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

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Management of Unanticipated Difficult Intubation

ABSTRACT
Airway management, ensuring uninterrupted oxygenation and ventilation, is a fundamental part of the practice of anesthesia and of emergency and critical care medicine. Endotracheal intubation is an airway management technique indicated in a variety of clinical situations, most commonly for the maintenance of the upper airway during general anesthesia, but also in any situation involving the maintenance and protection of the upper airway when the airway may be compromised or positive pressure ventilation is necessary. A difficult intubation is defined by the American Society of Anesthesiologists as tracheal intubation requiring more than three attempts, in the presence or absence of tracheal pathology. Unanticipated difficulty with endotracheal intubation may result in catastrophic outcomes, including cerebral anoxia and death. Of the anesthesia events involving complications reported to the Pennsylvania Patient Safety Authority in 2009, 36 reports involved a difficult intubation. In 23 reports, difficult intubation was described as unanticipated. Even the most thorough assessment of the airway may not detect the possibility of a difficult intubation, and every anesthetist should have a predetermined strategy for dealing with this situation. Alternative methods of managing the airway should be initiated after two or three unsuccessful attempts at intubation. This article discusses assessment of the airway, identification of patients at risk for a difficult intubation, and risk reduction strategies, including plans for dealing with an unexpected difficult intubation. Recent advances in airway management techniques and devices will be summarized. (Pa Patient Saf Advis 2010 Dec;7[4]:113-22.)

Introduction
Airway management, specifically ensuring uninterrupted oxygenation and ventilation, is a fundamental part of the practice of anesthesia and of emergency and critical care medicine. Difficulty in airway management can be categorized as difficult mask ventilation and/or difficult tracheal intubation, which is defined by the American Society of Anesthesiologists (ASA) as tracheal intubation requiring multiple attempts in the presence or absence of tracheal pathology. Of the anesthesia events involving complications reported to the Pennsylvania Patient Safety Authority in 2009, 36 involved difficult preoperative tracheal intubation. These will be the focus of this article, although the information may also be of value in other settings.

Endotracheal intubation (ETI) meets the following goals of airway management: the maintenance of airway patency, protection of the lungs from aspiration, and creation of a conduit for ventilation. Indications for ETI vary with clinical scenarios. In the operating room (OR) setting, ETI is used to ensure airway patency and protection for the unconscious patient. ETI is based on the need for reliable oxygenation or ventilation. Difficulty with ETI may occur unexpectedly even under controlled situations such as during induction of anesthesia in the OR.

Airway management difficulty is an important factor in mortality and morbidity related to anesthesia. The ASA Closed Claim Project involves analysis of closed anesthesia malpractice claims files. Cheney et al. analyzed 6,750 claims in the database for events that occurred between 1975 and 2000 and found that 39% were claims for death or permanent brain damage. Respiratory-related damaging events were responsible for 50% or more of those claims. In the respiratory events category, the most frequent events were difficult intubation (23% of the respiratory events) and inadequate ventilation/oxygenation (22%). Although some difficult airways can be predicted, even the most thorough assessment of the airway may not detect the possibility of a difficult intubation and associated problems with ventilation of the patient. Every clinician should have a predetermined strategy for dealing with this situation. This article will discuss the assessment of the airway, identification of patients at risk for a difficult intubation, and risk reduction strategies designed to maintain oxygenation and ventilation of the patient, including predetermined and rehearsed plans for dealing with an unexpected difficult intubation.

Authority Reports
In 2009, the Authority received 448 event reports involving complications related to anesthesia. Of these reports, 36 involved a difficult intubation. Six events were reported as an anticipated difficult airway involving patients with the following risk factors:
- Known history of difficult intubation (two patients)
- Anterior larynx (one patient)
- Small mouth (one patient)
- Kyphosis resulting in difficult positioning (one patient)
- Severe neck swelling due to bleeding (one patient)

For 23 events, difficult intubation was reported as unanticipated. In the seven remaining reports, it was indeterminable whether the difficult intubation was
anticipated. Nine events involving a difficult intubation resulted in harm to the patient. 

Reports of difficult intubation in which the patient was harmed include the following:

- **Intubation took three attempts. The larynx was anterior and made for difficult intubation. The patient had difficulty swallowing postoperatively and was found to have an esophageal perforation.**

  The anesthesiologist was attempting to insert the [endotracheal] tube using a GlideScope®. The patient’s mouth was small, and the size of the tube prevented direct visual placement. Several attempts were made; then, copious amounts of blood were noted in the oropharynx. A laceration of the tonsil occurred.

- **A patient was admitted for shoulder surgery under general anesthesia. It was a difficult intubation.**

  During intubation, an approximate 1 cm laceration of the soft palate occurred.

**Evaluation of the Airway**

A published analysis of 4,000 incidents reported to the Australian Incident Monitoring System emphasizes the importance of preoperative assessment of the airway. In 76 (52%) of 147 reports of difficult intubation, the difficulty with intubation was unanticipated. The most frequently reported complications included oxygen desaturation, unrecognized esophageal intubation, and pulmonary reflux with aspiration. The most common remediable cause of unpredictable difficult intubation was inadequate preoperative assessment. The components of preoperative airway evaluation include taking patient history and performing a physical examination to identify clinical risk factors that might predict difficult intubation.

**Clinical Risk Factors**

Clinical risk factors that may be associated with difficult intubation in adult patients include increased age, male gender, high body mass index, and history of obstructive sleep apnea (OSA). Obesity (i.e., a body mass index above 30 kg/m²) is an increasingly important risk factor to consider. In a prospective observational controlled study of 204 patients, the authors compared intubation difficulty among obese and nonobese patients using an intubation difficulty score, intubation duration, and lowest oxygenation saturation levels during intubation. Scores were found to be higher among obese patients due to poor glottic exposure, increasing lifting force needed during laryngoscopy, and the need to apply external laryngeal pressure to improve glottis exposure. The results concurred with an earlier study comparing scores between obese patients and lean patients. Chung et al. showed an association between OSA and unexpected difficult intubation. Thirty-three patients classified as a difficult intubation cases were referred to a sleep clinic for polysomnography. Of these, 66% were diagnosed as having OSA. The authors suggest that patients with difficult intubation are at high risk for OSA and should be screened for signs and symptoms of sleep apnea. Although it was not evaluated, the study also suggests that thorough screening for signs and symptoms of OSA, including a short thick neck, limited head extension, and reduced thyromental distance, is an important aspect of predicting difficult intubation. Clinical signs and symptoms associated with sleep apnea include snoring, excessive daytime sleepiness, falling asleep while driving, frequent nighttime awakenings, difficulty falling asleep, and a neck circumference greater than 16 inches in a woman or greater than 17 inches in a man.

Clinical risk factors for difficult intubation in pediatric patients are related to the anatomic differences between pediatric patients and adults, including the relative position of the larynx in the neck, a less rigid airway, the size of the occipital bones, tongue size, decreased functional pulmonary reserve, less developed accessory muscles of respiration, and smaller airway diameter. Most cases of acute airway compromise in children are the result of infections, the presence of foreign bodies, or trauma. Additional predictors of a difficult intubation in pediatric patients include the following:

- Small mouth opening
- Mental-hyoid distance (a measure to evaluate the submandibular space) of 1.5 cm or less in a newborn or infant and 3 cm or less in a child
- Impaired head and neck mobility
- Micrognathia (small lower jaw)
- Retrognathia (receding mandible or maxilla)
- Mandibular dysplasia or hypoplasia
- Macroglossia (enlargement of the tongue)
- Space-occupying airway lesions
- Supralaryngeal inflammatory pathology
- Nasal airway obstruction
- Pathologic obesity
- Craniofacial abnormalities

In the obstetric patient, anatomic and physiological changes may place the patient at increased risk for difficulty with intubation. The effects of estrogen and increased blood volume may contribute to edema and friability of the upper airway mucosa. This change may result in nasal congestion and in increased risk of mucosal bleeding with airway manipulation. Hormonal changes induced by pregnancy increase the subcostal angle of the ribs and, combined with displacement of the diaphragm by the gravid uterus, result in a decreased functional residual capacity in the lungs. These changes will accelerate the onset of oxygenation desaturation during hypoventilation and apnea.

**History and Physical Examination**

According to the ASA Task Force on Management of the Difficult Airway, an airway history should be conducted, when feasible, before the initiation of
Quantitative Evaluation of Difficult Intubations

Tracheal intubation is most commonly performed using a direct laryngoscopy technique. When a patient is prepared for intubation, a laryngoscope is used to visualize the airway and the tracheal tube is inserted. Visibility of the glottis is often documented to describe predicted ease of intubation.\(^1\) The Cormack-Lehane (CL) classification is a grading system commonly used to describe the view of the larynx during direct laryngoscopy.\(^6\) Grades 3 and 4, in which the glottis is not visualized, are considered difficult intubations. Despite widespread use of the CL classification, researchers have questioned its reliability. Krage et al. evaluated knowledge of the CL classification among anesthesiologists and its reliability in a simulated clinical setting.\(^7\) A survey of 120 anesthesiologists showed that 3 out of 4 anesthesiologists claimed to know the CL classification, yet only 1 out of 4 was able to define all grades correctly. Intra- and interobserver reliabilities were tested with a patient simulator. The CL classification showed fair interobserver reliability and poor intraobserver reliability.

Another commonly used predictor of difficult intubation, the Mallampati score, estimates the size of the tongue relative to the oral cavity and the ability to open the mouth. Originally, this system graded the patient (grades 1 to 3) based on the structures visible in the oropharynx with maximal mouth opening; a fourth grade was subsequently added. Grade 3 or 4 suggests a significant chance that the patient will be difficult to intubate.\(^17\) In a series of 1,956 patients undergoing elective general anesthesia, Cattano et al. demonstrated a good correlation between the Mallampati scale and the CL classification, although the Mallampati scale lacked the sensitivity to be predictive when used alone. The Mallampati score is also not specific since there may also be a high incidence of false positives.\(^19\)

Another common approach to predicting difficult intubation is an evaluation guided by the mnemonic LEMON (see “LEMON Airway Assessment Method”).

Other bedside tests that assess for anatomic indicators of a potentially difficult intubation include measurement of thyromental, sternomental, hyomental, and interincisor distances. Thyromental distance (TMD) is a measurement taken from the thyroid notch to the tip of the chin with the head extended. Determination of TMD can be difficult in patients who are overweight, patients who are immobilized, and patients with goiters or other neck diseases.\(^20\) Sternal distance (SMD) is the distance from the tip of the chin to the sternal notch with the mouth closed and head in full extension.\(^21\) Hyomental distance is the distance from the hyoid bone to the mentum (chin).\(^22\) Interincisor distance (IID) measures the distance between the patient’s incisor teeth. The upper lip bite test assesses the patient’s ability to bite the upper lip with the lower teeth.\(^22\)

Risk indexes have been developed based on quantitative evaluations. Wilson et al. developed a risk scoring system based on body weight, head and neck movement, jaw movement, and the presence or absence of mandibular recession and protruding teeth.\(^23\) The Naguib model considers TMD, Mallampati score, IID, and height.\(^23\) The El-Ganzouri risk index was devised from prospective evaluation of 10,507 patients.\(^24\) The multivariate risk index combined and stratified seven variables derived from parameters and observations individually associated with difficult intubation.

**LEMON Airway Assessment Method**

- **L** = Look externally for anatomic feature that may make intubation difficult.
- **E** = Evaluate the 3-3-2 rule.
  - Mouth opening (3 finger-breadths)
  - Hyoid-chin distance (3 finger-breadths)
  - Thyroid cartilage-floor of mouth distance (2 finger-breadths)
- **M** = Mallampati score.
  - Class 1: soft palate, uvula, pillars visible
  - Class 2: soft palate, uvula visible
  - Class 3: soft palate, base of uvula visible
  - Class 4: hard palate visible
- **O** = Obstruction: examine for partial or complete upper airway obstruction.
- **N** = Neck mobility.

Arne et al. prospectively evaluated 1,200 patients and, using univariate and multivariate analysis, identified 7 criteria as independent predictors of difficult tracheal intubation. Risk factors were assigned a point value; a score of less than 11 indicated that a difficult intubation could be excluded, with a risk of false prediction of 1% to 2%. Recently, Eberhart et al. prospectively evaluated 3,763 patients for potential risk factors of difficult intubation. A random sample was subjected to multivariate logistic regression analysis, and the most powerful independent risk factors were used to develop a simplified multivariate risk score. The presence of the upper front teeth, a history of difficult intubation, Mallampati classification between 2 and 4, and mouth opening of less than 4 cm are independent risk factors for difficult tracheal intubation. With each risk factor, the likelihood of difficult intubation increases from 0% (no risk factors) to 17% when 4 or 5 factors are present.

A case-controlled, double-blind study examined three multivariate risk indexes, the Wilson, Arne, and Naguib risk models, to determine the most sensitive model in the prediction of difficult intubations. The Naguib model demonstrated the highest sensitivity (82.5%) and specificity (86.5%).

A meta-analysis by Shiga et al. evaluated bedside tests for predicting difficult intubation, including the Mallampati classification, TMD, SMD, mouth opening, and the Wilson risk score. These tests had poor-to-moderate discriminative power when used alone. Combinations of tests add incremental diagnostic value; the most useful combination of tests for prediction of difficult intubation was the Mallampati classification and TMD. Similarly, a systematic review of the accuracy of the original and modified Mallampati score concluded that when used alone, the Mallampati test is insufficient to predict a difficult intubation. Forty-two studies enrolling 34,513 patients were included.

Accurate preoperative prediction of difficulty with intubation can help reduce the risk of catastrophic outcomes but may not always be possible using available quantitative tests, which lack in sensitivity and specificity, resulting in false positives and a low positive predictive value for any single test. Despite the limitations of predictive tests, overestimation of the difficulty of airway management might result in “much ado about nothing,” while underestimation may result in brain damage or death. Moreover, the prediction of airway difficulty is useful in focusing on the identification of potential airway strategies.

Risk Reduction Strategies

Airway Management

In the event that intubation unexpectedly becomes difficult or impossible, a predetermined plan will allow anesthesia providers to manage the airway and ensure uninterrupted oxygenation and ventilation of the patient. An unanticipated difficult intubation, if associated with difficult mask ventilation, allows only a short period of time to solve the problem before hypoxemia, hypercarbia, and hemodynamic instability occur. Early skilled assistance is critical, followed by advancement through a series of predetermined and rehearsed strategies. The ASA task force has recommended, based on consensus opinion, limiting intubation attempts to three, with subsequent use of accessory airway devices or alternative techniques to secure the airway when difficulty with intubation is encountered. Analysis of a large quality-improvement database has confirmed the recommendations of the ASA task force. Mort analyzed 283 questionnaires following conventional laryngoscopic-intubation to determine the incidence of airway and hemodynamic complications during emergency tracheal intubation outside the OR and to determine any relationship between the number of conventional intubation attempts and the incidence of complications. The rate of airway-related complications significantly increased as the number of laryngoscopic attempts increased (from 2 or fewer attempts to 2 or more attempts: hypoxemia (11.8% versus 70%), regurgitation of gastric contents (1.95% versus 22%), aspiration of gastric contents (0.8% versus 13%), bradycardia (1.6% versus 21%), and cardiac arrest (0.7% versus 11%).

The following methods of securing the airway form the basis of a structured approach and are presented, in general, from the least to most invasive method.

Mask Ventilation

Mask ventilation is used during induction of anesthesia before intubation and as a rescue technique during an unsuccessful intubation attempt. Hyperoxegenation of the patient by mask ventilation provides time for intubation and consideration of the next approach. However, a mask does not protect against aspiration, and air may be forced into the esophagus or stomach.

Tracheal Intubation

While the patient is being prepared for intubation, if the vocal cords are not observed during laryngoscopy, different maneuvers can be tried to help visualize the glottis. The following steps may provide adequate exposure for direct visualization of the true vocal cords:

- Modified Jackson position. Position the head into a “sniffing” or “drinking” position.
- External laryngeal manipulation. Direct an assistant to apply backward pressure on the cricoid cartilage (BURP maneuver: backward, upward, rightward pressure). Compress the cricoid cartilage against the cervical spine with three fingers of the opposite hand (Sellick maneuver).
- Laryngoscope blade. Use a larger blade. In patients with a large lower jaw or deep pharynx, use of a larger, size 4 Macintosh blade rather than the more common size 3 (for consistency) can facilitate the tip of the blade reaching the vallecula for
optimal elevation of the epiglottis. Alternatively, using a straight blade such as a Miller 2 or 3 may facilitate intubation.

- Lighted stylet.\textsuperscript{13,30} The lighted stylet (i.e., a malleable metal or plastic rod with a fiberoptic light source that is passed through the endotracheal tube to adjust its curvature) helps facilitate blind intubation (i.e., when the glottis is poorly visualized or not observed). Greater intensity of light visible through the soft tissue of the anterior neck as the light passes beyond the vocal cords helps distinguish the tracheal lumen from the esophagus.

- Gum elastic bougie.\textsuperscript{13,30} Use a semirigid gum elastic bougie (i.e., a blunt-ended malleable rod that may be passed through the nonvisualized larynx by bending a J-shape at the tip and passing it blindly in the midline beyond the base of the epiglottis). The endotracheal tube can be guided along the bougie, which is then withdrawn. Another technique involves inserting the gum elastic bougie into the trachea under direct visualization and then inserting the tube over the bougie.

- Fiberoptic intubation.\textsuperscript{13,30} Pass a flexible fiberoptic bronchoscope through the endotracheal tube and then through an anesthetized naris or through the oral cavity of an awake patient. Pull the mandible and tongue anterior to expose the larynx. The bronchoscope serves as a visual guide and as a stylet for the endotracheal tube. The technique may also be used if the patient has been anesthetized; however, loss of muscle tone will allow the epiglottis and tongue to fall back against the posterior pharynx. Pulling the jaw forward is likely to be required.

