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About the Pennsylvania Patient Safety Advisory

OBJECTIVE

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

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Leadership Series: Executive Patient Safety Walkrounds

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As we near the ninth anniversary of the Institute of Medicine's watershed report on medical harm in the U.S. healthcare system, *To Err is Human: Building a Safer Health System*, boards of trustees and administrators at many institutions remain uncertain and/or uncomfortable with their role in the patient safety arena. The Commonwealth of Pennsylvania encouraged closer trustee engagement under Act 13 by allowing trustee membership on the Act 13-mandated patient safety committee to be formed within each hospital. While this was a positive step, board members often remain distanced from the bedside in this traditional structure where much of the content may remain "reporting" of staff activities. More recently, the Institute for Healthcare Improvement's 5 Million Lives Campaign has included as one of its "planks" to "Get Boards on Board"[1] and strongly encouraged the meaningful, active participation of the board in goal-setting, resource allocation, public transparency, and accountability of medical staff and management for the achievement of safety and quality objectives. Realization of "Get Boards on Board" will require a deeper understanding of the promise and perils of patient safety and quality and the failure to attain them, respectively, in an increasingly scrutinized environment.

How can we begin the in-depth education of our board and administration and begin to bridge the clinical comfort gap? One potential and highly satisfying approach for both trustees/administration and the clinical staff of the hospital is the conduct of Executive (or Leadership) Patient Safety Walkrounds. Walkrounds were brought forward as such a bridge by Allan Frankel and his colleagues, who have demonstrated successful deployment at the Brigham and Women's Hospital in Boston.[2] Conceptually appealing and based on the philosophy that "the currency of leadership is attention," Executive Patient Safety Walkrounds have been introduced in many hospitals. While Frankel et al. did not include trustees in their initial efforts, the format allows both board members and senior executives to visibly place their imprimatur on the patient safety efforts of the clinical staff and learn quite directly the challenges to success in the domain of patient safety from frontline staff.

Abington Memorial Hospital's patient safety staff members have been conducting patient safety walkrounds for several years and have witnessed an increasing level of participation and robustness in the exercise. We have found that less structure places both staff and trustees/executives more at ease. We offer walkrounds in the morning, afternoon, and evening, as well as on night shift and following monthly board meetings. The frequency of our walkrounds is generally one or two times per month, and because of their increasing popularity with the board, we now conduct two walkround visits in different areas of the hospital simultaneously. We often provide advance notice to the nurse manager or department director (e.g., pharmacy) as a courtesy and will generally visit two areas in each session. Before the walkround begins, we review with the trustee(s) and executive(s) the objectives of the walkround and provide some common questions or points of focus that they may wish to engage in with the staff (see below for examples of the former and latter). Additionally, we provide them with a simple trifold brochure containing this information.

Objectives

- Provide senior leaders an opportunity to listen to the issues (this is important to staff as it pertains to the safe care of our patients).
- Provide regular forums with staff to learn about issues related to team practice, communication, and a transparent culture of reporting near misses and errors in order to create improvements.
- Provide a regular opportunity for senior leaders including board members to demonstrate their commitment to Abington Memorial Hospital's patient safety efforts.

Common Questions/Focus Points for Conversation

- Can you think of any incidents or adverse events that happened in the past few days that have resulted in prolonged hospitalization for a patient?
- Can you think of patients we have harmed as a result of problems with how we deliver care?
- What is the next thing that could happen on your unit that might lead to a patient being harmed?
- Have there been any near misses that have been averted because of existing systems or an individual's actions?
- What proactive steps should we take to prevent the next adverse event?
- Can you think of a way in which the system or the environment fails you on a consistent basis?

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- What specific actions from leadership would make the work you do safer for patients?
- What changes could be made in your unit to promote patient safety more consistently?
- What "keeps you up at night" when it comes to caring for your patients?
- How are we actively promoting a blame-free culture and working on the development of a blame-free reporting policy?
- Are you treated with non-negotiable mutual respect by others on the care team?
- What things do you do on your unit to create situational awareness of the risks in patient care every day?

It is highly apparent and gratifying that our low-tech intervention of walkrounds has energized our trustees by their successful interactions in the clinical context, which they substantially influence along with management by policy decisions and resource allocation. Further, the board genuinely enjoys meeting the staff and engaging them in clinical discussions on quality and safety—topics that were the impetus for their volunteering their energies in the first place. In addition, it is an excellent employee satisfier. Neither management nor board members should shy away from starting this simple yet intimate tool for demonstrating commitment to patient safety and beginning to harvest the vast, largely untapped learning imbued with those at the bedside. We urge you to get started today. As one of our board members recently exclaimed after his first walkround, "This was the most enjoyable and meaningful exercise I've had in my five years as board member . . . it's the reason I joined the board in the first place."

Note

1. Institute for Healthcare Improvement. Get boards on board [online]. [cited 2008 Jun 11]. Available from Internet: http://www.ihi.org/IHI/Programs/Campaign/BoardsonBoard.htm.
2. Frankel A, Graydon-Baker E, Neppl C, et al. Patient safety leadership walkrounds. *Jt Comm J Qual and Saf* 2003 Jan;29(1):16-26.

Correction

Medication assessment: one determinant of falls risk. *Pa Patient Saf Advis* 2008 Mar;5[1]:16-8. This article contained statements in error on pages 16 and 17 that need correction about the 33,882 falls reported in 2006 to PA-PSRS. The statements should indicate that the 33,882 falls represented all falls in 2006, not just those associated with medications, from which the pool of 4,009 falls associated with concomitant use of two or more medications was examined, as noted in Table 2. These corrections have been made to the online version of the article. The editor regrets the error.

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Care at Discharge—A Critical Juncture for Transition to Posthospital Care

ABSTRACT

Discharge is a critical juncture for transitioning to posthospital care, and incomplete discharge processes may cause harm to patients. From June 2004 to December 2007, more than 800 reports were submitted from hospitals through PA-PSRS identifying a variety of problems occurring at discharge. Approximately 30% of patients did not receive verbal or written discharge instructions before they left the facility. Lack of medication reconciliation was also evident. Essential components of the discharge process include educating the patient and his or her family, assessing the patient's understanding of the plan, scheduling follow-up appointments, organizing post-discharge services, confirming the medication plan, and reviewing with the patient what to do if a problem occurs. Understanding the pertinent requirements of healthcare regulatory agencies is an important part of discharge planning. Implementation of discharge planning upon patient admission, assignment of discharge coordinators, and use of checklists to facilitate standardization within the facility are risk reduction strategies to consider. (Pa Patient Saf Advis 2008 Jun;5[2]:39-43.)

Inadequate care and incomplete information at discharge can result in patient harm. From June 2004 to December 2007, more than 800 reports were submitted through PA-PSRS identifying a variety of problems occurring at discharge. The emergency department (ED) was identified as the care area in more than 300 reports. Approximately 500 reports were submitted from inpatient care areas. Less than 1% of reports were submitted by ambulatory surgical facilities. Approximately 30% of all reports indicated patients left the facility without receiving verbal and/or written discharge instructions. The causes identified indicate patients knowingly left without written instructions (most often from the ED), did not receive complete instructions, or received another patient's instructions due to an error in the discharge process. Lack of medication reconciliation was also evident in the reports, including issues such as a patient receiving incomplete medication instructions, incomplete prescriptions, or another patient's prescriptions or instructions. Many patients did not have their intravenous (IV) access removed prior to leaving the ED or other inpatient care area. The PA-PSRS reports indicated some patients returned to the hospital with an IV site infection and/or phlebitis. Additionally, reports indicated patients were discharged prior to test results being made available to the attending physician who might have postponed the discharge based on the final results. The narratives below illustrate some of the issues reported through PA-PSRS.

> *Patient discharged to nursing home. Discharge orders for 50 mg fentanyl but were written as 500 mg. The nursing home did not catch error until patient became very drowsy. Narcan was administered.*

> *Patient brought to [emergency room (ER)] by parent with [chief complaint] of [shortness of breath] for the last 24 hours. Patient diagnosed with exacerbation of asthma. Discharge instructions written along with [prescriptions]. Patient's nurse tied up with another patient. All staff were busy, and the ER was full. Patient and parent were witnessed leaving ER. Phone call was made to home, and [patient and parent were] encouraged to return for instructions and prescriptions. Patient never picked up documents.*

> *Patient was discharged with the wrong discharge medication list. The discharge medication list was for another patient.*

> *Patient was admitted with diagnosis of thrombus right arm. An x-ray of right elbow was ordered. Patient was discharged to an extended care facility via ambulance before right elbow x-ray done. Orthopedic doctor was notified of x-ray not being done.*

> *Patient was discharged to another facility with the right femoral triple lumen catheter still in place. Staff from the other facility called asking how long and how much pressure to hold on the femoral site when removing the catheter.*

> *Family member called this nursing unit stating the discharge instructions were unclear. The nurse discovered the medication discharge instructions were not completed. The patient had received a coronary artery stent and the booklet was still with the chart. The daughter was also unclear of the pacemaker instructions. [She was] also unclear on length of time the antibiotic was to be continued.*

Inadequate Discharge Planning May Lead to Patient Harm

The discharge process is intended to provide patients with adequate information and necessary resources to improve or maintain their health during the posthospital period and to prevent adverse events and unnecessary rehospitalization.[1] Inconsistent practices in the discharge process may result in unsafe outcomes.[2,3] High rates of unnecessary rehospitalization have been shown to be related to poorly managed discharge processes.[3] In a study conducted at an 800-bed urban teaching hospital, Forster et al. found that approximately 20% of 300 patients interviewed at 3 weeks postdischarge had experienced an adverse event. One-third (33%) of these adverse events were preventable, and most resulted from inadequate

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communication between the healthcare provider and the patient at the time of discharge.[4] These adverse events and rehospitalizations are preventable if comprehensive discharge processes are implemented.[5] The following narratives from PA-PSRS demonstrate how incomplete discharge instructions can lead to rehospitalization.

Patient had a brief pause on the cardiac monitor. The monitor strip was placed on the medical record but the physician was not notified. The patient was discharged the following morning. The patient's spouse called to report the patient passed out after leaving the hospital. As instructed, they returned to the ED, and the patient was admitted. The patient had a dual chamber pacemaker inserted the next day.

Patient resumed Coumadin postoperatively (time frame unknown) and developed bleeding, requiring admission to the hospital and return to the operating room for cauterizing of bleeding site. Doctor signed standard discharge instruction sheet of surgery center, stating the patient was to resume medication unless otherwise instructed, and did write for patient to not resume Coumadin.

Patient had a new medication started during this hospitalization for acute [myocardial infarction (MI)] with angioplasty and stent. Discharge medication list included Plavix and physician's prescription was available. The prescription was not given to patient at time of discharge. Patient was readmitted one day postdischarge for MI and repeat angioplasty.

Discharge instructions for steroid tapering not clearly written. Patient stopped taking medication abruptly and required readmission.

Essential Components of the Discharge Process

The Joint Commission and federal law require hospitals to provide patients with discharge plans.[6] (For more information on these requirements, see "Regulatory Requirements.") Discharge planning begins as soon as a patient is admitted to a hospital.[1,6,7] This dynamic process changes throughout the hospitalization until time of discharge.[1,6,7] There are few studies describing the fundamental components of the discharge process.[3] However, Greenwald et al. identified 11 essential components to the re-engineered discharge process at Boston Medical Center, as follows:[5]

1. Educating patients and families about their diagnosis throughout the hospital stay
2. Assessing the patients' understanding of the plan by asking them to explain the plan in their own words
3. Advising the patient and family of any tests completed in the hospital with results pending at time of discharge and identifying the clinician responsible for the results
4. Scheduling follow-up appointments and tests to be done following discharge
5. Organizing services to be initiated following discharge
6. Confirming the medication plan
7. Reconciling the discharge plan with national guidelines and critical pathways when relevant
8. Reviewing with the patient what to do if a problem occurs
9. Expediting the transmission of the discharge summary to the healthcare providers who are accepting responsibility for the patient's care
10. Giving the patient written discharge instructions
11. Providing telephone follow-up two to three days after discharge

Barriers to Successful Discharge Planning

Hospital systems and individual patient characteristics create several challenges for clinicians to provide comprehensive discharge plans that will ensure patients maintain or improve their health postdischarge. The challenges are developing and implementing an appropriate discharge plan, providing the physician

Regulatory Requirements

The Joint Commission requires that the discharge planning process be initiated early in the patient's care and treatment and that the patient and family be informed from the outset regarding the need for transfer to another healthcare setting.[1] In addition, the Joint Commission requires hospitals to develop a discharge summary for patients that includes the reason for hospitalization, significant findings, procedures performed, treatment rendered, the patient's condition at discharge, and specific instructions given to the patient and family. The summary is written and signed by the attending physician and is part of the medical record. The Joint Commission also requires that the discharge summary be completed within 30 days of discharge.[1] The Centers for Medicare & Medicaid Services (CMS) requires hospitals to implement a discharge planning process for all patients as part of its Conditions of Participation in the Medicare program.[2] As of July 1, 2007, CMS requires hospitals to notify Medicare beneficiaries who are hospital inpatients about their hospital discharge rights within two days of admission and to obtain the signature of the beneficiary or his or her representative.[3]

Notes

1. Joint Commission. Comprehensive accreditation manual for hospitals: the official handbook. Oakbrook Terrace (IL): Joint Commission; 2004 [updated 2007 Sep].
2. 42 CFR § 482.43 (2004).
3. Centers for Medicare & Medicaid Services. Medicare program; notification of hospital discharge appeal rights; final rule. *Fed Regist* 2006 Nov 27;71(227)68708-25.

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summary in a timely manner to the next provider of healthcare, and providing comprehensive written instructions to the patient. Greenwald et al. classified factors that contribute to medical errors at the time of hospital discharge into three types: (1) hospital care system characteristics, (2) patient characteristics, and (3) clinician characteristics.[5]

Hospital Care Systems

Patient discharge summaries provide information about a patient's hospital course and plan for after hospital care. Unfortunately, many hospital systems are unable to provide these summaries to the community healthcare providers in a timely manner.[5] A barrier that is common to hospital systems is the failure to prevent avoidable adverse drug events (ADEs). Forster et al. found approximately one-third of ADEs were preventable.[4] The flow of medications during and after hospitalization is complex,[5] but medication reconciliation throughout the hospital stay and especially at discharge may reduce preventable ADEs. The Joint Commission's National Patient Safety Goal for medication reconciliation requires a process for obtaining and documenting a complete list of the patient's current medications upon admission and with the involvement of the patient. A complete list of the patient's medications is communicated to the next provider when a patient is referred or transferred to another setting, service, practitioner, or level of care within or outside the organization. The complete list of medications is also provided to the patient on discharge.[8] Many facilities have implemented a medication reconciliation process, but reports submitted through PA-PSRS indicate that patients often do not receive a written list of medications or that the list is incomplete or incorrect, leading to medication errors.

