Statement before the
Committee on Health, Education, Labor and Pensions
Subcommittee on Primary Health and Aging
United States Senate

Hearing on:
"More Than 1,000 Preventable Deaths a Day
Is Too Many:
The Need to Improve Patient Safety."

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Chairman Sanders and the Subcommittee on Primary Health and Aging are to be commended for examining the current crisis of preventable deaths (PDs) that occur each year in the United States and for developing the compelling title of this hearing. The estimate by James (2013) that possibly 400,000 PDs occur each year is more accurate than the previous Institute of Medicine (IOM) projection of 98,000/year (1999). However, I would respectfully suggest that the title of this hearing understates the problem – and the title of the hearing should be changed to *'More than 1000 preventable deaths - and 10,000 preventable serious complications a day - is too many…"* While PDs are certainly to be avoided, I would note that serious preventable complications (SPCs) can result in a quality of life that might be comparable to death for some, such as the woman from Minnesota who, approximately 10 years ago, underwent a bilateral mastectomy for cancer, only to find out shortly after surgery that there had been a mix-up in the biopsy reports – and she had not had cancer.

My points are three: (1) the impact of preventable events – death and serious preventable complications - is even more extensive than the gripping title of this hearing suggests (James, 2013); (2) it is possibly the most bi-partisan issue that exists today – since many, if not most, of us here have likely had the experience of being a patient or family member who experienced one of these events, or will in the future; and (3) it is one of the few issues that money alone

can not solve. As I have often said when lecturing on this topic: "Even Bill Gates cannot guarantee safe care for himself or his family."

This morning, I will highlight some of the key factors influencing patient safety, and make three recommendations which I know, from my 46 years as a nurse, make a difference: (1) assuring an adequate and appropriately educated supply of registered nurses at the bedside; (2) actively engaging patients and families as partners in their care; and (3) moving hospitals and other health care settings to embrace a safety culture and become *high reliability organizations*. My comments focus on the hospital setting since that is where we have the most data, although the principles apply to other settings

Factors compromising patient safety

The factors that contribute to these events have been extensively outlined, and range from the minor to the most comprehensive. They include the complexity of health care, the rapid generation of new knowledge and interventions, the patchwork nature of our health care system, the incentives to do too many interventions and not enough assessment and prevention, and the use of technology (both too much and too little).

ECRI, an "independent, nonprofit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care" has begun to compile an annual Top Ten list of technology-related issues that jeopardize safety. Table 1 includes the list for 2013.

Table 1: The Top 10 list of technology-related issues that compromise patient care

1, Alarm hazards that result in fatigue and inadequate response by care providers
2. Medication administration errors using infusion pumps
3. Unnecessary exposures and radiation burns from diagnostic radiology procedures
4. Patient/data mismatches in EHRs and other health IT systems
5. Interoperability failures with medical devices and health IT systems
6. Air embolism hazards
7. Inattention to the needs of pediatric patients when using "adult" technologies
8. Inadequate reprocessing of endoscopic devices and surgical instruments
9. Caregiver distractions from smartphones and other mobile devices
10. Surgical fires

Some factors relate to health care providers (HCPs) themselves, such as fatigue, disruptive behavior (Rosenstein & O'Daniel, 2008), lack of adequate preparation, and either failure to keep up with current practice or persistence in following outdated practices (Disch, 2012). Amalberti and colleagues (2005) identified five system barriers that would prevent unsafe professional behavior, among them, the (1) the need to abandon status and self-image in exchange for inclusion and respect for the contributions of all providers; and (2) the need to reduce provider autonomy, i.e., doing what one chooses to do over evidence-based practices. Makary (2012) described inadequate levels of transparency and outright concealment of certain results in his riveting book *Unaccountable: What hospitals won't tell you and how transparency can revolutionize health care*.

