



## Patient Safety Authority Update

It has been nine months since PA-PSRS was implemented throughout Pennsylvania, and more than 110,000 reports of Serious Events and Incidents will have been submitted by the time this publication goes to press. But, as we repeatedly stress, the point of PA-PSRS is not in the number of reports we receive but in what facilities do with the information contained in those reports.

That is why the articles included in the Patient Safety Advisories are based on actual reports submitted through PA-PSRS. In the recent User Survey conducted late last year, an overwhelming majority (95%) of respondents found the Advisories a useful resource, and nearly one-third of respondents reported making changes in their facilities as a result of Advisory articles. These are significant statistics, given a 62% response rate from more than 420 facilities subject to Act 13 reporting requirements.

While a large majority of Patient Safety Officers distribute the Advisories to other staff, only a third reported distributing it to all staff in their facility. This is substantiated by our own conversations with physicians, nurses, and other clinical staff—many of whom are unfamiliar with the Advisories. The infor-

mation contained in Advisory articles is relevant for all clinicians, and we hope you will distribute the document to as many people in your facility as possible, especially given the ease of electronic email distribution.

We also want to encourage you to use the analytical tools built into the system. Of those facilities responding to the User Survey who use these tools, many report using them for risk and quality management, trend analysis, and Patient Safety Committee meetings. Many others use the tools to prepare reports for senior management and trustees.

As we noted during our commemoration of Patient Safety Awareness Week earlier this month, patient safety is everyone's business, and it must be everyone's priority—from hospital trustees and administrators to individual physicians, nurses, pharmacists, technicians, and other healthcare workers. If your facility is going to be successful in creating a "culture of safety" which encourages full and open disclosure, then you must include your entire facility staff in patient safety initiatives and quality improvement efforts.

## When Patients Speak—Collaboration in Patient Safety

The patient is one of the most important allies in reducing medical errors.<sup>1</sup> Research indicates that when patients actively participate in their overall healthcare management, medical errors are reduced.<sup>2,3</sup> The Institute of Medicine (IOM) reports have supported this concept, as well. *To Err is Human: Building a Safer Health System* not only reported that as many as 98,000 deaths occur annually due to medical errors, but also indicated that poor physician-patient communication was one of the root causes.<sup>4</sup> The next IOM report, *Crossing the Quality Chasm: A New Health System in the 21<sup>st</sup> Century*,<sup>5</sup> encouraged patients to exercise control of healthcare decisions by using a shared decision-making process with their physicians, with the goal of improving the quality of care.<sup>2</sup> In its most recent report, *Patient Safety: Achieving a New Standard of Care*, the IOM suggested that

"patient safety programs...invite the participation of patients and their families and be responsive to their inquiries."<sup>6</sup>

Though improving patient safety in healthcare historically has not included the patient's perspective,

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**When Patients Speak—Collaboration in Patient Safety (Continued)**

patients have a key role in promoting their own safety.<sup>7</sup> Some of the ways in which patients can help their clinicians in this respect include: identifying side effects or adverse events quickly so that appropriate action can be taken; ensuring that treatment is given, monitored, and complied with appropriately; choosing an experienced, safe practitioner; deciding upon a strategy for management or treatment of health problems; and helping to achieve an accurate diagnosis or analysis of a health-related issue.<sup>7</sup>

**PA-PSRS Reports**

Reports submitted to PA-PSRS indicate that patients and family members who speak up about patient care issues have not only identified medical errors but have also prevented errors and injuries. Following are just a few examples of the hundreds of such reports submitted to PA-PSRS over the past six months:

- A nurse was providing education to a patient and spouse prior to flushing a PICC line. When the nurse mentioned Heparin, the spouse spoke up and said that the patient was allergic to Heparin. The nurse reviewed the chart and found no Heparin allergy documented. The allergy had been documented on the patient’s transfer record and had not been transcribed onto the chart. New orders were obtained for flushing this patient’s PICC line using saline only.
- An OR schedule indicated that the patient was to have a tonsillectomy and adenoidectomy. The parent stated, however, that the child was to have a tube removal, excision of polyp, and application of a tympanic membrane patch. An investigation revealed that the initial reservation from the surgeon’s office was incorrect. Clarifications were made, and the correct procedure was performed.
- A patient’s husband approached nursing staff asking if “that band is still supposed to be tied so tight around her arm.” When the patient’s IV had been started two hours earlier, the nurse had forgotten to remove the tourniquet.
- The patient’s son picked up his father who was discharged from the hospital. While en route home, he noticed that his father still had IV access in place. The son telephoned the hospital, and arrangements were made for removal of the IV access.
- A technician was paged for a stat chest X-ray on a patient in a certain bed number. The order was not yet in the computer system. The parent questioned the test. The tech confirmed with the secretary that the test was for that bed. The parent continued to resist the test, at which time the physician was contacted. The X-ray was indeed intended for another patient in a bed that was mislabeled with the incorrect bed number.

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## When Patients Speak—Collaboration in Patient Safety (Continued)

### Opportunities for Improvement

In most instances, PA-PSRS reports indicate that when patients speak up, clinicians listen and take appropriate action. However, sometimes an error still occurs despite the opportunity for recovery provided by a patient's attentiveness and communication. In order to reveal communication barriers, examples of such occurrences are presented below. Opportunities for improvement present themselves through these cases.

### Explaining Medical Terminology

Medical errors may occur when a patient or family member doesn't understand medical terminology.

- A patient with a dye allergy was ordered a CT scan with contrast. "No allergies" was noted on the admission orders. The allergy was noted on the MAR, but not on the Patient Care Kardex. The nurse asked the patient if he had an allergy to "contrast," but the patient said "no" because he did not realize that the term meant IV dye. The patient was started on the contrast infusion and only later reported the allergy.
- A physician called the spouse of an elderly patient to obtain consent for a PEG tube insertion, and the spouse agreed. The next day, the daughter visited and complained that a PEG/feeding tube was against the family's wishes. Upon investigation, the spouse did not understand that what he agreed to was a feeding tube procedure.

These occurrences may have been prevented if lay terms had been used instead of professional terminology.

### Not Listening

There are some PA-PSRS reports that indicate that the patient's concern may have been minimized or dismissed.

- A laboratory technician came to the incorrect patient's room to draw blood for cardiac enzymes. The patient asked why she was having the blood drawn when her diagnosis was kidney stones and she had already had blood drawn that morning. The tech said to the patient that she didn't know why and drew the blood anyway, even though a patient ID band and name tag above the bed were present.
- A patient told a lab tech not to draw blood from the right arm, but blood was drawn from that arm anyway. There was an order not to use that

arm because it was to be used for a dialysis shunt. The patient also was wearing a color-coded bracelet indicating that the arm should not be used for blood draws.

*Patients have a key role to play in promoting their own safety in the healthcare system.*

Sometimes, such errors occur because the healthcare worker is busy caring for many patients. The focus may be upon accomplishing a multitude of tasks, and sensory overload may occur. As a result, the patient's words may not be heard. Another potential contributing factor may be the traditional model of healthcare interaction that has historically been instilled in healthcare workers. This is a dominance-subordination (parent-child) model in which clinicians are considered the experts and the primary decision makers regarding the patient's care. In this model, patients are expected to be passive and compliant, supplying information when asked, and following through with the healthcare professional's advice.<sup>8-12</sup>

A clinician imbued with the traditional medical model may simply disregard patients' comments as being uninformed and without merit. This dominance-subordination medical model subverts patient care by discouraging collaboration.<sup>8</sup> Communication is inhibited, and the potential for patient involvement in patient safety is prevented.

Over the past 30 years, however, the asymmetrical power distribution between clinicians and patients has become more balanced.<sup>10</sup> The relationship is becoming similar to an adult-adult relationship, rather than that of parent-to-child.<sup>11</sup> The new patient role is one of empowerment. The distribution of power between the patient and clinician is such that patients are in greater control of their health and encounters with clinicians.<sup>10</sup> The clinician respects the patient and is a resource in assisting the patient in making informed decisions.<sup>9,12</sup>

The patient empowerment model has been used to address diverse health issues such as: ethical decision making,<sup>10</sup> diabetes management,<sup>14-16</sup> total hip and knee replacement recovery,<sup>17</sup> improving staff handwashing in hospitals,<sup>18</sup> management of end-stage renal disease,<sup>19</sup> and prevention of medical errors.<sup>2</sup> Collaboration with patients and their families provides for more safeguards to be built into healthcare systems and processes.<sup>8</sup> With several different perspectives that patients, families, and clinicians

## When Patients Speak—Collaboration in Patient Safety (Continued)

can provide, safety improvement opportunities can be identified more quickly and effectively.<sup>8</sup>

### Respect, But Verify

Many reports submitted to PA-PSRS indicate that, instead of ignoring the patient, the patient's word is too hastily accepted as accurate. This can result in an error when the patient's information is not independently verified prior to an intervention.

- A patient was scheduled for a right shoulder ORIF. The anesthesiologist asked the patient if she was having surgery on her left shoulder, to which the patient replied, "Yes." The anesthesiologist performed an intrascalene block on the left shoulder. After the block was administered, the nurse informed the anesthesiologist that the surgical consent was for a *right* shoulder ORIF. Having a time out protocol that requires all surgical team members and the patient to be present for site verification may have prevented this occurrence. Also, avoiding the use of a leading question may have avoided this event, i.e., asking which site was to undergo surgery, rather than designating a specific site in the verification question.
- A patient was scheduled for a CT scan of the abdomen. She denied pregnancy in the ED, and the CT scan was performed. Thereafter, a physician notified the Imaging Department that at the time of the CT scan, the patient was 12 weeks pregnant. An HCG test prior to imaging may have prevented this occurrence.

### No/Delayed/Inappropriate Patient Communication

Several reports submitted to PA-PSRS reflect patients not communicating or delays in communicating with clinicians. For example, a patient being interviewed for the presence of metallic objects in preparation for an MRI forgot she had an implanted insulin pump. After the MRI, the pump alarm was sounding, and the pump indicated "motor error." Sliding scale insulin coverage was implemented, and a replacement pump was ordered.

At times, patients/families speak out in inappropriate ways. A patient's husband was anxious and impatient, stating he wanted a "real" doctor to assess his wife's pain. There were four nurses present at the patient's bedside. The husband called out to the unit clerk to call a code. The code was called unnecessarily. While the communication may have been inappropriately conveyed, patients and families are speaking out about an unmet need. The challenge

for clinicians is to identify that need and address it effectively and constructively.

### Healthcare Professional Communication Skills

Studies of physician communication indicated that physicians redirect and interrupt a patient's initial descriptions of their concerns after an average of only 18 to 23.1 seconds.<sup>20,21</sup> This discourages patients from providing complete histories, and can result in missed opportunities to gather important information. The order in which patients discuss their problems does not necessarily relate to their clinical importance.<sup>20</sup> Assuming that the chief complaint is the first complaint mentioned by the patient may be inaccurate.

