Innovations in Responding to Patient Harm

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Timothy McDonald, MD, JD, Patient Safety Expert and Director of the Center for Open and Honest Communication, MedStar Institute for Quality and Safety
Kenneth Sands, MD, MPH, Chief Epidemiologist and Patient Safety Officer, Hospital Corporation of America (HCA)

The Case for CRPs
## A Paradigm Shift

<table>
<thead>
<tr>
<th></th>
<th>Traditional Response</th>
<th>Communication and Optimal Resolution (CANDOR) Process</th>
</tr>
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<tbody>
<tr>
<td>Incident reporting by clinicians</td>
<td>Delayed, often absent</td>
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<td>Event analysis</td>
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<td>Quality improvement</td>
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<td>Drive value through system solutions, disseminated learning</td>
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<td>Financial resolution</td>
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<td>Patient, family involvement</td>
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## The Appeal of the CRP Approach

**It doesn’t require legislative action.**

**It offers something for both provider organizations and patients.**

**When done right, it can produce impressive results.**
Current Developments, Lessons Learned

- CRPs hold promise for both improving patient safety and reducing medical malpractice liability
- Replicating and scaling pioneering CRP programs is challenging
- Adoption of CRPs continues to rise
- The ongoing problem of incomplete CRP implementation
  - Use of some CRP key elements but not others
  - Use of CRP for only fraction of eligible cases
- Longer-term research and evaluations needed

<table>
<thead>
<tr>
<th>Agenda</th>
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<tbody>
<tr>
<td><strong>Topic</strong></td>
<td><strong>Presenter</strong></td>
<td><strong>Time</strong></td>
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<td>Introduction, context</td>
<td>Gallagher</td>
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<tr>
<td>Peer support</td>
<td>McDonald</td>
<td>:05::15</td>
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<tr>
<td>Multi-insurer cases</td>
<td>De Kleine</td>
<td>:15::25</td>
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<tr>
<td>Regional consortium model</td>
<td>Sands</td>
<td>:25::35</td>
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<tr>
<td>New training models</td>
<td>Boothman</td>
<td>:35::45</td>
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<tr>
<td>Discussion</td>
<td>All</td>
<td>:45-1:00</td>
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Care for the Caregiver
Timothy McDonald, MD, JD, Patient Safety Expert and Director of the Center for Open and Honest Communication, MedStar Institute for Quality and Safety

The Seven Pillars: A Comprehensive Approach to Adverse Patient Events

[Diagram showing flow of events and decision points]

- **Data Base**
  - **Patient Communication Consult Service 24/7 Immediately Available**
  - **Patient Harm?**
    - Yes
    - Unexpected Event reported to Safety/Risk Management
    - "Near misses"
    - Process Improvement
    - Activation of Crisis Management Team
  - No
    - **Inappropriate Care?**
      - Yes
      - Full Disclosure with Rapid Apology and Remedy
      - **Consider "Second Patient" Error Investigation Hold bills**
      - Process Improvement
    - No
### Paradigm Shift

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**Communication AND Optimal Resolution**

1. Identification of CANDOR Event
2. CANDOR System Activation
3. Response and Communication (CFC)
4. Investigation and Analysis – Event Review
5. Resolution
History of the Problem

Adverse event investigations – individuals at the “sharp end” noted to be experiencing predictable behaviors post event

The Second Victim

Definition: “a health care provider involved in an unanticipated adverse patient event, medical error and/or a patient-related injury who becomes victimized in the sense that the provider is traumatized by the event.” Albert Wu, BMJ, 2000.
Patient Care Consequences

Studies have shown that stress and burnout can lead to:

▪ Increased risk of future errors.
▪ Avoidance of patient care.
▪ Decreased patient satisfaction.

What Second Victims Want

▪ Formal and informal emotional support
▪ Prompt debriefing for individual or team
▪ Opportunity to take time out from clinical duties
▪ Help communicating with patient and/or family
▪ Clear and timely information about review process
▪ Last but not least....Remain a trusted member of the team!
University of Missouri Health System
Scott Three-Tier Model of Support

Tier 1
“Local” (Unit/Department) Support

Tier 2
Trained Peer Supporters Patient Safety & Risk Management Resources

Tier 3
Expedited Referral Network

Established Referral Network with
• Employee Assistance Program
• Chaplain
• Social Work
• Clinical Psychologist
• Holistic Nursing Support
  Ensure availability and expedite access to prompt professional support/guidance.

