Clinical Results of a Medical Error Reduction Software Program in Radiation Oncology

by

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Acknowledgements

A debt of appreciation goes out to the physicians, management and staff of New Mexico Cancer Center located in Albuquerque, NM for their permission to use the MERP medical error reduction software program in their clinic and share their experience.
Introduction

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

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

Introduction

• This presentation describes the design, implementation, and results of two QA/medical error reduction programs
  – Paper-based
  – Software

• Both programs are designed for
  – Reducing preventable systems-related medical errors (i.e., sentinel events, “near misses”)  
  – Preventing violations of regulatory requirements (i.e., State/NRC, CMS)  
  – Ensuring compliance with recommended standards (i.e., JCAHO, ACR, ACRO, etc.)
History

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

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History

• Federal initiatives\(^7\) taken by former President Clinton on 2/22/00 based on IOM recommendations\(^8\)
  – Comprehensive strategy for health providers to reduce medical errors
  – Creation of external reporting systems to identify and learn from errors so as to prevent future occurrences
  – Creation of national patient safety center to set goals
  – At least 50% reduction of errors over 5 years

\(^7\) Announced by President Clinton and senior administration officials in James S. Brady Press Briefing Room on February 2, 2000.

\(^8\) Recommendations issued in report entitled *To Err is Human: Building a Safer Health System* by the Institute of Medicine (IOM) of the National Academies (11/29/99).
History

• Key legislation
  – Patient Safety Quality Improvement Act\(^9\)
    • Certifies patient safety organizations in each State to collect data and report on medical errors
  – State Patient Safety Centers
    • In past 5 years, 6 states have enacted legislation supporting creation of state patient safety centers
    • 5 of the 6 states now operate patient safety centers
    • Separate mandatory reporting systems for serious adverse events
    • Centers are housed within state regulatory agencies

History

• Patient safety centers include\textsuperscript{10}
  – The Florida Patient Safety Corporation
  – The Maryland Patient Safety Center
  – The Betsy Lehman Center for Patient Safety and Medical Error Reduction (Massachusetts)
  – The New York Center for Patient Safety
  – The Oregon Patient Safety Commission
  – The Pennsylvania Patient Safety Authority

History

• **State reporting:** adverse event reporting systems\(^{11, 12}\)
  
  – **Mandatory reporting:** Colorado, Florida, Kansas, Nebraska, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington, Georgia, Maine, Maryland, Minnesota, Nevada, Utah, Colorado, Illinois, Indiana, Kansas, Nevada
  
  – **Voluntary reporting:** District of Columbia, New Mexico, North Carolina, Oregon, Wyoming
  
  – **Considering new legislation:** Arizona, California
  
  – **Mandatory reporting but considering new legislation:** Massachusetts, New Jersey

\(^{11}\)National Conference of State Legislatures, National Academy for State Health Policy, 12/03, Accessed through [www.nashp.org](http://www.nashp.org).

\(^{12}\)Rosenthal, J., Booth, M. Maximizing the Use of State Adverse Event Data to Improve Patient Safety, National Academy for State Health Policy, 10/05.
History

• JCAHO revises standards
  – 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\textsuperscript{13}

\textsuperscript{13} Patient Safety - Essentials for Health Care, 2\textsuperscript{nd} edition, Joint Commission on Accreditation of Healthcare Organizations. Oakbrooke Terrace, IL: Department of Publications, 2004.
History

• JCAHO’s sentinel event policy\textsuperscript{14}
  – Implemented in 1996
  – Identify sentinel events
  – Take action to prevent their recurrence
  – Complete a thorough and credible root cause analysis
  – Implement improvements to reduce risk
  – Monitor the effectiveness of those improvements
  – Root cause analysis must focus on process and system factors
  – Improvements must include documentation of a risk-reduction strategy and internal corrective action plan
  – Action plan must include measurements of the effectiveness of process and system improvements to reduce risk

History

• JCAHO’s Office of Quality Monitoring
  – Receives, evaluates and tracks complaints and reports of concerns about health care organizations relating to quality of care issues
  – Conducts unannounced on-site evaluations

• JCAHO and CMS agreement\(^{15}\)
  – Effective 9/16/04
  – Working together to align Hospital Quality Measures (JC’s ORYX Core Measures and CMS’7th Scope of Work Quality of Core Measures)

