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

by

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Introduction

- Presentation describes
  - Historical basis for error reduction initiative
  - Design, implementation, and results of two QA/medical error reduction models
    - Paper-based
    - Software-based
  - How well the models worked
    - Reducing preventable systems-related errors (sentinel events, “near misses”)
    - Preventing violations of regulatory requirements (State/NRC, CMS)
    - Ensuring compliance with recommended standards (JCAHO, ACR, ACRO, etc.)
    - Improving overall efficiency

Introduction

- Patient safety
  - Freedom from accidental injury due to medical care, or absence of medical errors[1,2]

    or
  - Absence of misuse of services[3,4]
- In radiation oncology, variety of injuries and errors can occur in the diagnostic imaging or therapeutic treatment delivery processes

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

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

[3] 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.

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

History

- Institute of Medicine (IOM) report[5]
  - Focused a great deal of attention on the issue of medical errors and patient safety
  - 44,000 to 98,000 deaths per year in U.S. hospitals each year as the result of medical errors
  - 10,000 deaths per year in Canadian hospitals
  - Exceeds annual death rates from road accidents, breast cancer, and AIDS combined in U.S.

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

History

- IOM Costs[6]
  - Approximately $37.6 billion per year
  - About $17 billion are associated with preventable errors
  - Of that $17 billion, about $8 to $9 billion are for direct health care costs

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

History

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

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

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

History

- Key legislation
  - Patient Safety Quality Improvement Act[9]
    - Certifies patient safety organizations in each State to collect data and report on medical errors
  - State Patient Safety Centers[10]
    - In past 7 years, 6 states now operate patient safety centers
    - Separate mandatory reporting systems for serious adverse events
    - Centers are housed within state regulatory agencies

[9] *Reducing Medical Errors*, Issue Module, Kaiser EDU.org, Accessed through www.kaiseredu.org.

[10] Jill Rosenthal and Maureen Booth, State Patient Safety Centers: *A new Approach to Promote Patient Safety*, (Portland, Maine: National Academy for State Health Policy, 2004). Retrieved 22 March 2007. http://www.nashp.org/Files/final_web_report_11.01.04.pdf.

History

State quality collaboratives involve multiple agencies[11]

Table 4 State collaboratives and plans

State	Plan/agenda	Structure or task force
Alabama	•	
Arizona	•	•
Arkansas	•	•
California	•	•
Maine	•	•
New Mexico	•	•
N. Carolina	•	
Pennsylvania	•	•
Rhode Island	•	•
S. Dakota	•	•
Virginia	•	•
Wisconsin		•
Total (12 of 33 responding)	11	10

[11] Jill Rosenthal and Maureen Booth, State Patient Safety Centers: *A new Approach to Promote Patient Safety*, (Portland, Maine: National Academy for State Health Policy, 2004). Retrieved 22 March 2007. http://www.nashp.org/Files/final_web_report_11.01.04.pdf.

History

Publicly reported quality and safety information: State-mandated and non-mandated[12]

Table 5 States that publicly report quality and safety information

State	Legislative mandate to report quality information	Legislative mandate to report safety information	Quality reporting not mandated by legislation	Safety reporting not mandated by legislation
Arkansas			•	•
California	•		•	
Connecticut	•	•	•	
Idaho			•	
Kentucky	•			
Maine	•	•	•	•
Massachusetts	•	•	•	•
Missouri	•			
New Jersey		•		
New Mexico	•		•	•
Ohio	•			
Oklahoma		•	•	•
Oregon	•	•	•	•
Pennsylvania	•	•		•
Rhode Island	•			
South Dakota			•	
Utah	•			•
Virginia	•	•		
Wisconsin	•		•	•
Total (n=19 of 33 states)	14	8	11	9

[12] Jill Rosenthal and Maureen Booth, State Patient Safety Centers: *A new Approach to Promote Patient Safety*, (Portland, Maine: National Academy for State Health Policy, 2004). Retrieved 22 March 2007. http://www.nashp.org/Files/final_web_report_11.01.04.pdf.

History

- Patient safety centers created[13]
  - The Florida Patient Safety Corporation
  - The Maryland Patient Safety Center
  - The Betsy Lehman Center for Patient Safety and Medical Error Reduction (Massachusetts)
  - The New York Center for Patient Safety
  - The Oregon Patient Safety Commission
  - The Pennsylvania Patient Safety Authority

[13] *State Patient Safety Centers: A New Approach to Promote Patient Safety*, The Flood Tide Forum, National Academy for State Health Policy, 10/04, Accessed through www.nashp.org.

History

- JCAHO revises standards
  - Patient safety standards effective 7/1/01
  - Requires all JCAHO hospitals (5,000) to implement ongoing medical error reduction programs
  - Almost 50 percent of JCAHO standards are directly related to safety[14]

[14] *Patient Safety - Essentials for Health Care*, 2nd edition, Joint Commission on Accreditation of Healthcare Organizations. Oakbrooke Terrace, IL: Department of Publications, 2004.

History

- JCAHO's sentinel event policy[15]
  - Implemented in 1996
  - Identify sentinel events
  - Take action to prevent their recurrence
  - Complete a thorough and credible root cause analysis
  - Implement improvements to reduce risk
  - Monitor the effectiveness of those improvements
  - Root cause analysis must focus on process and system factors
  - Improvements must include documentation of a risk-reduction strategy and internal corrective action plan
  - Action plan must include measurements of the effectiveness of process and system improvements to reduce risk

[15] *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 agreement[16]
  - 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)

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

History

- CMS quality incentives[17]
  - Quality Improvement Organizations (QIOs)
    - Contracted by CMS to operate in every State
    - 67% of QIOs perform independent quality audits
  - Premier Hospital Quality Initiative
    - 3-year demonstration project with 280 hospitals recognizes and provides financial reward
    - CMS partnership with Premier Inc., nationwide purchasing alliance
    - Hospitals in top 20% of quality for 5 clinical areas get financial reward
      - Top decile gets 2% Diagnosis Related Group (DRG) bonus
      - 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

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

History

- CMS quality incentives
  - CMS consumer website
    - CMS contracted with NQF & worked with JCAHO to develop hospital quality measures for public reporting
    - In 4/05, hospital quality data became available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
  - Data indicators[18]
    - In 2006, hospitals reporting quality data to Medicare receive 3.7% increase in inpatient payments
    - Non-reporters receive 3.3% increase
    - Data covers 10 quality indicators for cardiology
    - Plans are to expand into other disciplines

[18] *Medicare to Pay Hospitals for Reporting Quality Data*, Modernhealthcare, accessed through www.modernhealthcare.com.

History

- CMS quality incentives
  - Announced 8/23/05, Medicare/State Children's Health Insurance Program (SCHIP) Quality Initiative
  - Pay-For-Performance (P4P)[19]
    - 12 states have adopted some form
      - Performance measurement is critical for reimbursement
      - Efforts are to align payment with quality
      - Working with JCAHO, NCQA, HQA, AQA, NQF, medical specialty societies, AHRQ, and VA
    - Medicare service payments are tied to efficiency, economy, and **quality of care standards**

[19] *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 2005[20]
    - P4P attempts to "introduce market forces and competition to promote payment for quality, access, efficiency, and successful outcomes."
    - Expect P4P to extend beyond HMOs to include specialties, PPOs, self insured, and consumer-direct programs.
    - Senators Charles Grassley (R-Iowa) and Max Baucus (D-Mont) introduced Medicare Value Purchasing (MVP) Act of 2005. Requires Medicare implement a P4P program covering at least a portion of payments made.[21]

[20] *Pay for Performance's Small Steps of Progress.* PricewaterhouseCoopers. *8/2/05. Accessed through www.pwchealth.com*

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

History

- CMS quality incentives
  - 2006 Physician Voluntary Reporting Program[22]
    - 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

[22] *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)[23]
    - Financial incentive to participate in voluntary reporting
      - 66 evidence-based quality measures (8 additional to be added)
      - Reporting period 7/1/07 – 12/31/07
      - Bonus payment of 1.5%
      - Covers charges for Medicare physician fee schedule
      - Claims-based reporting
        - » CPT Category II codes (or temp G-codes where Category II codes not available yet)

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

History

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

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

Now

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

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

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

Now

- CMS quality incentives
  - Proposed Value-Based Purchasing Program in 2008[27]
    - 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

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

Now

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

[28] *State's Rights and Wrongs: Part 2*, Modern Health Care, 12/10/07. Accessed through www.modernhealthcare.com.
[29] *AETNA to Quit Paying for "Never Events", 1/15/08.* Accessed through www.modernhealthcare.com.
[30] *Wellpoint to Stop Paying for "Never Events", 4/2/08.* Accessed through www.modernhealthcare.com.

Now

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

[31] *Premier Cites Gains Under CMS P4P Initiative*, Modern Health Care, 1/31/08. Accessed through www.modernhealthcare.com.

[32] *State Rewarding Doctors for Quality Care*, Washington Post, 4/12/08. Accesses through www.washington post.com.

Now

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

[33] *CMS Aims for Greater Oversight of QIOs*, Modern Health Care, 2/3508. Accessed through www.modernhealthcare.com.

Now

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

[34] *Patient-Safety Groups Allowed Under Proposed Law*, Modern Health Care, 2/12/2008. Accessed through www.modernhealthcare.com.

US Grades

- 5th Annual "HealthGrades Patient Safety in American Hospitals" assessment report for Medicare patients[35]
  - 1.12 million patient safety accidents, or medical errors, occurred between 2004 and 2006
    - 238,000 potentially preventable deaths 2004 - 2006
  - 570,000 preventable deaths were caused by medical errors to the entire population (including Medicare) 2001 - 2004
  - $8.6 billion in preventable costs 2003 - 2005[36]
  - Medical errors cost $500 billion a year in avoidable medical expenses – approximately 30% of all health care costs[37]

[35] *Errors Still Costing Medicare Billions: HealthGrades Study.* Modern Health Care, 4/8/2008. Accessed through www.modernhealthcare.com.

[36] *Quality Chasm Still Exists: Study*, Modern Health Care, 2/12/2008. Accessed through www.modernhealthcare.com.

[37] *Fixing Hospitals*, Forbes, (6/20/05).

