Artificial Intelligence Within a Medical Error Reduction Compliance Software Environment in Radiation Oncology

Introduction

- Part I - Brief History of Errors
- Part II - Characterization of Medical Errors
- Part III - Radiation Oncology Errors
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Part I

Brief History of Errors

What is Patient Safety?

- 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).

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
2000

- Influential Report: "An Organization with a Memory"[9]
  - Goal #1: Create/support culture of learning
  - Goal #2: Operationalize lessons learned
  - Goal #3: Implement a systems approach to minimizing errors
  - Goal #4: Create a unified reporting mechanism

[9]https://www.aagbi.org/sites/default/files/An%2Organisation%20with%20a%20memory.pdf.

Impact
Today

- Six Dire Facts[10]
  - Estimate preventable medical errors leading to patient death at 210,000 to 400,000 per year
    - 3rd leading cause of death behind heart disease and cancer
  - $765,000,000,000, or 30% of all US healthcare costs, each year is wasted
    - Of $2.5 trillion spent on domestic healthcare costs in 2009, $765 billion (or 30%) was attributed to preventable errors

[10]http;//www.forbes.com/sites/robertscerba/2013/10/22./six-frightening-facts-you-need-to-know-about-healthcare/.

Impact
Today

- Six Dire Facts (conti.)[11]
  - 33% of hospital patients suffer some form of preventable harm during their hospital stay
  - 58% of clinicians felt unsafe about speaking up about a problem they observed or were unable to get others to listed
  - 92% of US physicians admitted to making some medical decisions based on avoiding lawsuits, as opposed to the best interest of their patients

[11]http://www.forbes.com/sites/robertscerba/2013/10/22./six-frightening-facts-you-need-to-know-about-healthcare/

Impact
Today

- Society of Actuaries (SOA)[12]
  - Estimated 6.3 million injuries & deaths from adverse events each year
  - Estimated 1.5 million inpatient preventable medical errors each year
  - Estimated total impact $19.5 billion per year
    - Cost of treating injuries
    - Lifetime wages lost
    - Insurance costs (disability & death)

[12] *The Cultural Cure for Sentinel Events.* Industry Focus – Patient Safety & Quality Healthcare, www.PSQM.com, July/August 2016, pgs. 49-54.

Impact
Today

- British Medical Journal (BMJ)[13]
  - Medical errors kill an estimated 251,000 Americans every year
  - 3rd leading cause of death … behind heart disease and cancer

[13]http://www.bm.com/content/353/bm.i2139.

Bottom-line

- Patient Safety & Quality Healthcare (PSQH)[14]
  - "Despite numerous resources, training courses, webinars, standards, certain sentinel events continue to happen with alarming frequency"
  - "Despite an intense 17-year focus to improve safety of medicine, it appears little – if any – improvement has been made"

[14] *The Cultural Cure for Sentinel Events.* Industry Focus – Patient Safety & Quality Healthcare, www.PSQM.com, July/August 2016, pgs. 49-54.

Bottom-line

- Barriers Continue to Exist[15]
  - Open reporting culture is not accepted
  - Local systems are inadequate to
    - Investigating incidents
    - Identifying contributory factors
    - Implementing & embedding learning

[15] *The Cultural Cure for Sentinel Events.* Industry Focus – Patient Safety & Quality Healthcare, www.PSQM.com, July/August 2016, pgs. 49-54.

Bottom-line

- "Top 10" Patient Safety Concerns for Healthcare Organizations 2016[16]
  - #10: Failure to Embrace a Culture of Safety
    - Foundation for mitigating any of the listed concerns on the "Top 10" list
    - Safety culture must span entire organization & permeate each department

[16]www.ECRI.org/patientsafetytop10.

Part II

Characterization of Medical Errors

Disclosure of Errors

- Survey of 603 patients who experienced 845 adverse events showed[17]
  - 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

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

Consumer Beliefs[18]

- 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

[18]*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[19]

- 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[20]

[19]*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.
[20]Duffy J, *The QAIP* Quest. Advance News Magazines. Accessed thru www.health-care it.advanceweb.com.

Medical Errors

- In U.S., adverse events occur to approx. 3 - 4% of patients[21]
- Average intensive care unit (ICU) patient experiences almost 2 errors per day[22]
  - 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[23]

[21, 22, 23] *Doing What Counts for Patient Safety - Federal Actions to Reduce Medical Errors and Their Impact.* Access thru www.quic.gov.

Medical Errors

- Underreporting of adverse events is estimated to range between 50 – 60% annually[24]
- No "comprehensive nationwide monitoring system" exists for medical reporting[25]
- Recent attempts to estimate error rates show little improvement in actual error incidence nationwide[26]

[24] *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.

[25, 26] *National Survey of Medical Error Reporting Laws*, Yale Journal of Health Policy, Law, and Ethics, 2008, citing Agency for Healthcare Research & Quality, 2004.

Part III

Radiation Oncology Errors

Radiation Oncology Errors

- 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

Radiation Oncology Errors

- Not well established
- No comprehensive numbers available for number of errors resulting in death[27]
- Reported error rates
  - 0.1% to 0.2% of fields treated[28]
  - 0.17% per patient treated[29, 30]
  - Studies not relying on self-reporting show actual rates of up to 3%[31]

[27, 28, 29]French, J, *Treatment Errors in Radiation Therapy*. Radiation Therapist, Fall 2002, Vol.11, No. 2; 2002.
[30]E.C. Ford and S. Tereakis, *How safe is safe?: Risk in radiotherapy*, Int. Radiat. Oncol. Biol. Phys. 78, 321 (2010).
[31]S. Mutic, R.S. Brame, S. Oddirau, P. Parikh, M.A. Westfall, M.L. Hopkins, A.D. Medina, .C. Danieley, I.M. Ed Naqa, D.A. Low, and B. Wu, *Event (error and near-miss) reporting and learning system for process improvement in radiation oncology*, Med. Phys. 37, 5027-5036 (2010).

Radiation Oncology Errors

- Most current data suggests[32]
  - Approx. 0.04% to 4.7% of patients undergoing RT experience some operational and clinical shortcoming
  - Approx. 0.003% to 0.01% experience some level of harm per treatment
  - Approx. 100 & 500 patients experience some harm annually in the US and worldwide, respectively.
  - This corresponds to approx. 6 to 100 serious events per million treatments …. some lead to death

[32]Howell C, Tracton G, Amos, A, Chera B, Marks L, Maur LM, *Predicting Radiation Therapy Process Reliability Using Voluntary Incident Learning System Data*, Pract Radiat Oncol. 2018; 9: e210-217.

Radiation Oncology Errors
How We Compare

Not That Well

- Commercial aviation experience[33]
  - Approx. 0.06 deaths per million large commercial passenger flights & approx. 15 accidents per year, or approx. 0.1 accidents per million commercial flight
- Nuclear power plants[33]
  - Directly caused 31 fatalities between 1969 and 2000, with an average of 0.75 unplanned automatic reactor safety events per year between 2004 and 2007 across the globe
  - Estimated probability of 0.04 and 0.1 accidents per reactor year.

[33]Howell C, Tracton G, Amos, A, Chera B, Marks L, Maur LM, *Predicting Radiation Therapy Process Reliability Using Voluntary Incident Learning System Data*, Pract Radiat Oncol. 2018; 9: e210-217.

Radiation Oncology Errors

How We Compare

How About Within Medicine?

- Anesthesiology experience[34]
  - 8.2 deaths from anesthesia complications per million hospital surgical discharges.
- Hospitalized Medicare beneficiaries[35]
  - 135,000 per million experience adverse events
  - 15,000 per million experience an event that contributed to their death
  - 6,000 per million have a serious/reportable event, of which 31% are due to medication errors and 26% to surgery or other procedure.

[34, 35]Howell C, Tracton G, Amos, A, Chera B, Marks L, Maur LM, *Predicting Radiation Therapy Process Reliability Using Voluntary Incident Learning System Data*, Pract Radiat Oncol. 2018; 9: e210-217.

Radiation Oncology Errors

Experts believe radiation therapy accidents are chronically underreported and some states do not require any error reporting[36]

[36]*Fast facts about radiation therapy*. American Society for Radiation Oncology website. www.astro.org/News-and-Media/Media-Resources/FAQs/Fast-Facts-About-Radiation-Therapy/Inde.asps, Accessed December 2, 2016.

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."[37]

[37]ICRP. *Radiological Protection and Safety in Medicine.* ICRP 73. Annuals of the ICRP, 1996, Vol. 26, Num. 2.

Part IV

Radiation Oncology Surveys

Who Reports the Errors Within a RO Center?[38]

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%

[38] *ROSIS* database. 2/25/10. Accessed through www.rosis.info.

Radiation Oncology Surveys

- Survey of radiation therapists comfort levels in reporting errors[39]
  - 29% of respondents expressed a fear of reprimand as a barrier to error reporting

[39] Adams R. *National study to determine the comfort levels of radiation therapists to report errors*. Study presented at: 35th Annual ASRT Radiation Therapy Conference; October 2-4, 2011; Miami, FL.

Radiation Oncology Surveys

- Patient safety perceptions among US radiation therapists[40]
  - Hospital-level dimensions measuring patient safety culture ranked "average"
  - Management ranked "average" in commitment to patient safety
  - Nearly 10% of respondents were afraid to ask questions either "most of the time" or "always" in situations where something did not seem right

[40]Jeffrey S. Legg, Melanie C. Dempsey, and Laura Aaron, *Patient safety perceptions amongst U.S. radiation therapists*, Radiation Therapist, Spring 2013, Vol. 22, No. 1, pgs. 9-20.

Part V

Incident Reporting Systems

Hospital Incident Reporting Systems[42]

- Medicare Beneficiaries Study
  - Hospitalized patients still have unacceptably high rates of harm and injury
  - Hospital incident reporting systems **do not** capture most harm that occurs in hospitals
  - Only about 14% of events are reported

[41] *Whole-Patient Measure of Safety: Using Administrative Data to Assess the Probability of Highly Undesirable Events During Hospitalization.* Rocco . Perla, Samuel F. Hohmann, Karen Annis, Journal for Healthcare Quality, Vol. 35, Issue 5, pgs. 20-31, September/October 2013.

Radiation Oncology "Needs"[42]

- Safety performance in radiotherapy is worse than in some other areas of medicine such as modern anesthesiology
- Radiation oncology patient safety "needs"
  - #1: Reporting/learning system specifically designed for discipline of radiation oncology
  - #2: Standards established that describe the structure and function of the incident reporting system

[42]E.C. Ford, L. Fong de Los Santos, T. Pawlicki, S. Sutlief, and P. Dunscombe, *Consensus recommendations for incident learning database structures in radiation oncology*, Med. Phys. 39, 7272-7290 (2012).

Elements of Transformation[43]

- Core Elements
  - #1: Have an incident reporting system or data collection tool
  - #2: Enter patient safety events into a incident reporting system
    - Allow staff to easily report events
    - Disseminate information to right people
    - Track investigation within tool
    - Capture chain of reporting, investigation, education & follow-up
  - #3: Use robust data analytics
    - Actionable data → intervention → "close the loop"

[43] *Whole-Patient Measure of Safety: Using Administrative Data to Assess the Probability of Highly Undesirable Events During Hospitalization*. Rocco . Perla, Samuel F. Hohmann, Karen Annis, Journal for Healthcare Quality, Vol. 35, Issue 5, pgs. 20-31, September/October 2013.

Radiation Oncology "Reporting Systems"[44]

- Voluntary Incident Reporting in Radiation Oncology
  - ASTRO: Radiation Oncology–Incident Learning System (RO-ILS)
  - Radiation Oncology Safety Information System (ROSIS)
  - International Atomic Energy Agency (IAEA): Safety in Radiation Oncology (SAFRON)
  - Othea Relir (All Radiological Incidents-France)

[44]E.C. Ford, L. Fong de Los Santos, T. Pawlicki, S. Sutlief, and P. Dunscombe, *Consensus recommendations for incident learning database structures in radiation oncology*, Med. Phys. 39, 7272-7290 (2012).

Part VIII

Where is the Risk?

Risk Management

- At the Clinical & Insurer Level
  - Qualify & quantify risk
  - Reduce risk
  - Retain risk
  - Transfer risk
  - Limit losses
  - Cavitation of risk

Risk

Radiation Oncologists

- Total Number of Cancer Centers[45]
  - Estimated at 2,170 radiation therapy facilities
  - Facilities, on average, have 2.3 linear accelerators and treat 52.7 patients per day
  - Types of Services
    - Average facility offers 12.0 radiation therapy and related services
    - Most commonly offered services
      - Intensity-modulated radiation therapy (IMRT) (95.2% of facilities)
      - Conformal radiation therapy delivery (92.9% of facilities)
      - CT simulation (92.5% of facilities)
    - Least commonly offered services
      - Proton therapy (2.7% of facilities)
      - Hyperthermia (2.9% of facilities)
      - Dynamic adaptive radiation therapy (4.8% of facilities)

[45] *Radiation Therapy Staffing and Workplace Survey 2014*, ASRT, wwww.asrt.org, 5/14.