History

- CMS quality incentives\(^\text{16}\)
  - Quality Improvement Organizations (QIOs)
    - Contracted by CMS to operate in every State
    - 67% of QIOs 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
      - 2\(^{\text{nd}}\) decile get 1% DRG bonus
    - In year 3, hospitals performing below 9\(^{\text{th}}\) and 10\(^{\text{th}}\) decile baseline levels, DRG payments reduced 1% and 2%, respectively

\(^{16}\text{Medicare Looks for Ways to Boost Quality Care Comments Sought on New Plan for Quality Improvement Organizations, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.}\)
History

• CMS quality incentives
  – CMS consumer website
    • CMS contracted with NQF & worked with JCAHO to develop hospital quality measures for public reporting
    • In 4/05, hospital quality data became available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
  – Data indicators\textsuperscript{17}
    • In 2006, hospitals reporting quality data to Medicare receive 3.7% increase in inpatient payments
    • Non-reporters receive 3.3% increase
    • Data covers 10 quality indicators for cardiology
    • Plans are to expand into other disciplines

\textsuperscript{17} Medicare to Pay Hospitals for Reporting Quality Data, Modernhealthcare, accessed through www.modernhealthcare.com.
History

• CMS quality incentives
  – Announced 8/23/05, Medicare/State Children’s Health Insurance Program (SCHIP) Quality Initiative
  – Pay-For-Performance (P4P)\textsuperscript{18}
    • 12 states have adopted some form
      – Performance measurement is critical for reimbursement
      – 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

- CMS quality incentives
  - 104 P4P provider programs in US
    - P4P attempts to “introduce market forces and competition to promote payment for quality, access, efficiency, and successful outcomes.”
    - Expect P4P to extend beyond HMOs to include specialties, PPOs, self insured, and consumer-direct programs.
    - Senators Charles Grassley (R-Iowa) and Max Baucus (D-Mont) introduced Medicare Value Purchasing (MVP) Act of 2005. Requires Medicare implement a P4P program covering at least a portion of payments made.

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19 Pay for Performance’s Small Steps of Progress. PricewaterhouseCoopers. 8/2/05. Accessed through www.pwchealth.com
History

• CMS quality incentives
  – 2006 Physician Voluntary Reporting Program\textsuperscript{21}
    • 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

\textsuperscript{21} \textit{Medicare Takes Key Step Toward Voluntary Quality Reporting for Physicians}, Centers for Medicare & Medicare Services (CMS), Accessed through \url{www.cms.hhs.gov}. 
Now in US

• 3rd annual “HealthGrades Patient Safety in American Hospitals” assessment report for Medicare patients
  – 1.24 million patient safety accidents, or medical errors, occurred between 2002 and 2004, up from 1.8 million between 2001 and 2003
  – Over the same time period
    • 304,702 deaths were caused by medical errors
    • 250,246 of which were potentially preventable
  – 570,000 preventable deaths were caused by medical errors to the entire population (including Medicare) between 2001 and 2004
  – Medical errors cost $500 billion a year in avoidable medical expenses – approximately 30% of all health care costs.

22 250,000 Medicare Patients Killed by Preventable Medical Errors. Protecting Your Rights. Association of Trial Lawyers of America (4/10/06).
23 Fixing Hospitals, Forbes, (6/20/05).
Now in Canada

• 185,000 adverse events occur annually in Canadian hospitals$^{24}$
• Approximates a 7.5% error rate
• Similar rates found in other countries

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

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

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Radiation Oncology Errors

- Not well established
- No comprehensive numbers available for number of errors resulting in death\(^{28}\)
- Reported error rates range 0.1% to 0.2% of fields treated\(^{29}\)
- Studies not relying on self-reporting show actual rates of up to 3%\(^{30}\)

