



Policy and Perspective on 'Never Events'



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What are Never Events?

“Never Events” are serious and costly health care errors that should never happen. These events—such as surgery on the wrong body part or a mismatched blood transfusion—cause serious injury or death and often result in increased health care costs to treat the consequences of the error. In 1999, the Institute of Medicine reported that as many as 98,000 people die each year from medical errors that occur in hospitals. Most medical errors are preventable and the unintended consequences of a highly complex health care system with inadequate safety checks.

In 2002, the National Quality Forum (NQF) developed a standardized list of “serious reportable events in health care”—popularly known as “Never Events.” The list was revised in 2006. Among its motivations, the NQF sought to propel the development of a national state-based medical error reporting system and to improve public accountability. With better reporting, we can better understand where and when errors occur, paving the way for policies and procedures that improve care and save lives.

For an error to make NQF’s Never Event list, it must be:

- Unambiguous: The error can be clearly defined and easily measured;
- Usually Preventable: The event could have been anticipated and safety precautions exist, but it typically occurs because of an error or other system failure;
- Serious: The event results in death or serious disability or signals a problem in a health care facility’s safety systems.

Since the NQF list was created, states and other entities have also taken action to require reporting of so-called Never Events. Beyond reporting requirements, Medicare, Medicaid, and private insurers have begun to implement “no pay” policies that deny reimbursement for hospital complications related to Never Events and other preventable medical errors. Although the NQF list aimed to standardize the reporting of medical errors, the health care events subject to reporting requirements and “no-pay” policies differ from list to list. As a result, the term “Never Events” is no longer specific to the NQF list but subsumes the multiple policies that take aim at medical errors that are reasonably preventable through safety procedures and/or the use of evidence-based guidelines.

Table 1 This table compares the NQF list with the Medicare and Colorado Medicaid “no pay” lists.	National Quality Forum Serious Reportable Events in Health Care (2006)	CMS* Medicare Hospital Acquired Conditions (HACs)	Colorado Medicaid Serious Reportable Events (2009)
SURGICAL EVENTS			
Surgery performed on the wrong body part	■		■
Surgery performed on the wrong patient	■		■
Wrong surgical procedure performed on a patient	■		■
Leaving a foreign object in a patient after surgery or other procedure	■	■	■
Death of a healthy person during surgery or right after surgery	■		
Artificial insemination with the wrong sperm or donor egg	■		
Surgical site infection/swelling between the lungs (mediastinitis) after coronary artery bypass graft (CABG) surgery		■	■
Surgical site infection following bariatric surgery for obesity		■	■
Surgical site infection after certain orthopedic procedures		■	■
Blood clots in legs or lungs (Deep Vein Thrombosis and pulmonary embolism) after certain orthopedic procedures		■	■

*Centers for Medicare & Medicaid Services

(Continued on page 3)

What is Deep Vein Thrombosis?

About 300,000 people die each year from pulmonary embolism, a condition in which blood clots travel to the lungs.

Pulmonary embolism may be the most common preventable cause of hospital death, according to the American Public Health Association.

Deep vein thrombosis (DVT) is a blood clot in a deep vein, most commonly in the lower leg or thigh. The clot can block blood flow and cause pain, swelling and skin discoloration.

But in the most serious cases, deep vein thrombosis can lead to a pulmonary embolism (PE)—when part of the blood clot breaks loose and travels through the bloodstream to the lungs, where it can block a lung artery, causing damage to the lungs or other organs from lack of oxygen.

There are proven and effective measures to prevent and treat DVT and PE, but the majority of individuals who could benefit from them do not receive them. The problem was serious enough for the National Quality Forum to add the condition to its Never Events list. And last year, the U.S. Surgeon General issued a call to action to prevent deep vein thrombosis and pulmonary embolism.

Guidelines for prevention including putting certain patients on blood-thinning medications and using special compression socks after surgery that improve circulation in the legs.

The Leapfrog Group

The Leapfrog Group, based in Washington, D.C., is a coalition of large purchasers of health care looking to promote high-value health care by improving hospital safety.

In 2006, Leapfrog developed a Never Events policy that governs how providers should handle the aftermath of an error. This policy includes:

1. Apologizing to the patient and family;
2. Publicly reporting the event;
3. Conducting an analysis of what caused the event;
4. Waiving all costs directly related to the care for the event.

Hospitals that adopt the policy are recognized in Leapfrog's Patient Safety Ratings, which can be found online at www.leapfroggroup.org. The site includes data on Colorado hospitals. According to the ratings, 29 Colorado hospitals have implemented Leapfrog's policy on Never Events.

In 2009, The Leapfrog Group added one more item to the policy:

5. Hospitals should provide a copy of the hospital's policy to all patients, patients' families, and payers upon request.

