

Definition of Never Events

The National Quality Forum, a nonprofit national coalition of physicians, hospitals, businesses and policy-makers, has identified 28 events as occurrences that should never happen in a hospital and can be prevented. They termed them "serious reportable events", or never events. They include surgical events, such as performing the wrong surgical procedure; product or device events, such as contaminated drugs or devices; and criminal events, such as abduction of a patient. See a complete list of never events:

<http://www.qualityforum.org/pdf/news/prSeriousReportableEvents10-15-06.pdf>

General Information about Never Events

Adverse events in health care are one of the leading causes of death and injury in the United States today. The National Quality Forum's list of 28 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 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." (Press Release. Source: National Quality Forum. 13 October, 2006)

It is difficult to assess how often never events occur. By definition, they are – or should be – quite rare, but since they are also rarely disclosed except to

confidential reporting programs, precise numbers on their frequency are not available. Minnesota has had a mandatory reporting program for never events in place for 3 years and has averaged roughly 100-150 reported never events per year.

The Leapfrog Group wants to promote patient safety and quality in a standardized manner by supporting the consensus work of the National Quality Forum which based its standardized set of never events from an extensive review of the research as well as clinical and consumer input on the subject of never events.

Leapfrog's Policy on Never Events

Leapfrog's policy asks hospitals to commit to 4 actions if a never event occurs within their facility: 1) apologize to the patient, 2) report the event, 3) perform a root cause analysis, and 4) waive costs directly related to the event.

- 1) It is Leapfrog's belief that it is within the best interest of all parties involved for the hospital staff to give 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 the most anger when they perceive that no one is willing to take responsibility for what has happened. A sincere apology from the responsible hospital staff can help to heal the breach of trust between doctor/hospital and patient and may reduce the hospital's risk of liability. (When Things Go Wrong: Responding to Adverse Events. Mass Coalition for the Prevention of Medical Errors. Boston, 2006)

Never Events

- 2) According to the National Quality Forum, "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 healthcare." (Serious Reportable Events in Healthcare: A Consensus Report. NQF. 2002) Since the U.S. health care system does not currently have one national reporting program in place, the Leapfrog Group asks hospitals to choose at least 1 of 3 reporting options: the Joint Commission, a state reporting program, or a Patient Safety Organization. It asks that the hospital reports to its chosen entity within 10 days of its self-determination that a never event has occurred.
- 3) Perhaps the most important action for a hospital to take in the aftermath of a never event is a prompt and thorough root cause analysis. An 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 Leapfrog endorses have instructions for how to perform an RCA of adverse events that will help to guide the hospital through the necessary steps.
- 4) Leapfrog'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, Leapfrog 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 no third-party payer receives a bill for those costs. Leapfrog understands that specific details of what constitutes "waiving cost" requires the hospital to rigorously examine the individual set of circumstances surrounding the never event; our policy asks the hospital staff to use its best judgment during this examination to protect the patient from inappropriate payment.

Policy Implementation

- 1) Hospitals can adopt the policy by incorporating each of its four points into an internal policy that is implemented in their facility.
- 2) Hospitals that report to the Leapfrog Hospital Quality and Safety Survey will have an opportunity to indicate their implementation of the policy in a section of the survey. If they have not yet implemented the policy at the time of submission, they have an opportunity to commit to doing so in the next 60 days.
- 3) Hospitals' answers to the survey questions about whether or not they have implemented the Leapfrog never events policy will be publicly accessible on the consumer display of The Leapfrog Group's web site.

References

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When Things Go Wrong: Responding to Adverse Events. Massachusetts Coalition for the Prevention of Medical Errors. Boston, 2006.

