

# Error Reduction Software Program in Radiation Oncology

by  
Ed Kline



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## Acknowledgements

A debt of appreciation goes out to the  
physicians, management and staff of



Located in Philadelphia, PA



Located in Albuquerque, NM

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

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## Introduction

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

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## Introduction

- Patient safety
  - Freedom from accidental injury due to medical care, or absence of medical errors<sup>1,2</sup>
- or
- Absence of misuse of services<sup>3,4</sup>
- Error
  - The failure of planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)<sup>5</sup>

<sup>1</sup>Hurtado M, Swift E, Corrigan JM, eds. *Envisioning the National Health Care Quality Report*. Washington, DC: National Academy of Sciences; 2001.

<sup>2</sup>McNitt R, Abrams R, Astrom D. *Patient Safety Efforts Should Focus on Medical Errors*. *JAMA*. 2002;287(15):1997-2001.

<sup>3</sup>Department of Health and Human Services. *The Challenge and Potential for Assuring Quality of Health Care for the 21st Century*. Washington, DC: Department of Health and Human Services; 2000.

<sup>4</sup>The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

*Quality First: Better Health Care for All Americans*; 1998.

<sup>5</sup>*To Err is Human: Building a Safer Health System*. Institute of Medicine (IOM). *The National Academies* (11/29/99).

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## Introduction

- In radiation oncology, variety of injuries and errors can occur in the diagnostic imaging or therapeutic treatment delivery processes.
- Various descriptors
  - Unintended deviation
  - Incident
  - Accident
  - Error
  - Mistake
  - Unusual occurrence
  - Recordable event
  - Adverse event
  - Misadministration
  - Medical event
  - Sentinel event

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## History

- Institute of Medicine (IOM) report<sup>6</sup>
  - 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.

<sup>6</sup>*To Err is Human: Building a Safer Health System*. Institute of Medicine (IOM). *The National Academies* (11/29/99).

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## History

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

<sup>7</sup> *To Err is Human: Building a Safer Health System*. Institute of Medicine (IOM). [National Academies](#) (11/29/99).

<sup>8</sup> *2007 Guide to State Adverse Event Reporting Systems: State Health Policy Survey Report*. *National Academy for State Health Policy*, Vol. 1, No. 1, December 2007.

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## History

- Federal initiatives<sup>9</sup> taken by former President Clinton on 2/22/00 based on IOM recommendations<sup>10</sup>
  - Comprehensive strategy to reduce medical errors
  - Creation of external reporting systems
  - Creation of national patient safety centers
  - At least 50% reduction of errors over 5 years

<sup>9</sup> Announced by President Clinton and senior administration officials in James S. Brady Press Briefing Room on February 2, 2000.

<sup>10</sup> 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).

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## History

- Key legislation
  - Patient Safety Quality Improvement Act<sup>13</sup>
    - Certifies patient safety organizations in each State to collect data and report on medical errors
  - State Patient Safety Centers<sup>14</sup>
    - Since 2000, 27 states and the DC have passed legislation or regulations related to hospital reporting of adverse events to a state agency
    - Mandatory reporting systems for serious adverse events
    - NASHP's directive, as part of Health Reform legislation: States MUST **Demand Quality and Efficiency from the Health Care System**

<sup>13</sup> *Reducing Medical Errors*, Issue Module. [Kaiser EDU.org](#). Accessed through [www.kaiserechu.org](#).

<sup>14</sup> *Authorizing Statutes and Regulations*. National Academy for State Health Policy. Accessed September 28, 2010 through [www.nashp.org](#).

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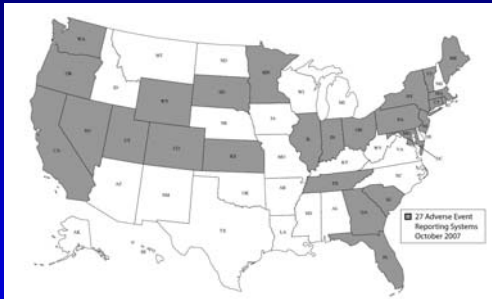
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### Authorized Adverse Event Reporting Systems, October 2007<sup>15</sup>



<sup>15</sup> Jill Rosenthal et al., *2007 Guide to State Adverse Event Reporting Systems*, National Academy for State Health Policy, State Health Policy Survey Report - December 2007.

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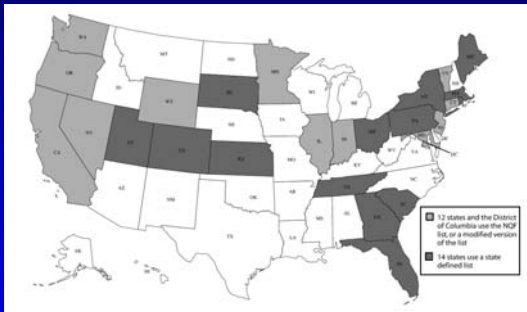
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### Source of Reportable Events List Used in Adverse Event Reporting Systems<sup>16</sup>



<sup>16</sup> Jill Rosenthal et al., *2007 Guide to State Adverse Event Reporting Systems*, National Academy for State Health Policy, State Health Policy Survey Report - December 2007.

