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}

• 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

• 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)
  – 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).
History

- **IOM Costs**\(^6\)
  - 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

History

• Federal initiatives\textsuperscript{7} taken by former President Clinton on 2/22/00 based on IOM recommendations\textsuperscript{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

\textsuperscript{7} Announced by President Clinton and senior administration officials in James S. Brady Press Briefing Room on February 2, 2000.

\textsuperscript{8} Recommendations issued in report entitled \textit{To Err is Human: Building a Safer Health System} by the Institute of Medicine (IOM) of the \textbf{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: mandatory vs voluntary\textsuperscript{11}
  – \textbf{Mandatory reporting}: Colorado, Florida, Kansas, Nebraska, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington
  – \textbf{Voluntary reporting}: District of Columbia, Georgia, New Mexico, North Carolina, Oregon, Wyoming
  – \textbf{Considering new legislation}: Arizona, California, Maine
  – \textbf{Mandatory reporting but considering new legislation}: Massachusetts, New Jersey

\textsuperscript{11}\textit{National Conference of State Legislatures, National Academy for State Health Policy, 12/03, Accessed through www.nashp.org.}
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{12}

\textsuperscript{12} 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
  – 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\textsuperscript{14}
  – Effective 9/16/04
  – Working together to align Hospital Quality Measures (JC’s ORYX Core Measures and CMS’\textsuperscript{7}th Scope of Work Quality of Core Measures)

\textsuperscript{14}Joint Commission, CMS to Make Common Performance Measures, Joint Commission on Accreditation of Healthcare Organizations, Accessed through www.jcaho.org/accredited+organizations/long+term+care/sentinel+events.
History

• CMS quality incentives
  – 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 recognizes and provides financial reward
    • CMS partnership with Premier Inc., nationwide purchasing alliance
    • Hospitals in top 20% of quality for specific diagnosis get financial reward
      – Top decile gets 2% Diagnosis Related Group (DRG) bonus
      – 2nd decile get 1% DRG bonus
    • Hospitals performing below 9th and 10th decile baseline levels, DRG payments reduced 1% and 2%, respectively

History

• CMS quality incentives
  – CMS consumer website
    • Beginning in 4/05, hospital quality data available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
  – Data indicators\(^{16}\)
    • 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

\(^{16}\) Medicare to Pay Hospitals for Reporting Quality Data, Modernhealthcare, accessed through www.modernhealthcare.com.
History

• CMS quality incentives
  – Physician Voluntary Reporting Program\textsuperscript{17}
    • Beginning in 1/06
    • 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{17} Medicare Takes Key Step Toward Voluntary Quality Reporting for Physicians, Centers for Medicare & Medicare Services (CMS), Accessed through \url{www.cms.hhs.gov}. 
Radiation Oncology Errors

• Not well established
• No comprehensive numbers available for number of errors resulting in death\(^\text{18}\)
• Reported error rates range 0.1\% to 0.2\% of fields treated\(^\text{17}\)
• Studies not relying on self-reporting show actual rates of up to 3\%\(^\text{17}\)

