



## Never Events: Nurses' Key Role

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### **Purpose and Objectives**

The purpose of **Never Events: Nurses' Key Role** is to explain the evolution of Never Events and related safety initiatives and to identify nurses' key role in preventing Never Events and assuring patient safety. Please note: Never Events are now termed Serious Reportable Events (SREs).

### **After successful completion of this course, you will be able to:**

1. Define Never Events and related safety initiatives of the National Quality Forum and other organizations such as the Center for Medicare and Medicaid Services, the Joint Commission, the American Nurses Association, and the Leapfrog Group.
2. Identify the categories of National Quality Forum Never Events and examples of specific Never Events.
3. Describe the current status of safety in USA healthcare facilities.
4. Explain the economic impact of Never Events and Centers for Medicare and Medicaid (CMS) Hospital-Acquired Conditions (HACs).
5. Explain the relationship between nurse staffing and adverse events.
6. Identify aspects of nursing practice that are especially significant in preventing Never Events, including surveillance capacity.
7. Describe elements of the work environment that support patient safety.

### **Introduction**

Safety issues pervade the healthcare environment today more than ever. Nurses, as well as other healthcare providers, are adopting a safety-minded attitude. Organizational initiatives revolve around safety; professional practice issues are safety-focused, and today, more than ever, the individual caregiver is committed to patient safety.

The terms "Never Events" or "Serious Reportable Events" are two of the most commonly used terms to describe any number of occurrences that are considered unacceptable.

## ***Not in our unit. Not on our watch. Not to our patients.***

(AACN, 2009, p. 15)

### **What Are SREs?**

Serious Reportable Events emerged as one safety initiative in the wake of the landmark Institute of Medicine (IOM) report, *To Err is Human* (IOM, 1999). The report presented the alarming finding that 44,000 – 98,000 Americans die each year from medical errors.

As one response to these findings, U.S. Department of Health & Human Services Agency for Healthcare Research and Quality (AHRQ) requested the National Quality Forum (NQF), a private not-for-profit organization, to create a set of patient safety measurements to be a medical errors reporting system.

NQF published *Serious Reportable Events in Healthcare: A Consensus Report*, which listed 27 events that were “serious, largely preventable and of concern to both the public and healthcare providers” (NQF, 2002). These events and subsequent revisions to the list became known as Never Events. QF later updated the list to include 28 items (CMS, 2010). In subsequent years, the terminology changed from Never Events to Serious Reportable Events (SREs) and was expanded to include 29 different events.

### **In June 2011, NQF again updated the list in order to:**

1. Ensure the continued currency and appropriateness of each event in the list.
2. Ensure the events remain appropriate for public accountability.
3. Provide guidance to those just beginning to report these events, across hospitals and for three newly specified settings of care: office-based practices, ambulatory surgery centers, and skilled nursing facilities (NQF, 2011).

### **Categories of Never Events/SREs**

#### **NQF created 7 categories of Never Events / SREs:**

- Surgical Events
- Product or Device Events
- Patient Protection Events
- Care Management Events
- Environmental Events
- Radiologic Events
- Potential Criminal Events

#### **Never Events: Surgical**

##### **Surgical Events:**

- Surgery or other invasive procedure performed on the wrong body part
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient

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- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Intraoperative / post procedure death in an ASA Class I patient

**Never Events: Product or Device**

**Product or Device Events:**

- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
- Patient death or serious disability 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 disability associated with intravascular air embolism that occurs while being cared for in a healthcare setting

**Never Events: Patient Protection**

**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

**Never Events: Care Management**

**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 injury 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
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Patient death or serious injury associated with a fall while being cared for in a healthcare setting
- Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
- Artificial insemination with the wrong donor sperm or wrong egg
- Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

**Never Events: Environmental**

**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 is 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 bed rails while being cared for in a healthcare setting

#### **Never Events: Radiologic**

##### **Radiologic Events:**

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

#### **Never Events: Potential Criminal Events**

##### **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 of any age
- Sexual assault on a patient or staff member within or on the grounds of a healthcare setting
- Death or significant 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

#### **Criteria for Never Events/ SREs**

Events listed as Never Event/ SREs must be:

