Medical Errors
Human Errors

AAPM
Spring 2012
Dallas, TX

Christopher Serago, Ph.D.
Mayo Clinic
No financial disclosures
Mostly radiation therapy examples
Medical Errors Course

Root Cause Analysis (RCA)
Failure Mode and Effect Analysis (FMEA)
Training, education, policy & procedures
Institute of Medicine (IOM) Report
To Err is Human
November, 1999

- Betsy Lehman, a health reporter for the Boston Globe, died from an overdose during chemotherapy
- Willie King had the wrong leg amputated.
- Ben Kolb was 8 years old when he died during “minor” surgery due to a drug mix up.
As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.
“There are some patients we cannot help; there are none we cannot harm”.

Arthur Bloomfield, MD
IOM Report: To Err is Human

Colorado: 2.9 percent of hospitalizations result in adverse events. 6.6 percent of the adverse events led to death.

New York: 3.7 percent of hospitalizations result in adverse events. 13.6 percent of the adverse events led to death.

- Colorado: (.029)(.066) = .0019 or 0.19%
- New York: (.037)(.136) = .005 or 0.5%
In both the Colorado and New York studies, over half the adverse events resulted from medical errors and could have been prevented.
IOM Report: To Err is Human

Extrapolating the Colorado and New York data to the 33.6 million hospital admissions to U.S. hospitals implies that 44,000 to 98,000 patients die each year as a result of medical errors.
More people die in a given year as a result of medical errors than from motor vehicle accidents (43,000), breast cancer (42,000), or AIDS (16,000).
“Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety. Aviation has focused extensively on building safe systems and has been doing so since World War II.”
Florida Senate Bill 1558

Enacted July 1, 2001

The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to the prevention of medical errors as part of the licensure and renewal process.

The 2-hour course shall count towards the total number of continuing education hours required for the profession.

The course shall include a study of root-cause analysis, error reduction and prevention, and patient safety.
Errors Happen

What can we do to reduce their probability?
A typical, and good response

- Root Cause Analysis (RCA)
- Failure Mode and Effect Analysis (FMEA)
- Error prevention strategies
- Training, education, policy & procedures
Misadministrations are caused when several of the “checks and balances” go wrong at the same time.

They most often occur when there are changes to the routine and assumptions are made.
Most facilities have good procedures. They are not always followed because they are in a hurry or the procedures are thought of as “unnecessary.”

Some facilities do not have written procedures for things that are “understood” to be good practice. Many were handled verbally when the facility was smaller but has since grown in staff size and compartmentalization of duties.
New equipment, especially treatment planners
Change in personnel, especially duties such as entering data on charts or reviews normally done by others.
Redundancy checks are seen as not necessary and not done with attention or not done at all.
Short cuts are used for calibration factors.
Poor communication between therapists and physicists, or therapists and physicians.
Some issues with verbal changes to Rx. (if not documented, it did not happen)
International Atomic Energy Agency, 2000
Event No. 1: Dosimeter calibration report used incorrectly. The calibration was in terms of dose to water, but interpreted as dose in air.

Result: 11% overdose to patients for at least 1 year

Contributing factors:

a) insufficient education, training
b) no independent calibration by 2nd person
Event No. 2: Incorrect use of parallel plate chamber. A label on the chamber indicated the wrong side on which the beam should be incident. Chamber used upside down.

Result:
- 6 MeV: 20% overdose
- 9 MeV: 10% overdose
- 12 MeV: 8% overdose

Contribution factors:
- a) insufficient education, training
- b) no independent check by 2nd person
Event No. 3: Error in correction for atmospheric pressure. Pressure used from airport was corrected to sea level, but site was at 1000 m.

Result: 13% overdose to all machines, all patients

Contribution factors:

a) insufficient education, training
b) lack of equipment (barometer on site)
More references
Causes of medical errors in radiotherapy
- Deficiencies in education and training
- Deficiencies in procedures and protocols
- Lack of independent checks
- Lack of quality control procedures
- Deficient communication and transfer of essential information
- Inattention and unawareness
SRS Output factor error

- Florida (2004-2005)
- ~50% overdose, Affected 77 patients
- Error caught by RPC
  - Toulouse, France (2006-2007)
  - Vendor caught the error
  - Affecting 145 patients
  - Up to 50% overdose, Affected 152 patients
  - New physicist caught error

SRS Jaw Collimator Settings

Right

Wrong

Slide courtesy of Ryan Flynn, Ph.D. University of Iowa
Backup jaw setting error

- Occurred in France
- Single arteriovenous malformation was treated
- Circular collimators used
- Incorrect backup jaw setting used
- Patient developed oeso-tracheal fistula
  - Surgery required
  - Hemorrhage occurred
  - Patient subsequently died

Slide courtesy of Ryan Flynn, Ph.D. University of Iowa
Backup jaw setting error

- Occurred in Evanston, IL
- 3 patients affected
- Trigeminal neuralgia patient “nearly comatose”
- Vendor’s solution: add decal to cone accessory to remind the user to close the backup jaws.

