

Error Reduction Software Program in Radiation Oncology

by
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Acknowledgements

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



Located in Philadelphia, PA



Located in Albuquerque, NM

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

Introduction

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

Introduction

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

¹Hart JH, M. Swift E, Corrigan JM, eds. *Envisioning the National Health Care Quality Report*. Washington, DC: National Academies of Sciences; 2001.

²McNutt R, Abrams R, Aarons D. *Patient Safety Efforts Should Focus on Medical Errors*. *JAMA*. 2002;287(15):1997-2001.

³Department 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.

⁴The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. *Quality First: Better Health Care for All Americans*; 1998.

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

Introduction

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

History

- Institute of Medicine (IOM) report⁶
 - 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.

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

History

- IOM Costs⁷
 - 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 nationwide⁸

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

⁸ *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.

History

- Federal initiatives⁹ taken by former President Clinton on 2/22/00 based on IOM recommendations¹⁰
 - 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

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

¹⁰ 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).

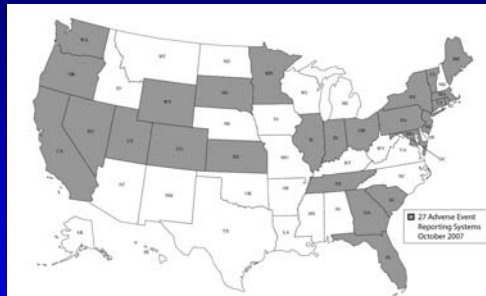
History

- Key legislation
 - Patient Safety Quality Improvement Act¹³
 - Certifies patient safety organizations in each State to collect data and report on medical errors
 - State Patient Safety Centers¹⁴
 - 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

¹³ *Reducing Medical Errors*, Issue Module, Kaiser EDU.org. Accessed through [www.kaiseredu.org](#)

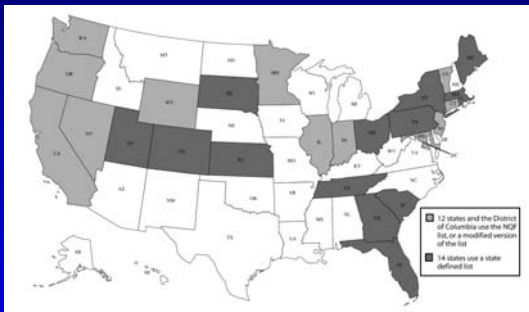
¹⁴ *Authorizing Statutes and Regulations*, National Academy for State Health Policy, Accessed September 28, 2010 through [www.nashp.org](#).

Authorized Adverse Event Reporting Systems, October 2007¹⁵



¹⁵ 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.

Source of Reportable Events List Used in Adverse Event Reporting Systems¹⁶



¹⁶ 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.

History

- Patient safety advisory groups created¹⁷
 - 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)

¹⁷ *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](#).

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 safety¹⁸
- JCAHO's sentinel event policy¹⁹
 - Identify sentinel events
 - Take action to prevent their recurrence
 - Complete a thorough and credible root cause analysis
 - Implement action plan

¹⁸ *Patient Safety - Essentials for Health Care*, 2nd edition, [Joint Commission on Accreditation of Healthcare Organizations](#), Oakbrook Terrace, IL: Department of Publications, 2004.
¹⁹ *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.

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 agreement²⁰
 - 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)

²⁰ *Joint Commission, CMS to Make Common Performance Measures*, [Joint Commission on Accreditation of Healthcare Organizations](#), Accessed through www.jcaho.org/accredited+organizations/long+term+care/sentinel+events.

History

- CMS quality incentives²¹
 - 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
 - 2nd decile get 1% DRG bonus
 - In year 3, hospitals performing below 9th and 10th decile baseline levels, DRG payments reduced 1% and 2%, respectively

²¹ *Medicare Looks for Ways to Boost Quality Care Comments Sought on New Plan for Quality Improvement Organizations*, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.

History

- CMS quality incentives
 - CMS consumer website
 - CMS contracted with NQF & worked with JCAHO to develop hospital quality measures for public reporting
 - In 4/05, hospital quality data became available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
 - Data indicators²²
 - 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

²² *Medicare to Pay Hospitals for Reporting Quality Data*, [Modernhealthcare](#), accessed through www.modernhealthcare.com.

