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

by

Ed Kline

RadPhysics Services LLC
Acknowledgements

A debt of appreciation goes out to the physicians, management and staff of
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
  • Design, implementation, and results of two QA/medical error reduction models
    – Paper-based
    – Software-based
  • How well the models worked
    • Reducing preventable systems-related errors (sentinel events, “near misses”)
    • Preventing violations of regulatory requirements (State/NRC, CMS)
    • Ensuring compliance with recommended standards (JCAHO, ACR, ACRO, etc.)
    • Improving overall efficiency
Introduction

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

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

History

- Institute of Medicine (IOM) report\(^5\)
  - 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.

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\(^7\) 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\(^10\)
    • In past 7 years, 6 states now operate patient safety centers
    • Separate mandatory reporting systems for serious adverse events
    • Centers are housed within state regulatory agencies


State quality collaboratives involve multiple agencies.  

### Table 4  State collaboratives and plans

<table>
<thead>
<tr>
<th>State</th>
<th>Plan/agenda</th>
<th>Structure or task force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
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<td>Arizona</td>
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<td><strong>Total</strong></td>
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<tr>
<td><strong>(12 of 33 responding)</strong></td>
<td><strong>11</strong></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

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History

Publicly reported quality and safety information: State-mandated and non-mandated\(^\text{12}\)

Table 5  States that publicly report quality and safety information

<table>
<thead>
<tr>
<th>State</th>
<th>Legislative mandate to report quality information</th>
<th>Legislative mandate to report safety information</th>
<th>Quality reporting not mandated by legislation</th>
<th>Safety reporting not mandated by legislation</th>
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<td>Arkansas</td>
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| Total (n=19 of 33 states) | 14 | 8 | 11 | 9 |

History

• Patient safety centers created\(^\text{13}\)
  – 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

• 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{14}

\textsuperscript{14} 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

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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
  – 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)

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History

• CMS quality incentives\(^{17}\)
  – 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\(^{nd}\) decile get 1% DRG bonus
    • In year 3, hospitals performing below 9\(^{th}\) and 10\(^{th}\) decile baseline
      levels, DRG payments reduced 1% and 2%, respectively

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](http://www.HospitalCompare.hhs.gov) or 1-800-MEDICARE
  - Data indicators\(^{18}\)
    - 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

\(^{18}\) *Medicare to Pay Hospitals for Reporting Quality Data*, *Modernhealthcare*, accessed through [www.modernhealthcare.com](http://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{19}
    • 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 \textbf{quality of care standards}

\textsuperscript{19} Letter Announcing Medicare/State Children’s Health Insurance Program (SCHIP) Quality Initiative, Centers for Medicare & Medicare Services (CMS), Accessed through \texttt{www.cms.hhs.gov}.  

History

- CMS quality incentives
  - 104 P4P provider programs in US in 2005\(^\text{20}\)
    - 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.\(^\text{21}\)

\(^\text{20}\) Pay for Performance’s Small Steps of Progress. PricewaterhouseCoopers. 8/2/05. Accessed through www.pwchealth.com
\(^\text{21}\) Baker, G., Carter, B., Provider Pay for Performance Incentive Programs: 2004 National Study Results. 8/2/05. Accessed through www.medvantageinc.com
History

• CMS quality incentives
  – 2006 Physician Voluntary Reporting Program
    • 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

History

• CMS quality incentives
  – 2007 Physician Quality Reporting Initiative (PQRI)\textsuperscript{23}
    • Financial incentive to participate in voluntary reporting
      – 66 evidence-based quality measures (8 additional to be added)
      – Reporting period 7/1/07 – 12/31/07
      – Bonus payment of 1.5%
      – Covers charges for Medicare physician fee schedule
      – Claims-based reporting
        » CPT Category II codes (or temp G-codes where Category II codes not available yet)

\textsuperscript{23} Physician Quality Reporting Initiative, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.
History

• CMS quality incentives
  – 2007 Physician Quality Reporting Initiative (PQRI)\textsuperscript{24}
    • MO: 3 measures
      – Hormone therapy for Stage IC-III, ER/PR Positive Breast CA
      – Chemotherapy for Stage III Colon CA Patients
      – Plan for Chemotherapy Documented Before Chemotherapy Administered
    • RO: 1 measure
      – RT for Invasive Breast CA Patients Who Have Undergone Breast Conserving Surgery
    • Thresholds
      – If no more than 3 measures, each measure \textbf{MUST} be reported for at least 80\% of cases
      – If 4 or > measures apply, at least 3 measures \textbf{MUST} be reported for at least 80\% of cases
  – PQRI data available for public in 2008 \textbf{WITH} performance rates

