Patient Safety in Radiation Therapy:

A History of Errors &
A Methodology to Prevent Them
About the speaker:
About the speaker:

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• BS, Health Physics, Francis Marion College, 1992
• MS, Health Physics, University of Florida, 1994
• Senior Medical Physicist, MRMC
• Practicing MP since 1995
• Physics surveyor for the ROPA program of the ACR
Disclosures
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• sole proprietor of Carolina Physics, LLC
About MRMC Radiation Therapy:
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- MRMC serves NE South Carolina and Southern North Carolina
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- Accredited by the American College of Radiology ROPA
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- Presentation and discussion of these incidents are provided to establish a “burning platform” for change within clinical practice, and to highlight the use of the P-FMEA
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- Introduction & History of the P-FMEA
- Application of the P-FMEA to Radiation Therapy
- Future Applications of the P-FMEA
The Radiation Therapy Process - Global View

- Patient Assessment
- Decision to Treat
- Prescription
- Positioning & Immobilization
- Simulation, Imaging, & Volume Determination
- Planning
- Commissioning
- Treatment Setup
- Treatment Delivery
- Treatment Data Transfer
- Treatment Verification & Monitoring

Monday, April 8, 2013
How Many Errors are Occurring in Radiation Therapy?
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- 2008 World Health Organization (WHO) published the “Radiotherapy Risk Profile”
- retrospective review of 30 years of reported radiation therapy incidents
- findings included:
  - from 1976 to 2007, 3125 patients were reported to be affected by radiotherapy incidents that led to adverse events (38 reported fatalities; differs from the 53 reported in this presentation)
  - from 1992 to 2007, 4616 “near misses” (incident that did not cause harm) were reported
  - Total of 7741 “events”
  - weaknesses/flaws? result of investigations of major events, relates mainly to developed countries
2008 WHO Report - Fatalities

- Patient Assessment
- Decision To Treat
- Prescription
- Positioning & Immobilization
- Simulation, Imaging & Volume Determination
- Commissioning
- Planning
- Treatment Data Transfer
- Patient Setup
- Treatment Delivery
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• New York Times reported:
  • between 2001-2008, 621 events were reported in New York State
  • most were minor, however...
    • 133 reported incidents of devices being left out or wrongly positioned (causation of 2 fatalities and a third incident of over-dose)
    • 284 reported incidents were geometric miss
How Many Errors are Occurring in Radiation Therapy?
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- in 2005, Eric Klein, et. al., (Washington University, St. Louis, MO) reported:
  - 103 “events” in 3964 (2.5% incidence rate per course) courses of therapy initiated (over a 30-month period)
  - stratified each error type in terms of frequency, longevity, and dosimetric impact (low, medium, high)
  - 76 of the 103 (74%) were categorized as >/= medium in terms of dosimetric impact
- Was this the “first” FMEA in the Radiotherapy Arena?
Errors in Radiation Therapy - Handicaps
Errors in Radiation Therapy - Handicaps

- Lack of a national database
- Voluntary reporting
- Lack of reporting structure for incidents and near misses
- Dissemination of events/data to other parties
- “Knee-jerk” response to errors - not resolving the “root cause” - we all jump to box 5
SCDHEC Misadministration - defined

- South Carolina Department of Health and Environmental Control defines a therapy “Misadministration” as (RHB 9.153):
  - Radiation delivered to the wrong patient
  - Radiation delivered to the wrong site
  - Radiation delivered with the wrong mode of treatment
SCDHEC Misadministration - defined

- Performance of a therapeutic procedure other than that ordered by the prescribing physician
- Error in calibration, time of exposure, or treatment geometry that results in a calculated total dose > the total prescribed treatment dose by more than 20%
- 3 fractions or less > 10%
- Weekly treatment dose exceeds weekly prescribed dose by 30% or more
RT Errors - Historical

- Description of the incident
- Tobin’s Taxonomy
  - Equipment Design
  - Process
  - Human Error
RT Errors - Historical

- Therac-25 (TX, W, Canada)
- 1982-1990
- 3 fatalities; 4 others with severe or debilitating injuries
- Treatment programming change resulted in electron beam at x-ray tube currents - dose > 40Gy
- Manufacturers response was “slow”
- Taxonomy - Equipment Design
- Photo courtesy of Fritz Hager
RT Errors - Historical

- Incorrect Linac Repair (Spain)
- 1990
- 15 fatalities (most within 1 year; lung & spinal cord injury)
- Repair of accelerator led to 36MeV electron beam delivery regardless of console input
- Physics did not verify operation after maintenance
- Taxonomy - Process, Human Error
RT Errors - Historical

