Human error reduction- How to translate it into better cardiac outcomes

Sol Aronson, Duke University

Today the role of Sol Aronson will be played by Gary Roach, Kaiser San Francisco

Why does it really matter

• Headlines like this

Dead By Mistake In California
State Collects Data; Some Charge It’s Under-Reported

Hearst Newspapers/San Francisco California August 8, 2009

The FOCUS Initiative
Flawless Operative Cardiovascular Unified Systems
Human Error Reduction in Cardiovascular Surgery
Society of Cardiovascular Anesthesiologists Foundation

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Clinical Strategies

SCA and SCAF MISSION
“IMPROVE PATIENT CARE”

• Cardiovascular patients are unsafe due to:
  – Collective lack of knowledge:
    • When none of us know how to treat this disease/event
    • We improve patient safety here through research
  – Individual lack of knowledge:
    • When the collective intelligence knows how to treat, but the individual practitioner is unaware
    • We improve patient safety here through education
Cardiovascular patients are unsafe due to:

- **Human error:**
  - “To err is human”
  - Irreducible rate of occurrence, and not due to lack of knowledge

We must improve patient safety by designing processes to capture and correct error before harm occurs.

“Individuals can and will forever commit errors, but teams have the ability to be flawless.”

– John Nance

### Suggested Reading

- Additionally, to gain a better understanding surrounding the theories related to value-based management, please peruse the following websites:
  - http://www.valuebasedmanagement.net/methods_quinn_competing_values_framework.html
  - http://www.valuebasedmanagement.net/methods_vroom_expectancy_theory.html

### Lessons learned from pediatric cardiac surgery

- Errors exist at all levels of cardiac surgery programs:
  - Hiring procedures
  - Lack of monitoring
  - Lack of complaints procedure
  - Low caseload experience

- Need effective systems of clinical audit
- Need strong and shared vision/ values about QI
  - Create “organizational culture of quality”
  - Strong and effective clinical leadership
  - Strong corporate focus
  - Resource investment
  - Involve patients in their care
  - Credentials do not equal experience: Continue education in quality for all providers

### Bristol & Winnipeg: Two Disasters Across the Pond

- Pediatric cardiac surgical deaths
  - Bristol: 30-35 more deaths than avg. (1984-95)
  - Winnipeg: 12 deaths over 1 year

- Bristol
  - Anesthetist raised concerns in 1988
  - Internal conflicts resulted in Dept of Health involvement
  - Temporary moratorium not until 1995
  - Premise that quality of clinical care cannot be taken for granted in any specialty or location

### Communication: Lack of redundancy

- Event: Duke, February 2003, case of Jessica Santillan
  - 17 year-old Hispanic female with restrictive cardiomyopathy and pulmonary hypertension underwent heart-lung transplantation with ABO incompatibility that was realized at the end of the surgery
  - Underwent immunosuppressive therapy and a second heart-lung transplantation within 2 weeks, but died shortly afterward
Communication: Lack of redundancy

- Event: Children’s Medical Center of Dallas/Baylor, July 2002, case of Jeanella Aranda
  - 1 year-old with liver hamartoma resection with complications that required liver transplantation
  - Partial liver donation came from her father
  - ABO incompatibility was realized 19 days post-op by her mother, who noted the blood type being transfused; the infant died on the following day

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Data collection:

- Both cases
  - Results of the Root Cause Analysis
  - Reported in the lay press (NY Times, US News and World Report)

- Findings of lack of redundant communication
  - Santillan case: Surgeon claimed responsibility, but there were numerous points in organ procurement where blood type information was optional (and missed)
  - Aranda case: Laboratory mix-up confused mother’s and father’s blood types, leading to miscommunication

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Wong et al. 2006

- Prospective anonymous reporting of precursor events in the COR
  - 3 University affiliated teaching facilities
  - Reports could come from any member of the team.
  - 464 cardiac procedures with 1,627 reports of problematic precursor events (990 unique)
  - Mean was 3.5 ± 3.9 events

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Precursor events

- 33.3% prior to incision
- 31.2% while on Bypass
- 15.7% post bypass
- 90% were compensated for
- 30.9% not discussed by the team
- Nurses primary reporters - 28%
- Anesthesiologist reports - 20.4%
- Perfusionist reports - 16.3
- Surgeons, residents, PA/NP - reports 35.3

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Wong et al. studies, 2006-2009

- Three studies of “precursor events”-- events that precede and are requisite for adverse events
- Precursor events occurred more often in cases with death or near miss outcomes than with no adverse outcomes
- A new surgical center had more precursor events than established centers but quickly reduced them

