

Risk Reduction Strategies for Radiation Oncology Programs

Ed Kline

COO
US Cancer Therapies
a division of



Founder
RadPhysics Services



RadPhysics™

Completing cancer care.



Disclosure

Founder – RadPhysics Services LLC



Introduction

- Part I - Brief History of Errors
- Part II - Surveys of Medical Errors
- Part III - Radiation Oncology Errors
- Part IV - Who Reports Radiation Oncology Errors
- Part V - Incident Reporting Systems
- Part VI - Where is the Risk?
- Part VII - Requirement vs Incentive
- Part VIII - Medical Error Reduction Program (MERP)
- Part IX - Lessons Learned
- Part X - AI in Risk Management



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

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

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

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

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

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



History

1999

- Institute of Medicine (IOM) Report⁶
 - Focused a great deal of attention on the issue of medical errors and patient safety
 - 44,000 to 98,000 deaths per year in U.S. hospitals each year as the result of medical errors
 - 10,000 deaths per year in Canadian hospitals
 - Exceeds annual death rates from road accidents, breast cancer, and AIDS combined in U.S.

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



History

1999

- IOM Costs⁷
 - Approximately \$37.6 billion per year
 - About \$17 billion are associated with preventable errors
 - Of that \$17 billion, about \$8 to \$9 billion are for direct health care costs
 - Updated estimates place costs between \$17 billion and \$29 billion per year in hospitals nationwide⁸

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

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



History

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%20Organisation%20with%20a%20memory.pdf>.



Impact Today

- Society of Actuaries (SOA)¹⁰
 - 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)

¹⁰The Cultural Cure for Sentinel Events. Industry Focus – Patient Safety & Quality Healthcare, www.PSQM.com, July/August 2016, pgs. 49-54.



Impact Today

- Claims Data¹¹
 - From medical errors, about \$17 billion per year are directly associated with additional medical costs
 - Of approximately \$80 billion in costs associated with medical injuries, around 25% are the result of avoidable medical errors
- Liability Costs¹²
 - Overall annual medical liability system costs, including defensive medicine, are estimated to be \$55.6 billion in 2008 dollars, or 2.4% of total health care spending
- Economic Impact¹³
 - Preventable medical errors may cost the U.S. economy up to **\$1 trillion** in “lost human potential and contributions”
 - Preventable deaths due to medical errors are 10 times higher than the IOM estimate based on Quality-Adjusted Life Years (QALYs)

¹¹The Economic Measurement of Medical Errors, Society of Actuaries' Health Section, 2010.

¹²Health Aff (Millwood). 2010 Sep; 29(9): 1569–1577.

¹³Economic Impact of Preventable Medical Errors Nearly \$1 Trillion, Researchers Say, Wolters Kluwer's Journal of Health Care Finance, October 2012.



Impact Today

- British Medical Journal (BMJ)¹⁴
 - Medical errors kill an estimated 251,000 Americans every year
 - 3rd leading cause of death ... behind heart disease and cancer
- Projections¹⁵
 - Annual, direct costs of overall cancer care are expected to be \$157.77 billion in 2020
 - Worldwide cancer cases are expected to increase by 50% thru 2030

¹⁴<http://www.bm.com/content/353/bm.i2139>.

¹⁵*Cancer Prevalence and Cost of Care Projections*, National Cancer Institute, Accessed through www.costprojections.cancer.com, February 15, 2020.



Outcome Today

- In U.S., adverse events occur to approx. 3 - 4% of patients¹⁶
- Average intensive care unit (ICU) patient experiences almost 2 errors per day¹⁷
 - 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 hour¹⁸



Bottom-line

- Patient Safety & Quality Healthcare (PSQH)¹⁹
 - “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”

¹⁹*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 Exist²⁰
 - Open reporting culture is not accepted
 - Local systems are inadequate to
 - Investigating incidents
 - Identifying contributory factors
 - Implementing & embedding learning

²⁰*The Cultural Cure for Sentinel Events*. Industry Focus – Patient Safety & Quality Healthcare, www.PSQM.com, July/August 2016, pgs. 49-54.



Part II

Surveys of Medical Errors



Surveys²¹

6 in 10 Americans have not encountered a medical error, while 4 in 10 have experienced a medical error personally, in someone else's care, or both.

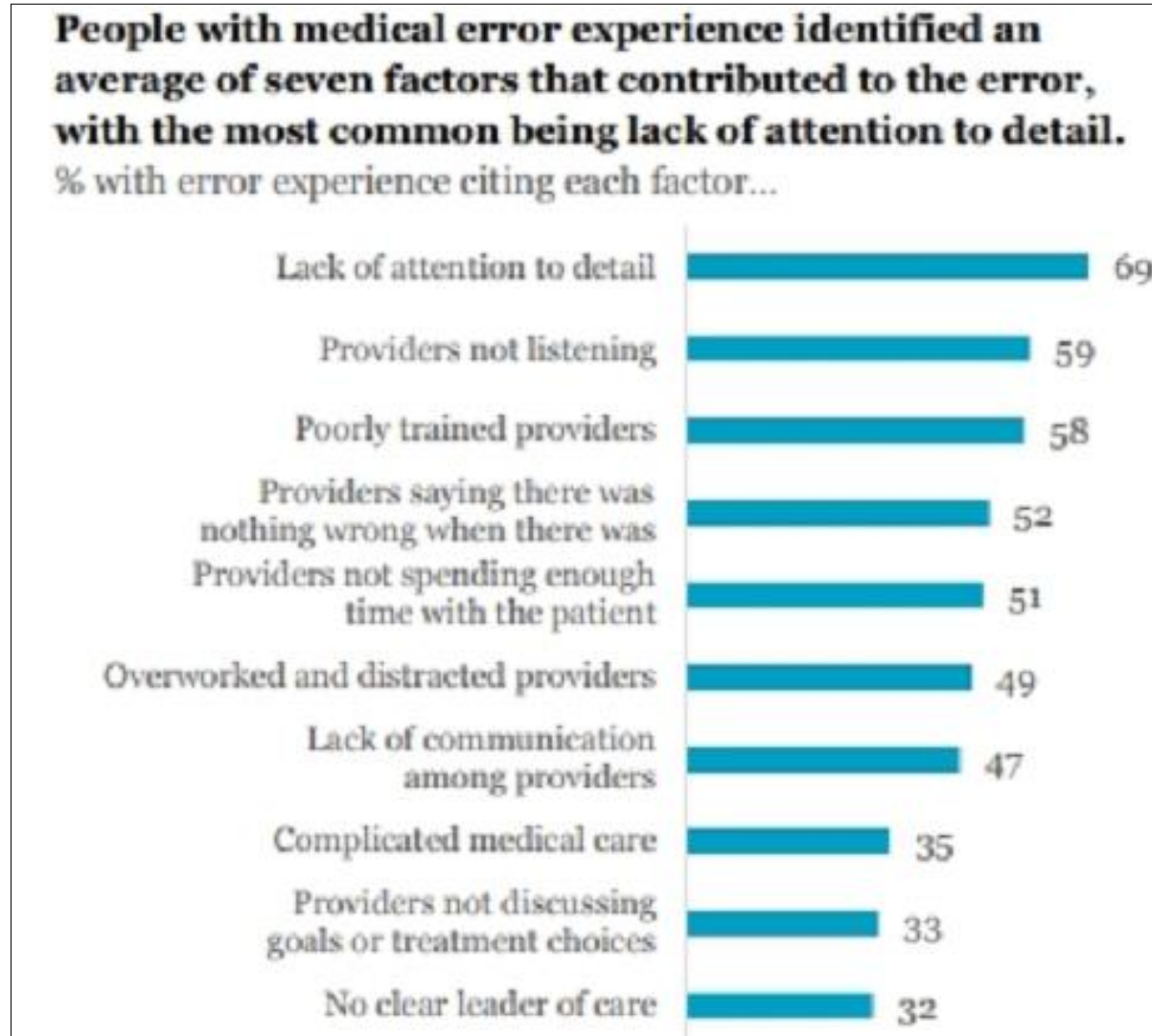
% of adults who ...



²¹Americans' Experiences with Medical Errors and Views on Patient Safety. Institute for Healthcare Improvement, September 28, 2017. Accessed through www.ihi.org.



Surveys²²



²²Americans' Experiences with Medical Errors and Views on Patient Safety. Institute for Healthcare Improvement, September 28, 2017. Accessed through www.ihp.org.



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 death²³
- Reported error rates
 - 0.1% to 0.2% of fields treated²⁴
 - 0.17% per patient treated^{25, 26}
 - Studies not relying on self-reporting show actual rates of up to 3%²⁷

^{23, 24, 25}French, J, *Treatment Errors in Radiation Therapy*. Radiation Therapist, Fall 2002, Vol.11, No. 2; 2002.

²⁶E.C. Ford and S. Tereakis, *How safe is safe?: Risk in radiotherapy*, *Int. Radiat. Oncol. Biol. Phys.* 78, 321 (2010).

²⁷S. Mutic, R.S. Brame, S. Oddirau, P. Parikh, M.A. Westfall, M.L. Hopkins, A.D. Medina, .C. Danieleley, 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 suggests²⁸
 - 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

²⁸Howell 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 Do We Compare With HROs?

Not That Well

- Commercial aviation experience²⁹
 - 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 plants³⁰
 - 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

²⁹, ³⁰Howell 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 Within Medicine?

Mixed Results

- Anesthesiology Experience³¹
 - 8.2 deaths from anesthesia complications per million hospital surgical discharges
- Big Picture Problems - Hospitalized Medicare beneficiaries³²
 - 135,000 patients per million experience adverse events
 - 15,000 patients per million experience an event that contributed to their death
 - 6,000 patients per million have a serious/reportable event, of which 31% are due to medication errors and 26% to surgery or other procedure

³¹, ³²Howell 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 reporting³³

³³*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.aspx, Accessed March 2, 2017.



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.”³⁴

³⁴ICRP. *Radiological Protection and Safety in Medicine*. ICRP 73. Annals of the ICRP, 1996, Vol. 26, Num. 2.



