SAFETY IN THE CLINIC

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Air France Flight #447
35,000 ft
Unremarkable flight
Passengers relaxed, read, watched movies, slept

A few hours into the flight, with no communication to the ground or air traffic control, flight 447 disappeared. All 228 on board died.
What Happened?

Long flight.
  Pilot and 2 co-pilots.
  Work in shifts – 2 on, 1 sleep.

Automated system flying the plane had suddenly shut off.

Co-pilots did not know what to do
  Felt he needed to gain elevation
    Thought system would augment action
  Plane went into a stall
    Warning system told them it was in a stall, yet they ignored it.

4 minutes later, the plane crashed into the Atlantic, instantly killing all 228 on board.
Automation:

"Years of depending on automation had left the pilots unprepared to take over the controls."

"These pilots had experience stripped away from them for years."

Captain had logged 346 hrs of flying over past 6 months, but within those 6 months, there were only about 4 hours of flying over the past 6 months! - Takeoffs and landings.

"This lack of experience left the pilots unprepared to do their jobs."

Common phrase from pilots: "What's it doing now?"

Automation has turned pilots into "Children of the Magenta."

"Children of the Magenta (Automation Paradox, Part 1) ".
- Episode 170, 99 Percent Invisible, 99percentinvisible.org
Estimated rate of mis-administrations for each patient in the U.S. is approx. 0.2% or 1 in 600.

How bad is that?
Airline Industry – Gold Standard

- Ave 19 serious injuries or fatalities each year on U.S. airplanes from 2002 – 2008
- 712 million flew each year
- Ave passenger flies 3.8 times per year
- Odds of dying or serious injury is 1 in 10 million
- 16,000 times lower than risk of similar mistake during radiotherapy
Majority of radiation treatment errors result in far less severe injuries
- 94% were judged to be of “little or no clinical significance”
- Therefore, perhaps only 6% of incidents are serious
- The risk of serious injury is now only perhaps 1,000 times higher than the airline industry
  - (down from 16,000 times higher)
- Feel better?
- Previous studies estimate rates around 1%-5% per treatment course
  - Much higher than the previous 0.2%
- Is everything reported?
  - No one really knows the actual rate of injury in our field.
In 2000, Aviation Safety Action Program (ASAP) adopted a national anonymous near-miss reporting system.
- Serves as a learning resource
- 2nd simple tool: preflight safety checklist
- Can we learn from their experience?
- Radiation treatment is complicated:
  - Complexity of the disease
  - Sophistication of the technologies
  - Intricacies of communication amongst treatment team
  - Humans are involved

- A routine course of radiation therapy contains approx. 270 separate points of potential error.
- In the last 10 years, complexity has increased markedly
  - IMRT - IGRT
  - VMAT - HDR
  - SBRT

- So we invested in new tech and quality control
  - Led us to believe that patients are treated more effectively and safely.
  - True?
June, 2010 in Miami: “Safety in Radiation Therapy: A Call to Action”, sponsored by AAPM and ASTRO

- 400 participants, including AAMD
- Intent was to identify causes of mistakes and equipment failures in radiation oncology
- Make treatment safer by developing methods to address the causes
Deductions

- We depend on computer-aided design of treatment plans and computer-control of treatment machines.
- Has led to diminished knowledge about and direct control over the actual treatment by the radiation therapists at the point of care.
- Have you seen this?
  - Button pushers? Say it ain’t so!
Other Factors

- Cluttered therapy workstations
  - Multiple computer monitors
- Staff traffic patterns
  - Distracting conversation and interruptions
- Inadequate warning alerts when something is amiss
- Inability or unwillingness of users to attend product training educational sessions
Other Factors

- Lack of empowerment of staff to challenge decisions made higher in the hierarchy
- Lack of specific policies and procedures defining staff responsibilities
- Several other factors listed.
Conclusions

- These problems are best addressed through a multidisciplinary approach:
  - Radiation Oncologists
  - Medical Dosimetrists
  - Nurses
  - Administrators
  - Regulators
  - Medical Physicists
  - Radiation Therapists
  - PAs
  - Vendors

- What?
Conclusions

- Errors can be reduced
  - But they cannot be eliminated
    - Complex treatment process
    - Hardware/ software technology can malfunction
    - Humans!

