

High Reliability Organizations and Patient Safety

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Development Alliance

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

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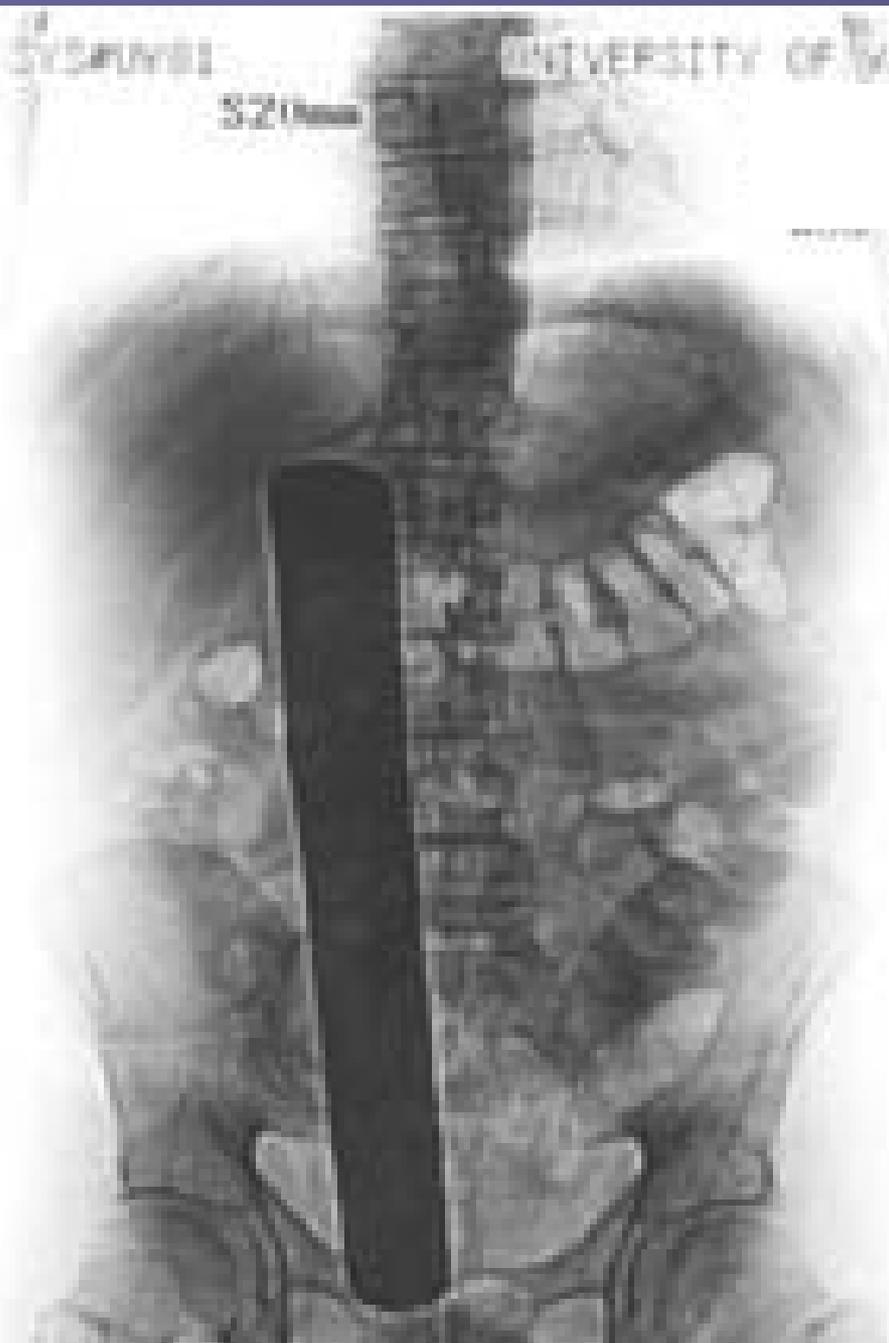
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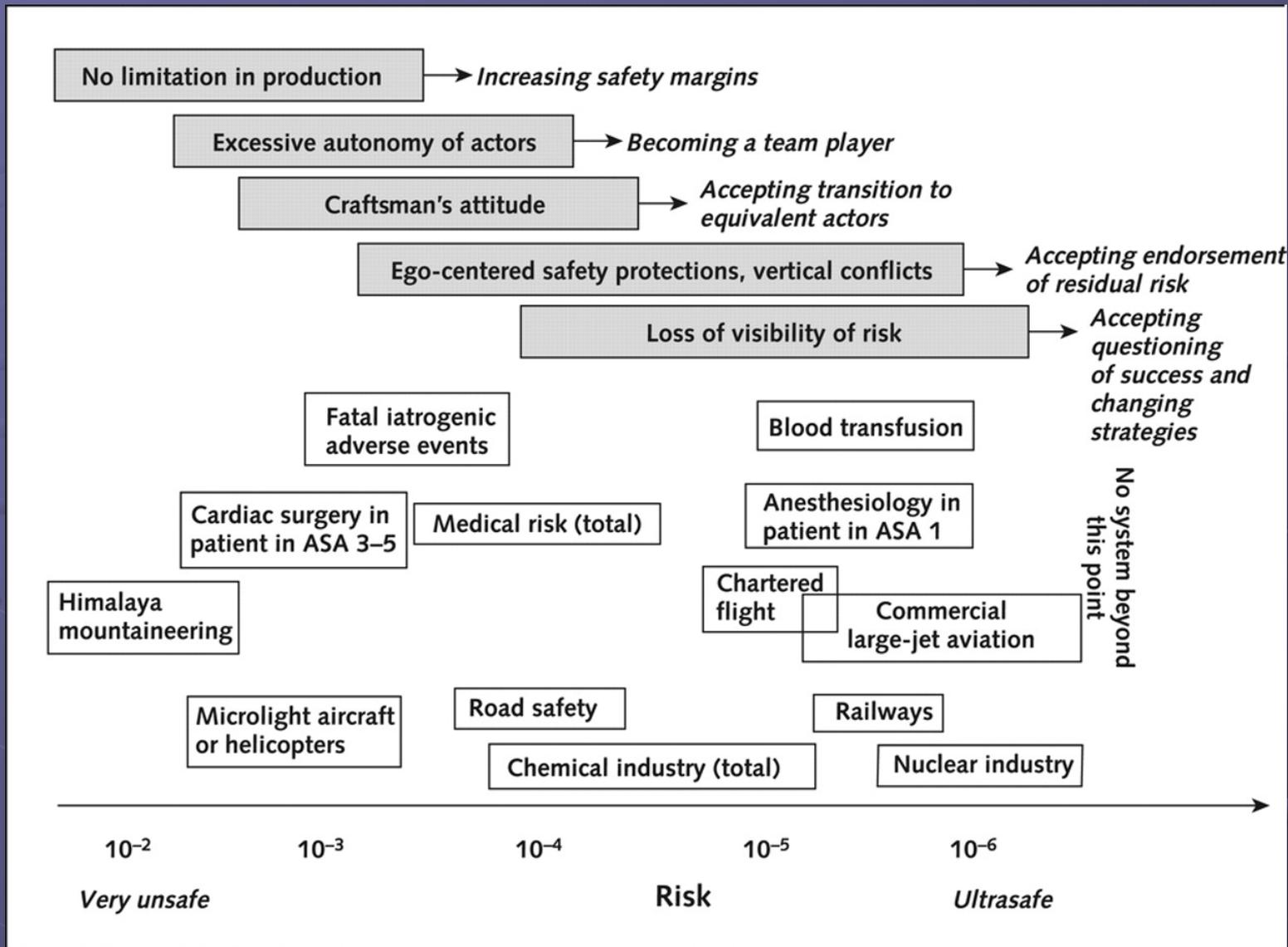
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How safe do you think
medical care really is?