Risk

Radiation Oncologists

- Total Number of Radiation Oncologists
  - In 2012, there was total of 16,347 oncologists and radiation oncologists[46]
    - Oncologists: 13,070
    - Radiation Oncologists: 3,277
  - In 2015, there were approximately 5,000 radiation oncologists[47]
  - In 2025, projected[48]
    - Oncologists and radiation oncologists: 21,066

[46] *Projected Supply of and Demand for Oncologists and Radiation Oncologists Through 2025: An Aging, Better-Insured Population Will Result in Shortage,* Wenya Yang, James H. Williams, Paul Hogan, Suanna S. Bruinooge, Gladys I. Rodriguez, Michael P. Kosty, Dean F. Bajorin, Amy Hanley, Ashley Muchow, Naya McMillian, and Michael Goldstein, The American Society of Clinical Oncology, www.jop.ascopubs.org, January 2014.

[47] *ASTRO Legislative Priorities – 2015*, ASTRO, www.astro.org and www.rtanswers.org, Washington, DC 20002

[48] *Projected Supply of and Demand for Oncologists and Radiation Oncologists Through 2025: An Aging, Better-Insured Population Will Result in Shortage,* Wenya Yang, James H. Williams, Paul Hogan, Suanna S. Bruinooge, Gladys I. Rodriguez, Michael P. Kosty, Dean F. Bajorin, Amy Hanley, Ashley Muchow, Naya McMillian, and Michael Goldstein, The American Society of Clinical Oncology, www.jop.ascopubs.org, January 2014.

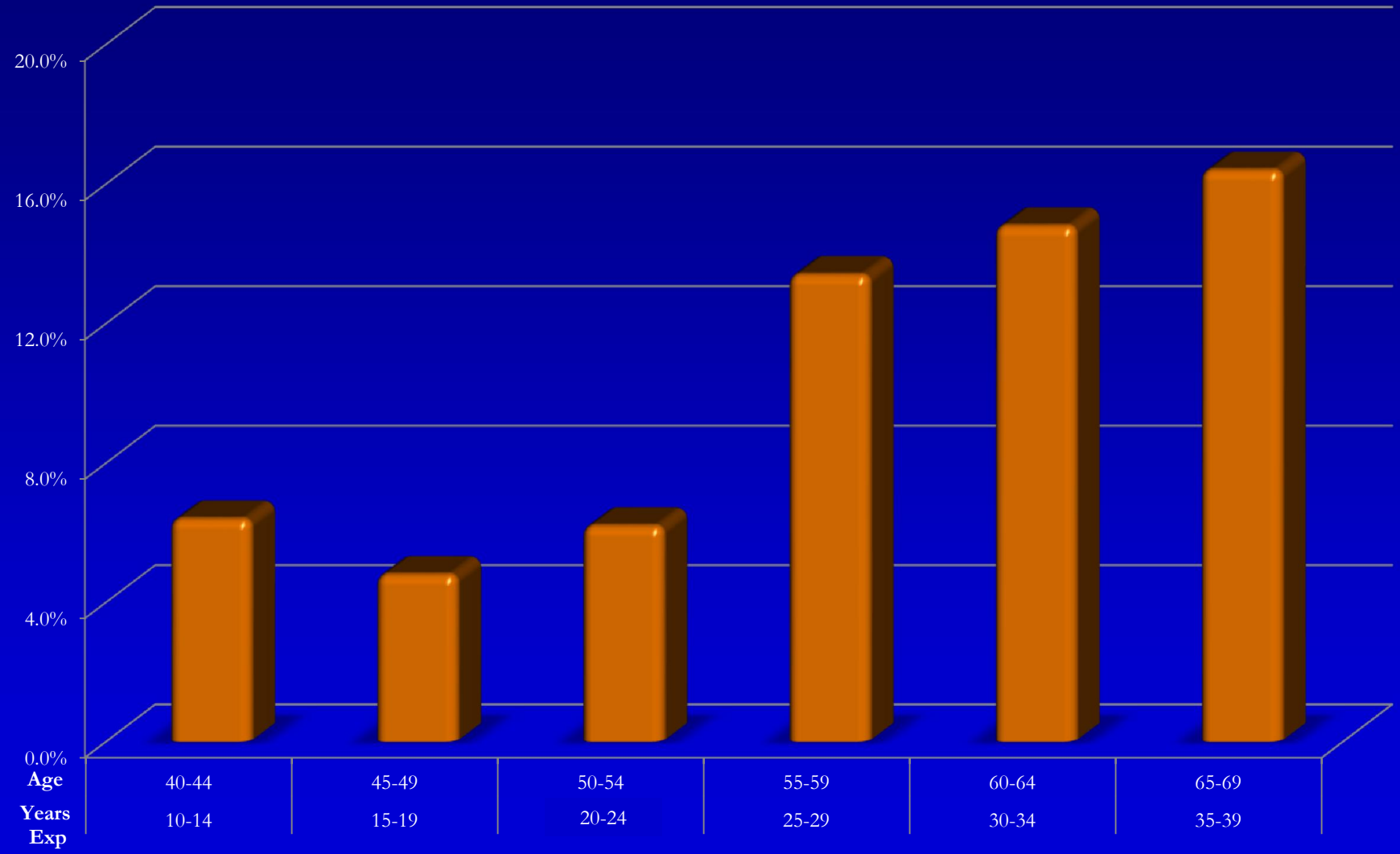
Risk

Radiation Oncologists

- Total Number of Patients[49]
  - In 2004, nearly one million patients were treated with radiation therapy
    - In 2004, patients made about 23.4 million radiation therapy treatment visits to 2,010 hospitals and freestanding radiation therapy centers
    - An average linear accelerator is used for 4,500 to 6,500 treatments/year
    - Average patient receiving external beam radiation therapy receives 29 treatments
    - In 2004, radiation therapy centers in U.S. employed an estimated 29,970 people full time, including 3,900 radiation oncologists; 8,900 radiation therapists; 3,400 nurses; 2,600 radiation physicists; 2,500 dosimetrists; 5,300 clerical employees; 2,400 administrative staff and 900 other full-time employees, such as block cutters, tumor registrars and social workers
  - The average radiation oncologist sees between 200 and 300 patients annually

[49] *Physician Characteristics and Distribution in the U.S.,* 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.

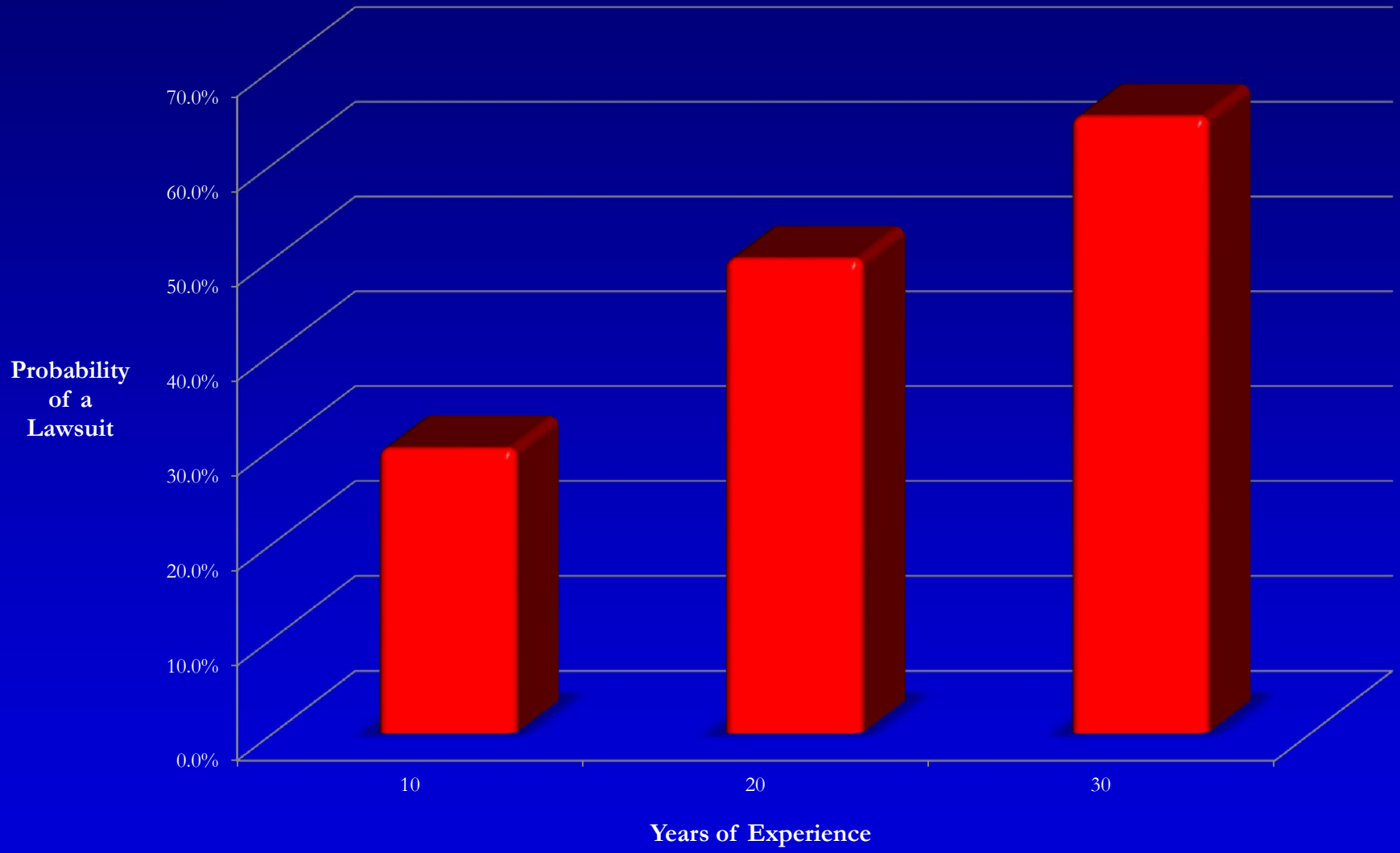
Probability of a Malpractice Lawsuit[50] by Age and Years of Experience[51] for Radiation Oncologist



[50]Based on survey data from *Medscape Malpractice Report 2015: Why Oncologists Get Sued*, Carol Peckham and Sarah Gresham, 1/22/16.

