Establishing a Safety Culture in the Cath Lab

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Case Example 1

• A 65 yo woman with HTN, DM, CRI presents for a complex planned PCI. The labs at her diagnostic angiogram 3 weeks prior showed a Cre of 1.5, and normal electrolytes.

• Her labs are drawn, but come back partially hemolyzed. They are redrawn, but it will take up to an hour before they return a result.
Case Example 1

- The physician is told labs were drawn, and proceeds with PCI. After the first balloon inflation, the patient develops ventricular tachycardia and fibrillation, refractory to CPR and defibrillation.

- Labs drawn that morning subsequently show a Cre of 1.8, and K of 6.7 mEq/L.
Case Example 2

• A 60 yo gentleman with stable angina is found to have an intermediate coronary stenosis in the LAD. Heparin is ordered, and a pressure wire is placed across the lesion.

• The patient begins to experience chest pain, and angiography shows thrombosis of the entire LAD requiring thrombus aspiration and multiple stents.

• An ACT was checked and was <150 sec. Heparin was never given, because the (new) nurse says she never heard the order.
Case Example 3

- A 50 yo ICU patient is ordered for unfractionated heparin infusion for DVT.
- Heparin ordered/delivered as 10,000 units/ml concentration
- The pharmacist dispenses and ICU nurse administers heparin at 10,000 units per hour for 6 hours.
“To Err is Human”

- Institute of Medicine Report, 1999
- 44,000 – 98,000 deaths annually from adverse events
- Equivalent to 1 airplane crash each day.
Ian D Coombes, Danielle A Stowasser, Judith A Coombes and Charles Mitchell
 Adapted from Reason’s model of accident causation
What makes for a successful cath lab team?

Effective teams possess the following features:

- a common purpose
- measurable goals
- effective leadership and conflict resolution
- good communication
- good cohesion and mutual respect
- situation monitoring
- self-monitoring
- flexibility
Barriers to teamwork

- Conflict
- Distractions
- Fatigue
- Workload
- Lack of role clarity
- Medical Hierarchy
- Lack of information sharing
- Inconsistent team membership
Importance of Communication

- Joint Commission data continues to demonstrate the importance of communication in patient safety
  - 1995 - 2005: Ineffective communication identified as root cause for nearly 66 percent of all reported sentinel events*
  - 2010 - 2013: Ineffective communication among top 3 root causes of sentinel events reported**

** (JC Sentinel Event Data (Root Causes by Event Type) 2004-2012)
TeamSTEPPS® 2.0

Communication

- **Complete**
  - Communicate all relevant information

- **Clear**
  - Convey information that is plainly understood

- **Brief**
  - Communicate the information in a concise manner

- **Timely**
  - Offer and request information in an appropriate timeframe
  - Validate or acknowledge information
A number of techniques have been developed to promote communication in health care including:

- SBAR
- call-out
- closed-loop
- handoff
- debriefings
### Real-life Cath Lab Communication

#### Medication readback rate

<table>
<thead>
<tr>
<th>Interval</th>
<th>Complete</th>
<th>Partial</th>
<th>Acknowledgement</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interval #1</td>
<td>38%</td>
<td>21%</td>
<td>21%</td>
<td>20%</td>
</tr>
<tr>
<td>Interval #2</td>
<td>62%</td>
<td>23%</td>
<td>6%</td>
<td>9%</td>
</tr>
<tr>
<td>Interval #3</td>
<td>69%</td>
<td>12%</td>
<td>11%</td>
<td>8%</td>
</tr>
</tbody>
</table>

#### Equipment readback rate

<table>
<thead>
<tr>
<th>Interval</th>
<th>Complete</th>
<th>Partial</th>
<th>Acknowledgement</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interval #1</td>
<td>58%</td>
<td>7%</td>
<td>11%</td>
<td>24%</td>
</tr>
<tr>
<td>Interval #2</td>
<td>49%</td>
<td>12%</td>
<td>12%</td>
<td>25%</td>
</tr>
<tr>
<td>Interval #3</td>
<td>59%</td>
<td>2%</td>
<td>10%</td>
<td>27%</td>
</tr>
</tbody>
</table>

