Seven Pillars: Addressing Patient Safety Culture

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Culture eats strategy for breakfast
The Problem

Institute of Medicine: 1999 report that shook the medical world

Making Matters Worse
Family lends hand after deadly error
Another communicating openly and resolving early

Death gives new life to friend

ORGAN DONOR | Daughter dies in surgery, dad offers kidney to pal

BY PIET LEVY
Post-Tribune

In death, Michelle Ballog has given new life to a family friend in need of a second chance.

On Sunday, Ballog’s kidney was given to Lake County (Ind.) Police Chief Marco Kuyachich, who has been awaiting a transplant for two years. Ballog, 39, was the daughter of former Hobart Mayor Robert Malizzo.

“She was always there to help everyone,” Malizzo said. “Even in her death, she wanted to help, and that’s why she’s a donor.”

Ballog, who had two daughters, died during liver surgery Saturday at the University of Illinois Medical Center.

Despite his grief, Malizzo remembered his friend Kuyachich needed a kidney. So, he called him.

“Sometimes there’s a bright side out of a bad situation,” Malizzo said. “My daughter gave [Kuyachich] the gift of life. What greater gift can you give anyone?”

Kuyachich said: “I’m hoping others will learn from this and follow her lead. You don’t realize how much you can do for others until you have it done to you.”

Comment at suntimes.com.
October 7, 2011

Medical mistake spurs relatives to join hospital panel, not sue
Process improvement: Significant change in national guidelines

- July 1, 2012 ASA
- Specifically, in section 3.2.4 of the Standards for Basic Anesthetic Monitoring, the ASA states, "...During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment."
One approach when things went wrong years ago

- The beginning circa 2000
  - The K.C. case, COO of sister hospital
  - Preoperative testing prior to plastic surgical procedure
  - Evening before surgery - lab tests done
  - WBC <1,000 (normal value 4-12,000)
  - Only Hgb & Hct checked on day of surgery
  - Repeated CBC (complete blood count) postop
  - WBC <600
  - Called as critical result to the unit – reported to “Mary, RN”
  - Never found out who “Mary, RN” was
One approach when things went wrong years ago

- Patient discharged from hospital on post-op day 3
- Died 6 weeks later from leukemia
- Physician colleagues/friends reported death to Risk Management
- Legal Counsel & Claims Office were approached with a plan for “making it right”
- All attempts to disclose, apologize, or provide remedy were rejected by University
What about an Extremely Honest “Principled Approach”?  

- Barriers  
- Benefits
Taking a “Principled Approach”

**Barriers**
- Culture
- No institutional support
- Loss of job
- Reputation
- “Shame and blame”
- Loss of control
- Loss of license
- Fear of lawyers, litigation
- **Non-standard process**
- Money

**Benefits**
- Maintain trust
- Learn from mistakes
- Improve patient safety
- Employee morale
- Psychological well-being
- Accountability
- Money
- Less litigation
2005 UIC Board approves “communication-resolution” program

- Comprehensive
- Integration of safety, risk, quality and credentials
- Linkage to claims and legal – deal with the fears
- Longitudinal patient safety education plan
  - UGME
  - GME
  - CME
Need a process

• Reporting
• Investigation
• Initial communication with patient/family
• Identification of preventive measures
• Resolution
• Follow-up and ongoing data collection
• Education of event/improvements
A process supported by best practices - and accreditation standards

- Leadership
- Culture
- Informed consent
- Identification and mitigation of risks/hazards
- Disclosure
- Care for the Caregiver
A Comprehensive Response to Patient Incidents: The Seven Pillars.
McDonald et al *Quality and Safety in Health Care*, Jan 2010

- Reporting
- Investigation
- Communication
- Apology with remediation
- Process and performance improvement
- Data tracking and analysis
- Education – of the entire process
The Seven Pillars: A Patient and Family-Centered Comprehensive Approach to the Prevention and Response to Patient Safety Events
LD.04.04.05

Data Base

Patient Harm?

Yes

Consider “Second Patient” Error Investigation
Hold bills

No

Inappropriate Care?

Yes

Full Disclosure with Rapid Apology and Remedy
RI.01.02.01

No

Unexpected Event reported to Safety/Risk Management

“Near misses”

Process and Performance Improvement

Activation of Crisis Management Team

Yes

RI.01.02.01

Patient Communication Consult Service 24/7 Immediately Available

Yes

Data Base

Patient Harm?

No

RI.01.02.01

Process and Performance Improvement

Activation of Crisis Management Team

Near misses

Yes

Full Disclosure with Rapid Apology and Remedy
RI.01.02.01
Timeline of another case of harm with multiple causes

- Patient with critical cardiac disease 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
Timeline of another case of harm with multiple causes

- 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?
NBC Today Show: November 1, 2011
Fire in the OR: increasing awareness
12-1-2011

Woman's Face Catches On Fire During Routine Surgery

Kim Grice, shown before and after her face caught on fire during surgery Tuesday to remove cysts in her head.
Fire in the OR...what next?

• Report
• Respond
• Resolve
Fire in the OR...what next?