- Laryngeal mask airway (LMA).\textsuperscript{13,30} Place an LMA (i.e., a small latex mask mounted on a hollow plastic tube) blindly in the lower pharynx overlying the glottis. The inflatable cuff on the mask wedges the mask in the hypopharynx and helps seal the gastrointestinal tract from the airway. Use a modification of the LMA, an intubating LMA (ILMA), which has a more rigid, wider tube with a handle for insertion. A modified tracheal tube can then be passed through the ILMA into the trachea either blindly or with the aid of a fiberoptic scope.\textsuperscript{32}

- Esophageal-tracheal double-lumen airway.\textsuperscript{32} Use a Combitube®, a combined esophageal obturator and tracheal tube. This twin-lumen device is inserted without the need for visualization into the oropharynx and usually into the esophagus. It has a low-volume inflatable distal cuff and a much larger proximal cuff designed to occlude the oro- and nasopharynx. If the tube has entered the trachea, ventilation is achieved through the distal lumen as with a standard endotracheal tube. More commonly, the device enters the esophagus and ventilation is achieved through multiple openings in the tube situated above the distal cuff. In the latter case, the proximal and distal cuffs must be inflated to prevent air from escaping through the esophagus or back out of the oro- and nasopharynx.\textsuperscript{32}

- Retrograde guidewire.\textsuperscript{31} A Seldinger guidewire is inserted by needle through the cricothyroid membrane and bounced toward the mouth off the back wall of the trachea. It is then retrieved in the mouth. The endotracheal tube is introduced through the vocal cords over the guidewire, which is removed as the tube passes down the trachea.

### Surgical Intervention

When the aforementioned methods are unsuccessful, the inability to intubate and ventilate the patient, commonly referred to as the “can’t intubate, can’t ventilate” scenario, typically requires rapid surgical access to the trachea for adequate ventilation and oxygenation. Rapid access is usually achieved through a cricothyroidotomy.\textsuperscript{32} Cricothyroidotomies may be performed using three techniques: needle, wire-guided percutaneous, and surgical. Needle cricothyroidotomy entails insertion of a catheter (e.g., an intravenous catheter) through the cricothyroid membrane. In a wire-guided percutaneous approach (i.e., the Seldinger technique), a needle punctures the cricothyroid membrane and a wire is advanced into the airway through the needle, which is then removed. The wire becomes the guide for a series of dilators and a tracheostomy tube. The cricothyroid membrane may also be accessed by a surgical cutdown and the insertion of a tube directly into the trachea. The surgical technique has been shown to be quicker and produce more effective ventilation. A tracheotomy may be performed when the airway can be maintained and the patient can be ventilated and is not hypoxic.\textsuperscript{33}

### New Devices

Optical and video laryngoscope devices allow intubation to be performed under indirect visualization, overcoming the restrictions in patient anatomy that may make direct laryngoscopy difficult or impossible. Using fiberoptic and video technology, semirigid or rigid devices have been designed for intubation: they may be stylet-like (e.g., the Shikani optical stylet), flat (e.g., the Bullard laryngoscope), or hollow (e.g., the WuScope System) or they may resemble a conventional laryngoscope (e.g., the Karl Storz Video Macintosh, GlideScope).\textsuperscript{31} Lighted stylets rely on transillumination of the tissues of the anterior neck to demonstrate the location of the tip of the endotracheal tube.\textsuperscript{31} Video laryngoscopes use fiberoptic or digital imagery and allow indirect visualization of the airway on a monitor.\textsuperscript{31} Although the devices vary with respect to diameter, image resolution, and flexibility, most are similar in structure and function. They are all inserted within an endotracheal tube and, through an eyepiece or video monitor, allow the practitioner to view the device’s advancement. The main advantage of these devices is that they may not be affected by many of the anatomic factors that may lead to difficult direct laryngoscopy and intubation.\textsuperscript{31} While it is beyond the scope of this article to discuss all available devices, a review of recently
developed airway management devices is available at http://www.anesthesiologynews.com/download/ AirwayMgmt_AN0509_WM.pdf.

ECRI Institute has evaluated the clinical literature on optical and video laryngoscopic devices and has identified 41 randomized control trials, 19 comparison studies, and 24 case series. A 2008 quantitative review and meta-analysis by Mihai et al. summarized studies of rigid fiberoptic laryngoscopy systems. The intubation success rate was greater than 90% in 6,622 “normal” patients using the BONFILS (a videolaryngoscope with a small video camera at the blade tip) and CTrach (an LMA with video-guidance) systems. In patients (n = 1,110) with predicted or diagnosed difficult intubation, first-time success rate was greater than 90%. However, data for comparative studies with the Macintosh direct laryngoscope was insufficient. The authors concluded that currently available information did not support the hypothesis that these devices should replace direct laryngoscopy for routine or difficult intubation. A technology assessment report by the Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat, reviewed the effectiveness and cost-effectiveness of video-assisted laryngoscopy for tracheal intubation. The report included two devices: (1) the Bullard and (2) the GlideScope. The authors concluded that compared to direct laryngoscopy, video-assisted systems provide a better view of the upper airway but are more expensive. A recent prospective study compared conventional blade laryngoscopy with direct-coupled interface (DCI) video-assisted blade laryngoscopy and the GlideScope. One hundred twenty patients with at least one predictor for a difficult airway who were undergoing elective minor surgery requiring ETI underwent repeated laryngoscopy with the three devices. The GlideScope enabled significantly better laryngoscopic views than both direct and DCI video laryngoscopes.

Airway Management Guidelines

Preplanned strategies as described above have been linked to form airway management algorithms. ASA developed its Difficult Airway Algorithm, last updated in 2003. The algorithm first indicates assessment for basic airway management problems, if any. Next, the best approach to the patient’s airway management should be evaluated. If the airway is predicted to be difficult to manage, a primary, preferred approach should be developed, followed by the identification of alternative approaches if the primary approach fails or is not feasible. In the event of difficulty that was not predicted in the surgical patient, an anesthesia provider should immediately call for help, take steps to ensure ongoing ventilation and oxygenation, and consider awakening the patient. Beyond this point, the decision-making algorithm depends on whether face-mask ventilation is effective after attempts at direct laryngoscopy fail. If face-mask ventilation is adequate (nonemergency pathway), then the next options include placing a supraglottic ventilation device, such as an LMA, or using alternative approaches to intubation (e.g., a different laryngoscopy blade, a stylet, fiberoptic intubation). If face-mask ventilation is inadequate, the emergency pathway indicates considering or attempting an LMA. If unsuccessful, attempting emergency, noninvasive airway ventilation is indicated, such as using rigid bronchoscope or esophageal-tracheal Combitube ventilation, followed by surgical techniques (e.g., cricothyrotomy, tracheostomy).

The ASA task force recommends that intubation be attempted three times; however, as previously noted, Mort has demonstrated that the rate of intubation-related complications increases beyond two intubation attempts. Mort suggests that the increase in the rates of complications may warrant further refinement of the ASA algorithm recommendations to fewer than three intubation attempts. A refinement to the nonemergency pathway of the algorithm has been suggested. Noting that most anesthesiologists can identify a difficult intubation on the first laryngoscopy, Saxena describes the use of a video laryngoscopy or a GlideScope if difficulty is encountered on the first attempt at intubation (assuming that good ventilation can be maintained using a face mask). The ASA Difficult Airway Algorithm has been described as “limited” for emergent airway management in nonsurgical settings (e.g., emergency department, critical care units, hospital wards) due to several factors, including the limited time in the emergent setting to fully evaluate the patient and the presumption that the patient has a full stomach. These differences require airway strategies beyond the scope of this article.

The Difficult Airway Society (DAS) guidelines for the management of unanticipated difficult tracheal intubation are based on a series of escalating management plans: if Plan A does not work, backup plans C, D, or E can be executed. The plans are as follows:

**Plan A.** Initial tracheal intubation plan.

**Plan B.** Secondary tracheal intubation plan, when Plan A fails.

**Plan C.** Maintenance of oxygenation and ventilation, postponement of surgery, and awakening of the patient when earlier plans fail.

**Plan D.** Rescue techniques for “can’t breathe, can’t ventilate” situations.

Each plan describes a sequence of actions to be followed in the event of the following scenarios: (1) unanticipated difficult tracheal intubation during routine induction of anesthesia in an adult patient, (2) unanticipated difficult tracheal intubation during rapid sequence induction of anesthesia in a nonobstetric patient, and (3) failed intubation (i.e., “can’t intubate, can’t ventilate”). Two principles are emphasized in these guidelines: maintenance of oxygenation during the execution of each plan and seeking the best assistance available as soon as difficulty with laryngoscopy is experienced.
Frova and Sorbello compared algorithms for difficult airway management from the United States (the ASA algorithm), the United Kingdom (the DAS algorithm), France, Italy, Germany, and Canada, explaining the primary differences, weaknesses, and strengths of concepts in the management of a difficult airway. The following are mandatory points to include during guideline development based on their analysis:

- Importance of prediction
- Need for a preplanned high safety/low trauma strategy
- Importance of oxygenation/ventilation rather than intubation
- Familiarity with instruments and techniques
- Correct role of devices and techniques
- Skill development and maintenance

An optimal guideline is not proposed; however, the primary importance of the guidelines is attributed to the change in anesthetists’ practice and effect on patient outcomes. The authors conclude that because no clear science-based evidence supports any of the proposed guidelines and because the documents are derived from expert opinion and experience, the ideal algorithm is the one that best conforms to an anesthesiologist’s experience and to a facility’s available devices and instruments.

**Pediatric Difficult Airway Algorithm**

The ASA Difficult Airway Algorithm is not specific to pediatric patients. Odnik et al. modified a simplified algorithm that specifically addresses the management of the difficult airway in the pediatric population. See the accompanying materials for the pediatric airway algorithm.

**Comprehensive Difficult Airway Program**

Considering that the literature is replete with bedside tests, predictive models, and devices intended to assist in management of airway difficulties, a comprehensive approach requires a combination of best practices in preoperative evaluation, communication of prior experiences, availability of airway equipment, and training to avoid poor outcomes. Berkow et al. describe how a comprehensive difficult airway program that was started in 1996 contributed to a significant reduction in emergency surgical airways, which represents the endpoint of the ASA and DAS algorithms. In the four-year period before 1996, there were six to seven emergency surgical airways required per year due to a “can’t intubate, can’t ventilate” scenario. In the 11-year period following institution of the program, the number of emergency surgical airways required decreased to between 0 and 3 per year, even though the patient population had increased by 50%. Core components of the program include the following:

- Communication
  - Patients were reported to a centralized database.
  - Patients with a known difficult airway were given a color-coded wristband.
  - After discharge, a letter was sent to the patient’s home with details of the airway anatomy and techniques used to secure the airway.
  - Patients were encouraged to enroll in the MedicAlert® program.
  - The anesthesia preoperative evaluation form was redesigned to include documentation of an objective airway examination.
  - A difficult airway alert was placed on the OR schedule, alerting the OR coordinator to verify whether the anesthesia assignment was appropriate and necessary equipment was available in the OR before the start of the case.
- Equipment
  - Standardized difficult airway carts were designed to hold advanced airway management equipment (e.g., flexible fiberoptic bronchoscopes, light sources, LMA airway exchange catheters, cricothyroidotomy kits).
  - Difficult airway carts were made available in the obstetric and intensive care units.
  - A laminated card with the ASA Difficult Airway Algorithm was attached to each cart.
- Personnel
  - An interdisciplinary team was organized to assist in airway management when problems arose with intubation or face-mask ventilation. The team included an anesthesiologist, an otolaryngologist, and an equipment technician who would bring the difficult airway cart.
  - Anesthesia technical staff was trained to set up, clean, stock, and maintain the equipment and supplies.
- Education
  - Regularly scheduled training sessions were developed for staff and residents, including a “difficult airway” rotation for residents and twice yearly interdisciplinary grand rounds.

Patient education was found to be vitally important for future anesthetic planning. Knowledge of how a patient’s airway was handled in the past was tremendously helpful to anesthesia staff. In a few difficult airway cases, patients were unaware that they had histories of difficult airways, but staff later learned that family members knew the patients’ histories. According to the authors, anticipation and preparation for a difficult airway and intubation can potentially reduce surgery cancellation, adverse outcomes, malpractice claims, and loss of life. See the accompanying materials for a sample airway alert letter that may be sent to a patient to alert subsequent anesthesia providers to potential airway difficulty and a difficult airway identification card that may be adapted for use by your institution.
Simulation Training

Kuduvalli et al. conducted a prospective controlled study on a medium-fidelity simulator,* designed to measure the effect of training on compliance with DAS guidelines for the management of unanticipated failed intubation and/or ventilation. It also assessed the effect of formal training on performance over time. The study showed that adherence to the DAS guideline process was sustained for six to eight months for the aforementioned “can’t intubate, can’t ventilate” scenario, but only six to eight weeks for the “can’t intubate” scenario. The result was thought to be partly because management of the “can’t intubate” scenario involves more alternatives in a less critical situation compared with the “can’t intubate, can’t ventilate” scenario. The authors concluded that long-term retention of both technical and decision-making skills requires reinforcement, and they recommended conducting workshops at intervals of six months or less.

Conclusion

Anesthesia providers always need to be prepared to manage an unanticipated difficult intubation. An assumption that the current method of securing the airway will not work will facilitate readiness to advance to the next method. In other words, the anesthesia provider can assume the possibility that anything may go wrong and plan accordingly. Poor outcomes can be avoided by implementing a comprehensive approach that includes thorough patient evaluation, multidisciplinary cooperation with a predetermined airway management strategy, skillful use of standardized equipment, frequent staff education, dissemination of important patient information, and a willingness to ask for assistance.

Notes


(See Self-Assessment Questions on next page.)
Self-Assessment Questions

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

A patient was scheduled to have a hysterectomy. During her preoperative anesthesia assessment, the patient told the anesthesiologist that she had surgery two years ago where they “put her under” and that she “didn’t have any problems.” Her preoperative assessment showed a class II Mallampati score. During induction of anesthesia, the resident anesthesiologist was unable to intubate after three attempts using direct laryngoscopy, before successfully using a different laryngoscope blade, because a GlideScope® was unavailable to facilitate intubation. Adequate ventilation and oxygenation were maintained throughout the intubation attempts. Postoperatively, the patient experienced vocal cord paralysis that required surgery and prolonged her hospitalization. After the surgery, a family member mentioned to the surgeon that he remembered that the patient had some kind of anesthesia problem during her surgery two years ago.

1. Which of the following statements is the most accurate about the prediction of this patient’s difficult intubation?
   a. Intubation difficulty may have been most accurately predicted by measurement of the thyromental distance, inter-incisor distance, or the upper lip bite test.
   b. A combination of the Mallampati score and thyromental distance would have had incremental diagnostic value over any test used alone.
   c. Since tests to predict difficult intubation lack in sensitivity and specificity, the accurate way to predict a difficult intubation is by determining the presence of clinical risk factors.
   d. A focused bedside medical history and review of the medical records would have been sufficient to predict intubation difficulty, according to the American Society of Anesthesiologists (ASA) Task Force on difficult intubation.

2. Select the most effective strategy, according to the ASA Difficult Airway Algorithm, to manage the female patient’s difficult airway.
   a. After failed attempts at direct laryngoscopy, the anesthesia provider should have called for help, taken steps to ensure adequate ventilation and oxygenation, and considered awakening the patient.
   b. After two intubation attempts, the next step to consider would have been a supraglottic airway device.
   c. After direct laryngoscopy attempts failed, a surgical technique to secure the airway would have been most appropriate.
   d. Since oxygenation and ventilation were sufficient throughout the intubation attempts, more than three intubation attempts would have been appropriate.

3. Components of a difficult airway program to decrease the likelihood of a similar patient’s unanticipated difficult intubation include all of the following EXCEPT:
   a. A difficult airway alert form to be sent to the patient and primary care physician after the patient’s previous surgery.
   b. An interdisciplinary team to assist in airway management when problems arise with intubation.
   c. Standardized difficult airway carts with advanced airway management equipment.
   d. Annual simulation training for residents on the management of unanticipated difficult intubation.

   A 36-year-old male undergoes anesthetic induction in preparation for a laparoscopic cholecystectomy. The anesthesia team has tried to intubate the patient three times (once by trainee, twice by staff).

4. According to the Difficult Airway Society’s unanticipated difficult tracheal intubation algorithm, which of the following interventions is the most appropriate?
   a. Check neck flexion, head extension, and laryngoscopic technique, and apply laryngeal manipulation.
   b. Request that another anesthesia provider assist with anesthesia.
   c. Use a fiberoptic intubation technique.
   d. Postpone surgery and awaken the patient.

5. All of the following are accurate statements about management of the male patient’s unanticipated difficult intubation EXCEPT:
   a. Key points in managing an unanticipated difficult intubation include familiarity with instruments and techniques, the need for a preplanned strategy, and the importance of oxygenation/ventilation.
   b. Techniques that would help visualize the glottis include a modified Jackson’s position and external laryngeal manipulation.
   c. If face-mask ventilation is inadequate to maintain oxygenation and ventilation, the next most appropriate intervention, according to the ASA guidelines, is the placement of a supraglottic device, such as a laryngeal mask airway.
   d. An intubating laryngeal mask airway would assist in passing the endotracheal tube into the trachea either blindly or with the use of a fiberoptic scope.