- Error in the calculation of the dose rate of a Co-60 teletherapy unit (Costa Rica)
- 1996
- 13 fatalities (varies by report from 4-17)
- Value of 0.3 min interpreted as 30 seconds (rather than 18 seconds)
- 73% overdose (including patients from the children’s hospital)
- Side effects included ulceration, bleeding, epilation, and anemia
- Taxonomy - Process, Human Error
RT Errors - Historical

- TPS modification - block entry (Panama)
- 2000
- 17 fatalities from radiation overexposure
- Limitations in the TPS with regards to block entry led to 20-100% overdose (treatment times calculated incorrectly)
- Taxonomy - Process, Human Error
RT Errors - Historical

- Machine Malfunction (Poland)
- 2001
- 5 reported overdoses
- Power outage led to a burned out fuse on a control board for the accelerator; failure of the interlock circuit governing this CB resulted in the dose rate increasing five-fold when returned to service; patients reported “itching and burning” of the skin following treatment prompting staff to cease use of the equipment
- 3 patients received 60 to 80 Gy
- Taxonomy - Process
Severe skin changes following a radiation burn
all the thickness of the left chest wall in the internal two thirds of the electron field, and severe superinfection by pseudomonas aeruginosa. The beating heart of Patient 4 was visible in the depth of the wound. The status of the local injury is shown in Fig. 23.

Patient 4 was first treated topically, using antibiotic therapy and pain relievers. The following analyses allowed the treatment to be focused further:

(a) Isotopic ventricular left ejection fraction examination (27 May): 60%, normal.
(b) MRI (28 May): pericardial and left pleural effusion, left ventricular anterior lesion (confirming previous Polish MRI data).
(c) Telethermography (6 June): all the irradiated volumes of the chest wall appeared to be 'cooler' and therefore were believed to be prenecrotic.
(d) Bacteriology: persistence of pseudomonas superinfection, despite treatment with antibiotics.

On 6 June, Patient 4 underwent her first surgical procedure after the overexposure. This procedure consisted of several steps: exploration of the

Performed by Dr. Clough, Dr. Couturaud and Prof. Chapelier.

FIG. 23. Patient 4 in May 2002: Local injury before reparative surgery.
RT Errors - Historical

- Change from physical wedges to Dynamic Wedges (France)
- 2004
- 1 fatality; others with severe complications
- Clinic moved from PW to DW; continued to calculate MU for physical wedges resulting in 20-30% overdose
- Taxonomy - Process
RT Errors - Historical

- Improper jaw size during SRS (France)
- 2004
- Normal tissue irradiated; patient developed “fibrosis & oesotracheal fistula” requiring surgery; patient died from “brutal haemorrhage” a few days after surgery
- Physician instructed therapist to set a “40x40” field size, which the therapist interpreted as 40cmx40cm (40mmx40mm)
- Taxonomy - Process
RT Errors - Historical

- Procedure change (Scotland)
- 2005
- 15-year old patient undergoing whole CNS irradiation (brain + spine) received 67% overdose to whole brain due to calculation error
- Patient died 9 months post irradiation - recurrent tumor
- Taxonomy - Process
RT Errors - Historical

- Commissioning (mis)-measurements (France)
- 2007
- Large chamber used to make small field measurements for SRS
- 200% overdose for some patients
- Taxonomy - Human Error
RT Errors - Historical

The U.S. is not immune...
RT Errors - Historical

- Failure to follow accepted practice/protocol (USA)
- March 2005
- Detailed in NY Times article (“Radiation Boom” series by Walt Bogdanich)
- Plan change after treatment initiation was not “QA’d” in a timely fashion; patient received IMRT MU with NO mlc-modulation (jaws were wide open), resulting in a brutal overdose for 3 fractions
- After suffering from swelling of the brain, loss of sight, loss of hearing, inability to swallow, and finally, difficulty breathing, the patient died of his overdose in 2007
- Same error (mlc retracted) occurred several months later; patient received 6x prescribed dose, but caught after 1 fraction!!!
- Taxonomy - Process & Human Error at the Physics and Therapist level

Monday, April 8, 2013
RT Errors - Historical

- Failure to implement treatment plan (USA)
- April 2005 (significance with previous case; state inspectors had reinforced need to ensure proper accelerator programming)
- Detailed in NY Times article ("Radiation Boom" series by Walt Bogdanich)
- Physical wedge was either incorrectly positioned or left out entirely, resulting in tissue damage/necrosis of soft tissue, rib, and lung; the resulting burn required a skin/tissue graft and hyperbaric treatment for necrosis; condition lasted for over a year; the patient died several months after the damage from the radiation healed
- Taxonomy - Process & Human Error at the Physics and Therapist level
RT Errors - Historical

