PENNSYLVANIA PATIENT SAFETY ADVISORY

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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 Authority, 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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Improving the Safety of the Blood Transfusion Process

ABSTRACT

Patient death or disability associated with incompatible blood is one of the Centers for Medicare and Medicaid Services Hospital-Acquired Conditions and is listed as one of the National Quality Forum's Serious Reportable Events. The Joint Commission's 2009 National Patient Safety Goal 01.03.01 lists the elimination of transfusion errors related to patient identification. Blood component transfusions to nondesignated recipients occur in about 1 of 10,000 transfused units. Two-thirds of these errors are associated with incorrect blood recipient identification occurring at the patient's bedside. There were 535 reports of blood transfusion-related events submitted to the Pennsylvania Patient Safety Authority during the 13-month period from July 2008 through July 2009. Reports involved mismatched units; events related to blood component collection; blood products dispensed, distributed, or administered; or wrong patients being transfused. Recipient identification at blood collection and administration are essential to the safety of the total blood transfusion process. The safe transfusion of blood components is a complex process involving many departments, multiple staff, and several steps. This article focuses on the process for safe transfusion and the risk reduction strategies that decrease the incidence of transfusion errors by developing adequate quality systems to ensure correct patient identification of the transfusion candidate, assigning clear responsibilities to qualified staff including a transfusion safety officer, and using identification technologies such as bar-coding or radiofrequency identification tags. (Pa Patient Saf Advis 2010 Jun;7[2]:33-40.)

Problem

The Agency for Healthcare Research and Quality's report, "Statistics on Hospital-Based Care in the U.S., 2007," found that the number of blood transfusions from 1997 to 2007 increased 140% from 1.1 million to nearly 2.7 million.[1] Blood transfusions occurred in 1 of every 10 hospital stays that included a procedure during the same time period. Patient death or disability associated with incompatible blood is one of the Centers for Medicare and Medicaid Services Hospital-Acquired Conditions[2] and is listed as one of the National Quality Forum's Serious Reportable Events.[3] The Joint Commission's 2009 National Patient Safety Goal regarding blood transfusions includes the elimination of transfusion errors related to patient identification.[4] Blood component transfusions to unintended recipients occur in about 1 out of 10,000 transfused units, and two-thirds of these errors are associated with incorrect blood recipient identification that occurs at the patient's bedside.[5]

Pennsylvania Patient Safety Authority Data

There have been 535 blood transfusion-related reports submitted to the Pennsylvania Patient Safety Authority's reporting system from July 2008 through July 2009. Analysts queried the database for events associated with blood transfusions, errors related to procedure, and complications of procedures, treatments, and tests. These included 14 Serious Events, 1 of which resulted in death. The death occurred in the operating room, and additional patient identification was identified as a recommendation to prevent future blood transfusion errors. Other Serious Events and Incidents involved mismatched units; events related to blood component testing collection; blood products dispensed, distributed, or administered; or the wrong patient being transfused.

Events reported to the Authority can be organized into three stages: (1) errors during pre-analysis including sample collection, (2) errors in laboratory through issue, and (3) errors post issue in clinical areas. Some events occurred in multiple stages (see Table 1).

Pre-Analysis Area Errors

According to Pagliaro and Rebulla, the most common adverse event during blood transfusion therapy occurs during pre-analysis (e.g., blood specimen collection), typically at the patient's bedside.[5] This pattern was also evident in reports to the Authority, with 61% of reports describing errors in this stage of the blood transfusion process (see Table 1). Pre-analysis errors during blood specimen collection may include delays in collection, wrong blood in tube collected, or incorrect or no label applied to the specimen. Of the 344 errors identified in the pre-analysis area, 141 (41%) events involved the wrong patient because the specimens did not match historical records or failed the Delta checks (comparing prior test results from a patient to determine if a newly obtained test result is

Table 1. Stages in the Blood Transfusion Process, July 2008 through July 2009

STAGES*	NUMBER OF REPORTS (N = 535)	%	PATIENT HARM
Pre-analysis (e.g., sample collection, specimen labeling)	344	61	2
Lab (e.g., serology, computer transcription, transfusion unit labeling)	101	18	5
Clinical at the bedside with transfusion units (e.g., bedside testing, transfusion unit mix-ups)	115	21	10

* Some events involving patient harm occurred in multiple stages.

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likely to be in error) or because the wrong labels were placed on the tubes. Other pre-analysis area errors included those with incorrect patient information (19%), missing independent double checks (7%), missing computer transcription (6%), miscommunications (6%), blood bank armband issues (5%), missing consents (1%), and others (15%) (see Table 2). Examples reported to the Authority include the following:

There was an outstanding, [unlabeled blood] specimen from the morning collection. The [phlebotomist] found the missing labels in a [patient] room, remembered drawing the blood from a patient [with the missing specimen labels], and [realized] she must have placed these labels on a [blood] specimen from another patient. [It was] determined [that another] patient had been labeled incorrectly.

Type and cross was ordered for a patient. When the lab [completed testing, the result] did not match [the patient's] previous blood type. The [original] blood had been drawn from another patient, and the wrong label [had been] applied.

A lab phlebotomist collected a specimen for a type and cross match on a patient. Blood bank typed the specimen as A+. The patient was on record in the blood bank as being O+. The phlebotomist drew the original specimen on the wrong patient [and mislabeled the specimen at the time of collection].

Type and cross match specimens were received in the blood bank. No phlebotomist's initials were on the labels.

Table 2. Errors in the Pre-Analysis Stage of Blood Transfusion, July 2008 through July 2009

ERRORS	NUMBER OF OCCURRENCES (n = 344)	PATIENT HARM (n = 2)
Wrong patient (e.g., did not match historical records, failed Delta test, wrong label on tube)	141	1
Incorrect patient information (e.g., missing blood bank number on band, incorrect date of birth, first and last name mix up, two different names used for same patient)	64	
Missing two independent double checks	25	
Computer issue (e.g., wrong order, no order, transposed numbers)	22	
Communication issues (e.g., special instructions, between healthcare providers)	20	1
Blood bank armband issues (e.g., missing armband, incorrect armband number)	17	
Missing signed consent	4	
Other	51	

Laboratory Errors

Laboratory errors are those that occur in the blood bank and may include errors in computer transcription, patient identifier mismatches, testing errors, or incorrect blood component released from the blood bank. Of the 101 errors identified in the laboratory areas, 15 (15%) involved the wrong blood component dispensed. Other laboratory area errors included those with delays (13%), blood components that were dispensed before all testing was completed (12%), computer entry errors (11%), missing or incorrect unit tags (11%), incorrect antibody screening (9%), expired blood components (7%), missing patient identifier information (5%), mislabeled blood specimen tubes (3%), special orders not followed (2%), inability to open blood storage cabinet (1%), and others (12%) (see Table 3). Examples of laboratory errors reported to the Authority include the following:

When the lab staff was signing out a unit of blood [to dispense to the nurse], it was noted [that] the unit number on the blood bank slip was incorrect. Upon investigation, [a transcription error was found].

[The blood bank issued] one unit of blood for this patient. When the nurse went to transfuse [the blood], the bracelet and the medical record number on the bracelet were checked but did not match. [It] appeared that [the numbers] were transposed between [the medical record number and the patient account number].

A patient's blood was sent for type and screening. The patient's blood type in the chart was O+. The blood bank called and stated that the blood type [for this patient] was A+. The patient had a blood redraw, and the lab [staff] stated that blood bank [staff] had made an [incorrect] computer entry.

Clinical Errors

Blood transfusion errors that occurred or were reported in clinical areas that excluded pre-analysis errors consist of events that involve bedside testing or equipment used at the bedside, mix-up of transfusion units, and actual transfusion of the blood to the incorrect patient. Of the 115 errors identified in the clinical stage of the blood transfusion process, 40 (35%) involved patient reactions to the blood components. Other clinical area errors included intravenous line issues (17%), incorrect blood components administered (12%), expired or wasted blood component (8%), no type and cross laboratory testing before blood component administered (7%), incomplete documentation (6%), identification band issues (5%), incorrect patient received blood component (4%), inadvertent transfusion of type and hold component (1%), and others (5%) (see Table 4). Examples of clinical errors reported to the Authority include the following:

The blood product was released from the blood bank according to the patient identification on the form, and [the blood] was administered without confirming the product label to the patient's [identification]. The patient received an incorrect unit of packed red blood

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Table 3. Errors in the Laboratory Stage of Blood Transfusion, July 2008 through July 2009

ERRORS	NUMBER OF OCCURRENCES (n = 101)	PATIENT HARM (n = 5)
Wrong blood component dispensed	15	2
Delay (e.g., staffing, no available blood)	13	1
Dispensed before testing (e.g., cross match, ABO compatibility, type and cross)	12	
Computer issues (e.g., incorrect ABO)	11	
Incorrect or missing blood bank unit tags (e.g., machine broken)	11	
Incorrect antibody screening	9	
Expired (e.g., cross match, unit)	7	
Missing armband information (e.g., missing date of birth, wrong blood bank identification number)	5	1
Mislabeled blood specimen tube	3	1
Special orders (e.g., transfusion prepared without leukocyte filter, blood component not irradiated)	2	
Unable to open blood storage cabinet (e.g., access code not working)	1	
Other	12	

cells, resulting in an intravascular hemolytic reaction that required fresh frozen plasma and platelets to correct the coagulopathy.

A patient was ordered to have a transfusion of fresh frozen plasma. Approximately 100 mL infused when the physician [cancelled the order.] Two patient records [had been] opened at the [time of the transfusion order, which had been written on the wrong patient's chart].

Guidelines

Several organizations and regulatory bodies provide safety guidance for transfusion medicine. The U.S. Food and Drug Administration (FDA) licenses and registers blood and transfusion centers. FDA's role is to inspect each facility's documentation of each step during collection, processing, compatibility testing, storage, distribution of blood components, and adverse event investigation.[6] AABB (formerly the American Association of Blood Banks) is a standard-setting professional organization in transfusion medicine.[7] In 2006, AABB, the U.S. Department of Health and Human Services, and representation from government and nongovernment organizations formed the U.S. Biovigilance Network. Reporting recommendations from this group included using the Centers for Disease Control and Prevention's National Healthcare Safety Network as the national surveillance system for recipient outcomes of blood and blood products.[7] The College of American Pathologists (CAP) offers accreditation that focuses on the quality of laboratory testing and transfusion services that meets national and local standards. CAP's focus is on patient and blood sample identification, testing procedures and equipment, identification and investigation of transfusion reactions, and competency of staff.[8] Blood and transfusion centers may also be accredited by the Joint Commission, which focuses on the use, prescription, and administration of blood components.[9]

Blood Transfusion Process

While each element of the blood transfusion process presents inherent risk, every aspect depends on the accurate and successful completion of the prior step. (A reprinted, sample diagram of this process, titled "Transfusion Process Map," is available from the Authority online at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.) The blood transfusion process outlines the precise and detailed description of each step during standard *and* exceptional conditions.[10] Stainsby et al. analyzed 2,087 blood transfusion adverse events during a seven-year period and found that there were 1,393 (67%) instances of incorrect blood components being transfused.[11] Approximately 50% of these occurrences involved multiple errors in the blood transfusion process, which most frequently occurred during the pretransfusion bedside check.[5,11]

Osby et al. outlined specific steps in the blood transfusion process that organizations can use to identify risk areas: prescribing blood components, submitting blood samples to the blood bank, issuing blood components from the blood bank, transfusing the patient, and monitoring the patient for transfusion reactions.[12]

Prescribe Blood Components

Blood hemoglobin concentration is only one determinant of tissue oxygenation.[13] Medical indications for transfusion should exist and be thoroughly documented before prescribing blood components. Absent signs of hypoxia, a patient may not necessarily require blood products. A decision to transfuse is based on clinical presentation and supported by laboratory results.[11] If the laboratory results and the patient's clinical presentation do not match, a decision to transfuse may occur based on incorrect results or analytical errors. In addition, telephoned results may be erroneously transcribed or assigned to the incorrect patient, even if the reading back of test results is properly performed.[11] Patient consent for transfusion allows the patient to make an informed choice regarding the risks, benefits, indications, and alternatives for elective or nonemergency blood transfusion, which also includes the right to refuse the transfusion.[10,12]

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Table 4. Errors in the Clinical Stage of Blood Transfusion, July 2008 through July 2009

ERRORS	NUMBER OF OCCURRENCES (n = 111)	PATIENT HARM (n = 10)
Reaction (e.g., fever, rigors, tachycardia, hypotension, chest pain, headache, urticaria, dyspnea)	40	4
Intravenous line issues (e.g., infiltration, leaking, no filter, timing of greater than four hours)	19	2
Wrong blood component administered	14	3
Expired/wasted blood component	9	
No type and cross before receiving blood component (e.g., trauma, emergency department)	8	
Incomplete documentation (e.g., unit tag saturated, numbers obscured tag numbers, no identification numbers)	7	
Identification band issues (e.g., no blood bank band, blood bank identification number cut off, improperly labeled blood bank band)	6	
Wrong patient received blood component	5	1
Order to type and hold only but was mistakenly transfused	1	

Submit Blood Sample to the Blood Bank

Proper specimen collection is the one of the most important steps of transfusion safety.[14] Twenty-one months of data collection and analysis at a university hospital by Quillen and Murphy revealed that the emergency department accounted for the disproportionately high number of wrong blood in tube specimens with most errors having major mislabeled specimens.[14] Major mislabeling specimens are those that are unlabeled, have mismatched information on specimen and requisition, or for which the current specimen does not match the historical record on file.[14] According to Ahrens et al., obtaining the pre-analysis sample for testing is by far the weakest link in the safety chain of blood transfusion.[15] This pattern was also evident in reports to the Authority, with nearly two-thirds (61%) of the blood transfusion reports describing errors in the pre-analysis stage. Stainsby et al. identified other blood sample issues: labeling blood sample tubes away from the bedside, failing to check the patient's identity, failing to use preprinted labels, and using poor technique in blood sampling, which affects laboratory results.[11] Errors with specimen collection may be slip errors, which are caused by staff distraction, fatigue, or inattention. Such errors may result in the mislabeling of blood samples and inadvertent administration of the wrong blood to the wrong patient.

In June 2009, nine facilities in the northeast region of Pennsylvania began working collaboratively with the Authority to identify and eliminate phlebotomy specimen mislabeling—one of the most common pre-analysis errors. These facilities committed to a year-long process of monitoring, investigating, and redesigning systems across many disciplines and units. Identified best practices from this collaborative will be shared in future updates in the *Advisory*. To learn more about this collaborative, visit the Authority's Web site at http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Sep6(3)/Pages/107.aspx.