\textsuperscript{24} \textit{Physician Quality Reporting Initiative}, Centers for Medicare & Medicare Services (CMS), Accessed through \url{www.cms.hhs.gov}.
Now

• CMS quality incentives
  – 2008 Physician Quality Reporting Initiative (PQRI)\textsuperscript{25}
    • Physicians can now report on 119 quality measures
    • New is tracking of 5 quality measures in adoption of healthcare information technology (EMR)
  – 2009 proposed PQRI changes\textsuperscript{26}
    • A total of 175 quality measures
    • Requires reporting on 80% of applicable patients, with minimum of 15 patients

\textsuperscript{25} CMS Ups Quality-Reporting Program Measures, Modern Health Care, 12/10/07. Accessed through www.modernhealthcare.com
Now

• CMS quality incentives
  – Proposed Value-Based Purchasing Program in 2008
    • 2-5% of hospital’s base operating payment for each discharge payment (DRG) contingent on performance of specific of measures
      – 1st year, 100% incentive based on reporting
      – 2nd year, 50% reporting & 50% performance
      – 3rd year, 100% reporting

Now

• No Charge Policy in 2008
  – State associations have/are looking at policy where hospitals will discontinue billing patients and insurers for medical errors\(^{28}\)
    • Colorado, Massachusetts, Michigan, Minnesota, and Vermont
  – CMS will no longer pay for 8 specific hospital problems
  – AETNA will no longer pay for 28 so-called “Never Events”\(^{29}\)
  – Wellpoint (nation’s largest insurer by membership) will no longer pay for serious medical errors\(^{30}\)

Now

- Hospital costs and mortality rates are declining under P4P\textsuperscript{31}
  - Analysis of 1 million patient records from hospitals
    - Median hospital cost per patient declined > than $1,000.
    - Median mortality rate decreased by 1.87%
  - Hospitals could save an estimated 70,000 lives per year
  - Hospitals could reduce costs by > than $4.5 billion annually
- Almost 85% of State Medicare Programs plan to have P4P measures in place within 5 years\textsuperscript{32}


Now

- CMS changes to Medicare’s quality improvement organizations (QIOs)\(^{33}\)
  - Effective 8/1/08, QIOs must meet performance measures to receive financial incentives and future contracts
  - Must be more effective at helping healthcare facilities improve quality & performance
  - If no progress, contract goes to another organization

Now

• HHS proposes rule to create patient safety organizations (PSOs)\(^{34}\)
  – Public, private for-profit, and not-for-profit organizations could be certified by the Agency for Healthcare and Research
  – PSO will consult providers on patient-safety events and QI initiatives in confidential and privileged settings
  – HHS will develop patient-safety databases collected through PSO data

US Grades

• 5th Annual “HealthGrades Patient Safety in American Hospitals” assessment report for Medicare patients
  – 1.12 million patient safety accidents, or medical errors, occurred between 2004 and 2006
    – 238,000 potentially preventable deaths 2004 - 2006
  – 570,000 preventable deaths were caused by medical errors to the entire population (including Medicare) 2001 - 2004
  – $8.6 billion in preventable costs 2003 - 2005
  – Medical errors cost $500 billion a year in avoidable medical expenses – approximately 30% of all health care costs

37 Fixing Hospitals, Forbes, (6/20/05).
Canada Grades

- 185,000 adverse events occur annually in Canadian hospitals\textsuperscript{38}
- Approximates a 7.5% error rate
- Similar rates found in other countries

Physicians on Error-Reporting

• Most physicians believe error-reporting systems are inadequate\(^{39}\)
  – 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\(^{40}\)
  - 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\textsuperscript{41}

- 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\(^{44}\)
- Reported error rates range 0.1% to 0.2% of fields treated\(^{45}\)
- Studies not relying on self-reporting show actual rates of up to 3%\(^{46}\)

