RESPONDING TO PATIENTS AFTER ADVERSE EVENTS:
UPDATE ON RECENT DEVELOPMENTS AND FUTURE DIRECTIONS

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Michelle Malizzo-Ballog

--Timothy McDonald and AHRQ Medical Liability Communication and Optimal Resolution Project (CANDOR)
Story of Michelle Malizzo Ballog

- 39 year old presents for endoscopic GI procedure under heavy moderate sedation
  - Had failed stent placement two weeks prior due to discomfort despite large amounts of narcotics.
  - Repeat scheduled for 1 pm with anesthesia present
  - GI physician delayed. Arrives at 4pm, at which point anesthesia not available for elective case
  - Twice the dose of fentanyl, midazolam used
- Standard monitors for HR, BP, O2 Sat used
- Dark room, patient on side, unable to auscultate
- Physician asks monitoring nurse to get different stent. Nurse leaves room

--Timothy McDonald and CANDOR

(case continued)

- Upon return, patient found to be in respiratory distress
- Code called
- No response to reversal agents
- Team assumes allergic reaction to medication as etiology of arrest
- Michelle resuscitated but brain dead

--Timothy McDonald and CANDOR
The Malizzo’s Experience

• Video

Patient Safety Background

• 2010 data from Medicare:
  • 13.5% of hospitalized beneficiaries experience an adverse event
  • 1.5% experienced harm that contributed to death
  • 44% of adverse events were preventable

--Levinson D, et al.
OIG Report,
Nov 2010

--CANDOR
Following Harm: Not Always Transparent, Not Always Learning

Health Affairs

Survey Shows That At Least Some Physicians Are Not Always Open Or Honest With Patients

Lisa L. Iezzoni¹, Sowmya R. Rao², Catherine M. DesRoches³, Christine Vogeli⁴ and Eric C. Campbell⁵


--CANDOR

CAN A SINCERE "I'M SORRY" MAKE UP FOR MEDICAL MALPRACTICE?

During her operation, Celia Barbour's surgeon made an almost fatal error, one with long-term consequences on her health. He apologized for it profusely—should that be enough?

So now I've got a clot, just like I did the first day I walked into Dr. P's office. My right arm often gets achy and swollen when I use it, because the clot blocks the blood from draining effectively. In addition, my upper arm is numb because nerves were cut during surgery. The scars in my chest wall hurt when I take a deep breath. A surgery to remove this clot isn't an option, I've been told, so I inject myself with blood thinners each night, which leaves my stomach mottled with bruises. I face the possibility of lifelong damage from the blood thinners, and who knows what from the blood transfusions. And I have less money in the bank to cover it all.

--Michelle Mello
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

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The Benefits of the CRP Response

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

• U. Michigan
  • Average monthly rate of new claims decreased
  • Median time from claim reporting to resolution decreased
  • Average patient compensation costs decreased
  • Legal expenses decreased

• Stanford University Medical Indemnity and Trust
  • Frequency of lawsuits nearly 50% lower
  • Indemnity costs in paid cases 40% lower
  • Defense costs 20% lower for cases handled through the CRP

University of Illinois at Chicago CRP

• Reported data 2002-2014 from Seven Pillars program at UIC
• CRP implemented in 2006
• CRP’s impact at this hospital
  • Doubled number of incident reports
  • Halved number of claims
  • Reduced legal fees, total costs per claim
• Second analysis compared testing among patients with chest pain at UIC compared with 44 other Illinois hospitals
  • At CRP hospital, reduced growth rates in use of diagnostic testing and imaging services
• Challenging to replicate Seven Pillars at other participating hospitals
Constant Reminder

• CRPs are NOT primarily claims management strategies meant to minimize financial exposure posed by an individual injured patient
• CRPs are intended to serve a much bigger goal: the health care organization’s core mission to deliver the highest quality health care experience for our patients

Source: Richard Boothman, JD

The CANDOR Process

1 Identification of CANDOR Event
2 CANDOR System Activation
3 Response and Disclosure
4 Investigation and Analysis
5 Resolution
## CHANGE READINESS AND GAP ANALYSIS

### Current State Analysis

CRPs represent major culture change for almost all institutions. “We already do this” is often said but rarely accurate.

