The Demands of Leadership During a Safety Crisis

James Mandell, M.D.
President and Chief Executive Officer

Sandra L. Fenwick, M.P.H.
Chief Operating Officer

Children’s Hospital Boston
Crisis Management

“Almost every crisis contains within itself the seeds of success as well as the roots of failure. Finding, cultivating, and harvesting that potential success is the essence of crisis management.”

ADVERSE EVENT

• 5 year old male with severe seizure disorder admitted for placement of subdural electrodes on 5/9/03.

• Unexpected postoperative seizure, fever and cerebral edema.

• 5/11/03 patient expired.
Sequence of Event Management
May-June 2003

- 5/11/03 Patient Expired
- 5/15/03 Risk Management invited to NS M&M Rounds
- Internal multidisciplinary case investigation begun
- 5/22/03 Case reported to DPH and BRM
- 6/2 – 6/10 DPH initiated immediate investigation
- 6/25 Met with DPH to review recommendations of CPRC sub-committees
  * Care of Child with Multiple System Needs
  * Role of Attending/Resident Supervision
- 6/25 RM staff met with family
Key Internal Learnings and Immediate Actions

Initiated “Implementation Steering Committee” to make changes:

- Care planning and coordination
- Communication
- Lines of responsibility/accountability
- Challenging the clinical strategy
- Handoffs
- Attending Physician Oversight
- Team based practice with clear delineation of roles
In the Midst of Managing the First Event
Another Event Occurred

On July 3, 2003

A second sentinel event – child received radiologic intervention on wrong side (kidney)
Sequence of Event Management
July, 2003

- 7/03: 2nd event wrong side intervention
- 7/22: DPH on-site investigation for 2nd event
- 7/24: Clinical staff met with family
- 7/29: Clinical Leaders met with DPH surveyors
  DPH asked for data on two prior reported and closed cases including peer review data
- 7/31: CEO met with family
- 8/5: CEO met with DPH leaders
Media and Stakeholder Communications Planning
August, 2003

• CEO/COO met with all clinical staff involved in incidents

• Public Affairs coordinated plan for release of information to media with DPH, training videos

• Small press briefs in Boston Globe and Boston Herald

• Prepared written statements for employees, Board, Trust Board, parents

• Lists of internal and external stakeholders to communicate with one-on-one; email; fax; meetings
Sequence of Event Management
September, 2003

9/4
CH received statement violations of Conditions of Participation - Deficiencies in Governing Body, Medical Staff and Nursing

9/16
CH submitted Plan of Correction #1 to DPH/CMS

9/17
- DPH/CMS premature announcement: CH Out of Compliance with Conditions of Participation
- CH released brief statement to media
- Emails to employees, Boards

9/18
DPH accepted CH Plan of Correction #1

9/19
- CEO met with Boston Globe and Boston Herald
- CEO/COO met with senior clinical and administrative leaders
- Memos from CEO/COO with SOC & POC posted on intranet
- Press conferences for all broadcast local media
- Calls by senior leaders to key stakeholders
- TV, radio, newspaper coverage included apology and list of improvements

9/20
Open meetings for all employees
Broadcast Coverage
September 18-20, 2003

- WCVB-TV (ABC)
- WBZ-TV (CBS)
- WHDH-TV (NBC)
- NECN – cable
- UPN38

- WB56
- WJAR-TV (R.I.)
- NPR Radio
- WBZ Radio
- WBIX Radio
Print Coverage

Children's Hospital scrutinized

Doctors were unsure of roles as boy died at Children's Hospital

DPH probes Children’s Hospital

New England in brief

DPH investigates incident at Children's Hospital
Many specialists, one patient, one death

State investigators have found that a 5-year-old epileptic boy died without receiving proper treatment at Children’s Hospital despite the presence of two nurses, two doctors, and others who came later or were available by phone. The confusion at his bedside is emblematic of the sometimes tangled lines of communication at a sophisticated teaching hospital. Children’s is taking measures to improve the supervision of future patients.

