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# Adverse Event Reporting Promotes a Culture of Safety

Alan B.K. Rabinowitz, MA, William M. Marella, MBA, and Laurene Baker, MA

Adverse event reporting is a first step in dealing with issues of quality and safety. However, to date, Pennsylvania is the only state that mandates its 460 hospitals and ambulatory surgical facilities to report both “serious” adverse events and “near-misses.” Data collected through the Pennsylvania Patient Safety Reporting System (PA-PSRS), a Web-based reporting and analytical tool, is analyzed and reported in the quarterly *Patient Safety Advisory*, with an emphasis on what can be learned from these experiences. Not surprisingly, data show that patients older than 65 years were involved in 60% of all adverse events in 2005, and 65% of reported medication errors involved the use of “high-risk” medications. What’s more important is that, according to a PA-PSRS user survey, 75% of responding hospitals indicated that they had implemented new protocols as a result of clinical guidance contained in the *Patient Safety Advisory*.

## Patient Safety at the Foundation of Health Care

Although problems associated with quality and safety have been recognized for a long time, the 1999 Institute of Medicine (IOM) report was a wake-up call.<sup>1</sup> Today, public attention and expectations are focused on patient safety issues. There are frequent articles in professional literature and the popular press about patient safety, and television and newspaper reports routinely highlight health-care quality.

In the summer of 2006, the IOM issued *Preventing Medication Errors*, the latest report in its *Crossing the Quality Chasm* series, citing the frequency and po-

tentially tragic consequences of medication errors.<sup>2</sup> *Newsweek’s* October 16, 2006, issue devoted almost 25 pages to patient safety and healthcare improvement, and the Public Broadcasting Service (PBS) broadcast a 4-part series, entitled “Remaking American Medicine,” that focused on how physician champions and hospital managers are successfully implementing innovative solutions to prevent future complications and deaths from medical errors.<sup>3</sup>

The federal government is also actively engaged in issues of quality and patient safety. As the nation’s largest healthcare payer, the Centers for Medicare and Medicaid Services (CMS) has a financial incentive to

help ensure quality and safety. CMS has embraced the concept of transparency, making quality indicators on hospitals, nursing homes, and other providers available to consumers.<sup>4</sup> It has invested in the Medicare Patient Safety Monitoring System (MPSMS), a project to determine the rates of adverse events based on Medicare discharges and administrative data.<sup>5</sup> CMS has also declared its intention to eliminate payment for care related to the National Quality Forum’s “never events”—such as wrong-side surgery or patient death from a fall.<sup>6</sup> The Agency for Healthcare Research and Quality (AHRQ) is also an agent for patient safety improvement, funding numerous studies and projects to determine the evidence behind patient safety interventions and disseminating best practices through evidence reports, information clearinghouses, and Web sites.<sup>7</sup>

That patient safety is now part of the national consciousness is a significant advance, but healthcare organizations still struggle with their responses to individual errors. “What happened?” is the first question asked when a patient is injured by a medical error; the next question is typically, “Who did it?” When bad things happen because of negligence or intentionally unsafe acts, individual practitioners and facilities must be held account-

able. However, research indicates that the vast majority of medical errors occur as a result of “systems” problems, a series of events involving many people performing different functions in complex healthcare settings. Rather than ask “Who did it?,” it is more appropriate to ask, “How did it happen?” By investigating the causes of an adverse event, we can then turn to the next question the public rightfully asks, “How will you make sure that this tragedy doesn’t happen to someone else?”

These 3 questions—(1) “What happened?,” (2) “How did it happen?,” and (3) “What are you doing to prevent a reoccurrence?”—comprise the foundation for a “culture of safety” within the healthcare industry, in which people and institutions encourage full and open disclosure to patients, acknowledging mistakes while implementing procedures to prevent future errors. Individual providers must acknowledge that the public—specifically, patients and their families—deserve meaningful answers to their questions when they or a loved one suffers an unexpected adverse event or medical error.