To what would you compare the
risk?

Average rate per exposure of catastrophes and associated deaths in various industries and human activities



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

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

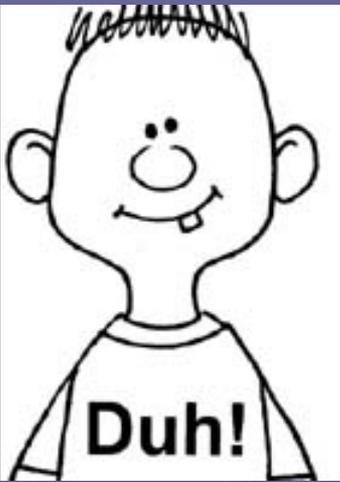
Why do we have safety problems?

- 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

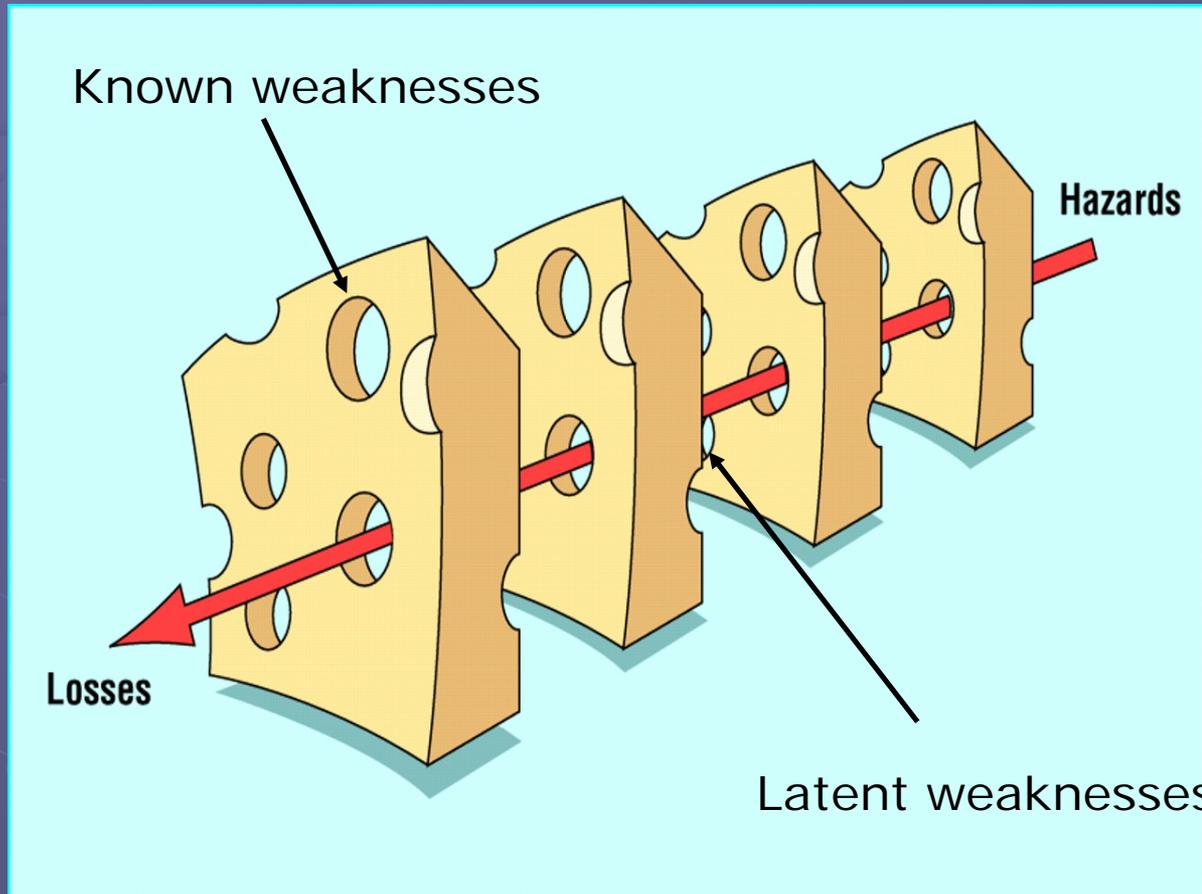


Batalden / Berwick Law

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

Donald Berwick, MD

Swiss cheese model of system failure



- 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

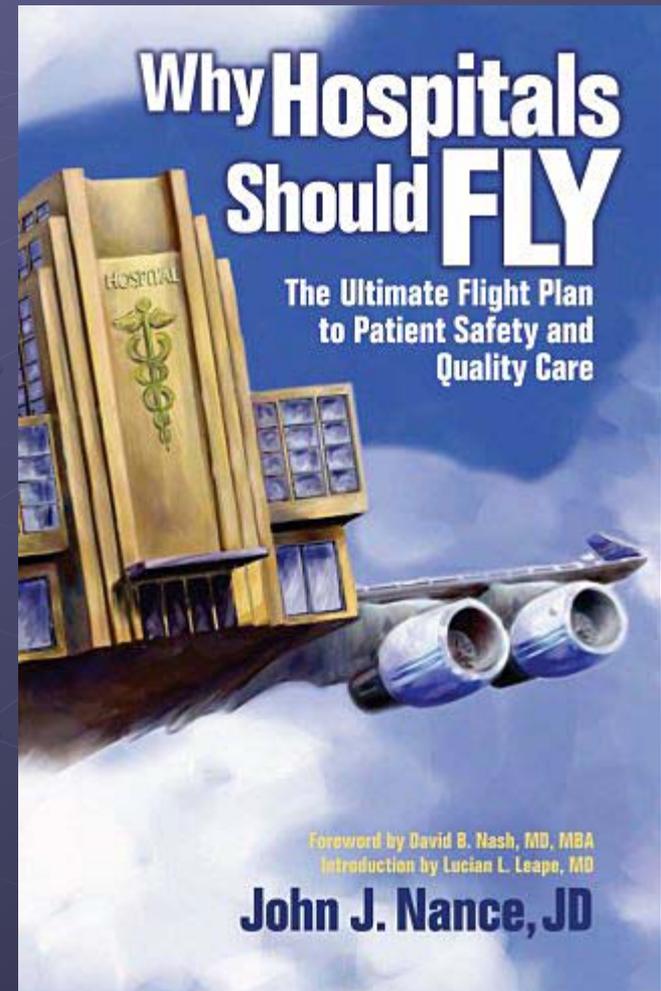
Physicians

- 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?

You must read this book

“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?

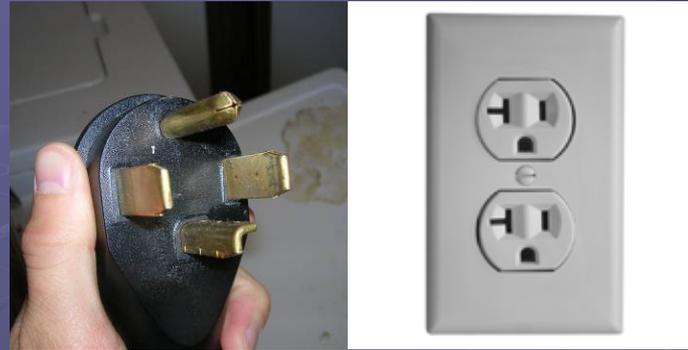
In January 2002, two women died during the same routine heart procedure in the same room. They were both mistakenly given nitrous oxide instead of oxygen because a device that regulates oxygen flow was plugged into a receptacle that dispenses nitrous oxide. The flow regulator was missing one of the index 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?

Design + Culture + Backup

- **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)





Crash site

Comair 5191, August 27, 2006

Why factors contributed to this airplane crash?