History

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

²³ *Letter Announcing Medicare/State Children's Health Insurance Program (SCHIP) Quality Initiative*, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.

History

- CMS quality incentives
 - 104 P4P provider programs in US in 2005²⁴
 - 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.²⁵

²⁴ *Pay for Performance's Small Steps of Progress*, [PricewaterhouseCoopers](#), 8/2/05. Accessed through www.pwchealth.com.

²⁵ Baker, G., Carter, B., *Provider Pay for Performance Incentive Programs: 2004 National Study Results*, 8/2/05. Accessed through www.mechamj.com.

History

- CMS quality incentives
 - 2006 Physician Voluntary Reporting Program²⁶
 - 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

²⁶ Medicare Takes Key Step Toward Voluntary Quality Reporting for Physicians, Centers for Medicare & Medicare Services (CMS). Accessed through www.cms.hhs.gov.

History

- CMS quality incentives
 - 2007 Physician Quality Reporting Initiative (PQRI)²⁷
 - 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

²⁷ Physician Quality Reporting Initiative, Centers for Medicare & Medicare Services (CMS). Accessed through www.cms.hhs.gov.

History

- CMS quality incentives
 - 2008 PQRI²⁸
 - 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 PQRI²⁹
 - A total of 153 quality measures
 - 2% incentive payment
 - E-prescribing removed, separate incentive program

²⁸ CMS Ups Quality-Reporting Program Measures, *Modern Health Care*, 12/10/07. Accessed through www.modernhealthcare.com

²⁹ Proposed 2009 Changes to Payment Policies and Rates Under Medicare Physician Fee Schedule, CMS, 6/30/08. Accessed through www.cms.hhs.gov.

History

- CMS quality incentives
 - 2010 PQRI³⁰
 - 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

³⁰ Proposed 2010 Changes to Payment Policies and Rates Under Medicare Physician Fee Schedule, CMS. Accessed through www.cms.hhs.gov.

Ongoing Mandates

- No Charge Policy Effective 2008
 - State associations have/are looking at policy where hospitals will discontinue billing patients and insurers for medical errors³¹
 - 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”³²
 - Wellpoint (nation's largest insurer by membership) no longer pays for serious medical errors³³

³¹ State's Rights and Wrongs: Part 2, *Modern Health Care*, 12/10/07. Accessed through www.modernhealthcare.com

³² AETNA to Quit Paying for “Never Events”, 1/15/08. Accessed through www.modernhealthcare.com

³³ Wellpoint to Stop Paying for “Never Events”, 4/2/08. Accessed through www.modernhealthcare.com

Ongoing Mandates

- Tax Relief and Health Care Act of 2006³⁴
 - 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

³⁴ 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.

Ongoing Mandates

- Hospital requirements³⁵
 - 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

³⁵ *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.

Ongoing Mandates

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

³⁶ *Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services – Office of the Inspector General, March 2010. Accessed through www.cms.hhs.gov.

Future Incentive

- Secretary of HHS Quality Incentive
 - Value-Based Purchasing Program in 2012³⁷
 - 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

³⁷ *Weems to Continue Push for Quality Compliance in 2008*, *Modern Health Care*, 12/19/08. Accessed through www.modernhealthcare.com.

³⁷ *Hospital Value-Based Purchasing Program*, *Bricker & Eckler Attorneys at Law*. Accessed through www.bricker.com.

US Grades

- 7th Annual “HealthGrades Patient Safety in American Hospitals” assessment report for Medicare patients³⁸
 - 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)

³⁸ *HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals*: March 2010, accessed through www.healthgrades.com.

US Grades

- Large safety gaps³⁹
 - 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 billion⁴⁰
- Medical errors cost \$500 billion a year in avoidable medical expenses – approximately 30% of all health care costs⁴¹

³⁹ *HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals*: March 2010, accessed through www.healthgrades.com.

⁴⁰ *Medication Errors Injure 1.5 Million People and Cost 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 through www.nationalacademies.org.

⁴¹ *Fixing Hospitals*, *Forbes*, (6/20/05).

US Grades

- Has patient safety improved?⁴²
 - 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”

⁴² *Patient Safety Improving Slightly, 10 Years After IOM Report on Errors*, *amednews.com*, December 28, 2009, accessed through www.ama-assn.org.

