Error Reduction in Radiation Oncology

Experience with a Software Tool at Multiple Cancer Centers

by

Ed Kline

Acknowledgements

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

PHILADELPHIA CANCER TREATMENT Radiation Oncology Center

Located in Philadelphia, PA

NMCC New Mexico Cancer Center

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]

[1] Hurt ado 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, Aarons 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.

[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
1999

- Institute of Medicine (IOM) report[6]
  - 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
1999

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

[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
1999

- Healthcare Research and Quality Act of 1999[9]
  - Required Agency for Healthcare and Research (ARHQ) to support research and build private-public partnerships
    - Identify causes of preventable health care errors & patient injury
    - Develop, demonstrate, and evaluate strategies for reducing errors & patient injury
    - Disseminate such strategies

[9]*Advancing Patient Safety – A Decade of Evidence, Design, and Implementation*, Agency for Healthcare Research and Quality, U.S. Department of Health & Human Services, Accessed through www.ahrq.gov/qual/advptsafety.htm .

History
1999

- Federal initiatives[10] taken by former President Clinton on 2/22/00 based on IOM recommendations[11]
  - Comprehensive strategy to reduce medical errors
  - Creation of external reporting systems
  - Creation of national patient safety centers

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

[11]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).

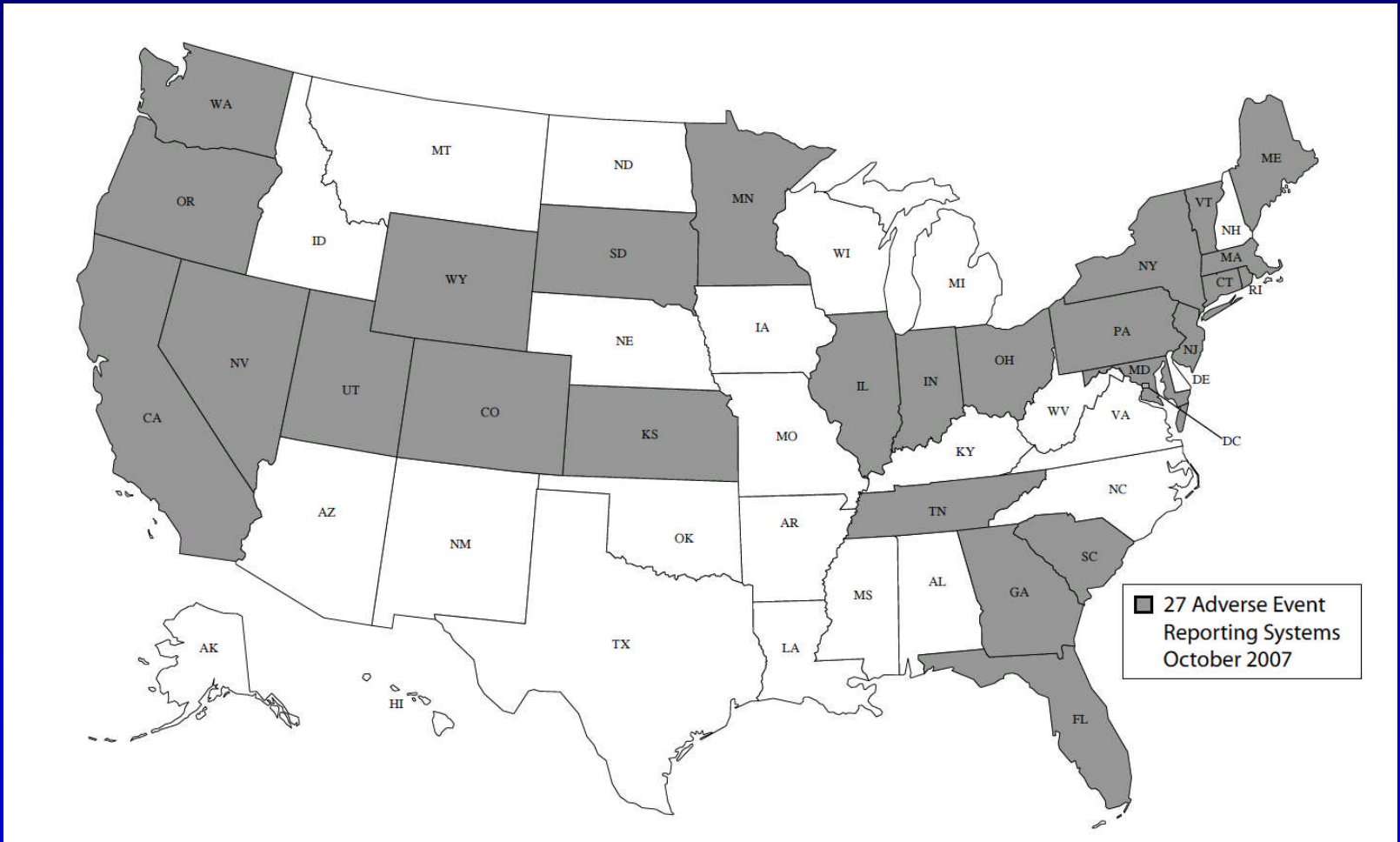
History
2000

- Key legislation
  - Patient Safety and Quality Improvement Act[12]
    - Certifies patient safety organizations in each State to collect data and report on medical errors
  - State Patient Safety Centers[13]
    - Since 2000, 27 states & DC have passed legislation or regulations related to hospital reporting of adverse events to state
    - Mandatory reporting systems for serious adverse events
    - National Academy for State Health Policy's directive:
      - States MUST **Demand Quality and Efficiency from Health Care System**

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

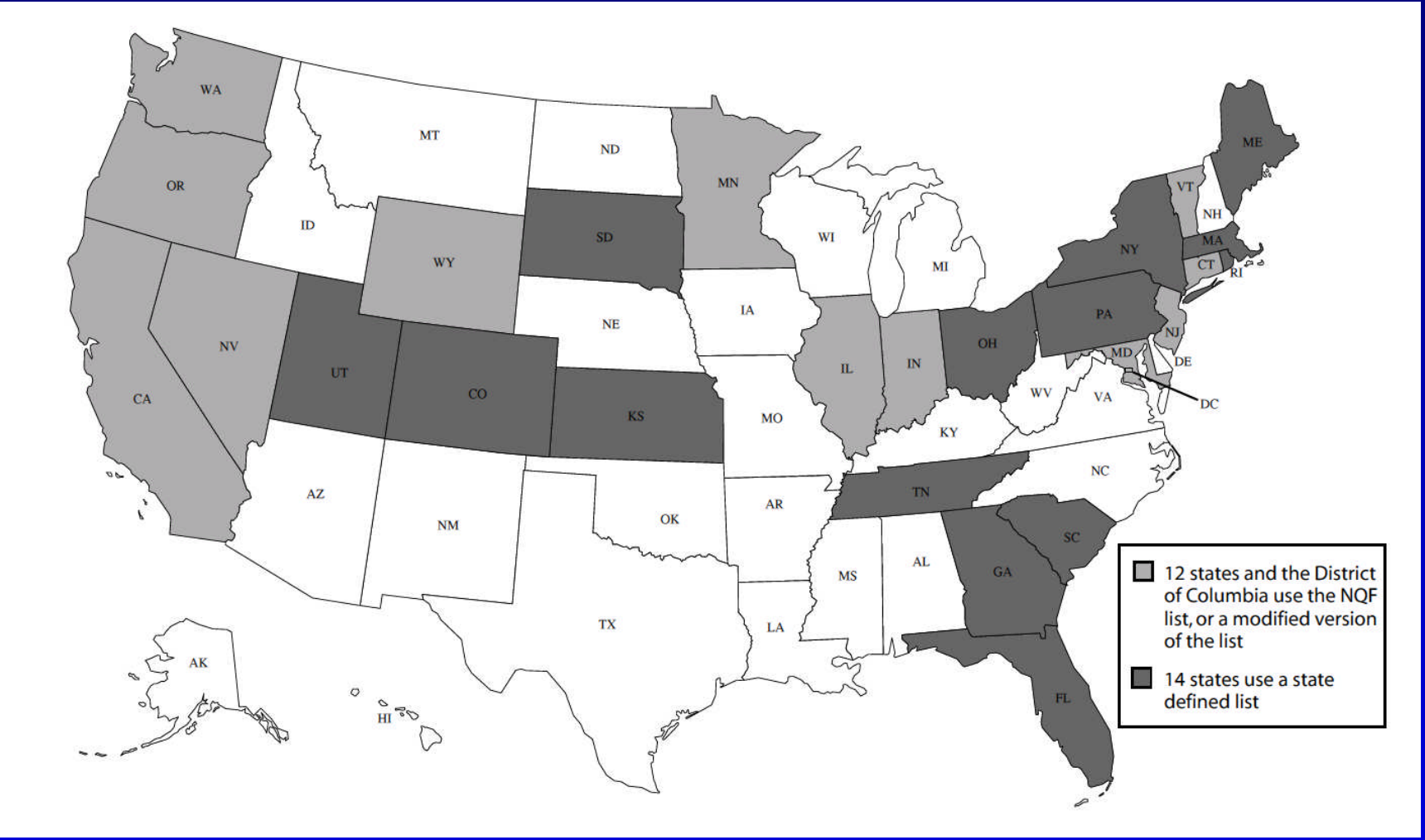
[13]*uthorizing Statues and Regulations*, National Academy for State Health Policy, Accessed September 28, 2010 through www.nashp.org.

Authorized Adverse Event Reporting Systems, 2000 to October 2007[14]



[14]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 Systems[15]



[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.

History

2000 to Present

- Patient safety advisory groups created[16]
  - 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)

[16]*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
2001

- JCAHO revises standards[17]
  - 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[18]
- JCAHO's sentinel event policy[18]
  - Identify sentinel events
  - Take action to prevent their recurrence
  - Complete a thorough and credible root cause analysis
  - Implement action plan

[17]*Patient Safety - Essentials for Health Care*, 2nd edition, Joint Commission on Accreditation of Healthcare Organizations. Oakbrooke Terrace, IL: Department of Publications, 2004.
[18]*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
2002

- National Quality Foundation (NQF)[19]
  - Issued list of 27 serious ("never") reportable events
  - State Medicare programs no longer reimburse providers for events

[19] *A National Survey of Medical Error Reporting Laws*, Yale Journal of Health Policy, Law, and Ethics, 2008.

History
2003

- AHRQ establishes safety indicators (PDIs)[20]
  - Measuring & monitoring tool
  - 20 hospital level & 7 regional measures
- AHRQ *WebM&M*
  - Online forum & journal for patient safety & quality issues

[20] *Advancing Patient Safety – A Decade of Evidence, Design, and Implementation*, Agency for Healthcare Research and Quality, U.S. Department of Health & Human Services, Accessed through www.ahrq.gov/qual/advptsafety.htm .

History
2004

- JCAHO's Office of Quality Monitoring
  - Receives, evaluates and tracks complaints and reports of concerns about health care organizations
  - Unannounced on-site evaluations
- JCAHO and CMS agreement[21]
  - Working together to align Hospital Quality Measures (JC's ORYX Core Measures and CMS'7th Scope of Work Quality of Core Measures)

[21] *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
2005

- CMS quality incentives[22]
  - Quality Improvement Organizations (QIOs)
    - Contracted by CMS to operate in every State
    - 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

[22] *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
2005

- CMS quality incentives
  - Medicare/State Children's Health Insurance Program (SCHIP) Quality Initiative
  - Pay-For-Performance (P4P)[23]
    - 12 states have adopted some form
      - Performance measurement
      - 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
2005

- CMS quality incentives
  - Medicare Value Purchasing (MVP) Act of 2005. Requires Medicare implement a P4P program covering at least a portion of payments made.[24]
  - 104 P4P provider programs in US in 2005[25]
    - P4P attempts to "introduce market forces and competition to promote payment for quality, access, efficiency, and successful outcomes."
    - P4P to extend beyond HMOs to include specialties, PPOs, self insured, and consumer-direct programs.

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

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

History
2005 - 2006

- CMS quality incentives
  - CMS consumer website
    - CMS contracted with NQF & worked with JCAHO to develop hospital quality measures for public reporting
    - Hospital quality data became available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
  - Data indicators[26]
    - Hospitals reporting quality data to Medicare receive 3.7% increase in inpatient payments
    - Non-reporters receive 3.3% increase
    - Starts with 10 quality indicators for cardiology
    - Expand into other disciplines

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

History
2006

- CMS quality incentives
  - 2006 Physician Voluntary Reporting Program[27]
    - 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

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

History
2007

- CMS quality incentives
  - 2007 Physician Quality Reporting Initiative (PQRI)[28]
    - Financial incentive to participate in voluntary reporting
      - 77 evidence-based quality measures
      - Bonus payment of 1.5%

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

History
2008 - 2009

- National Priority Partnership (NPP) in 2008[29]
  - Deemed 1 of 6 national priorities
  - 555 endorsed measures
  - Approx. 100 measures related to patient safety
- NPP in 2009 endorsed
  - 34 safe practices (*Safe Practices for Better Healthcare*)
  - 28 serious reportable events

[29]*Patient Safety Measures - National Voluntary Consensus Standards for Patient Safety*, Accessed thru www.qualityforum.org.