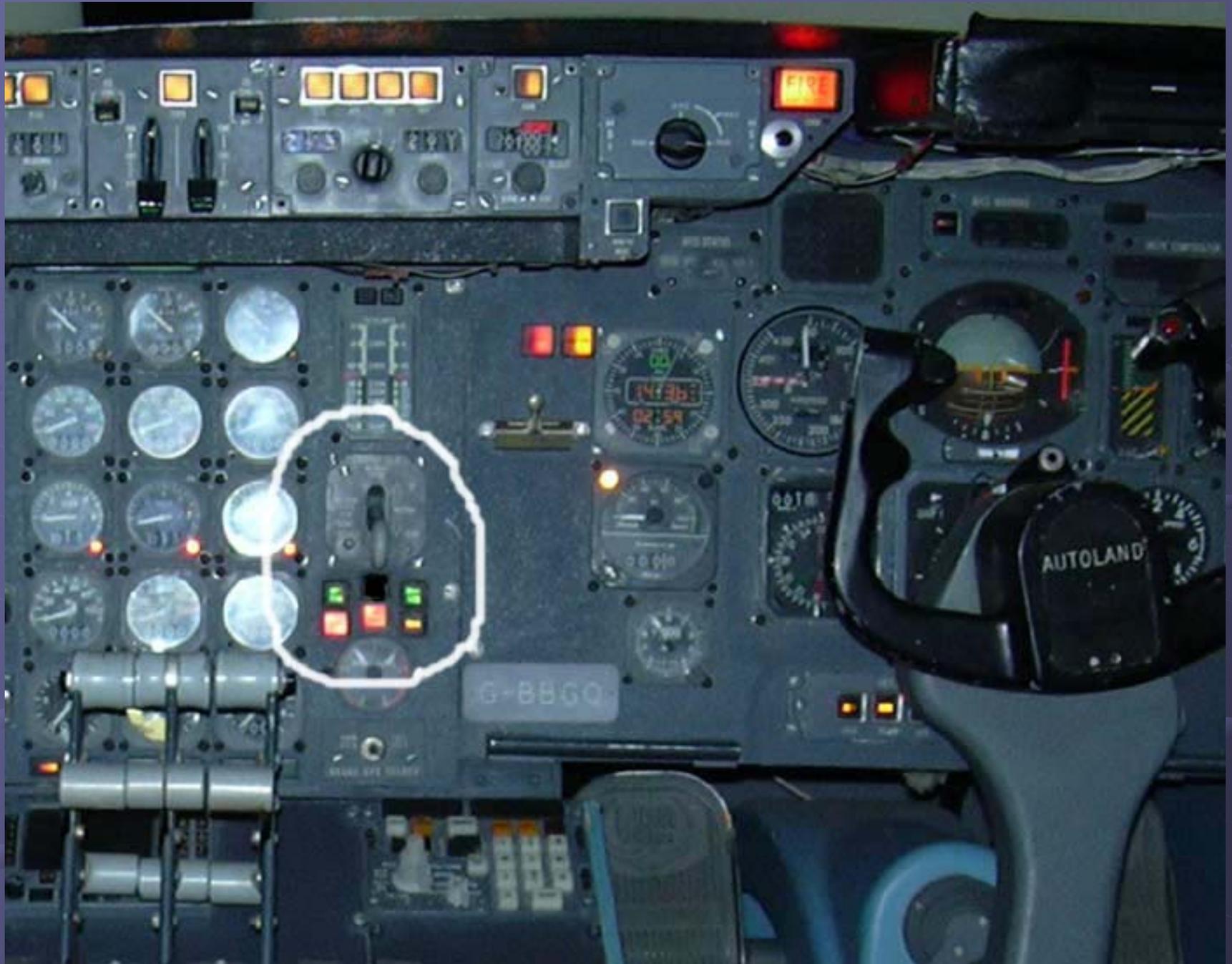
- Ambiguous dawn light
- Construction causing abnormal taxi path
- Distracting conversation during taxi
- Failure to cross check runway heading with instruments
- Loss of positional awareness
- Distracted Air Traffic controller