WHAT HAPPENED TO THE PATIENT
Six hours after successful surgery to implant brain sensors into the boy, he patient began suffering a whole-body seizure. Despite the presence of neurosurgeons, epilepsy specialists, and medical intensive care unit (MICU) staff, the patient suffered a heart attack more than 90 minutes after the seizure started. Even with successful emergency surgery to remove the brain sensors, he died two days after being admitted to the hospital.

POINTER THE FINGER
Both doctors at the scene and those in supervisory roles told federal investigators that other individuals or departments were responsible for managing the patient’s treatment during the seizure. The patient did receive anti-seizure drugs, but not in high enough dosages.

Neurosurgeon
Said epilepsy staff or medical intensive care unit (MICU) staff are responsible for post-operative care.

Epilepsy specialist #1
Said MICU staff or neurosurgical team were responsible for managing care during the seizure.

Epilepsy fellow
Said she was only a consultant. She was not at the hospital and assumed bedside doctors would manage care.

Epilepsy specialist #2
Said MICU staff was responsible for care.

Neurosurgery resident
Assumed the seizure was being managed by the MICU fellow and the epilepsy fellow on the phone.

MICU director
Said MICU staff don’t assume responsibility for surgical patients; the responsibility belongs to the surgical staff.

MICU attending
Said neurological staff was responsible for managing care during the seizure.

MICU fellow
Thought the seizure was being managed by neurosurgical resident at bedside and epilepsy fellow on the phone.

Two MICU nurses
Could not recall who was managing the patient’s seizure.

MICU charge nurse
Said surgical teams are responsible for surgical patients.

SOURCES: Investigation report by the federal Centers for Medicare & Medicaid Services; MedLine; National Heart, Lung, and Blood Institute

GLOBE STAFF GRAPHIC / SEAN McNAUGHTON
Sequence of Event Management
September 2003

- **9/22 – 9/30**
  - DPH/CMS Conditions of Participation Survey

- **9/24**
  - Proactively met with Boston Globe Editorial Staff

- **9/26**
  - Balanced AP story included apology and references to improvements in context of medical errors and complexity of care

- **9/28**
  - Balanced editorial appears in Boston Globe
Sequence of Event Management
October – December 2003

October

10/10
CH received CMS Statement of Correction #2

10/20-21
JCAHO sentinel event review in Chicago

10/24
CH Plan of Correction #2 submitted to DPH/CMS

November

11/5
Board of Registration in Medicine meeting to review reporting of cases

11/10-13
DPH/CMS follow-up onsite visit to determine if in compliance with Conditions of Participation

December

12/8-12
JCAHO Triennial Survey
What More Did We Learn?

- Culture - Thought we were doing excellent quality care
  Thought we had good Q & PS systems in place
  Not consistent, relentless questions, measurement/data
  Did not see this coming
  Focus of Board, leadership – on finances, larger strategy

- Failure to Act - Committees established post-review of 2 adverse events in 2002 with recommendations. Diligent, focused implementation of recommendations not pursued fast enough

- Unclear leadership accountability for patient quality

- Systems to support caregivers inadequate to close gaps in care delivery
These Events Occurred within System of 10+ Years of Focus on Patient Safety

Patient Safety Initiatives 2001-Present

2001

- Adverse Med Event Study Published- JAMA
- Methadone Conc. Changed in IP Areas
- Standard Dosing of Antibiotics
- Implementation of Oncology CPOE
- Online Sedation Monitoring Tool Pilot
- Stand. Maintenance Equipment Comm.
- Laterality Policy in OR
- Culture of Safety Survey
- Pt. Safety Leadership Self Assessment Tool
- Expansion of Multi-Drug Resistant Organism Screening
- Expansion of Surg. Site Infection Surveillance
- Hand Hygiene - Installation of Alcohol Gel Hospital-Wide & Training on its Use
- Artificial Nails Policy

2001 continued

- Templated Orders Sub-Committee
- Adverse Drug Events Sub-committee
- “Enhancing Patient Safety” & “Building Safe Practices” Conferences for Perioperative, Surgical and Anesthesia Departments
- Reuse of Single-Use Device Policy
- Response Plans for Bioterrorism
- Development of Standardized Drip Rate Spreadsheets (ICU/ED)
- Children’s Hospital publications