Canada Grades

- 185,000 adverse events occur annually in Canadian hospitals[38]
- Approximates a 7.5% error rate
- Similar rates found in other counries

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

Physicians on Error-Reporting

- Most physicians believe error-reporting systems are inadequate[39]
  - Of 1,100 physicians in Missouri and Washington State between July 2003 and March 2004:
    - 56% were involved in a serious medical error
    - 74% were involved with a minor error
    - 66% were involved with a near miss
  - Of those physicians, 54% believe that medical errors are usually caused by failures of care delivery, not failures of individuals
  - 45% of physicians do not know whether a reporting system exists at their facility

[39] *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 showed[40]
  - Only 40% of those events were disclosed
  - For preventable events, disclosure rate was only 28%
- Physicians reluctance to disclose events due to concerns over litigation
- However, findings show informed patients more likely to be pleased with quality of care

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

Consumer Beliefs[41]

- 40% do not believe nation's quality of health care has improved
- 48% are concerned about the safety of health care
- 55% are dissatisfied with quality of health care
- 34% say they or family member experienced a medical error in their life

[41] *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 Beliefs[42]

- 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[43]

[42] *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.
[43] Duffy J, *The QAIP* 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 death[44]
- Reported error rates range 0.1% to 0.2% of fields treated[45]
- Studies not relying on self-reporting show actual rates of up to 3%[46]

[44, 45, 46] French, J, *Treatment Errors in Radiation Therapy*. Radiation Therapist, Fall 2002, Vol.11, No. 2; 2002.

Significant Medical Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
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)
UK	McKenzie AL, British Institute of Radiology, 1996	1988	Overdose (+25%)	207		Teletherapy activity calculation error
UK	McKenzie AL, British Institute of Radiology, 1996	1982-1991	Underdose (-25%)	1,045		Misunderstanding of algorithm in Tx planning computer
Germany	IAEA, Safety Report Series No.38, 2006	1986-1987	Overdose (various)	86		Co-60 dose calculations based on erroneous dose tables, no independent checks
US	Ricks CR, REAC/TS Radiation Incident Registry, 1999	1944-1999	Overdose		**13 – Deaths** **(OH - 10, PA - 1, TX - 2)** **1 - Serious Injury (WA)**	Incorrect calibrations, incorrect computer programming, equipment maintenance/repair negligence
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

Significant Medical Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
Spain	IAEA, Safety Report Series No.38, 2006	1990	Overdose (+200-600%)	27	**15 – Direct Deaths** **2 – Deaths from complications**	Error in maintenance if linac, procedures not followed, conflicting signals not analyzed, no beam verification procedures
UK	IAEA, Safety Report Series No.38, 2006	1999-1989	Over and under dose (-20 to +10%)	22		Error in identification of Cs-137, brachytherapy sources, no independent check of source strength
Costa Rica	IAEA, Safety Report Series No.38, 2006	1996	Overdose (+60%)	114	**17 - Deaths**	Error in calibration of Co-60 unit, lack of independent beam calibration, recommendation of external audit ignored
Panama	IAEA, Safety Report Series No.38, 2006	2000	Overdose	28	**Several - Deaths from radiation**	Modified procedure for entry into Tx planning computer without verification
US	IAEA, Safety Report Series No.38, 2006	1989-1988	Overdose (+75%)	33		Computer file for use of trimmers not updated for new Co-60 source, no manual or independent verification of calculated Tx
Scotland	Scottish Ministers, Report of an Investigation, 2006	2006	Overdose (+58%)	1	**1 - Death**	Tx planning computer software was upgraded. Old correction factor was applied to new calculation program.

Medical Error Rates in Radiation Oncology – Table 1

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx	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	<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
	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

Medical Error Rates in Radiation Oncology – Table 2

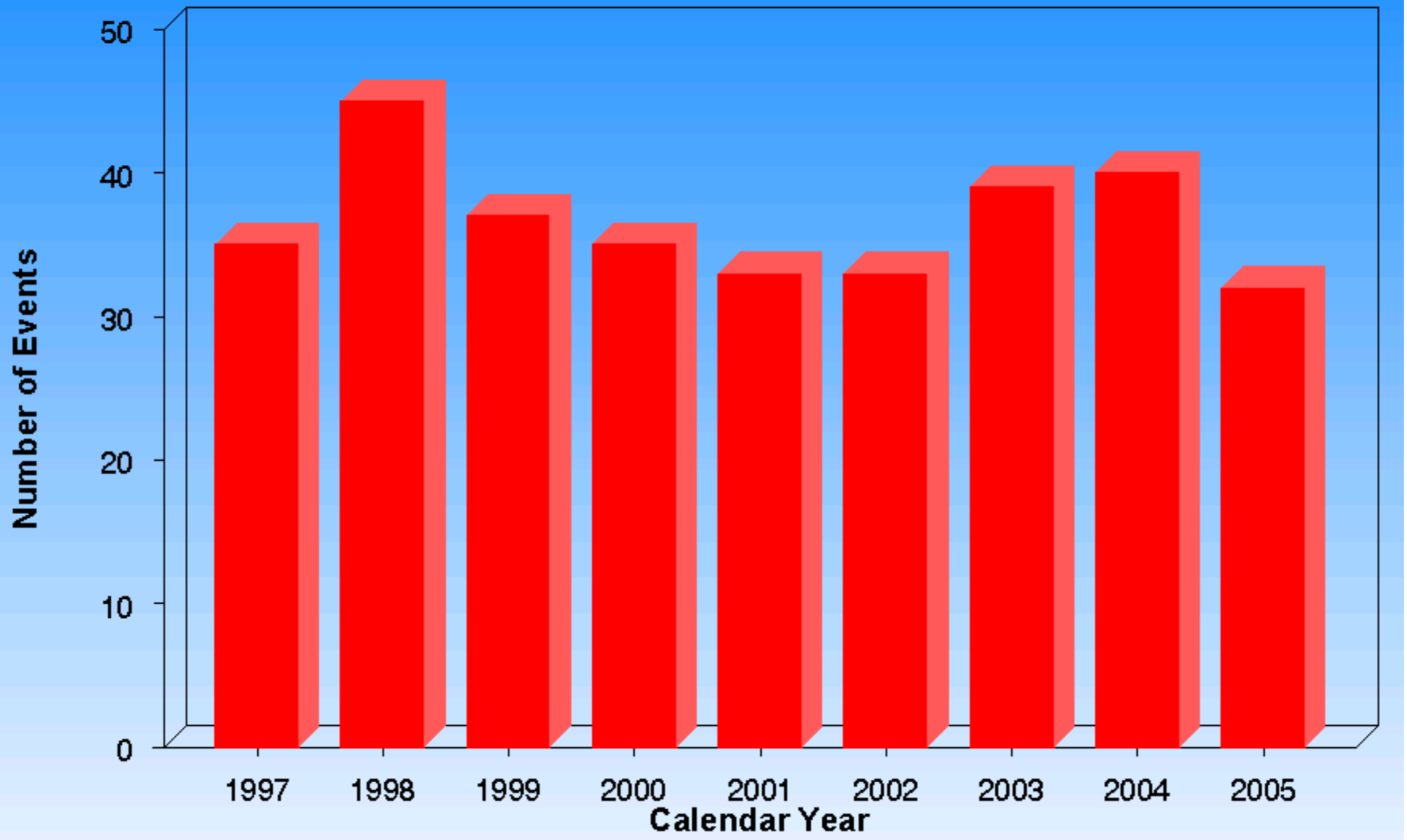
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
	Noel A, et al., Radiother Oncol, 1995	5 years					Of 7519 treatments: 79 total errors - Of 79, 78 are human origin - Of 78, 39 would have > 10% dose Δ	1.05%: errors per treatment
US	Kartha 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, 1998	1 year	1,925		93,332	168	15%: causally related to R&V	0.18%: reported error rate/year
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						3.22%: of all delivered Tx fields had at least 1 error
Canada	Yeung TK, Abstract-NEORCC, 1996	1994						3.3%

Medical Error Rates in Radiation Oncology – Table 3

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**
Canada	Grace H, et al., Int J Radiat Oncol Biol Phys, 2005	1/1/97-12/31/02	28,136				555 total errors - 87 (15.6%): incorrect programming in R&V	**1.97%: error rate per patient** **0.29%: error rate per fraction (7/00 - 12/02)**
US	Klein E, et al., J of Appl Clin Med Phys, 2005	30 months	3,964					**0.48 to <0.1%: for diff methods of detection w/R&V**

NRC Reported Medical Events

(10 CFR Part 35)



NOTE: *Abnormal Occurrences* Replaced Medical Events

2006: 2 NRC, 6 Agreement States

2007: 5 NRC, 6 Agreement States

Paper-Based Model

Objective of Paper-Based Model

- Provide a unified, total quality management and continuous improvement program
- Minimize occurrence of errors identified in the patient treatment process and regulatory arena
- Designed for 17 geographically dispersed radiation oncology clinics
- Located in 9 states of varying regulatory oversight and enforcement philosophy

Design of a Paper-Based Model

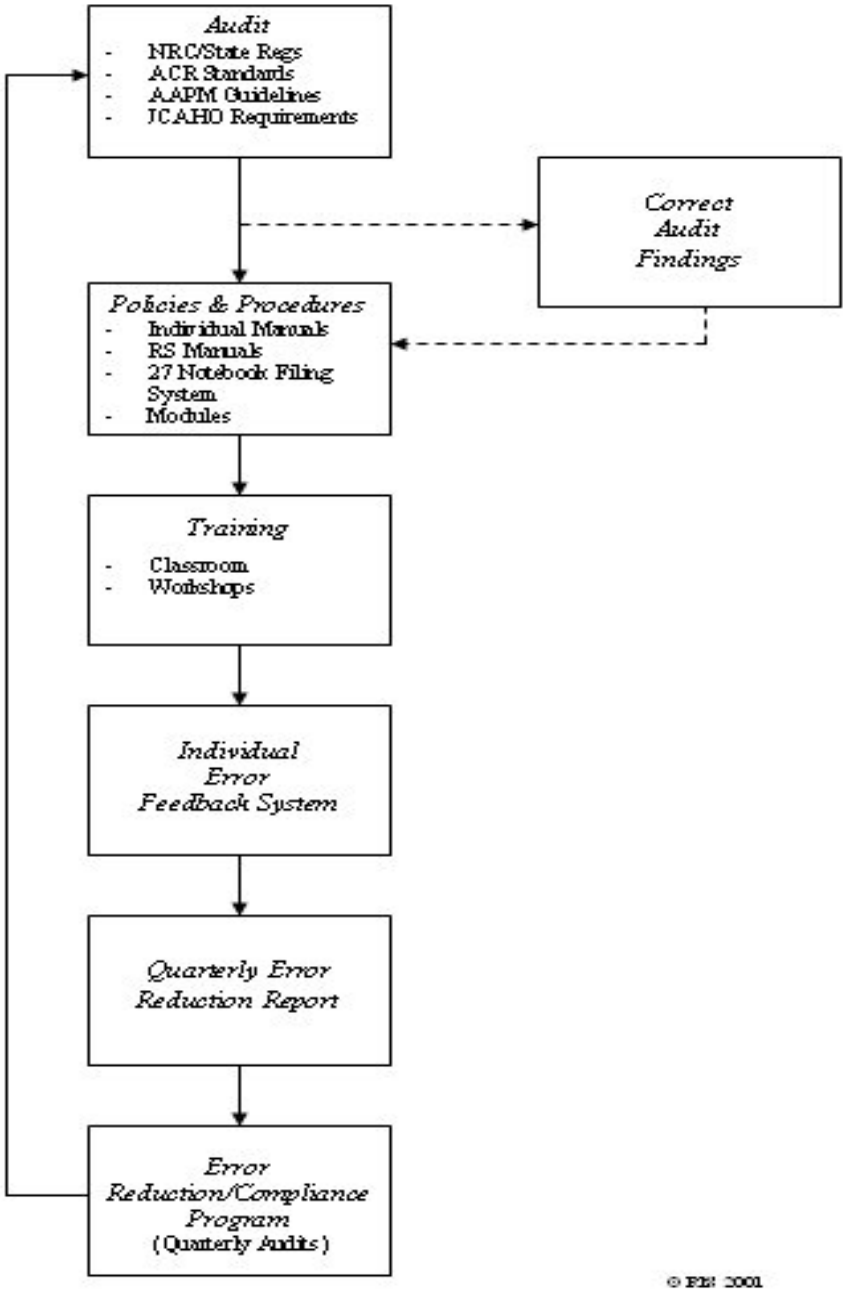
- Established a consistent set of QA procedures for the 17 facilities following the strictest state requirements in which each facility resides.
- Analyzed the process of delivering radiation therapy to identify the steps used in all aspects of this modality.
- Developed a reporting codification system for errors detected, and the appropriate forms and procedures for reporting these errors. This includes a staging system for classifying the importance of an error.