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

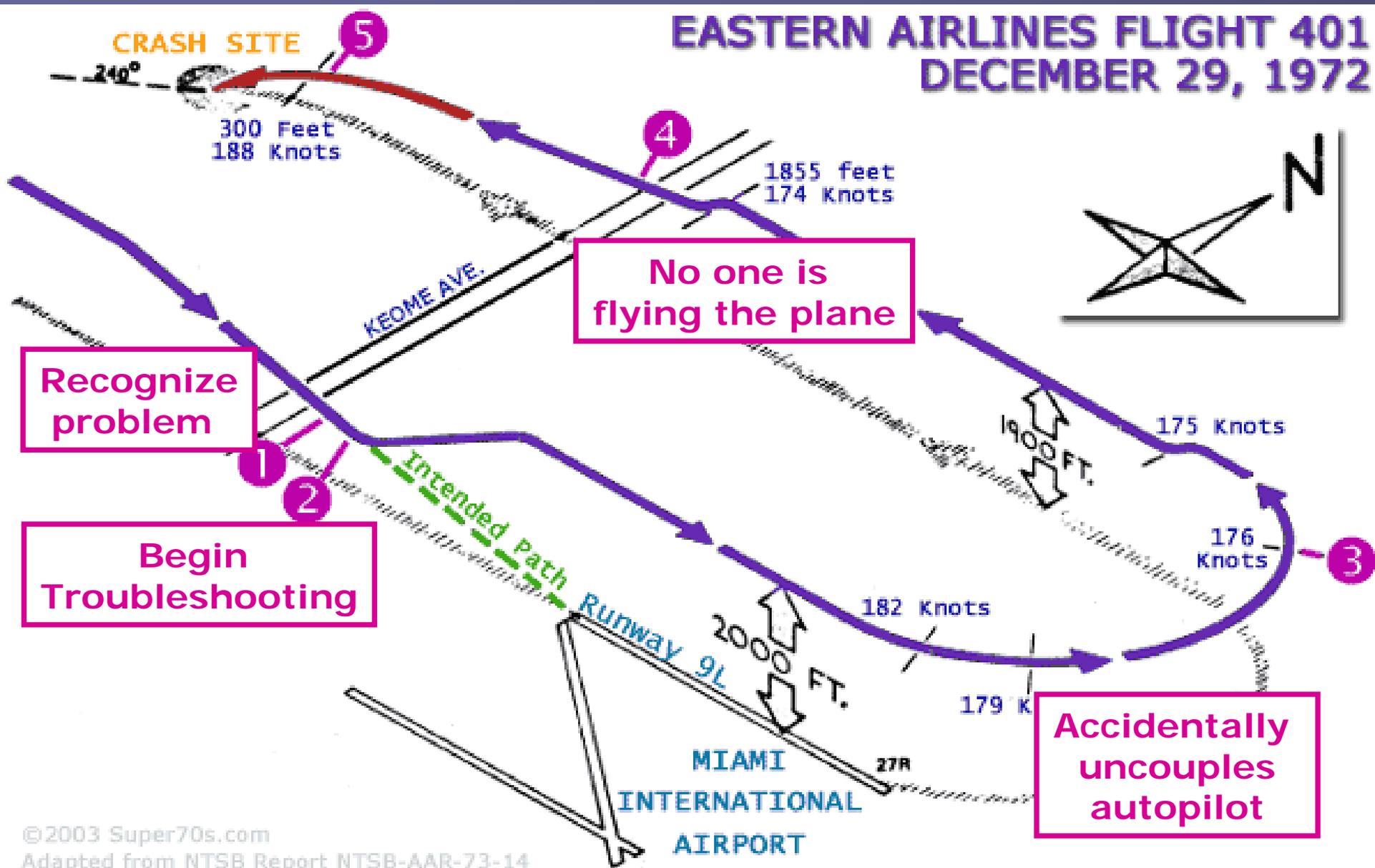
Case example

- 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.





EASTERN AIRLINES FLIGHT 401 DECEMBER 29, 1972



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

Cessna 172

Preflight Inspection Cockpit

Aircraft docs (ARROW)	Check
Weight & Balance	Check
Parking Brake	Set
Control wheel lock	Remove
Hobbs/Tach	Check/Remove
Ignition	Off
Avionics Power Switch	Off
Master Switch	On
Fuel quantity indicators	Check
Pitot Heat	On
Avionics Master Switch	On
Avionics Cooling Fan	Audible
Avionics Master Switch	Off
Static Pressure Alt Src Valve	Off
Annunciator Panel Switch	Test
Annunciator's Illuminate	Check
Annunciator Panel Switch	Off
Flaps	Extend
Pitot Heat	Off
Master Switch	Off
Pitot Tube	Test for Heat
Fuel shutoff valve	On (In)

Fuselage and Empenage

Baggage Door	Closed & Locked
Rivets	Check
Rudder Gust Lock	Remove
Tail Tie-Down	Disconnect
Control surfaces	Free & Secure
Trim Tab	Check Security
Antennas	Check Security

Right wing

Wing tie-down	Disconnect
Aileron	Free and Secure
Flaps	Secure
Main wheel tire	Inflated/Cond
Brakes	Not Leaking
Fuel tank sump	Sample
Fuel Quantity	Check
Fuel Filler cap	Secure

Nose

Engine oil level	Check
Fuel strainer	Sample
Propeller and spinner	Check

Preflight

Alternator belt	Check
Air intake	Check
Carburetor air filter	Check
Landing lights	Check
Nose wheel strut & tire	Check
Nose-Tie down	Disconnect
Static source opening	Check

Left Wing

Wing tie-down	Disconnect
Aileron	Free and Secure
Flaps	Secure
Main wheel tire	Inflated/Cond
Brakes	Not Leaking
Fuel tank vent open	Check
Fuel tank sump	Sample
Fuel Quantity	Check
Fuel Filler cap	Secure
Pitot tube	Uncover and Check
Stall warning	Check
Landing/Taxi Light(s)	Clean/Cond

Before starting engine

Preflight inspection	Complete
Passenger Briefing	Complete
Seats, belts	Adjust & Lock
Doors	Closed & Locked
Brakes	Test & Set
Circuit breakers	Check In
Electrical Equip/Autopilot	Off
Avionics Power Switch	Off
Fuel Selector Valve	Both
Fuel shutoff valve	On (In)

Starting Engine

Throttle	Open 1/4 inch
Mixture	Rich (IN)
Carb heat	Cold (IN)
Prime	As required; locked
Aux Fuel Pump	On
Propeller area	Clear
Master Switch	On
Beacon	On
Ignition	Start
Throttle	Adjust 1000 rpm
Oil Pressure	Check normal
Aux Fuel Pump	Off
Avionics Master Switch	On
Radios	On

Cessna 172

Transponder	Standby
Flaps	Up
Ammeter	Check
Heading Indicator	Set
ATIS/AWOS/ASOS	Obtain
Altimeter	Set
Autopilot	Engage
Flight Controls	Move Against AP
Autopilot	Disconnect (Sound)
Departure & Taxi Clmce	Contact