History
2008 - 2009

- CMS quality incentives
  - 2008 PQRI[30]
    - Physicians report on 119 quality measures
      - 2% incentive payment
    - New tracking of 5 quality measures in adoption of healthcare information technology (EMR)
      - 2% additional for e-prescribers
    - PQRI data available for public WITH performance rates
  - 2009 PQRI[31]
    - A total of 153 quality measures
      - 2% incentive payment
    - E-prescribing removed, separate incentive program

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

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

History
2010

- CMS quality incentives
  - 2010 PQRI[32]
    - 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

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

Ongoing Mandates

- Tax Relief and Health Care Act of 2006[33]
  - 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

[33] *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 requirements to comply with QAPI[34]
  - 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

[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

- How do hospitals comply?[35]
  - 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

[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

- No Charge Policy Effective 2008
  - State associations have/are looking at policy where hospitals will discontinue billing patients and insurers for medical errors[36]
    - Colorado, Massachusetts, Michigan, Minnesota, and Vermont
  - CMS no longer pays for 10 "reasonably preventable" conditions caused by medical errors
  - AETNA no longer pays for 28 so-called "Never Events"[37]
  - Wellpoint (nation's largest insurer by membership) no longer pays for serious medical errors[38]

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

Future Incentive

- Secretary of HHS Quality Incentive
  - Value-Based Purchasing Program in 2012[39]
  - 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

[39]*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 patients[40]
  - 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)

[40] *HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals*: March 2010, accessed thru www.healthgrades.com.

US Grades

- Large safety gaps[41]
  - Patients treated at top-performing hospitals
    - On average, 43% lower chance of medical errors vs. poorest-performing hospitals
- 400,000 preventable drug-related injuries occur each year in hospitals costing $3.5 billion[42]
- Medical errors cost $50 billion a year in avoidable medical expenses – approximately 30% of all health care costs[43]

[41]*HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals*: March 2010, accessed thru www.healthgrades.com.

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

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

US Grades

- Has patient safety improved?[44]
  - 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 [QAPI] 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"

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

Canada Grades

- 185,000 adverse events occur annually in Canadian hospitals[45]
  - 70,000 preventable
    - 9,000 to 24,000 people die each year[46]
- Approximates a 7.5% error rate
- Similar rates found in other countries

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

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

Medical Errors

- In U.S., adverse events occur to approx. 3 - 4% of patients[47]
- Average intensive care unit (ICU) patient experiences almost 2 errors per day[48]
  - Translates to level of proficiency of approx. 99%
  - Sounds good, right?
  - **NOT REALLY**
- If performance levels of 99.9%, substantially better than found in ICU, applied to airline & banking industries, this equates to:
  - 2 dangerous landings per day at O'Hara International Airport, and
  - 32,000 checks deducted from the wrong account per hour.[49]

[47, 48, 49] *Doing What Counts for Patient Safety - Federal Actions to Reduce Medical Errors and Their Impact*. Access thru www.quic.gov.

Medical Errors

- OIG thru Department of Health & Human Services[50]
  - Pilot study "Adverse Events in Hospitals: A case Study of Incidence Amongst Medicare Beneficiaries in Two Counties"
    - Estimated 15% of hospitalized Medicare beneficiaries in 2 counties experienced adverse events
    - Resulted in harm during their hospital stay
    - Another 15% experienced less serious occurrences "temporary harm events"

[50] *Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services, Office of Inspector General, March 2010.

Medical Errors

- Underreporting of adverse events is estimated to range between 50 – 60% annually[51]
- No "comprehensive nationwide monitoring system" exists for medical reporting[52]
- Recent attempts to estimate error rates show little improvement in actual error incidence nationwide[53]

[51]*Reporting and Preventing Medical Mishaps: Lessons Learned from Non-Medical Near Miss Reporting Systems*, BMJ, Vol. 320, March 18, 2000.
citing Agency for Healthcare Research & Quality, 2004.
[52, 53]*National Survey of Medical Error Reporting Laws*, Yale Journal of Health Policy, Law, and Ethics, 2008, citing Agency for Healthcare Research & Quality, 2004.

Radiation Oncology Errors

- Not well established
- No comprehensive numbers available for number of errors resulting in death[54]
- Reported error rates range 0.1% to 0.2% of fields treated[55]
- Studies not relying on self-reporting show actual rates of up to 3%[56]

[54, 55, 56] 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 2007[57]
  - 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

[57]WHO – 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."[58]

[58]ICRP. *Radiological Protection and Safety in Medicine*. ICRP 73. Annuals 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, REAC/TS Radiation Incident Registry, 1999	1974-1976	Overdose (+10 to 55%)		**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	**18 - 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

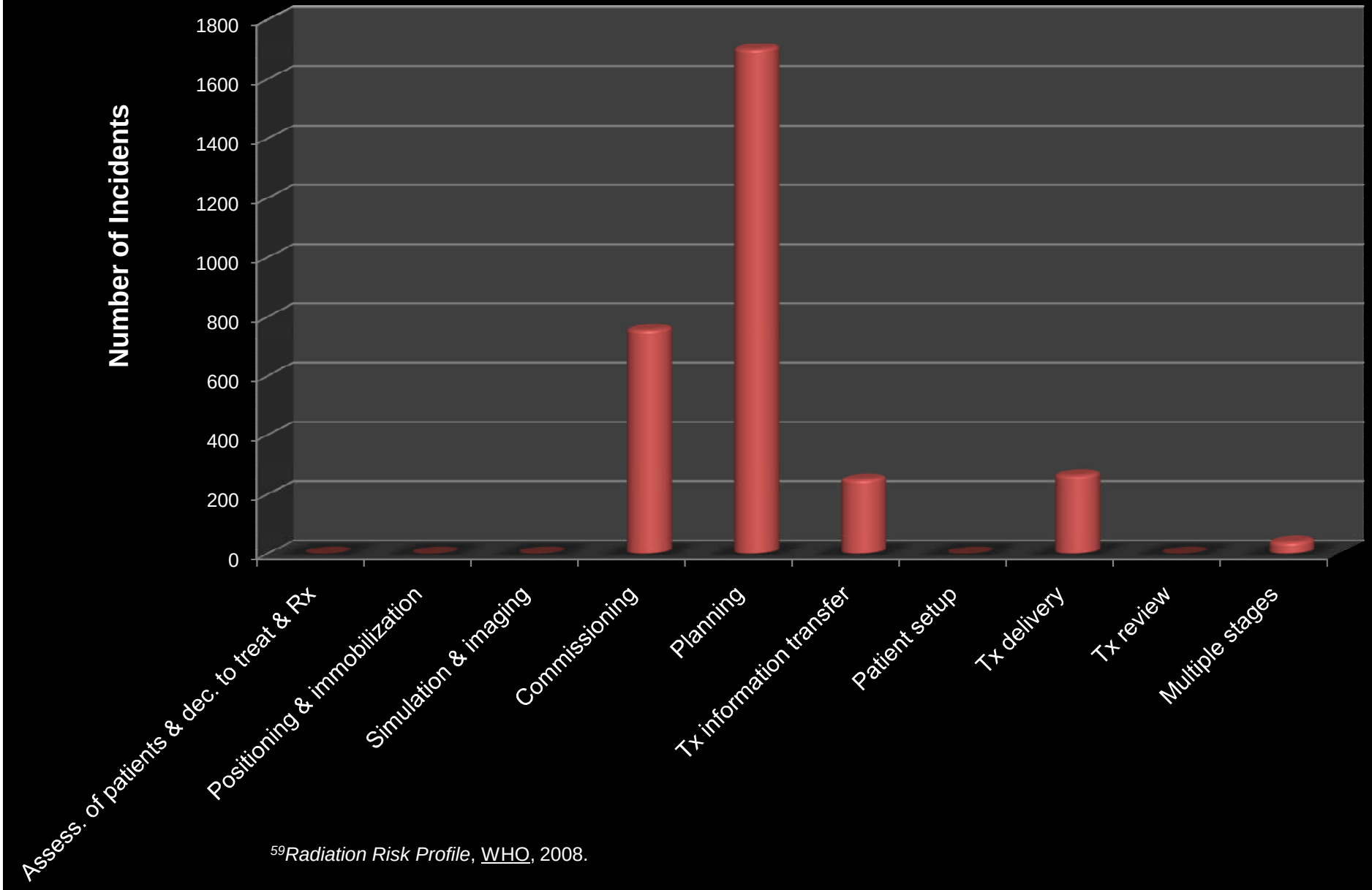
Adverse Events in Radiation Oncology

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 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 conseq.**	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	**5 - 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.

Adverse Events[59] N = 3125

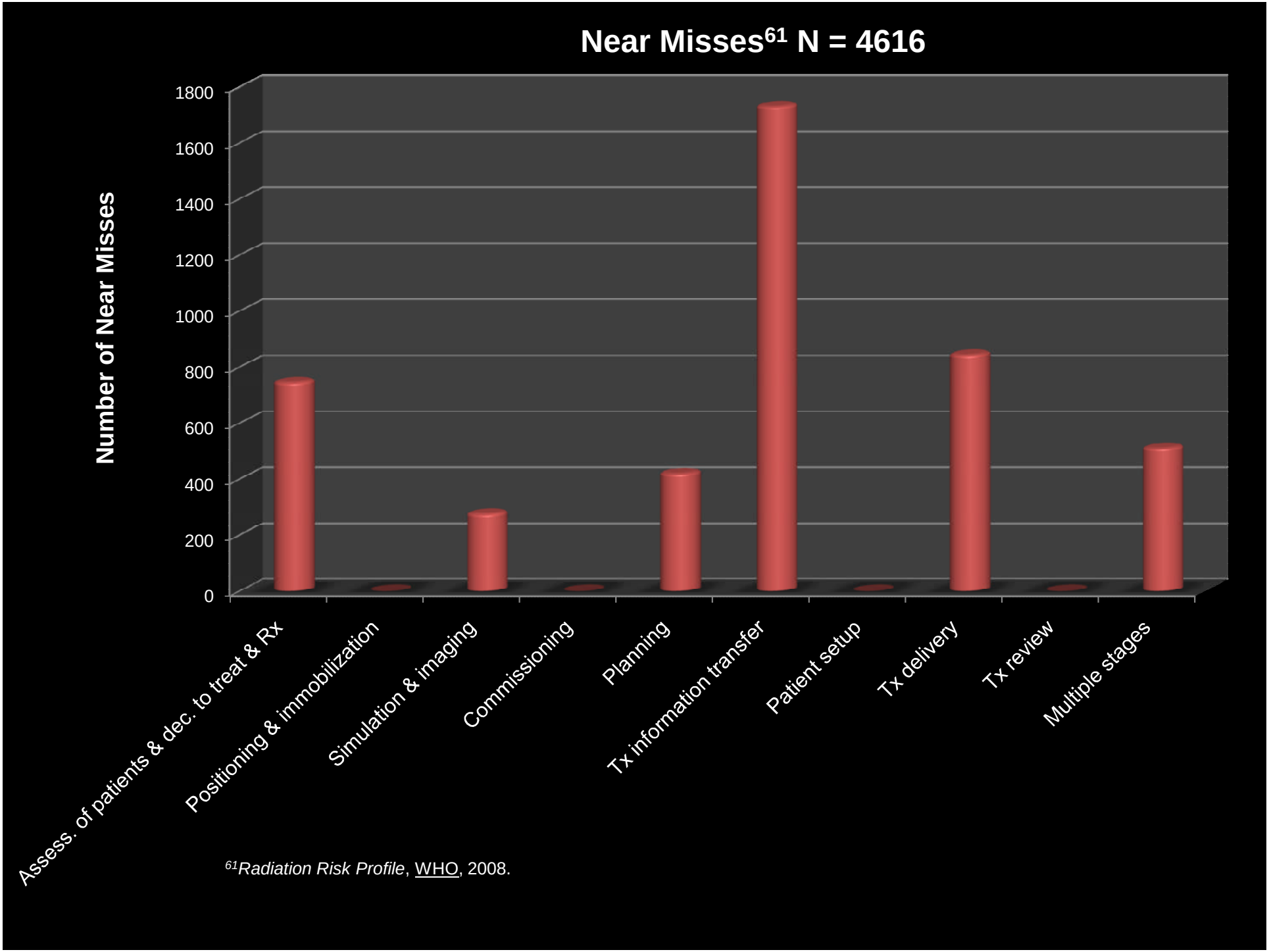


[59]*Radiation Risk Profile*, WHO, 2008.

Near Misses in Radiation Oncology

- Near Misses[60]
  - 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)

[60] *Radiation Risk Profile*, WHO, 2008.



[61] *Radiation Risk Profile*, WHO, 2008.

Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
UK	Sutherland WH, Topical Reviews in Radiother and Oncol, 1980	Over 6 years between 1970-1980					- Potential mistakes (found in checks): 4,122 - Potential errors of >5% from Rx dose: 742	**2.1% - 4% per year**
US	Swann-D'Emilia B, Med 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**
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	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
France	Noel A, et al., Radiother Oncol, 1994	5 years					Of 7519 treatments: 79 total errors - Of 79, 78 are human origin - Of 78, 39 would have > 10% dose Δ	**1.05%: errors per treatment**
Canada	Yeung TK, Abstract-NEORCC, 1996	1994						**3.3%**
US	Kartha 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%: error rate/field**
US	Fraas BA, et al., Int J Radiat Oncol Biol Phys, 1998	7/96-9/97		~34,000	~114,000			**0.44%: Tx fractions** **0.13%: Tx fields**
Belgium	Barthelemy-Brichant N, et al., Radiother Oncol, 1999	6 months					147,476 parameters examined: - 678 (0.46%) set incorrectly	**3.22%: of all delivered Tx fields had at least 1 error**

Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Canada	Pegler R, et al., Abstract-Clin Invest Med, 1999	2 years						**0.12 - 0.06%**
US	Pao WJ, et al., Abstract-ACSO, 2001	6 years	17,479 avg./yr.					**0.17% avg./year per patient**
Canada	French J, Radiat Ther, 2002	1/1/96-9/31/01	11,355	195,100	483,741	631	177 total incidents - 20: correctable - 129: noncorrectable and clinic. sig. - 28: noncorrectable and potentially clinically sig.	**0.13%: all units (fields tx'ed incorrect/ total no. fields tx'ed)** **0.32%: errors/fraction** **0.037%: errors/field**
US	Patton G, et al., Radiat Oncol Biol Phys 2002	1 year	22,542					**0.17%: errors/Tx**
Ireland & Sweden	Holmberg O, et al., J of Radioth Ther, 2002	3 years	15,386 Tx plans				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	11/92-12/02	13,385				624 incidents - 42.1%: documentation errors (data transfer/com-munication) - 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 1st Tx**
Canada	Huang G, et al., Int J Radiat Oncol Biol Phys, 2005	1/1/97-12/31/02	28,136				555 total errors	**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**
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

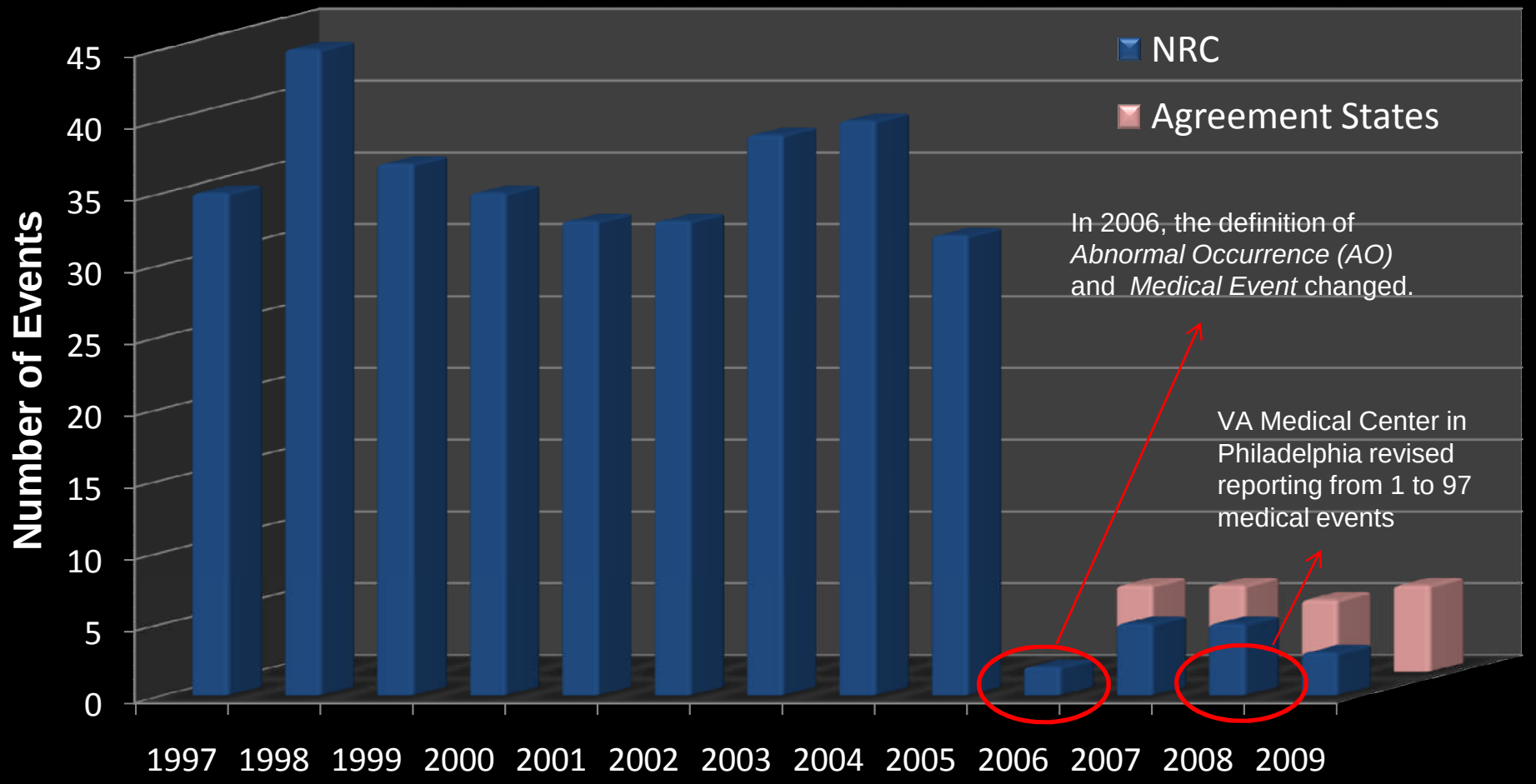
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Italy	Baiotto B, et al., J of Experi & Clinical Oncol Tumori, 2009	10/00 – 12/06	7,768	34,114	148,145		452 errors Error types: - 2.2%: general - 3.3%: dosimetric - 4.2% delivered dose	**0.69%: 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?[62]

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%

[62] *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 - 1/2009[63]		
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%**

[63]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 - 1/2009[64]

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%**

[64]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 - 1/2009[65]		
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%**

[65]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 unified error reduction and continuous improvement program
- Minimize occurrence of errors identified in patient treatment process and regulatory arenas
- Implement at 17 geographically dispersed radiation oncology clinics in 9 states

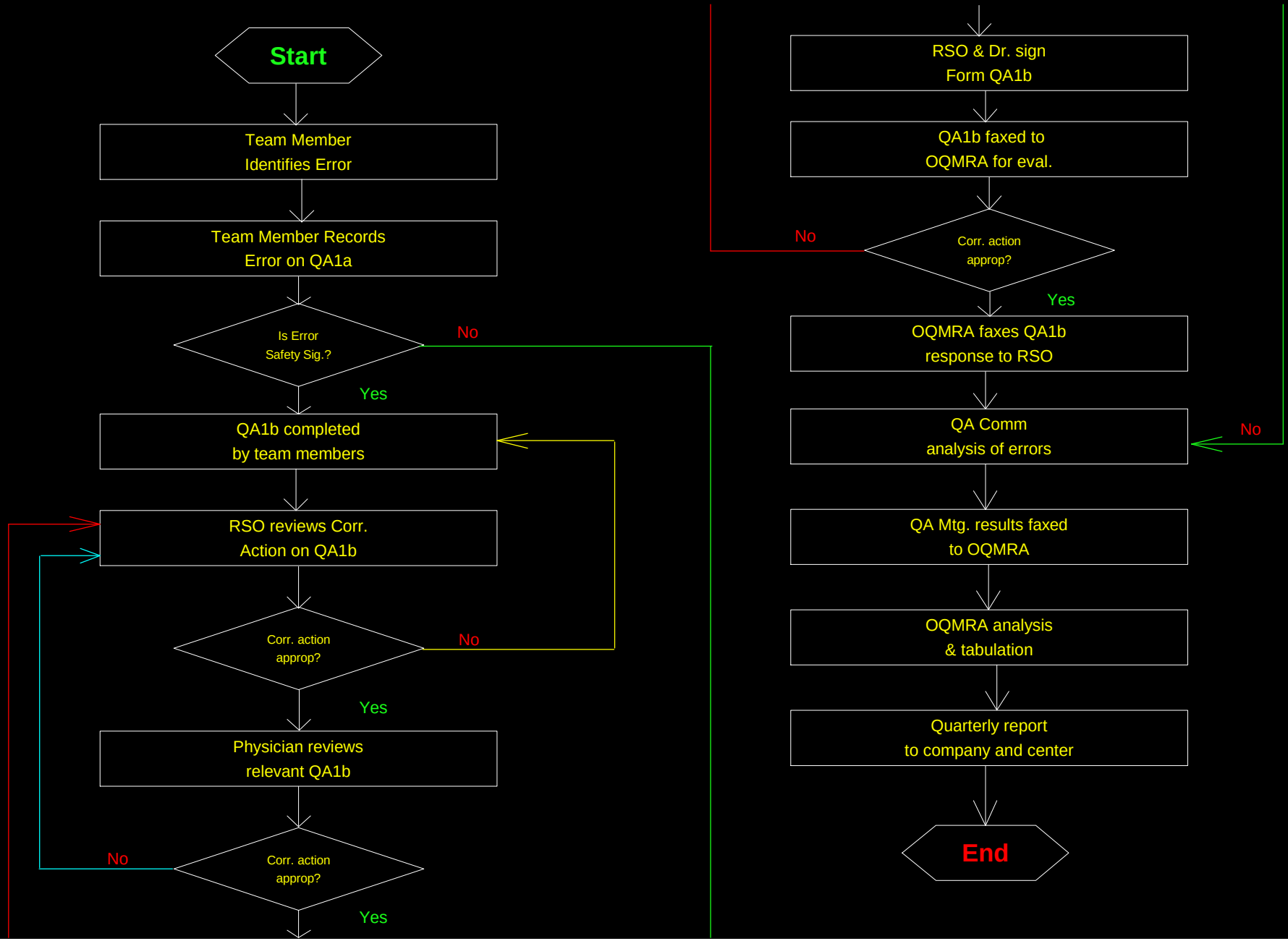
Design of a Paper-Based Model

- Establish consistent set of QA procedures
- Analyze process of delivering radiation therapy
- Identify steps used in all aspects
- Develop reporting codification system for errors
- Develop staging system for classifying importance of the error (SL 1 - 5)
- Develop appropriate forms and procedures for reporting errors

Design of a Paper-Based Model

- Provided an internal, independent feed-back mechanism of action plan to close the loop
- Produced a quarterly report summarizing errors/violations
- Broadcast action plans company wide

Unintended Deviation Reporting Process



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

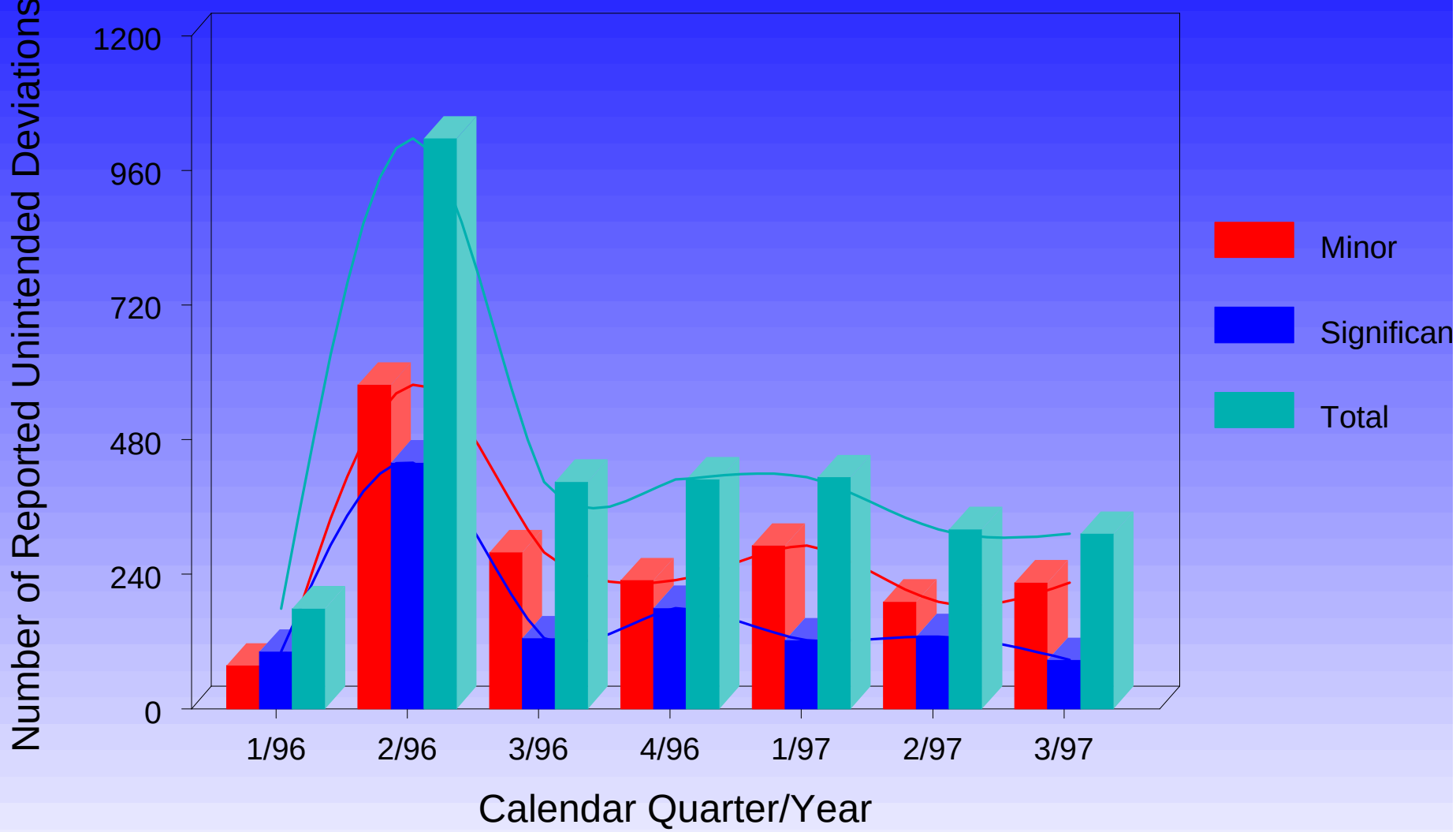
Code	Identified	Description/SL/Process/Resp. Party
Patient Simulation		
Patient Setup		
1310		Pt position not iso. to midline (SAD) 3 ◆ T
1311		Pt position not to specified SSD 3 ◆ T
1320		Missing AP SSD 2 ◆ T
1321		Missing PA SSD 2 ◆ T
1322		Missing RL/Medial SSD 2 ◆ T
1323		Missing LL/Medial SSD 2 ◆ 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.*

Summary of Total Unintended Deviations



Summary of Results

Paper-Based Model: 1/96 – 3/97

- Overall average error rate was 0.052% (SL 1 – 5)
- Calculated misadministration rate[66] was 0.018%
- Actual misadministration rate was 0.017%
- NRC speculated 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**
- Physician malpractice insurance premiums for 17 oncology centers were reduced by 10%

[66]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
  - 3 potentially significant treatment errors
  - If left undetected, would have required reporting to the State
  - 1 misadministration that occurred was mitigated by the State based on evidence it was an isolated event

Other Center Studies

Paper-Based Model

Summary of Results - 2002

Cancer Center #1

- The total decrease in errors between the 2nd and 4th quarters was **78.4%** (334 vs 72).