The Leapfrog Safe Practices Score Leap

The Leapfrog Safe Practices Score

There are many aspects of a hospital's operations that contribute to overall quality and safety of care. In an effort to recognize a more expansive set of hospitals' quality and safety activities, and bring information to consumers about the level of safety they can expect, The Leapfrog Group has based this leap on the National Quality Forum's (NQF) *Safe Practices for Better Healthcare: A Consensus Report*.¹

The National Quality Forum is a not-for-profit organization created to develop and implement a national strategy for health care quality measurement and reporting. It makes recommendations for improving health care quality through a rigorous consensus development process. The NQF published *Safe Practices for Better Healthcare: A Consensus Report* in May 2003 and most recently updated in October of 2006. The report endorsed 30 practices that should be universally used in applicable clinical care settings to reduce the risk of harm to patients. Included in the 30 practices are the original 3 Leapfrog leaps: Computer Physician Order Entry, ICU Physician Staffing and Evidence-based Hospital Referral for certain high-risk procedures. For the fourth leap, hospitals' progress on the remaining 27 safe practices is assessed. After completion of the Leapfrog hospital survey, each hospital's relative ranking, compared with other hospitals, will be displayed on the Leapfrog Web site, along with their results for the initial 3 Leaps. Hospitals may choose to update their survey monthly.

Leapfrog's initial 3 Leaps targeted urban hospitals. Non-urban hospitals are now invited on a voluntary basis to complete the survey for the Safe Practices Score. They may also choose to complete the survey for the first 3 Leaps. Results of submitted surveys will be posted on The Leapfrog Group Web site. Special exceptions and specific instructions for Rural and Pediatric hospitals are included in the FAQs that are provided with the survey.

What are the NQF Safe Practices?

The National Quality Forum-endorsed 30 Safe Practices cover a range of practices that, if utilized, would reduce the risk of harm in certain processes, systems or environments of care. One practice composed of four elements relates to leadership and to creating and sustaining a culture of safety, three to matching care needs to service capability, six to improving information transfer and communication, four to medication

management, five to healthcare associated infections, and seven to specific care processes.

The updated practices have specificity and provide implementation approaches that will assist hospitals in a number of areas, including imaging and laboratory services.

The original 2003 set was endorsed following a formal Consensus Development Process undertaken by a diverse group of health care stakeholders, who then recommended that the practices be universally adopted. Throughout 2005 and 2006, the original set was carefully updated, through combining some and adding three new practices. These were again taken through the formal Consensus Development Process.

The Leapfrog Safe Practices Score

The Texas Medical Institute of Technology (TMIT)², on behalf of The Leapfrog Group, consulted more than 260 clinical, administrative, and scientific experts to assess the NQF-endorsed Safe Practices Score and to develop the survey and hospital ranking system. The relative weightings for each individual safe practice were developed by the TMIT Medical Advisory Board, which consisted of 10 internationally recognized patient safety leaders. Rural and Pediatric Task Forces were established to address the unique aspects of these hospitals. TMIT has undertaken a national research initiative, through its national research test bed, to assess the adoption of the practices, which provided significant input to the subject matter experts.

Leapfrog scores hospitals' progress on the 27 NQF Safe Practice areas out of a total of 1,000 points. Each practice area is assigned an individual weight, which is factored into the overall score. Hospitals are then ranked by quartiles. The final ranking will be defined by one of four categories to be publicly displayed on the Leapfrog Group Web site.

The new survey for 2007 does not include partial credit opportunities which had been available in the prior version. The practices and the survey have been updated with input from research undertaken with more than 300 hospitals that were original submitters to this Leap over 2005 and 2006(TMIT)^{3,4}.

A hospital's total score will be used to initially rank hospitals into one of four groups:

- Fully meets progress goal

The Safe Practices

- Making good progress
- Good early stage effort
- Willingness to report

In order to achieve the highest level of recognition, a hospital must be in the top quartile of respondents and must have made real progress in those practices considered most significant by the expert panels. Full details regarding the survey, relative weighting, and ranking method is on The Leapfrog Group Web site at www.leapfroggroup.org

Challenges to Implementation

It is unlikely that any hospitals will fully satisfy all practice requirements, including the most sophisticated and well-resourced. Some hospitals do not have the financial and staff resources to direct at every safe practice. Other hospitals simply have not directed their resources toward these patient safety practices at all. It is expected that completion of the survey will help to initiate a change process through the four dimensions of progress: awareness, ability, accountability and action that, if followed, will increase a hospital's investment in structural, process and clinical improvement aimed at patient safety.