6. Which of the following are clinical risk factors that, when present in this patient, may indicate the possibility of a difficult intubation?
   a. Male gender and smoking history
   b. Short thick neck, snoring, and a body mass index greater than 30kg/m²
   c. Increased thyromental distance and limited head movement
   d. Poor dentition and a beard

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Managing Patient Access and Flow in the Emergency Department to Improve Patient Safety

ABSTRACT

From 1996 to 2006, the annual number of emergency department (ED) visits increased approximately 32% from 90.3 million to 119.2 million, according to the Centers for Disease Control and Prevention. Simultaneously, as the number of patient visits increased, the number of hospital EDs decreased from 4,019 to 3,833, increasing the number of annual visits per ED and contributing to crowding. In 2009, Pennsylvania healthcare facilities reported to the Pennsylvania Patient Safety Authority 1,930 events of complications of procedures or treatments or tests from the ED. Existing and proposed ED measures (e.g., from initial patient presentation to final departure)—specifically those from the Hospital Quality Alliance, the Centers for Medicare and Medicaid Services, the Oklahoma Foundation for Medical Quality, and the National Quality Forum—show that national payment and quality organizations have recognized the importance of standardizing ED performance measures. Facilities can use this data to manage patient access and flow in the ED, to increase patient satisfaction, to improve quality of care, and to optimize patient safety. This article focuses on strategies to increase patient safety and improve quality during the ED visit from the point of patient arrival to the diagnostic evaluation. (Pa Patient Saf Advis 2010 Dec;7[4]:123-34.)

Emergency Department Statistics

Emergency departments (EDs) are under pressure to provide care that is safe, effective, patient-centered, timely, efficient, and equitable—a difficult task under any circumstances, but one that is even more difficult in the presence of ED crowding. According to the Centers for Disease Control and Prevention (CDC), from 1996 to 2006 the annual number of ED visits increased approximately 32% from 90.3 million to 119.2 million. Simultaneously, as the number of patient visits increased, the number of hospital EDs decreased from 4,019 to 3,833, increasing the number of annual visits per ED. CDC also found that the ED was the portal of entry for more than 50% of the non-obstetric acute care admissions in the United States, an increase from 36% in 1996. Furthermore, the role of the ED has evolved from primarily life-saving treatment to providing urgent unscheduled care to patients unable to gain access to their primary care providers, as well as to providing care to Medicaid beneficiaries and to patients without insurance.

All these factors contribute to crowding in the ED, which can be measured by average patient wait times, average door-to-doctor times, and the percentage of patients who leave without being seen (LWBS), as well as by measuring other discrete blocks of time between patient initial presentation and final disposition. Delays in care and treatment can result in further patient illness or even death. According to Joint Commission sentinel event statistics, there was a 31% increase in the number of reports linked to delay in treatment, from 7.7% of total reports in 2007 to 10.1% of total reports in 2008. Recognizing that when patient flow becomes impeded EDs become crowded, a 2005 Joint Commission patient flow standard requires hospitals to plan, implement, monitor, and measure patient flow activities related to admitted patients who are in temporary bed locations in areas like the ED (“boarders”); patients who are placed in overflow locations; ambulance diversions; the supply of available beds; efficiency of areas where patients receive care; safety of areas where patients receive care; and access to patient support services.

Several studies have presented further evidence that ED crowding contributes to poor quality care. A retrospective analysis of patients older than 30 years with chest pain syndrome who were admitted to tertiary care hospitals from 1999 through 2006 (n = 4,574) showed an association between ED crowding and a higher risk of adverse cardiovascular outcomes. Additional studies show correlations between high ED wait times and the following: patient mortality, time to antibiotic for patients with pneumonia, time to thrombolysis, and time to analgesia for patients with severe pain. Addressing ED crowding and wait times may be the first step in addressing patient safety and quality of care in the ED.

National Payment and Quality Organizations Endorsing ED Metrics

Recognizing the potential problems associated with ED crowding, several national payment and quality organizations have developed ED metrics that measure periods between patient initial presentation to the ED and final departure from the ED. Currently, the Hospital Quality Alliance is collecting two voluntary emergency department parameters: (1) median time from ED arrival to ED departure for admitted ED patients and (2) admission decision time to ED departure time for admitted patients. These parameters are likely to be included in the Reporting Hospital Quality Data for Annual Payment Update in 2012, highlighting the importance of ED data collection and tracking for payment as well as for quality and patient safety purposes. Additionally, the Centers for Medicare and Medicaid Services (CMS) and the Oklahoma Foundation for Medical Quality propose a third metric, “median time from ED arrival to ED departure for discharged ED patients” to be included in the clinical quality measures for electronic
In 2008, the National Quality Forum (NQF) endorsed 10 ED quality measures for hospital-based ED care to help decrease patient wait time, increase physician productivity, and increase patient safety. Three of these NQF-endorsed benchmarks are being considered by CMS for inclusion in the public reporting system in 2012.

NQF's measures 1 and 3 represent length of stay in the ED. Measure 2 represents throughput in the ED—how efficiently patients are moved from the ED to the next care setting. Measures 4 and 5 represent patient arrival and triage efficiency.

### Care Along the ED Continuum of Quality Metrics

Table 1 shows that EDs must begin tracking—and will soon start reporting—this data to national payer groups. Once this data is consistently collected, it will be important to improve metrics without jeopardizing quality or negatively affecting patient safety. Two of the data metrics span the entire length of the ED encounter (ED arrival to final disposition for admitted and discharged patients). Two additional data metrics occur in the patient arrival to diagnostic evaluation phase (LWBS; door-to-diagnostic evaluation). Finally, the last data metric occurs in the final phase of ED treatment (admission decision to departure time) (see Figure).

The Pennsylvania Patient Safety Authority received 1,930 reports of complications of procedures or treatments or tests from the ED care setting in 2009.* One hundred were Serious Events (events that harmed patients; 5%), and 1,830 were Incidents (so-called near-miss or no harm events; 95%). Analysis of these events shows that potential threats to patient safety can occur during the patient arrival to diagnostic evaluation phase, the diagnostic evaluation to disposition decision phase, or the disposition decision to final discharge phase of ED treatment. The Figure shows a breakdown of these processes in the ED with correlating data collection points.

* As of January 16, 2005, the Authority ceased report classifications for “Complication of Procedure/Treatment/Test, Emergency Department, Left without Being Seen/Left before Visit Completed.” Reports submitted under these categories were not counted in the analysis.

### Table 1. Summary of Emergency Department (ED) Data Parameters under Consideration for Public Reporting in 2012 by the Centers for Medicare and Medicaid Services

<table>
<thead>
<tr>
<th>Measure No. Identifier</th>
<th>Metric Description</th>
<th>Developer</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Medicare &amp; Medicaid Services (CMS) Emergency Department-1</td>
<td>Median time from ED arrival to ED departure for admitted patients</td>
<td>CMS; Oklahoma Foundation for Medical Quality (OFMQ); Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)</td>
<td>MEDIAN TIME (IN MINUTES) FROM ED ARRIVAL TO ED DEPARTURE FOR ADMITTED PATIENTS (NQF 0495)</td>
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<tr>
<td>National Quality Forum (NQF) NQF 0495</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMS ED-2</td>
<td>Admission decision time to ED departure time for admitted patients</td>
<td>CMS; OFMQ; RHQDAPU</td>
<td>MEDIAN TIME (IN MINUTES) FROM ADMISSION DECISION TIME TO DEPARTURE FROM THE ED FOR ED PATIENTS ADMITTED TO INPATIENT STATUS (NQF 0497)</td>
</tr>
<tr>
<td>NQF 0497</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>CMS ED-3</td>
<td>Median time from ED arrival to ED departure for patients discharged from the ED</td>
<td>CMS; OFMQ</td>
<td>MEDIAN TIME (IN MINUTES) FROM ED ARRIVAL TO DEPARTURE FROM THE ED FOR PATIENTS DISCHARGED FROM THE ED (NQF 0496)</td>
</tr>
<tr>
<td>NQF 0496</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NQF 0498</td>
<td>Door-to-diagnostic evaluation by qualified medical personnel</td>
<td>Louisiana State University (LSU)</td>
<td>MEDIAN TIME (IN MINUTES) FROM FIRST CONTACT IN THE ED TO THE TIME WHEN THE PATIENT SEES QUALIFIED MEDICAL PERSONNEL* FOR THE FIRST TIME FOR EVALUATION AND MANAGEMENT (NQF 0498)</td>
</tr>
<tr>
<td>NQF 0499</td>
<td>Left without being seen by qualified medical personnel</td>
<td>LSU</td>
<td>PERCENTAGE OF PATIENTS LEAVING WITHOUT BEING SEEN BY QUALIFIED MEDICAL PERSONNEL (NQF 0499)</td>
</tr>
</tbody>
</table>

* The designation of qualified medical personnel must be set forth in a document approved by the board of trustees or governing body of the hospital and meet the requirements of CMS manual §482.55.

**Notes**


The Authority further analyzed 412 of the reports submitted from August 1, 2009, through December 30, 2009. Forty of these events occurred during the patient arrival to diagnostic evaluation phase, 258 during the diagnostic evaluation to disposition decision phase, and 114 during the disposition decision to discharge from the ED phase of treatment.

Eighty-eight contributing factors were identified as being associated with these 412 event reports (see Table 2).

Table 3 lists the variety of factors that can contribute to events that occur in the ED setting. For the 40 reports in the patient arrival to diagnostic decision phase, there were 17 contributing factors in 12 categories. The remainder of this article focuses on the strategies for optimizing patient safety and improving data metrics during the first phase of ED treatment: patient arrival in the ED to diagnostic evaluation (also referred to as the “door-to-doctor” phase).

**Patient Arrival in the ED to Diagnostic Evaluation**

Patient arrival in the ED to diagnostic evaluation encompasses the patient registration and triage processes, as well as placement in a treatment room or area to await diagnostic evaluation. These time intervals can pose threats to patient safety in a variety of ways. For example, as reported in a Philadelphia-area news source, the following event occurred in a Pennsylvania hospital in 2009:

A 63-year-old male had gone to an area ED and reported feeling pain in his left side. Security camera tapes showed that the man stopped moving 11 minutes after his arrival in the waiting room, and that he was found to be dead of a massive heart attack almost an hour after he had come to the ED—and only after another patient had alerted ED staffs to the motionless man.

The Pennsylvania Department of Health’s investigation found that ED employees were not aware of a facility policy for checking on patients in the waiting room and that no nursing staff monitored or maintained an awareness of activity in the ED waiting room.

The first step in improving the ED intake process is to collect the necessary data to analyze patient flow and front-end processes. The American College of Emergency Physicians’ (ACEP) Emergency Medicine Practice Committee defines the ED front-end process as the span of time from the patient’s initial arrival in the ED to the time the ED healthcare provider formally assumes responsibility for the evaluation and management of the patient (diagnostic evaluation by a qualified provider). Timeliness of care during this initial period can influence the outcome of the entire ED visit and is an important consideration for patient safety, as well as one of the strongest predictors of patient satisfaction. In order to improve timeliness of care, EDs must first understand facility-specific utilization and census patterns.

(continued on page 127)
Table 3. Contributing Factors Reported to the Pennsylvania Patient Safety Authority by Patient Treatment Phase, August through December 2009

<table>
<thead>
<tr>
<th>CONTRIBUTING FACTORS IDENTIFIED</th>
<th>FACTORS BY PATIENT TREATMENT PHASE</th>
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<tbody>
<tr>
<td></td>
<td>Patient Arrival To Diagnostic Evaluation</td>
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<tr>
<td>Team Factors</td>
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<td>Communication problems between providers</td>
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<td>Change of service</td>
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<td>Cross-coverage situation</td>
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<td>Shift change</td>
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<td>Work Environment</td>
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<td>Distractions/interruptions</td>
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<td>Equipment malfunction</td>
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<td>Total</td>
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<tr>
<td>Task Factors</td>
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<td>Training issues</td>
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<td>Emergency situation</td>
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<td>Total</td>
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<td>Staff Factors</td>
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<td>Inadequate system for covering patient care</td>
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<td>Insufficient staffing</td>
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<td>Issue related to proficiency</td>
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<td>Total</td>
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<td>Patient Characteristics</td>
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<tr>
<td>Lack of patient compliance/adherence</td>
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<tr>
<td>Lack of patient understanding</td>
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<tr>
<td>Lack of family member cooperation</td>
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<td>Total</td>
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<td>Organization/Management Factors</td>
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<td>Presence of boarder patient</td>
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<td>Unclear or ambiguous policies or procedures</td>
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<td>Procedures not followed</td>
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<td>Other Contributing Factors</td>
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<tr>
<td>Total Contributing Factors</td>
<td>17</td>
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Table 2. Pennsylvania Patient Safety Authority Serious Events and Incidents by Patient Treatment Phase, August through December 2009

<table>
<thead>
<tr>
<th>PATIENT TREATMENT PHASE</th>
<th>TOTAL REPORTS</th>
<th>SERIOUS EVENTS</th>
<th>INCIDENTS</th>
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<tbody>
<tr>
<td>Patient arrival in emergency department (ED) to patient assessment</td>
<td>40</td>
<td>2</td>
<td>38</td>
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<tr>
<td>Physician assessment to disposition decision</td>
<td>258</td>
<td>9</td>
<td>249</td>
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<tr>
<td>Disposition decision to discharge from ED</td>
<td>114</td>
<td>3</td>
<td>111</td>
</tr>
<tr>
<td>Total</td>
<td>412</td>
<td>14</td>
<td>398</td>
</tr>
</tbody>
</table>
Forecasting ED Utilization

Studying data over time permits accurate predictions regarding utilization. According to a May 2010 National Center for Health Statistics data brief, approximately one-fifth of the civilian, noninstitutionalized U.S. population had one or more ED visits in a 12-month period in 2007. The Emergency Department Benchmarking Alliance Annual Data Survey 2007 highlighted some recognizable trends in ED data, including the following:18

- Total arrivals increase from midmorning until noon and then hold steady until midnight, when they decrease.
- Pediatric arrivals surge before adult arrivals and decrease sooner.
- Senior citizen arrivals surge in the late afternoon, and these patients will wait longer before leaving without being seen.
- The census (see discussion below) increases until noon, stays high through the evening shift, and then quickly decreases to its lowest point at 5 a.m.; the cycle then repeats.
- The busiest days of the week are Saturdays and Mondays.
- The busiest months are July, August, and December.
- The most common chief complaints are abdominal pain, chest pain, and orthopedic injuries.

Individual ED statistics may not match the above list exactly, but the list provides a benchmark for facilities to analyze in the context of specific ED trends. Once facilities can accurately predict demand (utilization), they can begin to plan ED capacity to match the demand. Utilization patterns must be analyzed in conjunction with departmental census data.

Tracking Census Data

Census data describes what is happening in an ED during specific time intervals. For example, data can illustrate the following:

- Census by hour, day, month, or year
- Waiting room census
- ED occupancy (occupied beds/total beds)
- Percentage of patient admissions
- Percentage of trauma cases
- Percentage of patient admissions to the intensive care unit
- Percentage of pediatric patients
- Percentage of patients with certain clinical complaints

Census data allows EDs to predict utilization for given periods and avoid bottlenecks in ED intake processes before they occur. It is important to understand how different census measures correlate to facility capacity. For instance, a high waiting room census may indicate either a long triage queue or a high ED occupancy rate (during patient arrival to diagnostic evaluation phase). Occupancy (percentage of filled beds) may indicate that the department itself is at full capacity (during diagnostic evaluation to disposition decision phase). The number of boarders in the ED may indicate decreased capacity within the hospital units (during disposition decision to discharge from the ED phase).7

Once demand has been predicted through analysis of historical utilization and census data, staffing levels can be matched to the demand. Departments can develop a series of early warning signals (triggers) that signify a capacity-to-demand mismatch, and interventions aimed at mitigating the mismatch. For instance, if capacity (department census/total available beds) exceeds 80%, an ED may elect to implement a discharge team to quickly discharge stable patients, have physicians meet to determine whether any patients can return at a later time for diagnostic testing during low census times (offloading), or create an express admissions team to move admitted patients through the ED.18,20 These strategies must comply with the Emergency Medical Treatment and Labor Act (EMTALA) (i.e., the patient must receive a medical screening examination, and it must be determined that the patient does not have an emergency medical condition and is stable for discharge). Per EMTALA, “stable” means that the patient is unlikely to deteriorate during discharge within a reasonable medical certainty.21

Accurate utilization and census tracking has led to a number of EDs publicly posting forecasted ED wait times on their websites (e.g., Gulf Coast Medical Center: http://www.eugulfcoastmedical.com; Baton Rouge General: https://www.brgeneral.org/site.php).

Tracking Clinical Performance Metrics

In addition to the operational metrics listed in Table 1, EDs monitor a number of clinical performance measures, some of which are reported on the CMS website at http://www.hospitalcompare.hhs.gov/Hospital/Search/SearchMethod.asp. Most ED personnel are aware of the clinical performance measures for surgical care, myocardial infarction, heart failure, pneumonia, and childhood asthma care. NQF also endorses 10 quality measures for the ED, 4 of which are related to clinical performance measures (i.e., sepsis, pregnancy tests for females with abdominal pain, anticoagulation for acute pulmonary embolus patients, pediatric weights in kilograms). These are available at http://www.qualitymeasures.ahrq.gov/browse/nqfendorsed.aspx?term=emergency+department+and+national+quality+forum. Overlaying clinical performance metrics with utilization and census data can assist EDs with predictive utilization patterns. For instance, if the busiest time in the ED is from 10 p.m. to 1 a.m., analyzing the clinical presentation of patients during this high-census time can help managers ensure that the appropriate type and level of staff are available to handle the patient population. A large body of clinical literature suggests that...
ED crowding and long wait times are associated with both unfavorable clinical endpoints (mortality rates) and delays in various clinical process measures, such as time to treatment for conditions like acute myocardial infarction, thrombosis, antibiotic administration for pneumonia, and pain management.\textsuperscript{7,9-12}

**Front-End Patient Flow Processes and Patient Safety Concerns**

**Patient Triage**

The purpose of ED triage is to quickly assess and categorize incoming patients and to identify emergent patients. Triage nurses or other professionals are trained to quickly recognize patients who require immediate, life-sustaining care and to categorize and prioritize the remaining patient population. Rapid, accurate triage of patients in the ED is key to successful ED operations. Patients who are undertriaged are at risk for deterioration while waiting; patients who are overtreated may use scarce resources (e.g., taking an open bed, which may be needed for another patient requiring immediate care). Accurate triage categorization can only be accomplished when a reliable and validated triage tool, in which all applicable healthcare providers have been trained, is used.