Table 1 (Continued from page 2)	National Quality Forum Serious Reportable Events in Health Care (2006)	CMS* Medicare Hospital Acquired Conditions (HACs)	Colorado Medicaid Serious Reportable Events (2009)
DEVICES			
Death/serious disability from contaminated drugs, devices, or biologics	■		
Death/serious disability from improper use of a device	■		
Death/serious disability from air in a vein (intravascular air embolism)	■	■	■
CARE MANAGEMENT			
Death/serious disability from a drug error	■		
Death/serious disability from getting incompatible blood product(s)	■	■	■
Maternal death/serious disability associated with labor/delivery in low-risk pregnancy	■		
Death/serious disability from poor blood sugar control (hypoglycemia)	■	■	■
Death/serious disability from failure to identify and treat jaundice in newborns	■		
Very serious (stage 3 or 4) bed sores acquired after admission	■	■	■
Death/serious disability from spinal adjustments (spinal manipulative therapy)	■		
Urinary tract infection from a urinary catheter		■	■
Infection from a vascular catheter		■	■

(Continued on page 4)

The federal government and patient safety organizations: Moving toward non-payment.

Medicare and Hospital-Acquired Conditions

In October 2008, Medicare began denying payment for hospitals' extra costs to treat complications that result from certain hospital-acquired infections (HACs) and injuries, such as severe bedsores. Medicare, the federal health care program for senior citizens and the disabled, adopted the policy with the hope of saving lives and cutting costs. Conditions included on Medicare's "no pay" list of HACs were selected because they are:

- High cost or high volume (or both);
- Identifiable as complications through billing data;
- Preventable through use of evidence-based guidelines.

As illustrated in Table 1, the HACs on the Centers for Medicare & Medicaid Services list share some conceptual similarities with the NQF list, and some conditions appear on both lists of Never Events. However, there are also some important differences. Most of the events on the NQF list are rare, while some HACs occur more commonly and have a comparatively greater impact on cost. One of the more common HACs is deep vein thrombosis.

Despite this great emphasis on cost, a group of California researchers say savings from Medicare's new Never Events policy will be small. They argue that the list of "no pay" conditions is short, the policy relies on arcane billing assumptions to identify events, and the policy does not capture all downstream implications of a Never Event. For example, hospitals wouldn't be paid for removing a sponge left in a surgical patient if it is discovered before discharge. But if the patient is discharged and readmitted to remove the sponge, Medicare will foot the bill. Medicare officials say they are considering expanding the list of preventable conditions and changing how the program pays hospitals, among other things. [*Wall Street Journal* <http://online.wsj.com/article/SB125243928327493419.html>]

Another example that illustrates the difficulty of implementing this policy relates to the billing assumptions. If a patient enters the hospital, and develops a bedsore, then the Never Events policy should be applied. If, however, the patient already had the bedsore when that patient is admitted, then payment for treatment should be covered. When a claim is sent in for payment, the claim must now identify whether the bedsore was "present on admission."

Table 1 (Continued from page 3)	National Quality Forum Serious Reportable Events in Health Care (2006)	CMS* Medicare Hospital Acquired Conditions (HACs)	Colorado Medicaid Serious Reportable Events (2009)
PATIENT PROTECTION			
Infant discharged to the wrong person	■		
Death/serious disability after a patient disappears for more than 4 hours	■		
Suicide or attempted suicide that leads to serious disability	■		
ENVIRONMENTAL			
Death/serious disability resulting from an electric shock in a health care facility	■	Included in "falls and trauma"	Included in "hospital acquired injuries"
Any time when a patient gets the wrong gas or contaminated gas	■		
Death/serious disability resulting from a burn in a health care facility	■	Included in "falls and trauma"	Included in "hospital acquired injuries"
Death/serious disability resulting from a fall in a health care facility	■	Included in "falls and trauma"	Included in "hospital acquired injuries"
Death/serious disability from the use or lack of restraints or bedrails	■		
CRIMINAL			
Any time care is ordered/provided by someone impersonating a doctor, nurse or other provider	■		
Abduction of a patient	■		
Sexual assault on a patient	■		
Death/significant injury of patient or staff member from physical assault	■		

What's the state of things in Colorado?

In response to the NQF call-to-action on preventable medical errors, states have pursued both required and voluntary reporting of adverse events. In Colorado, both the Medicaid agency and Colorado Hospital Association have promulgated Never Events policies.

Medicaid

In March 2009, the State of Colorado Office of the Governor issued an Executive Order that directed the Colorado Department of Health Care Policy and Financing, which runs the Medicaid program, to develop rules for “denial or reduction in payments under Medicaid for serious reportable events.” The Medicaid policy largely follows in Medicare’s footsteps and refuses payment for complications arising from Medicare’s “no pay” list of 12 hospital acquired conditions. In addition, Medicaid will deny payment entirely for three NQF events: wrong surgical procedure, or surgeries performed on the wrong body part or wrong patient.