The key to creating effective provider-patient relationships is communication.<sup>8</sup> Improving communication skills of healthcare providers to encourage patient information sharing improves the accuracy and quality of the information received, thus reducing the potential for medical error,<sup>1</sup> missed diagnoses, and forgotten patient history information. In addition, clinicians who learn communication and information-sharing skills are better prepared to interact with empowered patients.<sup>8</sup>

Increasingly, improving communication skills have become a component of medical school curricula.<sup>11,22-24</sup> Common concepts in communication skills programs for clinicians include opening discussions by inviting/welcoming the patient's participation.<sup>1,24,25</sup> No question is considered too stupid/unreasonable, and no information is too trivial to share.<sup>1</sup>

Active listening is used to gather information, balancing the use of both open and closed questions.<sup>24-26</sup> Discussion is encouraged without interruption or premature closure.<sup>20</sup> Nonverbal indications, as well as how the information is spoken, are identified<sup>26</sup> that might suggest what the patient is experiencing—emotions, conflicts, concerns. This allows a fuller understanding of the patient's perspective.<sup>24</sup> Other skills include reflecting back to the patient by summarizing information that the patient has shared and requesting/accepting corrections and clarifications from the patient.<sup>26</sup> One concept is "Don't just do something, stand there!"—pausing several seconds may allow the patient to feel understood and that the information imparted is being respected and taken seriously.<sup>26</sup> Finally, clinicians can check with the patient repeatedly for any additional concerns.<sup>20</sup> The University of Colorado School of Medicine incorporates these techniques into the concepts of "Invite, Listen, Summarize."<sup>25</sup>

## When Patients Speak—Collaboration in Patient Safety (Continued)

Table 1. Phrases that May Encourage Patient Communication

### Questions

Can you tell me a little more about that?  
Is there anything else?  
What has this been like for you?  
Are you OK with that?

### Clarifications

Let me see if I have this right.  
I want to make sure I understand what you're telling me. I'm hearing that...  
When I'm done, please correct me if I don't have this right. OK?

### Responses

That sounds very difficult.  
Sounds like...  
I can imagine that this might feel...  
Anyone in your situation would feel that way...  
I can see that you are...  
I bet you're feeling pretty good about that.

Source: Adapted from Coulehan JL, Platt FW, Egener B, et al. "Let me see if I have this right...": words that help build empathy. *Ann Intern Med.* 2001;135:221-7.

Table 1 presents phrases clinicians can use to encourage open patient communication. Written instruction on such skills is helpful. But opportunities to practice these skills and to receive feedback on these new behaviors are vital to ensure that these skills are internalized and used effectively.<sup>11</sup>

### Patient Communication Skills

Just as clinicians benefit from programs to improve their communication skills, patients can also learn skills to effectively interact with clinicians. Patients can unlearn the old ways of interacting according to the traditional model. Communication skills education helps patients develop respect for their own abilities and opinions.<sup>12</sup> Educating patients to become knowledgeable about their healthcare needs and to assume active roles when interacting with healthcare professionals promotes more effective and efficient care and may help to prevent medical errors.<sup>2</sup>

Patients who feel powerless under the traditional medical model do not automatically become empowered, and need a process to find their own voice.<sup>12</sup> Most patient education programs promote disease-oriented information or develop self-care

skills, such as self-administration of medications or disease prevention concepts.<sup>11</sup> There are fewer patient education programs devoted to the development and improvement of communication skills.<sup>11</sup>

Communication skills that can help patients to be effective partners in their own care include: clearly describing medical problems or experiences with illness; clarifying expectations; asking for information, as well as clarification; exploring alternatives with the clinicians; providing information; stating preferences; working with an advocate, if necessary; providing feedback; active listening; being constructively assertive; negotiating differences; being mindful of interruptions and topic changes and re-focusing conversations with clinicians on mutual concerns.<sup>11</sup>

### Notes

- Meyer GS, Arnheim L. The power of two: improving patient safety through better physician-patient communication. *Family Practice Management* [online]. 2002 Jul/Aug [cited 2005 Jan 13]. Available from Internet: <http://www.aafp.org/fmp/20020700/47thep>.
- Awe C, Lin SJ. A patient empowerment model to prevent medication errors. *J Med Syst* 2003 Dec;27(6):503-17.
- Cohen M. Causes of medication errors. In: Cohen M, ed. *Medication errors*. Washington (DC): American Pharmaceutical Association; 1999.
- Institute of Medicine. *To err is human: building a safer health system*. Washington (DC): National Academy Press; 2000.
- Institute of Medicine. *Crossing the Quality Chasm: a new health system for the 21<sup>st</sup> century*. Washington (DC): National Academy Press; 2001.
- Institute of Medicine. *Patient safety: achieving a new standard of care*. Washington (DC): National Academy Press; 2004.
- Vincent CA, Coulter A. Patient safety: what about the patient? *Quality & Safety in Health Care* 2002;11:76-80.
- Spath PL. Can you hear me now? Providers must give patients a voice in efforts to reduce medical errors. *Hospital Health Network* 2003 Dec;77(12):36-40, 49. Citing: Spath PL. *Partnering with patients to reduce medical errors*. Chicago (IL): AHA Press; 2004.
- Lau DH. Patient empowerment – a patient-centered approach to improve care. *Hong Kong Med J* 2002 Oct;8(5):372-4.
- Williams T. Patient empowerment and ethical decision making: the patient/partner and the right to act. *Dimensions of Critical Care Nursing* 2002 May/Jun;21(3):100-104.
- Sharf BF. Teaching patients to speak up: past and future trends. *Patient Education and Counseling* 1988;11:95-108.
- Roberts SJ. Health promotion as empowerment: suggestions for changing the balance of power. *Clin Excell Nurse Pract* 1998 May;2(3):183-7.
- Bruegel RB. Patient empowerment – a trend that matters. *JAHIMA* 1998 Sep;69(8):30-3.
- Funnell MM, Anderson RM. Empowerment and self-management of diabetes. *Clinical Diabetes* 2004;22(3):123-7.
- MacKinnon M. Empowering people with diabetes helps them make informed choices. *Prof Nurs* 2003;19(3):168-70.

## When Patients Speak—Collaboration in Patient Safety (Continued)

16. Adolfsson ET, Smide B, Gregeby E, et al. Implementing empowerment group education in diabetes. *Patient Educ Couns* 2004 Jun;53(3):319-24.
17. Loft M, McWilliam C, Ward-Griffin C. Patient empowerment after total hip and knee replacement. *Orthopaedic Nursing* 2003 Jan/Feb;22(1):42-47.
18. McGuckin M. Improving handwashing in hospitals: a patient education and empowerment program. *Leonard Davis Institute of Health Economics* 2001 Nov;7(3):1-4.
19. Tsay SL, Hung LO. Empowerment of patients with end-stage renal disease – a randomized control trial. *Int J Nurse Stud* 2004 Jan;41(1):59-65.
20. Silverman J, Draper J. Identifying the agenda in consultation. *Br J Gen Pract* 1995 Jan;45(390):52-3.
21. Marvel MK, Epstein RM, Flowers K, et al. Soliciting the patient's agenda. *JAMA* 1999 Jan 20;281(3):283-7.
22. Ellner A, Hoey A, Frisch L. Speak up! *BMJ* 2003 Aug 9;327:303-304.
23. Laine C, Davidoff F. Patient-centered medicine: a professional evolution. *JAMA* 1996;275:152-6.
24. Haq C, Steele DJ, Marchand L, et al. Integrating the art and science of medical practice: innovations in teaching medical communication skills. *Jam Med* 2004 Jan Suppl;36:543-50.
25. Boyle D, Dwinnell B, Platt F. Invite, listen, and summarize: a patient-centered communication technique. *Acad Med* 2005 Jan;80(1):29-32.
26. Coulehan JL, Platt FW, Egener B, et al. "Let me see if I have this right..." words that help build empathy. *Ann Intern Med* 2001;135:221-7.

### Patient Safety Authority Recommends Two Patient Safety Discount Programs

The Patient Safety Authority has previously advised facilities that it has recommended two programs that may help reduce medical errors and other adverse events. Under provisions of Act 13, the Medical Care and Reduction of Error ("Mcare") Act, if healthcare facilities can demonstrate a reduction in Serious Events as a result of adopting one of these programs, they may be eligible for a discount on medical professional liability coverage under protocols developed by the Departments of Health and Insurance.

The two programs recommended are:

- "Stand Up for Patient Safety" developed by the National Patient Safety Foundation (NPSF). More information is available at the NPSF website: [www.npsf.org](http://www.npsf.org). For your information, the National Patient Safety Foundation has a new phone number: 413-663-8900.
- "100,000 Lives Campaign" developed by the Institute for Healthcare Improvement (IHI). More information is available at the IHI website: [www.ihf.org/ihf/programs/campaign](http://www.ihf.org/ihf/programs/campaign).

The Authority strongly encourages facilities to consider adopting one or both of these innovative programs. Numerous facilities have been in touch with NPSF about enrolling in the "Stand Up" initiative, and we are hopeful that many Pennsylvania hospitals will enroll in this program. In addition, the Authority is working collaboratively with the Hospital and Healthsystem Association of Pennsylvania (HAP), Quality Insights of Pennsylvania, VHA Pennsylvania, VHA East Coast, Delaware Valley Healthcare Council of HAP and the Hospital Council of Western Pennsylvania about ways to provide educational and technical support to facilities participating in the "100,000 Lives Campaign." You will hear more about this joint effort in the coming weeks.

NOTE: Recommendations from the Authority are the first step in a multi-step process involving the Departments of Health and Insurance. Individual facilities must demonstrate a measurable reduction in the number of Serious Events in their facilities as a result of having adopted a recommended program. For more information about the "Patient Safety Discount," see Section 312 of Act 13. The Act is accessible on the Authority's website at [www.psa.state.pa.us](http://www.psa.state.pa.us).

## “Give 40 of K ” (You Know What I Mean, Don’t You?)

Potassium (K) is an infusion commonly given on the basis of a verbal order in response to a laboratory value, particularly in the intensive care unit, where the urgency of correction is higher. Inappropriate potassium infusions are also dangerous, because either an overdose or too rapid an intravenous (IV) infusion of a therapeutic dose can lead to high serum levels, arrhythmia, and death. Reports of problems involving this “high alert” medication are therefore not surprising and are useful examples of the problems of verbal orders.

In one recent report to PA-PSRS, a nurse received a verbal order to give a patient “10 of K.” The patient was given 10 mg of vitamin K instead. The reverse problem has also occurred. A verbal order for Vitamin K was incorrectly transcribed as “potassium.”

It isn’t difficult to imagine how mistakes like these can happen. Consider the following hypothetical exchange between a physician and a nurse:

NURSE: Doctor, Mrs. Jones’ potassium is 2.5.

PHYSICIAN: Give 40 of K IV.

NURSE: Thank you.

Such a dialogue can be heard in many hospital settings, but much of the information in the verbally communicated order is implied information. For example:

“40” what? Milliequivalents? Milliliters? Milligrams?

“K” what? KCl? KPO4?

“IV” At what rate? Push (which would be fatal)? Or infused at how many milliliters per minute? And with what diluent: dextrose 5% in water (D5W) or normal saline (NaCl)?

“Thank you.” Did the nurse infer what the doctor implied, that the patient should receive 40 milliequivalents of KCL in 100 ml of D5W IV to be run at a standard rate of 20 ml/hour?

If the doctor were ordering two large pizzas (one with onions and peppers and the other with half pepperoni and half anchovies), would he or she be confident that the order would be delivered as requested if the person taking the order said only “Thank you”? Imagine if the doctor were flying to a conference and, listening to the conversation between the pilot and control tower, heard, “There’s lots of traffic today, so land on the runway on the left, because someone else is already making an approach on the right runway.” Would he or she get nervous?

Verbal orders are an error-prone, but sometimes necessary, practice. A verbal order from the doctor that includes all the elements (i.e., patient, drug, dose, route, rate) and is read back by the nurse for verification could reduce errors related to the verbal mode of prescribing.

## Risk of Arrhythmia During Activation of Electrohydraulic Lithotripter

PA-PSRS has received a report of a patient experiencing premature ventricular contractions (PVCs) during a procedure involving an intracorporeal electrohydraulic lithotripter (EHL). According to the hospital, a PVC occurred each time the EHL was activated.