Part IV

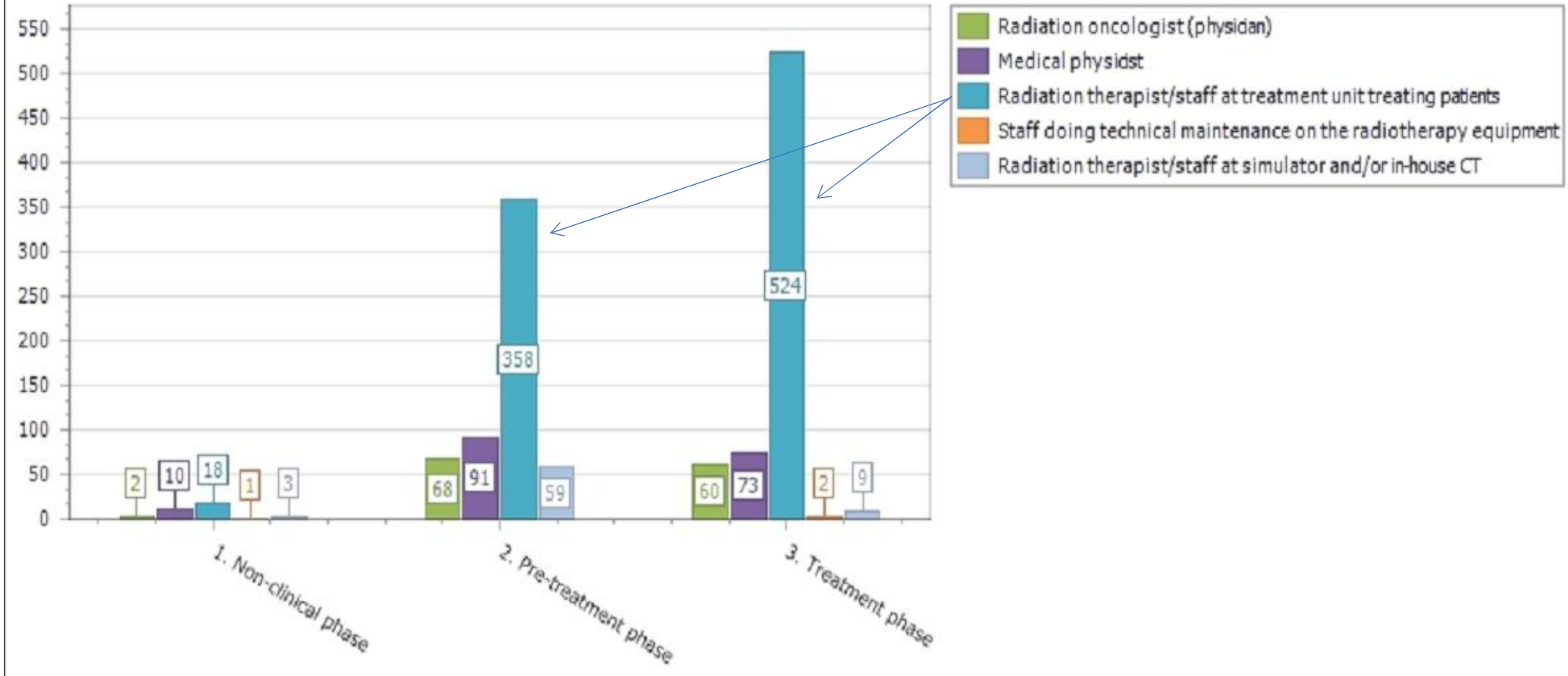
Who Reports Radiation Oncology Errors



IAEA SAFRON³⁵

Who Reports the Errors

All External Beam Radiotherapy Incidents

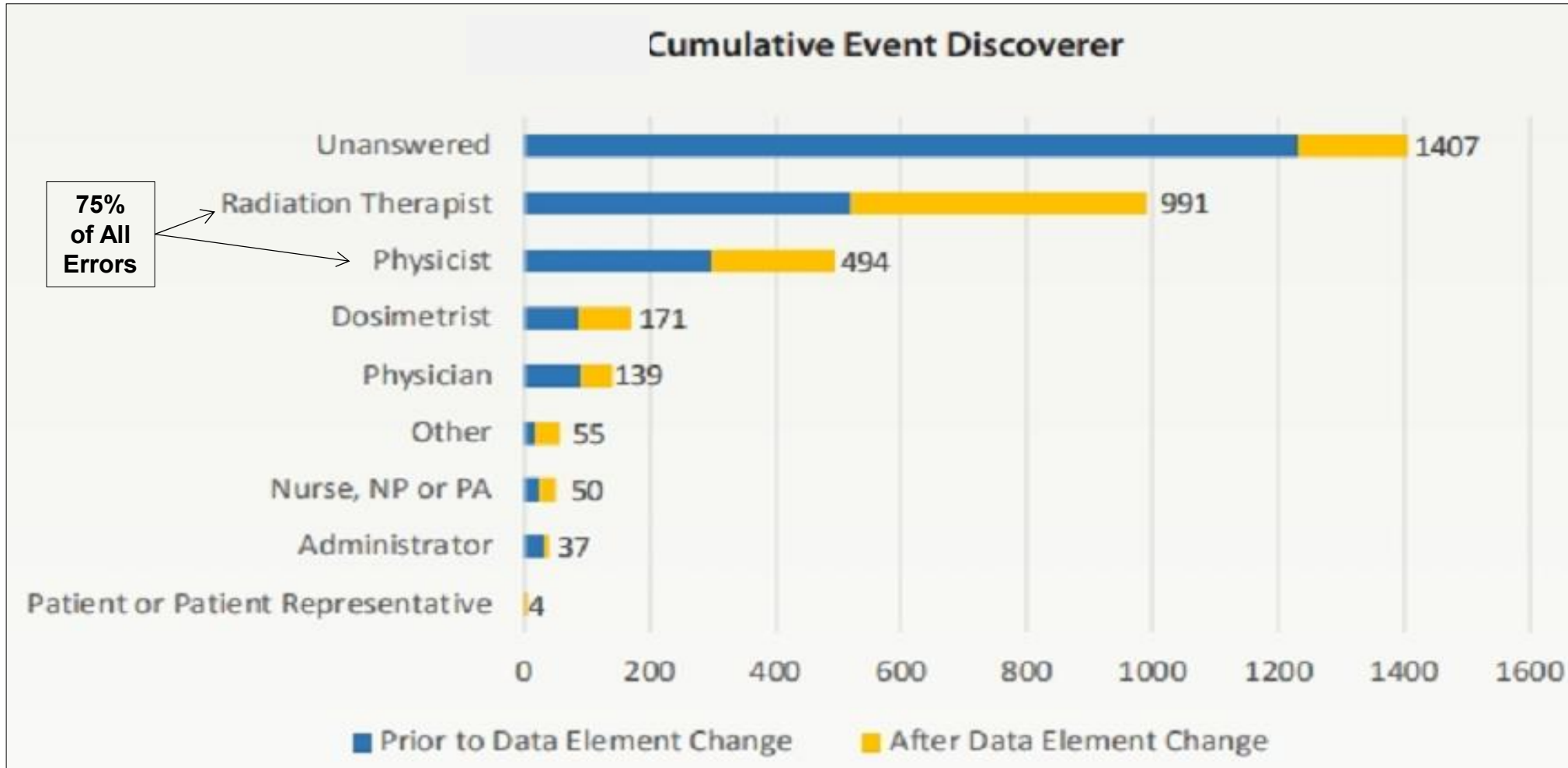


³⁵IAEA, Statistical Reports: Distribution by Who Discovered the Incidents. SAFRON. 2/15/20. Accessed through www.rpop.iaea.org/SAFRON/Report/ReportList.aspx.



RO-ILS³⁶

Who Reports the Errors



³⁶ASTRO, 2017 Year in Review. RO-ILS. 2/15/20. Accessed through [www.](https://www.astro.org/uploadedFiles/MAIN_SITE/Patient_Care/Patient_Safety/RO-ILS/2017YearInReview.pdf)
https://www.astro.org/uploadedFiles/MAIN_SITE/Patient_Care/Patient_Safety/RO-ILS/2017YearInReview.pdf.



Radiation Oncology Reporting Comfort

- Survey of radiation therapists comfort levels in reporting errors³⁷
 - 29% of respondents expressed a fear of reprimand as a barrier to error reporting

³⁷Adams 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 Reporting Comfort

- Patient safety perceptions among US radiation therapists³⁸
 - 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

³⁸Jeffrey 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 Systems³⁹

- 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

³⁹*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”⁴⁰

- 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

⁴⁰E.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 Transformation⁴¹

- 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 analytic
 - Actionable data → intervention → “close the loop”

⁴¹Whole-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”⁴²

- Voluntary Incident Reporting in Radiation Oncology
 - ASTRO: Radiation Oncology–Incident Learning System (RO-ILS)(US)
 - Radiation Oncology Safety Education and Information System (ROSEIS)(IRL)
 - International Atomic Energy Agency (IAEA): Safety in Radiation Oncology (SAFRON)(AUT)
 - Radiotherapy Incident Reporting & Analysis System (RIRAS)(US)
 - Relir Othea (FR)
 - National Reporting and Learning System (NRLS)(UK)
 - National System for Incident Reporting in Radiation Therapy (NSIR-RT)(CAN)



⁴²E.C. Ford, S.B. Evans, *Incident learning in radiation oncology: A review*, Med. Phys. 45(5), e101-e103 (2018).

Part VI

Where is the Risk?



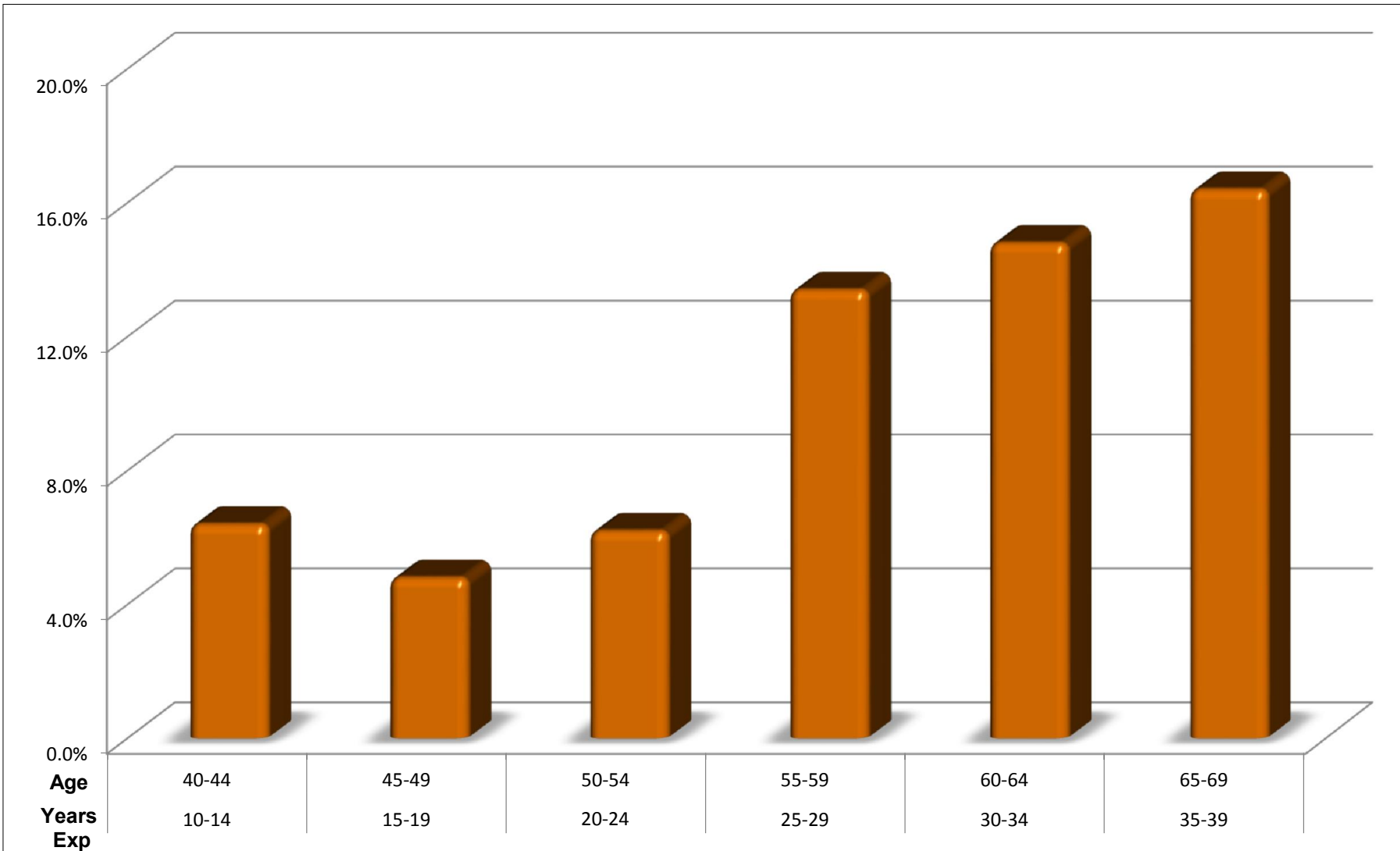
Risk - EMR Systems

- EMR-Related Malpractice Suits⁴³
 - Malpractice claims are on the rise
 - Since 2009, doctors using EMR systems rose from 1% to > 90%
 - Causes
 - System technology issues
 - Design issues
 - User-related issues
 - Top user-related issues
 - Entering incorrect information (13%)
 - Copy and paste (13%)
 - EHR conversion issues (13%)
 - Other user errors (12%)
 - Insufficient training/education (7%)
 - Alert issues/fatigue (2%)
 - Computer order entry workarounds (2%)



⁴³EHR-Related Malpractice Suits Are on the Rise, Posted by rufustherat, SERMO, August 30, 2019.

Probability of a Malpractice Lawsuit⁴⁴ by Age and Years of Experience^a for Radiation Oncologist

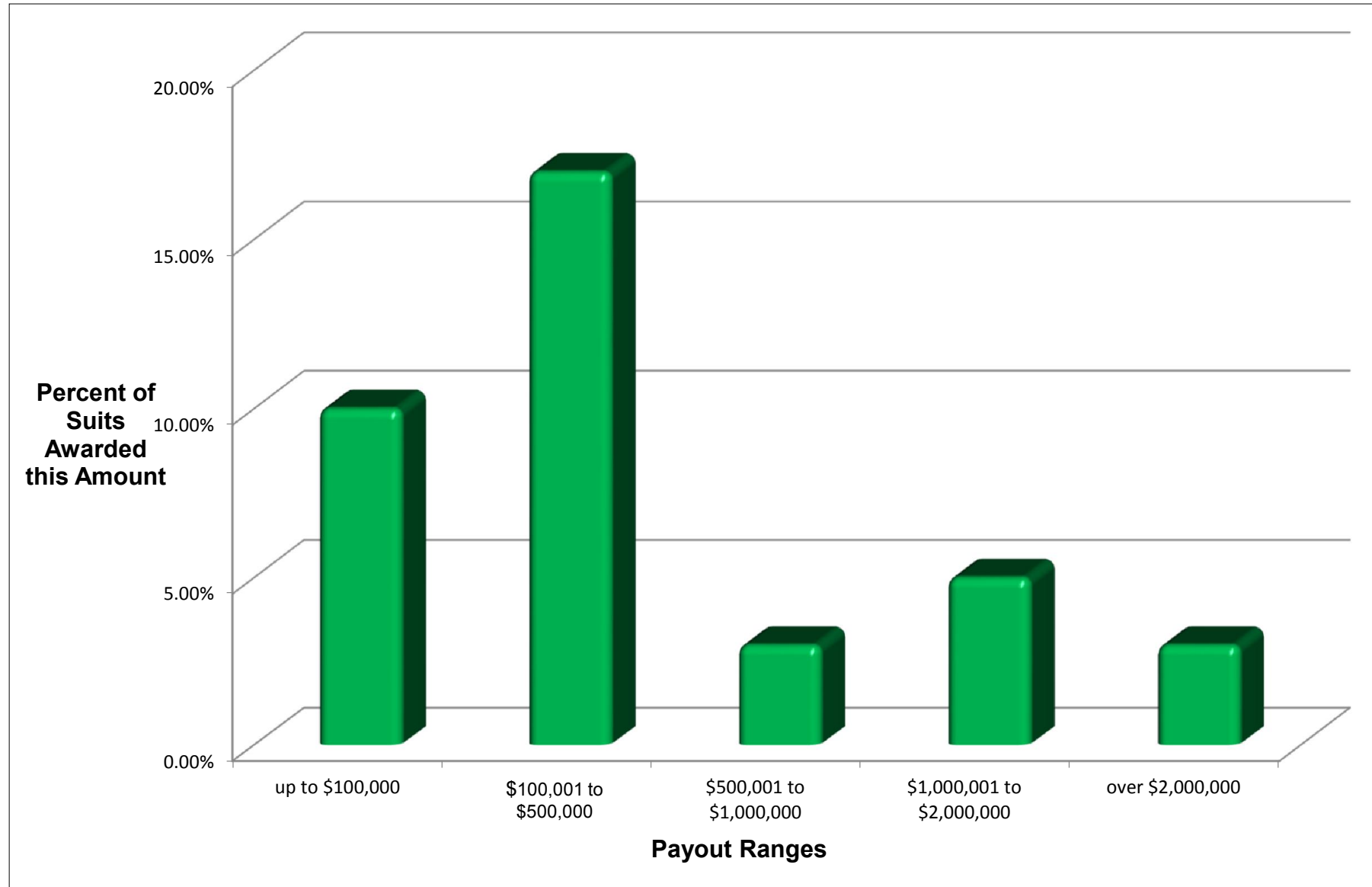


⁴⁴Based on survey data from *Medscape Malpractice Report 2015: Why Oncologists Get Sued*, Carol Peckham and Sarah Gresham, 1/22/16.