Trained peer supporters and support individuals (such as patient safety officers or risk managers) who provide one on one crisis intervention, peer supporter mentoring, team debriefings & support through investigation and potential litigation.

Department/Unit support from manager, chair, supervisor, fellow team member who provide one-on-one reassurance

What's Happening in the Field

- Large interest in more formal care for caregiver programs
- Very popular with medical staffs
- Sometimes incorporated into physician wellness programs
- Extending beyond just physicians
- Increased dialogue around patient safety and “second victims”.
One Systems Response: WeCare

“...The CANDOR program has brought together our community--nurses, physicians, and administration to collaborate and communicate as a team when an unexpected clinical event occurs. It has helped us to focus on doing the right thing for patients and their families, inspiring us to communicate early and openly with those impacted. We anticipate that with implementing WeCare (the caregiver program), we will further enhance our sense of support within our community and culture of safety.”

– A.C., CMO
Multi-Insurers in CRP cases: Professional Liability Insurance Program for the Hospital Independent-Affiliated Physicians
Cheryl De Kleine, Senior Director, Claims & Litigation, Ascension

Three of These Things Belong Together...

Or is it FOUR? The TIME has come!
Challenges to CRP’s When Multiple Providers with Different Malpractice Insurers Are Involved:

- Potentially conflicting vision
- Differing claims handling philosophy/practices
- Difficulty including non-employed physicians in hospital culture that promotes early resolution
- Lessened ability to attract/require participation in CRP educational events
- Lack of Risk Management programs for non-employed staff physicians and their practices

Steps Necessary To Ensure Success When Multiple Insurers are Involved in Organizations Where CRP’s Operate:

- Identify all insurers and prepare in advance
- Share the CRP vision and educate the insurers
- Allow the insurers to educate you
- Agree on the common goal of improvement of healthcare
- Communicate, Communicate, Communicate!
The program was created in 2011 as a medical professional liability insurance program by our Risk Services division and underwritten by a commercial medical malpractice carrier for physicians and related professionals who are affiliated with our Health Ministries.

The commercial medical malpractice carrier is in the top five medical malpractice carriers nationwide, is rated A+ (Superior) by A.M. Best. The carrier has a commitment to fair treatment and transparency (and an over 38-year history of management excellence), it offers physicians strong coverage with a tough defense of medicine befitting the tort environment.

Find a Way: CRP Innovation with Commercial Carrier

The program offers medical professional liability insurance for our health ministries’ independent staff physicians—and affiliated mid-level providers—to:

- Enhance physician focused professional liability coverage and services
- Enhance physician focused risk management services
- Advance and strengthen patient care and safety at our facilities
- Control cost and defense coordination on medical malpractice claims involving our Health facilities and staff physicians

Objective
The Program’s Value Proposition

Program Pillars

• Partnership: Commitment to Early Resolution when Appropriate
• Customized / Hands On Risk Management
• Joint Defense/Coordinated Defense when Defending Good Medicine

Providing Physicians with the Best Defense when Appropriate

• Claims Management
• Joint Defense/Coordinated Defense

Making Care Safer with this program

• Supportive of CORE™
• Promotion of our healthcare system’s based risk trends
• Risk Resources Advisors available from commercial insurance carrier

Why the Claims Philosophy Works

The program promotes a collaborative defense approach to claims that need to be defended.

Collaborative defense agreements (joint defense or coordinated defense agreements) promote unity between defendants.

When there is unity between defendants (no finger pointing) there is an increased chance the case will be dismissed without indemnity payments and/or the case will be won at trial.
Program Affiliation

The program brings together the financial strength and commitment of our healthcare system and the commercial insurance carrier—two national healthcare leaders.

With risk-sharing by our captive insurance company, the commercial carrier underwrites the program (physician receives a policy from the commercial carrier)

The commercial carrier has been named as a Ward’s 50® top property & casualty company every year since 2007, its values and infrastructure enable a system-wide program. It is a carrier that is rated A+ (Superior) by A.M. Best.