Patient Characteristics

Several characteristics reported in the literature identify patients at risk for rehospitalization, including lack of social, financial, and familial support.[2,3]

Furthermore, low patient literacy levels can be a barrier to successful discharge.[5] Patients with low literacy rates may struggle to read and comprehend the written instructions given at discharge, prescriptions, follow-up appointment information, and health education pamphlets.[9] Baker et al. studied 3,260 patients enrolled in a Medicare-managed care plan and found patients with low literacy levels were at risk for readmission, whereas patients with moderate and adequate literacy were not. Patients are at greater risk for adverse events postdischarge when there is lack of follow-up and adherence to treatments.[5]

Clinician Characteristics

Clinician characteristics are modifiable issues focusing on quality and effectiveness of communication and the timeliness and completeness of discharge summaries provided to subsequent caregivers.[5] Lack of or limited clinician time and effort put into educating patients at discharge may lead to lack of patient understanding of and compliance with treatment plans.[2] In a randomized controlled trial by Coleman et al., a "transition coach" was assigned to assist and empower patients as active participants in their medical care. The transition coach, a nurse, provided education on medications, helped maintain personal health records, ensured timely follow-up appointments, and explained signs and symptoms of possible complications and appropriate follow-up actions. These actions resulted in a reduction in rehospitalization rates at 30 and 90 days.[10] The readmission rate at 30 days was 8.3 for the intervention group compared to 11.9 for the control group, and at 90 days it was 16.7 compared to 22.5.[10] There is no accepted standard format or content for discharge summaries, which frequently lack critical patient information and are not readily available to the patient's next provider.[5] Modifications to improve this process are suggested below.

Risk Reduction Strategies

Planning and providing for successful patient discharge from the hospital to the home or to another healthcare facility (e.g., acute rehabilitative, long-term care) is a complex process that begins at admission and is complete when the patient receives all the information and services needed to recover or maintain health during the period following hospitalization. Risk reduction strategies encompass the essential components identified by Greenwald et al., addressed in the following categories: assigning, screening, evaluating, assessing, and implementing.[2,8]

Assigning a healthcare worker to be responsible for discharge planning and defining the scope of their responsibilities can positively impact the discharge process. A social worker or nurse case manager who provides discharge planning services could undertake actions that include the following:

- Identify a process to educate patients and families about their disease.[5,7]
- Provide patients with disease-specific, low-literacy, and language- and age-appropriate educational materials.[7]
- Ensure development of clinical pathways includes discharge steps that are consistent with evidence-based strategies to guide treatment. Pathways may include disease process, diagnostic tests and therapies, medications, and actions to take if problems or variances occur.[7]
- Reconcile medications throughout the hospital stay and specifically at discharge to guarantee patients receive a complete and appropriate medication list.[8]
- Provide complete and accurate written discharge instructions to the patient. Instructions may include the following: medication administration instructions and drug action and side effects, follow-up appointments, activity level, diet, signs and symptoms that may develop, and when to call physician or seek emergency medical care.[7]

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Screening all patients on admission can help to identify discharge planning needs. Facilities may identify high-risk patients who require additional attention to discharge planning, such as patients with cancer, stroke, chronic disease with acute exacerbation, and dementia. Furthermore, certain circumstances (e.g., elder and child abuse, patients living alone) may require special attention when preparing for discharge.[8] Strategies include the following:

- Assign a social worker or nurse case manager to function as a discharge planner to patients as needed to implement the discharge plans.[7]
- Develop multidisciplinary teams to evaluate and implement discharge needs.[7]

Evaluating patients on admission and throughout the hospital stay for discharge planning, especially during changes in level of care, can identify needs that will exist at discharge and at the next level of care. One such strategy is as follows:

- Assign evaluation to specific team members; for example, physical therapists may assess a patient's ability to perform the activities of daily living, identify environmental barriers existing in the post-discharge care area, and determine services that may be needed.[7]

Assessing available resources can help to ensure that appropriate services are provided postdischarge. Knowledge of resources available in the community and the patient's covered benefits is essential. This component of the discharge process requires the expertise of a social worker or nurse case manager assigned to discharge planning. Staff developing and implementing discharge plans may perform the following actions for patients:

- Verify that the patient is aware of follow-up appointments with specific physicians. For example, if a follow-up appointment with a specialist is needed for a specific time frame, the discharge planner can collaborate with the patient and family to schedule follow-up appointments and any further diagnostic tests that were ordered.[7]
- After the patient is offered a choice of appropriate and available postacute care providers, make referrals for services that are identified patient needs and are ordered by the patient's physician.[7]
- Confirm services to be received before the patient leaves the hospital.[7]

Accompanying Resource

Visit the Pennsylvania Patient Safety Authority Web site (http://www.psa.state.pa.us) for a sample checklist to help staff assess that all discharge components are completed upon patient discharge.

To view the checklist, click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Next, click on "Resources Associated with Patient Safety Advisory Articles."

Implementing the plan on the day of discharge completes the process that began on admission. Referrals for follow-up care may be arranged before the day of discharge and validated for appropriateness on the day of discharge. Completion of the process may need to be accomplished during a short hospital stay or an extended length of stay. The staff assigned this responsibility will need to adjust to patients' needs and complete all discharge planning steps. Strategies include the following:

- Develop a standardized checklist to assess that all discharge components are completed.
- Finalize the plan with the patient. Have the patient verbalize his or her understanding of the plan.[7]
- Provide the patient with legible, written discharge instructions that are reviewed and signed by the patient, indicating that he or she understands the plan of care.[7]
- Perform a final physical assessment with attention to removal of IV lines and other access ports.
- Standardize the discharge instruction document to include the following elements: primary and secondary diagnosis, patient education, services to be provided, dietary and other lifestyle modifications, medications, follow-up appointments, pending tests, adverse events or complications to watch for, and provider contact information for any problems that occur.[11] Facilities can implement processes to facilitate timely transfer of the discharge summary to the receiving healthcare provider and follow up by telephone two to three days after discharge to assess optimal care and recovery after hospitalization.[11]

Discharge is a critical transition period for patients leaving the hospital to continue their recovery at home or in another healthcare facility. Continuity of care is the main goal for patients discharged from an acute care setting. Adverse events and high rehospitalization rates have been linked to poor discharge processes. According to the medical literature, a standardized comprehensive approach to discharge planning may reduce harm to patients and improve quality of care after hospitalization.

Notes

1. ECRI Institute. Discharge planning. *Healthc Risk Control* 2007 May;2:Patient support services 3:1-12.
2. Anthony D, Chetty VK, Kartha A, et al. Re-engineering the hospital discharge: an example of a multifaceted process. In: Advances in patient safety: from research to implementation [online]. AHRQ 050021 (2). Agency for Healthcare Research and Quality. 2005 Feb [cited 2008 Apr 16]. Available from Internet: http://www.ahrq.gov/downloads/pub/advances/vol2/Anthony.pdf.
3. Strunin L, Stone M, Jack B. Understanding rehospitalization risk: can hospital discharge be modified to reduce recurrent hospitalization? *J Hosp Med* 2007 Sep;2(5):297-304.
4. Forster AJ, Murff HJ, Peterson JF, et al. The incidence and severity of adverse events affecting patients after

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Self-Assessment Questions

1. All of the following may be barriers to successful discharge planning EXCEPT?
   a. Incomplete medication reconciliation process
   b. Inattention to social, financial, and familial support
   c. Patients' recital of their understanding of the discharge instructions
   d. Incomplete, ineffective communication between provider and patient
2. Comprehensive discharge planning may prevent adverse events and unnecessary rehospitalization.
   a. True
   b. False
3. What is the most common and preventable patient outcome associated with inadequate discharge planning?
   a. Patient develops an infection
   b. Patient does not understand the discharge plan
   c. Patient does not follow up with appropriate physician after discharge
   d. Patient experiences an adverse drug event and is readmitted to the hospital
4. Which healthcare team member should be assigned to develop and implement the discharge process?
   a. Primary care physician
   b. Staff nurse
   c. Nurse case manager
   d. Physical therapist
5. All of the following are components of a comprehensive discharge process EXCEPT?
   a. Providing written discharge instructions to the patient
   b. Educating patients about their diagnosis
   c. Filling medication prescriptions to be taken at home
   d. Providing telephone follow-up two days after discharge
6. All of the following risk reduction strategies may reduce the occurrence of adverse drug events EXCEPT?
   a. Verifying follow-up appointments that are necessary after discharge
   b. Developing a standardized checklist to assess completeness of the discharge process
   c. Having the patient verbalize understanding of the discharge plan
   d. Providing transportation for patients who are going home after discharge

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Prevention of Inadvertent Perioperative Hypothermia

ABSTRACT

Perioperative hypothermia may result in serious cardiac, coagulation, and wound-healing complications, especially among vulnerable pediatric and elderly patients. More than 50 reports have been submitted through PA-PSRS about patients experiencing perioperative hypothermia. Many reports involved hypothermia that was detected in the postanesthesia care unit. Only a few reports indicated that measures were in place to prevent hypothermia. Risk reduction strategies to prevent perioperative hypothermia include assessing the patient for increased risk of hypothermia, monitoring temperature throughout the perioperative period using optimal temperature monitoring sites, and using active and/or passive warming measures as appropriate. (Pa Patient Saf Advis 2008 Jun;5[2]:44-52.)

Avoiding hypothermia in the perioperative environment is a challenge. Hypothermia is defined as a core body temperature of less than 36°C (96.8°F). Patients can develop hypothermia perioperatively as a result of factors in the perioperative environment or the thermoregulatory response of the body to anesthetic agents. Hypothermia may even be planned as a method to mitigate neurological and cardiac injury.[1] Mild planned hypothermia has been shown to be beneficial after cardiac arrest and may lower intracranial pressure after traumatic brain injury.[2,3,4,5] However, unplanned or inadvertent perioperative hypothermia is associated with serious complications involving circulation of blood, coagulation, wound healing, and drug metabolism.[6,7,8]

Inadvertent perioperative hypothermia is detectable and preventable. This article discusses the physiology of thermoregulation, risk factors for inadvertent perioperative hypothermia, methods to detect and prevent perioperative hypothermia, and risk reduction strategies. Planned hypothermia will not be addressed.

PA-PSRS Reports

Since its inception in June 2004, PA-PSRS has received 44 reports of patients experiencing hypothermia (i.e., a core body temperature of less than 36°C) during the perioperative period (see "Patients Experiencing Perioperative Hypothermia Reported through PA-PSRS"). Another 11 reports indicated that patients experienced shivering postoperatively. Only 6% of the reports of patients experiencing perioperative hypothermia indicated that interventions such as warmed intravenous (IV) fluids, forced-air devices, or thermal pads were in place intraoperatively to prevent hypothermia.

Physiology of Thermoregulation

Humans are homeothermic mammals who strive to maintain core temperature within a narrow range regardless of the environment.[9] Normal body core temperature is controlled within tight parameters, generally within 0.2° of 37°C, ensuring a constant rate of metabolism, enhanced nervous system conduction, and optimal skeletal muscle contraction.[10,11] Thermoregulation is the process of maintaining normal core temperature and involves positive and negative feedback by the brain to minimize variations from preset normal values, or thresholds.[11] The primary thermoregulatory control center is the hypothalamus, which acts as a thermostat.[12] Thermoregulation is also based on signals from other areas of the body, including the midbrain, medulla, spinal cord, cortex, and deep abdominal and thoracic structures.[6,13]

Patients Experiencing Perioperative Hypothermia Reported through PA-PSRS

An elderly patient following abdominal surgery had a temperature of 95°F with a fluid warmer in use. The room temperature was less than 70°F. The error was noted, and a [forced-air warming device] was applied.

An elderly patient had a temperature of 94°F postoperatively in the recovery room. The patient was in the [operating room (OR)] for less than an hour and had been lying on wet linens. A [forced-air warmer] was applied in the recovery room.

An elderly patient was admitted to the [postanesthesia care unit (PACU)] after a procedure in the OR with a temperature of less than 95°F. The OR room temperature remained cold despite increasing the thermostat. Intraoperatively, a fluid warmer and multiple warm blankets were used. A [forced-air warmer] was applied in the PACU.

An elderly patient arrived in the PACU with a tympanic temperature of less than 92°F. No warming devices were used during the surgery. Warm blankets and a [forced-air warmer] were applied in the PACU. The patient had a prolonged stay in the PACU related to the patient's decreased temperature.

An elderly patient had a temperature of 97°F in the PACU after bilateral total knee replacements. A prolonged PACU stay was required to warm the patient.

An elderly patient undergoing a thoracotomy had an intraoperative temperature of less than 93°F. The [ambient air] temperature was less than 65°F. Thermal pads were in use during surgery. The patient had to remain on a ventilator due to hypothermia.

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A core temperature below the threshold for cold response will produce vasoconstriction and shivering; nonshivering thermogenesis occurs in infants. A core temperature above the threshold for heat response will produce vasodilation and sweating.[11,14,15]

Thermoregulation during Anesthesia

The cold temperatures of a typical operating room (OR) generally will not cause hypothermia in an *unanesthetized* patient due to the thermoregulatory response of shivering or vasoconstriction that acts to maintain core temperature.[16] However, the induction of general anesthesia results in a three-phase decrease in core temperature. Initially, redistribution of heat from the core to the periphery occurs as a result of vasodilatation because anesthetics inhibit the tonic vasoconstriction that normally maintains a core-to-periphery temperature gradient.[16] Following redistribution, core temperature decreases in a slow, linear manner for two to four hours, mostly due to loss of heat greater than metabolic heat production.[11,17] After three to four hours, core temperature reaches a plateau and remains steady throughout the duration of surgery.[11,18] This plateau is thought to reflect a state in which heat loss is equal to heat production and is more likely to occur in patients who are well insulated or effectively warmed.[11,18-22]

Epidural and spinal regional anesthesia decrease the threshold for the protective thermoregulatory responses of vasoconstriction and shivering.[11] Regional anesthesia decreases the threshold triggering the thermoregulatory responses of vasoconstriction and shivering above the level of the block.[11,23-25] In addition, regional anesthesia is frequently supplemented with analgesics and sedatives, which, with the exception of midazolam, significantly impair thermoregulatory responses.[11,21,26,27]

Factors Contributing to Hypothermia in the OR Environment

Perioperative hypothermia results from impaired thermoregulation induced by anesthetic agents;[18,28] a number of other factors in the operative environment have been suggested as causes, including the following:

- Exposure of a large body surface area to the typical low temperature and humidity in the OR environment[29]
- Administration of cold IV fluids[30]
- Evaporation from surgical sites[30]
- Administration of unwarmed irrigation fluid[30]
- Use of certain skin preparation methods that result in evaporation[31]

Patients at Increased Risk for Hypothermia

Certain characteristics may increase the risk of patients developing perioperative hypothermia. Older adults have less subcutaneous tissue and are less effective than younger adults at thermoregulating by means of vasoconstriction and shivering, even in the absence of anesthesia.[32] Neonates are at increased risk because of disproportionately larger heads and thinner skulls and scalps, which allow greater heat loss from the brain than occurs in adults.[33] Neonates, infants, and children have a greater surface area to body mass ratio, small stores of subcutaneous fat, and poor vasomotor control, making them more susceptible to intraoperative hypothermia.[32] Burn patients are also at increased risk, as well as patients with small body mass, impaired muscle mass, circulatory compromise, muscle atrophy, or thyroid disease.[32]

Complications of Inadvertent Hypothermia

Perioperative hypothermia may result in serious complications affecting the cardiovascular system, coagulation, and wound infection and healing.[34] The effect of hypothermia on drug metabolism may also lead to complications.[35]