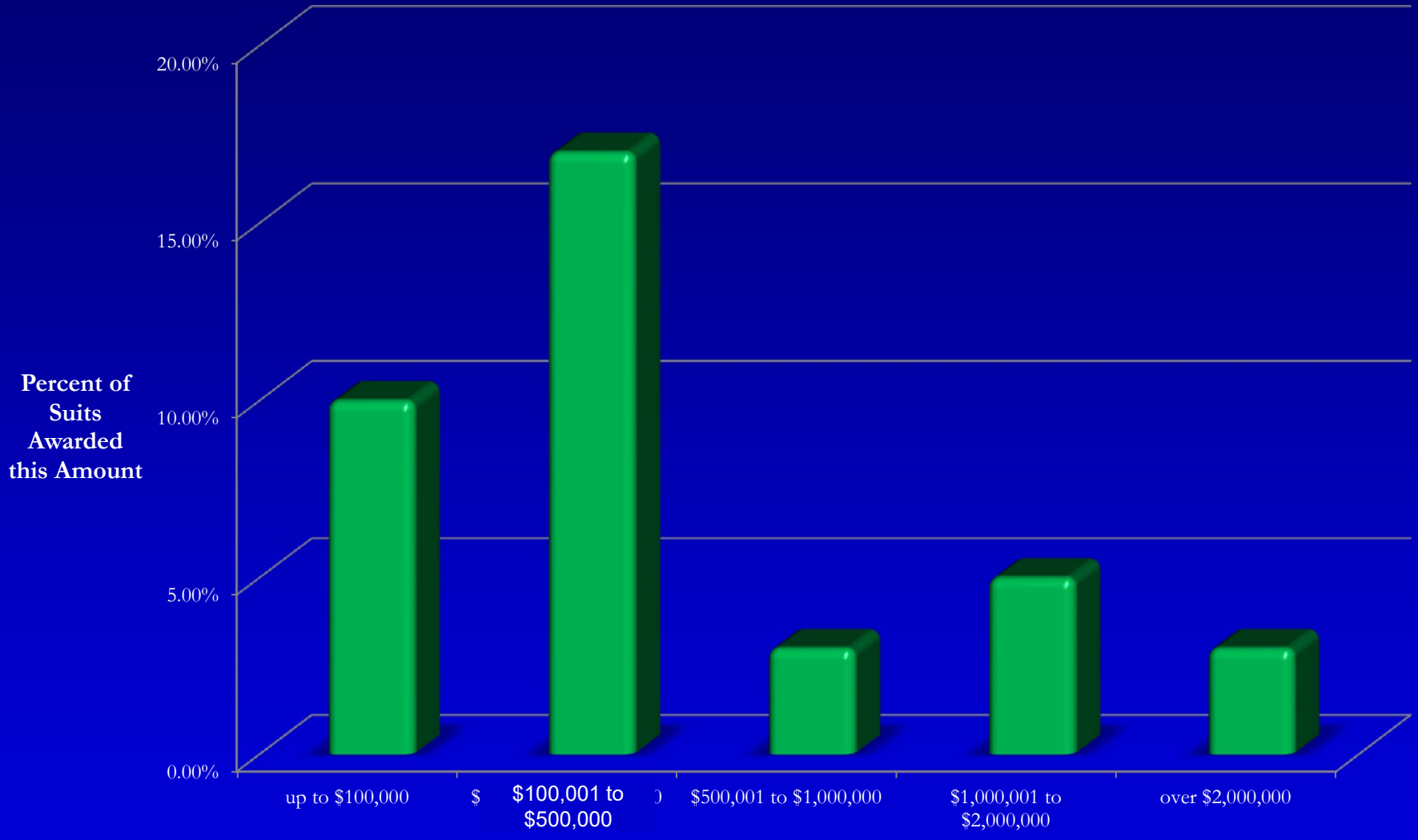
[51]Years of experience is based on the assumption that a Radiation Oncologist begins employment at age 30.

Probability of a Malpractice Lawsuit by Years of Experience for RO[52]



[52]Based on survey data from Int J Radiat Oncol Biol Phys, *Professional Liability in Radiotherapy: Experience of the Fletcher Society*, 1991 Mar. 20(3): 563-6.

Range of Payouts for Oncology Malpractice Suits Paid[53]



[53]Note that 61% went to trial but received no award. Based on survey data from *Medscape Malpractice Report 2015: Why Oncologists Get Sued*, Carol Peckham and Sarah Gresham, 1/22/16.

Risk

Radiation Oncologists[54]

Summary

- 65% chance of being sued after 30 years in practice
- 1985 to 2012: total of 1517 claims
- 22.5% resulted in payments to the plaintiff
- $276,792 and $122,500: Average and median indemnity payments, respectively
- Why the error occurred?
  - Peer review and other quality assurance mechanisms would reduce chance of errors

[54] *Radiation Oncology - Non-Clinical Skills Domain: A Syllabus, American Board of Radiology, 9/15/15.*

Part VII

Requirement vs Incentive

Requirement
2017

- Health Insurance Marketplace Quality Initiatives - Patient Protection and Affordable Care Act[55]
  - Patient Safety Evaluation System (PSES): Medicare rule effective 1/1/17
    - Qualified Health Plan insurers [that contract with hospitals with > than 50 beds] must verify, in part, that hospitals use a patient safety evaluation system (PSES)
    - The PSES must show the program comprises an evidence-based initiative to improve healthcare quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm

[55]Patient Protection and Affordable Care Act – *HHS Notice of Benefit and Payment Parameters for 2017*, Federal Register, Vol. 81, No. 45, March 8, 2016, Rules and Regulations: 45 CFR Parts 144, 147, 153, et al.

Incentive

2017

- Patient Protection and Affordable Care Act of 2015[56]
  - Medicare Access and CHIP Reauthorization Act (MACRA): Medicare rule effective 1/1/17
    - 30% of all Medicare payments are tied to quality or value by end of 2016, and 50% by 2018
    - Under MIPS model, penalties and bonuses start in 2019 and go thru 2022 & later years
    - Over time, penalties range from -4% to -9%

      and
    - Max bonuses range from +4% to +9% (potential for 3X adjustment)

[56] *Quality Payment Program*. http://go.cms.gov/QualityPaymentProgram. Accessed January 8, 2017.

Incentive

2017

- Patient Protection and Affordable Care Act of 2015[57]
  - 4 Major Performance Categories
    - Category no. 3 called "Clinical Practice Improvement Activities (CPIA)" (15% weighting)
    - Includes activities that improve the clinical practice or delivery of care such as patient safety
  - Over 90 Activity Options to Choose From
    - Each activity worth 10 points (max possible 40 points)
    - High weighting activity = 20 points each
    - Medium weighting activity = 10 points each
    - CPIA affects MIPS overall score by 15%

[57] *Quality Payment Program.* http://go.cms.gov/QualityPaymentProgram. Accessed January 8, 2017.

Part VIII

Medical Error Reduction Program

Risk Mgt Framework

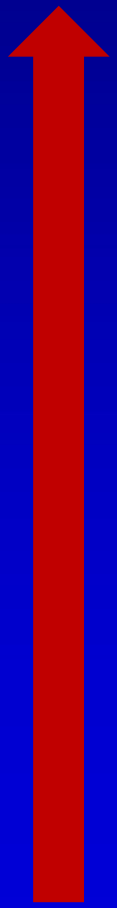
Treatment Process

1. **Identify risks**
   - List
   - Measure
   - Rank
2. **Identify techniques/strategies to manage risk**
   - Reduction of risk
   - Retention of risk
   - Transfer of risk
3. **Implement risk management strategy**
4. **Monitor effectiveness of solutions**

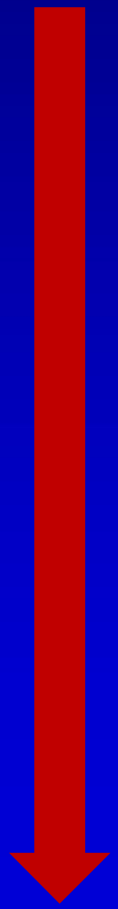
Risk Mgt Process

Reduction of Risk

Reduce likelihood & consequences of mistreatment



- Identify errors & violations
- Preset standardized data silos
- Benchmarked against professional standards
- Scoring of risk (FMEA)
- Analyze/evaluate
- Select action plan(s)
- Launch dose analysis/sentinel event/state reports
- Route error to responsible party
- In-house review/approval process
- Track/trend & chart results
- Generate policies & procedures
- Retrain



Workflow Features

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

Workflow Features

- **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**
  - Pre-set action plans to select
    - Short-term corrective action
    - Long-term corrective action
  - Assignment of responsible individuals
- **Patient Dose Error Calculation Wizard**
  - Calculates % error in daily, weekly & total doses
  - Launches clinical dose triggers alerts
- **Patient Dose Error Calculation Wizard (cont.)**
  - Automatically triggers levels for report generation
    - JC root cause analysis and action plans
    - State regulatory notifications
- **Procedure Generation**
  - Drafting of procedure as part of corrective action plan
  - Serves as tutorial in training new employees/annual refresher
- **Review and Approval**
  - Queue action plan(s) for review and approval
  - Accept or reject routine corrective action(s)

Workflow Features

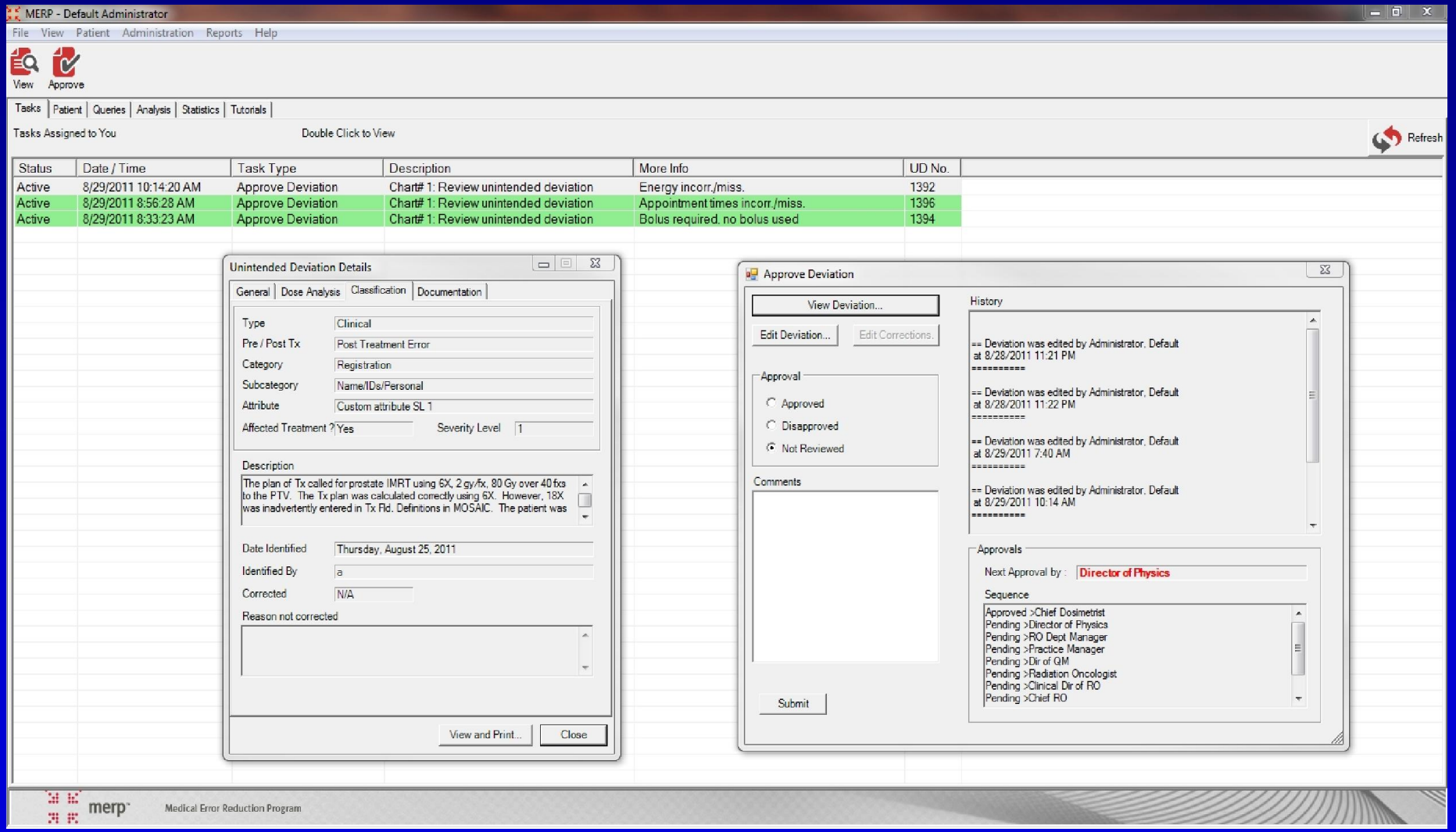
- **Reports and Chart Generation**
  - Generate reports showing characterization of errors and corrective actions
  - Show charts stratifying error types and severity levels
  - Select time intervals for charting of data
- **Customization vs Template Features**
  - Customize and create new data collection areas for monitoring
    - Categories
    - Subcategories
    - Attributes
  - Designate who reviews/approvals routine errors and corrective actions
  - Assign which errors violate State/Federal requirements (NRC,FDA, CMS)
  - Designate severity levels, clinically significant, significant unintended deviations, and RPN