Design of a Paper-Based Model

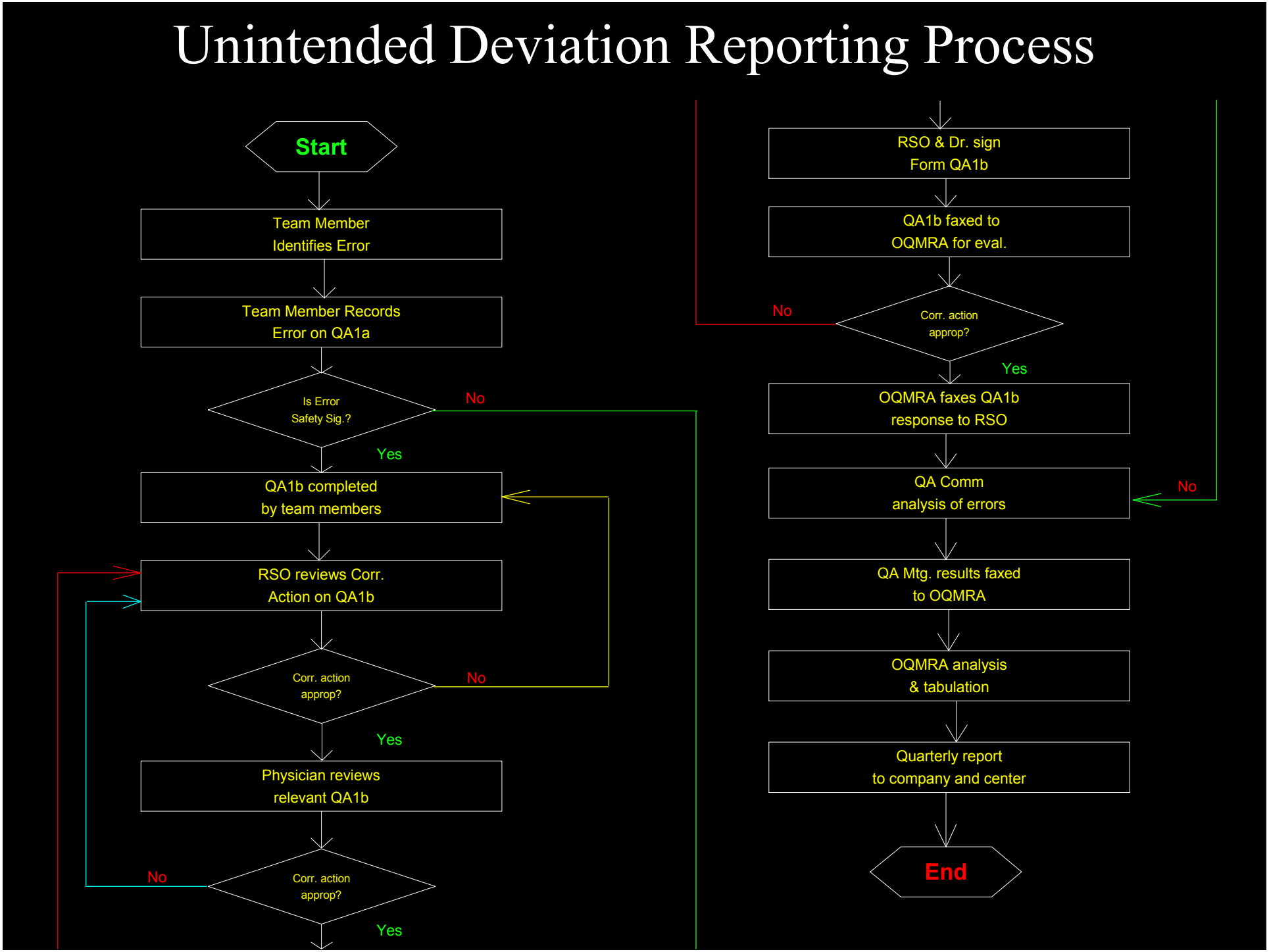
- Provided an internal feed-back mechanism of corrective action to close the loop
  - Independent review/recommendations for corrective action regarding all self-identified significant errors/violations
- Produced a quarterly report summarizing errors/violations
  - Perform trend analysis of reported errors at center and company levels
  - Recommended company wide corrective actions based on results of trend analysis

RPS

QA Implementation Process for a Radiation Oncology Center



Unintended Deviation Reporting Process



The Unintended Deviation System

- Name was selected to convey an unintentional error discovered either by the one having committed the error or by another physician/staff member.
- Management emphasizes that self-identification and reporting of errors will not result in disciplinary action.
- Provides for identification, evaluation, and documentation of all errors within the process of radiation therapy delivery.
- Suggests possible causes and solutions for correction of individual errors as well as programmatic errors with discoverable trends.

Definition - Unintended Deviation

- An unintended deviation is any error in the planned patient simulation, setup, treatment, or data entry in these processes.
- Any deviation from the planned course of treatment
- Any error in calculation
- Any missing or incomplete information
- Any failure to perform or follow required quality assurance and radiation safety policies or procedures
- Unintended deviations can be classified as:
  - Pre or post-tx error
  - A minor unintended deviation (Level 3-5)
  - A significant unintended deviation (Level 1-2)
    - A Recordable Event
    - A Misadministration

Name Cancer Center: Post-Treatment Unintended Deviations[4] - Page 1 of 2 **Dates of ___ to ___**

Code	Identified	Description/SL/Process/Resp. Party
Treatment Planning: Data Entry		
1010		Treatment site 2 ◆ P
1011		Plan identification 3 P
1012		Field names and numbers 3 ◆ P
R & V: Data Entry		
1110		Course 4 ◆ M
1111		Prescription site 2 ◆ M
1112		Technique 2 ◆ M
1113		Modality (photons or electrons) 1 ◆ M
1114		Dose specification 2 ◆ M
1115		Depth 2 ◆ M
1116		Total dose 1 ◆ M
1117		Fraction dose 1 ◆ M
1118		Fractions 2 ◆ M
1119		Pattern 2 ◆ M
1120		Prescription note[1] 2 ◆ M
1121		Elect. Approval before 1st Fx (R&V) 1 ◆ M
1130		Misc._____ M
Treatment Field Definition		
1210		Prescription site 1 ◆ P
1211		Field name 3 P
1212		Machine 3 P
1213		Type 3 ◆ P
1214		Modality 1 ◆ P
1215		Energy 1 ◆ P
1216		MU 3 ◆ P
1217		Dose > ±3% 2 ◆ P
1218		Dose < ±3% 3 P
1219		Incorrect wedge angle 2 ◆ P
1220		Incorrect wedge orientation 2 ◆ P
1221		No wedge specified, wedge in plan 1 ◆ P
1222		Incorrect compensator 2 ◆ P
1223		No comp specified; comp in plan 1 ◆ P
1224		Incorrect block entered 2 ◆ P
1225		No block specified; blocks in plan 2 P
1226		Incorrect bolus entered 3 ◆ P
1227		No bolus entered; bolus in plan 3 ◆ P
1228		Incorrect TSD 3 ◆ P
1229		Incorrect gantry angle 4 ◆ P
1230		Incorrect collimator angle 4 ◆ P
1231		Incorrect field size 4 ◆ P
1232		Incorrect asymmetric jaw 4 ◆ P
1233		Incorrect couch vertical 4 ◆ P
1234		Incorrect couch angle 4 ◆ P

Code	Identified	Description/SL/Process/Resp. Party
Patient Simulation		
Patient Setup		
1310		Pt position not iso. to midline (SAD) 3 ◆ T
1311		Pt position not to specified SSD 3 ◆ T
1320		Missing AP SSD 2 ◆ T
1321		Missing PA SSD 2 ◆ T
1322		Missing RL/Medial SSD 2 ◆ T
1323		Missing LL/Medial SSD 2 ◆ T
1324		Missing calc. pt. SSD 2 ◆ T
1325		Table vert. does not agree w/SSD 3 ◆ T
1326		SSD read incorrectly 2 ◆ T
1330		Separation does not agree w/SSD 3 ◆ T
1331		Separation missing 2 ◆ T
1340		Incorrect contour 3 ◆ T
1350		Failure to capture all Tx fields 2 ◆ T
1351		Failure to capture setup fields 2 ◆ T
1360		Setup instructions incorrect 3 ◆ T
1361		Setup instructions miss./incomp. 3 ◆ T
1370		Misc._____ T
Simulation Films		
1400		Miss./incorr. pt. info. 4 ◆ T
1401		Miss./incorr. field info 4 ◆ T
1402		Miss./incorr. field markers 3 ◆ T
1403		Miss./incorr. SFD 4 ◆ T
1410		Misc._____ T
Block Fabrication		
1500		Blocks cut incorr. 3 ◆ T
1501		Hand set blocks mounted incorr. 3 ◆ T
1502		Custom blocks mounted incorr. 3 ◆ T
1503		Missing or late block checks 4 ◆ T
1510		Misc._____ T
Dose Calculation		
1600		Incorr./miss. Tx site 2 ◆ P
1610		Incorr./miss. field names 3 ◆ P
Hand Calculations		
1620		Incorr. Energy 2 ◆ P
1621		Incorr. Field size 3 ◆ P
1622		Incorr. SSD 3 ◆ P
1623		Incorr. depth 2 ◆ P
1624		Incorr/miss. tray factor 3 ◆ P
1625		Incorr/miss. wedge factor 1 ◆ P
1626		Incorr/miss. bolus 3 ◆ P
1627		Calc w/bolus, bolus not Rx'd 3 ◆ P
1628		Wrong coll. scatt. factor 3 ◆ P

