again arisen over whether there is a true need for isolated power systems in ORs.

ECRI Institute is continuing to research the incidence of medical device failures in the OR when the failure caused a shock to patients or personnel (independent of electrosurgical current issues) or when there was an alarm of the line isolation monitor (LIM) on the isolated power supply system in the room. Not all ORs in the United States have isolated power systems installed, and such systems are not mandated by code. The question as to whether installation of such isolated power systems is indicated to mitigate perceived hazards should be evaluated based on evidence of the types of adverse events that may have occurred in recent years.

The evidence base for equipment failure resulting in patient or personnel shock incidents or LIM alarm incidents appears to be almost nonexistent. We are hopeful that the extensive database at PA-PSRS may have information that can address this question.

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Editor's Note

The PA-PSRS analysts thought that this question from one of the Pennsylvania Patient Safety Advisory editorial board members was interesting and potentially informative. We searched the

PA-PSRS database on September 18, 2008, (search conducted of more than 800,000 reports submitted since 2004) for the keyword "shock" and/or the phrase "line isolation monitor" in reports from the operating room (OR). We found five reports from ORs that met the search terms criteria:

1. *Staff member reported [receiving] a shock while touching patient and anesthesia machine during the same time [surgeon] touched patient with Bovie pencil. The Bovie pencil and cautery machine [were] taken out of use immediately and replaced.*
2. *While doing a cystoscopy and [a transurethral resection of the prostate] using Erbe Bovie CE 7090 [on a patient under spinal anesthesia, the] patient jumped and said felt something go up the back. At that same time, the Bovie stopped working. The Bovie cord and electrode were both changed, and the Bovie started to work. [The surgeon] said he also felt a shock in [the] finger twice. The Bovie pad site was OK. No burns were noted anywhere on body. The Bovie was taken out of service for check.*
3. *While using the Trivex [light source] machine, the light appeared to not be as bright as normal. The staff tried to reposition the light cord in the machine, and in doing so a staff member was shocked. The machine sparked a few times at the light source and began to smell hot. The machine was turned off, unplugged, and taken out of service. The patient was not injured.*
4. *[An employee pushed the] button on outside of OR doors for auto opening and received a large shock that could be felt all the way from arm to feet. [Another] employee also received [a] shock, holding onto the other [end] of the metal cart that the first employee was holding.*
5. *KCI Air Bed SN.BKOK 01612 was wired incorrectly and set line isolation monitor off. [Appropriate person] was called and [had to rewire] it. [This] corrected the problem. The patient was free from injury.*

Notification of Revision

IV infiltration: be alarmed even when your infusion pump isn't. *PA PSRS Patient Saf Advis 2007 Sep;4(3):97-9.* The Pennsylvania Patient Safety Advisory editorial staff has added the permission to reprint and copyright to the online version of this article for the infiltration scale that was reproduced on page 98.

Understanding Living Wills and DNR Orders

ABSTRACT

A living will is a document intended to convey a patient's preferences regarding end-of-life healthcare decisions when the patient cannot express them personally to a physician or other healthcare provider. A living will directs healthcare providers or a patient's authorized representative about the types of medical care the patient wishes to have provided or to forgo at the end of life, consistent with the patient's values and autonomy. A do-not-resuscitate (DNR) order is a medical order issued by a physician or other practitioner authorized to issue medical orders that directs clinicians not to provide cardiopulmonary resuscitation in the event of cardiac or respiratory arrest. A DNR order, by itself, does not address the withdrawal or withholding of any medical care other than resuscitation. Despite the prevalence of living wills and DNR orders, PA-PSRS reports received between June 2004 and September 2008 have revealed that healthcare providers, as well as patients and families, may not understand the differences between living wills and DNR orders. Misinterpretation of living wills and DNR orders may inadvertently result in the provision of unwanted care or the withdrawal or withholding of otherwise appropriate interventions. Accurate interpretation and implementation of these documents, in addition to effective planning and communication, is essential to ensure that a patient's end-of-life preferences for medical care are honored. (Pa Patient Saf Advis 2008 Dec;5[4]:111-7.)

The term “advance healthcare directive” refers to a number of different documents intended to convey a patient's preferences about healthcare.¹ Some advance healthcare directives are intended to appoint a person to make decisions on the patient's behalf when the patient is unable to do so; some authorize another individual to admit the patient to a nursing home or other type of healthcare facility under certain circumstances; and some give specific instructions about what kind of and under what circumstances medical care is to be provided or withheld. A living will is a type of advance healthcare directive, specifying the life-sustaining treatments a patient wishes to *receive or forgo* when the patient is no longer capable of making decisions for him- or herself *and* has an end-stage medical condition *or* is permanently unconscious.¹ A patient may revoke a living will at any time, even at the end of life. In order to implement the terms of a living will in a clinical setting, a physician must determine that the patient is no longer competent and certify in writing that the patient is in an end-stage medical condition *or* is permanently unconscious.¹

A do-not-resuscitate (DNR) order is a medical order to withhold cardiopulmonary resuscitation (CPR) in the event of cardiac or respiratory arrest. Typically, a DNR order is entered into a patient's medical record after a discussion between the physician and the patient and/or a patient's authorized representative.² A DNR order may be entered into a patient's medical record in the absence of a living will.

In addition to preserving a patient's autonomy, one of the underlying purposes of living wills and DNR orders is to give healthcare providers direction regarding a patient's preferences for end-of-life care and interventions. However, as reflected in PA-PSRS reports, there is confusion about how to interpret and implement these documents. From June 2004 to September 2008, PA-PSRS received more than 200 reports involving living wills and DNR orders. An understanding of the implications of living wills and DNR orders, as well as the understanding that these documents are not interchangeable, is important in providing appropriate and respectful clinical care. This article will discuss living wills and DNR orders as defined in the Commonwealth of Pennsylvania. Strategies are presented to assist clinical staff, patients, and families to understand what these documents mean to help ensure that a patient's wishes are communicated and appropriately carried out.

Background Living Wills

In the Commonwealth of Pennsylvania, patient self-determination is governed by the Living Will Act, which provides a statutory framework for healthcare decision making.^{1,3} The Living Will Act establishes that only competent adults or emancipated minors are able to make a living will. Pennsylvania law requires that the document be entered into the patient's medical record, but entry into the medical record does not make a living will operational. A living will becomes operational only when a physician determines that the patient is incompetent *and* certifies in writing that the patient has an end-stage medical condition *or* is permanently unconscious.¹ (See “Glossary of Selected Terms.”)

Certification of an end-stage medical condition can pose problems when the patient has an illness involving slow deterioration, such as with Alzheimer's disease. Determinations of competency can be very difficult and present a challenge to the determining physician as well as other healthcare practitioners involved in the patient's care. Competency is not static, and a patient's decision-making capability may fluctuate. A patient may become confused when experiencing a high fever but be lucid when the fever has resolved. In addition, a patient may be

Glossary of Selected Terms

Incompetency is a condition in which an individual—despite receiving appropriate medical information, communication support, and technical assistance—is documented by a healthcare provider to be unable to

- understand the potential material benefits and risks involved in and alternatives to a specific proposed healthcare decision;
- make that healthcare decision on his or her own behalf; or
- communicate that healthcare decision to another person.

End-stage medical condition is an incurable and irreversible medical condition in an advanced state caused by injury, disease, or physical illness that will, in the opinion of the attending physician to a reasonable degree of medical certainty, result in death, despite the introduction or continuation of treatment.

Permanently unconscious is a medical condition that has been diagnosed, in accordance with currently accepted medical standards and with reasonable medical certainty, as a total and irreversible loss of consciousness and capacity for interaction with the environment. The term includes an irreversible vegetative state or irreversible coma.

Life-sustaining treatment is a medical procedure or intervention that, when administered to a patient or principal who has an end-stage medical condition or is permanently unconscious, will only serve to prolong the process of dying or maintain the person in a state of permanent unconsciousness.

Source: 20 Pa. Cons. Stat. § 5442 (2008).

found incompetent to make some healthcare decisions, but competent to make others.⁴ For example, a patient may be competent to consent to a chest x-ray but incompetent to agree to complicated surgery. Incompetence does not mean that the patient made a choice that others would not make, such as when a competent patient chooses to forgo recommended treatment.

Studies have demonstrated the lack of understanding about the meaning of terms found in living wills. A survey examined whether cohorts consisting of patients, their physicians, and family members understood the meaning of terms used in living wills. The cohort groups had high concordance (83%) regarding understanding of the term “the use of life support to keep patients alive.” However, 71% of patients, 42% of family members, and 27% of physicians responded that a living will could be used to guide treatment decisions in non-end-of-life clinical situations, reflecting a lack of understanding about when a living will becomes operative.⁵ Another study demonstrated that

patients with living wills poorly understood the meaning of “life-sustaining therapies” and the implications of their advance directives. Of 755 patients admitted to a community teaching hospital during the study period, 264 study participants were surveyed regarding their understanding of CPR. Of these, 82 (31%) had living wills. Most (76%) created their living will with a lawyer or family member, and 7% involved a physician. After the patients were provided an explanation of the meaning of CPR, 37% of patients with living wills indicated they actually did not want CPR. Their living wills did not accurately reflect their treatment preferences.⁶

A DNR order is a medical order issued by a physician or other authorized practitioner that directs healthcare providers not to administer CPR in the event of cardiac or respiratory arrest. A DNR order may be written in the absence of a living will or the conditions that would make a living will operative. A living will may contain a provision indicating that a patient does not desire CPR. However, if a patient’s preference to forgo CPR is expressed only in a living will, CPR will be withheld only when a physician has determined that the patient is not competent and has certified in writing that the patient has an end-stage medical condition or is permanently unconscious.¹ Without such physician determination and certification or without a DNR order, the patient’s expressed preference for withholding CPR is not sufficient.² In order for a patient’s preferences to be carried out, patients, families, and healthcare providers must understand the distinction between the circumstances under which a living will and a DNR order are applicable.

A DNR order is not subject to the preconditions imposed by the Living Will Act. A DNR order becomes operative only in the narrow context of cardiac or respiratory arrest regardless of the precipitating clinical event and *does not* preclude otherwise appropriate treatments or life-sustaining interventions.^{2,7} Misinterpretation of DNR orders was demonstrated by a survey conducted in an outpatient cancer center, which showed that only 34% of the patients correctly understood the meaning of a DNR order; 66% of the patients did not realize that a DNR order would result in not being resuscitated even if the cause of the cardiac or respiratory arrest was potentially reversible.⁸

Patient Safety Risks Related to Living Wills and DNR Orders

The potential for misunderstanding the meaning and implications of a living will and DNR orders by healthcare providers, patients, and families may lead to withholding of desired interventions or administering unwanted interventions. Communication failures between providers, patients, and facilities may lead to the same results. These patient safety risks have been reported through PA-PSRS.

Unwanted Treatment

In the absence of a DNR order, CPR will be administered, if medically justified, unless a living will has become operative. A patient may undergo unwanted treatment (i.e., CPR) if he or she does not appreciate the important differences between a living will and a DNR order when expressing, in a living will, the wish not to undergo CPR. In addition, the risk of a patient receiving unwanted care or not receiving desired and appropriate care arises when healthcare providers do not interpret or implement a living will appropriately. Dobbins has shown that the existence of a living will may not affect healthcare decision making. A retrospective review was conducted of the records of 160 elderly patients who died in a community hospital to determine the effect of living wills on healthcare decisions. The findings demonstrated that a living will did not influence healthcare provider decisions about the use of life-sustaining treatment and the initiation of comfort care plans or the decision to treat the patient in the intensive care unit (ICU). The documents did influence healthcare providers to write DNR orders more often.⁹

From June 2004 to September 2008, 37 of the PA-PSRS reports related to living wills or DNR orders have involved patients receiving potentially unwanted interventions. Examples are as follows:

A patient was admitted through the [emergency department (ED)] after suffering a femoral fracture from a fall at home. The patient underwent an open reduction of the fracture and was transferred to the ICU post-operatively due to numerous preexisting comorbidities. The patient developed hypotension and tachycardia. A hospitalist was summoned to the bedside, and medications were administered. The patient then developed ventricular tachycardia. The patient did have DNR order but an attempt was made to resuscitate the patient. The resuscitation attempt was unsuccessful.

A patient was admitted through the ED with increased lung congestion and vomiting blood. Resuscitation status was not addressed on admission. The patient was diagnosed with acute respiratory distress due to pneumonia. No chest x-ray had been ordered. The patient was being assisted with breakfast and suddenly became unresponsive and stopped breathing. A resuscitation team was called. The patient had living will in the chart indicating no resuscitation. The hospitalist spoke with the attending physician, who stated the patient's wishes were . . . DNR; however, the order was never given. The resuscitation was stopped, and the patient expired.

A patient with numerous comorbidities had a DNR order in the chart; when the patient's vital signs changed, the patient was resuscitated despite the DNR order.