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### Major vs. Minor Events

<table>
<thead>
<tr>
<th>Minor</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing ID stickers</td>
<td>Perforating IVC with a chest tube</td>
</tr>
<tr>
<td>Contaminated 5G</td>
<td>CPB pump failure</td>
</tr>
<tr>
<td>Incorrect booking</td>
<td>Making vein graft too short</td>
</tr>
<tr>
<td>Incorrect count</td>
<td>Revising anastomosis secondary to bleeding</td>
</tr>
<tr>
<td>Dropping a retractor</td>
<td>Clot formation in heart while on pump</td>
</tr>
<tr>
<td>Bleeding from leg</td>
<td>Inotrope running out unnoticed</td>
</tr>
<tr>
<td>Asking for the wrong valve</td>
<td>Giving epinephrine instead of lidocaine bolus</td>
</tr>
<tr>
<td>And many others...</td>
<td></td>
</tr>
</tbody>
</table>


### Wong et al. 2007

- Same data as 2006
- Relationship of precursor events (PE) to adverse outcomes
- Cases with outcomes of death or near miss complications had more PE’s
- Distribution of PE’s:
  - 36% management
  - 29% technical
  - 23% environment-related
- “Most affected person” in PE’s
  - 43% Surgeon
  - 28% Anesthesiologist
  - 21% Nurse
  - 9% Perfusionist

Wong, Surgery; 141: 715.

### Wong et al. 2009

- Same data as 2006 study
- Across the first 101 cases at a new surgical center, precursor events were reduced from 9.4 to 2
- Stable PE’s at 2 established comparisons
- Decreased environment-related, communication and management PE’s
- Global reductions of PE’s for all team members

Wong, Surgery; 145: 131.

### Human Factors Analysis & Classification System (HFACS) for Cardiac Surgery

- Showed applicability of a human factors model (HFACS) for error detection in cardiac surgery
- HFACS model originally developed for use in aviation
- Structured interviews with 68 clinicians
- Unsafe acts (skill-based errors, routine violations, etc.) in cardiac surgery associated with following factors:
  - Organizational influences (climate, resource management, etc.)
  - Unsafe supervision (inadequate, etc.)
  - Preconditions to unsafe acts (environment, teamwork, etc.)


### Surgical Flow Disruptions and Errors

- Events
  - Surgical flow disruptions: System design factors
  - Surgical errors: Technical events in which intended outcome was not achieved
- Data collection:
  - Convenience sample of 31 cardiac surgical operations
  - Observed by one individual who stood at the patient’s head


### Surgical Flow Disruptions and Errors

- Identified surgical flow disruptions
  - Teamwork (52%)
  - Extraneous interruptions (17%)
  - Supervisory/training related issues (12%)
  - Equipment and technology (11%)
  - Resource-based issues (8%)
- Surgical errors increase with surgical flow disruptions (r=0.47*)
- Teamwork/communication
  - Only significant predictor of number of surgical errors (standardized Beta = 0.7 with p < 0.000)
  - Follow-up data analysis conducted on disruptions related to teamwork/communication

THE FOCUS INITIATIVE

**Goal:** To improve patient safety by human error reduction

The FOCUS initiative is a cooperative effort designed to raise the bar for patient safety through systems analysis and human factors engineering.

**THE FOCUS RFP PROCESS**

- Request for Proposals elicited from 60 institutions
- Six finalists selected
- "we seek a team of consultants with experience in the field of human factors, observational method and error analysis . . . To reduce human error in cardiovascular care"
  - SCA FOCUS RFP

**THE FOCUS PROJECT COLLABORATORS**

- Johns Hopkins chosen (team led by Peter Pronovost)

"Nearly a decade after the publication of this landmark report ("To Err is Human"), not a single healthcare organization can provide a credible answer to the question: ‘Are we safer?’"

Peter Pronovost, MD, Ph.D.
Quality and Safety Research Group
Johns Hopkins University

**Works Consulted**


**SYSTEM ERRORS**

- **Adverse outcomes**
  - rarely have a single cause
  - are the result of multiple system errors that “line up” to create a system failure
- **A human factors engineering “lens”** is needed to find and analyze these ailments in the system
- **Correction of system errors** must focus on the system processes, not the individuals

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**SYSTEM FAILURE**

- **Multiple Errors Line Up**
  - Communication between resident and nurse
  - Inadequate training and supervision
  - Catheter pulled with Patient sitting
  - Patient suffers venous air embolism
  - Lack of protocol For catheter removal

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**Worst Aviation Disaster Ever, Canary Islands 1977**

- **543 Dead**

  - What if?
  - Several seemingly small events occurred which, had any of them not happened, the tragedy would have been prevented:
    - If the bombing more than 100 miles away at another airport had not happened or if the chasing flight of another bombing threat had been crashed, these planes never would have been at Los Rodeos.
    - If the Pan Am hadn’t been allowed to remain in a holding pattern, it would not have been at Los Rodeos.
    - If the KLM hadn’t been delayed in its departure from the visibility would have been better.
    - If the Pan Am had been able to make it around the KLM when it was refueling, it wouldn’t have been there when the KLM was taking off.
    - If the Pan Am had been delayed by 3 minutes, it wouldn’t have been delayed in collision.
    - If the Pan Am and ATC hadn’t been speaking at the same time, the KLM would have had the instruction to hold for clearance.
    - If the visibility had been even slightly better, both aircraft may have had enough time to avoid one another.
    - Still, the KLM almost missed the Pan Am.