There are several triage systems in the United States, consisting of three-, four-, or five-level triage parameters. The National Center for Health Statistics converted to a five-level triage data collection system in the 2005 National Hospital Ambulatory Medical Care Survey (NHAMCS) for the ED.\textsuperscript{22} The prevailing triage method is the Emergency Severity Index (ESI), which is endorsed by the Emergency Nurses Association and ACEP.\textsuperscript{23} Other frequently used tools are the Australian Triage Scale (ATS) and the Canadian Triage and Acuity Scale (CTAS).

ESI is a five-level triage tool that categorizes ED patients by evaluating both patient acuity level and resource needs (see Table 4 for ESI level definitions).

Initially, the triage nurse assesses only acuity level, which is determined by the stability of vital functions and potential for life, limb, or organ threat. If a patient does not meet high acuity level criteria (ESI level 1 or 2), the triage nurse then evaluates expected resource needs to help determine a triage level (ESI level 3, 4, or 5). Resource needs are defined as the number of resources a patient is expected to consume in order for a disposition decision to be reached. Detailed information about the ESI triage system can be found at http://www.ahrq.gov/research/esi/esihandbk.pdf.

**Door-to-Doctor Time**

Door-to-doctor time is the median time (in minutes) from first contact in the ED to the time that the patient sees qualified medical personnel for the first time for evaluation and management of the medical condition (NQF 0498), also referred to as the patient arrival in the ED to diagnostic evaluation phase. The universal service quality goal is to have patients seen by a physician in less than 30 minutes.\textsuperscript{18} Data from the 2006 National Hospital Ambulatory Medical Care Survey (NHAMCS) (n = 119,191,000) shows that 61.8% of patients waited more than 30 minutes but less than one hour to see a physician (mean 55.8 minutes; median 31 minutes).\textsuperscript{2} When the door-to-doctor time increases, the percentage of patients who leave without being seen increases, too (see “Walkaway Population”). The national LWBS rate, according to the 2006 NHAMCS report, was approximately 2%.\textsuperscript{2} While ESI does not specify door-to-doctor benchmarks in minutes per acuity level, both ATS and CTAS do, as shown in Table 5.

In the ED, situational awareness is critical, and it encompasses patients in waiting rooms, as well as patients in various stages of treatment throughout the department. The Authority has received reports involving patients at various points during the patient arrival to diagnostic evaluation phase of ED treatment.

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### Table 4. The Emergency Severity Index (ESI)

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DEFINITION</th>
<th>STATISTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESI 1</td>
<td>Severely unstable patient, must be seen immediately by a physician, often requires an intervention (e.g., intubation) to be stabilized</td>
<td>Represents 2% of all patients; 73% of ESI 1 cases are admitted</td>
</tr>
<tr>
<td>ESI 2</td>
<td>Potentially unstable patient, must be seen promptly by a physician (within 10 minutes), often requires laboratory and radiology testing, medication, and admission</td>
<td>Represents 22% of all patients; 54% of ESI 2 cases are admitted</td>
</tr>
<tr>
<td>ESI 3</td>
<td>Stable patient, should be seen urgently by a physician (within 30 minutes), often requires laboratory and radiology testing and medication, and usually is discharged</td>
<td>Represents 39% of all patients; 24% of ESI 3 cases are admitted</td>
</tr>
<tr>
<td>ESI 4</td>
<td>Stable patient, may be seen nonurgently by a physician or midlevel provider, requires minimal testing or a procedure, and is expected to be discharged</td>
<td>Represents 27% of all patients; 2% of ESI 4 cases are admitted</td>
</tr>
<tr>
<td>ESI 5</td>
<td>Stable patient, may be seen nonurgently by a physician (or midlevel provider), requires no testing or procedures, and is expected to be discharged</td>
<td>Represents 10% of all patients; 0 of ESI 5 cases are admitted</td>
</tr>
</tbody>
</table>

Before patient registration:

The patient was found on the street and brought in by fire rescue and stated he wanted to stay warm and refused to be seen by a physician. The patient was in a wheelchair and was placed in the waiting room. Later, he was noted to be snoring in the wheelchair; subsequently, he was found unresponsive. [He was] taken to the treatment area and advanced cardiac life support protocol was initiated.

During and after the triage process:

The patient was triaged with a history of chest pain on and off, but not present at triage. [The patient was] sent back to waiting area and then developed pain. [The patient was] taken back to [the treatment] area, an EKG [electrocardiogram] was done and myocardial infarction noted. The patient was treated emergently. . . .

[A patient was] triaged, but not in lobby [several hours later]. The patient had complaint of chest heaviness, noncardiac reasons. . . .

The patient was triaged but was not in the waiting room when called [about four hours later]. . . .

While waiting for physician assessment:

The patient was not seen in the litter area. [The patient] was observed in a sitting position with a cord wrapped around the neck. [The patient was] assisted by ED staff in removing the cord . . . assisted by staff back to bed. [The patient was] placed on direct observation. . . .

The current state of crowding in many EDs has threatened patient safety and placed an increased focus on triage. Using a reliable triage scale such as ESI and implementing new triage strategies can help EDs improve on the data metrics outlined previously, which may consist of a “quick look” triage process whereby a nurse stationed at the ED entrance performs an abbreviated triage assessment in conjunction with a preregistration process designed to capture just enough demographic data to assign an ED account number and produce a patient identification band, ideally within 30 seconds. Upon this basic information is captured and entered into a system to generate a medical record, the rest of the patient registration information can be captured at any point during the ED stay. Combining registration and triage into parallel rather than serial processes can increase department efficiency.

Alternative Triage Strategies

Patient Registration

Door-to-triage time is the first detectable period within the patient arrival to diagnostic evaluation phase of the ED visit. Minimizing this time is an important patient safety goal. One efficient means to do this is through an evaluative registration process. This may consist of a “quick look” triage process whereby a nurse stationed at the ED entrance performs an abbreviated triage assessment in conjunction with a preregistration process designed to capture just enough demographic data to assign a patient account number and produce a patient identification band, ideally within 30 seconds. Once this basic information is captured and entered into a system to generate a medical record, the rest of the patient registration information can be captured at any point during the ED stay. Combining registration and triage into parallel rather than serial processes can increase department efficiency.

Using Midlevel Providers or Physicians in Triage

Many alternative triage strategies are described in the literature. One of the most successful strategies is to elevate the level of education and experience of the staff member in triage by placing a midlevel provider (e.g., advanced nurse practitioner, physician assistant) or a physician in triage. This intervention alone has been shown to reduce throughput time, reduce waits, and reduce the LWBS population. One study shows that emergency medical technicians can predict whether patients would need to be admitted from the ED 62% of the time. Other studies show that physicians can accurately predict patient outcome and disposition with 85% to 95% accuracy. Midlevel providers are typically stationed close to the triage station and receive patients to initiate the plan of care and order diagnostic testing. The patient’s care is then transferred to the ED physician for a definitive diagnosis and completion of treatment through patient disposition. Midlevel providers are frequently used during times of high acuity or volume. The success of this model depends on the competence of the midlevel providers and their ability to quickly begin treatment. When this model is used successfully, it has improved patient satisfaction scores, reduced the LWBS population, and improved the door-to-doctor benchmarks at a relatively low cost. The disadvantages are that midlevel providers tend to order more diagnostic tests and the number of patient handoffs is increased.

Another successful model is the placement of a board-certified emergency physician in triage. In addition to being able to accurately predict admission status, emergency physicians have both the knowledge and authority to make broad-based decisions, including those related to earlier patient admissions when warranted.

In the triage rapid initial assessment by doctor (TRIAD) study, the average patient wait time was reduced by 38% and the average processing time by

Walkaway Population

“Walkaways” are patients who leave the emergency department (ED) before treatment is completed, patients who leave against medical advice, and patients who leave without being seen (LWBS). While the Centers for Medicare and Medicaid Services is collecting data related to the LWBS population, many EDs realize the benefit of tracking all walkaways from the ED. Not only is it a patient safety issue when patients requiring medical treatment leave a facility before treatment is rendered, but this population also potentially increases facility liability and contributes toward lost revenue. Rapid patient assessment and triage is the most effective way to decrease the LWBS patient population.

Many simple medical conditions could be treated
Treatments for symptom control (e.g., pain
Prompt and succinct communication between a
Pennsylvania Patient Safety Advisory
Team Triage

<table>
<thead>
<tr>
<th>ACUITY LEVEL</th>
<th>ATS DOOR-TO-DOCTOR TIME1</th>
<th>CTAS DOOR-TO-DOCTOR TIME2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>Immediate</td>
<td>Immediate</td>
</tr>
<tr>
<td>Level II</td>
<td>10 minutes</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Level III</td>
<td>30 minutes</td>
<td>less than 30 minutes</td>
</tr>
<tr>
<td>Level IV</td>
<td>60 minutes</td>
<td>less than 60 minutes</td>
</tr>
<tr>
<td>Level V</td>
<td>120 minutes</td>
<td>120 minutes</td>
</tr>
</tbody>
</table>

Notes

23% without adding extra staff. Benefits highlighted in this study included the following:26

- Many simple medical conditions could be treated and patients discharged directly from triage.
- Patients were admitted faster when a physician identified an appropriate medical condition during triage.
- Treatments for symptom control (e.g., pain management) were initiated in triage, leading to symptom relief by the time a patient was evaluated by an attending physician, eliminating the time-consuming need for reassessment before discharge.
- Prompt and succinct communication between a triage physician and other attending ED physicians streamlined care in complicated cases.

Physicians in triage can decrease the LWBS patient population, because patients are more apt to stay in the ED once a physician has assessed their condition and explained the plan of care.18 Patient satisfaction scores tend to be higher with early physician assessment and care. Finally, board-certified emergency physicians tend to order fewer unnecessary diagnostic tests because of their knowledge and experience. Disadvantages to this model include the difficulty in recruiting board-certified emergency physicians to work in this triage model, the high cost of labor, and the reluctance of some physicians to hand off care to a subsequent emergency physician for care posttriage.26

Team Triage

Rapid triage can increase patient safety by decreasing bottlenecks in the front end of ED treatment because of shorter cycle times and because patients are guided to treatment areas immediately, decreasing the time to treatment.20 Team triage is one way to expedite patient evaluation and treatment. In this model, physicians, nurses, and ED technicians meet in the patient treatment area to perform the patient triage assessment and formulate the diagnostic plan of care. The emergency department at Vanderbilt University Medical Center, a Level I trauma center in Tennessee, established a program in which patients are quickly assessed in a triage area by a team consisting of a physician, a nurse, and a paramedic. Patients with urgent problems are promptly moved to a treatment room. Patients with nonurgent problems are tested and treated in the team triage area and then released or returned to the waiting area until test results and a treatment room become available. Because of this program, most patients see the triage doctor within 10 minutes of arriving, the percentage of LWBS patients has decreased from 5% to less than 1%, and patient satisfaction has increased markedly.27

No Triage

Another strategy being successfully used by a number of EDs involves directing patients immediately to an open bed in the ED and performing bedside registration while simultaneously triaging and treating the patient. In this model, the primary nurse performs the initial patient assessment, often with the ED physician in attendance performing a parallel medical evaluation, thereby decreasing the amount of time spent by the triage professional and improving communication between healthcare providers. Where it can be implemented, this model has led to reduced patient wait times, decreased overall length of stay, and reduced numbers of ED patients waiting to be seen.24

Advanced Triage Protocols

Advanced triage protocols are order sets that include diagnostic and therapeutic orders that are locally developed and are driven by the patient chief complaint. Most EDs have approximately 20 medical conditions, which are responsible for about 50% of ED patient visits.18 For example, protocols for treating patients presenting with chest pain may include immediate electrocardiogram and administration of aspirin followed by physician assessment. Developing evidence-based treatment protocols with regard to particular medical conditions can increase medical care reliability and patient safety and decrease medical errors and costs. Additionally, if diagnostic tests are ordered early in the triage process, results can be accessed by the treating ED physician as the patient enters the treatment room.

Patient Flow Managers

Many EDs are using patient flow manager positions to expedite patient treatment and to provide real-time troubleshooting of patient flow problems. Staten Island University Hospital in New York City uses a high-level manager, an administrator on duty, to directly escort patients to treatment areas. In addition to monitoring the progress of patient care, the administrator increases the direct-to-bed patient flow process and significantly decreases patient wait times for care.28
Environmental Design of ED Waiting Rooms

Facilities that have the opportunity to design or redesign the ED can use design principles to improve patient flow and communication among staff members. Considerations include embedding departments like radiology in the ED to reduce turn-around time; dedicating space for specialty staff (e.g., phlebotomy, radiology, high-demand consultants) in the ED; building pods of services for adults, pediatrics, and levels of “fast track” patients; and clustering registration and triage areas to facilitate parallel processing. Pod-type design structures allow teams of providers to work closely together and to keep benchmark and trigger information regarding ED census and turn-around time, as well as patient-specific clinical information, easily accessible.29 Conversely, pod-type models require a higher level of staffing and may be designed for a specific patient population that may or may not materialize at any given point in time. Designing space for needed equipment and supplies at the bedside and designing “universal” treatment rooms may significantly increase staff productivity and decrease the time-to-treatment for patients.

Authority reports and local news stories highlight the importance of maintaining keen awareness of activity in ED waiting rooms. In addition to specific triage strategies, it is important to configure existing ED waiting areas so that ED staff can easily track and monitor patients. Optimally, there is line of sight awareness of the waiting room patient population by the ED staff. If the waiting room is out of sight, EDs may elect to station a healthcare provider within or near the waiting room or use video monitoring technology. If medical staff is unavailable, specially trained volunteers or paraprofessionals can be used to facilitate information exchanges regarding patient condition to the triage professional. However, instead of performing and documenting repeat assessments of patients in waiting rooms, many organizations recommend that patients be assessed and moved expeditiously from waiting area to treatment area. If waiting must occur, it is best that patients wait on the back end of an ED visit, after assessment has been completed and diagnostic evaluation begun.30

Fast-Track Service Lines

Urgent care or fast-track service lines can improve front-end ED patient flow by routing low-acuity patients to separate treatment areas where they are evaluated and treated separately from acutely ill ED patients. In this model, either a physician or a mid-level provider can treat patients in the fast-track area. This allows the more acutely ill patients to receive treatment in closely monitored areas. Two studies have shown that dedicated fast-track service lines can decrease ED length of stay,30 decrease door-to-doctor time, and lower the ED walkaway rate.31

Information Technology

Information technology used within most ED departments can be as simple as an electronic patient registration system or as complex as a comprehensive emergency department information system (EDIS). EDISs are electronic health record systems designed specifically to manage data and workflow in support of emergency department patient care and operations. The EDIS patient tracking component is either patient- or department-centered and takes into account both clinical course and physical location tracking. Clinical course tracking follows the patient’s care throughout the ED process, providing information such as patient status, completed and anticipated events, order status, vital signs, and other clinical information. Physical location tracking follows the patient through the physical space in all phases of the ED visit, from prearrival to disposition, and can be accomplished manually through data entry into the system or through the use of radio-frequency identification (RFID) or other similar technologies.32

Customer Service Culture and Communication

While it is unrealistic to believe that all wait times in the ED could be eliminated, preparing for and explaining wait times to patients is important from both a patient safety and a customer service point of view. Previous Authority reports have shown that unmonitored patients in the initial phase of ED treatment can quickly become a liability. Patients who spend more than two hours in the ED report less overall satisfaction with their visit than those who are there for less than two hours.28 Since much of the time in the ED is spent waiting (e.g., to see a physician, for consultations, for tests and test results), understanding the psychology of waiting can lead to innovative solutions. Consider the following principles of waiting:

- People want to get started.
- Anxiety makes waits seem longer.
- Uncertain waits seem longer than known, finite waits.
- Unexplained waits seem longer than explained waits.
- Unfair waits seem longer than equitable waits.
- The more valuable the service, the longer the customer will wait.
- Solo waits feel longer than group waits.
While decreasing delays in the ED would certainly improve customer satisfaction, Press Ganey data shows that keeping patients informed about delays in the department and having a caring attitude toward patients can mitigate the negative effects of patient wait times in the ED. Some innovative strategies that hospitals have implemented to decrease wait times include the abbreviated triage model, the parallel processing of registration and triage, bedside triage, patient involvement in progress tracking throughout the ED stay, shifting patient waiting to the end of the ED visit (after receiving the diagnostic evaluation), designing ED waiting areas with patient comfort in mind, and providing activities to occupy both patients and families while they wait for ED disposition.

Communication is important throughout the ED visit, both between healthcare providers and patients and their families, and also between healthcare providers themselves in the ED. Handoffs are a known risk factor for increased medical errors; in a busy ED, handoffs can become even more dangerous. Bedside transitions during shift change, when possible, can help facilitate the transfer of information from one practitioner to the next in busy ED environments. Customer satisfaction surveys can provide the ED with cost-effective feedback regarding patient perceptions of timeliness and quality of care in the ED.

**Risk Reduction Strategies for Front-End ED Processes**

Consider the following strategies to simultaneously decrease the amount of time patients spend in the “patient arrival in the ED to physician assessment” phase of ED treatment and to enhance patient safety:

- Implement a predictive model of staffing in the ED and staff accordingly. Analyze a minimum of four weeks of volume, key metrics, and admissions (see sample “Emergency Department Census Tracking Tool” available on the Authority website). Determine the average daily demand for each day of the week and for time periods throughout the day.

- Use strategies to optimize low-census/low-utilization times in the ED, and prepare for busier times. Ensure that staffing is adequate during the busiest parts of the day. Expedite patients early in the day (or during less busy times) so that beds are open during the busier times. During shift changes, have practitioners do bedside transitions to facilitate accurate flow of information.

- Monitor ED capacity in real time. Develop early warning systems (e.g., number of patients waiting to be seen, capacity) to alert staff to large fluctuations in demand or capacity (see sample “Emergency Department Front-End Process Measures Threshold Tool” on the Authority website). When an ED is at 80% capacity, initiate a variety of actions to prevent increases in capacity such as sending boarders to units; assembling a discharge team to quickly discharge waiting patients; having physicians determine whether any patients can return for diagnostic testing at another time (offloading); or creating an express admissions team to expedite admissions out of the ED.

