Error Reduction Software Program in Radiation Oncology

by

Ed Kline
Acknowledgements

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Located in Philadelphia, PA
Located in Albuquerque, NM

for their permission to use the MERP medical error reduction software program in their clinic and share their experience.
Introduction

• Presentation describes
  • Historical basis for error reduction initiative
  • Published errors and rates of occurrence
  • Prototype paper-based model
  • Design and implementation of software-based model
  • Deployment of software-based model in 2 radiation oncology centers
  • Results of implementation
Introduction

• Patient safety
  – Freedom from accidental injury due to medical care, or absence of medical errors\textsuperscript{1,2}
  or
  – Absence of misuse of services\textsuperscript{3,4}

• Error
  – The failure of planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)\textsuperscript{5}

\textsuperscript{5} \textit{To Err is Human: Building a Safer Health System.} Institute of Medicine (IOM). \textit{The National Academies} (11/29/99).
Introduction

• In radiation oncology, variety of injuries and errors can occur in the diagnostic imaging or therapeutic treatment delivery processes.

• Various descriptors
  - Unintended deviation
  - Incident
  - Accident
  - Error
  - Mistake
  - Unusual occurrence
  - Recordable event
  - Adverse event
  - Misadministration
  - Medical event
  - Sentinel event
History
1999

• Institute of Medicine (IOM) report\textsuperscript{6}
  – Focused a great deal of attention on the issue of medical errors and patient safety
  – 44,000 to 98,000 deaths per year in U.S. hospitals each year as the result of medical errors
  – 10,000 deaths per year in Canadian hospitals
  – Exceeds annual death rates from road accidents, breast cancer, and AIDS combined in U.S.

\textsuperscript{6}To Err is Human: Building a Safer Health System. Institute of Medicine (IOM). The National Academies (11/29/99).
History
1999

- IOM Costs\textsuperscript{7}
  - Approximately $37.6 billion per year
  - About $17 billion are associated with preventable errors
  - Of that $17 billion, about $8 to $9 billion are for direct health care costs
  - Updated estimates place costs between $17 billion and $29 billion per year in hospitals nationwide\textsuperscript{8}

\textsuperscript{7}To Err is Human: Building a Safer Health System. Institute of Medicine (IOM). National Academies (11/29/99).

History

1999

- Healthcare Research and Quality Act of 1999
  - Required Agency for Healthcare Research and Quality (AHRQ) to support research and build private-public partnerships
  - Identify causes of preventable health care errors & patient injury
  - Develop, demonstrate, and evaluate strategies for reducing errors & patient injury
  - Disseminate such strategies

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• Federal initiatives\textsuperscript{10} taken by former President Clinton on 2/22/00 based on IOM recommendations\textsuperscript{11}
  – Comprehensive strategy to reduce medical errors
  – Creation of external reporting systems
  – Creation of national patient safety centers
  – At least 50% reduction of errors over 5 years

\textsuperscript{10}Announced by President Clinton and senior administration officials in James S. Brady Press Briefing Room on February 2, 2000.

\textsuperscript{11}Recommendations issued in report entitled \textit{To Err is Human: Building a Safer Health System} by the Institute of Medicine (IOM) of the National Academies (11/29/99).
History
2000

• Key legislation
  – Patient Safety and Quality Improvement Act\textsuperscript{12}
    • Certifies patient safety organizations in each State to collect data and report on medical errors
  – State Patient Safety Centers\textsuperscript{13}
    • Since 2000, 27 states & DC have passed legislation or regulations related to hospital reporting of adverse events to state
    • Mandatory reporting systems for serious adverse events
    • National Academy for State Health Policy’s directive:
      ➢ States MUST Demand Quality and Efficiency from Health Care System

Authorized Adverse Event Reporting Systems, October 2007

Source of Reportable Events List Used in Adverse Event Reporting Systems¹⁵

History
2000 to Present

• Patient safety advisory groups created\(^1\)\(^6\)
  – Health Care Risk Manager Advisory Council (FL)
  – Illinois Adverse Health Care Events Reporting Advisory Council
  – Betsy Lehman Center for Patient Safety and Medical Error Reduction (Massachusetts)
  – Nevada Hospital Association Sentinel Events Registry Work Group
  – Patient Safety Authority Board of Directors (PA)

2001

- **JCAHO revises standards**\(^{17}\)
  - Patient safety standards effective 7/1/01
  - Requires all JCAHO hospitals (5,000) to implement ongoing medical error reduction programs
  - Almost 50 percent of JCAHO standards are directly related to safety\(^{18}\)

- **JCAHO’s sentinel event policy**\(^{18}\)
  - Identify sentinel events
  - Take action to prevent their recurrence
  - Complete a thorough and credible root cause analysis
  - Implement action plan

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History

2002

• National Quality Foundation (NQF)\textsuperscript{19}
  – Issued list of 27 serious (“never”) reportable events
  – State Medicare programs no longer reimburse providers for events

History

2003

• AHRQ establishes safety indicators (PDIs)\textsuperscript{20}
  – Measuring & monitoring tool
  – 20 hospital level & 7 regional measures

• AHRQ WebM&M
  – Online forum & journal for patient safety & quality issues

• JCAHO’s Office of Quality Monitoring
  – Receives, evaluates and tracks complaints and reports of concerns about health care organizations
  – Unannounced on-site evaluations
• JCAHO and CMS agreement\(^{21}\)
  – Working together to align Hospital Quality Measures (JC’s ORYX Core Measures and CMS’ 7th Scope of Work Quality of Core Measures)

CMS quality incentives

- Quality Improvement Organizations (QIOs)
  - Contracted by CMS to operate in every State
  - Perform independent quality audits
- Premier Hospital Quality Initiative
  - 3-year demonstration project with 280 hospitals recognizes and provides financial reward
  - CMS partnership with Premier Inc., nationwide purchasing alliance
  - Hospitals in top 20% of quality for 5 clinical areas get financial reward
    - Top decile gets 2% Diagnosis Related Group (DRG) bonus
    - 2nd decile get 1% DRG bonus
  - In year 3, hospitals performing below 9th and 10th decile baseline levels, DRG payments reduced 1% and 2%, respectively

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History
2005

• CMS quality incentives
  – Medicare/State Children’s Health Insurance Program (SCHIP) Quality Initiative
  – Pay-For-Performance (P4P)\(^{23}\)
    • 12 states have adopted some form
      – Performance measurement
      – Efforts are to align payment with quality
      – Working with JCAHO, NCQA, HQA, AQA, NQF, medical specialty societies, AHRQ, and VA
  
• Medicare service payments are tied to efficiency, economy, and quality of care standards

History
2005

• CMS quality incentives
  – Medicare Value Purchasing (MVP) Act of 2005. Requires Medicare implement a P4P program covering at least a portion of payments made.\textsuperscript{24}
  – 104 P4P provider programs in US in 2005\textsuperscript{25}
    • P4P attempts to “introduce market forces and competition to promote payment for quality, access, efficiency, and successful outcomes.”
    • P4P to extend beyond HMOs to include specialties, PPOs, self insured, and consumer-direct programs.


• CMS quality incentives
  – CMS consumer website
    • CMS contracted with NQF & worked with JCAHO to develop hospital quality measures for public reporting
    • Hospital quality data became available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
  – Data indicators\textsuperscript{26}
    • Hospitals reporting quality data to Medicare receive 3.7% increase in inpatient payments
    • Non-reporters receive 3.3% increase
    • Starts with 10 quality indicators for cardiology
    • Expand into other disciplines

\textsuperscript{26}Medicare to Pay Hospitals for Reporting Quality Data, Modernhealthcare, accessed through www.modernhealthcare.com.
History

2006

• CMS quality incentives
  – 2006 Physician Voluntary Reporting Program\textsuperscript{27}
    • Physicians voluntarily report information to CMS
      – 36 evidence-based measures
      – Information collected through Healthcare Common Procedure Coding System (HCPCS)
    • CMS will provide feedback on physician’s level of performance
    • Discontinued and replaced with Physician Quality Reporting Initiative (PQRI) in 2007

\textsuperscript{27} Medicare Takes Key Step Toward Voluntary Quality Reporting for Physicians, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.
History
2007

• CMS quality incentives
  – 2007 Physician Quality Reporting Initiative (PQRI)\textsuperscript{28}
    • Financial incentive to participate in voluntary reporting
      – 77 evidence-based quality measures
      – Bonus payment of 1.5%

\textsuperscript{28}Physician Quality Reporting Initiative, Centers for Medicare & Medicare Services (CMS), Accessed through \url{www.cms.hhs.gov}. 
History
2008 - 2009

• National Priority Partnership (NPP) in 2008
  – Deemed 1 of 6 national priorities
  – 555 endorsed measures
  – Approx. 100 measures related to patient safety

• NPP in 2009 endorsed
  – 34 safe practices (Safe Practices for Better Healthcare)
  – 28 serious reportable events

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History
2008 - 2009

• CMS quality incentives
  – 2008 PQRI\(^{30}\)
    • Physicians report on 119 quality measures
      – 2% incentive payment
    • New tracking of 5 quality measures in adoption of healthcare
      information technology (EMR)
      – 2% additional for e-prescribers
    • PQRI data available for public WITH performance rates
  – 2009 PQRI\(^{31}\)
    • A total of 153 quality measures
      – 2% incentive payment
    • E-prescribing removed, separate incentive program