### **Pennsylvania’s Approach to Patient Safety**

In the wake of the 1999 IOM report and concurrent with crises related to medical malpractice liability insurance and physician supply, the Pennsylvania State Legislature passed comprehensive legislation in 2002 that, among other provisions, established the Pennsylvania Patient Safety Authority as an independent, nonregulatory, state agency charged with reducing and eliminating medical errors by identifying problems



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and recommending solutions that promote patient safety.

Under the enabling legislation, all Pennsylvania hospitals, ambulatory surgical facilities, and a few other facilities (currently numbering about 460) are required to submit reports of adverse events that result in patient harm (called *serious events* in the legislation). Near-misses that could have but did not result in patient harm (called *incidents* in the legislation)

must also be reported.<sup>8</sup> Pennsylvania was, and remains, the only state in the nation to mandate the reporting of both adverse events and near-misses.<sup>9</sup>

In June 2004, the Authority implemented the Pennsylvania Patient Safety Reporting System (PA-PSRS), a secure, Web-based reporting and analytical tool. All information submitted is confidential and nondiscoverable, and the system does not collect any identifiable patient or provider information. Reports are submitted through a facility’s internal patient safety protocols, not by individual providers. Healthcare workers who identify reportable events have whistleblower protections. With the exception of limited, deidentified statewide aggregate data, facilities only have access to their own data and cannot access data from other facilities.

### **Case Study 1**

#### **Use of Color-coded Patient Wristbands Creates Unnecessary Risk**

**Problem:** A hospital reported that healthcare workers nearly failed to rescue a patient who had cardiac arrest because the patient had been incorrectly designated as DNR (do not resuscitate). A nurse had incorrectly placed a yellow wristband on the patient. In this hospital, the color yellow meant that the patient should not be resuscitated. In a nearby hospital, in which this nurse also worked, yellow meant that this arm is not to be used for drawing blood or obtaining IV access.

**Prevention advice:** Although there is no standardized use of colors to convey clinical information, there are a number of steps facilities can take to make the use of color-coded wristbands safer. For example, individual facilities can limit the number and colors of patient wristbands and use printed text to reinforce the meaning of specific colors. For the complete article, see “Use of color-coded patient wristbands creates unnecessary risk” in the December 2005 Supplement of the *Patient Safety Advisory* at: [www.psa.state.pa.us/lib/psa/advisories/v2\\_s2\\_sup\\_\\_advisory\\_dec\\_14\\_2005.pdf](http://www.psa.state.pa.us/lib/psa/advisories/v2_s2_sup__advisory_dec_14_2005.pdf).

The PA-PSRS staff, comprised of a team of clinicians headed by a trauma surgeon, review and analyze all reports to identify trends and best practices that can help prevent future patient harm or injury. The staff include professionals with education and experience in medicine, nursing, law, pharmacy, biomedical engineering, health administration and risk management, among other fields, and they have access to a large pool of subject matter experts in virtually every medical specialty.

### Lessons Learned

PA-PSRS research findings are published in the *Patient Safety Advisory*, a quarterly publication containing articles about actual reports submitted by Pennsylvania facilities. Articles include analyses of and lessons learned from those reports and evidence-based risk reduction strategies based on research in the clinical literature. As of October 2006, the Authority published 11 quarterly and 4 supplementary issues of the *Patient Safety Advisory*, containing more than 150 articles. Many of these articles relate to situations in which elderly patients are likely to be involved.

The *Advisory* is widely distributed and made available electronically through numerous national and international news services and Listservs. Readers are encouraged to subscribe, at no cost, to the *Advisory* on the Authority's Web site ([www.psa.state.pa.us/psa/cwp/view.asp?a=1293&q=445966&psaNav=1](http://www.psa.state.pa.us/psa/cwp/view.asp?a=1293&q=445966&psaNav=1)).