Market Presence

2017 – Available at 22 Ministries in 12 states and the District of Columbia
2885 Physicians in the program, over 3800 Risks Covered

- Michigan
- Indiana
- Florida
- Texas
- Illinois
- Wisconsin
- Alabama

- Washington DC
- Maryland
- Connecticut
- Oklahoma
- Kansas
- Tennessee
- New York
Examples of the Success: Proof that an Unlikely Pair Can Work Together

Impact of CORE®
Average Number of Lawsuits

CORE® significantly reduces lawsuits

7 Year average prior to 7/1/2010 compared to 7 year average post 7/1/2010. Includes all open, reopened, and closed suits.
Turning CRP Challenges Into Opportunities

“We cannot accomplish all that we need to do without working together.”

Bill Richardson

Thank You!

Cheryl De Kleine, Senior Director, Claims & Litigation, Ascension
Office: 314.733.8780
Mobile: 973.452.4045
Cheryl.DeKleine@ascension.org
why the slow uptake of crps?

- scary for an institution to “go it alone”
- multiple involved stakeholders, many outside the provider institution
- a change effort that requires advocacy as well as implementation
- logistically complex – multiple heads better than one
If this is so great, why is adoption so slow?

AHRQ Planning Grant - Massachusetts

- 1 Yr - 300K AHRQ Planning Grant - MMS / BIDMC
- Key informant interview study of 27 knowledgeable individuals from all leading stakeholder constituencies in Massachusetts
- Twelve significant barriers were identified along with multiple strategies to overcome each one
- Strategies for each barrier were then evaluated and prioritized to develop our Roadmap
- **CARe is the best of all options for liability reform, the right thing to do and broad support exists for change**
  
  — Results published in Milbank Quarterly, 2012

Implementation with Continued Stakeholder Engagement

“CARe” (Communication, Apology, and Resolution) is MACRMI’s preferred way to reference the process.
Implementation with Continued Stakeholder Engagement

“CARe” (Communication, Apology, and Resolution) is MACRMI’s preferred way to reference the process.
WELCOME
MACRMI is a Massachusetts alliance of patient advocacy groups, teaching hospitals and their insurers, and statewide provider organizations committed to transparent communication, sincere apologies and fair compensation in cases of avoidable medical harm. We call this approach Communication, Apology, and Resolution (CAR) and we believe it’s the right thing to do. It supports learning and improvement and leads to greater patient safety.

This site is a central resource for information on the CAR approach and the health care institutions implementing it. Here you will find answers to many of your questions regarding medical injury resources and support for patients, families and clinicians, education and training resources for health care providers; sample guidelines and policies, research and articles; and ways to connect with each other. By sharing what we learn from medical errors and near misses, we are enhancing patient safety together and improving our health care system. Thank you for participating.

CARe Timeline

<table>
<thead>
<tr>
<th>Program Setup</th>
<th>24-48 hours after event</th>
<th>2-4 weeks after event</th>
<th>1-3 months after event</th>
<th>2-5 months after event</th>
<th>3-6 months+ after event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Internal Investigation takes place</td>
<td>Patient Safety and Patient Relations maintain contact with providers and patients respectively</td>
<td>Determination of CAR criteria fit</td>
<td>Initial meeting with insurers, providers, patient safety staff, patient, counsel, and other parties</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Additional resolution meetings occur as necessary</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Financial offer to patient made and accepted or rejected (settlement may be negotiated)</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>5</td>
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Resources
- Sample Communication Policy
- Risk Managers/Staff
- Best Practices for Interfacing with Patients
- Patient Relations
- Unexpected Outcome Sheet
- Patients

Resources
- DPH SRE Letter Templates
- Callie Algorithms
- Risk Managers
- Insurer Referral Document (to be finished)
- Patient Relations/Risk Managers

User Login
- For Patients
- For Providers
- For Attorneys

Website: www.macrmi.info
Protocols Available

CARe Algorithm #2 CARe
Insurer Case Protocol

Available Defined Management Protocols and Outcomes

The Daily Work

MACRM

CARe Timeline

Program Setup

24-48 hours after event
(algorithm steps 1, 2)