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## History

- Patient safety advisory groups created<sup>17</sup>
  - Health Care Risk Manager Advisory Council (FL)
  - Illinois Adverse Health Care Events Reporting Advisory Council
  - Betsy Lehman Center for Patient Safety and Medical Error Reduction (Massachusetts)
  - Nevada Hospital Association Sentinel Events Registry Work Group
  - Patient Safety Authority Board of Directors (PA)

<sup>17</sup> *State Patient Safety Centers: A New Approach to Promote Patient Safety*, The Flood Tide Forum, National Academy for State Health Policy, 10/04. Accessed & updated through [www.nashp.org](http://www.nashp.org).

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## 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<sup>18</sup>
- JCAHO's sentinel event policy<sup>19</sup>
  - Identify sentinel events
  - Take action to prevent their recurrence
  - Complete a thorough and credible root cause analysis
  - Implement action plan

<sup>18</sup> Patient Safety - Essentials for Health Care, 2<sup>nd</sup> edition, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL: Department of Publications, 2004.  
<sup>19</sup> Sentinel Event Policies and Procedures - Revised July 2002, Joint Commission on Accreditation of Healthcare Organizations. Accessed through [www.jcaho.org/accredited+organizations/long+term+care/sentinel+events/index.htm](http://www.jcaho.org/accredited+organizations/long+term+care/sentinel+events/index.htm).

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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<sup>20</sup>
  - Effective 9/16/04
  - Working together to align Hospital Quality Measures (JC's ORYX Core Measures and CMS'7<sup>th</sup> Scope of Work Quality of Core Measures)

<sup>20</sup> 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](http://www.jcaho.org/accredited+organizations/long+term+care/sentinel+events).

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## History

- CMS quality incentives<sup>21</sup>
  - 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<sup>nd</sup> decile get 1% DRG bonus
    - In year 3, hospitals performing below 9<sup>th</sup> and 10<sup>th</sup> decile baseline levels, DRG payments reduced 1% and 2%, respectively

<sup>21</sup> 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](http://www.cms.hhs.gov).

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## 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<sup>22</sup>
    - 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

<sup>22</sup> Medicare to Pay Hospitals for Reporting Quality Data, Modernhealthcare, accessed through [www.modernhealthcare.com](http://www.modernhealthcare.com).

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## History

- CMS quality incentives
  - Announced 8/23/05, Medicare/State Children's Health Insurance Program (SCHIP) Quality Initiative
  - Pay-For-Performance (P4P)<sup>23</sup>
    - 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

<sup>23</sup> Letter Announcing Medicare/State Children's Health Insurance Program (SCHIP) Quality Initiative, Centers for Medicare & Medicare Services (CMS), Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## History

- CMS quality incentives
  - 104 P4P provider programs in US in 2005<sup>24</sup>
    - 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 & passed Medicare Value Purchasing (MVP) Act of 2005. Requires Medicare implement a P4P program covering at least a portion of payments made.<sup>25</sup>

<sup>24</sup> Pay for Performance's Small Steps of Progress, PricewaterhouseCoopers, 8/2/05. Accessed through [www.pwc.com](http://www.pwc.com)

<sup>25</sup> Baker, G., Carter, B., Provider Pay for Performance Incentive Programs: 2004 National Study Results, 8/2/05. Accessed through [www.medbauminstitute.com](http://www.medbauminstitute.com)

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## History

- CMS quality incentives
  - 2006 Physician Voluntary Reporting Program<sup>26</sup>
    - 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

<sup>26</sup> Medicare Takes Key Step Toward Voluntary Quality Reporting for Physicians, Centers for Medicare & Medicare Services (CMS). Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## History

- CMS quality incentives
  - 2007 Physician Quality Reporting Initiative (PQRI)<sup>27</sup>
    - Financial incentive to participate in voluntary reporting
      - 77 evidence-based quality measures
      - Reporting period 7/1/07 – 12/31/07
      - Bonus payment of 1.5%
      - Covers charges for Medicare physician fee schedule
      - Claims-based reporting

<sup>27</sup> Physician Quality Reporting Initiative, Centers for Medicare & Medicare Services (CMS). Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## History

- CMS quality incentives
  - 2008 PQRI<sup>28</sup>
    - Physicians report on 119 quality measures
      - 2% incentive payment
    - New tracking of 5 quality measures in adoption of healthcare information technology (EMR)
      - 2% additional for e-prescribers
    - PQRI data available for public [WITH performance rates](#)
  - 2009 PQRI<sup>29</sup>
    - A total of 153 quality measures
      - 2% incentive payment
    - E-prescribing removed, separate incentive program

<sup>28</sup> CMS Ups Quality-Reporting Program Measures, *Modern Health Care*, 12/10/07. Accessed through [www.modernhealthcare.com](http://www.modernhealthcare.com).