Slide text courtesy of Ryan Flynn, Ph.D. University of Iowa
Backup jaw setting error

- Bar code verification now available
That would never happen to me

Oh my Goodness! That could be me!

If they would only follow proper procedures, this would never happen
An Introduction to Just Culture

“People make errors, which lead to accidents. Accidents lead to deaths. The standard solution is to blame the people involved. If we find out who made the errors and punish them, we solve the problem, right? Wrong. The problem is seldom the fault of an individual; it is the fault of the system. Change the people without changing the system and the problems will continue.”

Don Norman
Author, the Design of Everyday Things
Today, I’d like to discuss the thought that it is a **normal** human cognitive process to make and repeat errors.

And we should plan for that when designing medical devices and processes.
Culture change

- **OLD:** It is a common assumption that patient safety can be improved simply by reminding healthcare personnel to be more careful. But, careful people still will make mistakes.

- **NEW:** Assume that people will occasionally make mistakes and then design the system accordingly.
Incompetent people are, at most, 1% of the problem. The other 99% are good people trying to do a good job who make very simple mistakes and it’s the processes that set them up to make these mistakes.

*Dr. Lucien Leape M.D., Harvard School of Public Health*
Why people make mistakes

even with proper training, procedures, second checks

- Fatigue
- Inattention/distraction
- Seeing a repetitious pattern, even when the pattern changes
- Lack of training
- Equipment design flaws
- Medication labeling, packaging similarities
- Communication gaps
- Incomplete instruction, illegible writing
- Environmental: poor lighting, noise
- Using an old solution for a new problem
Fatigue

Does your staffing match your workload?

Federal Aviation Regulations limit the number of hours that airline pilots can fly. Pilots flying passengers domestically within continental U.S. are typically limited to 8 hours flight time per day, **30 hours per week**, 100 per month, and 1,000 per year.
Duty hours

- Limited to 80 hours per week, averaged over a 4 week period (320 hours/4 weeks)
- Continuous on-site duty, including in-house call, must not exceed 24 consecutive hours. Residents may remain on duty for up to 6 additional hours to participate in didactic activities, transfer care of patients, conduct outpatient clinics, and maintain continuity of medical and surgical care.
Airline vs. Health Care

- Commercial airline staffing is mandatory.
- Is the same true for the health care industry?
Why people make mistakes

even with proper training, procedures, second checks

- Fatigue
- Inattention/distraction
- Seeing a repetitious pattern, even when the pattern changes
- Lack of training
- Equipment design flaws
- Medication labeling, packaging similarities

- Communication gaps
- Incomplete instruction, illegible writing
- Environmental: poor lighting, noise
- Using an old solution for a new problem
Inattention/distraction

We normally associate this problem with a person performing more than one task at a time.

We need to consider that this is a normal human cognitive process.
Inattention/distraction

We normally associate this problem with a person performing more than one task at a time.

We need to consider that this is a normal human cognitive process.
Guarding against inappropriate interruptions

Slide courtesy of Ryan Flynn, Ph.D. University of Iowa
• The Sterile Cockpit Rule is an FAA regulation requiring pilots to refrain from non-essential activities during critical phases of flight,[1] normally below 10,000 feet.
• The FAA imposed the rule in 1981 after reviewing a series of accidents that were caused by flight crews who were distracted from their flying duties by engaging in non-essential conversations and activities during critical parts of the flight.[2]
• One such notable accident was Eastern Air Lines Flight 212, which crashed just short of the runway at Charlotte/Douglas International Airport in 1974 while conducting an instrument approach in dense fog.
• The National Transportation Safety Board (NTSB) concluded that a probable cause of the accident was distraction due to idle chatter among the flight crew during the approach phase of the flight.[3]
What to Do?

Create a quiet area in Pharmacy IV Room which will be used when performing verification of chemotherapy medications.
Why people make mistakes

even with proper training, procedures, second checks

- Fatigue
- Inattention/distraction
- Seeing a repetitious pattern, even when the pattern changes
- Lack of training
- Equipment design flaws
- Medication labeling, packaging similarities
- Communication gaps
- Incomplete instruction, illegible writing
- Environmental: poor lighting, noise
- Using an old solution for a new problem
• The Dog Mat is a valuable aid in training your dogs to avoid areas you want to protect.

• When he touches the Dog Mat, he receives a mild static shock and will quickly learn to stay away from that area.