A major challenge for hospitals has been the lack of national standards and measures, resulting in duplicative or widely scattered efforts to meet slightly different standards for each quality and safety organization. This Leap utilizes consensus-based nationally endorsed standards, increasing the efficiency and coordination of hospital reporting. The Leapfrog Group has pilot tested the new survey and received and incorporated input from hospitals into the survey, instructions, and FAQs. Pilot tests indicate that hospitals can gather survey information within a three-day period, and complete this section of the on-line survey in approximately one hour.

Why Purchasers Need to Get Involved

Using their leverage as purchasers, Leapfrog members can recognize and reward hospitals that meet NQF-endorsed Safe Practices standards. The addition of this fourth leap gives more tools with which to measure and reward hospital performance, and extends the reach of the survey to rural as well as urban hospitals, covering more of the hospitals which provide services to purchasers and plans.

Purchasers, including health plans, can promote the Safe Practices Score by educating employees and consumers

and calling attention to the importance of choosing the right hospital.

Purchasers, through their community involvement in healthcare settings (as board members, volunteers, donors), can also be persuasive with health care providers about the need to extend their efforts in safety and quality. Purchasers can also contract for specific safety and quality improvements with their health care providers and health plans.

Public reporting of the results of The Leapfrog Group survey can serve to both inform and motivate improvements in the safety of care.

Benefits

Unfortunately, there is continued evidence of problems in patient safety and the quality of care in inpatient settings. The practices included in the Safe Practices Score were endorsed by a broad group of stakeholders to provide high-impact improvements in patient safety. The criteria used to select these practices included reduction in mortality, experiential data from clinical practice and transferable evidence from other industries where research had shown efficacy. The implementation of these practices can reduce harm and save lives. Making hospital results available on the level of implementation will provide important information to consumers, enabling them to make more informed hospital choices.

References

¹ National Quality Forum. *Safe Practices for Better Healthcare: A Consensus Report- Updated*. 2006.

² Charles Denham, M.D., (Chairman) and, Franck Guilloteau (C.T.O) led the TMIT program.

³ Denham CR. From Harmony to Healing: Join the Quality Choir. *Journal Patient Saf.* 2006 Dec;2(4):225-232.

⁴ Denham CR. The New Patient Safety Officer: A Lifeline for Patients, A Life Jacket for CEO's. *Journal Patient Saf.* 2007 Mar;3(1): PENDING

THELEAPFROGGROUP

Why Hospital Choice Matters

Millions of Americans undergo elective surgery every year. For many procedures, patients should be able to expect very low risks no matter where they choose to have surgery.

For some high-risk procedures, however, the choice about where to have surgery can mean the difference between life and death. With heart surgery, for example, studies have found more than three-fold differences in surgical mortality rates across hospitals.^{1,2} Similar variation in quality has been described for non-surgical conditions as well.³

Choosing the Right Hospital and Surgeon

Patients can expect the safest possible surgery at hospitals with low mortality rates or high rates of adherence to clinical practices (or processes) known to improve surgical outcomes. This information is becoming increasingly available to patients through public reporting mechanisms. The Leapfrog Group has worked to harmonize its process measures and coordinate with state and national outcomes assessment systems. For example, California, New Jersey, New York and Pennsylvania regularly publish adjusted mortality rates for coronary artery bypass graft surgery. Unfortunately, robust programs are available in only four states, and similar information is not available for most other high-risk procedures and conditions. Although some states are now beginning to publish reports on surgical and other types of hospital related infections.