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**Is Aviation the appropriate model?**

- CRM Introduced

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**Hull Loss Accidents**

- All Aircraft — Worldwide Commercial Jet Fleet

- CRM Introduced

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**Elements of the Surgical Safety Checklist**


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**Selected Process Measures before and after Checklist Implementation, According to Site**

OVERALL APPROACH

- Develop partnerships between SCA, Hopkins, other societies (STS, AORN, ASECT to date), organizations, and hospitals to create learning communities
- Identify hazards
  - Literature review
  - Error report data
  - In depth observations at selected sites
- Design, implement and evaluate safety improvement efforts
- Disseminate broadly to all cardiac operating rooms

LEARNING FROM ERROR REPORTING

- National Reporting and Learning System (NRLS)
  - Web-based error reporting system in the United Kingdom
  - Incident reports on a diverse and comprehensive range of medical errors
  - Currently over 1.5 million reports in the national database
    - The largest known error reporting system in the world.
- Reviewed Errors in Cardiac Surgery
  - 4,828 errors designated
  - 999 identified as occurring in the operating room

SUMMARY OF LITERATURE REVIEW

- Errors common and often lethal
- Distractions and disruptions limited ability to recover and increase risk for harm
- Multiple types of hazards exists
  - Organizational
  - Cultural and group dynamics
  - Interpersonal dynamics
  - Training and supervision
  - Equipment
- High profile cases
- Generally used a single lens

PROACTIVE RISK ASSESSMENT – LENS PROJECT

- Apply variety of “lenses” to identify hazards in cardiac surgery
- Design, implement and evaluate interventions to mitigate those hazards
- Broadly implement self assessment and risk reduction tools
- Apply methodology to other areas
**DOMAINS OF LENS PROJECT**

- Organizational Sociology
- Human Factors Engineering
- Applied Organizational Psychology
- Industrial Psychology
- Cardiovascular Anesthesia

**RESEARCH STAGES of FOCUS project**

- **Stage 1**: Observe cardiac procedures at 3-5 cardiac anesthesia sites
- **Stage 2**: Based on analysis of observational studies, select hazards for interventions
- **Stage 3**: Design, implement and evaluate safety program at beta sites
- **Stage 4**: Broadly disseminate self assessment tool and safety program

**EARLY FINDINGS**

- Common concerns across cardiac operating rooms and hospitals
- Identifying good practices
- Many opportunities to improve care
- Opportunities for each lens

**OPPORTUNITIES FOR IMPROVEMENT APPLYING SCIENCE TO SAFETY**

- Standardize routine processes
  - Prep
  - Line placement
  - Intra-operative transitions
- Structure communication
- Provide training on medical devices
- Ensure correct interpretation of local policies
- Address distractions
- Schedule safely
- Use horizontal space efficiently
- Optimize utilization of technology available for use (e.g. Smart IV pumps)

**NEXT STEPS**

- Complete site visits and analysis of qualitative data
  - Data reviewed 8/13/09
  - Numerous problems noted
    - Lack of “huddles” and debriefing (1/20)
    - Numerous communication issues
    - Chlorhexidine vs. povidone (or even alcohol)
    - Distractions/diversions
    - Breaks in sterile technique
    - Ergonomic issues
  - Next step is to categorize and develop survey instruments
- Develop Risk Assessment tool
- Based on evidence, prioritize tools to be developed & processes of care to be changed
- Conduct focus groups of experts to decide where to start
  - Fall “Summitt”
- Design interventions, pilot test, & revise for ease of implementation and management for all
- Link measurable processes of care and clinical outcomes
**FORMALIZE PARTICIPATION**

- Make FOCUS a collaborative project
- Endorse FOCUS formally

**INVITE MEMBERS TO PARTICIPATE**

- Public Relations, Data Analysis, Publication

**CONTRIBUTE; IDENTIFY SOURCES OF FUNDING**

- FOCUS will cost >$1.5M over 3-5 years from SCA alone
- We need other intellectual and financial contributions

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**Society of Cardiovascular Anesthesiologists**

- Established in 1978
- ~7000 members worldwide
- Dedicated to:
  - Excellence in patient care through education and research in perioperative care for patients undergoing cardiothoracic and vascular procedures.

**SCA Foundation**

- Established in 2007 to enhance funding for the missions of the Society
- In Nov 2007, assumed oversight and financial responsibility for FOCUS
- JHU contract signed in 2008; initial observations complete

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**CONTACT US**

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Thank you for your attention.