The lithotripter electrode is inserted through the urethra using a cystoscope to remove stones from the bladder or nephroscope to remove stones from the kidney. With saline used for irrigation and the electrode placed near the bladder or kidney stone, the lithotripter is activated, generating a series of high-voltage sparks at the electrode tip. Sparks in the liquid medium generate a series of hydraulic shock waves, causing the stone to fracture.

Cardiac arrhythmias, though rare, can occur during EHL procedures. A review of FDA's Manufacturer and User Facility Device Experience (MAUDE) database, from 1992 to the present, revealed three reports of patients' experiencing abnormal cardiac rhythms during activation of the EHL generator. In two reports, patients experienced asystole. The rhythm returned to normal sinus rhythm when the EHL device was turned off. In the third report, the patient's heart rate decreased, and the procedure was aborted with no reported injury to the patient.

Respective EHL device manufacturers' responses in the MAUDE reports did not include definitive causes, but did suggest possible causes for the abnormalities in two of the three reports. One report in which the patient experienced asystole included a potential cause: that the patient was electrically grounded through the anesthesiologist, who may have been in physical contact with the patient during activation of the device. In the report concerning the patient's decreased heart rate, the suggested cause was that the patient may have been electrically grounded through the patient electrodes and lead wires to the physiologic monitoring system used to monitor the patient's vital signs during the procedure.

A review of MAUDE, also from 1992 to the present, revealed approximately 25 reports of electrical shocks experienced by the patient, anesthesiologist, surgeon, or a combination of individuals during EHL device activation.

In 1982, ECRI published a Hazard Report concerning anesthetists receiving electrical shocks during EHL bladder stone removal procedures.<sup>1</sup> Based on the hospital reports, ECRI conducted experiments with several EHL device models. They determined that the magnitude of the electric current was sufficient to be perceived by a locally anesthetized patient or a clinician who becomes part of the current's path to ground. The 1982 reports also described the possible occurrence of an electrical path to ground for stray lithotripter current from an intracardiac catheter or electrode. ECRI stated that the occurrence was rare, but potentially hazardous. With the use of an intracardiac or pacemaker catheter, the electrical pathway for current would be directed through cardiac tissue, possibly resulting in cardiac arrhythmias.

Methods that can help to mitigate the problem of electrical shocks or arrhythmias include:

- Informing surgical staff of the possibility of shocks or cardiac arrhythmias occurring during EHL procedures.
- Avoiding physical contact as much as possible between surgical staff and patients during activation of the EHL device.
- Minimizing patient contact with grounded metal surfaces during procedures.
- Avoiding EHL device use on patients who have externally connected intracardiac catheters.

### Notes

1. ECRI. Electrohydraulic Lithotripters [Hazard Report]. Health Devices 1982 Dec;12(2):46-7.

## Multiple Messages, Multiple Tasks

A recent PA-PSRS report concerned a patient admitted with head trauma who was evaluated with a CT scan, then monitored. He showed signs of worsening, prompting a repeat CT. The radiologist noted a change warranting treatment and called the ICU to inform the surgeon who was responsible for the patient. The ICU nurse transcribed the reading and called the surgeon in the OR, reaching the anesthesiologist. The anesthesiologist conveyed the reading to the surgeon, who was doing an emergency operation. The surgeon found the message confusing.

He explained to the circulating nurse how to retrieve the CT on the PACS system in the OR. The nurse displayed the first early morning film instead of the second late morning film. The surgeon, thinking he was viewing the second film, read it as unchanged, requiring no further treatment. After leaving the OR hours later, the surgeon discovered the error and instituted the indicated treatment, but belatedly. The family was notified of the problem. The hospital's assessment found the root cause to be ineffective communication. Policies were changed to ensure direct physician-to-physician conversation.

The hospital is to be commended for a thorough investigation and identification of the importance of effective communication. Two components of communication are salient to this report. One is that the fewer intermediaries, the less the chance for misunderstanding. The second, less obvious point, is that the less the intermediary understands about the content, context, and implications of the message, the greater the chance of misrepresentation.

The clinical staff involved in this occurrence already understood the importance of transmitting changes noted in obviously urgent studies, of writing down what is said, of shortening the information chain, of making the information accessible, and of being transparent to the family.

In commentary, we also note that this report indicates the hazards of multi-tasking. The surgeon attempted to process critical information while doing another important task. Under these conditions, the probability of error is known to increase.<sup>1</sup> Multi-tasking cognitive tasks is not an indicator of efficiency. In this case, individuals were being called upon to do too much at once. Safety experts warn against trying to solve safety problems solely by being more careful, or working harder, or being more efficient. Experts who have studied highly reliable systems mention reserves and reorganization: the ability to bring more resources to the problem.<sup>2</sup> Others describe this as capacity. If the system has adequate capacity, it is not necessary for a nurse assisting a surgeon to become a radiology file clerk or for the surgeon in the middle of an operation to make a decision about another patient.

### Notes

1. Schacter DL. The seven sins of memory: how the mind forgets and remembers. Houghton Mifflin (NY); 2001.
2. Roberts KH, Yu K, Van Stralen D. Patient safety as an organizational systems issue: lessons from a variety of industries. In Youngberg BJ, Hatlie MJ, eds. The patient safety handbook. Sudbury MA: Jones & Bartlett; 2004:169-86.

## Dangers Associated with Unlabeled Basins, Bowls, and Cups

Beginning in 1997, the Institute for Safe Medication Practices (ISMP) reported on cases in which patients have inadvertently received the incorrect product due to mistakes involving unlabeled medications and solutions. Reports submitted to PA-PSRS reveal that unlabeled bowls, basins, and cups continue to present a problem.

One report described an occurrence in an operating room (OR) where Monsel's solution (20% ferric subsulfate) and Lugol's solution (potassium iodide) were both on the surgical field. The surgeon, wanting to use the Lugol's solution, removed the Monsel's bowl off the field without asking the scrub nurse to identify the solution. No further information was contained in the report. In another report highlighting what could have been a dangerous situation, three unlabeled basins that contained water, saline, and renografin solutions were found on a sterile back table in the OR.

Several reports outside of PA-PSRS that gained national attention illustrate the potential hazards of this practice. In one case, a 37-year old male patient's genitals were severely burned when his physician mistakenly applied TBQ (a cationic germicidal detergent with a pH of 13) instead of vinegar for a wart removal. In another case, a patient was accidentally injected with hydrogen peroxide instead of lidocaine for local anesthesia. During the surgical procedure hydrogen peroxide was drawn into a syringe from an unlabeled basin instead of the intended lidocaine, which was also in an unlabeled cup. Even in the radiology department, unlabeled products can lead to tragic outcomes. For example, a patient was accidentally injected with lidocaine 2% instead of contrast media [Omnipaque (iohexol)] during angiography. The patient suffered a grand mal seizure but recovered.<sup>1</sup>

A report from *Hospital Pharmacy* in 1989 described the case of a patient who died during a surgical procedure to remove a cancerous eye. In this case, an unlabeled specimen cup was filled with glutaraldehyde to preserve the patient's enucleated eye, but was mistaken as spinal fluid. The fluid had been removed to reduce pressure because the malignancy had spread to the brain. The spinal fluid was in an identical unlabeled cup. Near the end of the procedure, an anesthesiologist accidentally injected the glutaraldehyde intrathecally, believing it was the patient's spinal fluid.<sup>2</sup>

Recent findings from the 2004 *ISMP Medication Safety Self Assessment*<sup>®</sup> for hospitals, gathered

from more than 1,600 hospitals across the country, show that less than half (41%) of the hospitals always label containers (including syringes, basins, or other vessels used to store drugs) on the sterile field, even when just one product or solution is present. Eighteen percent do not label medications and solutions on the sterile field at all, and another 41% apply labels inconsistently. Although this represents an improvement from the 2000 findings (25% reported full labeling; 24% reported no labeling), surprisingly, this rather basic safety measure is not widely implemented in most hospitals.<sup>3</sup>

While you may not have experienced a Serious Event involving unlabeled medications and solutions, it is important to develop and implement policies and procedures for the safe labeling of these items, which are often used in sterile settings. These settings include operating rooms, ambulatory surgery units, labor and delivery rooms, physician's offices, cardiac catheterization suites, endoscopy suites, radiology departments, and other areas where operative and invasive procedures are performed. Consider the following measures, most of which are mentioned in the Association of Perioperative Registered Nurses (AORN) Guidance Statement: Safe Medication Practices in the Perioperative Practice Settings.<sup>4</sup>

Examples of safe practices to consider include:

- Making labeling easy by purchasing sterile markers, blank labels, and preprinted labels prepared by the facility or commercially available (e.g., Healthcare Logistics) that can be opened onto the sterile field during all procedures. To minimize staff time, prepare surgical packs in advance with sterile markers, blank labels, and preprinted labels for all anticipated medications and solutions that will be needed for the case.
- Using labels on all medications, syringes, medicine cups basins, or other containers of solutions as well as chemicals, reagents on and off the sterile field, even if there is only one medication or solution involved.
- If drug or solution names are similar, using tall man lettering on the labels to differentiate them (e.g., HYDR**O**morphine) or highlight/circle the distinguishing information on the label.
- When possible, purchasing skin antiseptic products in prepackaged swabs or sponges to clearly differentiate them from medications or

## Dangers Associated with Unlabeled Basins, Bowls, and Cups (Continued)

- other solutions to eliminate the risk of accidental injection.
- Individually verifying each medication and completing its preparation for administration, delivery to the sterile field, and labeling on the field before another medication is prepared.
- Verifying with the physician any medication on the physician's preference list before delivery to the sterile field, labeling, and/or administration.
- Having the scrub person and circulating nurse concurrently verify all medications/solutions visually and verbally by reading the product name, strength, and dosage from the labels. If there is no scrub person, the circulating nurse could verify the medication/solution with the licensed professional performing the procedure.
- When passing a medication to the licensed professional performing the procedure, visually and verbally verifying the medication, strength, and dose by reading the medication label aloud.
- Keeping all original medication/solution containers the room for reference until the procedure is concluded.
- At shift change or relief for breaks, having entering and exiting personnel concurrently note and verify all medications and their labels on the sterile field.
- Not making assumptions about what is in an unlabeled basin, bowl, cup or syringe.
- Discarding any unlabeled medication/solution found and considering the occurrence as a near miss.
- Performing regular safety rounds in areas that routinely have basins, bowls, cups, etc., to observe labeling procedures, promote consistency, and inquire about barriers to change.

### Notes

1. ISMP. Medication Safety Alert! 18 June 1997. (2), 12.
2. Cohen MR. Medication Error Reports. Hospital Pharmacy. 1989;24(7):549.
3. ISMP. Medication Safety Alert! 12 December 2004. (9), 24.
4. Association of periOperative Registered Nurses (AORN). AORN Guidance Statement: Safe Medication Practices in Perioperative Practice Settings [online]. 2004. [Cited 22 Feb 2005.] Available on Internet: <http://www.aorn.org/about/positions/pdf/7f-safemeds-2004.pdf>

### Patient Safety Authority Board of Directors

Robert S. Muscalus, DO, Pennsylvania's Physician General and Chair of the Patient Safety Authority Board of Directors, submitted his resignation effective March 21, 2005. Under Act 13, the Physician General, who is appointed by the Governor, serves as Board Chair. Dr. Muscalus was appointed Physician General in 1999 and served as chair of the Authority Board since the Board was constituted on July 2, 2002. As chair, he was instrumental in helping develop and implement the PA-PSRS system and was a frequent speaker around the state on patient safety and adverse event reporting. Dr. Muscalus has joined Highmark Blue Shield as the Medical Director for Clinical Client Relationships.