Issue Blood Components from the Blood Bank

As previously noted, the laboratory discovery of the wrong blood in a tube specimen when comparing the results of two or more specimens from the same patient that have been collected at different times is known as a Delta check. If there is no historical laboratory data on the patient, an error such as the wrong blood in tube could escape detection and result in the wrong blood component being transfused, leading to an acute hemolytic transfusion reaction.[12] A disproportionately high number of laboratory errors take place outside the usual blood bank hours, particularly when there are fewer staff.[11] While routine blood groupings are automated in the blood bank, manual techniques may be needed for urgent blood grouping. These manual techniques are inherently unsafe and have the potential for errors in interpretation and documentation.[11]

Transfuse the Patient

The bedside check verifies the identity of the intended recipient and matches it to the identity of the person about to receive the blood transfusion. Verification takes place in the presence of the patient, using two licensed persons and a three-way check that includes the blood component tag, compatibility slip, and patient wristband.[12] This is the most critical step of transfusion safety and the final opportunity to interrupt any incorrect blood component.[13]

Administer Blood Components

According to AABB, "No medications or solutions may be routinely added to or infused through the same tubing with blood or blood components with the exception of 0.9% Sodium Chloride, Injection (USP), unless (1) they have been approved for this use by the FDA or (2) there is documentation available to show that the addition is safe and does not adversely affect the blood or blood component."[16] Other considerations for blood component safety include types of administration tubing, intravenous access, and filters used with transfusions; infusion rates; and the use of infusion pumps.[12] Bar-coded systems and other technologies are better suited to the repetitive data matching that occurs with blood transfusions. Bar-coded systems are not subject to distraction and

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can help organizations improve the labeling of blood samples, dispensing of blood components, and identifying the patient at the bedside.[13] Studies indicate that many facilities use bar-coded labels, but there continue to be issues of the incorrect bar-coded label from one patient to another, wrong blood in tube, or blood being administered to a nondesignated blood recipient with blood that appears correctly labeled. The positive donor-recipient identification at blood collection and administration is essential to the total blood transfusion process, so that if a transfusion error is detected, process monitoring and any action taken may be tracked.[13,17]

Other technologies such as radiofrequency identification tags (RFID) hold considerably more information, are more user friendly than bar-code equipment, and may help organizations to ensure the correct blood and amount is administered to the correct patient.[5,13,15,18] There are two kinds of RFID technology: active and passive. Active RFID refers to technology in which the chip is battery-powered and emits energy that can be read over a distance (e.g., cellular phone). Tags with active RFID technology can be used for asset tracking within facilities to locate valuable equipment.[13] Passive RFID technology is read only when it is brought in close proximity to an electronic RFID reader.[13] Machine-readable identification technology is ideally suited to meet the needs of the bedside check prior to the administration of blood components.[13]

Monitor for Transfusion Reactions

Patients who receive any blood component transfusion are monitored for early and late complications. Routine monitoring includes documentation that a patient is tolerating the transfusion without adverse events. If the patient exhibits any signs of a transfusion reaction, the transfusion is stopped immediately, vital signs are obtained, and a comparison of the patient's armband with the blood component tag and label are performed.[12] Patient monitoring is a crucial part of the safe transfusion process so transfusion reactions can be promptly recognized and safely managed. The patient should be very closely monitored in the first half hour of an elective transfusion, according to the organization's transfusion policy, and when adequate staffing in the patient care area is ensured to provide adequate monitoring for a transfusion reaction. Any sign, symptom, or untoward event of the blood transfusion is documented so that the patient may be treated appropriately.[12] Examples of early noninfectious complications include febrile nonhemolytic transfusion reaction, circulatory overload, hemolysis, transfusion-related acute lung injury, mild to severe allergic reaction, and electrolyte or coagulation abnormalities, which may have an occurrence onset during or within hours of the transfusion.[12,19] Noninfectious late complications may include the formation of red cell antibodies with secondary complications, iron overload, immune suppression with secondary complications, formation of human leukocyte antigen antibodies with secondary complications, formation of platelet-specific antibodies, and graft-versus-host disease. Late complications may have an onset of days to months following the transfusion.[12,19]

Risk Reduction Strategies

Risk reduction strategies assist facilities to improve the safety of blood transfusions by including all steps in the process from collection, compatibility test, product issue from the blood bank, to blood administration at the bedside, monitoring of transfusion reactions, and thorough documentation.[14] Though some strategies may be considered "low-tech," a simple approach may have more appeal and be easier to implement than some of the automated interventions.[20] Consider the following strategies for formally engineering or re-engineering the blood transfusion process:

- Establish an interdisciplinary transfusion committee that includes a transfusion safety officer.[5,12]
- Evaluate current organizational blood transfusion practices, and re-engineer needed changes to transfusion systems or processes.[12]
- Develop organizational blood transfusion policies and procedures using AABB guidelines that include the use of two patient identifiers. All blood components should be refrigerated or frozen and stored according to FDA and AABB requirements and transfused before the expiration date indicated on the blood component label. Any component that was previously frozen must have an expiration time assigned when the unit is thawed.[6,7,12]
- Review prescriber ordering procedure of blood components. The use of computerized prescriber order entry (CPOE) provides a structured, legible, and traceable communication between the prescriber and the blood transfusion service. CPOE combined with computer-assisted decision support provides readily available information intended to assist the clinician in making proper transfusion decisions using the alerts built into the system. These alerts provide the prescriber with valuable guideline information at the time of the blood request and provide feedback to the clinician on the indication for the transfusion.[13]
- Consider the use of a blood transfusion record that guides the prescriber to indicate the basis for the transfusion when one is ordered.[12] Algorithms may be used to identify appropriate transfusions.[13] Davies et al. indicated a 12% decrease in transfusions in the year following the introduction of the electronic prescribing of blood components using algorithms which incorporated guidelines.[21] The prescription for the administration of a blood component provides instructions regarding the rate and volume of the transfusion. Particular care must be exercised when prescribing for infants, children, and small adults, during which failure to adjust the quantity can result in overtransfusions and can lead to serious morbidity or mortality.[11]

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- Review patient consent for blood components and ensure right for refusal clause appears on the consent. The consent includes information about the infectious and noninfectious risks of transfusion, given in an appropriate reading level and in the patient's native language. The consent also includes the opportunity for the patient to ask questions about the transfusion and should be obtained as soon as it has been determined that there is a possibility that a transfusion may be needed.[12]
- Monitor, track, and trend all blood samples for type and cross, type and hold, wrong blood in tube, mislabeled tubes, and issued blood components from blood bank. Blood bank hours of operation and staffing issues should be considered with the review or development of blood transfusion safety. (For example, elective transfusion should be strongly discouraged in the off hours due to possible staffing shortages in the laboratory and on the patient care area.)[11]
- Consider the use of a statistical process control to monitor the quality of an organization's errors in patient specimen collection of the blood transfusion processes.[13,17]
- Consider the use of a bedside checklist that lists safe handling of blood components when transfusions are administered.[10] Positive patient identification includes matching wristband identification to the blood compatibility label and matching the two patient identifiers with the blood request.[13,20] In addition, the review of blood component compatibility, expiration date, unit number, and ABO/Rh type for both the recipient and the unit should be present as well as special attribute alerts.[12,13]
- Consider the use of bar-codes or RFID to ensure the correct blood and amount goes to the correct patient.[13]
- Ensure that patients have appropriate IV access before picking up blood from blood bank.[12]
- Transfuse patient within 30 minutes of blood component pickup from the blood bank.[12]
- Monitor patients for early and late transfusion reactions.[12]
- Document allergic reactions.[12]
- Provide ongoing structured educational opportunities for healthcare practitioners that include annual assessment of blood transfusions competence.[5,9]

Conclusion

The process for safe transfusion is a complex one that involves several hospital departments and types of staff, multiple steps, and hundreds of individuals.[17] Facilities may consider risk reduction strategies that decrease the incidence of transfusion errors by the development of adequate quality systems to uncover prescribing practices that may be inappropriate, ensure correct patient identification of the transfusion candidate, assign clear responsibilities to qualified staff, and consider the development of a transfusion safety officer. Guidelines should be clear, unambiguous, and readily accessible.

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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. Which is the most critical strategy to improve the safety of the blood transfusion process?
   a. Use manual techniques when the laboratory has performed routine blood grouping.
   b. Use identification technologies such as bar-coding systems or radiofrequency identification tags to improve proper specimen labeling.
   c. Obtain positive donor-recipient identification and verification during blood collection and administration.
   d. Provide patient monitoring during blood or blood component administration.

2. Risk reduction strategies to ensure the safety of the blood transfusion process include all of the following EXCEPT:
   a. Guide prescribers to use algorithms and blood transfusion records to indicate the basis for transfusions when ordered.
   b. Use a standardized algorithm for all patient populations.
   c. Implement a standardized checklist for the safe handling of blood components when transfusions are administered.
   d. Standardize labeling of blood samples using bar-coded systems.

3. A patient was admitted to the hospital for exacerbation of congestive heart failure (CHF). Laboratory results were hemoglobin 6.4, hematocrit 21, and red blood cells 2.6. The attending physician ordered a transfusion, although mindful of the patient's CHF. The physician had considered that the risk of fluid overload was outweighed by the patient's deteriorating condition and laboratory values. Precautions were taken pretransfusion, including the administration of medication in an attempt to prevent any transfusion reaction. The patient was transfused with one unit of packed red blood cells and, two hours later, became acutely short of breath and hypoxic. Oxygen was administered to the patient, and the physician was summoned to the patient's bedside. Repeated laboratory testing of the original blood specimen revealed that the results did not match the patient's previous blood type. The original blood had been drawn from a different patient, and the wrong label had been applied. The patient had received an incorrect unit of packed cells based on an incorrect blood type.

   In the case study described above, breakdowns or errors that led to wrong blood delivery associated with transfusions likely included all of the following EXCEPT:
   a. Verification took place in the presence of the patient.
   b. Prescribed blood or blood components were based on clinical presentation.
   c. Failed Delta test occurred in the laboratory.
   d. Unlabeled blood samples were submitted to the blood bank.

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4. Select the stage in the blood transfusion process in which the most common errors occur.
   a. The laboratory stage, which begins when the blood specimen is delivered to the laboratory through the distribution of the blood or blood components
   b. The pre-analysis stage, which begins during collection of blood specimens and typically occurs at the bedside
   c. The clinical stage, which begins in the clinical area, excludes the pre-analysis stage, and includes additional bedside testing or equipment used at the bedside
   d. The monitoring stage, which begins in the clinical area after the blood or blood component has been transfused and includes monitoring the patient after the transfusion is complete
5. Routine medication and solutions may be added to or infused through the same tubing with blood or blood components.
   a. True
   b. False

Probiotic Use for *Clostridium Difficile* Infection

The Pennsylvania Patient Safety Authority received responses to an article that appeared in the March 18, 2010, supplement to the *Pennsylvania Patient Safety Advisory*. Representatives of Pennsylvania nursing homes commented that their facilities administer probiotics (live microorganisms) for the prevention and treatment of *Clostridium difficile* infection (CDI).

Probiotics are considered dietary supplements and are therefore not approved by the U.S. Food and Drug Administration.[1,2] Conflicting media reports about the use of probiotics have created confusion among healthcare professionals and the public, and further studies are needed to determine their efficacy.[3]

Authority analysts reviewed the clinical literature to determine the efficacy of probiotics for the prevention and treatment of gastrointestinal illness, including CDI. The Authority's review found conflicting results. For example, McFarland reviewed various studies that tested probiotics to prevent antibiotic-associated diarrhea. Findings included that there may be a true benefit in using these supplements, as evidenced by the reduction of frequency of diarrhea in the probiotic group versus placebo groups. In contrast, other studies revealed little or no benefit with respect to control of diarrhea.[4] Another example includes Bartlett's review of several studies that found similar results to McFarland.[1] In addition, Bartlett also reported the incidence of fungemia (i.e., fungal infection of the blood) as a result of probiotic use.[1]

The most recent *C. difficile* guidelines released in March 2010 by the Society for Healthcare Epidemiology of America and the Infectious Diseases Society of America do not recommend the administration of currently available probiotics because "there are limited data to support this approach, and there is a potential risk of bloodstream infection."[5]

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Tubing Misconnections: Making the Connection to Patient Safety

ABSTRACT

Some patients may have multiple tubing lines connected to them for reasons such as delivery of medication and nutrition therapy. With these multiple lines, the potential for tubing misconnections becomes more prevalent. Tubing misconnections can occur with intravenous catheters, feeding tubes, hemodialysis tubes, and tracheostomy cuffs, among other devices. One of the main reasons for tubing misconnections is that many types of tubing for different types of medical devices incorporate luer connectors. These connectors contribute to misconnections because they allow functionally dissimilar tubes or catheters to be connected together. Between January 2008 and September 2009, 36 events of tubing misconnections were reported to the Pennsylvania Patient Safety Authority involving various types of misconnections. Methods for reducing the likelihood of tubing misconnections include equipment design solutions and administrative controls (policies and work practices). Equipment design solutions either prevent the user from making a misconnection or prompt the user to make the correct connection. Administrative controls are policies and practices that reduce the risk of misconnections such as tracing lines back to their source. (Pa Patient Saf Advis 2010 Jun;7[2]:41-5.)

Introduction

Depending on acuity level, patients may have many tubing lines connecting them to medical devices and/or for delivering medication or nutrition therapy. Medical devices connected to patients may also have tubing lines connecting the devices with other medical devices. Under these circumstances, tubing misconnections can occur with potentially fatal results. Misconnections have been recognized as a serious problem for many years. One of the earliest published reports of misconnections was the inadvertent delivery of breast milk via intravenous (IV) administration in 1972.[1] However, misconnections have garnered more attention in recent years, especially in the United States, due in part to the tubing misconnection *Sentinel Event Alert* issued by the Joint Commission in April 2006.[2]

The *Sentinel Event Alert* describes the types of tubing and catheter misconnections reported to Joint Commission, including central intravenous catheters, peripheral intravenous catheters, nasogastric feeding tubes, tracheostomy cuff inflation tubes, and automatic blood pressure cuff insufflation tubes. The *Alert* also described misconnection events reported to U.S. Pharmacopeia (USP), including intravenous infusions connected to epidural lines and infusions intended for IV delivery connected to nasogastric tubes.[2] The *Alert* offers risk reduction strategies and recommendations, which are included in the overall risk reduction strategies below.