Medicare & State Compliance

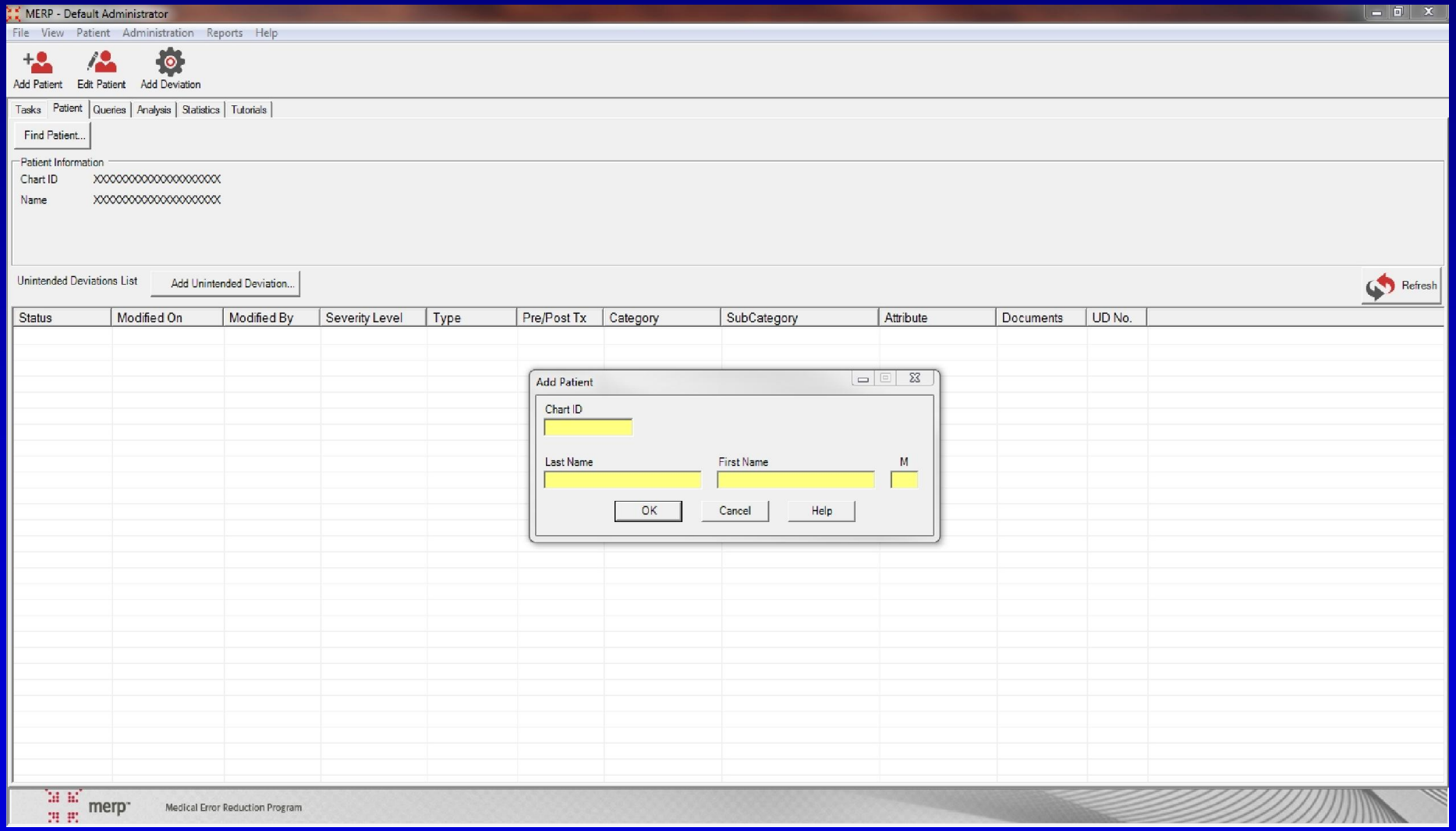
- **Audit Compliance Tool**
  - MERP can be used to inspect regulatory performance
    - Complies with State radiation safety requirement for annual reviews
    - Meets State QMP rule for annual reviews
    - Follows CMS safety & billing compliance objectives
    - Complies with JC standards
- **Standards/Requirements Referenced by Code**
  - Complies as Patient Safety Evaluation System (Medicare rule eff 1/1/17)
  - Qualifies for MIPS credit in 4/4 medium weight activities for IA (max credit) & 15% of formula (Medicare rule eff 1/1/17)
  - JC 2019 patient safety standards show basis for question
  - ACR and ACRO standards demonstrate benchmark for measuring performance
  - CRCPD (Agreement State) recommended regulations (as of 9/14) show legal text

Software Look

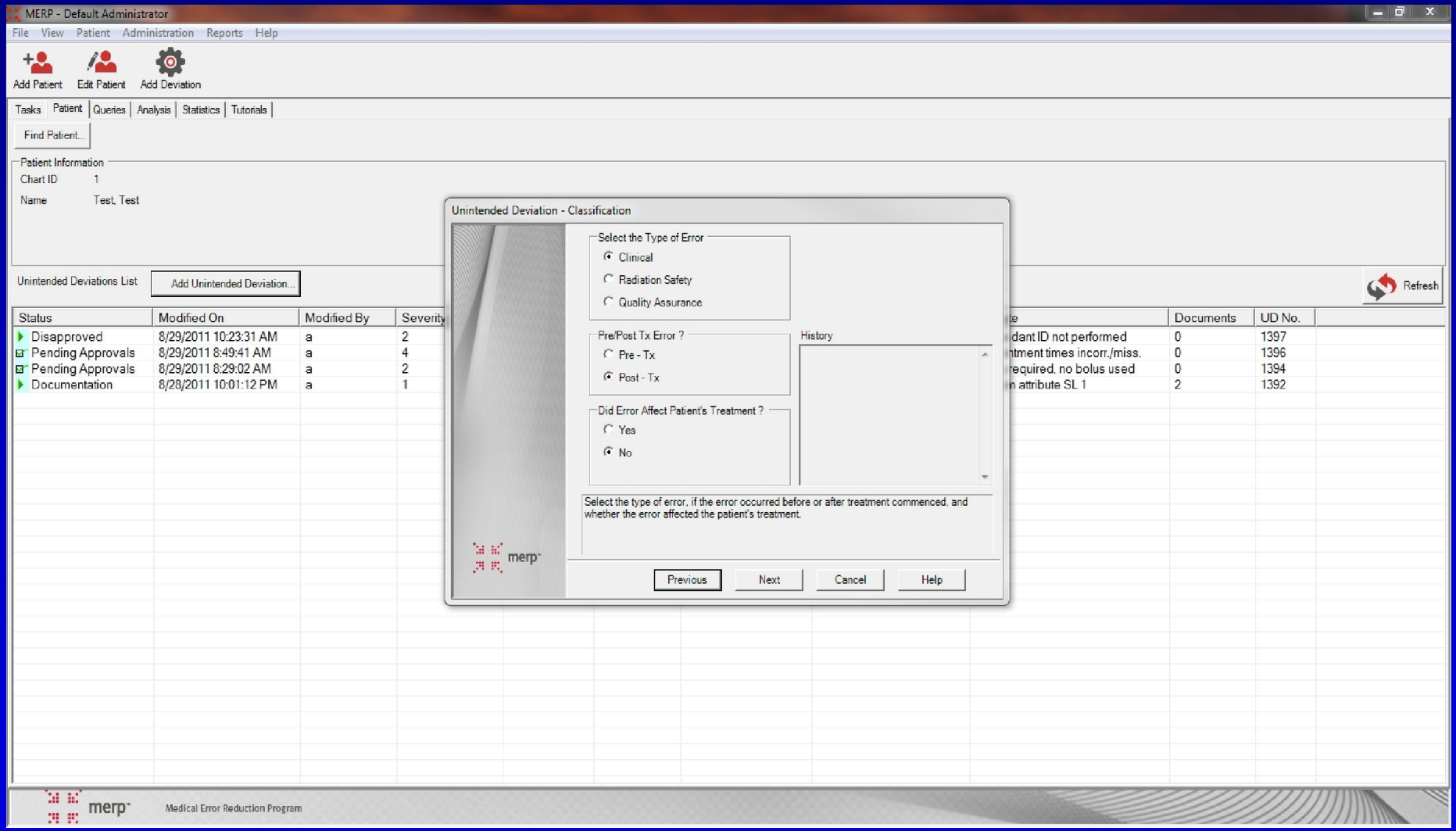
Mailbox


MERP - Default Administrator
File View Patient Administration Reports Help
View Approve
Tasks Patient Queries Analysis Statistics Tutorials
Tasks Assigned to You
Double Click to View
Refresh
Status | Date / Time | Task Type | Description | More Info | UD No.
Active | 8/29/2011 10:14:20 AM | Approve Deviation | Chart# 1: Review unintended deviation | Energy incorr./miss. | 1392
Active | 8/29/2011 8:56:28 AM | Approve Deviation | Chart# 1: Review unintended deviation | Appointment times incorr./miss. | 1396
Active | 8/29/2011 8:33:23 AM | Approve Deviation | Chart# 1: Review unintended deviation | Bolus required, no bolus used | 1394
Unintended Deviation Details
General Dose Analysis Classification Documentation
Type: Clinical
Pre / Post Tx: Post Treatment Error
Category: Registration
Subcategory: Name/IDs/Personal
Attribute: Custom attribute SL 1
Affected Treatment ?: Yes
Severity Level: 1
Description
The plan of Tx called for prostate IMRT using 6X, 2 gy/fx, 80 Gy over 40 fxs to the PTV. The Tx plan was calculated correctly using 6X. However, 18X was inadvertently entered in Tx Rd. Definitions in MOSAIC. The patient was
Date Identified: Thursday, August 25, 2011
Identified By: a
Corrected: N/A
Reason not corrected
View and Print... Close
Approve Deviation
View Deviation...
Edit Deviation... Edit Corrections...
Approval
Approved
Disapproved
Not Reviewed
Comments
Submit
History
== Deviation was edited by Administrator, Default at 8/28/2011 11:21 PM ==========
== Deviation was edited by Administrator, Default at 8/28/2011 11:22 PM ==========
== Deviation was edited by Administrator, Default at 8/29/2011 7:40 AM ==========
== Deviation was edited by Administrator, Default at 8/29/2011 10:14 AM ==========
Approvals
Next Approval by : Director of Physics
Sequence
Approved >Chief Dosimetrist
Pending >Director of Physics
Pending >RO Dept Manager
Pending >Practice Manager
Pending >Dir of QM
Pending >Radiation Oncologist
Pending >Clinical Dir of RO
Pending >Chief RO
merp Medical Error Reduction Program

