The Seven Pillars: Crossing the Patient Safety – Medical Liability Chasm

ACMQ
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Disclosure Information:
David Mayer, MD
Tim McDonald, MD JD

Dr. Mayer has the following information to disclose:
1. Eli Lilly = Patient safety advisory panel member
2. Transparent Health = Partner, educational film company

Dr. McDonald has the following information to disclose:
1. Transparent Health = Partner, educational film company
How should we respond when things go wrong?

- 63 yo patient with critical aortic stenosis presents to OR with bilateral subdural hematomas and need for burr holes.
  - Excessive risk of general anesthesia
  - Proceeds with intravenous sedation
  - Fentanyl, midazolam titrated
  - Nasal canula
  - Duraprep used for surgical site infection prevention
  - “Draped in usual fashion”
  - Incision made
How should we respond when things go wrong?

- Cautery used to stop bleeding at incision site
- Patient begins to complain of discomfort
- More sedation provided
- Smoke begins to billow from under drapes
- Patient sits up
- Flames and smoke engulf the patient
- Fire immediately extinguished
- What next?
What are the factors that control the transparency of the response?

- Barriers
- Benefits
A “Transparent Approach”

Barriers
- Institutional
- Money
- Reputation
- “Shame and blame”
- Loss of control
- Loss of license
- Resource intense
- Uncertainty
- Bad advice

Benefits
- Maintain trust
- Learn from mistakes
- Improve patient safety
- Employee morale
- Psychological well-being
- Accountability
- Money
- Reputation
Institute of Medicine: 1999 report that shook the medical world

Making Matters Worse
How can institutions “encourage” a transparent approach?

- Affirm your values and principles
- Support the necessary cultural transformation
- Make it an expectation
- Hire to it
- Anticipate fears of those involved in adverse events.
- Establish a reliable process – at a minimum NQF 1,2,4,5,7, 8
- Establish, create and support the necessary and sustainable structures and systems
Linking transparency with patient safety

Event

Transparency, Learning and Accountability

Becomes the Trojan Horse for Cultural Transformation
Foundational Principles of Seven Pillars

- The principles
  - We will provide effective and honest communication to patients and families following adverse patient events
  - We will apologize and compensate quickly and fairly when inappropriate medical care causes injury
  - We will defend medically appropriate care vigorously
  - We will reduce patient injuries and claims by learning from the past
  - Credit to Rick Boothman, CRO, University of Michigan
Bridging the Patient Safety – Medical Liability Chasm
“The Seven Pillars”

Data Base

Patient Communication Consult Service

Concern or unexpected event reported to Safety/Risk Management

No

Patient Harm?

Yes

Event Investigation
Consider “Care for Care Provider” hold bills?

No

Unreasonable Care?

Yes

Full Disclosure with Apology and Remedy

Process Improvements

Activation of Crisis Management Team

“Near misses”
Building the Foundation: An approach to the NQF SPs

- 1 Leadership
- 2 Culture measurement and feedback
- 4 Identification and mitigation of risks and hazards
- 5 Informed consent
- 7 Disclosure
- 8 Care of the Caregiver
Key elements of the Seven Pillars

Quality and Safety in Healthcare, March 1, 2010

- Adopt principles
- Comprehensive process design
- Teach [1] to all of it:
  - Reporting [2]
  - Investigation [3]
  - Communication [4]
  - Apology & remedy, when indicated [5]
  - Process improvements [6]
  - Data tracking [7]
The Connection Between Patient Safety and Medical Malpractice: April 2010
www.rand.org/pubs/research_briefs/RB9524/

INSTITUTE FOR CIVIL JUSTICE

TECHNICAL REPORT

Is Better Patient Safety Associated with Less Malpractice Activity?
The Connection Between Patient Safety and Medical Malpractice

For every reduction of 10 PSEs claims dropped by 3.7

Table 2.1
Frequency of Patient Safety Events by Indicator Type, California, 2001–2005