# Significant Medical Events in Radiation Oncology

<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>Panama</td>
<td>Vatnisky S, et al., Radiother Oncol., 2001</td>
<td>2001</td>
<td>Overdose</td>
<td>23</td>
<td>8 - Deaths</td>
<td>Incorrect entry of shielding blocks in Tx planning computer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15 - Severe late complications</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>McKenzie AL, British Institute of Radiology, 1996</td>
<td>1988</td>
<td>Overdose (+25%)</td>
<td>207</td>
<td></td>
<td>Teletherapy activity calculation error</td>
</tr>
<tr>
<td>UK</td>
<td>McKenzie AL, British Institute of Radiology, 1996</td>
<td>1982-1991</td>
<td>Underdose (-25%)</td>
<td>1,045</td>
<td>Several - Deaths or serious injury</td>
<td>Misunderstanding of algorithm in Tx planning computer</td>
</tr>
<tr>
<td>World Wide</td>
<td>IAEA, 2000</td>
<td></td>
<td>Overdose (up to 166%)</td>
<td>50</td>
<td></td>
<td>Miscalibration of dosimeters; incorrect calc techniques, calibration of Tx machines, and use of Tx machines</td>
</tr>
<tr>
<td>US</td>
<td>Ricks CR, REAC/TS Radiation Incident Registry, 1999</td>
<td>1944-1999</td>
<td>Overdose</td>
<td>13</td>
<td>13 - Deaths</td>
<td>Incorrect calibrations, incorrect computer programming, equipment maintenance/repair negligence</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(OH - 10, PA - 1, TX - 2 ) 1 - Serious Injury (WA)</td>
<td></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>Study</td>
<td>Author</td>
<td>Time Interval</td>
<td>Crse of Tx</td>
<td>Total Tx</td>
<td>Total Tx Fx’s</td>
<td>Tx</td>
</tr>
<tr>
<td>-------</td>
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<td>------------</td>
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<td>----</td>
</tr>
<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>
</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>
</tr>
<tr>
<td></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>
</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: - 33 total errors</td>
<td>3.7%: total error rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>Valli MC, et al., Radiother Oncol, 1994</td>
<td>10.5%: incorrect or missing data</td>
<td>17 serious errors</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Medical Error Rates in Radiation Oncology – Table 2

<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>Noel A, et al., Radiother Oncol, 1995</td>
<td>5 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Of 7519 treatments: 79 total errors - Of 79, 78 are human origin - Of 78, 39 would have &gt; 10% dose Δ</td>
<td>1.05%: errors per treatment</td>
<td></td>
</tr>
<tr>
<td>US Kartha PKI, Int J Radiat Oncol Biol Phys, 1997</td>
<td>1997</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Error rates per patient setup</td>
<td>1.4%: linear accelerators 3%: cobalt units</td>
<td></td>
</tr>
<tr>
<td>US 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>15%: causally related to R&amp;V</td>
<td>0.18%: reported error rate/year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>US 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 0.13%: Tx fields</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium Barthelemy-Brichant N, et al., Radiother Oncol, 1999</td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.22%: of all delivered Tx fields had at least 1 error</td>
<td></td>
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<tr>
<td>Canada Yeung TK, Abstract-NEORCC, 1996</td>
<td>1994</td>
<td></td>
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<td></td>
<td>3.3%</td>
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</tbody>
</table>
## Medical Error Rates in Radiation Oncology – Table 3

<table>
<thead>
<tr>
<th>Study</th>
<th>Author</th>
<th>Time Interval</th>
<th>Case 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>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></td>
<td>11,355</td>
<td>195,100</td>
<td>483,741</td>
<td>631</td>
<td>0.13% overall (fields tx’ed incorrect/ total no. fields tx’ed)</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td>177 total incidents</td>
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<td>- 20: correctable</td>
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<td>- 129: noncorrectable and clinically sig.</td>
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<td>- 28: noncorrectable and potentially clinically sig.</td>
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<td></td>
<td></td>
<td>0.32% errors/fraction</td>
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<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>0.037% errors/field</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>Grace H, et al., Int J Radiat Oncol Biol Phys, 2005</td>
<td>1/1/97-12/31/02</td>
<td></td>
<td>28,136</td>
<td></td>
<td></td>
<td>555 total errors</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>- 87 (15.6%): incorrect programming in R&amp;V</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.97% error rate per patient</td>
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<td></td>
<td></td>
<td></td>
<td>0.29% error rate per fraction (7/00 - 12/02)</td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>Klein E, et al., J of Appl Clin Med Phys, 2005</td>
<td>30 months</td>
<td></td>
<td>3,964</td>
<td></td>
<td></td>
<td>52.5%</td>
<td>0.48 to &lt;0.1% for diff methods of detection w/R&amp;V</td>
</tr>
</tbody>
</table>