\(^{30}\)CMS Ups Quality-Reporting Program Measures, Modern Health Care, 12/10/07. Accessed through www.modernhealthcare.com

History
2010

• CMS quality incentives
  – 2010 PQRI\textsuperscript{32}
    • Physicians report on 179 quality measures
      – 2% incentive payment
    • New tracking of 10 quality measures in adoption of electronic health record (EHR)
      – 2% additional for e-prescribers

Ongoing Mandates

• Tax Relief and Health Care Act of 2006\textsuperscript{33}
  – OIG must report to Congress on “never events/adverse events”
    • Payment by Medicare or beneficiaries for services
    • Process that CMS uses to identify such events and deny or recoup payments
  – Hospitals, as a condition of participation in Medicare and Medicaid, must develop and maintain a quality assessment and performance improvement (QAPI) program

Ongoing Mandates

- **Hospital requirements to comply with QAPI\(^3^4\)**
  - Hospitals must measure, analyze, and track quality indicators, including adverse patient events.
  - Hospitals must implement preventive actions and mechanisms w/ feedback & feedback/learning throughout hospital

Ongoing Mandates

• How do hospitals comply?35
  – State survey agencies perform surveys and review functions for Medicare
  – Hospitals may report adverse events to Patient Safety Organizations (PSO)
  – PSOs are public, private for-profit, and not-for-profit organizations
  – AHRQ certifies that PSOs have process to collect and analyze reported events
  – PSOs report data to Health & Human Services

36 Adverse Events in Hospitals: Methods for Identifying Events, Department of Health and Human Services
Ongoing Mandates

• No Charge Policy Effective 2008
  – State associations have/are looking at policy where hospitals will discontinue billing patients and insurers for medical errors\(^{36}\)
    • Colorado, Massachusetts, Michigan, Minnesota, and Vermont
  – CMS no longer pays for 10 “reasonably preventable” conditions caused by medical errors
  – AETNA no longer pays for 28 so-called “Never Events”\(^{37}\)
  – Wellpoint (nation’s largest insurer by membership) no longer pays for serious medical errors\(^{38}\)

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Future Incentive

- Secretary of HHS Quality Incentive
  - Value-Based Purchasing Program in 2012\(^{39}\)
  - Applies to certain cancer treatment facilities
  - Must meet minimum number of measures for performance standards
    - Proposed 2-5% of hospital’s base operating payment for each discharge payment (DRG) contingent on performance of specific measures
      - 1st year, 100% incentive based on reporting
      - 2\(^{nd}\) year, 50% reporting & 50% performance
      - 3\(^{rd}\) year, 100% reporting

\(^{39}\textit{Hospital Value-Based Purchasing Program, Bricker & Eckler Attorneys at Law. Accessed through www.bricker.com.}\)
US Grades

• 7th Annual “HealthGrades Patient Safety in American Hospitals” assessment report for Medicare patients
  – Evaluated 39.5 million hospitalization records from 5,000 nonfederal hospitals between 2006 and 2008
  – Rate of medical harm estimated to be > than 40,000/day
  – 958,202 total patient safety events occurred
    – $8.9 billion of excess cost
  – Good: 6 of 15 patient safety indicators improved
  – Bad: 8 of 15 indicators worsened
  – Medicare patients experiencing 1 or > patient safety events had 1 in 10 chance of dying (99,180 patients)

US Grades

• **Large safety gaps**\(^{41}\)
  – Patients treated at top-performing hospitals
  – On average, 43% lower chance of medical errors vs. poorest-performing hospitals

• **400,000 preventable drug-related injuries occur each year in hospitals costing $3.5 billion**\(^{42}\)

• **Medical errors cost $50 billion a year in avoidable medical expenses – approximately 30% of all health care costs**\(^{43}\)

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\(^{43}\) *Fixing Hospitals*, Forbes, (6/20/05).
US Grades

- Has patient safety improved?  
  - For 2009, patient safety received a B - minus  
  - In 2004, received a C - plus  

- According to Dr. Wachter - editor of AHRQ Web M & M  
  - “In that [QAPI] error-reporting system, it looks like a hospital with fewer error reports is much safer, but it may not be”  
  - “Hospital self-reporting in an unreliable indicator of quality”

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Canada Grades

• 185,000 adverse events occur annually in Canadian hospitals\textsuperscript{45}
  • 70,000 preventable
    • 9,000 to 24,000 people die each year\textsuperscript{46}
• Approximates a 7.5\% error rate
• Similar rates found in other countries

\textsuperscript{46} Baker GR, et. al., \textit{The Canadian Adverse Events Study: The Incidence of Adverse Events Amongst Hospital Patients in Canada}. Canadian Medical Association Journal (2004).
Physicians on Error-Reporting

• Most physicians believe error-reporting systems are inadequate\(^{46}\)
  – Of 1,100 physicians in Missouri and Washington State between July 2003 and March 2004:
    • 56\% were involved in a serious medical error
    • 74\% were involved with a minor error
    • 66\% were involved with a near miss
  – Of those physicians, 54\% believe that medical errors are usually caused by failures of care delivery, not failures of individuals
  – 45\% of physicians do not know whether a reporting system exists at their facility

Disclosure of Errors

• Survey of 603 patients who experienced 845 adverse events showed:
  – Only 40% of those events were disclosed
  – For preventable events, disclosure rate was only 28%

• Physicians reluctance to disclose events due to concerns over litigation

• However, findings show informed patients more likely to be pleased with quality of care

Consumer Beliefs

- 40% do not believe nation’s quality of health care has improved
- 48% are concerned about the safety of health care
- 55% are dissatisfied with quality of health care
- 34% say they or family member experienced a medical error in their life

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Consumer Beliefs

• 92% say reporting serious medical errors should be required
  – 63% want information released publicly
• 79% say requiring hospitals to develop systems to avoid medical errors would be “very effective”
• 35% have seen information comparing of health plans and hospitals in last year
• 19% have used comparative quality data information about health plans, hospitals, or other providers to make decisions about their care
• 11-14% have sued that experienced a medical error

\[49\]

\[50\]


Medical Errors

• In U.S., adverse events occur to approx. 3 - 4% of patients\(^{51}\)

• Average intensive care unit (ICU) patient experiences almost 2 errors per day\(^{52}\)
  – Translates to level of proficiency of approx. 99%
  – Sounds good, right?
  – NOT REALLY

• If performance levels of 99.9%, substantially better than found in ICU, applied to airline & banking industries, this equates to:
  – 2 dangerous landings per day at O’Hara International Airport, and
  – 32,000 checks deducted from the wrong account per hour.\(^{53}\)

Medical Errors

• OIG thru Department of Health & Human Services\(^{54}\)
  – Pilot study “Adverse Events in Hospitals: A case Study of Incidence Amongst Medicare Beneficiaries in Two Counties”
    • Estimated 15% of hospitalized Medicare beneficiaries in 2 counties experienced adverse events
    • Resulted in harm during their hospital stay
    • Another 15% experienced less serious occurrences “temporary harm events”

\(^{54}\text{Adverse Events in Hospitals: Methods for Identifying Events, Department of Health and Human Services, Office of Inspector General, March 2010.}\)
Medical Errors

• Underreporting of adverse events is estimated to range between 50 – 60% annually\textsuperscript{55}

• No “comprehensive nationwide monitoring system” exists for medical reporting\textsuperscript{56}

• Recent attempts to estimate error rates show little improvement in actual error incidence nationwide\textsuperscript{57}

Radiation Oncology Errors

• Not well established
• No comprehensive numbers available for number of errors resulting in death\(^{58}\)
• Reported error rates range 0.1% to 0.2% of fields treated\(^{59}\)
• Studies not relying on self-reporting show actual rates of up to 3%\(^{60}\)

Radiation Oncology Errors

• WHO research of errors 1976 to 2007\textsuperscript{61}
  – Peer-review journals
  – Conference proceedings
  – Working papers
  – Organizational reports
  – Local, national, and international databases

• 7,741 incidents & near misses
  – 3,125 incidents of harm (underdose increasing risk of recurrence to overdose causing toxicity)
  – 38 patient deaths

• Risk of mild to moderate injurious outcome
  – 1,500 per 1,000,000 treatment courses

• Review hampered by lack of data & systematic bias in reporting mistakes caused by clinical judgment

Radiation Oncology Errors

“... it is likely that many more incidents have occurred but either went unrecognized, were not reported to the regulatory authorities, or were not published in the literature.”^62

