Clearing the Err

Reporting Serious Adverse Events and "Never Events" in Today's Health Care System

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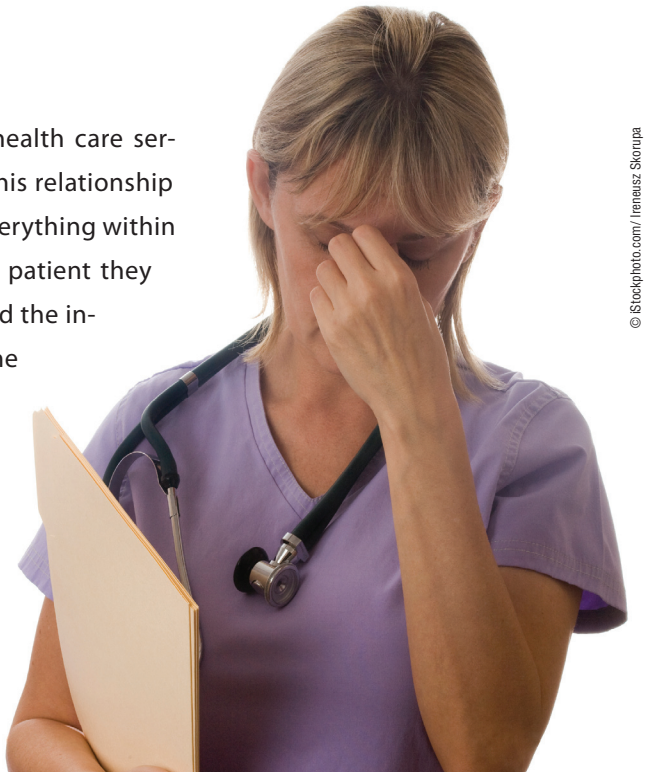
ABSTRACT

Absent an infinitesimal percentage, most Americans seek health care services due to a legitimate health issue. Fundamental within this relationship is the understanding that health care professionals will do everything within their power and expertise to alleviate the suffering of each patient they treat. Unfortunately, preventable medical errors do occur, and the innocent patient is left to suffer. In 1999, the Institute of Medicine released *To Err Is Human: Building A Safer Health System*, the first mainstream publication calling for a change in the culture of health care and the eradication of preventable medical errors. In the 10 years since its publication, federal and state governments and agencies have been proactive in attempting to meet the recommendations originally proposed in *To Err Is Human*. This article will review what has been accomplished in this time frame.



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The authors disclose that they have no significant financial interests in any product or class of products discussed directly or indirectly in this activity, including research support.

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doi:10.3928/00989134-20091016-01

"I've made a mistake." This simple statement, or its mere thought, is enough to strike fear within the most experienced and knowledgeable of health care professionals. No matter how many times a procedure has been done or a medication administered, there is always the likelihood of preventable error. Each year, the public is reminded of the potential for mistakes as the media report medical horror stories where, for example, unknowing patients have surgery performed on the wrong body part, a wrong medication administered, or a foreign object errantly left inside their bodies. These reports highlight the biggest fear of health care workers—their own fallibility. Through carelessness, assumption, overt act, or omission, the health care professional can easily err and cause harm to the patient. In addition to the pain caused to the patient, health care providers also understand the devastating impact that such errors can wreak on their own personal and professional lives. The purpose of this article is to

discuss the trend in today's health care systems toward the reporting of serious adverse events or "never events," as well as the impact—both impending and current—on the role of geriatric nurses.

REFOCUSING AND REBUILDING A SAFE HEALTH CARE SYSTEM

In November 1999, the Institute of Medicine (IOM) released a profound call to action for everyone involved in the health care community. This statement, entitled *To Err Is Human: Building A Safer Health System*, began with a grim statistic, estimating that between 44,000 and 98,000 people died per year from preventable medical errors as hospital patients. The IOM (1999) report defined *medical error* as the use of a wrong plan of action to achieve an aim or the planned action's failure to be completed as intended. In economic terms, these errors were estimated to cost between $17 billion and $29 billion per year across the country (IOM, 1999). These financial estimates include the costs of lost income, lost household productivity, and the cost of the additional health care necessitated by the errors (IOM, 1999). The more specific recommendations posited by the IOM (1999) for the prevention of medical errors are discussed below.