Cancer Center #2

- The total decrease in errors between the 2nd and 4th quarters was **72.6%** (113 vs 31).

Lessons Learned

Paper-Based Model

Problems?

- Inefficient
- Time sink
- Lots of paper
- Learning process
- Faxing
- Tabulating data
- Generating reports
- Disseminating action plan
- Broadcasting events

Software-Based Model

Design of Software-Based Model

Approach

- Automation
- Ease in data gathering
- Standardization in data collection
- Scoring of risk (FMEA)
- Immediate analysis
- Short & long-term corrective actions
- Tracking & trending
- Automated report launching

Features of Software-Based Model

Specifics

- **Performance Measures**
  - Clinical
  - QA
  - Radiation Safety
- **Identification of Errors**
  - Standardized error codes
  - Pre and post-treatment errors
  - Severity levels (I - V)
  - Calculation of *Risk Priority Number (RPN)*
  - Clinical significance settings
- **Identification of Errors (conti.)**
  - Significant unintended deviation settings
  - "Near Miss“ designation
  - Sentinel events
  - Analysis of patterns and trends
  - Recordable events
  - Medical events (misadministrations)
  - Regulatory violations
  - Possible regulatory violations

Features of Software-Based Model

Specifics

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

Features of Software-Based Model

Specifics

- **Reports and Chart Generation**
  - Characterizes errors and action plans
  - Stratifying error types, severity levels, RPN
- **Audit Tool**
  - Verify regulatory performance
    - Complies with State radiation safety requirement for annual reviews
    - Satisfies State QMP rule for annual reviews
    - Complements CMS compliance objectives
    - Meets JCAHO standards

Features of Software-Based Model

Specifics

- **Customization**
  - Create data collection areas for performance improvement
    - Categories
    - Subcategories
    - Attributes
  - Designate error routing review/approval order
  - Assign which errors violate State requirements
  - Designate severity, RPN, and clinical significance
- **Regulation/Standards/Recommendations Referenced by Code**
  - JCAHO 2010 patient safety standards
  - ACR and ACRO standards
  - CRCPD (Agreement State) recommended radiation safety regulations show legal text

Software Implementation Strategy

Preparation

- **Step #1 - Process**
  - Created manual
  - Drafted step-by-set procedures
  - Addressed technical delivery system
    - QA
    - Radiation safety
    - QMP
- **Step #2 - Training**
  - Provided classroom hours
    - 18 hours in procedures
    - 6 hours in software
  - Given at new center start-up (center A) and over 1 hour lunch break (Center B)
  - Took 3 days (Center A) vs 2 months (Center B)
  - Issued ASRT category ‘A’ credit
  - Complied with annual state radiation safety training requirements

Software Implementation Strategy

Phased Rollout

- **Step #3 - Superusers**
  - Designated point guards
    - Supervised data input
    - Tracked status of errors
    - Tracked completion of action plans
- **Step #4 - Phases**
  - Group 1
    - Therapists
    - CT therapists or technologists
    - Physics (physicists & dosimerists)
    - Billing
  - Group 2
    - Radiation oncologists
  - Group 3
    - Admissions/registration staff

