Transforming Medical Liability in Massachusetts: Background, Accomplishments, and Updates

Alan C. Woodward, MD
Past President and Chair of Committee on Professional Liability
Massachusetts Medical Society
Background: Investigation and Planning

- Failings of current system
- Options for reform (taskforce)
- Disclosure, Apology and Offer
- Evidence and Advantages
- AHRQ Planning Grant
- Roadmap for State
Failings of the current system

**Patients** - unfair, slow, inequitable, inefficient, isolating and no apology

**Physicians** - expensive, stressful, impacts health, modify practice and motivates defensive medicine

**Healthcare system** - compromises patient safety, workforce and access to care and drives defensive medicine, healthcare costs and number of underinsured
Rising Costs

Per Capita Health Expenditures: 550 in 2020
Per Capita GDP: 337 in 2020
Wages and Salaries: 325 in 2020
Consumer Price Index (CPI): 224 in 2020

Source: Mass. Dept. of Health Care Finance and Policy
Overuse: Resource Drivers

- Payment system
- Defensive medicine
- End of life care
- Poor Communication
- Unrealistic expectations
- DTC advertising
- Overregulation
- Others
The result . . .

“The current liability system is the number one toxic impediment to patient safety improvement.”

-Lucian Leape, Harvard School of Public Health

“For compensation, deterrence, corrective justice, efficiency and collateral effects, the system gets low or failing grades.”

- Michelle Mello, Harvard School of Public Health

Our liability system is unduly onerous for the patient and provider, and undermines the integrity, safety and efficiency of our entire health care system.
Options for Reform

- Tort system alternative

- A fundamentally different system
  - Fair, efficient, reliable, just and accountable
  - Supports patient safety improvement
  - Reduces the fear driving defensive medicine
DA&O Components

- Baseline culture of safety
  - Root cause analysis and safety improvement
- Full disclosure
- Apology when appropriate
- Timely fair compensation
- Alternative dispute resolution
- Tort is the last resort
Principles of DA&O

• Compensate patients quickly and fairly when unreasonable medical care caused injury.
• If the care was reasonable or did not adversely affect the clinical outcome, support caregivers and the organization vigorously.
• Reduce patient injuries (and therefore claims) by learning through patients‘ experiences.

“Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions.” Boothman, et al; Frontiers of Health Service Management 28:3; study at the University of Michigan Health System
Evidence: University of Michigan

- Started in 2001 (262 claims and > 300 open cases)
- By 2007, only 73 new claims and < 80 open cases
- Average case resolution time down from 20 months to 8 months
- Transaction expenses reduced $48k to < $20k/case
- Stopped buying reinsurance
- Reduced reserves $72M to $19M, funding patient safety initiatives
- Court cases reduced more than 90% (1-2/yr)
- Provide unlimited coverage with lower premiums
- Incident reporting - increased many fold
- Culture change - fear factor reduced - don’t teach DM
Advantages (Transformational)

- Reactive $\Rightarrow$ Proactive
- Adversarial $\Rightarrow$ Advocacy
- Culture of secrecy $\Rightarrow$ Full disclosure / transparency
- Denial $\Rightarrow$ Apology (healing)
- Individual blame $\Rightarrow$ System repair
- Patient/MD isolation $\Rightarrow$ Supportive assistance
- Fear $\Rightarrow$ Trust
- Defensive medicine $\Rightarrow$ Evidence-based medicine
# AHRQ Planning Grant

## Sponsorship:
- 1 Year planning grant
- $300 K
- Agency for Healthcare Research and Quality
- Medical Liability & Patient Safety Demonstration Project program

## Project Team:

**BIDMC:**
- Kenneth Sands, MD (PI)
- Sigall Bell, MD
- Peter Smulowitz, MD
- Anjali Duva

**MMS:**
- Alan Woodward, MD
- Elaine Kirshenbaum, MPH
- Charles T. Alagero, JD
- Liz Rover Bailey, JD
- Robin DaSilva, MPH
- Therese Fitzgerald, PhD

**HSPH:**
- Michelle Mello, JD, PhD

**U. Michigan:**
- Rick Boothman, JD
Project Goals

- Identify barriers to implementation of a DA&O model patient safety initiative in Massachusetts
- Develop strategies for overcoming barriers
- Design a Roadmap to reform medical liability and improve patient safety based on study findings
- Examine the degree to which the proposed plan for Massachusetts has applicability for other states.
Methodological Approach

- Key informant interview study of 27 knowledgeable individuals from all leading stakeholder constituencies in Massachusetts
- Semi-structured in-person interviews of 45-60 minutes, 2 physician interviewers (one exception)
- Interview transcripts excerpted, coded by theme and analyzed using standard content analysis methods
- Strategies for barriers were evaluated by frequency mentioned, feasibility, importance and time frame
- Road Map drafted and circulated back to interviewees then presented
## Barriers to DA&O Model Implementation