With all of these factors contributing to preventable deaths and complications, it can be overwhelming to know where to focus first and with the greatest impact. The Joint Commission has created a list each year of the most frequently identified root causes of sentinel events derived from Root Cause Analyses of the serious events that must be reported whenever they occur. There are 28 of these events, and include serious medication errors, falls that result in significant harm or death, hospital acquired infections, decubitus ulcers (bed sores). Over the years, the analyses have found that the majority of events have several root causes. In 2013, the most frequently identified root causes of 887 sentinel events are listed in Table 2:

Table 2: Most frequently identified causes of sentinel events reviewed in 2013

Human factors (635)
Communication (563)
Leadership (547)
Assessment (505)
Information management (155)
Physical environment (138)
Care planning (103)
Continuum of care (97)
Medication use (77)
Operative care (76)

It is important to note that the first three factors relate to people:

- Human factors – staffing levels, staffing skill mix, staff orientation, in-service education, competency assessment, staff supervision, resident supervision, medical staff credentialing and privileging, rushing, fatigue, distraction, complacency, bias
- Communication – oral/written/electronic, among staff, with/among physicians, with administration, with patient or family
- Leadership – organizational planning and culture, community relations, service availability, priority setting, resource allocation, complaint resolution, collaboration, standardization and best practices, inadequate policies and procedures, non-compliance with policies and procedures.

This is not to suggest that the cause of preventable deaths are the people involved. The challenges facing HCPs are complex; system barriers make doing the right thing hard; time pressures reinforce doing things quickly without fixing underlying problems; long standing traditions that demand errorless performance and discourage examination of systems' fallibility create a chilling environment; and the whole field of safety science is unknown to most HCPs who graduated more than 10 years ago. The point here is that the changes that are needed will require changes in behavior and mindset – and these are the most difficult to achieve. It would be easier if we could just allocate more money. Common wisdom used to be that those of us in health care just needed to be vigilant to prevent mistakes. There is still a role for vigilance but that is woefully inadequate in today's health care environment. There are certainly responsibilities that we as care providers have, but safety science suggests that we

must also fix the underlying system issues for sustainable change which requires significant change from all of us.

The critical role of the nurse in patient safety

Nurses are the cornerstone of the American health care system. Registered nurses form the largest element (2.6 million), with more than half (58%) working in medical and surgical hospitals (BLS, 2013). They provide care 24/7 and are on the 'ground floor' of care delivery. They are the eyes and ears of patients and their families, as well as physicians and other HCPs who are interacting with the patient intermittently. The nurse's role is to assess the patient's condition and response to treatment; perform indicated treatments; prevent complications; assist the patient and family in adjusting to the treatment or impact of chronic illness; and create a safe environment within which health, healing or a peaceful death can occur. It is the nurse who sees a skin breakdown that will lead to a bedsore; it is the nurse who notices the older woman's unsteady gait and puts in place strategies to prevent a fall; it is the nurse who notices that the dose of the drug ordered is not relieving the pain and who initiates a conversation with the physician to get the order changed. Individuals who have been hospitalized, or have had a family member hospitalized, understand the essential role of the nurse. Actually, nursing care is the reason for hospitalization…and it is the nurse who is the 'last line of defense' against error.

Who could argue with this point of view? Our current health care system is built on the belief that the physician is the captain of the ship and needs to be in charge in every setting and situation. However, given the complexity of health care today, that is impossible, may be dangerous – and is actually unnecessary. Rather, today we need interprofessional teams of caregivers who can each contribute their own expertise and perspectives. Sometimes the physician would be in charge, at other times the nurse or social worker or pharmacist, depending on the patient's needs.

The elderly are particularly vulnerable to complications and the consequences can be more serious when errors occur. Older individuals are often less physically stable, have chronic conditions for which multiple drugs and treatments are ordered, can have sensory deficits, and memory impairment. If they are unsteady on their feet, they are more prone to falls; if they are not active, they are prone to bedsores and other complications. Inadequate levels of RN staffing in hospitals and nursing homes decrease the nurse's ability to prevent complications. It is vital that nurses – and really any HCP – be respected for their knowledge and skills, and be encouraged to actively speak up when they think that something can be improved or a problem prevented. But that is not common practice in every setting today.