Canada Grades

- 185,000 adverse events occur annually in Canadian hospitals⁴³
 - 70,000 preventable
 - 9,000 to 24,000 people die each year⁴⁴
- Approximates a 7.5% error rate
- Similar rates found in other countries

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

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

Physicians on Error-Reporting

- Most physicians believe error-reporting systems are inadequate⁴⁵
 - 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

⁴⁵ Docs See Error-Reporting as Inadequate. *Modern Health Care*. 1/10/08. Accessed through www.modernhealthcare.com

Disclosure of Errors

- Survey of 603 patients who experienced 845 adverse events showed⁴⁶
 - 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

⁴⁶ Transparency in Adverse Event Reporting Pleases Patients. *Medscape Medical News*. 4/8/08. Accessed through www.medscape.com

Consumer Beliefs⁴⁷

- 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

⁴⁷ 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

Consumer Beliefs⁴⁸

- 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 error⁴⁹

⁴⁸ 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

⁴⁹ Duffy J. *The QALP Quest*. *Advance News Magazines*. Accessed thru www.health-care.it.advanceweb.com

Radiation Oncology Errors

- Not well established
- No comprehensive numbers available for number of errors resulting in death⁵⁰
- Reported error rates range 0.1% to 0.2% of fields treated⁵¹
- Studies not relying on self-reporting show actual rates of up to 3%⁵²

^{50,51,52} French, J. *Treatment Errors in Radiation Therapy*. *Radiation Therapist*, Fall 2002, Vol. 11, No. 2; 2002.

Radiation Oncology Errors

- WHO research of errors 1976 to 2007⁵³
 - Peer-review journals
 - Conference proceedings
 - Working papers
 - Organizational reports
 - Local, national, and international databases
- 7,741 incidents & near misses
 - 3,125 incidents of harm (underdose increasing risk of recurrence to overdose causing toxicity)
 - 38 patient deaths
- Risk of mild to moderate injurious outcome
 - 1,500 per 1,000,000 treatment courses
- Review hampered by lack of data & systematic bias in reporting mistakes caused by clinical judgment

⁵³WHO – World Alliance for Patient Safety, *Radiotherapy and Oncology, International Review of Patient Safety Measures in Radiotherapy Practice*, 2009, Vol. 92:1, pp.15-21.

Radiation Oncology Errors

“... it is likely that many more incidents have occurred but either went unrecognized, were not reported to the regulatory authorities, or were not published in the literature.”⁵⁴

⁵⁴ICRP. *Radiological Protection and Safety in Medicine*. ICRP 73. *Annals of the ICRP*, 1996, Vol. 26, Num. 2.

Adverse Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
US	Ricks CR, REACTS Radiation Incident Registry, 1999	1974-1976	Overdose		426 - Overdose toxicity	Incorrect calibration of Co-60 unit at commissioning, falsified documentation
UK	McKenzie AL, British Institute of Radiology, 1996	1982-1991	Underdose (<5 to 35%)	1,045	492 - Developed local recurrences	Misunderstanding of algorithm in Tx planning computer
USA & Canada	WHO, Radiotherapy Risk Profile, 2008	1985-1987	Overdose	6	6 - Overdose toxicity; 3 - Deaths	Therac-25 software programming error in Tx delivery
Germany	IAEA, Safety Report Series No.38, 2006	1986-1987	Overdose (various)	86	86 - Overdose toxicity	Co-60 dose calculations based on erroneous dose tables, no independent checks
UK	McKenzie AL, British Institute of Radiology, 1996	1988	Overdose (+25%)	250	250 - Overdose toxicity	Teletherapy activity calculation error during commissioning
UK	IAEA, Safety Report Series No.38, 2006	1988-1989	Over and under dose (-20 to +10%)	22	22 - Overdose toxicity	Error in identification of Cs-137, brachytherapy sources, no independent check of source strength