• After one or two encounters, your dog will associate the corrections with the area and avoid those areas.
Volunteers please

- The sound a frog makes is a ....  
  Croak

- Before there’s fire there is .......  
  Smoke

- A tree that grows from acorns is an .....  
  Oak

- A funny story is called a .......  
  Joke

- The white of an egg is called a .....  
  Yolk...white
“The more predictable varieties of human fallibility are rooted in the essential and adaptive properties of human cognition. They are the penalties that must be paid for our remarkable ability to model the regularities of the world and then to use these stored representations to simplify complex information-handling tasks.

They represent the debit side of the cognitive ‘balance sheet’, where each entry also carries significant advantages.”
Rasmussen’s skill-rule-knowledge framework of human cognitive activity

- **Skill based activity** (unconscious thought)
  - Human performance governed by stored or preprogrammed instructions, unconscious thought process (example: walking, tying your shoes)

- **Rule based activity**
  - Tackling familiar problems by following rules
  - Examples: Procedures, checklists, if, then programming

- **Knowledge based activity**
  - Problems that must be solved using conscious analytical thought process
The benefit of unconscious thought
Cognitive errors
Unconscious Slips

While driving car along commuting path to work on the weekend, the intention is to go to the hardware store, but follow the path to work instead.
Reason: Human Error
Failure modes

Skill-based performance

Inattention    Over-attention

Double-capture slips  Omissions
Omissions after interruptions  Repetitions
Reduced intentionality  Reversals
Perceptual confusions

Over-attention on the small details (and checklists) and missing the big picture
# Reason: Human Error Failure modes

**Rule-based performance**

<table>
<thead>
<tr>
<th>Misapplication - good rules</th>
<th>Application - bad rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>First exceptions</td>
<td>Encoding deficiencies</td>
</tr>
<tr>
<td>Countersigns and non-signs</td>
<td>Action deficiencies</td>
</tr>
<tr>
<td>Information overload</td>
<td>Wrong rules</td>
</tr>
<tr>
<td>General rules</td>
<td>Inelegant rules</td>
</tr>
<tr>
<td>Redundancy</td>
<td>Inadvisable rules</td>
</tr>
<tr>
<td>Rigidity</td>
<td></td>
</tr>
</tbody>
</table>
Reason: Human Error

Failure modes

Knowledge-based performance

Selectivity
Workspace limitations
Out of sight out of mind
Confirmation bias
Overconfidence (runway)
Biased reviewing
Illusory correlation
Halo effects
Problems with causality

Problems with complexity

delayed feedback
insufficient processes in time
exponential developments
thinking in casual series
thematic vagabonding
encysting
Seeing a repetitious pattern, even when the pattern changes
Seeing a repetitious pattern, even when the pattern changes
Seeing a repetitious pattern, even when the pattern changes
Seeing a repetitious pattern, even when the pattern changes, overconfidence

Jet Crew Didn’t Know It Was on Runway, Investigator Says

By MATTHEW L. WALD

WASHINGTON, Jan. 7 — The crew of an Israeli jumbo jet that got lost in a rainstorm at Kennedy International Airport last July apparently did not know that one of the taxiways was closed for reconstruction, one factor that caused the plane to blunder into the path of a cargo jet that was about to take off, according to the chief Israeli investigator.

A continuing investigation into the near collision also revealed that an airline official had ordered the crew to rewrite its report on the encounter to play down its seriousness.

As the jumbo jet, a Boeing 767, sat in the middle of Runway 22 Right on the night of July 6, with 262 passengers and crew members and enough fuel to fly to Tel Aviv, the crew believed it was on a taxiway rather than a runway, according to the investigator, Itzhak Raz. The co-pilot of the passenger plane saw the cargo plane rumbling toward him, but did not realize it was preparing to take off, and radioed the tower to ask who was taxiing his way, Mr. Raz said.

“They were misoriented,” said Mr. Raz, a condition he described as being worse than lost, because the crew was disoriented without knowing it. “They were so sure they were right, they didn’t see the lights were different.” To help prevent confusion, taxiway signs are black and yellow; runway signs are red and white.

A collision was averted by a series of chance factors, according to investigators. Planes taking off on that runway are often not airborne by the spot where the Israeli jet stopped.

Taxiway work is seen as a factor in a near collision at J.F.K.