<sup>29</sup> Proposed 2009 Changes to Payment Policies and Rates Under Medicare Physician Fee Schedule, CMS, 6/30/08. Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## History

- CMS quality incentives
  - 2010 PQRI<sup>30</sup>
    - Physicians report on 179 quality measures
      - 2% incentive payment
    - New tracking of 10 quality measures in adoption of electronic health record (EHR)
      - 2% additional for e-prescribers

<sup>30</sup> Proposed 2010 Changes to Payment Policies and Rates Under Medicare Physician Fee Schedule, CMS, Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## Ongoing Mandates

- No Charge Policy Effective 2008
  - State associations have/are looking at policy where hospitals will discontinue billing patients and insurers for medical errors<sup>31</sup>
    - Colorado, Massachusetts, Michigan, Minnesota, and Vermont
  - CMS no longer pays for 8 specific hospital problems
  - AETNA no longer pays for 28 so-called “Never Events”<sup>32</sup>
  - Wellpoint (nation’s largest insurer by membership) no longer pays for serious medical errors<sup>33</sup>

<sup>31</sup> State’s Rights and Wrongs: Part 2, Modern Health Care, 12/10/07, Accessed through [www.modernhealthcare.com](http://www.modernhealthcare.com).

<sup>32</sup> AETNA to Quit Paying for “Never Events”, 1/15/08, Accessed through [www.modernhealthcare.com](http://www.modernhealthcare.com).

<sup>33</sup> Wellpoint to Stop Paying for “Never Events”, 4/2/08, Accessed through [www.modernhealthcare.com](http://www.modernhealthcare.com).

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## Ongoing Mandates

- Tax Relief and Health Care Act of 2006<sup>34</sup>
  - OIG must report to Congress on “never events/adverse events”
    - Payment by Medicare or beneficiaries for services
    - Process that CMS uses to identify such events and deny or recoup payments
  - Hospitals, as a condition of participation in Medicare and Medicaid, must develop and maintain a quality assessment and quality improvement (QAPI) program

<sup>34</sup> Adverse Events in Hospitals: Methods for Identifying Events, Department of Health and Human Services – Office of the Inspector General, March 2010, Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## Ongoing Mandates

- Hospital requirements<sup>35</sup>
  - Hospitals must measure, analyze, and track quality indicators, including adverse patient events.
  - Hospitals must implement preventive actions and mechanisms w/ feedback & feedback/learning throughout hospital

<sup>35</sup> *Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services – Office of the Inspector General, March 2010. Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## Ongoing Mandates

- How do hospitals comply?<sup>36</sup>
  - State survey agencies perform surveys and review functions for Medicare
  - Hospitals may report adverse events to Patient Safety Organizations (PSO)
  - PSOs are public, private for-profit, and not-for profit organizations
  - AHRQ certifies that PSOs have process to collect and analyze reported events
  - PSOs report data to Health & Human Services

<sup>36</sup> *Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services – Office of the Inspector General, March 2010. Accessed through [www.cms.hhs.gov](http://www.cms.hhs.gov).

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## Future Incentive

- Secretary of HHS Quality Incentive
  - Value-Based Purchasing Program in 2012<sup>37</sup>
  - Applies to certain cancer treatment facilities
  - Must meet minimum number of measures for performance standards
    - Proposed 2-5% of hospital's base operating payment for each discharge payment (DRG) contingent on performance of specific of measures
      - 1st year, 100% incentive based on reporting
      - 2nd year, 50% reporting & 50% performance
      - 3rd year, 100% reporting

<sup>37</sup> *Weems to Continue Push for Quality Compliance in 2008*, *Modern Health Care*, 12/19/08. Accessed through [www.modernhealthcare.com](http://www.modernhealthcare.com).

<sup>38</sup> *Hospital Value-Based Purchasing Program*, *Bricker & Eckler Attorneys at Law*. Accessed through [www.bricker.com](http://www.bricker.com).