• Communicate openly
• Resolve early
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“Near misses”

Process Improvement

Activation of Crisis Management Team
Power of Reporting
Part of the solution

- Make reporting safe
- Allow confidential reporting
- Provide immediate and ongoing feedback
- Link to quality and process improvements
- Ensure non-retribution
- For resident physicians: focus on fatigue, supervision, hand-offs
- Study it
• Reporting established as an expectation and part of Core Competency assessment
Resident physician occurrence reporting data

Journal of Graduate Medical Education, June 2010
**Event data**

### Anesthesiology Resident Physician event reporting data:

<table>
<thead>
<tr>
<th>Category of occurrence</th>
<th>Number</th>
<th>Lack of adequate supervision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent/Documentation</td>
<td>3</td>
<td>2 of 3</td>
</tr>
<tr>
<td>Disruptive provider</td>
<td>7</td>
<td>0 of 7</td>
</tr>
<tr>
<td>Equipment</td>
<td>7</td>
<td>0 of 7</td>
</tr>
<tr>
<td>Patient fall</td>
<td>2</td>
<td>0 of 2</td>
</tr>
<tr>
<td>Lab specimen mislabeled</td>
<td>2</td>
<td>0 of 2</td>
</tr>
<tr>
<td>Medication issues</td>
<td>19</td>
<td>3 of 19</td>
</tr>
<tr>
<td>OB anesthesia complications</td>
<td>3</td>
<td>0 of 3</td>
</tr>
<tr>
<td>Delay in treatment/service</td>
<td>8</td>
<td>0 of 8</td>
</tr>
<tr>
<td>Unplanned extubation</td>
<td>2</td>
<td>0 of 2</td>
</tr>
<tr>
<td>Patient transport issues</td>
<td>12</td>
<td>0 of 12</td>
</tr>
<tr>
<td>Treatment/procedure complications [intubation, regional block, central line placement]</td>
<td>17</td>
<td>9 of 17</td>
</tr>
<tr>
<td>Resident needlestick</td>
<td>2</td>
<td>0 of 2</td>
</tr>
</tbody>
</table>
Aggregate resident physician occurrence reporting data: > 1,000 in 8Qs
Occurrence reports: if you don’t know about it you can’t fix it
After the report

• Back to the case
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Data Base

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Patient Harm?

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Inappropriate Care?

Full Disclosure with Rapid Apology and Remedy

Unexpected Event reported to Safety/Risk Management

“Near misses”

Process and Performance Improvement

Activation of Crisis Management Team
Investigation

- Value of early root and common cause analysis
- Consider possible active failures
- Consider latent conditions
- Systematic approach to harm and near misses
“Just Culture”

• Seeking balance
• Systems
• Individual/leadership accountability
Back to the case investigation

• What do you want to know?
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**

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**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.

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**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 8 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 servicing 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

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**Patient Take Home Instructions**

Your surgeon used 3M™ DuraPrep™ Surgical Solution, a bacteria-killing skin preparation. It is recommended that this 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 prepped 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 prepped area for at least 40 seconds. Lightly scrub to remove the solution.

If you have questions, call 1-800-228-9507.
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
What about “Universal Protocol”
Could this happen anywhere else?

Cleveland Clinic reports six operating room fires in past year, three patients injured

By Diane Suchetka, The Plain Dealer
May 01, 2010, 6:00AM
What about

- Open Communication
- Early resolution
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Process and Performance Improvement

Activation of Crisis Management Team
The Patient Communication Consult Service

- PCCS – immediately available 24/7
- Current options
- Empowerment
- Use of emotional intelligence
- Expectations
- Physician involvement
- Patient-family involvement
- Collective Accountability Approach
Elements of resolution
Elements of resolution

- Empathy
- Apology
- Accountability
- Future prevention
- Remediation
Elements of resolution/remediation

Patient Safety Compensation Card
The Seven Pillars: A Patient and Family-Centered Comprehensive Approach to the Prevention and Response to Patient Safety Events

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“Near misses”

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Process and Performance Improvement

Activation of Crisis Management Team
Pillar #6 Data
Occurrence reports: if you don’t know about it you can’t fix it
Communication is the key
UHC Derived Safety and Quality Measures

2010 Quality Index Report

Calendar Year

Safety
Core Measures
Readmission
Claims experience

![Graph showing claims experience over time with an intervention point.]
Grant: taking to scale

News Release

FOR IMMEDIATE RELEASE
Friday, June 11, 2010

Contact: HHS Press Office: (202) 690-6343
AHRQ Public Affairs: (301) 427-1855

HHS Announces Patient Safety and Medical Liability Demonstration Projects

Funds Allocated to Develop, Implement, and Evaluate Patient Safety Approaches and Medical Liability Reform Models

Largest federal investment connecting medical liability to quality

Demonstration Grants:

Timothy McDonald, M.D., J.D., University of Illinois at Chicago, IL, $2,998,083
Stanley Davis, M.D., Fairview Health Services, Minneapolis, MN, $2,982,690
Eric Thomas, M.D., M.P.H., University of Texas Health Science Center, Houston, TX, $1,796,575
Ann Hendrich, M.S., R.N., F.A.A.N., Ascension Health System, St. Louis, MO, $2,990,612
Thomas Gallagher, M.D., University of Washington, Seattle, WA, $2,972,209
Judy Kluger, J.D., New York State Unified Court System, New York, NY, $2,999,787
Alice Bonner, M.S., APRN, BC, Massachusetts State Department of Public Health, Boston, MA, $2,912,566
AHRQ/Seven Pillars Project focus

- Patient Safety first
- Improved communication
- Reduce preventable injuries
- Compensate patients/families fairly and timely
- Reduced medical malpractice liability
Lessons learned from Gap Analysis

• Variability - leadership engagement
• “Best” institutions - culture survey for PI
• Informed consent processes – view into culture
• Reporting – excellent measure of shame/blame
• Disclosure – struggling for process
• Care of caregiver – surprise interest
Conclusions
Questions

• Timothy B McDonald
  – tmcd@uic.edu