- other incidents within New York State reported by the NYT:
  - 14-year old girl received double the prescribed dose for 10 treatments (faulty calc, failure to verify)
  - 2 prostate cancer patient irradiated to the wrong location 32 of 38 treatments and 19 of 38 treatments (equipment not tested following repairs)
  - 31-year old vaginal cancer patient over-dosed by 80%; risk of fistula formation between rectum and vagina (inexperienced team performing IMRT)
  - 63-year old patient received >10x the prescribed dose in one location and 1/10th of the prescribed dose in another location
  - wrong patient irradiated
  - other cases reported in NYT series of articles

Monday, April 8, 2013
RT Errors - Historical

- SRS unit mis-calibrated (Florida, USA)
- 2005
- 77 brain cancer patients over-dosed by >50% (from 2004 to 2005); disposition of most of the patients was grave due to the disease
- discovered by independent audit by RPC
- Taxonomy - Human Error
RT Errors - Historical

- SRS unit - leakage outside of conical applicator due to incorrect field size (Illinois, USA) - Toulouse, France anyone?
- 2009
- 4 patients over-dosed to regions of the brain that were not intended to be treated
- 50-year old mother of 3 converted to an invalid (currently in a nursing home, unable to communicate other than “blinking her eyes and squeezing her husband’s hand”) after treatment for a benign condition (TriN)
- After procedure, patient #1 experienced vomiting, burning in her throat, weight loss, and swatches of hair falling out; patient #2 experienced irregular heartbeat, weakness, changes in mental status; patient #3 experienced nausea, vomiting and dehydration (classic ARS of the CNS)
- Taxonomy - Human Error
RT Errors - Historical

• SRS unit - improperly calibrated using an ion chamber “too large” for the purpose of the measurements (sound familiar, France?)

• 2004-2009

• 76 patients over-dosed by >25-100% (right location, wrong dose)

• results of over-dose varied from facial spasms to balance and memory problems (issues that were reported)
What does this have to do with me?

• in the span of 22 months between 2007 and 2009, 6 events which required reporting to the state of SC occurred at MRMC (read “misadministration”)

• No patients were injured, but they did not receive “optimal” care

• My platform is now burning...
Burning Platform

- 2 wrong patients (Tx Delivery)
- 3 wrong sites
- 2 instances where incorrect reference images were generated resulting in the patient being incorrectly setup/irradiated (Planning)
- 1 instance where a pretreatment shift was not performed to the correct area (Tx Delivery)
- 1 instance where a treatment block was incorrect, not detected for 17 fractions (Tx Delivery)
Organizational Factors:
- Excessive cost cutting
- Inadequate promotion policies

Unsafe Supervision:
- Deficient training program
- Improper team pairing

Preconditions for Unsafe Acts:
- Poor CRM
- Mental Fatigue/Distractions

Unsafe Acts:
- Failed to identify correct surgical site
- Failed to verify correct medication

Failed or Absent Defenses

Accident and Injury
What do we do?

- engaging our colleagues within Operational Effectiveness (OE), we decided to use Lean principles to analyze the “gap” in our processes
- live by the mantra “we don’t have bad people, just bad processes”
- OE suggested performing a Process-Failure Modes and Effects Analysis
P-FMEA

• we assembled a multidisciplinary team (physicists, dosimetrists, administrators, therapists, nurses), each with a stake in the process

• we mapped our current processes in as much detail as we could

• for each process step, we identified potential failure modes (91 total)

• each failure mode is scored for Occurrence, Detection, and Severity (scale of 1-10)
P-FMEA

- Occurrence = 1, rarely happens
- Occurrence = 10, happens all the time
- Detection = 1, easy to see
- Detection = 10, difficult/impossible to see
- Severity = 1, no impact to the patient (perhaps a delay)
- Severity = 10, death/misadministration (our designation)
- Take care to keep scoring “realistic” and “consistent”
P-FMEA

- for each failure mode, the product of the scores for Occurrence, Detection, and Severity is known as the RPN, or Risk Priority Number (1-1000)