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## US Grades

- 7<sup>th</sup> Annual “HealthGrades Patient Safety in American Hospitals” assessment report for Medicare patients<sup>38</sup>
  - Evaluated 39.5 million hospitalization records from 5,000 nonfederal hospitals between 2006 and 2008
  - Rate of medical harm estimated to be > than 40,000/day
  - 958,202 total patient safety events occurred
    - \$8.9 billion of excess cost
  - Good: 6 of 15 patient safety indicators improved
  - Bad: 8 of 15 indicators worsened
  - Medicare patients experiencing 1 or > patient safety events had 1 in 10 chance of dying (99,180 patients)

<sup>38</sup> HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals: March 2010, accessed thru [www.healthgrades.com](http://www.healthgrades.com)

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## US Grades

- Large safety gaps<sup>39</sup>
  - Patients treated at top-performing hospitals
    - On average, 43% lower chance of medical errors vs poorest-performing hospitals
- 400,000 preventable drug-related injuries occur each year in hospitals costing \$3.5 billion<sup>40</sup>
- Medical errors cost \$500 billion a year in avoidable medical expenses – approximately 30% of all health care costs<sup>41</sup>

<sup>39</sup> HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals: March 2010, accessed thru [www.healthgrades.com](http://www.healthgrades.com)

<sup>40</sup> Medication Errors Injure 1.5 Million People and Costs Billions of Dollars Annually: Report Offers Comprehensive Strategies for Reducing Drug-Related Errors. Office of News and Public Information, National Academy of Sciences, 7/20/06/March 2010, accessed thru [www.nationalacademies.org](http://www.nationalacademies.org).

<sup>41</sup> Fixing Hospitals, Forbes, (6/20/05).

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## US Grades

- Has patient safety improved?<sup>42</sup>
  - For 2009, patient safety received a B - minus
  - In 2004, received a C - plus
- According to Dr. Wachter - editor of AHRQ Web M & M
  - “In that error-reporting system, it looks like a hospital with fewer error reports is much safer, but it may not be”
  - “Hospital self-reporting in an unreliable indicator of quality”

<sup>42</sup> Patient Safety Improving Slightly, 10 Years After IOM Report on Errors, [amednews.com](http://amednews.com), December 28, 2009, accessed thru [www.ama-assn.org](http://www.ama-assn.org).

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## Canada Grades

- 185,000 adverse events occur annually in Canadian hospitals<sup>43</sup>
  - 70,000 preventable
    - 9,000 to 24,000 people die each year<sup>44</sup>
- Approximates a 7.5% error rate
- Similar rates found in other countries

<sup>43</sup> Lee RC. *Life, Death, and Taxes: Risk Management in Health Care*. Canadian Operations Society Annual Meeting (2005).

<sup>44</sup> Baker GR, et al. *The Canadian Adverse Events Study: The Incidence of Adverse Events Amongst Hospital Patients in Canada*. Canadian Medical Association Journal (2004).

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## Physicians on Error-Reporting

- Most physicians believe error-reporting systems are inadequate<sup>45</sup>
  - 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

<sup>45</sup> Docs See Error-Reporting as Inadequate. Modern Health Care. 1/10/08. Accessed through [www.modernhealthcare.com](http://www.modernhealthcare.com).

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## Disclosure of Errors

- Survey of 603 patients who experienced 845 adverse events showed<sup>46</sup>
  - 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

<sup>46</sup> Transparency in Adverse Event Reporting Pleases Patients. Medscape Medical News. 4/8/08. Accessed through [www.medscape.com](http://www.medscape.com).

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## Consumer Beliefs<sup>47</sup>

- 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

<sup>47</sup> Five Years After IOM on Medical Errors, Nearly Half of All Consumers Worry About the Safety of Their Health Care. Kaiser Family Foundation, 11/17/04. Accessed through [www.kff.org](http://www.kff.org).

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## Consumer Beliefs<sup>48</sup>

- 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<sup>49</sup>

<sup>48</sup> Five Years After IOM on Medical Errors, Nearly Half of All Consumers Worry About the Safety of Their Health Care. Kaiser Family Foundation, 11/17/04. Accessed through [www.kff.org](http://www.kff.org).

<sup>49</sup> Dally J. The QAIP Quest. Advance News Magazines. Accessed thru [www.health-care.it.advancewebs.com](http://www.health-care.it.advancewebs.com).

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## Radiation Oncology Errors

- Not well established
- No comprehensive numbers available for number of errors resulting in death<sup>50</sup>
- Reported error rates range 0.1% to 0.2% of fields treated<sup>51</sup>
- Studies not relying on self-reporting show actual rates of up to 3%<sup>52</sup>

<sup>50, 51, 52</sup> French, J. Treatment Errors in Radiation Therapy. *Radiation Therapist*, Fall 2002, Vol.11, No. 2; 2002.