The IOM (1999) report recommended a four-tiered approach to achieve a better safety record:

- Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.
- Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health care organizations and practitioners to develop and participate in voluntary reporting systems.
- Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and purchasers of health care.
- Implementing safety systems in health care organizations to ensure safe practices at the delivery level.

As a result of these broad recommendations, state and federal governments, agencies, and health care institutions were given notice about the increased focus on the prevention of medical errors and, consequently, the improved safety of the patient receiving treatment. During the 5 years following the IOM (1999) report, progress began to be made.

In 2001, the U.S. Congress appropriated an annual budget of $50 million for patient safety research (Leape & Berwick, 2005). From this appropriation, the Agency for Healthcare Research and Quality (AHRQ) was codified as the federal agency to oversee patient safety and its improvement (Leape & Berwick, 2005). AHRQ became an important player in the new patient safety movement by evaluating health care practices to determine effectiveness, educating health care institutions about how to best report errors and adverse events, and creating a roadmap of evidence-based best practices (Leape & Berwick, 2005).

Using the roadmap created by AHRQ, the National Quality Forum (NQF) (2007) created a list of 27 serious reportable events, also referred to as *never events*, which were offered as the basis for a potential national reporting system chronicling patient safety. The serious reportable events may be divided into six separate categories, including surgical events, product or device events, patient protection events, care management events, environmental events, and criminal events (NQF, 2007). For the purposes of this article, however, the individual events will not be discussed, as the focus is to remain on the implementation and evolution of patient safety standards.

In 2005, the American Medical Association (AMA) released a report by Leape and Berwick detailing the effects of the original IOM publication. The AMA report, while admitting there had been little measurable effect after the release of the IOM report and that no comprehensive nationwide system for monitoring had been put into existence, discussed how the focus of patient care had shifted from fixing blame to implementing a culture of safety (Leape & Berwick, 2005). This alone can be considered an impressive feat in today's increasingly litigious society. Furthermore, Leape and Berwick (2005) identified the four areas the health care system needed to advance in the following 5 years to facilitate the transition to a patient safety focus.

First, Leape and Berwick (2005) recommended the implementation of electronic medical records. It is argued that this implementation, although a substantial initial cost, will save the facility and pay for itself due to the decrease in charges of adverse events and increase in efficien-

cy of staff. Second, as more methods are implemented, newer and safer practices will be proven. The final two advancements named in the IOM (1999) recommendations can be met as newly learned information is disseminated through the health care system and, ultimately, training of health care workers continues to evolve and improve. Last, health care professionals should then be able to admit mistakes, apologize, and improve communication with patients, as it has been found that full disclosure of a mistake does not increase the risk of a lawsuit being filed (Leape & Berwick, 2005).

WHERE ARE WE NOW?

As the tenth year following *To Err is Human* (IOM, 1999) is drawing to a close, health care professionals can readily see and appreciate the changes being made to improve patient safety and their own practice. An inexhaustive list comparing several states, their attempts to improve patient safety, and new federal guidelines are discussed below.

Minnesota

In 2003, Minnesota became the first state to adopt a never events law (Minnesota Department of Health, 2008). Initially, this law required Minnesota's hospitals, regional treatment centers, and freestanding outpatient surgical centers to report these never events to the Minnesota Department of Health (2009). These events were then reported to the public by the Minnesota Department of Health (2008) on an annual basis. In 2005, however, an amended law took effect, requiring Minnesota hospitals to report the occurrence of a never event publicly, to the Minnesota Hospital Association's web-based Patient Safety Registry (Dotseth, 2004). In addition, Minnesota Statutes §144.7065 (2005) requires applicable facilities to investigate each reported event, report the underlying cause of each event, and take corrective action to prevent the recurrence of such an event. Lastly, an annual report required by Minnesota Statutes §144.7069 (2005) is published by the Minnesota Department of Health, thereby providing a forum for hospitals to share information and learn from each other's errors.