<table>
<thead>
<tr>
<th>Change Readiness</th>
<th>Gap Analysis</th>
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<tbody>
<tr>
<td>• First step is assessing where on CRP journey your institution is, how to get to next level</td>
<td>• Gap Analysis: Key informant interviews with various leaders, front-line staff</td>
</tr>
<tr>
<td>• Readiness Assessment: Self-evaluation of ability to perform key CRP tasks</td>
<td></td>
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</tbody>
</table>

--CANDOR
ADVERSE EVENT REPORTING 
AND 
INVESTIGATION

Adverse Event Reporting

- **Immediate reporting** of near misses, good catches, unsafe conditions, harm events to institution is critical first step in CRP process
  - Activates communication consultation and coaching
  - Starts event analysis, planning to prevent recurrences
  - Holds billing of patients and requests for donation
  - In Malizzo case, critical to understanding system failures that led to her death
- Important measure of culture
- Engagement of learners
- Barriers?

--CANDOR
Impact of CRP on Adverse Event Reports: UIC Experience

Effect of 7P on Adverse Event Reports
University of Illinois Hospital and Health Sciences System

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Who is to blame in Malizzo Case?

- Traditional approach
  - Nurse who left patient unmonitored
  - Physician who ordered way too much fentanyl, midazolam
  - GI attending who decided to proceed with case despite lack of anesthesia coverage
  - Others?

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--Timothy McDonald and CANDOR
Just Culture

• Seeks middle ground between historical “shame/blame-bad apple” approach and “blame-free” model after medical injury
• Distinguish between “human error” (console), “at-risk behavior” (coach), reckless behavior (punish)
• Conceptually appealing, hard to implement
  • Recent survey of 500,000 healthcare workers, half felt their mistakes were held against them
• Why do we still focus on blame?

--Marx, D. Whack a Mole: The price we pay for expecting perfection. Plano, TX: By Your Side Studios; 2009.
--Thomas Gallagher and CANDOR

Malizzo Case: System Solutions

• Routine use of capnography in heavy sedation cases
  • Adopted as ASA standard
• Better policies around anesthesia coverage
• Environmental strategies for patient monitoring
  • Equipment placement
  • Lighting
  • Alarms?

--CANDOR
TRANSPARENT COMMUNICATION

There’s no easy way I can tell you this – so I’m sending you to somebody who can…
A Disclosure Performance Gap Is Evident

- Harmful events are often not discussed
- Errors are often not disclosed
- When communication does take place, often falls short of expectations

Quality of Actual Disclosures?

- COPIC’s 3Rs: Disclosure and Compensation Program
- 2007 – 2009
  - 837 events
  - 445 patient surveys
  - 705 physician surveys
## Event Severity

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Patient Assessment</th>
<th>Physician Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely serious (I might have died)</td>
<td>31%</td>
<td>7%</td>
</tr>
<tr>
<td>Very Serious (permanent injury)</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>Somewhat serious (injury that resolved)</td>
<td>28%</td>
<td>61%</td>
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</tbody>
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## Quality of Disclosure

- **Bar Charts**
  - Comparison between Physicians and Patients' assessments.
Patient Rating of Disclosure Skills

<table>
<thead>
<tr>
<th>Sincere apology</th>
<th>66%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good listening skills</td>
<td>64%</td>
</tr>
<tr>
<td>Truthful explanation</td>
<td>63%</td>
</tr>
<tr>
<td>As much information as I wanted to know</td>
<td>54%</td>
</tr>
<tr>
<td>Why the event happened</td>
<td>50%</td>
</tr>
<tr>
<td>Whether the event was preventable</td>
<td>44%</td>
</tr>
<tr>
<td>Assurance that steps would be taken to prevent similar events</td>
<td>37%</td>
</tr>
</tbody>
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Real and Imagined Barriers to Disclosure

- Fear of litigation
- Misunderstanding of patient preferences
  - Does not know/would not want to know
  - It would harm patient to know
- Low confidence in communication skills
- Mixed messages from institution
- Specialty-specific challenges
  - Radiology, pathology, birth injury, delayed diagnosis
- Shame/embarrassment
Disclosure 101

• Patients need –
  • Truthful, accurate information
  • Emotional support, including apology
  • Follow-up, potentially compensation