<table>
<thead>
<tr>
<th>Barrier*</th>
<th># of Respondents</th>
</tr>
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<tbody>
<tr>
<td>Charitable immunity law</td>
<td>22</td>
</tr>
<tr>
<td>Physician discomfort with disclosure &amp; apology</td>
<td>21</td>
</tr>
<tr>
<td>Attorneys’ interest in maintaining the status quo</td>
<td>20</td>
</tr>
<tr>
<td>Coordination across insurers</td>
<td>20</td>
</tr>
<tr>
<td>NPDB or state reporting requirements</td>
<td>19</td>
</tr>
<tr>
<td>Concern about increased liability risk</td>
<td>16</td>
</tr>
<tr>
<td>Forces of inertia</td>
<td>13</td>
</tr>
<tr>
<td>Fairness to patients</td>
<td>12</td>
</tr>
<tr>
<td>May not work in other settings</td>
<td>11</td>
</tr>
<tr>
<td>Insufficient evidence</td>
<td>8</td>
</tr>
<tr>
<td>Supporting legislation</td>
<td>8</td>
</tr>
<tr>
<td>Accountability for the process</td>
<td>5</td>
</tr>
</tbody>
</table>

* Other barriers, not listed, were mentioned by <4 respondents
Roadmap: Key Points

- Education - programs for all involved parties
- Leadership - from all key constituencies
- Model Guidelines - support consistency
- Collaborative Working Groups - key issues
- Enabling Legislation - to create a supportive environment / broad adoption
- Data Collection and Dissemination
Summary

- Overall perception of DA&O was very favorable
  - Positive effects on patient safety frequently noted and it is the right thing to morally and ethically
  - No alternative viewed more favorably
- Most suggested strategies to overcome the twelve identified barriers were feasible
- Other stakeholders were highly interested
Implementation: Accomplishments (last 12-18 months)

- Secured local funding
- Developed our Alliance (MACRMI) and CARe
- Released Roadmap / Media Campaign
- Established Pilot Program in varied sites
- Enacted Consensus Enabling Legislation
- Launched Website
- Developed Education Programs and Materials and Best Practices
Funding for Implementation

- AHRQ - $3M / 3Yr Demonstration Grant
  - $50M in ACA - no appropriation

- Local sources - all contributed
  - CRICO and BHIC for pilots
  - BCBS, HPHC, TAHP
  - Coverys, MMS & Reliant
MACRMI
Massachusetts Alliance for Communication and Resolution following Medical Injury

- BIDMC System - Baystate System
- MMS - Education / Guidelines / Forums
- MHA - Education / Guidelines
- MCPME - Education / Resource Center
- BORIM - Reporting / Dissemination
- MITSS - Patient Education / Advocacy
- MBA – Patient Advocacy / Education
- HSPH - Assessment
- UM - Policies / Workbook / Coaching
MACRMI and CARe

CARe stands for Communication, Apology and Resolution; it is MACRMI’s preferred way to reference the Disclosure, Apology and Offer process.
Roadmap Released - Media

- Released April 2012 - >300 Media Outlets
- Press releases on our Consensus Language and Website Launch
- Study published in the Milbank Quarterly, December 2012:

Disclosure, Apology, and Offer Programs: Stakeholders’ Views of Barriers to and Strategies for Broad Implementation

SIGALI K. BELL,1 PETER B. SMULOWITZ,1 ALAN C. WOODWARD,2 MICHELINE M. MELLO,3 ANJALI MITTER DUVA,1 RICHARD C. BOOTHMAN,4 and KENNETH SANDS1

1Beth Israel Deaconess Medical Center of Harvard Medical School; 2Massachusetts Medical Society; 3Harvard School of Public Health; 4University of Michigan Health Systems/University of Michigan Medical School

Context: The Disclosure, Apology, and Offer (D&A&O) model, a response to patient injuries caused by medical care, is an innovative approach receiving national attention for its early success as an alternative to the existing inherently adversarial, inefficient, and inequitable medical liability system. Examples of D&A&O programs, however, are few.

Methods: Through key informant interviews, we investigated the potential for more widespread implementation of this model by provider organizations and liability insurers, defining barriers to implementation and strategies for overcoming them. Our study focused on Massachusetts, but we also explored themes that are broadly generalizable to other states.

Findings: We found strong support for the D&A&O model among key stakeholders, who cited its benefits for both the liability system and patient safety. The respondents did not perceive any insurmountable barriers to broad implementation, and they identified strategies that could be pursued relatively quickly. Such solutions would permit a range of organizations to implement the model without legislative hurdles.