^aYears of experience is based on the assumption that a Radiation Oncologist begins employment at age 30.



Range of Payouts for Oncology Malpractice Suits Paid⁴⁵



⁴⁵Note 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 Oncologists⁴⁶

Summary

- 16% chance of being sued after 35 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

⁴⁶Radiation 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 Act⁴⁷
 - Medicare Patient Safety Evaluation System (PSES)
 - Qualified Health Plan insurers must verify, in part, that hospitals use a patient safety evaluation system (PSES)
 - 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

⁴⁷Patient 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.



Medicare Access and CHIP Reauthorization Act (MACRA)⁴⁸

MIPS Incentive Payment Formula

Exceptional performers receive additional positive adjustment factor – up to \$500M available each year from 2019 to 2024



⁴⁸Quality Payment Program. <http://go.cms.gov/QualityPaymentProgram>. Accessed January 8, 2017.

*MACRA allows potential 3x upward adjustment BUT unlikely



Incentive 2017

- Patient Protection and Affordable Care Act of 2015⁴⁹
 - 4 Major Performance Categories
 - Category no. 3 called “Improvement Activities (IA)” (15% weighting of CPS)
 - Includes activities that improve the clinical practice or delivery of care such as patient safety
 - Over 100 Activity Options to Choose From
 - Each activity worth points (max possible 40 points)
 - High weighting activity = 20 points each
 - Medium weighting activity = 10 points each
 - IA affects MIPS overall score by **15%**

⁴⁹Quality Payment Program. <http://go.cms.gov/QualityPaymentProgram>. Accessed February 13, 2020.



Requirement + Incentive Medicare

A Risk Management Program Can Safety Requirements

- Medicare requires hospitals to have “evidence-based” patient safety programs.

A Risk Management Program Can Generate Revenue

- Medicare requires participation in MIPS bonus/penalty program.
- **A risk management (patient safety) program can pay** for itself and more as shown in this example¹:

MIPS		Medicare Part B Collections		
CY	% Bonus ²	\$4M	\$20M	\$100M
2020	+5%	\$30,000	\$150,000	\$750,000
2021	+7%	\$42,000	\$210,000	\$1,050,000
2022+	+9%	\$54,000	\$270,000	\$1,350,000

¹Risk Management Program when used in conjunction with activity descriptions IA PSAS 4, 17 and 20 for max IA credit of 15%.

²Does not include additional bonus points added to final score for small practices and exceptional performance.

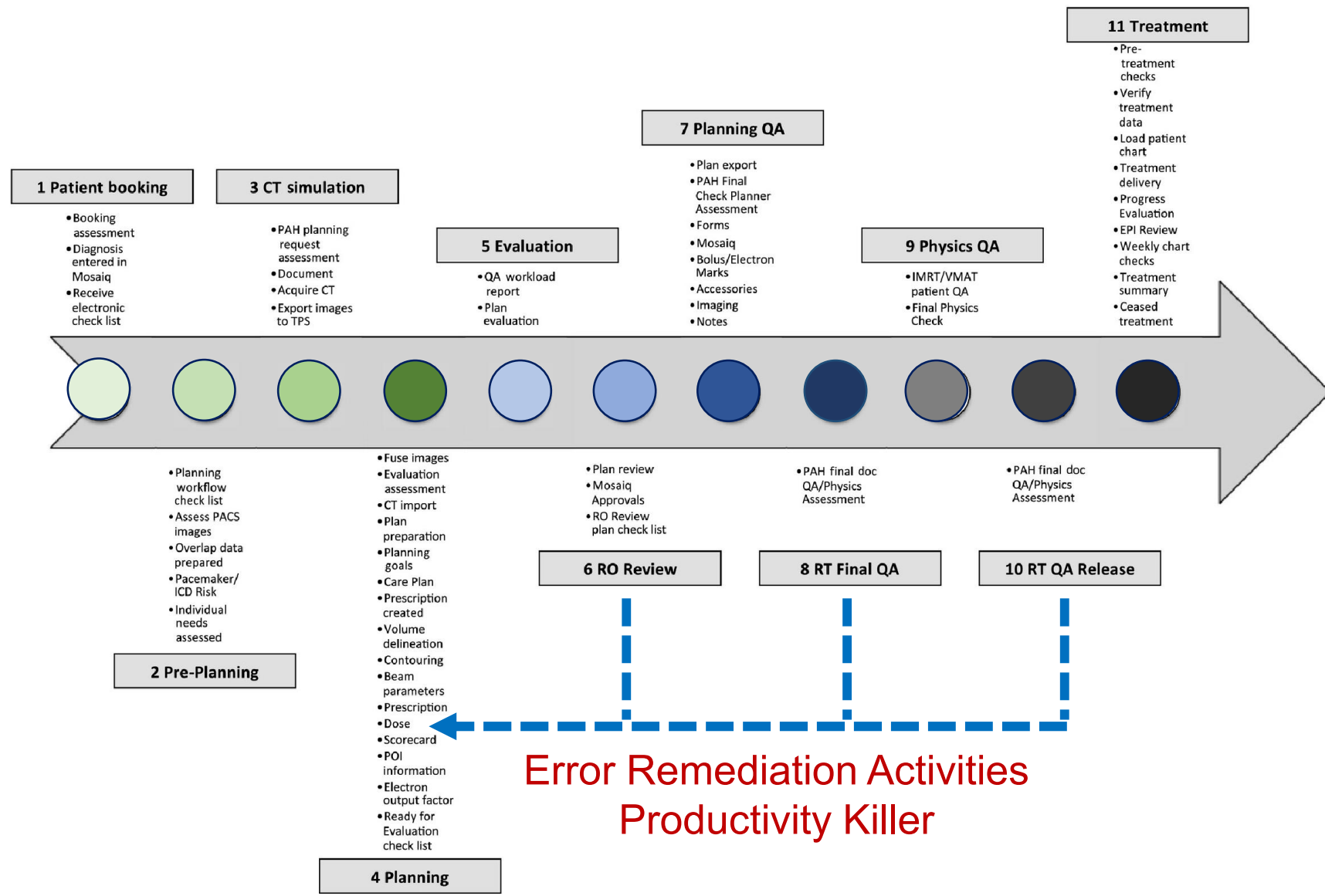


Part VIII

Medical Error Reduction Program



Entire Radiation Oncology Process

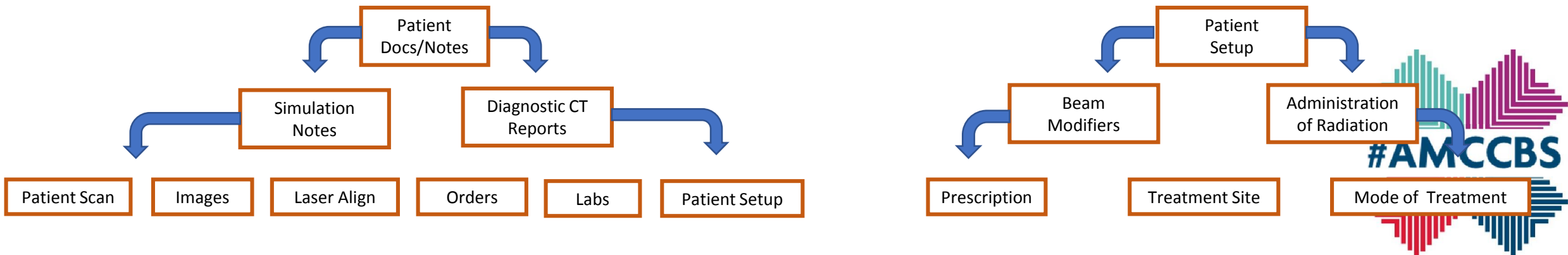
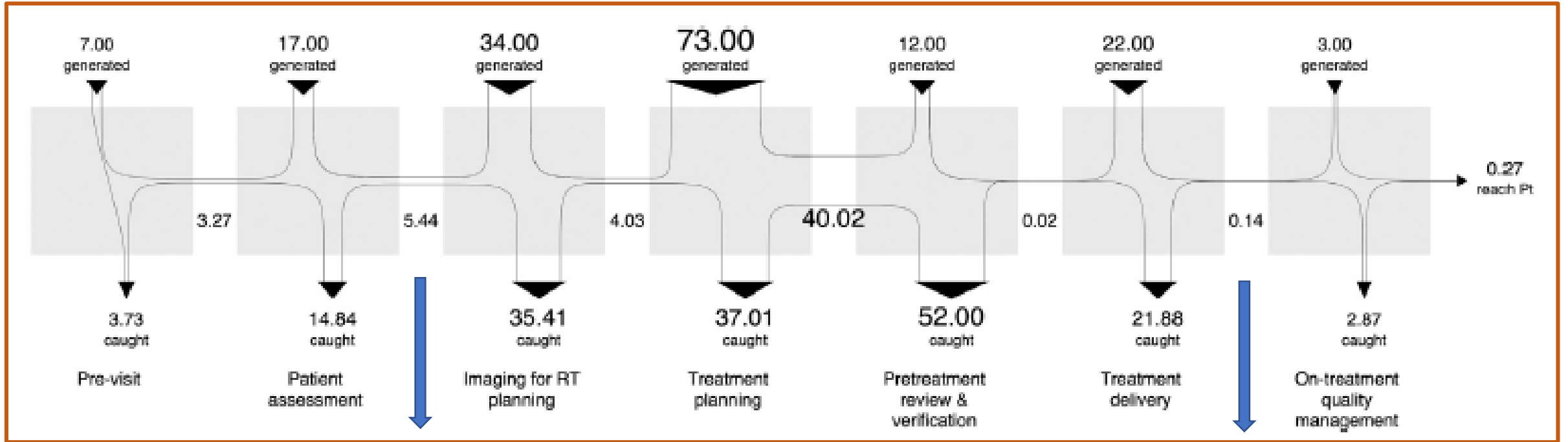


**Error Remediation Activities
Productivity Killer**



Example of Error Propagation

Ideal Solution



Improve Overall Safety and Reduce Harm⁵⁰

Healthcare Systems & Organizations Are Under Stress!

- **Safety I**

- Identify casual chains of events that lead to harm ... tracking, trending, measuring compliance

- **Safety II**

- Equip frontline workers with skills and tools to identify risks to patient safety and adapt their work environments to optimize safety
- Focus on reducing risk instead of overemphasizing “zero” harm goals
- Spotlight successes and adaptation + examine failures



⁵⁰E. Thomas, *The harms of promoting 'Zero Harm'*, *BMJ Qual Saf*, 1-3 (2019).

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

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**
 - 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 CMS Patient Safety Evaluation System
 - Qualifies for MIPS credit in 4 of 4 medium weight activities (when used in conjunction with IA PSAS 4, 17 and 20) for IA (max credit) of 15% of formula
 - JC patient safety standards show basis for question
 - ACR and ACRO standards demonstrate benchmark for measuring performance
 - CRCPD (Agreement State) recommended regulations (as of 9/18) 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/Ds/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 fx to the PTV. The Tx plan was calculated correctly using 6X. However, 18X was inadvertently entered in Tx Fld. 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



Patient Entry/HL7

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 xxxxxxxxxxxxxxxxxxxxxxxx
Name xxxxxxxxxxxxxxxxxxxxxxxx

Unintended Deviations List Add Unintended Deviation... Refresh

Status	Modified On	Modified By	Severity Level	Type	Pre/Post Tx	Category	SubCategory	Attribute	Documents	UD No.
--------	-------------	-------------	----------------	------	-------------	----------	-------------	-----------	-----------	--------

Add Patient

Chart ID

Last Name First Name M

OK Cancel Help

merp Medical Error Reduction Program



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...

