Leapfrog’s Never Events Policy, PACT Resources and Tools

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Introductions

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Agenda

I. Leapfrog’s Never Events Policy
II. Introduction to PACT Collaborative and Resources
III. Patient-led National Initiative focused on Disclosure
IV. Questions
Background

In 2006, the National Quality Forum released a list of 29 events that they termed “serious reportable events,” extremely rare medical errors that should never happen to a patient.

Often called 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 discharging an infant to the wrong person.

That same year, the Centers for Medicare & Medicaid Services came out with a public statement on Never Events, in which it announced its intention to work with Congress, hospitals, and other health care organizations to reduce payments for Never Events and to provide more information to the public about when they occur.
NQF List of Serious Reportable Events (Never Events)

- Surgical or Invasive Procedure Events
  - Examples: Wrong site, wrong patient
- Product or Device Events
  - Examples: Intravascular air embolism or contaminated medications
- Patient Protection
  - Examples: Patient disappearance or suicide
- Care Management
  - Examples: Death or serious injury due to medication error, Stage 3 or 4 pressure ulcers, death or serious injury due to failure to follow-up with lab results
- Environmental Events
  - Examples: Death or serious injury associated with use of restraints, or burning
- Radiologic Events
  - Examples: Death or serious injury due to introduction of metallic object in MRI
- Criminal Events
  - Examples: Abduction
In 2007, The Leapfrog Hospital Survey began asking hospitals if they have a policy for handling “never events” that included the following 5 elements:

<table>
<thead>
<tr>
<th>Policy Element</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>We apologize to the patient and/or family affected by the never event.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>We report the event to at least one of the following external agencies within 15 business days of becoming aware that the never event has occurred:</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>√ Joint Commission, as part of its Sentinel Events policy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>√ DNV GL Healthcare</td>
<td></td>
<td></td>
</tr>
<tr>
<td>√ State reporting program for medical errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>√ Patient Safety Organization (as defined in The Patient Safety and Quality Improvement Act of 2005)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>We perform a root cause analysis, which at a minimum, includes the elements required by the chosen external reporting agency.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>We waive all costs directly related to the never event.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><em>In order to respond “Yes” to this question, all costs directly related to the never event must be waived to both the patient and the payor.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>We make a copy of this policy available to patients, patients’ family members, and payers upon request.</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
**Never Events Policy Elements**

In 2017, Leapfrog added four additional principles to its policy statement to further ensure that patients and family caregivers receive appropriate follow-up if a never event occurs.

<table>
<thead>
<tr>
<th><strong>Policy Element</strong></th>
<th><strong>Yes</strong></th>
<th><strong>No</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>We interview patients and/or families, who are willing and able, to gather evidence for the root cause analysis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>We inform the patient and/or the patient’s family of the action(s) that our hospital will take to prevent future recurrences of similar events based on the findings from the root cause analysis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>We have a protocol in place to provide support for caregivers involved in never events and make that protocol known to all caregivers and affiliated clinicians.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>We perform an annual review to ensure compliance with each element of Leapfrog’s Never Events Policy for each never event that occurred.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Scoring Algorithm

To achieve Leapfrog’s standard, hospitals must implement a policy that includes all nine elements.

The standard is used in Leapfrog’s national Top Hospital Program and Value-Based Purchasing Program.

<table>
<thead>
<tr>
<th>Never Events Score (Performance Category)</th>
<th>Meaning that...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieved the Standard</td>
<td>The hospital has implemented a policy that adheres to <strong>all nine principles</strong> of The Leapfrog Group’s Policy Statement on Serious Reportable Events (“Never Events”).</td>
</tr>
<tr>
<td>Considerable Achievement</td>
<td>The hospital has implemented a policy that adheres to all the <strong>original five principles</strong>* of The Leapfrog Group’s Policy Statement on Serious Reportable Events (“Never Events”), as well as <strong>at least two additional principles</strong>.</td>
</tr>
<tr>
<td>Some Achievement</td>
<td>The hospital has implemented a policy that adheres to all the <strong>original five principles</strong>* of The Leapfrog Group’s Policy Statement on Serious Reportable Events (“Never Events”).</td>
</tr>
<tr>
<td>Limited Achievement</td>
<td>The hospital responded to the questions pertaining to adoption of this policy but does not yet meet the criteria for Some Achievement.</td>
</tr>
</tbody>
</table>
National Performance