Misperceptions of the Meaning of Living Will and DNR

Researchers have raised concerns that DNR orders and living wills may be misunderstood by healthcare

Key Points

- A living will applies *only* if the patient is incompetent *and* has an end-stage medical condition or is permanently unconscious.
- A living will does not apply to questions of day-to-day care, placement or treatment options, and other non-end-of-life circumstances.
- A do-not-resuscitate (DNR) order is a medical order issued by a physician or other authorized practitioner that directs clinicians *not* to provide cardiopulmonary resuscitation in the event of cardiac or respiratory arrest.
- A DNR order, by itself, does not include the withdrawal or withholding of any medical care other than resuscitation.

providers. A case series of patients with a living will presenting for treatment and their hospital course illustrated these concerns. In one case, the primary care physician (PCP) advised the emergency physician (EP) that a patient presenting with chest pain did not need to be admitted because the patient had a living will. The PCP interpreted the living will as imparting a DNR status. The EP disagreed with the PCP's interpretation, and the disagreement resulted in a delay in treatment. In another case, a nurse delayed notifying the attending physician of a change in the patient's clinical status. The nurse mistakenly interpreted the patient's living will as meaning a code status of DNR. In a third case, the EP and PCP misinterpreted a living will, believing it to be operative. This resulted in less aggressive treatment of a myocardial infarction.¹⁰ The case series author stated that "just because a living will exists, its existence does not cause it to become activated. Also, it must be re-iterated that a DNR does not equal 'do not treat.'"¹⁰

A recent study has shown that a misunderstanding of the meaning of a living will may unnecessarily put patients at risk when patients present for emergency care. A survey administered to physicians, nurses, and first responders at a 350-bed acute care and level II trauma center presented a fictitious living will and prompted respondents to assign a code status (DNR or full code) and define the level of care associated with the DNR code status. Seventy-nine percent of respondents assigned a DNR code status, and 70% construed DNR to mean "comfort care/end-of-life care."¹¹ Other studies support that DNR orders may be applied to broader treatment decisions and that interventions such as hospitalization, blood transfusion, central line placement, and intubation may be withheld based on the existence of a DNR order, even when a patient has not requested that these treatments be withheld.^{12,13,14}

From June 2004 to September 2008, 93 of PA-PSRS reports regarding living wills or DNR orders indicated that a DNR order may have been misinterpreted as

a directive to withdraw or withhold care, suggesting staff may not have understood the narrow scope of a DNR order. It is important to note that the reports do not convey the clinical context of the decision to withdraw or withhold care, which may have been based on other factors unrelated to the DNR order. Examples include the following:

A patient was transferred from the ICU to the telemetry unit. No monitors were available. . . . Staff phoned the doctor to see if they could discontinue the monitor on [another] patient who was DNR to use on this patient.

A patient was intubated and restrained due to the patient pulling on lines. . . . The patient was unable to be weaned from ventilator. Family and physician discussion revealed code status had been changed from full code to DNR. Restraints were removed, and the patient was extubated and expired.

A patient presented to the ED in cardiac arrest. After admission, the patient developed a fever. Blood cultures were positive for methicillin-resistant Staphylococcus aureus. The patient expired after the family made the patient a DNR and did a terminal wean [from the ventilator].

Shortly after admission, the patient went into respiratory arrest. The patient was intubated, and restraints were applied to prevent the patient from removing the endotracheal tube. The patient then requested DNR status, restraints and endotracheal tube were removed, and the patient expired.

A patient was on a Levophed® drip. When the drip began running out, no Levophed was available to mix another dose. The patient was a DNR, and Levophed was discontinued.

Miscommunication

PA-PSRS reports show that there is a potential for a breakdown in communication between healthcare providers and between healthcare providers, patients, and families. Seventy-one reports submitted through PA-PSRS from June 2004 to September 2008 related to living wills or DNR orders indicated some form of communication breakdown. The majority of reports involved a lack of understanding of the meaning of the documents by families, lack of communication of the presence of a DNR order among healthcare providers, misidentification of patients, and failure to identify patients with DNR orders. All these issues may lead to a patient's preferences not being carried out. Examples of these issues reported through PA-PSRS include the following:

A patient was admitted through the ED from a long-term care facility (LTCF). The patient's [living will] was not sent with information from the LTCF. Shortly after admission, the patient had a respiratory arrest. A code was called, and the patient was successfully resuscitated. The family was called to notify of code. [The family] advised staff that the patient had [a living will] and was a DNR.

The physician ordered a DNR status; subsequently, the physician noted a DNR sticker was not placed on patient's chart. No report was given to the nurse from the previous shift regarding code status, and no DNR armband was placed on the patient.

Patient was admitted from another facility as level 2 DNR. Family member states family discussed level of intensity with doctor and requested change to level 1 (DNR). Per family, doctor agreed that it was appropriate and told them that he would take care of it. The patient coded with family present. The family requested a code. The staff initiated resuscitation but then noted level 2 status and code stopped. A nurse spoke to the family, who stated the code status had been changed. The code team was recalled and resumed resuscitation. The patient was resuscitated successfully.

A patient was wearing a purple wristband (DNR) indicating code status. The band was removed, and an appropriate band for "do not use extremity" applied.

A DNR order was entered for a patient. The unit secretary prepared a DNR band and gave it to the nurse's aide to apply to the patient. The nurse's aide then passed it on to a second nurses' aide, who applied the band to the wrong patient.

Patient had a blue armband indicating DNR order. No DNR order was found on the patient's chart. [The discrepancy was] discussed with the patient, and the patient wanted full code status. The blue armband was removed.

Risk Reduction Strategies

As the above PA-PSRS reports indicate, living wills and DNR orders may be misunderstood by healthcare providers, families, and patients. Communication breakdowns, including the lack of appropriate documentation and patient misidentification, also present patient safety risks. Several strategies may be used to reduce this risk. (For additional resources, see "Companion Online Information.")

Improving Communication

The implementation of a DNR order may preclude a number of procedures, including chest compressions, cardiac defibrillation, medications, and endotracheal intubation.² A DNR order may apply to any combination of these interventions, potentially leading to confusion. For example, a patient may want to be intubated but may not wish to receive any other treatment. DNR protocols have been developed that integrate these procedures; however, these protocols may differ among facilities in terminology, scope, and content. For example, PA-PSRS reports from different facilities throughout the state include the following terms: DNR A through D, DNR levels I through V, modified DNR II, and DNR/DNI.

In addition to inconsistent terminology, in Pennsylvania, a DNR order is not portable after the patient is discharged or transferred to another facility. The Physician Orders for Life-Sustaining Treatment (POLST)

Companion Online Information

Caring Connections

- Caring Connections, a program of the National Hospice and Palliative Care Organization, provides a variety of information about advance directives for patients and families. Available from Internet: <http://www.caringinfo.org/Home.htm>.

Pennsylvania Department of Aging

- The department provides a brochure, which includes an advance directive statutory form. See "Advance Directives for Health Care, Living Wills and Powers of Attorney in Pennsylvania." Available from Internet: http://www.aging.state.pa.us/aging/lib/aging/Advance_Directives_brochure1.pdf.

Pennsylvania Medical Society

- The Pennsylvania Medical Society provides an online summary of the Living Will Act. Available from Internet: <http://www.pamedsoc.org/mainmenucategories/Government/LawsAffectingPhysicians/AdvanceDirectives/Act169facts.aspx>.

The Hospital & Healthsystem Association of Pennsylvania (HAP)

- HAP provides an informational brochure on advance directives. See "Decide for Yourself: A Guide to Advance Healthcare Directives." Available from Internet: <http://www.haponline.org/downloads/decideen.pdf>.

Hamot Medical Center

- Ferdinando L. Mirarchi, DO, medical director, emergency medicine, Hamot Medical Center, presented an informational lecture on living wills and DNR orders at the University at Buffalo on September 10, 2008. See "To Live or Let Die! Living Wills and DNR Orders." Available from Internet: <http://www.hamot.org/livingwillvideo/>.

form has been recommended in other states as one mechanism for issuing a single medical order that reflects a patient's end-of-life preferences expressed through a living will and is transferrable across care settings to help ensure the patient's wishes are honored throughout the healthcare system.^{2,15,16} (The POLST form has not been adopted in Pennsylvania, however, and current healthcare regulations preclude physicians from issuing medical orders that transfer from one facility to another in most cases. The Pennsylvania Department of Health currently has a task force reviewing the advisability of adopting a POLST-like medical order statewide.)

Healthcare providers can use a number of strategies to facilitate communication with patients and

families regarding end-of-life treatment preferences. The following have been identified as key elements of a successful advance directive program and may be applied to the process of obtaining a DNR order.^{2,16}

- Develop an individualized plan of care through a process of interaction with the patient that is specific to the patient's values and goals, including consideration of the patient's relationships, culture, and medical condition.
- Engage individuals who are close to the patient so that they understand and support the plan. Discuss with the patient and surrogate how much leeway the surrogate has in decision making.
- Document the plan, including identification of the designated surrogate in the event the patient is deemed no longer competent or able to communicate, in the form of an actionable directive that addresses wishes for treatment with specific medical orders reflecting the patient's current treatment preferences.
- Plan for a proactive but appropriately staged and timed discussion about healthcare decisions. The discussion must be revisited when the patient's prognosis becomes known or changes. Healthy adults can benefit from advance care planning to prepare for sudden, severe illness or injury. For individuals with advanced chronic disease and frailty, include a discussion regarding changing treatment goals as the patient's prognosis changes. Plans should be updated over time and available when needed.
- Ensure that patients, families, and/or surrogates understand the terminology contained in a living will and/or DNR order, as appropriate.

Healthcare providers can improve their own understanding and their communication with each other about a patient's wishes as expressed in a living will, the DNR order, or both, by implementing the following strategies:

- Establish ongoing education about living wills and DNR orders for residents, attending physicians, and nursing staff.²
- Ensure that residents, attending physicians, and nursing staff understand when a living will becomes operative.^{10,16}
- Ensure that residents, attending physicians, and nursing staff understand that the existence of a living will does not imply that a patient has a DNR order.¹⁰
- Ensure that residents, attending physicians, and nursing staff recognize that a DNR order applies only to cardiopulmonary arrest and has no effect on any other treatment decision. In other words, a DNR order does not mean "do not treat."¹⁰
- Encourage physicians to obtain skills training in communication about end-of-life decision making.²

- Establish policies that require a discussion and documentation of any exception to a DNR order during the perioperative period, such as suspension of a DNR order during surgery.²
- Ensure that the existence of a living will is established on admission and documented in the patient's medical record.²
- If the facility uses color-coded wristbands to communicate DNR status to clinicians, ensure that policies address who is responsible for applying and removing DNR color-coded wristbands and how DNR wristband information is documented and communicated.¹⁷

Conclusion

A living will is an important mechanism for providing guidance and direction to healthcare providers regarding a patient's end-of-life preferences. A DNR order is one way a physician or other authorized practitioner can direct clinicians to respect a patient's wishes about receiving CPR in the event of cardiac or respiratory arrest. However, there is no substitute for collective, informed decision making and clinical judgment, requiring open communication between patients, families, and physicians. In order to communicate effectively, all parties involved must understand the meaning and implications of living wills and DNR orders. Living wills and DNR orders are intended to honor a patient's end-of-life preferences. Through planning, education, and effective communication, healthcare providers can assist patients in realizing their end-of-life treatment goals.

Notes

1. Living Will Act, enacted as part of Act 169 of 2006, 20 Pa. Cons. Stat. § 5441 *et seq.* (2008).
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(See Self-Assessment Questions on next page.)

Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. A patient safety risk related to the misinterpretation of a do-not-resuscitate (DNR) order by healthcare providers is the withholding or withdrawing of otherwise appropriate clinical interventions.
 - a. True
 - b. False
2. A living will becomes applicable when all of the following conditions occur EXCEPT:
 - a. A copy is provided to the attending physician.
 - b. The patient is determined to be incompetent by the attending physician.
 - c. The patient is determined to have an end-stage medical condition or to be permanently unconscious.
 - d. The determination of all applicable conditions is confirmed with a second opinion.
3. Living wills may be applicable to questions about day-to-day care, placement or treatment options, or other healthcare decisions involving patients who lack capacity in non-end-of-life circumstances.
 - a. True
 - b. False
4. An elderly patient with a medical history of stroke, myocardial infarction, and congestive heart failure is admitted after a fall at home. The patient is diagnosed with a hip fracture. The patient has a living will indicating she does not wish to undergo cardiopulmonary resuscitation (CPR), which is placed in her medical record. Before surgery to repair her fractured hip, the patient reminds her physician that she does not wish to undergo CPR. After a discussion

about the implications of the DNR order, the physician enters a DNR order in the patient's medical record. On her second postoperative day, the patient's condition deteriorates and she suffers a cardiopulmonary arrest.

Which of the following is an accurate statement about the appropriateness of CPR for this patient?

- a. CPR may be withheld in the presence of the DNR order only if the patient was determined to be incompetent.
 - b. CPR may be withheld based on the living will since the patient suffered a cardiopulmonary arrest.
 - c. A healthcare provider may not withhold CPR based on the DNR order without the existence of the living will.
 - d. The healthcare provider may withhold CPR based on the DNR order without the provisions expressed in the patient's living will becoming applicable.
5. All of the following are strategies that would help reduce the risk of misinterpretation and/or miscommunication of a living will or DNR order EXCEPT:
 - a. Determine on admission whether a patient has a living will, and ensure that it is appropriately documented in the patient's medical record.
 - b. Recognize that obtaining skills training in communication about end-of-life decision making is best delegated to the hospital ethics committee.
 - c. Ensure that residents, attending physicians, and nursing staff recognize that a DNR order applies only to cardiopulmonary arrest and has no effect on any other treatment decision.
 - d. Ensure that patients, families, and/or surrogates understand the terminology contained in a living will and/or DNR order.

Pressure Ulcers: New Staging, Reporting, and Risk Reduction Strategies

ABSTRACT

The 2007 National Pressure Ulcer Advisory Panel pressure ulcer update and the October 2008 facility reimbursement changes by the Centers for Medicare & Medicaid Services for Stage III or IV pressure ulcers add resource burdens to healthcare facilities. The ultimate goal of these updates and changes is to decrease the overall rate of hospital-acquired pressure ulcers. In 2007, nearly 13% of all pressure ulcers reported through PA-PSRS were categorized as Stage III or IV; more than 26% of the total reports did not include any pressure ulcer staging information. The admission diagnosis and documentation of Stage III or IV pressure ulcers are essential to overall pressure ulcer identification, care, and ultimately, reduction. Risk reduction strategies include pressure ulcer protocol development, implementation, consistent documentation, and communication systems that extend along the entire continuum of care. (Pa Patient Saf Advis 2008 Dec;5[4]:118-21.)

In 2007, the National Pressure Ulcer Advisory Panel (NPUAP) updated pressure ulcer staging, following a lengthy synthesis of current literature review and expert opinion, adding two stages to create a total of six pressure ulcer stages.^{1,2} The goal of this revision was to increase the number of correctly staged pressure ulcers.¹ In June 2008, the Pennsylvania Patient Safety Authority incorporated this change in its reporting system for skin integrity/pressure ulcer stages. When a facility reports a pressure ulcer event through PA-PSRS, the two additional staging options appear in the event detail questions. These stages include Suspected Deep Tissue Injury (SDTI) and Unstageable (see Table 1 for definitions of these and other stages).