Status	Modified On	Modified By	Severity
Disapproved	8/29/2011 10:23:31 AM	a	2
Pending Approvals	8/29/2011 8:49:41 AM	a	4
Pending Approvals	8/29/2011 8:29:02 AM	a	2
Documentation	8/28/2011 10:01:12 PM	a	1

Unintended Deviation - Classification

Select the Type of Error

- Clinical
- Radiation Safety
- Quality Assurance

Pre/Post Tx Error ?

- Pre - Tx
- Post - Tx

Did Error Affect Patient's Treatment ?

- Yes
- No

History

Select the type of error, if the error occurred before or after treatment commenced, and whether the error affected the patient's treatment.

merp

Previous Next Cancel Help

	Documents	UD No.
patient ID not performed	0	1397
appointment times incorr./miss.	0	1396
bolus required, no bolus used	0	1394
missing attribute SL 1	2	1392

Refresh



Error Entry - Conti.

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...

Status	Modified On	Modified By	Severity Level
Disapproved	8/29/2011 10:23:31 AM	a	2
Pending Approvals	8/29/2011 8:49:41 AM	a	4
Pending Approvals	8/29/2011 8:29:02 AM	a	2
Documentation	8/28/2011 10:01:12 PM	a	1

Unintended Deviation - Classification

Select Category and Attribute energy Apply Clear

- [-] Dose Calculations
 - [-] Manual Calculations
 - Energy incorr./miss.
 - [-] Computer Calculations
 - Energy incorr./miss.
 - [-] Electron Cutouts
 - [-] Measurements
 - Energy incorr.
 - Energy used incorr.
 - [-] R & V
 - [-] Prescription
 - Energy and modality (photons or electrons) incorr./miss.
 - [-] Treatment Field Definitions
 - Energy incorr./miss.

Custom Attribute

Standards

Previous Next Cancel Help

	Documents	UD No.
performed	0	1397
s incorr./miss.	0	1396
bolus used	0	1394
L 1	2	1392

Refresh

More Information

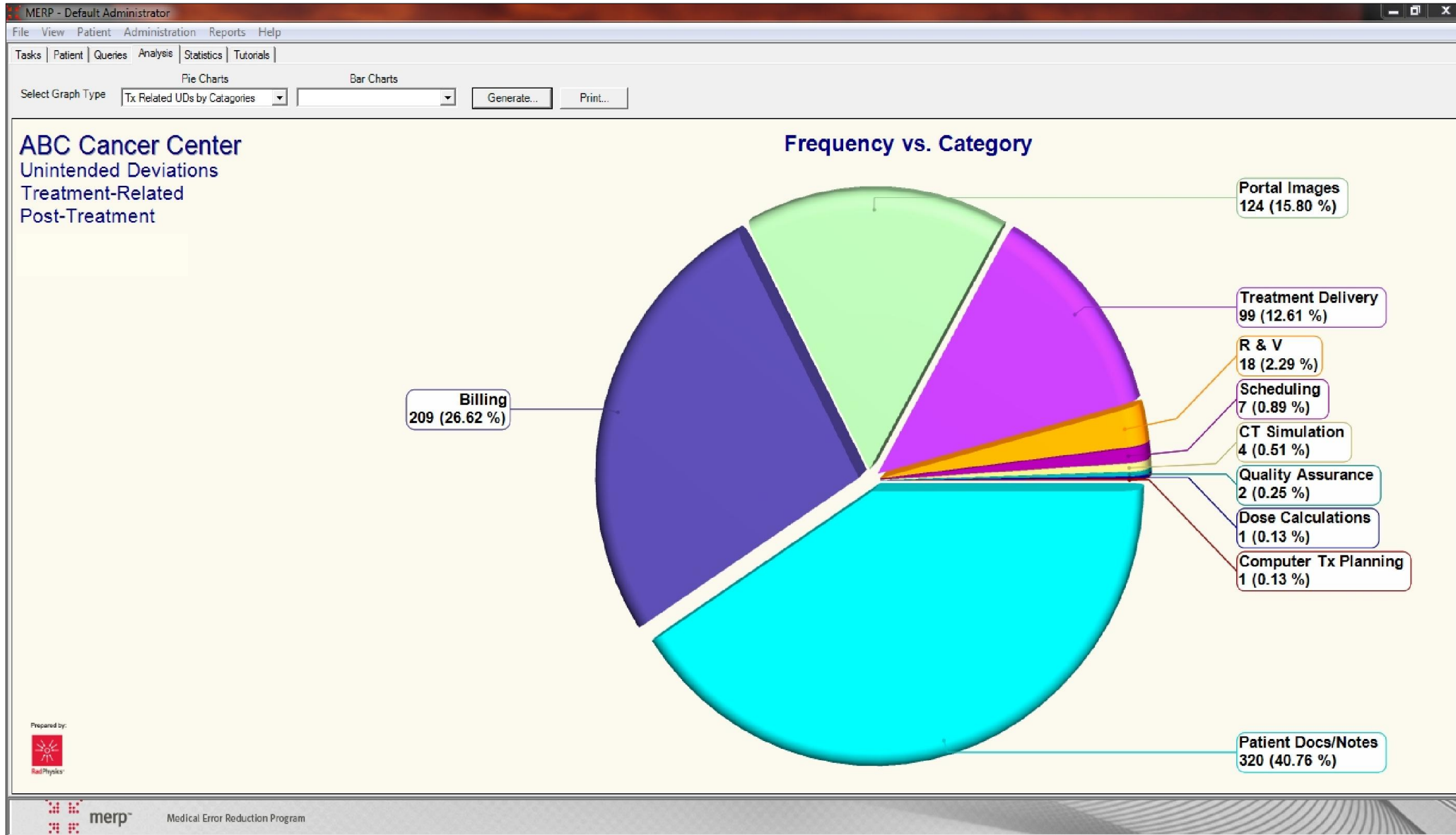
ACR
Must

Correct verification of the 3D external beam plan in the actual setting requires proper understanding, interpretation, transfer, and documentation of all of the aspects of the patient's clinical setup, positioning, and immobilization, as well as treatment unit parameters such as jaw setting, treatment aids, gantry angle, collimator angle, patient support table angle and position, treatment distance, and monitor unit setting. Record and verify systems couple computer monitoring and control to the delivery aspects of the treatment unit. These systems serve to verify proper settings on the treatment unit and capture all details of the actual treatment unit parameters in a computer record for each patient. (ACR Practice Guideline for 3D External Beam Radiation Planning and Conformal Therapy – Rev. 2006 (Res. 22) Part VI. Image-Based 3-D Treatment Verification and Delivery - Section A. Verification and Documentation)

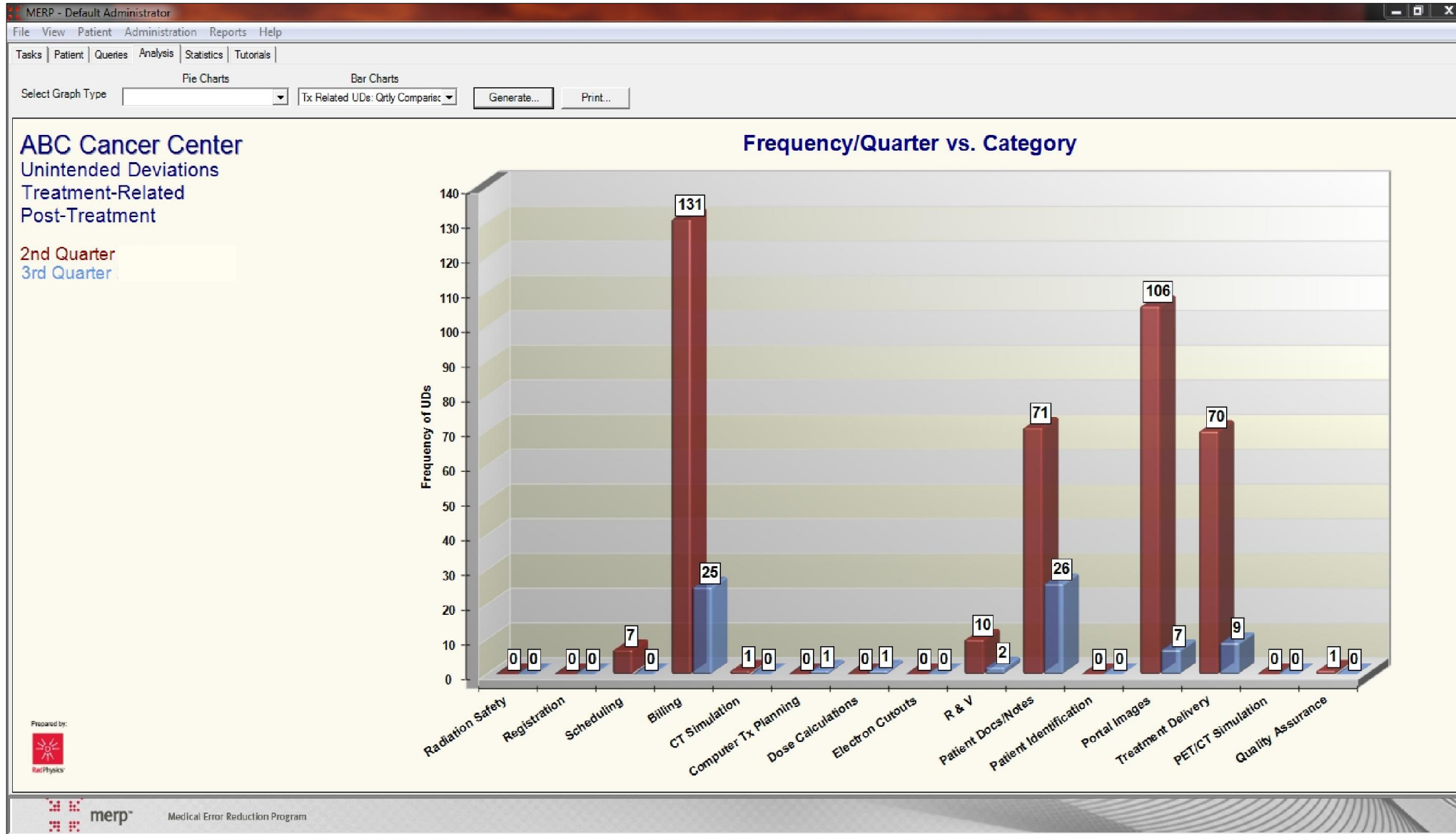
Close

merp Medical Error Reduction Program

Types of Errors



Quarterly Comparison





Error Query

MERP - Default Administrator

File View Patient Administration Reports Help

Tasks Patient Queries Analysis Statistics Tutorials

UD Statistics

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 :

Results

Pre/Post	Category	Subcategory	Attribute	Occurrences
Pre-Tx	Computer Tx Planning	Tx Plan	Custom attribute SL 2	20
Post-Tx	Billing	Codes	CPT code incor./miss.	14
Post-Tx	Patient Docs/Notes	Default	Custom attribute SL4	9
Post-Tx	Scheduling	Appointments	Custom attribute SL 3	8
Post-Tx	Portal Images	Electronic Imager	Daily/weekly images not approved	8
Post-Tx	Quality Assurance	Checks	Weekly physics chart checks miss./late	7
Post-Tx	Quality Assurance	Checks	Custom attribute SL 5 (Least Severe)	6
Post-Tx	Quality Assurance	Checks	Physics sign-off/approval of QA checks miss./late	5
Post-Tx	Patient Docs/Notes	Default	Custom attribute SL3	4
Post-Tx	Quality Assurance	Checks	Physics sign-off/approval of field service reports miss./late	3
Post-Tx	Billing	Codes	Custom attribute SL 2	3
Pre-Tx	Patient Docs/Notes	Default	Custom attribute SL 4	3
Pre-Tx	Patient Docs/Notes	Default	Custom attribute SL 5 (Least Severe)	3
Post-Tx	Patient Docs/Notes	Default	Custom attribute SL2	2
Post-Tx	Quality Assurance	Checks	Physics sign-off/approval of linac fault log miss./late	2
Post-Tx	Patient Docs/Notes	Default	Custom attribute SL5 (Least Severe)	2
Post-Tx	Patient Docs/Notes	Simulation Notes	Custom attribute SL5 (Least Severe)	1
Post-Tx	R & V	Patient Care Plan	Custom attribute SL 5 (Least Severe)	1
Post-Tx	R & V	Plan Scheduling/Tx Calendar	Scheduled plan/set of Tx fields incor.	1
Post-Tx	Quality Assurance	Checks	Check/test exceeding tolerance, no action taken	1
Post-Tx	Quality Assurance	Meetings	Weekly chart rounds miss./late	1
Pre-Tx	Patient Docs/Notes	Simulation Notes	CT sim note not completed	1
Post-Tx	Billing	Codes	No. of charges incor./miss.	1
Pre-Tx	Patient Docs/Notes	Default	Initial consultation note not completed	1
Pre-Tx	Patient Docs/Notes	Default	IMRT planning note incor./miss.	1
Post-Tx	Radiation Safety	Reviews	Annual review of QMP miss./late	1
Pre-Tx	Scheduling	Appointments	Custom attribute SL 3	1
Pre-Tx	Billing	Codes	No. of charges incor./miss.	1
Pre-Tx	Billing	Codes	Diagnosis (ICD) code(s) incor./miss.	1
Pre-Tx	Billing	Codes	Custom attribute SL4	1
Post-Tx	Quality Assurance	Accelerator	Field service reports miss./late	1
Post-Tx	Quality Assurance	Accelerator	Custom attribute SL 2	1
Post-Tx	Quality Assurance	Simulator	Annual CT sim calibration miss./late	1
Post-Tx	Quality Assurance	Equipment	Custom attribute SL 1 (Most Severe)	1
Post-Tx	Quality Assurance	Tx Planning Computer	Initial commissioning of Tx planning/dose calc programs miss....	1