In addition to outcomes measurement systems, The Leapfrog Group recognizes the importance of adoption of specific clinical processes for high-risk procedures. The Leapfrog Group has revised its indicators for clinical processes to harmonize where possible with national performance measurement groups. These process measures are associated with improved outcomes for certain high-risk procedures: coronary artery bypass graft surgery, percutaneous coronary intervention and abdominal aortic aneurysm repair. Another important factor related to better surgical outcomes is volume — how many procedures of a given type a hospital performs each year.⁴ More than 100 studies have demonstrated better results at high-volume hospitals with cardiovascular surgery, major cancer resections, and other high-risk procedures.^{5,6} For example, compared to those at high-volume hospitals (50+ procedures per year), patients undergoing abdominal aneurysm repair at low-volume hospitals are more than 30% more likely to die following surgery.⁷

Lower surgical mortality at high-volume hospitals does not simply reflect more skillful surgeons and fewer technical errors with the procedure itself. More likely, it reflects more proficiency with all aspects of care underlying successful surgery, including patient selection, anesthesia and postoperative care.⁸

Choosing the right hospital also means, choosing hospitals with high volume surgeons. Evidence has shown that surgeons with more experience have better outcomes, especially in high risk procedures, such as: CABG, PCI, AAA, pancreatotomy, esophagectomy, valve replacement, bariatric.^{9,10} See Fact Sheets for Bariatric Surgery and Surgeon Volume for more information.

Choosing the right hospital is not just important in surgery. For examples, babies with very low birth weight or major congenital anomalies are much more likely to survive if they are delivered and treated at hospitals with large, neonatal intensive care units.^{3,13}

Potential Benefits of EBHR

Evidence-based hospital referral means making sure that patients with high-risk conditions are treated at hospitals with characteristics shown to be associated with better outcomes. EBHR could be very effective at preventing unnecessary deaths.

The Leapfrog EBHR Safety Standard

Under the advisement of national experts in quality improvement, The Leapfrog Group adopted EBHR as one of its Safety Standards. Procedures, conditions, and safety criteria were initially selected after review of published research in the field and consultation with leading experts in surgery and neonatal intensive care. These have since been reviewed and revised, incorporating even more current data and input from the hospital and physician communities.¹²

Hospitals fulfilling the EBHR Safety Standard will meet the hospital and surgeon volume criteria shown in the table below. Hospitals that do not met these criteria but adhere to the Leapfrog endorsed process measures for coronary artery bypass graft surgery, percutaneous coronary intervention, abdominal aortic aneurysm repair, and care for high-risk neonates, will

Evidence-based Hospital Referral

receive partial credit toward fulfilling the EBHR Safety Standard.

Recommended Annual Volumes: Hospitals and Surgeons	
1. Coronary artery bypass graft	≥ 450 / 100
2. Percutaneous coronary intervention	≥ 400 / 75
3. Abdominal aortic aneurysm repair	≥ 50 / 22
4. Aortic Valve Replacement	≥ 120 / 22
5. Pancreatic resection	≥ 11 / 2
6. Esophagectomy	≥ 13 / 2
7. Bariatric surgery	>100 / 20
High-risk delivery:	Neonatal ICU with Average Daily Census ≥15
▪ Expected birth weight < 1500 grams,	
▪ Gestational age < 32 weeks, or	
▪ Pre-natal diagnosis of major congenital anomaly	

In its latest version, Leapfrog places primary emphasis on direct outcome measures (i.e., risk-adjusted mortality) for coronary artery bypass graft and percutaneous coronary interventions, using robust and approved measurement systems for the EBHR Safety Standards. While the standards also include specific process measures for coronary artery bypass graft, percutaneous coronary interventions, abdominal aortic aneurysm repair and certain high-risk deliveries, there is somewhat less emphasis on these measures. The Leapfrog website provides specific details about these performance measures.

The Leapfrog Group, working in partnership with The MEDSTAT Group, invites hospitals to record their volume and process or performance measures for these procedures and conditions on the Leapfrog Web site. Leapfrog purchasers will work to recognize and reward hospitals providing care for their enrollees for meeting EBHR standards. Hospitals achieving intermediate levels of risk reduction for certain EBHR standards will earn partial recognition. An EBHR standard does not apply to hospitals that do not perform the procedure or treat the condition. Patients under 18 are excluded, except in the NICU standards.