An SDTI indicates a localized discolored area of intact skin or a blood-filled blister. Compared to surrounding tissue, the area may be firm, boggy, warm, cool, or painful. An SDTI may be difficult to detect in patients with dark skin tones, so accurate assessment skills are critical. An SDTI may manifest as a thin blood-filled blister over a dark wound bed evolving into a thin escher layer (see Figure).³ Though optimal treatment may be instituted, the evolution of an SDTI may be rapid, exposing additional layers of tissue.¹ The Unstageable category is defined as full-thickness tissue loss with slough (yellow, tan, gray, green, or brown) and/or eschar (tan, brown, or black) in the bed of the wound.¹ The true depth of the wound cannot be established until enough slough and/or eschar is removed to expose the wound base.^{1,3}

As of October 2008, Stage III or IV pressure ulcers are considered one of eight preventable conditions or

never events identified as hospital-acquired conditions by the Centers for Medicare & Medicaid Services and Pennsylvania Department of Public Welfare.^{4,5} Facility reimbursement for Stage III or IV pressure ulcers is severely limited, particularly if the ulcers occur as a sole major complication or complicating condition throughout hospitalization. If Stage III or IV pressure ulcers are not present upon admission but appear at the time of discharge, associated patient care will not be reimbursed. Patients may be admitted from home or other facilities with existing pressure ulcers, and hospitals are faced with the challenge of identifying, staging, and carefully documenting such conditions upon admission. Physicians or any qualified healthcare practitioners documenting the patient's admitting diagnosis must indicate the presence and clinical data of pressure ulcer upon admission, so documented detailed and accurate admission skin assessments are essential to avoid any question as to when an ulcer occurred.^{2,6}

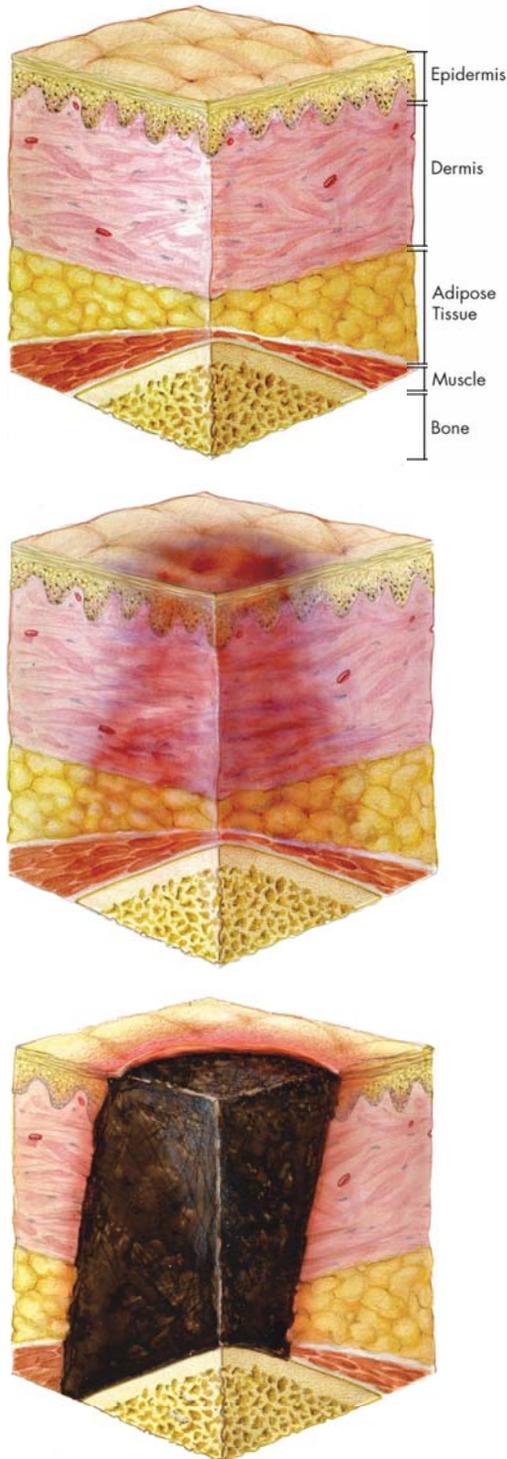
In 2007, nearly 13% of all pressure ulcers reported through PA-PSRS were categorized as Stage III or IV (see Table 2). More than 26% of the total pressure ulcer reports did not include the staging information. This percentage has remained unchanged from the

Table 1. PA-PSRS Definitions—Skin Integrity Stages

SUSPECTED DEEP TISSUE INJURY	A localized area of discolored (purple or maroon) intact skin or blood-filled blister. The area may be painful, firm, mushy, boggy, warmer or cooler compared to adjacent tissue.
STAGE I	A reddened area on the skin that, when pressed, is "nonblanchable" (does not turn white.) This indicates that a pressure ulcer is starting to develop.
STAGE II	The skin blisters or forms an open sore. The area around the sore may be red and irritated.
STAGE III	The skin breakdown now looks like a crater where there is damage to the tissue below the skin.
STAGE IV	The pressure ulcer has become so deep that there is damage to the muscle and bone, and sometimes tendons and joints.
UNSTAGEABLE	Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Source: National Pressure Ulcer Advisory Panel. Pressure ulcer stages revised by NPUAP [online]. 2007 Feb [cited 2008 Dec 4]. Available from Internet: <http://www.npuap.org/pr2.htm>.

Figure. Normal Tissue (Top), Suspected Deep Tissue Injury (Middle), and Unstageable Skin (Bottom) Illustrations



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June 2004 to December 2005 reports data discussed in the September 2006 issue of the *Patient Safety Advisory*.⁷ Clearly defined pressure ulcer reporting criteria includes pressure ulcer assessment, documentation, and precise ulcer staging. The implementation of an effective pressure ulcer protocol allows facilities to accurately detect, assess, and treat existing ulcers; track care interventions; monitor ulcer changes; identify patients at risk; reduce risks of further skin injury; and improve patient safety by consistent and routine monitoring of skin integrity. The ultimate goal is to decrease the overall rate of hospital-acquired pressure ulcers.

The number of PA-PSRS pressure ulcer reports that lack staging information, coupled with the new SDTI and Unstageable stages and the cost to treat these pressure ulcers add resource burdens to healthcare facilities. Facilities are obliged to provide education to all clinicians conducting skin assessments as to the pressure ulcer stages and documentation requirements. Physicians must be involved in the prevention of pressure ulcers and in the documentation of skin assessments upon patient admission so that pressure ulcers that are present on admission are not mistaken for hospital-acquired pressure ulcers.⁸

Facilities may consider the development of a multidisciplinary pressure ulcer prevention taskforce composed of wound ostomy and continence nurses, physicians, nurses, dietitians, physical therapists, and any departments involved with pressure ulcer prevention such as patient transport. Typically, the pressure ulcer taskforce develops a hospitalwide standard of care with protocols in risk assessment, documentation, and communication systems that extend along the entire continuum of care in pressure ulcer prevention.^{6,9} The hospital's portal of entry, the emergency department, where initial admission skin assessment occurs, is now vitally important as identifying Stage III and IV pressure ulcer existence.

Risk Reduction Strategies

The following risk reduction strategies based on NPUAP practice standards, expert opinion, and case series where published supporting data are unavailable, may be considered when facilities develop or update pressure ulcer protocols, documentation, and communication systems to include SDTI and Unstageable skin integrity stages.

Assess/Reassess

Conduct pressure ulcer admission assessments, and document findings using a standard and age-appropriate risk scale that includes assessment for patients at high risk for pressure ulcer formation (e.g., Braden Scale). High-risk patients may include those who are bedridden or those who have comorbid conditions such as poor circulation, poor nutrition, incontinence, obesity, and dry skin. Use a standard reassessment tool to reassess daily a patient's pressure ulcer risk, as condition changes indicate, and with transfers to the next level of care. Perform daily skin inspections, including skin temperature, turgor, color,

Table 2. 2007 Pressure Ulcer Reports with Stages Submitted through PA-PSRS

PRESSURE ULCER EVENTS	STAGE I	STAGE II	STAGE III	STAGE IV	NOT GIVEN	TOTAL
Patient admitted from other facility with ulcer	1,043	3,498	781	650	2,230	8,202
New ulcer less than 24 hours after admission	156	313	49	22	156	696
New ulcer more than 24 hours after admission	779	2,103	106	37	1,024	4,049
Other event type (nonpressure ulcer)	19	51	4	1	58	133
TOTAL	1,997	5,965	940	710	3,468	13,080

moisture, and integrity status. Pay close attention to bony prominences, particularly the sacrum and heels, as these are the most common adult pressure ulcer locations. Check the skin beneath tubes and other potential pressure-ulcer causing devices. Frequency of pressure ulcer reassessment may vary according to the healthcare setting (e.g., homecare, long-term care).^{6,10,11}

Position

Turn or reposition patients at least every two hours or more often for those with fragile skin or with little subcutaneous fat to minimize pressure. Use lift devices or heel-protector devices to assist in turning, repositioning, lifting, or transferring patients to prevent friction or shearing forces, which may contribute to skin integrity issues. Evaluate the facility’s support surfaces such as mattresses (including those in the operating room suites), pillows, and chair cushions to ensure that pressure-relieving surfaces are used. Establish and maintain par-levels for skin care devices and products in each patient care area to ensure that resources are available to healthcare providers to deliver consistent pressure ulcer prevention.^{3,6,11}

Monitor

Assess and monitor patient’s calorie intake, and notify the prescriber or dietitian if the patient has an unintentional weight loss, as this and poor nutrition often contribute to pressure ulcer risk. A comprehensive nutritional assessment addressing risk factors, protein intake, hydration, caloric needs, vitamins, and minerals is essential to pressure ulcer prevention. Monitor laboratory levels, including serum albumin and prealbumin levels. Vitamin or dietary supplementation may be indicated for nutritionally compromised patients.^{6,10,11}

Protect

Protect patient’s skin from excessive moisture and dryness due to incontinence, perspiration, or wound drainage. Standardize product use by the development of a skin product formulary. Only use products that wick moisture away from the body.^{6,10}

Educate

Provide pressure ulcer prevention education about assessments, protocols, documentation, and communication systems to all levels of healthcare providers. Provide prompt communication of modifications or

additions to skin protocols or products to all healthcare providers.^{6,10}

Notes

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Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. Risk reduction strategies to prevent overall pressure ulcer development include which of the following?
 - a. Development of interdisciplinary pressure ulcer prevention taskforce
 - b. Use of pressure-relieving patient support surfaces
 - c. Consistent documentation of skin assessments
 - d. Communication systems that extend along the entire continuum of care
 - e. All of the above
2. All of the following are clinical manifestations of Suspected Deep Tissue Injury (SDTI) EXCEPT:
 - a. The skin involved has a localized discolored area of intact skin.
 - b. The skin involved is painful.
 - c. The skin involved is mushy or boggy to touch.
 - d. The wound depth is clearly visualized.
3. The components of the treatment plan in which SDTI is diagnosed include all of the following EXCEPT:
 - a. Comprehensive nutritional assessment with vitamin and mineral supplementations that address protein intake, hydration, and caloric needs
 - b. Regular monitoring of serum albumin and prealbumin levels
 - c. Regular skin reassessments for skin integrity changes that include skin temperature, turgor, color, and moisture
 - d. Initiate treatment when the SDTI progresses to a Stage III pressure ulcer

4. Physicians or qualified healthcare practitioners identifying patients with existing Unstageable pressure ulcers being admitted to the hospital must document detailed and accurate skin assessments and indicate the presence and staging in the admitting diagnosis.
 - a. True
 - b. False
5. A patient's admission skin assessment indicates that the patient is a 72-year-old man admitted with a hip fracture, congestive heart failure, and malnutrition. Previous medical history includes a cerebrovascular accident and hypertension.

Which factors may lead to hospital-acquired pressure ulcer formation for this patient?

- I. Lack of lift devices for patient transfer assistance
 - II. Use of occlusive dressing over bony prominences
 - III. Lack of skin protection from tubes or lines
 - IV. Inconsistent skin reassessments
- a. all of the above
 - b. all but I
 - c. all but II
 - d. all but III
 - e. all but IV

Medication Errors Occurring with the Use of Bar-Code Administration Technology

ABSTRACT

Bar-code medication administration (BCMA) systems can improve medication safety by verifying that the right drug is being administered to the right patient. Studies have shown that BCMA technology can reduce medication errors by 65% to 86%. But BCMA technology alone does not ensure a safe medication-use system. A number of reports submitted through PA-PSRS describe medication errors that occurred in organizations that used a bar-code system for administration. Some of these errors result from failures to use this technology appropriately, employing workarounds or overriding alerts, disruptions in the medication administration process, and dispensing errors that arise in the pharmacy. Strategies to address problems with this technology include reviewing BCMA logs to evaluate overrides and identify system weaknesses and monitoring and measuring compliance with the technology to identify and remove any barriers to its appropriate use. (Pa Patient Saf Advis 2008 Dec;5[4]:122-6.)

A prospective cohort study of medication errors by Leape et al.¹ determined that 39% of errors occurred during the prescribing phase, 12% during transcription, 11% during dispensing, and 38% during administration. Close to half of the errors that occurred during the prescribing phase were intercepted before they reached the patient; in contrast, only 2% of errors that occurred during the administration phase were intercepted. Another study using direct observation in 36 healthcare facilities found that medication administration errors occurred in almost 20% of doses administered.² Data from U.S. Pharmacopeia's (USP's) medication error reporting database, MEDMARX®, indicates that an error at the point of administration is least likely to be intercepted before reaching the patient, compared to other phases of the medication-use process.³

One form of technology that may address administration errors is a bar-code medication administration (BCMA) system. BCMA can improve medication safety through several levels. At the most basic level, the system helps to verify that the right drug is being administered to the right patient in the right dose and at the right time. The 1999 Institute of Medicine report *To Err Is Human* noted that point-of-care bar coding offers a simple way to ensure that the identity and dose of the drug are as prescribed, that the drug is being given to the right patient, and that all of the steps in the dispensing and administration processes are checked for timeliness and accuracy.⁴ Since the late 1990s, the use of bar coding in drug administration has increased.

