RadPhysics™

Completing cancer care.

Risk Reduction Strategies for Radiation Oncology – Stepping Towards Predictive Analysis

Ed Kline - RadPhysics

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a division of
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- Part I - State of Affairs
- Part II - How Big is the Problem?
- Part III - Devil is in the Details
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Part I

State of Affairs

History
1999

- Institute of Medicine (IOM) Report[1]
  - 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 (initial forecast)
  - 10,000 deaths per year in Canadian hospitals
  - Exceeds annual death rates from road accidents, breast cancer, and AIDS combined in U.S.

[1]Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds.). (2000). To Err is Human: Building a Safer Health System. National Academies Press (US).

Performance
Today

- In U.S., adverse events occur to approx. 3 - 4% of patients[2]
- Average intensive care unit (ICU) patient experiences almost 2 errors per day[3]
  - Translates to level of proficiency of approx. 99%
  - Sounds good, right? …… **NOT REALLY**
- If performance levels were 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[4]

[2, 3, 4] *Doing What Counts for Patient Safety - Federal Actions to Reduce Medical Errors and Their Impact*. Access thru www.quic.gov.

Patient Safety
Today

- Society of Actuaries (SOA)[5]
  - 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)

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

Impact
Today

- Claims Data[6]
  - 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 Costs[7]
  - 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 Impact[8]
  - 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)

[6] *The Economic Measurement of Medical Errors,* Society of Actuaries’ Health Section, 2010.

[7] Mello, M. M., Chandra, A., Gawande, A. A., & Studdert, D. M. (2010). National costs of the medical liability system. Health affairs (Project Hope), 29(9), 1569–1577.

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

Part II

How Big is the Problem?

Radiation Oncology
Global Perspective

- Cancer Projections[9,10]
  - Between 2008 and 2030, new cancer cases are projected to increase more than
    - 80% in low-income countries
    - 40% in high-income countries
  - Global radiotherapy market is projected to reach $11.5 billion by 2027

[9]Tumor Ablation Market Size, Share & Trends Analysis Report By Technology (Radiofrequency, Microwave), By Treatment (Surgical, Laparoscopic, Percutaneous) By Application, By Region, And Segment Forecasts, 2020 – 2027, Grand View Research, 2/20, Accessed through www.grandviewresearch.com.

[10]Radiation Oncology Market Size, Share & Trends Analysis Report By Type (External Beam Therapy, Internal Beam Radiation Therapy), By Application, By Technology, By Region, And Segment Forecasts, 2020 – 2027, Grand View Research, 2/20, Accessed through www.grandviewresearch.com.

Radiation Oncology
US Perspective

- 3,000 radiation therapy centers
- Approximately 50% of cancer patients receive radiation therapy as part of their care
- Direct costs of cancer care is projected at $173B in 2020[11]

[11]Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States. 2010-2020. J Natl Cancer Inst 2011; 103:117–285. (www.who.int 2020).

Part III

Devil is in the Details

Radiation Oncology
Complexity

- Requires very high level of precision to reach the tumor while sparing the surrounding healthy tissue.
- Long chain of specialized activities customized for individual patients whose tumor size and locations can change during treatment.
- Numerous subsystems from multiple vendors and medical staff (radiation oncologist, nurses, dosimetrists, therapy technologists, physicists, engineers, and administrative personnel).
- The specialized computer systems and devices are functionally connected, not digitally, with manual activities and visual inspections using paper and spreadsheets.

Barriers

- Barriers Continue to Exist[12]
  - Open reporting culture is not accepted
  - Local systems are inadequate to
    - Investigating incidents
    - Identifying contributory factors
    - Implementing & embedding learning
  - In spite of an intense 17-year focus to improve safety of medicine, it appears little – if any – improvement has been made

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

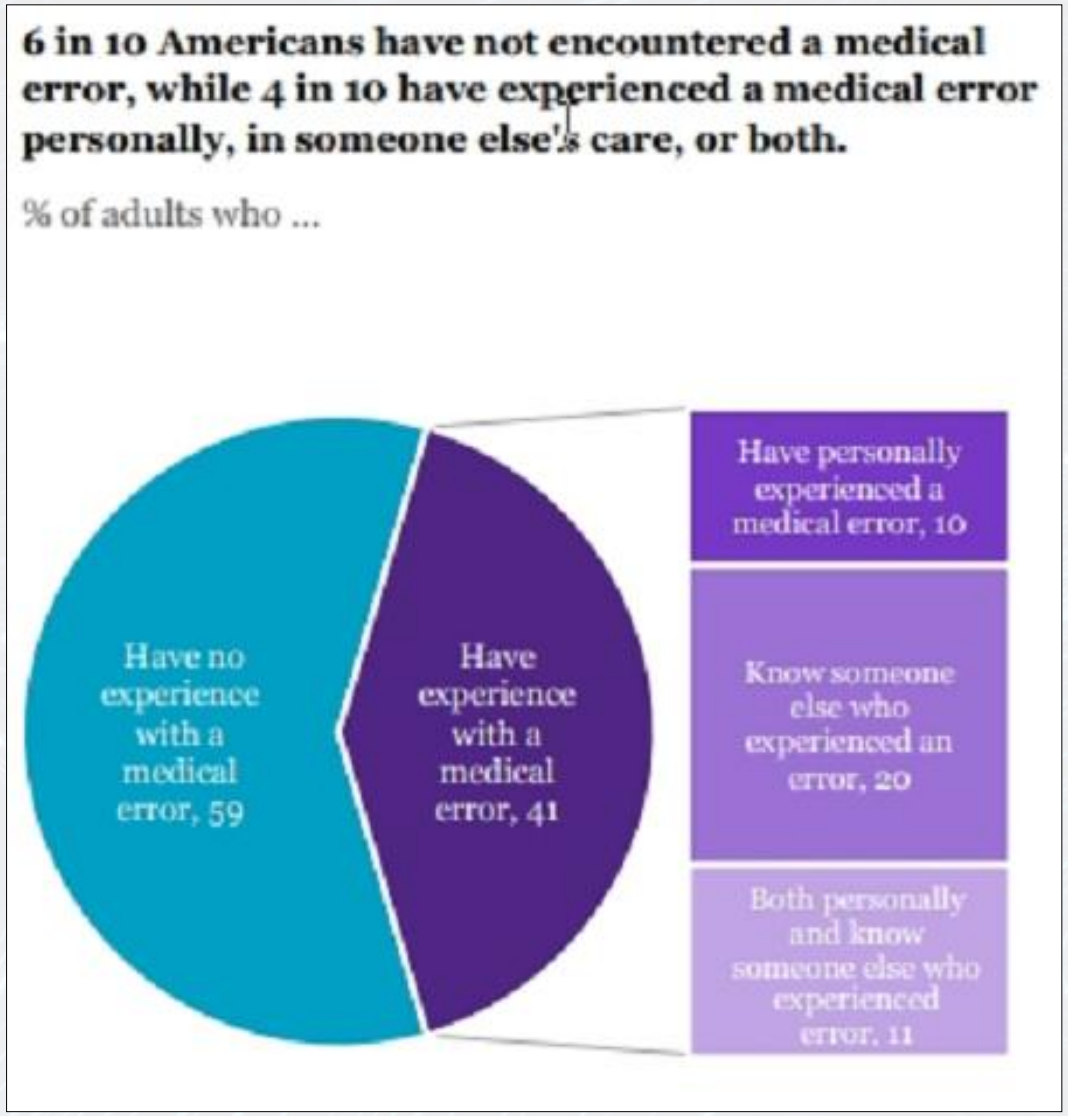
Bottom-line

- The scale of radiation oncology makes it a key area for pro-active management
- The complexity makes this a difficult problem
- Errors propagate! Hence, not just whether we can detect an error, but also, how quickly?

Part IV

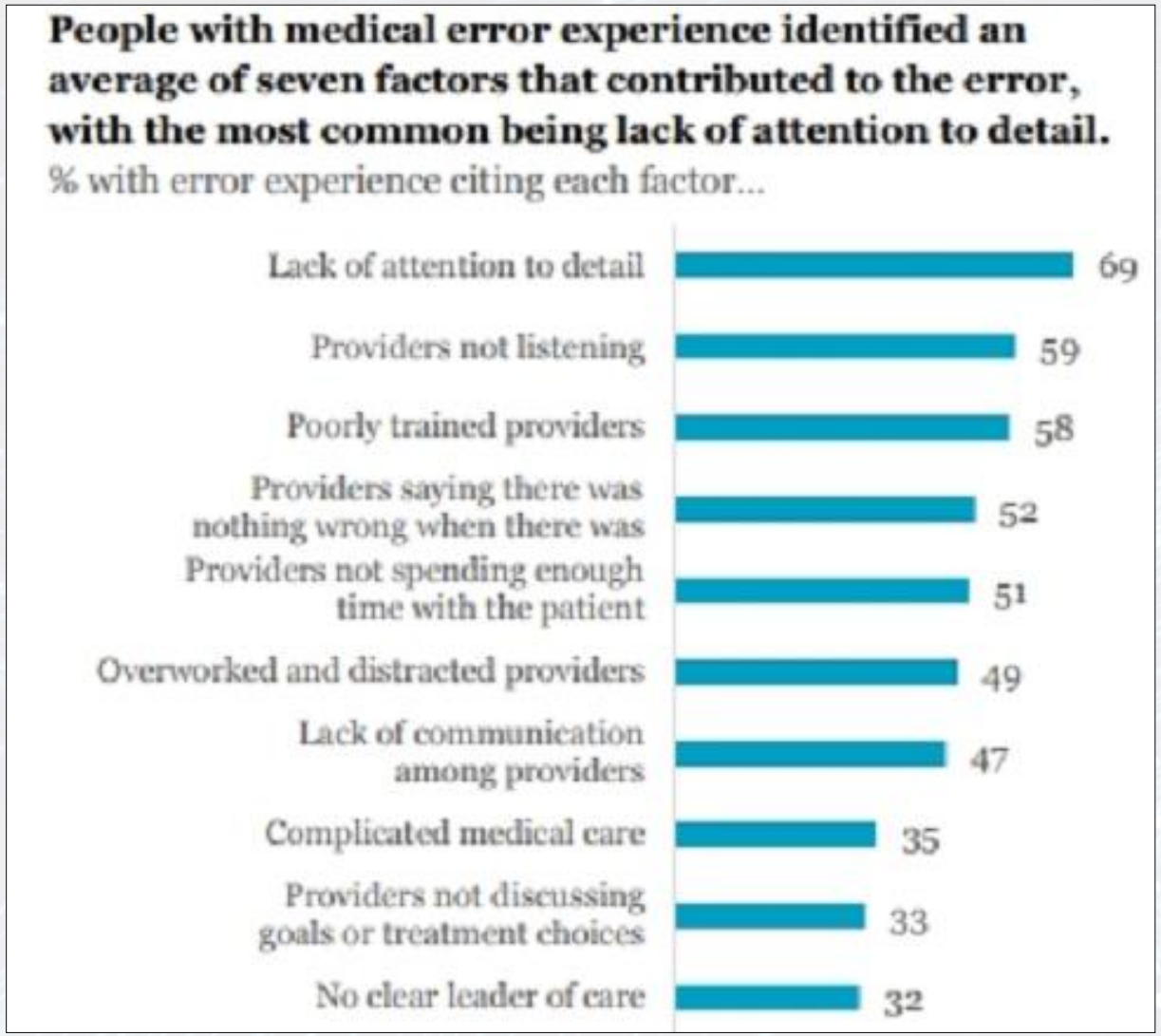
Surveys of Medical Errors

Surveys[13]



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

Surveys[14]



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

Part V

Radiation Oncology Errors

Radiation Oncology Errors

- Most current data suggests[15]
  - 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

[15]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 Do We Compare With HROs?

Not That Well

- Commercial aviation experience[16]
  - 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[17]
  - 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

[16, 17]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 Within Medicine?

