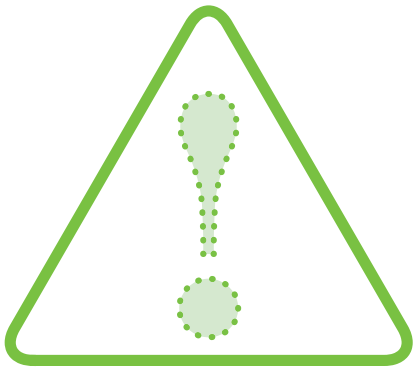
WHITEPAPER

CMS NEVER EVENTS: RESEARCH REPORT

Exploring the connection between tracking near misses, organizational learning and reducing never events in healthcare organizations



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ABSTRACT

Healthcare organizations are facing mounting pressure from consumers, state governments, funders and the Centers for Medicare and Medicaid Services (CMS) to improve patient safety and embed more accountability and transparency. Healthcare organizations have been reporting adverse events for many years, yet a significant number of events still go unreported. This industry trend has lead to a more critical view of preventable and serious adverse events, coined "Never Events" by the National Quality Forum. The focus on tracking 'near miss' events is also a challenge, as some healthcare organizations do not see the value in tracking and analyzing them to identify deficiencies in patient safety initiatives.

This paper will propose how capturing and learning from near misses in healthcare organizations could lead to the prevention of actual adverse events. Also, how implementing an electronic system to manage this data can do the following: support CMS' Never Event tracking, facilitate mandatory reporting requirements from governing bodies, heighten the success of patient safety initiatives and improve the culture of safety within healthcare organizations.

BACKGROUND

National Quality Forum's 'Never Events'

Spearheaded by the Institute of Medicine's (IOM) study To Err is Human: Building a Safer Health System, the National Quality Forum (NQF) created a list of 27 serious, reportable events (SREs) in 2002. These 'never events' were ones deemed to be largely preventable when they occurred within a hospital. NQF expanded the list to 28 events in 2006 and to 29 in 2011. During that time, the name 'never events' was also changed to Serious Reportable Events (SREs) and the list of locations was expanded to cover outpatient and office-based surgery centers, skilled nursing facilities and ambulatory practice settings, in addition to hospitals. The NQF implemented this update in December 2011 to:

1. Ensure the continued currency and appropriateness of each in event list
2. Ensure the events remain appropriate for public accountability
3. Provide guidance for new implementers in hospitals, office-based practices, ambulatory surgery centers and skilled nursing facilities.

This update of NQF's SREs presents the results of evaluating the SREs with recommended modifications and 12 new events. Twenty-nine events are recommended as voluntary consensus standards as of December 2011. A new category of Radiologic Events was also added to the SRE list in December 2011. According to the NQF, these never events are:

"Of concern to both the public and healthcare professionals and providers; clearly identifiable and measurable (and thus feasible to include in a reporting system); and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare organization.[1]

Subsequently, over 25 states incorporated voluntary SRE reporting and three states (Minnesota, Connecticut and New Jersey) implemented mandatory legislation to report SREs within their own state-based reporting system; several other states have similar legislation pending or are considering it. In addition, the Department of Defense now requires health plans that it contracts with under the TRICARE program to report these events.[30] Furthermore, they indicated that the state would not require patients who experienced an identified never event to pay for their treatment, which directly affects Medicare and TJC reimbursements.

CMS HOSPITAL-ACQUIRED CONDITIONS

CMS identified 10 hospital-acquired conditions (HACs) for which Medicare will not cover. In October 2008, CMS stated that "Medicare will no longer pay hospitals at a higher rate for the increased costs of care that result when a patient is harmed [in hospital]"[2]. These conditions overlap with the list of 29 never events identified by the NQF, but the CMS list does not include all of the 29 events.

This decision has prompted many private insurance providers to adopt the same non-payment policies. CMS has stated that its intent with this major initiative is to make hospitals safer, improve quality of care, decrease the likelihood of hospital-acquired conditions and reduce preventable medical errors. In furthering its attempt to reduce these events and associated additional costs, CMS is also recognizing the principle of "pay for performance" [3].

