High Reliability Organizations and Patient Safety

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At the end of this section you should be able to:

- Objectively describe the current level of medical care safety
- Distinguish adverse events and error
- Discuss a model that demonstrates how errors occur and how they might be prevented or mitigated
- Describe the features of a high reliability organization and its resultant culture
- Discuss the high reliability culture of aviation, how it has changed in the last 30 years, and its relevance to medical safety
- Outline things you can do tomorrow that will make a difference in the culture of safety within your organization
How safe do you think medical care really is?

To what would you compare the risk?
Average rate per exposure of catastrophes and associated deaths in various industries and human activities

- No limitation in production → Increasing safety margins
- Excessive autonomy of actors → Becoming a team player
- Craftsman's attitude → Accepting transition to equivalent actors
- Ego-centered safety protections, vertical conflicts → Accepting endorsement of residual risk
- Loss of visibility of risk → Accepting questioning of success and changing strategies

- Fatal iatrogenic adverse events
- Cardiac surgery in patient in ASA 3–5
- Medical risk (total)
- Anesthesiology in patient in ASA 1
- Chartered flight
- Commercial large-jet aviation
- Microlight aircraft or helicopters
- Road safety
- Chemical industry (total)
- Railways
- Nuclear industry

- Risk
  - $10^{-2}$
  - $10^{-3}$
  - $10^{-4}$
  - $10^{-5}$
  - $10^{-6}$
- Very unsafe
- Ultrasafe

Medical care is a leading cause of death in the U.S.

Medical errors are one of the nation's leading causes of death and injury.

Institute of Medicine estimates that as many as 44,000 to 98,000 people die in U.S. hospitals each year as the result of medical errors.

More people die from medical errors than from motor vehicle accidents, breast cancer, or AIDS.
Definitions

IOM definition of error:
- the failure of a planned action (error of execution)
- the use of a wrong plan to achieve an aim (error of planning).

Adverse event (AE):
- an injury resulting from a medical intervention
- not due to the patient's underlying condition

Adverse events and errors may be related
- Error may cause AE (fatal overdose)
- Error may not cause AE (Abx given 2 hours late)

But... the absence of an adverse event does not make the error disappear – you still have the failure of a plan
1999 IOM Report: *To Err is Human*

**Building a Safer Health Care System**
- One million injuries and 98,000 deaths each year from preventable medical errors
- 8th leading cause of death in the U.S.
- Cost: between $17 and $29 billion per year

**The call to action**
- non-punitive error reporting systems
- legislation for peer review protections
- performance standards for safety assurance
- visible commitments to safety improvement
- attention to medication safety

Source: Institute of Medicine 2000.
The rest of Cicero’s famous quote

To err is human...

...but to persevere in error is only the act of a fool.
Sources of human error

1. Perception
   We see and hear what we expect

2. Assumption
   We believe that things are a certain way

3. Communication
   We say what we mean, but others hear what they perceive

Example: the childhood game, *Telephone*
Recipe for failure

- Start with a complex system
- Engage multiple interconnected parts
- Operate it 24/7
- Resist standardization
- Adopt a culture of individualism
- Pay irrespective of level of quality
Why do we have safety problems?

- Increased complexity of systems
- Rapid rate of technological change
- Focus on cost-effectiveness
- Information overload
- Multiple, competing regulations
- A culture of autonomy in medicine
Why do we have safety problems?

- Relying too much on human memory
- Poor communication
- Unreliable handoffs at care boundaries
- Multiple kinds of equipment - few standards
- Inadequate orientation, induction and rehearsal
Person vs. System

- People make errors
- Find the cause and blame, shame and train
- To improve safety, **fix the person**

- Systems fail
- Focus on the multiple components that contribute
- To improve safety, **fix the system**

Both and neither are the problem – Personal awareness and systems thinking are necessary for safety
Batalden / Berwick Law

Every system is perfectly designed to produce just the results it produces.