Mixed Results

- Anesthesiology Experience[18]
  - 8.2 deaths from anesthesia complications per million hospital surgical discharges
- Big Picture Problems - Hospitalized Medicare beneficiaries[19]
  - 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

[18, 19]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[20]

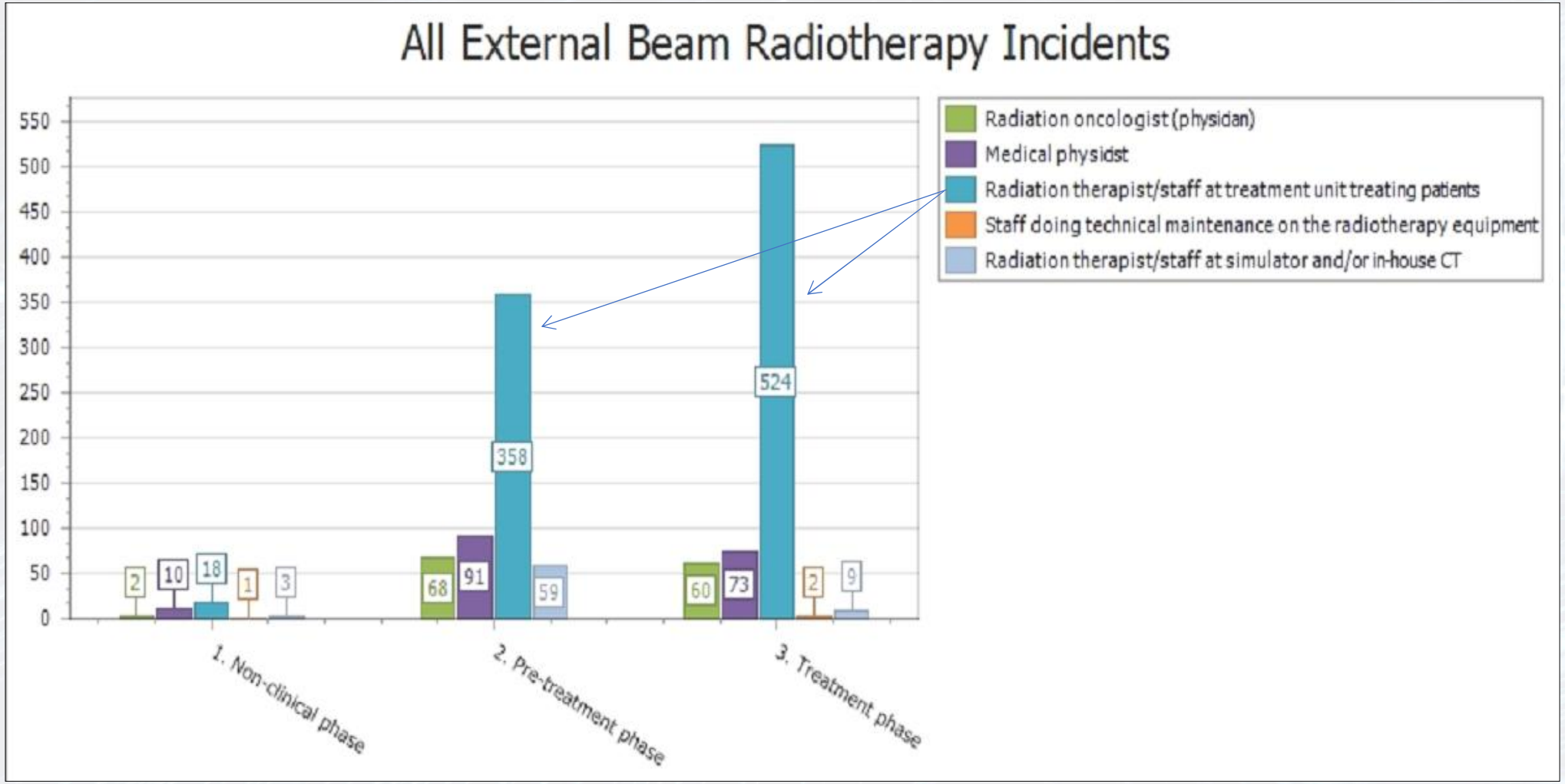
[20] *Fast facts about radiation therapy.* American Society for Radiation Oncology website. www.astro.org/News-and-Media/Media-Resources/FAQs/Fast-Facts-About-Radiation-Therapy/Inde.asps, Accessed March 2, 2017.

Part VI

Who Reports Radiation Oncology Errors?

IAEA SAFRON[21]

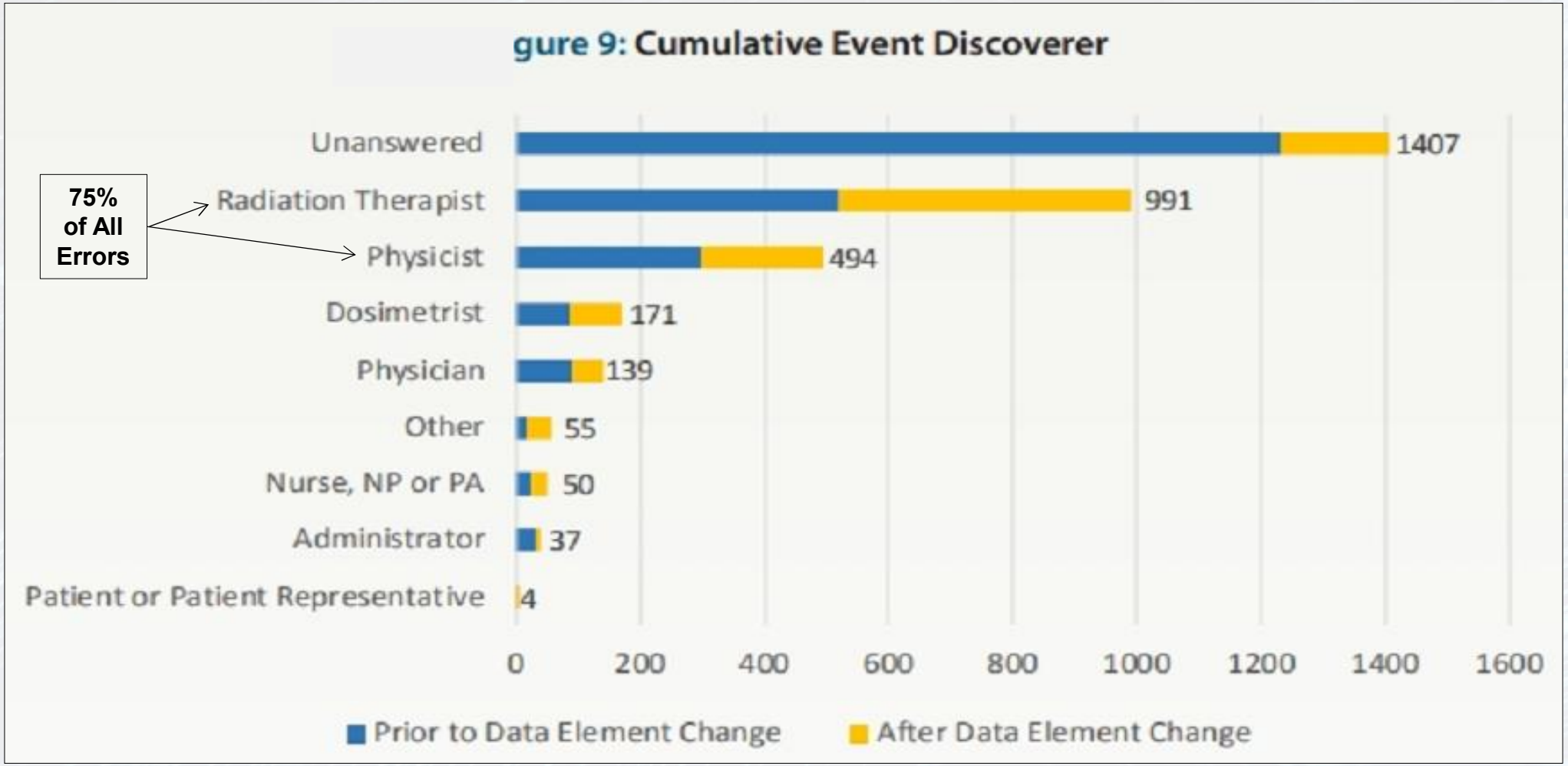
Who Reports the Errors



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

RO-ILS[22]

Who Reports the Errors



[22]ASTRO, 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.

Radiation Oncology
Reporting Comfort

- Survey of radiation therapists comfort levels in reporting errors[23]
  - 29% of respondents expressed a fear of reprimand as a barrier to error reporting

[23]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
Reporting Comfort

- Patient safety perceptions among US radiation therapists[24]
  - 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

[24]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 VII

Incident Reporting Systems

Hospital Incident Reporting Systems[25]

- 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

[25]*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"[26]

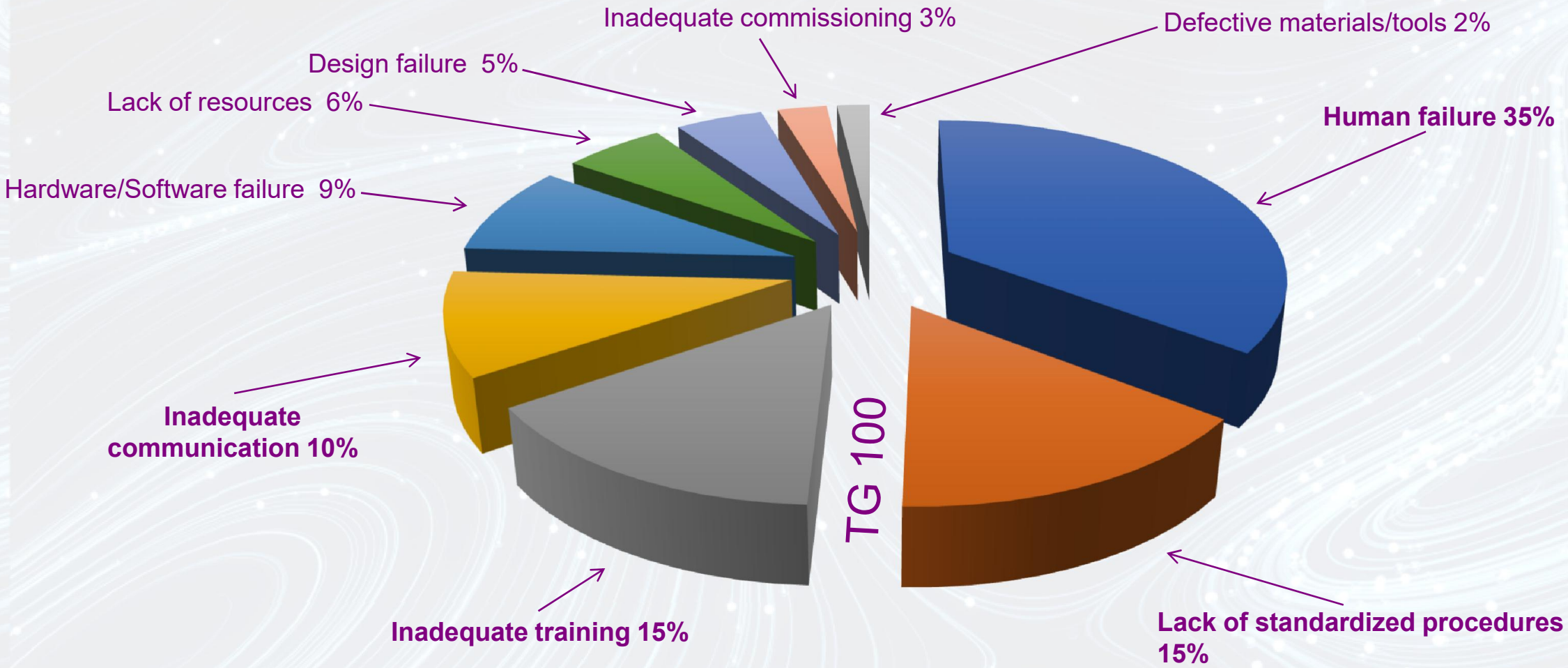
- Voluntary Incident Reporting in Radiation Oncology
  - ASTRO: Radiation Oncology–Incident Learning System (RO-ILS)(US)
  - Radiation Oncology Safety Education and Information System (ROSEIS)(IRL)
  - International Atomic Energy Agency (IAEA): Safety in Radiation Oncology (SAFRON)(AUT)
  - Radiotherapy 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)

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

Part VIII

Where is the Risk?

TG-100 Report: Sources of Error



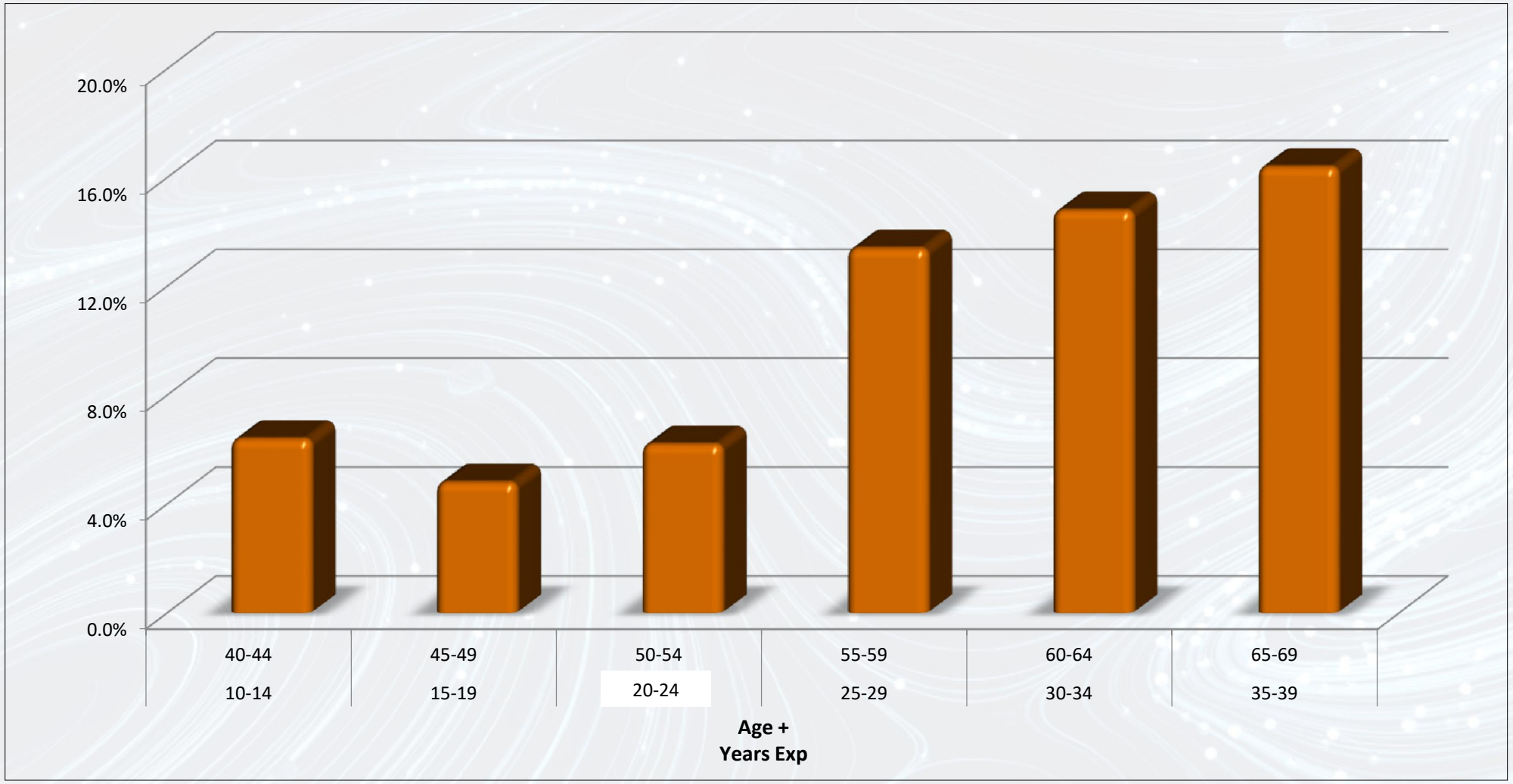
From: The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Med Phys 43: 4209-4262, 2016.