Code	Identified	Description/SL/Process/Resp. Party
1630		Wrong inverse sq. factor 2 ◆ P
1631		Math error 3 ◆ P
1632		Calc. using incorr. dose 2 ◆ P
1633		Tx plan not approved 1 ◆ M
1640		Misc._____ P
Computer Calculations		
1650		Incorr. energy 1 ◆ P
1651		Incorr. mode of Tx 1 ◆ P
1652		Incorr. field size 3 ◆ P
1653		Incorr. asymmetric jaw 3 ◆ P
1654		Incorr. SSD 3 ◆ P
1655		Incorr depth 2 ◆ P
1656		Incorr. gantry angle 3 ◆ P
1657		Incorr. coll. angle 3 ◆ P
1658		Incorr. tray factor 3 ◆ P
1659		Incorr. wedge angle 2 ◆ P
1660		Incorr. bolus 3 ◆ P
1661		Calc. to wrong point 2 ◆ P
1662		Calc. using wrong dose 2 ◆ P
1663		Calc. not normalized correctly 2 ◆ P
1670		Misc._____ P
Cutout Measurements		
1680		Used incorr. cutout 2 ◆ P
1681		Dose incorr. 2 ◆ P
1682		Energy incorr. 1 ◆ P
1683		Cone size incorr. 2 ◆ P
1684		SSD incorr. 2 ◆ P
1685		Depth incorr. 2 ◆ P
1686		Isodose line incorr. 2 ◆ P
1687		Depth of meas. incorr. 2 P
1688		Energy or modality used incorr. 1 ◆ P
1690		Misc._____ P
Treatment Chart		
1700		Diagnosis 1 ◆ M
1701		Histology 4 ◆ M
1702		H/P grade 4 ◆ M
1703		TNM stage 4 ◆ M
1704		Treatment intent 3 ◆ M
1705		Surgery 4 ◆ M
1706		Chemotherapy 2 ◆ M
1707		Previous RT 2 ◆ M
1708		Special precautions 3 ◆ M
1709		Rx: Date 2 ◆ M

Legend: Significance Level - 1 (most significant), 2, 3, 4, 5 (least significant) ◆ - Key Process M - M.D. P - Physics T - Therapist R - Facility RSO Q - QI Coordinator

Footnotes: [1] To include wedges, blocks, bolus, compensator, and no. of fr./day & fr./wk. (if not recorded under *Pattern*)
[2] Misadministration (Note: Some Agreement states have more restrictive dose requirements.)
[3] Recordable Event
[4] All information contained in this document is *Client-Attorney Privileged.*

Name Cancer Center

Unintended Deviation Reporting Form [1]
For Significance Level 1 and 2 Events (Recorded on Forms QA1a and QA1b)

Date(s) of Occurrence: _____ **Identified By:** _____
Date Identified: _____ **Patient Chart/UD No:** _____ / _____

☐ **Pre-Treatment Unintended Deviation** ☐ **Post-Treatment Unintended Deviation**

Category	Frequency	Code	Category	Frequency	Code
Treatment Planning			Treatment Chart		
R & V			Treatment of Patient		
Patient Simulation			Patient Identification		
Block Fabrication			Port Films		
Dose Calculation			Quality Assurance		
Cutout Measurement			Radiation Safety		

Description: _____

_____

_____

Evaluation: _____

_____

☐ **Δ Daily Dose (±)** _____% ☐ **Δ Weekly Dose (±)** _____% ☐ **Δ Total Dose (±)** _____%

☐ **Recordable Event** ☐ **Misadministration** ☐ **Personnel Overexposure**

Immediate Corrective Action Taken (Check all that apply):
Date of Immediate Action: _____

☐ Correction of documentation ☐ Adjustment of equipment or machine
☐ Adjustment of treatment (if necessary) ☐ Other: _____

Long-Term Corrective Action (Check all that apply):

☐ Additional training ☐ Increased oversight or supervision
☐ Improved procedure ☐ Other: _____

Approved:

☐ *Physicist initials/date:* _____ ☐ *RSO initials/date:* _____ ☐ *MD initials/date:* _____

Physicist or RSO Use Only

Evaluation: _____

_____

_____

Recommendations: _____

_____

_____

Date Received: _____ **Date Reviewed:** _____
Date of Feedback to Facility: _____ **Reviewer's Initials:** _____

[1] Complies with state and federal enforcement policies regarding licensee-identified violations and recording of unintended deviations pursuant to the Quality Management Program. All information in this document and any attachments are *Client—Attorney Privileged*.

Name Cancer Center

Post-Treatment
Quarterly Unintended Deviation
Summary Report[1, 2]

☐1st ☐ 2nd ☐3rd ☐-4th Calendar Quarter 200

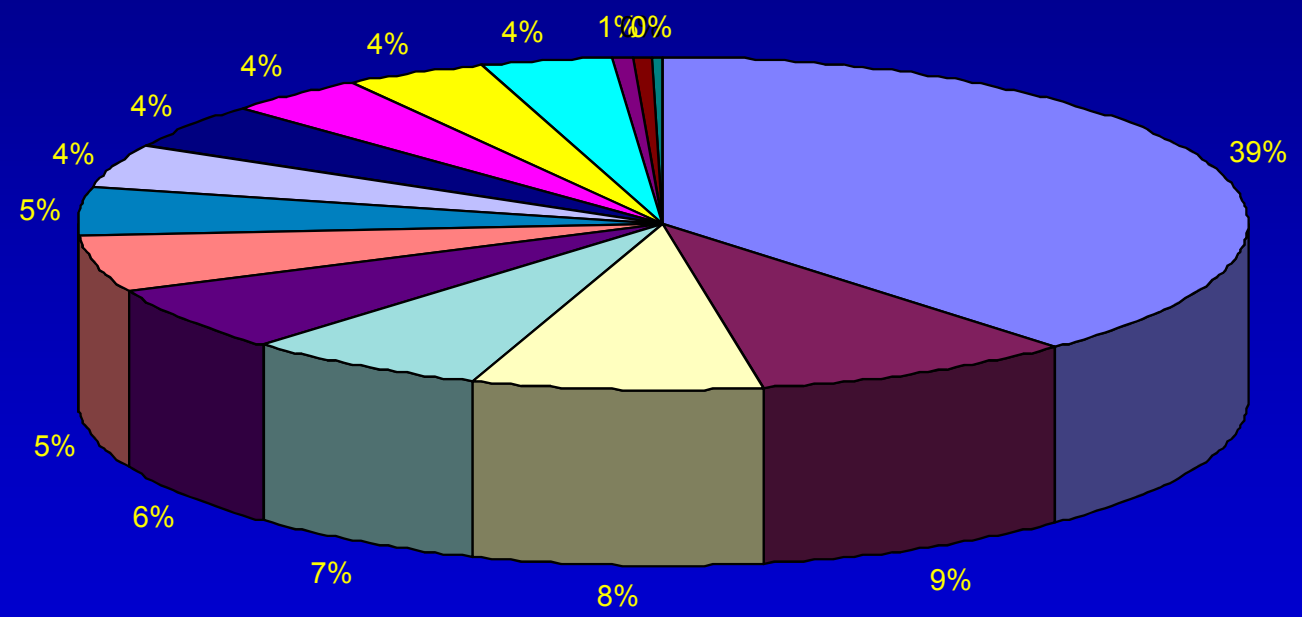
Monitored Category	Frequency By Category	Frequency By Significance Level					Frequency By Key Processes ?	
		1	2	3	4	5	Yes	No
Tx Planning								
R & V - Prescription								
R & V - Tx Field Definition								
Sim - Patient Setup								
Sim - Films								
Block Fabrication								
Dose Calc - Hand								
Dose Calc - Computer								
Cutout Measurements								
Tx Chart - Rx								
Tx Chart - Patient Setup Doc								
Tx Chart - Tx Field info								
Tx of Patient - Daily Tx								
Tx of Patient - Patient ID								
Tx of Patient - Port Films								
Tx of Patient - Patient Setup								
Tx of Patient - Beam Modifiers								
Admin of Radiation								
QA								
Radiation Safety								
	Total Activity	Total	Total	Total	Total	Total	Total	Total

[1] File in Incidents Notebook XX - Section A.3. Send copy to QIC.
[2] All information contained in this document and any attachments are *Client-Attorney Privileged*.