Donald Berwick, MD
Swiss cheese model of system failure

- Known weaknesses
  - Distraction
  - Autonomy desires
  - Non-standardization
  - Inadequate processes
  - Unanticipated events
  - Schedule changes
  - Random noise
  - Communication
  - Arrogance
  - Cognitive errors
  - Perceptual errors
  - Busting the rules
  - Being ‘creative’
  - Not admitting failure was a possibility

Reason, J. BMJ 2000;320:768-770
The need for high reliability

- **Reliability** – the degree to which an action or test produces a consistent result
  - In CQI language: *Doing things right*

- **Validity** – whether or not the correct result was achieved
  - In CQI language: *Doing right things*

A high reliability process **consistently** achieves the **correct** outcome
Medicine is a cottage industry

- We work one patient at a time
- Individualized solutions
- Perfection of individual outcomes
- Autonomy is revered
- Technical skill more important than interpersonal skill in training
- Initial focus on scientific training may not be maintained over time (e.g., evidence-based medicine)
MD’s are different than administrators

**Administrators**
- Work in teams
- Healthcare is a business
- Focus on organization
- Systems training
- Optimize big picture
- Lead by training
- Standards driven
- Compliance focus
- Quality is a property of the organization

**Physicians**
- Work alone
- Healthcare is a profession
- Focus on patient
- Science training
- Optimize single outcome
- Lead by personality
- Autonomy driven
- Edge of envelope focus
- Quality is a property of the doctor-patient relationship
What have we learned from other industries, such as aviation, that have focused on safety?
“Nine long years after the Institute of Medicine told us nearly 100,000 patients die each year from avoidable errors in our hospitals (To Err Is Human, 1999), the struggle to significantly reduce major patient injuries has barely begun. The primary reason it’s so tough to change the system is that no less than the culture of medical practice has been challenged and is, in effect, resisting change. This is cultural inertia, the ‘This is the way we’ve always done it’ syndrome, yet the root cause of poor patient safety performance lies squarely in the mythology that human perfection in medicine is achievable—the presumption that humans can practice without mistakes.”
Perspective: 5 years between 2001 to 2006

- Aviation: Zero commercial aviation deaths
- Medical Care: 250,000 – 600,000 patient deaths attributed to medical error
- This is the equivalent of flying 1,400 fully loaded 747s into the ground
- Why is aviation so much safer?

Nance, “Why Hospitals Should Fly”
The Tenerife Story

In 1977 two fully loaded 747s collided on a foggy runway killing 583 people.

Major contributors to the accident:
- Perception
- Assumption
- Communication
- Halo effect
- Normalized deviance in not following standard procedures
- Loss of situational awareness

In the next 30 years commercial aviation transformed into a high reliability industry.
What did aviation learn over those 30 years?

- Some errors can be eliminated by engineering redesign.
- But... the overwhelming majority of errors can not be engineered out of the system.
- Why? Because humans make errors. Any process with people is prone to error.
- No amount of prevention will change this.
The best defense

- You can catch errors if you have good systems, processes and teams.
- The best defense is a **collegial interactive team**.
- It pays to be a little paranoid when you’re doing things with high error potential:
  - I must assume I will make mistakes
  - I must believe that the most likely outcome of my next action will be an error if I’m not mindful
  - If I don’t remain focused, this is the time I will get caught.
Error proofing... is it reliable?

In January 2002, two women died during the same routine heart procedure in the same room. They were both mistakenly given nitrous oxide instead of oxygen because a device that regulates oxygen flow was plugged into a receptacle that dispenses nitrous oxide. The flow regulator was missing one of the index pins designed to prevent such mix-ups. The mistake-proofing depended on pins connecting the oxygen regulator at 12 and 6 o’clock and the nitrous oxide regulator at 12 and 7 o’clock. The missing pin broke off. A mistake-proofing device failed.

How would you have error proofed this system?
Avoid the errors that you can by good system design (engineering)

Trap the errors you cannot prevent through collegial interactive teams (behavior change)

Mitigate the consequences of the errors you cannot trap (back up strategies)

Evolution of CRM in Aviation, Robert Helmreich
Why factors contributed to this airplane crash?