Adverse Events in Radiation Oncology

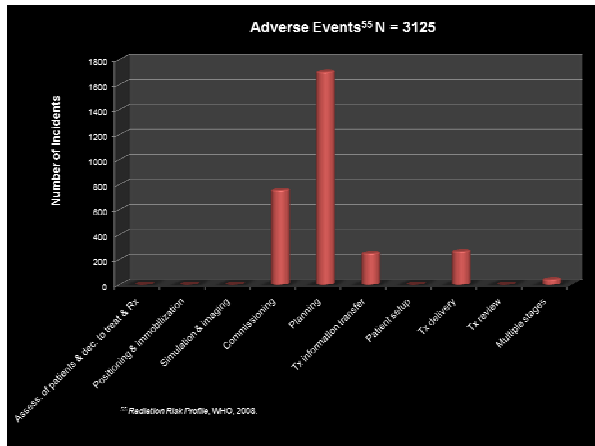
Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
US	IAEA, Safety Report Series No.38, 2006	1988-1989	Overdose (+75%)	33	33 - Overdose toxicity	Computer file for use of trimmers not updated for new Co-60 source, no manual or independent verification of calculated Tx
Spain	IAEA, Safety Report Series No.38, 2006	1990	Overdose (+200-600%)	27	16 - Overdose toxicity; 9 - Deaths	Error in maintenance of linac, procedures not followed, conflicting signals not analyzed, no beam verification procedures
Japan	WHO, Radiotherapy Risk Profile, 2008	1990-1991 1995-1999	Overdose	276	276 - Overdose toxicity	Differences of interpretations for prescribed dose between RO & RT, lack of communication
		1998-2004		146	146 - Overdose toxicity	Wedge factor input error in renewal of treatment planning system
US	WHO, Radiotherapy Risk Profile, 2008	1992	Overdose	1	1 - Overdose toxicity; 1 - Death	Brachytherapy source (High Dose Rate) dislodged and left inside the patient
Costa Rica	IAEA, Safety Report Series No.38, 2006	1996	Overdose (+60%)	114	114 - Overdose toxicity; 6 - Deaths	Error in calibration of Co-60 unit, lack of independent beam calibration, recommendation of external audit ignored

Adverse Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
Japan	WHO, Radiotherapy Risk Profile, 2008	1999-2003	Underdose	31	31 - Underdose	Output factor input error in renewal of treatment p planning system
		1999-2004		256	256 - Underdose	Insufficient dose delivery caused by an incorrect operation of dosimeter
Panama	IAEA, Safety Report Series No.38, 2006	2000-2001	Overdose	28	28 - Overdose toxicity; 11 - Deaths	Error shielding block related data entry into TPS resulted in prolonged treatment time
Poland	IAEA, Safety Report Series No.38, 2006	2001	Overdose	5	5 - Severe injuries	Failure of more than 1 layer of safety in electron accelerator (monitor chambers and interlock)
Japan	WHO, Radiotherapy Risk Profile, 2008	2003	Suspected Overdose	1	1 - Suspected death	Input error of combination of transfer total dose and fraction number
		2003-2004	Overdose	25	25 - Overdose toxicity	Misapplication of tray factor to treatment delivery without tray
France	WHO, Radiotherapy Risk Profile, 2008	2004-2005	Overdose	18	18 - Overdose toxicity; 5 - Deaths	Wrong setting of linac after introduction of new TPS
				8	2 - Overdose toxicity; 1 - Death; 5 - Unknown health outcome	Miscommunication of field size estimation, error in patient identification, incorrect implantation of source during brachytherapy

Adverse Events in Radiation Oncology

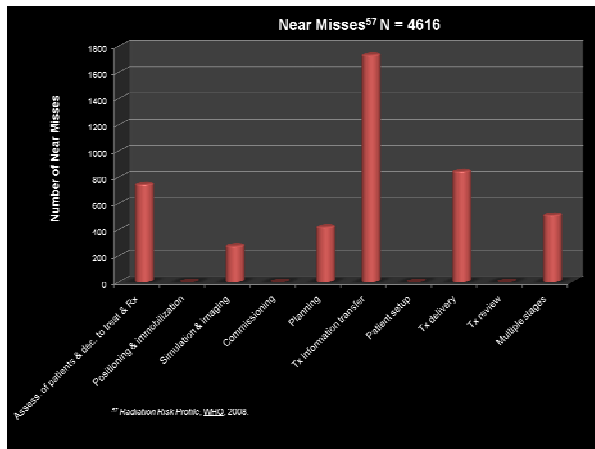
Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
Canada	Keen C, auntannie.com 2008	2004-2007	Underdose (-83%)	326		Error in calculation of output tables on orthovoltage unit, understaffed & overworked physicists, no comprehensive independent check, inadequate QA program
	WHO, Radiotherapy Risk Profile, 2008		Underdose (3-17%)		326 - Underdose	
US	Healthimaging.com, 2010	2004-2009	Overdose (+50%)	76		Error in calculation of output factor of SRS unit, wrong measurement equipment, no independent check
US	Sickler M, St. Petersburg Times, 2005	12 Months	Overdose (+50% or >)	77	19 - Unsafe Levels	Programming error using wrong formula in Tx planning computer, no independent second dose verification
UK	WHO, Radiotherapy Risk Profile, 2008	2005-2006	Overdose	5	3 - Overdose toxicity; 1 - Death	Change in operational procedures while upgrading data management systems resulting in incorrect treatment dose
Scotland	Scottish Ministers, Report of an Investigation, 2006	2006	Overdose (+58%)	1	1 - Overdose toxicity; 1 - Death	Tx planning computer software was upgraded. Old correction factor was applied to new calculation program.