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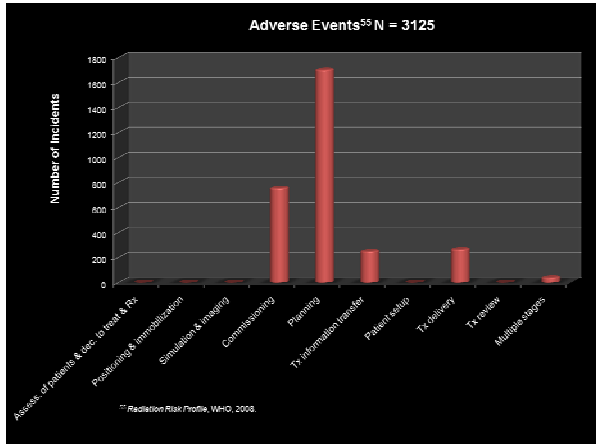
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## Near Misses in Radiation Oncology

- Near Misses<sup>56</sup>
  - 1992 to 2007: Australia, UK, Other European Countries, and US
  - How many?
    - 4,616 reported incidents that lead to near misses
    - No recognized patient harm
  - How collected?
    - Published literature
    - Unpublished incident reporting databases (ROSIS)

56 Radiation Risk Profile, WHO, 2008.

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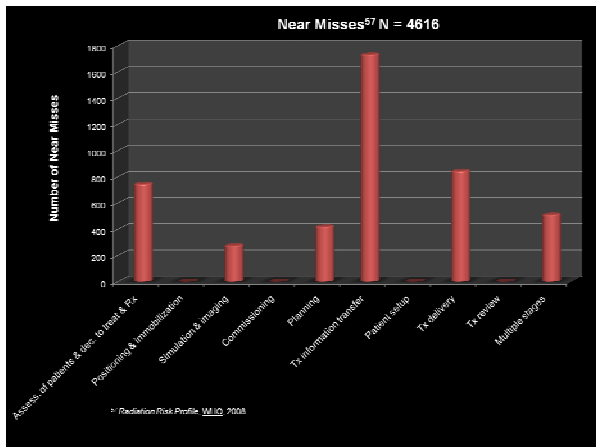
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Error Rates in Radiation Oncology								
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
UK	Sutherland WH, Topical Reviews in Radiother and Oncol, 1980	Over 6 years between 1970-1980					- Potential mistakes (found in checks): 4,122 - Potential errors of >5% from Rx dose: 742	2.1% - 4% per year
US	Swann-D'Emilia B, Med Dosim, 1990	1988-1989					87 misadministrations	<0.1% based on no. of fields Tx'ed
US	Muller-Runkel R, et al., 1991	1987-1990					- Before R&V: 39 major, 25 minor errors - After R&V: 4 major, 5 minor errors	90% overall reduction
Belgium	Leunens G, et al., Radiother Oncol, 1992	9 months					Data transfer errors: 130 of 24,128	Affected 26% of overall treatments Sig. potential 5%
Italy	Calandrino R, et al., Radiother Oncol, 1993	9/91-6/92					Out of 890 calculations: - 33 total errors - 17 serious errors	3.7% total error rate
Italy	Valli MC, et al., Radiother Oncol, 1994							10.5% incorrect or missing data

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Error Rates in Radiation Oncology								
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
France	Noel A, et al., Radiother Oncol, 1994	5 years					Of 7519 treatments: 79 total errors - Of 79, 78 are human origin - Of 78, 39 would have > 10% dose Δ	1.05% errors per treatment
Canada	Yeung TK, Abstract-NEORCC, 1996	1994						3.3%
US	Kartha PK, Int J Radiat Oncol Biol Phys, 1997	1997					Error rates per patient setup	1.4% linear accelerators 3% cobalt units
US	Macklis RM, et al., J Clin Oncol, 1998	1 year	1,925		93,332	168	15% causally related to R&V	0.18% error rate/field
US	Fraas BA, et al., Int J Radiat Oncol Biol Phys, 1998	7/96-9/97		~34,000	~114,000			0.44% Tx fractions 0.13% Tx fields
Belgium	Barthelemy-Brichant N, et al., Radiother Oncol, 1999	6 months					147,476 parameters examined - 678 (0.46%) set incorrectly	0.22% of all delivered Tx fields had at least 1 error

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Error Rates in Radiation Oncology								
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Canada	Pegler R, et al., Abstract-Clin Invest Med, 1999	2 years						0.12 - 0.06%
US	Pao WJ, et al., Abstract-ACSO, 2001	6 years	17,479 avg/yr.					0.17% avg./year per patient
Canada	French J, Radiat Ther, 2002	1/1/96-9/31/01	11,355	195,100	483,741	631	177 total incidents - 20: correctable - 129: noncorrectable and clinic. sig. - 28: noncorrectable and potentially clinically sig.	0.13%: all units (fields tx'ed incorrect/total no. fields tx'ed) 0.32%: errors/fraction 0.037%: errors/field
US	Patton G, et al., Radiat Oncol Biol Phys, 2002	1 year	22,542					0.17%: errors/Tx
Ireland & Sweden	Holmberg O, et al., J of Radioth Ther, 2002	3 years	15,386 Tx plans				10.8 near misses/each reported Tx error in Tx preparation chain	3.4%: error rate per Tx plan