- Ambiguous dawn light
- Construction causing abnormal taxi path
- Distracting conversation during taxi
- Failure to cross check runway heading with instruments
- Loss of positional awareness
- Distracted Air Traffic controller

A nearly exact recreation of this event at this same airport occurred in 1993 when the tower retracted a takeoff clearance after it realized a commercial just was on the wrong runway.
Case example

December 29, 1972, at about 2330 EST Eastern Flight 401 crashed in the Florida Everglades as 3 pilots flew a mechanically intact aircraft into the ground while trying to troubleshoot a landing gear problem signaled by a non-illuminated light bulb.
Recognize problem

Begin Troubleshooting

No one is flying the plane

Accidentally uncouples autopilot
How could these two accidents have been prevented?

- What were the contributory design flaws in these two accidents?
- What cultural issues contributed to inability to detect the errors?
- What mitigation strategies could have been in place to minimize the effect of undetected errors?

Design + Culture + Backup
Elements of Aviation Safety

- Checklists to reinforce habit patterns
- Recurrent proficiency recertification
- Standardized Communication
- Pilot in Command concept
- Aviation Safety Reporting System
- Air Traffic Control Procedures
- Crew Resource Management
- NTSB utilizes FMEA and RCA procedures

See how many of these have analogs in medical care
If a new drug were as effective at saving lives as Peter Pronovost’s checklist, there would be a nationwide marketing campaign urging doctors to use it.
## Surgical Safety Checklist

**Before induction of anaesthesia**
(with at least nurse and anaesthetist)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the patient confirmed his/her identity,</td>
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<tr>
<td>site, procedure, and consent?</td>
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<tr>
<td>Is the site marked?</td>
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<tr>
<td>Is the anaesthesia machine and medication</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>check complete?</td>
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<tr>
<td>Is the pulse oximeter on the patient and</td>
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<tr>
<td>functioning?</td>
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<tr>
<td>Does the patient have a:</td>
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<tr>
<td>Known allergy?</td>
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<td>No</td>
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<tr>
<td>Yes</td>
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<tr>
<td>Difficult airway or aspiration risk?</td>
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<tr>
<td>No</td>
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<tr>
<td>Yes, and equipment/assistance available</td>
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<tr>
<td>Risk of &gt;500ml blood loss (7ml/kg in</td>
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<tr>
<td>children)?</td>
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<tr>
<td>No</td>
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<tr>
<td>Yes, and two IVs/central access and fluids planned</td>
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</tbody>
</table>

**Before skin incision**
(with nurse, anaesthetist and surgeon)

<table>
<thead>
<tr>
<th>Task</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirm all team members have introduced themselves by name and role.</td>
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<tr>
<td>Confirm the patient’s name, procedure, and where the incision will</td>
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<tr>
<td>be made.</td>
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<tr>
<td>Has antibiotic prophylaxis been given within the last 60 minutes?</td>
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<tr>
<td>Anticipated Critical Events</td>
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<td></td>
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<tr>
<td>To Surgeon:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What are the critical or non-routine steps?</td>
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<tr>
<td>How long will the case take?</td>
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<tr>
<td>What is the anticipated blood loss?</td>
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<tr>
<td>To Anaesthetist:</td>
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<td></td>
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<tr>
<td>Are there any patient-specific concerns?</td>
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<tr>
<td>To Nursing Team:</td>
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<tr>
<td>Has sterility (including indicator results) been confirmed?</td>
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<tr>
<td>Are there equipment issues or any concerns?</td>
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<td></td>
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</tbody>
</table>

**Before patient leaves operating room**
(with nurse, anaesthetist and surgeon)

<table>
<thead>
<tr>
<th>Task</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse Verbally Confirms:</td>
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<tr>
<td>The name of the procedure</td>
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<tr>
<td>Completion of instrument, sponge and needle counts</td>
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<tr>
<td>Specimen labelling (read specimen labels aloud, including patient</td>
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<tr>
<td>name)</td>
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<tr>
<td>Whether there are any equipment problems to be addressed</td>
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</tbody>
</table>

**To Surgeon, Anaesthetist and Nurse:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the key concerns for recovery and</td>
<td></td>
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<tr>
<td>management of this patient?</td>
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</tbody>
</table>

*This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.*

Revised 1 / 2009 © WHO, 2009
Recurrent Recertification

- Biennial Flight Review q 2 years
- Aircraft inspected q year
- Rented aircraft inspected q 100 hrs
- Flight physical q 6-24 months
- Navigation radios, altimeter, Emergency Locator Transmitter batteries q 3-24

What do we do similarly in medical care?
Standardized Communication

- Phraseology is standardized
  - “American Four Seven Zero, descend and maintain Two Niner Thousand.”

