MAYO CLINIC

Connecting the gap between radiotherapy care delivery & incidence learning

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Michael G. Herman, Ph.D.

Disclosures

- Nothing to disclose

Thank You

- Peter Dunscombe

Objectives

- Review what can happen in the clinical setting in terms of medical incidents and potential and real consequences
- Discuss the relevance and clinical implementation of incident reporting and incident learning
- Review the criticality of the open and team nature of incident learning and error reduction.

What can Happen-Therac 25 – 1985-86

- Four different hospitals
- Unexpected occurrences
  - Patient felt “burned”, “shocked”, “sizzled”
- Accidental massive overdoses
- System (machine + human) safety failure
- No-body knew, about others, what errors meant!!

IAEA - Prevention of accidental exposure in radiotherapy – online series ~2009

TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM

OK that was THEN,

1999 - Errors are not caused by bad people, but by bad systems

And Now?

What can Happen-More recently (2005,6)

- Incorrect manual parameter transfer → 67% higher fractional dose to patients
- Large ion chamber used to measure small field outputs – substantial systematic dose errors
- PDD ref depth incorrect in absolute calibration "spreadsheet" → systematic patient overdose
- IMRT plan delivered with MLC retracted → death

IAEA - Prevention of accidental exposure in radiotherapy – online series ~2009

No organized solution

- Manual systems, incomplete safety checks, poor software integration, poor interlock messaging, communication break downs
- Data hard to find, incomplete, not analyzed, lessons "partially" learned
- 100% of these previous errors reached the patient – that's when we found out!

Attention!! – 2010 We made the news

We had begun to work earnestly on error analysis, reduction, …. BUT

Time to learn/change

Better QA Reduces Errors

Standardize:
– processes, messages, terms

Understand Workflow

Recognize Human Factors

Education

Awareness: Something "strange"

Central Database for Incident Learning

Environment:
- Facility, equipment, interfaces

BEGIN the Incident Learning/Reporting Era

What Can Happen (post ILS ~2015)?

- From RO-ILS analysis of >2000 events of which 396 considered substantial potential risk
  - Focus on 176: Problematic plan approved for treatment," "wrong shift instructions given to therapists," and "wrong shift performed at treatment.
- Incorrect laterality
- Incorrect imaging structure labeled as target
- Mixed up Dose-Fx

Ezzell et.al. PRO, 2018

Post ILS ~2015 cont'd

- Isocenter of reference images off by 5cm
- CBCT alignment missed by 3cm (vertebral body)
- A significant and difficult to expose error set is the physician incorrectly defining targets or prescribing incorrect dose-fraction values.
- "only" 44% of these reached the patient !
- ILS provides a method to provide education and information to all users in a standardized fashion.

How do we get there? Implement ILS

- Implementing the ILS
  - Core group, institutional support/infrastructure
  - Core team with given time to work
  - Numerous models RO-ILS, other commercial systems – some are "smart" - CARS
  - Culture, planning, investment
  - Culture of safety and open communication

Core concepts from the WHO (2013)

- The primary purpose of patient safety reporting systems is to learn from experience.
- A reporting system must produce visible, useful results from data analysis and investigation to formulate and disseminate recommendations for systems change.

ILS for Radiation Oncology

- Engage departmental leadership
  - Resources + nonpunitive and just culture
- Establish and formalize the process
  - Logging and investigating incidents
  - Specific to RO
  - Electronic
  - Define “event”, standard terms, + near miss!
  - Scoring and analysis protocol

Ford Med Phys 2018

ILS for RO

- Encourage reporting, provide feedback
  - Actions taken, support for strong reporting
- Build/maintain a positive culture
- An effective ILS improves patient safety by:
  - Recording near misses and creating awareness and process improvement
  - Being easy for any staff member to report in a non-punative manner
  - Ensuring not only errors that cause patient harm are addressed.

Can an ILS make a difference? Example

- 2007-2015, Brachy practice encouraged to report all deviations, high & low risk.
- Review committee assigned root causes and risk scores
- ILS evidence based practice changes made
- Incidents were communicated to all staff

Deufel radiother oncol 2017

Can an ILS make a difference?

YES!

- 2238 incidents in 5258 procedures
- ILS reporting ramp-up observed 2007 (0.12 report/case) → 2011 (1.55 report/case).
  - stable after 2011
- during the stable years (2011-2015)
  - 60% decrease in the risk of dose error or violation of radiation safety policy ($p < 0.001$)
  - 70% decrease in frequency of high composite-risk scores. ($p < 0.001$)

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Think Globally, Act Locally

- Local ILS, however simple can reduce errors and plug into a national or international reporting system
- Improves statistics and learning at the larger level

Partnerships for Safety

- Teamwork, partnerships, clinical staff, industry
- Multiple safety working groups within the various professional organizations
- Radiation Oncology Safety Stakeholders Initiative

Example-AAPM Workgroup on the prevention of errors in RO:

- Recognizing Incident learning is an invaluable tool.
- The consensus recommendations in this report are intended to facilitate the implementation of (ILS) within individual clinics as well as on broader national and international scales.
- Standardization! – with input from 8 other national and international orgs

Ford Med Phys 2012

Consensus standards for

- Definitions: common terms
- Process maps: core workflow essentials
- Severity metrics: calibrated hazard scale
- Causal taxonomies: common causes/contributors
- Data elements: key items for meaningful reporting
- BASIS for MODERN ILS!

RO-SSI (Safety Stakeholders Initiative)

- Ad-hoc self-organized collaborative group
  - radiation oncology physicists, physicians, vendors, regulators, administrators, therapists, dosimetrists, government employees
  - Independent of respective groups
  - Began 2010, meets at ASTRO/AAPM annually
  - Working groups to focus on improving safety
    - Error messages, QA, Training, Usability, Risk Management, Workplace Safety/Culture, Rx consistency.

Summary

- Errors in the clinical setting can be lethal.
- This is not new
- A number of systems and standards including Incident reporting can substantially reduce error
- Any system must be implemented openly, with support, in a team environment
  - Team in the broadest sense.
- We must act locally, think globally, work tirelessly