## Focusing on Eye Surgery

Two distinct patterns emerge from a number of Serious Events and Incidents reported to PA-PSRS involving eye surgery: wrong side surgery and problems with intraocular lens (IOL) implants.

While marking the surgical site has received much attention as a promising safety practice, marking the eye—by virtue of its unique anatomy—may present a problem for clinicians. Any mark placed near or around the eye may be obscured by surgical drapes and may not be visible during a pre-procedure time out.

Problems associated with intraocular lenses reported to PA-PSRS concern the implantation of a different lens than the clinical team intended. IOLs may vary by size, power and type. After reviewing case studies of several reports, we discuss protocols that may help to promote positive outcomes.

### Case Studies in Wrong-Side Procedures

*Case #1—In this well documented report, a patient undergoing surgery was asked to identify the operative site, which the scrub nurse marked with an “X” above the eye. A physician finished the surgical prep and draped the site. Several members of the surgical team verified the operative site, and all sources of information were consistent regarding the correct side for surgery. As the procedure progressed team members believed they were operating on the correct eye. Intra-operative and postoperative documentation listed the correct eye as having surgery. However, when the patient arrived in the PACU, the wrong eye was draining and surgically tender.*

Several elements of this case may have contributed to this error. First, the use of an “X” as the surgical mark is nonspecific. It could indicate the surgical site, but could easily be misinterpreted as a warning indicating the non-operative site. In a follow-up contact, the Patient Safety Officer at this facility stated that their policy is to use the surgeon’s initials as the surgical mark, consistent with guidance from other organizations.<sup>1</sup>

As stated previously, the surgical mark was obscured after the operative site was draped. The mark was placed above the eye rather than in a location that would still be visible after draping, which is an element of the guidance on site marking published by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).<sup>1</sup> Just beyond

the eye’s medial or lateral angles might be a suitable alternative in some cases. Another alternative could be to mark the eyelid of the operative eye, and to verify the presence of the surgical mark on the right or left side when applying lid clamps. The lid clamps could then be a proxy for the surgical mark.

The scrub nurse (who made the initial surgical mark) was not present during the operative site verification. We can only conjecture whether the scrub nurse might have caught this error had she been present, but a possible systems solution to this problem would include having all team members present for a pre-procedure time out. Another preventive measure might include making the surgeon responsible for making the surgical mark. The American Association of Ophthalmologists (AAO) suggests that “the surgeon/assistant surgeon marks the skin next to the operative eye with his/her initials.”<sup>2</sup> JCAHO’s Universal Protocol, which has been endorsed by AAO and the American Society of Ophthalmic Registered Nurses (ASORN), also specifies that the person performing the procedure be responsible for site marking.<sup>1</sup> Yet, a June 2004 survey conducted by ASORN found that 58% of respondents from 216 sites reported that markings are being performed by RNs, and only 22% reported that markings are being performed by physicians.<sup>3</sup>

*Case #2—A patient having cataract surgery verified the side for surgery with a nurse. The operating room schedule, the permit, and the history and physical were in agreement with the patient. The nurse proceeded to mark the site for surgery and dilated the eye. A physician administering a local anesthetic placed the needle in the wrong eye. The nurse stopped the physician just before the anesthetic was administered. Thereafter, the procedure proceeded correctly.*

The report of this case does not mention a final time out before beginning the procedure, and the surgical mark may also have been obscured in this case. We previously reported on the JCAHO Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery<sup>1</sup> in the September 2004 PA-PSRS Patient Safety Advisory. The hallmarks of this protocol are pre-operative verification, marking the operative site, and conducting a time out immediately prior to beginning the procedure. The AAO has developed the following guidance, consistent with the Universal Protocol:

## Focusing on Eye Surgery (Continued)

- Prior to administration of anesthetic injection or sedation, the anesthesia staff/surgeon verifying the operative eye with the patient, informed consent and/or the ophthalmic history and exam, and confirming that they all match.
- Immediately prior to incision, the surgeon verifying the operative eye with the ophthalmic history and exam.
- In the event of any discrepancy among the patient's response, the informed consent, the doc-

tor's order, and the ophthalmic history and exam, the surgeon making the final determination and correcting the discrepancy before proceeding with the procedure.

- Developing a checklist for verification that all documents are congruous and that all parties involved, including the patient, agree on the location of surgery.<sup>2</sup>

*Your ophthalmology staff and surgeons will want to know if your facility changes IOL vendor. Variations in the A-constant across different manufacturers' lenses may invalidate their calculations for the correct diopter for the patient.*

**Table 1. Suggestions for Minimizing Wrong IOL Implantation**

1. The ophthalmic history and exam and form that contains keratometry and axial length, primary and alternate lens/es for each patient are available in the operating room.
2. The surgeon/assistant surgeon selects the primary and alternate IOL/s before the start of the case. The surgeon verifies the IOL number, diopter, optic, A constant, and length against the appropriate form or documentation and/or patient medical record.
3. When the surgeon requests the IOL, the circulating nurse shows the IOL box to the surgeon and verbally states the IOL model number and lens power and the surgeon acknowledges the communication.
4. The circulating nurse then repeats this procedure with the scrub nurse/technician (i.e., shows the IOL box and verbally states the model number and lens power).
5. The scrub nurse/technician verbally states the model number and lens power as he/she passes the lens to the surgeon for implantation.
6. The surgeon performs visual inspection of the IOL under the microscope for appropriateness and any lens defect or deposit.
7. If there is a discrepancy the surgeon reviews the ophthalmic history and exam and/or designated institute form.
8. The circulating nurse puts the IOL labels on the IOL card, operative record/patient chart right after the surgeon implants the IOL.
9. Have good communications among the surgeon/assistant surgeon and operating room personnel, and check the lens power against the medical record in the operating room.
10. The correct lens should be in the operating room prior to sedation/anesthesia.

Source: American Association of Ophthalmologists. Reprinted with permission.

In any complex environment, the potential always exists for human error. Patient safety protocols, such as site marking and the time out, do not necessarily reduce the rate of human error. Rather, they are mechanisms by which we aim to make human error more observable and by which we build redundancy into the system, hopefully mitigating the consequences of errors by catching them before they reach the patient.

### Intraocular Lens (IOL) Problems

PA-PSRS has received several reports in which the wrong intraocular lens was implanted in the patient's eye. Half of the reports indicate that the patient returned to the OR for implantation of the correct lens. In one case the patient was satisfied with the level of correction obtained even with the incorrect lens. One report refers to the physician's selection of the incorrect lens from a cart.

The magnitude of the problem is evident from a review of a decade of claims. The Ophthalmic Mutual Insurance Company reviewed 168 claims which occurred from 1987 to 1997. Cataract procedures represented 33% of all closed claims during this period, and IOL cases were the largest group in the sample.<sup>4</sup> Causative factors identified with implanting the wrong IOL include: use of an outdated IOL formula for the patient, incorrect biometry or keratotomy readings, mistakes in entering data into an IOL calculation program, incorrect IOL labeling or packaging, and mistakes in providing the IOL during surgery.<sup>5</sup>

Different formulas can be used to determine the correct IOL, and each formula includes a variable known as a "lens constant." A widely used formula uses the "A-constant," which is dependent on the

## Focusing on Eye Surgery (Continued)

“specifics of the IOL design” and, as required by the FDA, is printed on the IOL packaging by the manufacturer.<sup>6,7</sup> This A-constant is used in a string of interconnected calculations to determine the best lens for each patient. A quick review of five companies’ products revealed A-constants ranging from 114.2 to 119, with different A-constants for the same lens diopter.

If your facility changes vendors or lens manufacturers, it would be helpful to notify all ophthalmologists so the calculations can be adjusted accordingly. Ideally, the surgeon would select the lens prior to entering the operating room and note the change in vendor. However, this is often a delegated responsibility, and surgeons may unknowingly implant a different manufacturer’s lens, not recognizing that a formula change is necessary because of differences in the A-constant between different manufacturers’ products.<sup>8</sup>

Suggestions for IOL verification in the operating room advocated by the American Academy of Ophthalmology, the American Society of Ophthalmic Registered Nurses, and the American Association of Eye and Ear Hospitals are presented in Table 1.<sup>5</sup>

### Notes

1. Joint Commission on Accreditation of Healthcare Organizations. Universal protocol for preventing wrong site, wrong proce-

dures, wrong person surgery [online]. 2003 Jul 18 [Cited 12 Nov 2004]. Available from Internet: [http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/wss\\_universal+protocol.htm](http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/wss_universal+protocol.htm).

2. American Association of Ophthalmologists. Eliminating wrong site surgery, patient safety bulletin 1 [online]. [Cited 10 Nov 2004.] Available from Internet: <http://www.aao.org/education/library/safety/site.cfm>.

3. American Society of Ophthalmic Registered Nurses. ASORN Quick Question #6, [online] June 2004. [Cited 10 Nov 2004.] Available from Internet: <http://webeye.ophth.uiowa.edu/asorn/QQ/QQ06.htm>.

4. Brick DC. Risk management lessons from a review of 168 cataract surgery claims. OMIC Publication Archives, Digest, [online]. Summer 1997, 1-9. [Cited 21 Feb 2005] Available from Internet: [http://www.omic.com/resources/risk\\_man/deskref/clinical/41.cfm](http://www.omic.com/resources/risk_man/deskref/clinical/41.cfm).

5. American Association of Ophthalmologists. Minimizing wrong IOL placement, patient safety bulletin number 2 [online]. [Cited 10 Nov 2004.] Available from Internet: <http://www.aao.org/aao/education/library/safety/iol.cfm>.

6. Schwiegerling J. Optics of intraocular lenses. Clinical Optics [online]. [Cited 11 Mar 2005.] Available from Internet: [http://www.opthalmic.hyperguides.com/tutorials/clinical/optics\\_lenses/tutorial.asp](http://www.opthalmic.hyperguides.com/tutorials/clinical/optics_lenses/tutorial.asp)

7. Wallace B. Refractive cataract surgery. Clinical Optics [online]. [Cited 11 Mar 2005.] Available from Internet: [http://www.opthalmic.hyperguides.com/tutorials/cateracts/refractive\\_cataract/tutorial.asp](http://www.opthalmic.hyperguides.com/tutorials/cateracts/refractive_cataract/tutorial.asp)

8. Gordon A. Telephone Conversation with: Monica Davis. 2005 March 4.

## Mismatching Medical Devices and Accessories

Pennsylvania facilities have submitted reports to PA-PSRS describing injuries to patients from the use of incompatible device parts. For example, one report involved a patient that received deep cuts from a dermatome device in the thigh during harvesting of a skin graft. The facility determined that a cutting blade from a manufacturer other than the dermatome manufacturer was used with the dermatome device to obtain the graft. Another report involved excessive bleeding during circumcision. During the procedure, a Gomco®-type circumcision clamp broke apart. The facility concluded that mismatched parts of different clamps were assembled during the sterilization process.

These reports demonstrate the need for clinical staff to be aware of the compatibility of medical devices and their associated accessories and devices that require assembly prior to use.

The example involving the dermatome is not new. In 1994, ECRI published a Hazard Report and a Hazard Alerts Action Item about a similar incident involving deep lacerations to a patient due to a dermatome blade manufactured by Padgett that was inserted into a Zimmer dermatome device.<sup>1</sup> Though the Padgett blade appeared to fit well into the Zimmer dermatome, there were no identifying marks on the blade as to the manufacturer or the correct blade orientation. The specific shape of the Zimmer blade was such that it could only be installed into the Zimmer dermatome in the correct orientation, unlike the Padgett blade used in this case. The Hazard Report further stated that, in their user manuals, both manufacturers (Zimmer and Padgett) warn against using incompatible manufacturers' blades.