Risk - EMR Systems

- EMR-Related Malpractice Suits[27]
  - 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%)

[27] *EHR-Related Malpractice Suits Are on the Rise,* Posted by rufustherat, SERMO, August 30, 2019.

Probability of a Malpractice Lawsuit[28] by Age and Years of Experience[a] for Radiation Oncologist



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

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

Part IX

Requirement vs Incentive

Requirement
2017

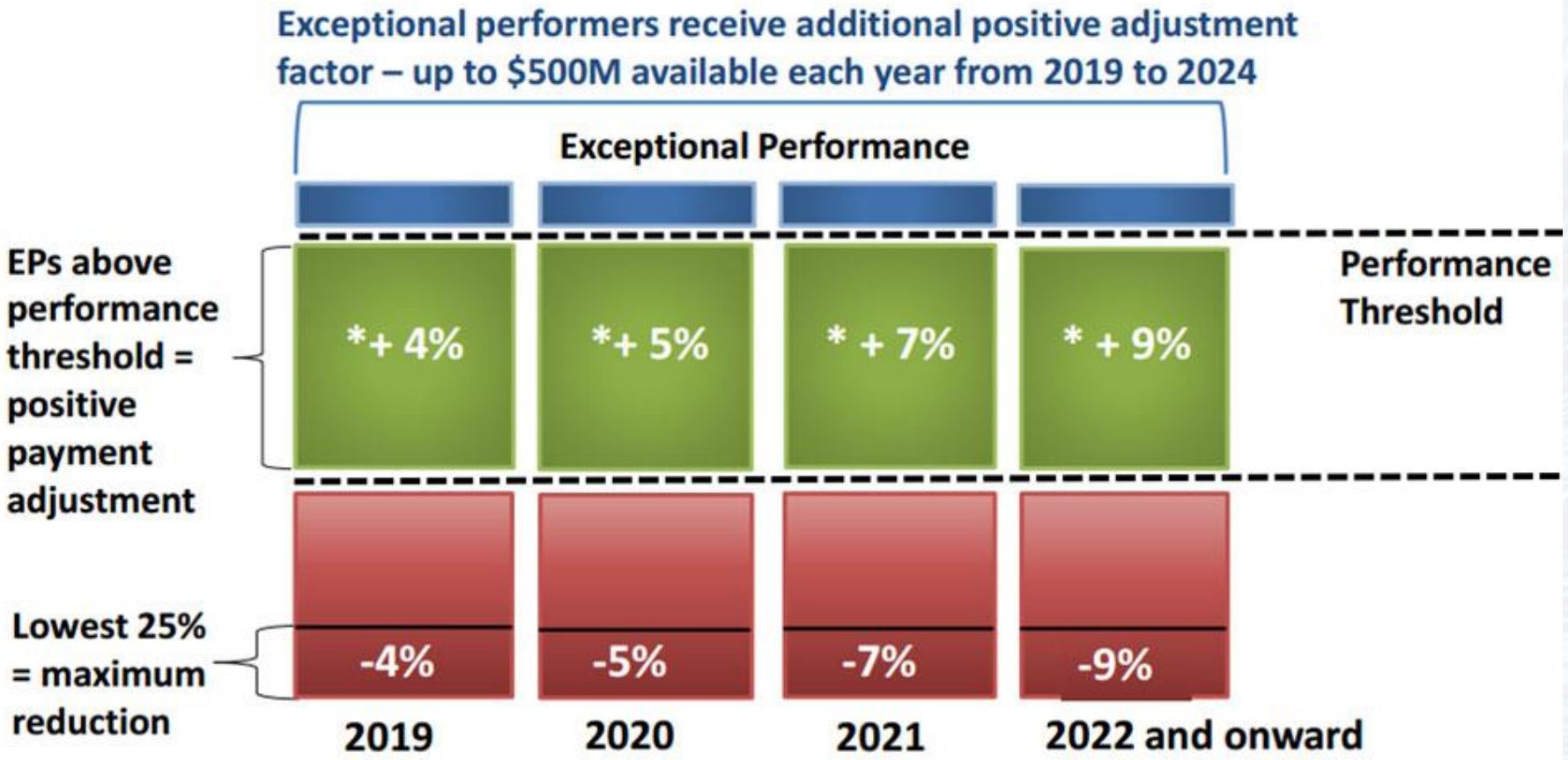
- Health Insurance Marketplace Quality Initiatives - Patient Protection and Affordable Care Act[29]
  - Medicare Patient Safety Evaluation System (PSES)
    - Qualified Health Plan insurers must verify, in part, that hospitals use a patient safety evaluation system (PSES)
    - PSES must show the program 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

[29]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.

Medicare Access and CHIP Reauthorization Act (MACRA)[30]

MIPS Incentive Payment Formula

Incentive 2017



MACRA allows potential 3x upward adjustment BUT unlikely

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

MIPS Incentive
2017

- Patient Protection and Affordable Care Act of 2015 (MIPS)[31]
  - 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 (risk management program)
  - 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%**[a]

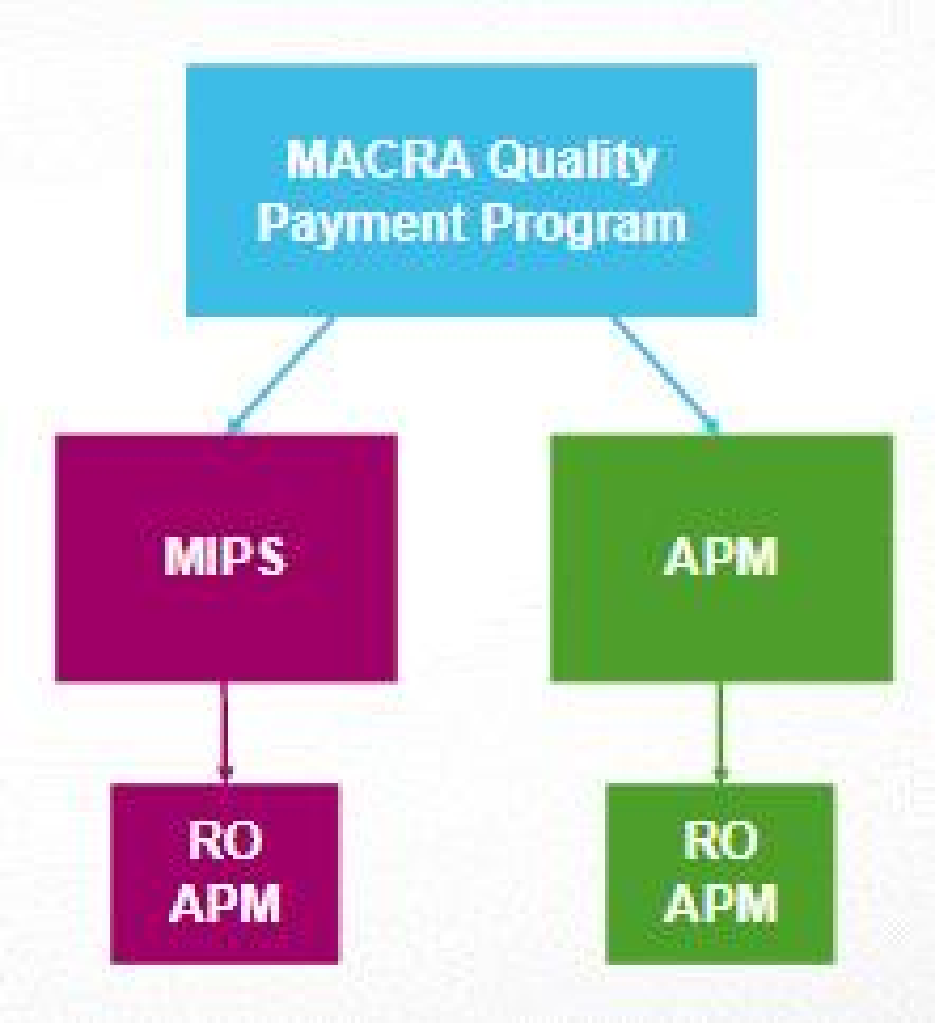
[31] *Quality Payment Program.* http://go.cms.gov/QualityPaymentProgram. Accessed February 13, 2020.

[a] *Risk Management Program can be used to achieve max IA credit of 15% when used in conjunction with activity descriptions IA PSAS 4, 17 and 20.*

RO Model (APM) Incentive
2021

The RO Model is considered an Advanced APM (APM) and a MIPS APM.

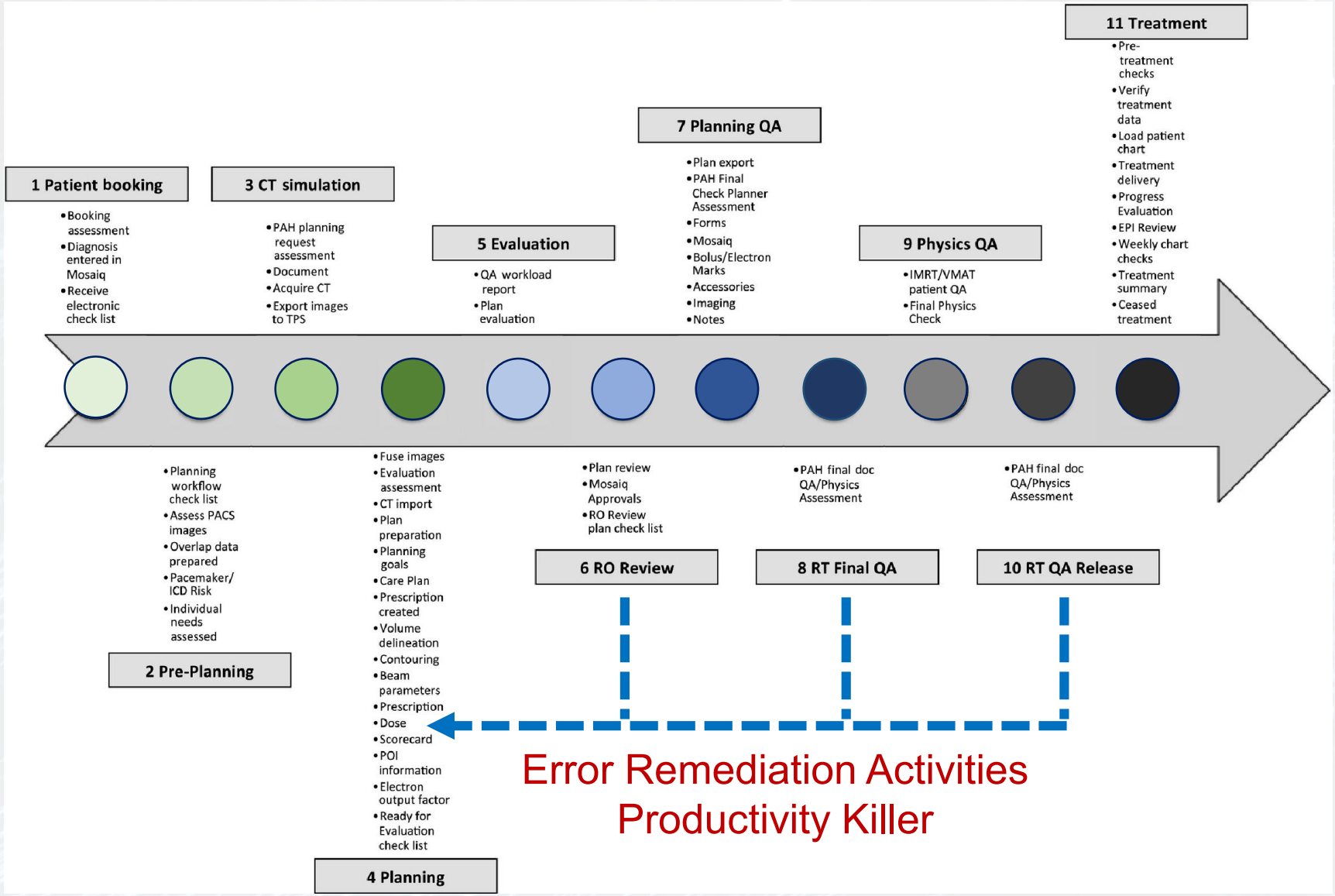
The RO Model includes continuation of the QPP & 4 performance categories, including the **Improvement Activity (IA)** category.