There are many types of misconnections; however, this article will focus on liquid-to-liquid and liquid-to-gas misconnections because these misconnections can pose the most serious harm to patients and are the most frequently reported to the Pennsylvania Patient Safety Authority. Liquid lines are typically those that administer medications or nutrition but can also include solution lines such as flush lines. Medical gas lines are typically used for respiratory support or to power pneumatic medical devices. Liquid-to-liquid misconnections can result in a liquid substance entering the wrong body part or the wrong substance entering the patient. Liquid-to-gas misconnections are incorrect connections that can result in gas introduced into patients' blood vessels or liquid entering patients' respiratory tracts.[3]

A common reason for tubing misconnections, whether liquid-to-liquid or liquid-to-gas, is that many types of tubing lines for different medical devices incorporate common luer connectors. The International Organization for Standardization (ISO) characterizes a luer connector as a conical fitting with a 6% (luer) taper for syringes, needles, and other medical equipment.[4] The luer connection system consists of male and female counterparts that are joined together either by push (luer slip) or screw-in threaded (luer lock) fittings. Luer connectors contribute to misconnections because they easily allow functionally dissimilar tubes or catheters to be connected together.[2]

Misconnections in Pennsylvania

Between January 2008 and September 2009, 36 tubing misconnection events were reported to the Authority: 35 liquid-to-liquid events and 1 liquid-to-gas event. (See the Table for a breakdown of the types of misconnections reported.) Examples of the Serious Events and Incidents involving misconnections reported to the Authority include the following:

> *The patient is a 4-week-old infant admitted . . . to determine need for surgery. The physician ordered a 75 ml bolus of NS [normal saline]. A . . . nurse connected the bag of NS at the patient's lower "Y" site and set the pump correctly. 500 ml of the NS was administered over 30 minutes . . . [because the connection bypassed the infusion pump].*

> *The physician found the feeding tube connected to the G-tube and the J-tube connected to suction in error . . . Tubes were corrected . . .*

> *The patient had both an epidural and PCA [patient-controlled analgesia]. Investigating a case*

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Table. Tubing Misconnections Reported to the Pennsylvania Patient Safety Authority, January 2008 to September 2009

MISCONNECTION	NUMBER OF REPORTS
Secondary intravenous (IV) infusion connected to lower "Y" port of primary IV tubing set	8
Hemodialysis arterial and venous tubing lines reversed	5
G-tube and J-tube lines reversed	3
Incorrect tubing connection (no further explanation provided in reports)	3
Epidural and patient-controlled analgesia (PCA) tubing sets reversed	2
Nonhemodialysis arterial and venous tubing lines reversed	2
Cell saver tubing connected to cell saver reservoir	1
Feeding tube set connected to Broviac®	1
Feeding tube set connected to peripherally inserted central catheter (PICC) line	1
Feeding tube set connected to suction port	1
Imaging contrast tubing set connected to tracheostomy cuff	1
IV tubing set connected to dialysis catheter	1
IV tubing set connected to PICC line	1
IV tubing set connected to tracheostomy cuff	1
Knee irrigation connected to peripheral IV tubing	1
Miscommunication (arterial line noted in medical record as peripheral IV)	1
Oral medication delivered through peripheral IV line	1
Suction line connected to water seal	1
Suction and feeding tubing sets reversed	1
Total	**36**

of pain . . . The tubings [sic] were connected incorrectly, and the patient received one narcotic epidural (ordered via PCA) and the other narcotic via PCA (ordered via epidural).

Patient arrived at MRI [magnetic resonance imaging] suite for an abdominal study. Subclavian catheter and tracheostomy to be present and all ports having similar injection valves [sic]. The technologist was scanning, and the anesthesiologist connected the injector tubing attached to the patient's IV site. Contrast and saline were injected. The scan showed no signs of contrast. The patient was then pulled out of the MRI, and [it was] discovered that the contrast was injected into the tracheostomy cuff.

The patient, status post thoracoabdominal surgery, had a Jackson Pratt and sump drain inserted into the mediastinal cavity. The patient also had a jejunal feeding tube placed. Upon assessment of the patient's Jackson Pratt drain, it was noted that it was draining a whitish substance which was determined to be the tube feeding. The physician was notified and discovered that the tube feeding was connected to the sump instead of the jejunal feeding tube . . .

Wrong route: connect[ed] a 1000 cc bag to a peripheral site when the bag was intended for knee irrigation.

Prevention Methods

Two methods for reducing or eliminating misconnections are addressing equipment design and developing or revisiting hospital policies and work practices. National and international standards address connector design to minimize misconnections; however, for many technologies, these standards have been neither widely adopted nor fully successful.[3] One standard, currently in draft form, by the Association for the Advancement of Medical Instrumentation (AAMI) and ISO,* will aim to reduce misconnections by addressing design requirements for small bore connectors for liquids and gases in healthcare applications. This standard will propose development of alternative, non-interconnectable, small bore connectors for various healthcare applications. The AAMI/ISO small bore standard is expected to be finalized by early 2010.[3]

When equipment designs to prevent misconnections are unavailable, healthcare facilities must rely on hospital policies and work practices, also referred to as administrative controls, to minimize misconnections. An example of an administrative control is a policy to trace all lines back to their origin before a connection is made. Another example is limiting the use of adapters to those that are necessary for a specific application.[3] Misconnections can occur when incorrectly using adapters to connect two or more devices together that would not normally pair.

Equipment design solutions, especially forcing functions, are more effective in reducing or eliminating misconnections than administrative controls. A forcing function design impels an individual to make the correct decision or connection. An example of a forcing function commonly cited in literature is the

* AAMI/ISO 80369-01 1ed. *Small bore connectors for liquids and gases in healthcare applications–part 1: general requirements.*

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gear shift of an automobile. In newer automobile designs, the gear shift cannot be moved from the park to the reverse position until the operator first depresses the brake pedal.

However, neither equipment design solutions nor administrative controls alone are sufficiently effective. Equipment design solutions exist for some devices but are not widely available, and ensuring that staff always make the correct connection is impractical.[3] Additionally, even well-designed equipment safety features can be circumvented by untrained individuals or those who do not fully understand the risks associated with defeating the features.[3] Using equipment designs and administrative controls together is the optimal approach in reducing misconnection risks. When possible, healthcare facilities could purchase equipment with misconnection safety features such as nonluer connectors on tubing used with nonintravenous devices (e.g., nebulizers) and institute appropriate policies and work practices as part of a misconnection mitigation action plan.

Tubing Misconnections Risk Reduction Strategies

The following misconnection risk reduction strategies include incorporating equipment design solutions and hospital policies and work practices.[2,3] The lists are separated into strategies for clinical staff and nonclinical staff. Nonclinical staff include patient safety, clinical/biomedical engineering, risk management, purchasing (materials management) personnel, patients, and visitors.[3] (Risk reduction strategies specific to enteral feeding misconnections are listed separately.)

Clinical Staff[2,3]

- Trace all lines back to their point of origin to verify that correct connections are made. While this step increases a clinician's time with a patient, it is a necessary step in preventing misconnections.
- Recheck connections and trace all lines to their point of origin after the patient's arrival to a new care area or as part of a handoff process.
- Do not force connections. If a great amount of effort is needed to make a connection, then there is a good chance that the connection should not be made.
- Only use adapters that are clearly indicated for a specific application. Additionally, the need for an adapter may mean that the connection should not be made.
- Label certain high-risk catheters as to the type of catheter (e.g., epidural, intrathecal, arterial).
- Route lines (e.g., tubes, catheters) with different purposes in unique and standardized directions (e.g., route IV lines toward the patient's head, route enteral feeding lines toward the patient's feet).
- Identify and manage conditions that may contribute to worker fatigue, which could result in inattentiveness when making tubing connections, and take appropriate action.

Nonclinical Staff[2,3]

- Provide regular misconnection prevention education, emphasizing the risk of misconnections, to all personnel working in patient care environments. Include nonclinical personnel (e.g., housekeeping), patients, and visitors in the training process. For example, explain the need to request help rather than attempting to disconnect or reconnect lines.
- Assess the need for adapters throughout the facility, and limit or restrict their routine use. Adapter assessment should be performed by a multidisciplinary team that includes nursing, risk management, clinical/biomedical engineering, and purchasing personnel.
- Revise and/or establish purchasing policies that include, when possible, purchasing equipment with misconnection safeguards. For example, avoid purchasing nonintraveneous equipment (e.g., noninvasive blood pressure devices) that can mate with female luer IV connectors.
- Perform prepurchase evaluations and acceptance testing for safety and efficacy on tubing and catheters, as appropriate, to assess the potential for misconnections.

Enteral Feeding Misconnections Risk Reduction Strategies

Enteral feeding is the delivery of nutrients through a tube for patients who have a functioning gastrointestinal tract but cannot orally receive food and nutrition due to a health condition. Misconnections during enteral feeding typically include one of the two following scenarios:[3]

1. Nutrients intended for the gastrointestinal (GI) tract are inadvertently delivered elsewhere (e.g., vascular system).
2. Inappropriate fluids (e.g., IV solutions) are inadvertently delivered to the GI tract.

The first type of misconnection listed above (nutrients for GI tract delivered elsewhere) can have the most serious consequence for patients. Death can easily result due to embolus or sepsis.[3] The Joint Commission *Sentinel Event Alert* describes a few enteral misconnection errors such as enteral feeding tubes connected to central venous catheters, enteral feeding tubes connected to hemodialysis lines, and infusions intended for IV delivery connected to nasogastric tubes, among others.[2]

The methods for preventing enteral feeding misconnections are similar to those for preventing other tubing misconnections: equipment design solutions and policies and work practices. As with other tubing, there are no standards for universal connector designs unique to enteral feeding devices and sets.[3] However, there are currently a few enteral feeding systems that incorporate designs addressing misconnection

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safeguards. The lists are also separated into strategies for clinical and nonclinical staff.

Clinical Staff[2,3]

- Do not use standard luer syringes for oral medications or enteral feedings.
- Prohibit modifying or adapting IV or enteral feeding devices. Modifying devices may jeopardize design safety features.
- Route lines with different purposes in unique and standardized directions (e.g., route IV lines toward the patient's head, route enteral feeding lines toward the patient's feet).
- Identify and manage conditions that may contribute to worker fatigue, which could result in inattentiveness when making tubing connections, and take appropriate action.
- Review identification labels before administering solutions to ensure that the intended delivery route is correct. The solution's appearance alone is not an adequate method for identification because enteral formulas may resemble some IV solutions that have milky appearances (e.g., lipid-containing solutions). Properly identifying the correct solution prior to administering reduces the risk that an enteral container will be mistakenly spiked with an IV administration set. Placing labels with warnings such as "WARNING! For Enteral Use Only—Not for IV Use" may also reduce the likelihood of a misconnection.

In the U.S. Pharmacopeia Medication Safety Forum position statement, labeling or color-coding feeding tubes and connectors and educating staff on the labeling or color-coding system were suggested as a risk reduction strategy.[5] However, in the tubing misconnection *Sentinel Event Alert*, Joint Commission acknowledges this risk reduction approach, but noted the following potential unintended consequences if implemented:[2]

- Users may rely on color-coding rather than assuring a clear understanding of correct connections between tubes or catheters and body inlets.
- Continual attention to education and training of the color-coding system will be needed for staff, including temporary and travel staff.
- Various color-coding systems may be used across facilities within the same geographic area, which could lead to confusion particularly for temporary and travel staff.

Nonclinical Staff[2,3]

- Ensure that an adequate number of distinctly labeled enteral pumps are purchased to reduce or eliminate the use of infusion pumps for enteral administration to adult patients. When using syringe pumps for neonatal feedings, ensure that the pumps are clearly distinct from syringe pumps used for IV administration or other medical purposes. However, a more reliable approach is using enteral pumps for neonatal feedings, except if using nonluer tubing technologies.
- Establish or reinforce existing purchasing policies that mandate purchasing only enteral feeding sets that are incompatible with female luer connectors.
- Purchase only non-IV-compatible enteral feeding containers.
- Secure enteral administration sets with enteral feeding containers (e.g., with rubber band) or use preattached sets (e.g., from the manufacturer) before sending them to the patient care unit.
- Perform prepurchase evaluations of enteral feeding systems under the guidance of a multidisciplinary task force before purchasing decisions are made.

Notes

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(See Self-Assessment Questions on next page.)

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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. Which of the following is NOT a tubing misconnection risk reduction strategy for clinical staff?
   a. Trace all lines back to their point of origin after the patient's arrival to a new care area or as part of a handoff process.
   b. Use standard Luer-connection syringes to administer oral medications.
   c. Do not force connections.
   d. Only use adapters that are clearly indicated for a specific application.
2. Which of the following is NOT a tubing misconnection risk reduction strategy for nonclinical staff?
   a. Provide regular misconnection prevention education.
   b. Develop a multidisciplinary team to assess the need for adapters throughout the facility, and limit or restrict routine use of adapters.
   c. Train nonclinical staff on the proper technique for connecting or disconnecting devices or infusions.
   d. Perform prepurchase evaluations and acceptance testing for safety and efficacy on tubing and catheters to assess the potential for misconnections.
3. Which of the following is NOT an enteral feeding tubing misconnection risk reduction strategy for clinical staff?
   a. Use standard luer syringes for oral medications or enteral feeding.
   b. Route lines with different purposes in unique and standardized directions (e.g., route intravenous [IV] lines toward the patient's head, route enteral feeding lines toward the patient's feet).
   c. Prohibit modifying or adapting IV or enteral feeding devices.
   d. Review identification labels before administering solutions to ensure that the intended delivery route is correct.
4. Which of the following is NOT an enteral feeding tubing misconnection risk reduction strategy for nonclinical staff?
   a. Ensure that an adequate number of distinctly labeled enteral pumps are purchased to reduce or eliminate the use of infusion pumps for enteral administration to adult patients.
   b. Ensure that syringe pumps for neonate feedings are clearly distinct from syringe pumps used for IV administration or other medical purposes.
   c. Purchase only IV-compatible enteral feeding containers.
   d. Secure enteral administration sets with enteral feeding containers before sending them to the patient care area.
5. A nurse inadvertently connects a patient's IV tubing to the nasal oxygen cannula upon the patient's arrival to the medical/surgical unit. Approximately five hours later, the patient complains of chest pain and shortness of breath.

   Select the *most appropriate* strategy to prevent this misconnection from occurring.
   a. Trace all lines back to their point of origin after the patient's arrival to a new care area or as part of a handoff process.
   b. Rely on color-coding to distinguish between various types of tubing.
   c. Educate and train staff on an ongoing basis about preventing tubing misconnections.
   d. Only use adapters that are clearly indicated for a specific application.
6. While changing a patient's gown, a family member inadvertently connected the patient's IV tubing to his gastric feeding tube. The misconnection was quickly noticed before the patient was seriously harmed.

   Select the *most appropriate* strategy to prevent this misconnection from occurring.
   a. Rely on color-coding to distinguish between various types of tubing.
   b. Educate about the need to request help rather than attempting to disconnect or reconnect lines.
   c. Trace all lines from the patient back to their point of origin.
   d. Perform prepurchase evaluations and acceptance testing for safety and efficacy on tubing and catheters, as appropriate, to assess the potential for misconnections.

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Safeguarding the Storage of Drug Products

ABSTRACT

A well-organized drug-storage system can reduce the risk of medication errors. However, events reported to the Pennsylvania Patient Safety Authority describe how breakdowns in the storage of medications have contributed to drug product mix-ups. More than 200 events have been reported to the Authority from June 2004 through October 2009 that indicate drug storage as a contributing factor to the event. Analysis reveals that nearly 73% of the events reached the patient. The most frequently reported event type was wrong drug (99 [46%] of the events reported). Events occurred in more than 50 different units, indicating that drug storage issues can and do occur throughout a facility. Strategies to address these problems include carefully selecting drugs stocked in each patient care area based upon the needs of each patient care unit and staff expertise, storing individual medications in a separate bin or in a bin with dividers between different products, sequestering chemicals currently used for compounding in a section of the pharmacy, and requiring periodic review of storage areas throughout the organization by a pharmacist or pharmacy technician. (Pa Patient Saf Advis 2010 Jun;7[2]:46-51.)

Medication use is a complex process and comprises medication prescribing, order processing, dispensing, administration, and effects monitoring. Key elements that affect the medication-use process[1,2] and the interrelationships among these elements form the structure within which medications are used. The storage of drug products is part of one of the key elements of the medication-use process.