2002

- Violence and De-escalation Staff Training in ED
- Hospital-Based Simulator Suite Created, & Simulator Suite Training for the ICU Conducted On-Site
- Templated Orders Implemented
- Oral Antibiotics Dose Standardization
- Revised Antimicrobial Order Form
- Standardized Narcotic Reversal
- Enhanced Pharmacy Webserver for Intranet Use
- KCL FMEA
- Blood Bank FMEA
- Vancomycin MUE
- “Team Role in Implementing Patient Safety” & “Medical Simulation in Patient Safety” Conferences for Perioperative, Surgical and Anesthesia Departments
- Implemented IC Risk Assessment for Construction Projects

2002 continued

- Pain Assessment MUE
- Enoxaparin MUE
- Standardized Abbreviations
- Verbal Order Policy Revision
- Non-Oncology Chemotherapy Guidelines Revised
- Credentialing for Procedural Sedation
- Established Patient Safety Leadership Group
- Timing of Antibiotic Prophylaxis Audit
- Cardiovascular Pre-op Staph. Aureus Screening Project
- CJD Action Plan
- Updated IC Guidelines for CF Patients
- Food-drug Interaction Notification Service
- Hospital Quality Scorecard
- Children’s Hospital publications

2003

- Safety Core Metric Measures
- Nursing Call and Communication System
- Suicide Screening Tool on Medical Floors
- Remove Concentrated KCL from ICUs
- Anti-Coagulation Service
- Approval for Closed Loop Medication System
- Patient Safety Executive Walkrounds
- Evaluation and Implementation of Chloraprep
- Time-Out Audit in OR
- Handwashing and Glove Use Audit in OR
- Ongoing Audits of Labeling and Medication & Solution in Sterile Field in OR
- Children’s Hospital publications

2003 continued

- High Risk Medication Review
- Implementing Pyxis Profiling
- Implementing Pyxis Digital Scanning
- IRB-Developed Pharmacy Held Informed Consent Database
- Standardization of PO Non-Antibiotics
- Removing all Floor Stock-Pharmacy to Review 100% of Orders
- Pharmacy Review of ED Orders
- Implement JCAHO 6**
- SARS Response Plans
- ISMP Newsletter Distribution
- Housestaff Duty Hours

2004

- Enhanced Competency Based Orientation Program for Nurses
- Development of Web Based Incident Reporting System

** JCAHO 6
- Safety of Infusion Pumps
- Read-back Feedback Verbal Orders (2002)
- Remove Concentrated KCL from ICUs (2000)
- Standardization of Drug Concentrations Available (2002)
- Maintenance and Testing of Clinical Alarm Systems
- Laterality Policy (2001)

These Events Occurred within System of 10+ Years of Focus on Patient Safety

Itemized List of Initiatives:

Adverse Med Event Study
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What Did We Decide to Do With This Information?

• These events must be used as a “call to action”

• We must continue a non-punitive approach while holding leadership accountable

• There must be transparent learning for ALL
How Did We Organize for Change? Quality Oversight Committees

- Board of Trustees
  - Physician-in-Chief
  - Surgeon-in-Chief
  - Nurse-in-Chief
  - Quality Improvement and Risk Management

- CEO/COO
  - Senior Clinical Leadership Committee (SCLC)
    - Clinical Practice Committee (CPC)
    - Data Collection and Auditing Committee (DCAC)
  - Medical Staff Executive Committee (MSEC)
  - Patient Care Assessment Committee (PCAC)
  - Patient Care Committee (PCC)
  - Clinical Peer Review Committee (CPRC)
What Did the Senior Clinical Leadership Committee Do?

• Managed Immediate Crisis
  - Communications
  - Regulatory agencies
  - Plans of Correction
  - Measurement of achievement

• Developed Policies
  - Attending/resident supervision
  - Associate attending
  - Consultation
  - Single standard of care in MSICU
  - 24/7 attending coverage in MSICU
  - On call lists
  - Standard mandatory computer use for clinical notes

• Called for external review of NS and QI/RM

• Created ombudsman
What Did the Senior Clinical Leadership Committee Do?