2-4 weeks after event
(algorithm steps 3)

1-3 months after event
(algorithm steps 4, 5)

2-5 months after event
(algorithm steps 6, 7, 8, 9)

3-6 months+ after event
(algorithm steps 10, 11)

Preparation

Sure that the culture at your station supports

time program

up resources

take providers

Address Checklist

Implementation Team

Implementation Guide

Implementation Teams

Best Practices for CARe

Assessment Teams

Resources

Audience

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Sample Document

**Best Practices for Attorneys Representing Patients in Resolution of Medical Injury using the CARE Approach**

1. **Approach resolution as a comprehensive, collaborative process.** Resolution should be the goal in all cases, and all resolutions, regardless of whether compensation is involved, should be adequate and fair. The attorney should help the patient and provider obtain an appropriate resolution, which should include an explanation of the causes of the event and any patient safety improvements that the healthcare facility has implemented, as well as other provisions to help meet the medical, psychological, emotional, and financial needs of the patient.

2. **Have expertise representing patients in a resolution of medical injury, and knowledge and experience with the CARE approach.** The attorney should have a clear sense of what the patient’s needs are and what the patient should ask for: knowledge of the true value of the loss is critical to representation. A strong understanding of medical liability law and the CARE approach will help facilitate a collaborative discussion and timely and fair resolution.

3. **Help the patient access and interpret information from the healthcare facility.** The attorney should clarify medical and legal information for the patient, and assist in communicating with the healthcare facility/insurers, so as the patient may be able or unprepared to do so. Support by the attorney can help the patient avoid feeling overwhelmed and allow them to ask appropriate questions.

4. **Facilitate the exchange of relevant medical records in a timely manner, so that appropriate evaluations can be made to resolve the case as stated in Chapter 229, Section 229B of the Massachusetts General Laws.**

5. **Review the terms of any potential resolution and the substantive legal provisions of a resolution.** This review would include an assessment of whether the proposed resolution is adequate to meet the patient’s financial and emotional needs. This also involves reviewing and explaining the written settlement agreement (e.g., release) and all appropriate documents, which impose legal obligations on the patient after settlement, and which the patient will be asked to sign upon receiving any compensation.

6. **Ensure that the patient develops realistic expectations of fair compensation.** In cases where compensation is deemed appropriate, the discussions should include identification of both long-term as well as short-term financial needs to ensure that compensation is adequate and fair. The attorney should discuss the full implications of medical malpractice litigation with patients in helping them to decide whether to accept or reject pre-settlement compensation. The attorney should also assist them in feeling comfortable accepting fair and appropriate compensation if the process achieves that result.

7. **Help create an environment that is supportive and collaborative.** The CARE process is designed to achieve a resolution for everyone involved, through cooperation, and an environment that supports that goal is essential to the process functioning in it should. The attorney should support the creation and maintenance of an environment that encourages open, honest communication and promotes a spirit of cooperation among all parties involved.
Pilot Program Implementation

<table>
<thead>
<tr>
<th>Site</th>
<th>#Beds</th>
<th>Location</th>
<th>Teaching (Y/N)</th>
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</thead>
<tbody>
<tr>
<td>Beth Israel Deaconess Medical Center</td>
<td>642</td>
<td>Inner City</td>
<td>Y</td>
</tr>
<tr>
<td>BID-Milton</td>
<td>88</td>
<td>Community</td>
<td>N</td>
</tr>
<tr>
<td>BID-Needham</td>
<td>58</td>
<td>Community</td>
<td>N</td>
</tr>
<tr>
<td>Baystate Medical Center</td>
<td>716</td>
<td>Inner City</td>
<td>Y</td>
</tr>
<tr>
<td>Baystate Franklin Medical Center</td>
<td>93</td>
<td>Community</td>
<td>N</td>
</tr>
<tr>
<td>Baystate Mary Lane Hospital</td>
<td>31</td>
<td>Community</td>
<td>N</td>
</tr>
<tr>
<td>Atrius Health*</td>
<td>n/a</td>
<td>Ambulatory</td>
<td>N</td>
</tr>
<tr>
<td>Sturdy Memorial*</td>
<td>128</td>
<td>Community</td>
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*Not yet in full implementation
Study Hospitals Demonstrated Good Adherence to Protocol