The Institute of Medicine (2011) has recommended that "Nurses should be full partners, with physicians and other health professionals, in redesigning health care in the United States." In most instances, physicians are actively involved in decision-making. And the focus in improving health care has often been to assure enough physicians are educated. However, this crisis will not be solved by focusing only on an adequate supply of physicians, both in the pipeline and in

practice. Registered nurses and other HCPs are equally essential and need to be actively funded and included. This issue of nurses being involved and engaged in individual patient and system-wide decision-making is not simply a matter of *parity*, i.e., that nurses should be included because physicians are. Rather it's a matter of *perspective*, i.e., that nurses bring a vital viewpoint to safety concerns that is often absent yet essential if workable solutions for safe care are to be put in place.

The question that nurses often ask is "Does this work at 2 am?" We have a very pragmatic appreciation for what works round the clock, and on weekends. We often have solutions for seemingly intractable system issues, or personal situations. One recent example: A nurse and physician were talking with a patient with congestive heart failure who was needing his medications adjusted. The doctor provided detailed instructions and asked the patient to weigh himself daily, and to call back if he gained more than 3 pounds. After the physician left, the nurse asked the patient if he had a scale on which to weigh himself, recalling his housing situation and that he was homeless. To adapt the directions to his situation, she asked him to carefully note whether his shoes became tighter– and to call back if that happened. That is an example of a nurse personalizing care to prevent a complication and needless hospitalization.

In considering what can be done to reduce preventable deaths, we must redirect our efforts. First, rather than continuing to work at the margin we must now turn toward fundamental change in our health care organizations; and second we have to focus on three crucial strategies that are often overlooked because they seem so simple and apparent – and yet they are essential if we are to make progress.

1. Assure an adequate number of appropriately prepared registered nurses

For nurses to make their optimal contribution to improving the safety of health care, there have to be enough nurses and they have to be equipped with the right educational preparation. According to the BLS (2013), the Registered Nurse is listed among the top occupations for job growth through 2022, with an expected increase from 2.71 million in 2012 to 3.24 million in 2022 (19% increase). The BLS also projects the need for 525,000 replacement nurses, so that the total number of job openings for nurses from both causes would be 1.05 million by 2022. The good news is that more people are entering nursing – in 2013, there was a reported 2.6% enrollment increase in entry-level baccalaureate programs in nursing (AACN, 2013), yet this increase is insufficient to meet projected demands for nursing services in all settings. More than 32 million Americans are gaining access to healthcare services provided by registered nurses and advanced practice registered nurses (APRNs). Of great concern is that U.S. nursing schools turned away 79,659 qualified applicants from baccalaureate and graduate nursing programs in 2012 due to insufficient number of faculty, clinical sites, classroom space, clinical preceptors, and budget constraints (AACN, 2013). Also the most recent information indicates that the average age of today's nurse is 47 years (HHS, 2010).

There is a significant body of research, both here and abroad, that shows that registered nurses with a minimum of a baccalaureate degree, and at adequate staffing levels in hospitals, have a

positive impact on patient safety, including mortality rates (Needleman et al, 2006; Aiken et al, 2014). Key implications are that nursing staffing cuts to save money jeopardize patient safety and hiring more nurses with baccalaureate degrees could decrease the number of preventable deaths. However, the most recent data indicate that only 50% of nurses have baccalaureate or higher degrees (HRSA, 2010); and if we look at the percentage of nurses in baccalaureate programs as their first educational program, it is only 35% (IOM, 2011). The IOM has recommended that it be 80% by 2020. [There is currently a bill being proposed in Congress called the Registered Nurse Safe Staffing Act to assure an adequate number of nurses with baccalaureate degrees be hired. This would have significant impact on patient safety]

In addition to formal education, however, nurses and all HCPs need to be knowledgeable and competent in the IOM's required competencies for achieving safe patient care: patient-centered care, teamwork and collaboration, informatics, safety, evidence-based practice and quality improvement. Many nurses, physicians and other HCPs received their educational preparation more than 10 years ago when health professions' curricula did not contain this content so that both health professionals' students and practicing HCPs need to be educated in these competencies.