Implementing a well-organized drug-storage system, as well as standardizing and limiting the availability of multiple doses and concentrations of drugs in patient care areas, can reduce the risk of medication errors or minimize adverse outcomes should an error occur. Event reports submitted to the Pennsylvania Patient Safety Authority have described how storage of medications in locations including the pharmacy, patient care areas, automated dispensing cabinets (ADCs), and anesthesia carts, have contributed to drug product mix-ups. Other national patient safety groups have also observed errors, some tragic, related to unsafe storage conditions. For example, occult blood test solutions have been confused with eye drops and corrosive tissue fixatives, and disinfectants have been mistaken for oral liquid medications.[3,4]

The Numbers

Although the Authority's reporting system allows users to indicate the location of the medication involved in a medication error (e.g., ADC, inpatient pharmacy, floor stock), this reporting mechanism does not include fields that facilities can use to capture the role that storage may have played with medication errors. However, routine review and analysis of medication error events reported to the Authority indicated that the storage of a drug can play a role in these events. In response, analysts have created standardized monitor codes that could be entered into the program database to record/note those events in which an organization explicitly states that drug storage may have played a role in the event. These monitor codes, along with the phrase "next to," were then used to query the data to identify trends and risk reduction strategies.

From events reported from June 2004 through October 2009, analysts identified 215 medication error events implicating drug storage as a contributing factor to the event. Breakdown of these events by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention harm index,[5] shows that 156 (73%) of the events reached the patient (harm index = C to I), and 53 (25%) of the events resulted in harm significant enough to require additional treatment.

The five most common medication error event types represented 171 (80%) of the 215 events, with the most commonly reported event type being wrong drug (46%) (see Table 1). "Other" represented the second largest category of event types (14%). Ten (33%) of these events appear to have involved either stocking the wrong drug/dosage form in an ADC bin or removing the wrong drug/dosage form from the ADC. The "other" events also included error types such as extra dose, monitoring error-documented allergy, and unauthorized drug.

Table 2 lists events by the top five units in which the event occurred, representing more than half (53%) of the total events. The top three units associated with

Table 1. Top 5 Event Types Involving Drug Storage Issues (n = 171) from June 2004 through October 2009

EVENT TYPE	NUMBER	% OF TOTAL EVENTS (N = 215)
Wrong drug	99	46%
Other	30	14
Wrong dose/ overdosage	22	10
Wrong dosage form	11	5
Wrong strength/ concentration	9	4

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these errors include the medical/surgical unit (21%), the pharmacy (14%), and the medical unit (7%). However, events occurred in more than 50 different care areas (e.g., ambulatory surgery, anesthesia, labor and delivery, medical/surgical unit, imaging, operating room [OR], pharmacy, psychiatric unit, skilled nursing unit), indicating that drug storage issues can and do occur throughout a facility.

Patient Care Areas

Floor Stock

While the primary storage of drug products is in the pharmacy or central supply department, there are a number of items that are stored in patient care areas (e.g., medical/surgical unit, emergency department [ED]). Typically, these are frequently used drugs, such as hydration solutions. Other drugs (e.g., opiates) may also be stored in patient care areas in locked cabinets or ADCs. However, facilities should evaluate what other drug products are often stored as part of floor stock. For example, high-alert medications (e.g., concentrated electrolytes, labetalol injection), especially those that require intravenous (IV) admixing or compounding, should not be stored in patient care areas, as these can cause serious harm when used in error.

The classic example of error-prone floor stock storage of a drug involved concentrated potassium chloride vials. In the 1980s and 1990s, many patients were seriously harmed, and a number of them died, as a result of errors that occurred when concentrated potassium chloride vials were stored in patient care areas.[6-9] Sometimes the errors in these cases were due to knowledge deficits about the dangers of rapid IV administration of concentrated potassium or, more often, were mental slips or wrong drug selection when choosing a vial of medication. Patient safety organizations called for the removal of concentrated potassium chloride vials from patient care areas, and in 2002, the Joint Commission published a National Patient Safety Goal (NPSG) mandating accredited hospitals follow suit. Limiting access to this drug has reduced fatal errors.[10,11]

Information contained in 97 (45%) of the 215 events reported to the Authority indicated that the events involved drug products stored as floor stock. Seventy-three (75%) of these events reached the patient. Some of these events show problems when multiple concentrations of the same drug are stored in close proximity in the same storage area. Other events demonstrate problems when multiple-dose containers are stored and used as floor stock rather than pharmacy providing patient-specific doses. Examples of events reported to the Authority include the following:

> *[I] gave patient 10 mg of morphine as opposed to 2 mg of morphine because the boxes of 10 mg were next to the 2 mg of morphine in the drawer. The boxes are identical in color. I did not immediately sign out the medication because I was distracted by other patient events at the time of medication dispensing.*

> *The patient was ordered Trandate® 10 mg IV push. The nurse removed Trandate multidose vial from ACUDOSE [ADC] and administered 10 ml of medication (50 mg) IV push. The physician was notified. IV fluids were administered, and the patient was monitored.*

There have been occurrences of harmful events involving floor stock storage of drugs reported elsewhere. One such event occurred when an anesthesiologist from an OR placed a vial of atracurium, a neuromuscular blocking agent (NMBA), in the refrigerator near vaccine vials of similar appearance.[12] Seven infants were subsequently administered atracurium subcutaneously instead of hepatitis B vaccine. The infants developed respiratory distress; five infants recovered, one sustained permanent injury, and another died. The Institute for Safe Medication Practices (ISMP) noted that NMBAs had never been available as floor stock in the nursery.

Table 2. Top Five Care Areas Associated with Drug Storage Issues (n = 113) from June 2004 through October 2009

CARE AREA	NUMBER	% OF TOTAL EVENTS (N = 215)
Medical/surgical unit	45	21%
Pharmacy	30	14
Medical unit	15	7
Acute specialty rehab unit	12	6
Emergency department	11	5

Night Closet

In hospitals where 24-hour pharmacy services are not available, nurses need access to limited supplies of essential medications during off hours. To help safeguard this need, the Joint Commission has established a medication management standard that requires that accredited facilities limit after-hours, nonpharmacist access to supplies of medication to a secure location or a night/weekend cabinet outside the pharmacy.[13] Additionally, medications that are made available should be limited to only those drugs approved by the hospital. Despite these standards, some facilities continue to allow nurses access to the entire pharmacy inventory after hours. The accessibility and variety of medications available, as well as a potential lack of an independent double check of the original order to the obtained medication, contribute to medication errors.

Information contained in 88 (41%) of the 215 events indicated the involvement of drug products that were stored in some type of night closet or after-hours pharmacy area. Sixty-seven (76%) of these events reached the patient. The most frequently reported event type for cases involving night closet storage was wrong drug. This event type accounted for 39 (44%) of these

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events. Two examples of wrong drug errors submitted to the Authority are as follows:

Order for Xopenex 1.25 mg nebs three times a day. Xanax 1.25 mg was pulled from night locker and given to patient.

Lovastatin 20 mg by mouth ordered. Lovenox 30 mg subcutaneous was removed from pharmacy night box by the supervisor. The nurse gave the medication.

While none of the reported events describe incidents of patient injury, serious harm and even death can occur when safeguards are not in place for night closet storage and access. In 2007, ISMP reported a case in which a patient presented to a critical access hospital extremely short of breath. His physician had prescribed an IV dose of furosemide.[14] However, the pharmacy was closed, so a nurse entered the secured section of the pharmacy to obtain the drug. She mistakenly selected a vial of potassium chloride instead of furosemide, both of which were kept on adjacent shelves just above the floor. She took the vial to the care area, withdrew the medication, and administered it to the patient. An erroneous association of potassium on the label with the potassium-excreting diuretic likely resulted in the nurse's failure to recognize the error until she went back to the pharmacy to document removal of the drug. The patient died as a result of this error.

Pharmacy

The pharmacy department, including the central pharmacy and any satellite pharmacies, is the primary location where drugs are purchased, stored, prepared, and dispensed. This results in a large volume of drug products being stored in one area of the facility. Also, many pharmacy departments order from a single wholesaler that offers preferred, low-cost products. For example, a wholesaler may purchase all hydration and frozen premixed IV products from a single manufacturer that uses a consistent brand appearance, layout, and label design for their products. This increases the risk of look-alike products being stored in the pharmacy.[15]

Thirty (14%) of the 215 storage-related events implicated pharmacy as location of the error, making pharmacy the second most often reported location of these errors (see Table 2). Often, the facilities that reported these events identified, within the error description, that side-by-side storage of the drug products contributed to the event. Examples include the following:

A nurse received a syringe containing a red liquid, and the label read that the medication was "Dilantin 60 mg." The nurse knew that Dilantin® was an orange liquid and not red. The syringe was brought to pharmacy, and she obtained the correct medication (Dilantin). The medication in the original syringe was phenobarbital. Pharmacy investigated and found that the medications were positioned next to each other, and the names looked the same to the pharmacy tech (phenobarbital and phenytoin). These medications are separated in the satellite pharmacy, but they ended up next to each other on the counter, and the incorrect bottle was selected.

When a nurse retrieved Senokot®, she realized that the medication in the syringe was clear; Senokot is dark brown. The syringe was returned to the pharmacy, and the correct medication was dispensed. An investigation revealed that the medication was sodium bicarbonate, which is stored next to the Senokot.

A patient was ordered Neomycin®. When the nurse went to give the medication, [the nurse] noted that naproxen had been sent. The pharmacy was contacted, and the correct medication was sent. The medications were stored near each other in pharmacy ([in] alphabetical [order]), and the pharmacy technician had inadvertently selected the wrong med. Pharmacist did not check the med prior to leaving the pharmacy.

In the book *Medication Errors*, Cohen and Smetzer describe how unsafe storage of mivacurium, an NMBA, next to the antibiotic metronidazole resulted in several patients receiving mivacurium by mistake.[16] One patient died while three others went into respiratory arrest. A review of the event found that look-alike, foil-wrapped, premixed IV products had been stored next to one another in the bulk IV storage area. Several other factors contributed to the mix-up and eventual administration of mivacurium, including the following: (1) the addition of mivacurium to the hospital formulary was not communicated to all staff; (2) prior to mivacurium being added to the formulary, metronidazole was the only premixed IV product with a foil overwrap; and (3) the products in the bulk IV storage area were organized alphabetically, and mivacurium was placed next to metronidazole.

Refrigerator

Refrigerators, in both pharmacy departments and patient care areas, are locations of drug storage. Refrigerators present unique challenges to safeguarding drug product storage, such as limited space or lacking built-in discrete pockets or bins. Also, depending on the location of the refrigerator, it may be used to store manufacturer-packaged products for floor stock use, as well as patient-specific or patient-labeled products. This increases the risk that a healthcare practitioner may select the wrong drug (e.g., a vial of rapid acting insulin rather than an insulin mix) or retrieve the wrong patient's medication (e.g., the drug labeled for the patient in bed 100-A instead of the drug for the patient in bed 100-B) from a refrigerator. How much space is available in the refrigerator, as well as the facility's decisions about what products to store and how to organize them, will impact the safety of refrigerator storage.

From events reported to the Authority, analysts found the following examples of refrigerator-related drug storage.

Patient was ordered "Ativan 1mg IV prn HS." Label was prepared correctly by pharmacist, and the order was filled incorrectly by a technician with famotidine

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20 mg vials. Both medications are stored in the refrigerator in the pharmacy. The error was caught when the drug reached the floor. The pharmacist was alerted, and the correct medication was then dispensed.

A TPN [total parenteral nutrition] additive was to be famotidine 20 mg. A vial of fosphenytoin 100 mg/2 ml was accidentally used in the compounding. The error was caught during required review by the pharmacist. The reporter noted that both vials are similar in appearance, and both are a 2 ml size. The medications were stored next to each other in the refrigerator due to a temporary move of the IV room outside the pharmacy. Now that the IV room has returned, these two products are again segregated into two different refrigerators.

Many examples have also been published by national patient safety organizations. For example, a respiratory therapist in a pediatric intensive care unit obtained what he thought was a sterile water vial to prepare a nebulizer treatment.[12] Fortunately, he noticed that he had grabbed a vial of the NMBA atracurium that someone had inadvertently returned to a respiratory box in the refrigerator. The atracurium and sterile water vials both had similar purple color accents.

Errors related to unsafe storage of medications in refrigerators have caused serious patient harm and death. One such case involved intrathecal injection of an undiluted dose of rifampin to a 32-year-old woman.[17] The physician ordered vancomycin 20 mg intrathecally each evening and rifampin 450 mg IV each morning for a central nervous system staphylococcal infection. The pharmacy placed both the evening dose of vancomycin and the morning dose of rifampin in syringes next to each other in the refrigerator. A medical student removed both syringes, thinking that, together, they contained a single dose of intrathecal vancomycin, and administered the medication. He also did not notice the label on the rifampin syringe that stated the medication need to be diluted in 250 mL of fluid prior to administration. The patient experienced nystagmus, nausea, and vomiting, and within a few days developed left hemiparesis and required mechanical ventilation.

Risk Reduction Strategies

Healthcare facilities should take steps to safeguard the storage of drug products throughout the institution. This includes storing and dispensing medications according to manufacturers' guidelines for temperature, light, and expiration date. Consider the strategies described below, which are based on a review of events submitted to the Authority, as well as observations at ISMP and in the literature.

Patient Care Areas

- Carefully select drugs stocked in each patient care area by considering the needs of each patient care area and the expertise and familiarity of staff with specific drugs, with the risk of error associated with each drug, and with the age and diagnoses of typical patients being treated on the units.[18]
- Review the list of items that staff from each patient care area can order manually or automatically through materials management. Ensure that pharmaceutical products cannot be provided without prior pharmacy agreement and supervision.[19]
- Ensure that drugs stocked in patient care areas are available in the least number of doses, concentrations, and forms that will meet essential patient needs between replenishment (not to exceed 72 hours).[18]
- Ensure that drugs, including emergency medications, stocked in patient care areas are in age-specific, ready-to-administer, unit-dose forms (i.e., are not stored in bulk containers).[18]
- Ensure that NMBAs are not available as floor stock and/or in ADCs (except in OR/anesthesia stock).[18] Based on the results of the 2004 ISMP Medication Safety Self-Assessment, NMBAs were available as floor stock outside the OR in 80% of hospitals responding; of the respondents, 59% said that when available outside the OR, these drugs were not sequestered from other floor stock items or labeled with auxiliary warnings.[20]
- When possible, dispense NMBAs from the pharmacy as prescribed for patients. Outside the pharmacy, limit access to these agents to the OR, ED, and critical care units where patients can be properly ventilated and monitored.
- When NMBAs must be available as floor stock, have the pharmacy department assemble the vials in a sealed box with warnings affixed as noted below. Sequester the boxes in both refrigerated and nonrefrigerated locations.
- Place vials, bags, and syringes of drug products in a sequestered bin for immediate pharmacy pick-up after the drug has been discontinued or the patient has been discharged or transferred.
- Use strategies of product separation and segregation to improve safe drug storage. Store individual medications in a separate bin or in a bin with dividers between different products. Label each section in a manner that clearly identifies the drug stored within.
- If using ADCs, convert the large matrix drawers to drawers with locking lids, which enables limiting drug removal to the product selected on the ADC screen.
- Isolate medications used by respiratory therapists into one location in the ADCs (e.g., one matrix drawer), and restrict therapist access to those drawers only.
- Review guidelines for the safe use of ADCs, such as those from ISMP (available at www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf) and the American Society of Health System Pharmacists (available at www.ashp.org/DocLibrary/BestPractices/AutoITGdlADDs.aspx), to enhance

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organizational practices related to ADC stocking, drug dispensing, storage, and administration.