Although some reports involve sophisticated or complex procedures or equipment, numerous reports of adverse events and near-misses can be attributed to such

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routine procedures as failure to comply with accepted hand washing protocols, breakdown in communication, misuse of abbreviations, use of incomplete or inadequate patient identification, and failure to identify problems associated with high-alert medications. Many reports reflect situations that are well documented in the literature, in some cases prominently highlighted by national organizations such as the Joint Commission on Accredita-

tion of Healthcare Organization's (JCAHO) annual National Patient Safety Goals (NPSGs) or the Institute for Healthcare Improvement's (IHI) 100,000 Lives Campaign.

### Focus on Older Patients

Elderly patients are generally considered to be a vulnerable population, and this reality is reflected in PA-PSRS reports. More than half (53.0%) of all reports submitted by hospitals in 2005 involved patients aged 65 or older, even though these patients accounted for only 40.9% of inpatient hospitalizations.<sup>10</sup> Table 1 shows a breakdown by patient age of reports received in 2005.

Compared to younger patients, older patients may be at increased risk for injury during clinical care. Patients aged 65 and older were involved in 60% of all adverse events reported in 2005.

### Case Study 2

#### Health Care-associated Infections (HAI)

**Problem:** *Clostridium difficile* is a potentially harmful bacterium that can result in patient deaths. Most patients (86%) in PA-PSRS reports involving *C. difficile* were 70 years of age or older and using antibiotics to guard against infection following elective surgery. Although there are obvious symptoms of the infection, many patients, especially older patients, failed to return to the healthcare system until the disease had progressed significantly.

**Prevention advice:** For *C. difficile*, as for all infections, healthcare workers and the general public should thoroughly wash their hands and clean surfaces to prevent contamination of supplies and transmission of the infection to others. It's also important, particularly for *C. difficile*, to limit the use of antibiotics in the time immediately before and after surgery since antibiotics not only destroy bad organisms but also promote the growth and spread of the *C. difficile* bacterium. For the complete article, see "*Clostridium difficile*: a sometimes fatal complication of antibiotic use" in the June 2005 *Patient Safety Advisory* at: [www.psa.state.pa.us/psa/lib/psa/advisories/v2n2june2005/vol\\_2-2-june-05-article\\_a-clostridium\\_difficile.pdf](http://www.psa.state.pa.us/psa/lib/psa/advisories/v2n2june2005/vol_2-2-june-05-article_a-clostridium_difficile.pdf).

There are a number of possible explanations for this finding. Older patients may be more likely than younger ones to be harmed by the same occurrence. For example, a fall that might result in a fracture in an elderly patient may result in little injury to an adolescent. Older patients may also seek health care for more serious illnesses that require more complex interventions. When admitted to a hospital, older patients typically remain in the hospital longer than younger patients, which may also increase the chances that older patients will be harmed.

Certain types of injury are more likely to affect elderly patients than younger ones. As shown in Table 2,

**Table 1.**  
**PA-PSRS reports submitted by age cohort in 2005**

Age cohort (y)	No.	%
0-4	7,038	4.2%
5-14	3,289	1.9%
15-24	7,067	4.2%
25-34	8,650	5.1%
35-44	12,358	7.3%
45-54	18,567	11.0%
55-64	22,710	13.4%
65-74	29,333	17.3%
75-84	40,026	23.7%
85+	20,034	11.8%
<b>Total</b>	<b>169,069</b>	<b>100.0%</b>

falls were among the most frequently reported occurrences among elderly patients. Reports of falls involving elderly patients accounted for 64% of all reports of patient falls,

significantly greater than the rate among younger patients. Report volume also reflects elderly patients' greater risk of skin-integrity problems, such as pressure sores, bruises,

**Table 2.**  
**Reports involving elderly patients by event type in 2005**

Event Type*	Patients Aged 65 and Older		Patients Aged 64 and Younger		Total	
	No.	%	No.	%	No.	%
Medication errors	22,139	52%	20,230	48%	42,369	25%
Adverse drug reactions (not medication errors)	1,390	41%	1,967	59%	3,357	2%
Equipment, supplies, or devices	1,026	40%	1,521	60%	2,547	2%
Falls	21,534	64%	12,117	36%	33,651	20%
Errors related to procedure, treatment, or test	16,094	45%	19,510	55%	35,604	21%
Complications of procedure, treatment, or test	10,639	46%	12,419	54%	23,058	14%
Transfusions	945	58%	688	42%	1,633	1%
Skin integrity	11,027	73%	4,089	27%	15,116	9%
Miscellaneous	4,599	39%	7,135	61%	11,734	7%
<b>Total</b>	<b>89,393</b>	<b>53%</b>	<b>79,676</b>	<b>47%</b>	<b>169,069</b>	<b>100%</b>