Cardiac Events

Two thermoregulatory responses to hypothermia may have detrimental cardiovascular effects. The first response is sympathetically mediated vasoconstriction, which increases arterial blood pressure.[34-36] The second is shivering, which increases metabolic demands.[35,36] Studies conflict regarding the extent to which an increased metabolic rate results in increased oxygen consumption, which may in turn lead to hypoxemia and myocardial ischemia.[35,37-39] Hypothermia depresses myocardial contraction and slows conduction velocity through the heart.[40] Atrial fibrillation may occur when core temperature approaches 30°C.[39] Profound hypothermia, a core temperature between 24° and 28°C, results in ventricular fibrillation.[41] Hypothermia-induced ventricular fibrillation is refractory to pharmacologic therapy.[39] High-risk surgical patients with a core temperature of less than 35°C have a two- to threefold increased incidence of early postoperative myocardial ischemia, independent of age and anesthetic technique.[39] Patients who are aggressively warmed during surgery have been shown to experience a decreased incidence of postoperative cardiac morbidity.[35]

Coagulation and Need for Transfusion

Hypothermia significantly impairs the coagulation system through three mechanisms: platelet function, the coagulation cascade, and fibrinolysis.[37] Platelet numbers remain normal during mild hypothermia,[37] but their function is impaired because of inhibition of the formation of the initial platelet plug.[41] The function of enzymes in the coagulation cascade is slowed by hypothermia.[37,42] Studies suggest that fibrinolysis is enhanced by hypothermia, impairing clot formation.[37,43]

Studies conflict about whether hypothermia increases blood loss and the need for transfusions. However, a meta-analysis of study results from randomized controlled trials indicated that even mild hypothermia (less than 1°C) significantly increases blood loss by approximately 16% and increases the risk of requiring a transfusion by approximately 22%.[44]

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Wound Infection and Healing

Hypothermia may contribute to postoperative wound infection by directly impairing immune function and by triggering vasoconstriction, which decreases cutaneous blood flow and reduces the oxygen delivery to tissues.[37,45,46] A randomized controlled study demonstrated that patients with a drop of average core temperature of approximately 2°C were three times more likely to develop surgical site infections.[45] This effect was thought to be due to decreased macrophage function and decreased tissue oxygen tension, the latter of which is related to decreased tissue perfusion.[45] The same study found that hypothermia contributed to delay in the time thought appropriate to remove sutures. Hospitalizations in hypothermic patients were demonstrated to be 20% longer than those of normothermic patients.[45]

Pharmacokinetics and Pharmacodynamics

Perioperative hypothermia affects the metabolism of drugs because the enzymes that moderate organ function and metabolize duration of action drugs are highly temperature sensitive.[35,40] Several anesthetic drugs have been studied; however, the mechanism by which hypothermia may prolong the effects of muscle relaxants is not clear.[47] The pharmacodynamics of vecuronium has been found to be unaffected by mild hypothermia.[48] Mild hypothermia alters propofol pharmacokinetics and increases the duration of action of atracurium.[47,48] During a constant infusion of propofol, the plasma concentration is approximately 30% greater than normal when individuals are 3°C hypothermic.[40,47]

Hypothermia alters the pharmacodynamics of volatile anesthetics.[37] The solubility of inhaled anesthetics is increased with hypothermia; consequently, at a steady-state plasma partial pressure, body anesthetic content increases.[37] Inhaled anesthetic potency is related to partial pressure, not concentration, and remains unaffected.[37] The increased solubility of volatile anesthetics and increased duration of the action of muscle relaxants suggests that hypothermia may delay emergence and recovery from general anesthesia.[37,40]

Core Temperature Monitoring

Some risk factors for inadvertent perioperative hypothermia, such as age or body mass, may not be changed or avoided. Consequently, monitoring of core temperature and prevention of hypothermia are indispensible in preventing the complications associated with inadvertent perioperative hypothermia.

When to Measure

Core temperature usually decreases 1°C during the first 30 to 40 minutes of anesthesia induction due to initial core-to-peripheral redistribution of body heat.[9,30,49] Monitoring core temperature alerts the provider to the need for preventative and corrective action.[28]

Several professional groups, including the Association of periOperative Registered Nurses (AORN) Recommended Practices Committee, the American Society of Anesthesiologist (ASA), and the American Association of Nurse Anesthetists (AANA), have made recommendations regarding when to monitor patient temperature.[28,50,51] The recommendations from the groups include the following:

1. Monitoring temperature on an ongoing basis during the perioperative period[28]
2. Monitoring temperatures of patients given general anesthesia and expected to undergo procedures exceeding 30 minutes and during regional anesthesia when changes are anticipated or suspected[11,28]
3. Continuously monitoring temperature "when clinically significant changes in body temperature are intended, anticipated or expected."[11,50]
4. Continuously monitoring temperature in pediatric patients receiving general anesthesia[11,51]
5. Monitoring of temperature when patients undergo large procedures under regional anesthesia[9,30,39]
6. Postoperatively monitoring temperature to provide a basis for evaluation of the effectiveness of intraoperative measures to prevent hypothermia[11]
7. Communicating abnormal patient temperatures to the appropriate patient care providers.[11]

How to Measure Temperature Perioperatively

Core temperature may be monitored during general anesthesia in the pulmonary artery, nasopharynx, tympanic membrane, and distal esophagus, which are all sites that are reliable and accessible during surgery.[30]

- Pulmonary artery catheters allow measurement of central blood temperature, which is considered the gold standard for the measurement of core temperature.[9,52] However, pulmonary artery catheters are generally reserved for patients requiring intensive hemodynamic monitoring due to the invasiveness and cost of the catheters.[9,30]
- Distal esophageal temperature accurately reflects core temperature, but may be affected by the use of humidified gases if the probe is not inserted far enough and may be affected during open heart or lung surgery because the chest cavity is exposed to ambient air.[9,30]
- Nasopharyngeal temperature is measured with an esophageal probe above the soft palate and is close to brain and core temperature. Temperature measurement may be affected by inspired gases.[9,28,30]
- Tympanic membrane temperature monitoring is often the preferred method in the preoperative and perioperative areas. The tympanic membrane is close to the carotid artery and hypothalamus and is a noninvasive and accurate measure of core temperature.[9,30]

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If the above-mentioned core temperature sites cannot be used in a particular clinical setting, the bladder, rectum, axilla, and skin may be used.[9]

- Temperature in the bladder can be measured with a urinary catheter containing a temperature transducer.[9,28] Accuracy of bladder temperature monitoring decreases with low urine output and during procedures of the lower abdomen.[9,30]
- Rectal temperature measurement approximates core temperature but may be affected by the presence of stool and bacteria that generate heat.[9,30]
- Axillary temperature may accurately reflect core temperature if the arm is positioned at 0 degrees adduction and the probe is placed over the axillary artery.[9,30]
- Skin temperature may be measured with a crystal skin-surface thermometer.[28] Skin surface temperature is affected by several factors, including core-to-peripheral redistribution, intraoperative thermoregulatory vasoconstriction, and changes in ambient temperature.[9,28,30,52,53]

Hypothermia during regional anesthesia may be undetected because temperature may not be routinely monitored.[9,54] A study comparing temperature monitoring sites during regional anesthesia found that rectal temperature monitoring was the most accurate. Measurements at other sites underestimated core temperature due to compensatory cutaneous vasoconstriction above the level of the regional block and effects of thermoregulatory vasoconstriction on skin temperature.[55]

Methods of Preventing Hypothermia

To prevent hypothermia, the body's heat balance must be maintained by balancing heat loss with heat gain, either from the body's own internal metabolic heat production or from an external source of heat. A number of methods and devices may be used to maintain perioperative normothermia.

Cutaneous Warming

Room temperature is the most critical factor in preventing perioperative heat loss from the patient because it determines the rate at which heat is lost by radiation and convection from the skin and by evaporation from within surgical incisions.[18,30] Increasing the ambient OR temperature to 26°C (79°F) has been found to reduce the incidence of core hypothermia in younger and older patient populations.[56] However, most OR personnel find this temperature uncomfortably warm.[18,30] Nonetheless, about 90% of metabolic heat is lost through the skin surface, making it imperative to prevent cutaneous heat loss through other methods, which may include passive insulation and the use of active cutaneous warming systems.[18,30]

Passive Insulation

Passive insulators readily available in most ORs include cotton blankets, surgical drapes, plastic sheeting, and reflective composites or "space blankets." A study found that a single layer of each type of insulator may reduce heat loss by 30% with no differences noted among the insulation types.[57] The comparable efficacy between different types of insulators was credited to the still layer of air between the cover and the skin.[57] A subsequent study found relevant differences among types of insulating materials and that the addition of layers of insulating material increases efficacy.[58,59] Despite conflicting findings regarding the efficacy of types and layers of insulation, cutaneous heat loss is roughly proportional to the surface area of the entire body. Accordingly, the efficacy of passive insulators is directly proportional to the covered surface area.[11,18,30]

Active Cutaneous Warming Systems

Active skin warming systems include the following:

- Forced-air warming is widely used and usually maintains normothermia even during extended operations.[30] Forced-air uses convective heating, (heat absorbed from air passing over the skin) to warm the patient.[29,30] The system includes a thermostatically controlled fan heater (blower) and a warming blanket. Warm air entering the blanket fills channels in the blanket, causing them to inflate and flex concavely around the patient.[30] Air slits or small holes on the patient side of the blanket allow warmed air to flow over the patient. The efficacy of forced-air warming system in preventing perioperative hypothermia is well supported by a number of clinical trials.[17,60,61]
- Circulating-water garments circulate warm water through a conductive heating garment wrapped around the patient. Circulating-water devices use convective heating (heat absorbed from hotter objects in contact with the skin) to warm the patient.[29] This method has been found effective with both adult and pediatric patients and has been demonstrated to transfer more heat to patients than forced air, especially during the first hour of warming.[62-64] Circulating-water mattresses have been found to be ineffective since the back represents only a small percentage of surface area available for heat exchange. Moreover, the combination of heat and decreased local perfusion due to compression by the patient's weight increases the risk for pressure and/or heat necrosis.[37,65]
- Resistive heating (an electric blanket) has been found to be as effective as forced-air heating.[37,66] Another type of resistive heating, consisting of energy pads containing circulating heated water that are in contact with the patient's skin, was found to be more effective than a combination of warmed IV fluids, increased OR temperature, and the use of a convective forced-air warming system in reducing hypothermia in patients undergoing off-pump cardiac surgery.[28,67]

Other Warming Methods

- Warming of IV fluids and blood is indicated when more than two liters of fluid per hour are

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administered to an adult, because of potential heat loss from cold IV fluids or blood.[9,30,37] In volumes of less than two liters, warming has little effect because fluid-induced cooling is minimal. For example, a unit of refrigerated blood or one liter of an IV solution administered at room temperature only decreases mean body temperature by 0.25°C in adults.[68] However, warming of IV fluids alone may not maintain normothermia, and studies support the use of this method as an adjunct to forced-air warming to decrease the risk of hypothermia.[9,28,37,68,69]

- Warmed irrigation fluids decrease intraoperative heat loss as an adjunct to other methods and alone are insufficient to prevent intraoperative hypothermia.[28,70] A study of patients undergoing arthroscopic surgery of the shoulder concluded that core temperature may be influenced by irrigation fluid temperature and recommended that fluid be warmed to 36°C.[71] AORN recommends warming irrigation fluids to body temperature, or 37°C.[28]
- Prewarming of patients before induction of anesthesia has been studied as a method to maintain perioperative normothermia.[7,72-74] Studies have demonstrated the efficacy of intraoperative methods to prevent hypothermia; however, intraoperative cutaneous heat transfer, such as in forced-air warming, does not prevent initial redistribution-induced hypothermia.[75-77] This initial hypothermia results from redistribution of heat from the warm core compartment to cold peripheral tissues, due to anesthesia-induced vasodilation.[37,75] Several studies have evaluated the effect of preoperative warming on this initial redistribution-induced hypothermia. One determined that redistribution hypothermia in surgical patients would be markedly reduced by the use of forced-air prewarming for 30 minutes and almost eliminated if active warming was maintained for 1 hour.[74] However, this study was performed using a group of seven healthy volunteers in a laboratory. Another randomized controlled study of women undergoing elective cesarean sections found that 15 minutes of prewarming in addition to routine intraoperative warming was sufficient to maintain core temperature and prevent hypothermia and shivering.[7,75] One study of patients receiving 45 minutes of forced-air prewarming found that patients reported increased thermal comfort and decreased complaints of shivering and that the patients maintained a significantly higher mean temperature on arrival to the postanesthesia care unit (PACU).[7,72] This result was supported by a later study demonstrating that 90 minutes of preinduction skin-surface warming reduced initial postinduction hypothermia and postoperative shivering for procedures lasting three hours or longer.[75]

Additional Strategies

Professional societies including ASA, the American Society of PeriAnesthesia Nurses (ASPAN), and AORN endorse recommended practices for the prevention and management of unplanned perioperative hypothermia. A summary of their recommendations includes the following.