Observational trial 2015-2017 at Christiana Care Health

Tested readback aspect of closed-loop across 3 intervals:

- #1) Staff not informed of nature of study
- #2) 8 months after education/retraining
- #3) 8 months after Rapid Improvement Six Sigma initiative
Sample Errors in Communication

<table>
<thead>
<tr>
<th>Case</th>
<th>Physician Order</th>
<th>Readback</th>
<th>Executed order</th>
<th>Sequellae</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>92</td>
<td>100mcg nicardipine, 100mcg nitroglycerine</td>
<td>None</td>
<td>2.5mg verapamil, 100mcg nitroglycerine</td>
<td>Incorrect drug given</td>
</tr>
<tr>
<td>109</td>
<td>“Turn off the heparin”</td>
<td>None</td>
<td>Heparin infusion increased to 25,000 units/hour</td>
<td>Incorrect drug given for 9 minutes (“Turn up heparin” heard)</td>
</tr>
<tr>
<td>121</td>
<td>“Heparin 8000 units IV”</td>
<td>None</td>
<td>Nothing done</td>
<td>Omission discovered 22 minutes later</td>
</tr>
<tr>
<td>144</td>
<td>“Fentanyl 50 mcg &amp; midazolam 0.5 mg IV”</td>
<td>None</td>
<td>Fentanyl 50mcg &amp; midazolam 1 mg</td>
<td>Incorrect drug given</td>
</tr>
<tr>
<td></td>
<td>Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>3.0mm x 16 mm drug eluting stent</td>
<td>None</td>
<td>3.0 x 20 mm drug eluting stent</td>
<td>Incorrect stent inserted into patient</td>
</tr>
<tr>
<td>46</td>
<td>3.0 x 11 mm drug eluting stent</td>
<td>Acknowledgement only</td>
<td>2.5 x 12 mm drug eluting stent</td>
<td>Incorrect stent inserted into patient</td>
</tr>
<tr>
<td>98</td>
<td>3DRC 6F diagnostic catheter</td>
<td>Partial (“3DRC”)</td>
<td>3DRC 6F guide catheter</td>
<td>Incorrect equipment used</td>
</tr>
<tr>
<td>116</td>
<td>6F slender sheath</td>
<td>None</td>
<td>5F slender sheath</td>
<td>Incorrect equipment used</td>
</tr>
<tr>
<td>147</td>
<td>2.5 x 28 mm drug eluting stent</td>
<td>Partial</td>
<td>2.75 x 28 mm drug eluting stent</td>
<td>Incorrect stent inserted into patient</td>
</tr>
<tr>
<td>149</td>
<td>300cm guidewire.</td>
<td>Complete but incorrect (“200 cm guidewire”)</td>
<td>200 cm guidewire</td>
<td>Incorrect equipment used. Incorrect readback was not appreciated</td>
</tr>
<tr>
<td></td>
<td>Other (not medication or equipment)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>“Charge defibrillator for shock” (patient in ventricular tachycardia)</td>
<td>None</td>
<td>Nothing</td>
<td>Second request 15-25 seconds later acted upon</td>
</tr>
<tr>
<td>74</td>
<td>“Call the cardiac surgeons STAT” for an emergency</td>
<td>None</td>
<td>Nothing</td>
<td>Second request 22 minutes later acted upon</td>
</tr>
</tbody>
</table>
Real-life Cath Lab Communication

- Readback rates declined with more acute cases (PCI, STEMI)
- Readback rates declined with more people in the control room

Doorey, CCI 2019
“Dr.” William Hamman

• "This is Your Captain Speaking: What can we learn about patient safety from the airlines?"