New Jersey

In 2004, the State of New Jersey put into effect The Patient Safety Act, requiring every health care facility licensed by the New Jersey Department of Health and Senior Services (2008) to report serious preventable adverse events. Specifically, the law required hospitals to report these events to the New Jersey Department of Health and Senior Services (Patterson, 2009). Interestingly, the law keeps hospital-specific information confidential after its release, leaving consumers uninformed about where the never events actually occurred; however, unlike other states, the law requires immediate disclosure of medical errors to patients who were harmed by them (Patterson, 2009).

Connecticut

Also in 2004, the State of Connecticut adopted into law Public Act No. 04-164: An Act Concerning the Quality of Health Care, a combination of NQF and state-specific reportable events. Originally, Connecticut only required facilities to report injuries associated with or caused by medical management that resulted in measurable disability or death, thereby allowing nonlethal and less catastrophic errors to remain confidential from the public; however, after review, the law was amended to require the disclosure of the never events as proposed by NQF (Public Act No. 04-164, 2004). Both hospitals and outpatient surgical facilities are required to report such events to the state Department of Public Health; however, the disclosure of the reports is restricted (Public Act No. 04-164, 2004).

Illinois

On January 1, 2008, Illinois became the fourth state to require the public reporting of never events with the implementation of the Illinois Adverse Health Care Events Reporting Law of 2005. Initially, this mandatory reporting law, the Hospital Assessment Act of 2005, required ambulatory surgical centers and hospitals to report these events to the Illinois Department of Public Health (Illinois Hospital Association, 2008). In addition, it should be noted that only the published annual report is available publicly. Further, any findings, corrective action plans, and records are unavailable to the public and are not discoverable or admissible at law (Illinois Hospital Association, 2008).

California

The State of California began the implementation of a law, effective in 2007, mandating that general acute care hospitals, special hospitals, and acute psychiatric hospitals report the occurrence of one of their statutorily defined adverse events to the California Department of Public Health (California Health and Safety Code §1279.1 *et seq*., 2008). Interestingly, California has two unique provisions to its medical error reporting system. First, reporting is required of an event or series of events that causes the serious disability or death or a patient, visitor, or personnel (California Health and Safety Code §1279.1 *et seq*., 2008). This requirement is an expansion of whom to include within the definition of *adverse event*. Second, the requirements call for the patient to be notified within 24 hours of the discovery of the error (California Health and Safety Code §1279.1 *et seq*., 2008). This second feature creates several potential and currently unresolved issues, including how the patient should be informed of the error, who should inform the patient of such an error, and how

this information will be communicated and later analyzed by the California Department of Public Health.

Geriatric Patient Populations

Of specific interest to professional nurses practicing with geriatric patients in skilled nursing, long-term care, extended care, assisted living, or other facilities recognized by the individual state, is the current incantation of the state's existing law. For example, in the NQF (2007) update, only New Jersey, Oregon, and Wyoming appear to have laws in place that specifically address the locations most often associated with geriatric care.

Furthermore, on May 18, 2006, the Centers for Medicare & Medicaid Services (CMS) spoke for the first time about never events. In this statement, CMS reported it was investigating ways for Medicare to reduce or eliminate the occurrence of these events. CMS provided its plan on April 14, 2008, when it announced that Medicare will cease payment for eight specific kinds of never events. Since releasing these statements, CMS has extended this policy of nonpayment from inpatient hospital services to both service of nonfacility providers, including physicians, and to outpatient services. Frequent updating and research will be required as the focus of today's health care system changes.

CONCLUSION

Nursing is one of the most dynamic and ever-changing professions in health care. In a relatively short time, the focus of nursing has begun shifting from that of assigning blame and determining liability to the promotion of safety and prevention of error. As the focus of the practice of medicine shifts more from diagnosis and treatment to screening and prevention, so too does the practice of nursing. As this continues, nurses must always strive to learn and implement the most current best practices while remaining knowledgeable of their state's applicable laws and federal guidelines. The changing landscape of nursing and health care presents an especially difficult challenge for those providing care to geriatric patients who are not located in acute care settings. Only by researching the current law and forecasting state and federal trends will nurses be able to provide the best and safest care for their patients while limiting personal risk and liability. Unfortunately, errors will probably never be eradicated, but with education and care, nurses will be able to focus their practice on the most important aspect in health care—the patient.

The changing landscape of nursing and health care presents an especially difficult challenge for those providing care to geriatric patients who are not located in acute care settings.

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