Studies have shown that BCMA can reduce medication errors by 65% to 86%.^{5,6,7} To determine the effectiveness of its newly implemented bar-code system, one hospital in Pennsylvania showed that the direct-observation accuracy rate before BCMA was 86.5%; after BCMA, the rate rose to 97%.⁸ But technology alone does not ensure a safe medication-use system, and the process changes that accompany any technology can introduce new sources of error.⁴

Clinical analysts from PA-PSRS queried the database using keywords related to BCMA such as "bar code" and "scanned" as well as reports coded as involving BCMA when reviewing individual case reports. A review of medication error reports submitted through PA-PSRS since June 2004 revealed that there are reports that describe potential events that were detected and caught by BCMA technology. However, a number of reports submitted through PA-PSRS describe medication errors that occurred in organizations that used a bar-coding system for administration. Some of these errors are indirectly associated with the bar-code administration system, and some are the result of issues with the use and misuse of this technology.

Dispensing Node

Some errors associated with BCMA do not originate with the technology. Rather, they occur earlier in the medication-use process (i.e., dispensing phase) and are perpetuated by bar-code verification at administration. For example, pharmacy may mistakenly place the correct (e.g., right drug, right dose, right patient) pharmacy-generated label on the wrong medication. This type of error, especially if the pharmacy-generated label obscures critical information on the manufacturer's label, could make its way to the patient, as the BCMA system would read the bar code as the correct medication for the patient.

A review of medication errors associated with bar-code technology submitted to the USP MEDMARX program between June and August 2006 showed that the most frequent cause of BCMA-related errors was mislabeling. Sixty-five of the 128 (51%) reported labeling errors resulted from attaching a bar code associated with one product to a different product. Another 29 (22.7%) of the reports of mislabeling indicated that the bar code was affixed to the wrong strength of the correct medication.⁹

These types of errors may occur for many reasons. Reports submitted through PA-PSRS demonstrate that a wide variety of contributing factors may lead to selecting the wrong product from the pharmacy inventory, including similar packaging and labeling of medications, pharmacy order-entry errors, look-alike

names, and selection of the right drug but wrong concentration. For example, consider the following reports.

A patient was due to have hydrogen peroxide applied to her face. The medication was obtained from the medication room, as sent up from pharmacy. It was labeled correctly, but the bottle was magnesium citrate. The label was placed partially covering the magnesium citrate label. This would not have been picked up from scanning because staff scans the label.

Lamictal® (lamotrigine) 150 mg [orally twice daily] was ordered for a patient, but was transcribed into the [BCMA] system as lamivudine 150 mg po bid by the pharmacy. Both the bar code and Pyxis scanned correctly due to order being verified by nurse as correct drug. Error noticed by doctor when reviewing medication list.

A patient was ordered for a “now” dose of Thorazine (chlorpromazine) 25 mg. The pharmacy filled the order and dispensed Librium® (chlordiazepoxide) 25 mg. The nurse used the electronic scanner, and the device indicated a “wrong drug” error. The nurse looked at the drug, thought the name was correct, and overrode the device and administered the incorrect medication.

Vancomycin was dispensed for a neonate in a syringe labeled with the ordered dose, but with the wrong concentration of drug. The medication scanned correctly in [BCMA], since label with correct information. The error was discovered by pharmacy. The doses were retrieved from the floor.

In order to maximize the safety mechanisms that BCMA technology provides, medications need to be packaged in unit-dose or ready-to-use formats. However, the availability, or lack thereof, of manufacturer-supplied, bar-coded unit dose medications does not fully support this. Although the U.S. Food and Drug Administration requires bar codes on containers, it does not require that unit-dose containers be available for all medications. As a result, unit-dose packaging of some established products has been discontinued. Fully implementing a BCMA system, therefore, may involve repackaging many medications and relabeling each dose with a bar code. This may include the purchasing of automated repackaging equipment, increasing pharmacy staff, providing adequate space within the pharmacy to prepare these medications, and implementing a verification process to ensure that the bar code is correct and readable by the same scanners and database used by the nurses on the patient care units. In addition, some pharmacies do not prepare medications in a patient-specific ready-to-use form—for example, breaking tablets in half before unit-dosing the products for “half-tablet” orders or providing patient care areas with bulk bottles of liquid medications from which a nurse is required to measure a dose. In the following report submitted through PA-PSRS, a whole tablet was

administered to a patient when only one half of a tablet was ordered.

Nurse scanned Bumex® (bumetanide) 1 mg tab but forgot to break tab prior to administering 0.5 mg dose ordered; wrong dose error. The vital signs were monitored and serum electrolytes were rechecked.

Administering Node

BCMA technology can improve medication safety through several levels of functionality. At the most basic level, the system helps verify that the right drug is being administered to the right patient in the right dose and at the right time. When one of these items does not match, most systems alert the practitioner before administration. Alerts can also be generated when patients do not have an active order or are allergic to the scanned medication. However, problems may occur despite the display of an alert. Examples of reports submitted through PA-PSRS in which these alerts signaled a problem, yet an error occurred, include the following:

Nurse was assisting another nurse by giving a patient a dose of insulin. The nurse scanned and administered the insulin despite [BCMA] firing a “no order in system” warning. The insulin was given to wrong patient.

Patient who was on weight-based heparin protocol was ordered “No Bolus Ever” by the physician. [BCMA] fired a “no order in system” alert, but the nurse continued and administered bolus. No untoward reaction was reported.

[Morning] dose of Avandia® (rosiglitazone) administered early by the night shift nurse. Student nurse noted Avandia dose on [BCMA] worksheet and administered second dose. [BCMA] displayed appropriate “early dose” and “exceeding maximum daily dose” warnings; student proceeded through warnings and administered dose.

Patient’s order for Cardizem® (diltiazem) 120 mg four times a day was discontinued, and the dose was changed to 60 mg every six hours. The pharmacy entered the transcribed orders into the [BCMA] systems, awaiting confirmation by the nurse. The nurse administered the 120 mg dose, despite an alert from [BCMA] that stated the medication was discontinued and that there were medications that required confirmation. The nurse then confirmed orders and administered 60 mg dose within 2 hours of 120 mg dose. No untoward reaction was reported.

Alerts that are generated by BCMA systems often may not be noticeable. For example, a system may generate a visual display of the alert but not provide a distinct auditory alert. If a nurse does not look at the screen for any alerts after scanning a patient’s wristband and/or bar-coded medications, errors will ensue. Additionally, the alerts are not hard-stops, meaning that the system does not physically stop a practitioner from proceeding with scanning or administering a medication. The alert is merely a warning that may or

may not require a simple key stroke (e.g., hitting the “Enter” key on a keyboard) to override. One Pennsylvania facility submitted the following report through PA-PSRS that illustrates this.

A nurse drew up a medication for a patient in another room and mistakenly administered the medication to [another] patient. The [nurse] scanned each medication; however, the nurse went into the wrong room, scanned the patient’s bar code, and did not check the screen prior to giving medication to the patient. The screen did verify that it was the wrong patient. The patient received three incorrect medications.

Problems have also occurred when other processes surrounding medication administration have broken down. Although the steps directly involved with the scanning of the medication and patient may be completed, errors can be introduced if distractions occur or medications are laid down after the scanning process. Patients in Pennsylvania have received the incorrect medication or dose due to these types of process breakdowns, as evident from the following PA-PSRS reports.

Nurse pulled Unasyn® (ampicillin and sulbactam) 1.5 mg to hang for patient’s dose. She scanned the medication and the patient’s wristband appropriately. The nurse put down the medication on the medication cart to answer a call bell. She returned to the medication cart within approximately five minutes, took the medication into the wrong patient room, and hung on wrong patient.

Nurse removed morphine syringe for patient-controlled analgesia (PCA) to change the PCA pump since the previous syringe was empty. The doctor wrote an order for “sodium bicarbonate [intravenous] IV push x1.” The nurse scanned the sodium bicarbonate per protocol, but after scanning the patient and the medication, the nurse picked up PCA morphine syringe and administered morphine to patient instead of the sodium bicarbonate. The nurse began to scan the morphine PCA syringe to change PCA and then realized that morphine was given.

A patient with diabetes was to receive 4 units of regular insulin per sliding scale insulin coverage, but the patient received 10 units of regular insulin and 20 units of NPH insulin that was intended to be given to the patient’s roommate. The nurse drew both insulin doses from the automated dispensing cabinet and had properly labeled the syringes by bar coding them. Prior to administering the insulin, she scanned the patient and the syringe. She then obtained an alcohol swab, picked up the wrong syringe, and administered the wrong dose to the patient. The nurse immediately realized her mistake and notified the physician.

Failure to Scan Medications

The effectiveness of bar coding technology in safeguarding patients is limited by the extent to which it is correctly and consistently used at the bedside by each clinician administering medications. In a study

of the 85 facilities under the Hospital Corporation of America facilities using BCMA in June 2004, only 64% of patient armbands were scanned and only 86% of medication labels were scanned.¹⁰ Many reports submitted through PA-PSRS suggest that some medications and patient armbands continue to not be scanned.

A nurse found Brevibloc® (esmolol) to be infusing instead of a heparin infusion as ordered. Heparin was ordered to be resumed, and the nurse started wrong infusion. The nurse did not scan medication.

Nurse connected peripherally inserted central catheter line to central venous pressure transducer as ordered but used a heparin flush bag on patient with HIPA (+) [sic] history instead of normal saline flush. Nurse did not scan heparin bag into [BCMA] prior to administration so allergy alert could not fire.

Phenylephrine drip [was found] infusing at 35 mL/hour instead of ordered insulin drip at 7 units/hour (35 mL/hour). When hanging new bag of insulin, nurse failed to scan bar code into [BCMA] and hung wrong medication. There was no adverse effect to blood pressure or glucose noted.

Altace® (ramipril) was given in the morning by the nurse but was not scanned or documented into [BCMA] system. Later, another nurse noted that the medication was still profiled for administration on [BCMA], and she also administered the medication, which resulted in an extra dose error.

The patient’s bedtime medications were given but were not immediately recorded into the [BCMA] system because the nurse was suddenly called to a code blue elsewhere. Another staff member, in an effort to assist, checked to see if the patient’s medications were given, saw that they had not been scanned, and assumed they were not given. The medications were administered a second time at bedtime resulting in an extra dose.

Why practitioners choose not to use this technology when giving medications is a key question to ask in order to maximize the impact BCMA can have on medication safety. To determine the factors that influenced the bar-code verification undertaken by nurses during medication administration, one Dutch hospital asked the nurses why the bar-code system was not always used. The five most frequently cited reasons for not verifying bar codes were difficulties in scanning bar codes on the medication labels, lack of awareness of bar codes on medication labels, delays in responses from the computerized system, shortage of time, and administration of medication before prescription.¹¹

Workarounds and Overrides

A workaround is a method of accomplishing an activity when the usual system/process is not working well.¹² While a workaround provides a temporary solution to the immediate problem, it is also an indication that the system may need improvement. To save time, nurses may work around the safety features

of a BCMA system. For example, nurses may type the patient's Social Security number (which can be used as a patient identifier) into the system rather than scanning the patient's wristband. This avoids perceived difficulties (e.g., a damaged bar code, the curvature of the band on patients with small wrists) in scanning the wristband. Other examples of workarounds used to identify patients include keeping a second set of printed patient wristbands on a ring for scanning in the medication room or patient bedside or affixing the patient wristband to the bedside rather than on the patient to expedite scanning (e.g., when a new IV bag is hung and the patient is asleep).

Like automated dispensing cabinets (ADCs), BCMA systems allow overrides in case medications need to be administered in an emergency. All caregivers administering medications must understand that using an override bypasses the important safety checks. One workaround identified by the Institute for Safe Medication Practices (ISMP) that led to an error involved an order for digoxin elixir, which was stocked on the patient care unit as a 60 mL (0.05 mg/mL) multidose bottle (the usual dose is 0.125 to 0.25 mg [2.5 to 5 mL]).¹³ The nurse misinterpreted the dose of digoxin elixir as 60 mL. In addition, she accidentally retrieved a bottle of doxepin (an antidepressant) from unit stock and attempted to administer a 60 mL dose of what she thought was digoxin. Scanning the bar code on the bottle of doxepin generated an error window on the electronic medication administration record screen stating "drug not on profile," but the nurse did not investigate the warning. Instead, she manually entered the doxepin national drug code (NDC), overriding the digoxin NDC that had been entered by the pharmacy. The result was administration of 60 mL doxepin to the patient.

Another example of a workaround includes a failure to scan every tablet or capsule included in a patient's dose. A number of reports have been submitted by Pennsylvania facilities that illustrate this at-risk behavior.

A nurse withdrew the incorrect amount of Dolophine® (methadone) tablets from the ADC and administered the medication. The nurse scanned one tablet and manually entered the prescribed dose in [BCMA] instead of scanning each individual tablet until the total prescribed dose was obtained.

Risk Reduction Strategies

New technology will not be a panacea for medication errors, but it can provide safeguards not possible with fully manual processes. Organizations may consider some of the following steps to maximize BCMA's impact on medication safety.

- Analyze BCMA logs, and evaluate all overrides to identify system weaknesses and areas in need of process improvement.