Severity and RPN Classification

MERP - Default Administrator

File View Patient Administration Reports Help

Tasks | Patient Queries | Analysis | Statistics | Tutorials |

Query Type: Filter By:

Category	SubCategory	Attribute	Severity Level	RPN	Date Reported	
Billing	Codes	Custom attribute SL 2	2	8	1/2/2020	U...
Billing	Codes	Custom attribute SL 2	2	8	12/12/2019	U...
Billing	Codes	No. of charges incor./miss.	2	160	10/30/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/23/2019	U...
Billing	Codes	Custom attribute SL 2	2	8	8/21/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	8/12/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	7/16/2019	U...
Billing	Codes	CPT code incor./miss.	2	128	7/16/2019	U...
Patient Docs/Notes	Default	Custom attribute SL2	2	8	2/5/2020	U...
Patient Docs/Notes	Default	Custom attribute SL2	2	8	12/27/2019	U...
Patient Docs/Notes	Default	Custom attribute SL2	2	8	12/5/2019	U...
Patient Docs/Notes	Default	Custom attribute SL3	3	6	2/6/2020	U...

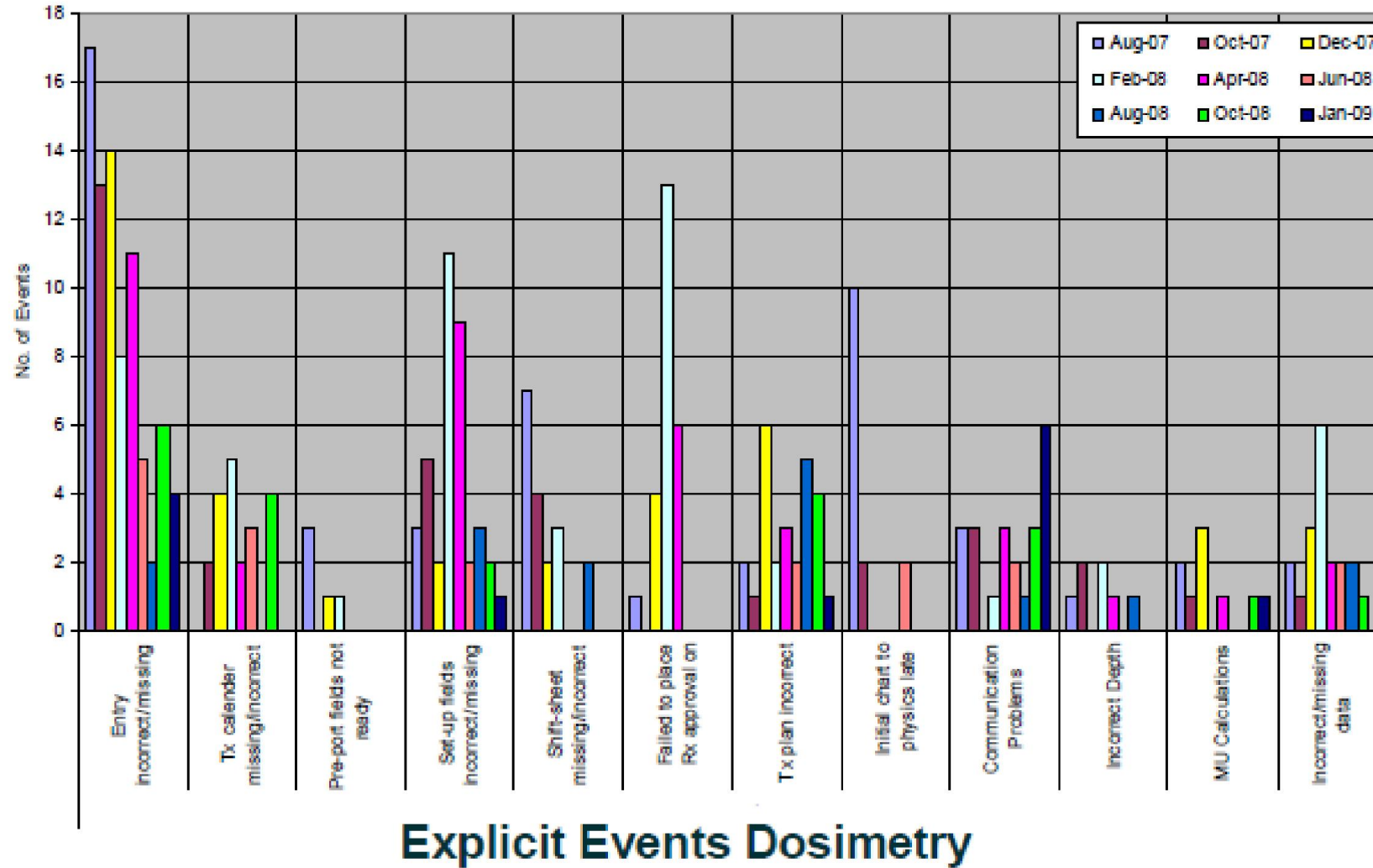


Case Examples



Process Improvement Board

Note: The table below reflects the actual number of each event reported by month. It is not in percentage.



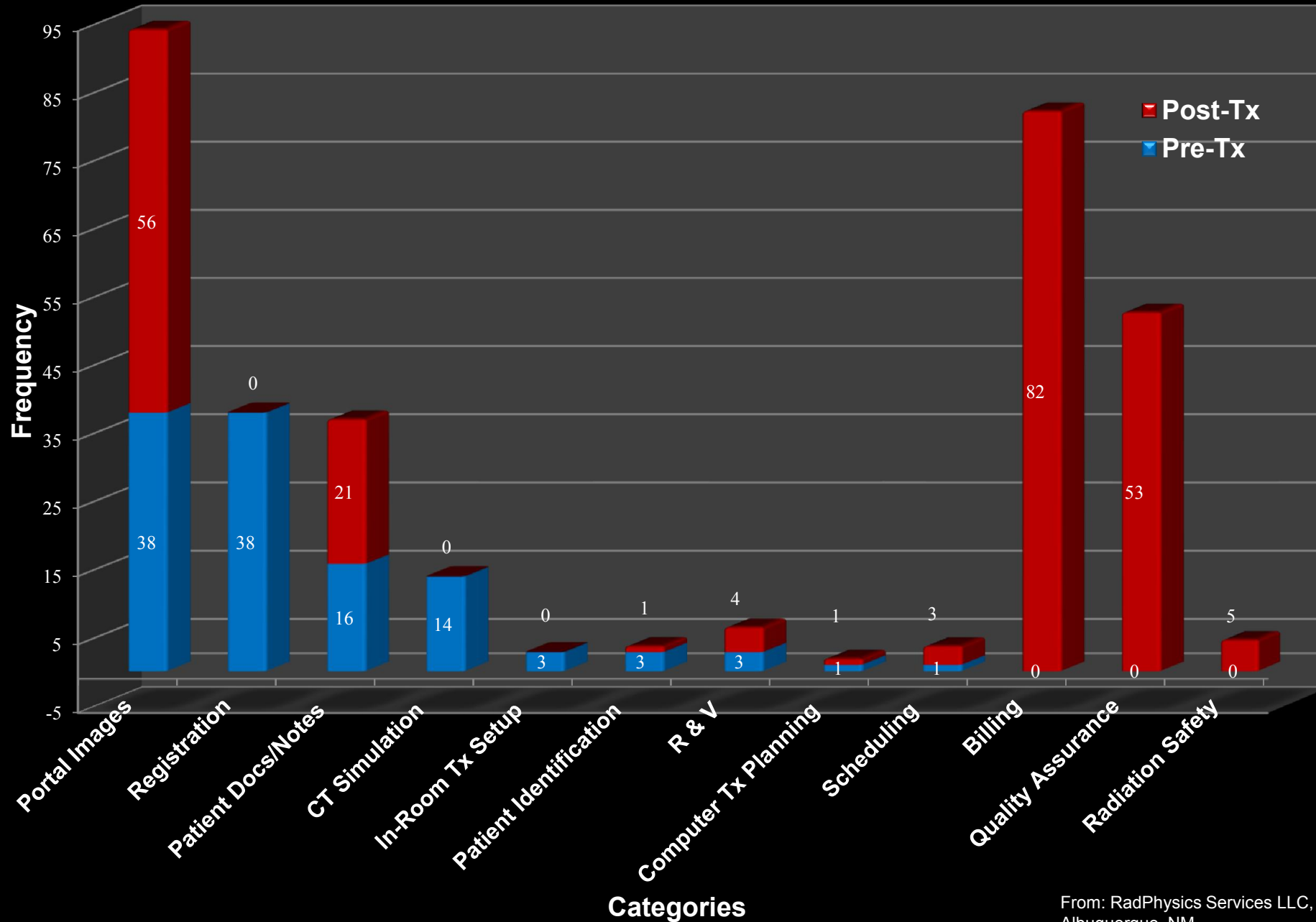
Study 1

Cost of Mistakes in Radiation Therapy

- No. Events: 317
- Avg. Time to Mitigate Each Problem: 15.0 hrs.
- Avg. Hourly Salary for Personnel: \$95.00
- Avg. Cost per Error: \$1,425
- **Total Cost: \$451,725**



Errors: Pre & Post Tx - Center A



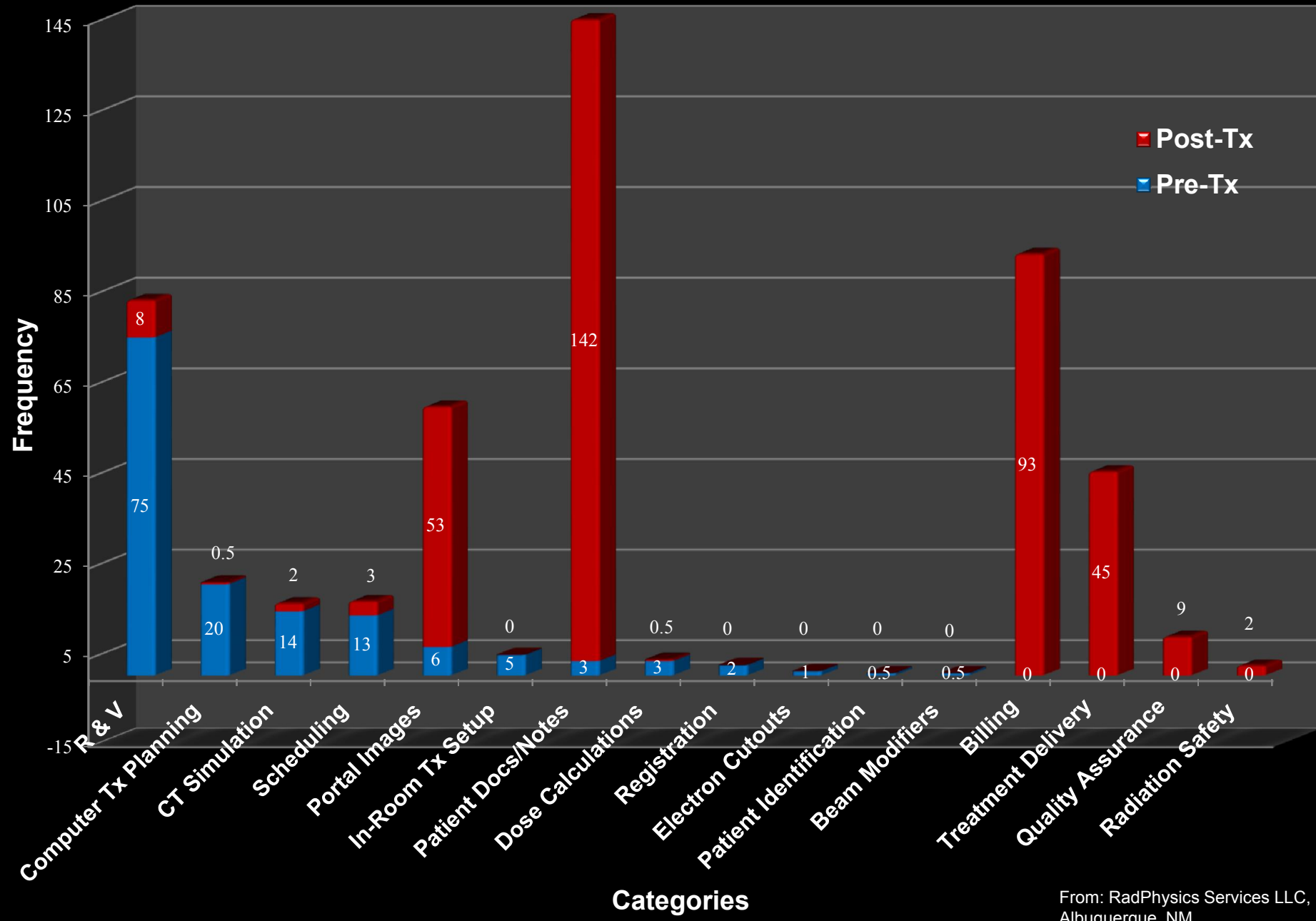
Study 2
Cost of Mistakes in Radiation Therapy¹

- No. Events: 343
- Avg. Cost per Error: \$1,425
- **Total Cost: \$488,775**

¹Assumptions taken from Study 1: Washington University School of Medicine, Mallinckrodt Institute of Radiology, St. Louis, Missouri.