- Of concern to both the public and healthcare professionals and providers
- Clearly identifiable and measurable and thus feasible to include in a reporting system
- Of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility

In addition, to qualify for the list, an event must be unambiguous, usually preventable, serious – resulting in death, loss of a body part, or disability, and any of the following:

- Adverse
- Indicative of a problem in a healthcare facility's safety systems
- Important for public credibility or public accountability

#### **Confusing Terminology**

In addition to Never Events, there are other terms used to describe healthcare-related events that have negative patient outcomes. The different terminology relates to the organizations responsible for monitoring these negative occurrences in healthcare:

#### **Never Events / SREs:**

The National Quality Forum (NQF) has identified 29 specific negative occurrences in healthcare that have

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serious adverse patient outcomes and are reportable events. An example of SRE is the retention of a surgical instrument in a patient.

**Hospital-Acquired Condition (HAC):**

A medical condition or complication that a patient develops during a hospital stay, which was not present at admission. The Centers for Medicare and Medicaid (CMS) denies reimbursement for HACs. A HAC may or may not include a Never Event. An example of a HAC is pressure ulcers.

**Sentinel Event:**

An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Such events are called "sentinel" because they signal the need for immediate investigation and response. Sentinel Events are tracked by the Joint Commission (TJC). Every JC-approved healthcare organization is required to identify their own Sentinel Events. Some examples of Sentinel Events include patient suicide, serious medication error resulting in major impairment or death, patient abduction or assault.

**Test Yourself**

The term "Never Event" or "Serious Reportable Event" was coined by the:

CDC

CMS

NQF – Correct!

**Never Events and Hospital-Acquired Conditions (HACs)**

The Center for Medicare & Medicaid Services (CMS) implemented a related safety initiative in 2008. CMS now denies Medicare reimbursement for treatment of specific National Coverage Determinations and hospital-acquired conditions (HACs).

Many of the conditions for which CMS denies reimbursement overlap the 29 NQF Never Events, such as blood incompatibility, stage 3 and 4 pressure ulcers, falls and trauma injuries, air embolism, foreign object retained after surgery, and surgery involving wrong site, wrong patient, or wrong procedure.

**However:**

The 29 NQF SREs list includes some items which are not HACs, such as: patient death or disability associated with a medication error; maternal / neonatal death or serious injury in low-risk pregnancy, and other events.

**And:**

The HAC list includes some items which are not among the 29 NQF SREs, such as catheter-associated urinary tract infection, catheter-associated blood stream infection, and in association with specific surgical procedures: surgical site infections; deep vein thrombosis; or pulmonary embolism.

**Test Yourself**

There is overlap between HAC and SREs in the areas of blood transfusion errors, pressure ulcers, falls and air embolism.

True – Correct!

False

## **Most Frequent HACs**

The most frequent medical errors in decreasing order of frequency were:

- Pressure ulcer
- Postoperative infection
- Postlaminectomy syndrome
- Hemorrhage complicating a procedure
- Accidental puncture or laceration during a procedure
- Mechanical complication of device, implant or graft
- Ventral hernia without mention of obstruction or gangrene
- Hematoma complicating a procedure
- Unspecified adverse effect of a drug, medicinal and biological substance not elsewhere classified
- Mechanical complication of cardiac device, implant or graft (Shreve, et al., 2010)

## **Expanding Never Events**

Although Never Events began with the NQF list of 28 events, other safety-oriented initiatives have applied the term Never Events to additional preventable, adverse events.

For example, The American Association of Critical Care Nurses (AACN) collaborated with the American College of Chest Physicians (ACCP), the Society of Critical Care Medicine (SCCM), the National Association for Medical Direction of Respiratory Care, and the American Thoracic Society (ATS) to identify **4 Never Events in the critical care setting** (AACN, 2009):

- Ventilator-associated pneumonia (VAP)
- Iatrogenic pneumothorax (caused by a therapeutic intervention such as mechanical ventilation or tracheostomy)
- Deep vein thrombosis/pulmonary embolism (when not related to orthopedic procedures)
- Delirium in critically ill patients

Some healthcare facilities have designated specific Never Events as a part of safety and quality improvement programs.