Though hospital performance is generally high, a substantial gap remains among 2022 Leapfrog Hospital Survey Participants (YE 2022):

- Achieved the Standard: 79%
- Considerable Achievement: 4%
- Some Achievement: <1%
- Limited Achievement: 16%
More Information on the Never Events Policy

Fact Sheet on Never Events

https://ratings.leapfroggroup.org/measure/hospital/2022/responding-never-events

Case Study: How One Health System Leads on Ethical Management of Never Events

• “The moment if think there is a perception that something went wrong, we have to start these conversations to have trust. In order to do that well, you don’t need to know if there’s anything to apologize for. You need to be transparent and tell the family you’ll be honest with them even if it hurts.”

• “People talk about making a safety coach program and we create safety coaches every time something like this happens because people understand, become more vigilant, and feel safe reporting hazards.”

https://www.leapfroggroup.org/how-one-health-system-leads-ethical-management-never-events
Reflections on this work
The PACT Collaborative
Content We Will Cover

• What is a highly reliable Communication and Resolution Program (CRP) and why does it matter?
• Overview of the Pathway to Accountability, Compassion, and Transparency (PACT)
• Tools and resources you can access and use today!
  • Driver diagram
  • Process map
  • Harm communication tip sheet
  • PACT Patient and Family Pathway
What is a Highly Reliable CRP and Why Does it Matter?
Why Do We Struggle to Respond to Harm Events?

- Human nature to want to keep problems to ourselves, to avoid difficult discussions
- Fear of punitive consequences, shame/embarrassment, lack of skills
- Mixed messages from institutions
- Different elements of response not integrated and hard-wired
### Elements of the CRP response

<table>
<thead>
<tr>
<th>Incident reporting by clinicians</th>
<th>Traditional Response</th>
<th>CRP Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication with patient, family</td>
<td>Delayed, often absent</td>
<td>Immediate</td>
</tr>
<tr>
<td>Event analysis</td>
<td>Deny/defend</td>
<td>Transparent, ongoing</td>
</tr>
<tr>
<td>Quality improvement</td>
<td>Physician, nurse are root cause</td>
<td>Focus on Just Culture, system, human factors</td>
</tr>
<tr>
<td>Financial resolution</td>
<td>Provider training</td>
<td>Drive value through system solutions, disseminated learning</td>
</tr>
<tr>
<td>Care for the caregivers</td>
<td>Only if family prevails on a malpractice claim</td>
<td>Proactively address patient/family needs</td>
</tr>
<tr>
<td>Patient, family involvement</td>
<td>None</td>
<td>Offered immediately</td>
</tr>
<tr>
<td></td>
<td>Little to none</td>
<td>Extensive and ongoing</td>
</tr>
</tbody>
</table>
Benefits of a CRP

01. Preserve trust and meet patient/family expectation
02. Reduce distress of clinicians
03. Reduce likelihood of litigation
04. Promote learning
05. Strengthen institutional culture
06. Increase public trust in healthcare
The Challenge of Inconsistent Implementation

- Use of CRP for some cases but not others
- Use of some but not all CRP elements for individual case
- Fuels skeptics’ concern that CRPs are actually a claims management strategy

Ultimately, fewer patients, families, clinicians, and organizations benefit from CRP process
Consequences of Failed Response to Adverse Events

- Compounds suffering of patients and family
- Heightens distress of clinicians
- Increases likelihood of litigation
- Lost opportunity for learning within and across institutions
- Degrades institutional culture/climate
- Reduces public trust in healthcare

May T, Aulisio MP. Kennedy Inst Ethics J. 2001; 11(2):135-146
FALSE APOLOGY CARDS

I'M SORRY YOU'RE MAKING SUCH A BIG DEAL OUT OF THIS
I'M SORRY YOU FEEL THAT WAY

I'M SORRY YOU GOT MAD
I'M SORRY YOU MISUNDERSTOOD

I'M SORRY, I DON'T CARE
I'M SORRY YOU'RE SUCH A LOSER

I'M SORRY... JUST KIDDING, I'M NOT
Overview of PACT
What is PACT?