QAId

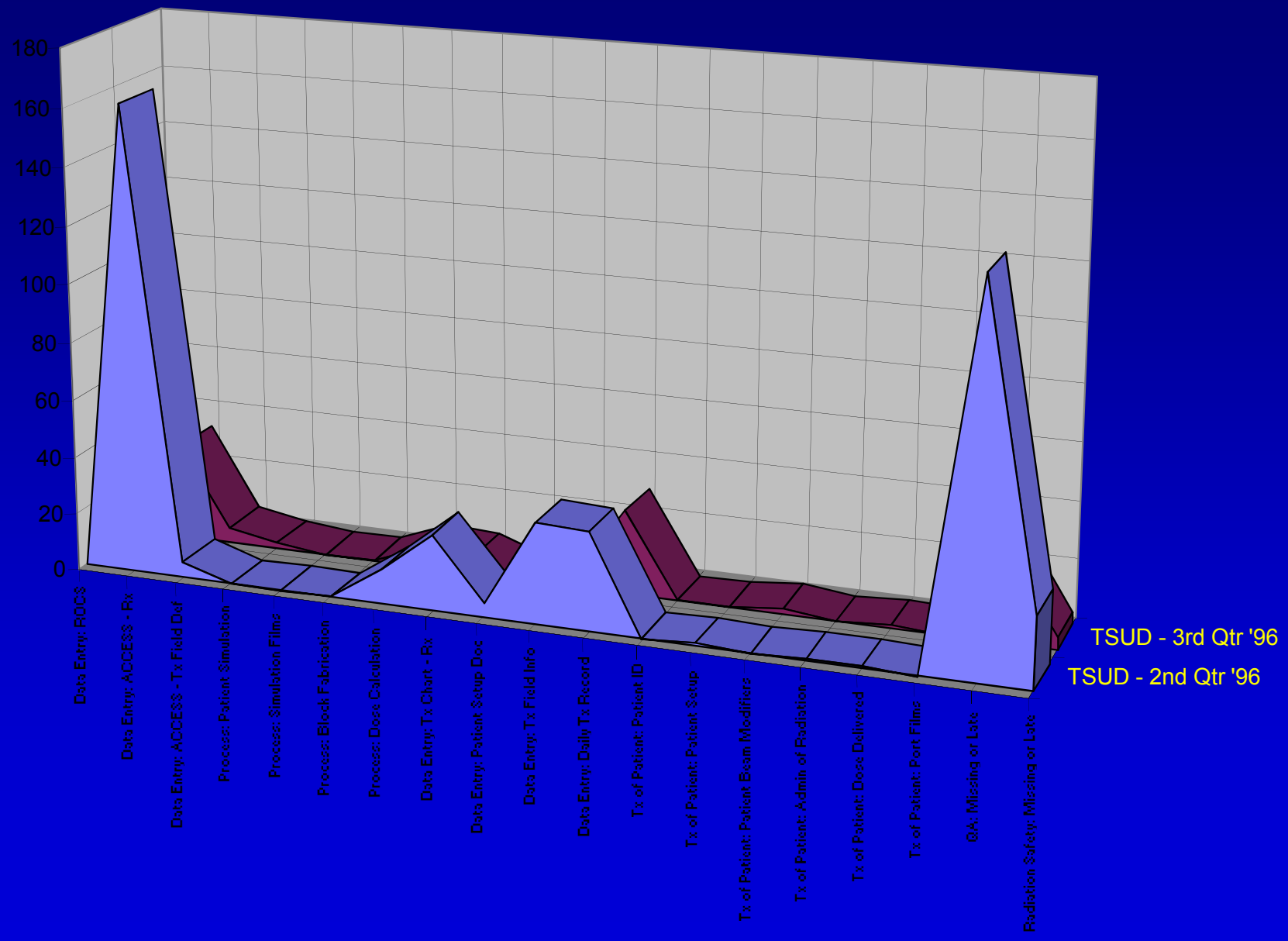
Unintended Deviations	TMUD - 2nd Qtr '96	TSUD - 2nd Qtr '96	Total - 2nd Qtr '96	TMUD - 3rd Qtr '96	TSUD - 3rd Qtr '96	Total - 3rd Qtr '96
Data Entry: ROCS	0	0	0	0	0	0
Data Entry: ACCESS - Rx	0	162	162	0	33	32
Data Entry: ACCESS - Tx Field Def	25	5	30	19	5	23
Process: Patient Simulation	59	0	59	22	2	23
Process: Simulation Films	24	0	24	25	0	21
Process: Block Fabrication	20	0	20	12	0	9
Process: Dose Calculation	17	12	29	11	7	18
Data Entry: Tx Chart - Rx	34	26	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 Modifiers	32	0	32	12	2	10
Tx of Patient: Admin of Radiation	2	1	3	0	0	0
Tx of Patient: Dose Delivered	0	1	1	0	1	1
Tx of Patient: Port Films	23	0	23	18	0	18
QA: Missing or Late	34	132	166	10	33	36
Radiation Safety: Missing or Late	3	25	28	2	4	5
TOTAL	**578**	**439**	**1017**	**279**	**126**	**370**
ABSOLUTE DIFF BETWEEN QTRS				**-299**	**-313**	**-647**
PERCENT INCREASE/DECREASE				**-51.7%**	**-71.3%**	**-63.6%**

Minor Unintended Deviations: 3rd Qtr. 1996

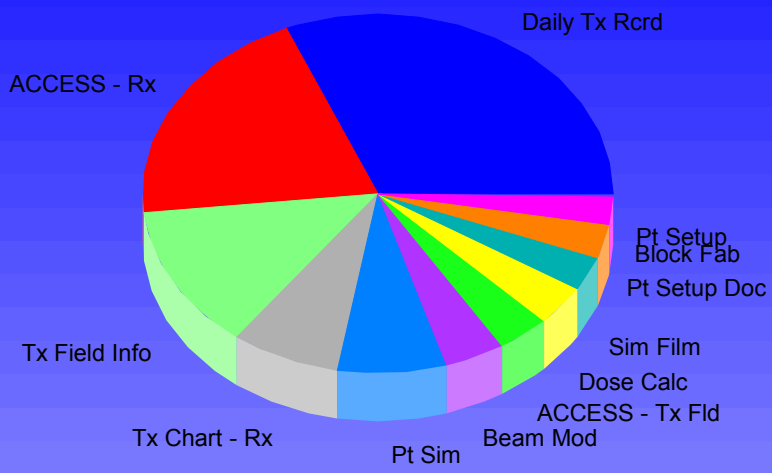


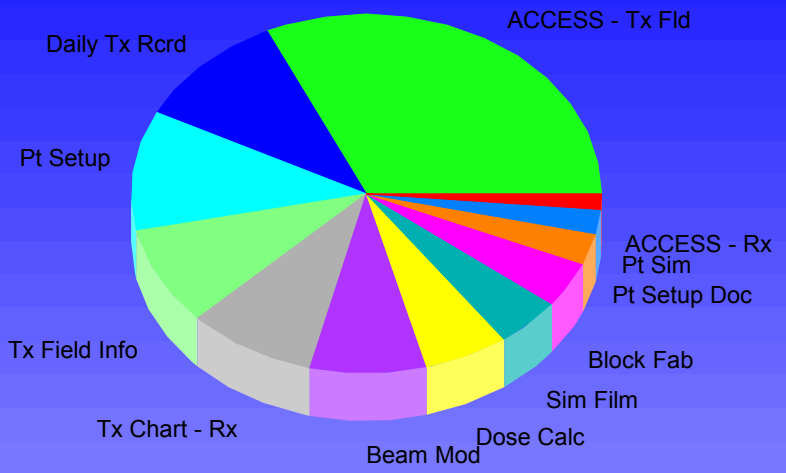
- Data Entry: Daily Tx Record
- Process: Simulation Films
- Process: Patient Simulation
- Data Entry: ACCESS - Tx Field Def
- Tx of Patient: Port Films
- Data Entry: Tx Chart - Rx
- Data Entry: Tx Field Info
- Process: Block Fabrication
- Tx of Patient: Patient Beam Modifiers
- Process: Dose Calculation
- Data Entry: Patient Setup Doc
- QA: Missing or Late
- Radiation Safety: Missing or Late
- Tx of Patient: Patient ID
- Tx of Patient: Patient Setup

Significant Unintended Deviations: 2nd & 3rd Qtr. 1996



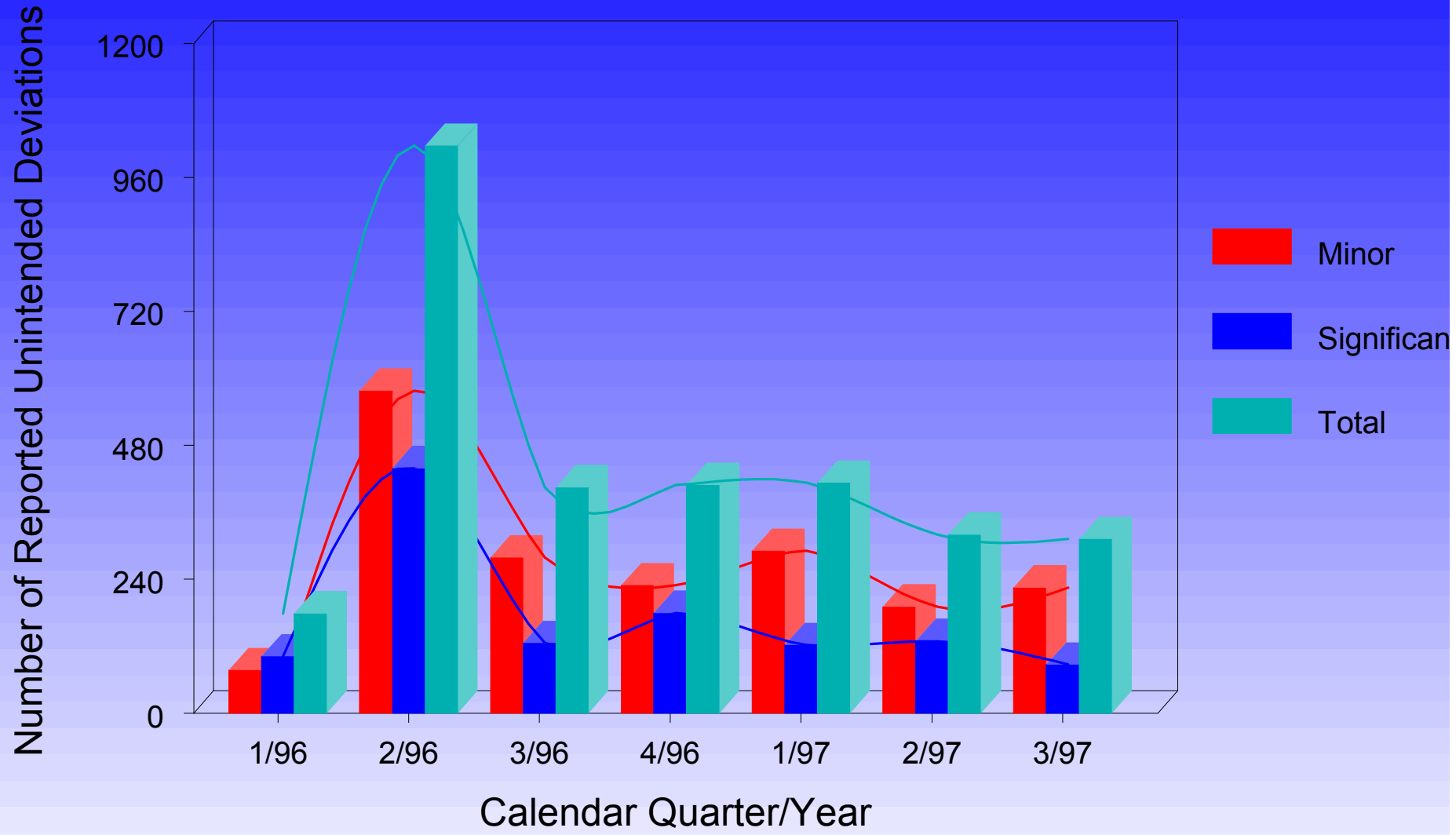
Total Unintended Deviations versus Time





Parameter	2nd Quarter '96	2nd Quarter '97	% Change	Parameter	2nd Quarter '96	2nd Quarter '97
Data Entry: ROCS	0	0	0	Data Entry: Daily Tx Rcd	250	125
Data Entry: ACCESS - Rx	162	9	-1800	Tx of Pt: Pt ID	0	0
Data Entry: ACCESS-Tx Field Def	30	45	+150	Tx of Pt: Pt Setup	2	1
Process: Pt Sim	59	6	-983	Tx Pt: Pt Beam Mod	32	12
Process: Sim Films	24	5	-480	Tx Pt: Admin of Rad	3	0
Process: Block Fab	20	4	-500	Tx of Pt: Dose Deliv	1	0
Process: Dose Calc	29	8	-363	Tx of Pt: Port Films	23	3
Data Entry: Tx Chart-Rx	60	25	-240	QA: Missing/Late	166	24
Data Entry: Pt Setup Doc	23	3	-768	RS: Missing/Late	28	6
Data Entry: Tx Field Info	105	44	-239			

Summary of Total Unintended Deviations



Reported Misadministration Rate In Radiation Oncology

Published rates[47] 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.