Near Misses in Radiation Oncology

- Near Misses⁵⁶
 - 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.



Error Rates in Radiation Oncology

Study	Author	Time Interval	Cause 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 Dosime, 1990	1988-1989					87 misadministrations	40.1% 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: 139 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

Error Rates in Radiation Oncology

Study	Author	Time Interval	Cause 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 PKI, 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, 1999	1 year	1,925	93,332	168		15% causally related to R&V	0.18% error rate/field
US	Fraiss BA, et al., Int J Radiat Oncol Biol Phys, 1998	7/98-9/97		~34,000	~114,000			0.44% Tx fractions 0.19% Tx fields
Belgium	Barthelemy-Brichant N, et al., Radiother Oncol, 1999	6 months					147,476 parameters examined: - 678 (0.46%) set incorrectly	3.22% of all delivered Tx fields had at least 1 error

Error Rates in Radiation Oncology

Study	Author	Time Interval	Cause 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 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		15,388 Tx plans				13.8 near misses/each reported Tx error in Tx preparation chain	3.4% error rate per Tx plan

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 st Tx
Canada	Huang C, 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 0.29%: error rate per fraction (7/00 - 1/29/02)
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 in R&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

Error Rates in Radiation Oncology

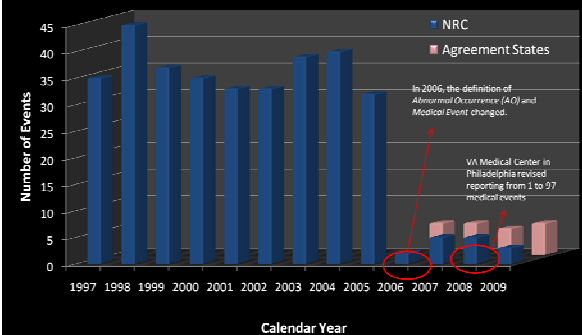
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Italy	Baiotto B, et al., J of Expert & Clinical Oncol Tumori, 2009	10/00 - 12/06	7,768	34,114	148,145		452 errors Error types: - 2.2%: general - 3.3%: dosimetric - 4.2%: delivered dose	0.69%: 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

Who Reports the Errors Within a RO Center?⁵⁸

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%

⁵⁸ ROSIS database, 2/25/10. Accessed through www.rosis.info.

NRC Reported AO/Medical Events



PA Patient Safety Authority

Radiation Oncology Event Types Reported to the Pennsylvania Patient Safety Authority, 6/2004 - 1/2009⁵⁹

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%
Total	25	100%

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

PA Dept. of Environmental Health

Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, 2/2004 - 1/2009⁶⁰

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%
Total	37	100%

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

State of NY: Published Tx Errors

Radiation Mistakes in the State of New York as Analyzed by The New York Times, 1/2001 - 1/2009⁶¹

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

⁶¹ The New York Times, Radiation Mistakes: One State's Tally. www.nytimes.com/1/24/10.

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

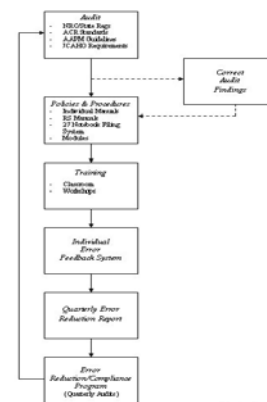
Design of a Paper-Based Model

- 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.

