QUALITY SAFETY
RESEARCH GROUP

The FOCUS Initiative
Flawless Operative Cardiovascular Unified Systems
Human Error Reduction in Cardiovascular Surgery
The Society of Cardiovascular Anesthesiologists Foundation
Cardiovascular patients are at risk for injury or error due to:

1. **Collective lack of knowledge:**
   - When none of us know how to treat a disease or event, we improve patient safety through *research*.

2. **Individual lack of knowledge:**
   - When the collective intelligence knows how to treat, but the individual practitioner is unaware, we improve patient safety through *education*.
Cardiovascular patients are at risk due to:

3. **Human error:**
   - “To err is human”
   - Varying rates of occurrence, not due to lack of knowledge or dedication
   - Must design 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
Cardiovascular patients are at risk due to:

4. **Insufficient systematic study:**
   - Traditional emphasis on QI
   - Influence of institutional politics
   - Clinician discipline or dismissal
   - Few multi-site studies
   - Little error or near-miss reporting

Spiess, Wahr, Nussmeier, 2009
Resident told to pull central catheter: Patient sitting up

Lack of communication between resident and nurse

Lack of protocol for catheter removal

Inadequate training and supervision

OUTCOME: Patient suffers air embolism

System Factors
Impact Safety

Adapted from Vincent, *Brit Med J*
Systems Errors

- **Adverse outcomes**
  - rarely have a single cause
  - are the result of multiple system errors that “line up” eventually to create a system failure

- **Correction of system errors** must focus on the system processes, not the individuals

- **A human factors engineering** “lens” is needed to find and analyze these ailments in the system
FOCUS INITIATIVE

- **Flawless O**perate **C**ardiovascular **U**nified **S**ystems
- Improve patient safety by *human error reduction*
- The FOCUS initiative is a *complementary and cooperative* effort designed to raise the bar for patient safety through human factors engineering
History and Development

• 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
FOCUS Collaboration

• Quality and Safety Research Group (Johns Hopkins University) chosen
• Team led by Peter Pronovost
  • “6 years 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
Proactive Risk Assessment
LENS Project

• Apply a 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
A set of “lenses” are needed to identify and rectify latent system hazards.
Overall Approach

- **Develop partnerships** between SCA, Johns Hopkins, other societies, organizations, and hospitals to create learning communities

- **Identify hazards**
  - Literature review
  - Error report data
  - In depth observations at selected sites
QSRG Scientific Approach

• Identify hazards
  – Literature review
  – Error report data (National Learning & Reporting System)
  – In depth observations at selected sites

• Design, implement and evaluate safety improvement efforts

• Disseminate broadly to all cardiac anesthesiologists
Research Stages

- **Stage 1:** Review literature re cardiac surgery errors
  Review Error Reporting Data from the UK
  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
Summary of Literature Review

- Errors common and often lethal
- Distractions and disruptions limiting ability to recover and increase risk for harm
- Multiple types of hazards exist
  - Organizational
  - Cultural and group dynamics
  - Interpersonal dynamics
  - Training and supervision
  - Equipment
- High profile cases
- Generally used a single lens, or viewpoint, to study
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
Learning from Observations

- Five observational sites selected
  - Diverse geography, setting (academic, private), size
  - Trained observers used the “lenses” to observe cardiac surgery over several days at each site
  - Surveys of organizational and safety culture performed to understand the systemic influences
A set of “lenses” are needed to identify and rectify latent system hazards

Martinez et al. Anes Analg 2010.110;307
Summary of Observations

- Hundreds of hazards were observed – over 800 in fact!
  - Communication
  - Medical devices
  - Inappropriate application of known best practices (infection prevention)
  - Treatments and procedures
Task Hazards: Workarounds

Workarounds to compensate for poor interface design or functionality
Tools to Improve

• A series of interventional tools have been developed by FOCUS and QSRG to address the hazards seen.
  – Preop Briefing and Debriefing Tool
  – Learning from Defects
  – Handoff Tool

• AHRQ has funded testing of these tools in the Cardiac Surgery Translational Study (CSTS).