CMS HOSPITAL ACQUIRED CONDITIONS

The 10 categories of HACs include[2]:

- Foreign Object Retained After Surgery
- Air Embolism
- Blood Incompatibility
- Stage III and IV Pressure Ulcers
- Falls and Trauma
  - » Fractures
  - » Dislocations
  - » Intracranial Injuries
  - » Crushing Injuries
  - » Burns
  - » Electric Shock
- Manifestations of Poor Glycemic Control
  - » Diabetic Ketoacidosis
  - » Nonketotic Hyperosmolar Coma
  - » Hypoglycemic Coma
  - » Secondary Diabetes with Ketoacidosis
  - » Secondary Diabetes with Hyperosmolarity
- Catheter-Associated Urinary Tract Infection (UTI)
- Vascular Catheter-Associated Infection
- Surgical Site Infection Following:
  - » Coronary Artery Bypass Graft (CABG) - Mediastinitis
  - » Bariatric Surgery
    - · Laparoscopic Gastric Bypass
    - · Gastroenterostomy
    - · Laparoscopic Gastric Restrictive Surgery
  - » Orthopedic Procedures
    - · Spine
    - · Neck
    - · Shoulder
    - · Elbow
- Deep Vein Thrombosis (DVT)/ Pulmonary Embolism (PE)
  - » Total Knee Replacement
  - » Hip Replacement[2]

Event Reporting in Healthcare Organizations

The Joint Commission (TJC) mandated in 1995 that US hospitals track adverse events or incidents resulting in harm. As well, the widely referred IOM report *To Err is Human*... recommended that hospitals implement computerized reporting systems to track errors, adverse events and near misses[4,5]. The intent is to enhance the accountability of healthcare organization to:

1. Discover vulnerabilities leading to adverse events
2. Determine causation or contributing factors of events that occur
3. Apply what is learned to improve quality
4. Enable other organizations to apply lessons learned and prevent recurrence through public reporting.

Another recommendation was for states to create mandatory reporting systems for their healthcare organizations.[4] Even with these recommendations, underreporting of actual adverse events in healthcare organizations remains significant, both internally and externally[6,7,8,9]. The Institute for Healthcare Improvement notes that 80-90% of errors are never reported10 with some estimates as high as 95%[7].

In a study of hospitalized patients who experienced adverse events or near misses, 8% of the patients experienced 20 adverse events and 4% of the patients experienced 13 near misses. However, no one captured those events in the organization's incident reporting system[11].

The causes of underreporting within an organization can include a lack of supportive culture, accessibility of reporting mechanism, fear of punishment and misunderstanding on what needs to be reported.[7] Underreporting results in a reduction of quantitative and qualitative data combined with a missed opportunity for analysis, process improvements and shared learning.

Pennsylvania's Patient Safety Authority

In 2004, the Commonwealth of Pennsylvania passed the MCARE Act mandating its healthcare organizations report on adverse events and near misses. The Pennsylvania Patient Safety Reporting System (PA-PSRS) dictates that all reports are confidential and non-discoverable. Also, patient and provider names must be de-identified and whistleblower protection policies in place[13].

In 2005, the Patient Safety Authority noted that more than 75% of its surveyed hospitals indicated they have instituted changes because of the feedback from the system. Even more impressive, 80% of the healthcare executives believed that the culture of safety in their facility had improved since the implementation of the reporting system.[13]

By 2006, the Authority received more than 385,000 reports of actual adverse events and near misses[14]. The Authority now has over 1.3 million event reports, making it one of the largest databases of its kind. Pennsylvania is acknowledged as providing leadership in the collection of patient safety data, analysis and guidance[15].

Electronic Reporting Systems

Given the pressure on hospitals to prevent adverse events and the potential loss of revenue and public credibility when patients are harmed, hospitals are focusing efforts and resources on implementing preventative tools to curb these problems. Of all tools healthcare organizations are considering, electronic reporting systems are at the forefront.

According to the 2008 Healthcare Informatics Survey Trends in Patient Safety Technologies, "electronic event reporting is one of the key tools in patient safety technologies to improve quality of care and assist healthcare organizations meet the expectations for regulatory bodies, patients, funders and state governments"[16]. Also, in HIMSS' 2007 leadership survey, 54% of Chief Information Officers identified that implementing technology to reduce medical errors and increase patient safety was an IT priority[17]. This is evident by many healthcare organizations implementing web-based, electronic reporting systems to capture adverse events and near misses.

Part of the 2009 American Recovery and Investment Act (ARRA) was to supply $1.2 billion in grants to help healthcare providers implement

and use electronic health records. $598 million was allocated to 70 regional centers to provide technical assistance and support for implementing Electronic Health Records, as well as $564 million in state grants to share information nationwide[29].