## 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>
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</thead>
<tbody>
<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>
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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>
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<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>
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<td>Misunderstanding of algorithm in Tx planning computer</td>
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<td>Germany</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1986-1987</td>
<td>Overdose (various)</td>
<td>86</td>
<td></td>
<td>Co-60 dose calculations based on erroneous dose tables, no independent checks</td>
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<tr>
<td>US</td>
<td>Ricks CR, REAC/TS Radiation Incident Registry, 1999</td>
<td>1944-1999</td>
<td>Overdose</td>
<td></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>
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<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>
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<tr>
<td>Incidents</td>
<td>Author</td>
<td>Time Interval</td>
<td>Event</td>
<td>Total Patients</td>
<td>Outcome</td>
<td>Direct Causes</td>
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<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><strong>15 – Direct Deaths</strong>&lt;br&gt;<strong>2 – Deaths from complications</strong></td>
<td>Error in maintenance if linac, procedures not followed, conflicting signals not analyzed, no beam verification procedures</td>
</tr>
<tr>
<td>UK</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1999-1989</td>
<td>Over and under dose (-20 to +10%)</td>
<td>22</td>
<td></td>
<td>Error in identification of Cs-137, brachytherapy sources, no independent check of source strength</td>
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<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><strong>17 - Deaths</strong></td>
<td>Error in calibration of Co-60 unit, lack of independent beam calibration, recommendation of external audit ignored</td>
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<tr>
<td>Panama</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>2000</td>
<td>Overdose</td>
<td>28</td>
<td><strong>Several - Deaths from radiation</strong></td>
<td>Modified procedure for entry into Tx planning computer without verification</td>
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<tr>
<td>US</td>
<td>IAEA, Safety Report Series No.38, 2006</td>
<td>1989-1988</td>
<td>Overdose (+75%)</td>
<td>33</td>
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<td>Computer file for use of trimmers not updated for new Co-60 source, no manual or independent verification of calculated Tx</td>
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<tr>
<td>Scotland</td>
<td>Scottish Ministers, Report of an Investigation, 2006</td>
<td>2006</td>
<td>Overdose (+58%)</td>
<td>1</td>
<td><strong>1 - Death</strong></td>
<td>Tx planning computer software was upgraded. Old correction factor was applied to new calculation program.</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 Error Specifics</th>
<th>Error Rate</th>
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</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></td>
<td></td>
<td></td>
<td>- Potential mistakes (found in checks): 4,122</td>
<td>2.1% - 4% per year</td>
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<td>- Potential errors of &gt;5% from Rx dose: 742</td>
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<tr>
<td>US</td>
<td>Swann-D'Emilia B, Med Dosime, 1990</td>
<td>1988-1989</td>
<td></td>
<td></td>
<td>87 misadministrations</td>
<td>&lt;0.1%: based on no. of fields Tx'ed</td>
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<td></td>
<td></td>
<td></td>
<td>- After R&amp;V: 4 major, 5 minor errors</td>
<td></td>
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<tr>
<td></td>
<td>Leunens G, et al., Radiother Oncol, 1992</td>
<td>9 months</td>
<td></td>
<td></td>
<td>Data transfer errors: 139 of 24,128</td>
<td>Affected 26% of overall treatments</td>
<td>Sig. potential 5%</td>
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<td>Italy</td>
<td>Calandrino R, et al., Radiother Oncol, 1993</td>
<td>9/91-6/92</td>
<td></td>
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<td></td>
<td>Out of 890 calculations:</td>
<td>3.7%: total error rate</td>
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<td></td>
<td>- 33 total errors</td>
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<td></td>
<td>Valli MC, et al., Radiother Oncol, 1994</td>
<td></td>
<td></td>
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<td>- 17 serious errors</td>
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<td>Italy</td>
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<td>10.5%: incorrect or missing data</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>
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<td>---------------------------------------------</td>
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<td>US</td>
<td>Noel A, et al., Radiother Oncol, 1995</td>
<td>5 years</td>
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<td>Of 7519 treatments: 79 total errors</td>
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<td>- Of 79, 78 are human origin</td>
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<td></td>
<td></td>
<td>- Of 78, 39 would have &gt; 10% dose Δ</td>
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<td>3%: cobalt units</td>
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<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>
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<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>
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<td>0.13%: Tx fields</td>
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<td>Belgium</td>
<td>Barthelemy-Brichant N, et al., Radiother Oncol, 1999</td>
<td>6 months</td>
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<td>Canada</td>
<td>Yeung TK, Abstract-NEORCC, 1996</td>
<td>1994</td>
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## Medical Error Rates in Radiation Oncology – Table 3