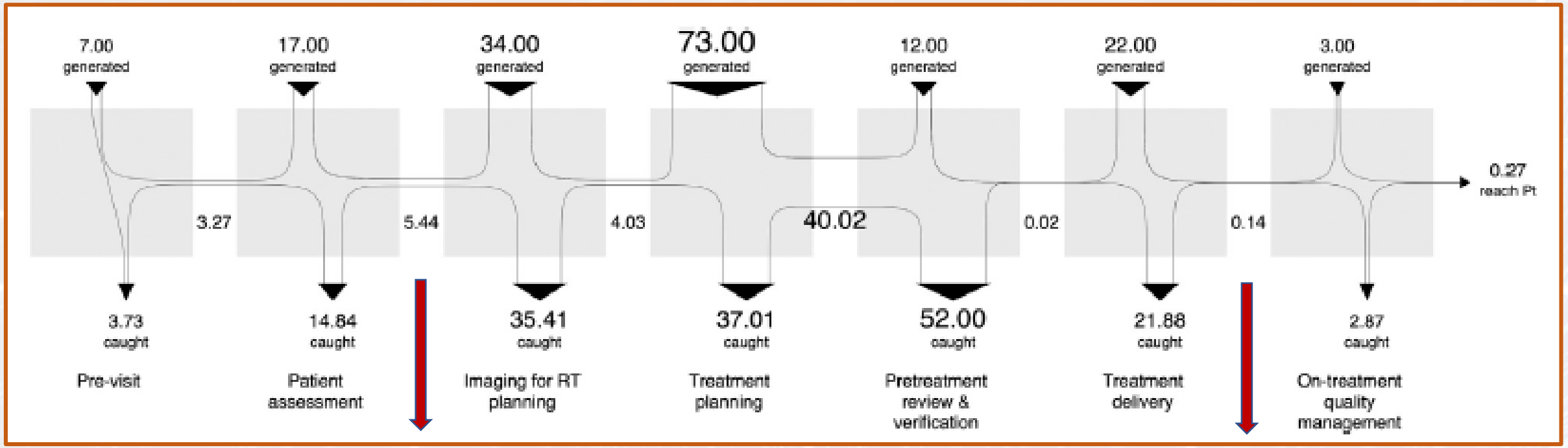
Part X

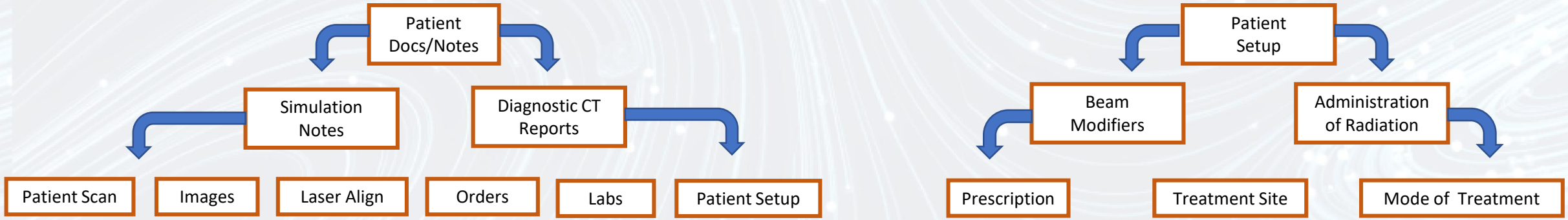
Prototype Model of Error Reduction Program

Entire Radiation Oncology Process



Example of Error Propagation
Ideal Solution





From: Howell C, Traction G, Alison, A, Bhishamjit C, Lawrence M, Lukasz M. Predicting Radiation Therapy Process Reliability Using Voluntary Incident Learning System Data. *Prac Rad Oncol. 2019;9: e215.*

Improve Overall Safety and Reduce Harm[32]

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 environment s to optimize safety
- Focus on reducing risk instead of overemphasizing “zero” harm goals
- Spotlight successes and adaptation + examine failures

[32]E. Thomas, *The harms of promoting ‘Zero Harm’*, BMJ Qual Saf,1-3 (2019).

Our Prototype Model Called “SoterRO”

Inspired by Soter, Greek spirit of safety, preservation, and deliverance from harm

1. Identify risks

- List
- Measure
- Rank

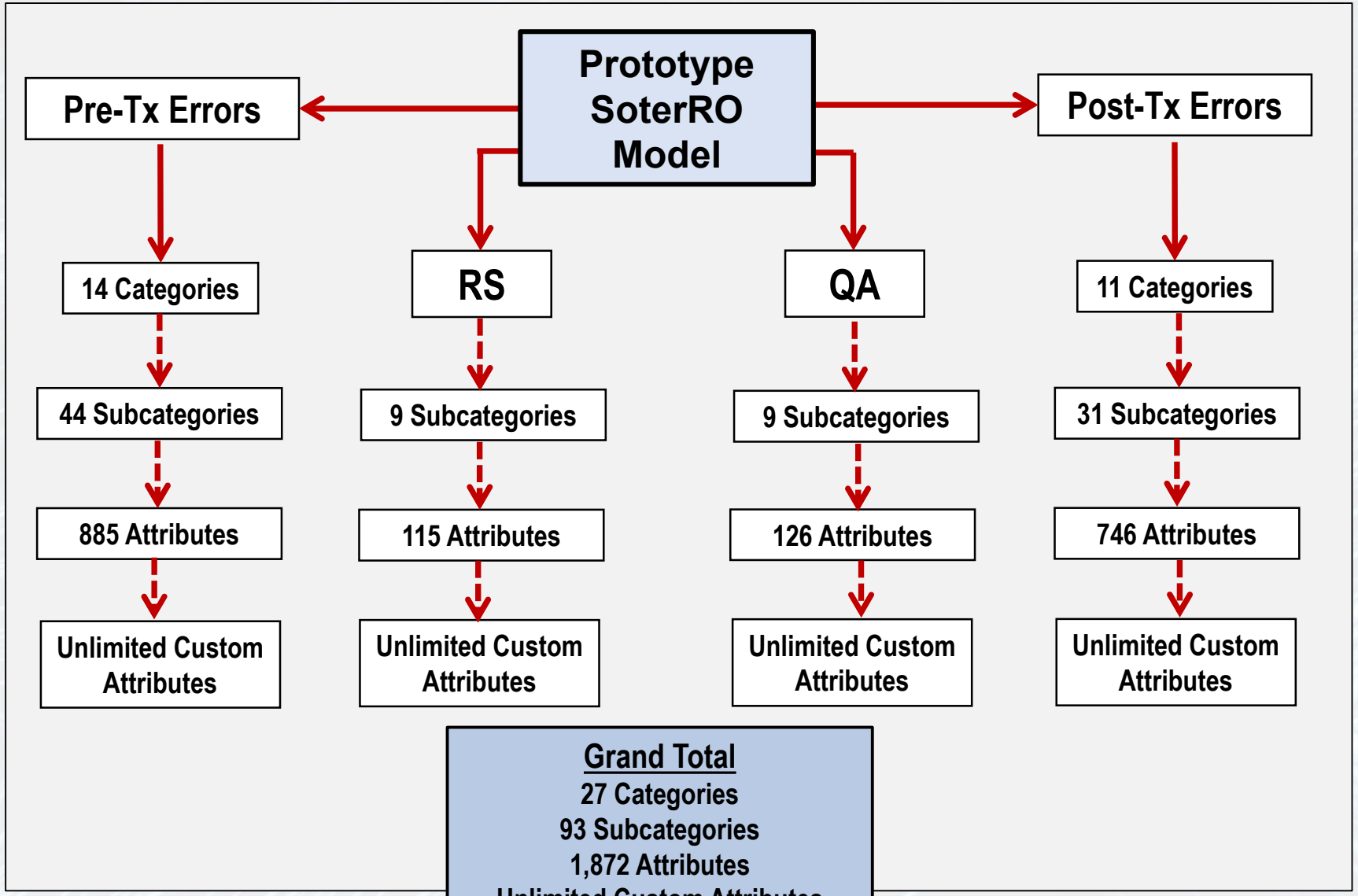
2. Identify techniques/strategies to manage risk

- Reduction of risk
- Retention of risk
- Transfer of risk

3. Implement risk management strategy

4. Monitor effectiveness of solutions

Prototype Model
Data Collection Framework



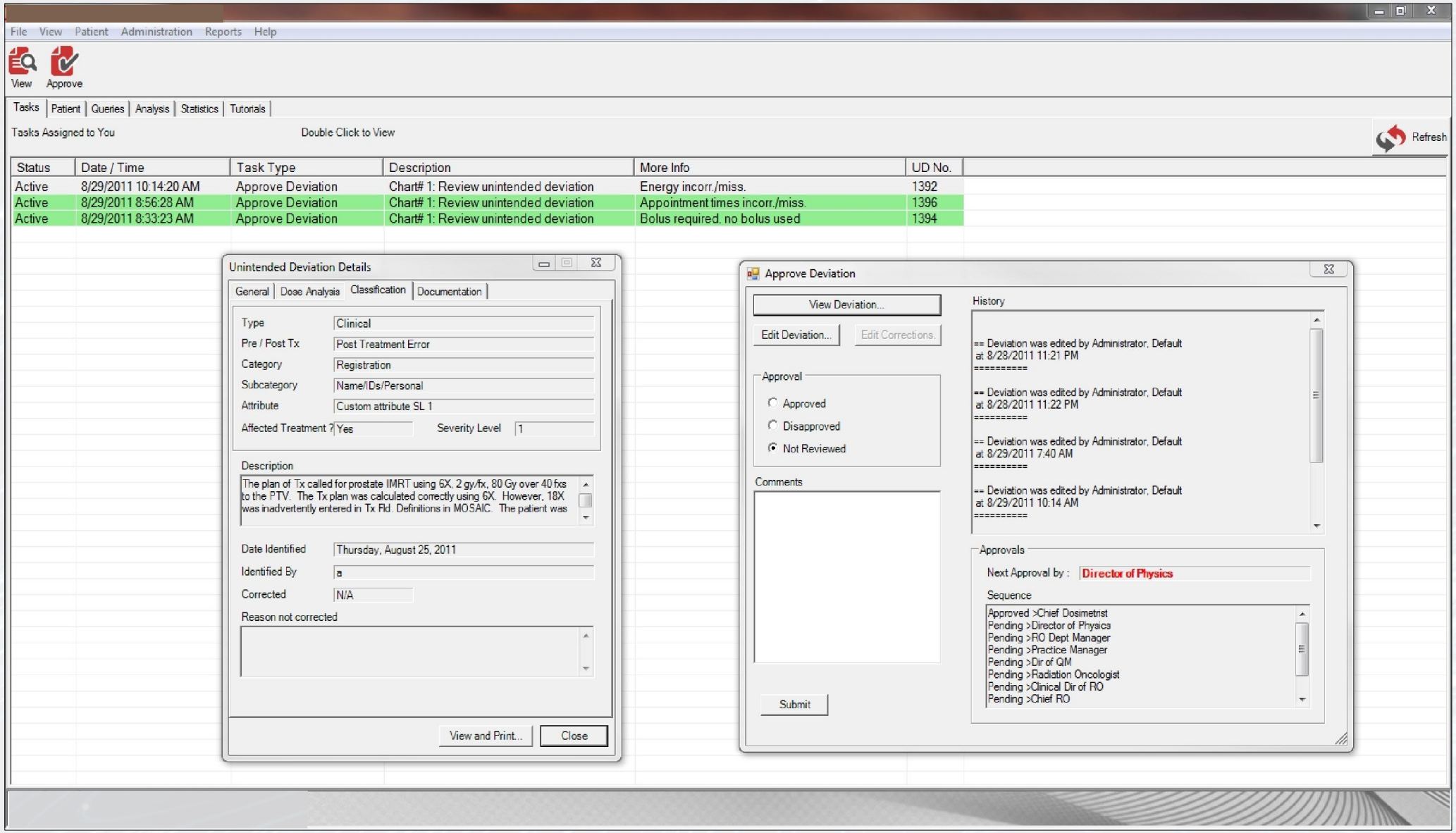
Prototype Model
Workflow Features

- Monitored Areas
- Identification and Tacking of Errors
- Step-By-Step Root Cause Analysis
- Action Plan Road Map
- Patient Dose Error Calculation Wizard
- Procedure Generation
- Review and Approval
- Reports and Chart Generation
- Customization vs Template Features
- Audit Compliance Tool
- Standards/Requirements Referenced by Code

