Leapfrog's Never Events Policy, PACT Resources and Tools

February 14, 2023

THELEAPFROGGROUP

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

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Leapfrog's Never Events Policy

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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

Never Events Policy Elements (Note 2023 Update)

In 2007, The Leapfrog Hospital Survey began asking hospitals if they have a policy for handling "never events" that included the following 5 elements:

We apologize to the patient and/or family affected by the never event.	*Yes* *No*
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: √ Joint Commission, as part of its Sentinel Events policy √ DNV GL Healthcare √ State reporting program for medical errors √ Patient Safety Organization (as defined in The Patient Safety and Quality Improvement Act of 2005)	*Yes* *No*
We perform a root cause analysis, which at a minimum, includes the elements required by the chosen external reporting agency.	*Yes* *No*
We waive all costs directly related to the never event. *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.*	*Yes* *No*
We make a copy of this policy available to patients, patients' family members, and payers upon request.	*Yes* *No*

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.

We interview patients and/or families, who are willing and able, to gather evidence for the root cause analysis.	*Yes* *No*
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.	*Yes* *No*
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.	*Yes* *No*
We perform an annual review to ensure compliance with each element of Leapfrog's Never Events Policy for each never event that occurred.	*Yes* *No*

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.

Never Events Score (Performance Category)	**Meaning that…**
Achieved the Standard	The hospital has implemented a policy that adheres to **all nine principles** of The Leapfrog Group's Policy Statement on Serious Reportable Events ("Never Events").
Considerable Achievement	The hospital has implemented a policy that adheres to all the **original five principles*** of The Leapfrog Group's Policy Statement on Serious Reportable Events ("Never Events"), as well as **at least two additional principles**.
Some Achievement	The hospital has implemented a policy that adheres to all the **original five principles*** of The Leapfrog Group's Policy Statement on Serious Reportable Events ("Never Events").
Limited Achievement	The hospital responded to the questions pertaining to adoption of this policy but does not yet meet the criteria for Some Achievement.

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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

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Reflections on this work

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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?

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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