- For additional strategies to safeguard the use of ADCs, review the September 2005 *Patient Safety Advisory* article "Problems Associated with Automated Dispensing Cabinets."

Pharmacy

- Remove and discard unnecessary hazardous bulk chemicals from the chemical/compounding storage area, particularly those that have not been used within the last 6 to 12 months. Ensure permanent, secure labeling of hazardous chemicals. Apply large cautionary labels to products as appropriate (e.g.,"MUST BE DILUTED," "FOR COMPOUNDING USE ONLY").
- Segregate those chemicals currently used for compounding, and continue to store them in a fully sequestered section of the pharmacy.
- Segregate and store electrolytes for IV compounding together in one location: the IV preparation area.
- Store sterile water bags away from medication supplies. Never allow IV compounding products to leave the pharmacy's sterile compounding area. Segregate these solutions, and store them with warnings to not distribute them outside the pharmacy.[19,21]
- Sequester and affix warning labels to vials of NMBAs stocked in the pharmacy. Be sure the warning labels do not obscure the vial label in any way.
- Maximize the pharmacy's ability to provide patient-specific unit-dose solid and liquid medications (either commercially obtained or prepared by the pharmacy) throughout the institution.
- Ensure that all medications are stored in individual labeled bins within easy access (and visualization) for all staff.
- Investigate implementing technologies such as barcode on dispense in the pharmacy to reduce the risk of selecting the wrong medication from stock.

Quality Processes

- Require periodic review by a pharmacist or pharmacy technician of storage areas in the organization, including the pharmacy and patient care areas (e.g., ED, radiology, OR, medication rooms) to identify potential storage issues.

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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. Four of the following five areas were included in a list of the top five locations associated with errors involving the storage of drug products.

   Select the location that was NOT reported as one of the top five locations.

   a. Acute specialty rehab unit
   b. Emergency department
   c. Medical/surgical unit
   d. Medical unit
   e. Operating room

2. The most frequently reported type of medication error involving the storage of drug products is:

   a. wrong dosage form.
   b. wrong dose/overdosage.
   c. wrong drug.
   d. wrong strength/concentration.
   e. wrong time.

3. All of the following are true about access to drug products after the pharmacy is closed EXCEPT:

   a. Nearly 41% of events related to drug storage that were reported to the Authority involved drug products that were stored in some type of night closet or after-hours pharmacy area.
   b. The Joint Commission permits facilities to allow non-pharmacists access to the pharmacy after hours.
   c. Roughly 76% of events reported to the Authority involving drug products stored in some type of night closet or after-hours pharmacy area reached the patient.
   d. Medications that are made available for staff access after hours are limited to those approved by the hospital.
   e. The accessibility and variety of medications available after hours, as well as a potential lack of an independent double check of the original order, contribute to medication errors.

4. All but one of the following are effective strategies to reduce the risk of medication errors involving drug storage.

   Select the INEFFECTIVE strategy.

   a. If using automated dispensing cabinets (ADC), organize stock using large matrix drawers.
   b. Isolate medications used by respiratory therapists into one location in the ADCs (e.g., one matrix drawer), and restrict therapist access to those drawers only.
   c. Ensure that drugs stocked in patient care areas are available in the least number of doses, concentrations, and forms that will meet essential patient needs between replenishment periods.
   d. Apart from the pharmacy, limit access to neuromuscular blocking agents to the operating room, emergency department, and critical care units where patients can be properly ventilated and monitored.
   e. Require periodic review by a pharmacist or pharmacy technician of storage areas in the organization, including the pharmacy and patient care areas.

5. A nurse received a syringe containing a red liquid and the label read "Dilantin 60 mg." The nurse knew that Dilantin® was an orange liquid and not red. The medication in the original syringe was identified as phenobarbital. The pharmacy's investigation found that the medications were positioned next to each other in the pharmacy, and the names looked the same to the pharmacy technician (phenobarbital and phenytoin).

   Select the appropriate strategy to help prevent this event from reoccurring.

   a. Ensure that drugs stocked in patient care areas are in age-specific, ready-to-administer, unit-dose forms.
   b. Educate pharmacy staff that these two products will be stored next to one another.
   c. Store therapeutically similar products together on pharmacy shelves.
   d. Implement barcode on dispense technologies in the pharmacy.
   e. Apply large cautionary labels that read "MUST BE DILUTED" or "FOR COMPOUNDING USE ONLY" to hazardous bulk chemicals as appropriate.

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Clinical Emergency: Are You Ready in Any Setting?

ABSTRACT

Emergency equipment and supplies often are not readily available when a patient experiences a life-threatening emergency. The location of these clinical emergencies varies, but there is a common theme: lack of the correct equipment and supplies to optimally manage the emergency. There are three distinct factors of rapid response preparedness that must be addressed in virtually every clinical point of care area: (1) rapid access to functioning equipment and up-to-date supplies; (2) knowledgeable and trained staff to manage the clinical emergency; and (3) after systems are in place, maintaining a state of readiness to manage a clinical emergency at any time. The Pennsylvania Patient Safety Authority identified 56 reports over the course of a 12-month reporting period specifically related to emergency equipment; 35 reports referenced issues with emergency carts and 21 reports referenced issues with missing supplies or malfunctioning equipment during an emergency situation. Strategies for facilities to achieve preparedness include convening a team to evaluate the needs of the floor or unit, establishing a written plan, selecting appropriate equipment and supplies (e.g., automated external defibrillators, rapid response teams), training and educating staff, and maintaining a state of readiness (e.g., through mock drills). (Pa Patient Saf Advis 2010 Jun;7[2]:52-60.)

Introduction

The Pennsylvania Patient Safety Authority conducted a data review encompassing a 12-month reporting period (2008) to determine whether or not there may be an issue with event reports related to crash carts and missing or unavailable equipment, specifically during a clinical emergent or rapid response situation. The review identified 56 reports that highlighted emergency or rapid response situations in which supplies or equipment were missing or outdated. The locations of these incidents varied as did the types of medical emergencies (see Table 1), but the common theme was *lack of the appropriate equipment and supplies to successfully manage the emergency in a timely manner*. Reports identified issues such as incorrect size supplies, missing items, empty oxygen tanks, drained batteries on equipment, or unstocked or unlocked crash carts.

Analysis of the event reports submitted to the Authority and review of the literature identifies three factors of clinical emergency preparedness that warrant attention in virtually every clinical point of care area: (1) having rapid access to functioning equipment and up-to-date supplies; (2) having knowledgeable and trained staff to manage the clinical emergency; and (3) once systems are in place, monitoring those systems to ensure that clinical staff maintain a state of readiness to manage clinical emergencies.

This article describes means to assess and evaluate the ability of a clinical setting or facility to manage a rapid response or a clinical emergency and offers specific strategies to improve preparedness. While much of the literature written about managing clinical emergencies deals with the office setting, many of the concepts are appropriate for a clinical emergency in any setting (e.g., inpatient unit, outpatient unit, other ambulatory setting in a hospital).

Evaluating Needs and Risk

The first step in assessing preparedness for a clinical emergency is convening an interdisciplinary team within the clinical area or department to review specific needs. This is important because there may be specific logistics, space, or staffing issues that need to be considered when planning for an emergency situation in a given clinical setting.

While published data may help identify areas of focus within an identified clinical area, physicians should be prepared to treat the emergencies most likely to occur within the patient population of the clinical area or department. For example, a clinical unit with many patients with epilepsy must be more prepared to treat seizures. Units with children or adolescents should have a wider range of equipment sizes as well as specific medications which may be more appropriate for this age group. Physicians should also prepare for any possible adverse reactions resulting from common procedures.[1]

The following questions can help evaluate the facility's ability to manage a clinical emergency.

1. What is the patient population and age range of the unit?[2]
2. What types of procedures are performed in the clinical area (e.g., invasive procedures, cardiac testing)?[2]
3. Are injectable drugs administered?[2]
4. How comfortable and skilled in emergency care are the physicians?[2]
5. Is staff trained in and competent to assist with emergency care?[2]
6. What equipment, drugs, and supplies are available? What additional equipment, drugs, and supplies might be required?[2]
7. Where are the supplies kept? How often are they inventoried and updated?[2]

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8. What is the location of the clinical area in relation to emergency care at a hospital, and what is the typical response time for those attending the emergency?[2]
9. If the facility is located outside of a hospital, how long does it take the emergency medical services (EMS) in the area to respond?[3,4]

While the probability may be low of a life-threatening clinical emergency occurring in certain clinical settings, the possibility remains. For example, behavioral health and psychiatric units may be vulnerable to cardiac or respiratory arrest through coexisting physical illness, self-harm, and the effects of medication, including rapid tranquilization. These patients are also vulnerable to choking or aspiration associated with illnesses like dementia, food bolting, substance abuse, or intentional self-harm.[5] As clinical teams convene in these seemingly low-risk areas, having plans in place to manage the infrequent emergency may be a wise patient safety strategy. For hospitals in the United States, the Joint Commission states that "Resuscitation services [must be] available throughout the hospital." The phrase "throughout the hospital" is crucial. It implies that equipment, supplies, oxygen, and medical personnel must all be present and ready to respond to cardiac arrest—not just in emergency departments (EDs), intensive care units (ICUs), and wards but also in less acute areas, such as inpatient mental health facilities.[6] In many cases, facilities also must be prepared for clinical emergencies that may happen with family members or visitors.

Establishing a Written Plan

After evaluating the potential needs of a clinical area, the next step is developing or adopting a written emergency response plan.[7] Questions to consider about existing plans include the following:

- When was the last time the clinical emergency or rapid response plan had been reviewed?
- Do staff know that a plan exists; if so, do they adhere to it? Is it included as part of new employee orientation?
- Is the plan still current and appropriate for the clinical services and procedures that are performed on the unit?

For facilities accredited by the Joint Commission, there are requirements that speak directly to the provision of emergency services and the need for a written plan. When emergency services are provided at the hospital or one or more off-campus locations, the medical staff must have written policies and procedures for appraisal of emergencies, initial treatment, and referral of patients at the off-campus locations.[8]

The written plan should include clinical protocols, specific employee responsibilities during the emergency, and details on where and how the emergency care should be delivered. Written clinical protocols for clinical emergencies typically follow the "airway, breathing, circulation" model of emergency care taught in formal life support classes.[9] Additionally, protocols should account for the emergency skills of each employee and the assignment of each employee to specific responsibilities. Designating a location for the delivery of emergency care and for storing all emergency equipment is a good start to the planning process. If the layout of the clinical area makes this difficult, emergency equipment should be portable (e.g., on a rolling cart, within carrying cases) and stored in a common location.[9]

At a minimum, a written plan addresses equipment, supplies, medications, ordering and maintenance, emergency protocols, training and competency of staff, emergency drills, and assignment of responsibility for continued oversight of the process.[2] Consider the following aspects of a written plan:[10]

- How will staff notify others in the clinical area to a life-threatening emergency?
- Who will contact the code team, the rapid response team (RRT), or EMS?
- Who will bring the emergency supplies to the scene?
- If the patient requires a backboard, is staff trained and competent in how to position the patient?
- Who will initiate cardiopulmonary resuscitation (CPR)? Who will assist?
- Who will document the emergency? In what format is documentation supposed to occur?
- Who will take vital signs?
- What information should be provided to EMS, the code team, or the RRT? Who will assemble that information?
- Who will start an intravenous line, if necessary? Who will help set it up?
- Who will administer medications?
- Who will assist family members during an emergency?
- How will staff be educated about the emergency plan?
- How often will practice drills be conducted?
- Who is responsible for the supplies (e.g., inventory and maintenance)?
- Who will manage other patient needs on the floor during the emergency?

Since the written plan should include specific details about supplies, equipment, and medications to be used, the next step is to outline items that are needed for the specific clinical area and who needs to be involved in the selection process (e.g., hospital administration, pharmacy, central supply).

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Table 1. Pennsylvania Patient Safety Authority 2008 Reports and Corresponding Failure Modes

LOCATION OF EVENT	DESCRIPTION OF REPORT	FAILURE MODE*
Cardiac intermediate unit	The crash cart defibrillator battery was dead. The oxygen tank was empty.	Failure to identify expired materials.
Cardiac unit	[There was an] expired code cart. It was not replaced until 24 hours later.	Code cart refurbishment does not occur after usage and will be missing essential items. No one responsible for delivery, maintenance, or refurbishment.
Cardiology—invasive	During code/intubation, staff found a suction canister on the code cart that was not functioning. Equipment services examined the suction apparatus and determined the regulator was broken. The equipment was removed from service.	Failure to identify expired materials.
	Ambu bags were missing from the code cart. Suction was not located in the proper place.	Incomplete list of items in the crash cart.
Cardiovascular/surgical intensive care unit (ICU)	Patient was in ventricular fibrillation. The defibrillator on the crash cart would not charge on paddles. The second defibrillator was readily available for use. The patient was successfully defibrillated.	Failure to identify expired materials.
Emergency department (ED)	Staff discovered [during a] check of crash cart drawer that only one epinephrine [injection was] used. Two epinephrine [injections were] ordered by the doctor. The patient was in cardiac arrest. [The patient arrived at] ED via ambulance. Patient was in ventricular fibrillation/ asystole on arrival. Nurse involved was unable to reconcile discrepancy.	Crash cart refurbishment does not occur after usage and will be missing essential items. No one responsible for delivery, maintenance, or refurbishment.
	The crash cart was used for this patient during the night. The [ED registered nurse (RN)] never called for the crash cart to be replaced, and the open cart was not found until a code was called during the next shift. [There was an] issue of safety with a used crash cart open on the unit.	
	One of the crash carts in the ED was opened [in the afternoon] and the pharmacy was not called until [the following morning] to replace the cart. [There was a] safety issue with an open crash cart if it was needed for a true code. Policy states the cart is to be replaced after being opened for any reason.	
	During rapid response, a patient needed to be intubated and the intubation box had no stylet. The RN needed to go to another unit to get a box with a stylet. The patient's intubation was delayed five to eight minutes.	Incomplete list of items in the crash cart.
Medical/surgical/cardiac intermediate unit	An intubation 16 Fr stylet was unavailable on the code cart. A stylet was retrieved from another code cart located on floor. No harm [occurred].	Code cart refurbishment does not occur after usage and will be missing essential items. No one responsible for delivery, maintenance, or refurbishment.
	A code was called and the [code] cart was opened [during the morning] The floor [staff] did not call the pharmacy to exchange the open crash cart until [late afternoon]. [There was a] safety concern that an open, incomplete [code] cart was on the floor for several hours without being exchanged.	
	Code was called for this patient. [Staff] did not call to have the [code] cart replaced until [late afternoon]. Cart was not cleaned up before the exchange, and used needles and a blade were left lying on top of the cart. Medications were used also. [There was a] safety concern with a partial cart on the floor for five hours.	
	The orange resuscitation bag [was discovered] opened [during response] to a patient needing to be intubated. Propofol and succinylcholine missing from bag. Medications obtained and patient intubated.	
	A code was called and when the physicians went to place a central line, there was no central line insertion kit on the code cart.	Incomplete list of items in the code cart.
	A code was called. [There was] no monitor on the unit. The labor and delivery staff did not bring their monitor initially.	
	Reported inadequate supplies with rapid response called. The patient was transferred to the ICU.	