In the circumcision clamp example above, the specific mismatch of parts was not stated in the report submitted to PA-PSRS. However, an example of a mismatch of clamp parts would be the bell or base plate arm from one manufacturer assembled to the base plate of another manufacturer (see Figure 1). Another scenario of an injury occurring during circumcision is using a damaged or worn clamp, which can result in inadequate clamping force.<sup>2,3</sup>

Gomco-type circumcision clamps are used to crush the foreskin distal to the glans penis. The foreskin is then removed without damaging the glans. The bell of the clamp assembly is placed over the glans beneath the foreskin. The bell is positioned through a hole in the base plate. The arm of the plate is used to pull the bell through the hole by adjusting the nut

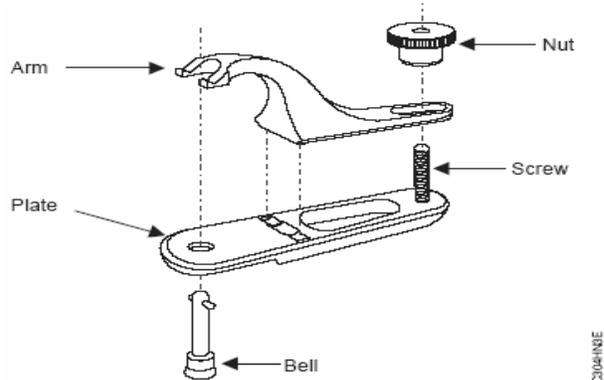


Figure 1. Exploded View of Gomco-type Circumcision Clamp. Source: ECRI. Reprinted with permission.

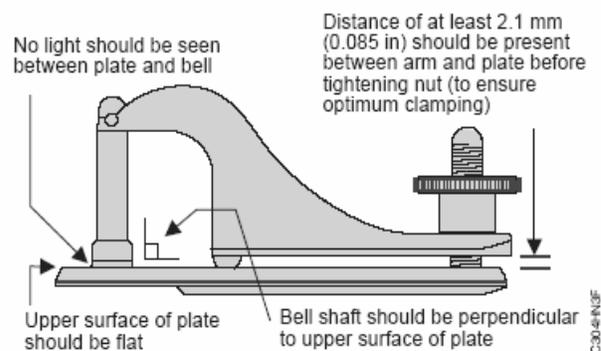


Figure 2. Correctly Assembled Gomco-type Circumcision Clamp. Source: ECRI. Reprinted with permission.

(see Figure 2). A properly assembled, properly applied clamp results in an evenly distributed force around the foreskin between the bell and plate, allowing the foreskin to be removed with a scalpel. If the bell and plate of the clamp are not uniformly positioned around the hole surrounding the foreskin, bleeding from the cut foreskin may occur.

Mismatching parts of devices or devices and associated accessories can have a significant impact on patient safety. Examples of mismatching parts and/or accessories include:<sup>4</sup>

- Mixing devices and parts or accessories from different manufacturers or incompatible parts and accessories from the same manufacturer.
- Attaching an accessory to the wrong connector of a device.
- Cleaning and/or processing different disassembled devices together.
- Using parts or accessories from sources other than the original device manufacturer that may

## Mismatching Medical Devices and Accessories (Continued)

not be completely compatible or that have been modified.

To minimize the likelihood of injuries due to mismatches, some hospitals provide education to users in proper disassembly and reassembly of device parts and accessories and in identifying which accessories are for use with specific medical devices. Other examples of ways to mitigate mismatches are to place unassembled parts of each device in separate instrument sterilization trays or bags, to use pictures of correctly assembled devices to guide device reassembly, and to verify the proper operation of a device after assembly or before use.

### Notes

1. ECRI. Use of Incompatible Dermatomes and Blades [Hazard Report]. Health Devices 1994 Apr;23(4):145.
2. ECRI. Incompatibility of Different Brands of Gomco-Type Circumcision Clamps [Hazard Report]. Health Devices 1997 Feb;26(2):76-77.
3. Food and Drug Administration. Potential for injury from circumcision clamps [online]. 29 Aug 2000. [Cited 21 Feb 2005.] Available from the Internet: <http://www.fda.gov/cdrh/safety/circumcision.html>.
4. ECRI. Hazards of Mismatched Parts and Accessories [Guidance Article]. Health Devices 1996 Jan;25(1):31.

### Ask the Analyst: Securing Tracheal Tubes

PA-PSRS recently received a report describing a male patient who self-extubated an oral endotracheal tube. The report stated that the patient did not experience respiratory distress due to the extubation. The tube was taped to the patient's face; however, the patient had a beard, and the report suggests this may have played a role in the extubation. The patient's beard may have inhibited the adhesive tape from strongly adhering to the face, allowing unintentional movement of the tube, which could result in self-extubation. In the report, clinical staff posed the question, "Should we consider looking at the tape we are using?"

Adhesive characteristics vary depending on the type of tape. For instance, paper tape may not have as strong adhesion properties as cloth or vinyl tapes. However, strong adhesion may cause discomfort or injury to sensitive skin when removed. Clinicians may want to consider choosing tape to

secure tracheal tubes based on an assessment of each patient's physical characteristics (e.g., frail skin, beard) to ensure that the tube is securely in place and to minimize discomfort or injury from tape removal.

Adhesive tape is not the only means of securing a tracheal tube to a patient. Disposable, single-use, restraints are available to secure an intubated tracheal tube to a patient. The restraint, attached to the tracheal tube, may be made of foam or cloth/cotton strips placed around a patient's neck or head secured with a fastener such as Velcro®, a Velcro-like product, or tape. A restraint may provide better support than tape alone.

**If you have questions regarding specific patient safety issues you would like PA-PSRS to investigate—particularly related to equipment or medications—we would like to hear from you. E-mail us at: [Support\\_papsrs@state.pa.us](mailto:Support_papsrs@state.pa.us).**

## Topical Anesthetic–Induced Methemoglobinemia

Healthcare professionals know that intravenous or inhaled anesthetics are not innocuous substances. Yet, the widespread availability of anesthetics like benzocaine, dyclonine, and lidocaine in many topical over-the-counter (OTC) products, such as Cepacol® Anesthetic Troches and Suctrets® Maximum Strength Lozenges may lead to the perception of their safety. Many topical anesthetic sprays such as **CETACAINE** (benzocaine 14%, tetracaine 2%) and **HURRICAIN** (benzocaine 20%) have been implicated in cases of methemoglobinemia, a serious and sometimes fatal adverse drug reaction.

Methemoglobinemia occurs when iron in hemoglobin is changed from its ferrous to its ferric form.<sup>1</sup> Unlike hemoglobin, methemoglobin cannot accept oxygen to carry to tissues. It can be hereditary, but methemoglobinemia is typically acquired from drugs and chemicals, such as nitrites and aniline derivatives, which includes virtually all local anesthetics. The condition can be life-threatening, potentially causing cyanosis, confusion, hemodynamic instability, and coma if not recognized and treated appropriately. Methemoglobin concentrations greater than 10-15% of total hemoglobin will cause cyanosis,<sup>2</sup> and levels over 70% have been fatal.<sup>3</sup> Identifying this condition while administering topical anesthetics such as benzocaine usually requires pulse oximetry, though it can be implied by symptoms. Treatment involves an immediate intravenous (IV) dose of 1 to 2 mg/kg of methylene blue.<sup>4</sup> **[Please note that patients with G6PD deficiency are treated with transfusion or dialysis since methylene blue can cause hemolytic anemia in these patients.]**

Methemoglobinemia from local anesthetic has been estimated to occur in one out of every 7,000 bronchoscopies.<sup>5</sup> A recent article analyzing adverse event reports received by the FDA between November 1997 and March 2002 revealed 132 cases of benzocaine-induced methemoglobinemia.<sup>6</sup> Given that millions of doses of topical anesthetics are used each year during endoscopic procedures and endotracheal intubation, the occurrence of methemoglobinemia may seem rare. However, this is a preventable event that often is due to using multiple sprays of agents like benzocaine or spraying the area for a longer duration than recommended.

PA-PSRS has received multiple reports in which patients receiving Hurriceine or Cetacaine topical

spray have required treatment with methylene blue. Following are a few examples:

During intubation, benzocaine spray was administered to a patient, who then developed decreased oxygen saturation to 89%. The patient was diagnosed with methemoglobinemia and subsequently treated with methylene blue.

Hurriceine Topical Spray was used at the initiation of a procedure, and the patient experienced decreased oxygen saturation during recovery in the Post Anesthesia Care Unit. Because methemoglobinemia was suspected, methylene blue was administered, which increased the oxygen saturation.

Topical oral cetacaine spray was administered to a patient who was desaturating while on a 100% aerosol tracheotomy mask with oxygen saturations in the low 80's. The patient continued to be cyanotic despite multiple interventions. Fortunately methemoglobinemia was diagnosed, and the patient was treated with methylene blue.

Doses of topical anesthetics administered during endoscopic procedures may exceed manufacturers' recommendations for several reasons. First, unclear package instructions for using the products may lead to overdoses. The directions for use of topical sprays are prone to misinterpretation and could result in patient harm. A portion of one label states, "Spray in excess of two seconds is contraindicated," but the directions state, "To activate spray, press cannula in any direction with forefinger for approximately one second. Maximum anesthesia is produced in one minute" (meaning one minute after a quick spray). This could be misinterpreted to mean that a continuous spray of up to one minute is permitted, even desirable, for maximum anesthesia.

Clinicians may be unfamiliar with the significant absorption of topical anesthetics, so they may not realize how much medication they are giving patients when using the sprays. Patients also could self-administer topical anesthetics in doses that exceed manufacturers' recommendations. Since some products are available without a prescription (e.g., Hurriceine), a patient could apply too much spray or gargle too often with a liquid formulation (or swallow the solution), since the directions for use may be vague (e.g., "apply a small amount"). Methemoglobinemia has also occurred when an OTC vaginal cream was used to treat an infant's diaper rash.<sup>8</sup>

## Topical Anesthetic–Induced Methemoglobinemia (Continued)

Because methemoglobinemia is easily treated, it is important to recognize its symptoms when topical anesthetics are used. Heightened awareness of proper dosing and the risk of methemoglobinemia is particularly important for clinicians involved in endoscopy, intubation, bronchoscopy, or similar invasive procedures using topical anesthetic-containing sprays. These drugs are not intended to be used in high doses, especially in patients who may be predisposed to methemoglobinemia.

Predisposing factors for methemoglobinemia include:

- Age (infants under 6 months of age and older patients with cardiac problems may be sensitive to even low methemoglobin levels).
- The status of the area being sprayed (inflamed areas and broken skin absorb more of the drug).
- Concomitant use of other drugs which also have been implicated in causing methemoglobinemia.
- The genetic make-up of the patient (due to altered hemoglobin, G6PD deficiency, or methemoglobin reductase enzyme deficiency).<sup>9</sup>

To help avoid adverse outcomes associated with this problem, consider the following strategies:

- Asking questions while taking the medical history to identify these risk factors in patients who may receive topical anesthetics.
- To document the amount of drug being administered, measuring and recording the number and duration of sprays applied. A chart that lists maximum doses for topical anesthetics also may be helpful as a reference for staff that perform endoscopic procedures.

- Stocking just one topical anesthetic spray also could enhance staff familiarity with the product and its' dosing.
- If cyanosis or hypoxia develops after the application of topical anesthetics, consider a diagnosis of methemoglobinemia.
- Having supplemental oxygen and methylene blue readily available to treat methemoglobinemia wherever topical anesthetics are used in the facility.
- It also may be helpful to apply auxiliary labels to topical anesthetic spray bottles to alert staff to avoid excessive use.