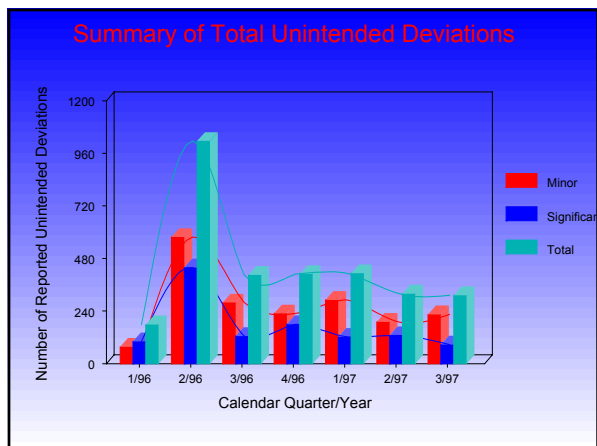
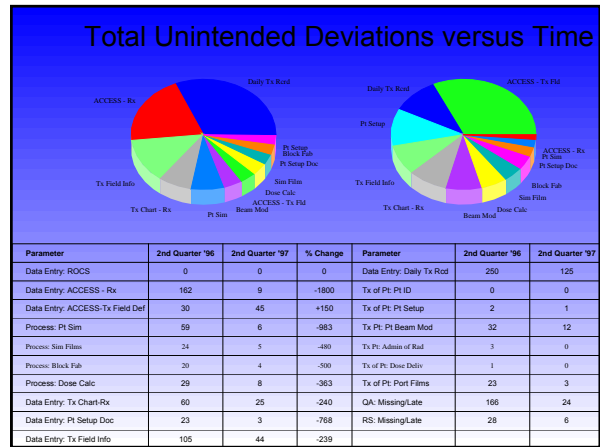
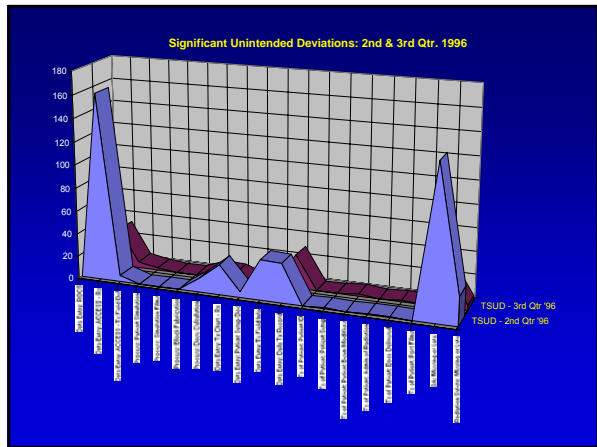
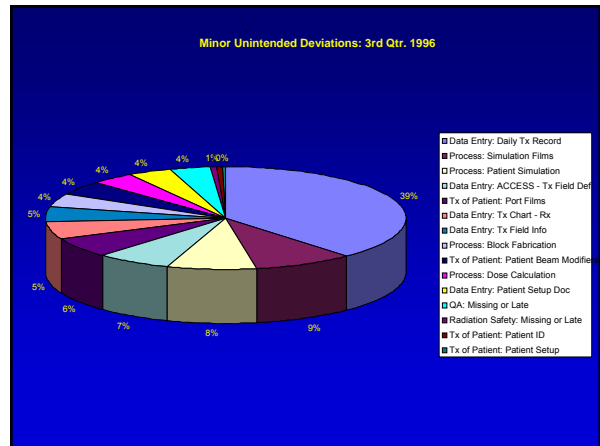
Design of a Paper-Based Model