*Note: Error rates are expressed as percentages.*
Paper-Based Model
Objective of Paper-Based QA/Medical Error Reduction Program

• 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 QA/Medical Error Reduction Program

• 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 QA/Medical Error Reduction Program

• 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 Regs
- ACR Standards
- AAA National Standards
- JCAHO Requirements

Policies & Procedures
- Individual Manuals
- FS Manuals
- IS Notebook Filing System
- Modules

Correct Audit Findings

Training
- Classroom
- Workshops

Individual Error Feedback System

Quarterly Error Reduction Report

Error Reduction/Compliance Program (Quarterly Audits)
Start

Team Member Identifies Error

Team Member Records Error on QA1a

Is Error Safety Sig.? Yes No

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

RSO & Dr. sign Form QA1b

QA1b faxed to OQMRA for eval.

Corr. action approp.? Yes No

OQMRA faxes QA1b response to RSO

QA Comm analysis of errors

QA Mng. 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
### Name Cancer Center: Post-Treatment Unintended Deviations

#### Data of

<table>
<thead>
<tr>
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<th></th>
<th></th>
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</tr>
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<tbody>
<tr>
<td>100</td>
<td>1010</td>
<td>Treatment Date</td>
<td>157</td>
<td>1571</td>
<td>Wrong inverted factor 2 3 F</td>
</tr>
<tr>
<td>1011</td>
<td>1572</td>
<td>Plan Identification</td>
<td>158</td>
<td>1581</td>
<td>Mat. error 2 3 F</td>
</tr>
<tr>
<td>1012</td>
<td>1582</td>
<td>Plan names and number</td>
<td>159</td>
<td>1591</td>
<td>Calc. using incorrect dose 2 3 F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Entry</th>
<th>Code</th>
<th>Identified</th>
<th>Description/IL/Process/Resp. Party</th>
</tr>
</thead>
<tbody>
<tr>
<td>1102</td>
<td>1101</td>
<td>Dosage 4 M</td>
<td>Missing PA SSD 4 F</td>
</tr>
<tr>
<td>1111</td>
<td>1112</td>
<td>Prescription 2 M</td>
<td>Missing SSD 2 F</td>
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<tr>
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#### Legend
- **Significance Level**: 1 (most significant), 2, 3, 4, 5 (least significant)
- **-**: Key Process
- **M**: M.D.
- **P**: Physicist
- **T**: Therapist
- **F**: Facility M.D.
- **Q**: QI Coordinator

#### Footnotes
- To include w/ and w/o complaints, and to specify if no complaint is recorded in the pattern

#### Notes
- This document contains some agreement states and no non-compliance desiderata statements.

#### QAMs Note
- Re: 2003

---

**Pre-Treatment Udders, Yoyo, Zorro, 0001-0200**
**Name Cancer Center**

Unintended Deviation Reporting Form

For Significance Level 1 and 2 Events (Recorded in Annex QAC and QAD)

**Date of Occurrence:**

**Identified By:**

- Date Identified:
- Patient Chart/NIC:

**Pre-Treatment Unintended Deviation**

<table>
<thead>
<tr>
<th>Category</th>
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<tr>
<td>Quality Assurance</td>
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**Post-Treatment Unintended Deviation**

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<td>Radiation Safety</td>
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</table>

**Description:**

**Evaluation:**

- Daily Dose (%)
- Weekly Dose (%)
- Total Dose (%)

**Recordable Event**

- Maladministration
- Personal Overexposure

**Immediate Corrective Action Taken (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 initial date:
- ESO initial date:
- MD initial date:

**Evaluation:**

**Recommendations:**

**Date Received:***

**Date Reviewed:***

**Date Approved:***

**Date Final:***
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Minor Unintended Deviations: 3rd Qtr. 1996

- Data Entry: Daily Tx Record
- Process: Simulation Films
- Process: Patient Simulation
- Data Entry: ACCESS - Tx Field Def
- Tx of Patient: Port Films
- Data Entry: Tx Chart - Rx
- Data Entry: Tx Field Info
- Process: Block Fabrication
- Tx of Patient: Patient Beam Modifiers
- Process: Dose Calculation
- Data Entry: Patient Setup Doc
- QA: Missing or Late
- Radiation Safety: Missing or Late
- Tx of Patient: Patient ID
- Tx of Patient: Patient Setup
Significant Unintended Deviations: 2nd & 3rd Qtr. 1996
Total Unintended Deviations versus Time