A metered-dose product is currently available (20% benzocaine). However, even a metered-dose product will not prevent an overdose if multiple sprays are used.

### Notes

1. Dinneen SF, et al. Methemoglobinemia from topically applied anesthetic spray. *Mayo Clin Proc* 1994; 69: 886-8.
2. Jacobs DS, ed., et al. *Laboratory Test Handbook*. Lexi-Comp Inc. 1996, Cleveland, OH, 642-3.
3. Wintrobe MM. Methemoglobinemia and other disorders usually accompanied by cyanosis. *Clinical Hematology*. Philadelphia, Lea and Febiger. 1974:1009-1016;
4. ISMP. Medication Safety Alert! 17 June, 2004; (9)12.
5. Douglas WW, Fairbanks VF. Methemoglobinemia induced by a topical anesthetic spray (Cetacaine). *Chest*. 1977;71:587.
6. Moore TJ, Walsh CS, Cohen MR. Reported adverse event cases of methemoglobinemia associated with benzocaine products. *Arch Intern Med* 2004;164:1192-1196.
7. ISMP. Medication Safety Alert! 15 May, 2002; (7)10.
8. Tush GM, et al. Methemoglobinemia induced by an OTC medication. *Ann Pharmacother*. 1996;30:1251-4.
9. Wurdeman RL, et al. Benzocaine-induced methemoglobinemia during an outpatient procedure. *Pharmacotherapy*. 2000;20:735-38.

## Abbreviations: A Shortcut to Medication Errors

Throughout healthcare, “shortcuts” such as abbreviations and symbols are often used to save time when communicating medication orders, especially in handwritten communication. However, some of these shortcuts can be very time-consuming for the person on the receiving end and can be dangerous to the patient. Abbreviations and nonstandard dose designations are frequently misinterpreted, and they often lead to errors resulting in patient harm.

PA-PSRS has received over 200 reports describing situations in which the use of abbreviations has led to medication errors. Some of the common error-prone abbreviations involved in errors in PA-PSRS include:

- “U” for unit
- “QD” for daily
- “QID” for four times daily
- “QOD” for every other day
- “<” for less than
- “>” for greater than
- “cc” for cubic centimeter
- “D/C” for discontinue
- “AU” for both ears
- “OU” for both eyes
- Drug name abbreviations
  - MSO4 for morphine sulfate
  - MgSO4 for magnesium sulfate
  - HCTZ for hydrochlorothiazide

One of the error-prone abbreviations most commonly reported to PA-PSRS is the abbreviation “U” used to indicate “units.” This abbreviation contributes to errors when it is misread as a zero (0) or as the number 4. These errors often result in potential 10-fold or greater overdoses. In one example, an older male patient was ordered 5 units of Humalog (insulin lispro recombinant) but received 50 units of Humalog on two occasions. The order on the medication record was written as “5U” instead of “5 units.” A contributing factor to the insulin overdose identified by the institution was the use of “U” for units.

Through the USP-ISMP Medication Errors Reporting Program (MERP), ISMP has also received a number of reports where patients have received overdoses of insulin or heparin when “U” for unit has been used. In one report, a nurse who was taking a patient’s medication history recorded his insulin dose using the abbreviation “U” instead of writing the word “unit” (see Figure 1). The physician then

misread the “U” as a “4” and wrote for “Humalog 44 U/24 U/64 U.” The patient received a single overdose of insulin but was not harmed. Further overdoses were averted because the nurse said to the patient “Here’s your insulin, 44 units.” The patient responded “44 units? I take 4 units!”<sup>1</sup>

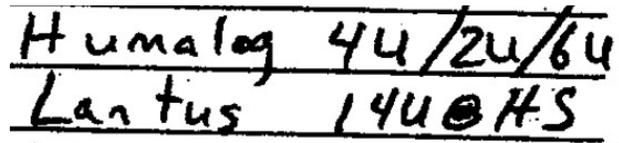


Figure 1. “4U” Mistaken for “44.” Image provided courtesy of ISMP.

Some abbreviations used to indicate the frequency of drug administration (e.g., QD and QOD) can be problematic as well. In one report received through the MERP, an order (see Figure 2) for Flomax (tamsulosin) 0.4 mg QD was misinterpreted as Flomax 0.4 mg QID. Fortunately, the error was caught prior to the patient’s being harmed.<sup>2</sup>

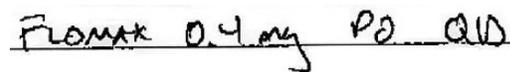


Figure 2. “QD” Mistaken for “QID.” Image provided courtesy of ISMP.

Several instances of this abbreviation causing errors have also been reported to PA-PSRS. In one case, an order for Zithromax (azithromycin) 500 mg written as QD was misinterpreted as QID. Luckily, there was no harm despite the patient’s receiving the medication four times daily. In another report, an order was written for Digoxin 0.125 mg po QOD (every other day), but the medication was given QD (every day). The patient received two extra doses before the error was discovered.

Other examples of reports including the use of error-prone abbreviations submitted to PA-PSRS include:

- An elderly female patient received a Coumadin (warfarin) dose that should have been held because her INR was 2.8. The original order stated to give Coumadin if INR < 2.5 (less than 2.5). However, the “<” (less than) symbol was misinterpreted as “greater than,” and the patient was administered Coumadin, despite the lack of sense in such an interpretation of the order.
- An elderly female patient received Vasotec (enalaprilat) 1.25 mg IV with a systolic blood

## Abbreviations: A Shortcut to Medication Errors (Continued)

pressure less than 180 mmHg. The prescriber's order included a parameter to hold the medication if the patient's "SBP<180." However, the nurse confused the "<" and ">" signs and administered the medication when the patient's systolic blood pressure measured only 140 mmHg.

- A physician wrote an illegible and confusing order to increase Diovan to 80 mg BID. An up arrow (↑) symbol was used to indicate "increase" but was read as the numeral 1. The pharmacy interpreted the order to be Diovan 160 mg BID (since no 180 mg form is available), and one dose of Diovan 160 mg was administered to the patient. Luckily she suffered no harm from this overdose.
- A prescriber used an abbreviation for magnesium sulfate and wrote "MgSo4 2g IV x 1 dose" for a 45-year-old female patient. However, the unit clerk and nurse misinterpreted the order as morphine sulfate (MSO4) 2 mg IV x 1 dose, and the patient received a 2 mg dose of morphine sulfate. MSO4 is an error-prone abbreviation commonly used in place of writing out morphine sulfate. Contributing to this error was the fact that the patient was having pain, so morphine seemed reasonable. The prescriber was notified, and magnesium was administered to the patient.
- An elderly patient was ordered Dilaudid (HYDRomorphone); however, the order was written without the use of leading zeroes (.2-.4 mg). As a result, the order was misread as 2-4 mg instead of the intended 0.2-0.4 mg. The nurse recognized the error after giving the initial dose. The patient experienced no ill effects.

The use of error-prone abbreviations and dose designations has become a concern of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). A National Patient Safety Goal (NPSG) in 2004,<sup>3</sup> the elimination of dangerous abbreviations has been carried over into the 2005 NPSG with two changes: (1) pre-printed forms are now included in the scope of the goal, and (2) the goal now applies only to orders (all orders) and other medication-related documentation, not all patient-specific documentation.<sup>4,5</sup>

To address the difficulty of achieving compliance with this NPSG, JCAHO offers several helpful tips.<sup>6</sup> Most focus on educating, advocating, and reminding staff. One tip seems to be directly related to en-

forcement: "Direct pharmacy not to accept any of the prohibited abbreviations. Orders with dangerous abbreviations or illegible handwriting must be corrected before being dispensed." A corollary to that—enlisting nurses to help notify physicians—may also be employed. Unfortunately, following this advice has spurred numerous reports of burdensome workloads for those making the calls and strained relationships between the medical staff and nurses and pharmacists who are being forced to police the issue.

The real issue is that enforcement of prohibited abbreviations requires more than asking pharmacists or nurses to alert prescribers to lapses in compliance. This is an organizational problem that requires peer-to-peer interaction along with full support from hospital and medical staff leadership. Hospitals that have been working on this initiative relentlessly for years report that the most effective way to enforce physician compliance is to make it a physician-owned process.<sup>7,8</sup> When educational efforts failed to produce significant change, these hospitals pursued operational changes such as pre-printed orders, targeted pages, and email reminders, to initially improve compliance. Then, after enacting a zero tolerance policy, medical staff leaders interacted with physicians who were noncompliant. Pharmacists and nurses still played a role in collecting data about noncompliance, and even notifying individuals when there was a lapse in policy. But the medical staff took responsibility and addressed all issues of repeated physician non-compliance.

In an effort to help increase compliance, JCAHO surveyors in January were instructed to score prescribers' use of any abbreviation on the National Patient Safety Goal "dangerous - do not use" list as noncompliance once the abbreviation is written on the chart.<sup>9</sup> Facilities are no longer considered compliant if pharmacists or nurses call a prescriber for clarification and document the intended meaning. The goal is to place responsibility for prescriber compliance on the medical and administrative staff instead of nurses and pharmacists.

While it seems likely that this latest move will improve compliance, there are other strategies that facilities can employ to help eliminate the use of dangerous abbreviations, such as:

- Encouraging all hospital personnel including medical staff, pharmacists, and nurses to avoid using error-prone abbreviations in all written and electronic communication.

## Abbreviations: A Shortcut to Medication Errors (Continued)

- Identifying and promoting “Physician Champions” who support accreditation-related activities and advocate for full compliance with the NPSGs.
- Providing educational seminars and updates to all staff including the medical staff and administrators, and providing instruction to new staff and residents before or at the beginning of their employment period.
- Disseminating posters and laminated cards with dangerous abbreviations and dose designations throughout the hospital and staff.
- Removing any error-prone abbreviations from computerized prescriber order entry and other computer systems.
- Avoiding use of abbreviations on computer-generated labels, labels for drug storage bins/shelves, and in guidelines, charts, and protocols.

Such steps are already being taken in many Pennsylvania facilities.

### Resources for Facilities

ISMP List of Error-Prone Abbreviations, Symbols and Dose Designation—[www.ismp.org/PDF/ErrorProne.pdf](http://www.ismp.org/PDF/ErrorProne.pdf)

JCAHO “Do not use” List—[www.jcaho.org/accredited+organizations/patient+safety/04+npsg/index.htm#abbreviations](http://www.jcaho.org/accredited+organizations/patient+safety/04+npsg/index.htm#abbreviations))

JCAHO Implementation Tips for Eliminating Dangerous Abbreviations—[www.jcaho.org/accredited+organizations/patient+safety/05+npsg/tips.htm](http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/tips.htm)

### Notes

1. ISMP. Medication Safety Alert! Acute Care Edition. 21 Oct 2004;(9)21.
2. ISMP. Medication Safety Alert! Community/Ambulatory Edition. Nov 2004;(3)11.
3. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). 2004 National Patient Safety Goals [online]. [cited 18 Feb 2005] Available from Internet: <http://www.jcaho.org/accredited+organizations/patient+safety/04+npsg/index.htm#abbreviations>
4. JCAHO. Facts about the 2005 National Patient Safety [online]. [cited 18 Feb 2005] Available from Internet: [http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/npsg\\_facts.htm](http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/npsg_facts.htm)
5. JCAHO. 2005 National Patient Safety FAQs [online]. [cited 18 Feb 2005] Available from Internet: [http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/05\\_npsg\\_faqs.htm#goal\\_3](http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/05_npsg_faqs.htm#goal_3)
6. JCAHO. Implementation Tips for Eliminating Dangerous Abbreviations [online]. [cited 18 Feb 2005] Available from Internet: <http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/tips.htm>
7. Traynor K. Enforcement outdoes education at eliminating unsafe abbreviations. *Am J Health-Syst Pharm* 2004; 16:1314-5.
8. Joint Commission Resources. A guide to JCAHO's medication management standards. Oakbrook Terrace, IL: JCAHO; 2004. p. 142-6.
9. ISMP. Medication Safety Alert! Acute Care Edition. 10 Feb 2005;(10)3.