MERP Results

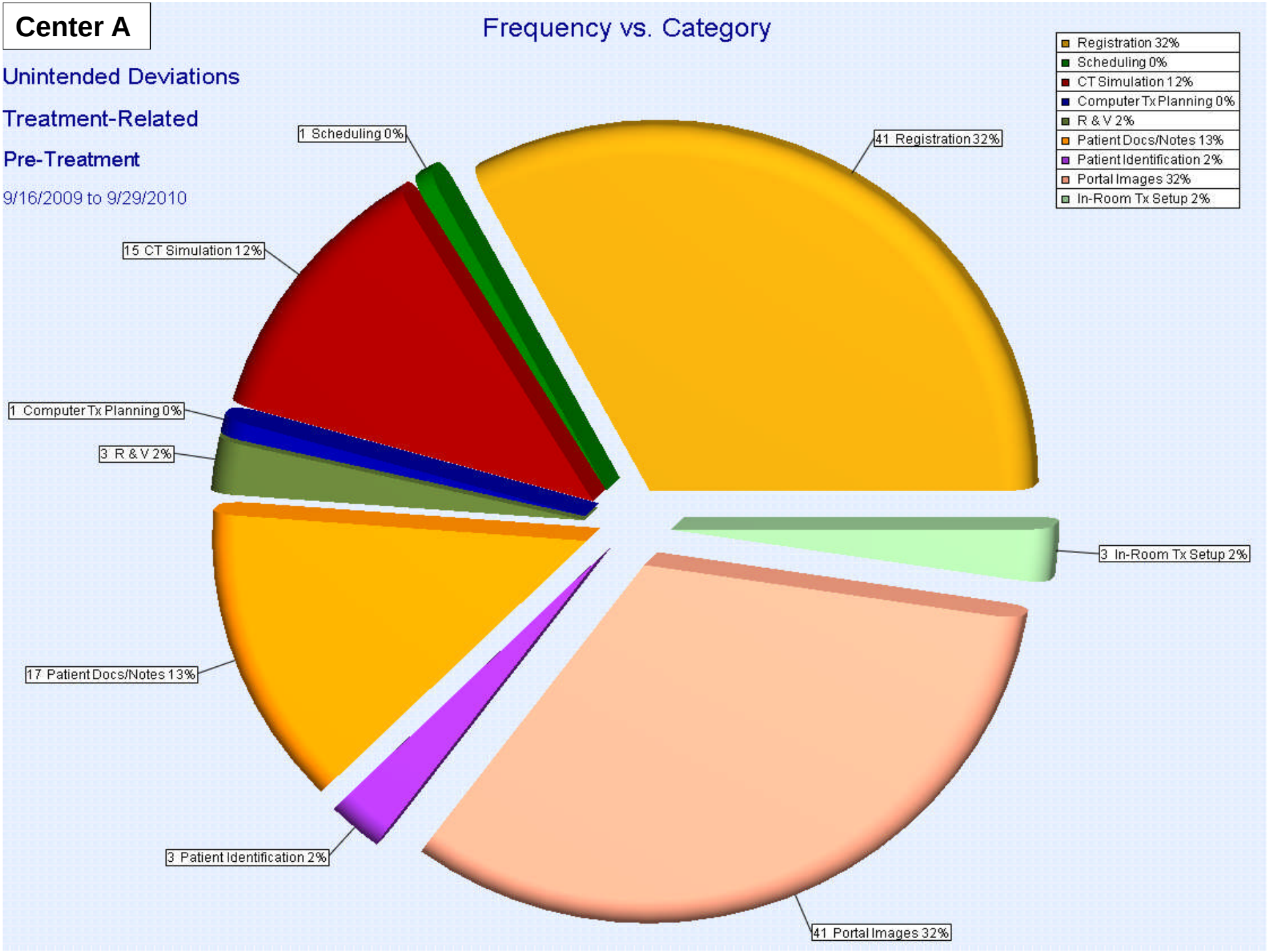
Center A

Unintended Deviations

Treatment-Related

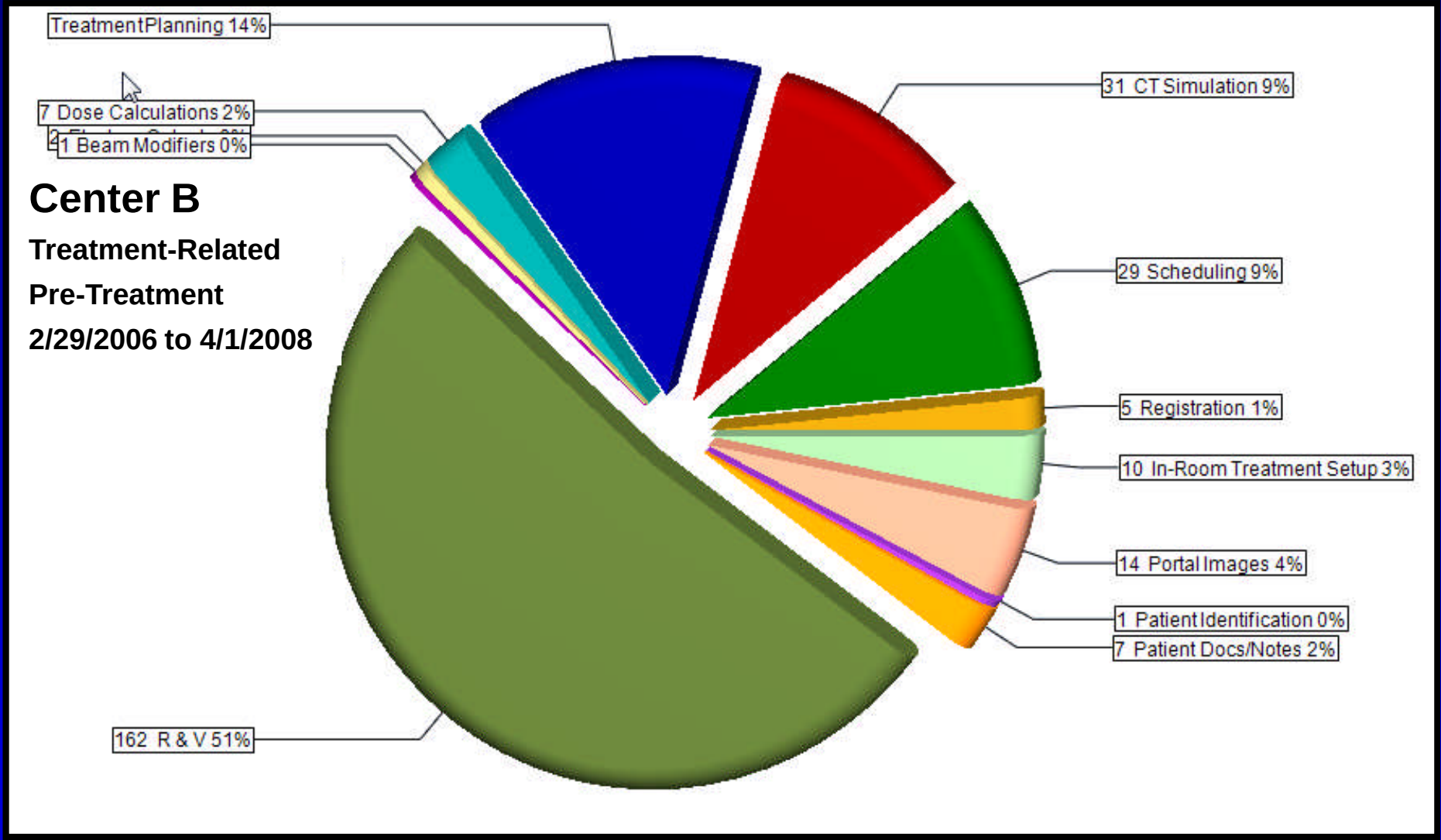
Pre-Treatment

9/16/2009 to 9/29/2010



MERP Results

Center B



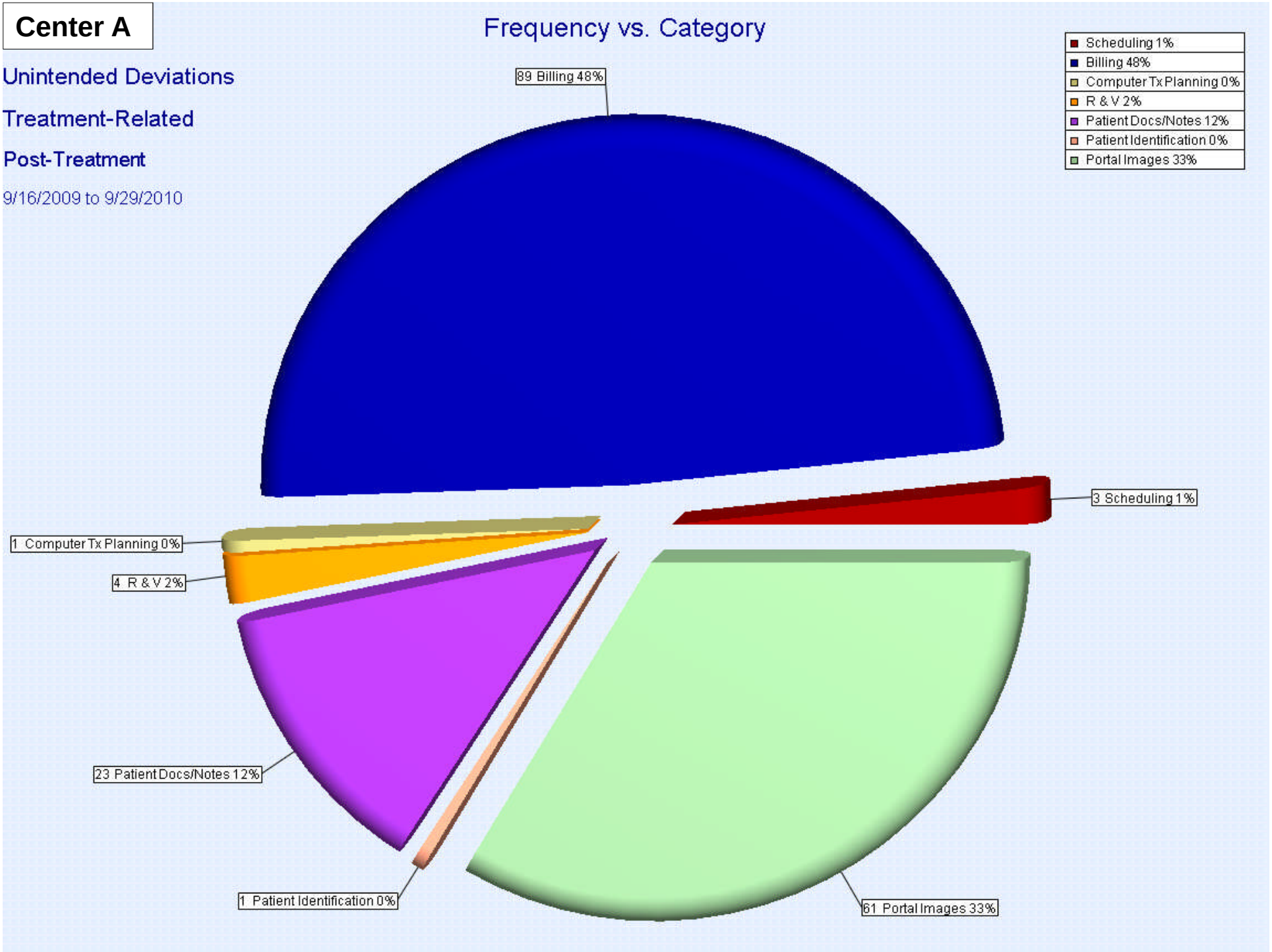
Center A

Unintended Deviations

Treatment-Related

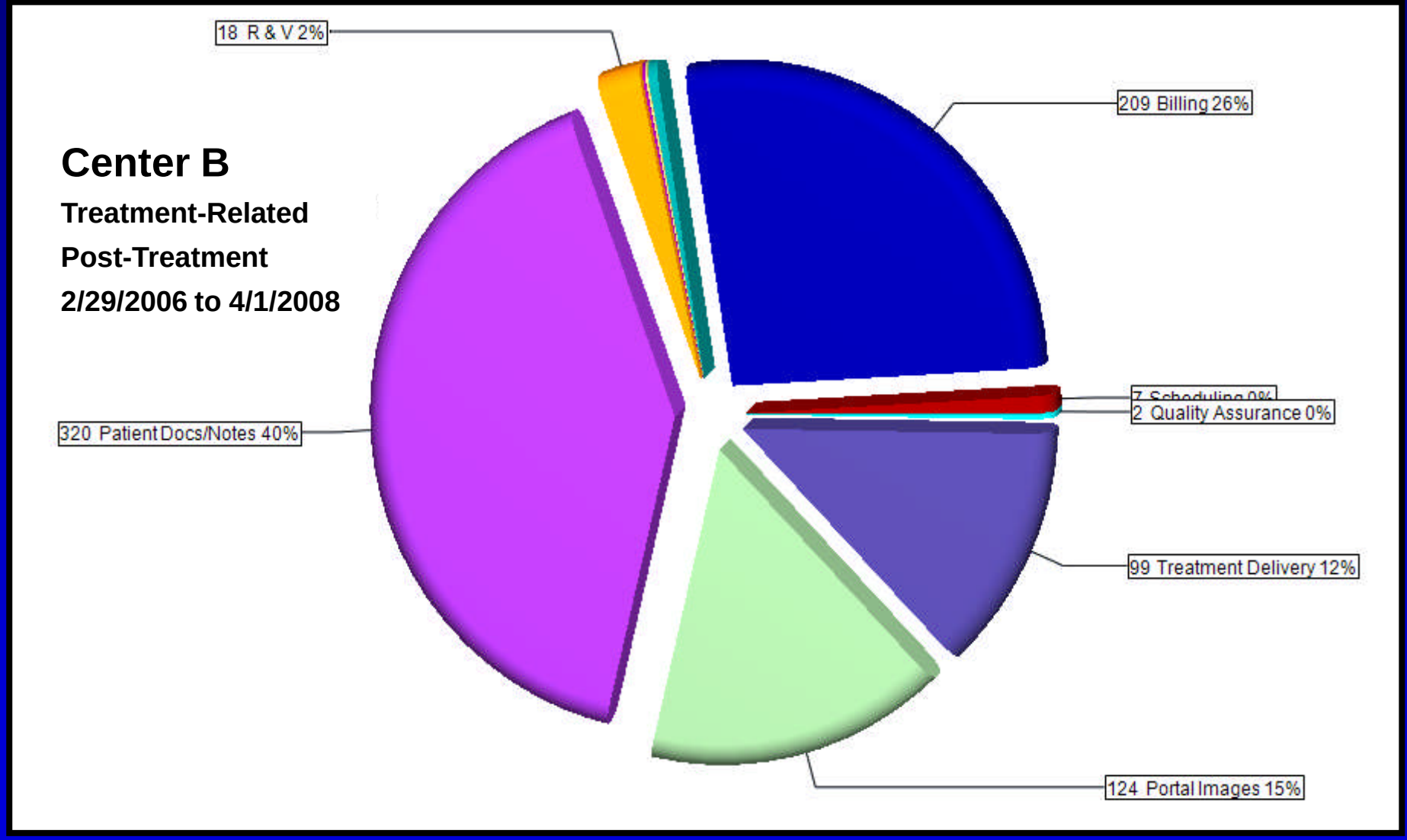
Post-Treatment

9/16/2009 to 9/29/2010



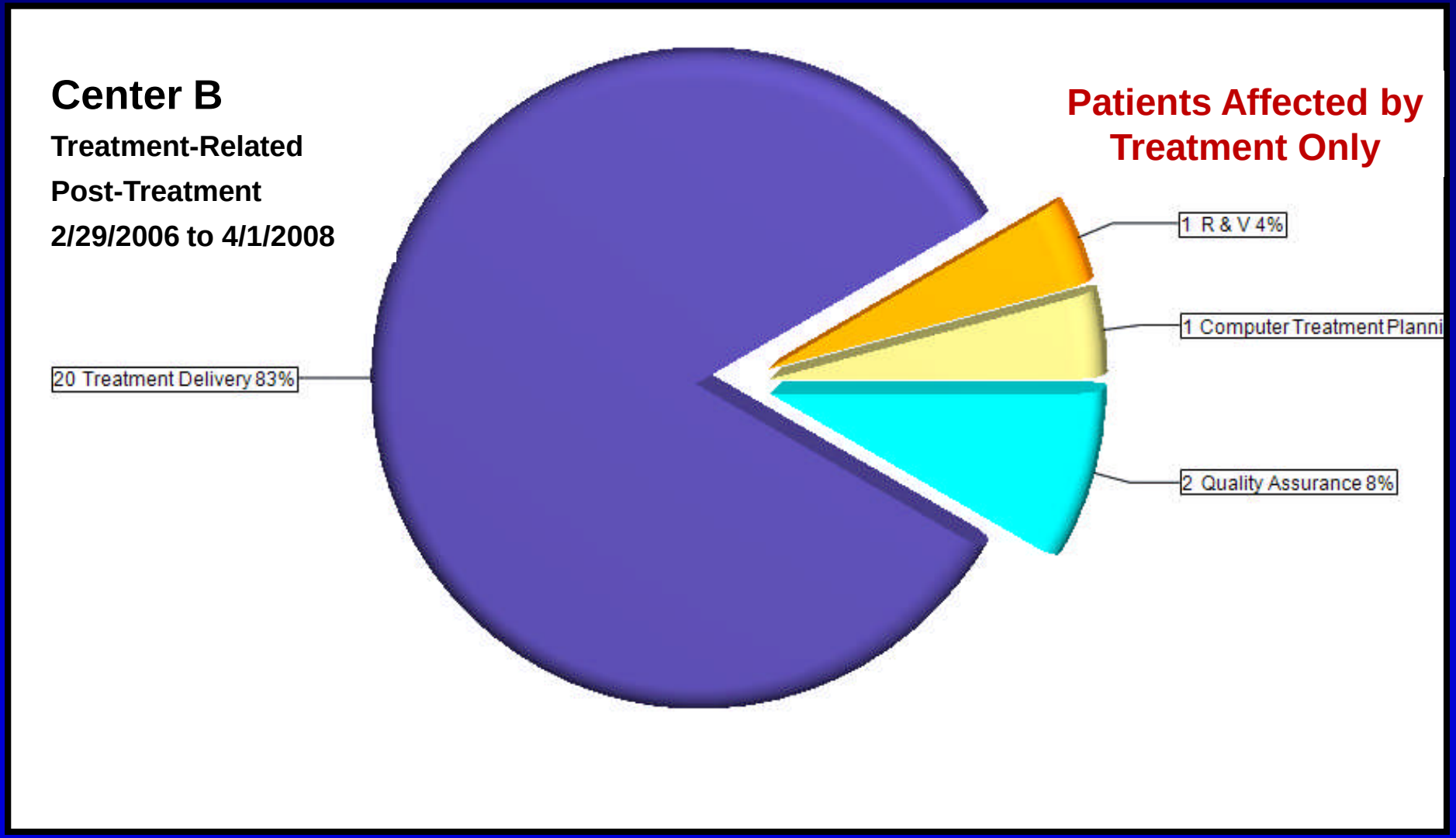
MERP Results

Center B



MERP Results

Center B



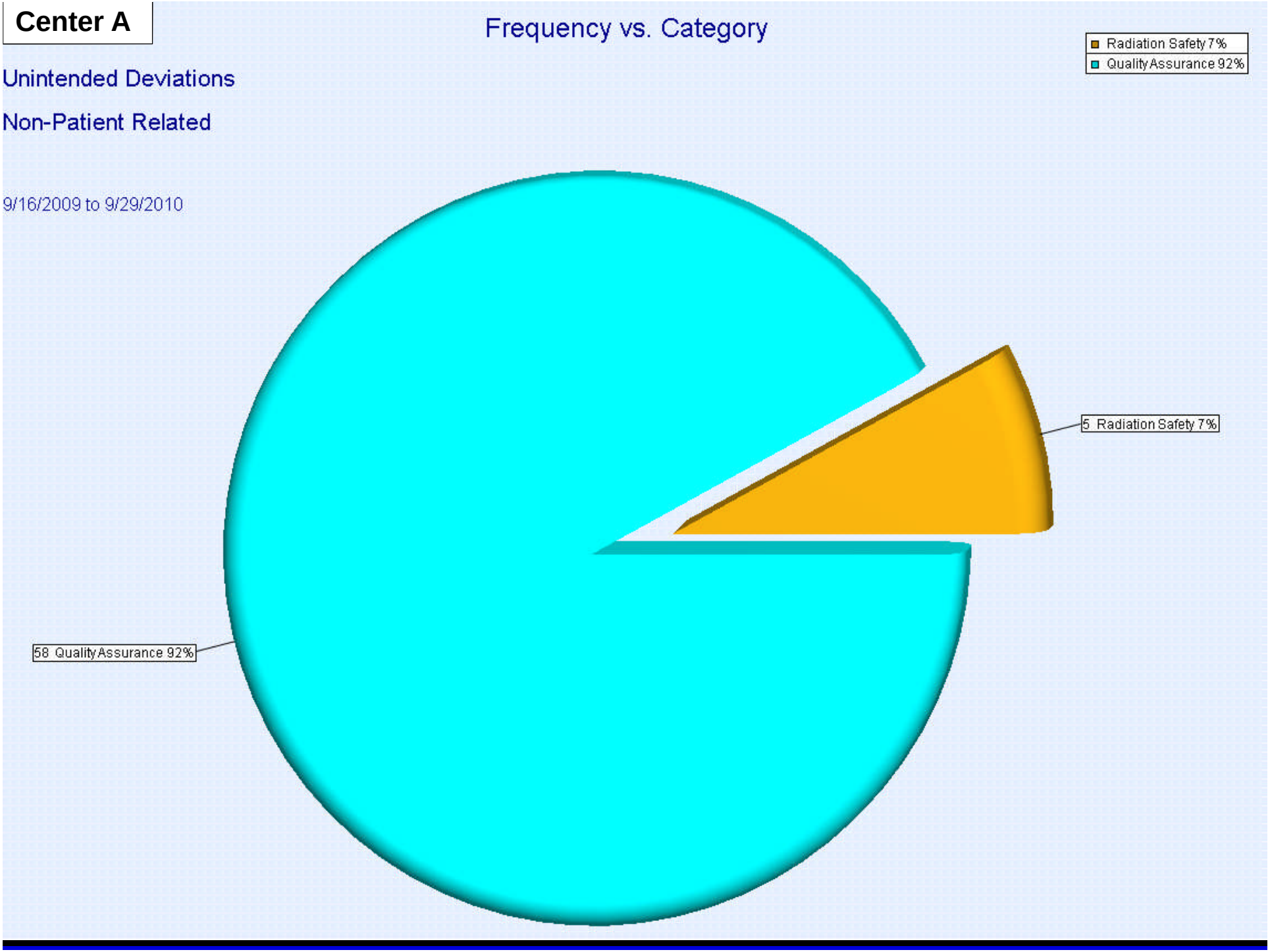
Center A

Frequency vs. Category