Advantages of these systems include the ease of use, real time review, oversight, intervention and promoting the flow of information[7]. Further, according to Clarke[18], these systems can be integrated with other clinical and administrative databases so that "medical errors can be linked to patient characteristics and team characteristics to further expand the understanding of at-risk situations" (p. 1089).

Reports from these large-scale databases can identify trends and areas for improvement. In addition, distributing these reports is easy via a web-based, security-enabled system. Electronic reporting systems can provide meaningful information to help healthcare providers capture events and provide insight into trends, not to mention promoting shared learning with the goal of prevention of actual adverse events. Reinforcing its recommendation for hospitals to implement computerized reporting systems, the IOM stated, "such systems hold providers accountable for their performance in addition to providing information that leads to improved safety by preventing the recurrence of errors"[7]. Furthermore, these systems provide a more cost-effective and efficient tool to capture events as compared to traditional methods, such as retrospective chart review and monitored observational studies[7].

Reporting Near Miss Events

The patient safety movement has been propelled by learning from other industries with similar complexities to healthcare organizations[19], such as aviation, nuclear power, petrochemical processing, steel production and military operations.[6,8] However, in those industries there is much more emphasis placed on reporting and learning from near misses as a key foundation for ongoing improvement and safety initiatives.[6,20,21]

There is more than one definition of a near miss:

> *Agency for Healthcare Quality and Research:* "when an error does not result in an adverse event for a patient, because the error was 'caught', it is a near miss; if the absence of injury is owed to chance it is a no harm event." [22]
>
> *Barach and Small:* "Any event that could have had adverse consequences but did not and was distinguishable from fully fledged adverse events in all but outcome (p. 4)."[8]

Irrespective of any specific definition, the capture of data on near miss events is key to successfully eliminating never events in healthcare organizations across the country. Near misses are more common and frequent than actual adverse events[6,18,21,23] with estimates ranging from 3 to 300 times[8]. This analysis further expands the individual, organizational and shared learning required to identify and reduce errors.

NEAR MISS REPORTING STATISTICS

- Approximately 97% of all reports submitted to the Pennsylvania Patient Safety Authority in 2010 were incidents or did not cause harm to the patient, whereas only 3% were serious events.[15]
- Rowin, et al. studied 29 acute-care hospitals and one long-term care facility that implemented a secure, web-based reporting system between August 2000 and December 2005. They identified that out of a total of 266, 224 reported events over 7.3 million inpatient days, about 12% of these reports were classified as near misses.[25]
- The Weingart study on learning from adverse events from hospitalized patients indicated that the rate of near miss events was 5.7 per 100 admissions.[11]
- Clarke indicates anecdotal evidence that an effective near miss reporting system may generate one report per bed per month.[8]

According to Killen and Beyea:

> "Large numbers of near misses provide helpful data about the nature, frequency and types of safety issues…reports of near misses can provide meaningful insights about how harm was avoided, as well as understanding the degree of patient risk. Sharing near miss data is a critical strategy in efforts to protect patients from injuries caused by medical errors (p. 1)." [21]

Clarke discusses how near misses indicate "signals of weaknesses in the system", providing data and pointing to solutions; he concludes, "near miss reports increase awareness of the constant potential for disaster (p. 1089)".[18] Further Barach and Small advocate that focusing on near miss data may add significantly more value towards quality improvement processes than just focusing on adverse events.[8]

The Association for Operating Room Nurses (AORN) launched its own web-based near-miss reporting system in February 2003. Underscoring this major initiative for a national database was the belief that collecting near miss data was instrumental in its overall strategy to prevent harm to patients and to identify patterns and trends.[21]

One of the recommendations in the IOM report *To Err Is Human*… was that healthcare organizations capture and learn from near misses "to detect system weaknesses before the occurrence of serious harm".[4] However, not all healthcare organizations and state reporting systems are capturing near miss events, focusing instead on standardization around NQF never events.[5] Pennsylvania was the first state reporting system to mandate near miss reporting as integral to its patient safety program.

In connection to collecting near misses and proactively identifying risk, Wald and Shojania[6] discuss how "multiple failures often contribute to a single adverse event, and early detection of the first such failure provides an opportunity to intervene and stop what could have become a chain of failures leading up to a serious event" (p. 18).