Address correspondence to: Sigali K. Bell, Beth Israel Deaconess Medical Center, Division of Infectious Diseases, 110 Francis St. IMOB-GB, Boston, MA 02215 (email: sbell@bidmc.harvard.edu); Peter B. Smulowitz, Beth Israel Deaconess Medical Center, Department of Emergency Medicine, One Deaconess Road, WCC 2, Boston, MA 02215 (email: psmulow@bidmc.harvard.edu).
Liability Reform Provisions of Ch. 224

- Six Month Pre-Litigation Resolution Period*
- Sharing all Pertinent Medical Records*
- Apology Protection - unless contradictory*
- Full Disclosure - significant complication*
- Pre-judgment Interest Reduction - T+2
- Charitable Immunity Cap Increase - 100k

Signed into law as part of Chapter 224 - Payment Reform Legislation; Effective November 5, 2012

* MMS, MATA & MBA Consensus
Pilot Sites for CARe Program

- BIDMC
- BID-Milton
- BID-Needham
- Baystate Medical Center
- Baystate Franklin Medical Center
- Baystate Mary Lane Hospital

Enrollment Start Date: December 1, 2012
Website: www.macrmi.info
Updates

- Reporting - NPDB and BORIM
- Other States - Oregon
- Data from MA - Reliant

The decrease in Suits for last three years (FY10-FY12) is statistically significant.
Conclusion - Multiple Benefits

Right and Smart thing to do

- For Patients (you)
- For Patient Safety
- For Providers
- For Hospitals / ACOs
- For Healthcare Access and Affordability
THE PILOT SITES: PROCESSES AND PROGRESS

Kenneth Sands, MD MPH
Senior Vice President, Health Care Quality
Beth Israel Deaconess Medical Center
# The Massachusetts Pilot Sites

<table>
<thead>
<tr>
<th>Site</th>
<th>#Beds</th>
<th>Location</th>
<th>Teaching (Y/N)</th>
</tr>
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<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>N</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>
</tbody>
</table>
A Path to CARe Implementation

1. Take stock of current processes and Patient Safety structures
2. Review CARe-type guidelines of facilities with similar programs
3. Develop algorithms outlining CARe process and to select events for CARe process
4. Develop educational strategy and materials for clinicians, leadership, & patients
5. Obtain policy approvals through various site boards and committees
6. Develop a unified Adverse Event Policy and Patient Safety/Risk Management CARe Procedure for all sites
7. Develop Best Practices, continue education and materials creation; fortify support mechanisms
8. LAUNCH
Take Stock of Current Processes

- Determined what adverse event procedures already exist, and their compatibility with CARe principles
- Worked with front-line risk/safety staff to determine their perceptions about CARe and solicit ideas for ways that CARe might fit into current processes
- Found common elements in processes among all sites and worked together from that commonality
A Path to CARRe Implementation

1. Take stock of current processes and Patient Safety structures
2. Review CARRe-type guidelines of facilities with similar programs
3. Develop algorithms outlining CARRe process and to select events for CARRe process
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8. LAUNCH
Review data and resources from other CARRe Programs

- We reviewed policies, algorithms, guides, etc. from:
  - The University of Michigan Health System
  - The University of Washington
  - Stanford Hospital and Clinics
- Goal: To determine what pieces of existing work will integrate well with our systems and what still needs to be developed due to the unique attributes of Massachusetts’ medical liability environment
A Path to CARE Implementation

1. Take stock of current processes and Patient Safety structures
2. Review CARE-type guidelines of facilities with similar programs
3. Develop algorithms outlining CARE process and to select events for CARE process
4. Develop educational strategy and materials for clinicians, leadership, & patients
5. Obtain policy approvals through various site boards and committees
6. Develop a unified Adverse Event Policy and Patient Safety/Risk Management CARE Procedure for all sites
7. Develop Best Practices, continue education and materials creation; fortify support mechanisms
8. LAUNCH
Develop Algorithms

There are two CARe Algorithms:

- A “filter” to determine whether an adverse event case should go through the full CARe process
  - “Defining a CARe Case”
- The full CARe process that will be followed if a case is selected by the filter
  - “CARe Protocol”
“Defining a CARRe Case” Algorithm

Process followed for all A.E.s (includes support)

Service Recovery Possibility for Non-Protocol Cases

A significant adverse event occurs

Possible early service recovery
Communication with patient re: event as currently understood; document in record (See Appendix C of AEM Policy)
Internal investigation (with insurer involvement as permitted)

Was the Standard of Care met?

Was the case originated as a Litigation Notice?

Was the patient significantly harmed due to the unmet SOC? (See SH definitions)

Communication to patient re: results of investigation and any improvements to be made; include empathetic apology; consider service recovery.

Outcome F (F1= SOC not met but did not cause significant harm; F2= SOC met)

Initiate CARRe Protocol; consult providers, chiefs, and department heads.