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Summary of Total Unintended Deviations

- **Minor**
- **Significant**
- **Total**

Number of Reported Unintended Deviations

Calendar Quarter/Year

- 1/96
- 2/96
- 3/96
- 4/96
- 1/97
- 2/97
- 3/97
Reported Misadministration Rate In Radiation Oncology

• Published rates\textsuperscript{31} for \textit{reported} misadministrations in therapeutic radiation oncology is 0.0042 percent (4.2/100,000 administrations) based upon 20 treatments/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{31}NRC memorandum dated March 8, 1993: Data based on information obtained from the American College of Radiology (\textit{Manpower Committee, Patterns of Care Study}, and \textit{Commission of Human Resources}). Additional reference from Institute of Medicine (\textit{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 treatments).

• The minor unintended deviation reporting rate for the same period was approximately 0.034%.
Measured vs Published Misadministration Rate
Radiation Oncology

- 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 treatments).\(^{32}\)
- 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%.

\(^{32}\) 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\(^{33}\) 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

\(^{33}\) Misadministration criteria based on definitions found in NRC 10CFR35.2, rev. 1996.
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 UD.
  – 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
  – 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 Tacking of Errors
  - Preset standardized error codes
  - Classification of pre and post-treatment errors
  - Assignment of severity levels (I - V)
  - Designation of clinical significance
  - Designation of significant unintended deviation
  - "Near Miss” categorization
  - Sentinel events (internal and JCAHO reportable)
  - Instant analysis of patterns and trends

- Identification and Tacking of Violations
  - Preset standardized unintended deviation codes
  - Assignment of severity levels (I - V)
  - Recordable events
  - Misadministrations (medical events)
  - Regulatory violations
  - Possible regulatory violations
  - Instant analysis of patterns and trends
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

- **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**
  - Use MERP to inspect regulatory performance
    - Complies with State radiation safety requirement for annual review
    - Meets State QMP rule for annual review
    - 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 2006 patient safety standards show basis for question
  - ACR and ACRO standards demonstrate benchmark for measuring performance
  - CRCPD (Agreement State) recommended regulations (as of 9/04) 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
    • 15 hours in procedures
    • 6 hours in MERP
  – Presented over 1 hour lunch break
  – Took 2 months
  – Issued category ‘A’ credit thru ASRT
  – Met annual state radiation safety training requirements
MERP Implementation Strategy
Phased Rollout

• **Step #3 - Superusers**
  – Designated key point guards
    • Controlled data input
    • Tracked status of UDUs
    • Tracked completion of corrective action plans

• **Step #4 - Current Phases**
  – Group 1
    • Therapists
    • CT/X-ray technologists
    • Physics (physicists & dosimerists)
    • Billing
  – Group 2
    • Radiation oncologists
  – Group 3
    • Admissions/registration staff
MERP Implementation Strategy
Future Plan

• **Step #5 - Future Phases**
  – Group 4
    • Nurses and aides
    • PET/Nuc med
    • MRI
    • PET/CT (new machine)

• **Step #6 - Medical Oncology**
  – Develop software
  – Cover areas
    • Infusion
    • Lab
    • Research
  – Follow RO blue print rollout
**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 □</td>
</tr>
<tr>
<td>Pre-Tx □</td>
<td>Post-Tx □</td>
</tr>
</tbody>
</table>

Description of UD:

________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

Initials: ___________________  Date: ___________________
Summary of Total Unintended Deviations

Paper Based System

Number of Reported Unintended Deviations

Calendar Quarter

Minor
Significant
Total

MERP

0 5 10 15 20 25
0 200 400 600 800 1000 1200

1 2 3 4 5 6 7
MERP Results
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
Conclusion

• Based on the experience gained from the clinical application of the paper-based model at over 42 centers throughout the country (29 described in this presentation), a software-based medical error reduction program (MERP) was developed.

• In its first clinical test, MERP provides a non-intrusive and efficient means to address medical error reduction in a systematic manner, while minimizing the occurrence of regulatory violations.

• The initial results from MERP appear very promising.