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LOCATION OF EVENT	DESCRIPTION OF REPORT	FAILURE MODE*
(continued)	There was no adult bag valve mask in the [code] cart during a cardiopulmonary arrest resuscitation. The code sheets on the clipboard were in the utility room instead of on the cart. The appropriate equipment was obtained from ICU and utility room. The [code] cart was restocked with medications and supplies.	Personnel working off of different check sheets for inventory.
	There was a code situation, and the airway box was needed. The box was labeled with an expiration date that had past. Upon opening the box, there were no endotracheal tubes. The patient had to be bagged until the airway box from the ICU was brought out with the proper supplies in it.	Failure to identify expired materials.
Medical ICU	Code cart opened. All epinephrine boxes in drawer had needles on them. Not able to use.	Incomplete list of items in the code cart.
	The patient's heart rate was greater than 160 beats per minute and sustained. Following American Heart Association advanced cardiac life support guidelines, adenosine was [administered intravenously]. There was not adequate stock of adenosine in crash cart to give recommended protocol. The patient was transferred to the ICU and cardioverted. A normal heart rhythm was obtained.	
	During a code, staff found that [code] cart only had one size of Mac blade. The physician was aware.	
	The red respiratory box on the low side of code cart was found to be unlocked and dirty.	Code cart refurbishment does not occur after usage and will be missing essential items. No one responsible for delivery, maintenance or refurbishment.
Outpatient dialysis unit	The Ambu bag was pulled off the code cart; the bag was sealed. When Ambu bag was opened, there was no mask in bag. [Staff were] unable to use Ambu without mask. The patient needed to be resuscitated with a nonrebreather mask.	Incomplete list of items in the code cart.
	During a code, it was noted that the triple lumen tray was not on the code cart. [Staff] used dialysis needles until triple lumen tray was obtained.	
Orthopedic unit	A patient coded and the Ambu bag on code cart did not have a mask. The patient was intubated.	Incomplete list of items in the code cart.
Outpatient area	[The patient] became unresponsive. The rapid response team was called. The code cart was brought, but then taken away. Supplies to treat the patient, including intravenous (IV) supplies were not available.	Incomplete list of items in the code cart.
Pediatric unit	Yankaur, suction tubing, and IV tubing were missing from the crash cart during a code.	Incomplete list of items in the crash cart.
	The replacement crash cart lock was never locked when received from central.	Crash cart refurbishment does not occur after usage and will be missing essential items. No one responsible for delivery, maintenance or refurbishment.
Pharmacy	A code [occurred in early morning], but no replacement crash cart was available [and none were nearly four hours later]. Central [was requested] to page nursing director when one was ready. [This was the] second time [in a] week the issue occurred in which approximately three to four hours without a crash cart [available].	Crash cart refurbishment does not occur after usage and will be missing essential items. No one responsible for delivery, maintenance, or refurbishment.
Rehabilitation unit	A [patient] was transported to the hospital's outpatient rehabilitation unit for therapy. While in the rehab unit, the patient became unresponsive. A code was called. During the code, it was discovered that the oxygen on the crash cart could not be used because the spigot was missing. Other tanks in the unit were empty. The reporting facility amended the report to indicate that other oxygen tanks were available for use.	Incomplete list of items in the crash cart.
	[Cardiac] monitor was applied to patient but was not working properly [no rhythm]. Patient monitored by electrocardiogram machine until crash cart/monitor obtained. [There was] no delay in monitoring. The monitor was tagged and sent to central.	
Telemetry unit	Stylet was not replaced in crash cart after last event.	Incomplete list of items in the crash cart.

* Source of failure modes is as follows: Long EK. Crash cart standardization. 2007 Jan 31 [cited 2009 Apr 30]. Available from Internet: http://www.ihi.org/ihi/workspace/tools/fmea/ProcessDetailDataReport.aspx?ToolId=5431&ScenarioId=6443&Type=1.

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Selecting Equipment and Supplies

When determining what equipment, supplies, and medications will be available in a clinical setting, consider how much medical intervention is appropriate to the setting.[2] The physician or department chair is responsible for deciding the level of emergency care necessary for the type of practice and what drugs and equipment to stock to deliver that care.[7]

Once the equipment and supplies have been selected, maintain them in a centralized container (crash cart or emergency box) in a location easily accessible to the clinical areas, and standardize the contents of each emergency supply box or cart.[2,7,9] Standardizing the equipment and medications contributes to a safe system by improving a number of logistic issues, including staff training, performance, error reduction, equipment maintenance and replacement after a crisis, and the institution's ability to revise medication and equipment resources for crises. Improving efficiency and reliability can reduce delays and errors and contribute to the primary goal of improving patient outcomes following a crisis event.[11]

In the hospital setting, supplies may be readily available (via designated locations for crash carts or code carts), but often the stocking and replenishing of these carts is done by another department in the hospital. To avoid shortages of supplies and equipment, the Joint Commission (in its Environment of Care standards) recommends a continual process to manage its inventory.[12] If the pharmacy or the central supply departments are involved with maintaining the emergency equipment and supplies for the clinical area, representatives should be involved in the needs assessment as well as be included as part of the written plan.

Use of Automated External Defibrillators

The American Heart Association's 2005 guidelines on emergency cardiopulmonary resuscitation recommend that hospitals consider the use of automated external defibrillators (AEDs) as a way to facilitate early defibrillation.[13] AEDs may be particularly helpful in areas where staff do not have rhythm recognition skills and would not be able to use manual defibrillators, as well as in areas where defibrillators are infrequently used. Healthcare facilities must ensure that healthcare workers and other staff who may activate AEDs are properly trained in AED use, that quality improvement processes are in place to monitor resuscitation efforts, and that AEDs are properly managed.[14] Many AEDs come with a routine maintenance checklist. This checklist should be used or incorporated into the overall facility/unit emergency equipment checklist. Checklist items may include noting AED visibility and proximity to a phone, verifying battery installation, checking the status and/or service indicator light, noting the absence of visual and/or audible service alarms, and inspecting exterior components and sockets for cracks.[15]

Training and Educating Staff

While many of the issues discussed in reports to the Authority may be resolved through written policies and increased accountability among staff members, staff training and education is an essential element to ensure staff readiness for a clinical emergency.

At a minimum, all clinical staff should be certified in basic life support (BLS). Consider the value of available personnel trained in advanced cardiac life support (ACLS) in settings in which high-risk procedures are conducted. All staff should be trained on the location and use of emergency supplies.[2]

A code team or rapid response team may be able to easily reach a patient in the hospital within the established time frame. However, patients at sites away from the main hospital building may be less accessible to a code team. Patient Safety Officers can work with their facilities to ensure that a process is in place to respond to cardiac arrest at all the sites that the hospital operates, including outpatient imaging centers, physician practices, and long-term care facilities. Staff at those facilities can be trained to provide CPR and activate an AED to respond to individuals in cardiac arrest.[14] Staff training can also include an overview of the campus (e.g., map) as well as knowledge of the different clinical areas within the facility.

One of the Joint Commission's National Patient Safety Goals (Goal 16)[16] addresses improving recognition of and response to changes in a patient's condition, since a significant number of critical inpatient events are preceded by warning signs. A majority of patients who have cardiopulmonary or respiratory arrest demonstrate clinical deterioration in advance. Early response to changes in a patient's condition by a specially trained individual may reduce cardiopulmonary arrests and patient mortality. The steps include the following:[16]

- Select an early recognition and response method most suitable for the hospital's needs and resources.
- Develop criteria for calling additional assistance to respond to a change in the patient's condition or a perceived change by the staff, the patient, and/or family.
- Develop a no-blame policy that encourages use of the early recognition system. Key champions including physicians must be involved to develop a collaborative culture.
- Based on the hospital's criteria, facilitate means for staff to seek additional assistance when they have concerns about a patient's condition.
- Conduct a formal training about urgent response policies and practices for the staff, licensed independent practitioners who may request assistance, and caregivers who may respond to those requests.

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Table 2. Pennsylvania Patient Safety Authority Missing Items and Equipment with Suggested Action Plan, 2008

TYPE	ISSUE*	SUGGESTED ACTION
Airway	No Ambu bag available (2)	Include on crash cart inventory checklist
	Ambu bag missing mask (2)	
	No stylet in intubation box (3)	
	Bronchial set missing prisms	
	Missing blade sizes (2)	
	Airway box missing endotracheal tube and outdated	Include expiration date checks on inventory checklist
	No adult bag mask available	Make sure inventory checklist includes all required sizes
	No suction machine available on unit (4)	Identify locations/areas for accessible suction equipment
	Suction machine failed	Include testing of suction equipment during crash cart checks
	Oxygen tank empty	Include oxygen tank level checks as part of cart checklist
	Missing spigot on oxygen tank	Include all parts in oxygen checklist (tank, tubing, spigot)
Cardiac	Red respiratory box unlocked and dirty	Set frequency of box/cart checks
	Defibrillator paddle failed	Include testing of defibrillation equipment during crash cart checks
	Defibrillator did not have pacing capabilities	Consider purchase of defibrillation equipment with pacing capabilities
	Defibrillator battery dead (3)	Include testing of defibrillation equipment during crash cart checks
	Pacemaker wire and introducer mislabeled and not compatible	Include on crash cart inventory checklist
Medication	No monitor available on unit	Identify locations/areas for accessible monitors
	Cardiac monitor failed (goes blank)	Include testing of monitors during crash cart checks
	Intravenous (IV) pump channel failed to deliver medication	Include testing of IV pumps during crash cart checks
	No IV pump available	Identify locations/areas for accessible IV pumps (including backups)
	No IV tubing available	Include on crash cart inventory checklist
	No IV supplies available	
	No central line insertion kits available	
	No propofol or succinylcholine on cart	Include on crash cart medication inventory checklist
	Insufficient amount of adenosine on cart to comply with American Heart Association protocols†	
	No amphodextrose on cart	
	No vasopressin on cart	
	No triple lumen tray on cart	
	No epinephrine on cart	
	Mislabel ephedrine versus epinephrine	Educate staff on sound-alike, look-alike medications
	No atropine syringes available	Specify type(s) and dosages on the medication crash cart inventory checklist
	Wrong doses of epinephrine stocked on cart	
	Lack of knowledge in use of calcium glugonate	Include medication guidelines (dosage) in crash cart
Communication/Training	Busy signal when trying to call code blue (2)	Include testing of communication system as part of mock drill
	Code intercom announcement not heard in all units	
	Pagers did not notify all code responders	
	Inadequate training in an emergency	Develop and review training to a rapid response with identified staff
Other	Used medications found in crash cart	Include disposal of equipment/medications as part of postcheck following a rapid response
	Incomplete crash cart (not restocked after last emergency) (6)	Set time frames for exchanging and restocking crash carts within facility
	Unlocked cart (2)	Include locks with numbers as part of the crash cart inventory checklist

* Number in parentheses signifies the number of reports or the number of times that the issue was identified, if greater than one.

† The 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care are discussed in context in the main article.

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Considering Rapid Response Teams

More than 3,000 hospitals—representing an estimated 75% of all U.S. hospital beds—have signed on to the Institute for Healthcare Improvement (IHI) 5 Million Lives Campaign, implementing six quality improvement changes in their facilities aimed at saving lives. One of the six measures is the advent of a RRT.[17,18]

Healthcare facilities and departments have found success in the use of RRTs to manage clinical emergencies. A RRT consists of ICU personnel who can be summoned to assess and treat any patient outside the ICU who shows signs of deterioration and who may be at risk for cardiac arrest or death. Team makeup varies, but often includes one or more ICU nurses, a respiratory therapist, and a physician who can be called upon when needed.[19]

Maintaining a State of Readiness

The final, and arguably most critical, step (based on events reported to the Authority) is putting systems in place that can ensure that all of the preceding steps are up-to-date and that the clinical area is in a state of readiness to manage a clinical emergency, no matter how infrequent, at any time.

Checking and Maintaining Inventory

Outdated medications or supplies on an emergency crash cart pose two problems: (1) the outdated medications or supplies can expose a delay in treatment if discovered when a clinical emergency arises, and (2) the fact that the equipment or supplies have not been regularly checked may result in additional problems such as malfunctioning or powerless equipment. In an ambulatory surgical facility, crash carts should be checked weekly (and include the disposal and replacement of outdated medications) and always after use in an emergency.[20] In the hospital setting, standards for checking vary and are governed by hospital policy. Checking and documenting the lock numbers of the emergency crash cart and testing the defibrillators can be done as frequently as every shift.

Nursing staff should check the carts and kits daily to ensure that seals are unbroken and all expiration dates are acceptable. This is often one of the first tasks to be abandoned at change of shift, when staffing tends to be short. Further, the monotony of checking without finding problems day after day often leads to a lackluster approach, increasing the chance that problems will be missed. Staff must be trained to review checklists properly and to conduct more thorough preventive maintenance periodically.[21]

Many facilities find it helpful to develop and use a standardized checklist for the crash cart. Designated staff members use this checklist to ensure that the emergency supplies and equipment are periodically monitored and evaluated. (A reprinted, sample checklist, titled "Emergency Crash Cart Checklist (2010)," is available from the Authority online at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.)

As an example of an innovative way to manage emergency crash cart checking in a large institution, a Florida hospital developed a Web-based crash cart tracking system that enabled the nursing management team to remotely track and monitor which departments or units in the hospital checked their crash carts. This Web-based system replaced paper logs on each crash cart. In addition to monitoring the carts, monthly cart checks alert staff to any item near expiration, prompting the appropriate departments to change the medicines and supplies. The system sends the management team three notifications daily, beginning at noon, of which carts have and have not been checked. By 7 p.m., management can be assured that they are 100% compliant in checking the crash carts. The system also helps to identify the clinical areas where there are opportunities for improvement.[22]

Performing a Failure Mode and Effects Analysis

IHI hosts on its Web site a failure mode and effects analysis (FMEA) tool that addresses the risk of nonstandardized crash carts.[23] After considering these failure modes, facilities may develop policies to address the facility-specific failures of the crash cart system that may occur over time. As an example, Table 1 correlates events by location reported to the Authority with the failure modes identified in an FMEA posted on IHI's Web site.