The objective is not to reduce costs but to ensure patient safety and the quality of care, stressed Jenny Nate, a policy analyst with the department. “We realize the savings will be nominal,” she said, “due to the low incidence rate of Never Events among our Medicaid providers.”

Hospitals

In 2008, the Colorado Hospital Association Board of Trustees recommended all Colorado hospitals adopt a common set of core principles in developing payment policies for “serious preventable events.” The principles, CHA said, will help avoid confusion among insurers and other payers, as well as patients, and encourage consistent approaches across hospitals and health plans.

The principles are:

- Colorado hospitals will consider adjusting charges for services directly related to NQF’s Never Events.
- If a hospital readmits a patient because of a Never Event, the hospital will not expect to be paid for services directly related to the event.
- If the event results in a longer hospital stay, more care or a significant intervention, the hospital will do its best to separate those additional charges and adjust the bill as soon as possible.
- These principles apply to the care related to and made necessary by the preventable event, not the entire episode of care.
- The hospital will work in consultation with physicians and other providers to the extent possible to minimize the financial impact to patients and payers resulting from the event.

- When a serious preventable event occurs, a thorough analysis will be conducted and reported, and steps will be taken to correct the problem
- These guiding principles are specific to the NQF list of serious reportable health care events and not the Medicare HAC list.

According to the Colorado Hospital Association, all hospitals in Colorado have reported that they have a Never Events policy in place.

Colorado Business Group on Health

The Colorado Business Group on Health is a nonprofit coalition representing large purchasers of health care services. This coalition engages health plans, physician groups, hospitals, mental health organizations, hospice providers and others to drive positive change in the accountability, transparency and value of the health care system to the benefit of all Coloradans.

In 2009, the Colorado Business Group on Health sent a letter of request to Colorado hospitals for a copy of their approved Never Events policy and 33 hospitals responded.

1. Arkansas Valley Regional Medical Center (La Junta)
2. Boulder Community Hospital (Boulder)
3. Centura Health—Avista Adventist Hospital (Louisville)
4. Centura Health—Littleton Adventist Hospital (Littleton)
5. Centura Health—Parker Adventist Hospital (Parker)
6. Centura Health—Penrose—St. Francis Medical Center (Colo. Springs)
7. Centura Health—Porter Adventist Hospital (Denver)
8. Centura Health—St. Anthony Central Hospital (Denver)
9. Centura Health—St. Anthony North Hospital (Westminster)
10. Centura Health—St. Anthony Summit Medical Center (Frisco)
11. Centura Health—St. Mary Corwin Medical Center (Pueblo)
12. Centura Health—St. Thomas More Hospital (Cañon City)
13. Delta County Memorial Hospital (Delta)
14. Exempla Saint Joseph Hospital (Denver)
15. Exempla Good Samaritan Medical Center (Lafayette)
16. Exempla Lutheran Medical Center (Wheat Ridge)
17. Gunnison Valley Hospital (Gunnison)
18. Heart of the Rockies Regional Medical Center (Salida)
19. Longmont United Hospital (Longmont)
20. Medical Center of Aurora (Aurora)
21. Medical Center of the Rockies (Loveland)
22. National Jewish Health (Denver)
23. North Suburban Medical Center (Thornton)
24. Parkview Medical Center (Pueblo)
25. Poudre Valley Hospital (Fort Collins)
26. Presbyterian/St. Luke’s Medical Center (Denver)
27. Rose Medical Center (Denver)
28. Saint Mary’s Hospital & Medical Center (Grand Junction)
29. Sky Ridge Medical Center (Lone Tree)
30. Swedish Medical Center (Englewood)
31. University of Colorado Hospital (Aurora)
32. Valley View Hospital (Glenwood Springs)
33. Yuma District Hospital (Yuma)

Rocky Mountain Patient Safety Organization: The difference is confidentiality.

Following high-profile reports about patient safety that garnered national attention, President George W. Bush signed the Patient Safety and Quality Improvement Act in 2005. The act created a voluntary system for health care providers to confidentially report medical errors and other patient safety concerns to “patient safety organizations.” These organizations will collect and analyze the medical error reports and develop strategies to improve patient safety.

In Colorado, the Colorado Hospital Association worked with a broad coalition of health care leaders to establish the Rocky Mountain Patient Safety Organization (RMPSO) in January 2009. RMPSO is the first PSO in the region to be certified by the Agency for Healthcare Quality and Research.

The RMPSO will:

- Serve as an independent, external partner to collect, analyze and aggregate patient safety information. The RMPSO will use that information to better understand what leads to medical errors.
- Provide confidential and privileged advice to health care providers so they can better understand and minimize the risks associated with delivering patient care.
- Foster collaboration among health care providers in all settings without fear of legal liability or professional sanctions.