A learning community dedicated to changing the way healthcare responds to harm

> PACT Collaborative:
  • Five virtual learning sessions presenting best practices in a structured curriculum and one simulation-rich in person session
  • Action Periods with coaching from nationally recognized experts, regular check-ins, a community forum for support, and data submission with automatically generated reports
  • Innovative suite of tools and resources
  • Shared learning and innovation across the nation

> PACT Leadership and Innovation Network:
  • Ongoing support and data sharing for PACT Collaborative “graduates” & mature CRPs
  • Recognition program for comprehensive, highly reliable systems
  • National leadership opportunities

> PACT Community of Practice:
  • Introducing tools and asynchronous guidance
  • Monthly webinars and quarterly group consultation with PACT faculty

The PACT Collaborative
Organizations Leading PACT
Tools and Resources You Can Access Today
PACT Driver Diagram

Aim: Develop, implement and achieve a comprehensive, highly reliable CRP in every participating organization

Primary Drivers:
- Accountability
- Compassion
- Transparency

Secondary Drivers:
- Prioritizing CRP as "mission critical"
- Establishing highly reliable CRP processes to support harmed patients, families and involved staff
- Ensuring that event review uses best practices and reduces recurrence
- Collecting, monitoring, and learning from CRP metrics
- Promptly and fairly offering financial/non-financial resolution
- Acknowledging and reducing suffering of patient, families, and staff involved in harm events
- Treating all patient and families with kindness, dignity, and respect
- Aligning CRP processes with the unique needs of each patient and family
- Creating and maintaining a non-punitive just culture
- Providing tools and skills to communicate appropriateness and transparency with patients, families, employees, and the organization
- Communicating transparently with patients and families about harm events
- Internally sharing CRP performance data
- Externally disseminating learning about harm events and CRP processes

Leadership Engagement: to inspire commitment, provide resources, and remove barriers to success

Patient/Resident & Family Engagement: to co-design all processes, ensuring equity and accessibility

Foundation for Success
Pathway to Accountability, Compassion, and Transparency (PACT): Process Map
A step-by-step map of the activities involved in responding to a harm event

**RESPONSES AFTER HARM EVENT**

**Early 0-3 days**
- Stabilize patient and identify CRP Lead and Patient Liaison
- Gather initial information about event
- Offer peer support and initial communication coaching to clinician(s)
- Communicate with patient/family and offer patient support
- Ensure bills are held

**Middle 1-6 weeks**
- Coordinate event review and ongoing communication (with Patient Liaison) and comply with local, state, and federal reporting requirements
- Review event and identify action items/improvements
- Interview clinician(s)
- Interview patient/family
- Provide ongoing support for patient/family and communicate re: review and action items
- Initiate claim event review for standard of care/preventability assessment
- Ensure account adjustment is processed and communicated

**Later 6 weeks-5+ months**
- Plan (with Patient Liaison) for implementation of action items, communication
- Initiate implementation of action items/improvement
- Follow up with peer support and feedback re: improvement opportunities using Just Culture
- Close loop with clinician(s) and solicit feedback on CRP experience
- Close loop with patient/family and solicit feedback on CRP experience
- Proactively offer compensation and/or non-financial resolution if appropriate

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**ACTIVITIES**

- **Event Management**
  - Enter event in management software

- **Event Review**
  - Stabilize patient and identify CRP Lead and Patient Liaison
  - Gather initial information about event
  - Offer peer support and initial communication coaching to clinician(s)
  - Communicate with patient/family and offer patient support
  - Ensure bills are held

- **Clinician Engagement**
  - Interview clinician(s)
  - Interview patient/family
  - Provide ongoing support for patient/family and communicate re: review and action items

- **Patient/Family Engagement**
  - Communicate with patient/family and offer patient support

- **Resolution/Reconciliation**
  - Initiate claim event review for standard of care/preventability assessment
  - Ensure account adjustment is processed and communicated

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**POTENTIAL HARM EVENT**

- Enter event in management software
- Stabilize patient and identify CRP Lead and Patient Liaison
- Communicate with patient/family and offer patient support
- Ensure bills are held

**CRP Eligible**

- Low Harm

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INTERACTIVE EXERCISE

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Communication Tip Sheet
Initial Conversations with Patients and Families about Harm Events

Overview
This tool provides guidance to a CRP team member on having initial discussions with a patient who has experienced harm during their care and/or their family. It provides suggested language that should be adapted to the individual situation.