- Adopt an accurate and reliable triage methodology, and ensure that staff are trained in its use.

- Consider alternative triage strategies to expedite patient door-to-registration time, including the following:
  - Abbreviate patient registration: collect only as much data as needed to generate the medical record and create the patient wristband. All other data can be collected at any point during the ED stay.
  - Elevate the level of experience or education of the triage personnel: consider using midlevel staff (e.g., physician assistant; nurse practitioner) or ED physicians in triage.
  - Implement team triage: use a team of nurses and physicians to perform triage at the bedside in order to decrease front-end cycle time and decrease patient time to treatment. This model helps pull patients directly into treatment rooms—a much safer place for ED patients to wait for treatment.
  - Bypass triage completely, and place patients in available beds immediately. Abbreviated registration and bedside triage combine to make this model efficient and safe for patients when beds are available.
  - Use evidence-based advanced triage protocols for the department’s common ED chief complaints.

- Assign a patient flow manager to facilitate patient arrival into, and flow through, the ED department.

- Implement fast-track or urgent care treatment areas where low-acuity patients receive separate but parallel care from dedicated practitioners. This practice helps preserve beds for acutely ill patients who need closer oversight and monitoring services.

- Consider environmental design principles in ED areas:
  - Look for and decrease waste and non-value-added steps. Observe patient flow processes, and redesign staff work areas to be closer to patients. Stock needed items in each room or by each bed.
  - Consider embedding high utilization personnel (e.g., laboratory, radiology, consultants) in the ED department.
  - Maintain line-of-sight and situational awareness of all patients in ED waiting rooms.
  - Redesign the ED to ensure that the majority of patient wait time occurs at the back end of the ED visit, after the patient has received the diagnostic evaluation.
Develop a culture of customer service that takes into account the psychology of waiting. Realize that parallel processes are better than serial processes whenever possible. Create and maintain a way to inform patients about probable wait times and potential delays. Collect and use information from patient satisfaction surveys. Consider creating comfortable patient waiting areas, preferably at the back end of the ED visit, equipped with room for family, and find ways to keep patients and families occupied.

**Conclusion**

EDs in the United States provide a critical service for patients in need of urgent, often life-saving medical care. Additionally, the role of the ED has evolved from providing primarily life-saving treatment to providing urgent unscheduled care to patients unable to gain access to their primary care providers, to providing care to Medicaid beneficiaries, and to providing care to patients without insurance. These factors contribute to crowding in the ED. Timeliness of care in the ED is a matter of patient safety, and it starts with the period of the patient’s arrival through to the diagnostic evaluation segment of the patient visit. This treatment phase can influence the timeliness of care for the remainder of the visit and has been connected to clinical outcomes and patient safety issues. Standardizing front-end operations not only improves important time metrics, it also directly contributes to the safety of patients in this phase of ED treatment.

**Notes**


The Dirt on Flexible Endoscope Reprocessing

ABSTRACT

To avoid cross contamination of infectious pathogens, endoscopes and their associated accessories are cleaned and disinfected or sterilized (reprocessed) between each patient use. Failure to properly reprocess endoscopes and accessories could potentially expose patients to bloodborne pathogens and harmful bacteria, which may result in serious patient injury or death. Often, these exposures affect large numbers of patients who must be notified of the potential risk and may need to return to the facility for testing. Patient notification of endoscopy-related cross contamination or suspected contamination can be challenging when appropriate identifying information associating a specific endoscope with a specific patient is not captured. Between 2004 and 2009, the Pennsylvania Patient Safety Authority received 107 reports describing potential patient contamination due to inadequate or improper endoscope reprocessing techniques. Of the 107 reports, 62 made reference to potentially contaminated endoscopes being used on patients, while the remainder described potentially contaminated endoscopes getting to the patient (e.g., surgical field), but not used, or lacked information to determine patient involvement. To reduce the likelihood of cross contamination, healthcare facilities need to consider developing and adhering to comprehensive, model-specific reprocessing protocols. (Pa Patient Saf Advis 2010 Dec;7[4]:135-40.)

Endoscopes are optical instruments used to visually examine internal organs or cavities within the human body to diagnose and treat various medical conditions. Endoscopes and their accessories (e.g., irrigation tubing) need to be reprocessed (cleaned and disinfected or sterilized) between each patient use. Failure to reprocess or inadequate reprocessing of endoscopes and accessories places patients at risk of exposure to various pathogens. Because of the severity of this potential risk, ECRI Institute designated cross contamination from flexible endoscopes as the number 1 hazard of the top 10 medical technology hazards for 2010. A March 2006 Patient Safety Advisory article described potential contamination of surgical instruments, including endoscopes, due to inadequate cleaning and inspection of the instruments before sterilization.

Much of the literature on infection prevention in endoscopy identifies failure to follow established cleaning and disinfection/sterilization processes and use of damaged or malfunctioning reprocessing equipment or endoscopes as the leading causes of cross contamination. Damaged equipment should be removed from service immediately or as soon as possible. If the endoscope is left in use, organic debris may enter areas of the device that are not typically exposed to disinfecting or sterilizing agents. Endoscope reprocessing typically involves a six-step protocol that includes precleaning, leak testing, manual cleaning, high-level disinfecting or sterilizing, rinsing and drying, and endoscope storing (for more information on the reprocessing steps, see the sidebar “Typical Endoscope Reprocessing Protocol”). A breakdown in any one of these steps could compromise the integrity of the process leading to an endoscopy-related contamination risk. This risk can result in transmission of infectious agents (e.g., hepatitis C, HIV, mycobacterium tuberculosis) and potentially lead to patient injury or death. Often in these cases, large numbers of patients are affected and must be notified about exposure to potentially contaminated endoscopic equipment.

Large-Scale Cross-Contamination Risks and Analyses

Reports of endoscopy-related patient cross contamination have garnered media attention due in part by the large number of potentially affected patients. Between December 2008 and April 2009, the U.S. Department of Veteran Affairs (VA) notified approximately 10,000 patients who received endoscopic procedures at 3 VA facilities between April 2003 and March 2009 that they may have been exposed to bloodborne pathogens due to improperly processed endoscopy equipment. In 2004, the California Department of Health Services called for a review of endoscope reprocessing procedures in the wake of reports of improper reprocessing of flexible endoscopes from eight healthcare facilities. As a result of these breakdowns in reprocessing procedures from the 8 facilities, more than 5,000 patients were notified of potential exposure to hepatitis B, hepatitis C, and in some cases, HIV. Palomar Medical Center notified 3,400 patients that received endoscopic-related care between December 2008 and March 2010 to return for tests for infectious diseases because the endoscopic equipment used in their care may not have been properly disinfected.

* There are two basic types of endoscopes: rigid and flexible. While reprocessing procedures are similar for rigid and flexible endoscopes, this article focuses on flexible endoscope reprocessing because of the complexity of the procedures.

† The process of high-level disinfection and sterilization of endoscopes can be automated using automated endoscope reprocessors (AERs) and sterilizers, respectively. For convenience, the terms endoscope reprocessors or reprocessors will be used in this article to refer to both AERs and sterilizers.
Typical Flexible Endoscope Reprocessing Protocol

Typically, an endoscope reprocessing protocol will include the following steps in order:

**Precleaning.** This step is performed in the procedure room. An enzymatic detergent solution is used to wipe the exterior of the endoscope and to flush all the channels. During precleaning, irrigating the channels with an enzymatic detergent solution helps moisten and soften debris in preparation for the subsequent, more vigorous manual cleaning step.1,2

**Leak testing.** This step is performed in the processing room after precleaning but before manual cleaning begins. This test consists of pressurizing the endoscope with air and submerging it in water to check for damage (i.e., leaks). If damage exists, air bubbles should be visible while the endoscope is submerged. If damage is evident, the endoscope is removed from service and repaired. If no damage is evident, the endoscope continues to the manual cleaning stage.1,2

**Manual cleaning.** The endoscope is first immersed in an enzymatic detergent solution, and then debris is wiped and/or brushed from the endoscope’s exterior surfaces. All the channels—even those not used during the endoscopic procedure—are brushed, aspirated, and flushed with the detergent. All the endoscope’s removable parts are cleaned separately. The endoscope is then rinsed with water. Rinsing may also include using forced air to remove excess water from the endoscope before disinfection or sterilization.1,2

**High-level disinfection/sterilization.** The endoscope is either high-level disinfected or sterilized. Sterilization inactivates all microbes, including bacterial endospores, while high-level disinfection inactivates all vegetative bacteria, mycobacteria, fungi, and viruses, but not necessarily all bacterial endospores. This step can be performed manually or by using an endoscope reprocessor.1,2 The decision to disinfect or sterilize an endoscope is typically based on the Spaulding classification system (accepted by the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration).3

The Spaulding classification system is described as follows:3

- Critical devices: devices that enter sterile tissue or the vascular system are sterilized (e.g., scalpel).
- Semicritical devices: devices that come into contact with mucous membranes and do not penetrate sterile tissue are, at a minimum, high-level disinfected (e.g., bronchoscope).
- Noncritical devices: devices that do not touch the patient or that touch only intact skin are cleaned, followed by low-level disinfection (e.g., stethoscope).

Flexible endoscopes typically fall into the semicritical device category, requiring at least high-level disinfection. However, endoscopes that enter sterile body cavities are classified as critical devices requiring sterilization.3

**Rinsing and drying (with alcohol flush).** The first part of rinsing includes flushing the endoscope with filtered water. This is typically performed for endoscopes that are exposed to a liquid chemical germicide. Pressurized air is then passed through the endoscope to remove the water. For endoscopes subjected to high-level disinfection, the endoscope channels are then flushed with 70% to 90% ethyl or isopropyl alcohol and dried using forced air. Most automated endoscope reprocessors can perform this step; however, this step can be performed manually.1,2

**Storing.** For endoscopes that have undergone high-level disinfection, the endoscope is hung vertically with caps, valves, and other detachable components removed. Endoscopes are stored in a well-ventilated area that is not prone to moisture collection. However, some endoscope reprocessor manufacturers recommend not storing sterilized endoscopes but using them immediately after sterilization to ensure that the endoscope’s sterility is not compromised. Other reprocessor manufacturers may require that sterile endoscopes be wrapped for storage and only unwrapped in a sterile environment.1,2

Notes


If a risk of endoscopy-related contamination has been identified, a review is typically undertaken to determine at which point a breakdown in procedures may have occurred that led to the potential exposure. For example, staff may review documentation of endoscope reprocessing procedures for a specific endoscope in which cleanliness and/or sterility is in question. This review may reveal that one or more steps involved in reprocessing this particular endoscope were not followed, leading to a review of reprocessing documentation for other endoscopes. From this, a timeframe may be found as to when the deviation from the reprocessing procedures occurred (e.g., failing to perform the precleaning step). Once a timeframe is determined, to identify exposures or as a precaution, a facility will notify all patients who had an endoscopic procedure during that period to be tested even though there may have been no actual exposure.
Additionally, even if a patient tests positive for an infection, such as hepatitis C, there may not be a definitive link between an improperly reprocessed endoscope and the infection. For example, in the VA incident described, some patients tested positive for hepatitis B, hepatitis C, or HIV; however, these infections could not be directly linked to the endoscopic procedures. Subsequently, VA undertook an epidemiologic study to determine whether an association between the infections and the procedures existed.\(^3\) Properly tracking and documenting endoscope use—capturing appropriate identifying information such as patient information, procedure date, procedure type, the responsible physician’s name, and endoscope-unique identification number—so that the endoscope can be linked to the patient should a gap in reprocessing occur is an important part of the process to improve patient notification.

**Patient Notification**

Patient notification of endoscopy-related cross contamination or suspected contamination can be challenging when appropriate identifying information associating a specific endoscope with a specific patient is not captured. If an outbreak occurs or is suspected due to an inadequately reprocessed endoscope, a healthcare facility should assess the risk to patients whose procedures were performed with the suspect endoscope. A 2004 report from the California Department of Health Services (DHS) on endoscope reprocessing established the following recommendations to aid investigation of endoscope sterility issues:\(^2\)

- Maintain a log of the patient’s name, medical record number, date of procedure, specific procedure(s) performed, physician’s name performing the procedure(s), and endoscope type and model/serial number (or other unique identifier).

- Identify each automated endoscope reprocessor (AER) used to process each endoscope (for multiple AERs) and the endoscope reprocessing cycles used on each endoscope. (Note that although the California DHS recommendations specify only AERs, the same recommendations can be applied to sterilizer units.)

Not addressed in the California DHS recommendations is identification of endoscopes in the patient record. However, implementing this identification practice may be difficult due to the following:\(^2\)

- **Inaccurate recording.** Some endoscopes can have long serial numbers and may often be affixed with other identifiers (e.g., model number) that are not unique and could be mistaken for unique identifiers.

- **Changing inventory.** For healthcare facilities that take part in leasing or repair programs, endoscopes are typically returned to the supplier for repair or replacement. Often, the endoscopes are replaced with new or loaner devices, which can make tracking these instruments difficult.

**Clinical resistance.** Some users may shy away from following an endoscope identification practice, believing that it will add work without providing clear-cut benefit to the practice.

Notwithstanding these challenges, developing and following unique endoscope identification practices will help facilities associate contaminated or potentially contaminated endoscopes with specific patients during the notification process. For consistent compliance, any practices must be highly efficient.

**Pennsylvania Patient Safety Authority Data**

From June 2004 through 2009, the Pennsylvania Patient Safety Authority received 107 reports describing potential patient contamination due to inadequate or improper endoscope reprocessing techniques. While this article focuses on flexible endoscope reprocessing, the data submitted to the Authority may also include reports related to rigid endoscopes because in some reports the term “scope” was the only descriptor identifying the equipment involved. Of the 107 reports, 62 made reference to potentially contaminated endoscopes being used on patients. In the remaining 45 reports, potentially contaminated endoscopes either reached patients, but were not used, or the reports lacked sufficient information to determine patient involvement. Authority analysts established five categories based on a review of the narratives in the event description field of the reports.

**Not Cleaned or Deviation from Endoscope Reprocessing Protocol (65 Reports)**

This category captures reports to the Authority that describe endoscopes that either were not cleaned or were improperly cleaned during reprocessing. Reports include the following:

- A bronchoscope that was used on patient was not properly disinfected after use on previous patient. The room was not turned over and equipment was not changed or cleaned before the next patient was brought in. Per infection control, the first patient did not have any infections disease that would harm the second patient, and there was no direct exchange of body fluids. The second patient will have follow-up visits . . . to ensure no injury occurred.

  [Staff] obtained a clean gastroscope from instrument room; upon testing the scope, blood leaked out of the end of the scope.

**Endoscope not Sterile (22 Reports)**

This category captures reports that describe endoscopes that may have been cleaned properly but not sterilized before subsequent use. Reports include the following:

- A bronchoscope was used at the beginning of a case [and then] washed and put in case tray to be sterilized. The physician needed a bronchoscope immediately, and used the same scope that was used earlier. The patient was deteriorating and no other scope was immediately available.

  A case was delayed due to scope not sterilized for procedure.
Documentation/Indicator Strip Missing or Unchanged after Sterilization Process (17 Reports)

This category captures reports that describe situations in which documentation or indicator test strips verifying endoscopes had been sterilized were either missing or the indicator strips did not change color (a change in color of the strip indicates that the endoscope sterilization process was successful). Reports include the following:

A flexible ureteroscope was decontaminated, but the indicator did not change to indicate sterility. The physician opted to use scope anyway.

Upon taking the scope to the OR, it was noted by the tech that there was no indicator in the tray.

Knowingly Used Unsterile Endoscope (3 Reports)

While this category is not a breakdown in endoscope reprocessing, it is included here to demonstrate that behavior can also contribute to the potential risk of endoscopy-related cross contamination. Reports include the following:

[Staff] sent for flexible scope as per physician. The scope was clean but not sterile. The physician wanted the scope, and stated that the patient already had infection, [so the scope] would not hurt the patient.

A flexible cystoscope was requested from the urology clinic and the only [available] scope was unsterile.

This was needed for the procedure and was used.

Reprocessing Breakdowns That Risk Cross Contamination

Other reported breakdowns that produced cross-contamination were reported in the VA studies. Endoscopes used for ear, nose, and throat procedures may not have been adequately disinfected or sterilized. Colonoscopy patients may have been exposed to cross contamination due in part to a failure to disinfect tubing between procedures. In one facility, staff were not following manufacturer’s recommendations when reprocessing auxiliary water tubing and other irrigation components between patients. Additionally, while not a reprocessing issue but a cross contamination issue, staff had, in some cases, connected the irrigation channel of the colonoscopes to irrigation pumps using tubing with an incorrect valve. This incorrect connection could potentially allow backflow of contaminated fluid into the irrigation system.3

Developing and strictly following endoscope reprocessing protocols for each specific endoscope model in a facility’s inventory and for each newly purchased model can greatly reduce the likelihood of cross contamination of pathogens between patients. Reprocessing involves not only the endoscope, but also accessories (e.g., irrigation tubing) and the equipment used to clean the endoscopes (e.g., brush). Some reports to the Authority involved the tips of cleaning brushes found inside endoscope channels after reprocessing between patients. Failure to include these items for reprocessing (as well as failure to regularly inspect and, if necessary, replace these items) also contributes to the risk of contamination. The importance of performing precleaning and manual cleaning of endoscopes, including all channels (used and unused), cannot be overstated. Without effective and thorough cleaning, it would not be possible to fully high-level disinfect or sterilize the endoscope. Neither high-level disinfection nor sterilization will remove gross contamination nor will the germicidal agent (e.g., orthophthalaldehyde, ethylene oxide) used during these processes be able to penetrate surfaces beneath gross contamination to disinfect them; organic material deactivates some disinfectants.2 Additionally, precleaning and manual cleaning are still to be performed when using an endoscope reprocessor as part of the reprocessing protocol; the endoscope reprocessor is not a substitute for manual cleaning.