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

Calculated Error Rates

Paper-Based Model

- Based upon the total number of treatment fields delivered as recorded by R&V at 17 radiation oncology centers and the total number of unintended deviations self-reported by the system, excluding the initial two quarters for the "learning curve effect", the overall average error rate for both minor and significant unintended deviations within the system was approximately 0.052% (5.2 in 10,000 patient 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).[48]
- Based upon the model's experience of one reported misadministration (having no deterministic or measurable effect) over 2 years, the measured misadministration rate was 0.017%.

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

Measured vs Published Misadministration Rate

Radiation Oncology

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

Cost Benefit Analysis

Paper-Based Model

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

Cost Benefit Analysis

Paper-Based Model

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

Summary of Results

Paper-Based Model

- Overall average error rate was 0.052% (SL 1 – 5)
- Calculated misadministration rate[49] was 0.018%
- Actual misadministration rate was 0.017%
- NRC misadministration rate was 0.042% (a factor of 2.35 higher than actual misadministration rate)
- Reduced overall error rate by 326% over 21 months
- Direct cost savings of **$450,000**
- Direct & indirect cost savings of **$600,000**
- Other significant incidents averted by using program

[49] Misadministration criteria based on definitions found in NRC 10CFR35.2, rev. 1996; and CRCPD recommended Agreement State regulations dated 2007.

Other Center Studies

Paper-Based Model

Summary of Results - 1998

Oncology Company With 10 Freestanding Centers

- Three significant radiation treatment errors, that if left undetected would have required reporting to the State and notifying the referring physician and patient, were caught.
- A misadministration at one center, involving possible civil penalties and sanctions, was mitigated by the State by demonstrating that the error leading to the misadministration was isolated based on empirical data.

Other Center Studies

Paper-Based Model

Summary of Results - Calendar Year 2002

Cancer Center #1

- Aside from the 1st quarter "learning curve", total errors decreased by **70.5%** (334 vs 99) between the 2nd and 3rd quarters.
- Total errors decreased by **27.3%** (99 vs 72) between the 3rd and 4th quarters.
- The total decrease in errors between the 2nd and 4th quarters was **78.4%** (334 vs 72).

Cancer Center #2

- Aside from the 1st quarter "learning curve", total errors decreased by **66.4%** (113 vs 38) between the 2nd and 3rd quarters.
- Total errors decreased by **18.4%** (38 vs 31 between the 3rd and 4th quarters
- The total decrease in errors between the 2nd and 4th quarters was **72.6%** (113 vs 31).

Lessons Learned
Paper-Based Model

- **Limitations**
  - Inefficient
  - Time intensive
  - Intrusive
  - Complex industrial engineering model
  - Requires paper trail

- **Weaknesses**
  - Learning error codification system
  - Triggering required regulatory actions
  - Faxing of errors
  - Tracking UDs
  - Management review
  - Trending and analysis
  - Report generation
  - Timely action
  - Credible root cause analysis

Software-Based Model

Design of Software-Based Model

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

Design of Software-Based Model

MERP Program

- **Monitored Areas**
  - Clinical
  - QA
  - Radiation Safety
- **Identification and Tacking of *Errors***
  - Preset standardized error codes
  - Classification of pre and post-treatment errors
  - Assignment of severity levels (I - V)
  - Designation of clinical significance
  - Designation of significant unintended deviation
  - "Near Miss" categorization
  - Sentinel events (internal and JCAHO reportable)
  - Instant analysis of patterns and trends
- **Identification and Tacking of *Violations***
  - Preset standardized unintended deviation codes
  - Assignment of severity levels (I - V)
  - Recordable events
  - Misadministrations (medical events)
  - Regulatory violations
  - Possible regulatory violations
  - Instant analysis of patterns and trends

Design of Software-Based Model

MERP Program

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

Design of Software-Based Model

MERP Program

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

Design of Software-Based Model

MERP Program

- **Customization Features**
  - Customize and create data collection areas for performance improvement priorities
    - Categories
    - Subcategories
    - Attributes
  - Designate who reviews/approvals routine errors and corrective actions
  - Assign which errors violate State requirements
  - Designate severity levels, clinically significant, and significant unintended deviations
- **Standards/Requirements Referenced by Code**
  - JCAHO 2007 patient safety standards show basis for question
  - ACR and ACRO standards demonstrate benchmark for measuring performance
  - CRCPD (Agreement State) recommended regulations (as of 9/08) show legal text

MERP Implementation Strategy

Preparation

- **Step #1 - Benchmark Procedures**
  - Created manual
  - Included step-by-set processes
  - Covered technical delivery system
    - QA
    - Radiation safety
    - QMP
- **Step #2 - Training**
  - Provided classroom hours
    - 15 hours in procedures
    - 6 hours in MERP
  - Presented over 1 hour lunch break
  - Took 2 months
  - Issued category ‘A’ credit thru ASRT
  - Met annual state radiation safety training requirements

MERP Implementation Strategy

Phased Rollout

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

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 ☐	QA ☐	RS ☐	QA ☐	RS ☐
Pre-Tx ☐	Post-Tx ☐	Affected Tx ☐		

Description of UD:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

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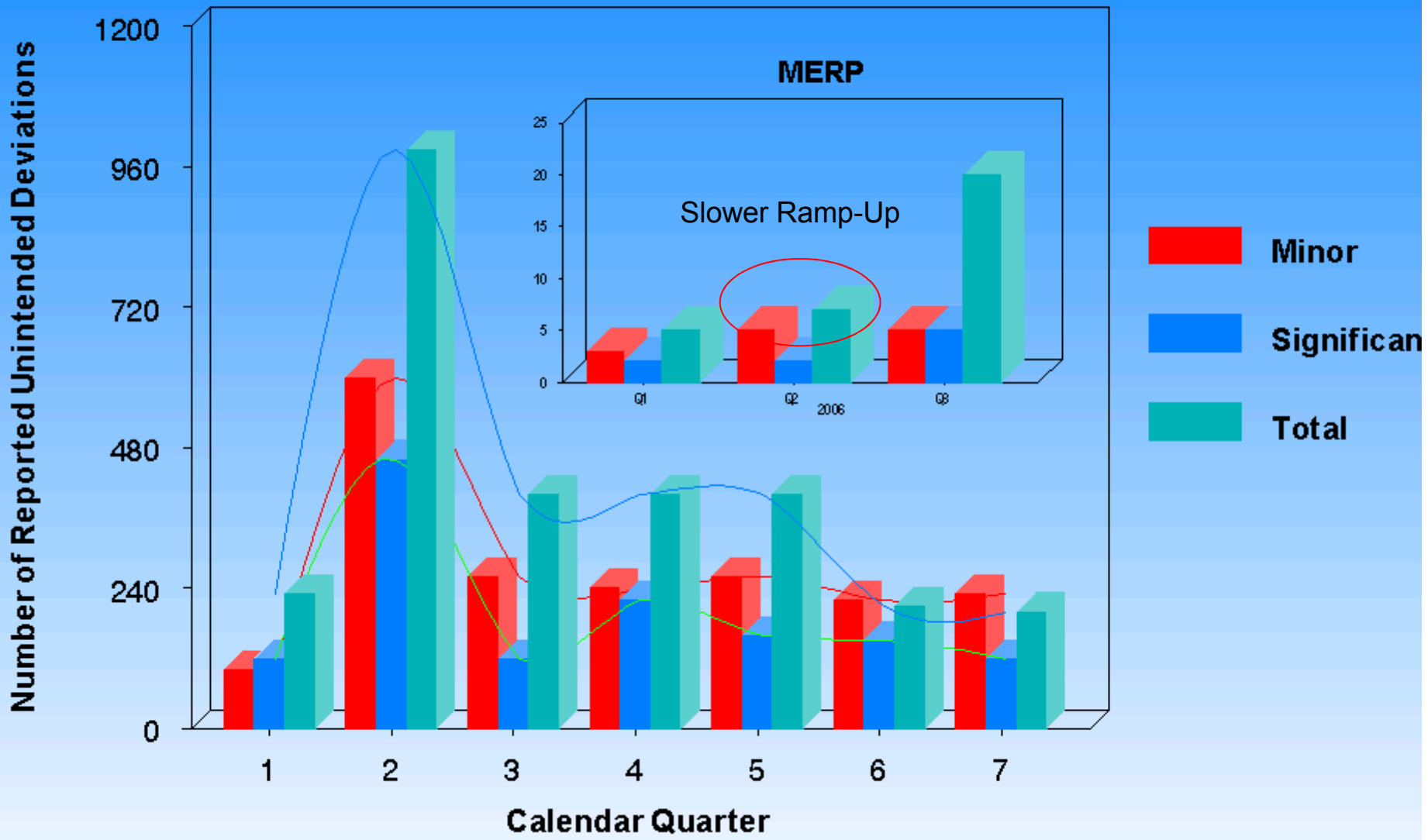
_____