• http://www.safercare.net/CSTS/Home.html
Not Yet!
Change in FOCUS

- Develop implementation partnerships between SCA, Hopkins, other cardiac operative societies, organizations, and hospitals to create learning communities
  - Surgeons
  - Perfusionists
  - Anesthesiologists
  - Perioperative nurses
  - Johns Hopkins University

FOCUS was founded & funded by the SCA Foundation
We have some plans!
Society of Cardiovascular Anesthesiologists

- Established 1970
- 4,000 active members internationally
- **Mission:** Research, Education, Patient Care
- FOCUS began in 2004 and has been funded primarily through the philanthropic arm of the SCA, the SCA Foundation
Contact Us

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2209 Dickens Road
Richmond, VA 23230

804-565-6324

foundation@scahq.org
www.scahqgive.org
Received the wrong heart and lungs, then died

17-year-old Jésica Santillán died 2 weeks after receiving the heart and lungs of a patient whose blood type did not match hers. Doctors at the Duke University Medical Center failed to check the compatibility before surgery began. After a rare second transplant operation to attempt to rectify the error, she suffered brain damage and complications that subsequently hastened her death.

Santillán, a Mexican immigrant, had come to the United States three years before to seek medical treatment for a life-threatening heart condition. The heart-lung transplant that surgeons at Duke University Hospital in Durham, N.C., hoped would improve this condition instead put her in greater danger; Santillán, who had type-O blood, had received the organs from a type-A donor.

The error sent the patient into a comalike state, and she died shortly after an attempt to switch the organs back out for compatible ones failed. The hospital blamed human error for the death, along with a lack of safeguards to ensure a compatible transplant. According to reports, Duke reached an undisclosed settlement with the family. Neither the hospital nor the family is allowed to comment on the case.

An open heart invasive procedure... on the wrong patient

Joan Morris (a pseudonym) is a 67-year-old woman admitted to a teaching hospital for cerebral angiography. The day after that procedure, she mistakenly underwent an invasive cardiac electrophysiology study. After angiography, the patient was transferred to another floor rather than returning to her original bed. Discharge was planned for the following day. The next morning, however, the patient was taken for a open heart procedure. The patient had been on the operating table for an hour. Doctors had made an incision in her groin, punctured an artery, threaded in a tube and snaked it up into her heart (a procedure with risks of bleeding, infection, heart attack and stroke). That was when the phone rang and a doctor from another department asked “what are you doing with my patient?” There was nothing wrong with her heart. The cardiologist working on the woman checked her chart, and saw that he was making an awful mistake. The study was aborted, and she was returned to her room in stable condition.

Not so funny: wrong artery bypassed

Two months after a double bypass heart operation that was supposed to save his life, comedian and former Saturday Night Live cast member Dana Carvey got some disheartening news: the cardiac surgeon had bypassed the wrong artery. It took another emergency operation to clear the blockage that was threatening to kill the 45-year-old funnyman and father of two young kids. Responding to a $7.5 million lawsuit Carvey brought against him, the surgeon said he’d made an honest mistake because Carvey’s artery was unusually situated in his heart. But Carvey didn’t see it that way: “It’s like removing the wrong kidney. It’s that big a mistake,” the entertainer told People magazine.
Table 1. Elements of the Surgical Safety Checklist,*

<table>
<thead>
<tr>
<th>Sign in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before induction of anesthesia, members of the team (at least the nurse and an anesthesia professional) orally confirm that:</td>
</tr>
<tr>
<td>The patient has verified his or her identity, the surgical site and procedure, and consent</td>
</tr>
<tr>
<td>The surgical site is marked or site marking is not applicable</td>
</tr>
<tr>
<td>The pulse oximeter is on the patient and functioning</td>
</tr>
<tr>
<td>All members of the team are aware of whether the patient has a known allergy</td>
</tr>
<tr>
<td>The patient’s airway and risk of aspiration have been evaluated and appropriate equipment and assistance are available</td>
</tr>
<tr>
<td>If there is a risk of blood loss of at least 500 ml (or 7 ml/kg of body weight, in children), appropriate access and fluids are available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time out</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before skin incision, the entire team (nurses, surgeons, anesthesia professionals, and any others participating in the care of the patient) orally:</td>
</tr>
<tr>
<td>Confirms that all team members have been introduced by name and role</td>
</tr>
<tr>
<td>Confirms the patient’s identity, surgical site, and procedure</td>
</tr>
<tr>
<td>Reviews the anticipated critical events</td>
</tr>
<tr>
<td>Surgeon reviews critical and unexpected steps, operative duration, and anticipated blood loss</td>
</tr>
<tr>
<td>Anesthesia staff review concerns specific to the patient</td>
</tr>
<tr>
<td>Nursing staff review confirmation of sterility, equipment availability, and other concerns</td>
</tr>
<tr>
<td>Confirms that prophylactic antibiotics have been administered ≤60 min before incision is made or that antibiotics are not indicated</td>
</tr>
<tr>
<td>Confirms that all essential imaging results for the correct patient are displayed in the operating room</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sign out</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before the patient leaves the operating room:</td>
</tr>
<tr>
<td>Nurse reviews items aloud with the team</td>
</tr>
<tr>
<td>Name of the procedure as recorded</td>
</tr>
<tr>
<td>That the needle, sponge, and instrument counts are complete (or not applicable)</td>
</tr>
<tr>
<td>That the specimen (if any) is correctly labeled, including with the patient’s name</td>
</tr>
<tr>
<td>Whether there are any issues with equipment to be addressed</td>
</tr>
<tr>
<td>The surgeon, nurse, and anesthesia professional review aloud the key concerns for the recovery and care of the patient</td>
</tr>
</tbody>
</table>