Preoperative Period

- Assessment
  - Identifying risk factors for unplanned hypothermia through patient interview, chart review, physical assessment, review of anesthesia plan, and planned procedure[8,28]
  - Measuring a preoperative baseline temperature[8,28]
  - Determining patient's thermal comfort level[8]
  - Assessing the patient for signs and symptoms of hypothermia (e.g., shivering, piloerection, cold extremities).[8]
- Intervention
  - Instituting preventive warming measures for patients who are normothermic, such as using passive insulation and increasing ambient room temperature[8]
  - Considering whether to prewarm patients for a minimum of 15 minutes immediately prior to induction of anesthesia for patients at risk of unplanned hypothermia[28]
  - Instituting active warming measures for patients who are hypothermic[8]

Intraoperative Period

- Assessment
  - Selecting equipment to monitor core temperature based on reliability and accessibility of the monitoring site[28]
  - Monitoring core temperature intraoperatively to allow early identification of temperature changes[8,28,77] (ASA recommends that patient temperature be continually monitored and evaluated when "clinically significant changes in body temperature are intended, anticipated or expected."[8,51] AANA recommends monitoring of core temperature continuously in pediatric patients undergoing general anesthesia and in patients undergoing general anesthesia continuously or intermittently.[8,78] ASPAN recommends that temperature be monitored at least every 30 minutes if a procedure lasts longer than 30 minutes.[8])
  - Communicating abnormal temperature to the perioperative team[28]
- Interventions
  Measures to prevent unplanned hypothermia may include the following:
  - Minimization of skin exposure by covering parts of the body not involved in the surgical procedure[28]
  - Passive insulation[8]

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- — Forced-air warming[8,28]
- — Circulating-water garments[28]
- — Energy transfer pads[28]
- — Warming IV fluids[8,28]
- — Warming irrigation fluids to body temperature[8,28]
- — Increasing ambient room temperature (minimum 20° to 24°C or 68° to 75°F)[8,28]
- — Warming and humidifying inspired gases[8,28]
- — Increasing ambient room temperature to higher than 26°C (78.8°F) for neonates[28]
- — Increasing ambient temperature to greater than 29.4°C (85°F) for patients with severe trauma or extensive burns[11,28]
- — Continuous monitoring of intraoperative temperatures in infants, neonates, severe trauma patients and patients with extensive burns[28]

Postoperative Period

- Assessment
  - — Obtaining patient's temperature on admission to PACU[8] (If hypothermic, monitor serial temperatures every 30 minutes at a minimum until patient becomes normothermic. If normothermic, assess the patient's temperature before discharge from the PACU or as ordered.[8])
  - — Determining the patient's thermal comfort level every 30 minutes[8]
  - — Assessing for signs and symptoms of hypothermia[8]
- Interventions
  - — If normothermic, initiating appropriate preventive warming measures[8]
  - — If hypothermic, initiating appropriate passive and active warming measures, in addition to warming IV fluids and humidifying and warming inspired gases[8]
  - — Assessing temperature every 30 minutes or as appropriate if the patient's thermal comfort level decreases or signs of hypothermia are present[8]
  - — Measuring the patient's temperature discharge from the PACU[8]
  - — Maintaining ambient room temperature (minimum 20° to 24°C or 68° to 75°F).[8,28]

In addition to the above practices, the AORN promotes the following:[28]

- Providing personnel with initial education and competence evaluation on the prevention of unplanned hypothermia
- Documenting on the patient record patient assessment and evaluation, the plan of care, and any interventions undertaken to prevent unplanned hypothermia
- Developing and periodically reviewing policies and procedures for the prevention of unplanned hypothermia in collaboration with anesthesia care providers
- Evaluating the structures, process, and outcomes of interventions used to prevent unplanned hypothermia through a performance improvement plan

Potential Barriers to Maintaining Normothermia

The Anesthesia Patient Safety Foundation has identified the following potential barriers to maintaining normothermia in the perioperative environment:[78]

- Staff turnover may contribute to inconsistent practice patterns.
- Appropriate monitoring sites (e.g., the esophagus, nasopharynx, tympanic membrane, pulmonary artery) may be unavailable during certain types of procedures.
- Lack of evidence-based guidelines on how to best warm patients (especially ASA guidelines) results in practice guidelines that are general and nonspecific.
- The benefits of warming may not be immediately apparent. Changes in body temperature occur slowly, so despite active warming, the clinician may doubt the effectiveness of the intervention.
- The appropriate stakeholder may not make the decisions about what happens in the OR. Decisions about adopting warming technology may be made at an institutional level without regard to the benefits of normothermia.
- Some patients are difficult to warm effectively despite appropriate interventions to maintain normothermia (e.g., trauma patients undergoing multiple operations, patients undergoing major cardiac and vascular procedures in which poor perfusion in the lower extremities is common.)

Conclusion

Despite the potential barriers to maintaining perioperative normothermia, the literature suggests that, for patients at risk for complications, monitoring perioperative temperature and maintaining normothermia will improve outcome. However, hypothermia may occur in any patient and may result in serious postoperative complications. Fortunately, a number of methods exist to detect and prevent hypothermia, allowing the prevention of perioperative hypothermia to be an obtainable goal.

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Self-Assessment Questions

1. Factors in the operating room (OR) environment that may contribute to perioperative hypothermia include all of the following EXCEPT?
   a. Exposure of a large body surface area
   b. Administration of cold intravenous (IV) fluids
   c. Evaporation from the surgical site
   d. Ambient OR temperatures of 21° to 23°C
2. During general anesthesia, a patient's core temperature will continue to decrease in a gradual, linear manner unless warming devices are applied.
   a. True
   b. False
3. Sites that provide an accurate measurement of a patient's core temperature include all of the following EXCEPT?
   a. Pulmonary artery
   b. Axilla
   c. Nasopharynx
   d. Tympanic membrane
   e. Distal esophagus
4. Hypothermia may affect the coagulation system in all of the following ways EXCEPT?
   a. Platelet numbers decrease
   b. Formation of the initial platelet plug is inhibited
   c. The function of enzymes in the coagulation cascade is slowed
   d. Fibrinolysis is enhanced
5. Methods that have been shown to be adequate to maintain core body temperature intraoperatively include all of the following EXCEPT?
   a. Forced-air warming devices
   b. Ambient OR temperature greater than 26°C
   c. Circulating water garments
   d. Warmed IV fluids

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Sterile Water Should Not be Given "Freely"

ABSTRACT

Severe hypernatremia can be challenging to treat. There appears to be a failure among healthcare practitioners to recognize the danger of infusing plain sterile water intravenously. Bags of sterile water for injection and inhalation also are being mistaken for intravenous (IV) solutions. Sterile water is hypotonic (0 mOsm/L). Serious patient harm, including hemolysis, can result when it is administered by direct IV infusion. PA-PSRS and other medication error reporting programs have received reports of IV administration of sterile water to patients, some of which have resulted in patient deaths. Risk reduction strategies include recognizing the problem, developing protocols to treat hypernatremia, establishing safeguards, assessing for safe storage, and ensuring that sterile water bags cannot be provided without prior pharmacy agreement and supervision. (Pa Patient Saf Advis 2008 Jun;5[2]:53-6.)

Severe hypernatremia, when the plasma concentration of sodium is greater than 145 mEq/L,[1] can be challenging to treat, especially in patients with conditions such as hyperglycemia that may seem to limit treatment options. It appears there is a failure among healthcare practitioners to recognize the danger of infusing plain sterile water intravenously to treat hypernatremia. Also, bags of sterile water for injection and inhalation are being mistaken for intravenous (IV) solutions when they are stocked on patient care units. Serious patient harm can result when sterile water is administered by direct IV infusion due to hemolysis related to the hypotonic nature of the product.

Sterile water for injection is sterile water that is intended to be used by pharmacy to compound IV products such as parenteral nutrition solutions. It also is used in small quantities to solubilize drugs—the drug solutes then contribute the osmotic pressure to the solution to keep it safe. To prepare isotonic IV solutions from sterile water for injection, solutes such as sodium chloride or dextrose may need to be added. It takes 9 g of sodium chloride or more than 50 g of dextrose in a liter of sterile water to make it isosmotic (about 308 mOsm/L) with blood. Potassium chloride is similar to sodium chloride—about 154 mEq/L in sterile water for injection is needed to be nearly isotonic. For cefazolin sodium, a 100 mg/mL solution in sterile water for injection is nearly isotonic. Sterile water for injection is 0 mOsm/L, which can be fatal. It should never be given intravenously to patients.

PA-PSRS and other medication error reporting programs have received reports of events involving the IV administration of sterile water to patients. There are two main reasons for these errors. First, healthcare practitioners may have a knowledge deficit about the risks of IV administration of sterile water. For example, prescribers are ordering sterile "free water" to treat hypernatremia. Free water refers to water not associated with organic or inorganic ions. Because hypernatremia usually results from a loss of free water relative to solute, it is likely that prescribers intend to replace this deficit when writing these orders. Water can be replaced by mouth or nasogastric tube; however, if given intravenously without additives to normalize tonicity, hemolysis may occur. Second, inadvertent IV administration of sterile water is occurring due to the look-alike nature of bags of sterile water and other IV solutions.

Errors in the Prescribing Phase

In one particular event reported through PA-PSRS, a physician ordered 2 L of sterile water for injection to treat an intensive care unit (ICU) patient's elevated sodium level.

> *Nurse was told to give the patient 2 L sterile water bolus IV for high sodium level. Nurse received IV sterile water from pharmacy. Nurse hung 1 L sterile water after getting order for doctor. Other doctor was aware of sterile water hanging. Nurse called pharmacist to receive second liter and was told it cannot be given IV. The infusion was stopped. The doctor was made aware.*

The infusion was stopped in time to prevent any harm to the patient.

The Institute for Safe Medication Practices (ISMP) has reported a similar event in which a physician decided to give sterile water for injection intravenously to an elderly patient who had been admitted to an ICU with pneumonia, congestive heart failure, respiratory failure, severe hyperglycemia, and severe hypernatremia.[2] The physician was concerned about giving dextrose-containing fluids due to the patient's hyperglycemia. The physician contacted a pharmacist, confirmed "large bags of sterile water for injection" were available, and changed the patient's existing intravenous fluids to free water at 100 mL/hr. When he received the order, the pharmacist entered it into the computer. A pharmacy intern retrieved a bag from the sterile compounding area, placed the pharmacy-generated label on the back of the bag, and dispensed it to ICU. The nurse began the infusion without question because she was aware of the patient's hypernatremia and overheard the physician ask the pharmacist if bags of sterile water were available. She did not see red lettering on the bag that stated "Pharmacy Bulk Package, Not For Direct Infusion" because the pharmacy label was on the opposite side of the bag. Another nurse noticed the statement and stopped the infusion. The patient experienced a hemolytic reaction and acute renal failure, and died after 550 mL had infused.

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Error Related to Packaging, Labeling, and Storage

Bags of sterile water, especially 1 L size bags, can look like and be confused with other IV solutions. For example, a 1,000 mL bag of sterile water for injection was mistakenly dispensed by pharmacy to a dialysis unit and administered intravenously to a patient instead of a 1,000 mL bag of 0.9% sodium chloride injection.[3] The two products looked similar despite a red, boxed warning under the name on the bag of sterile water (see Figure 1). The IV fluids were obtained by a pharmacy technician, checked by a pharmacist, delivered to the dialysis unit, and later taken from stock and administered by the dialysis nurse. The error was caught after 400 mL was administered.

Sterile water bags are also being stocked in patient care areas. A pediatric patient was ordered 0.9% saline, according to a PA-PSRS report.

> *Normal saline solution was ordered as a fluid bolus; sterile water hung. Blood work was drawn, and no changes [were observed]. Sterile water in bags was removed from nursing units.*

No harm was noted. In order to prevent this error from occurring again, the facility removed IV bags of sterile water from nursing units.

Figure 1. Sodium Chloride Solution (Left) and Sterile Water for Injection (Right)

Image provided courtesy of ISMP.

Hospital materials management departments may provide patient care areas with liter bags of sterile water. One hospital reported through the ISMP-U.S. Pharmacopeia Medication Errors Reporting Program that their purchasing department stocked automated dispensing cabinets (ADCs) with IV solutions.[4] In one instance, a wholesaler mistakenly delivered 1 L bags of sterile water for injection instead of 5% dextrose solution. The error was not caught when the product was received nor when the ADC was restocked. A nurse accidentally retrieved and hung one of the sterile water bags. A physician discovered the error when investigating the patient's complaint of discomfort at the IV site. Sterile water was also found hanging on another patient, but only a small volume had infused. Both patients suffered no permanent harm.

Emergency malignant hyperthermia boxes found in the operating room and postanesthesia care unit can be another source of sterile water bags. Based on a recommendation from the Malignant Hyperthermia Association of the United States, these boxes often are stocked with 1 L bags of sterile water to dilute dantrolene sodium for injection, a skeletal muscle relaxant used to treat malignant hyperthermia.[5,6] Unused or partially used bags of the solution may find their way into IV stock or be hung as an IV solution during emergent treatment.

Respiratory therapy staff may also store or bring bags of sterile water to patient care units for humidification devices used with ventilators or continuous positive airway pressure (CPAP) devices. Humidification of inspired gases helps prevent cilial damage as well as heat and water loss.[7,8] While there are several ways to humidify the gases, a "wet" setup may require the use of a sterile water bag, which is attached to a humidification receptacle on the ventilator or CPAP device. For example, some units contain tubing that must be spiked into a water container with a traditional IV-like port (see Figure 2). This means that only

Figure 2. Sterile Water Bag Connected to a Humidification Unit

Image provided courtesy of ISMP.

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bags of sterile water can be used with these specific units to provide the humidification.

Sterile water for inhalation is available in 250 mL, 500 mL, 1 L, 2 L, and 3 L bags that can be used for wet setups. Some of these bags not only look similar to other IV solutions, but they can also be attached to IV tubing (and may be listed for purchase as "IV solutions"). One hospital reported to ISMP that a respiratory therapist left a liter bag of sterile water for inhalation unwrapped in the patient's room to replace the current bag attached to the ventilator.[4] A nurse, responding to an IV pump's low volume alarm, replaced the empty IV bag with the sterile water bag, believing it had been left as an IV replacement. The patient received 500 mL before the error was noticed, but he suffered no harm. Sterile water for inhalation bags also may be stored on respiratory supply carts, right next to IV fluids, or hanging on an IV pole so the nurse could change the bag at night (see Figure 3).

Risk Reduction Strategies

Sterile water for injection, inhalation, and irrigation (excluding pour bottles) has been added to ISMP's List of High Alert Medications.[9] ISMP encourages healthcare organizations and practitioners to establish special safeguards to reduce the risk of errors with high-alert medications. Below are a number of strategies that may be considered to reduce the risk of IV administration of free water or sterile water for injection.

- Alert practitioners to the danger—primarily hemolysis—of infusing sterile water. Educate clinicians about the physiology behind infusing hypotonic, isotonic, and hypertonic solutions, especially in relation to the patient's electrolyte levels.[2]
- Develop protocols to guide safe and effective treatment of hypernatremia. Treatment of severe hypernatremia generally consists of infusions that contain smaller amounts of sodium to reduce blood levels slowly. Too rapid correction of hypernatremia may result in cerebral edema, seizures, and possibly death.[2,10,11]
- If concerns exist about using dextrose solutions, elevated blood sugars can be treated with insulin. If there are concerns about fluid volume, patients can be given diuretics.[2]
- Program the pharmacy computer system to provide an alert, "Use Only as a Diluent," when these products are entered. Avoid offering sterile water for injection as a choice in prescriber order entry systems.[2]
- Clarify any order for sterile water with the prescriber as the order will likely will cause hemolysis.[2]
- 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.[2,3]
- Affix auxiliary warnings to both sides of sterile water bags.
- Sterile water for injection is available in 2 L (or larger) containers for IV compounding. The difference in size of these larger bags can help reduce the risk of confusion with other 1 L IV solutions.[3]
- For emergency malignant hyperthermia boxes, some hospitals have replaced the 1 L sterile water bags with an adequate supply of 50 mL vials[4] or 2 L bags of sterile water for injection.
- If a wet setup is considered necessary to humidify inspired gases, humidification units that do not require the use of sterile water bags can be considered. Some manufacturers offer wet humidification setups with self-contained plastic bottles of sterile water for inhalation, so bags of sterile water are not required. Heat and moisture exchangers, which are self-contained disposable units that do not require a continuous flow of water, are another option. If these alternatives are not possible, establish guidelines for safe storage and handling of the sterile water for inhalation bags.[4]
- Alert respiratory staff to avoid leaving bags of sterile water in medication rooms or patient rooms or hung on IV poles.[4]
- Special poles that attach to the ventilator for the purpose of hanging sterile water bags for use with humidification units are available from some manufacturers. Consider using them when possible.[4]
- Arrange for pharmacists and pharmacy technicians trained in safe drug storage to conduct regular rounds on patient care units, the respiratory department, and other areas where medications are stored or given so they can assess the storage of medications and solutions.[4]
- Review the list of items that patient care units can order manually or automatically through materials management. Ensure that pharmaceutical products

Figure 3. Sterile Water Bag On IV Pole

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(including sterile water bags) cannot be provided without prior pharmacy agreement and supervision.[2]

- Share information about these errors with purchasing staff to increase awareness of errors.[2]

Notes

1. Porter RS, Kaplan JL, Homeier BP, et al., eds. Hypernatremia. In: The Merck manual for healthcare professionals [online]. 2005 Nov. [cited 2008 May 3]. Available from Internet: http://www.merck.com/mmpe/sec12/ch156/ch156e.html.
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Self-Assessment Questions

1. Sterile water for injection is intended for all of the following EXCEPT?
   a. Compound intravenous (IV) products
   b. Prepare parenteral nutrition solutions
   c. Infuse intravenously
   d. Solubilize small quantities of drugs
2. Rapid correction of severe hypernatremia can result in all of the following EXCEPT?
   a. Seizure
   b. High-output renal failure
   c. Cerebral edema
   d. Death
3. Sterile water for injection can cause hemolysis when administered intravenously.
   a. True
   b. False
4. All of the following factors contribute to errors involving sterile water for injection or sterile water for inhalation EXCEPT?
   a. Look-alike nature of bags of sterile water and other IV solutions
   b. Knowledge deficit about the risks of IV administration of sterile water
   c. Storage of bags of sterile water for injection in medication rooms or patient rooms
   d. Humidification units with self-contained plastic bottles of sterile water for inhalation
   e. Bags of sterile water for injection from emergency malignant hyperthermia boxes find their way into IV stock
5. All of the following steps would help to reduce the risk of inadvertent IV administration of sterile water EXCEPT?
   a. Stock sterile water for injection, irrigation, and inhalation in 1 L bags
   b. Store sterile water bags away from medication supplies
   c. Develop protocols to guide safe and effective treatment of hypernatremia.
   d. Avoid offering sterile water for injection as a choice in prescriber order entry systems
   e. Pharmacists and pharmacy technicians trained in safe drug storage make regular rounds on patient care units, respiratory department, and other areas where medications are stored and given to assess the storage of medications and solutions

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Colon Perforations Complicating Colonoscopies: What is the Best Known Evidence for Prevention?