• Health care workers need
  • Communication coaching
  • Emotional support

• Process, not an event
  • Initial conversation
  • Event analysis
  • Follow up conversation

Understanding the Reflexes

• It is normal and expected following any care breakdown for clinicians to:
  • Keep what happened to themselves
  • Minimize
  • Rationalize
  • Avoid emotion, both their own, colleagues’, and the patients’

• Patients have normal reflex reactions as well
  • Traditional stages of “grief”
  • Blame, sometimes themselves, oftentimes those caring for them

• Families, esp parents can have exaggerated reactions
  • Heightened sense of responsibility, helplessness and guilt

• How can you understand and adapt to these reflexes?
Key Disclosure Planning Skills

- Most common failure – lack of planning
- Solicit team members’ views
- Plan roles for discussion
- Advocate for full disclosure
- Anticipate patient questions
- Avoid jargon, blame

What Does the Patient Want?
Empathy

- They want to be heard. They won’t listen until they are heard. Clear the emotion first.
- What skill accomplishes that?
- Reflective listening is not intuitive – Why?
Video

PEER SUPPORT
Peer support

- Involvement in a medical error increases:
  - Burnout
  - Likelihood of involvement in future errors
  - Risk of depression
  - Risk of suicide
  - Leaving practice

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--CANDOR

National Quality Forum Safe Practice #8

- Care of the Caregiver:
  - Available to all employees involved
  - Timely and systematic
  - Just treatment
  - Respectful
  - Compassionate
  - Supportive medical care
  - Participation in event investigation, risk identification, and mitigation activities to prevent future events.

- Supporting providers helps them care for their patients

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--CANDOR
Resolution Principles

- Compensate quickly and fairly when inappropriate medical care causes injury.
- Support staff vigorously when the health care involved was reasonable.
- Reduce patient injuries (and claims) by learning from patients’ experiences.

--Richard Boothman
PUTTING IT ALL TOGETHER
Back to the Malizzo Family

- Multiple conversations after event
- Abundant emotional first aid to all
- All hospital and professional fees waived
- Early financial resolution to provide support for two small surviving children
- After one year, family invited to help with safety efforts at hospital leadership event
- New policies in place to prevent recurrences

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Lessons from the Field

- It’s not business as usual
- CRP is a quality/safety program, not a risk management initiative
- Local adaptation is key
- Multiple, visible champions
- CRP will rise/fall around clinician engagement

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More Lessons

• Bandwidth challenges must be addressed directly
• Culture change is slow, painstaking process
  • Some, not all, results will be felt immediately
  • Don’t let difficulty of culture change become excuse for incomplete implementation
• Process must be trustworthy
• Metrics can help drive implementation
• Needs to be principled approach
  • Especially for those cases that are hard, embarrassing, patient is unaware of

-Thomas Gallagher and CANDOR

Getting Started

• Educational opportunities
  • CRP 101
  • Board/C-suite engagement
  • CRP Leader Training
  • Gap analysis
  • On-site trainings for each CRP element
• CANDOR Toolkit
• Implementation roadmaps
Physician Engagement

- Once they understand how CRPs actually work, physicians are usually the most enthusiastic advocates
- Importance of MD champion
- Early engagement of Medical Association, liability insurers
- Need to link CRP and peer review processes
- Peer support often ideal place to start

Opportunities and Challenges for Smaller Hospitals

- CRPs can work as well, if not better, at small hospitals compared with large healthcare institutions

  **Opportunities**
  - Ability to adopt strategic initiatives quickly
  - Fewer organizational silos

  **Challenges**
  - Maintaining trust in setting where patients have few healthcare choices
  - Ensuring sufficient event analysis/process improvement resources are available
Benefits of Statewide CRP Consortium

• Great examples to learn from
  • Massachusetts
  • Oregon
  • Washington
  • Iowa
• Work is led by broad stakeholder groups
• Opportunities to rapid implementation and ongoing support

Summary

• CRPs represent a new and exciting opportunity to prevent and respond to adverse events
• CRPs are a quality/safety, not a risk management undertaking
• Resources exist locally and nationally to support HonorHealth in advancing its CRP program
Collaborative
FOR ACCOUNTABILITY
AND IMPROVEMENT

Reaching resolution after patient harm

CANDOR Video