Conducting Mock Emergency Drills

When properly conducted, mock drills allow the staff to practice all steps in the emergency protocol as well as individual lifesaving skills. Often, unanticipated problems with the protocol or medical equipment can be identified and corrected.[7]

In one study, 11 group pediatric practices participated, which were representative of urban, suburban, and rural offices in southwestern Pennsylvania. Ninety-seven of a total 164 (59%) physicians and staff members completed both pre- and postintervention surveys following completion of an emergency mock drill. Practitioner participants were analyzed in two groups. Group 1 consisted of physicians, nurse practitioners, and physician assistants; group 2 consisted of registered nurses, licensed practical nurses, and medical assistants. Comparison of pre- versus postintervention surveys in both of these groups revealed significant improvement in reported confidence to perform resuscitation skills that were included in the mock drill after the training.[24]

Mock drills may help hospitals nationwide improve dismal outcomes by focusing attention on fast action and the highly detectable events that lead up to such failures before they occur in real patients.[25]

Consider conducting an emergency or "mock code blue" at least twice a year so the staff remains familiar and comfortable with the protocol and equipment and the emergency response protocol can be evaluated for efficacy.[2] All staff on all shifts should be included in at

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least one mock drill annually to ensure familiarity with emergency response protocols at all times.

Conclusion

Emergencies can and do occur, and being prepared for them requires an investment of time, effort, and resources. As is evidenced by the types and clinical locations of the Authority reports, emergencies can and do happen anywhere (Table 1). Even though the incidence of an emergency occurring in a given clinical area may be low, the risk to patient safety associated with not being adequately prepared or not managing one efficiently is high. Organization and planning are important for preventing chaotic emergency responses.[2]

Analyzing specific needs and types of emergencies that may occur in the particular department or clinical setting is an important first step towards determining the selection of supplies, medications, and equipment as well as the development of a written plan.

Identifying equipment failures as well as missing equipment may assist facilities in ensuring the development of thorough emergency checklists that address the specific needs of the unit's patient population. (See Table 2.)

Staff education and training is another essential element to ensuring adequate response to an urgent clinical situation. Documented training as well as periodic retraining of staff is warranted. Such staff training, when used effectively, can create accountability among both clinical and nonclinical staff members and can cultivate a proactive team approach in responding to emergency situations. Use of RRTs may also ensure that responding staff are both experienced and knowledgeable in the management of supplies, medication, and equipment during an emergency.[18]

Creating checklists and conducting mock codes can go a long way towards monitoring and maintaining a constant state of readiness. Periodically reviewing that checklists are being completed within the regularly scheduled intervals may prevent faulty equipment, missing items, or outdated medications when they are needed. Walking through and analyzing the steps of an emergency following a mock drill may help clinical areas identify opportunities for improvement or the need for additional clarification in procedure.

Finally, analyzing or conducting a post-review after a real emergency can ensure that all staff provide input regarding target areas for improvement.

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OR Fire Prevention Video Available

The Anesthesia Patient Safety Foundation offers a free 18-minute video, *Prevention and Management of Operating Room Fires*, on its Web site at http://www.apsf.org/resource_center/fire-safety.mspx. The video promotes best practices regarding the prevention of fires in the operating room (OR), including controlling oxygen concentration levels at or near the surgical site, and extrapolates OR fire statistics based in part on analysis of events reported to the Pennsylvania Patient Safety Authority.

The *Pennsylvania Patient Safety Advisory* archive also has several articles discussing OR fire prevention, including most prominently "Airway Fires during Surgery" (http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/mar4(1)/Pages/01b.aspx), which is accompanied by an educational poster that highlights ways to minimize and fight airway fires (http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/airway_fires/Pages/airway_fires.aspx).

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Management of MRSA in Ambulatory Surgical Facilities

Introduction

Hospitals, nursing homes, and ambulatory surgical facilities (ASFs) in Pennsylvania are required to develop and implement an internal infection control plan that includes procedures for identifying and designating patients known to be colonized or infected with multidrug-resistant organisms (MDROs), including methicillin-resistant *Staphylococcus aureus* (MRSA).[1] This mandate is in line with the nationwide effort to reduce the acquisition of MDROs and other infections in healthcare settings. At the federal level, the Centers for Medicare and Medicaid Services' conditions for coverage mandate that ASFs develop and implement an effective infection control program designed to prevent, control, and investigate infections and communicable disease based on nationally recognized infection control guidelines.[2]

Infection Control in ASFs

In comparison to hospitalized patients, ASF patients spend limited time in the facility. Most have a shorter duration of anesthesia, are generally healthier, and undergo same-day procedures. However, the risk remains the same regarding the transmission of organisms during surgery and the acquisition of surgical site infections. With the exponential increase in community-acquired MRSA, the risk of patients presenting with the organism for same-day surgery exists. Their MRSA status may or may not be known. The primary mode of MRSA transmission is identical in any healthcare setting: MRSA spreads mainly via the contaminated hands of healthcare workers after contact with a colonized or infected patient and/or the environment. As such, infection prevention practices are necessary in ASFs to mitigate the risk of spreading infection.[3]

Authority Data

Between January 2008 and March 2010, the Pennsylvania Patient Safety Authority received 37 reports from ASFs that were directly related to MRSA-positive patients. These cases included patients with a previously documented history of MRSA colonization or infection, positive screening results prior to same-day surgery, and postoperative wound infections attributed to surgical procedures conducted at ASFs. Of the 37 reports, 6 indicated cancelled or rescheduled procedures due to a positive history or preoperative screening results.

MRSA Management Workshops

In late 2008, various ASF Patient Safety Officers in Pennsylvania reached out to the Authority through its Patient Safety Liaison program for guidance on the management of MRSA patients in their facilities. In response to the request for guidance, the Authority conducted a series of MRSA management workshops between April and October 2009 for a total of 57 ASFs spanning three regions—northeast, central, and northwest. The ASF attendees provided feedback by means of verbal discussion and evaluations that revealed that close to 90% were highly satisfied with the workshop and felt that it was applicable to their facility. At the time of publication of this article, workshops are being scheduled for the southwest and southeast regions.

Highlights of these workshops are included below.

Facts and Clinical Features

MRSA is a potentially deadly strain of the common *S. aureus* bacteria that frequently inhabits the skin or nostrils.[4] Because of its resistance to antibiotics commonly used in treatment, MRSA is among the most common and the most problematic of healthcare-acquired infections.

MRSA can present in the form of colonization, which is defined as the presence of microorganisms without tissue invasion or damage (i.e., causing no signs or symptoms).[4] It can also present in the form of infection, which is the presence of microorganisms with tissue invasion and damage (i.e., causing symptoms). MRSA is transmitted mainly by direct contact via the hands of personnel from patient-to-patient or environment-to-patient. MRSA is the most common cause of community-acquired skin and soft tissue infection. However, it is easily eradicated by handwashing with soap and water or using alcohol-based hand sanitizers.

MRSA emerged in the United States soon after methicillin became commercially available in the early 1960s, and prevalence increased in the 1970s.[5] In 2007, MRSA accounted for approximately 50% to 70% of all *S. aureus* clinical isolates from patients with healthcare-associated infections acquired in intensive care units (ICUs). About 85% of all invasive MRSA infections are connected with healthcare settings.

Risk Factors

General factors that place patients at risk for acquiring MRSA include wounds, prolonged hospital stays, and antibiotic usage, including duration of administration, use of broad spectrum drugs, and multiple antibiotics given to individual patients.[4] In addition, severity of illness and the use of invasive lines in patients in ICUs, burn units, oncology units, and hemodialysis centers contribute to the acquisition of MRSA. Physical placement of patients with MRSA (particularly if they are in close proximity to at-risk patients) may also be a contributing factor.

Certain surgical procedures place patients at risk for MRSA and other infections.[6] These include open procedures of the hip and knee; spine, including lumbar laminectomies; cardiac surgery with mediastonotomy, coronary artery bypass graft (CABG) surgery, and valve replacements; and spinal fusions, including anterior/posterior cervical fusions. (It is understood

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that the preceding procedures are not conducted in outpatient settings and are considered major surgery; however, they were introduced during the workshop as examples of general risk factors.)

Components of a MRSA Prevention Program

Active Surveillance

Screening of high-risk individuals (usually undertaken in the hospital setting) by conducting active surveillance cultures through various combinations of interventions (e.g., rapid PCR [polymerase chain reaction]-based versus agar culture-based screening) will identify positive patients early and provide the opportunity to reduce the potential for transmission.[4] However, screening should be done as part of an overall infection prevention and control program, rather than as a stand-alone practice. Pennsylvania law requires hospitals to screen all patients received from nursing home facilities, as well as to identify other high-risk patients, as determined by the individual hospital (see "Risk Factors").

Screening by Means of History Taking

Screening includes taking a verbal history from the patient prior to surgery (e.g., obtaining information from the patient and/or surgeon) for the purpose of identifying the patient's physical status and his or her subsequent risk to others. In addition, patients may give a known MRSA history. Patients with uncontained or uncontrollable drainage and secretions have the potential to contaminate others, mainly via the environment, and could require additional precautions. Screening by this method enables facilities to identify both those patients who have a history of the organism, as well as those whose physical status may put others at risk in the event that they are unaware of harboring MDROs.

Isolation Precautions

Standard precautions and contact precautions apply to the outpatient setting for preventing transmission of MRSA.

Standard precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed diagnosis or presumed infection status. These precautions are the primary strategy for preventing pathogen transmission and are recommended for implementation in all healthcare settings, including ambulatory care. Components of standard precautions include proper hand hygiene, use of personal protective equipment (PPE), and environmental cleaning.[4]

The following principles apply for hand hygiene:

- Perform hand hygiene before and after patient contact, including after gloves are removed.[4]
- Perform hand hygiene any time there is a possibility that there has been contact with blood or other potentially infectious materials.[4]
- Avoid direct contact with potentially contaminated surfaces (e.g., equipment, drapes, sponges, other patient care devices) whenever possible.[4]
- Make alcohol-based hand sanitizer products readily available.[4]
- Strictly adhere to the Joint Commission's National Patient Safety Goal NPSG.07.01.01, which includes the prohibition of artificial nails.[7]
- Implement compliance monitoring programs.[4]

The Centers for Disease Control and Prevention (CDC) defines PPE as a variety of barriers (e.g., gloves, gowns, masks, goggles, face shields) which protect mucous membranes, airways, skin, and clothing from contact with infectious organisms such as MRSA. PPE selection is based on the nature of the patient interaction and/or the likely mode(s) of transmission.[8]

With regard to environmental cleaning, CDC recommends the use of "standard cleaning and disinfection protocols to control environmental contamination with MDROs for the operating room environment."[4] The Association of periOperative Registered Nurses states that "operating rooms should be cleaned after each surgical or invasive procedure" and "terminal cleaning and disinfection of operating and invasive procedure rooms should be done when the scheduled procedures are completed for the day, and each 24-hour period during the regular work week."[9]

Contact precautions are transmission-based and are used as an adjunct to standard precautions for the purpose of further isolating the patient and taking extra precautions with the items and equipment used on the patient. Implementation of contact precautions is determined by the individual facility on a case-by-case basis. Components of contact precautions, as well as enhanced strategies for ambulatory surgery, include the following:[3,4]

- House the patient in a private room at all times or in a specially designated room or area in the preoperative holding area and postanesthesia care unit (PACU). Keep the patient out of common areas.
- Ensure that the patient's isolation status is communicated to all staff members.
- Don gown and gloves upon entering the patient's room (including preoperative and PACU areas) and discard these items before exiting the room.
- Limit the movement and transport of the patient. When transporting the patient, wear gowns and gloves.
- Dedicate the use of noncritical patient care equipment and items (e.g., stethoscopes, blood pressure cuffs, electronic thermometers) to the patient in the preoperative area and PACU.
- Adequately clean and disinfect all surfaces and OR equipment,including anesthesia equipment, as well as noncritical patient care items (as described above if not discarded after use).

Pre- and Postpresentation Surveys

In order to develop the MRSA workshops, the Authority surveyed the registered participants to

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gain insight into facility practices. A postpresentation follow-up survey was sent to those facilities that participated in the prepresentation survey to ascertain whether the information shared had any influence on ASF practices. Results of the pre- and postpresentation survey are shown in Tables 1 and 2. Results include only those facilities that completed both surveys.

Summary of Findings

Pre- and postpresentation surveys revealed the existence of certain practices that were either redundant or not based on guidelines or recommendations, including practices that had little or no bearing on patient safety (e.g., performing surgery on MRSA-positive patients at the end of the day). Shortly after the presentation, positive changes were made as evidenced by the summary of survey findings.

The following results obtained from the prepresentation survey stand out and were not repeated in the postpresentation survey as the high incidence of these practices among the facilities did not warrant surveying for changes:

- 96% use alcohol hand sanitizer products as a form of hand hygiene.
- 92% include a general policy for MRSA in the infection control plan.
- 100% do daily terminal cleaning of the operating rooms.

Results from the postpresentation survey helped the Authority determine the efficacy of the workshops.

Changes noted between the results of the prepresentation survey and the postpresentation survey include the following:

A decrease in the percentage of facilities that conduct preoperative screening (44% to 36%). A possible explanation for this change is that implementing standard precautions and contact precautions reduces the need to single out patients for the purpose of treating those known to be colonized or infected any differently than those with an unknown status.

An increase in the percentage of facilities admitting MRSA-positive patients for surgery (48% to 56%). Feedback indicates increased comfort with including MRSA-positive patients on surgical schedules, versus turning them away. Some respondents expressed interest in obtaining permission from their administrators to include these patients during future scheduling.

A decrease in the percentage of facilities performing surgery on MRSA-positive patients at the end of the day (24% to 12%). Again, a possible explanation for this is that standard and contact precautions reduce the need to single out patients.

An increase in the placement of MRSA-positive patients on contact precautions (52% to 60%). Choosing to introduce contact precautions in addition to standard precautions in certain settings and under certain circumstances may be warranted. The workshops discussed assessing each patient individually for the purpose of using additional precautions.

Table 1. Pennsylvania Patient Safety Authority Prepresentation Survey of MRSA Practices in ASFs (N = 25)*

QUESTION	YES	%	NO	%	NON-RESPONSES	%
Does your facility require preoperative MRSA screening?	11	44%	14	56%	0	0%
Does your facility perform surgery on MRSA-positive patients?	12	48	13	52	0	0
Is surgery on MRSA-positive patients done at the end of the day?	6	24	13	52	6	24
Do your staff members use alcohol-based hand sanitizer products?	24	96	1	4	0	0
Does your facility's infection control plan include a general policy for MRSA?	23	92	2	8	0	0
Does your facility place MRSA-positive patients on contact precautions?	13	52	5	20	7	28

*Survey dates were March 2009 and September 2009.

Table 2. Pennsylvania Patient Safety Authority Postpresentation Survey of MRSA Practices in ASFs (N = 25)*

QUESTION	YES	%	NO	%	NON-RESPONSES	%
Does your facility require preoperative MRSA screening?	9	36%	16	64%	0	0%
Does your facility perform surgery on MRSA-positive patients?	14	56	11	44	0	0
Is surgery on MRSA-positive patients done at the end of the day?	3	12	18	72	4	16
Does your facility place MRSA-positive patients on precautions?	15	60	6	24	4	16

*Survey dates were June 2009 and October 2009.