Initials: _____ **Date:** _____

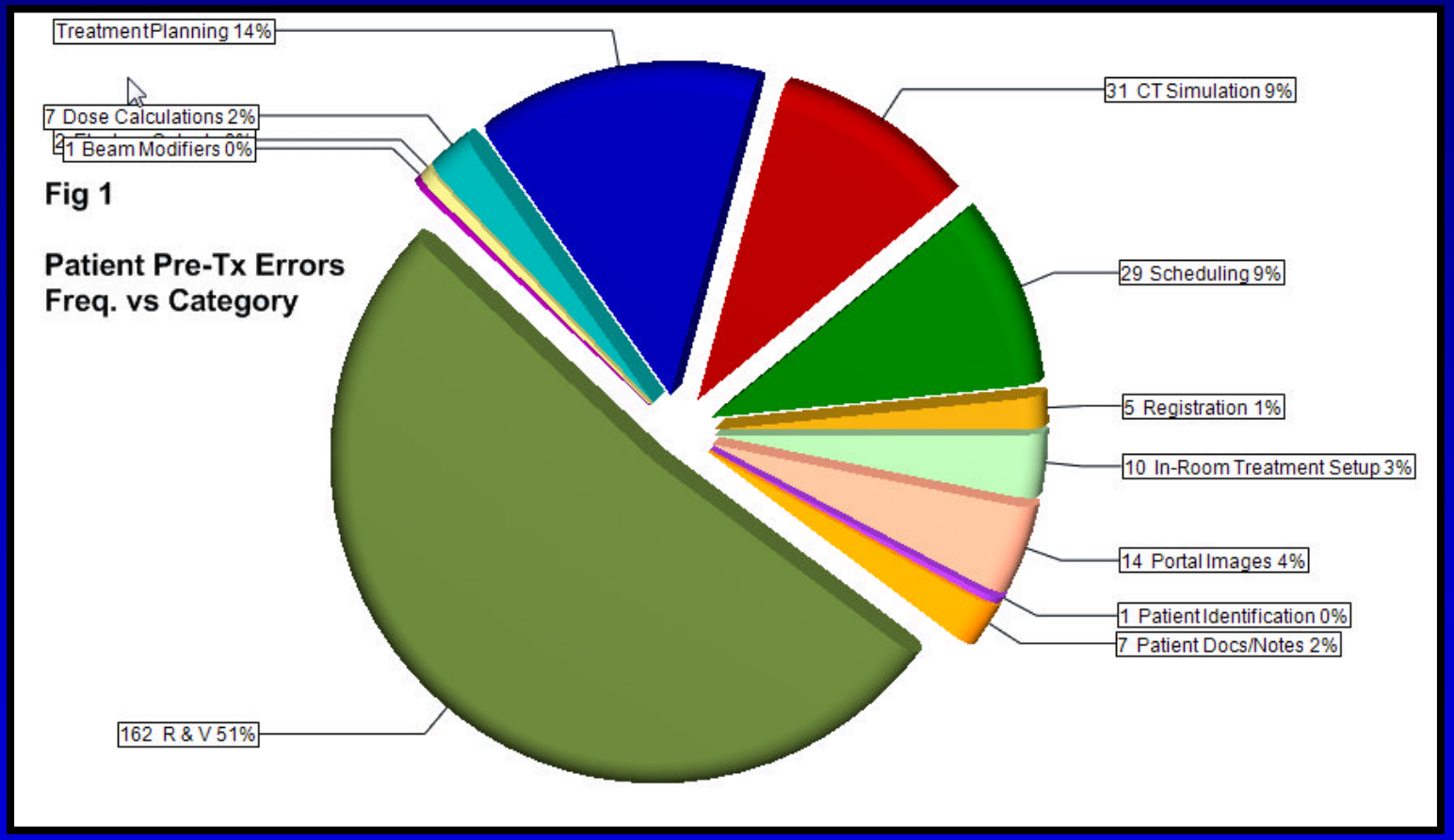
MERP Results

Summary of Total Unintended Deviations

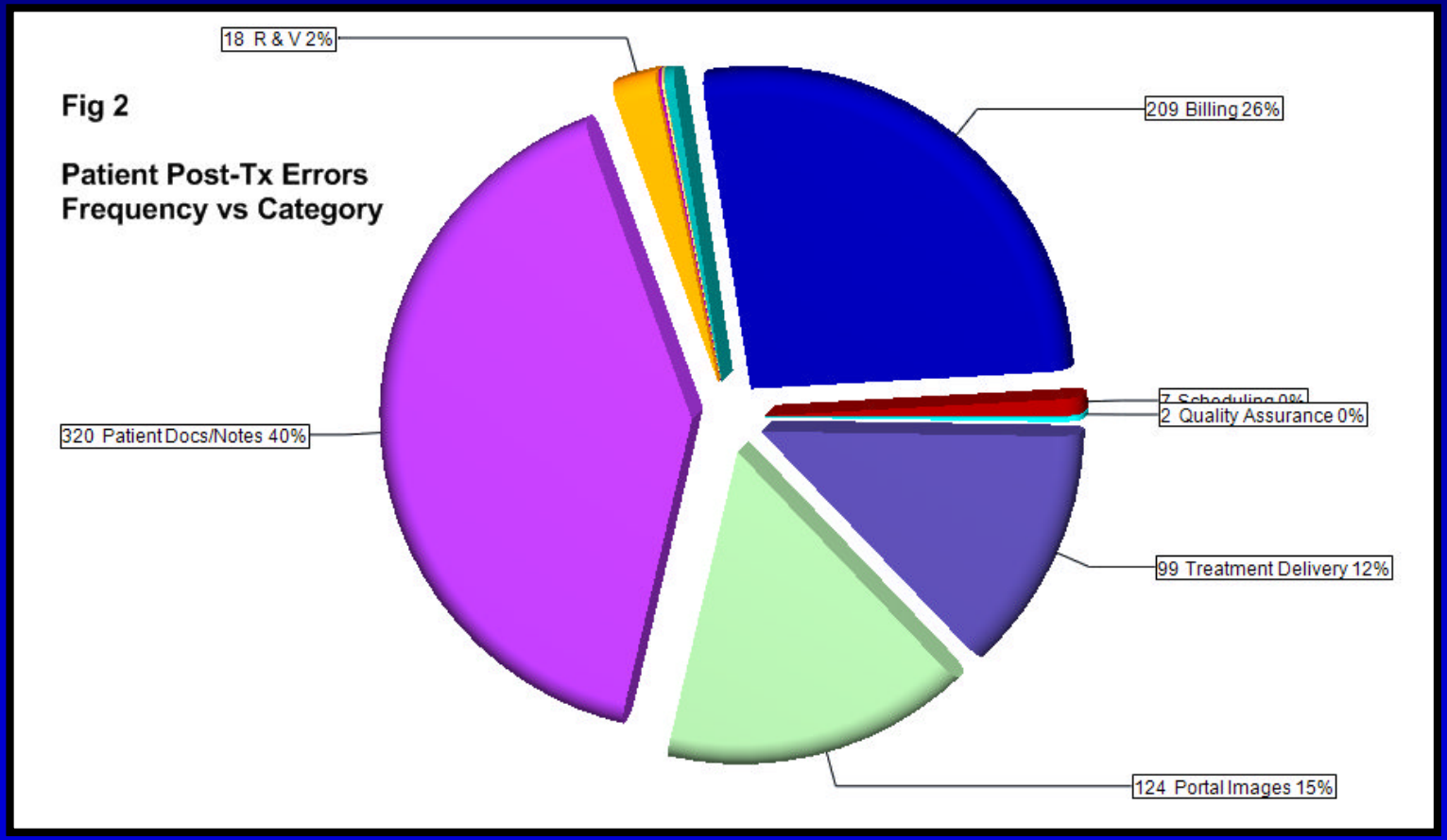
Paper Based System



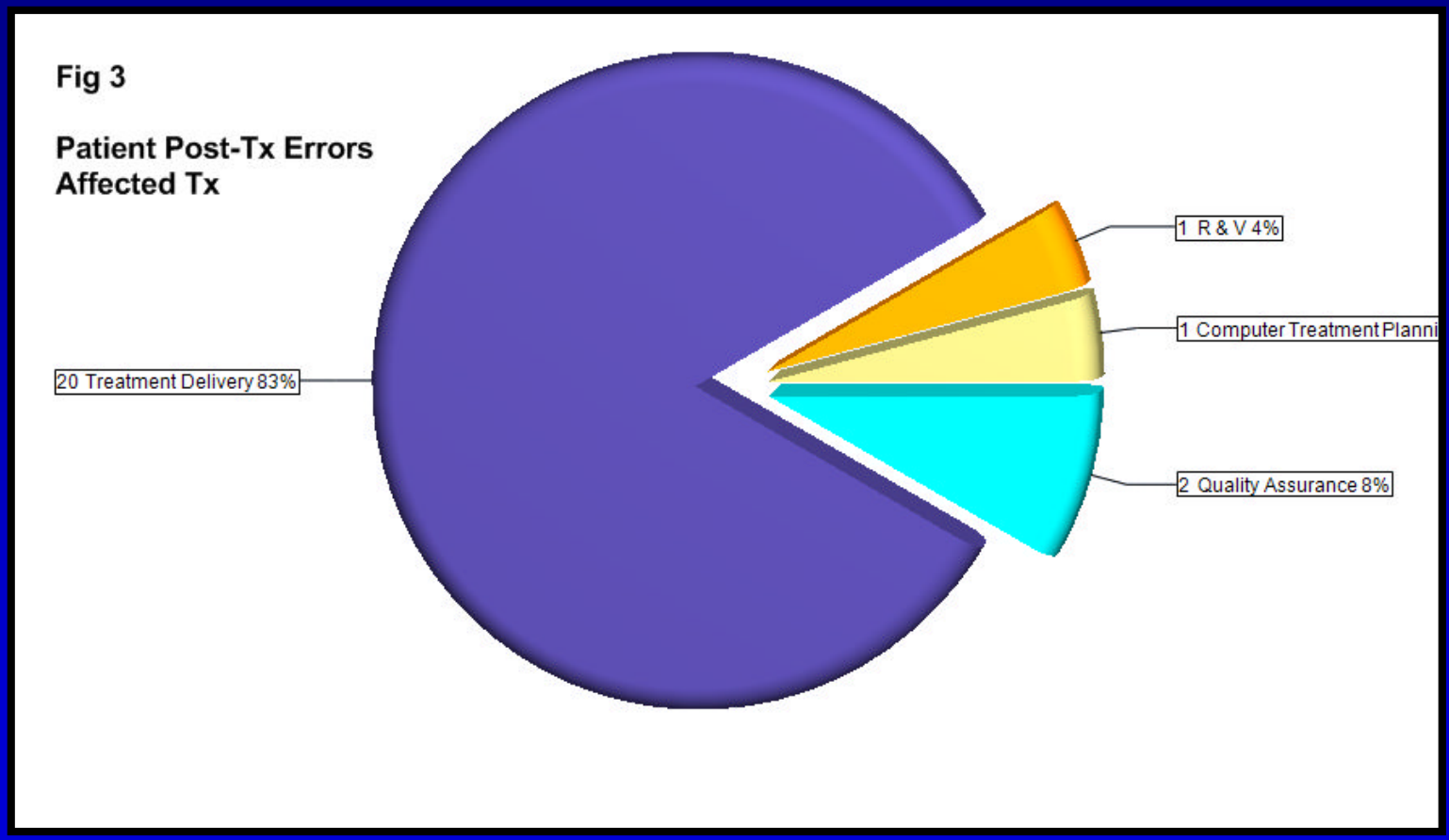
MERP Results



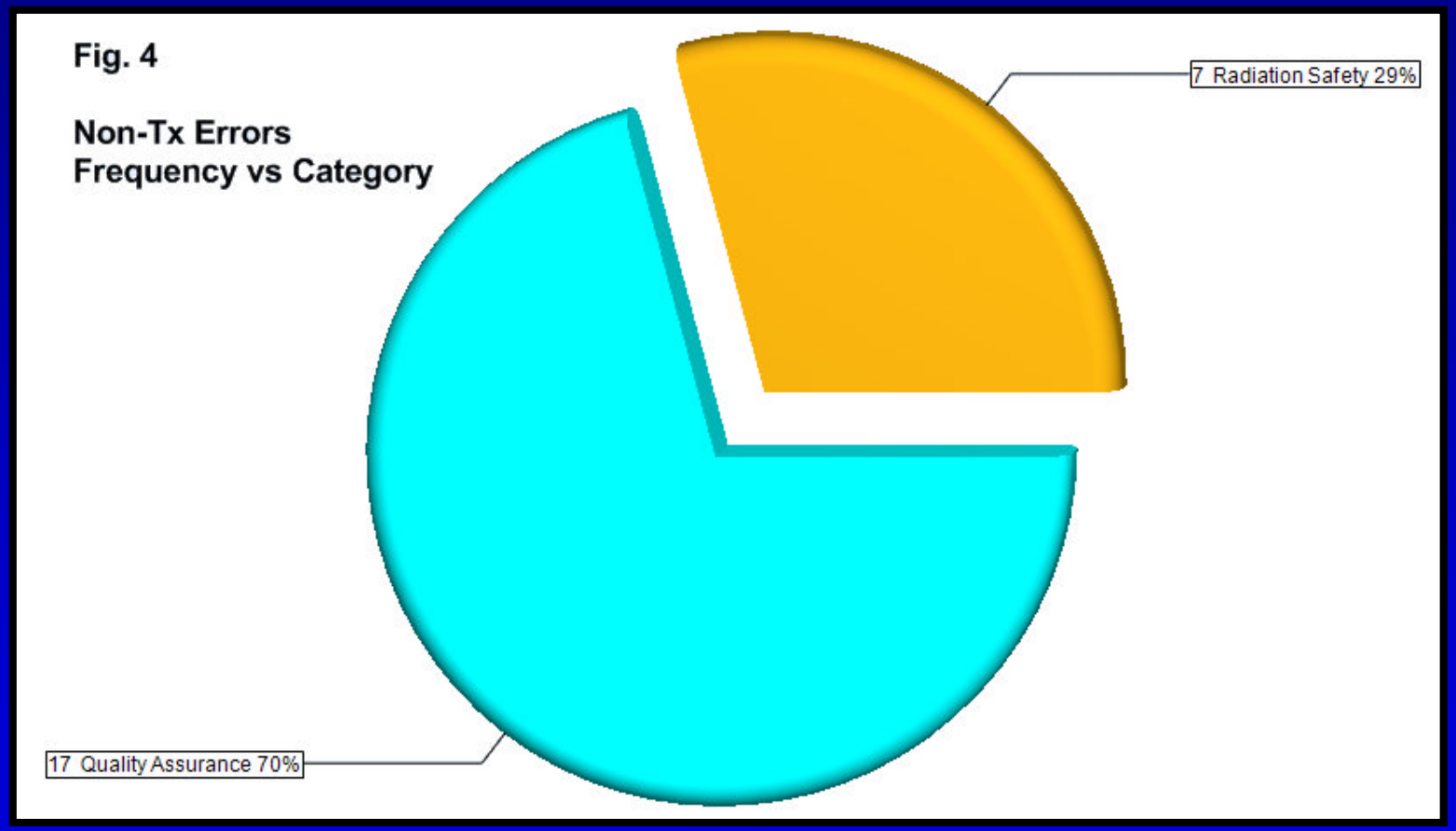
MERP Results



MERP Results



MERP Results

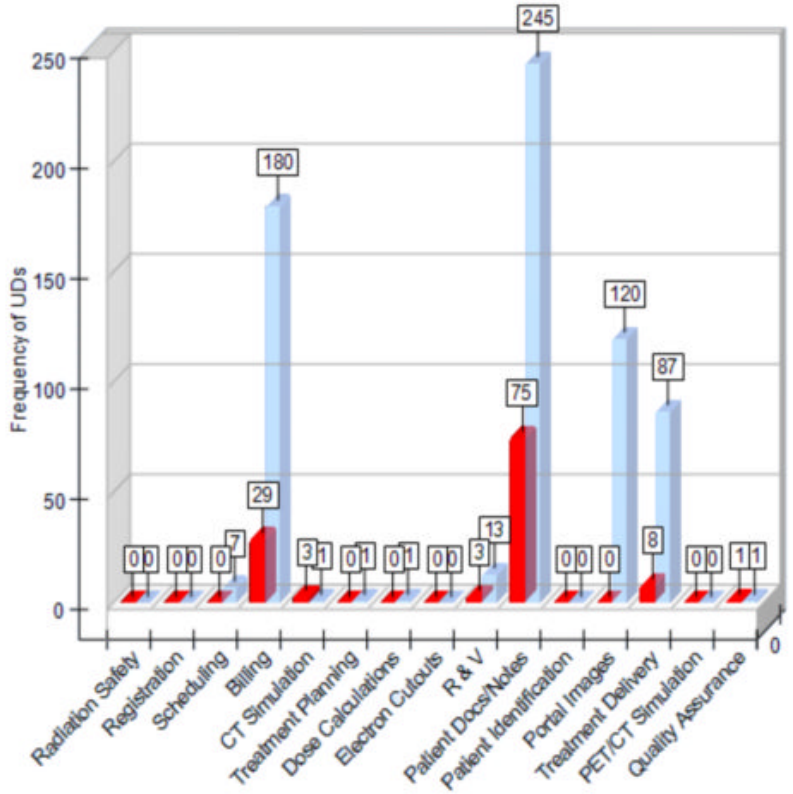


MERP Results

Fig 5

Patient Post-Tx Errors
Frequency vs Category

Beginning Year 2006
Ending Year 2007



Errors of Greatest Frequency

This screen shows you the list of all Errors which have been reported in this system in descending order of occurrence.

Select the Date Range for the query : Custom | Start Date 2/20/2006 | End Date 4/ 1/2008 | Search

Results

Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	141
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	112
Pre-Tx	R & V	Prescription	Electronic approval before 1st fx miss.	90
Post-Tx	Patient Docs/Notes	Simulation Notes	Tx planning sim note not completed	84
Post-Tx	Patient Docs/Notes	Simulation Notes	Field verification sim note not completed	74
Post-Tx	Patient Docs/Notes	Simulation Notes	Isocenter verification sim note not completed	60
Post-Tx	Patient Docs/Notes	Simulation Notes	CT sim note not completed	59
Post-Tx	Treatment Delivery	Patient Setup	RTT note incorr./miss.	50
Post-Tx	Billing	Audits	Final chart audits miss./late	47
Pre-Tx	R & V	Diagnosis	Diagnosis category (disease site) incorr./miss.	24
Pre-Tx	R & V	Diagnosis	Diagnosis type (new primary, recurrent) incorr./miss.	20
Post-Tx	Patient Docs/Notes	Simulation Notes	Special physics consultation request not completed	17
Pre-Tx	Computer Treatment Planning	Tx Plan	Tx plan not signed	17
Post-Tx	Billing	Codes	No. of charges incorr./miss.	12
Post-Tx	Patient Docs/Notes	Simulation Notes	Electron boost sim note not completed	11
Post-Tx	Portal Images	Electronic Imager	Weekly images not acquired	10
Post-Tx	Treatment Delivery	Patient Setup	Field setup photos incorr./miss.	10
Pre-Tx	CT Simulation	Patient Setup	Field note incorr./miss.	10
Pre-Tx	Scheduling	Appointments	Appointment activity incorr./miss.	10
Pre-Tx	Computer Treatment Planning	Tx Plan	Shifts from CT user origin to CAX incorr./miss.	9
Post-Tx	Treatment Delivery	Beam Modifiers	Bolus required, no bolus used	9
Pre-Tx	R & V	Treatment Field Definition	Field name incorr./miss.	8
Pre-Tx	Portal Images	Electronic Imager	Weekly images not approved	7
Pre-Tx	CT Simulation	Patient Setup	Sim note incorr./miss.	7
Post-Tx	Treatment Delivery	Patient Setup	Sim note incorr./miss.	7