In a compelling example of a near miss report from a small healthcare facility in Pennsylvania, an entire system of color-coding for patients was revised. This initiative – and subsequent new protocol – was so successful that other organizations in the US have adopted it.[14] Collecting and sharing successful recoveries from the near misses that did not prevent harm can be a powerful vehicle to promote the value of capturing near miss events.[18]

Interestingly, there are fewer barriers to collecting near miss data because they are often not as emotionally laden as actual adverse events, which can be accompanied by guilt, anxiety and fear.[9] Also, near misses have more limited liability and the opportunity to review the recovery activities.[8]

Focusing on near misses also promotes an increased awareness of the levels of risk inherent in any healthcare environment.[6] This reality, along with the volume of near miss events, provides a more positive vehicle for learning and implementation of required system changes.

Near Misses: A.k.a., 'Good Catches'

Many healthcare organizations have adopted the use of 'good catch' to describe and brand

PATIENT SAFETY TAXONOMIES & NEAR MISS REPORTING

The following organizations have included near miss reporting in their taxonomies:

- NQF Patient Safety Taxonomy (endorsed by JCAHO)
- AHRQ designed its taxonomy to support reporting of events to a Patient Safety Organization, or PSOs (as per the Patient Safety and Quality Improvement Act of 2005)
- Australian Incident Management System (AIMS), used in the Australian universal public health system
- World Health Organization Alliance for Patient Safety

their program of capturing and learning from near misses. This is in response to the negative connotation some perceive around the language of 'near miss' or 'close call'. For example, nurses at Houston's University of Texas M. D. Anderson Cancer Center have captured over 23,000 good catches since implementing their "Close Call Reporting System" in 2006.[24] The system identifies potential errors and has been highly successful not only in capturing near misses but in promoting organizational change.

Sharing Knowledge Throughout the Organization

The use of electronic reporting systems promotes and allows for extensive data collection around near misses and adverse events. Healthcare organizations must use this information to identify areas of improvement, gather insights, proactively promote staff to report near misses and provide vehicles to share the learnings from their systems.

Motivating staff to report events involves feedback, acknowledging their work and positive reinforcement of the value of the report.[18] Healthcare organizations can address the issue of not providing enough feedback to staff when they report events with the timely feedback mechanisms incorporated into electronic reporting systems.[7]

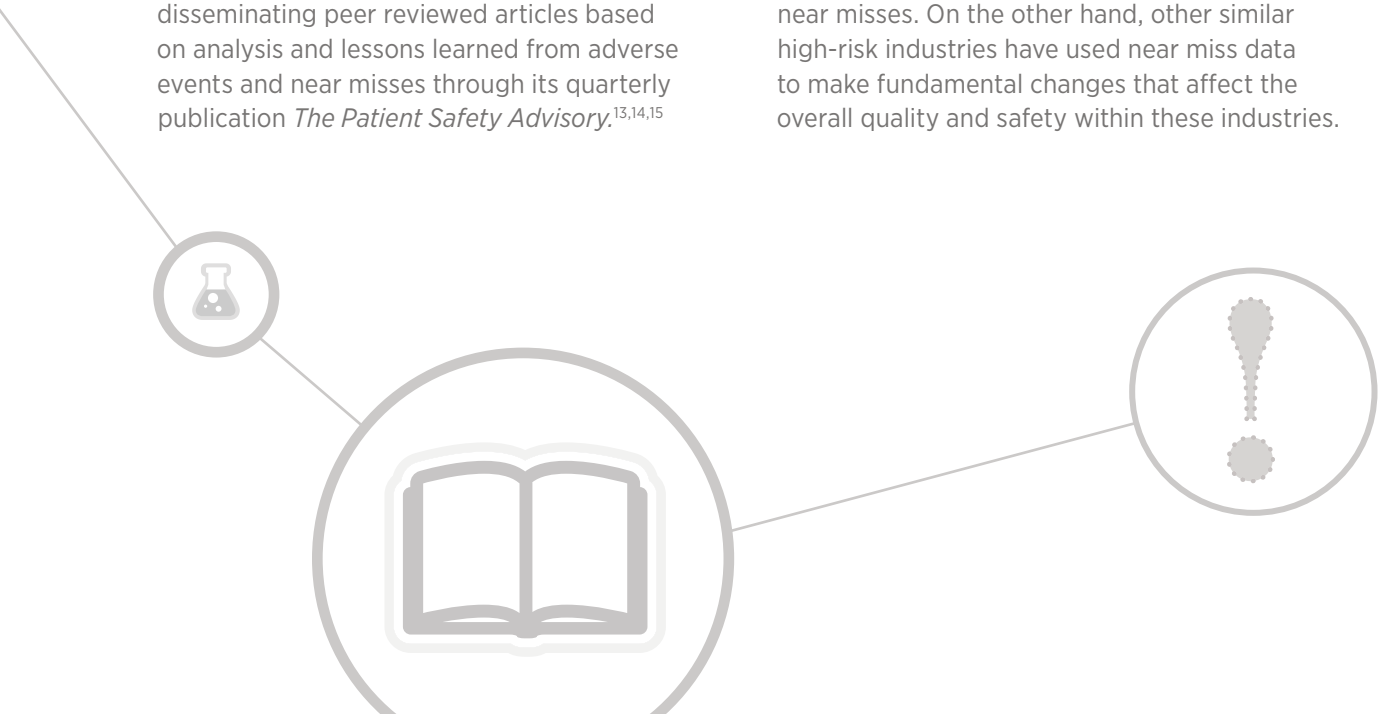
Clarke identifies that healthcare leaders need to champion reporting of adverse events and near misses and act upon the findings of the event analyses.[18] The Pennsylvania Patient Safety Authority has accomplished this by disseminating peer reviewed articles based on analysis and lessons learned from adverse events and near misses through its quarterly publication *The Patient Safety Advisory.*[13,14,15]