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## 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>Vtnisky S, et al., Radiother Oncol., 2001</td>
<td>2001</td>
<td>Overdose</td>
<td>23</td>
<td>8 - Deaths 15 - Severe late complications</td>
<td>Incorrect entry of shielding blocks in Tx planning computer</td>
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<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>
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<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></td>
<td>Misunderstanding of algorithm in Tx planning computer</td>
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<tr>
<td>World Wide</td>
<td>IAEA, 2000</td>
<td></td>
<td>Overdose (up to 166%)</td>
<td>50</td>
<td>Several - deaths or serious injury</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 - Deaths (OH - 10, PA - 1, TX - 2) 1 – Serious Injury (WA)</td>
<td>Incorrect calibrations, incorrect computer programming, equipment maintenance/repair negligence</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Author</td>
<td>Time Interval</td>
<td>Crse of Tx</td>
<td>Total Tx Fx’s</td>
<td>Total Tx Fields</td>
<td>Tx Error Specifics</td>
</tr>
<tr>
<td>-------</td>
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<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>----------------</td>
<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>2.1% - 4% per year</td>
<td>4% per year</td>
<td>742</td>
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<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 Sig. potential 5%</td>
<td></td>
<td></td>
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<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>
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<tr>
<td>Italy</td>
<td>Valli MC, et al., Radiother Oncol, 1994</td>
<td></td>
<td>- 33 total errors</td>
<td>10.5%: incorrect or missing data</td>
<td></td>
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**Medical Error Rates in Radiation Oncology – Table 1**
<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>US</td>
<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></td>
<td>15%: causally related to R&amp;V</td>
<td>0.18%: reported error rate/year</td>
</tr>
<tr>
<td>US</td>
<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</td>
<td>0.13%: Tx fields</td>
</tr>
<tr>
<td>Belgium</td>
<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>
</tr>
<tr>
<td>Canada</td>
<td>Canada Yeung TK, Abstract-NEORCC, 1996</td>
<td>1994</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.3%</td>
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<tr>
<td>Study</td>
<td>Author</td>
<td>Time Interval</td>
<td>Crse of Tx</td>
<td>Total Tx Fx’s</td>
<td>Total Tx Fields</td>
<td>Tx Field Errors</td>
<td>Error Specifics</td>
<td>Error Rate</td>
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<tr>
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<td>-----------</td>
</tr>
<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>17,479 avg./yr.</td>
<td></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 clinically sig. - 28: noncorrectable and potentially clinically sig.</td>
<td>0.13%: overall (fields tx’ed incorrect/ total no. fields tx’ed) 0.32%: errors/fraction 0.037%: errors/field</td>
</tr>
<tr>
<td>Canada</td>
<td>Grace H, et al., Int J Radiat Oncol Biol Phys</td>
<td>1/1/97-12/31/02</td>
<td>28,136</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.97%: error rate per patient</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></td>
<td>0.48 to &lt;0.1%: for diff methods of detection w/R&amp;V</td>
</tr>
</tbody>
</table>
NRC Reported Medical Events
(10 CFR Part 35)
Objective of a “QA/Medical Error Reduction Program”

Objective was to provide a unified, total quality management and continuous improvement program for minimizing the occurrence of errors identified in the patient treatment process and regulatory arena. The program was designed for 17 geographically dispersed radiation oncology clinics located in 9 states of varying regulatory oversight and enforcement philosophy.
Design of 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 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
Unintended Deviation Reporting Process

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.? Yes No

Physician reviews relevant QA1b

Corr. action approp.? Yes No

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 Mtg. results faxed to OQMRA

OQMRA analysis & tabulation

Quarterly report to company and center

End
The Unintended Deviation System

- The 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>
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<th></th>
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<tr>
<td>1010</td>
<td>Treatment planning: Data Entry</td>
<td>Patient Simulation</td>
<td>1650</td>
<td>Identified</td>
<td>Description/SL/Process/Resp. Party</td>
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<td>1011</td>
<td>Treatment site 2 P M</td>
<td>Patient Setup</td>
<td>1651</td>
<td>Math error 3 P M</td>
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<td>1110</td>
<td>Code 4 M</td>
<td>Missing RASD 2 M</td>
<td>1652</td>
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<td>1111</td>
<td>Course 4 M</td>
<td>Missing R/L SD 2 T</td>
<td>1653</td>
<td>Tx plan not approved 3 P M</td>
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<td>Technique 2 M</td>
<td>Computer Calculations</td>
<td>1654</td>
<td>Msc. 3 P M</td>
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<td>1113</td>
<td>Modality (photons or electrons) 1 M</td>
<td>Missing R/L SD 2 T</td>
<td>1655</td>
<td>Incorrect energy 3 P M</td>
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<td>Dose specification 2 M</td>
<td>Incorrect mode of 1x 3 P M</td>
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<td>1115</td>
<td>Depth 2 M</td>
<td>Incorrect field size 3 P M</td>
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<td>Incorrect asymmetry 3 P M</td>
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<td>Total dose 1 M</td>
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<td>Fraction dose 1 M</td>
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<td>Elect. Approval before 1 Tx (Rv) 1 M</td>
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<td>Dose ≥ 3x 2 P M</td>
<td>Blocks out ≥ 3x 3 P M</td>
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<td>Dose ≤ 3x 2 P M</td>
<td>Hand blocks mounted ≥ 3x 3 P M</td>
<td>1676</td>
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<tr>
<td></td>
<td>Incomp. wedge angle 2 P M</td>
<td>Custom blocks mounted ≥ 3x 3 P M</td>
<td>1677</td>
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<td>Incomp. wedge orientation 2 P M</td>
<td>Missing or late blocks ≥ 3x 3 P M</td>
<td>1678</td>
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<td>Incomp. compensator 2 P M</td>
<td>Energy or modality used ≥ 3x 3 P M</td>
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<td>Dose Calculation</td>
<td>Calibration Chart</td>
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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 weds, blocks, bolus, compensator, and no. of fr/day & fr/week (if not recorded under Pattern)
Misadministration (Note: Some Agreement states have more restrictive dose requirements.)
QAib Recordable Event
All information contained in this document is Confidential/Privileged.
Name: Cancer Center