Challenges to EBHR Implementation

Efforts to promote EBHR could meet resistance on many fronts. In isolated rural areas, EBHR could imply unreasonable travel burden for patients and their families. For this reason, the Leapfrog EBHR standard only applies to hospitals doing elective surgeries.

Not only might some patients resist EBHR, but some health

care providers are also likely to resist. Many low-volume hospitals may oppose giving up surgical revenue by referring patients elsewhere. They may also worry that EBHR would brand them as "second class." Some physicians may view EBHR as an affront to their professional judgment and competence in conducting surgery and/or referring patients.

Why Purchasers Need to Get Involved

Given these obstacles, greater use of EBHR is unlikely to happen without the involvement of purchasers.

Using their leverage as purchasers, Leapfrog members can recognize and reward hospitals that meet EBHR standards for selected procedures and conditions. Purchasers, including health plans also can promote EBHR by educating consumers and calling attention to the importance of choosing the right hospital.

Although it will not be easy to implement, referring patients for high-risk conditions and procedures to hospitals meeting Leapfrog's EBHR standards could have substantial benefits. Analysis by John Birkmeyer MD, Chief, Section of General Surgery, Dartmouth-Hitchcock Medical Center, suggests that 11,208 lives could be saved each year if EBHR were successfully implemented for the procedures and conditions selected by Leapfrog.¹²

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Evidence-based Hospital Referral

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FACT SHEET

THE LEAPFROG GROUP
Informing Choices. Rewarding Excellence.
Getting Health Care Right.

The Leapfrog Group

The Leapfrog Group is an initiative driven by organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. Leapfrog is a member supported program aimed at mobilizing employer purchasing power to alert America's health industry that big leaps in health care safety, quality and customer value will be recognized and rewarded. The Leapfrog Group was founded by a small group of large employers, initially supported by the Business Roundtable (BRT) and launched in November 2000. Leapfrog is supported by the BRT, The Robert Wood Johnson Foundation, Leapfrog members and others.

A 1999 report by the Institute of Medicine gave the Leapfrog founders an initial focus – reducing preventable medical mistakes. The report found that up to 98,000 Americans die every year from preventable medical errors made in hospitals alone. In fact, there are more deaths in hospitals each year from preventable medical mistakes than there are from vehicle accidents, breast cancer and AIDS. The report recommended that large employers provide more market reinforcement for the quality and safety of health care. Leapfrog's founders realized that they could take "leaps" forward with their employees, retirees and families by rewarding hospitals that implement significant improvements in quality and safety.

The Leapfrog Group's growing consortium of major companies and other large private and public healthcare purchasers provide health benefits to more than 37 million Americans in all 50 states. Leapfrog members and their employees spend tens of billions of dollars on health care annually. Leapfrog members have agreed to base their purchase of health care on principles that encourage quality improvement among providers and consumer involvement. If all hospitals implemented just the first three of Leapfrog's four "leaps" or recommended quality and safety practices: over 65,000 lives could be saved, more than 907,000 medication errors could be avoided (Birkmeyer 2004), and up to \$41.5 billion could be saved (Conrad 2005) each year.

The Mission

The Leapfrog Group's mission is to trigger giant leaps forward in the safety, quality and affordability of health care by:

- Supporting informed healthcare decisions by those who use and pay for health care; and,
- Promoting high-value health care through incentives and rewards.

This effort is rooted in four ideas:

1. American health care remains far below obtainable levels of basic safety, quality, and overall customer value.
2. The health industry would improve more rapidly if purchasers better recognized and rewarded superior safety and overall value.
3. Voluntary adherence to purchasing principles by a critical mass of America's largest employers would provide a large jump-start and encourage other purchasers to join.
4. These principles should not only champion superior overall value but should initially focus on a handful of specific innovations offering "great leaps" to maximize media and consumer support and adoption by other purchasers.