Unintended Deviations

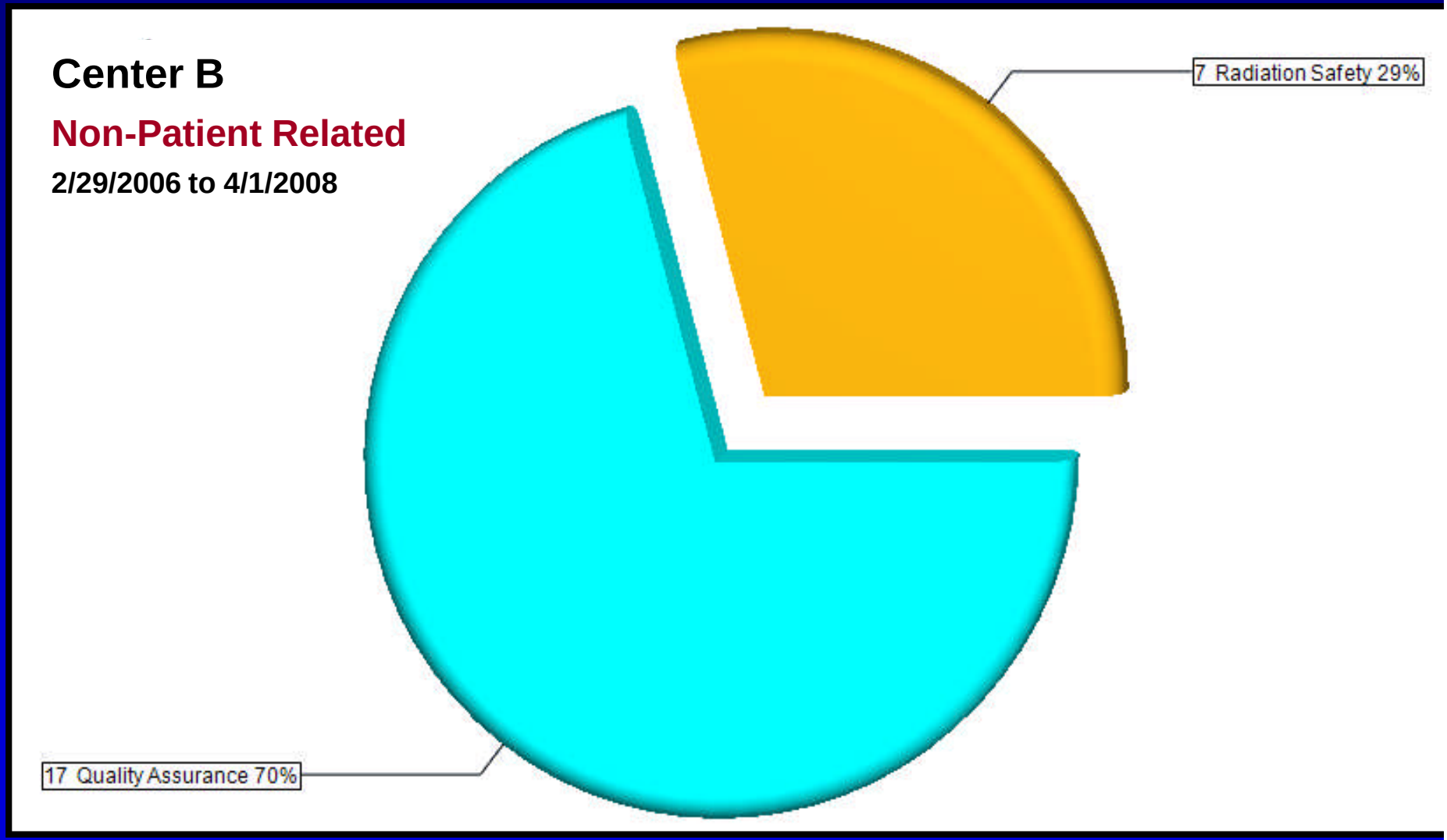
Non-Patient Related

9/16/2009 to 9/29/2010



MERP Results

Center B



Center B - 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

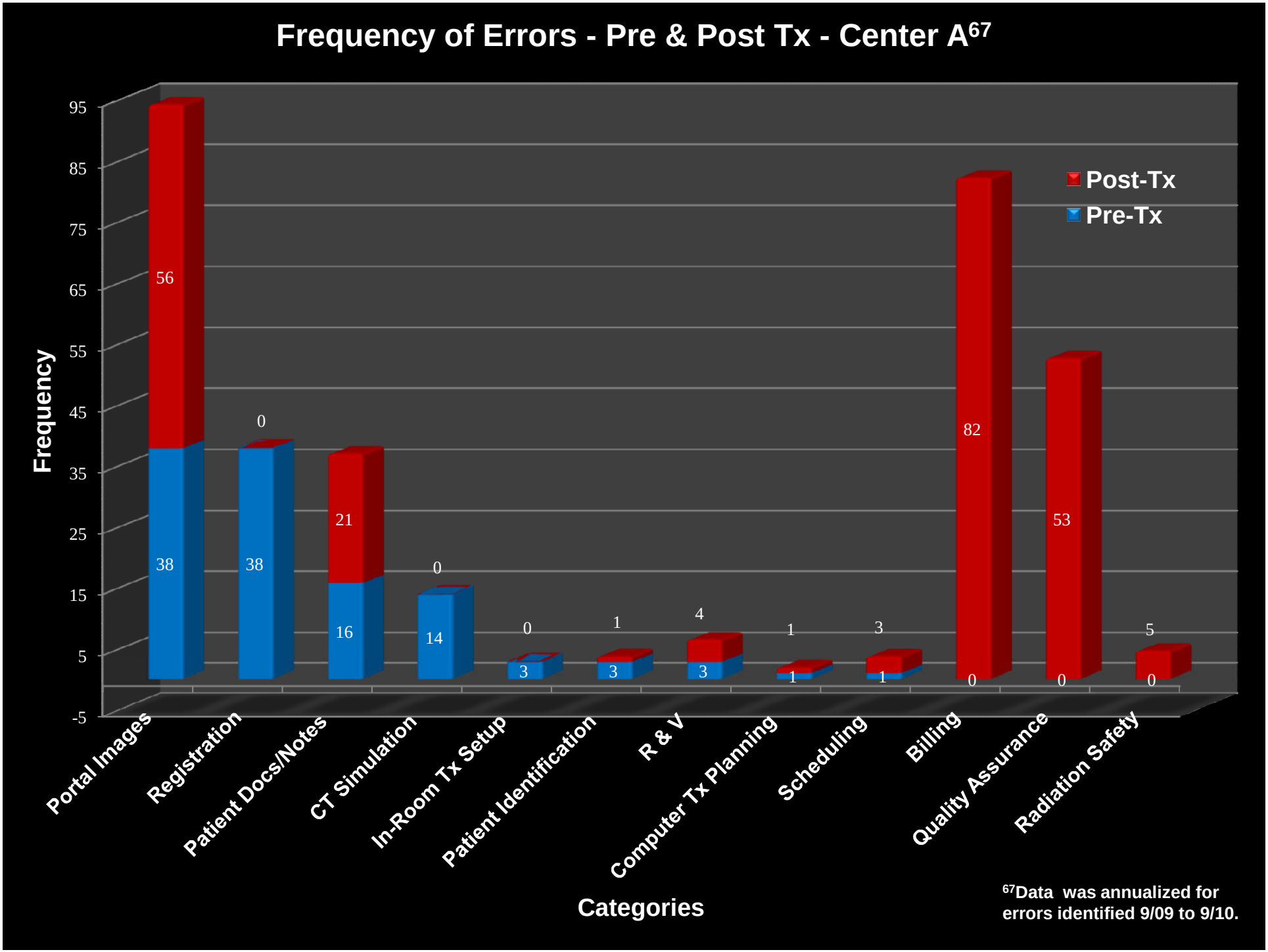
Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	141
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	112
Pre-Tx	R & V	Prescription	Electronic approval before 1st fx miss.	90
Post-Tx	Patient Docs/Notes	Simulation Notes	Tx planning sim 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