2. Engage the patient and family as partners in care

Another vital partner in assuring safe patient care is the patient and his/her family. Whereas health care has traditionally been offered in a well-intentioned, yet patriarchal fashion, with the physician knowing best, today's health care delivery requires that the patient and his/her family become "the source of control and full partner" (Cronenwett et al, 2007). This is distinctly different from the way health care has traditionally been provided, and in most settings, is currently provided today. As the IOM report *The Future of Nursing: Leading Change, Advancing Health* noted: "Practice still is usually organized around what is most convenient for the provider, the payer, or the health care organization and not the patient" (2011, p.51).

Patient-centeredness is actually not a new concept. Barnsteiner (2014) notes that Hippocrates taught the first medical students to "provide by listening to the patient" and prior to the establishment of hospitals, individuals were routinely cared for in their homes by family members. However, many contemporary factors have altered this relationship: professional autonomy, the medical model of health care, the education of health professionals, technology, the pressures of time, the complexity of the options available, and the perverse incentives for financing of health care.

Increasingly, the consumer movement (Disch, 2014) and the patient movement belief of "Nothing about me without me" are creating pressures for active engagement by individuals and their family members in health care decisions. This is a good thing: It has become increasingly apparent that better quality outcomes are achieved when patients partner with their care providers and assume responsibility for managing their own health (Balik, Conway, Zipperer & Watson, 2011). While HCPs know the science best, the patient and/or family know

the individual best. Appendix A includes a true story of the powerful impact and positive change that can occur when including a patient's preferences in managing her medications.

3. Institute a safety culture with High Reliability Organizations (HROs)

Over the past 15 years, the quality and safety (Q/S) literature has included findings from hundreds of studies examining strategies for improving Q/S, such as rapid response teams; rounds; patient safety audits; checklists; and patient safety officers. However it has become increasingly clear that while these efforts can improve safety at the margin, a more systemic, upstream approach is needed – an entire culture dedicated to safety.

According to the Agency for Healthcare Research and Quality (2010), a safety culture of an organization is

> the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures. [from Organising for Safety: Third Report of the ACSNI (Advisory Committee on the Safety of Nuclear Installations) Study Group on Human Factors. Health and Safety Commission (of Great Britain). Sudbury, England: HSE Books, 1993]

Sammer and colleagues (2010) conducted a comprehensive review of safety literature within US hospitals and identified seven sub-cultures essential for a safety culture: leadership; teamwork; evidence-based; communication; learning; a commitment to justice; and patient-centered. High-reliability organizations (HROs) – or settings with "consistent performance at high levels of safety over long periods of time" - share several key characteristics but most importantly they provide 'a collective mindfulness' which is embodied by everyone throughout the organization (Chassin & Loeb, 2011, 2013).

In these organizations, everyone is clear that even small failures in process or systems can result in catastrophic outcomes, and that everyone has a role to play in identifying errors and near-misses. Everyone is actively encouraged to be part of the problem-finding and solution-generating; models of shared governance and patient engagement are thriving. Everyone includes patients and their families. Of particular importance in HROs is the need for a "greater reliance on [interprofessional] teams and increased complexity in terms of team composition, skills required, and degree of risk involved" (Baker, Day & Salas, 2006) Also in HROs, the leaders are passionate advocates for preventing harm and alter their roles from the traditional one of focusing on the financial bottom line to one of being equally concerned about the Q/S bottom line.

At the core of high reliability organizations are five key concepts, which are essential for any improvement initiative to succeed (AHRQ, 2008):

Sensitivity to operations. Preserving constant awareness by leaders and staff of the state of the systems and processes that affect patient care. This awareness is key to noting risks and preventing them.

Reluctance to simplify. Simple processes are good, but simplistic explanations for why things work or fail are risky. Avoiding overly simple explanations of failure (unqualified staff, inadequate training, communication failure, etc.) is essential in order to understand the true reasons patients are placed at risk.

Preoccupation with failure. When near-misses occur, these are viewed as evidence of systems that should be improved to reduce potential harm to patients. Rather than viewing near-misses as proof that the system has effective safeguards, they are viewed as symptomatic of areas in need of more attention.