<table>
<thead>
<tr>
<th>PSI Number</th>
<th>PSI Name</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPPS 19</td>
<td>Obstetric Trauma – Vaginal without Instrument</td>
<td>30</td>
</tr>
<tr>
<td>TPPS 18</td>
<td>Obstetric Trauma – Vaginal with Instrument</td>
<td>15</td>
</tr>
<tr>
<td>TPPS 04</td>
<td>Failure to Rescue</td>
<td>12</td>
</tr>
<tr>
<td>TPPS 15</td>
<td>Accidental Puncture or Laceration</td>
<td>12</td>
</tr>
<tr>
<td>TPPS 12</td>
<td>Postoperative Pulmonary Embolism or Deep Vein Thrombosis</td>
<td>6</td>
</tr>
<tr>
<td>TPPS 17</td>
<td>Birth Trauma – Injury to Neonate</td>
<td>6</td>
</tr>
<tr>
<td>TPPS 07</td>
<td>Selected Infections Due to Medical Care</td>
<td>6</td>
</tr>
<tr>
<td>TPPS 03</td>
<td>Decubitus Ulcer</td>
<td>5</td>
</tr>
<tr>
<td>TPPS 09</td>
<td>Postoperative Hemorrhage or Hematoma</td>
<td>4</td>
</tr>
<tr>
<td>TPPS 06</td>
<td>Iatrogenic Pneumothorax</td>
<td>2</td>
</tr>
<tr>
<td>TPPS 02</td>
<td>Death in Low-Mortality DRGs</td>
<td>1</td>
</tr>
<tr>
<td>TPPS 20</td>
<td>Obstetric Trauma – Cesarean Delivery</td>
<td>1</td>
</tr>
<tr>
<td>TPPS 14</td>
<td>Postoperative Wound Dehiscence</td>
<td>1</td>
</tr>
<tr>
<td>TPPS 05</td>
<td>Foreign Body Left During Procedure</td>
<td>&lt;1</td>
</tr>
<tr>
<td>TPPS 08</td>
<td>Postoperative Hip Fracture</td>
<td>&lt;1</td>
</tr>
<tr>
<td>TPPS 16</td>
<td>Transfusion Reaction</td>
<td>&lt;1</td>
</tr>
<tr>
<td>TPPS 01</td>
<td>Complications of Anesthesia</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>
Gap Analysis

- In the context of the “Seven Pillars”
  - Reporting
  - Investigation
  - Communication
  - Apology and Remediation
  - Process and Performance Improvement
  - Data collection and analysis with feedback
  - Education of all elements
The Seven Pillars: Bridging the Patient Safety – Medical Liability Chasm
The Process

1. **Data Base**

2. **Patient Communication Consult Service**

   - **No**
   - **Yes**

   - **Patient Harm?**
     - **No**
     - **Yes**

   - **Event Investigation**
     - **Consider “Care for Care Provider” hold bills?**
       - **No**
         - **Unreasonable Care?**
           - **No**
           - **Yes**

       - **Yes**

   - **Full Disclosure with Apology and Remedy**

3. **Concern or unexpected event reported to Safety/Risk Management**

4. **“Near misses”**

5. **Process Improvements**

   - **Activation of Crisis Management Team**
Gap analysis

- NQF Safe Practice #1
  - Culture of Safety, Leadership, Structures and Systems
    - Awareness structures and systems
    - Accountability structures and systems
    - Action plan/education arm
Gap Analysis

NQF Safe Practice #2

- Culture Measurement, Feedback and Systems
  - Surveys
  - Feedback
  - Intervention
Gap Analysis

NQF Safe Practice #4

- Identification and Mitigation of Risks and Hazards
  - Organizational structures and systems
  - Identification of Risks and Hazards
    - Retrospective
    - “Real-Time”
    - Prospective

- Mitigation
  - Crisis Management
Gap Analysis

- NQF Safe Practice #5
  - Informed consent
    - Policy and Procedures
    - Process
    - Measurement
Gap Analysis

- NQF Safe Practice #7
  - Disclosure
  - Governance
  - Organizational structures and systems
    - Crisis Management Team is critical
  - Communication
  - Patient & Family Involvement
Gap Analysis

- NQF Safe Practice #8
  - Care of the Caregiver
    - Policies and Procedures
    - Institutional infrastructure
The Seven Pillars: Bridging the Patient Safety – Medical Liability Chasm
The Process

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Elements of a “Transparent” Response to Adverse Event Process

- Reporting
- Investigation
- Communication
- Apology with remediation
- Process and performance improvement
- Data tracking and analysis
Elements of a “Transparent” Response to Adverse Event Process

- Reporting
Resident Physician PSO

Life-Saving Incident Reporting Submission has never been easier.