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<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>
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<td>Canada</td>
<td>Pegler R, et al., Abstract-Clin Invest Med, 1999</td>
<td>2 years</td>
<td>0.12</td>
<td>0.06%</td>
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<td>0.12 - 0.06%</td>
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<tr>
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<td>Pao WJ, et al., Abstract-ACSO, 2001</td>
<td>6 years</td>
<td>17,479 avg./yr.</td>
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<td></td>
<td></td>
<td></td>
<td>0.17% avg./year per patient</td>
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<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>
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<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>28,136</td>
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<td></td>
<td></td>
<td>555 total errors - 87 (15.6%): incorrect programming in R&amp;V</td>
<td>1.97%: error rate per patient 0.29%: error rate per fraction (7/00 - 12/02)</td>
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<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>
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<td></td>
<td>0.48 to &lt;0.1%: for diff methods of detection w/R&amp;V</td>
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</table>
NRC Reported Medical Events
(10 CFR Part 35)

NOTE: Abnormal Occurrences Replaced Medical Events
2006: 2 NRC, 6 Agreement States  
2007: 5 NRC, 6 Agreement States
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 feed-back 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
- NEC/State Rags
- ACR Standard
- 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 (Quartely Audits)
Unintended Deviation Reporting Process

Start

Team Member Identifies Error

Team Member Records Error on QA1a

Is Error Safety Sig.? Yes

QA1b completed by team members

RSO reviews Corr. Action on QA1b

Corr. action approp.? Yes

Physician reviews relevant QA1b

Corr. action approp.? Yes

End

No

No

No

No

No

End

Yes

QA1b faxed to OQMRA for eval.

Corr. action approp.? No

RSO & Dr. sign Form QA1b

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
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<td>1011</td>
<td>Treatment step 3◆ P</td>
<td>1630</td>
<td>Math error 3 ◆ P</td>
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<td>1012</td>
<td>Plan identification 3 P</td>
<td>1631</td>
<td>Math error 3 ◆ P</td>
</tr>
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<td>1112</td>
<td>Field names and numbers 3◆ P</td>
<td>1632</td>
<td>Calc. using incorr. dose 2 ◆ P</td>
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<tr>
<td>1111</td>
<td>Pt position not iso. to midline (SAD) 3 ◆ T</td>
<td>1633</td>
<td>Tx plan not approved 1 ◆ M</td>
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<tr>
<td>1580</td>
<td>R &amp; V: Data Entry</td>
<td>1634</td>
<td>Misc.</td>
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<tr>
<td>1111</td>
<td>Course 4 ◆ M</td>
<td>1320</td>
<td>Missing SSD 3 ◆ T</td>
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<tr>
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<td>Prescription site 2 ◆ M</td>
<td>1321</td>
<td>Missing R/ML SSD 2 ◆ T</td>
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<td>1113</td>
<td>Technique 2 ◆ M</td>
<td>1322</td>
<td>Missing L/ML SSD 2 ◆ T</td>
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<td>Modality (photons or electrons) 1 ◆ M</td>
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<td>Missing calc. pt. SSD 2 ◆ T</td>
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<td>Depth 2 ◆ M</td>
<td>1325</td>
<td>Incomp. energy 1 ◆ P</td>
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<tr>
<td>1117</td>
<td>Total dose 1 ◆ M</td>
<td>1326</td>
<td>Incomp. mode of x 1 ◆ P</td>
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<tr>
<td>1118</td>
<td>Fraction dose 1 ◆ M</td>
<td>1327</td>
<td>Incomp. field size 3 ◆ P</td>
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<td>1119</td>
<td>Fracions 2 ◆ M</td>
<td>1328</td>
<td>Incomp. asymmetric jaw 3 ◆ P</td>
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<td>1120</td>
<td>Pattern 2 ◆ M</td>
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<td>Incomp. SSD 3 ◆ T</td>
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<td>Elect. Approval before 1Tx (R/RV) 1 ◆ M</td>
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<td>Misc.</td>
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<td>Dose (not approved)</td>
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<td>1371</td>
<td>Field name 3 ◆ P</td>
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<td>Misc.</td>
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<td>1500</td>
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<td>Hand fat blocks mounted incorr. 3 ◆ T</td>
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<td>Used incorr. cutout 2 ◆ P</td>
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<td>Custom blocks mounted incorr. 3 ◆ T</td>
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<td>Used incorr. SSD 2 ◆ T</td>
<td>1503</td>
<td>Missing or late block checks 4 ◆ T</td>
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<td>Depth of max. incorr. 2 ◆ P</td>
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<td>Energy incorr. 1 ◆ P</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 wedges, blocks, bolus, compensator, and no. of fr/day at fr/hour (if not recorded under Pattern)