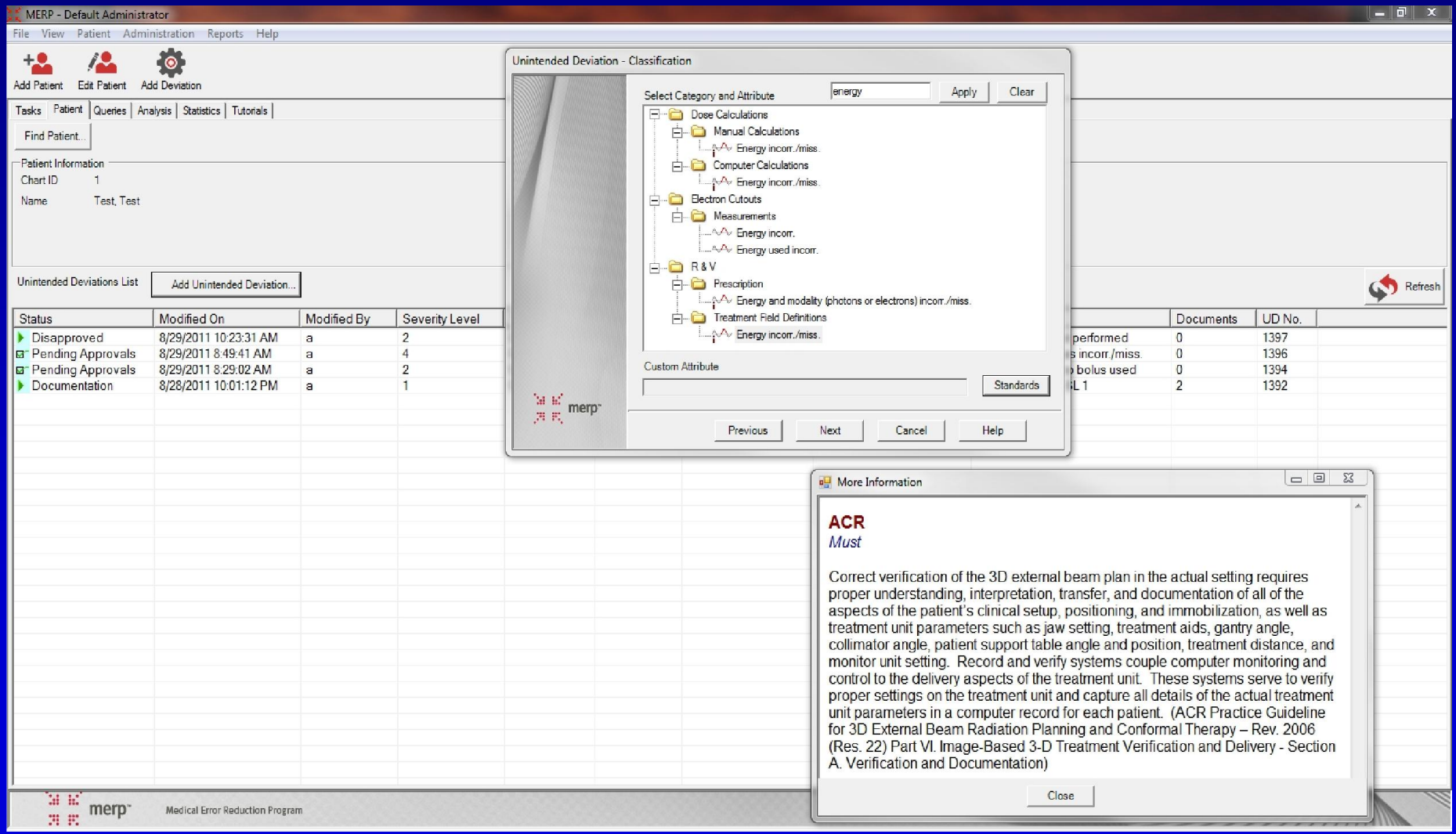
Patient Entry/HL7



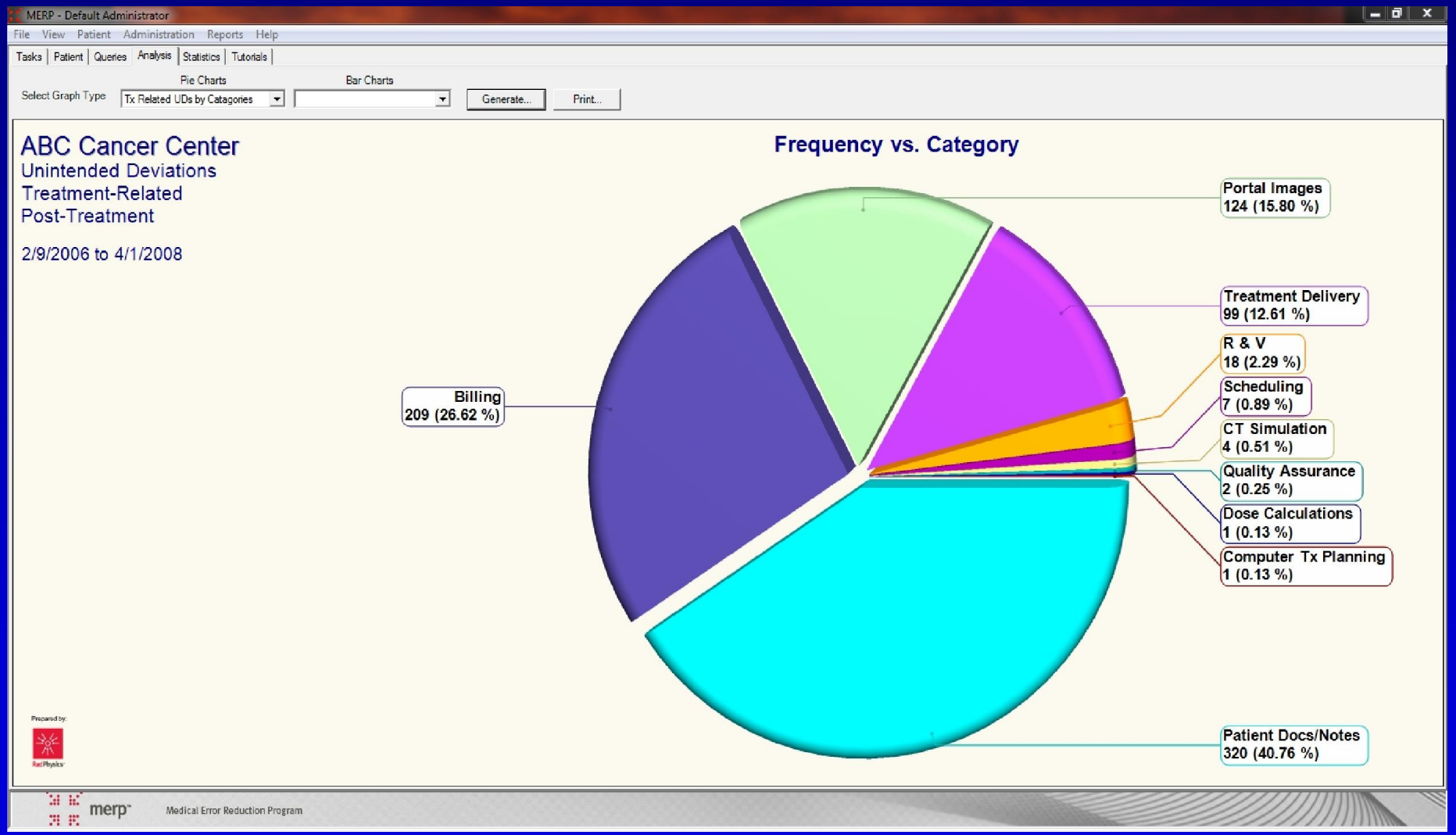
Error Entry


MERP - Default Administrator
File View Patient Administration Reports Help
Add Patient
Edit Patient
Add Deviation
Tasks Patient Queries Analysis Statistics Tutorials
Find Patient...
Patient Information
Chart ID 1
Name Test, Test
Unintended Deviations List
Add Unintended Deviation...
Refresh
Status Modified On Modified By Severity Documents UD No.
Disapproved 8/29/2011 10:23:31 AM a 2 0 1397
Pending Approvals 8/29/2011 8:49:41 AM a 4 0 1396
Pending Approvals 8/29/2011 8:29:02 AM a 2 0 1394
Documentation 8/28/2011 10:01:12 PM a 1 2 1392
Unintended Deviation - Classification
Select the Type of Error
Clinical
Radiation Safety
Quality Assurance
Pre/Post Tx Error ?
Pre - Tx
Post - Tx
History
Did Error Affect Patient's Treatment ?
Yes
No
Select the type of error, if the error occurred before or after treatment commenced, and whether the error affected the patient's treatment.
Previous
Next
Cancel
Help
merp
Medical Error Reduction Program

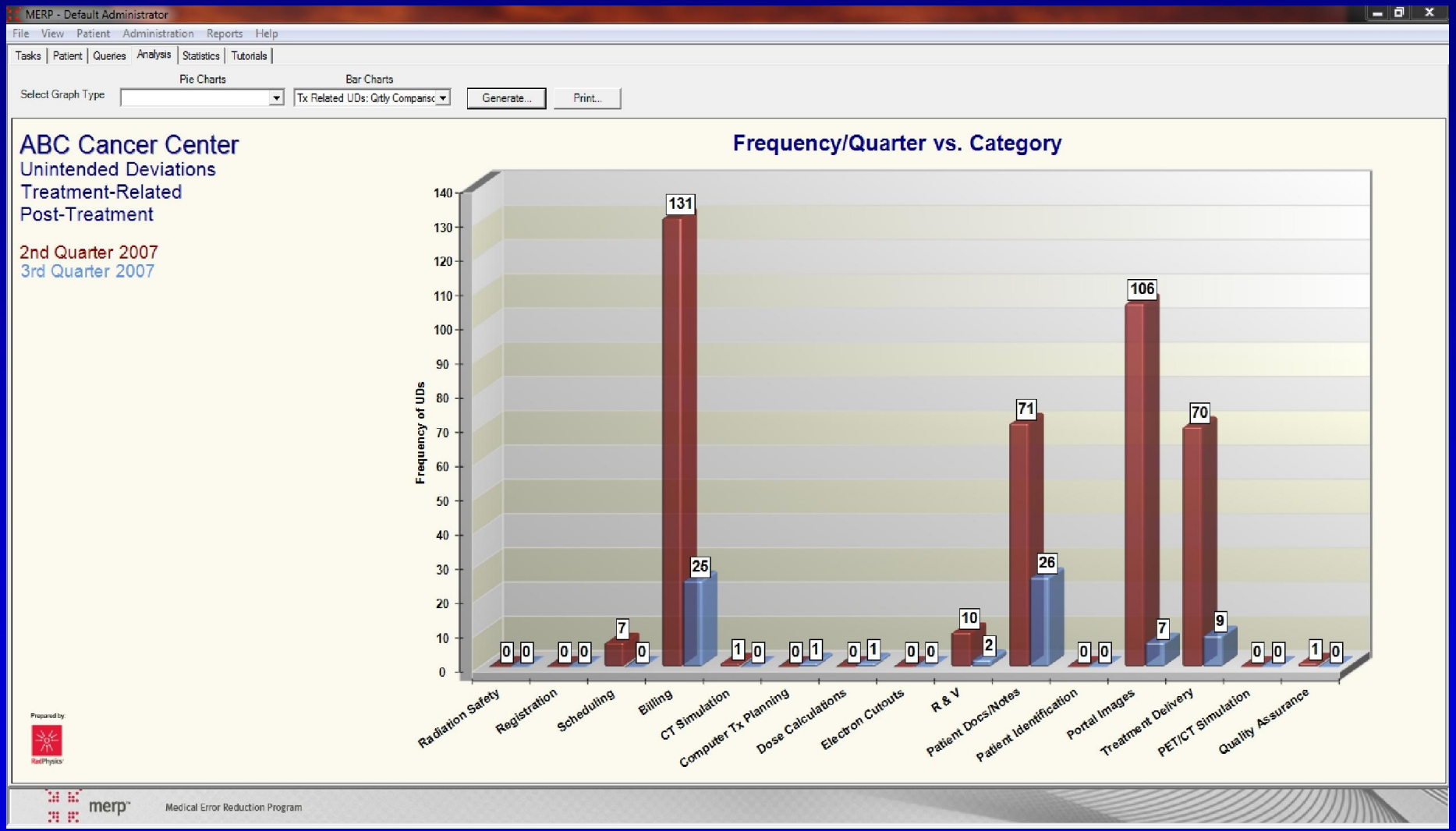
Error Entry - Conti.