Unintended Deviation Reporting Form for Significance Level 1 and 2 Events (Recorded on Forms QAa and QAb)

Date(s) of Occurrence: ___________________________ Date Identified: ___________________________

Identified By: ___________________________ Patient Chart/UDN: ___________________________

☐ Pre-Treatment Unintended Deviation

☐ Post-Treatment Unintended Deviation

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<th>Category</th>
<th>Frequency</th>
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Description: ____________________________________________________________

Evaluation: ___________________________________________________________

☐ □ Daily Dose (1) __%  ☐ □ Weekly Dose (2) __%  ☐ □ Total Dose (3) __%

☐ □ Recalculable Event  ☐ □ Misadministration  ☐ □ 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 or RSO Initials: ___________________________

☐ RSO Initials: ___________________________

☐ MD Initials: ___________________________

Physician or RSO Use Only

Evaluation: ___________________________________________________________

Recommendations: _____________________________________________________

Date Received: ___________________________ Date Reviewed: ___________________________

Date of Patients Follow-Up: ___________________________ Reviewer’s Initials: ___________________________

1 Complies with state and federal enforcement policies regarding licensee-identified violations and recording of unintentioned deviations pursuant to the Quality Management Program. All information in this document and any attachments are Client-Confidential Privileged.
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Minor Unintended Deviations: 3rd Qtr. 1996

- Data Entry: Daily Tx Record: 39%
- Process: Simulation Films: 5%
- Process: Patient Simulation: 5%
- Data Entry: ACCESS - Tx Field Def: 7%
- Tx of Patient: Port Films: 8%
- Data Entry: Tx Chart - Rx: 6%
- Data Entry: Tx Field Info: 9%
- Process: Block Fabrication: 7%
- Tx of Patient: Patient Beam Modifiers: 8%
- Process: Dose Calculation: 4%
- Data Entry: Patient Setup Doc: 1%
- QA: Missing or Late: 4%
- Radiation Safety: Missing or Late: 4%
- Tx of Patient: Patient ID: 4%
- Tx of Patient: Patient Setup: 5%
Total Unintended Deviations versus Time

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

Number of Reported Unintended Deviations

Calendar Quarter/Year

- Minor
- Significant
- Total
Reported Misadministration Rate In Radiation Oncology

• Published rates\(^{19}\) for *reported* misadministrations in therapeutic radiation oncology is 0.004 percent (4/100,000 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.

\(^{19}\)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 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).\textsuperscript{20}

• 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%.

\textsuperscript{20} 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.
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

• 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

• 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\(^{21}\) was 0.018%
- Actual misadministration rate was 0.017%
- NRC misadministration rate was 0.04% (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

\(^{21}\) Misadministration criteria based on definitions found in NRC 10CFR35.2, rev. 1996.
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 With 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 UDs
  – Management review
  – Trending and analysis
  – Report generation
  – Timely action
  – Credible root cause analysis
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 Features

- 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 Features

- **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 Features

- **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
Design of Software-Based Model

MERP Program Features

– **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 2005 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
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.

• MERP provides a non-intrusive and efficient means to address medical error reduction in a systematic manner. Through implementation of MERP, errors that affect patient safety and/or result in regulatory violations can be minimized and often prevented for recurring.

• The initial results from the clinical application of MERP appear very promising with clinical testing to completed by 3/06. MERP will be commercially available by 4/06.