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

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

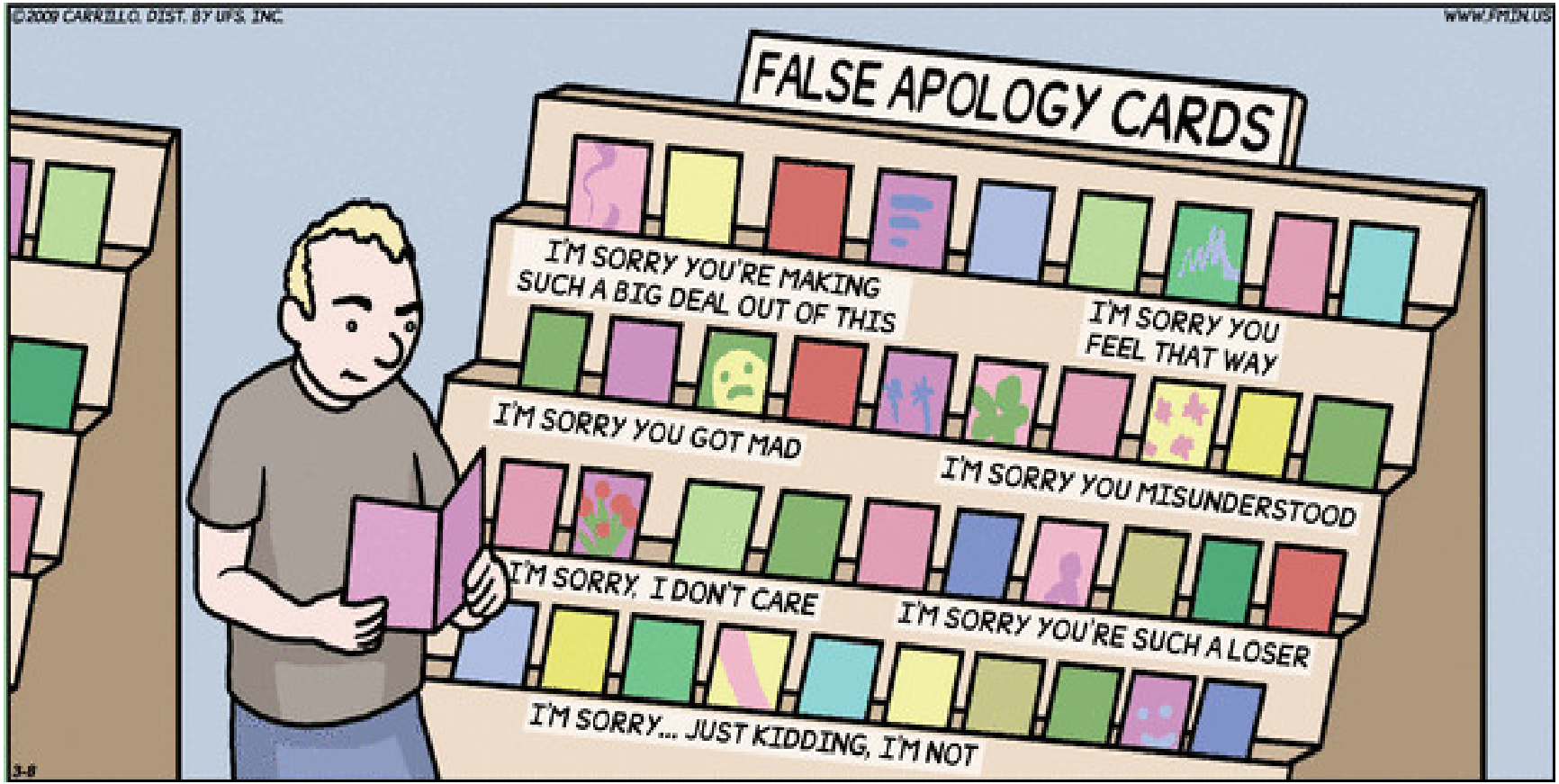
Increases likelihood of litigation

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


©2009 CARRILLO, DIST. BY UFS, INC.
WWW.FMIN.US
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
3-8

Overview of PACT

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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

Organizations Leading PACT

ARIADNE LABS

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S HOSPITAL
HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

Collaborative
FOR ACCOUNTABILITY AND IMPROVEMENT

Reaching resolution after patient harm

Tools and Resources You Can Access Today

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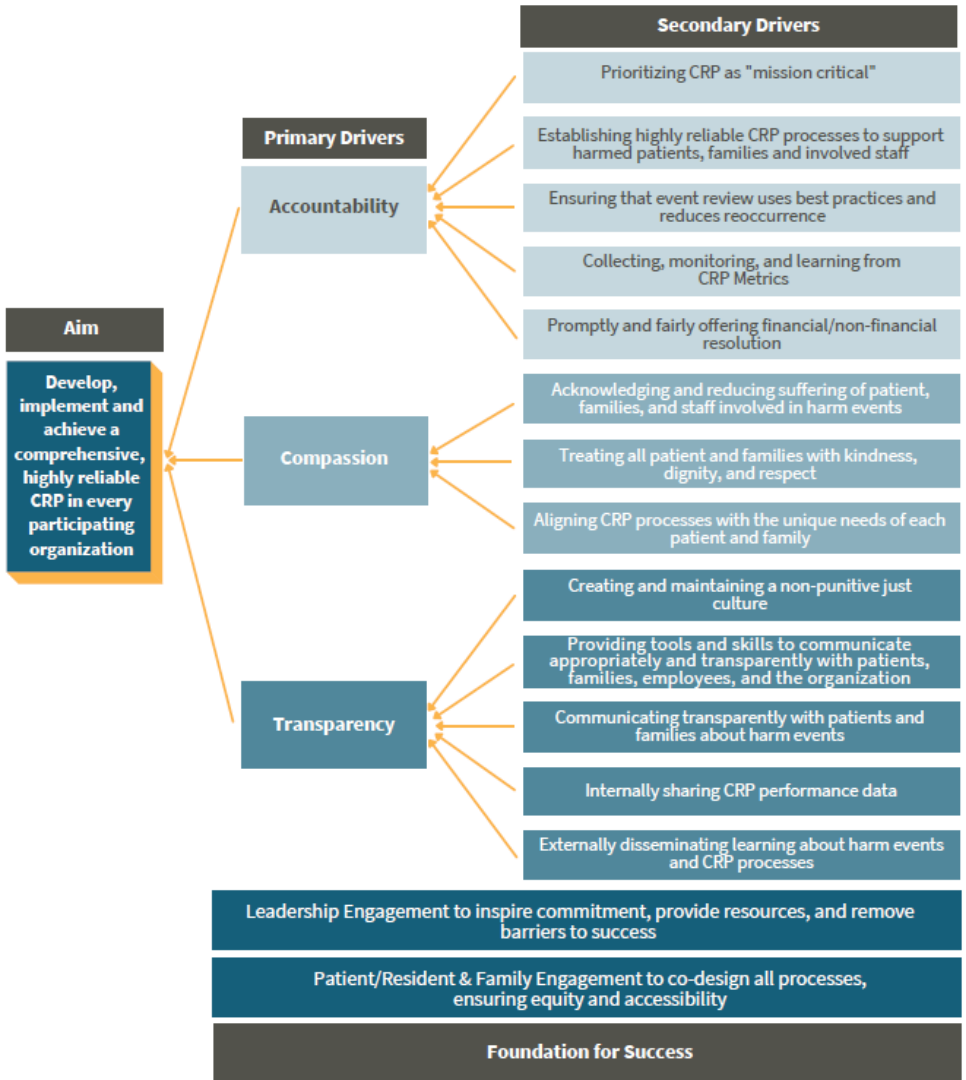
PACT
Driver Diagram



