

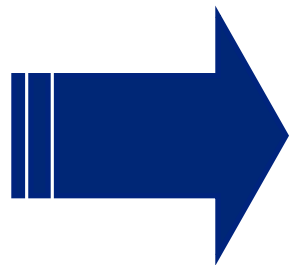
Serious Adverse Events & Never Events

Background and Policy Issues

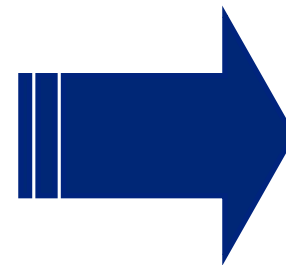
We want you to know™



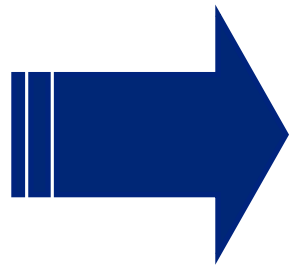
The Evidence



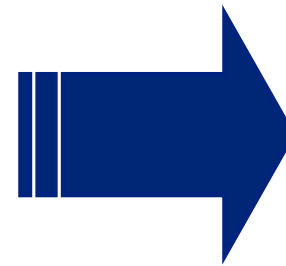
IOM reports that 44,000 to 98,000 Americans die each year from medical errors



Americans spend an estimated \$70 billion per year on incorrectly prescribed drugs



95% of Americans with heart failure do *not* receive the most appropriate therapy, resulting in 100,000 more deaths than would otherwise occur



60,000 strokes per year are preventable in individuals with atrial fibrillation

Reference: "To Err is Human - Building a Safer Health System"

Institute of Medicine (IOM), Committee on Quality of Health Care in America, Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors
National Academy Press, Washington DC, copyright 1999

Employers' Concerns

- Employers are absorbing alarming cost increases in providing medical benefits

- Employers have increasing concerns over quality of care such as:
 - Avoidable Medical errors
 - Inappropriate utilization of medical resources
 - Avoidable Complications that lead to additional costs, harm and disability

Hospital Acquired Condition (HAC)

Identified by specific diagnosis code or combination of diagnosis and procedure codes.

Present on Admission (POA)

A billing indicator to indicate if a condition was present at the time of an inpatient admission. Conditions that develop during an outpatient encounter, including emergency department, observation, or outpatient surgery, are considered POA.

Serious Adverse Events (SAE)

Twenty eight adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers.

Never Events (NE)

A term used originally by NQF to apply to a limited subset of SAEs, Leapfrog uses this term to reference all SAEs.

Types of Serious Adverse Events

There are six types of Serious Adverse Events:

1. Surgical events (e.g., surgery being performed on the wrong patient)
2. Product or device events (e.g., using contaminated drugs)
3. Patient protection events (e.g., an infant discharged to the wrong person)
4. Care management events (e.g., a medication error, infections)
5. Environmental events (e.g., electric shock or burn)
6. Criminal events (e.g., sexual assault of a patient)

Never Events

1. Artificial insemination with the wrong donor sperm or donor egg
2. Unintended retention of foreign object in a patient after surgery or other procedure
3. Patient death or serious disability associated with patient elopement (disappearance)
4. Patient death or serious disability 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)
5. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products
6. Patient death or serious disability associated with an electric shock or electric cardioversion while being cared for in a healthcare facility
7. Patient death or serious disability associated with a fall while being cared for in a healthcare facility

8. Surgery performed on the wrong body part
9. Surgery performed on the wrong patient
10. Wrong surgical procedure performed on a patient
11. Intraoperative or immediately post-operative death in an ASA Class I patient
12. Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by healthcare facility
13. 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
14. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

15. Infant discharge to wrong person
16. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility
17. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
18. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
19. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
20. State 3 or 4 pressure ulcers acquired after admission to healthcare facility
21. Patient death or serious disability due to spinal manipulative therapy

Never Events

22. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
23. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
24. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility
25. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
26. Abduction of a patient of any age
27. Sexual assault on a patient within or on the grounds of the healthcare facility
28. 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 the healthcare facility

Never Events

Through the 2007 Leapfrog Hospital Quality and Safety Survey, hospitals will be given the opportunity to receive public recognition for agreeing to do the following if a “never event” occurs within their facility:

- Apologize to the patient and/or family affected by the never event.
- Report the event to at least one reporting program: The Joint Commission on Accreditation of Healthcare Organizations (JCAHO); a state reporting program; or a Patient Safety Organization (e.g., Maryland Patient Safety Center).
- Perform a root cause analysis, consistent with the chosen reporting program.
- Waive all costs directly related to the never event and refrain from seeking reimbursement from the patient or a third party payer.