The typical pharmacy error rate is 4-8%. Would you fly an airline with a 99.9% success rate?
Eastern Air Lines Flight 401

- Broken landing gear indicator light
- Captain and 2 copilots discuss problem, get distracted
- Accidentally disengage autopilot
- Gradual loss of altitude
- Crash kills 101

Someone always has to be flying the plane. Watch the pressure, the respiration, and ECG!
Roles/Positions in the Cath Lab

- Recorder
- Moderate Sedation
- Circulator
- Scrub

- Instrument approach in dense fog to Charlotte.
- Plane crashed 3 miles short of the runway without evidence of malfunction.
- “Controlled flight in to terrain”
- Killed 72 out of 82 on board
- NTSB Review of cockpit voice recorder found that the flight crew engaged in unnecessary and "nonpertinent" conversation during the approach phase of the flight, discussing subjects "ranging from politics to used cars". Both pilots expressed “strong views” and “mild aggravation” about the subjects.

Everyone needs to be focused during critical phases!
The Sterile Cockpit Rule

• FAA regulation bans non essential communication/activities during critical phases of takeoff, landing, taxiing, or anytime below 10k ft.

• What are the critical portions of your procedures?
  • Timeout?
  • TAVR deployment?
  • Stenting?

MUSIC IN THE CATH LAB?
WWW.ACP-ONLINE.ORG/BLOG
Helios 522 - Checklists

- Crew of prior flight note frozen door seal, noises from door
- Ground engineer performs pressurization check, changes system to ‘manual’ mode
- Flight crew overlook this change on 3 checklists
- Loss of pressurization as airplane climbs
- Crew disable by hypoxia
- Crash kills 121

Checklists and Time outs are Important!
Ensuring Correct Procedures
Universal Protocol “Time - Out”

1. Correct patient identity (2 identifiers)
2. Correct procedure to be performed
3. Correct site/side
4. Correct consent form
5. Correct patient position
6. Procedure site marked/visible after draping
7. Correct imaging labeled and displayed
8. Correct implant available
9. Antibiotic prophylaxis given
10. Appropriate DVT prophylaxis
11. Blood availability
12. Special equipment available
13. Allergies confirmed

Abbreviated
TIME OUT

1. Correct patient identity (2 identifiers)
2. Correct procedure to be performed
3. Correct site/side
4. Correct consent form
5. Correct imaging (as applicable)
6. Allergies confirmed

DO WE ALL AGREE?

*SITE MAY NOT BE MARKED IF CONSENT OBTAINED BY PROVIDER AND PROVIDER DOES NOT LEAVE PRIOR TO PERFORMING PROCEDURE
Cath Lab Timeout:
Most important components

• Patient identification, consent, procedure confirmed
• Allergies (esp. contrast), and premeds
• Equipment needed available
• Access site planned
• Patient recent clinical status / potential complications reviewed (EF, CHF, shock)
• Medications stopped or proloaded appropriately
• Labs reviewed – K+, Creatinine
• Contrast limit (1x GFR goal, 3x GFR limit)
• Bleeding risk assessment
A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

Alex B. Haynes, M.D., M.P.H., Thomas G. Weiser, M.D., M.P.H.,
William R. Berry, M.D., M.P.H., Stuart R. Lipsitz, Sc.D.,
Abdel-Hadi S. Breizat, M.D., Ph.D., E. Patchen Dellinger, M.D.,
Teodoro Herbosa, M.D., Sudhir Joseph, M.S., Pascience L. Kibatala, M.D.,
Marie Carmela M. Lapitan, M.D., Alan F. Merry, M.B., Ch.B., F.A.N.Z.C.A., F.R.C.A.,
Krishna Moorthy, M.D., F.R.C.S., Richard K. Reznick, M.D., M.Ed., Bryce Taylor, M.D.,
and Atul A. Gawande, M.D., M.P.H., for the Safe Surgery Saves Lives Study Group*

RESULTS

The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward (P=0.003). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist (P<0.001).
Ad Hoc PCI/Stent Intra-procedural Checklist Questions

- Informed consent
- Lesion significance
- Appropriate use criteria classification/score assessment
- High-risk anatomy assessment
- Consider pros/cons of alternative options (medical/surgical therapy)
- Proper equipment available/appropriate facility and interventionalist

- Excess radiation (total air kerma at the reference point > 5 Gy)/excess contrast (> 3.7 x eGFR) risk assessment
- Absence of peri-procedural complications/hemodynamics optimized
- No operator/patient fatigue
- Adequate pretreatment with aspirin/P2Y12/statin
- Prolonged DAPT issues/DES vs BMS assessment
- No emergent or urgent cases impacted
2nd Time out for PCI

- **A** - Anticoagulation, Antiplatelet
  - Heparin or Bivalirudin?
  - Clopidogrel, Ticagrelor, Prasugrel, or GPI

- **E** – Equipment, Environment

- **I** – Indications
  - ACS? Stable Angina? Ischemia?