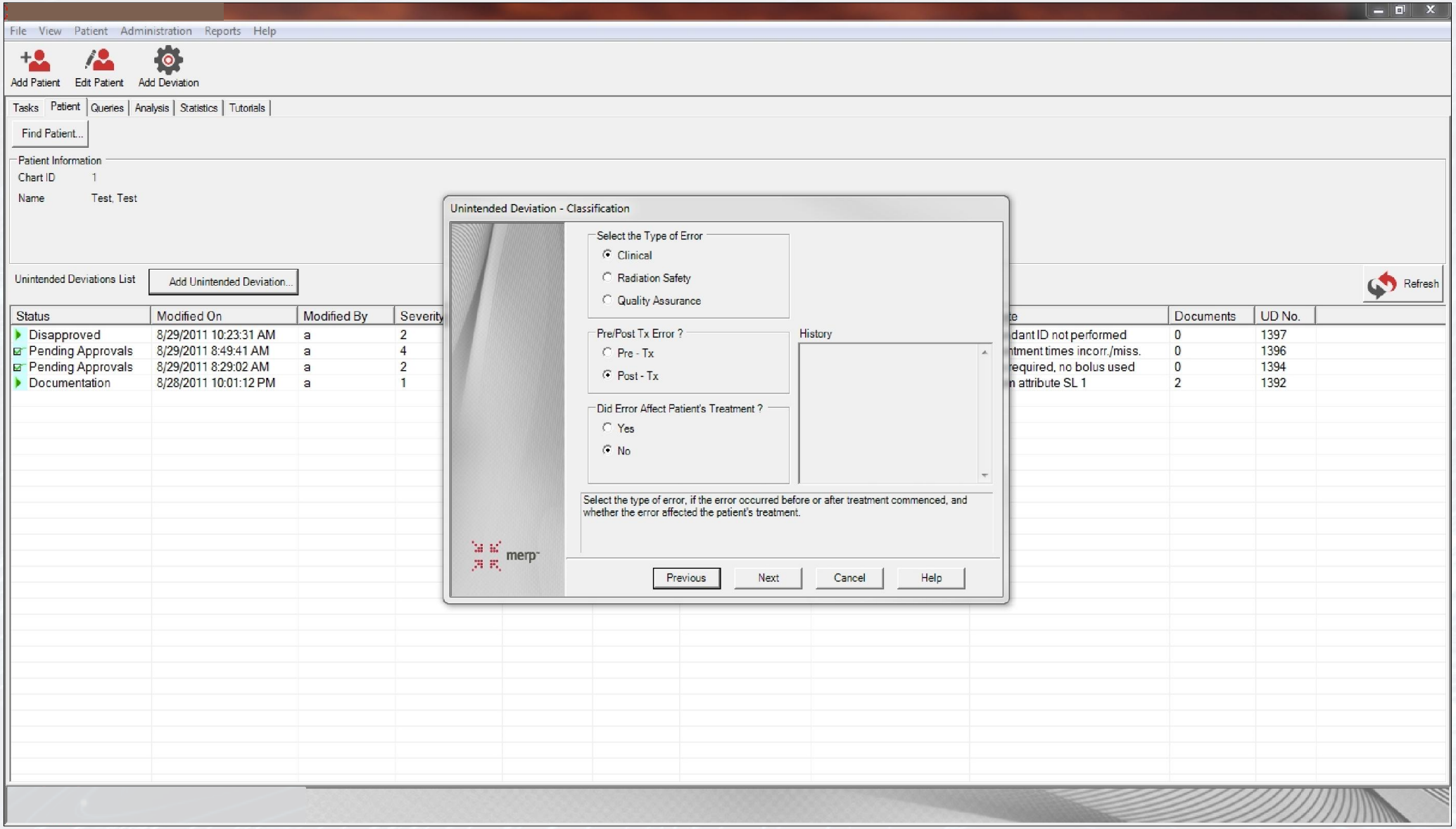
Part XI

Prototype Look

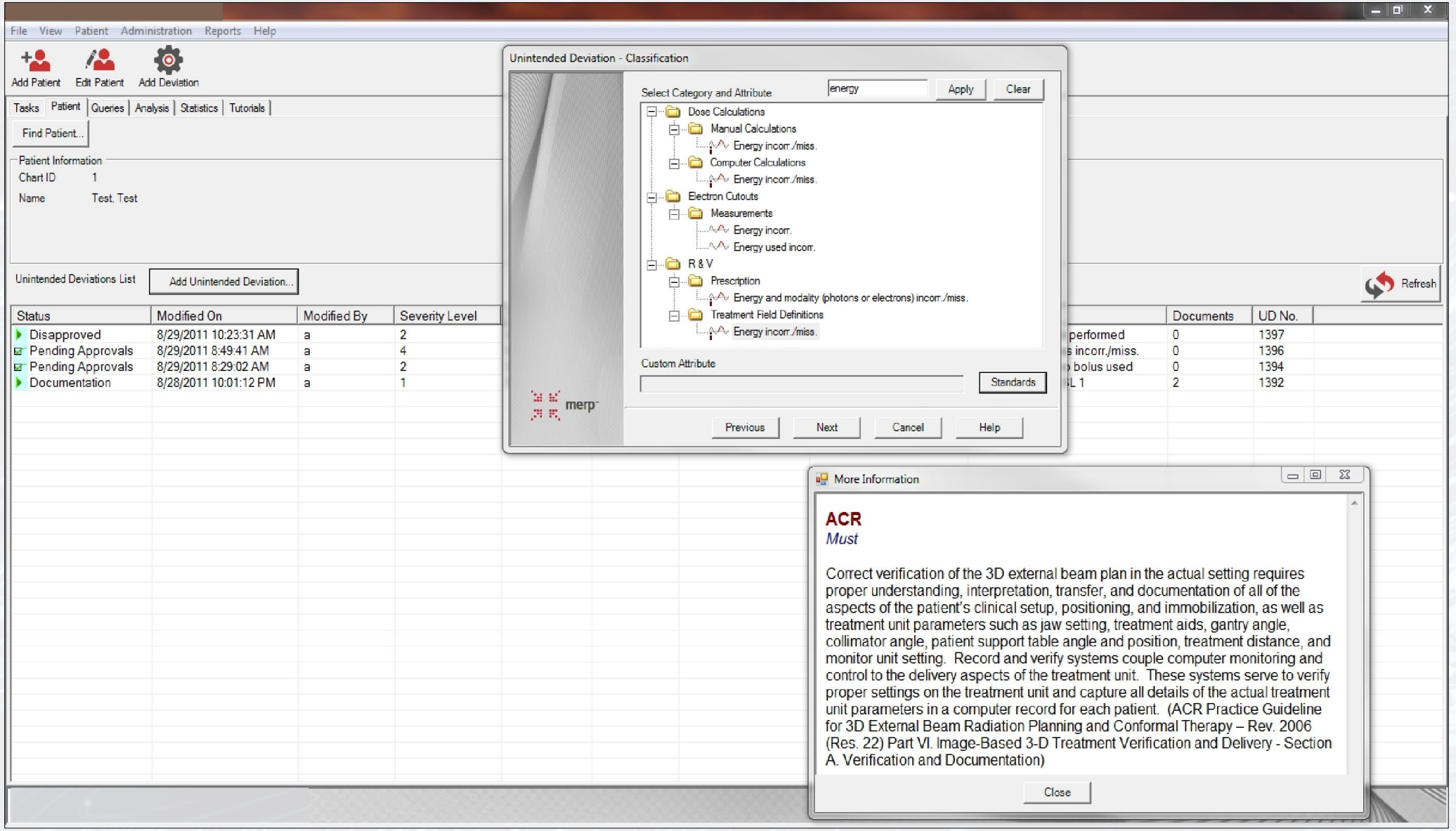
Mailbox


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 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

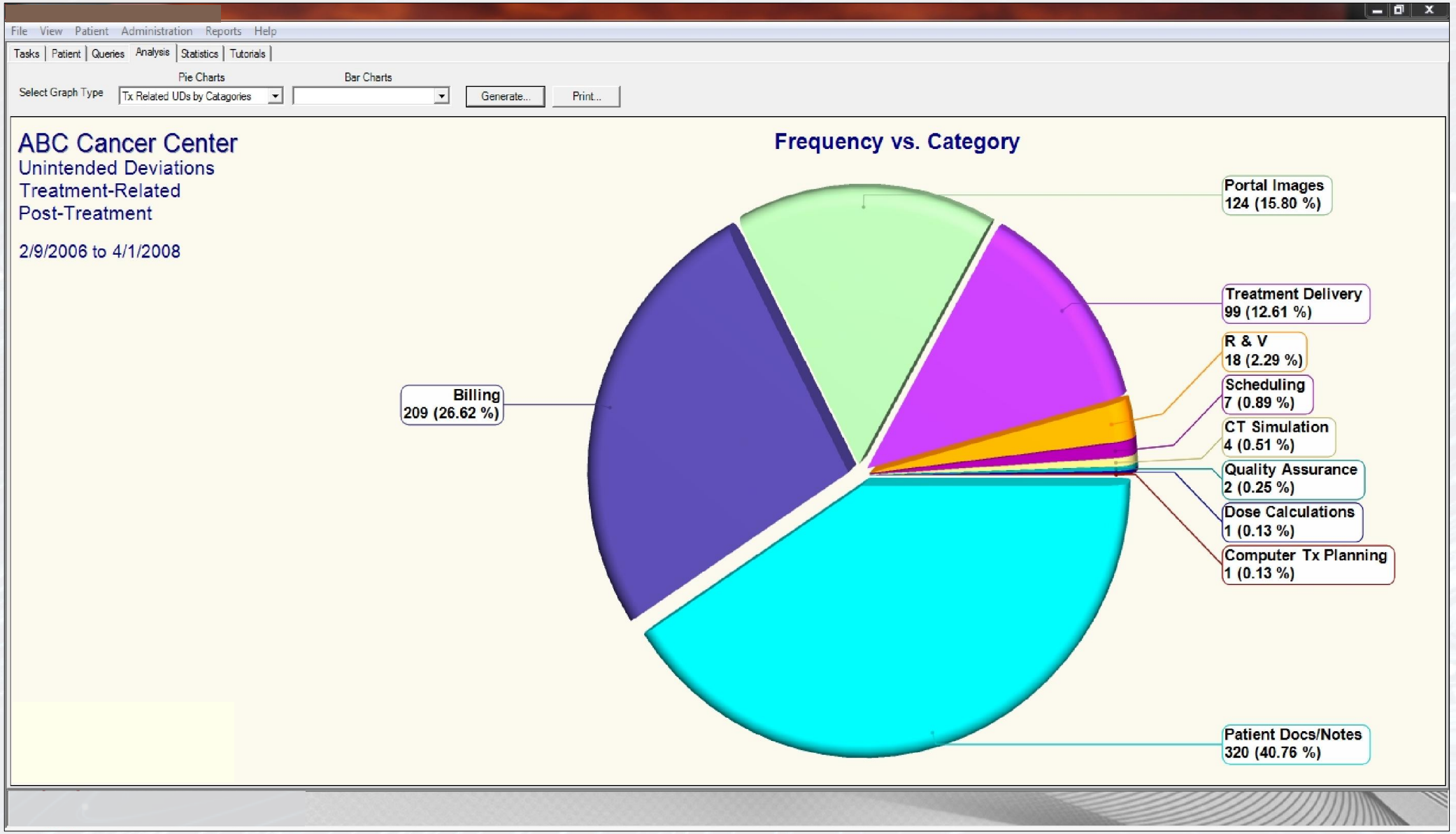
Error Entry


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
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

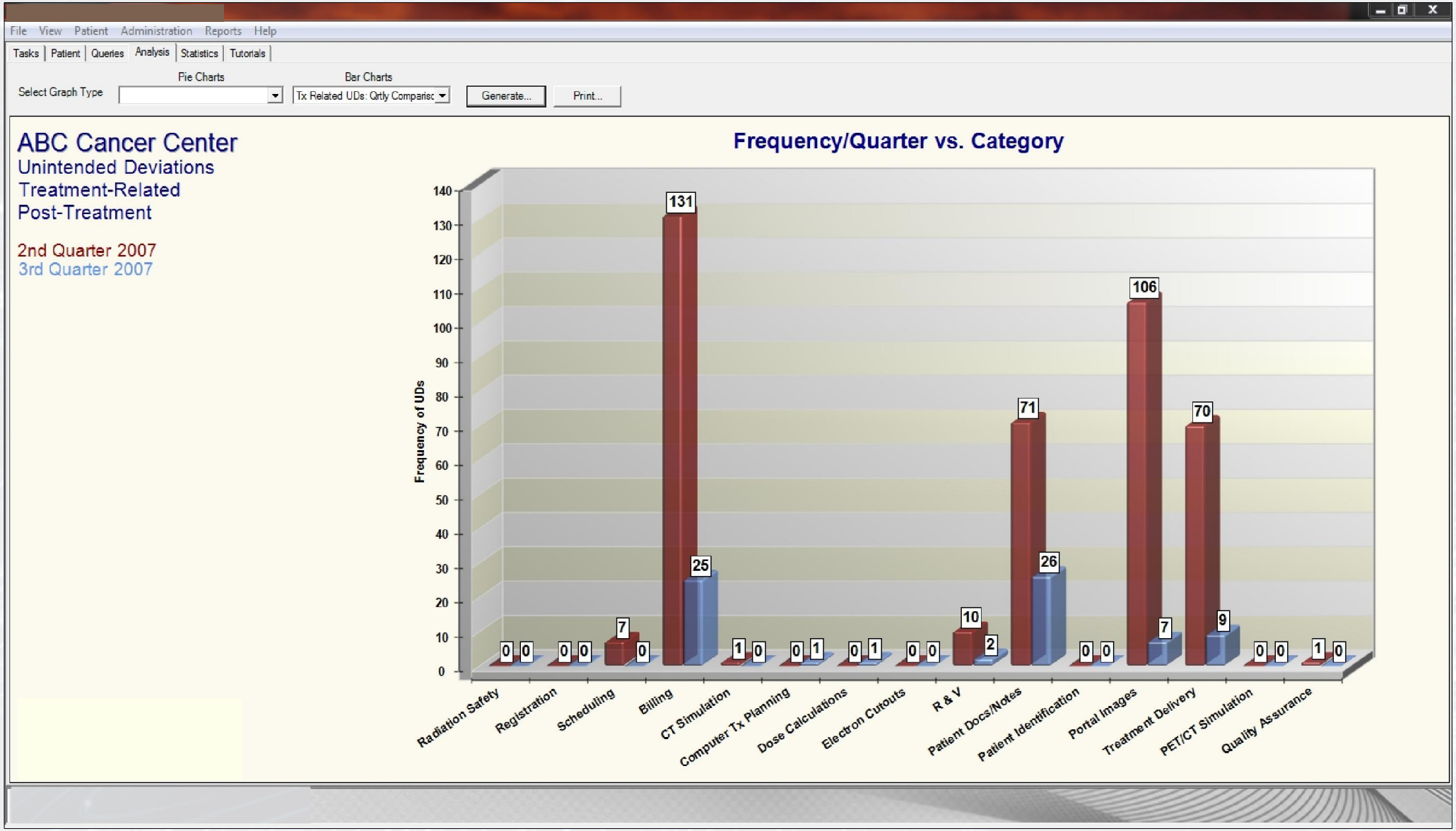
Error Entry - Conti.