Failure Modes in the BCMA Process

Examples of failure modes that can occur during the bar-code medication administration (BCMA) process include the following:

- Medication does not come packaged as bar-coded unit-dose product
 - Pharmacy does not scan products arriving in pharmacy for readability
 - Pharmacy applies correct label with bar code to wrong product
 - Drugs not available in ready-to-use unit-doses for nurse (e.g., tablets not broken in half)
 - Nurse fails to scan patient
 - Nurse fails to scan medication
 - Bar code on patient and/or medication is unreadable
 - Patient wristbands are not on patients but other locations (e.g., clipboards, med rooms)
 - Nurse overlooks alert displayed on computer screen
 - Nurse overrides alert without investigating its cause
-
- Monitor and measure compliance with the technology to identify and remove any barriers to the safe and appropriate use of BCMA.
 - Conduct focus groups and satisfaction surveys to solicit nursing feedback.
 - Conduct executive rounds and direct observation of medication administration to help identify and correct workarounds. Keeping an open door policy will allow staff opportunities to discuss barriers and workarounds. The nurse executive should encourage staff participation in the continuing process improvement activities that follow the implementation period.¹⁰
 - Dispense patient-specific doses with bar codes whenever possible. This includes half tablets, oral syringes that contain the exact dose of an oral solution, and IV syringes that contain the patient's exact dose.
 - Scan all medications upon arriving in the pharmacy to verify that the bar code is part of the current database, and scan medications before dispensing.
 - Develop a mechanism to alert pharmacy when there is a problem scanning medications on the patient care units.
 - Computer screens that display patient information, including allergies and medication lists, should be positioned so that they can be easily viewed and read by nurses.

- Bar-code label equipment, including printers and batteries, must be continually checked for accuracy and readability and undergo routine preventive maintenance by information technology (IT) or biomedical staff.¹³
- Do not have healthcare clinicians view the verification that BCMA provides as a nice but unnecessary feature. The alerts that arise from the system should not be allowed to be bypassed without serious consideration. For every error like those described above, many more have been prevented because BCMA has been employed. There is little doubt that BCMA can save lives if properly implemented and used appropriately.
- For those organizations that plan on introducing BCMA into their facilities, conduct a readiness assessment or other proactive risk assessment to gain commitment and create enthusiasm for BCMA, identify challenges and plan accordingly, and remedy process problems before implementation. A bar-code readiness assessment tool is available free of charge from ISMP. To obtain a copy, visit: <http://www.ismp.org/selfassessments/barcoding.asp>.
- Establish a multidisciplinary team, including nursing, IT, and pharmacy staff, as well as frontline practitioners, to determine best practices and guide implementation.

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Cohen Receives 2008 Eisenberg Award

The editorial staff of the *Pennsylvania Patient Safety Advisory* congratulate Michael Cohen, RPh, MS, ScD, for receiving the 2008 John M. Eisenberg Patient Safety and Quality Award for individual achievement. The National Quality Forum and the Joint Commission recognized Cohen for “his life-long professional commitment to promoting safe medication use and a safe medication delivery system.” Cohen, president of the Institute for Safe Medication Practices, which together with ECRI Institute produces the *Advisory*, also serves as an advisor for the quarterly publication. More information about him and the other Eisenberg honorees is available from the Joint Commission press release at http://www.jointcommission.org/NewsRoom/NewsReleases/nr_09_25_08.htm.

Tubular Dressing Retainer: Retention without Restriction

ABSTRACT

Tubular dressing retainers are commonly used to apply and hold dressings, creams, and other devices in place. However, improper application of the retainer and use of incorrect size, especially on digits, has caused harm to patients. Injury can occur if the tubular dressing retainer is mistakenly used as the gauze dressing, especially if multiple layers are applied with multiple turns. Since June 2004, PA-PSRS has received two reports indicating circulatory compromise to digits with tubular dressing retainer application. Additionally, the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database revealed events of vascular complications following application of tubular retention dressings on digits including the thumb. Although a small number of cases were reported in the MAUDE and PA-PSRS databases, the events described indicated significant harm to patients, including amputation of digits. Facilities may reduce harm to patients by implementing processes to improve the safety of tubular retention dressings. An inventory of tubular dressing retainers in a facility can help target strategies to be implemented. Education for physicians, nurses, and other healthcare providers involved in the application of these dressings is essential. Patient education and instructions regarding these dressings are necessary to reduce harm. (Pa Patient Saf Advis 2008 Dec;5[4]:127-9.)

Improper application and use of the incorrect tubular dressing retainer size can cause significant harm to patients. A review of the PA-PSRS and U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) databases identified cases of circulatory compromise associated with application of these dressing retainers. The reports identified in the databases described patients experiencing increased pain after application of the dressing and failure to seek further medical treatment, resulting in amputation of digits. Dressing retainers must be used properly for safe, high-quality patient care.

Reports of Patient Harm Associated with Use of Tubular Dressing Retainers

PA-PSRS

Since June 2004, PA-PSRS has received two reports indicating problems with tubular dressing retainers. The reports indicated that the patient's circulation was compromised due to use of incorrect size and improper application of the dressing. The reports below illustrate harm to patients.

[Patient] came to the emergency department (ED) for laceration of finger. [The laceration was] treated

and [patient was] released. [The patient] returned for dressing being wrapped too tight. The wound assessment identified the wound to be healing satisfactorily. The finger was dressed with the wrong dressing size; tubular dressing retainer size 1 had been used as the dressing. [emphasis added] It was meant to be used as a single strip to hold the actual dressing in place. The area [appeared necrotic], requiring amputation of the finger tip.

The patient [was seen in] the ED for cuts on two fingers. [Patient] presented again [a few] days later with impaired vascular status of digits. The wrong dressing was used: tubular dressing retainer size 1. This was meant to be a single strip to hold the actual dressing in place; instead, it was used as the dressing. It got tighter with each successive application and turn of the metal ring. The patient was referred to a plastic hand [specialist] for surgery. The patient is currently undergoing physical therapy.

MAUDE

A search of the MAUDE database using the keyword search term "tubular dressing retainer" revealed five reports between 1992 and 1998 describing events of vascular complications following application of tubular dressing retainers on digits including the thumb. Similar to the PA-PSRS reports, the MAUDE reports describe patients complaining of increased pain during a two-to-three-day period after application of the dressing retainer. Removal of the dressing and reassessment of the wound did not occur until several days after the dressing was applied, despite early onset of pain. Vascular compromise was identified during reassessment, and symptoms ranged from discoloration of the digit to permanent disability and, in some cases, amputation of the digit.

Dressing Retainers

Dressing retainers are a valuable tool for wound care procedures. They are made of conforming, hypoallergenic, nonlatex, elastic material. The dressing retainers have built-in windows that afford a view of the primary dressing and are available in a variety of sizes adjusted to the circumference of different body parts.¹⁻³

Tubular dressing retainers are easy to apply and remove. When properly applied, they are convenient and conform well to the shape of the bandaged part. When the proper size is used, they are comfortable for the patient.¹ Dressing retainers are designed to keep dressings, creams, intravenous lines, and devices (e.g. splints) in place without causing discomfort to the patient. Tubular dressing retainers are to be applied in a single layer; they are not to be used as the tubular dressing itself. Retention dressings eliminate the need for adhesive tape, which is a benefit for patients who

have friable or sensitive skin.³ Tubular dressing retainers should not be used to apply pressure or be applied to edematous limbs. Dressing retainers are made of elastic, which does not provide compression but secures dressings. They do not provide support and will not help in shifting fluid.²

Circulatory Compromise

A literature search revealed a limited number of articles and cases associated with tubular dressing retainers. Events involving these dressings appear infrequently in the literature and reporting systems, yet there is potential for significant harm to patients (i.e., compromised circulation requiring amputation). Circulatory compromise has been attributed to using the incorrect size and improper application of tubular retention dressings onto digits.^{1,4} Complications are the result of a tourniquet-type effect and occur due to application of the incorrect size, application of too many layers, and rolling or bunching of dressing elastic. Rolling occurs when the edges of the dressing roll together to form a constricting ring. Bunching occurs when the dressing bunches at the base of digits to produce a tourniquet effect.^{1,2,4}

Complications include the following:⁴

- Pain
- Edema
- Cyanosis
- Necrosis
- Amputation of digits

Risk Reduction Strategies

Facilities may reduce harm to patients by implementing processes to improve the safe use and application of tubular dressing retainers. Proficient bandaging skills are essential to reduce the risk of increased discomfort and pain or further injury.² Facilities should check the type of tubular dressing retainers stocked and used within the hospital. Education for physicians, nurses, and other healthcare providers involved in the application of these dressings should include correct application and awareness of the mechanisms that may result in complications. Finally, patient education and instructions regarding these dressings are necessary to reduce harm.

Inventory assessment is conducted to identify the availability of tubular dressing retainers and to determine what departments use the dressing. Department

managers can assess type and sizes of tubular retention dressings stocked in their area. An inventory can prompt managers to reevaluate the use of retention dressings and assess the appropriate sizes to stock. Establishing adequate stock and assigning appropriate staff to ensure that adequate supplies are available can reduce the risk of staff using the incorrect size. Additionally, with multidisciplinary input, facilities can determine which departments are appropriate to stock the dressings and to provide education to all staff applying the dressings.

Staff education involves all healthcare providers using the dressings. A small reminder card may be attached to the tubular dressing retainer box, clearly posted in the storage areas where the dressings are located, and/or can be easily carried by practitioners who use these dressings (see “Accompanying Patient Safety Tool”).

Include the following points when educating staff:

- Choose the appropriate size for the anatomical area.^{1,2,4}
- Because manufacturers’ recommendations may not always be reliable, use clinical judgment and common sense when choosing the appropriate size.⁴
- Apply only *one* layer of tubular dressing retainer to secure the dressing over the wound.¹
- Apply retention bandages from joint to joint to prevent tightness and discomfort.²
- Provide healthcare workers the opportunity to practice applying the dressing to different anatomical areas on each other.
- Require an annual retraining for staff applying tubular dressing retainers.

(Refer to the Figure for correct application of tubular dressing retainers.)

Figure. Correct Application of Tubular Dressing Retainer



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Accompanying Patient Safety Tool

Visit the Pennsylvania Patient Safety Authority Web site to view or obtain “Tips for Application of Tubular Dressing Retainer,” a quick reference card based on this article that can be carried by practitioners who apply tubular dressings or kept with the materials.

Patient education is a fundamental component to prevent harm from retention dressings. The majority of patients with tubular retention dressings are cared for in an outpatient setting. Patients will need to be made aware of signs and symptoms of problems and what to do if they occur. The following points are pertinent for written instructions provided to the patient:

- Elevate the bandaged extremity above heart level for the first 24 hours to decrease swelling.¹
- Examine exposed skin surrounding the retention dressing for color and temperature.¹
- Remove tubular dressing immediately in response to increased pain, and seek emergency care.¹

Tubular dressing retainers provide an easy method to secure nonadhesive dressings, especially on difficult anatomical areas such as digits, chins, knees, and elbows. When properly applied, the dressing retainer

promotes healing and provides patient comfort. However, when these dressings are applied inappropriately, they can cause significant harm to patients. Proper education to healthcare workers and understandable instructions to patients are strategies facilities may implement to reduce the risk of harm to patients.

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Surgical Site Markers: Putting Your Mark on Patient Safety

ABSTRACT

During the PA-PSRS preventing wrong-site surgery initiative, several inquiries were received regarding the performance and sterility of surgical site marking pens. The majority of surgical site marking pens contain gentian violet ink, which has antifungal properties. Other types of marking pens used by some hospital staff to mark surgical sites are permanent ink markers and, infrequently, ballpoint pens. The surgical site mark should not be easily removed with skin preparation but should not be so permanent as to last weeks or months after the surgical procedure. Three studies describing the performance of pens or markers used to mark surgical sites were reviewed. None was conclusive in determining the best performance of marks on skin when used with skin prep solutions. Also reviewed were three studies that described the sterility of single-use surgical site marking pens and two studies that looked at cross-contamination from surgical site marking pens used on multiple patients. Based on the results of each sterility study, no infection or contamination was observed from single-use pens; however, the potential exists for cross-contamination from pens used on multiple patients. The results of the reviewed studies are not definitive as to the type of surgical site marking pen or the type of skin prep solution to use to obtain the optimal mark at the surgical site. Healthcare facilities may wish to conduct their own studies of surgical site markers and/or skin prep solutions to determine performance between markers and skin prep solutions. (Pa Patient Saf Advis 2008 Dec;5[4]:130-5.)

Introduction

As part of its accreditation program, the Joint Commission established the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.TM Included in the protocol is marking the surgical site for procedures involving incisions, percutaneous punctures or insertions with respect to laterality (e.g., right/left distinction), levels (e.g., spine), or multiple structures (e.g., fingers, toes).

During the PA-PSRS preventing wrong-site surgery initiative, several healthcare facilities inquired about the performance and sterility of surgical site marking pens. Facilities were looking for information regarding the permanence of the mark when the skin has been prepared with a prep solution (e.g., Betadine®, alcohol) and infection issues with the use of the pens. A literature search found several studies evaluating the performance and sterility of surgical site marking pens. The information discussed below does not provide definitive conclusions but may provide

healthcare facilities with some insight in evaluating surgical site marking pens.

Marking Ink Composition

Gentian violet ink is water-based and is the predominant ink used in surgical site marking pens. Gentian violet has antifungal properties and has been used as a topical treatment for some types of fungus infections such as oral thrush,¹ a type of yeast infection.

Skin marking pens are classified by the U.S. Food and Drug Administration (FDA) as Class 1 medical devices.² According to FDA, Class 1 devices present minimal potential for harm.² As Class 1 medical devices, the markers are exempt from FDA premarket clearance (i.e., FDA clearance is not required before marketing the device). However, manufacturers of Class 1 devices are required to register with FDA.

There have been anecdotal reports, including one study described below, of some surgical facilities using permanent ink markers (e.g., Sharpie®)⁶ or ballpoint pens for marking surgical sites. Many of these permanent ink markers comply with the nontoxicity American Society for Testing and Materials D4236 standard for art materials; however, they are not necessarily cleared by FDA for direct skin use, nor have they been cleared or registered with FDA for use as surgical site marking pens.

The Association for periOperative Nurses (AORN) recommends using only nontoxic skin markers registered with FDA to mark the surgical site.³ AORN also recommends checking the marker label because some manufacturers sell markers for use on skin (i.e., surgical site markers) and markers for utility use (e.g., labeling medications).³

Surgical Site Marker Performance

One of the main issues associated with use of skin markers is the permanence of the mark (i.e., whether the mark will be visible after skin preparation to identify the appropriate surgical site). Ideally, the mark should not be easily removed when prepping the skin with a prep solution so that the mark is not visible before the time-out and the first incision. But, the mark should not be so permanent as to last weeks or months after the surgical procedure and may be an inconvenience or cause for embarrassment to the patient (e.g., facial markings on a patient undergoing plastic surgery).