Errors: Pre & Post Tx - Center B



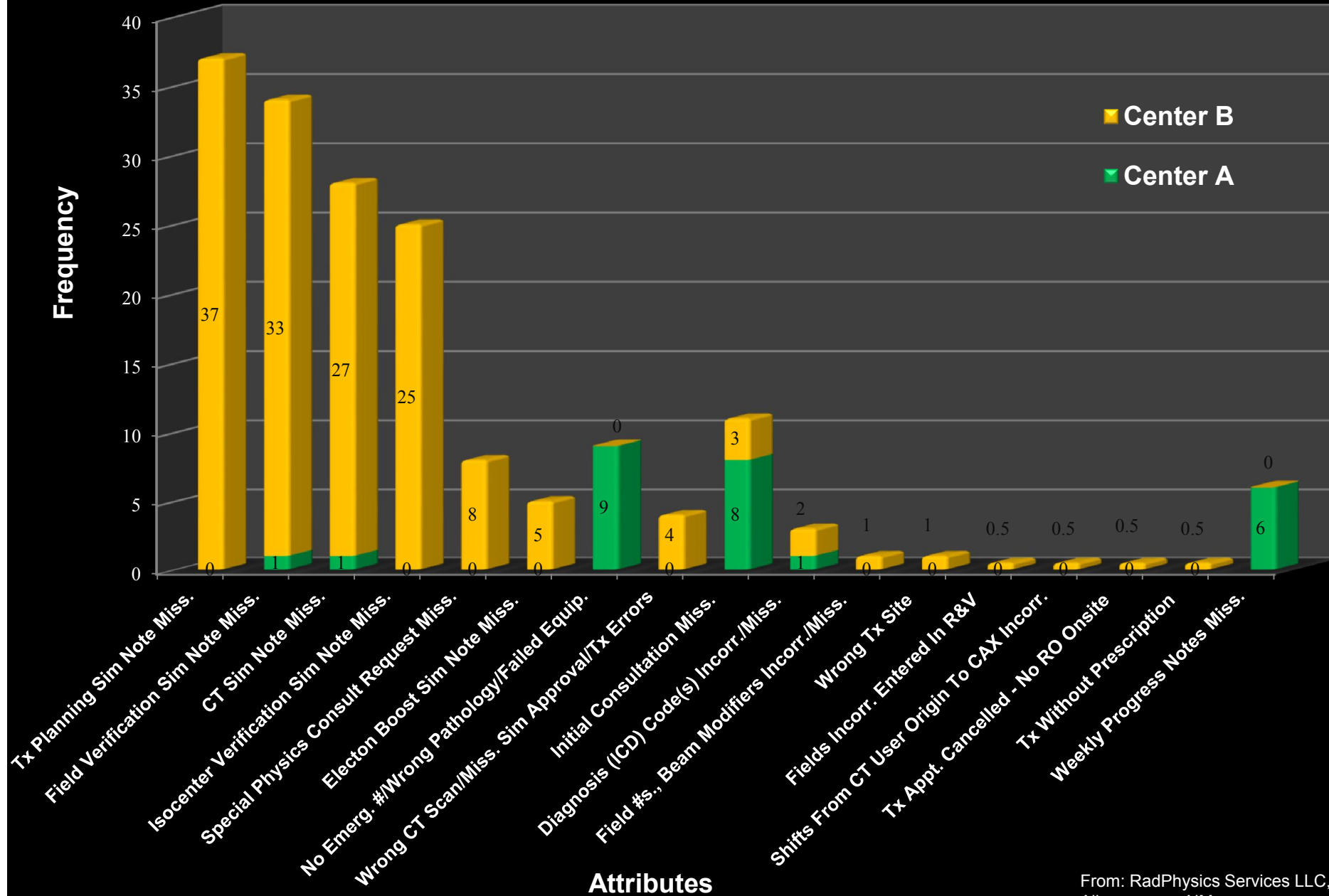
Study 3
Cost of Mistakes in Radiation Therapy¹

- No. Events: 501
- Avg. Cost per Error: \$1,425
- **Total Cost: \$713,925**

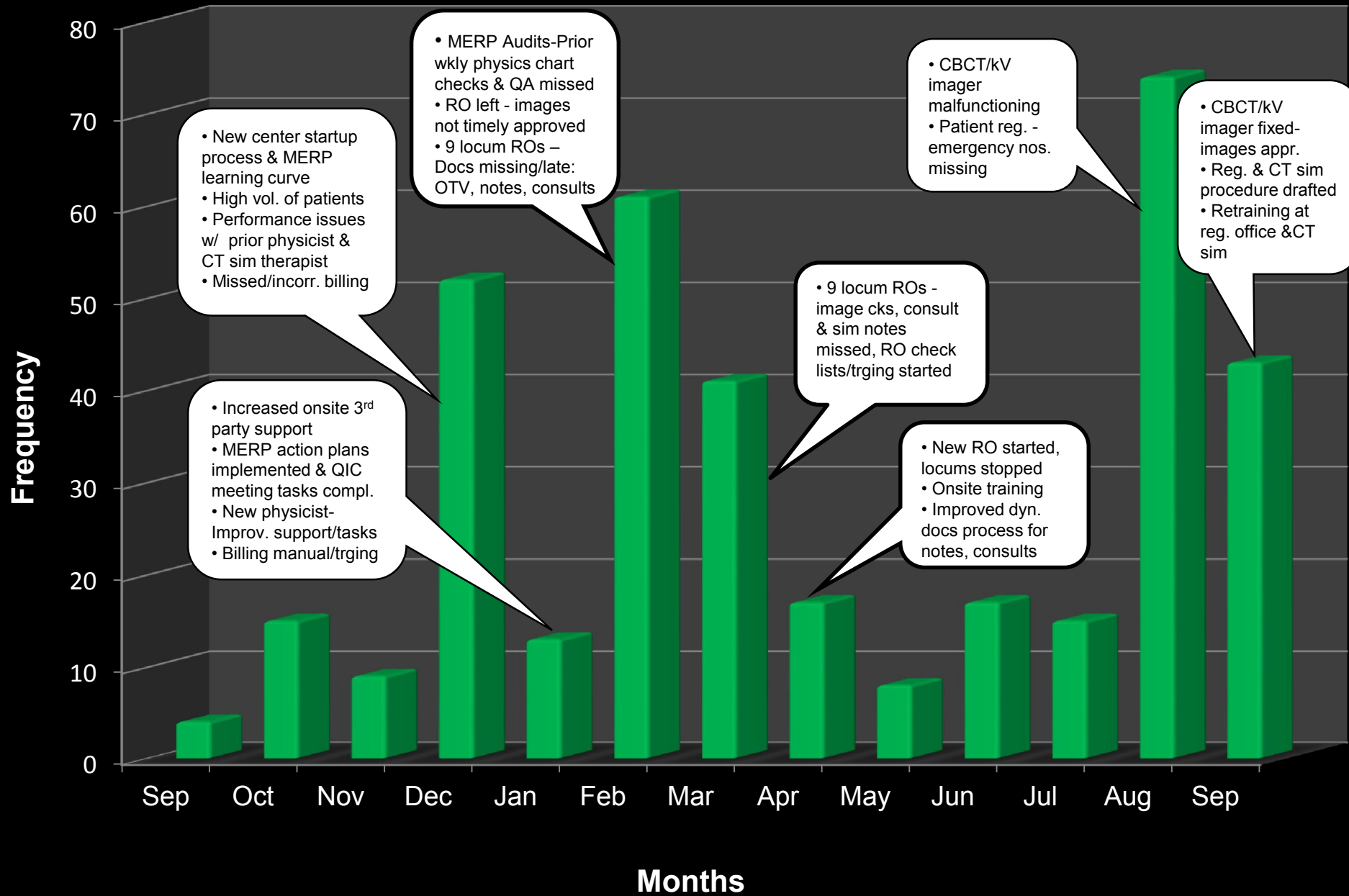
¹Assumptions taken from Study 1: Washington University School of Medicine, Mallinckrodt Institute of Radiology, St. Louis, Missouri.