## **Organization-based Safety Initiatives**

The patient safety initiatives and nursing quality measures of other organizations also intersect with Never Events.

### **Joint Commission (TJC)**

#### Sentinel Events:

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. TJC-accredited facilities must investigate and report sentinel events to TJC (TJC, 2014).

#### National Patient Safety Goals (NPSG):

2014 NPSG address ventilator-associated pneumonia, catheter-associated urinary tract infection, central line

associated bloodstream infection, surgical site infection, medication safety recommendations, and universal protocol to prevent wrong site, wrong procedure, wrong person surgeries.

### AHRQ Patient Safety Indicators (AHRQ, 2006)

Indicators for safety monitoring include nosocomial infection, pressure ulcers, blood incompatibility surgery associated safety risks, and device- and substance-related adverse events.

### NQF Standards and National Database of Nursing Quality Indicators

NQF Consensus Standards for Nursing-Sensitive Care (NQF, 2004) and American Nurses Association (ANA)-endorsed National Database of Nursing Quality Indicators (NDNQI) (University of Kansas Medical Center, n.d.):

Both the NQF Standards and the NDNQI include measures related to patient falls, infections associated with urinary catheters and central venous catheters, ventilator-associated pneumonia, pressure ulcers, injury in restraints, and failure-to-rescue defined as surgical patient death due to treatable complications.

### The Leapfrog Group

The Leapfrog Group, a private voluntary program dedicated to quality and value in healthcare, recognizes healthcare facilities which implement a policy when a Never Event occurs that includes apologizing to patient and family, waving charges associated with the event, and investigating and reporting the event.

### Test Yourself

Which Never Events are also among the top 10 Sentinel Events reported to Joint Commission?

| Sentinel Events Reported to Joint Commission           |   |   |
|--|---|---|
| Top 10<br>January – September 2010<br>(TJC, 2010a)     |   | Top 10<br>1995 through September 2010<br>(TJC, 2010b) |
| 1. Unintended retention of a foreign body*             | * = NQF Never Event   | 1. Wrong-site surgery*                                |
| 2. Wrong-patient, wrong-site, wrong-procedure surgery* | TJC and NQF definitions of each event may differ              | 2. Suicide*   |
| 3. Delay in treatment                                  |   | 3. Operative/post-operative complications             |
| 4. Operative/post-operative complications              | Certain post-operative complications may also be Never Events | 4. Delay in treatment                                 |
| 5. Suicide*  |   | 5. Medication error*                                  |
| 6. Patient fall*                                       |   | 6. Patient fall*                                      |



|                              |  |  |
|------------------------------|--|--|
| 7. Other unanticipated event |  | 7. Unintended retention of a foreign body* |
| 8. Medication error*         |  | 8. Assault/rape/homicide*                  |
| 9. Perinatal death/injury*   |  | 9. Perinatal death/loss of function*       |
| 10. Criminal event*          |  | 10. Patient death/injury in restraints*    |

### **Safety Problems Persist**

According to the Agency for Healthcare Research & Quality (AHRQ) National Healthcare Quality Report (2013), hospitals are leading the movement to improve the quality of care delivered to U.S. patients, outpacing improvements in other settings. The report confirms that Americans are receiving recommended medical services 70 percent of the time. Yet there is still room for improvement.

The report also found that the rates of some healthcare-associated infections (HAIs), are beginning to fall as processes to prevent hospital re-admission are improving.

Quality also has improved for measures on adolescent vaccination, HIV treatment, colon cancer surgical care and hospital care for patients with heart problems and pneumonia.

Quality worsened for measures on diabetes checkups, Pap smears, maternal deaths at delivery and preventive care for patients with asthma.

The reports includes data for most measures of quality and disparities from 2000-2002 to 2010-2011, which predate implementation of most of the Medicaid expansions and health insurance exchanges under the Affordable Care Act. The reports provide a baseline for tracking progress under the Affordable Care Act in upcoming years.

### **Economics of Never Events**

Adverse events in healthcare take a significant human and financial toll. Each year in the United States, more than two million healthcare-acquired conditions are responsible for 90,000 deaths and \$5.7 billion in added healthcare costs (NQF, 2008 IN NQF 2014).