Few published studies evaluate the performance of surgical skin marking inks or pens. One study (Mears et al.) compared the effects of two skin prep solutions (chlorhexidine and iodine povacrylex combined with isopropyl alcohol) on skin markings.⁴ Mears et al. examined the effects of skin prep solutions

on a permanent ink marker (e.g., Sharpie), not on skin markers specifically marketed for surgical site marking.

In the Mears et al. study, three skin flaps were harvested from the thighs of male cadavers. Twenty random three-letter combination marks were made on the skin flaps using the permanent ink marker. The marks were allowed to dry for approximately 15 seconds before applying the prep solutions; half the skin flaps were prepped with chlorhexidine, and half were prepped with iodine povacrylex and isopropyl alcohol. The chlorhexidine was applied using forward and backward strokes lasting 30 seconds, while the iodine povacrylex and isopropyl alcohol were applied in a single layer without scrubbing. The solutions were allowed to dry for approximately three minutes. Photographs of the marks were taken before and after the prep solutions were applied to the skins. The photographs were shown to 10 surgeons, separately, and each surgeon was asked to write down the letters in each photograph.⁴

The results of the study demonstrated that the chlorhexidine solution was 21.8 times more likely to erase the mark than the iodine povacrylex and isopropyl alcohol solution.⁶

Another study (Stromberg) compared 13 commercially available surgical site marking pens.⁵ All the pens contained gentian violet ink with varying tip widths. Stromberg evaluated the ability to make an easily discernable mark, assessed the performance of marking clarity after a one-year storage interval of the pens, and evaluated the effects that degreasing the skin had on the marking performance of the pens.

Four areas of the skin of a volunteer subject were used to assess the performance of the marking pens. One area of skin was not prepped, one area was prepped with povidone-iodine solution, one area was prepped with 3% hexachlorophene, and one area was prepped with 4% chlorhexidine gluconate. All areas were prepped in accordance with the instructions from each prep solution's respective supplier. After prepping the areas, marks were made on the volunteer's skin. Note that marking the surgical site is typically performed before applying the skin prep solution; however, for this study, the mark was made after the prep solution was applied to the skin, which the author does not explain. After storing the pens for one year, the testing was repeated. To determine the effects of degreasing, the skin was degreased with alcohol or acetone, marks were made on the skin, and then the skin was prepped similarly to the methods described above.

Stromberg observed that for the unprepped and prepped areas over the one-year period, the majority of pens performed uniformly well while a few pens performed poorly. One brand of pen did not produce a discernable mark during any of the testing. Stromberg also noted that a skin prep solution containing soap (3% hexachlorophene containing a synthetic

detergent) left a residue, which made marking more difficult.⁵ The length and clarity of the markings were not attributed to the ink used (all the pens used gentian violet ink), but differences in the marker tips affected the amount and ease of ink application.⁵ However, the performance level for the specific tip types was not described in the study. Testing also demonstrated that degreasing the skin before applying the marks did not appreciably reduce the visibility of the marks on the skin.⁵

A third study (Tatla et al.) evaluated six marking pens from various suppliers to determine their relative permanence and their ability to withstand surgical skin prep solutions.⁶ The specific ink used with each pen was not described, however. Testing was performed using chlorhexidine gluconate and povidone iodine skin prep solutions.

The forearm of a volunteer was used to assess the performance of the pens. Each marked area of the volunteer's forearm skin was cleaned with the prep solutions for a period of 60 seconds. The results demonstrated that the majority of the pens performed poorly when used with chlorhexidine gluconate and moderately well when used with povidone iodine.⁶

Sterility of Surgical Site Markers

Another concern of some surgical facilities has been the potential contamination of the surgical site from surgical marking pens. A search of the literature regarding the sterility of surgical marking pens revealed some anecdotal reports of infections attributed to marking pens used on only one patient (single-use) and reports of pens used on more than one patient (multiuse). The literature search revealed the following studies that assessed the sterility of surgical and nonsurgical marking pens on skin:

Cullan et al. evaluated the sterility of surgical marking pens on the skin of surgical wounds.⁷ Thirty patients having upper extremity surgery were included in the study. Half of the intended incision length for each surgical site was marked, with a nonsterile surgical marking pen, based on the Joint Commission guidelines for surgical site marking. Each upper extremity was prepped with iodine povacrylex and isopropyl alcohol using a "standard" surgical method.⁷ A single incision was made starting in the unmarked area through to the marked area of each extremity. Separate cultures were taken from the unmarked and marked areas. Sixty cultures were taken in all. After 72 hours, the cultures were analyzed; the analysis revealed no positive results.

Tenenhaus et al. examined the sterility of surgical marking pens (used and new markers) and nonsurgical, permanent marking pens (e.g., Sharpie). Cultures were taken of all markers and were reviewed every 48 hours for a one-week period.⁸ All cultures were negative for bacterial growth. The authors theorized that bacterial growth did not occur because the pens

specifically marketed for surgical site marking are typically sterilized by the manufacturer and shipped in sterile packages. Additionally, the authors believed that the pens containing gentian violet ink most likely demonstrated no bacterial growth because gentian violet ink is recognized as an antiseptic agent, whereas the permanent marking pens most likely demonstrated no bacterial growth due to the pens' high alcohol content.⁸

Cronen et al. evaluated the sterility of a surgical marking pen used on 20 volunteers. The upper extremities of each volunteer were chosen as the marked sites; one arm of each volunteer was used as the marked site, and the other arm of each volunteer was used as the unmarked (control) site. The authors used a typical surgical site marker for the experiment. The same marker was used for all volunteers. Each arm was prepped in a "standard" preoperative method of a 7.5% povidone-iodine scrub followed by 10% povidone-iodine paint. Cultures were taken of the unmarked and marked sites of each volunteer. A total of 41 cultures were collected, and after three days, no bacterial growth was observed in any of the cultures.⁹

Cross-Contamination of Surgical Site Markers

A more important sterility issue for healthcare facilities may be cross-contamination between patients from use of surgical marking pens on more than one patient. Two studies looked at the potential for cross-contamination in this manner.

One study (Ballal et al.) examined the potential for cross-contamination from two types of marking pens, not specifically marketed as surgical site markers, with each type containing different alcohol

concentrations. The authors wanted to determine the risks of cross-infection of the two markers over different time intervals.¹⁰

The study included 24 dry white-board markers with 75.5% alcohol concentration and 24 permanent markers with 60% alcohol concentration. Twenty-four patients, undergoing various elective surgeries, were divided into two groups. Included in the 24 patients were 4 patients with methicillin-resistant *Staphylococcus aureus* (MRSA)-positive ulcers. Each patient was marked with a dry white-board marker and a permanent marker. After marking the patients, the tips were then used to inoculate blood agar plates at different time intervals. Inoculation for the pen tips used on the first group (group A) occurred at 0 and 3 minutes, and the pens used on the second group (group B) occurred at 0 and 10 minutes. As a control, 24 new dry white-board and 24 new permanent markers were used to inoculate blood agar plates without any contact with the patients. The markers used as the control did not show any bacterial growth.

The authors observed that immediately following inoculation (0 minutes) 96% of the dry white-board markers showed positive growth for microorganisms while 29% of the permanent markers showed positive growth. Upon examination at 3 minutes and 10 minutes, all dry white-board markers remained positive for microorganisms, while microorganism growth decreased to 17% and 0%, respectively, for the permanent markers. The MRSA-positive sites stayed positive for MRSA for the dry white-board and permanent marker pens up to 3 minutes and stayed positive at a 10-minute interval for the dry white-board pens.

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Table 1. Included Performance Studies and Key Results

STUDY	YEAR PUBLISHED	SURGICAL MARKING PEN	NONSURGICAL MARKING PEN	PREP SOLUTION	RESULT
Stromberg	1987	✓		Povidone-iodine Hexachlorophene Chlorhexidine gluconate	Majority of pens performed similarly well. A few pens performed poorly. Hexachlorophene-containing synthetic detergent left residue, which made marking more difficult.
Tatla et al.	2001	✓		Povidone-iodine Chlorhexidine gluconate	Majority of pens performed moderately well with povidone-iodine. Majority of pens performed poorly when used with chlorhexidine gluconate.
Mears et al.	2008		✓ (permanent ink marker [e.g., Sharpie®])	Iodine povacrylex and isopropyl alcohol Chlorhexidine	Chlorhexidine was 21.8 times more likely to erase the mark than iodine povacrylex and isopropyl alcohol.

Sources: Stromberg BV. The surgical marking pen: a comparative study. *Plast Reconstr Surg* 1987 Jul;80(1):104-7; Tatla T, Tehrani HY, Shibu M. Preoperative surgical skin marking in plastic surgery. *Br J Plast Surg* 2001 Sep;54(6):556-7; Mears SC, Dinah AF, Knight TA, et al. Visibility of surgical site marking after preoperative skin preparation. *Eplasty* [online]. 2008 Jul 16 [cited 2008 Sep 3]. Available from Internet: http://www.eplasty.com/index.php?option=com_content&task=view&id=218&Itemid=36.

Table 2. Included Sterility Studies and Key Results

STUDY	YEAR	SURGICAL MARKING PEN	NON-SURGICAL MARKING PEN	METHOD	RESULT
Contamination					
Cullan et al.	2007	✓		Observed potential contamination of surgical marking pens on surgical wounds of 30 patients undergoing upper extremity surgery.	The outcome of 60 cultures was negative for bacterial growth 72 hours after inoculation on blood agar plates.
Tenenhaus et al.	2006	✓	✓	Observed potential contamination of surgical and nonsurgical marking pens taken from preoperative holding areas and operating rooms from three medical facilities.	All cultures were negative for bacterial growth after observations every 48 hours for a 1 week period.
Cronen et al.	2005	✓		Observed potential contamination of surgical marking pen on 20 volunteers.	All cultures were negative for bacterial growth 72 hours after inoculation on chocolate, blood, and MacConkey agar plates.
Cross-Contamination					
Ballal et al.	2007		✓	Observed potential for cross-contamination of nonsurgical marking pens on 24 patients, including 4 patients with methicillin-resistant <i>Staphylococcus aureus</i> - (MRSA-) positive ulcers, undergoing various elective surgeries.	<p>Cultures were positive for bacterial growth:</p> <ul style="list-style-type: none"> ■ 0 minutes following inoculation <ul style="list-style-type: none"> —96% of dry white-board markers —29% of permanent markers ■ 3 minutes following inoculation <ul style="list-style-type: none"> —100% dry white-board markers —17% permanent markers ■ 10 minutes following inoculation <ul style="list-style-type: none"> —100% dry white-board markers —0% permanent markers <p>MRSA:</p> <ul style="list-style-type: none"> ■ 0 minutes following inoculation <ul style="list-style-type: none"> —100% dry white-board markers —100% permanent markers ■ 3 minute following inoculation <ul style="list-style-type: none"> —8% dry white-board markers —8% permanent markers ■ 10 minutes following inoculation <ul style="list-style-type: none"> —8% dry white-board markers —0% permanent markers
Wilson et al.	2006	✓	✓	Observed potential for cross-contamination of MRSA between patients. A line from each surgical and nonsurgical pen was drawn onto bacteriologic plates containing MRSA. Each pen was then used to draw an arrow onto blood agar plates at various intervals after inoculation.	MRSA did not survive after 3 weeks from inoculation on the surgical marking pens nor did it survive after 15 minutes from inoculation of the nonsurgical marking pens

Sources: Cullan D, Wongworawat M. Sterility of the surgical site marking between the ink and the epidermis. *J Am Coll Surg* 2007 Aug;205(2):319-21; Tenenhaus M, Bhavsar D. Do marking inks pose an infection risk? A surgeon's perspective. *Surg Inf* 2006 Oct 1;7(5):481-3; Cronen G, Ringus V, Sigle G, et al. Sterility of surgical site marking. *J Bone Joint Surg Am* 2005 Oct;87-A(10):2193-5; Ballal MS, Shah N, Ballal M, et al. The risk of cross-infection when marking surgical patients prior to surgery—review of two types of marking pens. *Ann R Coll Surg* 2007 Apr;89(3):226-8; Wilson J, Tate D. Can pre-operative skin marking transfer methicillin-resistant *Staphylococcus aureus* between patients? A laboratory experiment. *J Bone Joint Surg Br* 2006 Apr;88(4):541-2.

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The authors noted that even though the dry white-board pens contained a higher concentration of alcohol than the permanent marking pens, they posed a greater risk of cross-contamination from one person to another when used within 10 minutes between patients than the permanent marking pens.¹⁰

Another study (Wilson et al.) evaluated the potential for marking pens to transmit MRSA between patients. The study included 31 marking pens specifically marketed for surgical site marking and 30 permanent marking pens not marketed for surgical site marking. A single line was drawn using each pen onto bacteriologic plates containing MRSA as a standardized contamination inoculum for each pen. Each pen was then used to draw an arrow onto blood agar plates at intervals of 0, 5, 15, and 60 minutes; 24 and 48 hours; and 1, 2, and 3 weeks after inoculation.¹¹

Results showed that MRSA did not survive on the permanent marking pens after 15 minutes from inoculation; however, the MRSA survived up to 3 weeks on the surgical marking pens. The authors theorized that MRSA did not survive on the permanent marking pens because the ink contained isopropyl alcohol and ethanol but was able to survive on the surgical marking pens because the ink contained water as the main solvent.¹¹

Conclusions

Healthcare facilities use a variety of marker types to mark surgical sites. Based on the results of our literature review, pens specifically marketed for marking surgical sites appear to be more prevalent, but some surgical facilities have used standard permanent markers (e.g., Sharpie), or even ballpoint pens,³ to mark sites. Our search identified no head-to-head clinical studies comparing the safety of different markers. Since gentian violet ink must undergo the FDA clearance process, facilities may be more compelled to use surgical marking pens containing gentian violet ink than standard permanent markers, which are not cleared by FDA.