Types of Errors

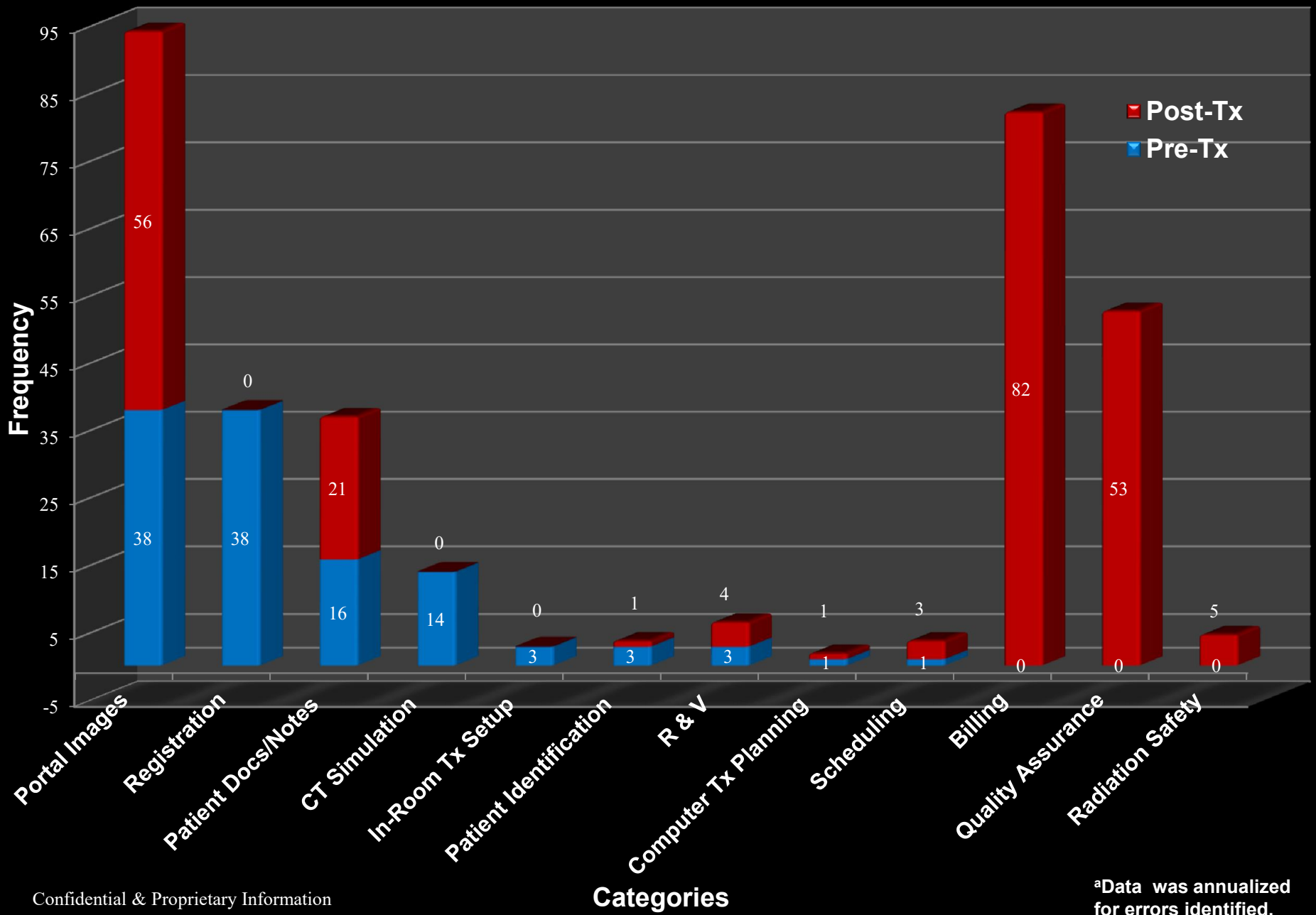


Quarterly Comparison



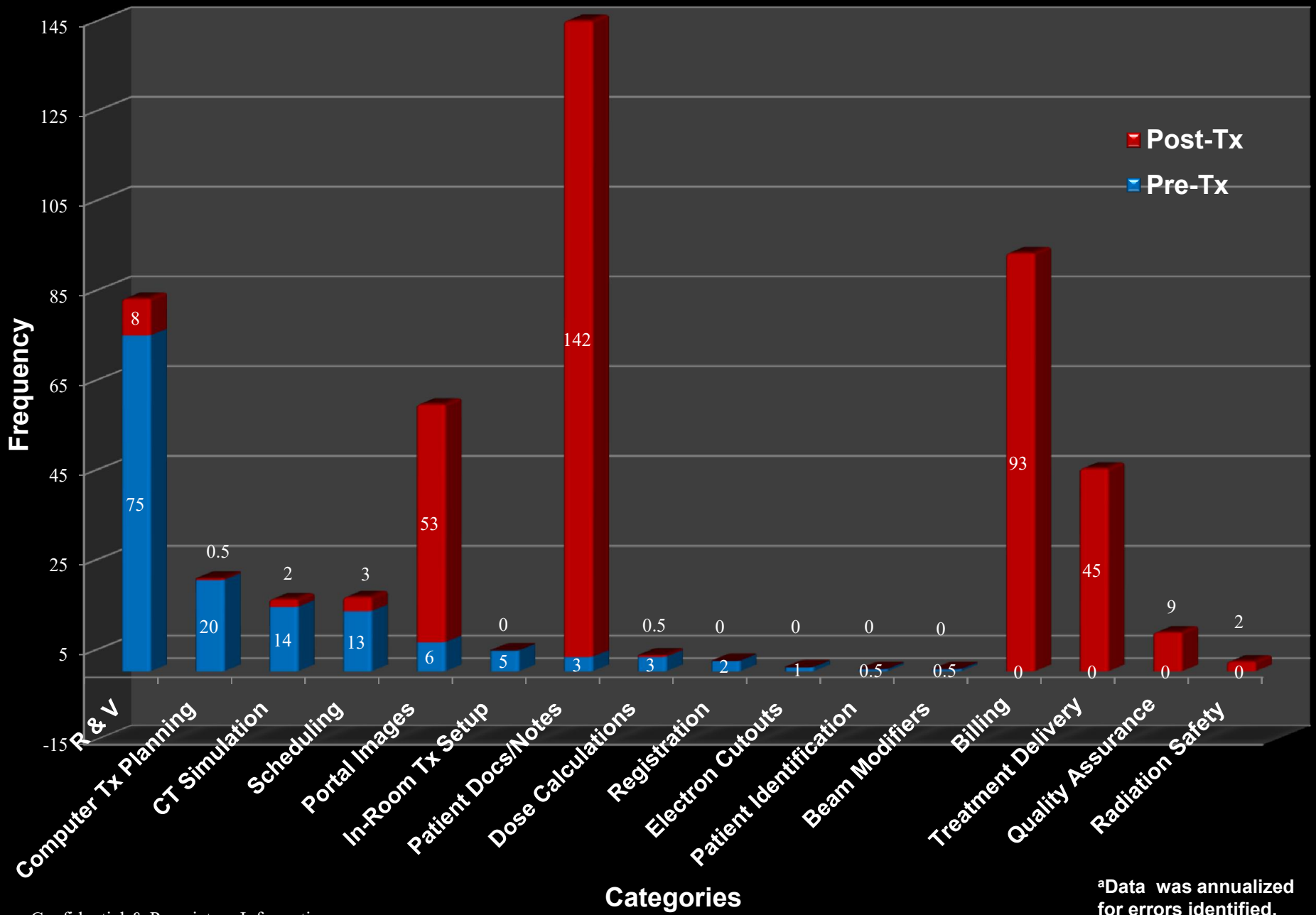
Case Examples

MERP: Frequency of Errors - Pre & Post Tx - Center A[a]



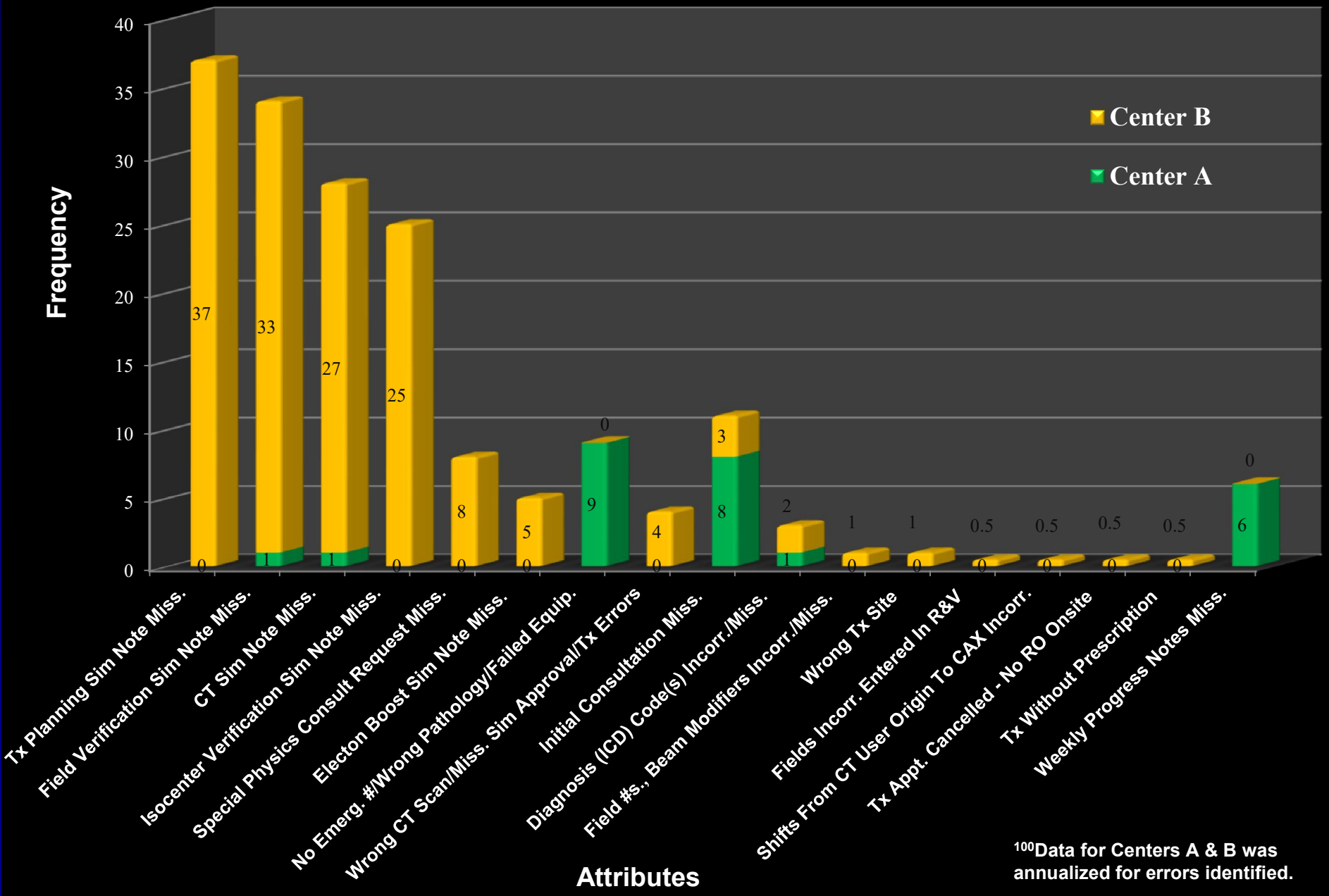
[a]Data was annualized for errors identified.

MERP: Frequency of Errors - Pre & Post Tx - Center B[a]