Full CARRe Protocol Filter
“Defining a CARe Case” –the Filter

If an internal investigation team determines that…

- The standard of care was **not** met, AND
- The unmet standard of care **caused** significant harm

…the case moves to the full CARe Protocol

(Pre Litigation Notices move directly into the protocol)
CARe Protocol: Part 1

Case enters CARe Protocol as a Litigation Notice

Case enters CARe Protocol as an Adverse Event

Hospital designee communicates with patient re: evaluation of case by Insurer(s) (See “Initial CARe Communication Guide”)

Insurer(s) disagree(s) with internal assessment or other Insurer assessment

Insurer(s) review(s) case with patient records and hospital review materials

Provider/System allocation by Insurer(s)

Lessons learned disseminated; patient safety improvements begin

Custom Solution Outcome E

Contact with patient lost Outcome X

Patient refuses to release records to Insurer(s)
CARe Protocol: Part 2
## Communication, Apology and Resolution Timeline

<table>
<thead>
<tr>
<th>Within...</th>
<th>24-48 hours</th>
<th>2-4 weeks</th>
<th>1-3 months</th>
<th>2-5 months</th>
<th>3-6+ months</th>
</tr>
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<tbody>
<tr>
<td><strong>Patient Safety</strong>&lt;br&gt;Alerted&lt;br&gt;Support services for providers and patients launched&lt;br&gt;Discussion with patient regarding error and known facts&lt;br&gt;(1,2)</td>
<td>Internal investigation takes place&lt;br&gt;Patient Safety and Patient Relations maintain contact with providers and patients respectively&lt;br&gt;(3)</td>
<td>Determination of CARe criteria fit&lt;br&gt;Providers, Chiefs, and Directors consulted&lt;br&gt;Team huddle; designee conducts Initial CARe&lt;br&gt;Communication with the patient; connects them to Insurer for record release&lt;br&gt;(4,5)</td>
<td>Insurer reviews case and develops offer parameters&lt;br&gt;Provider/System Allocation by insurer&lt;br&gt;Insurer invites patient to CARe Initial Meeting; recommends that counsel also attend&lt;br&gt;Lessons learned implemented at site&lt;br&gt;(6,7,8,9)</td>
<td>Initial meeting with insurers, providers, patient safety staff, patient, counsel, and other parties.&lt;br&gt;Additional meetings occur as necessary.&lt;br&gt;Final offer to patient made and accepted or rejected.&lt;br&gt;(10,11)</td>
<td></td>
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8. LAUNCH
Develop a Unified Adverse Event Policy

- Developing a policy that works within all existing Adverse Event Policies at the sites was essential to the CARe program’s functionality.

- The central components of CARe were inserted into existing hospital policy in a non-disruptive way, and more in-depth procedures were developed for the risk/safety departments to use as “on-the-ground” reference guides.

- Made sure that there were reliable systems for reporting adverse events at all sites.
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8. Launch
Obtain Leadership Approval and Increase Buy-in

- All hospital boards and other central committees were presented the model and approved the policy.
- This generated increased buy-in for the program and transformed it from “pilot” to “policy,” which will help to continue a positive culture change at each site.
- Policies also reviewed by the Liability Insurers, as part of a well-established working collaboration including:
  - Agreement on Goals of initiative
  - Agreement on Logistics
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8. LAUNCH
Develop Educational Strategy & Materials

- Strategy and materials
  - Targeted Presentations for clinicians, leadership, staff
  - Immediate reference sources; i.e. badge cards, posters
  - Website
- Multiple Reviewers of Materials
  - Clinicians
  - Patients and Families
  - Attorneys
  - Insurers
- Educate, educate, educate!
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8. LAUNCH
Launch – Begin Assessment

Assessment Strategy (enrollment began December 1, 2012)

- Volume and Financial Outcomes
  - Occurrence of events
    - Pre-claim settlements
    - Claims
    - Lawsuits
  - Costs
    - Litigation and non-litigation expenses
    - Costs going directly to patients
- Clinician experience (proposed, not yet funded)
- Patient Experience (proposed, not yet funded)
A Path to CARe Implementation

1. Take stock of current processes and Patient Safety structures
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4. Develop educational strategy and presentation templates for clinicians, leadership, & patients
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7. Develop Best Practices, continue education and materials creation; fortify support mechanisms
8. LAUNCH
The Post-Launch Phase

- Develop Best Practices
- Continue Education
- Fortify Support Mechanisms
  - Continue “just in time” support and coaching for a difficult communication (“disclosure”) in immediate aftermath of an adverse event
  - Formalize peer support / second victim programs
  - Publicize support resource list for patients and disseminate patient materials
A Picture of CARRe Today

39 Events with CARRe Potential

35 Cases investigated, communication with the patient about event, support given

4 Cases for CARRe Protocol

Unsure if Standard of Care met
Potential Significant Harm
Pre-litigation Notices