Pathway to Accountability, Compassion, and Transparency (PACT): Process Map

A step-by-step map of the activities involved in responding to a harm event

INTERACTIVE EXERCISE

Not Using | Sometimes Using | Consistently Using

Clinician uses Communication and Resolution Program (CRP) principles to respond with support as needed

Low Harm

POTENTIAL HARM EVENT

CRP Eligible

RESPONSES AFTER HARM EVENT

ACTIVITIES	Early *0-3 days*	Middle *1-6 weeks*	Later *6 weeks-5+ months*
Event Management	Enter event in management software	Stabilize patient and identify CRP Lead and Patient Liaison	Coordinate event review and ongoing communication (with Patient Liaison) and comply with local, state, and federal reporting requirements	Plan (with Patient Liaison) for implementation of action items, communication
Event Review	Gather initial information about event	Review event and identify action items/ improvements	Initiate implementation of action items/ improvement
Clinician Engagement	Offer peer support and initial communication coaching to clinician(s)	Interview clinician(s)	Follow up with peer support and feedback re: improvement opportunities using Just Culture	Close loop with clinician(s) and solicit feedback on CRP experience
Patient / Family Engagement	Communicate with patient/ family and offer patient support	Interview patient/family	Provide ongoing support for patient/family and communicate re: review and action items	Close loop with patient/family and solicit feedback on CRP experience
Resolution/ Reconciliation	Ensure bills are held	Initiate claim event review for standard of care/preventability assessment	Ensure account adjustment is processed and communicated	Proactively offer compensation and/or non-financial resolution if appropriate

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

Overview

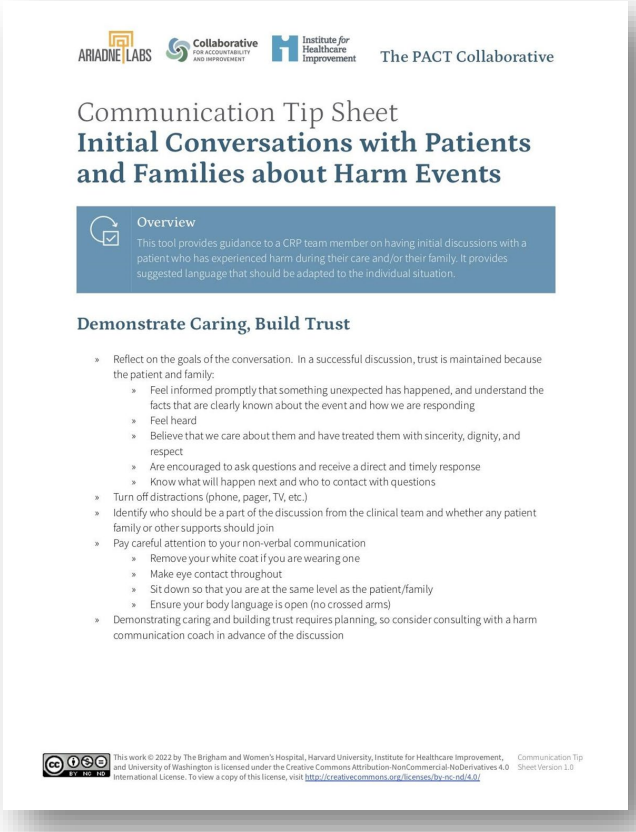
This tool provides guidance to a CRP team member on having initial discussions with a patient who has experienced harm during their care and/or their family. It provides suggested language that should be adapted to the individual situation.