Before Takeoff

Parking brake	Set
Cabin doors	Closed & Locked
Seats, belts	Adjust & Lock
Flight controls	Free & Correct
Instruments (4)	Set
Fuel Quantity	Check
Fuel Shutoff Valve	On
Mixture	Rich (IN)
Fuel Selector Valve	Both
Elevator Trim	Set for TAKEOFF
Throttle	1800 rpm
Magnetos	Check
Suction gage	Check
Engine Instruments	Check
Ammeter	Check
Mixture	Set for Density Alt
Carb heat	On
Annunciator Panel	Clear
Throttle	1000 rpm
Throttle Friction Lock	Adjust
Strobe Lights	On
Radios/Avionics	Set
Autopilot	Off
Flaps	Set for Takeoff (0°-10°)
Parking Brake	Release
Windows	Closed

Takeoff

Flaps	Up
Carb heat	Cold (In)
Transponder	Altitude
Trim	set for TAKEOFF
Throttle	Full
Tach, oil, airspeed	Check
Elevator	Lift at 55 KIAS
Climb	70-80 KIAS

In Flight

Cruise

Pitch	Set
Throttle	As required
Trim	Set
Mixture	Adjust

Pre-landing checklist

Fuel selector	On
Mixture	Rich
Carb Heat	On
Seatbelts	Fastened

Approach

Flight instruments	Ckd & Set
Radios	Checked
ATIS	Checked
Carb Heat	On (Out)
Mixture	Rich
Landing light	On
Airspeed	65-75 KIAS (Flaps Up) 60-70 KIAS (Flaps Dn)

After landing

Flaps	Up
Carb Heat	Cold (In)
Transponder	Standby
Landing light	Off

Parking

Avionics	Off
Electrical	Off
Throttle	1000 RPM
Mixture	Cut-off
Ignition switch	Off
Master switch	Off

Securing the aircraft

Control Lock	Install
Hobbs/Tach	Record
Door/Window	Secure
Tie-downs	Secure

Comm Freq

ATIS	
Ground	
Tower	
Club	
Fuel	

Procedures

Short field take-off

Take-off checklist	Complete
Taxi	Max runway
Brakes	Set and hold
Flaps	10°
Throttle	Full
Brakes	Release
Climb	57 KIAS
Flaps	Retract when clear
Airspeed	67 KIAS

Short field landing

Pre-landing check	Complete
Approach	62 KIAS
Flaps	30°
Throttle	Maintain glide
Touchdown	Power Off
Flaps	Up
Elevator	Full up
Braking	Heavy as required

Soft field take-off

Take-off checklist	Complete
Flaps	10°
Taxi	keep rolling
Climb	54 KIAS
Flaps	retract
Airspeed	67 KIAS

Soft field landing

Pre-landing check	Complete
Throttle	1500 RPM
Flaps	10°
Airspeed	60 KIAS
Touchdown	Main first, softly
Landing roll	Nose wheel up
Elevator	Up
Braking	As required

Go-around

Throttle	Full
Carb Heat	Cold (In)
Flaps	20°
Climb	55 KIAS
Flaps	10°
Climb	60 KIAS
Flaps	Up
Climb	>60 KIAS

Emergency

Engine failure

TAKEOFF	
Throttle	Idle
Brakes	Apply
Flaps	Retract
Mixture	IDLE cut-off
Ignition	Off
Master switch	Off

AFTER TAKEOFF	
Airspeed	65 KIAS (flaps UP) 60 KIAS (flaps DN)
Mixture	Idle Cut-off
Fuel shutoff valve	Off (Out)
Ignition	Off
Flaps	As Required
Master switch	Off
Cabin Doors	Unlatch
Land	Straight Ahead

DURING FLIGHT

Airspeed	65 KIAS
LOOK FOR A FIELD	
Fuel shutoff valve	On (In)
Fuel selector valve	Both
Aux Fuel Pump Switch	On
Primer	In & Locked
Mixture	Rich
Ignition	BOTH (or START)
Airspeed	65 KIAS (flaps UP) 60 KIAS (flaps DN)

Mixture	Idle Cut-off
Fuel shutoff valve	Off (Out)
Ignition	Off
Flaps	As Required
Mayday	Transmit 121.5
Mayday	Squawk 7700
Master switch	Off
Cabin Doors	Unlatch
Touchdown	Tail Low

Carburetor Icing

Throttle	Full
Carb Heat	On (Out)
Mixture	Adjust

Engine Roughness

Magnetos	Check
Mixture	Lean as necessary

Emergency

Engine Fire during start

Crank	Continue
Power	1700 RPM (2 min)
Engine	Shut down and inspect

Engine Fire during flight

Mixture	Idle Cut-off
Fuel shutoff valve	Off (Out)
Master Switch	Off
Boost Pump	Off
Cabin Heat/Air	Off
Airspeed	100 KIAS

Electrical failure

Load meter	Verify
Alternator	Off
Reduce load to minimum	
Breaker/alt	Check & Rest
Alternator	On
If still no power:	
Alternator	Off
Reduce load and land	

Electrical overload

Master Switch	Off
Master Switch	On
Over-voltage light	Off
or TERMINATE flight ASAP	

Spin Recovery

Ailerons	NEUTRAL
Throttle	IDLE
Rudder	Full opposite
Control wheel	Full forward
Rudder control/wheel	Neutral
Pitch	Level

Light Signals:

Signal	On Ground	In Flight
Steady Green	Takeoff	Land
Flashing Green	Taxi	Return to land
Steady Red	Stop	Give way
Flashing Red	Clear runway	Do not land
Flashing white	Return to ramp	--
Red/Green alternating	WARNING – USE CAUTION	