ABSTRACT

A systematic qualitative review was done of all modifiable risk factors reported in the medical literature to have a possible association with perforations associated with colonoscopies and of the recommendations in the medical literature and clinical practice guidelines for reducing the risks of these perforations. Inclusion criteria were defined a priori. Ten databases were searched, plus the National Guideline Clearinghouse and the National Quality Measures Clearinghouse. Only three clinical studies specifically addressed modifiable risk factors for perforations associated with colonoscopies. Another four publications addressed recommendations for avoiding perforation. The modifiable risk factors identified were the use of pediatric colonoscope in an adult and the duration and strength of coagulation. Seventeen recommendations were reported for reducing perforation rates associated with colonoscopy. The evidence used to support these recommendations was weak. The recommendations have not been definitively shown to reduce the risk of colon perforation. Critical prospective reporting and comparisons may be beneficial in providing sufficient evidence to support current conclusions. (Pa Patient Saf Advis 2008 Jun;5[2]:57-63.)

Introduction

Colonoscopy is considered the best way to screen for colorectal cancer, the second leading cause of cancer death in the United States.[1] Colonoscopy is used to remove precancerous polyps. It is also used to diagnose and treat other diseases of the colon. One of the most serious complications of colonoscopy is perforation. Perforation of the colon almost always requires operative repair of the resulting hole. As noted in a previous *Patient Safety Advisory* article, Pennsylvania healthcare facilities reported 125 to 152 perforations following colonoscopies through PA-PSRS over a one-year period.[2] The PA-PSRS clinical analysts estimated that the rate of this complication was between 39 and 47 per 100,000 colonoscopies, assuming all perforations for the 322,867 colonoscopies done that year were reported as "unanticipated" injuries.

The risk of a perforation during a colonoscopy may vary according to the patient's medical conditions and the techniques used by the endoscopist. In the previous *Advisory* article, some of the risk factors reported in the literature were mentioned.[2] Some risk factors are invariable. Others are modifiable. Identifying modifiable risk factors could lead to fewer perforations.

This article is a systematic qualitative review of all modifiable risk factors reported in the medical literature to have a possible association with perforations associated with colonoscopies and of the recommendations in the medical literature and clinical practice guidelines for reducing the risks of these perforations.

Methods

The analysts defined two questions to be answered by a systematic qualitative review of the medical literature and clinical practice guidelines:

1. What are the modifiable risk factors for perforations associated with colonoscopies?
2. What are the published recommendations for controlling modifiable risk factors?

For both questions, the analysts investigated the importance of modifiable factors related to the patient, the endoscopist, and the procedures or techniques.

The methods for answering those questions were defined *a priori* to preclude bias in selection or review of the literature and practice guidelines.

Inclusion Criteria

The clinical studies included in this systematic review were based on inclusion criteria that were determined *a priori* to reduce the risk of bias because the decision to include or exclude each study is independent of the results of the study. All publications had to meet the following criteria to be included in the review:

- The patients had either conventional colonoscopies or colonoscopies through enterostomy stomas. Publications reporting more than 15% of patients having endoscopies only involving the rectum, rigid or flexible sigmoidoscopies, or intraoperative colonoscopies were not included.
- The publications were in English.
- Only data collected since 1990 were included, in order to relate the findings to modern practice.
- In addition to clinical studies, literature reviews, reports, letters, editorials, clinical practice guidelines, and other publications were included.
- Only publications that provided an answer to either of the questions were included.

Literature Searches and Article Selection

The clinical studies included in this systematic review were identified using a multistaged study selection process. The analysts performed a comprehensive literature search using broad criteria and retrieved all articles that appeared to meet inclusion criteria, based on their titles and published abstracts. The analysts reviewed the full text of each retrieved article to verify that it met the inclusion criteria.

Ten databases were searched through November 1, 2007, including the following: the Cumulative Index to Nursing and Allied Health Literature, the

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Cochrane Central Register of Controlled Trials, the Cochrane Database of Methodology Reviews, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, EMBASE (Excerpta Medica), Healthcare Standards, Health Technology Assessment Database, MEDLINE/PubMed, and the NHS Economic Evaluation Database. The National Guideline Clearinghouse and the National Quality Measures Clearinghouse were also searched through the same time period. To supplement the electronic searches, the analysts reviewed the bibliographies of the retrieved publications, the contents of new issues of selected journals, and relevant gray literature (reports and studies produced by local government agencies, private organizations, educational facilities, and corporations that do not appear in the peer-reviewed literature). The advisory panel (see "Advisory Panel to Minimize Colonoscopy Perforations in Pennsylvania") provided guidance for the search process.

Results of the Literature Search and Article Selection

The literature searches identified 172 publications, of which 3 specifically addressed modifiable risk factors for perforations associated with colonoscopies. Another four publications addressed recommendations for avoiding perforation. These seven articles that were found to have met the inclusion criteria were used for the systematic review (see Table 1).

Advisory Panel to Minimize Colonoscopy Perforations in Pennsylvania

The members of the Advisory Panel are providing domain expertise for efforts to minimize perforations associated with colonoscopies.

The members of the Advisory Panel are as follows:

- James C. Reynolds, MD, Chairman of Medicine, Drexel University College of Medicine, Philadelphia (Chair of the Advisory Panel)
- Nancy Bacci, RN, Division of Gastroenterology, Hershey Medical Center, Hershey
- R. Bradley Hayward, MD, Tri-State Surgical Associates, Bridgewater
- Ann Ouyang, MD, Division of Gastroenterology, Hershey Medical Center, Hershey
- Robert E. (Rocky) Schoen, MD, Professor of Medicine, UPMC Presbyterian University Hospital, Pittsburgh
- Robert J. Sinnott, MD, Chief of Colorectal Surgery, Lehigh Valley Medical Center, Allentown
- Joel L. Weissfeld, MD, MPH, Associate Professor of Epidemiology, University of Pittsburgh, Pittsburgh

The PA-PSRS analysts are indebted to them for their guidance and contributions.

Table 1. Included Studies and Key Questions they Address

STUDY	YEAR PUBLISHED	YEAR(S) DATA COLLECTED	WHAT ARE THE RISK FACTORS FOR COLONIC PERFORATION?	WHAT ARE THE BEST PRACTICES FOR CONTROLLING MODIFIABLE RISK FACTORS?
Clinical Studies, Retrospective Chart/ Record Reviews				
Vokura	2004	1998 to 2002	✓	
Wexner et al.	2001	April 1998 to September 1999	✓	
Cobb et al.	2004	January 1997 through December 2003	✓	
Literature Reviews				
Fatima and Rex	2007	Not reported		✓
Reickert and Beck	2001	Not reported		✓
Clinical Practice Guidelines				
Rex et al. "Quality indicators . . . "	2006	Not reported		✓
Rex et al. "Quality in the technical . . . "	2002	Not reported		✓

Sources: Cobb WS, Heniford BT, Sigmon LB, Hasan R, et al. Colonoscopic perforations: incidence, management, and outcomes. *Am Surg* 2004 Sep;70(9):750-7; discussion 757-8; Fatima H, Rex DK. Minimizing endoscopic complications: colonoscopic polypectomy. *Gastrointest Endosc Clin N Am* 2007 Jan;17(1):145-56; Reickert CA, Beck DE. Complications of colonoscopy. *Clin Colon Rectal Surg* 2001;14(4):379-85; Rex DK, Bond JH, Winawer S, et al. Quality in the technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: Recommendations of the U.S. Multi-Society Task Force on Colorectal Cancer. *Am J Gastroenterol* 2002 Jun;97(6):1296-1308; Rex DK, Petrini JL, Baron TH, et al. Quality indicators for colonoscopy. *Am J Gastroenterol* 2006 Apr;101(4):873-85; Vokurka J. Iatrogenic perforation during an endoscopic examination of the gastrointestinal tract. *Bratisl Lek Listy* 2004;105(10-11):387-9; Wexner SD, Garbus JE, Singh JJ; SAGES Colonoscopy Study Outcomes Group. A prospective analysis of 13,580 colonoscopies. Reevaluation of credentialing guidelines. *Surg Endosc* 2001 Mar;15(3):251-61.

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Results of the Systematic Review

1. What Are the Modifiable Risk factors for Perforations Associated with Colonoscopies?

A total of three publications were identified that reported modifiable risk factors for colonoscopy-associated perforation. These clinical studies are summarized in Table 2.

All factors identified as modifiable risk factors for perforation, or modifiable factors identified as not being risk factors, are reported in Table 3, along with the type of evidence supporting each. These factors are grouped as follows:

Procedural factors. Only two of the publications reported modifiable procedural factors associated with colonoscopy. Cobb et al. described six colonoscopies in which the colonoscopy was attempted with a pediatric colonoscope in an adult.[3] Four of the six resulted in perforation. Both cases of pneumatic

Table 2. Characteristics of Clinical Studies Used in the Systemic Review

	WEXNER ET AL.	VOKURA	COBB ET AL.
Methodological Characteristics			
Year of publication	2001	2004	2004
Years data collected	April 1998 to September 1999	1998 to 2002	January 1997 through December 2003
Median year of data collection	1999	2000	2000
Method of data collection	Volunteer center reporting to centralized database	Hospital database review	Hospital database
Study type	Prospective database investigation	Retrospective record review	Retrospective quality assurance database review of single center
Method of patient selection	Consecutive	Consecutive	Consecutive
Site and Procedural Characteristics			
Location(s)	United States	Brno, Czech Republic	Not reported (probably Charlotte, North Carolina, United States)
Setting	Various centers, types not reported	University hospital gastroenterology or surgery department	Large, urban teaching hospital
Patient Characteristics			
Reason for colonoscopy	62.4% diagnostic, 37.6% therapeutic	Not reported	Not reported
Provider Characteristics			
Specialty	Not reported; some training fellows and surgeons	Gastroenterology and surgery departments	Not reported; cites surgeons and gastroenterologists
Perforation Rates			
Number of perforations	10	6	14
Number of colonoscopies	13,580	3,897	43,609
Comments	No association with practitioner experience and complications (including perforations).	The authors concluded that polypectomy of thick, rigid, polyps with wider bases was more likely to result in perforation, owing to longer time duration and strength of coagulation.	Rate of perforation with general surgeons 0.080% (1 of 1,243), with gastroenterologists 0.031% (13 of 42,366). Mechanical stress was considered the most common mechanism of perforation, accounting for 6 perforations. Remaining perforations were associated with cone biopsy (3), electrocautery (3), and pneumatic causes (2); 57% of perforations were in males; mean age of patients with perforations was 65.9 years (range 31 to 83). Six of the 43,609 colonoscopies were attempted using a pediatric scope in an adult patient and 4 of them resulted in perforation. Both pneumatic injuries were associated with pediatric colonoscope use.

Sources: Cobb WS, Heniford BT, Sigmon LB, et al. Colonoscopic perforations: incidence, management, and outcomes. *Am Surg* 2004 Sep;70(9):750-7; discussion 757-8; Vokurka J. Iatrogenic perforation during an endoscopic examination of the gastrointestinal tract. *Bratisl Lek Listy* 2004;105(10-11):387-9; Wexner SD, Garbus JE, Singh JJ; SAGES Colonoscopy Study Outcomes Group. A prospective analysis of 13,580 colonoscopies. Reevaluation of credentialing guidelines. *Surg Endosc* 2001 Mar;15(3):251-61.

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Table 3. Identification of Modifiable Risk Factors for Perforation

FACTOR	STUDY	YEAR	FOUND TO BE A RISK FACTOR?	EVIDENCE TYPE	COMMENTS
Procedural Factors					
Type of colonoscope	Cobb et al.	2004	Yes	Retrospective quality assurance database review of single center	Four of six colonoscopies attempted using a pediatric colonoscope resulted in perforation (age range of patients with perforation was 31 to 83). Both cases of pneumatic perforation in the entire sample were associated with the use of a pediatric colonoscope.
Polypectomy/biopsy	Vokura	2004	Yes	Retrospective record review	Longer time duration and strength of coagulation were associated with increased perforations.
Provider Characteristics					
Practitioner experience	Wexner et al.	2001	No	Prospective database investigation	How experience was determined was unclear.
Provider specialty	Cobb et al.	2004	No	Retrospective quality assurance database review of single center	Higher rate reported for general surgeons (1 of 1,243) than gastroenterologists (13 of 42,366) was not statistically significant.

Sources: Cobb WS, Heniford BT, Sigmon LB, et al. Colonoscopic perforations: incidence, management, and outcomes. *Am Surg* 2004 Sep;70(9):750-7; discussion 757-8; Vokurka J. Iatrogenic perforation during an endoscopic examination of the gastrointestinal tract. *Bratisl Lek Listy* 2004;105(10-11):387-9; Wexner SD, Garbus JE, Singh JJ; SAGES Colonoscopy Study Outcomes Group. A prospective analysis of 13,580 colonoscopies. Reevaluation of credentialing guidelines. *Surg Endosc* 2001 Mar;15(3):251-61.

perforation in the entire sample were associated with pediatric colonoscope use. Vokura et al. concluded that longer duration and strength of coagulation was associated with increased risk of perforation.[4]

Provider characteristics. Only two of the publications reported association between perforation and provider characteristics. Wexner et al. found that practitioner experience was *not* associated with perforation.[5] Cobb et al. reported that the rate of perforation was higher for general surgeons (1 of 1,243 or 0.080%) than for gastroenterologists (13 of 43,609 or 0.031%); however, the difference was not statistically significant.[3]

Summary of Modifiable Risk Factors Associated with Perforation following Colonoscopy

The small number of studies reporting on modifiable risk factors precludes the formation of any strong conclusions. Few modifiable risk factors were identified, limiting the potential impact of currently available published literature on clinical practice.