<table>
<thead>
<tr>
<th>Incidents</th>
<th>Author</th>
<th>Time Interval</th>
<th>Event</th>
<th>Total Patients</th>
<th>Outcome</th>
<th>Direct Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>McKenzie AL, British Institute of Radiology, 1996</td>
<td>1982-1991</td>
<td>Underdose (-5 to 35%)</td>
<td>1,045</td>
<td>492 - Developed local recurrences</td>
<td>Misunderstanding of algorithm in Tx planning computer</td>
</tr>
<tr>
<td>USA &amp; Canada</td>
<td>WHO, Radiotherapy Risk Profile, 2008</td>
<td>1985-1987</td>
<td>Overdose</td>
<td>6</td>
<td>6 - Overdose toxicity: 3 - Deaths</td>
<td>Therac-25 software programming error in Tx delivery</td>
</tr>
<tr>
<td>Germany</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1986-1987</td>
<td>Overdose (various)</td>
<td>86</td>
<td>86 - Overdose toxicity</td>
<td>Co-60 dose calculations based on erroneous dose tables, no independent checks</td>
</tr>
<tr>
<td>UK</td>
<td>McKenzie AL, British Institute of Radiology, 1996</td>
<td>1988</td>
<td>Overdose (+25%)</td>
<td>250</td>
<td>250 - Overdose toxicity</td>
<td>Teletherapy activity calculation error during commissioning</td>
</tr>
<tr>
<td>UK</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1988-1989</td>
<td>Over and under dose (-20 to +10%)</td>
<td>22</td>
<td>22 - Overdose toxicity</td>
<td>Error in identification of Cs-137, brachytherapy sources, no independent check of source strength</td>
</tr>
</tbody>
</table>
## Adverse Events in Radiation Oncology

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<tr>
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<th>Direct Causes</th>
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</thead>
<tbody>
<tr>
<td>US</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1988-1989</td>
<td>Overdose (+75%)</td>
<td>33</td>
<td>33 - Overdose toxicity</td>
<td>Computer file for use of trimmers not updated for new Co-60 source, no manual or independent verification of calculated Tx</td>
</tr>
<tr>
<td>Spain</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1990</td>
<td>Overdose (+200-600%)</td>
<td>27</td>
<td>18 - Overdose toxicity: 9 - Deaths</td>
<td>Error in maintenance of linac, procedures not followed, conflicting signals not analyzed, no beam verification procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1998-2004</td>
<td></td>
<td>146</td>
<td>146 - Overdose toxicity</td>
<td>Wedge factor input error in renewal of treatment planning system</td>
</tr>
<tr>
<td>US</td>
<td>WHO, Radiotherapy Risk Profile, 2008</td>
<td>1992</td>
<td>Overdose</td>
<td>1</td>
<td>1 - Overdose toxicity: 1 - Death</td>
<td>Brachytherapy source (High Dose Rate) dislodged and left inside the patient</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1996</td>
<td>Overdose (+60%)</td>
<td>114</td>
<td>114 - Overdose toxicity: 6 - Deaths</td>
<td>Error in calibration of Co-60 unit, lack of independent beam calibration, recommendation of external audit ignored</td>
</tr>
<tr>
<td>Incidents</td>
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</tr>
<tr>
<td>Japan</td>
<td>WHO, Radiotherapy Risk Profile, 2008</td>
<td>1999-2003</td>
<td>Underdose</td>
<td>31</td>
<td>31 - Underdose</td>
<td>Output factor input error in renewal of treatment planning system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1999-2004</td>
<td>Underdose</td>
<td>256</td>
<td>256 - Underdose</td>
<td>Insufficient dose delivery caused by an incorrect operation of dosimeter</td>
</tr>
<tr>
<td>Panama</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>2000 -2001</td>
<td>Overdose</td>
<td>28</td>
<td>28 - Overdose toxicity: 11 - Deaths</td>
<td>Error shielding block related data entry into TPS resulted in prolonged treatment time</td>
</tr>
<tr>
<td>Poland</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>2001</td>
<td>Overdose</td>
<td>5</td>
<td>5 - Severe injuries</td>
<td>Failure of more than 1 layer of safety in electron accelerator (monitor chambers and interlock)</td>
</tr>
<tr>
<td>Japan</td>
<td>WHO, Radiotherapy Risk Profile, 2008</td>
<td>2003</td>
<td>Suspected Overdose</td>
<td>1</td>
<td>1 - Suspected death</td>
<td>Input error of combination of transfer total dose and fraction number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2003-2004</td>
<td>Overdose</td>
<td>25</td>
<td>25 - Overdose toxicity</td>
<td>Misapplication of tray factor to treatment delivery without tray</td>
</tr>
<tr>
<td>France</td>
<td>WHO, Radiotherapy Risk Profile, 2008</td>
<td>2004-2005</td>
<td>Overdose</td>
<td>18</td>
<td>18 - Overdose toxicity: 5 - Deaths</td>
<td>Wrong setting of linac after introduction of new TPS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8</td>
<td>2 - Overdose toxicity: 1 - Death 5 - Unknown health conseq.</td>
<td>Miscommunication of field size estimation, error in patient identification, incorrect implantation of source during brachytherapy</td>
</tr>
</tbody>
</table>
## Adverse Events in Radiation Oncology

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</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Keen C, auntannie.com 2008</td>
<td>2004-2007</td>
<td>Underdose (-83%)</td>
<td>326</td>
<td></td>
<td>Error in calculation of output tables on orthovoltage unit, understaffed &amp; overworked physicists, no comprehensive independent check, inadequate QA program</td>
</tr>
<tr>
<td>WHO, Radiotherapy Risk Profile, 2008</td>
<td></td>
<td></td>
<td>Underdose (3-17%)</td>
<td></td>
<td>326 - Underdose</td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>Healthimaging.com, 2010</td>
<td>2004-2009</td>
<td>Overdose (+50%)</td>
<td>76</td>
<td></td>
<td>Error in calculation of output factor of SRS unit, wrong measurement equipment, no independent check</td>
</tr>
<tr>
<td>US</td>
<td>Sickler M, St. Petersburg Times, 2005</td>
<td>12 Months</td>
<td>Overdose (+50% or &gt;)</td>
<td>77</td>
<td>19 - Unsafe Levels</td>
<td>Programming error using wrong formula in Tx planning computer, no independent second dose verification</td>
</tr>
<tr>
<td>UK</td>
<td>WHO, Radiotherapy Risk Profile, 2008</td>
<td>2005-2006</td>
<td>Overdose</td>
<td>5</td>
<td>5 - Overdose Toxicity: 1 - Death</td>
<td>Change in operational procedures while upgrading data management systems resulting in incorrect treatment dose</td>
</tr>
<tr>
<td>Scotland</td>
<td>Scottish Ministers, Report of an Investigation, 2006</td>
<td>2006</td>
<td>Overdose (+58%)</td>
<td>1</td>
<td>1 - Overdose Toxicity: 1 - Death</td>
<td>Tx planning computer software was upgraded. Old correction factor was applied to new calculation program.</td>
</tr>
</tbody>
</table>
Adverse Events$^{63}$ N = 3125

Near Misses in Radiation Oncology

• Near Misses\textsuperscript{64}
  – 1992 to 2007: Australia, UK, Other European Countries, and US
  • How many?
    – 4,616 reported incidents that lead to near misses
    – No recognized patient harm
  • How collected?
    – Published literature
    – Unpublished incident reporting databases (ROSIS)

\textsuperscript{64}Radiation Risk Profile, WHO, 2008.
0
200
400
600
800
1000
1200
1400
1600
1800

Number of Near Misses

Near Misses\textsuperscript{65} N = 4616

\textsuperscript{65}Radiation Risk Profile, WHO, 2008.
## Error Rates in Radiation Oncology

<table>
<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Time Interval</th>
<th>Crse of Tx</th>
<th>Total Tx Fx’s</th>
<th>Total Tx Fields</th>
<th>Tx Field Errors</th>
<th>Error Specifics</th>
<th>Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>Sutherland WH, Topical Reviews in Radiother and Oncol, 1980</td>
<td>Over 6 years between 1970-1980</td>
<td>- Potential mistakes (found in checks): 4,122</td>
<td>- Potential errors of &gt;5% from Rx dose: 742</td>
<td>2.1% - 4% per year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>Swann-D'Emilia B, Med Dosime, 1990</td>
<td>1988-1989</td>
<td>87 misadministrations</td>
<td>&lt;0.1%: based on no. of fields Tx’ed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>Leunens G, et al., Radiother Oncol, 1992</td>
<td>9 months</td>
<td>Data transfer errors: 139 of 24,128</td>
<td>Affected 26% of overall treatments</td>
<td>Sig. potential 5%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>Calandrino R, et al., Radiother Oncol, 1993</td>
<td>9/91-6/92</td>
<td>Out of 890 calculations:</td>
<td>3.7%: total error rate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>Valli MC, et al., Radiother Oncol, 1994</td>
<td></td>
<td>- 33 total errors</td>
<td>- 17 serious errors</td>
<td>10.5%: incorrect or missing data</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Error Rates in Radiation Oncology