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Additional results not included in the tables are as follows:

For known MRSA-positive patients, 90% of the responding facilities dedicate equipment to the specific OR, and 100% clean nondedicated equipment between treating patients. About 67% do not isolate MRSA-positive patients from the common areas, and 56% dedicate a private room pre- and postoperatively for MRSA patients.

Conclusion

Pennsylvania ASFs are required to develop and implement an internal infection control plan that includes procedures for identifying and designating patients known to be colonized or infected with MRSA.[1] Implementing and sustaining changes in practice, including new approaches to infection prevention and control, takes time and effort at all levels. The Authority plans to continue conducting educational programs on infection control for healthcare facilities, including ASFs, to foster improving best practices for the benefit of patient safety.

Notes

1. Medical Care Availability and Reduction of Error (MCARE) Act. 40 P.S. § 1303.401, et. seq. (2007).
2. 42 CFR § 416.51 (2009).
3. Gruendemann BJ, Mangum SS. *Infection prevention in surgical settings.* Philadelphia (PA): 2001:339-343.
4. Healthcare Infection Control Practices Advisory Committee. Management of multidrug-resistant organisms in healthcare settings [online]. 2006 [cited 2010 Apr 4]. Available from Internet: http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf.
5. Klevens RM, Morrison MA, Nadle J, et al. Invasive methicillin-resistant *Staphylococcus aureus* infections in the United States. *JAMA* 2007 Oct 17;298(15):1763-71.
6. Healthcare Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection [online]. 1999 [cited 2010 Apr 4]. Available from Internet: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf.
7. Joint Commission. NPSG.07.01.01 [online]. 2009 Jun 4 [cited 2010 Apr 26]. Available from Internet: http://www.jointcommission.org/AccreditationPrograms/LaboratoryServices/Standards/09_FAQs/NPSG/Healthcare_associated_infections/NPSG.07.01.01/Hand+hygiene.htm.
8. Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings [online]. 2007 [cited 2010 Apr 26]. Available from Internet: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.
9. Association of periOperative Registered Nurses (AORN). Recommended practices for environmental cleaning in the perioperative setting. In: AORN. *Perioperative standards and recommended practices*. Denver (CO): AORN; 2010:241-5.

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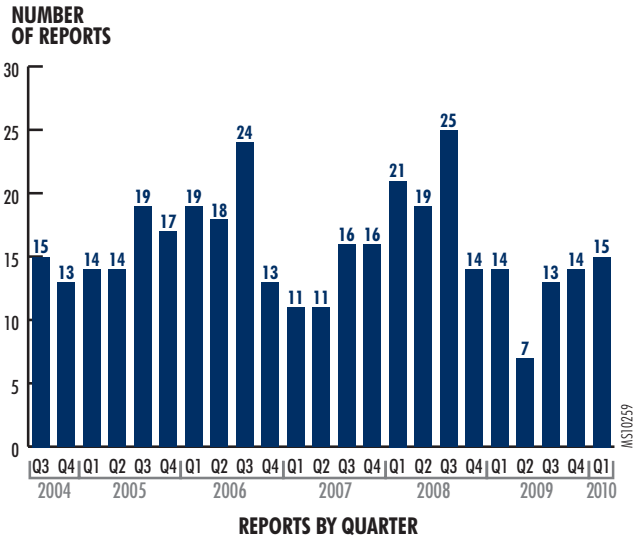
Quarterly Update on the Preventing Wrong-Site Surgery Project:

Some have changed. Most have not. Same approach. Same upshot.

The number of wrong-site surgeries in Pennsylvania increased during the first quarter of 2010 (see Figure 1), despite the availability of evidence-based best practices.* As usual, this quarterly article has been updated to include any belated additions and corrections from previous reporting quarters. Once again, wrong-site anesthetic blocks were the most commonly reported (three), with two reports of wrong vertebral level and two reports of wrong-site procedures on the breast.

Is elimination of wrong-site surgery possible? Anecdotal evidence suggests facilities can minimize their risk for this surgical "never event." Perhaps, others can benefit from these facility experiences.

Figure 1. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter



Eight Success Stories

In January 2010, the Pennsylvania Patient Safety Authority analysts identified eight hospitals that had dramatically reduced their incidence of wrong-site surgery reports. The Patient Safety Officer at each facility kindly provided either information about facility efforts to eliminate wrong-site surgery or contact with personnel within the facility who did. To maintain confidentiality, the results of these unstructured interviews have been aggregated. The common themes of the interviews highlight the main efforts associated with the successes (see Table).

At the time these eight hospitals were identified in January 2010, each had gone a minimum of 64 weeks without wrong-site surgery (the last report having been submitted in early October 2008) and a maximum of 103 weeks, with an average of 81 weeks without any wrong-site surgery for the eight facilities. In the approximately 3.5 to 4.25 years prior to their respective improvements, the eight hospitals had reported 68 wrong-site surgeries, with a minimum of 6 and average of 8.5 per hospital for an average of one wrong-site surgery from each facility every 24 weeks, one every 3 weeks from the group as a whole. (See Figure 2.)

The actions cited by each facility in each interview were categorized and aggregated. They are listed, in the table, in the order of the number of hospitals that cited them. They will be discussed in chronological order.

Five of the eight hospitals discussed the importance of leadership: the initial commitment and the ongoing support of hospital leaders, including vice presidents for medical affairs, chief medical officers, medical staff presidents, department chairs, directors, and surgeons. Support included empowerment of OR staff who stopped procedures to resolve concerns and mentorship of noncompliant physicians.

In several facilities, the initiative to eliminate wrong-site surgery was part of an overall patient safety program within the facility. Two facilities made prevention of wrong-site surgery a high priority goal. One made specific individuals responsible for implementing the solutions and chose to measure results against the process standard of perfect compliance with the Universal Protocol instead of the outcome measure of zero wrong-site surgeries. Another facility established a surgical patient safety committee.

One of the most commonly cited strategic decisions—mentioned by three quarters of the successful hospitals—was to standardize practices, in most instances not only within the operating room (OR), but extending to the anesthesia block area, the entire facility, and even entire systems. As one facility representative said, "All on the same page. All the same way."

Before deciding on a standard practice, five of the facilities specifically mentioned doing detailed assessments of their processes in one way or another, including root-cause analyses of wrong-site adverse events and near misses, with physician involvement in the analyses; use of mock tracer methodology; and information from the Authority.[1]

Half of the facilities specifically opined that involving the frontline OR personnel, including nurses, anesthesia providers, and surgeons, in the detailed

(continued on page 67)

* The Pennsylvania Patient Safety Authority has a Web page devoted to educational tools for preventing wrong-site surgery (available at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx). Its resources include all the Authority's publications on the subject, including self-assessment tools, sample forms and checklists, educational posters and videos, illustrative figures and tables, and patient education brochures, as well as links to information from other Web sites.

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Table. Actions Cited by Eight Hospitals Implementing Successful Programs to Reduce the Risk of Wrong-Site Surgery (ordered by number of times cited)

TIMES CITED	ACTIONS
6	Standardize policies and procedures across the facility. Educate all physicians and nursing staff about problems, impact, solutions, and policies and procedures. Use cases, including near misses as motivation for change. Use role models to assist in the process. Use information from the Pennsylvania Patient Safety Authority[a] to support evidence-based best practice. Monitor results and compliance regularly, with independent observers, and provide results to all relevant audiences, including the facility's board of directors.
5	Demonstrate leadership commitment and support.
4	Conduct root-cause analyses (RCAs) on all wrong-site events, including important near misses, and involve the physicians in the analyses. Involve operating room (OR) staff, anesthesia providers, and surgeons in the development of consensus around appropriate policies and procedures. Improve the use of a preoperative checklist for documentation verification and reconciliation. Develop a highly scripted time-out that engages all OR team members in the time-out process, and educate personnel about the script. Strictly enforce the agreed-upon policies and procedures, with peer review for repeatedly noncompliant physicians.
3	Share adverse events, near misses, and the results of RCAs with all relevant audiences, including the facility's board of directors. Conduct a detailed review and refinement of the appropriate policies and procedures, using mock tracer methodology, results of RCAs of events, information from the Authority,[a] and consensus from members of the OR team. Implement the World Health Organization surgical safety checklist. Establish a policy that at least two people, including a physician and a nurse, participate in the time-out for any invasive procedure, including bedside procedures. Establish a culture in which nurses are empowered to enforce policies and procedures, and can stop physician procedures if necessary for clarification.
2	Make prevention of wrong-site surgery a patient safety priority. Use mock tracer methodology to improve processes. Establish a sense of ownership by all involved in creating and following policies and procedures. Post enlarged time-out scripts in each OR. Follow up with a program for continued improvement of the processes.
1	Establish a surgical patient safety committee. Assign responsibilities for solutions. Make the intermediate objective of perfect compliance with Universal Protocol policies and procedures a goal, rather than making no wrong-site surgery a goal. Implement changes one service at a time. Focus on continuity of care. Identify and eliminate look-alike and sound-alike terms.[b] Emphasize the benefit to the patient. Establish a culture of respectful interactions between physicians and nurses. Have a program for explaining to patients the need for redundancy in asking questions.[a] Insist on accurate consents. Include anesthetic blocks in the procedures covered by the processes. Start each day in each OR with a daily preview. Do a formal patient identification on entering the OR.

a. Pennsylvania Patient Safety Authority (Authority). Preventing wrong-site surgery [patient safety tool collection online]. [cited 2010 May 3]. Harrisburg (PA): Authority. Available from Internet: http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx.

b. Potentially dangerous abbreviation in surgery. PA PSRS Patient Saf Advis [online] 2004 Mar [cited 2010 May 3] Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2004/Mar1(1)/Pages/02a.aspx.

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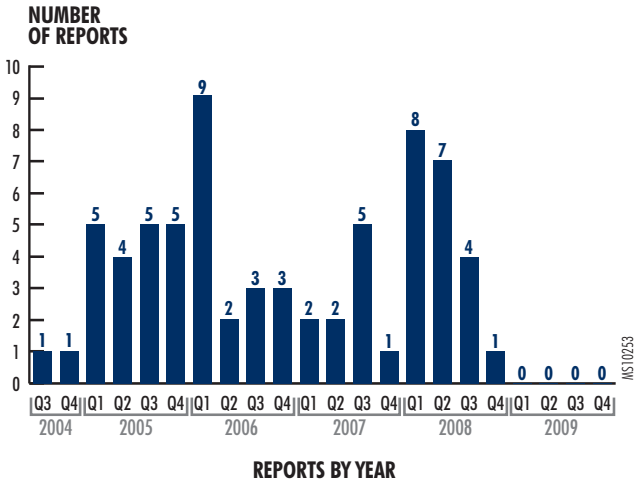
(continued from page 65)

improvement of the policies and procedures was critical to both their acceptance and their success. One person described the secret of success as "commitment from the top down; process from the bottom up." One hospital described consciously seeking to build consensus. Two mentioned the importance of establishing a sense of ownership in all those involved in the processes by engaging them in the creation of the policies and procedures. One had all their providers sign off on the final, agreed-upon, results.

The most common revisions were in the preoperative checklist (half) and in the time-out script (half). Three cited implementation of the World Health Organization's surgical safety checklist. Three identified the need to ensure that both a nurse and a physician were present to do a time-out for all invasive procedures, including bedside procedures throughout the hospital and anesthesia blocks. One hospital, perhaps mindful of the large percentage of wrong-site anesthetic blocks in the state,[2] made a special effort to evaluate the processes for verifying the site for regional and local anesthetic blocks. One hospital added an educational program to explain to patients why questions were asked repeatedly by different providers, possibly using the patient education brochure developed by the Authority.[1] One hospital included the elimination of look-alike and sound-alike terms in their reassessment, possibly based on reports referenced in the *Pennsylvania Patient Safety Advisory*.[3]

Another of the most commonly cited actions was to educate all the relevant healthcare providers, including the physicians, about the risks and causes of wrong-site surgery, the impact, any facility solutions, and the specifics of facility policies and procedures. Discussions of their own wrong-site surgeries and near misses, often by those who were involved, were done to illustrate vulnerability and to motivate change.

Figure 2. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports for Eight Hospitals with Successful Improvement Efforts



As one facility representative said, "The pain of prior events helps others change behavior." Several hospitals specifically mentioned the educational information available from the Authority.[1]

Three hospitals cited the importance of discussing the need to empower OR staff to halt the process if noncompliance, inconsistencies, or other concerns were noted. Leaders made it clear that OR staff would be supported when these situations arose. In some of the hospitals, this empowerment was part of a general discussion of respectful interactions between physicians and OR staff. In others, the emphasis was on the benefit to the patient: "It's not about you. It's not about me. It's about the patient."

Some hospitals focused on specific actions. One focused on the accuracy of the consents, specifically making sure they included a complete description of the site. Another focused on a formal identification of the patient upon entering the OR. Two made posters of their time-out script and put one in each room in the OR suite. One added a general briefing for each OR at the beginning of each day.

The last of the most commonly cited actions was to monitor compliance with the agreed-upon policies and procedures. Some monitored monthly, some weekly. Some used independent observers not otherwise associated with the process. Results provided feedback to the staff and physicians, who are being monitored. Results, in some hospitals, were also provided to the hospital's board of directors. One hospital set a goal of perfect compliance with the Universal Protocol. Two hospitals explicitly mentioned using the results to fine-tune the processes to ensure continuous quality improvement.

Half of the hospitals made it clear that they were strict about compliance with the agreed-upon policies and procedures. "They learn to feel better when they get it right all the time," said one representative. Nurses were empowered to halt the process if needed, with support of hospital management. Persistent noncompliance was considered a peer-review activity.

Listening to the interviews, the analysts were left with the impression that, like every other aspect of healthcare delivery, it is what you do and how well you do it that separates good performers from average performers.

The Wrong-Site Surgery Consultation Program

The Authority has begun an onsite consultation program for Pennsylvania facilities that wish to analyze their vulnerabilities for wrong-site surgery, particularly following a wrong-site event (or a close call) in a surgical suite. Requests can be made through the Authority office or the regional Patient Safety Liaison. The Authority clinical specialists will assist facilities in assessing their policies and procedures, measuring staff compliance, and thoroughly analyzing any events using resources developed by the Authority.[1]

The Authority is committed to having no patient experience wrong-site surgery.

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Notes

1. Pennsylvania Patient Safety Authority (Authority). Preventing wrong-site surgery [patient safety tool collection online]. [cited 2010 May 3]. Harrisburg (PA): Authority. Available from Internet: http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx.
2. Quarterly update on the preventing wrong-site surgery project: improving, but still room for perfection. Pa Patient Saf Advis [online] 2009 Dec [cited 2010 May 3]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Dec6(4)/Pages/141.aspx.
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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
- Aspiration screening
- Diagnostic radiation and pregnancy
- ASF patient screening and assessment
- Hospital bed safety
- Airway fires during surgery
- 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.

PATIENT SAFETY AUTHORITY

An Independent Agency of the Commonwealth of Pennsylvania

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 Authority, 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 Pennsylvania Patient Safety Authority, see the Authority's Web site at http://www.patientsafetyauthority.org.

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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.