Medical Errors Human Errers 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







BUILDING A SAFER HEALTH SYSTEM

INSTITUTE OF MEDICINE

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.



The New York Times

Radiation Offers New Cures, and Ways to Do Harm By WALT BOGDANICH Published: January 23, 2010

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



- 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.



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).



IOM Report

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



Fall Meeting 2005, FLAAPM Don Steiner, Bureau of Radiation Control, State of Florida "Medical Errors: Misadministrations and Common Causes"

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.





Fall Meeting 2005, FLAAPM Don Steiner, Bureau of Radiation Control, State of Florida "Medical Errors: Misadministrations and Common Causes"

- 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.



Fall Meeting 2005, FLAAPM Don Steiner, Bureau of Radiation Control, State of Florida "Medical Errors: Misadministrations and Common Causes"

- 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

Safety Report Series No.17 Lessons Learned from Accidental Exposures in Radiotherapy 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





Safety Report Series No.17 Lessons Learned from Accidental Exposures in Radiotherapy International Atomic Energy Agency, 2000

- 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





Safety Report Series No.17 Lessons Learned from Accidental Exposures in Radiotherapy International Atomic Energy Agency, 2000

- 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, trainingb) lack of equipment (barometer on site)





More references





(People Making) Medical Errors

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
- o Toulouse, France (2006-2007)
- o Vendor caught the error
- o Affecting 145 patients
- Springfield, MO (2004-2009)
- ➢ 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 http://www.nytimes.com/2010/12/29/health/29radiation.html

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 From Solberg et al, Prac. Rad. Onc., *In Press* (2011)

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



(C



mayo

If they would only follow proper procedures, this would never happen

29

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



IOM Report To err is human

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.





Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of a single individuals"

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.



ACGME

Residents duty hours

Accreditation council for graduate medical education

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 that 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 that 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 York...white



HUMAN ERROR Antipication of the second of the

"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 performanceInattentionOver-attentionDouble-capture slipsOmissionsOmissions after interruptionsRepetitionsReduced intentionalityReversalsPerceptual confusions

Over-attention on the small details (and checklists) and missing the big picture



Reason: Human Error Failure modes

Rule-based performance

Misapplication - good rules First exceptions Countersigns and non-signs Information overload General rules Redundancy Rigidity

Application- bad rules Encoding deficiencies Action deficiencies Wrong rules Inelegant rules Inadvisable rules





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

THE NEW YORK TIMES NEW YORK SUNDAY, JANUARY 8, 200

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 copilot 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

"They were so sure they were right, they didn't see the lights were differ ent." To help prevent confusion, taxiway signs are black and vellow: 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.



But the co-pilot of the cargo jet, at the controls that night, had started his takeoff roll from the beginning of the runway, spotted the passenger plane and then climbed at a very steep angle, missing it by less than 100 feet, by the cargo plane captain's estimate. Climbing that steeply was possible because the cargo plane was empty.

According to Mr. Raz, the Israeli crew had looked at the map of the

was disoriented without knowing it. 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 out, 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, vanked 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





Equipment design flaws Backup Collimator Settings





Right

Wrong



Slide courtesy of Ryan Flynn, Ph.D. University of Iowa http://www.nytimes.com/2010/12/29/health/29radiation.html

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





T MAYO CLINIC

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

Human Error = inadvertent action (lapse, slip, mistake) Response

Management

Console/ Learn

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

Risky (Drift) = behavioral choice that increases risk where risk is unrecognized or mistakenly believed to be justified

Reckless = behavioral choice to consciously disregard a substantial and unjustifiable risk Coach/ Learn

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

Behavioral Competency

Safe

Care

Preventable

Harm

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


Conclusion We need to think about system and human factors for a safe system of patient care





That's all folks