<table>
<thead>
<tr>
<th>Study</th>
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<th>Tx Field Errors</th>
<th>Error Specifics</th>
<th>Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>Noel A, et al., Radiother Oncol, 1994</td>
<td>5 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Of 7519 treatments: 79 total errors</td>
<td>1.05%: errors per treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Of 79, 78 are human origin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Of 78, 39 would have &gt; 10% dose Δ</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>Yeung TK, Abstract-NEORCC, 1996</td>
<td>1994</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.3%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3%: cobalt units</td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>Macklis RM, et al., J Clin Oncol, 1998</td>
<td>1 year</td>
<td>1,925</td>
<td>93,332</td>
<td>168</td>
<td></td>
<td>15%: causally related to R&amp;V</td>
<td>0.18%: error rate/field</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>Fraas BA, et al., Int J Radiat Oncol Biol Phys, 1998</td>
<td>7/96-9/97</td>
<td>~34,000</td>
<td>~114,000</td>
<td></td>
<td></td>
<td>0.44%: Tx fractions</td>
<td>0.13%: Tx fields</td>
</tr>
<tr>
<td>Belgium</td>
<td>Barthelemy-Brichant N, et al., Radiother Oncol, 1999</td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>147,476 parameters examined:</td>
<td>3.22%: of all delivered Tx fields had at least 1 error</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 678 (0.46%) set incorrectly</td>
<td></td>
</tr>
</tbody>
</table>
## Error Rates in Radiation Oncology

<table>
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<tr>
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<th>Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Pegler R, et al., Abstract-Clin Invest Med, 1999</td>
<td>2 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.12 - 0.06%</td>
</tr>
<tr>
<td>US</td>
<td>Pao WJ, et al., Abstract-ACSO, 2001</td>
<td>6 years</td>
<td></td>
<td>17,479 avg./yr.</td>
<td></td>
<td></td>
<td></td>
<td>0.17% avg./year per patient</td>
</tr>
<tr>
<td>Canada</td>
<td>French J, Radiat Ther, 2002</td>
<td>1/1/96-9/31/01</td>
<td>11,355</td>
<td>195,100</td>
<td>483,741</td>
<td>631</td>
<td>177 total incidents - 20: correctable - 129: noncorrectable and clinic. sig. - 28: noncorrectable and potentially clinically sig.</td>
<td>0.13%: all units (fields tx’ed incorrect/ total no. fields tx’ed) 0.32%: errors/fraction 0.037%: errors/field</td>
</tr>
<tr>
<td>US</td>
<td>Patton G, et al., Radiat Oncol Biol Phys 2002</td>
<td>1 year</td>
<td>22,542</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.17%: errors/Tx</td>
</tr>
<tr>
<td>Ireland &amp; Sweden</td>
<td>Holmberg O, et al., J of Radiotherapy Ther, 2002</td>
<td>3 years</td>
<td>15,386 Tx plans</td>
<td></td>
<td></td>
<td></td>
<td>13.8 near misses/each reported Tx error in Tx preparation chain</td>
<td>3.4%: error rate per Tx plan</td>
</tr>
</tbody>
</table>
### Error Rates in Radiation Oncology

<table>
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<tr>
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<th>Total Tx Fields</th>
<th>Tx Field Errors</th>
<th>Error Specifics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Yeung, et al., Radiother Oncol, 2004</td>
<td>11/92-12/02</td>
<td>13,385</td>
<td></td>
<td></td>
<td></td>
<td>624 incidents - 42.1%: documentation errors (data transfer/communication) - 40.4%: patient set-up errors - 13.0%: Tx planning errors</td>
</tr>
<tr>
<td>Canada</td>
<td>Huang G, et al., Int J Radiat Oncol Biol Phys, 2005</td>
<td>1/1/97-12/31/02</td>
<td>28,136</td>
<td></td>
<td></td>
<td></td>
<td>555 total errors</td>
</tr>
<tr>
<td>US</td>
<td>Klein E, et al., J of Appl Clin Med Phys, 2005</td>
<td>30 months</td>
<td>3,964</td>
<td></td>
<td></td>
<td></td>
<td>0.48 to &lt;0.1%: for diff methods of detection w/R&amp;V</td>
</tr>
<tr>
<td>Canada</td>
<td>Marks L, et al., Int J Radiat Oncol Biol Phys, 2007</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.5%: error rate per fraction 1.2 - 4.7%: error rate per patient</td>
</tr>
</tbody>
</table>
### Error Rates in Radiation Oncology

<table>
<thead>
<tr>
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<th>Total Tx Fields</th>
<th>Tx Field Errors</th>
<th>Error Specifics</th>
<th>Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>Baiotto B, et al., J of Experi &amp; Clinical Oncol Tumori, 2009</td>
<td>10/00 – 12/06</td>
<td>7,768</td>
<td>34,114</td>
<td>148,145</td>
<td>452 errors</td>
<td>Error types: - 2.2%: general - 3.3%: dosimetric - 4.2%: delivered dose</td>
<td>0.69%: error rate of audited patients</td>
</tr>
<tr>
<td>US</td>
<td>Margalit D, et al., J Clinical Oncol, 2010</td>
<td>1/04 – 1/09</td>
<td></td>
<td>241,546</td>
<td>155 total errors</td>
<td>Types: IMRT 0.033% vs 2D/3D RT 0.072%</td>
<td>0.064%: error rate per Tx field</td>
<td></td>
</tr>
</tbody>
</table>
### Who Reports the Errors Within a RO Center?\(^6\)

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Errors</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosimetrist</td>
<td>43</td>
<td>5%</td>
</tr>
<tr>
<td>Radiation Oncologist</td>
<td>70</td>
<td>8%</td>
</tr>
<tr>
<td>Other</td>
<td>22</td>
<td>3%</td>
</tr>
<tr>
<td>Physicist</td>
<td>92</td>
<td>11%</td>
</tr>
<tr>
<td>Engineer</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Therapist-Sim/CT</td>
<td>37</td>
<td>4%</td>
</tr>
<tr>
<td>Therapist-Tx machine</td>
<td>591</td>
<td>69%</td>
</tr>
</tbody>
</table>

\(^6\text{ROSIS database. 2/25/10. Accessed through www.rosis.info.}\)
In 2006, the definition of Abnormal Occurrence (AO) and Medical Event changed.

VA Medical Center in Philadelphia revised reporting from 1 to 97 medical events.
<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Number of Reports</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong dose</td>
<td>10</td>
<td>40%</td>
</tr>
<tr>
<td>Wrong patient</td>
<td>4</td>
<td>16%</td>
</tr>
<tr>
<td>Wrong location</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>Wrong side</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>Wrong setup</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>Wrong treatment</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Wrong treatment device</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Equipment other</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>25</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

### Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, 2/2004 - 1/2009

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Number of Reports</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect site</td>
<td>17</td>
<td>46%</td>
</tr>
<tr>
<td>Wrong patient treated</td>
<td>10</td>
<td>27%</td>
</tr>
<tr>
<td>Incorrect dosage</td>
<td>8</td>
<td>21%</td>
</tr>
<tr>
<td>Underestimated medical procedure duration</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Inattention to detail</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>37</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

---

# State of NY: Published Tx Errors


<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Number of Reports</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality assurance flawed</td>
<td>355</td>
<td>28%</td>
</tr>
<tr>
<td>Data entry or calculation errors by personnel</td>
<td>252</td>
<td>20%</td>
</tr>
<tr>
<td>Misidentification of patient or treatment location</td>
<td>174</td>
<td>14%</td>
</tr>
<tr>
<td>Blocks, wedges or collimators misused</td>
<td>133</td>
<td>11%</td>
</tr>
<tr>
<td>Patient's physical setup wrong</td>
<td>96</td>
<td>8%</td>
</tr>
<tr>
<td>Treatment plan flawed</td>
<td>77</td>
<td>6%</td>
</tr>
<tr>
<td>Hardware malfunction</td>
<td>60</td>
<td>5%</td>
</tr>
<tr>
<td>Staffing</td>
<td>52</td>
<td>4%</td>
</tr>
<tr>
<td>Computer, software or digital info transfer malfunction</td>
<td>24</td>
<td>2%</td>
</tr>
<tr>
<td>Override of computer data by personnel</td>
<td>19</td>
<td>2%</td>
</tr>
<tr>
<td>Miscommunication</td>
<td>14</td>
<td>1%</td>
</tr>
<tr>
<td>Unclear/other</td>
<td>8</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1264</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Paper-Based Model
Objective of Paper-Based Model

- Provide a unified, total quality management and continuous improvement program
- Minimize occurrence of errors identified in the patient treatment process and regulatory arena
- Designed for 17 geographically dispersed radiation oncology clinics
- Located in 9 states of varying regulatory oversight and enforcement philosophy
Design of a Paper-Based Model

• Established a consistent set of QA procedures for the 17 facilities following the strictest state requirements in which each facility resides.
• Analyzed the process of delivering radiation therapy to identify the steps used in all aspects of this modality.
• Developed a reporting codification system for errors detected, and the appropriate forms and procedures for reporting these errors. This includes a staging system for classifying the importance of an error.
Design of a Paper-Based Model

• Provided an internal feedback mechanism of corrective action to close the loop
  – Independent review/recommendations for corrective action regarding all self-identified significant errors/violations

• Produced a quarterly report summarizing errors/violations
  – Perform trend analysis of reported errors at center and company levels
  – Recommended company wide corrective actions based on results of trend analysis
RPS
QA Implementation Process for a Radiation Oncology Center

Audit
- NRC/State Regulations
- ACR Standards
- AAPM Guidelines
- JCAHO Requirements

Correct Audit Findings

Policies & Procedures
- Individual Manuals
- RS Manuals
- 27 Notebook Filing System
- Modules

Training
- Classroom
- Workshops

Individual Error Feedback System

Quarterly Error Reduction Report

Error Reduction/Compliance Program (Quarterly Audits)
Unintended Deviation Reporting Process

Start

Team Member Identifies Error

Team Member Records Error on QA1a

Is Error Safety Sig.? No

Yes

QA1b completed by team members

RSO reviews Corr. Action on QA1b

Corr. action approp.? No

Yes

Physician reviews relevant QA1b

Corr. action approp.? No

Yes

End

No

Yes

RSO & Dr. sign Form QA1b

QA1b faxed to OQMRA for eval.