• Closed ICU annex, reorganized with different staffing/patient population

• Reviews all adverse events within 24 hours

• Reviews all data from the Data Auditing and Compliance Committee

• Mandated quarterly reporting of the Data Auditing and Compliance Committee to the Patient Care Assessment Committee of the Board

• Mandated monthly meetings of the Patient Care Assessment Committee
How Are We Tracking Progress?

• Plan of Correction Tracking Document

• Plan of Correction Critical Success Factors.
### Plan of Correction Tracking Document

<table>
<thead>
<tr>
<th>Source</th>
<th>Section</th>
<th>Plan of Correction</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>POC 1. Governing Body (A 016, A 022)</td>
<td>1.B.</td>
<td>The Board has charged the Chief Executive Officer and will hold him accountable for putting in place the structures, policies, processes and tools necessary to implement this Plan of Correction. The specific action steps, timelines and remediation have been reviewed and approved by the Board and detailed progress reports will be monitored by the Board on a regular basis to make certain that these changes are embedded in the organization. More broadly, the Board charges the Chief Executive Officer with enhancing the culture of safety at Children’s Hospital, and ensuring that patient safety remains a part of every staff and employee’s responsibility.</td>
<td>G</td>
</tr>
<tr>
<td>POC 1. Governing Body (A 016, A 022)</td>
<td>1.B.1.</td>
<td>The Patient Care Assessment Committee will increase the frequency of its meetings from quarterly to monthly; additional lay members of the Board of Trustees will be added to the membership of the Committee along with a member of the public; all members of the Board of Trustees will be invited to attend and participate in meetings of the Committee; and the Committee will report quarterly to the full Board of Trustees, and more often as needed. At each meeting, in addition to existing reports, the Committee will receive reports from the Senior Clinical Leadership Committee and the Implementation Committee.</td>
<td>G</td>
</tr>
<tr>
<td>9-17 Response to DPH</td>
<td>Q1</td>
<td>1. Q: Who chairs the Patient Care Assessment Committee? A: The Vice Chair of the Board of Trustees Q: Who is a Risk Management/Quality Improvement person on the PCAC? A: The Corporate Director of Performance Improvement and Compliance and the two senior Risk Manager/Quality Specialists are present and staff the PCAC.</td>
<td>G</td>
</tr>
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# Plan of Correction Critical Success Factors

## 1. Associate Attending Physician Policy

<table>
<thead>
<tr>
<th>Metric</th>
<th>Current</th>
<th>Previous</th>
<th>Change</th>
<th>Data Frequency</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients with underlying medical problems identified</td>
<td></td>
<td></td>
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<tr>
<td>Number of cases presenting with an associate attending</td>
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<tr>
<td>Number of cases for which associate attending became involved as a result of this policy</td>
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</tbody>
</table>

## 2. Clinical Consultations (actual metrics pending feedback from Data Auditing Compliance Committee)

<table>
<thead>
<tr>
<th>Metric #1</th>
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</tr>
</thead>
</table>
What Worked: Communication Strategy

• Proactive strategy with strategic message points

• Balance of Apology/Accountability, Transparency and Confidence

• Accepted full responsibility

• Messaging varied by stakeholder

• Stakeholders: Board of Trustees, Medical Staff, employees, other patients and families, partners, donors, legislators, payers, community colleagues and leaders, media
What Worked: Overall

• Mobilized leadership
• Visibility
• Assured day-to-day operations
• Capitalized on opportunity for transforming the organization
• Communicated strategically to all stakeholders
• Created new systems to sustain gains
• Communicated results
What Are Ongoing Cultural Changes?

• Building a culture of safety
• Vigilance
• Accountability/Transparency
• Non punitive culture
• Continuous measurement and feedback
• Commitment to continuous improvement
• Openness to change, embrace a new way
• Never be satisfied
Conclusions

• Crises are inevitable

• Do the right thing

• Stay focused

• Convey humility, confidence, accountability and willingness to learn and improve.

• MEAN IT!