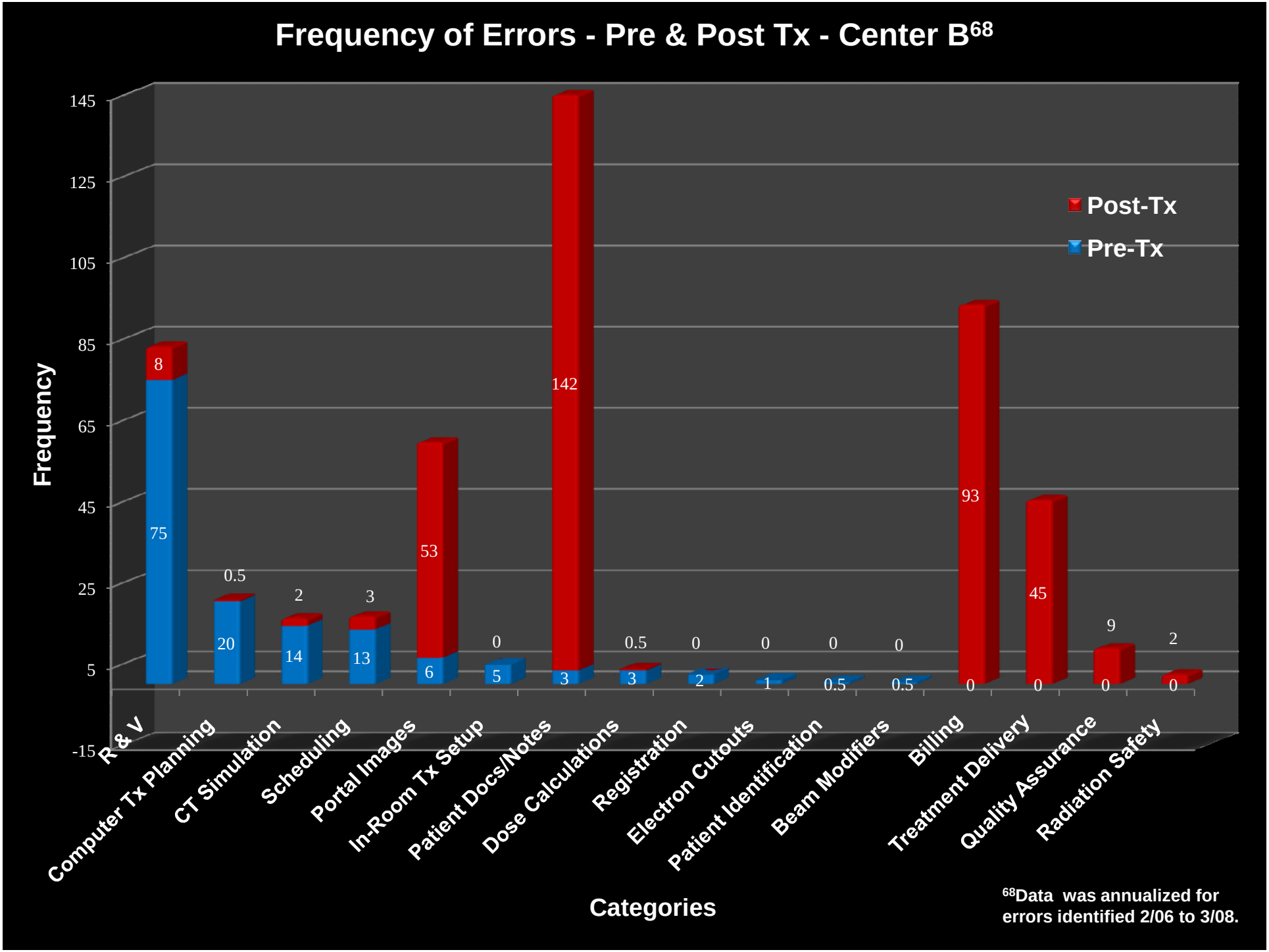
Center B - Errors of Greatest Frequency

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

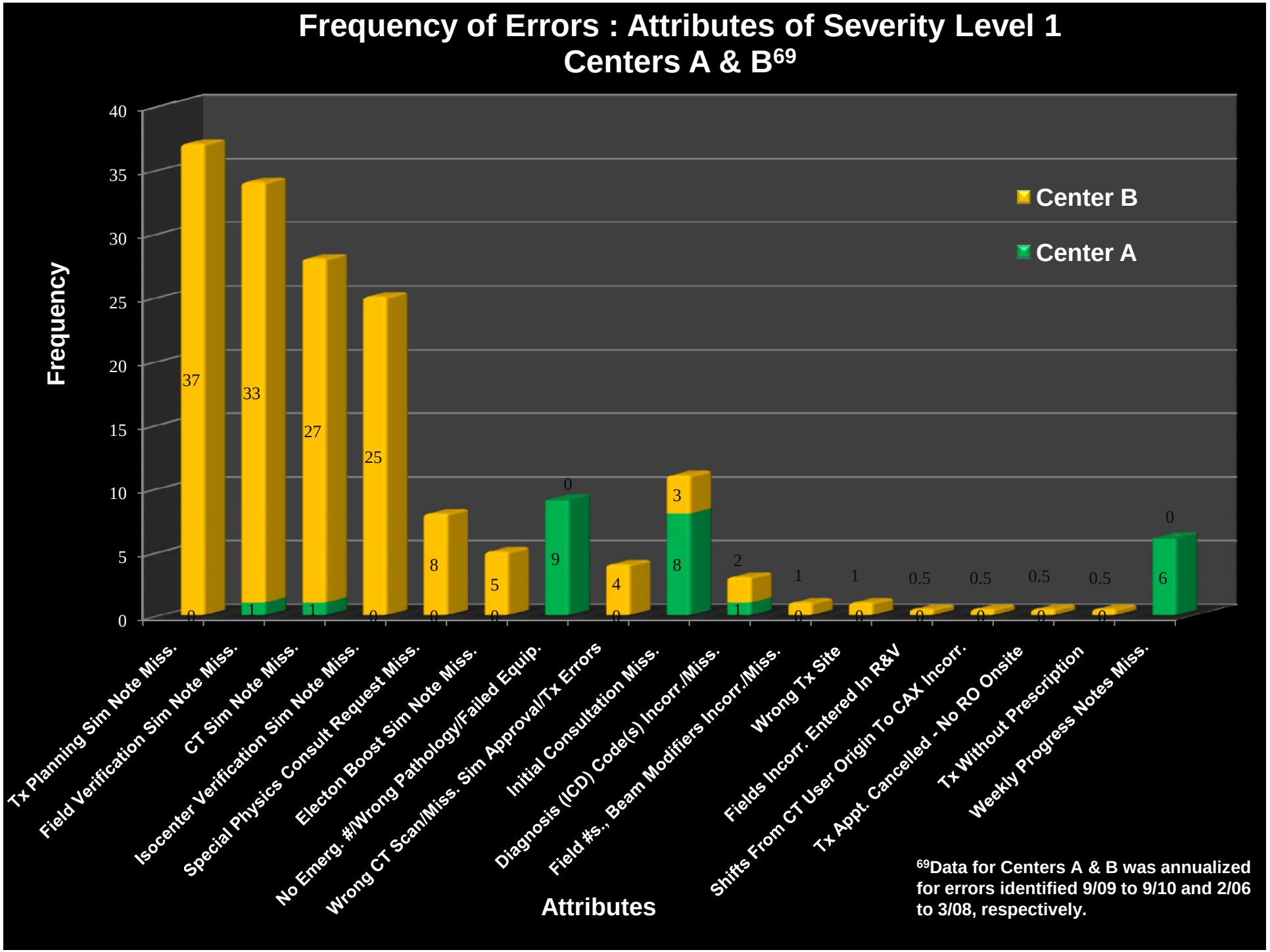
Center A - Errors of Greatest Frequency

Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	78
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	56
Pre-Tx	Portal Images	Electronic Imager	Custom attribute SL 2	40
Pre-Tx	Registration	Emergency	Home phone incorr./miss.	34
Post-Tx	Quality Assurance	Checks	Weekly physics chart checks miss./late	17
Pre-Tx	Patient Docs/Notes	Default	Initial consultation not completed	13
Pre-Tx	CT Simulation	Patient Setup	Sim note incorr./miss.	9
Post-Tx	Patient Docs/Notes	Default	Initial consultation not completed	9

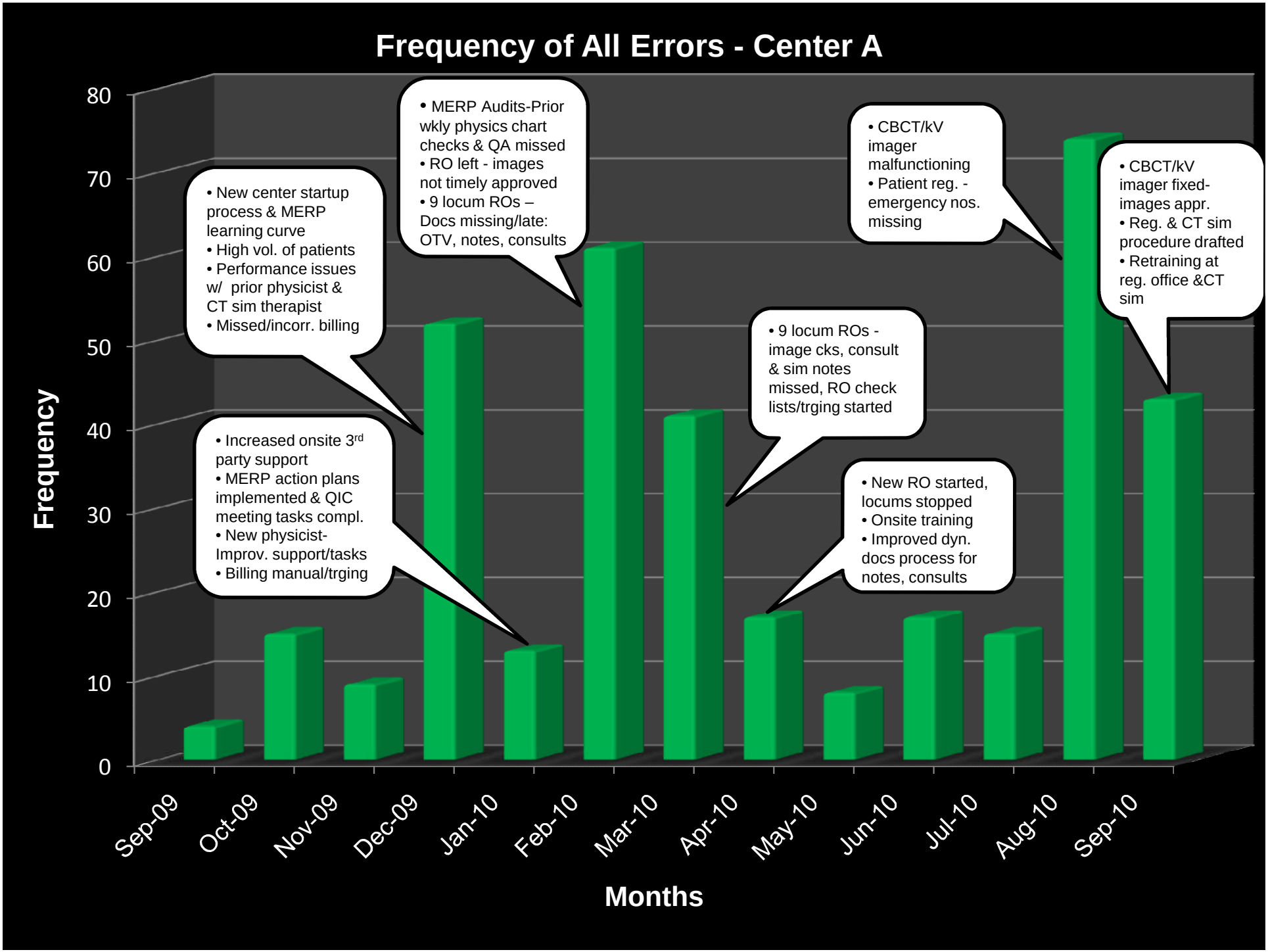

Frequency of Errors - Pre & Post Tx - Center A[67]
Frequency
95
85
75
65
55
45
35
25
15
5
-5
Post-Tx
Pre-Tx
56
38
0
38
21
16
0
14
0
3
1
3
4
3
1
1
3
1
82
0
53
0
5
0
Portal Images
Registration
Patient Docs/Notes
CT Simulation
In-Room Tx Setup
Patient Identification
R & V
Computer Tx Planning
Scheduling
Billing
Quality Assurance
Radiation Safety
Categories
[67]Data was annualized for errors identified 9/09 to 9/10.

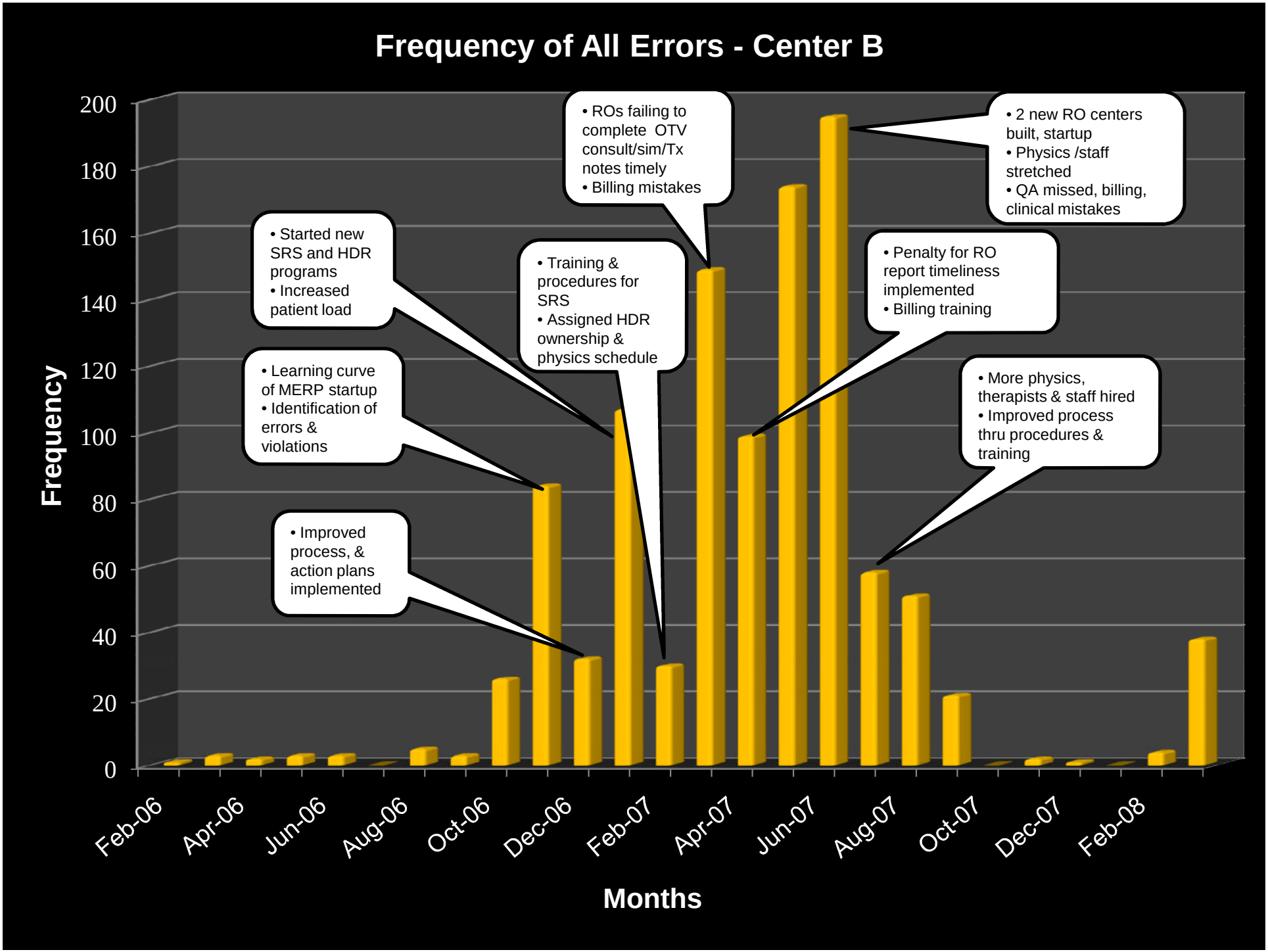

Frequency of Errors - Pre & Post Tx - Center B[68]
Frequency
145
125
105
85
65
45
25
5
-15
Post-Tx
Pre-Tx
8
75
0.5
20
2
14
3
13
53
6
0
5
142
3
0.5
3
0
2
0
1
0
0.5
0
0.5
93
0
45
0
9
0
2
0
R & V
Computer Tx Planning
CT Simulation
Scheduling
Portal Images
In-Room Tx Setup
Patient Docs/Notes
Dose Calculations
Registration
Electron Cutouts
Patient Identification
Beam Modifiers
Billing
Treatment Delivery
Quality Assurance
Radiation Safety
Categories
[68]Data was annualized for errors identified 2/06 to 3/08.