Proper Reprocessing Technique

Endoscope reprocessing equipment and endoscope compatibility are important aspects in reducing the risk of cross contamination. Flexible endoscopes can be reprocessed completely by manual means (e.g., manual cleaning, manual disinfection); however, a common part of the process involves using an endoscope reprocessor. After manual cleaning, endoscopes and endoscope channels must undergo exposure to a germicidal agent for high-level disinfection or sterilization.2 Endoscope reproducers help automate this process by exposing the endoscope to a germicidal agent at a particular temperature and for a particular duration to achieve adequate decontamination. Some units also rinse the endoscope with filtered water to remove any germicidal agent residues. Typically, the reprocessor and endoscope manufacturers provide users with information on model-specific compatibility with respective products. Compatibility means that a specific model endoscope can be used with a specific model endoscope reprocessor. This compatibility ensures that the components of the processor (e.g., connectors) match the components of the endoscope (e.g., air/water channel) for proper reprocessing.

In 2005, a Pennsylvania hospital notified approximately 200 patients that they may have been at risk of exposure to hepatitis and HIV infections due to improper disinfection procedures of colonoscopes.7 The hospital purchased two new colonoscopes that included a waterjet channel to flush gastrointestinal mucosa under observation. This water-channel feature was not included in the facility’s previous model colonoscopes, and hospital staff did not recognize this difference during reprocessing. Subsequently, the waterjet channel was not disinfected during reprocessing procedures.7 This event demonstrates the need to ensure compatibility of reprocessing equipment and endoscopes and to ensure that modelspecific reprocessing protocols are developed and followed.

Healthcare facilities can provide the endoscope reprocessor supplier with a modelspecific list of its
endoscopes to ensure compatibility with the supplier’s unit; the facility can also obtain a written statement confirming compatibility and specific reprocessing instructions when possible. Consideration also needs to be given to the compatibility of endoscopes with the germicidal agent. Endoscope and reprocessor manufacturers provide information on the specific germicidal agents that have been tested for compatibility with their respective products; germicidal agent product compatibility statements can also be obtained. In addition to germicidal agent compatibility, the potency of the reusable agent is to be regularly tested and documented (single-use agents are used with some endoscope reprocessors and would not be subject to this check). The strength/potency of a germicidal agent decreases with each use. Additionally, in the case of some germicidal solutions, once the solution container (single- or multiuse solution) is opened, the agent has a finite use period (e.g., 28 days) for optimal effectiveness.

The channel terminations of various endoscope models may require specific channel adapters to ensure proper reprocessing in the endoscope reprocessor. Not only will a facility need to maintain a supply of endoscope-specific adapters and, if necessary, purchase new compatible adapters for each newly purchased endoscope, but staff must be knowledgeable about which adapter correctly connects each endoscope to the reprocessor. Using an incorrect adapter may not provide adequate fluid flow (e.g., germicidal solution, water) through the endoscope channel during reprocessing in the endoscope reprocessor. The proper use and maintenance of endoscope reprocessors helps reduce the risk of endoscope contamination. For example, some reprocessors use tap water as a rinsing agent and therefore include a water filtration system with a bacterial filter to prevent waterborne bacteria from contacting the endoscope during rinsing. According to the reprocessor manufacturer’s instructions, it is important to periodically change this filter as part of the reprocessor maintenance process.

Endoscopes, including insertion tubes and channels, that are processed using liquid chemical germicides must be rinsed with filtered or sterile water to remove any chemical residue. Endoscopes that undergo high-level disinfection are typically flushed with alcohol and then dried with forced air after being disinfected. Drying prevents microbial growth from a moist environment. Even improper storage of reprocessed endoscopes can lead to cross-contamination risks. Proper storage reduces the likelihood of contamination of or damage to endoscopes (storage and handling instructions depend on the type of reprocessing method). Endoscopes subject to high-level disinfection are to be hung vertically—without touching each other—in a well-ventilated area with control valves, caps, and other detachable components removed to facilitate drying. However, endoscopes subjected to gas sterilization processes are wrapped for storage (to maintain sterility) and unwrapped only in a sterile environment. Some reprocessor manufacturers may require that a sterilized endoscope be used immediately after sterilization.

Risk Reduction Strategies

To reduce the likelihood of endoscopy-related cross contamination between patients, healthcare facilities can develop and adhere to comprehensive, model-specific reprocessing protocols. In developing endoscope reprocessing protocols, consider the following strategies to minimize cross contamination risks:

- Establish model-specific reprocessing protocols for each model flexible endoscope in the facility’s inventory. Identify (i.e., through device manuals or endoscope manufacturers) and include in each protocol document specific requirements for reprocessing each endoscope (e.g., cleaning procedure, channel adapters). This strategy also applies for each newly purchased endoscope model or related equipment.
- Regularly review each reprocessing protocol for clarity and comprehension, and ensure that they match the current setting (e.g., the protocols do not include obsolete workflows or equipment).
- Ensure that each reprocessing protocol contains all the steps involved in the process, from precleaning in the procedure room to aseptic transport back to the procedure room for subsequent use.
- For endoscope reprocessor use, ensure that:
  - the facility’s endoscopes (and related accessories) are compatible with the reprocessor and the disinfecting/sterilizing agent;
  - where applicable, all appropriate channel adapters are readily available to connect the endoscope to the reprocessor and that staff are familiar with the correct endoscope-adapter combinations; and
  - all appropriate staff are familiar with and adhere to the endoscope reprocessor maintenance schedules, including periodic replacement of particulate and bacterial filters, when applicable.
- Ensure that documented protocols are readily available to all reprocessing staff and that staff are properly trained to understand and follow the protocols.
- Assign responsibility to appropriate staff for monitoring compliance (competency review) with the reprocessing protocols.

Notes

3. ECRI Institute. U.S. Veterans Health Administration announcements highlight need for comprehensive endoscopy-reprocessing protocols [action item S0193]. Health Devices Alerts 2009 Apr 16.


Controlling the Annual Threat of Norovirus Gastroenteritis Outbreaks

ABSTRACT

The principal cause of acute gastroenteritis (AGE) epidemics is the highly contagious norovirus. The Centers for Disease Control and Prevention attributes a 254% increase in AGE outbreaks nationwide from 2005 to 2006 to the emergence of two new norovirus strains. Norovirus-like illness is a common cause of healthcare facility outbreaks and emergency department visits. It can be fatal among vulnerable populations (e.g., very young, elderly, immunocompromised). The reports of non-Clostridium difficile (non-C. diff) AGE cases in Pennsylvania nursing homes increased from 633 cases in the third quarter of 2009 to 812 cases in the fourth quarter of 2009 and then surged to 4,040 cases in the first quarter of 2010. Pennsylvania hospitals also reported an increase in non-C. diff AGE in the first quarter of 2010. Recurring, annual attacks of norovirus affect resident/patient and staff safety, disrupt healthcare facility operations, and may result in financial and operational burden to facilities. Published health department guidelines suggest that the best method to reduce the risk or mitigate the impact of a norovirus outbreak is to develop preseason preparation measures and to have a rapid response plan in place. Interviews with Pennsylvania healthcare facilities revealed successful strategies for controlling noroviral outbreaks. Key components of an outbreak prevention/containment program include addressing risk factors that increase the potential for norovirus infection and applying best practices to identify and control an AGE outbreak. (Pa Patient Saf Advis 2010 Dec;7[4]:141-8.)

Introduction

Norovirus is a highly contagious virus recognized as the principal cause of worldwide acute gastroenteritis (AGE) epidemics in all age groups. The illness can be introduced into a healthcare facility environment by patients/residents, visitors, or staff. It is a common cause of hospitalization. It can be severe and sometimes fatal, especially among vulnerable populations such as the elderly, the immunocompromised, and the very young. The Centers for Disease Control and Prevention (CDC) estimates that norovirus may be the causative agent in more than 23 million AGE cases every year in the United States, composing 60% of all AGE cases and 50% of AGE outbreaks reported by institutional settings. Pennsylvania hospitals and nursing homes reported marked increases in non-Clostridium difficile (non-C. diff) AGE during the first quarter of 2010.

In a nationwide comparison of AGE outbreaks in 2006 to those in 2005, U.S. AGE outbreaks increased 254%, which is attributed to the emergence of two new norovirus strains. The incidence increase was likely associated with potential increases in pathogenicity and transmissibility of new strains and decreased population immunity to the strains.

Recurring, annual attacks of norovirus disrupt healthcare facilities operations nationwide, affecting patient/resident and staff safety. Noroviruses spread rapidly in healthcare facilities and are difficult to control due to the low infectious dose, ease of transmission, short incubation period, environmental persistence, and lack of long-lasting immunity following infection. In 1998, norovirus was responsible for an outbreak of necrotizing enterocolitis and two deaths in a neonatal intensive care unit of a large Pennsylvania urban teaching hospital. A staff member recalled having gastroenteritis symptoms and giving care before the outbreak.

Outbreaks happen quickly in communal living settings with shared toileting facilities, social dining, and incontinence hygiene issues. The incidence of norovirus outbreaks tend to peak in cold weather when people are more likely to congregate indoors. For example, high wintertime occupancy of healthcare facilities as well as environmental factors (e.g., lower temperatures, diminished ultraviolet light) may increase the virus’ transmission potential. This in turn may trigger a seasonal epidemic, resulting in high levels of population immunity. By spring and the end of the virus season, population immunity is at its highest.

Outbreaks often result in significant financial and operational burden to facilities for the following reasons:

- Inability to manage infected patients/residents
- Staff sick leave and overtime
- Need for additional healthcare supplies
- Additional cleaning expenses
- Lost revenue due to temporary closures of affected facilities

Guidelines from the Philadelphia Department of Public Health suggest that the best method to reduce the risk or mitigate the impact of a norovirus outbreak is for healthcare facilities to develop preseason preparation measures and to have a standardized rapid response plan in place. Considerations in developing a facility-specific norovirus outbreak control plan include risk factors that increase the potential for a norovirus outbreak, best methods to identify an outbreak, and interventions that best prevent or contain gastroenteritis outbreaks.
**AGE Reports from Pennsylvania Nursing Homes and Hospitals**

According to CDC, reported outbreaks of AGE in Pennsylvania increased 443% from 2005 to 2006. Thirty-two percent of the outbreaks occurred in long-term care facilities. Norovirus was confirmed in 66% of the 2006 Pennsylvania outbreaks.† (See Table 1.)

Pennsylvania Patient Safety Authority analysts reviewed reports in the Authority’s reporting system and the National Healthcare Safety Network databases from a 12-month period from July 2009 through June 2010 and found that reports of non-C. diff AGE infections are consistent with the outbreaks of norovirus AGE during winter months. (See Figure 1 and Table 2.)

The reports of non-C. diff AGE cases in Pennsylvania nursing homes increased from 633 cases in the third quarter of 2009 to 812 cases in the fourth quarter of 2009 and then surged to 4,040 cases in the first quarter of 2010. Pennsylvania hospitals also reported an increase in non-C. diff AGE in the first quarter of 2010. An average of 25 cases occurred per nursing home outbreak, and an average of 6 cases occurred per hospital outbreak. Forty-two of the 67 counties in Pennsylvania reported nursing home AGE; the most outbreaks occurred in Philadelphia and Montgomery counties. Thirty-seven percent (25) of counties reported no nursing home outbreaks, 25% (17) of counties reported less than average outbreaks, and 37% (25) of counties reported greater than average outbreaks. Figure 2 illustrates the percentage of nursing home outbreaks by county.

**Features of Norovirus That Promote Epidemics**

**Host Factors**

Elderly or very young individuals, disabled individuals, and individuals with impaired immune systems are at increased risk for prolonged duration and recovery from diarrhea and vomiting. The chronically ill and the elderly are particularly vulnerable to complications resulting from AGE such as dehydration, electrolyte disturbances, aspiration of vomitus, and rarely, death from profound volume depletion. Norovirus infection is characterized by acute onset of vomiting, watery nonbloody diarrhea with abdominal cramps, nausea, and typically a low-grade fever. Children experience diarrhea more often than vomiting.

Norovirus transmission occurs by the fecal-oral route from contaminated food, water, environmental surfaces, and droplets, including the following:

- Consumption of food prepared by the contaminated hands of food handlers who are ill, followed by secondary person-to-person transmission
- Consumption of shellfish or water contaminated with raw sewage
- Oral contact after exposure to contaminated body fluids or skin surfaces
- Oral contact after exposure to environmental surfaces contaminated with fecal material
- Exposure to aerosolized vomitus resulting in droplets that can enter the oral mucosa and be swallowed

**Viral Factors**

Preventing norovirus transmission is a challenge because it spreads easily and rapidly leads to disease in 50% of inoculated individuals. Ease of transmission is related to a low infectious dose, environmental persistence, and lack of sustainable immunity following infection.

As little as 10 viral particles can cause noroviral infection, contributing to sustained transmission of norovirus and the potential for outbreaks in institutional settings. Vomiting patients/residents or staff members can disseminate the virus through airborne transmission. Generally, symptoms begin 12 hours to 2 days following exposure. Episodes typically resolve spontaneously within 24 to 72 hours. Viral particles are excreted in high numbers in feces and vomitus during the first 48 hours of illness; convalescing

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**Table 1. Number and Percentage of Reported Acute Gastroenteritis Outbreaks, by State, Number in Long-Term Care Facilities, and Number with Norovirus Confirmed—Multiple States, 2005 and 2006**

<table>
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<tr>
<th>STATE*</th>
<th>NO. OF OUTBREAKS DURING OCTOBER–DECEMBER 2005†</th>
<th>NO. OF OUTBREAKS DURING OCTOBER–DECEMBER 2006‡</th>
<th>% CHANGE FROM 2005 TO 2006</th>
<th>OUTBREAKS IN LONG-TERM CARE FACILITIES, OCTOBER–DECEMBER 2006§</th>
<th>OUTBREAKS WITH NOROVIRUS CONFIRMED, OCTOBER DECEMBER 2006†</th>
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* Only states that reported at least five outbreaks during October through December 2005 and October through December 2006 were included.
† Date of outbreak onset.
‡ Confirmed by reverse transcriptase–polymerase chain reaction.
individuals can continue to shed virus for two or more weeks after symptoms subside. No vaccine is available for norovirus, and generally no medical treatment exists other than symptomatic treatment and replacement of fluids and electrolytes.

Diarrhea is caused by damage to the small intestine causing malabsorption. Vomiting is related to a change in gastric motility and delayed gastric emptying. Prior exposure to norovirus appears to provide strain-specific immunity for only a few months, which explains the high rate of repeated infection in individuals of all ages. Reinfection and outbreak recurrence may be due to repeated introduction of 1 of 25 different strains of norovirus.

Environmental Factors
Norovirus is easily transmitted and difficult to remove from the environment. Some outbreaks have been traced to contaminated computer keyboards and to sinks in which foodservice workers first washed their hands and then rinsed fresh vegetables. Surfaces soiled with aerosolized vomitus droplets or contaminated hands can sustain an uncontrolled epidemic. Barker et al. found in a human challenge study that contaminated fingers could transfer norovirus to up to seven consecutive clean surfaces. Environmental contamination is frequently found in rooms of infected patients/residents. Environmental transmission of norovirus is facilitated by the following virus characteristics:

- Able to survive temperatures ranging from freezing to 60°C (140°F)
- Able to survive and continue to cause infection after prolonged periods of time on surfaces
- Able to transiently colonize healthcare workers’ hands, which then can transfer the pathogen
- Resistance to many disinfectants used on environmental surfaces

Methods to Detect an Outbreak of Norovirus
Early recognition of cases is a vital first step of outbreak control. CDC defines a case of norovirus as an acute onset of vomiting or diarrhea, with 3 or more loose stools within any 24-hour period. An outbreak of norovirus is likely when at least 3 patients/residents or staff members in a facility are experiencing symptoms of the virus during a 48-hour period. Continuous surveillance for symptoms of AGE will alert staff to respond to a surge or cluster of cases or a number of cases that is above average for the facility. Surveillance includes investigation for other causes of AGE such as C. diff or bacterial infections such as salmonella. As not all laboratories possess the ability to rapidly diagnose norovirus, the CDC IA recommendation is to use Kaplan’s clinical and epidemiologic criteria to aid in early detection of norovirus cases, as follows:

- Vomiting in more than half of symptomatic cases
- The mean or median duration of illness ranges between 12 to 60 hours
- The mean or median incubation period ranges between 24 to 48 hours
- No bacterial pathogen found in stool cultures

The current standard for identification of norovirus in stool and vomitus uses a reverse transcriptase polymerase chain reaction test, available from the Pennsylvania Department of Health Bureau of Laboratories. Stool specimens should be submitted as early as possible during a suspected outbreak and ideally obtained from infected individuals during the acute phase of the illness (two to three days after onset). Liquid stool or vomitus specimens from at least five individuals should be collected and put into dry, sterile, leak-proof containers and refrigerated until ready for transport.