2. What Are the Published Recommendations for Controlling Modifiable Risk Factors?

Four publications, comprised of 2 literature reviews and 2 clinical practice guidelines, reported 17 recommendations to reduce perforation rate associated with colonoscopy (See Table 4). The evidence used to support these recommendations was weak. The types of evidence that the recommendations were based on included observational studies, animal studies, and nonclinical (laboratory) studies. At least two recommendations were based upon anecdotal reports. For many recommendations, the supporting evidence was unclear but may have been based in medical opinion.

Preparation. Before colonoscopy begins, Reickert and Beck recommend assuring adequate bowel preparation, providing adequate sedation, and checking all equipment settings before using it.[6]

Technique. To reduce the risk of mechanical perforation during colonoscopy, the U.S. Multi-Society Task Force on Colorectal Cancer recommend against pushing against fixed resistance.[7] Reickert and Beck offered several recommendations, including proper insertion technique, maintenance of visualization, maintenance of "one to one motion with the scope," and minimizing endoscope looping or bowing.[6] To reduce the risk of barotraumatic perforation during colonoscopy, the American Society for Gastrointestinal Endoscopy (ASGE) and American College of Gastroenterology (ACG) Task Force on Endoscopy recommend using air judiciously, especially after passing the endoscope by strictures, replacing air with carbon dioxide, and ensuring proper equipment performance.[8] Reickert and Beck also recommended minimizing colonic distension.[6]

Polypectomy and biopsy. Several authors recommended strategies to reduce the risk of polypectomy or biopsy-associated perforation. Fatima and Rex,[9] the ASGE and ACG Task Force on Endoscopy,[8] and the U.S. Multi-Society Task Force on Colorectal Cancer[7] suggest cold techniques for small polyps with low risk of cancer. Submucosal saline injection is

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Table 4. Published Recommendations to Reduce the Risk of Perforation

PUBLICATION	ISSUING PARTY	YEAR PUBLISHED	RECOMMENDATION	SUPPORTING INFORMATION
Before Colonoscopy Begins				
Reickert and Beck	None reported	2001	"Assure that a thorough and adequate bowel preparation has been completed whenever possible."	Unclear
Reickert and Beck	None reported	2001	"Provide adequate sedation with experienced personnel and monitoring equipment."	Unclear
Reickert and Beck	None reported	2001	"Check endoscopic and electrocautery equipment settings prior to use."	Unclear
Mechanical				
Rex et al. "Quality in the technical . . . "	The U.S. Multi-Society Task Force on Colorectal Cancer	2002	"The most important rule to avoid mechanical perforation is not to push against the sensation of fixed resistance."	Unclear
Reickert and Beck	None reported	2001	"Use proper insertion technique, maintaining visualization of the lumen at all times."	Unclear
Reickert and Beck	None reported	2001	"Maintain one-to-one motion with the scope as much as possible."	Unclear
Reickert and Beck	None reported	2001	"Limit looping/bowing of the endoscope, with position changes or external counterpressure."	Unclear
Barotrauma-Related				
Rex et al. "Quality indicators . . . "	The American Society for Gastrointestinal Endoscopy (ASGE) and American College of Gastroenterology (ACG) Task Force on Endoscopy	2006	"Barotrauma perforations can probably best be avoided in most cases by judicious use of air during insufflation, particularly after passing strictures, perhaps by insufflation of carbon dioxide rather than air, and by ensuring that the air pump and light source will not continue to insufflate air when intraluminal pressures exceed the bursting pressure of the colon."	Observational studies
Reickert and Beck	None reported	2001	"Minimize colonic distension to minimize discomfort and the risk of barotraumas."	Unclear
Polypectomy/ Biopsy-Related				
Fatima and Rex	None reported	2007	"Because thermal injury from electrocautery is the cause of essentially all polypectomy-related perforations, using cold techniques (i.e. techniques that do not involve electrocautery) seems very appropriate for small polyps in which the risk of developing invasive cancer is extremely low."	Unclear
Fatima and Rex	None reported	2007	"Ancillary techniques to prevent perforation during resection of large sessile colorectal polyps include the use of submucosal injection. . . . It is unclear exactly which polyps are most appropriate for submucosal injection but in general the larger the sessile polyp and the closer it is to the cecum, the more appropriate would be submucosal injection techniques to prevent perforation."	Animal studies

(continued on page 62)

recommended by the same three groups. Reickert and Beck also recommend exposing the colon wall to the smallest amount of current possible.[6] Fatima and Rex recommend placing the snare on the stalk approximately "one third of the distance from the base of the polyp to the colon wall" to remove pedunculated polyps with electrocautery.[9]

Summary of Recommendations for Controlling Modifiable Risk Factors

Very few recommendations for best clinical practices to minimize the risk of perforation during colonoscopy are available in the peer-reviewed literature. The small amount of literature that is available is based upon weak types of evidence. The recommendations reported in this systematic qualitative review of the medical literature and clinical practice guidelines have not been definitively shown to reduce the risk of colon perforation.

Discussion

Identifying modifiable risk factors associated with perforation is desirable for improving the overall safety

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Table 4. Published Recommendations to Reduce the Risk of Perforation (continued from page 61)

PUBLICATION	ISSUING PARTY	YEAR PUBLISHED	RECOMMENDATION	SUPPORTING INFORMATION
Fatima and Rex	None reported	2007	"The risk [of perforation following removal of pedunculated polyps with electrocautery] is reduced by optimal location of the snare on the stalk, which is often said to be approximately one third of the distance from the base of the polyp to the colon wall."	Unclear
Rex et al. "Quality indicators . . . "	The ASGE and ACG Task Force on Endoscopy	2006	"Perforations may also result from polypectomy. In virtually every case, they are the result of the electrocautery burn. The risk of perforation is greatest with large polyps in the proximal colon. Submucosal saline solution injection is now frequently used by gastroenterologists, although no standardized guidelines regarding the size and location of polyps that require submucosal saline solution injection have been developed."(*sic*)	Observational studies
Rex et al. "Quality indicators . . . "	The ASGE and ACG Task Force on Endoscopy	2006	"Anecdotal reports have suggested an increased risk of complications associated with the use of hot biopsy forceps, and forceps removal of small polyps reduces the chance of complete removal. Cold snaring is attractive for the removal of small polyps because it effectively reduces small polyps and has been associated with exceedingly low risks of complications."	Anecdotal reports
Rex et al. "Quality indicators . . . "	The ASGE and ACG Task Force on Endoscopy	2002	"Injection of submucosal saline before piecemeal polypectomy of large sessile polyps reduces injury to the deep wall layers in experimental models but has not been convincingly shown to reduce perforation rates in clinical practice. . . However, the technique facilitates removal of some sessile polyps and probably reduces perforation."	An experimental model but no clinical study
Rex et al. "Quality in the technical . . . "	The U.S. Multi-Society Task Force on Colorectal Cancer	2002	"Anecdotal data suggest that perforations and bleeding are more likely with hot forceps, but definite proof of increased risk is lacking. Cold snaring is particularly attractive for polyps of <7-8mm in size, as anecdotal suggest no risk of perforation and a very low risk of post-polypectomy bleeding."	Anecdotal reports
Reickert and Beck	None reported	2001	"Minimize current exposure to the colon wall during therapeutic procedures."	Unclear

Sources: Fatima H, Rex DK. Minimizing endoscopic complications: colonoscopic polypectomy. ***Gastrointest Endosc Clin N Am*** 2007 Jan;17(1):145-56; Reickert CA, Beck DE. Complications of colonoscopy. ***Clin Colon Rectal Surg*** 2001;14(4):379-85; Rex DK, Bond JH, Winawer S, et al. Quality in the technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: Recommendations of the U.S. Multi-Society Task Force on Colorectal Cancer. ***Am J Gastroenterol*** 2002 Jun;97(6):1296-1308; Rex DK, Petrini JL, Baron TH, et al. Quality indicators for colonoscopy. ***Am J Gastroenterol*** 2006 Apr;101(4):873-85.

of colonoscopy. Although the risk of perforation to any individual is not high, minimizing the perforation rate is important given the large number of patients getting colonoscopy for screening, diagnostic, and therapeutic purposes. Prospective comparisons may be particularly helpful for identifying factors not typically available in reports of perforations that have occurred.

Conclusion

Colonoscopists should review these comprehensive lists of modifiable risk factors for perforation and clinical practice guidelines for prevention of this complication. The lack of good evidence supporting these conclusions is sobering. The PA-PSRS analysts will continue to review reports for stronger evidence that this information makes patients safer. Endoscopists and Pennsylvania Patient Safety Officers can help by ensuring that all perforations associated with colonoscopy are known and reported.

Notes

1. Jemal A, Murray T, Ward E, et al. Cancer statistics, 2005. *CA Cancer J Clin* 2005 Jan-Feb;55(1):10-30.
2. Pennsylvania Patient Safety Reporting System. Perforations of the colon during colonoscopy. PA PSRS Patient Saf Advis [online] 2006 Dec [cited 2008 Jun 2]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/v3n4december2006/perforations_of_the_colon_during_colonoscopy.pdf.
3. Cobb WS, Heniford BT, Sigmon LB, et al. Colonoscopic perforations: incidence, management,

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and outcomes. *Am Surg* 2004 Sep;70(9):750-7; discussion 757-8.

4. Vokurka J. Iatrogenic perforation during an endoscopic examination of the gastrointestinal tract. *Bratisl Lek Listy* 2004;105(10-11):387-9.
5. Wexner SD, Garbus JE, Singh JJ; SAGES Colonoscopy Study Outcomes Group. A prospective analysis of 13,580 colonoscopies. Reevaluation of credentialing guidelines. *Surg Endosc* 2001 Mar;15(3):251-61.
6. Reickert CA, Beck DE. Complications of colonoscopy. *Clin Colon Rectal Surg* 2001;14(4):379-85.
7. Rex DK, Bond JH, Winawer S, et al. Quality in the technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: Recommendations of the U.S. Multi-Society Task Force on Colorectal Cancer. *Am J Gastroenterol* 2002 Jun;97(6):1296-1308.
8. Rex DK, Petrini JL, Baron TH, et al. Quality indicators for colonoscopy. *Am J Gastroenterol* 2006 Apr;101(4):873-85.
9. Fatima H, Rex DK. Minimizing endoscopic complications: colonoscopic polypectomy. *Gastrointest Endosc Clin N Am* 2007 Jan;17(1):145-56.

"Manager Spoke with RN Involved: Reviewed Policy No. 750"

The response says it all!

The following report was submitted through PA-PSRS (some information in this report has been altered to deidentify the facility):

> *The [infant] patient received 500 mg (100 ml) bag of Flagyl® instead of 27.3 mg (5.46 ml). The outer bag was labeled 27.3 mg/5.46 ml but the inner bag was labeled from the manufacturer [500 mg (100 ml)]. . . . RN used outer pharmacy label when verifying correct medication, correct patient, and correct dose.* [RN] *did not read manufacturer bag prior to hanging medication. . . . Manager spoke with RN involved: reviewed policy No. 750. . . .*

Apparently, in the minds of administrators in this facility, the nurse (i.e., RN) had failed to either read or remember policy No. 750; had he or she done so, the error would not have occurred.

The patient safety analysts saw it differently, as follows:

> A person can't be expected to remember 750-plus policies.
>
> The organization may believe that "following policies and procedures" is an effective strategy to prevent errors. Patient safety experts know that patient safety solutions that are expecting humans to "be more careful," such as "follow the five rights," are ineffective system solutions.
>
> The labeling was ambiguous, increasing the risks of an inadvertent human error.
>
> The best way to avoid an overdose is to not deliver enough drug to the bedside to have an overdose. This medication error was due to the RN thinking he or she had to deliver the entire 100 ml. Had the nurse programmed an IV pump to deliver the correct amount, another error could have still resulted in the delivery of the full 100 ml overdose.
>
> From a nursing perspective, having a pharmacy technician prepare the medication as a unit dose that is checked by a pharmacy and labeled with the total dose and mg/ml will allow the nurse to triple check the infusion rate against the order. Obviously, pharmacy needs to have its own systems in place to prevent the error. The pharmacy could also send the medication in a syringe pump that doesn't allow large amounts of fluids to be administered.

The patient safety analysts believe a better solution would have been to deliver unit doses to the bedside, hopefully eliminating the need for every provider to remember policy No. 750 with every patient encounter to avoid an overdose.

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Icodextrin in Peritoneal Dialysis Solution May Cause Falsely High Blood Glucose Readings

ABSTRACT

Falsely elevated blood glucose level readings can lead to incorrect treatment and, subsequently, serious patient harm or death. Blood containing certain saccharides can falsely elevate the results obtained from point-of-care (POC) glucose meters using the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) enzyme/indicator test method. At-risk patients include peritoneal dialysis patients receiving dialysis solutions containing icodextrin, patients receiving certain types of immunoglobulin therapy, or patients receiving other drugs containing maltose, galactose, or xylose. GDH-PQQ meters cannot distinguish between maltose, galactose, or xylose contained in blood. Mitigation strategies to help facilities reduce or eliminate falsely elevated readings include educating staff and at-risk patients about the problem and becoming familiar with the enzymatic test methods used by POC glucose meters; labeling affected POC meters and contraindicating their use for patients receiving solutions containing icodextrin, maltose, galactose, or xylose; and instructing staff and at-risk patients to use POC meters not based on the GDH-PQQ method.
(Pa Patient Saf Advis 2008 Jun;5[2]:64-5.)

Blood containing maltose, galactose, or xylose can falsely elevate the results obtained from point-of-care (POC) glucose meters using the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) enzyme/indicator test method to determine blood glucose levels in patients. Falsely elevated readings can potentially lead to incorrect treatment and, subsequently, serious patient harm or death. The following report submitted through PA-PSRS describes a dialysis patient who was found unresponsive with an elevated blood glucose level, according to a POC glucose meter.

> *A patient . . . with a history of dialysis, presented to the emergency department with nonspecific complaints and weakness. The patient was evaluated and kept overnight for observation . . . Early in the morning, the patient was found to be unresponsive. The patient was intubated and required cardiopulmonary resuscitation with return of spontaneous circulation, but [the patient was] hypotensive. ACCU-CHEK [blood glucose level] at that time was greater than 180; however, the subsequent glucose [level] in the lab was reported to be less than 10. The patient was transferred to [the medical intensive care unit] where he remained in a comatose state until he ceased to breath later in the week.*

The Reason behind Falsely Elevated Blood Glucose Levels

Hypoglycemia (i.e., low blood glucose level) can be a serious medical condition, but is easily treated.[1]

Handheld POC glucose meters provide a quick diagnosis and afford rapid treatment. However, blood glucose readings can be falsely elevated by certain substances when using glucose meters.[2] Blood containing levels of maltose, galactose, or xylose can react with the GDH-PQQ used in some glucose monitoring systems.[3]* Icodextrin, used in peritoneal dialysis (PD) solutions, is one such substance. It is a colloidal osmotic agent consisting of a starch-derived, water-soluble glucose polymer. It is available under the brand name Extraneal® distributed by Baxter Healthcare.