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### Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Canada	Yeung, et al., Radiother Oncol, 2004	11/02-12/02	13,385				624 incidents - 42.1%: documentation errors (data transfer/communication) - 40.4%: patient set-up errors - 13.0%: Tx planning errors	Use of portal imaging reduced patient set-up errors by 85%. 40% of dose errors discovered before 1 <sup>st</sup> Tx
Canada	Huang G, et al., Int J Radiat Oncol Biol Phys, 2005	1/1/07-12/31/02	28,136				555 total errors	1.97%: error rate per patient 0.23%: error rate per fraction (7100 - 12902)
US	Klein E, et al., J of Appl Clin Med Phys, 2005	30 months	3,984					0.48 to <0.11%: for dB methods of detection w/RR&V
Canada	Marks L, et al., Int J Radiat Oncol Biol Phys, 2007							0.5%: error rate per fraction 1.2 - 4.7%: error rate per patient

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### Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Italy	Baietto B, et al., J of Experim & Clinical Oncol Tumori, 2009	10/00 - 12/06	7,768	34,114	148,145		452 errors Error types: - 2.2%: general - 3.3%: dosimetric - 4.2%: delivered dose	0.69%: error rate of audited patients
US	Margalit D, et al., J Clinical Oncol, 2010	1/04 - 1/09			241,546		155 total errors - Types: IMRT 0.033% vs 2D/3D RT 0.072%	0.064%: error rate per Tx field

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### Who Reports the Errors Within a RO Center?<sup>58</sup>

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

<sup>58</sup> ROSIS database, 2/25/10. Accessed through [www.rosis.info](http://www.rosis.info).

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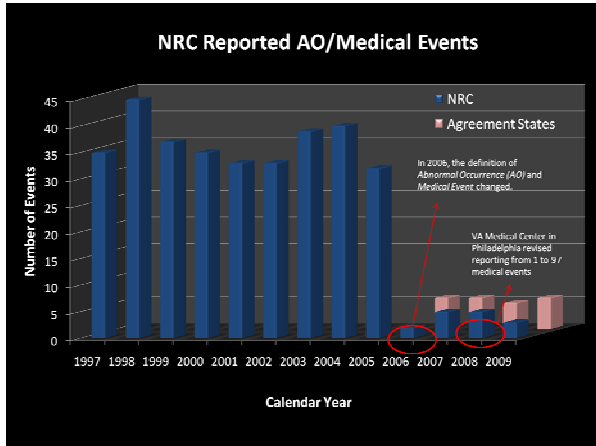
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### PA Patient Safety Authority

#### Radiation Oncology Event Types Reported to the Pennsylvania Patient Safety Authority, 6/2004 - 1/2009<sup>59</sup>

Type of Error	Number of Reports	% of Total
Wrong dose	10	40%
Wrong patient	4	16%
Wrong location	3	12%
Wrong side	3	12%
Wrong setup	2	8%
Wrong treatment	1	4%
Wrong treatment device	1	4%
Equipment other	1	4%
<b>Total</b>	<b>25</b>	<b>100%</b>

<sup>59</sup> Reprinted article - 2009 Pennsylvania Patient Safety Authority, Vol. 6, No. 3, September 2009.

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### PA Dept. of Environmental Health

#### Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, 2/2004 - 1/2009<sup>60</sup>

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

<sup>60</sup> PA Patient Safety Advisory, PA Department of Environmental Protection, Bureau of Radiation Protection, *Errors in Radiation Therapy*, 2/09.

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## 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.

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## 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

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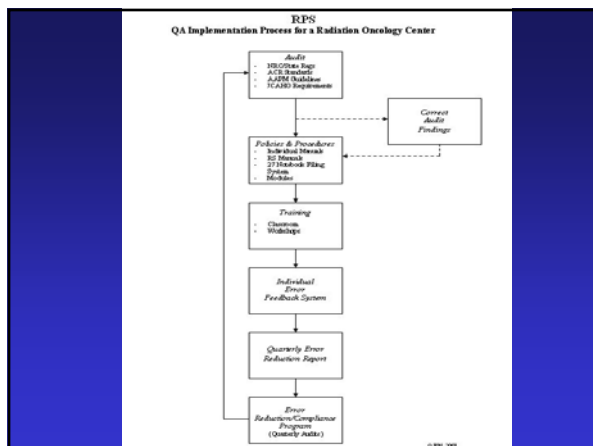
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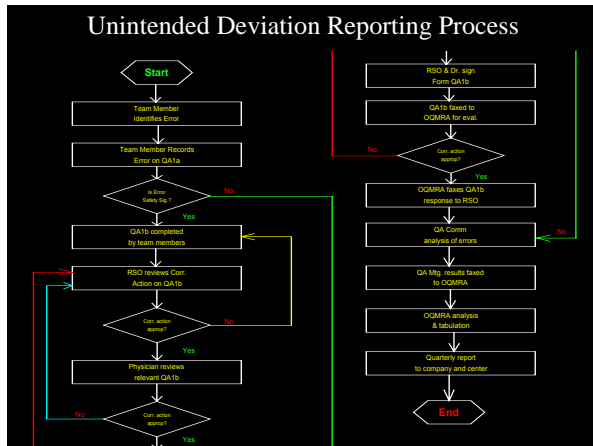
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## The Unintended Deviation System

- 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.