- 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



Unintended Deviations	1MD-2ndQr '96	1SD-2ndQr '96	1cd-2ndQr '96	1MD-3rdQr '96	1SD-3rdQr '96	1cd-3rdQr '96
Data Entry: ROCS	0	0	0	0	0	0
Data Entry: ACCESS - Rx	0	162	162	0	38	32
Data Entry: ACCESS - Tx Field Def	25	5	30	19	5	23
Process: Patient Simulation	59	0	59	22	2	23
Process: Simulation Films	24	0	24	25	0	21
Process: Book Fabrication	20	0	20	12	0	9
Process: Dose Calculation	17	12	29	11	7	18
Data Entry: Tx Chart - Rx	34	25	60	15	6	21
Data Entry: Patient Setup Doc	18	5	23	11	0	9
Data Entry: Tx Field Info	70	35	105	13	4	17
Data Entry: Daily Tx Record	216	34	250	107	29	125
Tx of Patient: Patient ID	0	0	0	1	0	1
Tx of Patient: Patient Setup	1	1	2	1	0	1
Tx of Patient: Patient Beam Modifies	32	0	32	12	2	10
Tx of Patient: Admin of Radiation	2	1	3	0	0	0
Tx of Patient: Dose Delivery	0	1	1	0	1	1
Tx of Patient: Port Films	23	0	23	18	0	18
QA Missing/Late	34	132	166	10	33	36
Radiation Safety: Missing/Late	3	25	28	2	4	5
TOTAL	518	439	1017	279	126	370
ABSOLUTE DIFFERENCE				-239	-313	-647
PERCENT INCREASE/DECREASE				-81.7%	-71.3%	-63.6%



Reported Misadministration Rate In Radiation Oncology

Published rates⁶² for *reported* misadministrations in therapeutic radiation oncology is 0.0042 percent (4.2/100,000 fractions) based upon 20 fractions/patient for NRC regulated states only. Based upon internal NRC documents, it is speculated that the rate may be as high as 0.04 percent.

⁶²NRC memorandum dated March 8, 1993: Data based on information obtained from the American College of Radiology (Manpower Committee, Patterns of Care Study, and Commission of Human Resources). Additional reference from Institute of Medicine (Radiation in Medicine - A Need For Regulatory Reform), 1996.

Calculated Error Rates

Paper-Based Model

- Based upon the total number of treatment fields delivered as recorded by R&V at 17 radiation oncology centers and the total number of unintended deviations self-reported by the system, excluding the initial two quarters for the “learning curve effect”, the overall average error rate for both minor and significant unintended deviations within the system was approximately **0.052%** (5.2 in 10,000 patient fractions).
- The minor unintended deviation reporting rate for the same period was approximately **0.034%**.

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).⁶³
- 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%**.

⁶³ Reporting rate is based on the number of significant interactions occurring in the treatment delivery process that could lead to a misadministration (criteria based on 10 CFR Part 35) vs the total number of treatment fields administered for 17 centers.

Measured vs Published Misadministration Rate

Radiation Oncology

- When compared to what the NRC speculates is the actual misadministration rate of 0.04 (4 in 10,000), this rate is a factor of **2.35** lower.
- Though this program helped in minimizing the occurrence of misadministrations, the overall focus was to reduce the number and nature of all errors in the therapy process.

Cost Benefit Analysis

Paper-Based Model

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

Cost Benefit Analysis

Paper-Based Model

- Experience with the one reported misadministration that occurred at a center in Florida between 3/96 and 12/97 (with no measurable effect) resulted in a total direct cost (man-hours, travel, etc.) of approximately \$25,000.
- Physician malpractice insurance premiums for the 17 oncology centers were reduced by 10%.

Summary of Results

Paper-Based Model

- Overall average error rate was **0.052%** (SL 1 – 5)
- Calculated misadministration rate⁶⁴ 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

⁶⁴ 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

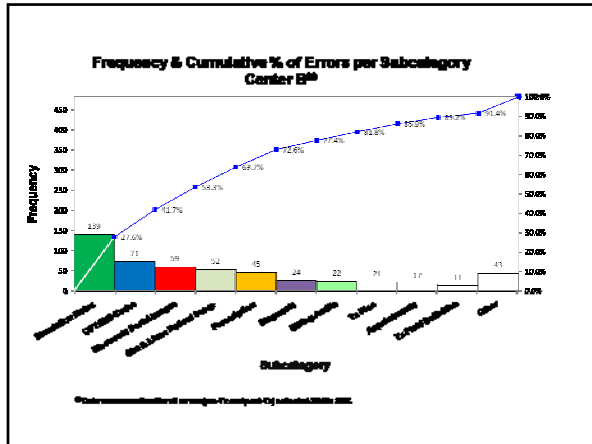
Design of Software-Based Model

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

Design of Software-Based Model

MERP Program

- **Monitored Areas**
 - Clinical
 - QA
 - Radiation Safety
- **Identification and 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 (cont.)**
 - "Near Miss" categorization
 - Sentinel events (internal and ICAHO reportable)
 - Instant analysis of patterns and trends
 - Recordable events
 - Misadministrations (medical events)
 - Regulatory violations
 - Possible regulatory violations