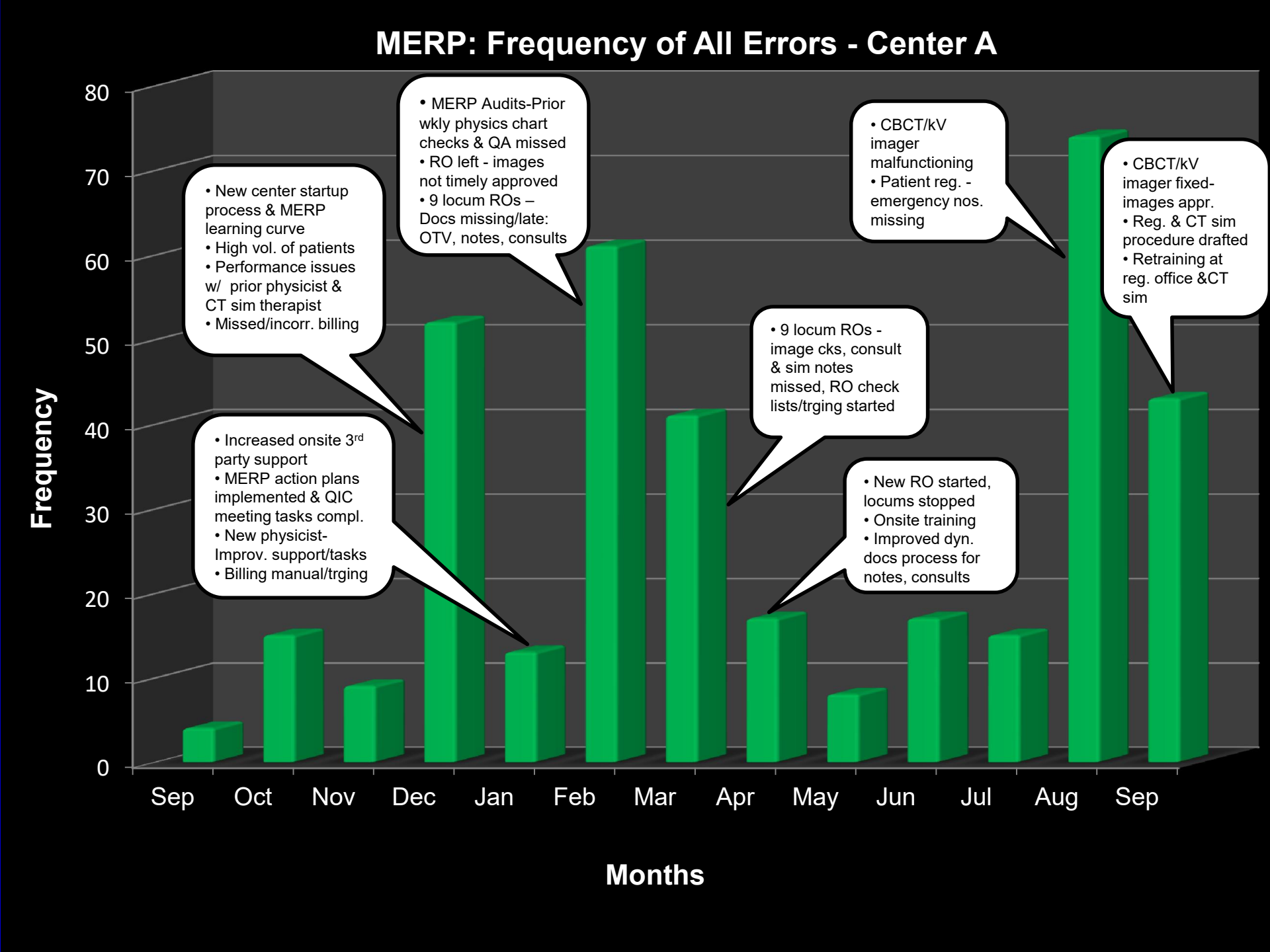


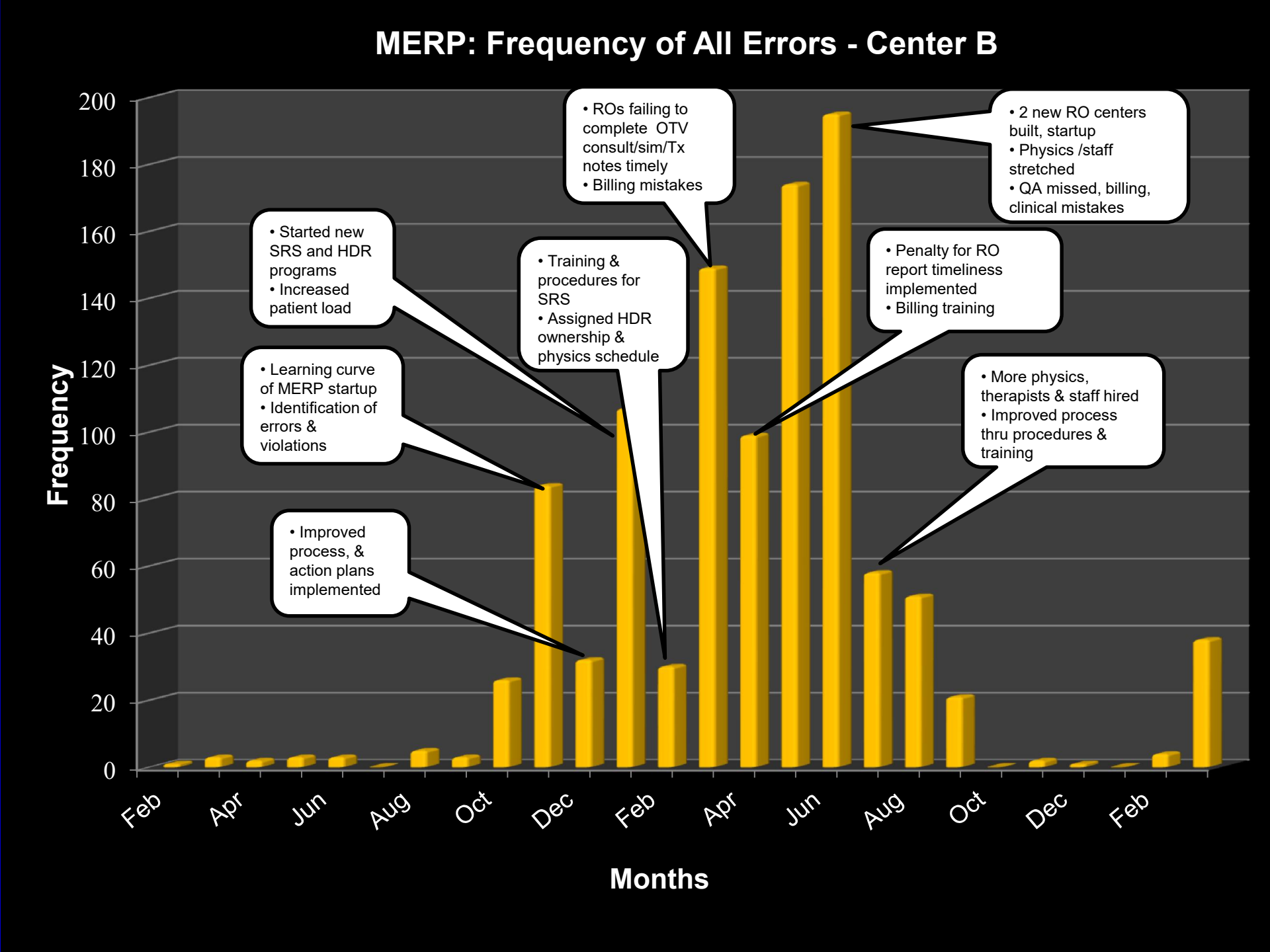
[a]Data was annualized for errors identified.

MERP: Frequency of Errors : Attributes of Severity Level 1 Centers A & B[100]

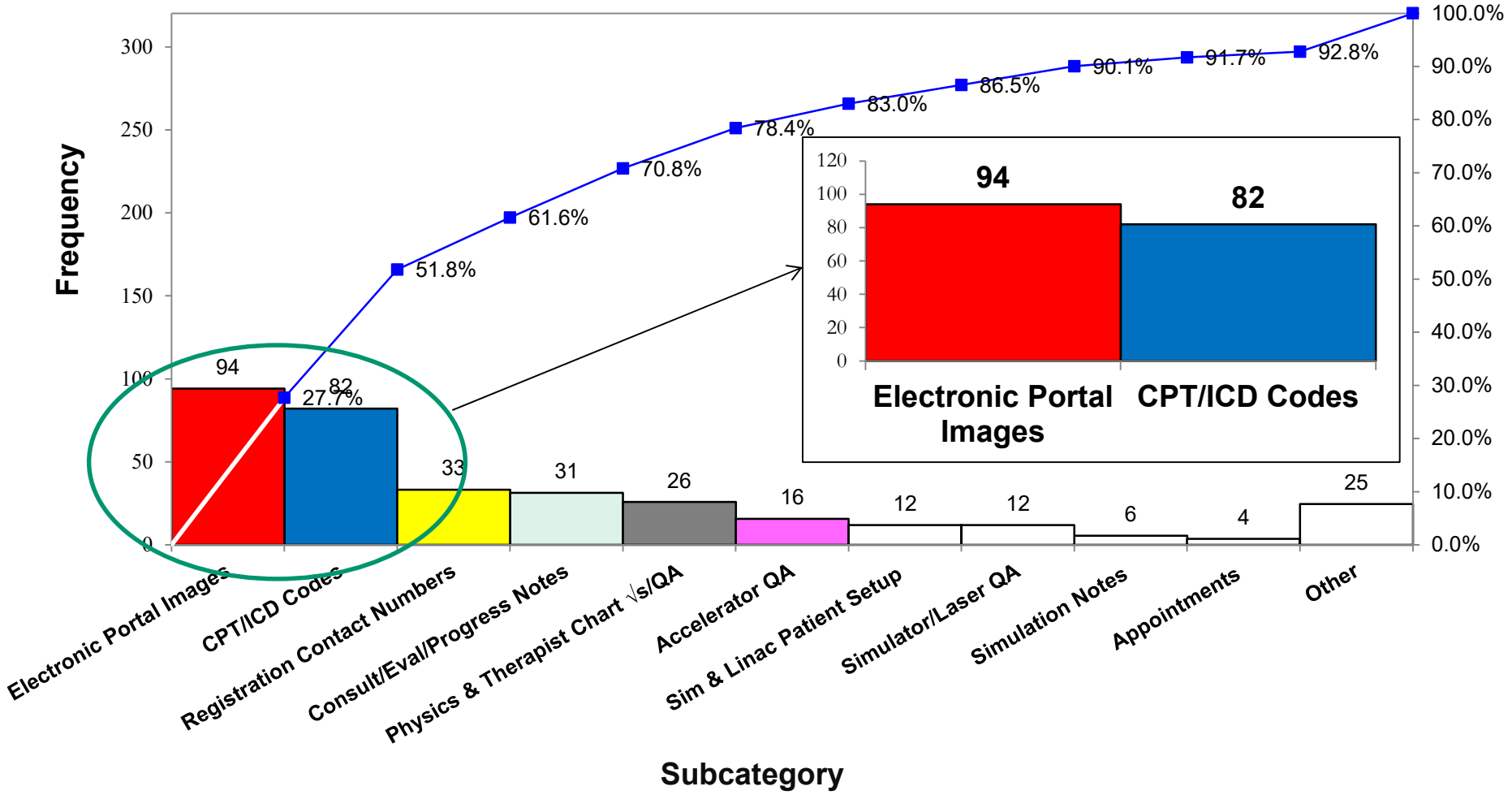


[100]Data for Centers A & B was annualized for errors identified.


MERP: Frequency of All Errors - Center A
Frequency
0
10
20
30
40
50
60
70
80
Sep
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Months
• New center startup process & MERP learning curve
• High vol. of patients
• Performance issues w/ prior physicist & CT sim therapist
• Missed/incorr. billing
• Increased onsite 3rd party support
• MERP action plans implemented & QIC meeting tasks compl.
• New physicist-Improv. support/tasks
• Billing manual/trging
• MERP Audits-Prior wkly physics chart checks & QA missed
• RO left - images not timely approved
• 9 locum ROs – Docs missing/late: OTV, notes, consults
• 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

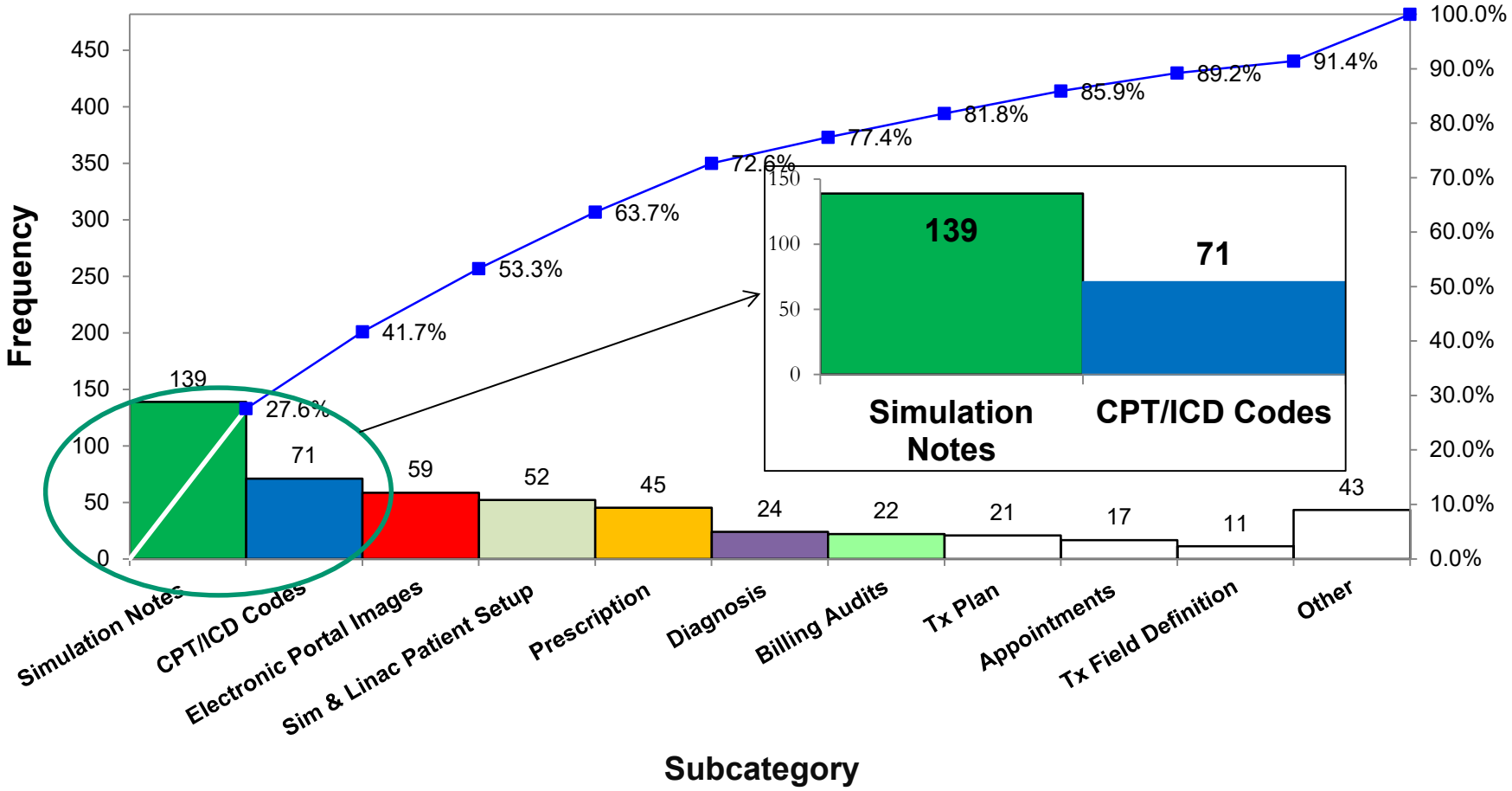

MERP: Frequency of All Errors - Center B
Frequency
200
180
160
140
120
100
80
60
40
20
0
Feb
Apr
Jun
Aug
Oct
Dec
Feb
Apr
Jun
Aug
Oct
Dec
Feb
Months
• Improved process, & action plans implemented
• Learning curve of MERP startup
• Identification of errors & violations
• Started new SRS and HDR programs
• 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

MERP: Frequency & Cumulative % of Errors per Subcategory Center A[101]



[101]Data was annualized for all errors (pre-Tx and post-Tx) collected.

