

Measure Background

The National Quality Forum (NQF) has issued a [list](#) of 29 events that they termed “serious reportable events,” which are extremely rare medical errors that should never happen to a patient. Often referred to as “never events,” these include errors such as surgery performed on the wrong body part or on the wrong patient, leaving a foreign object inside a patient after surgery, or death resulting from devices or contaminated drugs.

National Action on Never Events

Adverse events in health care are one of the leading causes of death and injury in the United States today. NQF’s list of 29 events is not intended to capture all of the adverse events that could possibly occur in hospital facilities. Rather, the list contains events that are of concern to patients, policy makers, and health care professionals and providers. These events are clearly identifiable and measurable (and thus feasible to include in a reporting system) and of a nature such that the risk of occurrence can be reduced by establishing protocols, policies, and procedures within health care organizations.

The Agency for Healthcare Research and Quality (AHRQ) and the National Patient Safety Foundation (NPSF) have both released resources developed to help health care organizations improve the way they investigate medical errors, adverse events, and near misses. AHRQ’s Communication and Optimal Resolution (CANDOR) process and toolkit were developed to assist health care institutions and practitioners to respond in a timely, thorough, and just way when unexpected events cause patient harm.¹ NPSF’s Root Cause Analysis and Action (RCA²) identifies methodologies and techniques that will lead to more effective and efficient use of RCA². Additionally, they provide tools to health care leaders to evaluate RCA² reviews so that significant flaws in individual RCA² reports can be identified and remediated to achieve the ultimate objective of improving patient safety.²

While more than 25 states and the District of Columbia have mandatory reporting of never events,³ only a few states report such events publicly. Minnesota has had a mandatory reporting program for never events in place since 2005 and has averaged roughly 100-150 reported never events per year.⁴

Never events are indeed relatively rare, and Leapfrog recognizes that processes sometimes fail and human error can occur. Leapfrog wants to recognize hospitals that are willing to take all the right steps in the rare event that a serious reportable adverse event occurs in their facility.

The Leapfrog Group promotes patient safety and quality in a standardized manner by supporting the consensus work of NQF, which based its standardized set of never events on an extensive literature review as well as clinical and consumer input.

Leapfrog’s Policy on Never Events

Beginning in 2007, The Leapfrog Group has asked hospitals to commit to five actions if a never event occurs within their facility: 1) apologize to the patient; 2) report the event; 3) perform a root cause analysis; 4) waive costs directly related to the event; 5) provide a copy of the hospital’s policy on never events to patients and payors upon request. In 2017, Leapfrog asked hospitals to commit to four additional actions: 6) interview patients and/or families to gather evidence for the root cause analysis; 7) inform patients and/or families of actions taken to prevent reoccurrence of the event; 8) provide support for caregivers involved in the event; and 9) perform an annual review to ensure compliance with each of these elements for each event.

Each of the nine actions is described in more detail below:

- 1) The Leapfrog Group believes it is in the best interest of all parties involved that the hospital staff gives a verbal apology and explanation of the known circumstances surrounding the never event to the patient and/or family affected. Research indicates that patients who are victims of adverse events feel most angry if they perceive that no one is taking responsibility for what happened to them. A sincere apology from the responsible hospital staff can help to heal the breach of trust between the doctor/hospital and patient, and may reduce the hospital’s risk of liability.⁵
- 2) According to NQF, “the primary reason for identifying a standardized set of serious reportable events that would be mandatorily reported is to

facilitate public accountability for the occurrence of these adverse events in the delivery of health care.”⁶ Since the U.S. health care system does not currently have a national reporting program in place, The Leapfrog Group asks hospitals to choose at least one of three reporting options: The Joint Commission, a state reporting program, or a Patient Safety Organization. The Leapfrog Group asks that the hospital report to its chosen entity within 10 days of determining a never event occurred.

- 3) Perhaps the most important action for a hospital to take in the aftermath of a never event is to conduct a prompt and thorough root cause analysis (RCA). A RCA gives the hospital a structured method to learn from its mistakes by identifying the basic or causal factors that underlay the never event and to improve its systems and processes. All of the reporting programs that The Leapfrog Group endorses have instructions for how to perform an RCA of adverse events that will help to guide the hospital through the necessary steps.
- 4) The Leapfrog Group’s policy on never events is about improving patient care. It goes without saying that a patient who is a victim of a never event should not have to pay for it. Therefore, The Leapfrog Group asks hospitals to determine, on a case-by-case basis, which costs are directly related to the never event and to waive those costs so that the patient and third-party payor do not receive a bill for those costs. The Leapfrog Group understands that specific details of what constitutes “waiving cost” requires the hospital to rigorously examine the individual set of circumstances surrounding the never event; the policy asks the hospital staff to use its best judgment during this examination to protect the patient from inappropriate billing.
- 5) A hospital that implements The Leapfrog Group’s policy on never events agrees to be transparent with key stakeholders on their implementation of this policy. A copy of the policy should be made available to all patients, patients’ families, and payors upon request.
- 6) In other safety-critical industries, event reviews are highly routinized and are one of the most important learning opportunities. Event reviews should involve

the patient/family in the interview process of understanding an event (if they are willing and able) because they often are the only people present throughout the entire course of an event.⁷

- 7) When an adverse patient event occurs, patients and their families often express the desire to help protect others from experiencing a similar event. Sharing with the patient and his/her family what steps the organization will take to help prevent the recurrence of similar events helps in rebuilding trust.
- 8) After a never event occurs, caregivers that were involved in the event often experience self-doubt, burnout, and other problems that cause personal anguish and hinder their ability to deliver safe, compassionate care. Hospitals should have in place programs that deliver “psychological first aid and emotional support” to health care professionals following these difficult events. This support should be both nonjudgmental and confidential.⁸
- 9) To ensure that hospitals actually followed the above principles when a never event occurred in their hospital, hospitals should conduct an annual review of their never events and ensure that each of the above principles were followed for each event.

Policy Implementation

1. Hospitals can adopt the policy by incorporating each of its nine points into an internal policy that is implemented in their facility.
2. Hospitals that report to the Leapfrog Hospital Survey will have an opportunity to indicate their implementation of the policy in the Survey.

Why Purchasers Need to Get Involved

Using their leverage as purchasers, employers can recognize and reward hospitals that have implemented The Leapfrog Group’s policy on never events. Purchasers and payors can promote dialogue about never events by educating consumers and calling attention to the importance of choosing hospitals with zero or low rates of never events. Purchasers and payors should also implement a no-payment policy for never events. Importantly, purchasers can continue to apply pressure

on hospitals to be transparent about incidents of never events, with a focus on prevention and transparency with patients and families.

References

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2. National Patient Safety Foundation. RCA2: Improving Root Cause Analyses and Actions to Prevent Harm. Version 2. 2016. Boston, MA. Available at: <https://psnet.ahrq.gov/issue/rca2-improving-root-cause-analyses-and-actions-prevent-harm>
3. OIG, Adverse Events in Hospitals: State Reporting Systems, OEI-06-07-00471, December 2008.
4. Minnesota Department of Health. Adverse Health Events in Minnesota: Fourth Annual Public Report. January 2008.
5. Massachusetts Coalition for the Prevention of Medical Errors. When Things Go Wrong: Responding to Adverse Events. Boston, 2006.
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7. Agency for Healthcare Research and Quality. System-Focused Event Investigation and Analysis Guide. Available at: <https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/module4-guide.html>
8. Johns Hopkins Medicine. Caring for the Caregiver. Available at: <https://www.johnshopkinssolutions.com/solution/rise-peer-support-for-caregivers-in-distress/>