Costs associated with other medical harm – including healthcare expenses, lost work productivity, lost income, and disability have been estimated as high as \$29 billion per year (Kelly, 2009 in NQF, 2014).

These statistics illustrate an urgent need and a significant opportunity to better measure and improve patient safety, as part of a broader effort to create a high-value healthcare system (NQF, 2014).

As you can see, preventable adverse events severely impact the financial strength of healthcare facilities.

### **Nurse Staffing and Never Events**

When nursing staff increases, the quality of patient care improves and preventable incidents decrease. Higher levels of nurse staffing can have a positive impact on both quality of care and nurse satisfaction rates.

Researchers have found that low nurse staffing levels are associated with higher rates of non-fatal adverse outcomes, and conversely, fewer adverse events occur when more nurses are caring for patients:

- Fewer pressure ulcers, falls with injury, bloodstream infections, and urinary tract infections (Buerhaus 2010).
- Reduced mortality, complications, failure-to-rescue, and length of stay (Kane et al., 2007; Lankshear, Sheldon, & Maynard, 2005; Lang, Hodge, & Olsen, 2004).

So far, research has not yet proven that increased nurse staffing **causes** a decrease in adverse events, only that the two are related.

However, researchers project that if increased nurse staffing **causes** a decrease in adverse events, then:

- Reducing patient to RN ratio from 6:1 to 2 (or fewer):1 would save 25 lives per 1,000 hospitalized patients and 15 lives per 1,000 surgical patients.
- Reducing patient to RN ratio from 2-4:1 to fewer than 1.5:1 would save four lives per 1,000 hospitalized patients and 9 lives per 1,000 surgical patients. Researchers acknowledge that a staffing ratio of 1.5 or fewer patients per RN is probably unrealistic (Kane, et al., 2007).
- Matching California's 4:1 mandated staffing ratio would lead to:
  - 14% fewer surgical deaths in New Jersey hospitals.
  - 11% fewer surgical deaths in Pennsylvania hospitals (Aiken, et al., 2010).

### Test Yourself

The ratio of nurses to patients is a direct cause of adverse patient outcomes.

True

False – Correct!

### In the Words of One Nurse

#### In the Words of One Nurse

*"That day, I had fewer patients to care for because this patient needed close monitoring; I had time to check in on him often. But what if I hadn't? By the time he was given an every-four-hour vital-signs check, his blood pressure could have dropped so much that he may not have made it."*

(Brown, 2010)

### Nursing Practice and Never Events

Adequate number of nurses in staffing can help prevent adverse events. It is not only numbers of nurses, but how nurses practice that assures patient safety.

Evidence-based practices and protocols recommend approaches for preventing adverse events such as falls, pressure ulcers, and infections. The CDC and other organizations publish recommended preventive techniques and practice bundles, such as CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HIPAC) [Guidelines for the Prevention of Intravascular Catheter Related Infections](#).

Healthcare organizations base policy and procedure on evidence-based practices and guidelines of organizations such as CDC and the Institute for Healthcare Improvement.

Nurses must follow facility policy meticulously even when a facility has not yet completed updating policies and procedures to align with evidence-based recommendations. You are legally accountable for following facility policy and procedure at all times.

National Patient Safety Goals recommend teaching patients and families safe practices in the hospital environment.

### **Surveillance Capacity and Never Events**

Nurses' effectiveness in preventing Never Events depends upon their ability to monitor, evaluate, and act upon emerging indicators of a patient's change in status. Researchers use the term **surveillance capacity** for this ability (Kutney-Lee, Lake, & Aiken, 2009).

### **Researchers use nine indicators to measure surveillance capacity:**

#### RN characteristics

- Staffing (patients cared for on the last shift worked)
- Education (proportion of RNs with baccalaureate degree or higher)
- Clinical expertise
- Years of experience

#### Practice Environment Scale of the Nursing Work Index (PES-NWI) Subscales

- Nurse participation in hospital affairs
- Nursing foundations for quality of care
- Nurse manager leadership, ability, & support of nurses
- Staffing and resource adequacy
- Collegial nurse-physician relations

Nurses in the hospitals that ranked highest in surveillance capacity took care of approximately two fewer patients than nurses in the hospitals which were lowest in nurse surveillance capacity.