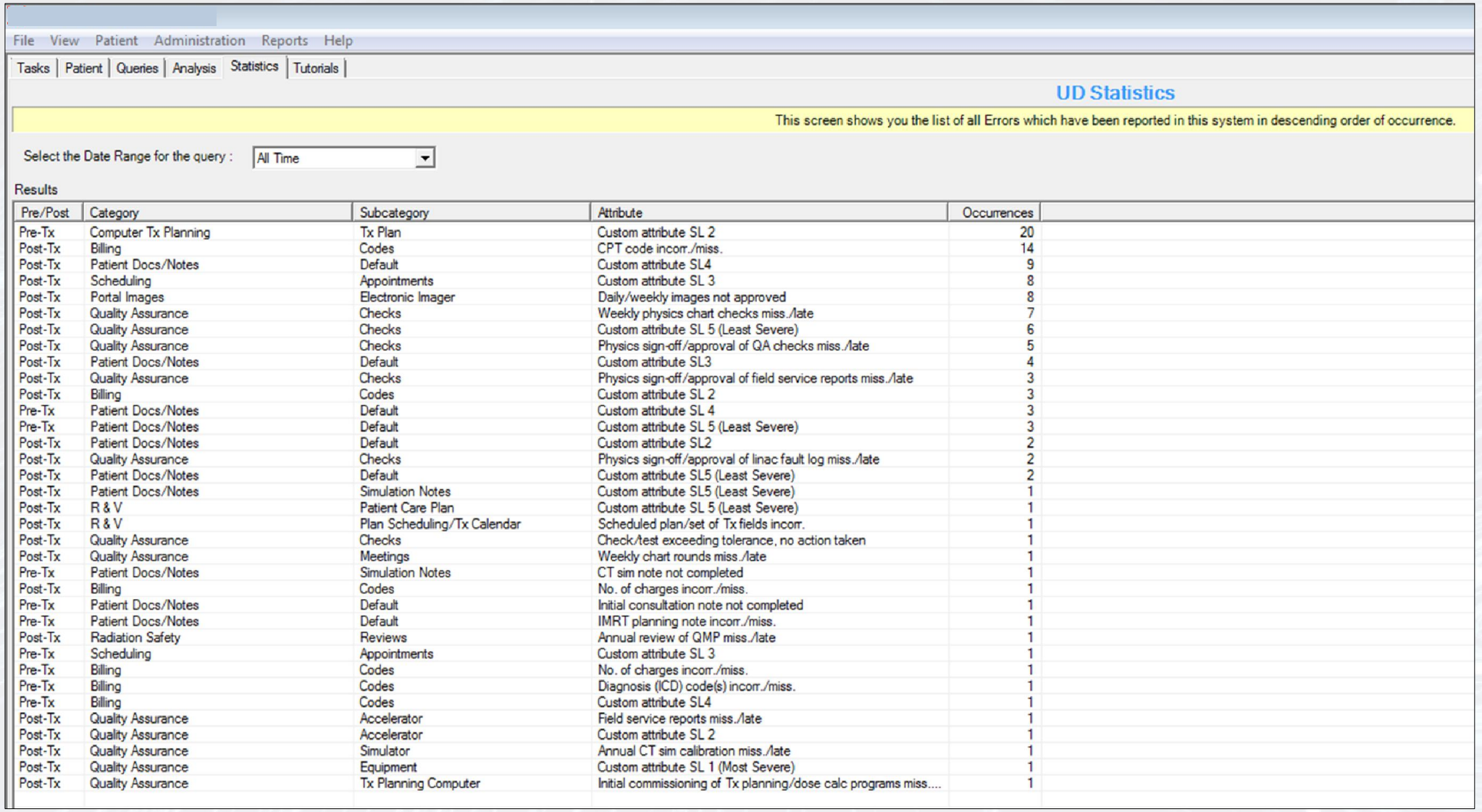
Types of Errors



Quarterly Comparison



Error Query



File View Patient Administration Reports Help

Tasks | Patient | Queries | Analysis | Statistics | Tutorials

UD Statistics

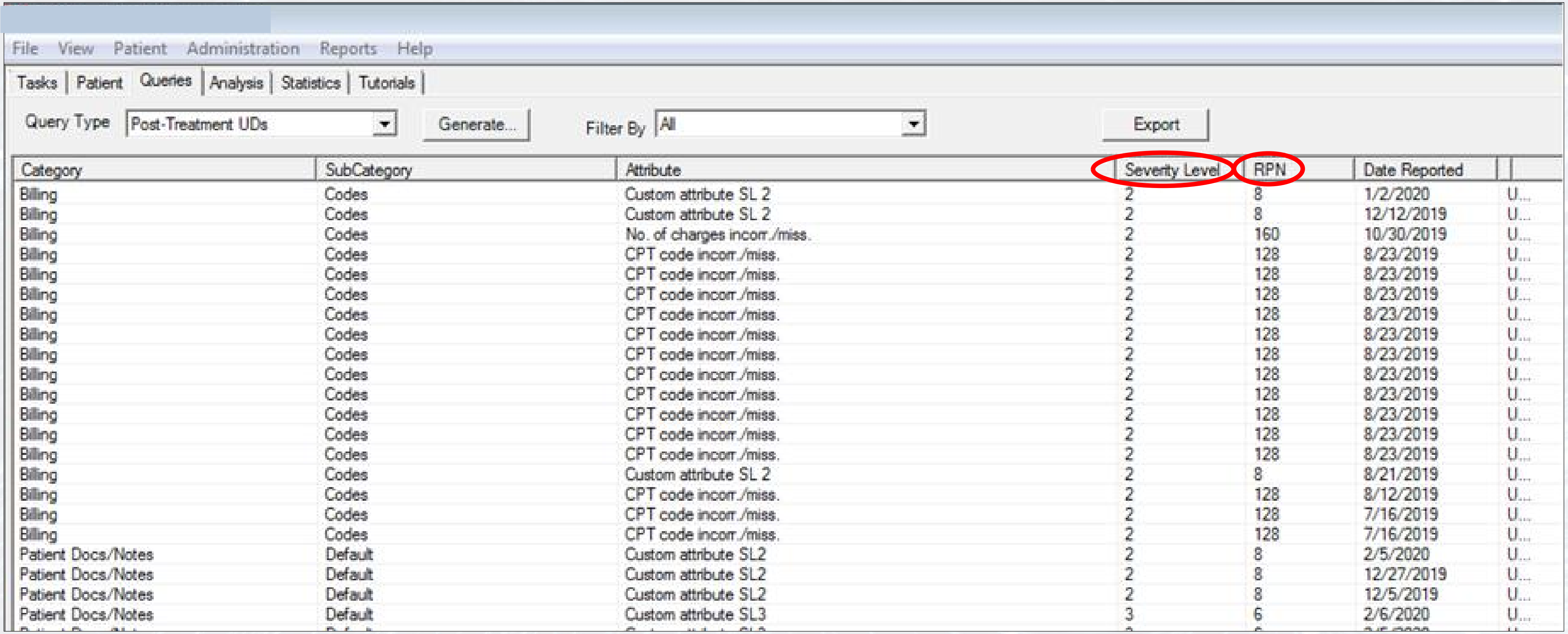
This screen shows you the list of all Errors which have been reported in this system in descending order of occurrence.

Select the Date Range for the query : All Time

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 incorr./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 incorr.	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 incorr./miss.	1
Pre-Tx	Patient Docs/Notes	Default	Initial consultation note not completed	1
Pre-Tx	Patient Docs/Notes	Default	IMRT planning note incorr./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 incorr./miss.	1
Pre-Tx	Billing	Codes	Diagnosis (ICD) code(s) incorr./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

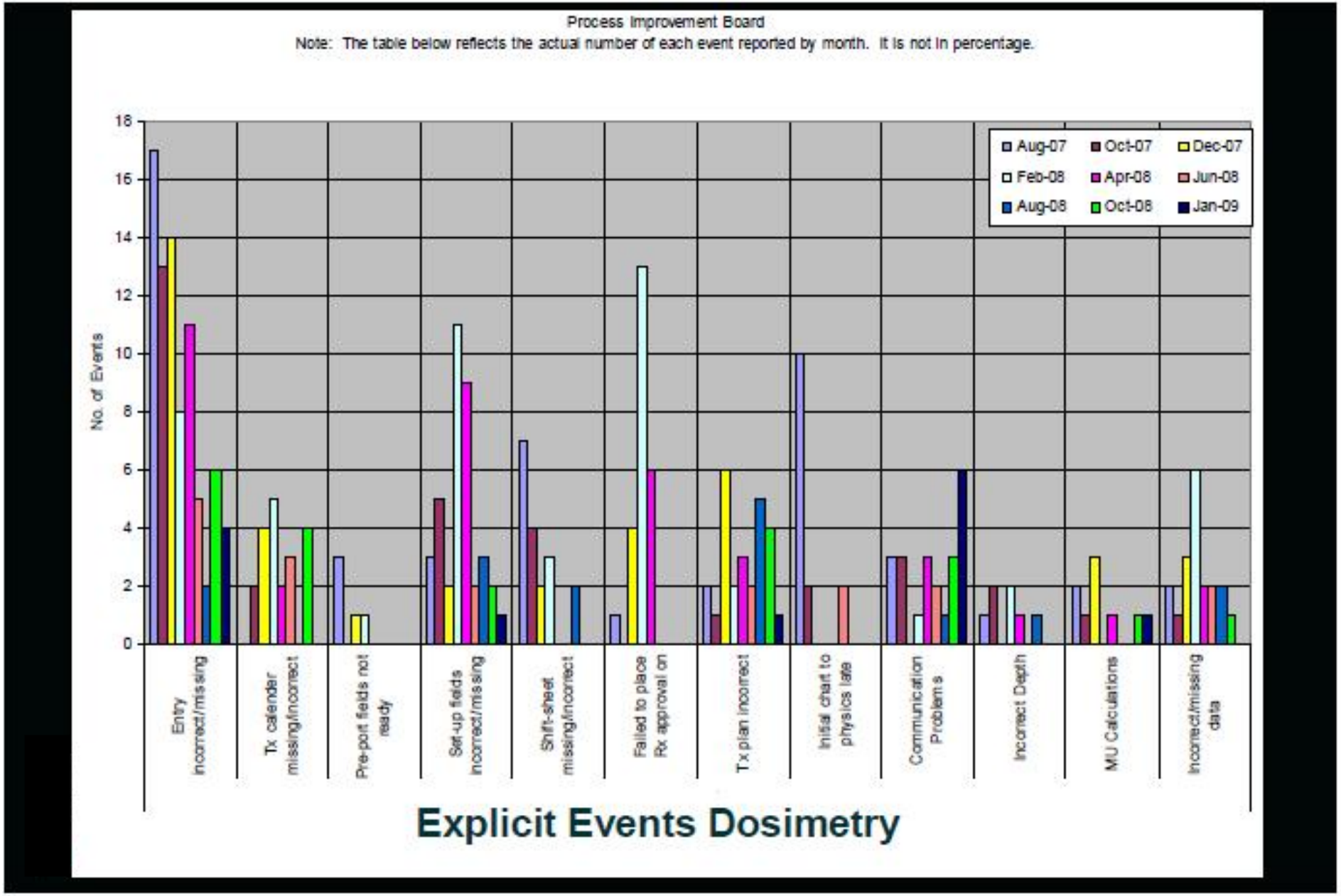
Severity and RPN Classification



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 incorr./miss.	2	160	10/30/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/23/2019	U...
Billing	Codes	Custom attribute SL 2	2	8	8/21/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	8/12/2019	U...
Billing	Codes	CPT code incorr./miss.	2	128	7/16/2019	U...
Billing	Codes	CPT code incorr./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...

Part XII

Case Examples



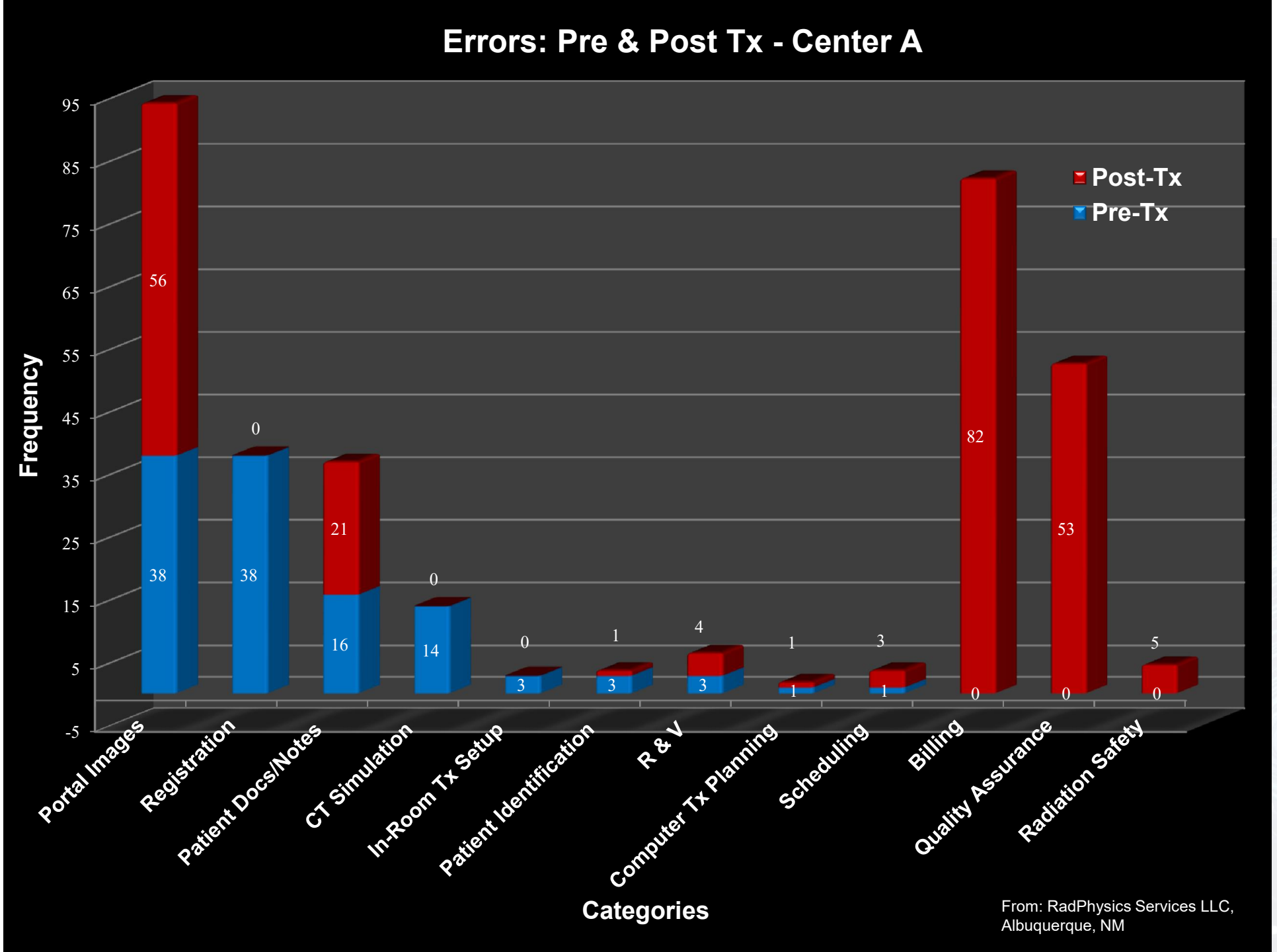
From: Washington University School of Medicine, Mallinckrodt Institute of Radiology, St. Louis, Missouri