Post-Tx	Patient Docs/Notes	Default	Initial consultation not completed	6
Post-Tx	Patient Docs/Notes	Default	Follow-up evaluation not completed	6
Post-Tx	R & V	Diagnosis	Diagnosis type (new primary, recurrent) incorr./miss.	6
Pre-Tx	Computer Treatment Planning	Tx Plan	DRRs incorr./miss.	6
Pre-Tx	CT Simulation	Patient Setup	Field setup photos incorr./miss.	5
Pre-Tx	Scheduling	Appointments	Appointment dates incorr./miss.	5
Pre-Tx	In-Room Treatment Setup	Fields	Immobilization device missing	5

Detailed Example of Above

Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	141
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	112
Pre-Tx	R & V	Prescription	Electronic approval before 1st fx miss.	90
Post-Tx	Patient Docs/Notes	Simulation Notes	Tx planning sim note not completed	84
Post-Tx	Patient Docs/Notes	Simulation Notes	Field verification sim note not completed	74
Post-Tx	Patient Docs/Notes	Simulation Notes	Isocenter verification sim note not completed	60
Post-Tx	Patient Docs/Notes	Simulation Notes	CT sim note not completed	59
Post-Tx	Treatment Delivery	Patient Setup	RTT note incorr./miss.	50

MERP Results

Error Rates in Treatment Delivery					
Error Category	**This Work Paper**	**This Work MERP**	**Frass et. al.**	**French**	**Grace et. al.**
Per Patient, %		3.2			1.97
Per Fraction, %		0.11	0.44	0.32	0.29
Per Field, %		0.0012	0.13	0.037	
Overall, %	0.052 [1]	0.0092 [2]		0.13 [3]	

[1] Errors per fraction [2] Errors per Tx field [3] Errors per total Tx units

MERP Results

Error Rates in Treatment Process[50] Using MERP			
Error Category	**Pre-Tx**	**Post-Tx**	**Pre-Tx + Post-Tx**
Per Patient, %	10.1	25.4	27.33
Per Fraction, %	0.34	0.85	0.92
Per Field, %	0.004	0.0092	0.01

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

MERP Results

Misadministration Rates			
Error Category	**This Work Paper**	**This Work MERP**	**US NRC**
Per Patient, %		0.065	
Per Fraction, %	0.017	0.0022	0.0042
Per Field, %		0.000023	

Lessons Learned With MERP Software Model

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

Conclusion

- The paper-based model identified 1,052 errors over 1.75 years and reduced error rate by 326%.
- Based on the experience gained from the paper-based model, a software-based medical error reduction program (**MERP**) was developed.
- **MERP** identified 1,122 errors over 2 years.
- **MERP** provides a non-intrusive and efficient means to address medical error reduction in a systematic manner while increasing efficiency and minimizing the occurrence of regulatory violations.