Want to know more? Take a tour of the benfits.
Resident Physician PSO

Type of Patient Safety-Related Event

- Incident
  A patient safety event that reached the patient, whether or not the patient was harmed.
- Patient Near Miss
  A patient safety event that did not reach the patient.
- Unsafe Condition
  Any circumstance that increases the probability of a patient safety event.
<table>
<thead>
<tr>
<th>Safety Event Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Hand-off of care</td>
</tr>
<tr>
<td>□ Fatigue or alertness</td>
</tr>
<tr>
<td>□ Stress</td>
</tr>
<tr>
<td>□ Lack of or inadequate attending supervision</td>
</tr>
<tr>
<td>□ Disruptive or unprofessional behavior</td>
</tr>
<tr>
<td>□ Excessive duty hours [beyond ACGME maximum]</td>
</tr>
<tr>
<td>□ Unsafe resident environment</td>
</tr>
</tbody>
</table>
IOM Aim(s) Did Not Meet

- Safe: Avoid injuries to patients from the care that is intended to help them.
- Effective: Match care to science; avoid overuse of ineffective care and underuse of effective care.
- Patient-Centered: Honor the individual and respect choice.
- Timely: Reduce waiting for both patients and those who give care.
- Efficient: Reduce waste.
- Equitable: Close racial and ethnic gaps in health status.
Resident Physician PSO

ACGME Core Competencies

☐ Patient Care
☐ Medical Knowledge
☐ Practice-Based Learning and Improvement
☐ Interpersonal and Communication Skills
☐ Professionalism
☐ Systems-Based
Resident Physician PSO

Portfolio Of Reports

To get started choose a folder to view the reports there, then choose a report to read in in the overview section of the page.

Folder List
Unsorted Reports
Top Level Folder
* Sub-Folder
** Sub-Folder

Reports
Report 0000187r7e6
My First Occurrence Report
Report 0000187r7e6
Report 0000187r7e6
Back to our case.

- Case reported by hotline – direct call.
- Leadership response < 5 minutes
What is protected?

- Investigation
Back to our case

- What was discovered?
Fire Triangle

Ignition Source
Surgeons—ESUs, lasers, etc.

Oxidizer
Anesthesia Providers—O₂, N₂O, etc.

Fuel
Nurses—drapes, prepping agents, etc.
Time line 3/24/10

9:05am
- Pt enters OR & positioned supine.
- 2L NC wrapped around pt’s ears, taped to both cheeks & placed on chest.
- Foam donut placed under pt’s head, egg crate under entire body, pillow under both knees & gel foam for the heels.
- Grounding pad is placed on right anterior thigh.
- Pt is prepped & draped (details to follow).
Time line 3/24/10 (cont’d)

- 9:55am:
  - 2 small 2cm incisions were made bilaterally. Both monopolar & bipolar cauteries were used to dissect the peristeum. Just before the right sided burr hole was attempted with the perforator drill, the pt sat up suddenly. Smoke was coming from behind the split sheet & turned into flames. Fire extinguished with saline & towels.

- 10:10am:
  - Incisions closed
Prepping & Draping Technique

1) Head shaved with clippers
2) 70% alcohol poured on 4X4’s to wipe head
3) 4 steri-drape 1000’s used
4) Incision site is marked
5) Head prepped with Duraprep 26ml.
   Lidocaine injected.
6) Upon return of surgeon after scrubbing, pt is prepped in a sterile fashion the second time with Duraprep 26 ml
7) 4 towels used to drape head
8) Ioban applied
9) Spilt sheet applied
DuraPrep™ Surgical Solution
Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w)
Patient Preoperative Skin Preparation for large prep areas below the neck

WARNING
Flammable

Keep away from fire or flame.
To reduce the risk of fire:
• Do not use 26-mL applicator for head and neck surgery.
• Do not use on an area smaller than 8 in. x 10 in.
• Use a small applicator instead.
• Solution contains alcohol and gives off flammable vapors.
• Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin).
• Avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.
• Do not allow solution to pool.
• Remove solution-stained material from prep area.

Single Use
Sterile Contents:
Applicator w/urethane sponge (1)
Cotton-tipped swabs (2)
Sterility of sterile contents guaranteed unless package is damaged or open.

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.9 fl oz (26mL) of solution which covers a 15 in. x 30 in. area (approximately from shoulder to groin in an average size adult).