OQMRA faxes QA1b response to RSO

QA Comm analysis of errors

QA Mtg. results faxed to OQMRA

OQMRA analysis & tabulation

Quarterly report to company and center
The Unintended Deviation System

• Name was selected to convey an unintentional error discovered either by the one having committed the error or by another physician/staff member.

• Management emphasizes that self-identification and reporting of errors will not result in disciplinary action.

• Provides for identification, evaluation, and documentation of all errors within the process of radiation therapy delivery.

• Suggests possible causes and solutions for correction of individual errors as well as programmatic errors with discoverable trends.
Definition - Unintended Deviation

- An unintended deviation is any error in the planned patient simulation, setup, treatment, or data entry in these processes.
- Any deviation from the planned course of treatment
- Any error in calculation
- Any missing or incomplete information
- Any failure to perform or follow required quality assurance and radiation safety policies or procedures

- Unintended deviations can be classified as:
  - Pre or post-tx error
  - A minor unintended deviation (Level 3-5)
  - A significant unintended deviation (Level 1-2)
    - A Recordable Event
    - A Misadministration
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1010</td>
<td>Treatment site 2 ● P</td>
<td>1310</td>
<td>Pt. position not is to midline (SAD) 3 ● T</td>
<td>1650</td>
<td>Wrong inverse sq. factor 2 ● P</td>
</tr>
<tr>
<td>1011</td>
<td>Plan identification 3 P</td>
<td>1311</td>
<td>Pt. position not specified SSD 3 ● T</td>
<td>1651</td>
<td>Math error 3 ● P</td>
</tr>
<tr>
<td>1012</td>
<td>Field names and numbers 3 ● P</td>
<td>1312</td>
<td>Missing SSD 2 ● T</td>
<td>1652</td>
<td>Calic. using incor. dose 2 ● P</td>
</tr>
<tr>
<td></td>
<td>R &amp; V: Data Entry</td>
<td>1320</td>
<td>Missing R Medial SSD 2 ● T</td>
<td>1653</td>
<td>Tx plan not approved 1 ● M</td>
</tr>
<tr>
<td></td>
<td>Course 2 ● M</td>
<td>1321</td>
<td>Missing L Medial SSD 2 ● T</td>
<td>1654</td>
<td>Misc.</td>
</tr>
<tr>
<td></td>
<td>Prescription site 2 ● M</td>
<td>1322</td>
<td>Computer Calculations</td>
<td>1655</td>
<td>Misc.</td>
</tr>
<tr>
<td></td>
<td>Technique 2 ● M</td>
<td>1323</td>
<td>Missing 1 med. SSD 2 ● T</td>
<td>1656</td>
<td>Misc.</td>
</tr>
<tr>
<td></td>
<td>Modality (photons or electrons) 1 ● M</td>
<td>1324</td>
<td>Missing calc. pt. SSD 2 ● T</td>
<td>1657</td>
<td>Misc.</td>
</tr>
<tr>
<td></td>
<td>Dose specification 2 ● M</td>
<td>1325</td>
<td>Dose not agree w/SSD 3 ● T</td>
<td>1658</td>
<td>Misc.</td>
</tr>
<tr>
<td></td>
<td>Depth 2 ● M</td>
<td>1326</td>
<td>Dose not agree w/SSD 3 ● T</td>
<td>1659</td>
<td>Misc.</td>
</tr>
<tr>
<td></td>
<td>Total dose 1 ● M</td>
<td>1330</td>
<td>Separation missing 2 ● T</td>
<td>1660</td>
<td>Misc.</td>
</tr>
<tr>
<td></td>
<td>Fraction dose 1 ● M</td>
<td>1331</td>
<td>Separation missing 2 ● T</td>
<td>1661</td>
<td>Calc. to wrong point 2 ● P</td>
</tr>
<tr>
<td></td>
<td>Fractions 2 ● M</td>
<td>1340</td>
<td>Incorrect contour 3 ● T</td>
<td>1662</td>
<td>Calc. using wrong dose 2 ● P</td>
</tr>
<tr>
<td></td>
<td>Pattern 2 ● M</td>
<td>1341</td>
<td>Incorrect coll. angle 3 ● P</td>
<td>1663</td>
<td>Calc. using norm. dose 2 ● P</td>
</tr>
<tr>
<td></td>
<td>Prescription note 2 ● M</td>
<td>1350</td>
<td>Failure to capture all x/y fields 2 ● T</td>
<td>1664</td>
<td>Calc. using norm. dose 2 ● P</td>
</tr>
<tr>
<td></td>
<td>Elect. Approval before Rx (R &amp; V) 1 ● M</td>
<td>1351</td>
<td>Failure to capture setup fields 2 ● T</td>
<td>1665</td>
<td>Calc. using norm. dose 2 ● P</td>
</tr>
<tr>
<td></td>
<td>Misc.</td>
<td>1360</td>
<td>Setup instructions incorrect 3 ● T</td>
<td>1666</td>
<td>Calc. using norm. dose 2 ● P</td>
</tr>
<tr>
<td></td>
<td>Treatment Field Definition</td>
<td>1370</td>
<td>Misc.</td>
<td>1667</td>
<td>Calc. using norm. dose 2 ● P</td>
</tr>
<tr>
<td></td>
<td>Prescription site 1 ● F</td>
<td>1400</td>
<td>Misc.</td>
<td>1668</td>
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</table>

Legend: Significance Level: 1 (most significant), 2, 3, 4, 5 (least significant) ● Key Process M: M.D. P: Physics T: Therapist R: Facility RSO Q: QI Coordinator

Footnotes: To include segments, blocks, bolus, compensator, and no. of fr/day & fr/tak. (if not recorded under Pattern)
Misadministration (Note: Some Agreement states have more restrictive dose requirements.)

QATb
Recordable Event
All information contained in this document is Client-Attorney Privileged.
Name Cancer Center

Unintended Deviation Reporting Form
For Significance Level 1 and 2 Events (Recorded on Forms QA1a and QA1b)

Date(s) of Occurrence: ____________________________ Identified By: ____________________________
Date Identified: ____________________________ Patient Chart/UD No.: ____________________________

☐ Pre-Treatment Unintended Deviation  ☐ Post-Treatment Unintended Deviation

<table>
<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>Code</th>
<th>Category</th>
<th>Frequency</th>
<th>Code</th>
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<tr>
<td>K &amp; V</td>
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<td>Dose Calculation</td>
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<td>Control Measurement</td>
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<td>Radiation Safety</td>
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<td>Radiation Safety</td>
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</table>

Description: __________________________________________________________

Evaluation: __________________________________________________________

☐ A Daily Dose(<5) ______%   ☐ A Weekly Dose(≤) ______%   ☐ A Total Dose(≤) ______%
☐ Recordable Event          ☐ Misadministration           ☐ Personal Overexposure

Immediate Corrective Action: (Check all that apply):
Date of Immediate Action: ____________________________
☐ Correction of documentation                   ☐ Adjustment of equipment or machine
☐ Adjustment of treatment (if necessary)         ☐ Other: ______________________________________

Long-Term Corrective Action: (Check all that apply):
☐ Additional Training                           ☐ Increased oversight or supervision
☐ Improved procedure                            ☐ Other: ______________________________________

Approved: ____________________________
☐ Physician's initials: ________________________  ☐ RSO initals: ________________________  ☐ MD initals: ________________________

Evaluation: __________________________________________________________

Recommendations: ______________________________________________________

__________________________  ____________________________  ____________________________
Date Received:    Date of Follow-up:    Date Proceeded:  Reviewer's Initals:  

1. Complete with center and federal requirementsPackageName indicating increases of identified deviations and recording of identified deviations.
2. Maintain reporting forms in the Quality Management Program. All information in this document and any attachments are Client-Confidential Privileged.

QAIC

Unintended Deviation Reporting Form Jan 2010 06/2020
# Post-Treatment Quarterly Unintended Deviation Summary Report

<table>
<thead>
<tr>
<th>Monitored Category</th>
<th>Frequency By Category</th>
<th>Frequency By Significance Level</th>
<th>Frequency By Key Processes</th>
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<td>Tx of Patient - Patient Setup Doc</td>
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<td>QA</td>
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Minor Unintended Deviations: 3rd Qtr. 1996

- Data Entry: Daily Tx Record: 5%
- Process: Simulation Films: 4%
- Process: Patient Simulation: 4%
- Data Entry: ACCESS - Tx Field Def: 4%
- Data Entry: Tx Chart - Rx: 4%
- Data Entry: Tx Field Info: 4%
- Process: Block Fabrication: 4%
- Tx of Patient: Port Films: 5%
- Data Entry: Patient Setup Doc: 9%
- QA: Missing or Late: 4%
- Radiation Safety: Missing or Late: 1%
- Tx of Patient: Patient ID: 7%
- Tx of Patient: Patient Setup: 6%
Significant Unintended Deviations: 2nd & 3rd Qtr. 1996
### Total Unintended Deviations versus Time

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<th>2nd Quarter '96</th>
<th>2nd Quarter '97</th>
<th>% Change</th>
<th>Parameter</th>
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</table>
Summary of Total Unintended Deviations

Number of Reported Unintended Deviations

- Minor
- Significant
- Total

Calendar Quarter/Year

[Graph showing the number of reported unintended deviations by quarter and year, with bars for minor, significant, and total deviations, and a line graph for the total deviations.]
Published rates\textsuperscript{70} for reported misadministrations in therapeutic radiation oncology is 0.0042 percent (4.2/100,000 fractions) based upon 20 fractions/patient for NRC regulated states only. Based upon internal NRC documents, it is speculated that the rate may be as high as 0.04 percent.