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## 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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## 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%**.

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## 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).<sup>63</sup>
- 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%**.

<sup>63</sup> 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.

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## 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.

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## 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**

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## 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%.

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## Summary of Results

### Paper-Based Model

- Overall average error rate was **0.052%** (SL 1 – 5)
- Calculated misadministration rate<sup>64</sup> 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

<sup>64</sup> Misadministration criteria based on definitions found in NRC 10CFR35.2, rev. 1996; and CRCPD recommended Agreement State regulations dated 2007.

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## 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.

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## 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 **76.4%** (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).

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## 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

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# Software-Based Model

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

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- ## 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)
    - Calculation of *Risk Priority Number*
    - Designation of clinical significance
    - Designation of significant unintended deviation
  - **Identification and Tacking of Errors (conti.)**
    - "Near Miss" categorization
    - Sentinel events (internal and JCAHO reportable)
    - Instant analysis of patterns and trends
    - Recordable events
    - Misadministrations (medical events)
    - Regulatory violations
    - Possible regulatory violations

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## Design of Software-Based Model

### MERP Program

- **Step-By-Step Root Cause Analysis**
  - Determination of credible root cause analysis
  - Identification of causal factors
  - Identification of opportunities for improvement
- **Action Plan Road Map**
  - Risk-reduction strategy
  - Short-term corrective action
  - Long-term corrective action
  - Assignment of responsible individuals
- **Patient Dose Error Calculation Wizard**
  - Calculates % error in daily, weekly & total doses
- **Patient Dose Error Calculation Wizard (cont.)**
  - Automatically triggers levels for report generation
    - JCAHO root cause analysis and action plans
    - State regulatory notifications
- **Procedure Generation**
  - Drafting of procedure as part of corrective action plan
  - Serves as tutorial in training new employees/annual refresher
- **Review and Approval**
  - Queue action plan(s) for review and approval
  - Accept or reject routine corrective action(s)

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## Design of Software-Based Model

### MERP Program

- **Reports and Chart Generation**
  - Generate reports showing characterization of errors and corrective actions
  - Show charts stratifying error types and severity levels
  - Select time intervals for charting of data
- **Audit Compliance Tool**
  - MERP used to inspect regulatory performance
    - Complies with State radiation safety requirement for annual reviews
    - Meets State QMP rule for annual reviews
    - Follows CMS compliance objectives
    - Complies with JCAHO standards

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## Design of Software-Based Model

### MERP Program

- **Customization Features**
  - Customize and create data collection areas for performance improvement priorities
    - Categories
    - Subcategories
    - Attributes
  - Designate who reviews/approvals routine errors and corrective actions
  - Assign which errors violate State requirements
  - Designate severity levels, clinically significant, and significant unintended deviations
- **Standards/Requirements Referenced by Code**
  - JCAHO 2010 patient safety standards show basis for question
  - ACR and ACRO standards demonstrate benchmark for measuring performance
  - CRCPD (Agreement State) recommended regulations (as of 9/08) show legal text

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## MERP Implementation Strategy

### Preparation

- **Step #1 - Benchmark Procedures**
  - Created manual
  - Included step-by-set processes
  - Covered technical delivery system
    - QA
    - Radiation safety
    - QMP
- **Step #2 - Training**
  - Provided classroom hours
    - 18 hours in procedures
    - 6 hours in MERP
  - Presented at new center start-up or over 1 hour lunch break (existing)
  - Took 3 days (new center) vs 2 months (existing center)
  - Issued category 'A' credit thru ASRT
  - Met annual state radiation safety training requirements

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## MERP Implementation Strategy

### Phased Rollout

- **Step #3 - Superusers**
  - Designated key point guards
    - Controlled data input
    - Tracked status of UDs
    - Tracked completion of corrective action plans
- **Step #4 - Phases**
  - Group 1
    - Therapists
    - CT/X-ray technologists
    - Physics (physicists & dosimetrists)
    - Billing
  - Group 2
    - Radiation oncologists
  - Group 3
    - Admissions/registration staff

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**NMCC**  
RO MERP

Unintended Deviation (UD) Reporting Form

Date(s) of Occurrence: \_\_\_\_\_ Date Identified: \_\_\_\_\_

Identified by: \_\_\_\_\_ Patient ID #: \_\_\_\_\_

Patient Name: \_\_\_\_\_ UD #: \_\_\_\_\_

Patient Related			Non-Patient Related	
Clinical <input type="checkbox"/>	QA <input type="checkbox"/>	RS <input type="checkbox"/>	QA <input type="checkbox"/>	RS <input type="checkbox"/>
Pre-Tx <input type="checkbox"/>	Post-Tx <input type="checkbox"/>	Affected Tx <input type="checkbox"/>		