- Readback of critical communications
  - “Cessna Four Seven Juliet hold short runway Two Five.”

- Important communications are structured and invariant
  - Clearances, weather reports, briefings

What do we do similarly in medical care?
Pilot in command (PIC)

“The pilot in command (PIC) of an aircraft is directly responsible for, and is the final authority as to, the operation of that aircraft.”

What if there are 2 pilots, or pilot and instructor?

- There can be only one PIC
- “I have the airplane”…. “You have the airplane”

What do we do similarly in medical care?
Two-thirds of all aviation accidents and incidents have their roots in human performance errors.

ASRS is a NASA program to identify deficiencies and discrepancies in the National Aviation System

Voluntary, confidential reporting

FAA will not to use ASRS information against reporters in enforcement actions

What do we do similarly in medical care?
Cessna 123WH cleared to Bellingham via the Needle 2 departure, direct Paine VOR then radar vectors to Bellingham. Expect four thousand. Squawk two one three six. Contact Seattle Departure one two five point one one five on reaching two thousand. Clearance void if not off by one two zero zero. ATC time one one four five and one half.

What do we do similarly in medical care?
Crew Resource Management

An approach to crew teamwork, often used in high reliability organizations, which emphasizes the management of human factors and the use of all available resources, i.e., information, equipment, people etc., to achieve safe and efficient system operations.

Focus on coordinated team effort

What do we do similarly in medical care?
CRM Components

- Situational Awareness
- Group Dynamics/ Team Decision Making
- Effective Communication
- Leadership
- Assertiveness
- Shift Planning and Event Analysis
- Conflict Resolution
- Workload Management
- Risk Management/Mitigation
- Stress Management
Recognize problem

Pilot troubleshoots
F/O Flies plane, radios

F/O still flying
Corrects autopilot

ATC involved
Recognizes autopilot error
Failure Modes and Effects Analyses and Root Cause Analyses

**RCA**
- Reactive
  - Specific Event
- Diagram chronological steps
- “What occurred?”
- Focus on an event’s system failures
- Prevents failures from reoccurring
  - Ask “why?” 7 times

**FMEA**
- Proactive
  - Specific Process
- Diagram process flow
  - “What could occur?”
- Focusing on a processes potential failures
- Prevents failures before they occur
  - Plan for what’s bad and likely

“Focusing on a process potential failures Prevents failures before they occur”
Things you can do tomorrow to make a difference in patient safety
Major themes

- Help design systems that minimize errors and prevent them from appearing
- Trap errors through collegial team work
- Mitigate and rectify errors
- Adopt Just Culture principles
  - Console the error
  - Counsel the at risk
  - Punish the reckless
- Learn from mistakes
Behavioral Approaches to Safety

- Reward and reinforce behavior ($, praise, etc)
- Appeal to altruism (doing the right thing)
- Alignment of goals
- Good system design
- Redundancy
- Dissatisfaction with complacency
- Checklist mentality
- Facilitating functions (convenience = compliance)
- Forcing functions (structures that do not allow alternatives to the desired outcomes)
- Avoid punishment:
  - it tells people *what not* to do, but not *what* to do
  - Undesired behavior usually returns
  - However – natural consequences are great teachers
Reflection Task

- Pick a patient safety failure event with which you are familiar
- Ask “why?” as many times as you can until you reach the root cause or causes or understand what is a complex multi-factor causality chain
- Think through the reason it occurred
  - How could you re-engineer the process so that the error could not occur?
  - How could you change the culture to detect the error if it did occur?
  - How could you mitigate the adverse outcome if the error went undetected?