For procedures requiring less coverage, a smaller applicator is available (8635). It contains 0.2 fl oz (6mL) of solution which covers an approximate 6 in. x 10 in. area. Do not use more than required for the area.

3M recommends all users participate in product in-service training prior to use. In-service is available on video, from your 3M sales representative, or at the 3M website (www.3M.com).

Cat. No. 8630 0.9 fl oz • 26 mL

3M
Mn Co. in U.S.A. for
3M Health Care
St. Paul, MN
55144-1000
1-800-222-3377

Product
US Patent 4,584,192
34-K070-9504-4

Patient Take Home Instructions
Your surgeon used 3M™ DuraPrep™ Surgical Solution, a bacteria-killing skin preparation. It is recommended that the film remain on the skin after the procedure. The film will gradually wear away. If, however, early removal is desired:
• Apply 8610 or 8611 3M™ Remover Lotion to the prepced area keeping away from the wound edge or puncture site. Wipe off with a disposable towel, or
• Soak gauze with 70% isopropyl alcohol and place on the prepced area for at least 40 seconds. Lightly scrub to remove the solution.
If you have questions, call 1-800-222-3377.
Warnings For external use only

Flammable
- keep away from fire or flame, heat, spark, electrical. Flash point 72°F.
- do not use with electrocautery procedures.

Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns

When using this product
- do not get into eyes
- do not apply over large areas of the body
- do not use longer than 1 week unless directed by a doctor

Stop use and ask a doctor if condition persists or gets worse

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- clean the affected area
- apply 1 to 3 times daily

Other information
- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- will produce serious gastric disturbances if taken internally

Inactive ingredient purified water
MORT Analysis

- Guidelines/Policy
- Information Management and Communication
- Equipment
- Medication Procedures
- Physical Environment
- Human Resource Factors – Task Performance
- Human Resource Factors – Supervisor
- Care Process
- Assumed Risk
- Disclosure
MORT Analysis (Policy & Procedure)

Guidelines/Policy

Surgical Services Policy:

Skin preparation:

- Flammable germicides are not used on operative site.
- Pooling of prep solutions under the pt can result in chemical burns. Fluids impervious barriers are used under dependent areas of the pt while prepping to prevent pooling.
MORT Analysis (Policy & Procedure)

- AORN 2010 Recommended practices
  - Electrosurgery, Recommendation IV
    - Active electrodes should not be activated in presence of flammable agents (ex: antimicrobial skin prep or antisepsis agents, tinctures, de-fatting agents, collodion, petroleum based lubricants, phenol, aerosol adhesives until the agents are dry & vapors have dissipated.
    - Caution should be used during surgery on the head & neck when using an active electrode in the presence of combustible anesthetic gases or oxygen.
MORT Analysis (Policy & Procedure)

• Alcohol based prep agents remain flammable until completely dry. Vapors occurring during evaporation also are flammable. Trapping of solution or vapors under incise or surgical drapes increases the risk of fire or burn injury. Alcohol based skin prep agents are particularly hazardous because the surrounding hair or fabric can become saturated. Pooling can occur in body folds & crevices.

• Surgical drapes should be arranged to minimize buildup of oxidizers under the drapes, to allow air circulation & to dilute additional oxygen.
MORT Analysis (Policy & Procedure)

- **Patient skin antisepsis: Recommendation VIII**
  - If a flammable prep is used, additional precautions should be taken to minimize the risk of surgical fire & pt injury.
  - The prep agent remains flammable until completely dry. Vapors occurring during evaporation are also flammable. Trapping of solutions or vapors under drapes increases the risk of fire or burn injury.
MORT Analysis (Policy & Procedure)

- The use of a flammable prep agent should be discussed during the “time out” period used to verify the surgical procedure & site. Active communication about the use of flammable prep agents alerts all personnel to inherent risks & verifies that appropriate precautions are taken.

- Active communication should include: 1) a flammable prep agent was used. 2) The application site was dry before draping. 3) Pooling of the prep solution did not occur or has been corrected.