Four Leaps in Hospital Quality, Safety and Affordability

A range of hospital quality and safety practices are the focus of Leapfrog's hospital ratings via the Leapfrog Hospital Quality and Safety Survey, as well as our hospital recognition and reward programs. Endorsed by the National Quality Forum (NQF), the practices are: computer physician order entry; evidence-based hospital referral; intensive care unit (ICU) staffing by physicians experienced in critical care medicine; and the Leapfrog Safe Practices Score.

- **Computer Physician Order Entry (CPOE):** With CPOE systems, hospital staff enter medication orders via computer linked to prescribing error prevention software. CPOE has been shown to **reduce serious prescribing errors in hospitals by more than 50%**.
- **Evidence-Based Hospital Referral (EHR):** Consumers and health care purchasers should choose hospitals with extensive experience and the best results with certain high-risk surgeries and conditions. By referring patients needing certain complex medical procedures to hospitals offering the best survival odds based on scientifically valid criteria — such as the number of times a hospital performs these procedures each year or other process or outcomes data — research indicates that a patient's **risk of dying could be reduced by 40%**.
- **ICU Physician Staffing (IPS):** Staffing ICUs with doctors who have special training in critical care medicine, called 'intensivists', has been shown to **reduce the risk of patients dying in the ICU by 40%**.
- **Leapfrog Safe Practices Score:** The National Quality Forum-endorsed 30 Safe Practices cover a range of practices that, if utilized, would reduce the risk of harm in certain processes, systems or environments of care. Included in the 30 practices are the three leaps above. This fourth leap assesses a hospitals' progress on the remaining 27 NQF safe practices.

Our leaps adhere to four primary criteria. (1) There is overwhelming scientific evidence that these quality and safety leaps will significantly reduce preventable medical mistakes. (2) Their implementation by the health industry is feasible in the near term. (3) Consumers can readily appreciate their value. (4) Health plans, purchasers or consumers can easily ascertain their presence or absence in selecting among health care providers. These leaps are a practical first step in using purchasing power to improve hospital safety and quality.

Because the health industry needs time to meet these standards, Leapfrog purchasers are working with the provider community to arrive at *aggressive but feasible* target dates for implementation of Leapfrog's recommended quality practices.

In addition to the Survey, the **Leapfrog Hospital Insights** measurement tool integrates the first nationally collected set of hospital *efficiency* measures with standardized clinical measures from JCAHO and the Survey. This broad array of hospital performance measures gives consumers and purchasers a complete picture of overall hospital performance in five clinical areas and is the basis of Leapfrog's Hospital Rewards Program (see below).

Buying Right: Leapfrog's Purchasing Principles

Leapfrog's member companies agree to adhere to the following four purchasing principles in buying health care for their enrollees:

- 1) Educating and informing enrollees about the safety, quality and affordability of health care and the importance of comparing the care health care providers give. Initial emphasis on the Leapfrog safety and quality practices.
- 2) Recognizing and rewarding health care providers for major advances in the safety, quality and affordability of their care.
- 3) Holding health plans accountable for implementing the Leapfrog purchasing principles.
- 4) Building the support of benefits consultants and brokers to use and advocate for the Leapfrog purchasing principles with all of their clients.

To help advance the purchasing principles, the **Leapfrog Hospital Rewards Program** allows implementers to reward hospitals that demonstrate excellence and/or sustained quality and efficiency improvement. It is an off-the-shelf pay for performance program that drives improvements in hospital quality and efficiency in five clinical areas while demonstrating dollar savings as performance improves. For more information, visit <https://leapfrog.medstat.com/hrp/index.asp>.

Current Progress

The Leapfrog Group began collecting hospital data in June 2001 by surveying urban and suburban hospitals in six regions. Today, we operate in 33. (To view the list of regions, visit http://www.leapfroggroup.org/for_members/members_resources/regional_roll_outs/1277465.) Leapfrog's 33 regions cover over half of the US population and 58% of all hospital beds in the country. Currently, more than 1,300 hospitals participate in the Survey. To view hospitals ratings, visit <http://www.leapfroggroup.org/cp>.