Key Components of an Outbreak Prevention/Containment Program
Healthcare facilities and their staff are better equipped to respond to norovirus when protocols for
Preventive measures are in place before the norovirus season arrives.\(^6\) Elements of an effective protocol (detailed below) include tasks needed to prepare for, manage, and report norovirus outbreaks.\(^2,15\) Outbreak control is greatly enhanced by the rapid action of a multidisciplinary team to advise and coordinate timely implementation of control measures. CDC has released evidence-based recommendations in its draft “Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings” to identify gaps in current facility protocols and develop detailed implementation guidance for prevention and control of norovirus AGE outbreaks.\(^2\)

Preparing for the Norovirus Season

**Education**

- Provide education on norovirus transmission, symptoms, and prevention. Reinforce hand hygiene and control measures with staff, patients/residents, and visitors by using in-services, notices, handouts, and posters as part of annual staff fall training, when cases are detected, and throughout the duration of an outbreak.\(^2,15\)

- Review, monitor, and reinforce adherence to facility protocols based on current CDC, health department, and evidence-based guidelines to promote correct and consistent implementation of control measures.\(^16\)

**Surveillance System**

- Develop and institute facility policies to enable rapid clinical confirmation of potential cases. The policies should include the following: \(^2,6,15\)
  - A clear case definition
  - Unit-based systems to find, monitor, and record case information
  - Use of line listing logs to record daily symptoms and case information for patients/residents and staff
  - Facility-specific AGE baseline
  - Facility-specific AGE attack rate by unit


**Resources**

- Ensure sufficient quantities, personal protection equipment (PPE) for isolation, single-use dedicated patient care equipment (e.g., commode, rectal thermometers), and toileting supplies, as well as sufficient quantities of precaution signs and education materials.\(^6\)

**Communication Plan**

- Designate which individuals are responsible for managing communication to patient/resident care areas, patients/residents, families, other
providers, the medical director, facility leadership, corporate bodies, and the local health department as required.2

- Include a plan for rapid dissemination of information, the location and extent of the infection, control measures, requirements for documentation, and notification of ongoing cases.2

**Staffing and Employee Health**

- Exclude ill staff members from work for a minimum of 48 hours after the resolution of symptoms. Exclude nonessential staff, students, and volunteers from working in areas experiencing outbreaks of norovirus gastroenteritis.2

- Establish protocols for staff cohorting in which staff provide care for only one patient group on their ward (i.e., symptomatic, exposed but asymptomatic, or unexposed), and do not move between patient cohorts.2,15

To aid in preparation for the norovirus season, the Authority has developed a “Norovirus Preparedness Checklist” that itemizes multidisciplinary tasks for implementing an outbreak prevention program (available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx).

**Basic Outbreak Control Measures**

**Contact Precautions**

The rapid, simultaneous implementation of multiple control measures, as follow, is key to controlling disease transmission and reducing the magnitude of outbreaks:2

- During an outbreak, place patients in private rooms or separate patients into separate cohorts. Cohorts include those who are symptomatic, exposed but asymptomatic, and unexposed. Precautions should continue for a minimum of 48 hours after the resolution of symptoms.2 Segregate patients and staff on affected wards from unaffected wards as possible.14 When necessary, facilities can discharge patients/residents on contact precautions for norovirus if receiving facilities are able to provide adequate cohorting or isolation.2

- Require separate toilets or commodes for symptomatic patients.2

- Isolate infants up to five days, as there is the potential for asymptomatic viral shedding and environmental contamination.2

- Ensure availability of PPE, including gloves and a gown.

A mask and eye protection may be necessary if there is a risk of splashes to the face during the care of patients/residents who are vomiting2 and for individuals who clean areas heavily contaminated with feces or vomitus.13 Visitors having close contact with symptomatic patients/residents should be instructed in proper use of PPE and hand hygiene.13

**Hand Hygiene**

Traditionally, CDC recommends hand washing with soap and water for at least 15 seconds or use of hand sanitizers until hands are dry. Barker et al. demonstrated in a human challenge study that hand washing with an antibacterial soap for at least 1 minute followed by rinsing for 20 seconds and drying with a disposable paper towel may be more effective in removing norovirus.12 An effective hand-hygiene program requires hand washing with soap and water in any of the following circumstances:13

- When hands are visibly soiled and have been in contact with diarrheal patients/residents

- When in contact with contaminated surfaces or body secretions

- After removing gloves

- Before any contact with food or beverages (e.g., preparing, serving)

**Environmental Cleaning**

Environmental contamination has been documented as a contributing factor in ongoing transmission of outbreaks. Environmental reservoirs of pathogens during outbreaks are often related to a failure to adhere to the following recommended procedures for cleaning and disinfection:16

- Clean and disinfect patient care areas at least twice daily; clean and disinfect frequently touched surfaces at least three times daily. Clean shared patient equipment between patient uses. Clean with an appropriate Environmental Protection Agency (EPA)-registered product approved for use in healthcare settings, and follow manufacturer’s recommendations for optimal disinfectant dilution, application, and surface contact time.2 A freshly made chlorine-based agent like sodium hypochlorite or 5 to 25 tablespoons of household bleach per gallon of water is recommended.10,14 (EPA lists registered products with activity against norovirus on its website at http://www.epa.gov/oppad001/list_g_norovirus.pdf.)

- Clean surfaces and patient equipment before applying a disinfectant. Presence of residual organic and protein loads on surfaces reduces the overall effectiveness of disinfectants. Clean and disinfect surfaces starting from the areas with a lower likelihood of norovirus contamination (e.g., tray tables, countertops) and progressing to areas with highly contaminated surfaces (e.g., toilets, bathroom fixtures). Change mop heads when new solutions are prepared or after cleaning large spills of emesis or fecal material. Discard disposable patient care items from isolation rooms upon discharge.2

- Immediately clean emesis or fecal material from upholstered furniture using a manufacturer-approved cleaning agent or detergent. Steam clean furniture upon patient discharge, or discard the furniture if cleaning is not possible.2
Handle foodservice items using standard precautions and normal processing and cleaning procedures. Avoid dispersing the virus by handling soiled linens without agitating them. Wear appropriate PPE to minimize the likelihood of personal contamination. Change privacy curtains when they are visibly soiled and upon patient discharge. Launder unused linens remaining in patient rooms before use on another patient. Double bagging of linen, incineration, or modifications for laundering are not recommended.

Enhanced Precautions
Uncontrolled or widespread outbreaks of norovirus gastroenteritis may prompt more stringent measures, as follow, to reduce the likelihood of environmental contamination and transmission of norovirus in unaffected clinical areas:

- Restrict symptomatic and recovering patients from leaving the patient care area other than for essential care or treatment.
- Suspend group activities (e.g., dining events), and close wards to new admissions or transfers to attenuate the magnitude of an outbreak of norovirus gastroenteritis. The threshold for ward closure varies and depends on individual state requirements and risk assessments by infection prevention personnel and facility leadership.
- Restrict nonessential visitors from affected areas during outbreaks of norovirus gastroenteritis. If visitors are permitted, a process for screening visitors for symptoms consistent with norovirus infection is encouraged.

Leadership
Leaders of healthcare facilities play a vital role in successful prevention of healthcare-associated infections (HAIs). As described by Saint et al., a 2005 survey of 516 hospitals revealed several key behaviors exhibited by hospital leaders who successfully implemented HAI prevention practices, including the following:

- Plan ahead to ensure that roles and tasks are clearly specified.
- Inspire staff at all levels to focus on a facility vision of clinical excellence and patient safety.
- Maintain high expectations.
- Focus on overcoming barriers.
- Deal directly with resistant staff.

Facility leaders can partner with frontline providers by meeting on the unit, discussing safety issues, and helping to remove barriers to implementation of outbreak improvement efforts.

Postoutbreak Activities
Monitoring compliance is fundamental to determine the effectiveness of norovirus improvement strategies and the existence and extent of barriers to safe care. Norovirus control measures can be assessed using an adaptation of the Society for Healthcare Epidemiology of America’s outcome and process measures for C. diff, including the following:

- Report process and outcome measures to leadership, staff, and clinicians.
- Express the norovirus outcome measure as the rate of infection for a unit or facility (divide the number of norovirus cases by the number of patient days in thousands).
- Measure performance, including observation of compliance with hand hygiene, contact precautions, and environmental cleaning. Monitor these processes through actual or simulated observation and employee interview. To calculate these measures, divide the number of observations that were compliant by the total number of observation performed.

Pennsylvania Success Stories
The Authority interviewed representatives from five Pennsylvania nursing homes—Vincentian Regency, Allison Park; Nottingham Village, Northumberland; Somerton Center, Philadelphia; Twin Oaks, Campbellsown; and Golden LivingCenter-East Mountain, Wilkes-Barre—to identify methods of influencing an effective and sustainable gastrointestinal illness prevention and control program. Analysts selected the facilities based on facility reports to the Authority that indicated an outbreak of norovirus AGE in the facility during one month for the first quarter of 2010 and on the facility’s successful and timely resolution of the outbreak. Standardized interview questions addressed preoutbreak plans, management of cases and outbreaks, postoutbreak activities, and which intervention was thought to be the most effective in AGE outbreak control. These facilities reported that the most effective practices contributing to a rapid, successful resolution of gastrointestinal outbreak included:

- Praising staff for rapid, effective handling of outbreak activities and ill patients/residents;
increasing education on the units;
- ensuring nursing leadership off shifts (supervising line listings, linen handling, environmental cleaning, and supplies);
- providing data feedback (graphs) on effectiveness of interventions to staff and physicians;
- monitoring of strict environmental cleaning/linen handling;
- ensuring visitor cooperation;
- providing access to a detailed plan; and
- ensuring administrative support.

Other practices thought by some to be influential in controlling norovirus outbreaks include a multidisciplinary team approach to tasks, direct involvement of the medical director and the director of nursing, use of commodes for symptomatic residents, and closed group activities. These findings validate the necessity for a structured norovirus control plan as described above.

**Conclusion**

Outbreaks of norovirus-associated AGE have increased nationwide in healthcare facilities. The experience of a select group of Pennsylvania healthcare facilities shows that the preseason development and implementation of a rapid response plan helps to reduce or mitigate the impact of a norovirus outbreak. Evidence-based strategies to modify host, viral, and environmental risk factors for outbreaks include preparing for norovirus season, ensuring basic outbreak control measures, using enhanced precautions, and conducting leadership and postoutbreak activities. Postoutbreak measurement of compliance with process measures is fundamental to determine the existence and extent of barriers to safe care and the effectiveness of norovirus improvement strategies.

**Notes**

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

**Five residents in ward A in a longterm facility are reported to have symptoms of acute gastrointestinal illness with complaints of vomiting, watery diarrhea, and abdominal cramps, as well as some with fever. Stool cultures rule out Clostridium difficile. Two days later, nine staff members, including several dietary staff, call out sick with the same symptom pattern. Within the next 48 hours, 16 new cases of gastrointestinal illness are reported on wards B and C. The director of nursing notifies the facility’s infection control personnel about a potential norovirus outbreak.**

1. Which of the statements below is appropriate as the first step to detect a norovirus outbreak at the facility?
   a. Immediately determine the facility-specific acute gastroenteritis (AGE) attack rate by unit.
   b. Conduct early continuous surveillance to rapidly confirm potential cases.
   c. Closely monitor all AGE cases with bloody stool.
   d. Send all diarrheal specimens to the state’s department of health bureau of laboratories.

2. Key components of an outbreak prevention/containment program for the facility include all EXCEPT:
   a. Clean surfaces and resident equipment before applying a disinfectant.
   b. Apply Kaplan’s criteria to clinically identify an outbreak.
   c. Wash hands with an antibacterial soap for 30 seconds followed by rinsing for 20 seconds.
   d. Separate residents into symptomatic, exposed but asymptomatic, and unexposed cohorts.

3. Which of the following criteria is recommended by CDC for rapid clinical diagnosis of norovirus cases such as described in the case study?
   a. Fifty percent of cases involve vomiting; incubation period ranges 24 to 48 hours; duration of illness ranges 12 to 60 hours; no bacterial pathogen in stool
   b. Nausea in 10% of cases; incubation period ranges 12 to 48 hours; bloody diarrhea 3 times in 12 hours; dehydration
   c. Vomiting twice in 24 hours; duration of illness ranges 12 to 60 hours; bacterial pathogen in stool culture; abdominal pain
   d. Fifty percent of cases involve vomiting; duration of illness ranges 12 to 24 hours; no bacterial pathogen in stool; low-grade fever

4. All of the following are risk factors that increase the potential for norovirus transmission EXCEPT:
   a. Patient age (i.e., elderly and very young)
   b. Amount of viral particles excreted by patients/residents in feces and vomitus during the first 48 hours of illness
   c. Lack of sustainable immunity following infection
   d. Viral resistance to sodium hypochlorite

5. Select the method that is least likely to contribute to transmission of norovirus.
   a. Touching mouth with hands exposed to the skin surface of a convalescing patient/resident
   b. Sanitizing environmental surfaces once a day with quaternary ammonium
   c. Cleaning the room of patients who are actively vomiting
   d. Eating fresh vegetables rinsed in the dietary hand washing sink

6. Select the appropriate measures to include in a preseason norovirus prevention plan.
   a. Education, communication protocol, staffing plan, contact precautions, resource evaluation
   b. Education, communication protocol, staffing plan, surveillance system, resource evaluation
   c. Education, communication protocol, staffing plan, surveillance system, hand hygiene
   d. Education, communication protocol, staffing plan, surveillance system, environmental cleaning

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Self-Assessment Questions

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Data Snapshot: Falls Reported by Behavioral Health Hospitals

In mid-2010, a Pennsylvania healthcare worker asked a Pennsylvania Patient Safety Authority Patient Safety Liaison which medications were related to falls in facilities licensed exclusively as behavioral health hospitals. The Authority believes that all facilities can learn from the results of a look at the Authority’s database.

The Authority looked specifically at falls reported from behavioral health hospitals. Reports from nonbehavioral health hospitals were used for comparisons. In 2009 (the last full calendar year of event reports preceding the request), falls reported by behavioral health hospitals constituted 0.9% of the overall number of falls reported to the Authority. Reports of falls in behavioral health hospitals were more likely to involve patient harm; 9.6% of behavioral health falls were Serious Events, compared to 3.7% of those submitted by other hospitals (p < 0.001 by chi-square). (See Table 1.) In 2009, falls accounted for 21.7% of submitted reports in behavioral health hospitals compared to 15.4% in nonbehavioral hospitals.

The leading associated medications at behavioral health hospitals differ from other hospitals. Table 2 lists the medication types mentioned in reports, sorted by hospital type. Antipsychotics and benzodiazepines were predominant among behavioral health hospitals and were less common in other hospitals, reflecting the differences in conditions being treated. Behavioral health hospitals reported a greater percentage of medications related to falls than other hospitals (70.3% versus 57.6%, p < 0.001 by chi-square).

The age of patients falling at behavioral health hospitals is noticeably younger than those falling at nonbehavioral health hospitals. The average age of the falling patient at behavioral health hospitals is 45 years whereas the average age at nonbehavioral hospitals is just over 65 years. The Figure presents the percentage breakdown by age cohort of behavioral health and nonbehavioral health hospitals.

Conclusion

Roughly 70% of falls reports from behavioral health hospitals and 58% from nonbehavioral health hospitals.

Table 1. Submission Type Associated with Falls Events Reported to the Pennsylvania Patient Safety Authority, 2009

<table>
<thead>
<tr>
<th>HOSPITAL</th>
<th>INCIDENT</th>
<th>Percentage</th>
<th>SERIOUS EVENT</th>
<th>Percentage</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral health hospitals</td>
<td>283</td>
<td>90.4%</td>
<td>30</td>
<td>9.6%</td>
<td>313</td>
</tr>
<tr>
<td>Nonbehavioral health hospitals</td>
<td>33,349</td>
<td>96.3%</td>
<td>1,292</td>
<td>3.7%</td>
<td>34,641</td>
</tr>
<tr>
<td>% behavioral health hospitals / total</td>
<td>0.8%</td>
<td>—</td>
<td>2.2%</td>
<td>—</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

Table 2. Medication Types Associated with Falls Events Reported to the Pennsylvania Patient Safety Authority, 2009

<table>
<thead>
<tr>
<th>MEDICATION TYPE</th>
<th>FALLS EVENTS AT BEHAVIORAL HEALTH HOSPITALS (N = 313)</th>
<th>FALLS EVENTS AT NON-BEHAVIORAL HEALTH HOSPITALS (N = 34,641)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percentage*</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>55</td>
<td>17.6%</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>54</td>
<td>17.3%</td>
</tr>
<tr>
<td>Antiseizures</td>
<td>33</td>
<td>10.5%</td>
</tr>
<tr>
<td>Cardiovasculars</td>
<td>17</td>
<td>5.4%</td>
</tr>
<tr>
<td>Opiates</td>
<td>7</td>
<td>2.2%</td>
</tr>
<tr>
<td>Diuretics</td>
<td>6</td>
<td>1.9%</td>
</tr>
<tr>
<td>Laxatives</td>
<td>4</td>
<td>1.3%</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>1</td>
<td>0.3%</td>
</tr>
<tr>
<td>Other</td>
<td>43</td>
<td>13.7%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>220</td>
<td><strong>70.3%</strong></td>
</tr>
</tbody>
</table>

* Percentages calculated on number of falls in each medication category, not accounting for the lack of medications involved nor multiple medications. Additionally, not all submissions noted medications.
hospitals indicate medications were possibly involved in the fall. This shows that facilities should consider the medications that are being administered and how they may increase their patients’ risk of falls.

1. Falls from behavioral health hospitals were more likely to be reported as harming the patient, according to the Authority data.

2. A higher proportion of falls reported from behavioral health hospitals are medication-related than at nonbehavioral health hospitals.

3. Patients in fall reports from behavioral health facilities are noticeably younger than in those from nonbehavioral health hospitals.
Wrong-site surgery continues in Pennsylvania, with the rate of approximately one report per week, despite the availability of evidence-based best practices (see Figure). As usual, this quarterly report has been updated to include any belated additions and corrections from previous quarters. The 13 reports for this quarter (July 1 through September 30) were similar to those for previous quarters; wrong-site anesthetic blocks were the most commonly reported events (three), with two reports of wrong vertebral level, two reports of wrong-site hand surgery, two reports of wrong-eye surgery, and two reports of wrong-side pain blocks.

This quarterly *Pennsylvania Patient Safety Advisory* article summarizes and updates the evidence base for the 18 best practices for preventing wrong-site surgery that are associated with the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™. Two more have been added for this update. Those principles addressing prevention of wrong-site surgery after the time-out are not included. Facilities may wish to use this information to inform surgeons and anesthesiologists of the rationale behind implementing best practices for following the Universal Protocol.