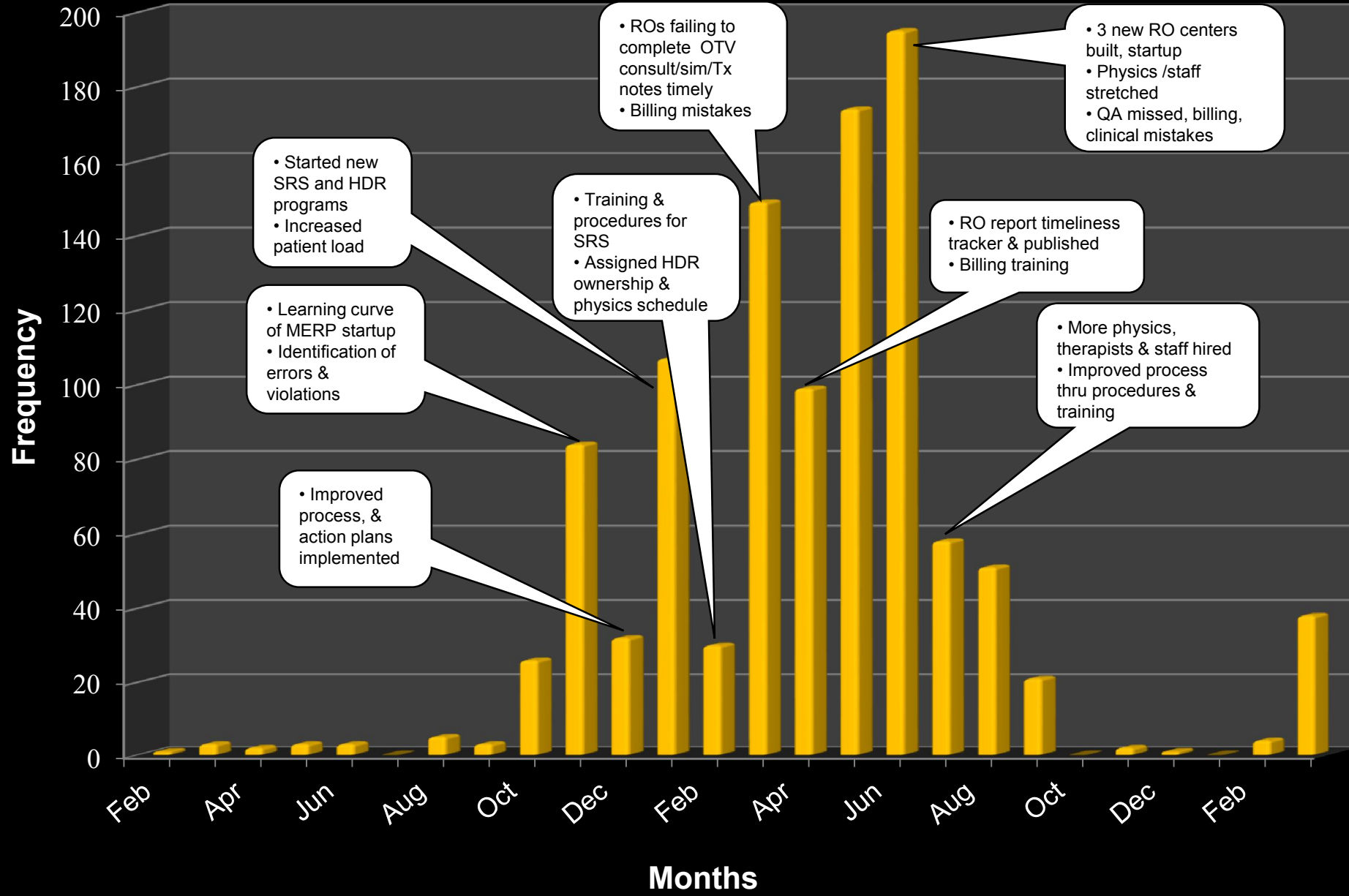
Errors : Severity Level 1 Centers A & B



All Errors - Center A



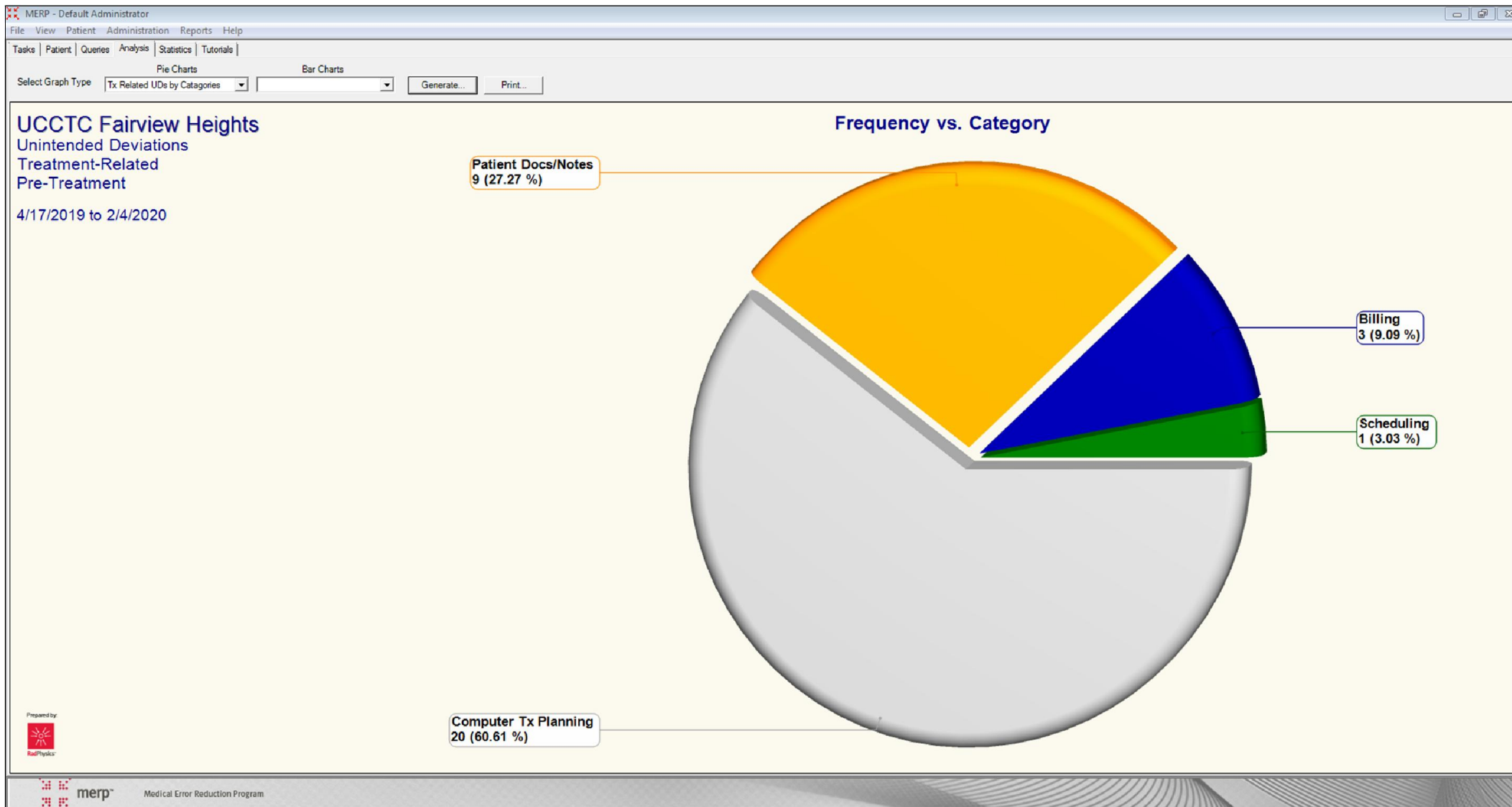
All Errors - Center B



From: RadPhysics Services LLC, Albuquerque, NM



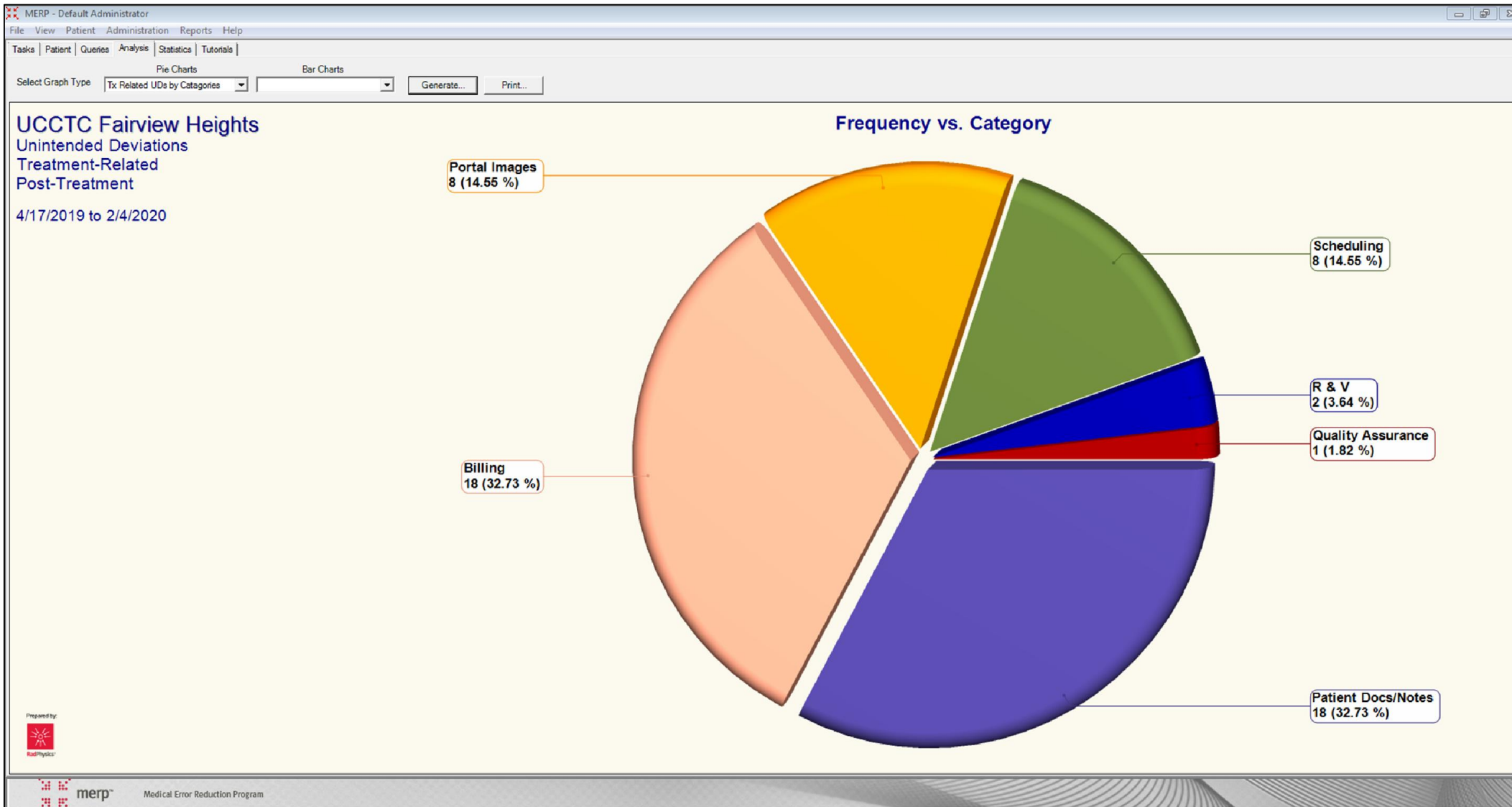
Errors: Pre-Tx - Center C



From: RadPhysics Services LLC,
Albuquerque, NM



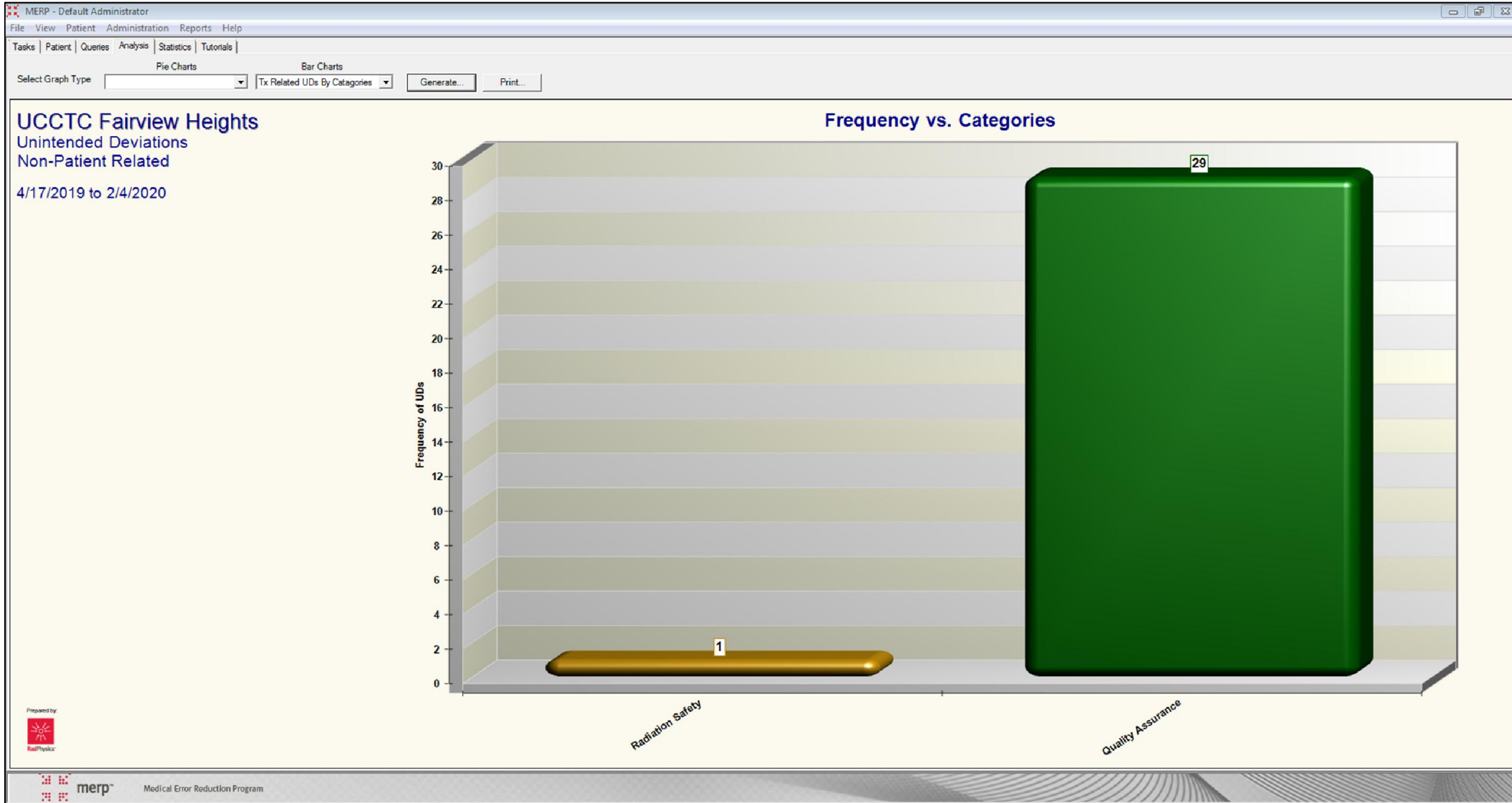
Errors: Post-Tx - Center C



From: RadPhysics Services LLC,
Albuquerque, NM



Errors: RS & QA - Center C





Results

Error Rates in Entire Treatment Process ^a									
Error Category	Pre-Tx			Post-Tx			Pre-Tx + Post Tx		
	Center A	Center B	Center C	Center A	Center B	Center C	Center A	Center B	Center C
	115 errors	145 errors	66 errors	225 errors	362 errors	37 errors	340 errors	477 errors	103 errors
Per Patient, %	37.20	10.10	61.01	72.80	25.40	77.85	81.8	27.33	98.91
Per Fraction, %	1.10	0.34	1.73	2.10	0.85	2.20	2.40	0.92	2.80
Per Field, %	0.14	0.004	0.11	0.28	0.009	0.14	0.31	0.01	0.17

^aData for Centers A , B, and C was annualized for all pre-Tx and post-Tx errors (all aspects of the treatment process from registration to completion of treatment). Does not include QA, RS, or billing errors.