Demonstrate Caring, Build Trust

» Reflect on the goals of the conversation. In a successful discussion, trust is maintained because the patient and family:
  » Feel informed promptly that something unexpected has happened, and understand the facts that are clearly known about the event and how we are responding
  » Feel heard
  » Believe that we care about them and have treated them with sincerity, dignity, and respect
  » Are encouraged to ask questions and receive a direct and timely response
  » Know what will happen next and who to contact with questions
Tip Sheet

> Demonstrate caring, build trust
> Start the conversation
> Discuss the facts
> Apologize and explore emotions
> Respond to common questions
> Close the conversation
> Document the conversation
> Avoid pitfalls
The Pathway to Accountability, Compassion, and Transparency for Patients and Families
Communication and Resolution Programs

After a harm event, our Communication and Resolution Program, or CRP, will:

2. Take care of your current needs (physical, emotional, and financial).
3. Ensure that we learn from the harm event and use this new knowledge to improve patient safety and experience.

Your CRP liaison, sometimes called your “point person,” will communicate with you throughout the entire process. The map on the next page is intended to help you navigate the conversations you can expect to have with our team. Each patient and family’s CRP experiences are unique, so you will move through the map in your own way and at your own pace.

We have also included more details about the CRP process, plus resources that our facility can offer to you and your loved ones.
PACT Patient-Family CRP Pathway

• What is a CRP?
• Who is on a CRP team?
• The CRP Pathway
  • Initial conversation
  • Ongoing conversation
  • Closing conversation
• Trauma and recovery
• Services
• Document designed so that organizations can customize
The CRP Pathway

Initial Conversations
After a harm event, our CRP team will talk with you and your family about next steps. In this early period, we will discuss your medical care, our process for learning all about what happened, and how we will stay in touch to share information and hear about your experience and needs. Your CRP Patient Liaison will reach out to you with information and be available to you for any questions that come up.

During this time, you may feel intense emotions. We encourage you and your loved ones to review the next page for more information and resources.

Ongoing Conversations
At this stage, our CRP team will learn all we can about the harm event and how it happened. Our team includes clinical team members, risk managers, claims specialists, attorneys, and a patient liaison. As they review facts and develop case information, they will also want to talk to and hear from you and/or your family to understand your experience of the harm event.

The event review may take weeks, or even months, and may include multiple conversations. Your CRP Patient Liaison can help you and your family if you have any questions and can also connect you with supportive resources if you are experiencing intense emotions or possibly physical symptoms.

Closing Conversations
During this period, our CRP team completes their review of the harm event. Your CRP Patient Liaison will reach out to you to share the outcome of the review and any next steps.
Dartmouth Experience

> We started a CRP in late 2018 and use CANDOR and CARe tools to launch our work

> Experience with Early Communication:
  
  • At first Communication to the patient around an event was measured in weeks

A CRP eligible event (as defined in the PACT Measurement Guide) is a harm known to the organization meeting one of the following criteria:

- Harm is judged by the clinical team or institution to be Temporary Major or greater, including permanent minor, permanent major, permanent grave, and, death;
- Patient reports a harm event described as NAC level 4 (Temporary Major) or greater;
- Patient, family, or provider requests that CRP be used to respond to an event (of any severity);
- Written demand for payment of or pre-Ergation notice received;
- A TJC “Serious Event” or an NQI “Serious Reportable Event.”

If your organization uses a harm scoring system other than the NAC, a harm Level crosswalk that contains common harm scoring methods can be found in appendix A. An event would be considered “Eligible” if it meets NAC Level 4 or its equivalent on the crosswalk or higher.
Dartmouth Experience Continued (2 stories)
Contact PACT

• Visit our website: www.ariadnelabs.org/pact
• Contact us
  • Evan Benjamin ebenjamin@ariadnelabs.org
  • Tom Gallagher thomasg@uw.edu
  • Melissa Parkerton mparkerton@ariadnelabs.org
Patient-led National Initiative focused on Disclosure
Our Motivation

Frustration with lack of progress and drift of patient safety as a priority in the U.S.