Reference

V-Speeds (KIAS)

Rotate	V _r	55
Normal Climb Out	V _{climb}	70-85
Max angle (Sea Level)	V _x	60
Max angle (10,000 ft)	V _x	65
Climb rate (Sea Level)	V _y	79
Climb rate (10,000 ft)	V _y	71
Maneuver	V _a	82-99
Flaps	V _{fb}	85
Normal max	V _{no}	127
Never exceed	V _{ne}	158
Stall (clean)	V _s	44
Stall (land)	V _{so}	33
Final Approach	Flaps	80-70
Approach	No flaps	65-75
Max Glide		60

Alpha
Bravo
Charlie
Delta
Echo
Foxtrot
Golf
Hotel
India
Juliet
Kilo
Lima
Mike
November
Oscar
Papa
Quebec
Romeo
Sierra
Tango
Uniform
Victor
Whiskey
Xray
Yankee
Zulu



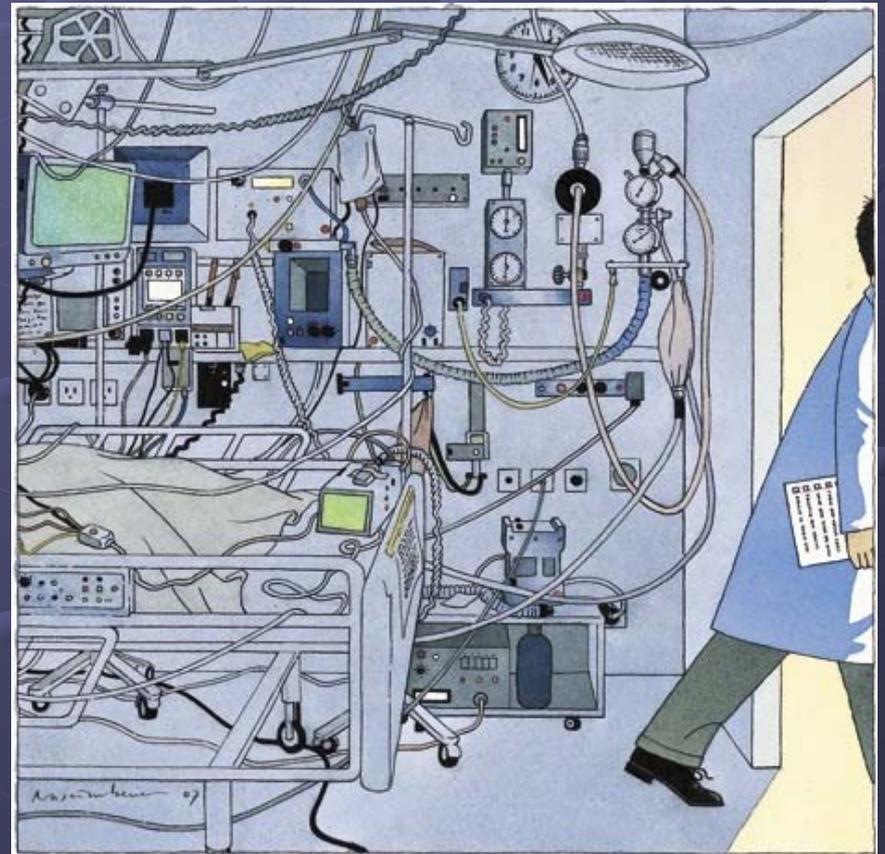
THE NEW YORKER

The Checklist

If something so simple can transform intensive care, what else can it do?
by Atul Gawande

December 10, 2007

“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



World Health
Organization

Patient Safety

A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?

Yes

Is the site marked?

Yes

Not applicable

Is the anaesthesia machine and medication check complete?

Yes

Is the pulse oximeter on the patient and functioning?

Yes

Does the patient have a:

Known allergy?

No

Yes

Difficult airway or aspiration risk?

No

Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

No

Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

Confirm all team members have introduced themselves by name and role.

Confirm the patient's name, procedure, and where the incision will be made.

Has antibiotic prophylaxis been given within the last 60 minutes?

Yes

Not applicable

Anticipated Critical Events

To Surgeon:

What are the critical or non-routine steps?

How long will the case take?

What is the anticipated blood loss?

To Anaesthetist:

Are there any patient-specific concerns?

To Nursing Team:

Has sterility (including indicator results) been confirmed?

Are there equipment issues or any concerns?

Is essential imaging displayed?

Yes

Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:

The name of the procedure

Completion of instrument, sponge and needle counts

Specimen labelling (read specimen labels aloud, including patient name)

Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:

What are the key concerns for recovery and management of this patient?