Never Events

- National and local consumer advocacy groups through the National Partnership for Women and Families are working with Leapfrog to educate consumers about never events and how hospitals can take steps to prevent them by implementing quality and safety processes.
- Health plans are also partnering with Leapfrog to encourage the hospitals with which they contract to adopt the Leapfrog never events policy. (Last year, Minnesota's HealthPartners led the way by initiating a policy that requires contracted hospitals to report, address, and refrain from billing for costs related to never events.)

Aetna Approach to Serious Adverse Events

- Engage with national Employer-based leadership groups, Leapfrog and Business Groups on Health
- Engage with national, state and local hospitals and hospital associations
- Establish Contractual shared commitments between hospitals and Aetna to implement the Leapfrog commitments for identification, reporting, patient notification, root cause analysis and process improvement
- Implement HAC/POA Policy 10/1/08
- Implement new Hospital Serious Adverse Event Policies: 1st Quarter 2009

Leapfrog and Aetna

Leapfrog Press Release 11/15/06:

“Aetna is the first health plan to support Leapfrog’s new policy. The following employers and employer groups have also declared their commitment.”

Aetna Press Release 1/05/08:

“As part of its commitment to improving patient safety, Aetna has incorporated language from the Leapfrog Group’s Never Events policy in its hospital contract templates for negotiations or renegotiations.”

“More than 600 hospitals across the country already have agreed to report these events voluntarily. We want to support their leadership and safer health care for all patients.”

Troy Brennan, CMO

Caterpillar Inc.	Midwest Business Group on Health
Colorado Business Group on Health	National Business Coalition on Health
Community Health Foundation of Western and Central New York	National Rural Electric Cooperative Association
GM	Nevada Health Care Coalition
Hannaford Brothers	New Jersey Healthcare Quality Institute
Health Policy Corporation of Iowa	New York Business Group on Health
HealthCare 21 Business Coalition	Pacific Business Group on Health
IBM	Savannah Business Group on Health
Indiana Employers Quality Health Alliance	St. Louis Area Business Health Coalition
Intel	The Dow Chemical Company
Iowa Health Buyers Alliance	UPS
Memphis Business Group on Health	

Issues & Opportunities:

- Significant financial savings vs. focus on root cause and process improvement
- No charge vs. working with health plans to fairly adjudicate claims for necessary services and not for the costs of preventable serious adverse events
- Holding hospitals accountable for the limited group of events that are truly never events
- Recognizing hospitals that commit to continuous improvement in patient safety

Hospital Contract Template Update

- Never Event language is included in hospital contract templates and is made available in Aetna's Strategic Contract Manager (SCM) system for all but 8 states where language is pending regulatory review
- The updated hospital contract templates containing language are used for all new hospital contracts and for rate renewals or amendments of any type
- Never Event language are reviewed as part of the Pre-signature Review process

Aetna's Never Event Reporting Requirements

Aetna's contract language states:

- Hospital shall notify Aetna and at least one of the following agencies within ten (10) days of becoming aware that a Never Event has occurred:
 - 1) Joint Commission;
 - 2) State reporting program for medical errors;
 - 3) Patient Safety Organization (e.g. state-specific patient safety center)

- In accordance with the reporting agency's instructions, Hospital representative will perform a root cause analysis identifying the basic or causal factors that underlay the Never Event and identify changes that result in improvements to Hospital's patient care systems and processes

- The Hospital representative will apologize to the Member and/or Member's family affected by the Never Event

- Hospital will waive all charges directly related to the Never Event

Impact of Contracting Approach

- For the first time, every hospital contract discussion, whether rate negotiation, new product addition or for any other purpose includes a discussion of hospital patient safety and continuous quality improvement
- 39% of hospital amendments filed since January 1, 2008 include language related to serious adverse event and hospital commitments
- Many hospitals provide copies of their existing or newly adopted policies for internal reporting, root cause analysis and process improvement

Never Event Contract Language Considerations

- Reporting to External Entities:
 - Critical to validating QI process, root cause analysis and error correction
- Reporting to Aetna:
 - Purpose is to identify such events for claims payment purposes
 - QM confirmation that root cause and plan of correction is implemented
- Billing and Reimbursement for SAEs:
 - Costs directly related to SAE
 - Costs for all 28 vs. partial list of SAEs
- Disclosure to Member vs. Apology to Member: particularly in States where apologies create liability risks

Questions?