Frequency of Errors : Attributes of Severity Level 1
Centers A & B[69]

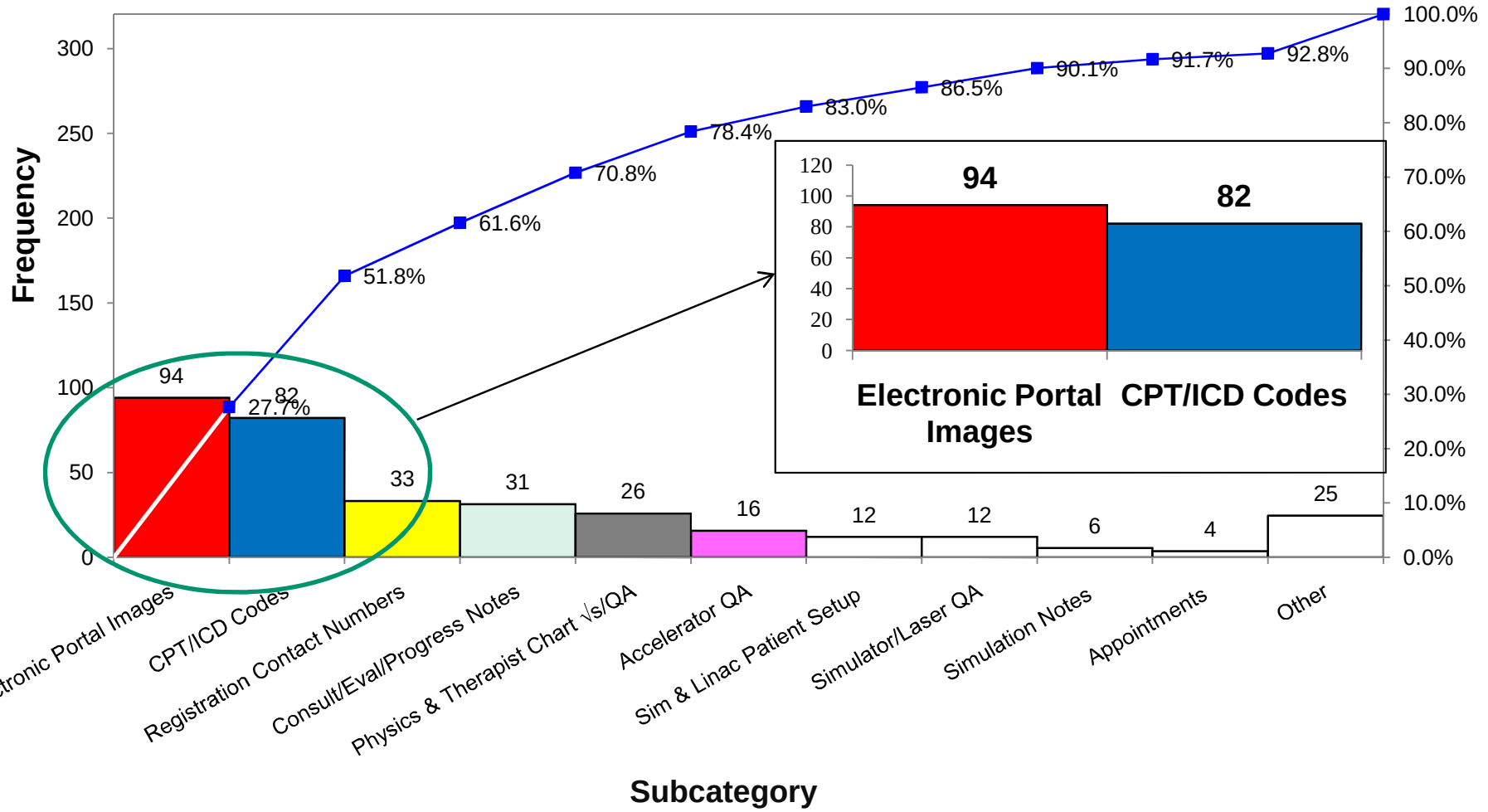


[69]Data for Centers A & B was annualized for errors identified 9/09 to 9/10 and 2/06 to 3/08, respectively.


Frequency of All Errors - Center A
Frequency
80
70
60
50
40
30
20
10
0
Sep-09
Oct-09
Nov-09
Dec-09
Jan-10
Feb-10
Mar-10
Apr-10
May-10
Jun-10
Jul-10
Aug-10
Sep-10
Months
• New center startup process & MERP learning curve
• High vol. of patients
• Performance issues w/ prior physicist & CT sim therapist
• Missed/incorr. billing
• MERP Audits-Prior wkly physics chart checks & QA missed
• RO left - images not timely approved
• 9 locum ROs – Docs missing/late: OTV, notes, consults
• Increased onsite 3rd party support
• MERP action plans implemented & QIC meeting tasks compl.
• New physicist-Improv. support/tasks
• Billing manual/trging
• 9 locum ROs - image cks, consult & sim notes missed, RO check lists/trging started
• New RO started, locums stopped
• Onsite training
• Improved dyn. docs process for notes, consults
• CBCT/kV imager malfunctioning
• Patient reg. - emergency nos. missing
• CBCT/kV imager fixed-images appr.
• Reg. & CT sim procedure drafted
• Retraining at reg. office &CT sim

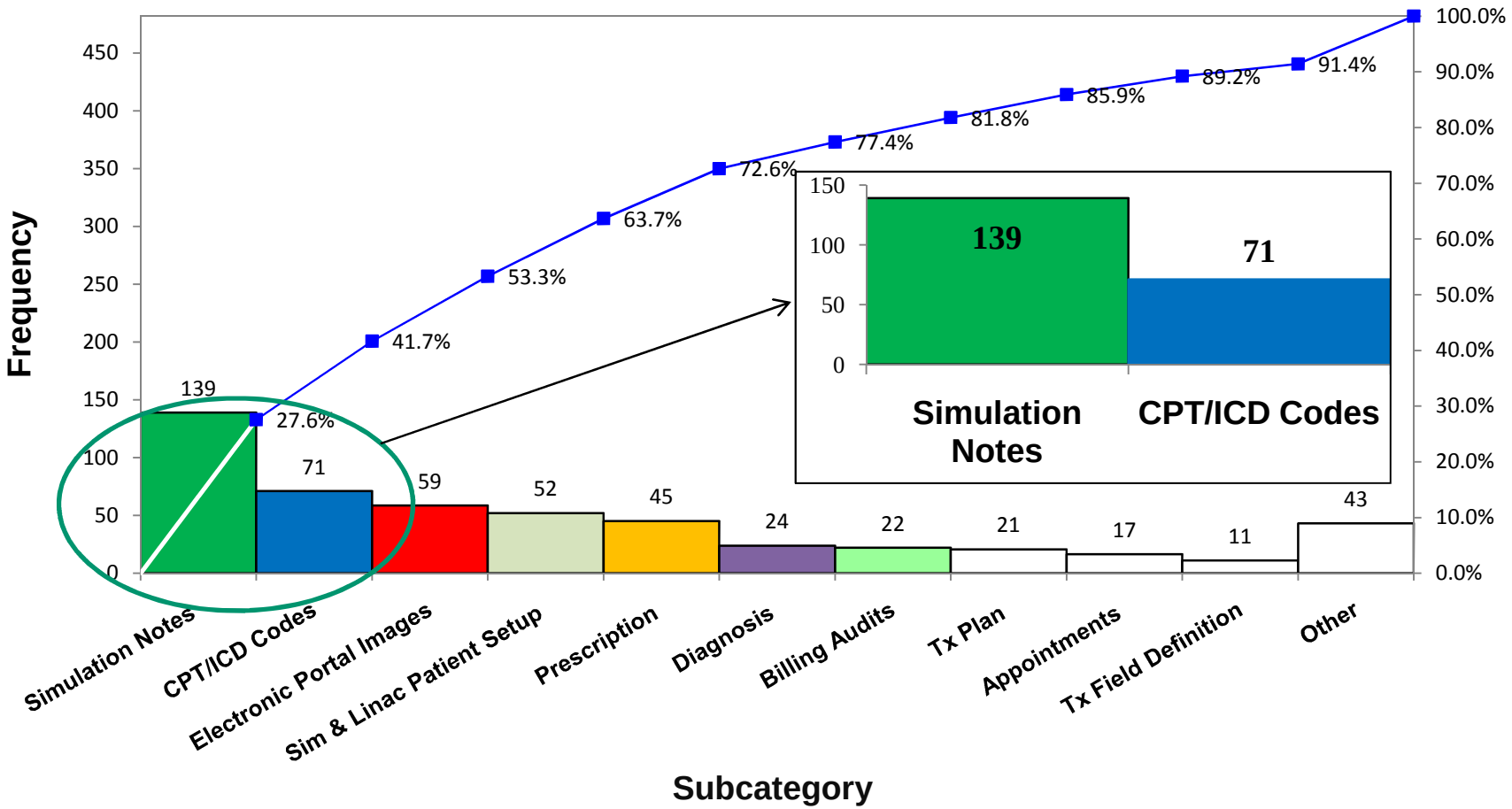

Frequency of All Errors - Center B
Frequency
200
180
160
140
120
100
80
60
40
20
0
Feb-06
Apr-06
Jun-06
Aug-06
Oct-06
Dec-06
Feb-07
Apr-07
Jun-07
Aug-07
Oct-07
Dec-07
Feb-08
Months
• Improved process, & action plans implemented
• Learning curve of MERP startup
• Identification of errors & violations
• Started new SRS and HDR programs
• Increased patient load
• Training & procedures for SRS
• Assigned HDR ownership & physics schedule
• ROs failing to complete OTV consult/sim/Tx notes timely
• Billing mistakes
• Penalty for RO report timeliness implemented
• Billing training
• 2 new RO centers built, startup
• Physics /staff stretched
• QA missed, billing, clinical mistakes
• More physics, therapists & staff hired
• Improved process thru procedures & training

Frequency & Cumulative % of Errors per Subcategory
Center A[70]



[70]Data was annualized for all errors (pre-Tx and post-Tx) collected 9/09 to 9/10.

Frequency & Cumulative % of Errors per Subcategory
Center B[71]



[71]Data was annualized for all errors (pre-Tx and post-Tx) collected 2/06 to 3/08.

MERP Results

Error Rates in Entire Treatment Process Using MERP[72]							
	Pre-Tx			Post-Tx		Pre-Tx + Post Tx	
Error Category	Center A 115 errors	Center B 145 errors		Center A 225 errors	Center B 362 errors	Center A 340 errors	Center B 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

[72]Data for Centers A and B was annualized for all pre-Tx and post-Tx errors (all aspects of the treatment process from registration to completion of treatment) identified from 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Error Rates in Treatment Delivery[73, 74]

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 [b]					

[73]Treatment delivery means the administration of radiation.

[74]Data for Centers A and B was annualized for post-Tx errors in the treatment delivery process identified from 9/09 to 9/10 and 2/06 to 3/08, respectively.

[a] Errors per field in the entire post-Tx delivery process (from initial patient consultation to completion of Tx).

[b] Errors per total Tx units.

MERP Results

QA & Radiation Safety Failures[75, 76]		
Error Category	**Center A**	**Center B**
Per Patient, %	18.8	0.78
Per Fraction, %	0.55	0.026
Per Field, %	0.072	0.0003

[75]Failures are non-patient related and include regulatory infractions.

[76]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 Rates[77]										
Error Category	**Kline et al.**		**This Work MERP Center A**		**This Work MERP Center B**		**US NRC[78]**		**US NRC + Agreement States[79]**
Per Patient, %			0		0.065				
Per Fraction, %	0.017		0		0.002		0.004		0.002
Per Field, %			0		0.00002				

[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. US NRC data was also annualized.

[78, 79]Institute of Medicine (IOM). *Radiation in Medicine: A Need for Regulatory Reform*.1996.

MERP Results

Clinically Significant Errors[80, 81]		
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

[80]*Clinically Significant* dose trigger levels: single fx (non-SRS) - 10%, weekly difference - 15%.

[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.

MERP Results

Likelihood of Occurrence - Infractions of Federal/State Regulations per Patient[82]		
Category	**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

[82]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[83, 84]		
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

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

[84]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 Misses[85]		
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

[85]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

- A total of 1,460 (438 pre-Tx and 1,022 post-Tx) errors were identified at both centers
- Centers A and B experienced 0 vs. 2 medical events and 2 vs. 4 near misses, respectively.
- Center B had 7 clinically significant errors, defined as a single fraction dose difference of > than 10% and weekly dose > than15%.

MERP Results
How to Make it Work

- **Upfront Work**
  - Present history of error reduction
  - Explain why we must embrace the concept to be competitive
  - Preach the philosophy of “goodness”
  - Practice **non-punitive** actions: it will be watched by everyone
  - Encourage reporting
- **Implementation**
  - Establish a rewards system
  - Select GOOD superusers to serve as point guards
  - Phase in the program to minimize user overload
- **Implementation (conti.)**
  - Consider initial paper recording of errors to prevents corrupt/inaccurate data entry
  - Use morning “Stand Up” meetings to briefly discuss errors and serve as a means to broadcast alerts
  - Assign responsibility for 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.