Other Work

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**



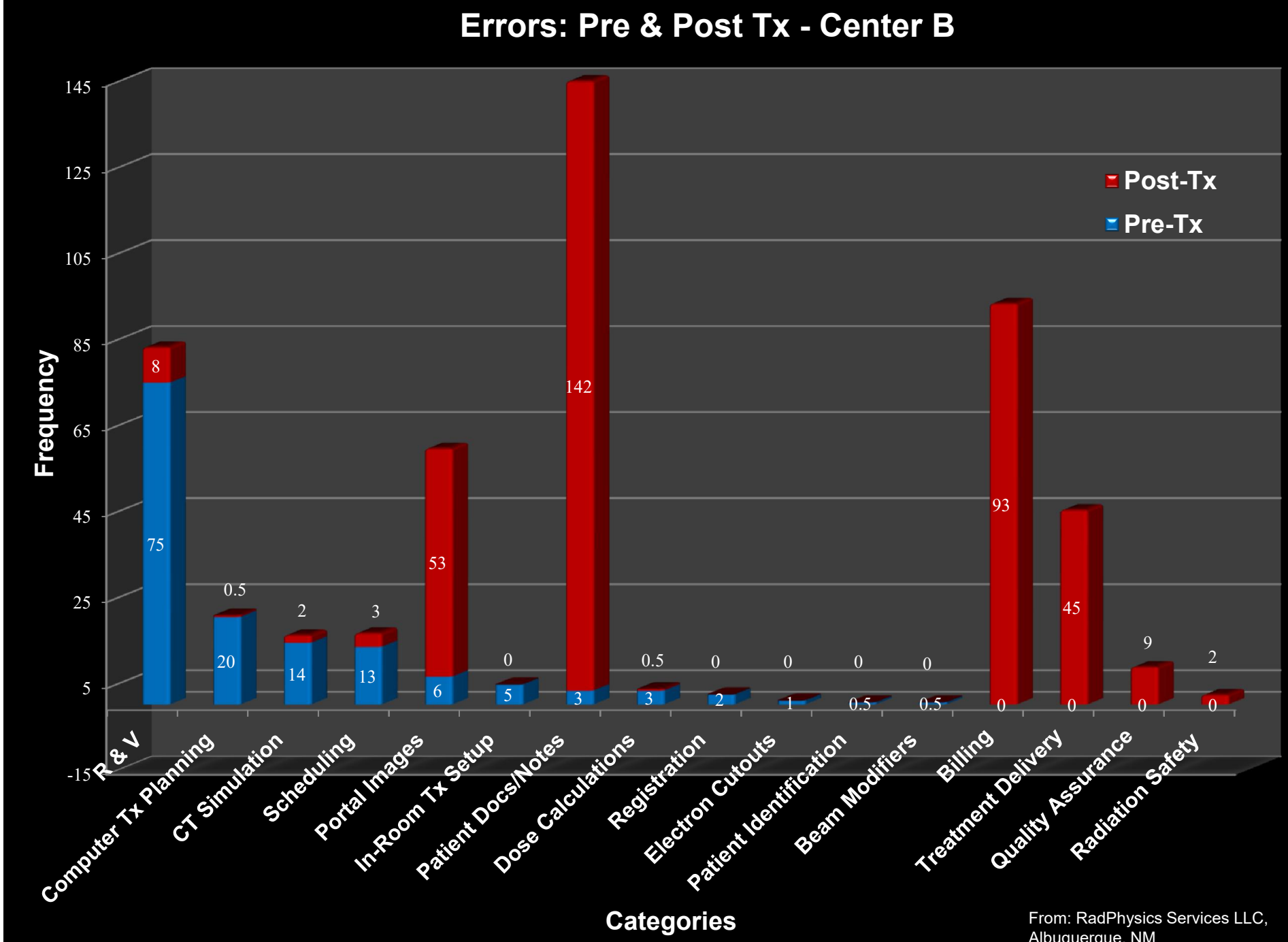
From: RadPhysics Services LLC, Albuquerque, NM

Study 2

Cost of Mistakes in Radiation Therapy[1]

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

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



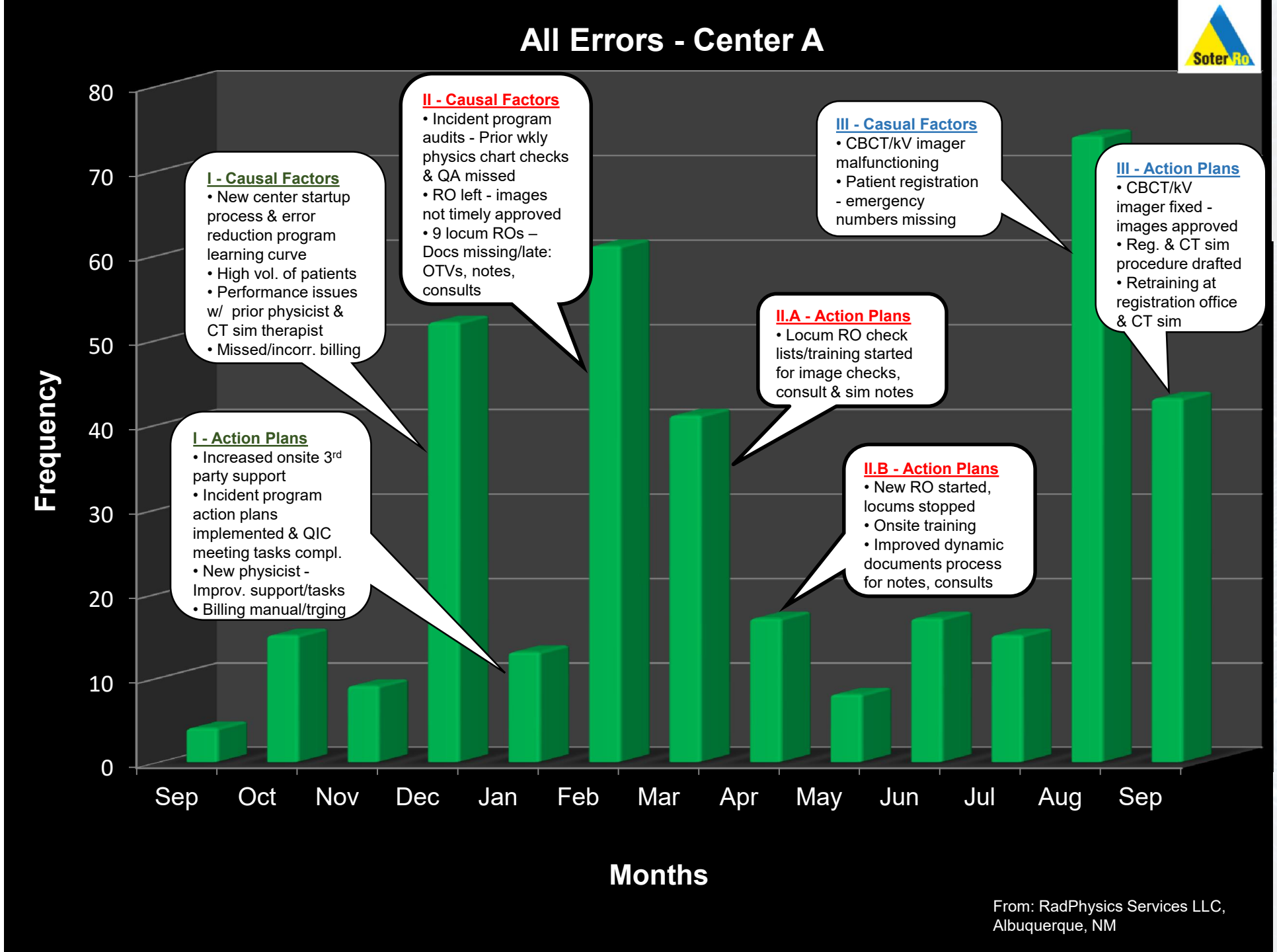
From: RadPhysics Services LLC, Albuquerque, NM

Study 3

Cost of Mistakes in Radiation Therapy[1]

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

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



From: RadPhysics Services LLC, Albuquerque, NM

Results

Error Rates in Entire Treatment Process[a]

Error Category	Pre-Tx			Post-Tx			Pre-Tx + Post Tx		
	Center A 115 errors	Center B 145 errors	Center C 66 errors	Center A 225 errors	Center B 362 errors	Center C 37 errors	Center A 340 errors	Center B 477 errors	Center C 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

[a]Data 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 Center A	This Work Center B	This Work 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]					

[a]Treatment delivery means the administration of radiation to a patient.

[b]Data for Centers A , B, and C was annualized.

[c]Comprises the entire treatment process (excluding QA, RS, and Billing).

[1]Errors per Tx units.

[2]Errors 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

[b]Data for Centers A, B, and C was annualized.

Results

Medical Event Rates[a]						
Category	**Kline et al.**	**Center A**	**Center B**	**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		

[a]Data 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 Report[33]
  - 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%**[34]
  - Top 2 reasons for errors among claims
    - Failing to send supporting documentation
    - Submitting records without a valid signature
- 2008 Provider Compliance Error Rate[35]
  - 10.9% Diagnostic Radiology
  - **11.8% Radiation Oncology**
  - 14.6% Independent Diagnostic Testing Facility
  - 22.2% Nuclear Medicine
  - 25.3% Interventional Radiology

[33]Comprehensive Error Rate Testing (CERT). Centers for Medicare & Medicaid Services. Accessed at *CMS.gov*, February 15, 2020.

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

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

Results

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

[a]Data for Centers A, B, and C 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 for billing.

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

[3]Approximately 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

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

[b]Data for Centers A, B, and C was annualized.

Part XIII

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 XIV

AI in Risk Management

A Compelling Argument

Voluntary event/incident reporting identities approximately 5% of adverse events[36]

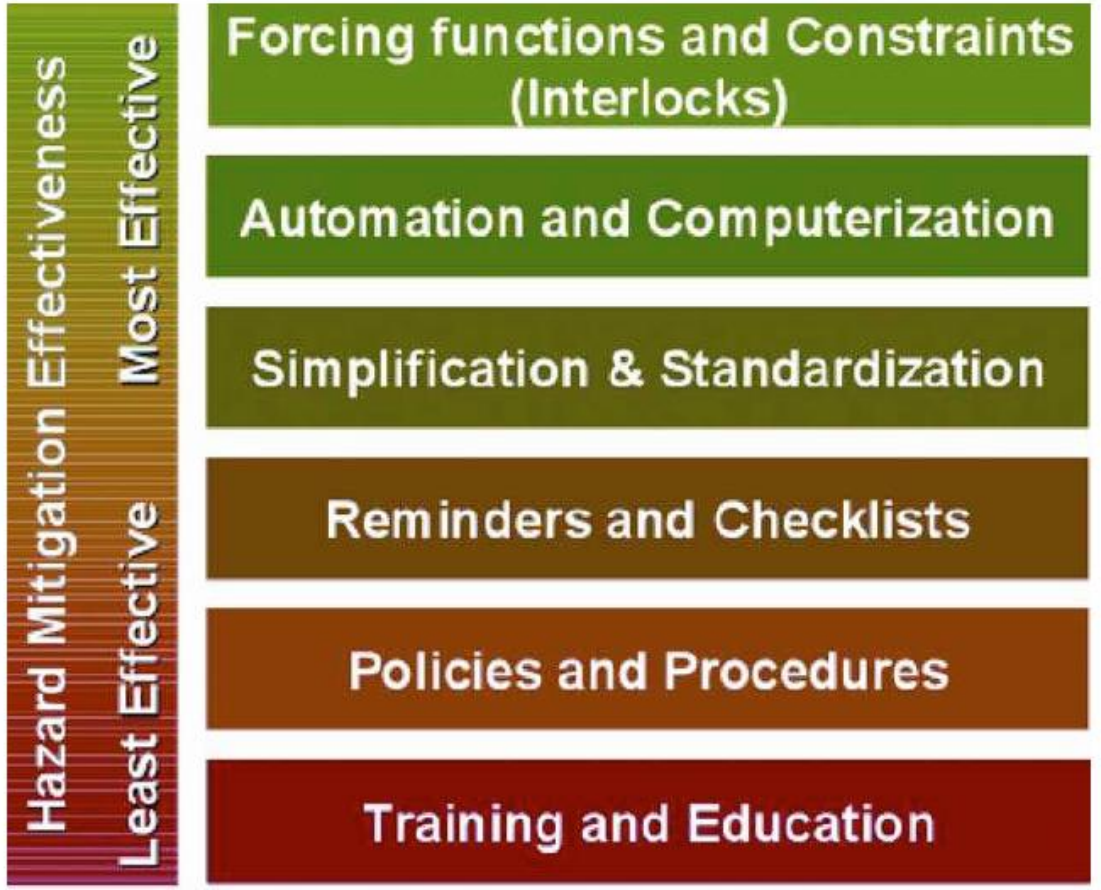
versus

AI has the potential to reduce medical errors by 30 – 40%, and treatment expenses by as much as 50% (Frost and Sullivan, 2016)[37]

[36]Landrigan, C. P., Parry, G. J., Bones, C. B., Hackbarth, A. D., Goldmann, D. A., & Sharek, P. J. (2010). Temporal trends in rates of patient harm resulting from medical care. The New England journal of medicine, 363(22), 2124–2134

[37]A. 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[38, 39]

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

[39]Heinzerling 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 oncology[40]
  - 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
- Remove **fear of reprimand** as a barrier to error reporting
- Create a high-reliability system that is quantitatively integrated with patient safety.