\textsuperscript{70}NRC memorandum dated March 8, 1993: Data based on information obtained from the American College of Radiology (Manpower Committee, Patterns of Care Study, and Commission of Human Resources). Additional reference from Institute of Medicine (Radiation in Medicine - A Need For Regulatory Reform), 1996.
Calculated Error Rates
Paper-Based Model

• Based upon the total number of treatment fields delivered as recorded by R&V at 17 radiation oncology centers and the total number of unintended deviations self-reported by the system, excluding the initial two quarters for the “learning curve effect”, the overall average error rate for both minor and significant unintended deviations within the system was approximately 0.052% (5.2 in 10,000 patient fractions).

• The minor unintended deviation reporting rate for the same period was approximately 0.034%.
• The significant unintended deviation reporting rate that could lead to a misadministration was calculated to be approximately 0.018% (1.8 in 10,000 patient fractions).  

• Based upon the model’s experience of one reported misadministration (having no deterministic or measurable effect) over 2 years, the measured misadministration rate was 0.017%.

\(^{71}\) Reporting rate is based on the number of significant interactions occurring in the treatment delivery process that could lead to a misadministration (criteria based on 10 CFR Part 35) vs the total number of treatment fields administered for 17 centers.
Measured vs Published Misadministration Rate
Radiation Oncology

• When compared to what the NRC speculates is the actual misadministration rate of 0.04 (4 in 10,000), this rate is a factor of 2.35 lower.

• Though this program helped in minimizing the occurrence of misadministrations, the overall focus was to reduce the number and nature of all errors in the therapy process.
Cost Benefit Analysis
Paper-Based Model

• After implementation of the QA/Medical Error Reduction Program, the 17 radiation oncology centers experienced a reduction of 326% in error rate from 3/96 to 12/97 (not including the “learning curve effect”):
  – Direct cost savings of approximately $450,000
  – Direct & indirect cost savings of approximately $600,000
Cost Benefit Analysis
Paper-Based Model

• Experience with the one reported misadministration that occurred at a center in Florida between 3/96 and 12/97 (with no measurable effect) resulted in a total direct cost (man-hours, travel, etc.) of approximately $25,000.

• Physician malpractice insurance premiums for the 17 oncology centers were reduced by 10%.
Summary of Results
Paper-Based Model

- Overall average error rate was 0.052% (SL 1 – 5)
- Calculated misadministration rate\(^{72}\) was 0.018%
- Actual misadministration rate was 0.017%
- NRC misadministration rate was 0.042% (a factor of 2.35 higher than actual misadministration rate)
- Reduced overall error rate by 326% over 21 months
- Direct cost savings of $450,000
- Direct & indirect cost savings of $600,000
- Other significant incidents averted by using program

\(^{72}\)Misadministration criteria based on definitions found in NRC 10CFR35.2, rev. 1996; and CRCPD recommended Agreement State regulations dated 2007.
Other Center Studies
Paper-Based Model
Summary of Results - 1998

Oncology Company With 10 Freestanding Centers

- Three significant radiation treatment errors, that if left undetected would have required reporting to the State and notifying the referring physician and patient, were caught.

- A misadministration at one center, involving possible civil penalties and sanctions, was mitigated by the State by demonstrating that the error leading to the misadministration was isolated based on empirical data.
Other Center Studies

Paper-Based Model

Summary of Results - Calendar Year 2002

**Cancer Center #1**

- Aside from the 1st quarter “learning curve”, total errors decreased by 70.5% (334 vs 99) between the 2nd and 3rd quarters.
- Total errors decreased by 27.3% (99 vs 72) between the 3rd and 4th quarters.
- The total decrease in errors between the 2nd and 4th quarters was 78.4% (334 vs 72).

**Cancer Center #2**

- Aside from the 1st quarter “learning curve”, total errors decreased by 66.4% (113 vs 38) between the 2nd and 3rd quarters.
- Total errors decreased by 18.4% (38 vs 31) between the 3rd and 4th quarters.
- The total decrease in errors between the 2nd and 4th quarters was 72.6% (113 vs 31).
Lessons Learned
Paper-Based Model

• **Limitations**
  – Inefficient
  – Time intensive
  – Intrusive
  – Complex industrial engineering model
  – Requires paper trail

• **Weaknesses**
  – Learning error codification system
  – Triggering required regulatory actions
  – Faxing of errors
  – Tracking UDIs
  – Management review
  – Trending and analysis
  – Report generation
  – Timely action
  – Credible root cause analysis
Software-Based Model
Design of Software-Based Model

• What is needed?
  – Automated tracking of errors
  – Non-intrusive data gathering
  – Preset standardized gathering
  – Scoring of risk (FMEA)
  – Immediate analysis of errors
  – Short and long-term corrective actions
  – Tracking and trending of errors
  – Automated regulatory report launching
Design of Software-Based Model

MERP Program

- **Monitored Areas**
  - Clinical
  - QA
  - Radiation Safety

- **Identification and Tracking of Errors**
  - Preset standardized error codes
  - Classification of pre and post-treatment errors
  - Assignment of severity levels (I - V)
  - Calculation of Risk Priority Number
  - Designation of clinical significance
  - Designation of significant unintended deviation

- **Identification and Tracking of Errors (cont.)**
  - "Near Miss" categorization
  - Sentinel events (internal and JCAHO reportable)
  - Instant analysis of patterns and trends
  - Recordable events
  - Misadministrations (medical events)
  - Regulatory violations
  - Possible regulatory violations
Design of Software-Based Model

MERP Program

– **Step-By-Step Root Cause Analysis**
  - Determination of credible root cause analysis
  - Identification of causal factors
  - Identification of opportunities for improvement

– **Action Plan Road Map**
  - Risk-reduction strategy
  - Short-term corrective action
  - Long-term corrective action
  - Assignment of responsible individuals

– **Patient Dose Error Calculation Wizard**
  - Calculates % error in daily, weekly & total doses

– **Patient Dose Error Calculation Wizard (cont.)**
  - Automatically triggers levels for report generation
    - JCAHO root cause analysis and action plans
    - State regulatory notifications

– **Procedure Generation**
  - Drafting of procedure as part of corrective action plan
  - Serves as tutorial in training new employees/annual refresher

– **Review and Approval**
  - Queue action plan(s) for review and approval
  - Accept or reject routine corrective action(s)
Design of Software-Based Model

MERP Program

- **Reports and Chart Generation**
  - Generate reports showing characterization of errors and corrective actions
  - Show charts stratifying error types and severity levels
  - Select time intervals for charting of data

- **Audit Compliance Tool**
  - MERP used to inspect regulatory performance
  - Complies with State radiation safety requirement for annual reviews
  - Meets State QMP rule for annual reviews
  - Follows CMS compliance objectives
  - Complies with JCAHO standards
Design of Software-Based Model

MERP Program

- **Customization Features**
  - Customize and create data collection areas for performance improvement priorities
    - Categories
    - Subcategories
    - Attributes
  - Designate who reviews/approvals routine errors and corrective actions
  - Assign which errors violate State requirements
  - Designate severity levels, clinically significant, and significant unintended deviations

- **Standards/Requirements Referenced by Code**
  - JCAHO 2010 patient safety standards show basis for question
  - ACR and ACRO standards demonstrate benchmark for measuring performance
  - CRCPD (Agreement State) recommended regulations (as of 9/08) show legal text
MERP Implementation Strategy
Preparation

- **Step #1 - Benchmark Procedures**
  - Created manual
  - Included step-by-set processes
  - Covered technical delivery system
    - QA
    - Radiation safety
    - QMP

- **Step #2 - Training**
  - Provided classroom hours
    - 18 hours in procedures
    - 6 hours in MERP
  - Presented at new center start-up or over 1 hour lunch break (existing)
  - Took 3 days (new center) vs 2 months (existing center)
  - Issued category ‘A’ credit thru ASRT
  - Met annual state radiation safety training requirements
• **Step #3 - Superusers**
  - Designated key point guards
    • Controlled data input
    • Tracked status of UDIs
    • Tracked completion of corrective action plans

• **Step #4 - Phases**
  - **Group 1**
    • Therapists
    • CT/X-ray technologists
    • Physics (physicists & dosimeterists)
    • Billing
  - **Group 2**
    • Radiation oncologists
  - **Group 3**
    • Admissions/registration staff
RO MERP