Glucose testing uses enzymes (glucose oxidase, glucose hexokinase, or glucose dehydrogenase) and an indicator such as PQQ or nicotine adenine dinucleotide (NAD). Glucose meters that use the GDH-PQQ-enzyme test method cannot distinguish between glucose, maltose, galactose, or xylose, while glucose meters using the other methods listed above do not have this limitation.

In the report described above, the patient's medical history included dialysis. The problem of falsely elevated glucose levels typically affects diabetic patients receiving continuous ambulatory PD treatment. Glucose-based dialysate is used in PD solutions for ultrafiltration. Ultrafiltration is the process of removing fluids from the bloodstream of a kidney dialysis patient during PD. The glucose-based dialysate acts as an osmotic agent, enabling water to pass across the peritoneum membrane to maintain the osmotic gradient, which prolongs the filtration process.[5] Ultrafiltration is important for end-stage kidney disease patients because their own kidneys have limited or no ability to eliminate excess fluid from the bloodstream.[6]

Patients at risk for falsely elevated blood glucose levels include those receiving PD solutions containing icodextrin (e.g., Extraneal), certain types of immunoglobulin therapy (e.g., Octagam®), or other drugs containing maltose, galactose, or xylose.

Falsely Elevated Blood Glucose Level Reports in MAUDE

A search of the U.S. Food and Drug Administration's (FDA's) Manufacturer and User Device Experience (MAUDE) database using the keyword search terms "glucose" and "Extraneal" revealed 28 reports between 2003 and 2008 describing events of falsely elevated blood glucose levels in patients receiving PD solutions containing Extraneal. Many of the MAUDE reports described patients with elevated blood glucose levels when tested using POC glucose meters; however, the elevated values were not consistent with the patients' physiologic conditions. Other reports

* The ACCU-CHEK brand POC glucose meter uses the GDH-PQQ test method.

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specifically describe patients experiencing hypoglycemic comas, some resulting in patient death, with elevated glucose levels when measured using POC glucose meters. The brand name Extraneal was employed as a search term because it is more commonly referred to by clinicians than the generic form of icodextrin.

What the Sources Say

Medical manufacturers and FDA provide information about and recommendations for the problem of falsely elevated glucose levels during POC testing (see "Public Information on Falsely Elevated Blood Glucose Levels during POC Testing"). Manufacturers of POC blood glucose meters typically provide warning information with the instructions for use of the meter and/or the glucose test strips on their respective Web sites. Baxter Healthcare also provides warning information on Extraneal packaging inserts and on its Web site. Most of the ACCU-CHEK series POC glucose meters use the GDH-PQQ test method to measure blood glucose levels. However, most of the other common brands of POC glucose meters use a test method not affected by falsely elevated glucose levels. FDA also provides a description on its Web site of the problem and methods to prevent the false reading from occurring.

The most common methods offered by the medical manufacturers and FDA to prevent falsely elevated blood glucose levels include the following:

- Labeling affected POC glucose meters to alert users not to use that meter for patients receiving icodextrin (Extraneal) or other solutions containing maltose, galactose, or xylose
- Educating staff and at-risk patients about the problem and becoming familiar with the enzymatic test method used by the relative POC glucose meter
- Instructing staff and at-risk patients to use an alternative POC glucose meter not based on the GHD-PQQ test method during therapy with interfering drugs

In addition to the methods described above to prevent falsely elevated blood glucose levels, PA-PSRS clinical analysts suggest that facilities also consider the following:

- Identifying patients who have received or will be receiving icodextrin-, xylose-, maltose-, or galactose-containing agents
- Making sure POC glucose meters not based on the GHD-PQQ method are available in areas with high-risk patients or only using laboratory glucose testing for high-risk patients
- Rechecking suspected hypoglycemia with a laboratory glucose test or a POC meter not based on the GHD-PQQ method if POC blood glucose results are inconsistent with a clinical suspicion of hypoglycemic coma

Public Information on Falsely Elevated Blood Glucose Levels during POC Testing

Baxter Healthcare

- EXTRANEAL (Icodextrin) Peritoneal Dialysis Solution [full prescribing information]. http://www.baxter.com/products/renal/downloads/extraneal_pi.pdf

LifeScan

- True Glucose Results with Glucose Oxidase Test Methods. http://www.lifescan.com/pdf/hospital/aw086-149.pdf

Roche Diagnostics

- Diabetes and Dialysis: Advice on Blood Glucose Strips and Patients on Peritoneal Dialysis [important product information]. http://www.rochediagnostics.com.au/accu-chek/ index.asp?s1=For%20Medical%20Professionals&s2=Important%20Product%20Information

U.S. Food and Drug Administration

- Fatal Iatrogenic Hypoglycemia: Falsely Elevated Blood Glucose Readings with a Point-of-Care Meter Due to a Maltose-Containing Intravenous Immune Globulin Product. http://www.fda.gov/cber/safety/glucfalse.htm
- FDA Reminders for Falsely Elevated Glucose Readings from Use of Inappropriate Test Method. http://www.fda.gov/cdrh/oivd/news/glucosefalse.html

Editor's Note

As of press time, Roche Diagnostics did not respond to a request to review this article. However, Roche does provide information about the issue of falsely elevated glucose readings in its ACCU-CHECK product information insert and on its Web site. See the link in the section "Public Information on Falsely Elevated Blood Glucose Levels during POC Testing." Another industry representative participated in review of this article.

Notes

1. King DA, Ericson RP, Todd NW, et al. Overestimation of blood glucose due to peritoneal dialysis fluid containing icodextrin [case report]. *Chest* 2007 Oct 23;132(4S):696S.
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3. ECRI Institute. Roche-ACCU-Chek blood glucose monitoring systems: manufacturer issues safety alert to remind users that drug interference may cause falsely high readings [action item A7779]. *Health Device Alerts* 2006 Oct 20.
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Act 52 of 2007: the Authority's Role, Progress to Date, and Future Goals

Healthcare-associated infections (HAIs) are a major threat to patient safety and are among the most common adverse events in healthcare. Approximately 2 million hospitalized patients develop HAIs annually in the United States, resulting in roughly 90,000 deaths.[1,2] These infections result in increased morbidity, mortality, and significant healthcare expenditure. Patient safety may be compromised by the failure to follow best practices for minimizing the HAIs and by injudicious use of antibiotics, which results in the emergence of virulent and resistant organisms.

More patients are discharged from hospitals at an acuity level requiring skilled nursing care, which increases the burden on the long-term care system. Lack of resources in nursing homes compromises safe practices and puts patients at risk of infection. HAI incidence in nursing homes is not widely studied, but in a 3-year prospective study conducted in a San Diego nursing home with 300 hundred residents, the author reports results of approximately 7.1 infections per 1,000 resident days.[3] Elsewhere in the United States, an average rate of approximately 4.1 infections per 1,000 resident days with a range of 0.8 to 9.5 has been reported.[4] A recent study reported in April 2008 was undertaken in 133 U.S. Department of Veterans Affairs nursing homes. A point prevalence rate of 5.2 infections per 1,000 resident days is cited.[5]

Although HAIs cannot be entirely eliminated, there are strategies that have been proven to be effective to significantly reduce numbers of cases and eliminate infections that are avoidable. An example includes implementation of evidence-based practices, including hand hygiene. The fact that some healthcare organizations have succeeded in managing infections and the risks to patients much better than others suggests a patient safety improvement gap between what is possible and what is currently widely implemented. Patient safety requires system- and discipline-wide action to identify and manage potential and actual HAI-related risks.

Pennsylvania became the first state in the nation to mandate reporting of HAIs, with public reporting of individual hospital data collected by the Pennsylvania Health Care Cost Containment Council (PHC4). Mandatory reporting by hospitals to PHC4 began in 2004, and the first public data report was released in July 2005.

Senate Bill 968 (Act 52) was signed into law by Governor Edward G. Rendell on July 20, 2007, as part of the Prescription for Pennsylvania healthcare reform plan. Act 52 focuses on the reduction and prevention of HAIs. It mandates that acute care facilities, nursing homes, and ambulatory surgery facilities develop and implement a comprehensive internal infection control plan for improving the health and safety of patients, residents, and healthcare workers. In addition, acute care facilities and nursing homes are required to report HAIs to the Pennsylvania Patient Safety Authority.

Under Act 52, an advisory panel of infection prevention and control experts was appointed by the Authority during fall 2007. The panel includes a subcommittee of long-term care experts. (For more information about the panel, see page 71 of the September 2007 issue of the *Patient Safety Advisory* at http://www.psa.state.pa.us/psa/lib/psa/advisories/sept_2007_advisory_v4_n3.pdf.)

To date, the panel has assisted in establishing requirements for the mandatory reporting of HAIs by hospitals and nursing homes. These requirements were published in the *Pennsylvania Bulletin* in a final notice for hospitals and a draft notice for nursing homes. (See "Notices in the *Pennsylvania Bulletin*.") A final notice for nursing homes will be published when the public comment period relating to the draft has been completed. It is expected that nursing homes will begin mandatory reporting at the beginning of 2009.

The panel has also developed "best practice" questions for hospitals. This information was published in the *Pennsylvania Bulletin* in March 2008. These best practice questions are answered when hospitals enter HAI data into the Centers for Disease Control and Prevention's Web-based surveillance system, the National Healthcare Safety Network (NHSN). On the advice of the panel, the Authority employed the "bundling" concept developed by the Institute for Healthcare Improvement* to develop questions about central line and ventilator-associated pneumonia prevention.[6] The Authority also developed questions to monitor the necessity of Foley catheters, as well as to monitor certain surgical procedures with the potential highest risk for infection. Using the Surgical Care Improvement Project (SCIP) measure of antibiotic prophylaxis,[7] the Authority will be monitoring several surgical procedure categories.†

Best practice questions are currently being developed for nursing homes utilizing resources such as F-tags (urinary incontinence F315), with assistance from the long-term care advisory subcommittee. These questions will be addressed in a final notice in the *Pennsylvania Bulletin* and in a future *Pennsylvania Patient Safety Advisory* article. The Authority will be conducting comprehensive educational programs for nursing homes relating to the reporting requirements and best practice questions.

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* Bundling denotes developing a collection of processes needed to effectively care for patients undergoing particular treatments with inherent risks.

† SCIP is a national campaign and partnership of leading public and private healthcare organizations aimed at reducing surgical complications by 25% by the year 2010.

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Notices in the *Pennsylvania Bulletin*

- Reporting Requirements for Health Care Facilities under the Medical Care Availability and Reduction of Error (MCARE) Act [final notice]. http://www.pabulletin.com/secure/data/vol38/38-9/374.html
- Reporting Requirements for Nursing Homes under The Health Care-Associated Infection and Prevention Control Act [draft notice]. http://www.pabulletin.com/secure/data/vol38/38-22/1036.html

Act 52 requires the Authority to develop and implement educational programs for hospitals and nursing homes. The Authority has developed question-and-answer sheets and video tutorials for reporting requirements and answering best practice questions on NHSN. The video tutorials are hosted online by the Department of Health at http://www.dsf.health.state.pa.us/health/cwp/view.asp?A=188&Q=250491. The PA-PSRS help desk and infection control analyst are available to provide assistance for individual hospitals on an as-needed basis. Educational programs have been presented during hospital council meetings in two regions to date. Development of the first set of nursing home programs to introduce reporting requirements and educate staff is underway and will be conducted in the near future.

Ongoing collection and analysis of HAI-related data from more than 250 hospitals and 800 nursing homes will assist the Authority in identifying trends, patterns, and potential process or system failures. Data analysis will allow the Authority to measure best practice outcomes and processes, and identify low and high performance, which will provide insight into barriers and strategies to overcome them.

Future HAI-related *Advisory* articles will convey information from event data analysis and the medical literature. These articles will provide strategies for process improvement and adoption of evidence-based best practices. The *Advisory* is new to nursing homes but the Authority intends it to be a useful information resource and tool for long-term care providers as well as acute care. The Authority will continue to provide up-to-date HAI-related information on its Web site (http://www.psa.state.pa.us).

Notes

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7. Colorado Foundation for Medical Care. Surgical care improvement project (SCIP) [online]. [cited 2008 May 27]. Available from Internet: http://www.cfmc.org/hospital/hospital_scip.htm.

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Dangers Associated with Shared Multidose Vials

Research shows that up to 25% of healthcare practitioners re-enter vials with needles just injected into patients.[1] There has been at least one report in PA-PSRS documenting this behavior, and similar actions may not have been reported because practitioners may be unaware that routinely re-entering vials with used needles and reusing syringes is placing patients at risk for infection from contamination.

The consequence of sharing multidose vials was dramatically illustrated by an occurrence elsewhere that made national news. In February 2008, the Southern Nevada Health District reported findings from an investigation arising from a cluster of hepatitis C virus (HCV) infections in their area. The health district's investigation uncovered that six patients infected with the HCV had undergone procedures at the Endoscopy Center of Southern Nevada. Genetic testing on five of the cases identified a common source, although the sixth patient did not share the same source.[2] As a result of these infections, 40,000 patients are being informed they should be tested for HCV, as well as for hepatitis B and HIV. As of May 2008, results show 77 individuals were likely exposed to HCV from a procedure performed at the clinic. These numbers are expected to rise since another 10,000 patients have yet to be tested for the virus.[3]

A full on-site investigation conducted by the Centers for Disease Control and Infection, the Nevada State Health Division, and the Southern Nevada Health District confirmed that during the past four years, syringes were reused by practitioners to withdraw additional doses of medication for the same patient; these findings substantiated that this practice was not a one-time occurrence.[4] This technique most likely contaminated the medication vial, and when used for subsequent patients, the bloodborne pathogens in the vial were inadvertently transmitted even though a clean needle and syringe were used. Since the 1970s, reports of iatrogenic patient-to-patient transmission of microbes due to contamination of multidose vials have been well documented.[5] Even when the multidose vials are bacteriostatic, the vials still support microbial growth; previously entered multidose vials exhibit viable organisms, and debris such as red blood cells, epithelia cells, and lint fibers can be detected.[6]

While goal 7 of the Joint Commission National Patient Safety Goals is intended to reduce the risk of healthcare-acquired infections, it does not address poor aseptic technique associated with multidose vials. Healthcare organizations must recognize that through either lack of knowledge or poor technique, some practitioners routinely re-enter vials with used needles, without any realization they are likely contaminating the contents of the vial.