* The checklist is based on the first edition of the WHO Guidelines for Safe Surgery. For the complete checklist, see the Supplementary Appendix.
Statistically significant correlations


*Arrows represent relationships of $r^2 \geq 0.10$, $P \leq 0.01$
• Catheter-related bloodstream infections are associated with significant morbidity
• In Michigan, a statewide initiative to reduce catheter-related bloodstream infections in intensive care units (ICUs) was implemented
• This simple intervention included washing hands, using full-barrier precautions with central-line placement, cleaning the skin with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters
• The median rate of infection per 1000 catheter-days decreased from 2.7 at baseline to 0 throughout all periods after implementation of the study intervention
An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

N Engl J Med
Volume 355(26):2725-2732
December 28, 2006
Original Article

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Study Overview

• Catheter-related bloodstream infections are associated with significant morbidity.

• In Michigan, a statewide initiative to reduce catheter-related bloodstream infections in intensive care units (ICUs) was implemented.

• This simple intervention included washing hands, using full-barrier precautions with central-line placement, cleaning the skin with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters.
### Table 5. Outcomes before and after Checklist Implementation, According to Site.\(^\text{*}\)

<table>
<thead>
<tr>
<th>Site No.</th>
<th>No. of Patients Enrolled</th>
<th>Surgical-Site Infection</th>
<th>Unplanned Return to the Operating Room</th>
<th>Pneumonia</th>
<th>Death</th>
<th>Any Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
<td>Before</td>
<td>After</td>
<td>Before</td>
<td>After</td>
</tr>
<tr>
<td>1</td>
<td>524</td>
<td>598</td>
<td>4.0</td>
<td>2.0</td>
<td>4.6</td>
<td>1.8</td>
</tr>
<tr>
<td>2</td>
<td>357</td>
<td>351</td>
<td>2.0</td>
<td>1.7</td>
<td>0.6</td>
<td>1.1</td>
</tr>
<tr>
<td>3</td>
<td>497</td>
<td>486</td>
<td>5.8</td>
<td>4.3</td>
<td>4.6</td>
<td>2.7</td>
</tr>
<tr>
<td>4</td>
<td>520</td>
<td>545</td>
<td>3.1</td>
<td>2.6</td>
<td>2.5</td>
<td>2.2</td>
</tr>
<tr>
<td>5</td>
<td>370</td>
<td>330</td>
<td>20.5</td>
<td>3.6</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>6</td>
<td>496</td>
<td>476</td>
<td>4.0</td>
<td>4.0</td>
<td>3.0</td>
<td>3.2</td>
</tr>
<tr>
<td>7</td>
<td>525</td>
<td>585</td>
<td>9.5</td>
<td>5.8</td>
<td>1.3</td>
<td>0.2</td>
</tr>
<tr>
<td>8</td>
<td>444</td>
<td>584</td>
<td>4.1</td>
<td>2.4</td>
<td>0.5</td>
<td>1.2</td>
</tr>
<tr>
<td>Total</td>
<td>3733</td>
<td>3955</td>
<td><strong>6.2</strong></td>
<td><strong>3.4</strong></td>
<td><strong>2.4</strong></td>
<td><strong>1.8</strong></td>
</tr>
<tr>
<td>P value</td>
<td>&lt;0.001</td>
<td>0.047</td>
<td>0.46</td>
<td>0.003</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

\(^\text{*}\) The most common complications occurring during the first 30 days of hospitalization after the operation are listed. Bold type indicates values that were significantly different (at P<0.05) before and after checklist implementation, on the basis of P values calculated by means of the chi-square test or Fisher’s exact test. P values are shown for the comparison of the total value after checklist implementation as compared with the total value before implementation.