### 7<sup>th</sup> Annual Patient Safety Congress; PA-PSRS to be Highlighted

The National Patient Safety Foundation (NPSF), one of the nation's leading organizations devoted to patient safety, is sponsoring its 7<sup>th</sup> annual Patient Safety Congress in Orlando, Florida, on May 4-6, 2005. This important conference brings together hundreds of participants and nationally recognized speakers for three days of lectures, breakout sessions, information-sharing, poster sessions and exhibits. Participants represent a broad spectrum of patient safety advocates, including facility administrators, trustees, patients, family members, doctors, nurses, pharmacists, risk managers, educators, researchers, legislators, manufacturers, government officials and many others. More details about the Congress, including information about registration and hotel reservations, can be found at <http://npsf.org/congress>.

As part of the Congress, staff from the Authority will facilitate a session on "Statewide Efforts to Reduce Medical Error" on May 5th. We will be highlighting "lessons learned" as a result of the reports Pennsylvania facilities have submitted through the PA-PSRS system and sharing feedback about systems changes facilities have instituted as a result of *PA-PSRS Patient Safety Advisory* articles.

## Changing the Culture of Seclusion and Restraint

The Commonwealth of Pennsylvania demonstrated leadership in behavioral health when the state hospitals participated in an aggressive statewide program to significantly reduce the use of seclusion and restraints. According to Steven Karp, DO, former Chief Psychiatric Officer of the PA Department of Public Welfare, seclusion hours:

“...dropped from more than 5,000 in February 1993 to just over 4 in February 2003. During this same period, the number of mechanical restraint hours dropped from almost 11,000 to slightly more than 90. Two state hospitals in Pennsylvania have not used restraints, and two others have not used seclusion, in more than two years.”<sup>1</sup>

Further, staff injuries did not increase during this period as a result of decreased use of seclusion and restraints.<sup>2</sup>

The clinical literature on mental health treatment frequently refers to this statewide success story as evidence that a safe environment can be attained for psychiatric patients without resorting to force. Restraints and seclusion became the exception rather than the rule in response to patient’s escalating behaviors. The state hospitals’ change in delivery of care was an extraordinary accomplishment which was acknowledged in October 2000, when Pennsylvania’s Seclusion and Restraint Reduction Initiative received the prestigious Harvard University Innovations in American Government Award.<sup>2</sup>

As the state hospitals met the challenge of providing support rather than control over the institutionalized mentally ill, a newspaper in Connecticut was reviewing deaths related to the use of seclusion and restraints in the nation. The investigative reporting of the *Hartford Courant* in October 1998 was precipitated by the death of a restrained 11-year-old. The article documented 142 deaths related to restraints nationwide over a decade.<sup>3</sup> The leading cause of death related to restraints was death secondary to unintentional asphyxiation that occurs during the restraining of the patient. The very act of restraining brings significant risk to the patient and staff, and today restraints are recognized as an extreme use of force. According to one researcher, “high restraint rates are now understood as evidence of treatment failure.”<sup>4</sup>

With the national focus on the behavioral health industry, both regulatory and accrediting bodies took on the mission of changing their standards to

address the goal of reducing seclusion and restraint use. Healthcare providers have changed not just policies and procedures but also their philosophical model for managing the combative patient. This model has shifted from control to collaboration, from force to facilitation, and from dominance to empowerment. Patient injuries associated with seclusion and restraint were the catalyst for an opportunity to explore alternatives in care delivery for this patient population.

*Healthcare providers have changed their philosophical model for managing the combative patient from one of control to one of collaboration, from force to facilitation.*

### Regulatory and Accrediting Obligations

The Centers for Medicare and Medicaid Services have revised the conditions of participation such that patients have the right to “freedom from restraint and seclusion use to manage violent or aggressive behavior unless clinically necessary.”<sup>5</sup> OSHA has provided Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers<sup>6</sup> and “has cited healthcare facilities under its general duty clause for failure to prevent patient violence against healthcare workers since at least 1993.”<sup>7</sup>

Accrediting bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have stringent standards on restraint use that are applied everywhere in the acute care setting where behavioral patients are managed, including the Emergency Department, medical/surgical units, and others.<sup>8</sup> The Proposed 2006 National Patient Safety Goals and Requirements and Rationale Statements for Behavioral Health Programs includes reducing “the risk of harm associated with emotional and behavioral crisis.”<sup>9</sup> These draft standards reinforce JCAHO’s commitment and focus on the issue of forceful patient management.

### Current Knowledge on Seclusion and Restraints

What do we know of the effectiveness and therapeutic value of restraints and seclusion? A 2003 literature review on the use of physical restraints and seclusion came to the following conclusions:

- Seclusion and restraints are used frequently, but the actual rate is unknown.
- Least restrictive alternatives are considered effective, though this has not been empirically studied.

## Changing the Culture of Seclusion and Restraint (Continued)

- Educational programs have been effective in reducing the use of seclusion and restraints.
- Legal and ethical issues will continue until research demonstrates the efficacy of seclusion and restraints.
- Until empirical research supports a change, there is consensus that the least restrictive measures are preferable.
- Restraints could be used “less arbitrarily, less frequently, and with less trauma” than in current practice.
- Staff education is an effective tool in reducing the incidence of restraint and seclusion.
- Research is critical to address the many issues related to predictive behaviors, effectiveness, alternatives, legal and ethical ramifications.<sup>10</sup>

### Organizational Responses to Minimizing Restraint and Seclusion Utilization

How can a multidisciplinary team respond to an escalating patient situation without resorting to force? Some clinical teams have changed the way they think about the needs of the patient and have moved toward a more humanistic approach of supportive negotiation rather than control. The successful change to less restrictive behavior management necessitates more than procedural changes but rather a philosophical and cultural change to the point where the patient is encouraged and supported as a participant in their treatment plan. “Values of respect and dignity must permeate the system, and disrespectful behavior by staff must be confronted and changed.”<sup>11</sup>

Strong leadership with management and staff accountability is essential. The physician’s role as clinical leader is critical in moving the multidisciplinary team toward a change in response to the patient with escalating behavior. *Learning from Each Other: Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health*<sup>12</sup> was published collaboratively by the American Psychiatric Association, the American Psychiatric Nurses Association, and the National Association of Psychiatric Health Systems. This online resource offers creative approaches to providing an environment of caring rather than one of control.

For example:

- Building a sensitive program by putting yourself in the patient’s place.

- Having patient-centered policies as the infrastructure of the program.
- Proactively negotiating with patients for their suggested alternatives to crisis management.
- Identifying alternative management strategies with your peers in collaborative workgroups.
- Rooting out the underlying causes of aggressive behavior.<sup>12</sup>

Communication is central when shifting the treatment model from one of force to one of support. Organizational and clinical leaders are encouraged to be in “constant dialogue with staff”<sup>12</sup> and to consistently reinforce the reframing of care such that “least restrictive” becomes “most facilitative.” The language and labels used in the clinical setting are important. Consider proactive prevention, by shifting from a show of force to a show of support. In this alternative environment, isolation for patient management shifts towards an upbeat and supportive setting such as a “comfort room” rather than the punitive-sounding “time out room.”<sup>13</sup>

Education is key to assure that staff at the front line are skilled in de-escalating techniques and are prompt in responding to defuse potentially volatile situations. Almost every article includes emphasis on staff education.<sup>14,15</sup>

Some additional considerations:

- Reading and reviewing policies according to a schedule.
- Developing a competency based education for interdisciplinary staff.
- Requiring staff to demonstrate their competence on an ongoing basis.
- Using role playing to reinforce de-escalation interventions.
- Delivering education conveniently around-the-clock.
- Holding staff accountable for their education.<sup>12</sup>
- Educating patients on the changes occurring.<sup>15</sup>
- In programs that manage children and adolescents, training in developmentally appropriate strategies for carrying out seclusion and physical and chemical restraint, including hands-on practice with restraint equipment and techniques and cardiopulmonary resuscitation (CPR) training.<sup>16</sup>

## Changing the Culture of Seclusion and Restraint (Continued)

- Incorporating cultural changes into the educational program requires integrating shared values of dignity and respect while minimizing the need for controlling measures which are reserved for the most extreme situations.<sup>11</sup>

### Team Development and Deployment

CPR is called by a code name in most institutions to provide discretion in a sensitive situation and to notify the team of clinical specialists skilled at resuscitative measures as to where to respond. Each member of the team has a specific responsibility. These team members do two things. First, they provide an advanced level of knowledge and skill to a life-threatening situation. Second, they provide supplemental staff to support the needs of a patient in crisis, thus allowing the staff to attend to the needs of the other patients.

Similarly, the behavioral health code involves pre-identified staff responding to the request for support

in managing a patient with challenging behavior. The behavioral team members are equally highly skilled and typically have certain physical characteristics of size and strength. More important than their size and strength is their commitment and competence in delivering a clinical intervention that supports the patient in a non-threatening manner.

These rapid response teams have been mentioned in some PA-PSRS reports. Two widely used terms are “Code Gray” for combative individuals and “Code Silver” if a weapon is brandished.<sup>7</sup> Pennsylvania state hospitals use the acronym “PERT,” Psychiatric Emergency Response Team, according to Dr. Karp.<sup>17</sup>

Behavioral health code teams provide advanced skills at negotiating, verbal de-escalation techniques, and safe methods of containing a struggling patient. Remaining supportive rather than controlling is the goal, but despite the best of efforts, some

### Reports Involving Seclusion and Restraint Submitted to PA-PSRS

Since its inception, PA-PSRS has received multiple reports describing restraint or seclusion of behavioral health patients. Typically these reports do not include the particulars of the efforts to manage the situation, but they do highlight what occurred when a patient’s behavior cannot be contained. Occasionally, reports describe staff interventions. For example:

- Escalating behavior requiring four staff to escort the patient to seclusion, administration of intramuscular medications and two hours later patient returned to the patient’s room to sleep.
- Peer to peer aggression, response team called to intervene, time out initiated, no injuries noted.
- Patient attempting to inflict harm to self, staff intervened, no harm occurred to patient.
- Crisis team and police called. Patient was holding another patient. Pepper spray was used to subdue the patient.

When a patient demonstrates escalating behavior the clinical team responds in an individualized, strategic, progressive manner. The efforts generated are to contain the situation yet remain supportive of the patient in crisis. When de-escalating techniques fail, the risk versus benefit of restraining is considered, and ultimately the situation may necessitate restraint to protect the patient or others. In these frustrating and disturbing situations the potential for injury—even death—exists. PA-PSRS has received reports of patient injuries which have occurred during restraining, most of which are lacerations, abrasions, and bruises. However, there are seven cases in which the patient sustained a fracture, and one of these cases re-

quired surgery. The demographics of the affected patients are revealing in that six of the seven patients are male, with ages ranging from 12 to 56.

One detailed report provides some insight into the extent of clinicians’ efforts to manage a challenging situation:

The patient was asked to take a time out due to verbally threatening behavior during a group session. Attempts to redirect were unsuccessful. While in time out, the patient began to push staff. He was placed in a manual hold and continued to be combative. He was placed in mechanical restraints until calm. The next day he complained of right shoulder discomfort. An x-ray indicated a fracture of the greater tuberosity of the humerus, which was later confirmed by the orthopedist.