Although the potential for time and cost savings is apparent, multidose vial use in any patient care area is risky, with an ever-present danger for iatrogenic cross-contamination. The safest practice is to use patient-specific vials and discard them immediately after use. If multidose vials must be used, provide frequent staff education and monitor for proper infection control techniques. When a multidose vial is used for an infected patient, transmission can be prevented by isolating the vial and using it exclusively for that patient.[7]

Notes

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4. Vegas clinic may have exposed 40k to hepatitis, HIV [online]. CNN.com 2008 Feb 28 [cited 2008 May 5]. Available from Internet: http://www.cnn.com/2008/HEALTH/02/28/vegas.hepatitis.ap/index.html.
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Quarterly Update on the Preventing Wrong-Site Surgery Project

The revised graph of the number of reports of wrong-site surgery events by quarter has been extended through the first quarter of 2008 and updated on the Pennsylvania Patient Safety Authority's Web site (see Figure 1).* One more wrong-site surgery event has been reported for the fourth quarter of 2007, increasing that number from 13 to 14, and 18 events have been reported for the first quarter of 2008. Five of the 18 were limited to punctures of the skin for the injection of local or regional anesthesia preparatory to the scheduled procedure, still wrong-site surgery as defined by the National Quality Forum.[1]

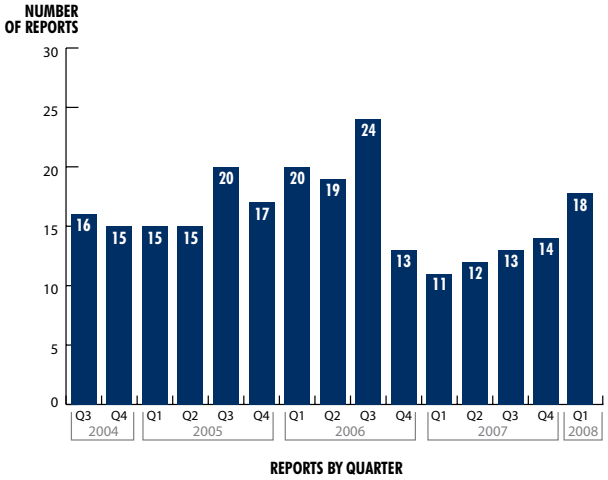
Detailed wrong-site surgery reports continue to be submitted by cooperating facilities in follow up to reports of near-miss and actual wrong-site events. By comparing the processes that were and were not significantly associated with trapping the error before harm occurred, PA-PSRS clinical analysts can better understand which processes are associated with successfully catching these rare events. As of May 29, 2008, a cumulative total of 70 results from in-depth surveys about near-miss events and a cumulative total of 28 results about actual wrong-site surgery events from 62 cooperating facilities have been received through PA-PSRS. The compliance rate with the request for detailed information within 30 days of the event has been more than 75%. In the previous quarterly update, six elements of a prevention program for wrong-site surgery were noted to be more commonly present when errors were trapped. This update identifies another eight elements that differ between the two groups (Table 1). Reports of near misses were significantly more likely to indicate the following:

- The time out was done after the patient was draped.
- The surgeon's records and diagnostic images were available in the operating room (OR).
- Diagnostic tests were reviewed by the surgeon before the incision was made.
- The patient's identification, the procedure, and antibiotic administration were addressed as part of a preoperative briefing with the surgeon.

Paradoxically, verification by the patient of the information in the documents was always done in the wrong-site surgery events, but not always done in the near-miss events. It is possible the near-miss reports that indicated a lack of verification intended to convey not that the patient was excluded, but that the patients' responses did not agree with the written information.

The analysts are pleased to report that 64 hospitals and 69 ambulatory surgical facilities voluntarily

Figure. PA-PSRS Wrong-Site Surgery Reports by Quarter



completed assessments of the elements on the Authority's "Self-Assessment Checklist for Program Elements Associated with Preventing Wrong-Site Surgery." By comparing facilities that did and did not report having each element on the checklist against existing reports of wrong-site surgery events, the analysts demonstrated that several elements were more commonly found in facilities that reported no wrong-site surgery events (see Table 2), including the following:

- Consents require the correct patient name, the exact description of the procedure, and the site or side, if applicable.
- The checklist prior to the day of surgery, for documentation of the preoperative verification and reconciliation, includes the schedule.
- The site marking occurs after reconciliation of *all* relevant documents.
- The time out with the entire surgical team, after prepping and draping, requires the surgeon to request other members of the OR team to speak up if their understanding is different than stated during the time out.
- The verification of the specimen specifically includes the patient name.

Two elements had paradoxical correlations, as follows:

- Involvement of an alert patient or surrogate in the site marking was more common among facilities that had reported wrong-site surgery. Possible explanations include an improvement after the reported event, vulnerability among those that have not reported an event, or a more critical inclusion of compliance, rather than just policy.
- An intraoperative time out to verify spine or rib level, if applicable, with verification by fluoroscopy

* The Pennsylvania Patient Safety Authority maintains an online collection of articles, educational resources, and data snapshots pertaining to wrong-site surgery. This collection, "Preventing Wrong-Site Surgery," is available at http://www.psa.state.pa.us/psa/cwp/view.asp?a=1293&q=448010.

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Table 1. Current Preliminary Associations between Elements of a Prevention Program for Wrong-Site Surgery and Success in Trapping Wrong-Site Errors before Harm Occurred

ELEMENT	NEAR MISSES	WRONG-SITE SURGERIES	SIGNIFICANCE (P LESS THAN)
Surgeon reconciled discrepancies in documents	31 of 36	6 of 18	0.001
Time out done after draping*	44 of 50	14 of 27	0.001
Someone raised a concern	38 of 48	6 of 24	0.001
Surgeon responded to the concern raised	31 of 33	10 of 19	0.001
Surgeon did a preoperative verification	44 of 47	18 of 27	0.01
Identification involved wristband and chart	47 of 47	22 of 26	0.01
Surgeon's records available in the operating room (OR)*	40 of 41	22 of 27	0.05
Diagnostic images available in the OR*	28 of 29	10 of 13	0.05
Diagnostic tests reviewed by surgeon before incision*	24 of 24	10 of 12	0.05
Patient identification verified during preoperative briefing with surgeon*	26 of 26	10 of 12	0.05
Procedure verified during preoperative briefing with surgeon*	26 of 26	10 of 12	0.05
Antibiotics verified during preoperative briefing with surgeon*	19 of 20	6 of 9	0.05
Mark visible during time out	37 of 43	13 of 21	0.05
Information verified against patient's response*,†	40 of 49	25 of 25	0.05

* One of eight additional elements of a prevention program for wrong-site surgery not present in results presented in March 2008.

† According to the submitted results, the patient verified information in the documents in every wrong-site surgery event, but not in every near miss. It is possible that near-miss reports were intended to convey that the patients' responses did not agree with the written information.

or radiograph (x-ray) using a radiopaque marker firmly affixed by the operating surgeon was also more common among facilities that had reported wrong-site surgery. Overall compliance with this element was low (49%). An additional explanation for this paradox might be that facilities not doing such surgery answered "no" rather than "not applicable."

A revised version of the checklist is available on the Authority's Web site for use by interested facilities and by states collecting wrong-site surgery events. The Authority encourages facilities to assess their program for preventing wrong-site surgery using the checklist.

What do these two surveys reinforce? Combined with earlier studies of events reported through PA-PSRS, the analysts feel confident making the following points:

- The exact procedure, including side or site, should be on the initial request to schedule the case.
- All personnel handling preoperative documentation should reconcile all discrepancies whenever the documents cross their desks.
- No patient should present to the facility the day of surgery with discrepancies in any of the essential preoperative documents; no patient should enter the OR with discrepancies; and the attending surgeon should correct all discrepancies.
- Both the preoperative verification of the documents on the day of surgery and the marking of the site should involve an alert patient or surrogate prior to the patient entering the OR. The healthcare provider who marks the site should precede the process by verifying all relevant documents with each other and the patient. The mark should be visible when the patient is prepped and draped for any procedure and should be referred to during the time out.
- Anesthesia providers should do time outs before regional blocks.
- The final time out should be done just before the incision is made. The information should be verified using the documents and marks, not memory.
- Surgeons should explicitly empower members of the OR team to speak up if their understanding is different than stated in the time out.

Anecdotally, the major problem discussed by facilities is the additional time surgeons feel it takes to see the patients in the preoperative holding area before transport to the OR. The analysts have no doubt that the visit is valuable. However, the time spent may not be trivial. Through the courtesy of 27 facilities in the Delaware Valley,* the analysts obtained 249 observations of the time spent doing a preoperative verification. The median time spent was 2 minutes and the average was 2.8 minutes, compared to a median of 1 minute and an average of 1.5 minutes for the 227 time outs. The analysts have calculated that a busy surgeon doing 500 operations per year, with a 1 minute walk each way, plus a 2.8- minute preoperative visit, would spend 40 hours over the course of the year on this activity. The analysts suggest that facilities make the process as convenient as possible for the surgeons to minimize any time expenditures other

* Observations were provided courtesy of the Health Care Improvement Foundation.

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Table 2. Statewide Survey of Elements in Facilities' Wrong-Site Surgery Prevention Programs

ELEMENTS	FACILITY TYPE	FACILITIES WITH WRONG-SITE SURGERIES			FACILITIES WITH NO WRONG-SITE SURGERIES			SIGNIF. (P LESS THAN)	OVERALL PERCENT COMPLY
		Yes	No	Yes (%)	Yes	No	Yes (%)		
The consent must include the correct patient name.	Hospitals	24	3	89%	37	0	100%	0.05	98%
The consent must include the correct patient name.	All	34	3	92%	96	0	100%	0.01	98%
The consent must include the exact description of the procedure.	Hospitals	24	3	89%	37	0	100%	0.05	98%
The consent must include the exact description of the procedure.	All	34	3	92%	96	0	100%	0.01	98%
The consent must include the site or side, if applicable.	Hospitals	23	4	85%	37	0	100%	0.05	96%
The consent must include the site or side, if applicable.	All	33	4	89%	95	1	99%	0.01	96%
The required standardized checklist prior to the day of surgery, for documentation of the preoperative verification and reconciliation, includes the schedule.	All	15	9	63%	45	9	83%	0.05	77%
Site marking occurs after reconciliation of *all* relevant documents.	Hospitals	16	10	62%	33	4	89%	0.01	73%
Time out prior to procedure, involving entire surgical team, after prep and drape, requires the surgeon to request other members of the operating room (OR) team to speak up if their understanding is different than stated during the time out.	Ambulatory surgical facilities	4	6	40%	35	11	76%	0.05	68%
Required verification of the identity of the specimen in OR must include the patient name.	All	23	6	79%	69	4	95%	0.05	90%
Site marking involves alert patient or surrogate.*	All	34	2	94%	69	23	75%	0.05	80%
Intraoperative time out to verify spine or rib level, if applicable, requires verification by fluoroscopy or radiograph (x-ray) with radiopaque marker firmly affixed by operating surgeon.*	All	25	11	69%	31	48	39%	0.01	49%

* Percentage of elements was higher in facilities with wrong-site surgeries.

than efficient verifications of the documents and the discussions with the patients before they enter the OR.

A new tool to monitor compliance with the elements of any policy for preventing wrong-site surgery is available on the Authority's Web site. The Authority encourages facilities to monitor their policies for preventing wrong-site surgery by using this tool.

The analysts are planning to collect experiences with marking pens and hope that facilities will help share those experiences with others.

The analysts will continue to track and study all reports of wrong-site surgery events and near misses. Hospitals and ambulatory surgical facilities are encouraged to continue to share, through PA-PSRS, facility assessments and the success or failure of any efforts to improve protocols to insure correct sites. Facilities have already provided some enlightening anecdotes, and the analysts anticipate that additional stories will be informative. Facilities outside Pennsylvania are also welcome to share this information.

Note

1. National Quality Forum. Serious reportable events in healthcare—2006 update. Washington DC: National Quality Forum; 2007.

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Bubble Gum Story

What does bubble gum have to do with patient safety? By the end of this article, we hope you'll see how they're connected.

The following report was submitted through PA-PSRS:

> *A patient was ordered a "bubble gum" enema. The nurse had a nursing assistant obtain bubble gum and give it to the patient. The patient chewed the bubble gum, which stuck to the patient's dentures. Thereafter, the unit coordinator spoke with the patient (without dentures) as the patient continued to roll the bubble gum around in her mouth.* [Afterward, the patient received the enema as ordered.]

Many healthcare workers may be unfamiliar with a bubble gum enema. It is an intervention used to resolve a fecal impaction. The facility's drug formulary lists the ingredients of this enema as equal parts mineral oil and docusate sodium (Colace®) syrup. There was only one reference to bubble gum enema located through a search engine—it was a comment on a listserv, in which the recipe includes a fleets enema, liquid Colace, hydrogen peroxide, and water.[1] While we cannot attest to this concoction, according to the registered nurse commenting on the listserv, it is extremely effective in breaking up this "log jam."

While this report may seem amusing, it also reflects a critical patient safety issue. It is obvious that a healthcare worker was unfamiliar with the facility's unique definition of a bubble gum enema. What factors were present that prevented the nurse from seeking an appropriate resource to learn about this intervention? Or, to determine whether such an intervention is even appropriate?

Here's another PA-PSRS report:

> *A laboratory technician placed a patient specimen for anaerobic culture in an aerobic environment for incubation. When questioned afterward, the technician stated he had not been trained how to process anaerobic cultures.* [Yet, an experienced technician was on duty at the same time as this inexperienced technician.]

Again, what prevented the new technician from asking for guidance? What degree of supervision was provided?

Now, here's a third PA-PSRS report:

> *A physician ordered a Jones dressing to be applied to a patient's wound. The staff was not familiar with this dressing and contacted the physician, who would not explain what this dressing was. The staff obtained appropriate information from another source.*

While these reports are from different facilities, they evoke similar patient safety issues. Much has been discussed about creating a culture of safety, in which reporting of occurrences that actually or potentially threaten patient safety is encouraged and viewed as opportunities to make the healthcare system better, rather than blaming individuals.[2] Another aspect of this culture, however, relates to teamwork—an environment in which questions are actively encouraged and effectively responded to for the sake of better patient care.

The American Association of Critical Care Nurses conducted a study called Silence Kills.[3] This survey of more than 1,700 healthcare workers revealed that 75% were concerned about a peer's poor teamwork, to the point that one-fifth of the respondents could not trust that patients in their area were receiving the correct level of care. Just as disturbing, more than three-fourths of those surveyed had experienced disrespectful and verbally abusive behavior from another healthcare worker, 44% of whom indicated that such behavior had continued for a year or more. Such behaviors have a chilling effect on communication and working together for the benefit of the patient.

Errors can be prevented and patients assured of receiving appropriate interventions if healthcare workers feel comfortable in asking questions—remember, no question is stupid, unless it is never asked. Just as important, however, is that questions (and the people who ask them) receive an appropriate answer. If the person who is asked the question does not know the answer, say so! And, work with the questioner to find the answer together, so that two people will learn something new, rather than just one.

Notes

1. Re: Impactions. In: EM-Nsg-L [listserv online]. 2002 Jan 24 [cited 2007 Feb 9]. Available from Internet: http://www.ucsf.edu/its/listserv/em-nsg-l/4357.html.
2. Agency for Healthcare Research and Quality. 30 safe practices for better health care [online]. 2005 Mar [cited 2007 Mar 2]. Available from Internet: http://www.ahrq.gov/qual/30safe.pdf.
3. Maxfield D, Grenny J, McMillan R, et al. Silence kills: the seven crucial conversations for healthcare [online]. 2005 [cited 2007 Mar 2]. Available from Internet: http://www.aacn.org/aacn/pubpolcy.nsf/Files/SilenceKills/$file/SilenceKills.pdf.

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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.psa.state.pa.us.
Topics addressed include the following:

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

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

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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,
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PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

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

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

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