\*The event types in the left-hand column reflect specific categories on the PA-PSRS report submission form.

and skin tears—accounting for 73% of all such reports. Though infrequent, transfusion problems are also more commonly reported among elderly patients. On the other hand, some types of reports—for example, adverse drug reactions, errors associated with actual procedures, and problems involving equipment or supplies—are significantly less likely to be associated with elderly patients than nonelderly patients.

PA-PSRS research confirms the relationship between medications and patient falls. Approximately 21% of all reports of patient falls submitted to PA-PSRS indicate that the patient was receiving one or more drugs known to contribute to the risk of falling or to increase the risk of injury when a fall occurs.<sup>11</sup>

Almost 25% of reported medication errors involve one or more “high-alert” medications. The most frequently cited high-alert drugs are pain management medications, insulin products, and anticoagulants such as heparin and warfarin (Coumadin). In fact, 65% of all medication-related adverse events involved high-alert medications.<sup>11</sup> PA-PSRS research identifies strategies to prevent these medication errors. These include limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, preparation, and administration of these products; and employing automated or independent double checks when necessary.

### **Promoting a Culture of Safety**

In the 30 months since mandatory reporting was initiated in Pennsylvania, PA-PSRS has received more than 410,000 reports, a signifi-

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cant data base that, contrary to some predictions, validates the utility of mandatory reporting, especially the mandatory reporting of near-misses. The point of mandatory reporting is not merely to collect reports but rather to learn from past experiences in one’s own facility and from the experiences of other facilities. In the last annual PA-PSRS user survey, 75% of responding hospitals indicated that they had implemented new protocols as a result of clinical guidance contained in

the *Patient Safety Advisory*.

By many measures, the PA-PSRS system has elevated Pennsylvania to the forefront of patient safety activities around the country. Other states, federal agencies, and national healthcare and quality improvement organizations are following this initiative with keen interest. In October 2006, the Authority was awarded the prestigious John Eisenberg Award, given jointly by the JCAHO and the National Quality Forum, for innovation and the promotion of patient safety throughout Pennsylvania and around the country.

Adverse event reporting is a first step in dealing with issues of quality and safety. The action of submitting a report is an acknowledgement that something actually or almost happened, but the next steps are more important—learning why it happened and implementing steps to prevent it from happening again. This is no easy

*(continued on page 42)*

### **PROVIDER ACTION**

#### **Impact to You**

Adverse events are a significant problem for our elderly patients. Data shows that patients older than 65 years were involved in 60% of all adverse events in 2005. In addition, eliminating adverse events and promoting quality outcomes is increasingly being tied to reimbursement through pay-for-performance initiatives as well as CMS’s refusal to pay for National Quality Forum’s “never events.”

#### **What You Need to Know**

It is essential to learn from experiences in one’s own facility and from the experiences of other facilities. Adverse event reporting is a first step in dealing with issues of quality and safety.

#### **What You Need to Do**

With each adverse event, answer three questions: What happened? How did it happen? And what are you doing to prevent a reoccurrence? Addressing these questions is the first step in developing a culture of safety in which people and institutions are encouraged to implement procedures to prevent future errors and improve quality.

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Harrisburg, PA. William M. Marella, MBA, is employed by the Pennsylvania Patient Safety Reporting System (PA-PSRS) in Harrisburg, PA, and by the Emergency Care Research Institute (ECRI) in Plymouth Meeting, PA.

The profit that the generic drug generates is usually less than the lost by the manufacturer.

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