As compared with hospitals ranked lowest in surveillance capacity, nurses in highest ranking hospitals rated quality of care more favorably and occurrence of nosocomial infections and patient falls with injury as less frequent.

### **Work Environment and Never Events**

RN judgment in recognizing early indicators of impending Never Events and other adverse events is key to prevention. For example, early recognition of patients at risk for sepsis and septic shock via aggressive screening and the rapid implementation of evidence-based guidelines saves lives (Moore, 2010).

The IOM report, *Keeping Patients Safe: Transforming the Work Environment of Nurses* recommended that nursing leaders "be provided with organizational resources to support the acquisition, management, and dissemination to nursing staff of the knowledge needed to support their clinical decision making and actions" (Page, 2004).

The report further asserts that redesigned work practices require sufficient numbers of nurses, but that numbers alone do not assure safety if the nurses suffer from fatigue, lack experience, or lack education and training.

Many environmental factors can compromise safe nursing practice, such as staff turnover, excessive overtime, lack of education in evidence-based protocols, and lack of safety systems such as hourly rounding, universal protocol, and procedures for verifying and reconciling medications.

A culture of safety includes a positive work environment in which nurses experience empowerment

and advocate for their patients and for safe practices.

### **Additional Recommendations**

Although the list of SREs is used in varying degrees across different states, there is still a need to improve the existing list. The NQF has outlined a number of recommendations:

- Research and evaluation should be conducted to determine which events convey a valid, reliable perspective of healthcare organization safety.
- Research should be conducted to evaluate the impact of public reporting of patient safety information on patients, consumers, and healthcare institutions.
- Organizations that design or collect patient safety reports from healthcare providers should come together and begin to standardize systems for defining, measuring, reporting, analyzing, and classifying patient safety information in a way that produces greater data integrity.
- Health information technology (HIT) systems should include provision for facilitating patient-safety related data capture in ways that can be used for public reporting.

Additionally, there is a need to:

- Explore effective mechanisms to collect data and communicate serious reportable events to the public.
- Examine how data derived from using the NQF list can be disclosed in a way that meets the public's needs, yet is balanced with the need for providers to learn from mistakes.
- Test the operational value and utility of the events on the list.
- Identify ICD, CPT, or other codes that correlate with each serious reportable event on the list.
- Identify effective mechanisms, to permit institutions to report an event that occurs in their organization only once to a single entity from which needed information can be extracted.
- Evaluate comparability of data reported across healthcare systems and improve comparability.
- Evaluate outcomes of public reporting in terms of both reduction in occurrences of these events and identification and use of practices to prevent such occurrences.

### **Conclusion**

Nurses play a critical role in preventing Never Events and assuring patient safety. Arm yourself with knowledge about Never Events and the serious consequences to both patients and healthcare facilities when adverse events occur. Follow facility policy and procedure scrupulously and be alert to introduction of new evidence-based practices in facility policies and procedures.

**Adopt the motto:**

***Not in our unit. Not on our watch. Not to our patients.***

(AACN, 2009, p. 15)

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## **Appendix One: List of SREs**

To review the full list of SREs, [click here](#).

## **Appendix Two: Sample Hospital Policy**

\*Reporting of Sentinel Events to the Joint Commission is voluntary for its accredited hospitals.

### **Sample Hospital Policy**

On DATE, X Hospital agreed to the following policy on the issue of serious reportable events (“never events”, as defined by the National Quality Forum’s 2006 report).

- We will apologize to the patient and/or family affected by the never event
- We will report to at least one of the following agencies within 10 days of becoming aware that the never event has occurred:
  - o The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as consistent with their Sentinel Event policy\*
  - o State reporting program for medical errors
  - o Patient Safety Organization (e.g. Maryland Patient Safety Center)
- Perform a root cause analysis, per instructions from the chosen reporting agency, to identify the basic or causal factors that underlay the never event and to improve our systems and processes

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- We will waive all costs directly related to a serious reportable event (“never event”) and will refrain from seeking reimbursement from the patient or a third party payer for costs related to it