**Principle.** The correct site of the operation should be specified when the procedure is scheduled.

**Evidence.** An analysis of data in the retrospective review of 161 serious reportable events of wrong-site surgery showed that 7 (4%) were associated with misinformation on the operating room (OR) schedule. A later regression of the number of wrong-site scheduling errors and wrong-site surgeries per facility showed that wrong-site scheduling errors accounted for 5% of wrong-site surgery errors ($R^2 = 0.05$) and there was an increase of 1 wrong-site surgery for every 10 wrong-site scheduling errors. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none showed that preadmission verification included verification of the schedule in 63% of the facilities that had wrong-site surgery and 83% of the facilities that had none, a statistically significant difference ($p < 0.05$).

**Principle.** The correct operation and site should be noted on the record of the history and physical examination.

**Evidence.** In the retrospective comparison of 253 near-miss reports, in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the information on the informed consent was 2.1 times more likely to be a source for correction ($n = 48$) than a source for error ($n = 23$). An analysis of data in the retrospective review of 161 serious reportable events of wrong-site surgery showed that 12 (7%) were associated with misinformation on the informed consent. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none showed that the side of the procedure, when applicable, was required to be included in the consent in 89% of the facilities that had wrong-site surgery and 99% of the facilities that had none, a statistically significant difference ($p < 0.01$).

**Principle.** Anyone reviewing the schedule, consent, history and physical examination, or reports documenting the diagnosis, should check for discrepancies among all those parts of the patient’s record and reconcile any discrepancies with the surgeon when noted.

**Evidence** (in addition to the above information about the value of appropriate information on the schedule, the record of the history and physical examination, and the informed consent). In the retrospective comparison of 253 near-miss reports, in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the preoperative verification of the patient’s record by the preoperative nurse was
Evidence. In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,\(^2\) patients were identified by both information from their charts and their wristbands in 99% of the near-miss events and in 85% of the wrong-site surgery events, a statistically significant difference ($p < 0.05$).

Principle. Any discrepancies in the information should be resolved by the surgeon, based on primary sources of information, before the patient enters the OR.

Evidence. As noted above, in the retrospective comparison of 253 near-miss reports,\(^2\) in which the potential error was caught before patient contact, and 174 events in which the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,\(^2\) the surgeon did a preoperative verification in 91% of the near-miss events and in 74% of the wrong-site surgery events, a statistically significant difference ($p < 0.05$).

Principle. The site should be marked by a healthcare professional familiar with the facility’s marking policy, with the accuracy confirmed both by all the relevant information and by an alert patient or patient surrogate if the patient is a minor or mentally incapacitated.

Evidence. An analysis of data in the retrospective review\(^2\) of 161 serious reportable events of wrong-site surgery showed that 6 (4%) were associated with misinformation based on the site marking. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none\(^4\) showed that the site markings were required to be verified against all documents in 62% of the facilities that had wrong-site surgery and 89% of the facilities that had none, a statistically significant difference ($p < 0.01$).

New Principle. The site should be marked by the provider’s initials.

Evidence. In recent, unpublished comparisons—in a second region of Pennsylvania—of 169 observations of compliance with the Universal Protocol in 12 facilities that had wrong-site surgery and 6 facilities that had none, all documents were verified during the time-out in 92% of the cases in facilities that had wrong-site surgery and 100% of the cases in facilities that had none, a statistically significant difference ($p < 0.05$).

Principle. All verbal verification should be done using questions that require an active response of specific information, rather than a passive agreement.

Evidence. In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,\(^3\) patients stated their dates of birth as part of the preoperative identification in 100% of the near-miss events and in 95% of the wrong-site surgery events, a statistically significant difference ($p < 0.05$).

Principle. Patient identification should always require two unique patient identifiers.
patient contact occurred at the wrong site, the circulating nurse was 5.3 times more likely to be a source for correction (n = 21) than a source for error (n = 4). An analysis of data in the retrospective review of 161 serious reportable events of wrongsite surgery showed that 12 (7%) occurred with misinformation on the consent, 11 (7%) occurred with misinformation on the history and physical examination, and 7 (4%) occurred with misinformation on the OR schedule.

**Principle.** Separate formal time-outs should be done for separate procedures, including anesthetic blocks, with the person performing that procedure.

**Evidence.** As reported in an Advisory update, wrongsite anesthetic blocks represent 29% of all reports of wrongsite procedures in the surgical suite as of December 2009.

**New Principle.** All noncritical activities should stop during the time-out.

**Evidence.** In recent, unpublished comparisons—in a second region of Pennsylvania—of 31 observations of the time-out processes in 10 facilities that had wrongsite surgery and 4 facilities that had none, noncritical activities stopped in 9% of the cases in facilities that had wrongsite surgery and 75% of the cases in facilities that had none, a statistically significant difference (p < 0.001).

**Principle.** The site mark should be visible and referenced in the prepped and draped field during the time-out.

**Evidence.** In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrongsite surgeries, using a common event analysis form, the time-out was done after the patient was prepped and draped in 88% of the near-miss events and in 64% of the wrongsite surgery events, a statistically significant difference (p < 0.01); the mark was visible in 87% of the near-miss events and in 69% of the wrongsite surgery events, a statistically significant difference (p < 0.05). In recent, unpublished comparisons—in a second region of Pennsylvania—of 169 observations of compliance with the Universal Protocol in 12 facilities that had wrongsite surgery and 6 facilities that had none, the time-out was done after the patient was prepped and draped in 85% of the cases in facilities that had wrongsite surgery and 100% of the cases in facilities that had none, a statistically significant difference (p < 0.01).

**Principle.** Verificaton of information during the time-out should require an active communication of specific information, rather than a passive agreement, and be verified against the relevant documents.

**Evidence.** In recent, unpublished comparisons—in a second region of Pennsylvania—of 169 observations of compliance with the Universal Protocol in 12 facilities that had wrongsite surgery and 6 facilities that had none, all documents were verified during the time-out in 66% of the cases in facilities that had wrongsite surgery and 86% of the cases in facilities that had none, a statistically significant difference (p < 0.05); critical diagnostic test results and/or imaging studies were verified during the time-out in 73% of the applicable cases in facilities that had wrongsite surgery and 100% of the applicable cases in facilities that had none, a statistically significant difference (p < 0.01).

**Principle.** All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.

**Evidence.** In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrongsite surgeries, using a common event analysis form, the nurse, the surgeon, and the anesthesia provider were all involved in 98% of the near-miss events and in 88% of the wrongsite surgery events, a statistically significant difference (p < 0.05).

**Principle.** The surgeon should specifically encourage operating team members to speak up if concerned during the time-out.

**Evidence.** The statewide comparison of policies and procedures in 37 facilities that had wrongsite surgery and 96 facilities that had none showed that including an explicit request by the surgeon for operating team members to speak up if concerned during the time-out was cited in 40% of the facilities that had wrongsite surgery and 76% of the facilities that had none, a statistically significant difference (p < 0.05).

**Principle.** Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed.

**Evidence.** In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrongsite surgeries, using a common event analysis form, operating team members raised concerns in 79% of the near-miss events and in 22% of the wrongsite surgery events, a statistically significant difference (p < 0.001).

**Principle.** Any concerns should be resolved by the surgeon, based on primary sources of information, to the satisfaction of all members of the operating team before proceeding.

**Evidence.** In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrongsite surgeries, using a common event analysis form, the surgeon addressed concerns that were raised in 82% of the near-miss events and in 40% of the wrongsite surgery events, a statistically significant difference (p < 0.001).

Notes


Letters to the Editor

Marking the Nonoperative Site

I’m writing to ask for the Pennsylvania Patient Safety Authority’s assistance and guidance on an issue related to our ongoing efforts to eliminate wrongsite or wrong-side surgery. We’re having an internal discussion within our organization as to the value or danger of marking the nonoperative site or side in addition to marking the operative site. As you know, all the literature rightly indicates that we should clearly and unambiguously mark the operative site. There are some in our organization who feel it increases safety to also mark the nonoperative site with something like “Not this side.” There are others who feel that this decreases safety in that marking a nonoperative site or side will eventually lead to a procedure being done on the wrong side by virtue of misinterpretation of the mark at that site. We’d be very interested in any guidance or information you or any of your readers can supply.

Gary A. Merica, RPh
Quality Manager for Pharmacy Services and Medication Safety Coordinator, York Hospital

Editor’s Note

The Pennsylvania Patient Safety Authority’s database contains no records of either someone doing wrongsite surgery because of a “No” mark or of someone avoiding wrongsite surgery because of a “No” mark, so the Authority’s opinion is based on theory. The purpose of the mark is to maintain proper orientation in the operating room. At a theoretical level, a “Not this side” mark could lead to two errors, one of which has been reported to the Authority. The first problem, which the Authority’s analysts have seen instigated by a variety of cues, is confirmation bias. The team could see the mark, without reading it properly or entirely, and be misled into thinking that it was the operative mark. This could be especially true if it was not standard practice throughout the hospital. The second problem is that the mark is referenced in the prepped and draped field, so that a partially visible mark, “this side,” might be interpreted as the correct-side surgical site mark. If the surgeon is adamant about marking the nonoperative site, the Authority’s analysts strongly suggest doing it in such a way that it could not possibly be confused with the site mark even by someone who could not read English. For example, the surgeon could use a large red-dot sticker or a large Band-Aid® on which he or she wrote “NO.”

Silver-Coated Catheters in an MR Environment

With the new catheter-associated urinary tract infection prevention strategies, some institutions, including ours, are starting to utilize silver-coated urinary catheters on certain high-risk patients. I was asked by other hospital staff if there are risks associated with the use of silver-coated urinary catheters in patients undergoing magnetic resonance imaging scans due to the metallic composition of the silver coating. I contacted a catheter manufacturer, and they assured me that their silver-coated catheter product was safe in a magnetic resonance environment. I would like to know if the Pennsylvania Patient Safety Authority is aware of any events that have occurred with silver-coated urinary catheters.

Eugene F. Anderson, RN, MSN, CCRN
Corporate-Clinical Educator
Good Shepherd Rehabilitation Network

Thank you for your inquiry regarding compatibility between silver-coated urinary catheters and magnetic resonance imaging (MRI) scans. Currently, Pennsylvania Patient Safety Authority analysts are not aware of any published literature addressing the use of silver-coated catheters in a magnetic resonance (MR) environment. To date, there have been no reports involving silver-coated catheters used in the MR environment submitted to the Authority through its reporting system. Additionally, a review of the U.S. Food and Drug Administration’s (FDA) Manufacturer and User Facility Device Experience database did not reveal any reports.

Because silver is a nonferromagnetic metal, the silver coating on the catheter would not be affected by the magnetic effects of the MR field. However, MRI scans do use radio-frequency energy, which can induce electric currents within electrical conductors, possibly heating the conductors and potentially causing patient burns. This phenomenon is unlikely with silver-coated catheters, but in the absence of empirical data, cannot be ruled out entirely. Image artifact or distortion may be an issue given the location of the silver-coated catheter in relation to the body part being scanned. The specific catheter manufacturer may be the best source for information regarding the compatibility between silver-coated catheters and MRI scans. With this, and any other MR procedure, the patient should be monitored and instructed to immediately report any unusual pain or heating and the scan suspended until the cause of the pain has been determined. Any occurrences of patient pain or burns related to silver-coated catheter use during MRI scans should be reported to the catheter manufacturer, to facility internal and external reporting systems (e.g., the Authority), and to regulatory agencies (e.g., FDA) to aggregate and analyze data to identify potential compatibility issues between silver-coated catheters and MRI.
Meeting the Challenges Associated with Morbidly Obese Patients

Richard M. Kundravi, BS
Patient Safety Liaison, Northwest Region
Pennsylvania Patient Safety Authority

Obesity is one of the most common chronic health problems in the United States. Because of the many diseases associated with obesity, an increasing number of obese individuals are in need of healthcare services. Caring for the morbidly obese patient poses a significant challenge. However, careful planning for the continuum of care of morbidly obese patients using a multidisciplinary approach associated with appropriate training and equipment will help prevent adverse outcomes and injuries. Planning and correct implementation also ensure that facilities can treat morbidly obese patients with the same dignity and respect as any other patient.

Hospitals in the northwest region of Pennsylvania have reported adverse diagnostic and treatment delays in caring for the morbidly obese patient. Further review of these events has identified causal factors such as weight and circumference restrictions for computed tomography scanning, inadequate transport equipment, and lack of appropriately sized resuscitation and monitoring equipment such as ventilation masks and blood pressure cuffs. According to the Centers for Disease Control and Prevention’s report, “State Specific Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, trends 1976-1980 through 2007-2008,” 49 states have obesity rates greater than 20%.1

Morbidly obese individuals often resist seeking healthcare and frequently defer hospitalization until the last minute.2 Morbidly obese patients may not present until late in the course of their illness due to mobility and transportation problems. Also, embarrassment and perceived or real resentment from healthcare providers may dissuade morbidly obese patients from seeking treatment.

According to the U.K.’s Dartford and Gravesham NHS Trust, morbidly obese patients represent a variety of medical, physical, and emotional challenges for healthcare providers, including the following:3

- Hyperventilation is the typical respiratory pattern of many morbidly obese patients, because the lungs do not increase in size with the patient.
- The diaphragm is unable to fully descend because of adipose tissue and chest expansion is impaired, which results in decreased vital capacity and tidal volume that compromises tissue oxygenation.
- The heart is typically enlarged as a result of the strain of supplying oxygenated blood to all tissues.
- Obesity can cause venous hypertension, which increases the risk of pulmonary embolism and decreases mobility due to insufficient circulation.
- Intravenous access can be difficult because the excessive amounts of subcutaneous tissue present in morbidly obese patients makes it difficult for the veins to be seen and very difficult to palpate.
- If an intravenous line is inaccessible, a central line has to be considered, but the morbidly obese patient is at risk for a possible yeast infection in the skin folds.
- The ratio of skin area to body mass is lower in the morbidly obese patient in comparison to the average-weight patient and this larger body mass, combined with smaller relative skin areas, leads to increased perspiration and difficulty controlling body temperature.
- Airway management of a morbidly obese patient is difficult due to a tendency for the morbidly obese patient to have a short thick neck, increased soft tissue (“double chin”), and an enlarged tongue, as well as the potential for subcutaneous emphysema.
- Morbidly obese patients will desaturate oxygen rapidly due to decreased functional reserve capacity.
- Morbidly obese patients have different body types that each need different treatment and techniques. The body type can affect breathing and tolerance to movement as well as the risk of falls sustaining unexpected injuries. For example, an “apple-shaped” patient will have excessive adipose tissue in the viscera or abdominal area. This adipose tissue can press on the aorta, vena cava, and small capillaries, causing increased stress on the cardiovascular and respiratory systems, increasing the risk of positional asphyxiation.
- Morbidly obese patients are at a higher risk of cellulitis and for skin breakdown associated with impaired mobility.
- Morbidly obese patients are subjected to intense prejudice and discrimination because their condition is often perceived to be under the control of the individual which leads to low self esteem. Because these medical and physical limitations pose significant clinical risks to the morbidly obese patient, some hospitals have taken a more proactive approach. For example, UPMC McKeesport, an acute care community hospital in the southwest region of Pennsylvania, conducted a failure mode and effects analysis in an effort to anticipate patient and staff needs associated with the
care and treatment of morbidly obese patients. The hospital identified opportunities for improvement associated with equipment availability, facility design, repositioning/transfer protocol, and the patient discharge process. To assist staff, the hospital developed algorithms for repositioning that addressed the lateral transfer to and from bed-to-stretcher/stretcher-to-bed and the transfer to and from bed-to-chair/chair-to-toilet/chair-to-chair. The hospital also developed morbidly obese patient discharge flow diagrams that address routine discharge and discharge with durable medical equipment. (Upon login, Pennsylvania patient safety officers and their delegates can view the algorithms and diagrams at the Pennsylvania Patient Safety Authority’s secure Patient Safety Knowledge Exchange (PassKey) website.)

In addition to meeting the medical and physical challenges of morbidly obese patients, it is also important for healthcare providers to effectively interact with and demonstrate consideration for morbidly obese patients. One paradigm healthcare providers can follow is the RESPECT Model, which identifies key patient needs and concerns as follows:

■ Rapport
■ Environment/Equipment
■ Safety
■ Privacy
■ Encouragement
■ Caring/Compassion/Tact

Obesity is a costly condition that can reduce quality of life and increases the risk for many serious chronic diseases and premature death. Careful planning and the development of training programs designed to educate staff on the medical, physical, and social needs of the morbidly obese patient can help ensure that these patients receive the same level of care and intensity of services as any other patient.

Notes


“EVAC” Sticker Program for Emergency Response

Allied Services has developed a program that helps to identify special needs individuals (e.g., those who have physical limitations) who may require additional assistance during emergency response.

While working to meet requirements of the Commission on Accreditation of Rehabilitation Facilities, Allied Services Rehabilitation Hospital (Scranton) noted a lack of ready resources to identify special needs individuals for emergency medical services (EMS) personnel during an emergency response. The hospital developed a green identifying sticker, an “EVAC” label, for this purpose and discussed it with local EMS providers and fire department representatives, who supported the idea to begin distributing the stickers to appropriate individuals. Currently, the Scranton location, Allied Services’ John Heinz Rehabilitation Hospital in Wilkes-Barre, and 15 outpatient centers distribute the stickers to appropriate patients during discharge.

For more information about the Allied Services program or to request stickers for distribution, visit https://www.allied-services.org/evacsticker. Patient safety officers in Pennsylvania can also read more about the initiative on the Pennsylvania Patient Safety Authority’s secure Patient Safety Knowledge Exchange (PassKey) website.
Online Resources Associated with Patient Safety Advisories

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

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

- Preventing wrong-site surgery
- Aspiration screening
- Diagnostic radiation and pregnancy
- ASF patient screening and assessment
- Hospital bed safety
- Airway fires during surgery
- Color-coded wristbands
- Common hazards in the behavioral health patient room

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

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

If you would like additional information, please contact us at (866) 316-1070, or e-mail support_papsrs@state.pa.us.
An Independent Agency of the Commonwealth of Pennsylvania

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

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

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