MERP: Frequency & Cumulative % of Errors per Subcategory Center B[102]



[102]Data was annualized for all errors (pre-Tx and post-Tx) collected.

Results

Error Rates in Entire Treatment Process Using MERP[a]						
	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

[a]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).

Results

Error Rates in Treatment Delivery[a,b]

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 [1]		0.13 [2]					

[a]Treatment delivery means the administration of radiation.

[b]Data for Centers A and B was annualized for post-Tx errors in the treatment delivery process identified.

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

[2]Errors per total Tx units.

Results

Errors in Tx Delivery Process[a,b]		
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

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

[b]Data for Centers A and B was annualized for all post-Tx errors collected.

Results

Near Misses[a]		
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

[b]Data for Centers A and B was annualized for all post-Tx errors collected.

Results

Misadministration Rates[a]				
Error Category	Kline et al.	This Work MERP Center A	This Work MERP Center B	US NRC[b]	US NRC + Agreement States[c]
Per Patient, %		0	0.065		
Per Fraction, %	0.017	0	0.002	0.004	0.002
Per Field, %		0	0.00002		

[a]Data for Centers A and B was annualized for all post-Tx errors collected. US NRC data was also annualized.

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

Billing

Billing in Radiation Oncology

- From July 2012 to June 2013, Radiation Oncology was among the Top 10 errors by type of service, with a projected error rate of **42.7%**[58]
  - Top 2 reasons for errors among claims
    - Failing to send supporting documentation
    - Submitting records without a valid signature
- 2008 Provider Compliance Error Rate[59]
  - 10.9% Diagnostic Radiology
  - **11.8% Radiation Oncology**
  - 14.6% Independent Diagnostic Testing Facility
  - 22.2% Nuclear Medicine
  - 25.3% Interventional Radiology

[58] *Radiation Oncology: Top Billing and Documentation Errors*, The Celerian Group Company, cgsmedicine.com, 3/10/14.

[59] *May 2008 Comprehensive Error Rate Testing CERT Report Issued, ACR Radiology Coding Source May-June 2008, acr.org.*

Results

Billing Infractions per Patient[a]		
Category	**Center A** 309 patients	**Center B** 659 patients
Billing, %	26.54 [1]	5.1 [2]

[a]Data for Centers A and B was annualized for all data collected.

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

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

QA & Radiation Safety

Results

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

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

[b]Data for Centers A and B was annualized for all data collected.

Results

Infractions of Federal/State Regulations per Patient[a]		
Category	**Center A** 309 patients	**Center B** 659 patients
QA, %	2.59	0.19
Radiation Safety, %	1.62	0.23

[b]Data for Centers A and B was annualized for all data collected.

Lessons Learned

Lessons Learned

- **Upfront Homework**
  - History of error reduction important
  - Why must we embrace to be competitive
  - Philosophy of "goodness"
  - Non-punitive actions will be watched by staff
  - Incentives to encourage reporting a must

- **Practical Implementation**
  - Rewards system must be established
  - Superusers serve as point guards
  - Phased in approach minimizes overload
  - Initial paper recording of UDs prevents corrupt/inaccurate data entry
  - Brief weekly group meetings serve as bulletin board for errors
  - Individuals must be assigned responsibility for drafting procedures required by corrective action plans
  - Track closure of corrective action plans
  - Present overall results at quarterly QIC meetings

Part IX

AI

A Futuristic Normal Day

"Smart Bot"

- It's the end of the work day.
- You leave the clinic.
- An automated script, or bot, prepares and executes a series of model runs to calculate risk points and outliers.
- The job is completed and results saved in a shared location
- The bot analyzes the results and sees that for a new prostate patient, the machine on-board imaging shifts (x, y, z) from the initial patient setup marks, are just within tolerance while some even exceed tolerance.
- The bot completes an analysis of the underlying drivers of on-board imaging shifts of all prostate setups.

A Futuristic Normal Day

"Smart Bot"

- The bot discovers a larger numerical shift in the "z" (superior) direction, relative to most other new prostate patient setups.
- The bot analysis the shifts from CT user origin to the CAX for that specific patient's treatment plan and others.
- The bot discovers the initial patient setup shifts in the "z" direction are inverted when compared to the "x" direction in the treatment planning system.
- The bot summarizes its findings using natural language generation in an analytics package, highlighting the trend in baseline setup shifts using a visualization dashboard.
- The next morning at 8am, you walk into the office, read an email containing the analytics dashboard from the bot.
- You have a quick conversation with dosimetry.

A Futuristic Normal Day

"Smart Bot"

- You learn the EMR's patient setup notes for that specific patient show inverted shift coordinates.
- You also learn there is a pattern, but infrequent, with other patients.
- The bot quantifies the type of failure & overall risk using metrics (RPNs).
- The bot suggests how to manage the risk (failure mode) thru a plan of action (incl. RCA), timeliness, and roles for corrections.
- Human error is mitigated.
- The connection between initial setup imaging shifts and inverting of treatment planning system shifts may have taken weeks or months to discover.
- This is the future of radiation oncology.

A Compelling Argument

AI has the potential to reduce medical errors by 30 – 40%, and treatment expenses by as much as 50% (Frost and Sullivan, 2016)[60]

[60] A. Chatterjee, *Use of Artificial Intelligence to Reduce Medical Errors*, Data Science and Technology, July 17, 2017.

Objective

- Develop a system to identify, prevent, and mitigate errors and their effects before they result in harm.
- Key areas of opportunity in radiation oncology[61]
  - Simulation
  - Treatment planning
  - QA and treatment delivery
- Predict high-risk error situations
- Automatically detect outliers
- Build into workflows
- Preclude preventable errors from occurring
- Drive value-based medicine with effectiveness and efficiency
- Create a high-reliability system that is quantitatively integrated with patient safety.

[61]Feng M, Valdes, G, Dixit, N, Solberg, T, *Big Data – Machine Learning in Radiation Oncology: Opportunities, Requirements, and Needs,* Perspective - Frontiers in Oncology, Vol.. 8, Article 110, pp. 1-7, April 2018.

Process Reliability

Short-Term Approach

- Predict RT Process Reliability[63]
  - Map RT process steps (categories, subcategories, attributes…)
  - Collect reported unintended deviations (errors) in a ILS such as MERP
  - Define error occurrence as pre-Tx vs post-Tx
  - Tabulate error rates and near miss rates
  - Use a best fit, logistic regression model for each process step
  - Estimate and predict failure points
  - Target these high-risk process points with resources
  - Look at reliability by illustrating how errors propagate thru stages of the process
  - Segregate out which errors result in near misses or actual hits
  - Integrate error risk classification (RPN) to measure effectiveness of action plan and severity of error on patient safety outcome.
  - Apply metrics with visual dashboards

[63]Howell C, Tracton G, Amos, A, Chera B, Marks L, Maur LM, *Predicting Radiation Therapy Process Reliability Using Voluntary Incident Learning System Data*, Pract Radiat Oncol. 2018; 9: e210-217.

Machine Learning

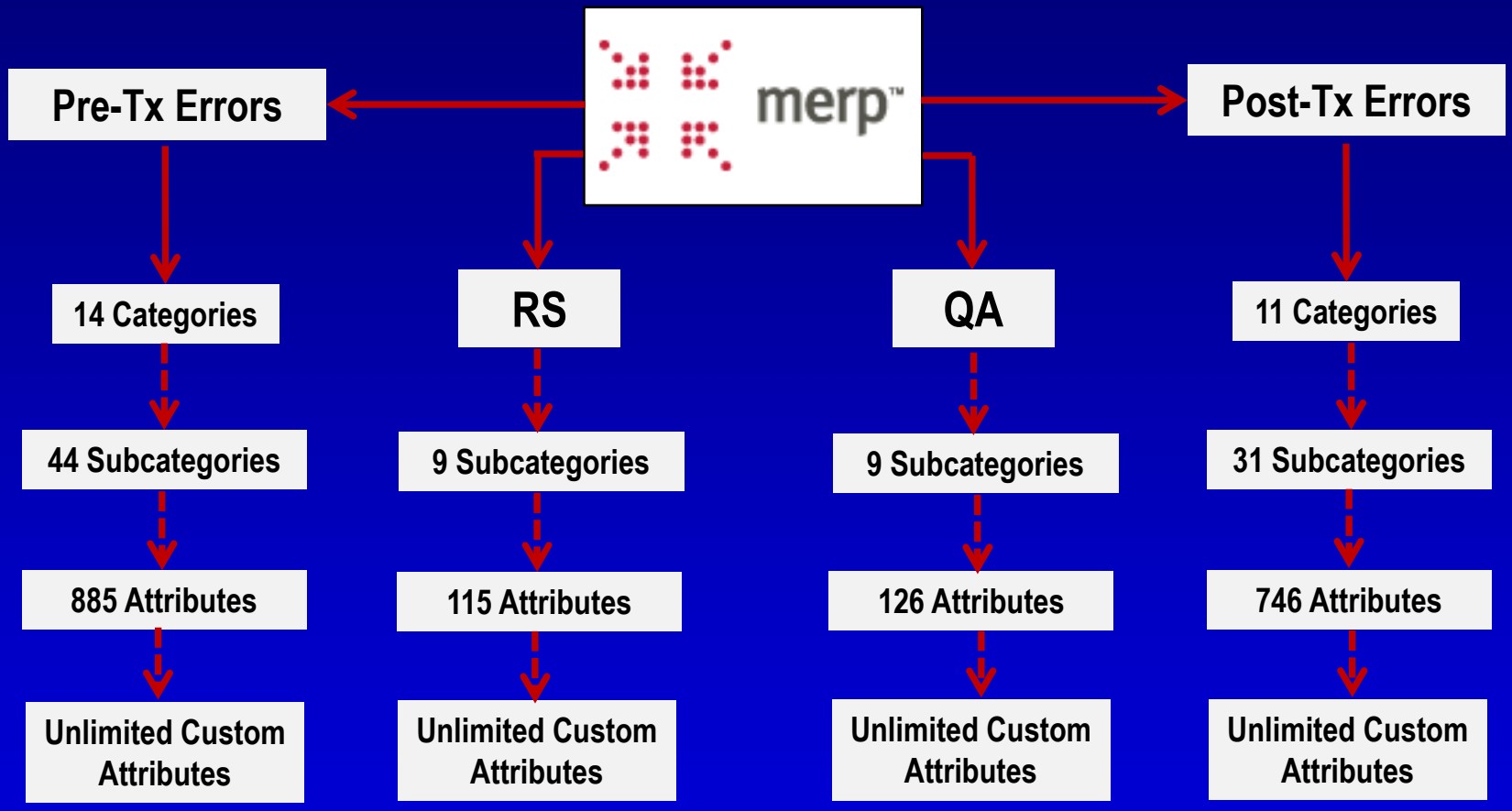
Long-term Approach

- Optimize big data[64]
  - Integrate and optimize big data collection
  - Use large sample sizes of errors evenly distributed throughout the RT process
  - Use well defined ontology (taxonomy and nomenclature)
  - Apply data mining & AI to extract models that can accurately predict failure points in the treatment process
  - Validate models using large data pooling
  - Divide the data into training and validation data sets
  - Data may be harvested from risk management (incident learning systems), EMRs (Aria, Mosaic, Epic, Cerner), treatment planning and imaging systems
  - Formulate a rapid-learning health management system
  - Provide knowledge to practicing clinicians to improve patient safety and outcomes

[64]Bienedict SH, et al., *Big Data – Overview of the American Society for Radiation Oncology-National Institutes of Health-American Association of Physicists in Medicine Workshop 2015: Exploring Opportunities for Radiation Oncology in the Era of Big Data,* Int J Radiation Oncol Biol Phys, Vol.. 95, No. 3, pp. 873-879, 2016.

Machine Learning

#1 - Availability and Quality of Data



Grand Total
27 Categories
93 Subcategories
1,872 Attributes
Unlimited Custom Attributes

Conclusion

- A safety culture needs to be embraced
- Risk can be managed at a number of levels
- A systems-based approach is needed for meaningful data
- MERP is an example of an incident reporting system
- IA is the next step for creating a highly reliable system