- 82% had a disclosure communication documented
- 61% had a feedback communication documented
- 87% of cases that met criteria for insurer referral were referred
- Compensation offers were made where criteria were met in all but 3 cases

Few Events Met Compensation Criteria

- 9% of events met compensation criteria
  - Standard of care met 74% of the time
  - Where SOC violated, 45% did not involve significant harm and 33% lacked causation

Median compensation payment: $75,000
[interquartile range, $22,500-$250,000; maximum $2 million]

“Service recovery” items offered in 181 cases
No Avalanche of New Claims

5% of events that did not originate as a claim or pre-litigation notice resulted in one by Oct 2016

Possible explanations:
- Patients came to understand they did not have a valid claim?
- Pessimism about ability to prevail in litigation or find an attorney?
CRP Developments: A new training program by The University of Michigan and Michigan Hospital Association

Richard C. Boothman
Chief Risk Officer, Michigan Medicine
Executive Director, Patient Relations and Clinical Risk

The challenge to define and preserve what makes a CRP unique; then train to the essential elements
The Training Challenge:

Stubbornly satisfy the fundamentals

. . . flexibly-enough to leverage institutional resources, meet institutional priorities amidst regional culture, demands,

. . . while maintaining relentless service to the healthcare mission

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Essential Elements of a True CRP

<table>
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<tr>
<th>Notification of unintended clinical outcome</th>
<th>Stabilize the clinical environment and protect other patients</th>
<th>Support the patient, listen, promise full disclosure</th>
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<tbody>
<tr>
<td>Support the caregiver, listen, promise full disclosure</td>
<td>Normalize honesty, rigorous investigation and review</td>
<td>Share facts and conclusions openly with caregivers and patients alike</td>
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<tr>
<td>Be principled and accountable. Compensate where warranted, consistent in peer review</td>
<td>Leverage lessons learned in safety, quality and peer review in continuous quality and safety improvement</td>
<td>Measure what's important, communicate, normalize, be relentless</td>
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Attributes

- Systematic
- Principled
- Relentless
- Normalized
- It’s stubbornly clinical until it’s not
- Risk management, legal and insurance serves the larger clinical mission and is careful not to impede it
- Locked and focused on the core clinical mission, uniting patients and caregivers in a singular mission: to put patients at the center of all we do

University of Michigan-Michigan Hospital Association Training Program

- The University of Michigan and the Michigan Hospital Association partnership
- Inspired by MACRMI’s success and model
- Credible, consistent, principle-based-yet-nimble
- Regional – start with 6 pilot hospitals
- Successful models to emulate
- Leverages the state hospital association network
- Available also to large hospital systems and international groups
- Self perpetuating
Typical Progression

- Leadership training
- Preliminary analysis of organizational structure and resources, multiple markers relating to claims, culture and climate
- Individualized “needs assessment”, identification of impediments/assassins, rollout trajectory plotted, metrics established
- Recruitment of a select leadership group to champion
- Tailored operational training and methodical approach to building the necessary resources, simulation
- Inclusion in research, data pool
- Continued support/reinforcement
- Ultimate goal: to normalize approach regionally

UM/MHA Training Program

- **UM offers:**
  - IP
  - Content, materials
  - Some faculty
  - Laboratory for site visits
  - Experience and brand credibility
  - Scholarly/research platform – potential “home” for the Collaborative
  - International outreach

- **MHA offers:**
  - Operational/admin staff
  - Business platform
  - Faculty
  - Facilities
  - Marketing
  - Publishing
  - Leverage leadership and experience with large patient safety “spread”
  - State and local outreach
Advantages

- Elements met and fidelity to the vision protected
- Diversity of approaches to satisfy consistent elements
- Create community of learners, self perpetuating as trainers
- Establish expectations, standards, measures organizationally and regionally
- Construct with certification potential
- Inclusion in research, multidisciplinary scholarly work, and data pool
- Ultimately, normalizing the approach will speed adoption
- Hospital association is a natural network, flexibility to train systems large-enough to warrant individual training
- International interest – already China and Singapore

Thank You!