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?**

Aviation Safety Reporting System



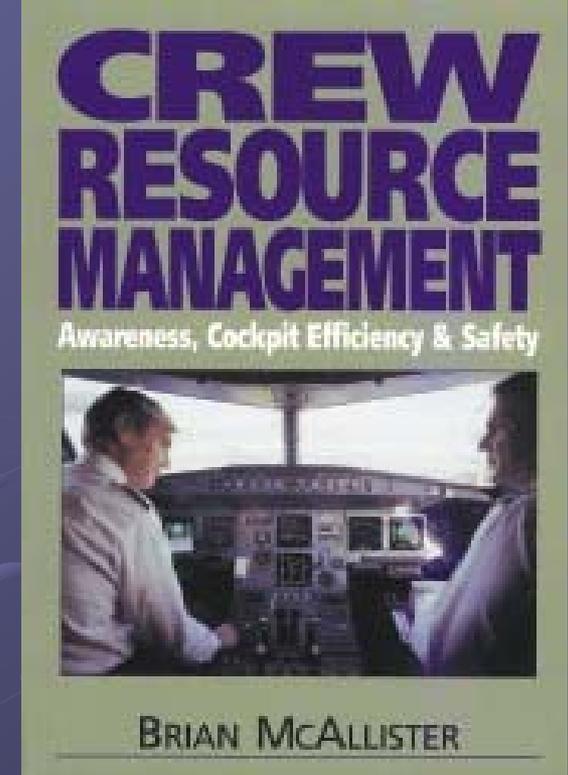
- Two-thirds of all aviation accidents and incidents have their roots in human performance errors.
- ASRS is a NASA program to identify deficiencies and discrepancies in the National Aviation System
- Voluntary, confidential reporting
- FAA will not use ASRS information against reporters in enforcement actions
- **What do we do similarly in medical care?**

Air Traffic Control Procedures

- *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 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

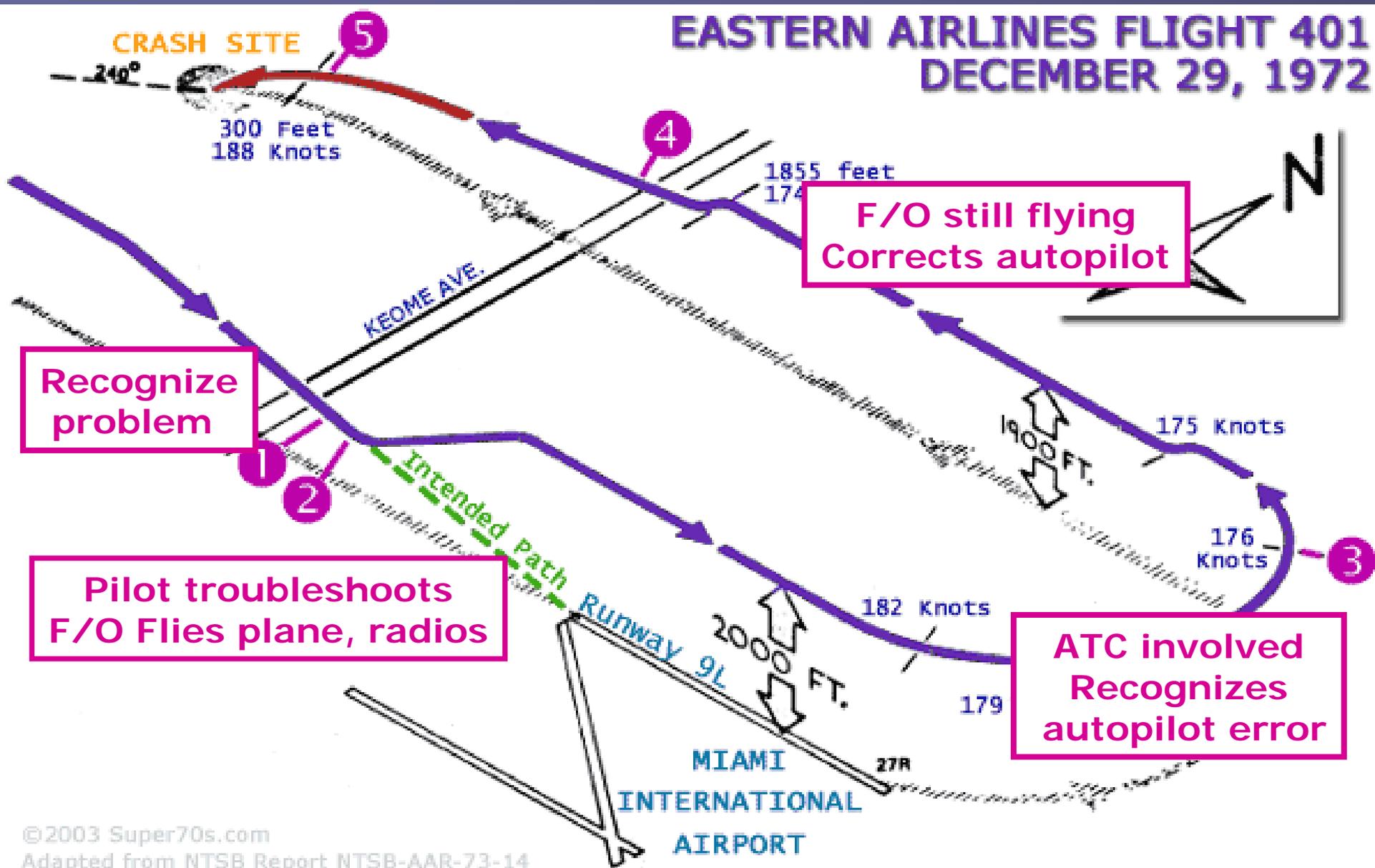
- An approach to crew teamwork, often used in high reliability organizations, which emphasizes the management of human factors and the use of all available resources, i.e., information, equipment, people etc., to achieve safe and efficient system operations.
- Focus on coordinated team effort
- **What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

EASTERN AIRLINES FLIGHT 401 DECEMBER 29, 1972



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

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?