- RPNs can then be sorted in terms of priority for problem solving
<table>
<thead>
<tr>
<th>Category</th>
<th>Process Step</th>
<th>Failure Mode</th>
<th>Effect</th>
<th>Occurrence (1-10)</th>
<th>Detection (1-10)</th>
<th>Severity (1-10)</th>
<th>Risk Profile Number</th>
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</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>Prescription Written by Oncologist</td>
<td>Orders Not Dated - Initial</td>
<td>Delay In Treatment</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>3</td>
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<tr>
<td>Prescription</td>
<td>Prescription Written by Oncologist</td>
<td>Illegible Prescription</td>
<td>Prescription Intent Not Carried Out</td>
<td>7</td>
<td>5</td>
<td>10</td>
<td>350</td>
</tr>
<tr>
<td>Prescription</td>
<td>Prescription Written by Oncologist</td>
<td>Unclear Prescription (Not enough info)</td>
<td>Wrong Treatment</td>
<td>3</td>
<td>1</td>
<td>4</td>
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<tr>
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<td>Prescription Written by Oncologist</td>
<td>No Written Orders</td>
<td>Wrong Treatment / Delay In Treatment</td>
<td>3</td>
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<td>2</td>
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<td>Prescription</td>
<td>Prescription Written by Oncologist</td>
<td>Unrecognized Changes In Prescription (Date)</td>
<td>Delay In Treatment</td>
<td>4</td>
<td>3</td>
<td>4</td>
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<td>Diagnostic</td>
<td>Patient Diagnostic Studies</td>
<td>Pull Study For Incorrect Patient</td>
<td>Incorrect Site</td>
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<td>5</td>
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<tr>
<td>Diagnostic</td>
<td>Patient Diagnostic Studies</td>
<td>No Access To Appropriate Study</td>
<td>Delay In Treatment</td>
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<td>1</td>
<td>3</td>
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<td>Immobilize / CT</td>
<td>Immobilization Initial Setup</td>
<td>Inadequate Immobilization</td>
<td>Incorrect Treatment / Re-Image / Delay</td>
<td>1</td>
<td>3</td>
<td>7</td>
<td>21</td>
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<tr>
<td>Immobilize / CT</td>
<td>Immobilization Initial Setup</td>
<td>Reproducibility Of Set-up</td>
<td>Incorrect Treatment / Re-Image / Delay</td>
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<td>3</td>
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<td>Immobilize / CT</td>
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<td>Insufficient Data</td>
<td>Re-Image / Delay</td>
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<td>2</td>
<td>5</td>
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<td>Planning CT</td>
<td>Inadequate Contrast Studies</td>
<td>Incorrect Treatment</td>
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<td>Nonstandard Patient Orientation</td>
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<td>Missing Accessory</td>
<td>Re-Image / Delay</td>
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<td>Assign Patient</td>
<td>Limited Communication Regarding Patient</td>
<td>Incorrect Treatment / Delay</td>
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<td>3</td>
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<td>Wrong Data Set Used</td>
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<td>MD Contour</td>
<td>Pull Diagnostic</td>
<td>Pull Wrong Data Set</td>
<td>Incorrect Treatment</td>
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<td>MD Contour</td>
<td>Tumor &amp; Targets</td>
<td>Inaccurate Volumes Set</td>
<td>Increased Side Effects / Delay In Treatment</td>
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<td>Delay In Treatment</td>
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<td>Incorrect Treatment</td>
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<td>Contour Normal &amp; Critical Structures</td>
<td>Contour Wrong Structure</td>
<td>Incorrect Treatment / Increased Side Effects</td>
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<td>MD Approval</td>
<td>Sign Off On Incorrect Plan / Film</td>
<td>Misadministration / Incorrect Treatment</td>
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<td>Wrong Placement</td>
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<td>Plan Output</td>
<td>DRRs To Impac</td>
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<td>Misadministration / Incorrect Treatment / Delay In Treatment</td>
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<td>MD Approves Error - Non Detection</td>
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<td>MD Approval</td>
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<td>Iso Verification / Treatment Fields</td>
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<td>Contour Normal &amp; Critical Structures</td>
<td>Contour Wrong Structure</td>
<td>Incorrect Treatment / Increased Side Effects</td>
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<td>Print Plan</td>
<td>Source Data for iso pair does not match DRR</td>
<td>Misadministration / Sentinel Event</td>
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<td>Send To Simulation</td>
<td>Send Incorrect Images</td>
<td>Misadministration / Incorrect Treatment / Delay In Treatment</td>
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<td>Send Incorrect Images</td>
<td>Misadministration / Incorrect Treatment / Delay In Treatment</td>
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<td>Verify Iso Coordinates</td>
<td>False +</td>
<td>Sentinel Event / Misadministration / Delay In Treatment</td>
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<td>Rad Calc Check MU</td>
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Monday, April 8, 2013
Value of the Work/Data

- From February 2007 to April 2009, 6 misadministrations requiring reporting to the patient and the state
- From April 2009 to now, NO treatment events have been detected or reported (48 months)
- Tracking the perceived impact of process changes on patient safety
Lean Healthcare - A3 Thinking

- named for “A3” paper format for printing - seriously!
- logical extension of the scientific method
- box 1 - Reason for Action
- box 2 - As Is Condition
- box 3 - Desired State
- box 4 - Gap (define the reasons for difference between box 2 and box 3)
- box 5 - Solutions
- box 6 - Rapid Experiments
- box 7 - Completion Plan
- box 8 - Confirmed State
- box 9 - Insights