Create a sense of urgency that drives transparency, oversight/responsibility and patient & family engagement at multiple levels: Government, Accreditation, Providers

Power together to create ideas and expand impact with leading organizations that influence safety
10 PFPS US Founding Members

Margo Burrows
Milwaukee, Wisconsin

Steve Burrows
Milwaukee, Wisconsin

Lt. Col. Steven L. Coffee
Woodbridge, Virginia

Alicia Cole
Los Angeles, California

Martin J. Hatlie
Chicago, Illinois

Carole Hemmelgarn
Denver, Colorado

Soojin Jun
Chicago, Illinois

Armando Nahum
Atlanta, Georgia

Sue Sheridan
Boise, Idaho

Beth Daley Ullem
Newport Beach, California

Bios: [https://www.pfps.us/about-us](https://www.pfps.us/about-us)
Towards eliminating avoidable harm in health care

Framework for Action - The 7x5 Matrix

1. Policies to eliminate avoidable harm in health care
   1.1 Patient safety policy, strategy and implementation framework
   1.2 Resource mobilisation and allocation
   1.3 Protective legislative measures
   1.4 Safety standards, regulation and accreditation
   1.5 World Patient Safety Day and Global Patient Safety Challenges

2. High-reliability systems
   2.1 Transparency, openness and No blame culture
   2.2 Good governance for the health care system
   2.3 Leadership capacity for clinical and managerial functions
   2.4 Human factors/ergonomics for health systems resilience
   2.5 Patient safety in emergencies and settings of extreme adversity

3. Safety of clinical processes
   3.1 Safety of risk-prone clinical procedures
   3.2 Global Patient Safety Challenges: Medication Without Harm
   3.3 Infection prevention and control & antimicrobial resistance
   3.4 Safety of medical devices, medicines, blood and vaccines
   3.5 Patient safety in primary care and transitions of care

4. Patient and family engagement
   4.1 Co-development of policies and programmes with patients
   4.2 Learning from patient experience for safety improvement
   4.3 Patient advocates and patient safety champions
   4.4 Patient safety incident disclosure to victims
   4.5 Information and education to patients and families

5. Health worker education, skills and safety
   5.1 Patient safety in professional education and training
   5.2 Centres of excellence for patient safety education and training
   5.3 Patient safety competencies as regulatory requirements
   5.4 Linking patient safety with appraisal systems of health workers
   5.5 Safe working environment for health workers

6. Information, research and risk management
   6.1 Patient safety incident reporting and learning systems
   6.2 Patient safety information systems
   6.3 Patient safety surveillance systems
   6.4 Patient safety research programmes
   6.5 Digital technology for patient safety

7. Synergy, partnership and solidarity
   7.1 Stakeholders engagement
   7.2 Common understanding and shared commitment
   7.3 Patient safety networks and collaboration
   7.4 Cross-geographical and multisectoral initiatives for patient safety
   7.5 Alignment with technical programmes and initiatives
PFPS US Priorities

- Transparency
- Accountability and Oversight
- Patient and Family Engagement
**AIM:** Establish a fully transparent health care system, to understand the magnitude of harm, maximize learning and engage patients and families to ensure durability

**Strategy**

- Mandate establishment of Communication and Resolution Programs (CRPs)
- Eliminate confidentiality agreements when patient harm claims are settled
- Expand spectrum of patient safety events that must be publicly reported
- Ensure patient access to complete medical records at no cost to patients
- Make Patient Safety Program (PSO) data available to regulators, researchers and the public

**Actions**

- CMS to require a transparency bundle as a Condition of Participation (CoP) with financial incentives and penalties:
  - CRPs, i.e. open and honest communication after harm
  - Reporting patient safety events to Federal and State reporting systems
  - Report patient safety events to Accreditors
  - Prohibit confidentiality clauses that gag patients
- DHHS to use its regulatory and payor leverage to expand public reporting of patient safety events beyond the HACs and establish effective incentives and penalties
- CMS and ONC to enforce compliance of 21st Century Cures Act and penalties for failure to provide patient access to records
- DHHS/AHRQ to lead in reforming the PSOs to require contributing to the National Patient Safety Database
I'm afraid the Prime Minister can't come out and speak to you right now. He's in his office, waiting for this problem to go away.