- **O** – Outcomes
  - PCI or CABG? BMS or DES?

- **U** – Unexpected complications
  - Dissection, Vessel Closure, Shock
Closing Timeout

- Is the procedure really done?
- All of the vessels/grafts imaged?
- Have we left anything behind?
- Access site management?
- What bed should the patient go to?
- Have we done everything we can to maximize the outcome?
Debrief Checklist

People don't learn from experience. They learn from reflecting on their experience.
Tenerife, 1977

- Latent factors: fog, runway design, communication
- Airlines diverted to small regional airport after closing of main airport due to threat
- KLM pilot frustrated by delay, starts to takeoff without ATC clearance
- Stops once with copilot’s warning. Starts again after unclear ATC message
- Crash kills 583 in two 747s

Don’t be afraid to speak up!
• Everyone on the team is responsible for patient safety.
• Anyone who sees anything should have the authority to say “STOP” if a potential safety issue is seen.
• Examples:
  ▪ Break in sterility
  ▪ Wet floor
  ▪ Broken ventilator
Two-Challenge Rule

Invoked when an initial assertion is ignored...
- It is your **responsibility** to assertively voice your concern at least two times to ensure that it has been heard
- The member being challenged must acknowledge
- If the outcome is still not acceptable
  - Take a stronger course of action
  - Use supervisor or chain of command
Conflict Resolution
DESC Script

A constructive approach for managing and resolving conflict

D—Describe the specific situation
E—Express your concerns about the action
S—Suggest other alternatives
C—Consequences should be stated

Ultimately, consensus shall be reached.

Let’s “DESC-It!”

- Have timely discussion
- Frame problem in terms of your own experience
- Use "I" statements to minimize defensiveness
- Avoid blaming statements
- Critique is not criticism
- Focus on what is right, not who is right
CUS – “Code words”

Please Use CUS Words
but only when appropriate!

I am Concerned!
I am Uncomfortable!
This is a Safety Issue

Team STEPPS
Mutual Support

Team Strategies & Tools to Enhance Performance & Patient Safety

- Minneapolis to International Falls, MN
- Aggressive landing approach to avoid icing led to crash in to trees
- Kills all 16 passengers and 2 pilots
- Captain known for failing multiple proficiency checks, being intimidating with colleagues, punching a co-pilot in anger, and being angry with company. Was telling copilot how to do routine tasks.
- NTSB: “captain’s actions led to a breakdown in crew coordination and the loss of altitude awareness by the flight crew”

Problem operators need corrective action or removal
How to deal with challenging physicians

• Counseling/Discussion

• Escalate
  - Other physicians/Supervisor
  - Medical Staff Office/Privileges
  - Chief of Staff
  - State Medical Board
  - Press

• Action plan
  - Anger management, Drug rehabilitation, Ethics
Ethiopian Airlines 302

- Boeing 737 MAX 8 redesign
- Larger, more fuel-efficient engines
- Mounted more forward, and tended to pull nose up
- To avoid stalling, Boeing installs MCAS software that forces nose down
- Original design allows signal from a single angle-of-attack sensor rather than more (single point of failure)
- Faulty data from one sensor causes inability to control nose attitude, crash

Trust your people, not automation!
A safety culture begins at the top.
Critical parts of a safe health care team:

- Mutual Respect
- Situational awareness and team resource management
- Effective, clear communication
- Formalized time-outs, checklists, sign outs, debriefs

Working together, you can keep your patients SAFE!
Miracle on the Hudson