According to Mr. Raz, the Israeli crew had looked at the map of the airport before leaving the terminal, and decided to turn left at the second taxiway, Bravo, and follow it to the beginning of the runway. But the first taxiway, Alpha, was under reconstruction. Its lights were turned off, and the pavement itself had been torn up, he said, making it invisible to the crew of the passenger plane, operated by Israir Airlines. So the Israir crew passed Bravo thinking it was Alpha, and prepared to turn left on Runway 22 Right, thinking it was Bravo, he said. But a third person in the Israir cockpit recognized the problem, a “relief pilot” whose job was to take a turn flying during the long flight across the Atlantic and Europe, to give the two others a chance to rest. Sitting in the “jump seat” at the back of the cockpit, he reached forward and shoved the throttles open and shouted to get off the runway, Mr. Raz said, but the captain, still oblivious, yanked the throttle closed again.

When the crew arrived back in Tel Aviv, the three men composed a report describing the near collision, but an Israir executive, the vice president for operations, ordered them to rewrite it “to reduce the severity,” Mr. Raz said. So the report submitted to the Israeli authorities said they had passed near another plane that was taking off, not that the other plane had flown directly over them.

Mr. Raz said he was first alerted to the seriousness of the encounter by an article in The New York Times on July 21. The misleading changes in the original report were first disclosed by an Israeli television news program, “Uvda.”

Israir, a new airline, began flying to Kennedy last March, with temporary permission from the Israeli government; it is seeking permanent permission.

The vice president has been removed from his job, and a hearing is pending, Mr. Raz said. Two Israeli crew members were demoted and sent for retraining, he said.

Mr. Raz, who was in Washington on Friday to brief the Federal Aviation Administration and the National Transportation Safety Board, said in an interview afterward that his investigation was continuing. The purpose of the investigation, he said, was not to find fault but to take steps to make similar mistakes less likely.

A spokeswoman for the F.A.A., Laura J. Brown, said her agency was waiting for the complete report by Mr. Raz and an Israeli board of investigators.
Why people make mistakes

even with proper training, procedures, second checks

- Fatigue
- Inattention/distraction
- Seeing a repetitious pattern, even when the pattern changes
- Equipment design flaws
- Medication labeling, packaging similarities

- Communication gaps
- Incomplete instruction, illegible writing
- Environmental: poor lighting, noise
- Using an old solution for a new problem
Equipment design flaws

Therac-25 accidents

Software control system permitted x-ray mode of treatment without flattening filter

Result: Severe injury and deaths to several patients at multiple health care facilities
Equipment design flaws

Increase Treatment Time by $\times 4.2$ (24% Duty Cycle)
Equipment design flaws
Backup Collimator Settings

Right
Wrong

Slide courtesy of Ryan Flynn, Ph.D. University of Iowa
Equipment design flaws

So, we have been told

- Be sure to start recording the respiratory motion data before starting the CT scan
- Check and double-check the collimator setting when using a SRS cone
- Write a procedure, train personnel
Fair and Just Culture

What can we learn from this to prevent future harm?

- Error, Event or Near Miss
  - Was it the system?
    - Faulty design or lack of system?
  - Was it the behavior?
    - Human error
    - Risky behavior
    - Reckless behavior

Near misses or undesirable outcomes reviewed and responded to in a consistent manner

Accountability is not determined by the outcome
Fair and Just Culture

The Behaviors We Can Expect

• Human error - inadvertent action; inadvertently doing other that what should have been done; slip, lapse, mistake.
• At-risk behavior – behavioral choice that increases risk where risk is not recognized or is mistakenly believed to be justified.
• Reckless behavior - behavioral choice to consciously disregard a substantial and unjustifiable risk.
Fair and Just Culture

Individual Behavioral Choices
- Human Error
- Risky (Drift)
- Reckless

Management Response
- Human Error = inadvertent action (lapse, slip, mistake)
  - Console/Learn
- Risky (Drift) = behavioral choice that increases risk where risk is unrecognized or mistakenly believed to be justified
  - Coach/Learn
- Reckless = behavioral choice to consciously disregard a substantial and unjustifiable risk
  - Corrective Action
Are we naturally self aware of risky behavior?

Not necessarily
Risky behavior? Not me
Risky behavior? Not me

Most facilities have good procedures. They are not always followed because they are in a hurry or the procedures are thought of as “unnecessary.”

Redundancy checks are seen as not necessary and not done with attention or not done at all.
Risky behavior? Not me

HDR treatment by therapists without medical physicist or radiation oncologist present
System Competency

Safe Care

Behavioural Competency

Standardization & Diffusion of Best Practices

- Handoffs and transitions
- Medication errors
- Rapid response team and deteriorating patient

Commitment to Safety in a fair & just culture

- Clearly Defined Behaviors
  - Pay attention to detail
  - Communicate clearly
  - Have a questioning and receptive attitude
  - Hand-off effectively
  - Support each other

Accountability for Behavior

Preventable Harm
Conclusion
We need to think about system and human factors for a safe system of patient care
That’s all folks