The performance studies described above are inconclusive in determining the optimal permanence of marks when using skin prep solutions. The studies are not directly comparable because they did not use the same types of ink or the same skin prep solutions, although there was some overlap. Additionally, based on Stromberg's observations in the first study about performance described in Table 1, differences in permanence may be due more to the type of pen tip (e.g., narrow, wide) than to the ink, since all the pens used in that study contained gentian violet ink. Although not stated in the study, an assumption could be made that a wider tip pen would make a more permanent mark on the skin.

Based on the sterility studies described in Table 2, contamination or infection does not appear to be an

issue for single-use pens; however, cross-contamination may be problematic when the same pen is used on more than one patient, at the very least during short intervals between patients. The results of the cross-contamination studies described above suggest that facilities may want to consider using surgical marking pens for single-use only.

The studies above do not provide definitive conclusions as to the type of surgical marking pen or the type of skin prep solution to use to obtain the optimal mark at the surgical site. However, two studies described above (Mears et al., Tatla et al.) demonstrated that surgical site markings may degrade more easily with chlorhexidine solution than with povidone iodine or iodine povacrylex and isopropyl alcohol solution. To help assess which surgical skin marker and skin prep solution to use, some facilities have sought advice from surgical skin marker and/or skin prep solution manufacturers that may have unpublished performance data.

Editor's Note

As of press time, the editorial staff were made aware of another study (Burton et al.) that evaluated cross-contamination between patients from using the same surgical marking or nonsurgical marking pen on more than one patient. The study was presented at the October 2008 Interscience Conference on Antimicrobial Agents and Chemotherapy/Infectious Diseases Society of America annual meeting, held jointly by the American Society of Microbiology and the Infectious Diseases Society of America. The study has not been published; however, it has been described in mainstream medical news sources such as medpagetoday.com (<http://www.medpagetoday.com/MeetingCoverage/ICAAC-IDS/11440>). Burton et al. evaluated the potential for cross-contamination of strains of MRSA, Escherichia coli, vancomycin-resistant Enterococcus faecalis, and Pseudomonas aeruginosa from the tips of surgical marking pens containing gentian violet-based ink and nonsurgical permanent marking pens (e.g., Sharpie) containing alcohol-based ink. The Burton et al. study was excluded from the discussion above because the study details have not yet been published. Once the study is published, the topic may be addressed further.

Notes

1. Mayo Clinic. Gentian violet (topical route) [online]. 2008 Jan 1 [cited 2008 Aug 28]. Available from Internet: <http://mayoclinic.com/health/drug-information/dr600723>.
2. U.S. Food and Drug Administration. Device classes [online]. 2002 Nov 21 [cited 2008 Aug 29]. Available from Internet: <http://www.fda.gov/cdrh/devadvice/3132.html>.
3. Moore DT. Clinical issues: nurses administering propofol; OR temperature and humidity; OR internet use; OR cleaning; approved skin markers. *AORN J* 2004 Nov;80(5):929-34.
4. Mears SC, Dinah AF, Knight TA, et al. Visibility of surgical site marking after preoperative skin preparation. *Eplasty* [online]. 2008 Jul 16 [cited 2008 Sep 3]. Available from Internet: http://www.eplasty.com/index.php?option=com_content&task=view&id=218&Itemid=36.

5. Stromberg BV. The surgical marking pen: a comparative study. *Plast Reconstr Surg* 1987 Jul;80(1):104-7.
6. Tatla T, Tehrani HY, Shibu M. Preoperative surgical skin marking in plastic surgery. *Br J Plast Surg* 2001 Sep;54(6):556-7.
7. Cullan D, Wongworawat M. Sterility of the surgical site marking between the ink and the epidermis. *J Am Coll Surg* 2007 Aug;205(2):319-21.
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10. Ballal MS, Shah N, Ballal M, et al. The risk of cross-infection when marking surgical patients prior to surgery—review of two types of marking pens. *Ann R Coll Surg* 2007 Apr;89(3):226-8.
11. Wilson J, Tate D. Can pre-operative skin marking transfer methicillin-resistant *Staphylococcus aureus* between patients? A laboratory experiment. *J Bone Joint Surg Br* 2006 Apr;88(4):541-2.

CT Contrast Media Power Injectors Can Rupture Conventional IV Sets

ABSTRACT

PA-PSRS has received reports of intravenous (IV) tubing rupturing during contrast media injections into patients during computed tomography scans. Many of these occurrences result in contrast or blood and fluids contacting patients or staff. Similar events have also been reported to the U.S. Food and Drug Administration (FDA). Contact with contrast media or blood and fluid could result in harm to patients or staff. In addition, rupture of a set would cause delay or cancellation of the contrast study. Often, conventional IV tubing, which can easily rupture, is used to introduce the contrast media through a power injector, spraying contrast medium or blood and fluid onto patients or staff. FDA has developed guidelines to prevent harm to patients and staff during contrast injections, which include checking the labeling of each vascular access device for its maximum pressure and flow rates, knowing the pressure limit setting for the power injector and how to adjust it, and ensuring that the pressure limit set for the power injector does not exceed the maximum labeled pressure for the tubing or other vascular access device. (Pa Patient Saf Advis 2008 Sep;5[3]:136-7.)

Contrast media are sometimes used during computed tomography (CT) and magnetic resonance imaging scans to enhance the contrast between blood vessels and their surroundings, such as in angiograms.¹ Typically, a contrast medium is introduced into a patient's blood vessel via a power injector. Contrast power injectors are typically flow-rate controlled with user-adjustable pressure-limiting capability. The flow rate is dependent on solution viscosity, solution volume, pressure, and the cross-sectional area of the tubing. Often, the contrast is introduced through conventional intravenous (IV) sets (i.e., sets used with infusion pumps to deliver medication therapy), which may rupture if the injector pressures exceed the pressure tolerance of the IV set. A ruptured IV set can expose a patient or staff member to the contrast solution or blood and fluid, potentially resulting in harm. For example, contrast solution or blood sprayed into the eyes of a patient or staff member could result in burning of the eyes or cross-contamination, respectively. Between July 2004 and March 2008, 29 reports were submitted to PA-PSRS related to IV tubing rupturing during contrast media injection into patients. Below are descriptions of a few of the reports submitted through PA-PSRS.

The patient underwent a CT scan with IV contrast. The IV tubing ruptured and the patient was splashed in the eyes with the contrast.

The patient IV tubing split during power injection of contrast; contrast went all over the patient.

The patient was given [brand name omitted] IV contrast during a CT scan when the IV tubing ruptured. Members of the staff were sprayed with blood and fluid.

A Breakdown of the Problem

To prepare the patient for a contrast study, the clinician connects the power injector to the proximal end of the tubing. The distal end of the tubing is connected to a vascular access port, typically at a peripheral intravenous access site (e.g., the hand) on the patient. The contrast medium is then delivered to the patient. For CT scans, typical power injector peak pressures can be between 300 to 325 psi, but could exceed those pressures because of problems related to the patency of the access or some other obstruction.¹ Those pressures can exceed the maximum pressure tolerances of conventional IV sets, which can typically tolerate 10 or 15 psi for IV or epidural delivery, respectively.¹ Therefore, the higher pressures of power injectors can readily cause conventional IV tubing to rupture. Even when the conventional IV tubing has not been visibly damaged by the high pressures of the injector, the seals of the IV tubing connectors may become compromised, potentially causing leaks or air entrained into the IV sets.¹

Conventional IV sets are often used for contrast media injection as a matter of convenience. For example, some patients may already have an IV set connected to an access port (e.g., for medication IV therapy) before undergoing a contrast study. Using this existing set is convenient for clinicians because they do not have to create a new access site or disconnect the set from a catheter and connect a high-pressure set specifically designed for use with power injectors. However, using the existing set creates opportunities for the set to rupture or leak. The consequences of such occurrences could result in harm to patients or staff.

The U.S. Food and Drug Administration (FDA) has identified some consequences of ruptured IV sets, including IV set fragmentation, sometimes with embolization or migration requiring surgical intervention; extravasation of contrast media; loss of venous access requiring set replacement; and contamination of the CT room and personnel with blood and contrast media.² Another consequence is compromised patient therapy, brought about by reuse of a conventional set for IV therapy after contrast injection, in which the set may have sustained a leak due to the high pressure of the injector. Additionally, when IV tubing ruptures during injection, as demonstrated in the PA-PSRS reports above, contrast is sprayed or

spilled from the IV set, resulting in delay or cancellation of the contrast study.

FDA Reports of Ruptured IV Tubing

A search of FDA's Manufacturer and User Device Experience (MAUDE) database, using the keyword search terms "power" and "injector" and "ruptured," revealed 158 reports between 1996 and 2008 describing similar events of conventional IV tubing rupturing during contrast media power injection, some resulting in patient blood loss. Many of the manufacturer narratives from the reports concluded that conventional IV sets were used instead of the recommended high-pressure sets appropriate for use with power injectors.

FDA Prevention Guidelines

FDA has developed the following guidelines to prevent or minimize harm to patients or staff and, as a secondary benefit, to prevent damage from ruptured IV tubing or other venous access devices when used with power injectors:^{1,2}

- When possible, avoid the use of conventional IV tubing with contrast media power injectors.

- Check the labeling of each vascular access device for its maximum pressure and flow rates. If none are provided, assume that the device is not intended for use with power injectors and do not use it.
- Know the pressure limit setting for your power injector and how to adjust it.
- Ensure that the pressure limit set for the power injector does not exceed the maximum labeled pressure for the vascular access device, but is not too low so as to compromise the quality of the study.

Notes

1. ECRI Institute. A high-pressure situation: conventional IV sets can burst when used with CT contrast media injectors [hazard report]. *Health Devices* 2004 Mar;33(3):100-2.
2. U.S. Food and Drug Administration. Reminders from FDA regarding ruptured vascular access devices from power injection [online]. 2004 Jul 7 [cited 2008 Aug 29]. Available from Internet: <http://www.fda.gov/cdrh/medicaldevicesafety/tipsarticles/reminder-rvad.html>.

Multidrug-Resistant Organisms—Strategies to Reduce Infection

Multidrug-resistant organisms (MDROs) are defined by the Centers for Disease Control and Prevention (CDC) as “microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.”¹ The challenges faced by the infectious disease and infection control community are rising exponentially as antimicrobial agents lose efficacy. Prevention of the spread of these organisms within healthcare facilities is becoming more critical each day.²

History of MDROs

Strains of gram-positive bacteria, including *Staphylococcus aureus*, account for almost 60% of the healthcare-associated infections (HAIs) noted in a report on data from SCOPE, the Surveillance and Control of Pathogens of Epidemiological Importance program.³ Methicillin-resistant *Staphylococcus aureus* (MRSA) was first noted in the United States around 1968, and infection rates have steadily increased since then. By 2003, according to National Nosocomial Infections Surveillance (NNIS) system data, 59.5% of the *S. aureus* isolates in intensive care units (ICUs) were identified as MRSA.⁴ Additionally, vancomycin-resistant *Enterococcus* accounted for approximately 28.5% of the pathogens noted in the same NNIS report. MRSA strain USA300-0114, identified within the past few years, is seen with increasing frequency; it is the predominant cause of community-acquired soft-tissue skin infections.^{5,6,7}

Increasing resistance among the gram-negative bacteria (e.g., *Acinetobacter*, *Enterobacter*, *Klebsiella*, *E. coli*) and the subsequent clinical manifestations represent the tip of yet another dangerous iceberg for patients and healthcare providers alike. Extended-spectrum beta-lactamases are a group of enzymes produced by a number of gram-negative bacteria, with resultant resistance to beta-lactam antibiotics such as penicillin and cephalosporins. First detected in Germany in 1983, these organisms can exhibit resistance patterns for which no antimicrobial therapies exist.⁸ They add to the alphabet of ever-increasing numbers of MDROs, and the potential to cause HAIs is daunting. Identification, isolation, and additional precautions are critical to preventing patient-to-patient spread of MDROs within facilities.

PA-PSRS Reports

A search of the PA-PSRS database yielded more than 700 reports from 2004 through 2007 that indicated inconsistencies relating to isolation precautions and identification of patients who were positive for MDROs. Examples included patients admitted with a known history of MDRO infection, for whom isolation was not promptly initiated; attending physicians not wearing proper isolation garb; and properly gowned and gloved residents who entered and left the isolation room numerous times. In addition, reports

indicated that active surveillance culture specimens were collected but were sent to the lab without sufficient patient identification, which delayed the process for timely identification of an MDRO.

One report noted concern by a patient’s family members when they received conflicting instructions regarding their need to adhere to contact precautions as the patient was moved from the ICU to a medical-surgical unit. The family members indicated that the healthcare workers’ use of personal protective equipment, such as gowns and gloves, was inconsistent. The family reported that while some staff members did wear gowns and gloves, others did not—including a dialysis nurse who provided direct patient care. This report illustrates how inconsistencies and mixed messages to patients and their families can erode confidence in healthcare providers’ ability to deliver appropriate care and prevent the spread of MDROs. It also demonstrates the role patients and their families can play in enforcing isolation protocols when they understand the requirements.