Description of UD:

\_\_\_\_\_

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Initials: \_\_\_\_\_ Date: \_\_\_\_\_

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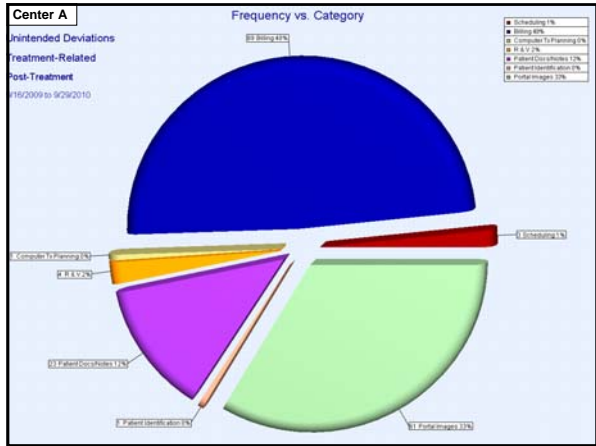
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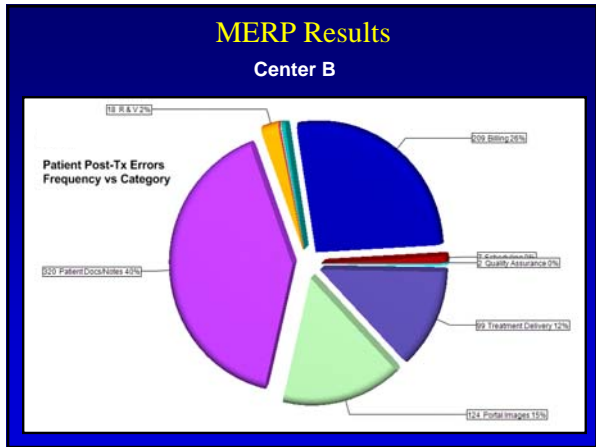
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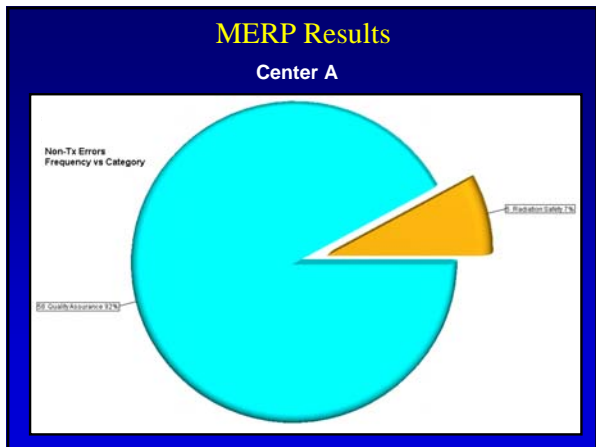
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## MERP Results

### QA & Radiation Safety Failures<sup>72,73</sup>

Error Category	Center A		Center B	
Per Patient, %	18.8		0.78	
Per Fraction, %	0.55		0.026	
Per Field, %	0.072		0.0003	

<sup>72</sup> Failures are non-patient related and include regulatory infractions.

<sup>73</sup> Data for Centers A and B was annualized for all data collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

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## MERP Results

### Misadministration Rates<sup>74</sup>

Error Category	Kline et. al.	This Work		US NRC <sup>2</sup>	US NRC + Agreement States <sup>75</sup>
		MERP Center A	MERP Center B		
Per Patient, %		0	0.065		
Per Fraction, %	0.017	0	0.002	0.004	0.002
Per Field, %		0	0.00002		

<sup>74</sup> Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively. US NRC data was also annualized.

<sup>75</sup> Institute of Medicine (IOM), *Radiation in Medicine: A Need for Regulatory Reform*, 1996.

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## MERP Results

### Clinically Significant Errors<sup>76,77</sup>

Error Category	Post-Tx	
	Center A 0 errors	Center B 7 errors
Per Patient, %	0	0.45
Per Fraction, %	0	0.02
Per Field, %	0	0.00002

<sup>76</sup> Clinically Significant dose trigger levels: single fx (non-SRS) - 10%, weekly difference - 15%.

<sup>77</sup> Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

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## 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 UD prevents corrupt/inaccurate data entry
  - Brief weekly group meetings serve as bulletin board for errors
  - Individuals must be assigned responsibility for drafting procedures required by corrective action plans
  - Track closure of corrective action plans
  - Present overall results at quarterly QIC meetings

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## Conclusion

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

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