Results

Error Rates in Treatment Delivery^{a,b}

Error Category	This Work MERP Center A	This Work MERP Center B	This Work MERP Center C	Kline et al.	Frass et al.	French et al.	Huang et al.	Marks et al.	Macklis et al.	Patton et al.	Margalit et al.
Per Patient, %	0.32	3.20	4.21				1.97	1.2 - 4.7			
Per Fraction, %	0.01	0.11	0.12		0.44	0.32	0.29	0.5			
Per Field, %	0.001	0.001	0.007		0.13	0.037 (0.17)			0.18	0.17	0.064
Overall Per Field, %	0.28^c	0.009^c	0.17^c	0.05 ²		0.13 ¹					

^aTreatment delivery means the administration of radiation to a patient.

^bData for Centers A , B, and C was annualized.

^cComprises the entire treatment process (excluding QA, RS, and Billing).

¹Errors per Tx units.

²Errors per field in the entire post-Tx delivery process (from initial patient consultation to completion of Tx).



Results

Near Misses ^a			
Error Category	“Good Catch”		
	Center A 2 near misses	Center B 4 near misses	Center C 1 near miss
Per Patient, %	0.650	0.607	2.10
Per Fraction, %	0.019	0.020	0.060
Per Field, %	0.003	0.0002	0.004

^aData for Centers A, B, and C was annualized.



Results

Medical Event Rates ^a						
Category	Kline et al.	Center A	Center B (2)	Center C	US NRC ^b	States ^c
Per Patient, %		0	0.065	0	0.004	
Per Fraction, %	0.017	0	0.002	0		0.002
Per Field, %		0	0.00002	0		

^aData for Centers A, B, and C was annualized. 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

- 2019 CMS - CERT Report⁵¹
 - Medicare Fee-For-Service program improper pay rate = **7.25%** (\$28.91 B)
- 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%**⁵²
 - Top 2 reasons for errors among claims
 - Failing to send supporting documentation
 - Submitting records without a valid signature
- 2008 Provider Compliance Error Rate⁵³
 - 10.9% Diagnostic Radiology
 - **11.8% Radiation Oncology**
 - 14.6% Independent Diagnostic Testing Facility
 - 22.2% Nuclear Medicine
 - 25.3% Interventional Radiology

⁵¹Comprehensive Error Rate Testing (CERT). Centers for Medicare & Medicaid Services. Accessed at [CMS.gov](https://www.cms.gov), February 15, 2020.

⁵²*Radiation Oncology: Top Billing and Documentation Errors*, The Celerian Group Company, [cgsmedicine.com](https://www.cgsmedicine.com), 3/10/14.

⁵³*May 2008 Comprehensive Error Rate Testing CERT Report Issued, ACR Radiology Coding Source May-June 2008*, [acr.org](https://www.acr.org).





Results

Billing Infractions per Patient^a			
Category	Center A 309 patients	Center B 659 patients	Center C 59 patients
Billing, %	26.54 ¹	5.1 ²	44.18 ³

^aData for Centers A, B, and C was annualized for all data collected.

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

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

³Approximately 90% of the infractions were caught/corrected at time of charge capture and before exporting to CMS or insurance company for billing.



QA & Radiation Safety





Results

QA & Radiation Safety Failures^{a,b}			
Error Category	Center A	Center B	Center C
Per Patient, %	18.8	0.78	63.1
Per Fraction, %	0.55	0.026	1.78
Per Field, %	0.072	0.0003	0.110

^aFailures are non-patient related and include regulatory infractions.

^bData for Centers A, B, and C was annualized.



Part IX

Lessons Learned





Lessons Learned

- **Upfront Homework**

- Leadership presents vision
- Why must we embrace safety to be competitive
- Philosophy of “goodness”
- Position descriptions require participation in risk management program
- History of patient safety
- Six (6) hours of ASRT CEUs
- Blame-free use of information
- Non-punitive action policy will be watched by staff

- **Getting Started**

- Superusers serve as point guards
- Managers champion the process
- Phased in approach minimizes worker load
- 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





Lessons Learned

- **Practical Implications**

- Present overall risk mgt. results at quarterly QIC meetings
 - Pie charts, histograms
- QIC agendas + minutes distributed to all attendees
- Staff (therapists rotate), management, and physicians attend all QIC meetings
- Send out monthly safety alerts
- Support true change
- Want buy-in? Stand by your staff

- **Reward System**

- Incentives to encourage reporting a must
- Certificates of achievement
- Gift cards issued on the spot
 - Starbucks cards
 - Chick-filet cards
- 'Near Miss' catch warrants dinner gift certificate
- Department lunches
 - Individuals acknowledged
- Performance reviews measure participation & provide vehicle for \$ increases



Part X

AI in Risk Management



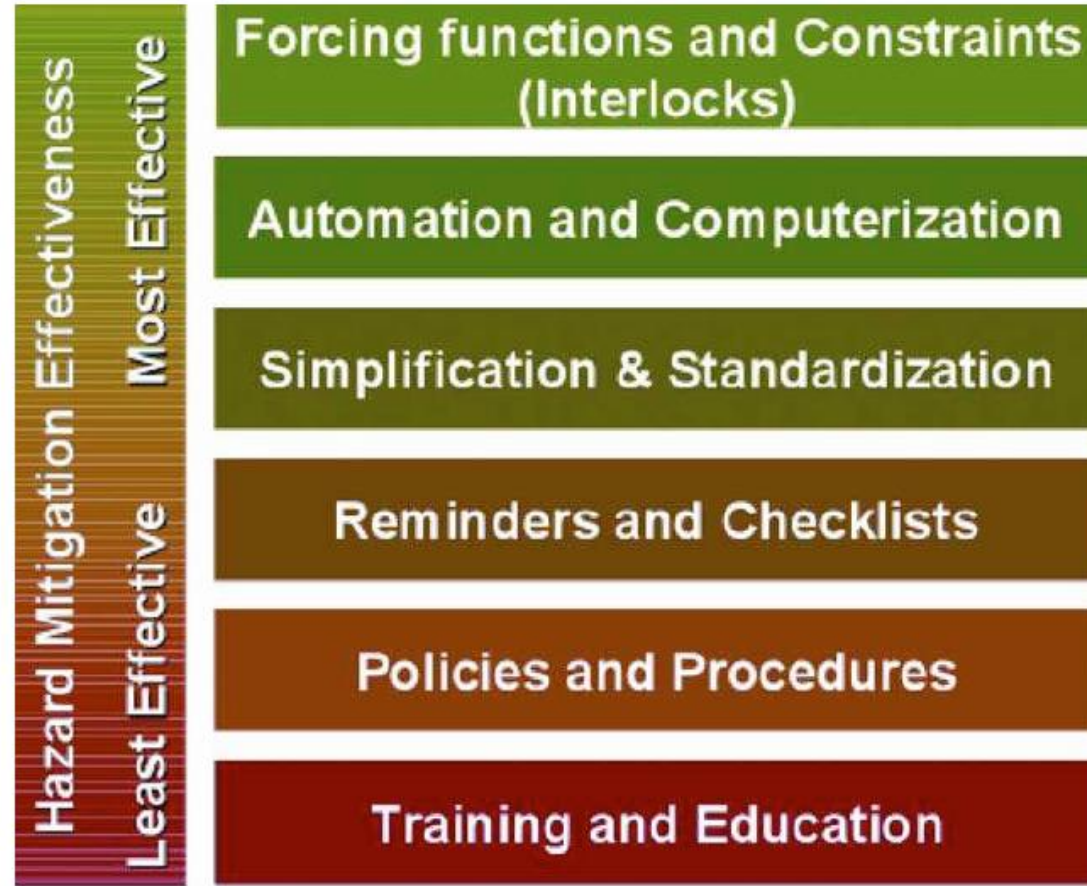
A Compelling Argument

AI has the potential to reduce medical errors by 30 – 40%, and treatment expenses by as much as 50% (Frost and Sullivan, 2016)⁵⁴



⁵⁴A. Chatterjee, *Use of Artificial Intelligence to Reduce Medical Errors*, Data Science and Technology, July 17, 2017.

Is Automation the Answer?



The addition of automation has been shown to reduce errors in many processes^{55,56}

⁵⁵Hendee, W. & Herman, M. 'Improving patient safety in radiation oncology', Medical Physics 38, 78-82 (2011).

⁵⁶Heinzerling J. *Maximizing patient safety with IGRT*. Study presented at: ASTRO 62nd Annual Meeting, September 15-18, 2019; Chicago, OH.



Future AI Risk Management Process

- Develop a system to identify, prevent, and mitigate errors and their effects before they result in harm.
- Key areas of opportunity in radiation oncology⁵⁷
 - 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.

⁵⁷Feng 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.



AI Key Objectives

Process Reliability

Short-Term

Predict RT Process Reliability⁵⁸



Machine Learning

Long-term Approach

Optimize big data⁵⁹

⁵⁸Howell 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.

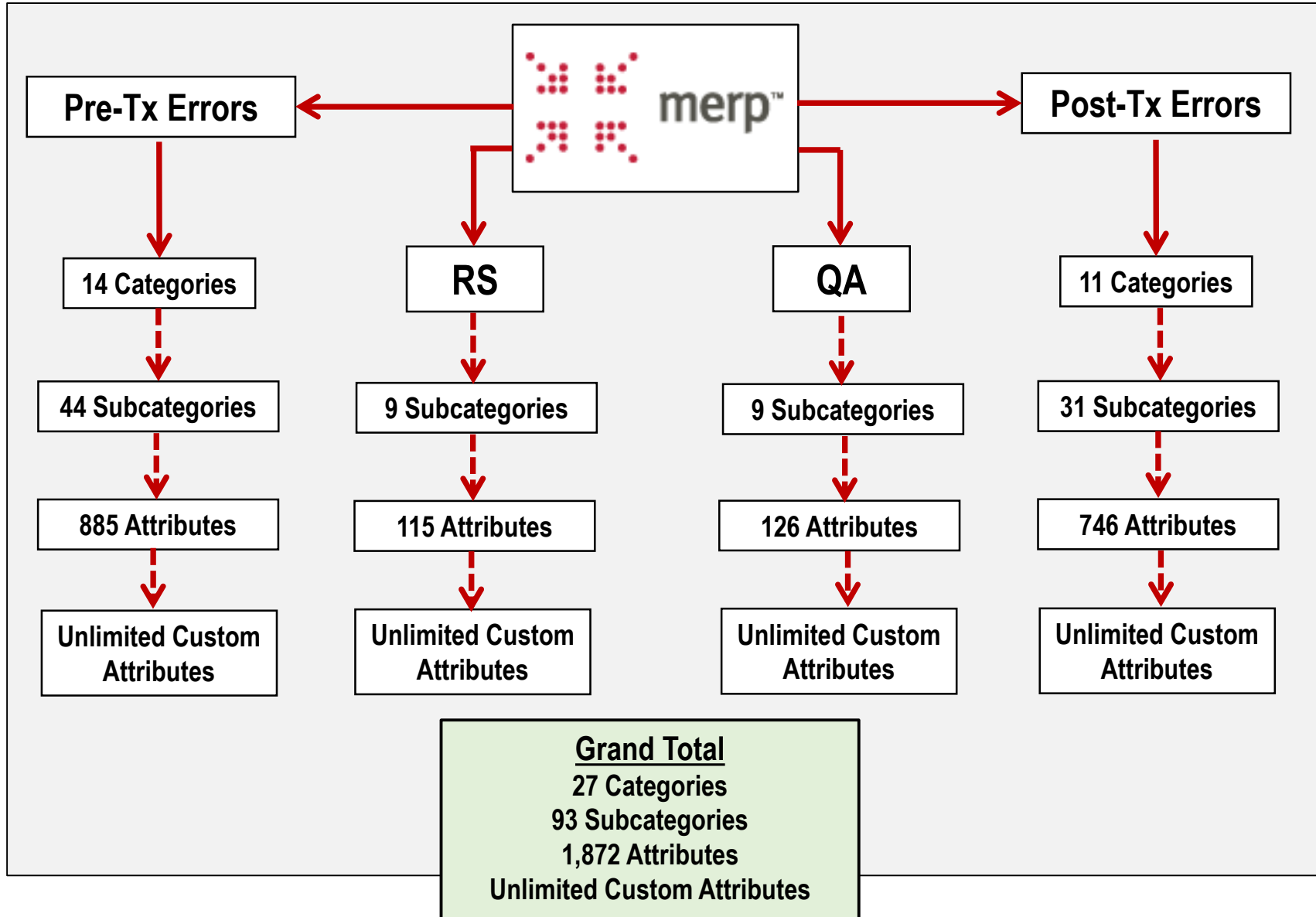
⁵⁹Bienedict SH, et al., *Big Data – Overview of the American Society for Radiation Oncology-National Institutes of Health-American Association of Physicists in Medicine Workshop 2015: Exploring Opportunities for Radiation Oncology in the Era of Big Data*, Int J Radiation Oncol Biol Phys, Vol.. 95, No. 3, pp. 873-879, 2016.





Machine Learning

#1 - Availability and Quality of Data



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 effective incident reporting system
- IA is the next step for creating a highly reliable system