Misadministration (Note: Some Agreement states have more restrictive dose requirements)

QA1b

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)

<table>
<thead>
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<th>Category</th>
<th>Frequency</th>
<th>Code</th>
<th>Category</th>
<th>Frequency</th>
<th>Code</th>
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<td>Treatment Dismissal</td>
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<td>E &amp; V</td>
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<td></td>
<td>Treatment of Patient</td>
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<tr>
<td>Patient Simulation</td>
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<td>Patient Identification</td>
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<tr>
<td>Block Fabrication</td>
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<td></td>
<td>Port Mis</td>
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<tr>
<td>Dose Calculation</td>
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<td></td>
<td>Quality Assurance</td>
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<tr>
<td>Control Measurement</td>
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<td></td>
<td>Radiation Safety</td>
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<td></td>
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</tbody>
</table>

**Description:**

**Evaluation:**

- [ ] □ Daily Dose(5) ____ %
- [ ] □ Weekly Dose(5) ____ %
- [ ] □ Total Dose(5) ____ %
- [ ] □ Recordable Event
- [ ] □ Misadministration
- [ ] □ Personal Overexposure

Immediate Corrective Action Taken (Check all that apply):

- [ ] 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 initial: __________________
- [ ] RSO initial: __________________
- [ ] MD initial: __________________

**Evaluation:**

**Recommendations:**

**[Form Information]**

- [ ] Date of Event
- [ ] Date of Follow-up

---

1. Complies with state and federal enforcement policies regarding licensee-identified violations and recording unintentional deviations pursuant to the Quality Management Program. All information in this document and any attachments are Client/observer Privileged.

QAIC

Envisioned Deviation Reporting Form 2014-03-03R2 2005
<table>
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<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>R &amp; V - Prescription</td>
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<td>R &amp; V - Tx Field Definition</td>
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<tr>
<td>Sim - Patient Setup</td>
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<td>4</td>
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</tr>
<tr>
<td>Sim - Films</td>
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<td>5</td>
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<td>Block Fabrication</td>
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<tr>
<td>Dose Calc - Hand</td>
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<td>Dose Calc - Computer</td>
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<tr>
<td>Control Measurements</td>
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<td>Tx of Patient - Beam ME thers</td>
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<td>Radiation Safety</td>
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1 File in Incident Notebook XX - Section A.3. Send copy to QIC.
2 All information contained in this document and any attachments are Client-Attorney Privileged.
<table>
<thead>
<tr>
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<th>TMU D-2nd Qtr '96</th>
<th>TSU D-2nd Qtr '96</th>
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<th>TMU D-3rd Qtr '96</th>
<th>TSU D-3rd Qtr '96</th>
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<td>10</td>
<td>33</td>
<td>36</td>
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<td>25</td>
<td>28</td>
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<td>PERCENT INCREASE/DECREASE</td>
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<td>-51.7%</td>
<td>-71.3%</td>
<td>-63.6%</td>
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Minor Unintended Deviations: 3rd Qtr. 1996

Data Entry: Daily Tx Record
Process: Simulation Films
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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>2nd Quarter '96</th>
<th>2nd Quarter '97</th>
<th>% Change</th>
<th>Parameter</th>
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<th>2nd Quarter '97</th>
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<td>RS: Missing/Late</td>
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<td>6</td>
</tr>
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<td>105</td>
<td>44</td>
<td>-239</td>
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</table>
Summary of Total Unintended Deviations
Reported Misadministration Rate In Radiation Oncology

Published rates\textsuperscript{47} for \textit{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{47} 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 fractions).

• 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 fractions).\textsuperscript{48}

• 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{48} 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
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 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

49 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 UDs
  – 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 2007 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
    • 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 UD's
    - 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
**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>
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<tbody>
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<td>Clinical ☐</td>
<td>QA ☐</td>
</tr>
<tr>
<td>Pre-Tx ☐</td>
<td>RS ☐</td>
</tr>
<tr>
<td>Post-Tx ☐</td>
<td></td>
</tr>
<tr>
<td>Affected Tx ☐</td>
<td>QA ☐ RS ☐</td>
</tr>
</tbody>
</table>

Description of UD:

<p>| |</p>
<table>
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<tr>
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<tr>
<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

Initials: ___________________  Date: ___________________
MERP Results
Summary of Total Unintended Deviations