Deference to expertise. If leaders and supervisors are not willing to listen and respond to the insights of staff who know how processes really work and the risks patients really face, you will not have a culture in which high reliability is possible.

Resilience. Leaders and staff need to be trained and prepared to know how to respond when system failures do occur.

Conclusion

A great deal of work has been done over the 15 years since *To err is human* was published (IOM, 1999), and progress is being made. A phenomenal amount of resources have been made available through AHRQ, the Department of Defense, Department of Veterans Affairs, and organizations such as the Institute for Health Improvement. Patient safety networks and consumer groups have been formed; surveys have been developed; incentive programs have been created. A lot of people are doing good work.

However, to increase the rate of improvement and reduce preventable deaths and serious implications, we must move upstream and implement some of the more challenging, yet fundamental strategies for a safe healthcare system. We must change the systems of care and how we fundamentally think about and work together to reduce preventable deaths and serious complications.

I have highlighted here three strategies that, from my perspective as a nurse for more than 45 years, yield the greatest benefit:

1. Assuring an adequate number of appropriately educated registered nurses
2. Engaging patients and their families in the care process
3. Establishing a safety culture where every hospital is a High Reliability Organization

Thank you for this opportunity to comment on this vital topic.

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Appendix A

News Story: *Patient-Centered Care Redistributes Responsibility*
Betty A. Marton, April 2012, HealthLeaders

In 2008, a 23-year-old woman with severe cystic fibrosis (CF) successfully carried and delivered a healthy, full-term baby girl at Long Island Jewish (LIJ) Medical Center, in New Hyde Park, NY. Despite that major achievement, the complex regimen of daily medications that Christina Marie McDonald needed to manage her disease created challenges. "On the maternity ward, no one understood anything about CF," says Ruben Cohen, MD, director of the adult CF program and co-director of the asthma center for the 888-bed tertiary teaching hospital. "She didn't receive her medications when she needed them."

"After that experience, the patient's father wrote a letter asking, 'Why does the hospital tie our hands and put these routine measures in the hands of busy medical personnel when the patients and their families know the illness very well and are experts in their own care?'" explains Fatima Jaffrey, MD, director of outcomes research at LIJ Medical Center. The hospital realized they needed a new way of doing things. LIJ Medical Center embarked on a process to explore how to improve the in-hospital delivery of daily medications to CF patients.

In February 2009, Jaffrey began coaching an interdisciplinary team of all the frontline caregivers, including Cohen, and a respiratory therapist, dietician, nurse, pharmacist, CF social worker, and Christina's father, in how to apply the methods of improvement science to improving CF care. The team focused on how it could support and empower the patient while still meeting regulatory requirements. "The goal," says Jaffrey, was to go from "a system of care that wasn't deeply connected to patients' experiences to one that is incredibly connected." Six months after it was established, the team met its first two goals of reducing the length of time patients had to wait for the delivery of the medications for which they were admitted—to two hours (from 15 or more) for the first breathing treatment and four hours (from 18) for IV antibiotics.

The program went live in March 2010, with patients who opt to self-administer receiving special locked boxes containing all of their medications. Patients keep a log of what they take and when and nurses review the log to determine if medications are being taken correctly. The nurses also work with the hospital's pharmacists to keep the box replenished. "The process gives the nurses oversight so we can still manage the documentation," says Margaret Murphy, RN, senior administrative director of patient care services. "It all seems so simple in retrospect, but at the time it required a lot of coordination and education. It offers a tremendous amount of efficiency while ensuring that the patients who know their medications are administering them correctly." Having dramatically reduced the time it takes to provide the care CF patients need has reduced the average length of stay in the hospital for CF patients to seven days from 11. The success of self-administration is also reflected in patient and professional satisfaction surveys: Satisfaction rates for both groups rose from less than 20% before the intervention to above 95%. "What's remarkable is that this sophisticated work can only be done at ground level," explains Jaffrey. "People who do the day-to-day work can get through these issues with so much velocity. When we empower them to be the change agents, we're leveraging the largest untapped resource we have in healthcare."