Key Points of a Successful Transmission Prevention Program

Evidence-based practice incorporating risk reduction strategies is essential for acute, long-term, and ambulatory care settings to prevent, control, and ultimately eliminate MRSA and other MDROs.⁹ Successful infection control programs incorporate the following key concepts detailed in the Association for Professionals in Infection Control and Epidemiology’s “Guide to the Elimination of Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Transmission in Hospital Settings”:¹⁰

- A baseline *risk assessment* for MDROs as a means to determine the incidence among the patient population
- *Active surveillance cultures* for patient care settings as mandated by state regulation (Pennsylvania Act 52 of 2007 requires that hospitals develop procedures necessary for requiring cultures and screenings for nursing home residents admitted to a hospital, as well as procedures for identifying other high-risk patients admitted to the hospital.)
- Evaluation of colonized nursing home residents for prompt placement and initiation of facility-specific precautions
- A well-established *hand hygiene program* that includes readily available alcohol-based handrubs
- Prompt initiation of *contact precautions* for acute care patients with either a positive culture or a known history of positive cultures for MDROs
- An effective method to *communicate* a patient’s MDRO status across the healthcare continuum

Antimicrobial Stewardship Programs

Antimicrobial stewardship is a key component of a multifaceted approach to preventing the emergence of resistant organisms. Studies indicate that antibiotic use is unnecessary or inappropriate in as many as 50% of cases in the United States. Over the past five years, focus has increased on interventions intended to decrease bacterial resistance or reduce superinfection, including infections associated with *Clostridium difficile* colitis. Consistent cost savings, together with a reduction in resistance patterns, have been recognized after these interventions were instituted. It is documented that in most instances, changes in infection control procedures were implemented at the same time as the antimicrobial interventions, which would influence the success of these programs. Data from well-controlled studies relating to the effect that these programs have on resistance are somewhat limited, but documentation does exist that antibiotic stewardship reduces rates of *Clostridium difficile*-associated disease, resistant gram-negative bacilli, and vancomycin-resistant *Enterococcus* infection.^{1,2}

The most effective means of improving antimicrobial stewardship involves a comprehensive program that incorporates multiple strategies and collaboration among various specialties within a given healthcare institution. This program should be considered an important component of patient safety in every healthcare institution and may become mandatory in the future.

Suggested Elements of a Stewardship Program

The following elements of a multifaceted program, recommended by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America "Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship," should be considered and implemented:³

- Form a multidisciplinary antimicrobial stewardship team including
 - an infectious disease physician,
 - a clinical pharmacist,

- a clinical microbiologist,
- an infection preventionist, and
- an information system specialist.

- Develop collaboration between the team and the hospital's pharmacy and therapeutics committee.
- Demonstrate support of and collaboration with facility administration and medical staff (i.e., "buy in from the top down").
- Promote education in collaboration with active intervention.
- Develop evidence-based practice guidelines incorporating local resistance patterns and antibiotic usage.
- Institute formulary restriction policies, including determining which drugs are placed on hospital formulary.
- Institute policies for de-escalation of empirical antimicrobial therapy on the basis of culture results.
- Institute policies for dose optimization based on a case-by-case review, causative organism, site of infection, and drug characteristics.
- Develop clinical criteria and guidelines allowing a switch from parenteral to oral agents.
- Audit antimicrobial usage, which should be conducted by an infectious disease physician or a clinical pharmacist trained in infectious disease drug management, together with feedback.

Notes

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- A system to monitor staff compliance with contact precautions and hand hygiene
- A system to provide feedback and education to staff
- An environmental cleaning checklist/audit tool to prevent/control the spread of MDROs via surfaces and patient care equipment

National Approach to MDRO Prevention

CDC's Campaign to Prevent Antimicrobial Resistance in Healthcare Settings notes the growing struggle with MDROs and includes the critical need for judicious use of antibiotics (see box article on

"Antimicrobial Stewardship Programs") as one of four main strategies. The other strategies include the diagnosis and treatment of clinical infection, infection prevention, and transmission prevention. CDC's online campaign includes tools for clinicians in various clinical settings, such as fact sheets, posters, slide sets, and tips for patients. Additional information about the campaign is available online at <http://www.cdc.gov/drugresistance/healthcare/default.htm>.¹¹

CDC's National Healthcare Safety Network recently added an additional patient safety component: the combined MDRO and *Clostridium difficile*-associated disease (CDAD) module. By employing this module,

facilities may choose to document and/or monitor infections, prevalence, and prevention process measures or active surveillance testing related to either MDROs or CDADs.¹²

Pennsylvania Mandates

The Pennsylvania Health Care-Associated Infection and Prevention Control Act of 2007, Act 52, mandates that the following be implemented in healthcare facilities:

- Procedures for requiring active surveillance cultures and screenings for all nursing home residents admitted to a hospital
- Procedures for identifying other high-risk patients admitted to the hospital, using active surveillance cultures (High-risk patients are not defined by Act 52 of 2007 and are to be determined by individual hospitals.)
- Procedures and protocols for staff who have potentially been exposed to a patient or resident known to be colonized or infected with MRSA or MDRO, including cultures and screenings, prophylaxis, and follow-up care (To date, industry standards for exposure of staff to MRSA or MDRO are nonexistent.)
- Procedures and processes for notifying a receiving healthcare facility or ambulatory surgical facility of any patient known to be colonized before transfer within or between facilities

Active surveillance cultures in combination with isolation precautions and the use of barriers are consistent with most guidelines for the control of these microbes.¹³

For a description of the Pennsylvania Patient Safety Authority's role and progress and goals of Act 52, see the article in the June 2008 issue of the *Pennsylvania Patient Safety Advisory* at http://www.psa.state.pa.us/psa/lib/psa/advisories/v5n2june_2008/jun_2008_v5_n2_article_act52.pdf.¹⁴

Summary points of the Act are available online from the Hospital & Healthsystem Association of Pennsylvania at http://www.haponline.org/downloads/HAP_Summary_Act_52_of_2007_07262007.pdf.¹⁵

The call to action against MDROs is ongoing across Pennsylvania. Active government, community, and healthcare alliances are forming and working together to gain control and prevent the spread of these multidrug-resistant threats to patient safety.¹⁶ CDC's MDRO/CDAD module will be strongly considered for integration into the mandatory reporting requirements in the future, as an additional step towards best practices.

Summary

The emergence of increasing bacterial resistance to antimicrobial measures, rising infection rates in facilities, and subsequent clinical manifestations represents the tip of another iceberg for patients and healthcare providers. Commitment, sufficient funding, and sufficient staffing, as well as behavioral and cultural changes and modified thought processes, are necessary in regional and national efforts to eliminate MDROs.

Notes

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- Near-miss reports indicated participation in the time-out of more members of the OR team.
- The operating surgeon was more likely to encourage members of the team to speak up if concerned during the time-out and to respond to concerns raised in reported near misses than in reported wrong-site surgeries.

Because of the successful use of the common analysis form for wrong-site surgery, near misses, and actual occurrences in Pennsylvania, the wrong-site error analysis form has been posted on the Pennsylvania Patient Safety Authority's Preventing Wrong-Site Surgery Web page.⁶ PA-PSRS analysts encourage anyone faced with a wrong-site surgery near miss or occurrence in his or her facility to use the form to aid in the analysis.

Multiple Wrong-Site Surgeries of the Same Type at Multiple Facilities

PA-PSRS analysts looked at the 64 facilities that had reported more than one wrong-site surgery since reporting began in June 2004; 25 had some similarities within their multiple reports of wrong-site surgery, suggesting a problem with the facility's system or with an individual provider's behavior. Of those 25 facilities, 21 had multiple reports of problems that also occurred multiple times at other facilities, suggesting system problems rather than individual provider problems. The problems that occurred multiple times at each of multiple facilities were as follows:

- Local anesthesia blocks, nerve blocks, regional blocks, periorbital blocks, nerve root injections, epidural injections, and other injections were done at the wrong site 40 times in 17 facilities that made this wrong-site error more than once.
- Other wrong-site errors associated with eye surgery occurred four times in two facilities.
- Wrong-site ureteral procedures occurred four times in two facilities.
- Cervical spine fusions, other spinal fusions, and other spinal procedures were done at the wrong vertebral level 16 times in five facilities that made this wrong-site error more than once.

These results suggest that the greatest potential for system improvement to prevent wrong-site surgery is adherence to the Universal Protocol for preliminary anesthetic procedures⁴ and strengthening of the system for radiographic confirmation of the correct vertebral level during spinal surgery.⁷

Rationale for Surgeons to See Patients in the Preoperative Holding Area, Rather Than Initially Greeting Them in the OR

As noted above, a significant contributor to physician behavior that prevents wrong-site surgery is the surgeon's practice of participating in the preoperative verification of written documents with awake patients in the preoperative holding area so that potential

wrong-site errors based on misinformation (rather than misperceptions of right and left) are corrected before the patient enters the OR. Informational errors should be corrected before the patient reaches the OR, freeing up the very busy operating team to worry only about errors of misperception due to right-left confusion, confirmation bias, and other causes.

Before a panel on OR safety at the 2008 Clinical Congress of the American College of Surgeons, the author asked the surgeons in the audience whether they would see their preoperative patients in the holding area if they were not required to do so and, if so, why. Of 29 respondents, 27 said they would; 2 said they would not. Time constraint was the common reason for not seeing patients. One of the 27 surgeons now sees patients in the holding area because of a previous experience of performing a wrong-site surgery associated with the practice of not seeing patients before they entered the OR the day of the surgery.

Altogether, the 27 surgeons gave 51 reasons for voluntarily seeing their patients in the holding area. These reasons were grouped into several categories. The most common reasons cited were to provide psychological support for the patient: to reassure patients and their families and decrease their anxiety (12), to affirm the surgeons' rapport with their patients within the context of the doctor-patient relationship (7), to convey caring and concern for their patients (3), and to address concerns or questions of patients or their families (5). More than two-thirds (19) of the surgeons gave one or more reasons related to psychological support of patients and their families as their rationale for seeing patients in the holding area.

Two other groups of reasons were related to acquiring information. One group of reasons was associated with the review of information to avoid treating patients based on incorrect information from faulty memories: to review information relevant to the patient and procedure (11), to specifically check information while the patient was still alert (1), to check documents such as the consent form (2), and to mark the site (1). About half (14) the surgeons gave the opportunity to refresh their memories by reviewing information as a reason for seeing patients in the holding area. The other information-related reason cited was a desire to see whether patients' conditions had changed since they had last been seen, which might alter or even lead to cancellation of the procedure. Interest in checking for changes in patients' conditions (4) added another two surgeons to those who visited patients in the holding area to acquire information from alert patients before bringing them into the OR.

Other reasons centered around the surgeons' sense of the standard of care: visiting the patient preoperatively was part of the doctor-patient relationship, as noted above (7), represented best medical care (1), was a safe practice (3), or was safer than not visiting the patient, based on personal experience (1). About

40% of the surgeons indicated their belief that visiting patients in the holding area was, for them, the standard of care.

Surgeons appear to be motivated to see patients in the preoperative holding area. For 93% of the surgeons surveyed, the reasons fell into one or both of the following categories:

1. Providing psychological support to the patient and/or family
2. Reviewing and updating information

These positive motivations may encourage compliance with the most recent revisions of the Universal Protocol.⁴

Setting the Patients' Expectations

Properly following the Universal Protocol involves asking a preoperative patient the same questions repeatedly. Prompted by reports of hospitals that have informed patients about what to expect as a consequence of following the Universal Protocol, the Pennsylvania Patient Safety Authority has developed a brochure that surgeons or facilities can give to preoperative patients so that they understand why so many providers ask the same questions. Surgeons and facilities can download the brochure from the Pennsylvania Patient Safety Authority's Preventing Wrong-Site Surgery Web page.⁶ They can add their logos or contact information to personalize the brochure to their environment.

Ongoing Projects to Prevent Wrong-Site Surgery

This issue of the *Advisory* contains a review of the literature addressing the sterility of site marking and the potential for cross-contamination with use of markers on multiple sites. The review also looks at the performance of site markers with various skin prep solutions. Because the literature on this latter topic is inconclusive, PA-PSRS analysts will be surveying the experiences of Pennsylvania facilities that use surgical site markers with their skin prep solutions. Pennsylvania Patient Safety Officers are encouraged to help their OR managers to complete the survey when it is distributed in the near future. Also, others are encouraged to tell PA-PSRS analysts about their experiences using site markers (see the contact information below).

Two submissions have been made to the Time-Out in the OR Competition mentioned in the previous issue of the *Advisory*. The contest remains open to more entries (see "Enter the Time-Out in the OR Competition").

The Pennsylvania Patient Safety Authority is committed to preventing wrong-site surgery. Comments, suggestions, and specific inquiries are welcome from facilities with particular problems or questions concerning wrong-site surgery. Communications should be directed to John Clarke, MD, FACS, clinical director of the Pennsylvania Patient Safety Reporting System at ECRI Institute, by telephone at (610) 825-6000 or by e-mail at JClarke@ecri.org.

Enter the Time-Out in the OR Competition

Does your facility have a particularly good script for the time out in the operating room (OR)? If so, please enter the Time-Out in the OR competition. Here's what you have to do:

Write down your script for a Time-Out in the OR for Mary Jones' (MR# 007) Left Total Hip Replacement as if it were a Shakespearean play. For example:

Circulating nurse: "Time-out. We are doing a left total hip replacement on Mary Jones, medical record number 007; is that right?"

Surgeon: "Right."

Anesthesia provider: "Agree."

Submit the script in a Word document or its electronic text equivalent to JClarke@ecri.org.

The entries will be posted for peer review and comments. The winning entries will be determined by a vote of your peers, posted on the Pennsylvania Patient Safety Authority Web site, and profiled in an upcoming issue of the *Advisory*.

This is your opportunity to share your expertise with others.

Notes

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Online Resources Associated with Patient Safety Advisories

Patient Safety Officers have expressed their interest in distributing educational resources within their healthcare facilities. The Pennsylvania Patient Safety Authority provides a growing collection of resources related to *Pennsylvania Patient Safety Advisory* articles to help increase situational awareness and patient safety within healthcare facilities. Examples include sample policies, educational videos and posters, brochures, interactive learning graphics, and reference materials.

This collection of resources is available online at <http://www.patientsafetyauthority.org>. Topics addressed include the following:

- ▶ Preventing wrong-site surgery
- ▶ Verbal orders
- ▶ Contrast-induced nephropathy
- ▶ Expressed breast milk
- ▶ Hospital bed safety
- ▶ Skin tears
- ▶ Color-coded wristbands
- ▶ Common hazards in the behavioral health patient room

More improvement comes from improving a system than improving the performance of individuals within an existing system.



Whether you would like to learn more about the topics described above, or you need tools to help you meet other challenges, these educational resources can help.

If you would like additional information, please contact us at (866) 316-1070, or e-mail support_papsrs@state.pa.us.

PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS



The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI Institute, as contractor for the PA-PSRS program, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the PA-PSRS program or the Pennsylvania Patient Safety Authority, see the Authority’s Web site at <http://www.patientsafetyauthority.org>.



ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute’s expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.



The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a nonpunitive approach and systems-based solutions.