Paper Based System

Number of Reported Unintended Deviations

Calendar Quarter

MERP

Slower Ramp-Up

Minor

Significant

Total
MERP Results

Fig 1
Patient Pre-Tx Errors Freq. vs Category
MERP Results

Fig 2
Patient Post-Tx Errors Frequency vs Category

- R & V: 2%
- Billing: 20%
- Treatment Delivery: 12%
- Port/Images: 16%
- Patient Docs/Notes: 40%
- CQI: 0%
- Plan Delivery: 8%
- Process: 0%
Fig 3
Patient Post-Tx Errors Affected Tx

- 20 Treatment Delivery 83%
- 1 R & V 4%
- 1 Computer Treatment Plan 4%
- 2 Quality Assurance 9%
MERP Results

Fig. 4
Non-Tx Errors Frequency vs Category

- 17 Quality Assurance 70%
- 7 Radiation Safety 29%
MERP Results

Fig 5
Patient Post-Tx Errors
Frequency vs Category

Beginning Year 2006
Ending Year 2007
## 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.

### Results

<table>
<thead>
<tr>
<th>Pre/Post</th>
<th>Category</th>
<th>Subcategory</th>
<th>Attribute</th>
<th>Occurrences</th>
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<td>CPT code incor./miss.</td>
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<td>Electronic Imager</td>
<td>Weekly images not approved</td>
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<td>R &amp; V</td>
<td>Prescription</td>
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<td>Simulation Notes</td>
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<td>Diagnosis</td>
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<td>No. of charges incor./miss.</td>
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<td>Weekly images not acquired</td>
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<td>Patient Setup</td>
<td>Field setup photos incor./miss.</td>
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<td>CT Simulation</td>
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<td>Field note incor./miss.</td>
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<td>Appointment activity incor./miss.</td>
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<td>Tx Plan</td>
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<td>Bolus required, no bolus used</td>
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<td>Diagnosis type (new primary, recurrent) incor./miss.</td>
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<td>Tx Plan</td>
<td>DRFs incor./miss.</td>
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<td>Pre-Tx</td>
<td>In-Room Treatment Setup</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>
<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>
</tbody>
</table>
## Error Rates in Treatment Delivery

<table>
<thead>
<tr>
<th>Error Category</th>
<th>This Work</th>
<th>This Work</th>
<th>Frass et. al.</th>
<th>Grace et. al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Patient, %</td>
<td>3.2</td>
<td></td>
<td>1.97</td>
<td></td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.11</td>
<td>0.44</td>
<td>0.32</td>
<td>0.29</td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0.0012</td>
<td>0.13</td>
<td>0.037</td>
<td></td>
</tr>
<tr>
<td>Overall, %</td>
<td>0.052 ¹</td>
<td>0.0092 ²</td>
<td>0.13 ³</td>
<td></td>
</tr>
</tbody>
</table>

¹ Errors per fraction  
² Errors per Tx field  
³ Errors per total Tx units
<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>Per Patient, %</td>
<td>10.1</td>
<td>25.4</td>
<td>27.33</td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.34</td>
<td>0.85</td>
<td>0.92</td>
</tr>
<tr>
<td>Per Field, %</td>
<td>0.004</td>
<td>0.0092</td>
<td>0.01</td>
</tr>
</tbody>
</table>

50 Treatment process includes all patient interactions throughout the entire course of therapy (from registration - simulation - Tx planning - Tx delivery - billing - end of Tx report).
## MERP Results

### Misadministration Rates

<table>
<thead>
<tr>
<th>Error Category</th>
<th>This Work Paper</th>
<th>This Work MERP</th>
<th>US NRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Patient, %</td>
<td></td>
<td>0.065</td>
<td></td>
</tr>
<tr>
<td>Per Fraction, %</td>
<td>0.017</td>
<td>0.0022</td>
<td>0.0042</td>
</tr>
<tr>
<td>Per Field, %</td>
<td></td>
<td>0.000023</td>
<td></td>
</tr>
</tbody>
</table>
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

• The paper-based model identified 1,052 errors over 1.75 years and reduced error rate by 326%.

• Based on the experience gained from the paper-based model, a software-based medical error reduction program (MERP) was developed.

• MERP identified 1,122 errors over 2 years.

• MERP provides a non-intrusive and efficient means to address medical error reduction in a systematic manner while increasing efficiency and minimizing the occurrence of regulatory violations.