Unintended Deviation (UD) Reporting Form

Date(s) of Occurrence: __________ Date Identified: ________________

Identified by: __________________ Patient ID #: __________________

Patient Name: _________________ UD #: __________________________

<table>
<thead>
<tr>
<th>Patient Related</th>
<th>Non-Patient Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical □</td>
<td>QA □ RS □</td>
</tr>
<tr>
<td>Pre-Tx □</td>
<td>Post-Tx □ Affected Tx □</td>
</tr>
<tr>
<td>QA □ RS □</td>
<td></td>
</tr>
</tbody>
</table>

Description of UD:
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

Initials: ___________________ Date: _____________________
MERP Results
Center A

Unintended Deviations

Treatment-Related Pre-Treatment

9/16/2009 to 9/29/2010

Frequency vs. Category

- Registration: 32%
- CT Simulation: 12%
- Computer Tx Planning: 0%
- R & V: 2%
- Patient Docs/Notes: 13%
- Patient Identification: 2%
- Portal Images: 32%
- In-Room Tx Setup: 2%

1. Scheduling: 0%
2. CT Simulation: 12%
3. R & V: 2%
4. Patient Docs/Notes: 13%
5. Patient Identification: 2%
6. Portal Images: 32%
7. In-Room Tx Setup: 2%
MERP Results

Center B

Treatment-Related Pre-Treatment
2/29/2006 to 4/1/2008

- Treatment Planning 14%
- 7 Dose Calculations 2%
- 4 Beam Modifiers 0%
- 81 CT Simulation 9%
- 29 Scheduling 9%
- 5 Registration 1%
- 10 In-Room Treatment Setup 3%
- 14 Portal Images 4%
- 4 Patient Identification 0%
- 7 Patient Docs/Notes 2%
- 162 R & V 51%
Center A

Unintended Deviations
Treatment-Related
Post-Treatment
9/16/2009 to 9/29/2010

Frequency vs. Category

89 Billing 48%
1 Computer Tx Planning 0%
1 R & V 2%
23 Patient DoseNotes 12%
1 Patient Identification 0%
1 Portal Images 33%
5 Scheduling 1%
MERP Results
Center B

Center B
Treatment-Related Post-Treatment
2/29/2006 to 4/1/2008

- 320 Patient Docs/Notes 40%
- 124 Portal Images 15%
- 99 Treatment Delivery 12%
- 209 Billing 26%
- 18 R & V 2%
- Scheduling 0%
- Quality Assurance 0%

2/29/2006 to 4/1/2008
MERP Results
Center B

Center B
Treatment-Related Post-Treatment
2/29/2006 to 4/1/2008

Patients Affected by Treatment Only

- 1 R & V 4%
- 1 Computer Treatment Planning
- 2 Quality Assurance 3%
Center A

Unintended Deviations

Non-Patient Related

9/16/2009 to 9/25/2010

Frequency vs. Category

- Radiation Safety: 7%
- Quality Assurance: 92%
MERP Results

Center B

Center B
Non-Patient Related
2/29/2006 to 4/1/2008

17 Quality Assurance 70%
7 Radiation Safety 29%
## Center B - Errors of Greatest Frequency

This screen shows you the list of all Errors which have been reported in this system in descending order of occurrence.

<table>
<thead>
<tr>
<th>Pre/Post</th>
<th>Category</th>
<th>Subcategory</th>
<th>Attribute</th>
<th>Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Tx</td>
<td>Billing</td>
<td>Codes</td>
<td>CPT code incor./miss.</td>
<td>141</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>R &amp; V</td>
<td>Prescription</td>
<td>Electronic approval before 1st fx miss.</td>
<td>90</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Tx planning sim note not completed</td>
<td>84</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Field verification sim note not completed</td>
<td>74</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Isocenter verification sim note not completed</td>
<td>60</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>CT sim note not completed</td>
<td>59</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Treatment Delivery</td>
<td>Patient Setup</td>
<td>RTT note incor./miss.</td>
<td>50</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Billing</td>
<td>Audits</td>
<td>Final chart audits incor./miss.</td>
<td>47</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>R &amp; V</td>
<td>Diagnosis</td>
<td>Diagnostic category (disease site) incor./miss.</td>
<td>24</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>R &amp; V</td>
<td>Diagnosis</td>
<td>Diagnostic type (new primary, recurrent) incor./miss.</td>
<td>20</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Computer Treatment Planning</td>
<td>Tx Plan</td>
<td>Tx plan not signed</td>
<td>17</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Treatment Delivery</td>
<td>Beam Modifiers</td>
<td>Bolus required, no bolus used</td>
<td>9</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>R &amp; V</td>
<td>Treatment Field Definition</td>
<td>Field name incor./miss.</td>
<td>8</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Portal Images</td>
<td>Electronic Imager</td>
<td>Weekly images not approved</td>
<td>10</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>CT Simulation</td>
<td>Patient Setup</td>
<td>Field setup photos incor./miss.</td>
<td>10</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>CT Simulation</td>
<td>Appointments</td>
<td>Appointment activity incor./miss.</td>
<td>10</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Computer Treatment Planning</td>
<td>Tx Plan</td>
<td>Shifts from CT user origin to CAX incor./miss.</td>
<td>9</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Treatment Delivery</td>
<td>Patient Setup</td>
<td>Sim note incor./miss.</td>
<td>7</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Default</td>
<td>Initial consultation not completed</td>
<td>6</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Follow-up evaluation not completed</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Diagnosis</td>
<td>Diagnosis type (new primary, recurrent) incor./miss.</td>
<td>6</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Computer Treatment Planning</td>
<td>Tx Plan</td>
<td>DRFs incor./miss.</td>
<td>6</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>CT Simulation</td>
<td>Appointments</td>
<td>Field setup photos incor./miss.</td>
<td>5</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>CT Simulation</td>
<td>Appointments</td>
<td>Appointment dates incor./miss.</td>
<td>5</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Scheduling</td>
<td>Fields</td>
<td>Immobilization device missing</td>
<td>5</td>
</tr>
</tbody>
</table>

## Detailed Example of Above

<table>
<thead>
<tr>
<th>Pre/Post</th>
<th>Category</th>
<th>Subcategory</th>
<th>Attribute</th>
<th>Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Tx</td>
<td>Billing</td>
<td>Codes</td>
<td>CPT code incor./miss.</td>
<td>141</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Portal Images</td>
<td>Electronic Imager</td>
<td>Weekly images not approved</td>
<td>112</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>R &amp; V</td>
<td>Prescription</td>
<td>Electronic approval before 1st fx miss.</td>
<td>90</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Tx planning sim note not completed</td>
<td>84</td>
</tr>
<tr>
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<td>Patient Docs/Notes</td>
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<td>74</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Isocenter verification sim note not completed</td>
<td>60</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>CT sim note not completed</td>
<td>59</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Treatment Delivery</td>
<td>Patient Setup</td>
<td>RTT note incor./miss.</td>
<td>50</td>
</tr>
</tbody>
</table>
### Center B - Errors of Greatest Frequency

<table>
<thead>
<tr>
<th>Pre/Post</th>
<th>Category</th>
<th>Subcategory</th>
<th>Attribute</th>
<th>Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Tx</td>
<td>Billing</td>
<td>Codes</td>
<td>CPT code incorr./miss.</td>
<td>141</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Portal Images</td>
<td>Electronic Imager</td>
<td>Weekly images not approved</td>
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</tr>
<tr>
<td>Pre-Tx</td>
<td>R &amp; V</td>
<td>Prescription</td>
<td>Electronic approval before 1st fx miss.</td>
<td>90</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Tx planning sim note not completed</td>
<td>84</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Field verification sim note not completed</td>
<td>74</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>Isocenter verification sim note not completed</td>
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<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Simulation Notes</td>
<td>CT sim note not completed</td>
<td>59</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Treatment Delivery</td>
<td>Patient Setup</td>
<td>RTT note incorr./miss.</td>
<td>50</td>
</tr>
</tbody>
</table>

### Center A - Errors of Greatest Frequency

<table>
<thead>
<tr>
<th>Pre/Post</th>
<th>Category</th>
<th>Subcategory</th>
<th>Attribute</th>
<th>Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Tx</td>
<td>Billing</td>
<td>Codes</td>
<td>CPT code incorr./miss.</td>
<td>78</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Portal Images</td>
<td>Electronic Imager</td>
<td>Weekly images not approved</td>
<td>56</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Portal Images</td>
<td>Electronic Imager</td>
<td>Custom attribute SL 2</td>
<td>40</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Registration</td>
<td>Emergency</td>
<td>Home phone incorr./miss.</td>
<td>34</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Quality Assurance</td>
<td>Checks</td>
<td>Weekly physics chart checks miss./late</td>
<td>17</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>Patient Docs/Notes</td>
<td>Default</td>
<td>Initial consultation not completed</td>
<td>13</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td>CT Simulation</td>
<td>Patient Setup</td>
<td>Sim note incorr./miss.</td>
<td>9</td>
</tr>
<tr>
<td>Post-Tx</td>
<td>Patient Docs/Notes</td>
<td>Default</td>
<td>Initial consultation not completed</td>
<td>9</td>
</tr>
</tbody>
</table>
Data was annualized for errors identified 9/09 to 9/10.
Data was annualized for errors identified 2/06 to 3/08.
Data for Centers A & B was annualized for errors identified 9/09 to 9/10 and 2/06 to 3/08, respectively.
• New center startup process & MERP learning curve
  • High vol. of patients
  • Performance issues w/ prior physicist & CT sim therapist
  • Missed/incorr. billing

• Increased onsite 3rd party support
  • MERP action plans implemented & QIC meeting tasks compl.
  • New physicist-
    • Improv. support/tasks
  • Billing manual/trging

• MERP Audits-Prior wkly physics chart checks & QA missed
  • RO left - images not timely approved
  • 9 locum ROs – Docs missing/late: OTV, notes, consults

• 9 locum ROs – Docs missing/late:
  • OTV, notes, consults

• CBCT/kV imager malfunctioning
  • Patient reg. - emergency nos. missing

• 9 locum ROs –
  • Images not timely approved

• CBCT/kV imager fixed-
  • Images appr.