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



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  - 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
- Turn off distractions (phone, pager, TV, etc.)
- Identify who should be a part of the discussion from the clinical team and whether any patient family or other supports should join
- Pay careful attention to your non-verbal communication
  - Remove your white coat if you are wearing one
  - Make eye contact throughout
  - Sit down so that you are at the same level as the patient/family
  - Ensure your body language is open (no crossed arms)
- Demonstrating caring and building trust requires planning, so consider consulting with a harm communication coach in advance of the discussion

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:

1. Help you understand what happened and why.
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

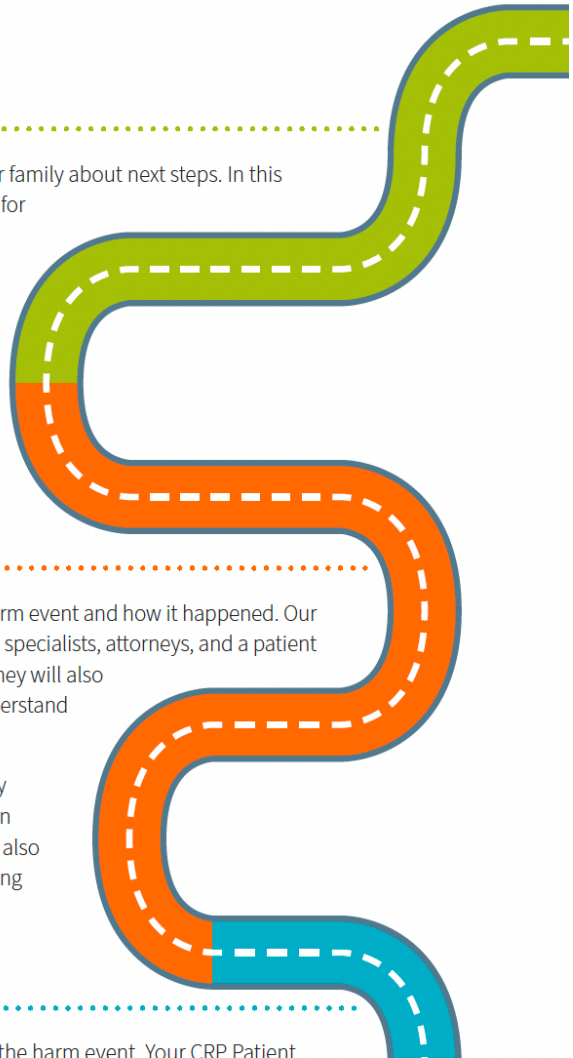
- What is a CRP?
- Who is on a CRP team?
- The CRP Pathway
  - Initial conversation
  - Ongoing conversation
  - Closing conversation
- Trauma and recovery
- Services
- Document designed so that organizations can customize

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

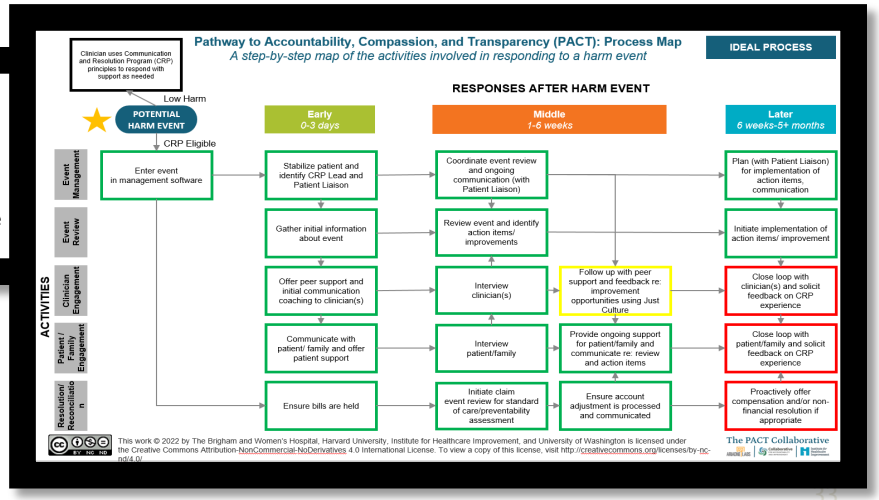
During this period, our CRP team completes their review of the harm event. Your CRP Patient

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 NAIC 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 or pre-litigation notice received;
- A TJC "Sentinel Event" or an NQF "Serious Reportable Event."
- If your organization uses a harm scoring system other than the NAIC, 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 NAIC level 4 or its equivalent on the crosswalk or higher.



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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

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Patients for Patient Safety US

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

PFPS US

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 mobilization 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 Challenge: *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 system 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

TRANSPARENCY

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 of 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 confidentially 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

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- 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.
RESPECT WOMEN
PM, PLEASE JUST LISTEN

Questions?

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