- Therefore, treatment approaches must be fault-tolerant
  - Must be designed to catch and correct errors before they can harm the patient.
Recommendations

- Interface of therapists with treatment machines should be streamlined, layered and standardized.
- Therapist workstations should be clutter-free.
- Therapist workstations should not be a collection of monitors and other gear.
- Should present information:
  - In tiered fashion
  - Single keyboard
  - Ergonomically designed interface
Recommendations

- Traffic near therapist workstation should be minimal
  - Extraneous noise
  - Idle conversation
- Therapists should not be interrupted while treatments are underway
  - By others or by themselves
- Greater control must be provided to the therapists so treatment can be terminated if something unexpected occurs.
Recommendations

- Early warnings/ warning systems should be provided.
  - Operator should not reset the system unless he/she is sure the warning is erroneous or the problem has been corrected.

- Billing process should be simplified and should not take place during patient treatments
  - Causes the therapist to multi-task
  - Insufficient diligence
Recommendations

- A covenant and commitment to safety should be expected of the treatment team
  - Covenant: a formal, solemn agreement

- Any member of the team should have the right and responsibility to speak out if he/she has concerns or questions about the plan/treatment.
  - This “time out” or “no fly zone” should be respected and addressed appropriately before proceeding.
  - No member of the treatment team shall be treated with disrespect.

- Many other recommendations as well, including the use of an Error Reporting System.
Culture of Safety

- Safety champions
  - Senior members of the team
  - Respected by all employees
- Everyone on the team should work together to ensure the safety of patients
- Each person should be:
  - Respected
  - Supported
  - Appreciated for his/her commitment to safety
Ottawa Hospital Cancer Centre has reported their results:

- “We have created a safety culture where every team member’s opinion is valued, regardless of position or seniority.”
- “… staff satisfaction has been evident by improved morale.”
Use of an ILS

- Incident Learning Systems (ILS)
  - Members of treatment team could be alerted to problems occurring
    - Within the department
    - Or elsewhere – but still relevant to their institution
    - E.g: Multiple reports of equipment problems would notify vendors to the need for rapid action.
Use of an ILS

- “Incident” – an unwanted or unexpected change from a normal system behavior (“event”)
  - Causes, or has the potential to cause, an adverse effect to persons or equipment
    - Includes actual deviations from normal system behavior
    - Includes near-misses, even if potential, direct clinical impact is small in one specific case

- Near Miss
  - A close call
  - Patient safety event that did not reach the patient
Use of an ILS

- An **anonymous** ILS provides a test of the whole radiotherapy process
- Where are errors occurring according to real, communicated data?
- Can we anticipate and correct for errors before they occur?
- How can we learn from the incidents of others?
- What education/in-service programs are needed?
- How are new initiatives working over time?
- Results in a level of safety and efficiency that a purely **reactive** system cannot achieve.
Implementing an ILS

- Understand that ultimate purpose of ILS is to learn from various events and improve existing processes.
- Culture of safety in which employees are motivated, encouraged, and feel sufficiently safe to report errors and near-misses.
- Use an efficient data collection method that is easy to use, yet sufficiently comprehensive to allow collection of all relevant data.
- Efficiently process events and promptly disseminate recommendations to all staff.
Implementing an ILS

- Develop constructive methods for providing feedback to individual reports and involved parts of the organization.
- Willingness to implement significant changes based on collected data and subsequent analyses.
- Recommendations that are focused on system and process changes, NOT on individual performance.
- Ability to share the collected data within the organization and also with a broader community.
  - Optional feature, but highly desirable.
Implementing an ILS

- Experienced employees usually know rapid work-arounds for errors that almost happen.
- But the study of near-misses is powerful in identifying problems with work processes that can lead to error.
- Significant in preventing future repeats wherein actual damage may occur.
- Foster a sense of openness, mutual respect, group participation and responsibility.
- Use an ILS
- Learn from
  - Incidents
  - Near Misses
  - Unsafe Conditions

**RO-ILS: Radiation oncology incident learning system: a report from the first year of experience.**

*Practical Radiation Oncology*