Sharing information about how a medical mistake occurred at one hospital should help other hospitals prevent such mistakes from occurring at their institutions.

The Centers for Disease Control and Prevention estimates that patients develop 1.7 million infections in hospitals each year, and it says those infections cause or contribute to the death of 98,000 people a year—about 270 a day.



Preventable errors that occur during or after surgery may cost employers nearly \$1.5 billion a year.
—2008 study by the Agency for Healthcare Research and Quality

Never Events timeline

The first step toward not paying for preventable errors began in 2002 when NQF defined the first list of Never Events. Since then, states, as well as the federal government, have taken different approaches to improving the quality of health care.

2002

The National Quality Forum releases its list of 27 “Never Events.”

2003

The Minnesota legislature is the first state to pass a statute requiring mandatory reporting of “Never Events.”

2004

New Jersey enacts a law requiring hospitals to report serious, preventable adverse events to the state and to patients’ families. Connecticut adopts a mix of 36 NQF and state-specific reportable events for hospitals and outpatient surgical facilities.

2005

President George W. Bush signed the Patient Safety and Quality Improvement Act. Illinois passes a law requiring hospitals and ambulatory surgery centers to report 24 “Never Events” beginning in 2008.

Who are the players?

National Quality Forum	Washington, D.C.–based nonprofit whose mission is to improve the quality of American health care	Developed original list of Never Events
The Leapfrog Group	Washington, D.C.–based coalition of employers that promote high-value health care	Developed original Never Events non-payment policy for hospitals
Medicare	Federal health insurance program for people 65 and older or who have certain disabilities	No longer pays for certain Never Events
Medicaid	State- and federally funded program for low-income individuals and families	No longer pays for certain Never Events
Rocky Mountain Patient Safety Organization	Denver-based nonprofit that collects and analyzes data from clinicians and health care organizations to improve quality	Will gather and analyze data to better understand what leads to Never Events

Policy implications

How do we know how common Never Events are and whether we're making any progress? This is a good question. Never Events are rarely disclosed, except confidentially to reporting programs like the Joint Commission.	While reporting of Never Events is beginning to take hold, it is not mandatory. Policy should explore how to best capture information about these errors from providers.
How do we know if some Never Events, such as bed sores, occurred before the patient was admitted to the hospital? Some conditions may be present when a patient is admitted.	Payers including Medicare now require providers to indicate whether certain conditions were present on admission. Health care providers should ensure policies and procedures are in place to accurately collect this data.

Never Events timeline *(Continued from page 6)*

2006

NQF revises their list of Never Events. President Bush signs the Deficit Reduction Act, which directs the head of Medicare and Medicaid to begin a process that limits payments to hospitals for preventable medical errors that harm patients.

2008

Medicare, the federal insurance program for the elderly and disabled, stops paying the extra costs of treating 10 hospital injuries and infections. Minnesota Department of Health publishes the “Consumer Guide to Adverse Health Events” that indicates 125 Never Events have been reported between October 2006 and October 2007.

2009

Colorado’s Medicaid program stops paying for certain “Never Events.” The Rocky Mountain Patient Safety Organization is certified by the Agency for Healthcare Research and Quality.

We're moving in the right direction, but not there yet. What are the next steps?

Thousands of patients die each year from preventable medical errors, but there are things employers can do to promote higher quality care. Employers pay for health care as if all care were equal. Not paying when avoidable mistakes occur gives hospitals and providers incentives to improve patient safety. Employers should also encourage the reporting of Never Events. With better data and an understanding of how errors happen, hospitals and health care providers can implement policies and procedures that improve the quality of health care. Finally, standardization of the Never Events lists across all payors and policies and across all hospitals would diminish confusion, and lead to a stronger implementation effort.

Action steps

Employers

- Provide information about Never Events to employees through newsletters, paycheck inserts, posters, online, etc. For articles and communication tips, contact the Colorado Business Group on Health at 303-922-0939.
- Require Never Events language in health plan contracts.
 - Advise your plan that: “My company and its employees are not paying for Never Events any more, and that has to be in our next contract.”
 - Ask your health plan:
 - What is your process for identifying Never Events?
 - What preventable errors are on your Never Events list?
 - What financial disincentives do you have in place to encourage hospitals, doctors and others to avoid Never Events?
 - What are you doing to prevent my company from paying for Never Events?

Employees

- There are some conditions and errors that you should not have to pay for. Learn what Never Events are.
- Research your health care providers' and health plan's policy on paying for Never Events.
- If you experience a Never Event, ask the hospital for an apology, for an explanation of how the event occurred, to report the event, and to waive the costs associated with the error.

Health plans

- Require reporting of Never Events to the Joint Commission or a Patient Safety Organization.
- Do not reimburse hospitals, doctors and other providers for Never Events.