• CBCT/kV imager fixed-
  • Images appr.

• CBCT/kV imager fixed-
  • Images appr.

• CBCT/kV imager fixed-
  • Images appr.

• CBCT/kV imager fixed-
  • Images appr.

• New RO started, locums stopped
  • Onsite training
  • Improved dyn. docs process for notes, consults

• Retraining at reg. office & CT sim
- Learning curve of MERP startup
- Identification of errors & violations
- Improved process, & action plans implemented
- Started new SRS and HDR programs
- Increased patient load
- ROs failing to complete consult/sim/Tx notes timely
- Billing Mistakes
- Training & procedures for SRS
- Assigned HDR ownership & physics schedule
- Penalty for RO report timeliness implemented
- Billing training
- More physics, therapists & staff hired
- Improved process thru procedures & training
- 2 new RO centers built, startup
- Physics/staff stretched
- QA missed, billing, clinical mistakes
Data was annualized for all errors (pre-Tx and post-Tx) collected 9/09 to 9/10.
Data was annualized for all errors (pre-Tx and post-Tx) collected 2/06 to 3/08.
## MERP Results

### Error Rates in Entire Treatment Process Using MERP

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Pre-Tx</th>
<th>Post-Tx</th>
<th>Pre-Tx + Post Tx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Center A</td>
<td>Center B</td>
<td>Center A</td>
</tr>
<tr>
<td>Per Patient, %</td>
<td>37.20</td>
<td>10.10</td>
<td>72.80</td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>1.10</td>
<td>0.34</td>
<td>2.10</td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0.14</td>
<td>0.004</td>
<td>0.28</td>
</tr>
</tbody>
</table>

Data for Centers A and B was annualized for all pre-Tx and post-Tx errors (all aspects of the treatment process from registration to completion of treatment) identified from 9/09 to 9/10 and 2/06 to 3/08, respectively.
## MERP Results

### Error Rates in Treatment Delivery

<table>
<thead>
<tr>
<th>Error Category</th>
<th>This Work MERP</th>
<th>This Work MERP</th>
<th>Kline et al.</th>
<th>Frass et al.</th>
<th>French</th>
<th>Huang et al.</th>
<th>Marks et al.</th>
<th>Macklis et al.</th>
<th>Patton et al.</th>
<th>Margalit et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Patient, %</td>
<td>0.32</td>
<td>3.20</td>
<td></td>
<td></td>
<td></td>
<td>1.97</td>
<td>1.2 - 4.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.01</td>
<td>0.11</td>
<td></td>
<td>0.44</td>
<td>0.32</td>
<td>0.29</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
<td>0.13</td>
<td>0.037</td>
<td></td>
<td></td>
<td>0.18</td>
<td>0.17</td>
<td>0.064</td>
</tr>
<tr>
<td>Overall Per Field, %</td>
<td>0.28 a</td>
<td>0.009 a</td>
<td>0.05 a</td>
<td>0.13 b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Notes

- **a** Errors per field in the entire post-Tx delivery process (from initial patient consultation to completion of Tx).
- **b** Errors per total Tx units.

---

79 Treatment delivery means the administration of radiation.

80 Data for Centers A and B was annualized for post-Tx errors in the treatment delivery process identified from 9/09 to 9/10 and 2/06 to 3/08, respectively.
## MERP Results

### QA & Radiation Safety Failures$^{81, 82}$

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Center A</th>
<th>Center B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Patient, %</td>
<td>18.8</td>
<td>0.78</td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.55</td>
<td>0.026</td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0.072</td>
<td>0.0003</td>
</tr>
</tbody>
</table>

$^{81}$Failures are non-patient related and include regulatory infractions.

$^{82}$Data for Centers A and B was annualized for all data collected 9/09 to 9/10 and 2/06 to 3/08, respectively.
## Misadministration Rates

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Kline et al.</th>
<th>This Work MERP Center A</th>
<th>This Work MERP Center B</th>
<th>US NRC(^{84})</th>
<th>US NRC + Agreement States(^{85})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Patient, %</td>
<td></td>
<td></td>
<td>0</td>
<td>0.065</td>
<td></td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.017</td>
<td>0</td>
<td>0.002</td>
<td>0.004</td>
<td>0.002</td>
</tr>
<tr>
<td>Per Field, %</td>
<td></td>
<td></td>
<td>0</td>
<td>0.00002</td>
<td></td>
</tr>
</tbody>
</table>

\(^{83}\)Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively. US NRC data was also annualized.

## MERP Results

### Clinically Significant Errors\(^{86, 87}\)

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Post-Tx</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Center A</td>
<td>Center B</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0 errors</td>
<td>7 errors</td>
<td></td>
</tr>
<tr>
<td>Per Patient, %</td>
<td>0</td>
<td>0.45</td>
<td></td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0</td>
<td>0.00002</td>
<td></td>
</tr>
</tbody>
</table>

\(^{86}\) Clinically Significant dose trigger levels: single fx (non-SRS) - 10%, weekly difference - 15%.

\(^{87}\) Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.
## MERP Results

### Likelihood of Occurrence - Infractions of Federal/State Regulations per Patient\(^{88}\)

<table>
<thead>
<tr>
<th>Category</th>
<th>Center A (309 patients)</th>
<th>Center B (659 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Billing, %</td>
<td>26.54 (^{a})</td>
<td>5.1 (^{b})</td>
</tr>
<tr>
<td>QA, %</td>
<td>2.59</td>
<td>0.19</td>
</tr>
<tr>
<td>Radiation Safety, %</td>
<td>1.62</td>
<td>0.23</td>
</tr>
</tbody>
</table>

\(^{88}\)Data for Centers A and B was annualized for all data collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

\(^{a}\)Approximately 80% of the infractions were caught/corrected at time of charge capture and before exporting to CMS or insurance company.

\(^{b}\)Approximately 50% of the infractions were caught/corrected at time of charge capture and before exporting to CMS or insurance company.
### MERP Results

#### Errors in Tx Delivery Process\(^{89, 90}\)

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Post-Tx</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Center A</td>
<td>Center B</td>
<td></td>
</tr>
<tr>
<td></td>
<td>62 errors</td>
<td>120 errors</td>
<td></td>
</tr>
<tr>
<td>Per Patient, %</td>
<td>20.10</td>
<td>18.20</td>
<td></td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.58</td>
<td>0.61</td>
<td></td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0.077</td>
<td>0.007</td>
<td></td>
</tr>
</tbody>
</table>

- \(^{89}\)Includes post-Tx errors in Tx delivery process except Registration, Patient/Docs/Notes, Scheduling, Billing, Radiation Safety, and QA.
- \(^{90}\)Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.
### Near Misses<sup>91</sup>

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Post-Tx Center A</th>
<th>Post-Tx Center B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 misses</td>
<td>4 misses</td>
</tr>
<tr>
<td>Per Patient, %</td>
<td>0.65</td>
<td>0.607</td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.019</td>
<td>0.020</td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0.003</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

<sup>91</sup>Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.
MERP Results

• A total of 1,460 (438 pre-Tx and 1,022 post-Tx) errors were identified at both centers
• Centers A and B experienced 0 vs. 2 medical events and 2 vs. 4 near misses, respectively.
• Center B had 7 clinically significant errors, defined as a single fraction dose difference of > than 10% and weekly dose > than 15%.
Lessons Learned With MERP Software Model

• **Upfront Homework**
  – History of error reduction important
  – Why must we embrace to be competitive
  – Philosophy of “goodness”
  – Non-punitive actions will be watched by staff
  – Incentives to encourage reporting a must

• **Practical Implementation**
  – Rewards system must be established
  – Superusers serve as point guards
  – Phased in approach minimizes overload
  – Initial paper recording of UDs prevents corrupt/inaccurate data entry
  – Brief weekly group meetings serve as bulletin board for errors
  – Individuals must be assigned responsibility for drafting procedures required by corrective action plans
  – Track closure of corrective action plans
  – Present overall results at quarterly QIC meetings
Conclusion

• The paper-based model was effective at minimizing errors but proved to be cumbersome and inefficient in practice.
• A software-based error reduction program (MERP) was developed.
• MERP proved efficient at identifying and correcting errors.
• Overall quality and regulatory compliance improved while reducing costs.