The Authority also distributes its findings in comprehensive, web-based educational toolkits to facilitate staff training and education, closing the feedback loop.[14] This underpins the need and requirement for staff to be informed if the organization makes changes based on their submitted reports.[7,14] This approach supports patient safety theory[26] and links with an overarching commitment to improve patient safety by enabling and sustaining a culture of safety, promoting accountability and honesty.

Healthcare organizations are typically characterized by fragmented learning confined to individuals and teams.[20] They need to mimic other high-risk industries by sharing findings across (and beyond) their organization. This approach should be further enhanced by the provisions of the Patient Safety and Quality Improvement Act of 2005 that will facilitate hospitals in reporting information confidentially and with legal protection to PSOs.[5,29] This will enable the sharing of significant data between healthcare organizations to further mine the inherent learning opportunities, policy and practice changes.

Conclusion

Hospitals are under increasing pressure from many sides to comply with external regulations and prevent adverse events. Patient safety theory supports the capturing of adverse events, near misses and learning from these events[27]. Historically, healthcare organizations have underreported actual adverse events and some do not capture near misses. On the other hand, other similar high-risk industries have used near miss data to make fundamental changes that affect the overall quality and safety within these industries.



Healthcare organizations should focus more of their efforts and resources on capturing near miss events. This is evident given the quality and quantity of near miss events, how easy they are to capture with electronic reporting systems and how they related to building a better safety culture.

As Pennsylvania's experience has shown us, other states can achieve meaningful change, improved quality of care and organizational learning by mandating the reporting of near misses. Preventing serious events requires collecting data from of all adverse events and near miss experiences. The National Quality Forum identifies that never events are "significantly influenced" by the organization's policies and procedures[1]. By extension, policies and procedures cannot be identified and improved upon without gathering meaningful data across the continuum of healthcare events to learn, share and develop strategies.

RL Solutions can help you review your software to help support near miss and never event reporting. For more information about our services, email clientexcellence@rlsolutions.com.

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APPENDIX

Current National Quality Forum Serious Reportable Events ("Never Events")
Retrieved January 25, 2010 from
www.qualityforum.org/Publications/2008/10/Serious_Reportable_Events.aspx

SURGICAL EVENTS

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intra-operative or immediately postoperative death in an ASA Class I patient

PRODUCT OF DEVICE EVENTS

- Patient death or serious injury associated with the use of contaminated drugs, devices or biologics provided by the healthcare setting
- Patient death or serious d injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting
- Patient Protection Events
- Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
- Patient death or serious injury associated with patient elopement (disappearance)
- Patient suicide, attempted suicide or self-harm, that results in serious injury while being cared for in a healthcare setting

CARE MANAGEMENT EVENTS

- Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
- Patient death or serious disability associated with unsafe administration of blood products
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting

ENVIRONMENTAL EVENTS

- Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
- Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas or are contaminated by toxic substances
- Patient or staff death or serious injury associated with a burn incurred from any source
- in the course of a patient care process in a healthcare setting
- Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

RADIOLOGIC EVENTS

- Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

POTENTIAL CRIMINAL EVENTS

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient/resident of any age
- Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
- Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting
- Sexual assault on a patient within or on the grounds of a healthcare facility
- Death or significant injury of a patient or staff member resulting form a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility

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