- Any material soaked with the prepping agent have been removed from the room.
MORT Analysis (Policy & Procedure)

- **Recommended Practice IX:**
  - Manufacturer’s written recommendations & Material Safety Data Sheet (MSDS) for handling, storing & handling of all skin preparation agents should be followed.
MORT Analysis

- **Information Management & Communication**
  - Pt was at high risk for fire & not discussed in time-out.
  - Stake holders in the OR were unaware of manufacturer warnings & the Material Safety Data sheet.
  - Documentation of events leading to fire were inaccurate & misleading.
MORT Analysis

**Equipment**

- Duraprep has been used in the OR for at least 7 years.
- No product can be identified to remove adhesive from the skin that is not alcohol based.
- The only Duraprep available from Materials Management was labeled “not to be used on head & neck procedures” because of high volume
  - 6ml Duraprep are approved for the use of the head & neck procedures. It was not made available from Materials Management.
MORT Analysis

- **Physical Environment**
  - Presence of nasal oxygen on head & neck cases posed a high risk to the pt that was unappreciated.
  - Trapping of the alcohol vapors under the drapes also contributed to the risk of fire.
MORT Analysis

- **Human Resource Factors – Task Performance**
  - AORN, ASA, Manufacturer & Fire Marshall recommendations & warnings were not followed.
  - No interactive communication between Anesthesiologist & Surgeon.
  - Surgery, Anesthesia & Nursing staff were not educated on the potential dangers from each recommendations.
UNSAFE ACTS ALGORITHM

Were the actions as intended? NO YES
Evidence of illness or substance use? NO YES
Were the consequences as intended? NO YES
Known medical condition? NO YES
Substance abuse without mitigation

Pass substitution test? (Could someone else have done the same thing)? NO YES
Deficiencies in training, selection, or inexperienced? NO YES
Blameless error, corrective training, counseling indicated

Were procedures available, workable, intelligible, correct and routinely used? NO YES
System induced violation

Possible reckless violation

Possible negligent behavior

Sabotage, malevolent damage

Substance use with mitigation

System induced error

MORT Analysis

- **Human Resources Supervisor**
  - Surgical, Anesthesia & Nursing leadership unaware of the high risk for a fire posed by Duraprep or other alcohol-based prep solutions.
  - Unaware of the National Advisory
  - Material was being used inappropriately & against manufacturer recommendation.
MORT Analysis

- Care Process
  - Goal of the World Health Organization Safety Surgical Check List adopted by the OR has not been met.
MORT Analysis

**Disclosure**

- Apology given to pt & family
- Physicians explained the events of the case to the wife & daughter.
- RM & Guest Services has been following up with patients care since discharge.
Pillar #4 of Gap Analysis

- Communication
  - What about all those situations in which the cause of unexpected outcomes is unclear or whether care was inappropriate or not?
The “Principled Approach” to Adverse Patient Events

Data Base

Patient Communication Consult Service

No

Patient Harm?

Yes

Event Investigation
Consider “Care for Care Provider” hold bills?

No

Unreasonable Care?

Yes

Full Disclosure with Apology and Remedy

Concern or unexpected event reported to Safety/Risk Management

“Near misses”

Process Improvements

Activation of Crisis Management Team
Pillar #4 Communication
The Patient Communication Consult Service

- PCCS
- Current options
- Empowerment
- Participation
- Expectations?
- Physician involvement?
- Patient-family involvement?
The “Principled Approach” to Adverse Patient Events

- **Data Base**

- **Patient Communication Consult Service**

- **Event Investigation**
  - Consider “Care for Care Provider” hold bills?
  - Unreasonable Care?
    - Yes
      - Full Disclosure with Apology and Remedy
    - No

- **Concern or unexpected event reported to Safety/Risk Management**

- **Process Improvements**
  - “Near misses”
  - Activation of Crisis Management Team
Core elements in communication

■ What patients want to hear:
  ■ The truth
  ■ Recognition: investigation
  ■ Regret [empathy]: apology, if applicable
  ■ Responsibility: accountability and prevention
  ■ Remedy – how will this be coordinated?
  ■ Need approved process and physician buy-in
  ■ How do we teach this?
The “Principled Approach” to Adverse Patient Events

Concern, question or unexpected event reported to Safety/Risk Management

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hold bills?

Unreasonable Care?

Data Base

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No

No

Yes

Yes

Process Improvements

Activation of Crisis Management Team

Full Disclosure with Apology and Remedy

“Near misses”
Pillar #5 Gap analysis

- Apology and remedy
The “Principled Approach” to Adverse Patient Events

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Unreasonable Care?

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Full Disclosure with Apology and Remedy
Pillar #6

- Gap analysis: Performance and process improvements
Pillar #7

- Gap analysis: data management plan
Questions?