MERP Results

Error Rates in Entire Treatment Process Using MERP⁷⁰

Error Category	Pre-Tx		Post-Tx		Pre-Tx + Post Tx	
	Center A	Center B	Center A	Center B	Center A	Center B
	115 errors	145 errors	225 errors	362 errors	340 errors	477 errors
Per Patient, %	37.20	10.10	72.80	25.40	81.80	27.33
Per Fraction, %	1.10	0.34	2.10	0.85	2.40	0.92
Per Field, %	0.14	0.004	0.28	0.01	0.31	0.01

⁷⁰ Data for Centers A and B was annualized for all pre-Tx and post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Error Rates in Treatment Delivery⁷¹

Error Category	This Work MERP Center A	This Work MERP Center B	Kline et. al.	Frass et. al.	French	Huang et. al.	Marks et. al.	Macklis et. al.	Patton et. al.	Margalit et. al.
	Per Patient, %	0.32	3.20				1.97	1.2 - 4.7		
Per Fraction, %	0.01	0.11		0.44	0.32	0.29	0.5			
Per Field, %	0.001	0.001		0.13	0.037			0.18	0.17	0.064
Overall Per Field, %	0.28 ^a	0.009 ^a	0.05 ^a		0.13 ^a					

⁷¹ Treatment delivery means the administration of radiation.
^a Errors per field in the entire post-Tx delivery process (all aspects).
^b Errors per total Tx units.

MERP Results

QA & Radiation Safety Failures^{72,73}

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

⁷² Failures are non-patient related and include regulatory infractions.
⁷³ Data for Centers A and B was annualized for all data collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Misadministration Rates⁷⁴

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

⁷⁴ 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.
⁷⁵ Institute of Medicine (IOM). *Radiation in Medicine: A Need for Regulatory Reform*. 1996.

MERP Results

Clinically Significant Errors^{76,77}

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

⁷⁶ Clinically Significant dose trigger levels: single fx (non-SRS) - 10%; weekly difference - 15%.
⁷⁷ Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Probability of Occurrence - Infractions of Federal/State Regulations per Patient⁷⁸

Category	Post-Tx	
	Center A 309 patients	Center B 659 patients
Billing, %	26.54 ^a	5.1 ^b
QA, %	2.59	0.19
Radiation Safety, %	1.62	0.23

⁷⁸ Data for Centers A and B was annualized for all data collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

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

^b Approximately 50% of the infractions were caught/corrected at time of charge capture and before exporting to CMS or insurance company.

MERP Results

Errors in Tx Delivery Process^{79,80}

Error Category	Post-Tx	
	Center A 62 errors	Center B 120 errors
Per Patient, %	20.10	18.20
Per Fraction, %	0.58	0.61
Per Field, %	0.077	0.007

⁷⁹ Includes post-Tx errors in Tx delivery process except Registration, Patient/Docs/Notes, Scheduling, Billing, Radiation Safety, and QA.

⁸⁰ Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Near Misses⁸¹

Error Category	Post-Tx	
	Center A 2 misses	Center B 4 misses
Per Patient, %	0.65	0.607
Per Fraction, %	0.019	0.020
Per Field, %	0.003	0.0002

⁸¹ 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.

Lessons Learned With MERP Software Model

- **Upfront Homework**
 - History of error reduction important
 - Why must we embrace to be competitive
 - Philosophy of "goodness"
 - Non-punitive actions will be watched by staff
 - Incentives to encourage reporting a must
- **Practical Implementation**
 - Rewards system must be established
 - Superusers serve as point guards
 - Phased in approach minimizes overload
 - Initial paper recording of UDs prevents corrupt/inaccurate data entry
 - Brief weekly group meetings serve as bulletin board for errors
 - Individuals must be assigned responsibility for drafting procedures required by corrective action plans
 - Track closure of corrective action plans
 - Present overall results at quarterly QIC meetings

Conclusion

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