This case exemplifies multiple, gradually escalating levels of intervention: time out, redirection of patient behavior, and manual hold necessitating the use of force. Finally, restraints were applied as a last resort.

In this case the hold used was not described beyond a “manual hold,” but holds have been associated with injuries even fatalities.<sup>1,2</sup> Certain holds (such as the chokehold or the basket hold) and positions (face down/prone) are particularly threatening to the patient, and many organizations have banned their use.<sup>3</sup> Restrictive measures applied to the neck or near the patient’s airway are particularly hazardous. Compression of the chest also carries the risk of positional asphyxiation if the chest’s normal respiratory expansion cannot occur.

*(Continued on next page)*

## Changing the Culture of Seclusion and Restraint (Continued)

situations may need to be managed with force. It is important to remember that restraining the already traumatized psychiatric patient can have long lasting physical and emotional consequences.

### Debriefing or Restraint Review

When it is necessary to use force and restrain a patient, an opportunity for improvement exists. How could this situation been handled differently? Did the patient provide clues to their changing needs? Were the interventions attempted sufficient? Could a compromise been employed? If we had intervened earlier, could the situation have been managed with a less restrictive intervention?

Reviewing interventions immediately after occurrence in a “debriefing” format allows the clinical team to confront the successes and shortcomings of the team response, the interventions, and alter-

natives attempted. Aside from dissecting the event, consideration of the attitudes and feelings of the staff, the victim, and those patients who witnessed the event are of value. A patient-centered program is sensitive to the perceptions of all involved in an effort to understand individual responses. Ultimately these internal reviews are intended to improve the response to future events.<sup>7,12,15</sup>

While Pennsylvania has assumed a leading role in reducing restraint and seclusion use, there is still room for improvement. Additional effort is necessary to reduce the need to resort to restraint and seclusion and, when restraint becomes necessary, to minimize the risk of patient injury. Though restraining the patient is recognized as “a treatment failure”<sup>4</sup> it is acknowledged that in some situations restraints are vital in preventing injury to patients and/or staff.

### Reports Involving Seclusion and Restraint Submitted to PA-PSRS (Continued)

*(Continued from previous page)*

The JCAHO Sentinel Event Alert on Preventing Restraint Deaths<sup>4</sup> reports that 30 percent of restraint-related deaths occurred during a therapeutic hold. When absolutely necessary and all other less restrictive measures have failed in managing a situation where the patient, other patients, and staff are threatened, restraining of an individual may be necessary. Certain factors or patient characteristics may place the patient at greater risk of fatality during restraint, such as:

- Neck holds
- Obstruction of nose, mouth, or chest expansion
- Prone or hobble tying
- Hyperflexion in a seated position
- Obesity
- Heart disease
- General poor health
- Exhaustion or prolonged struggling
- Illicit or prescribed medications
- Drug intoxication<sup>1,2,5</sup>

Recognizing the hazards of patient restraint, consider the following strategies to mitigate the risk:

- Redoubling efforts to reduce the use of physical restraint and therapeutic hold through the use of routine risk assessment and early intervention with less restrictive measures.
- Enhancing staff orientation/education with alternatives to physical restraints and proper application of restraints or therapeutic holding.

- Developing structured procedures for consistent application of restraints.
- Continuously observing any patient in restraints.
- If a patient must be restrained in the supine position, ensuring that the head is free to rotate to the side and, when possible, elevating the head of the bed to minimize the risk of aspiration.
- If a patient must be restrained in the prone position, ensuring that the airway is unobstructed at all times (for example, not covering or “burying” the patient’s face).
- Ensuring that expansion of the patient’s lungs is not restricted by excessive pressure on the patient’s back (with special caution for children, elderly patients, and obese patients).<sup>4</sup>

#### Notes

1. Horsburgh D. How, and when, can I restrain a patient? *Postgrad Med J* 2004;80:7-12
2. Paterson B, Bradley P, Stark C, et al. Deaths associated with restraint use in health and social care in the UK. The results of preliminary survey. *J Psychiatr Ment Health Nurs* 2003(10):3-15.
3. Stefan S. Legal and regulatory aspects of seclusion and restraint in mental health settings. Special edition violence and coercion in mental health settings: eliminating the use of seclusion and restraint. *Sum/Fall* 2002. 3
4. Joint Commission on Accreditation of Healthcare Organizations. Sentinel event alert [online]. 1998 Nov 18 [Cited 1 Mar 2005]. Available from Internet: [http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea\\_8.htm](http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_8.htm)
5. Masters KJ, et al. Practice parameter for the prevention and management of aggressive behavior in child and adolescent psychiatric institutions, with special reference to seclusion and restraint. *J Am Acad Child Adolesc Psychiatry*. 2002 Feb;41(2 Suppl):4S-25S.

## Changing the Culture of Seclusion and Restraint (Continued)

### Notes

1. Reducing seclusion and restraint use – what works! [online] May 2003. [Cited 11 Feb 2005] Available from Internet: <http://alt.samhsa.gov/seclusion/SRMay5report7.htm>
2. Pennsylvania Department of Public Welfare, Office of Mental Health and Substance Abuse Services. Leading the way toward a seclusion and restraint-free environment. Pennsylvania's seclusion and restraint reduction initiative. Harrisburg (PA): Office of Mental Health and Substance Abuse Services; 2000.
3. Weiss E. A nationwide pattern of death. Hartford Courant 1998 Oct 11-15.
4. Stefan S. Legal and regulatory aspects of seclusion and restraint in mental health settings. Special edition violence and coercion in mental health settings: eliminating the use of seclusion and restraint. Sum/Fall 2002. 3
5. Health Care Financing Association. Medicare and Medicaid Programs: Hospital Conditions of Participation: Clarification of the Regulatory Flexibility Analysis for Patients' Rights: Interim Final Rule. Fed Regist 2002 Oct 2;67(191):61805-8.
6. Occupational Safety and Health Administration. Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers [online]. 2004. [Cited 28 Dec 2004]. Available from Internet: <http://www.osha.gov/Publications/OSHA3148.pdf>.
7. ECRI. Patient violence healthcare risk control risk analysis, Jul 2002. Healthc Risk Cont 4(2).
8. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Behavioral health care. Restraint and seclusion. [online] Updated: 1 Jan 2004. [Cited 24 Jan 2005]. Available from Internet: [http://www.jcaho.org/accredited+organizations/behavioral+health+care/standards/faqs/provision+of+care/special+interventions/restraint\\_seclusion.htm](http://www.jcaho.org/accredited+organizations/behavioral+health+care/standards/faqs/provision+of+care/special+interventions/restraint_seclusion.htm)
9. JCAHO. Proposed 2006 national patient safety goals and requirements and rationale statements – behavioral health program [online]. [Cited 24 Jan 2005]. Available from Internet: [http://www.jcaho.org/accredited+organizations/behavioral+health+care/standards/field+reviews/06\\_npsg\\_bhc\\_fr.htm](http://www.jcaho.org/accredited+organizations/behavioral+health+care/standards/field+reviews/06_npsg_bhc_fr.htm)
10. Bower FL, McCullough C, Timmons M. A synthesis of what we know about the use of physical restraints and seclusion with patients in psychiatric and acute care settings: 2003 update. Online J Knowl Synth Nurs. 2003 Apr 22;10:1.
11. Karp S. Coercive Tactics Are No Longer Viable Treatment Methods. Special Edition Violence and Coercion in Mental Health Settings: Eliminating the Use of Seclusion and Restraint. Sum/Fall 2002:15.
12. American Psychiatric Association, American Psychiatric Nurses Association, National Association of Psychiatric Health Systems. Learning from each other: Success stories and ideas for reducing restraint/seclusion in behavioral health [online]. 2003. [Cited 2005 Feb 21.] Available from Internet: [http://www.psych.org/psych\\_pract/treatg/pg/LearningfromEachOther.pdf](http://www.psych.org/psych_pract/treatg/pg/LearningfromEachOther.pdf)
13. Bluebird G. Comfort and communication help minimize conflicts. Special edition violence and coercion in mental health settings: Eliminating the use of seclusion and restraint. Sum/Fall 2002;18
14. Jorgensen BA, Geisler C. Perspectives from the field education is key to system-wide change. Special edition violence and coercion in mental health settings: Eliminating the use of seclusion and restraint. Sum/Fall 2002;9.
15. McCue RE, Urcuyo L, Lilo Y, et al. Reducing restraint use in a public psychiatric inpatient service. J Behav Health Serv Res. Apr/Jun 2004;217-24.
16. Masters KJ, et al. Practice parameter for the prevention and management of aggressive behavior in child and adolescent psychiatric institutions, with special reference to seclusion and restraint. J Am Acad Child Adolesc Psychiatry. 2002 Feb;41(2 Suppl):4S-25S.
17. Karp, Steven (Rosewood Woman's Center for Eating Disorders, Wickenburg, AZ) E-mail to: Monica Davis. 2005 March 9.

### Patient Safety Resources

The Patient Safety Authority has identified major organizations that have a primary focus on patient safety. Their websites, which are accessible to the general public, provide useful information, other resources and additional linkages related to patient safety. The list is accessible under "Links" in the left navigation bar on the Authority's website: [www.psa.state.pa.us](http://www.psa.state.pa.us).

## The Need for Surgical Preparation

Surgeons understand the need to be properly trained to do a procedure. They also understand the need for a preoperative “time out” to verify that the correct patient is getting the correct procedure on the correct part of the body. However, preparation includes more than training and “time outs.” Consider these recent reports to PA-PSRS:

**Case #1:** A surgeon scheduled a patient for elective closure of a cranial defect from prior surgery. The surgeon brought prosthetic material to the operating room for the closure, but it was material suitable for temporary closure only, not permanent closure. The error was recognized before the operation began, and the procedure was cancelled and re-scheduled.

**Case #2:** A patient with an acute left femoral artery occlusion was brought to the operating room after confirmatory angiography. The consent for thrombectomy, obtained as an emergency by someone other than the surgeon, erroneously listed the wrong leg. The pre-operative “time out” was done with the surgeon, but based on the incorrect consent. While making the initial incision, the surgeon remembered that the occlusion was in the left leg. To reconcile the conflicting information, he had the films brought to the operating room. The films confirmed his recollection, so he closed his skin incision and proceeded to do the thrombectomy on the correct leg.

**Case #3:** A surgical patient was kept under general anesthesia for two hours before their

operation was begun. During this time the surgeon was on the phone with the technical representative of a medical device manufacturer. According to the facility’s report, the surgeon was “trying to figure out how to use [the] Neuro Navigator system.”

Preoperative preparation by the surgeon may need to go beyond verifying the consent and the correct patient, the correct procedure, and the correct site. A comprehensive preoperative checklist could also include:

- Re-assessment for recent changes in the patient’s condition.
- Verification of the indications for the operation with adequate information about the extent and exact location of the pathology available in the operating room for possible intra-operative decision making.
- Review of the patient’s other medical conditions, allergies, and medications, including medications at the time of surgery, such as prophylactic antibiotics.
- Confirmation that essential materials, such as blood products, implants, or prostheses, are available.
- Confirmation that essential equipment is working properly.
- Discussion with the team of possible intra-operative complications and how they should be managed.



An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority’s website at [www.psa.state.pa.us](http://www.psa.state.pa.us).



ECRI is an independent, nonprofit health services research agency dedicated to improving the safety, efficacy and cost-effectiveness of healthcare. ECRI’s focus is healthcare technology, healthcare risk and quality management and healthcare environmental management. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, and other organizations worldwide.



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 non-punitive approach and systems-based solutions.