[40]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.

Creating a Prototype AI Model

Key Objectives

Process Reliability

Short-Term

Predict RT Process Reliability[41]

Machine Learning

Long-term Approach

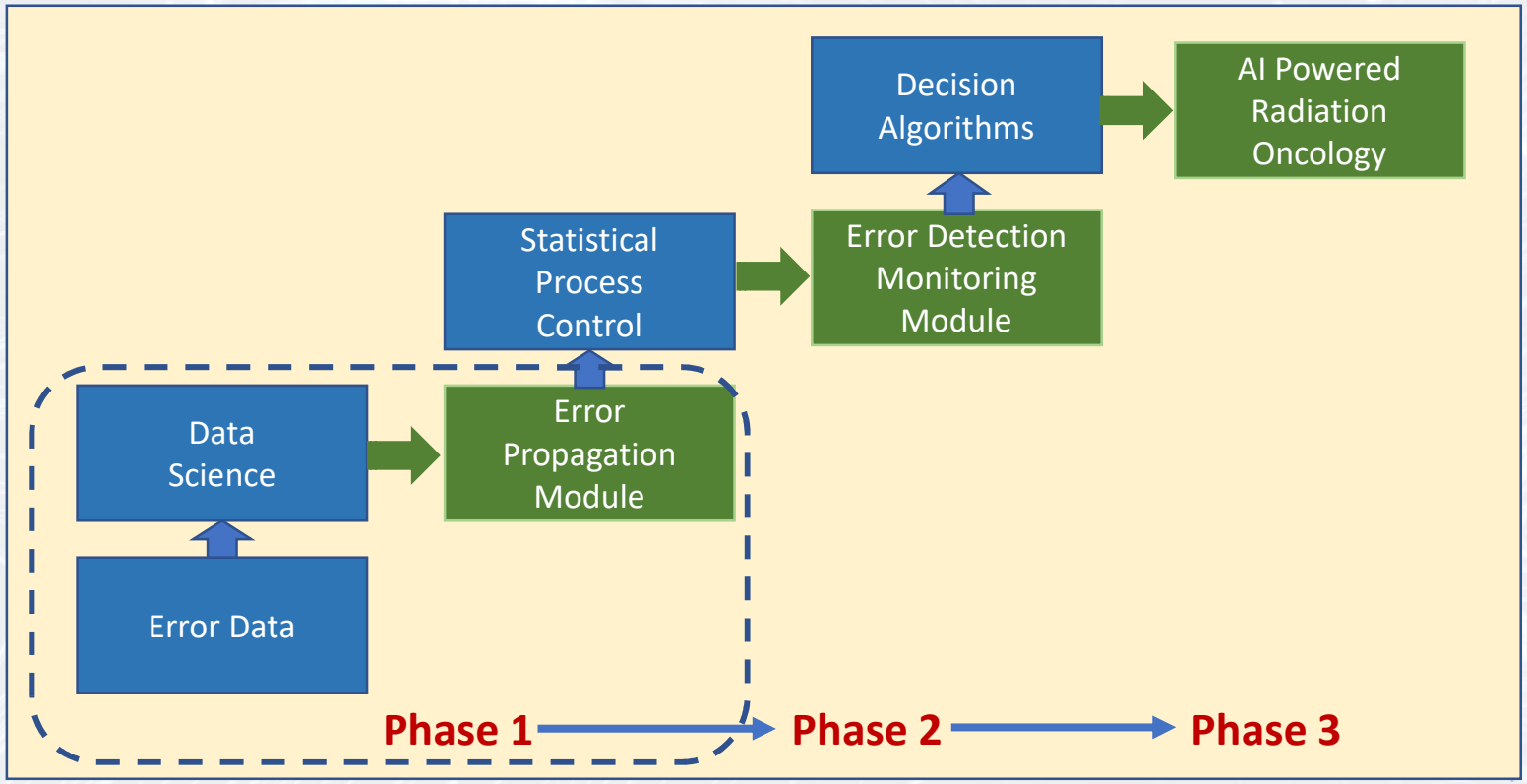
Optimize Big Data[42]

[41]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.

[42]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.

Development of AI Model

From Error Data Toward AI Radiation Oncology



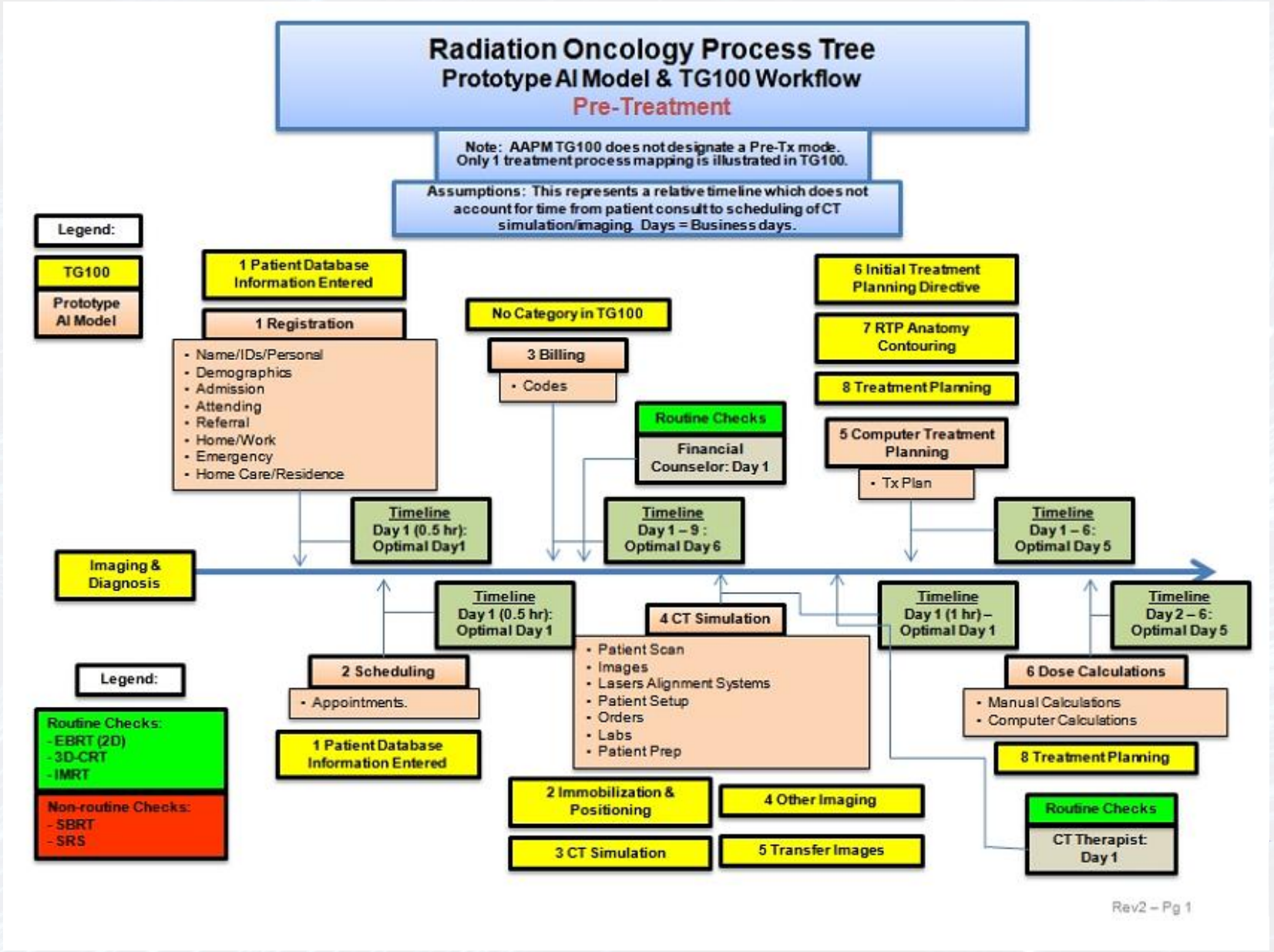
Step #1 – Collect the Data

Example of Partial SQL Database Screen Shot

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	DEVID	CHART_ID	STATUS	ERROR_CODE	DESCR_IF_MISC	DESCRIPTION	DATE_ID	IDENTIFIED_BY	DATE_CREATED	MODIFIED_BY	DATE_MODIFIED	AFFECTED_ TREATMENT	CORRECTED	CORRECTED	TX_INTENT	TX_METHOD	DEV_TYPE	ASSIGNED_ USER	ASSIGNED_ ROLE	HISTORY_ LOG
2	100	SYS_QA	7	0-9-11667-12531		Patient's weekly physics chart check was not completed on t	19:58.0	XXX	20:16.2	XXX	19:58.7	0	1		0	0	2			
3	101	SYS_QA	7	0-9-11667-12531		Patient's weekly physics chart check was not completed on t	20:18.0	XXX	20:33.4	XXX	20:18.4	0	1		0	0	2			
4	102	XXXXX	6	0-10940-10941-10945		Weekly physics chart check was not entered in on the prope	22:24.0	XXX	23:39.3	XXX	22:24.1	0	3		1	3	0			
5	103	XXXXX	6	0-10940-10941-10945		Weekly physics chart check was not entered in on the prope	24:20.0	XXX	24:33.2	XXX	24:20.0	0	3		1	3	0			
6																				
7	Deviation was edited by XXX																			
8	at 7/31/2019 7:46 AM																			
9	==========																			
10	104	SYS_QA	7	0-9-11667-12542	Notation of session nur	Notation of session numbers incorrect in Chart QA - listed as	30:21.7	XXX	37:38.1	XXX	30:21.7	0	1		0	0	2			
11	105	SYS_QA	7	0-9-11667-12542	Notation of session nur	Notation of session numbers incorrect in Chart QA. Patient's	37:40.7	XXX	39:02.3	XXX	37:40.7	0	1		0	0	2			
12	106	SYS_QA	7	0-9-11667-12533		Daily QA documents for the CT Simulator have not been appr	39:57.0	XXX	40:18.6	XXX	39:57.4	0	3		0	0	2			
13	107	SYS_QA	7	0-9-11667-12542	Notation of session nur	Notation of session numbers incorrect in Chart QA. Patient's	38:36.3	XXX	39:06.9	XXX	38:36.3	0	1		0	0	2			
14	108	XXXXX	7	0-11501-11520-12801		First of two scans on Monday 8/5/2019 was not marked as re	26:31.0	XXX	35:20.2	XXX	26:31.4	0	1		1	3	0			
15	109	XXXXX	7	0-11466-11468-12778	OTV	Physical Exam not entered on patient's OTV note	28:10.4	XXX	31:09.0	XXX	28:10.4	0	2	Not corre	1	3	0			
16	110	XXXXX	7	0-10940-10941-10945		Patient's physical exam that should be input by Dr. Good on	26:15.3	XXX	27:47.2	XXX	26:15.3	0	3		1	3	0			
17	111	XXXXX	7	0-11501-11520-12801		Neither scans for 8/13/19 were approved nor reviewed. Dr. (	39:45.1	XXX	41:17.1	XXX	39:45.1	0	1		1	3	0			
18	112	XXXXX	7	0-11501-11520-12801		First scan on 8/5/19 was not reviewed or approved by Dr. Go	53:50.2	XXX	54:28.5	XXX	53:50.2	0	1		1	3	0			
19	113	XXXXX	7	0-9-11713-11714		Weekly OTV note was not documented or completed.	47:47.5	XXX	51:37.8	XXX	47:47.5	0	1		0	0	2			
20	114	XXXXX	7	0-10282-10283-12220	Contours Changed	Contours changed to allow the 50% isodose line to bisect th	03:34.0	XXX	08:31.3	XXX	03:35.0	0	3		1	3	0			
21	115	SYS_QA	7	0-9-11667-12542	Notation of session nur	Notation of session numbers incorrect in Chart QA. Patient's	27:45.9	XXX	11:32.9	XXX	27:45.9	0	1		0	0	2			
22	116	SYS_QA	7	0-9-11667-12533		CT Simulator QA documents on 8/6/2019 and 8/19/2019 wer	29:59.8	XXX	48:54.4	XXX	29:59.8	0	3		0	0	2			
23	117	XXXXX	7	0-10940-10941-10961	Charge Not Billable Due	Dr. Good did not enter the patient's weekly OTV note on the	49:40.3	XXX	51:05.8	XXX	49:40.3	0	3		1	3	0			
24	118	XXXXX	7	0-10940-10941-10945		Charge capture of G6015 and 77014 correct. Billing departm	17:49.0	XXX	28:03.5	XXX	17:49.8	0	3		1	3	0			
25	119	XXXXX	7	0-10940-10941-10945		Charge capture of G6015, 77014, 77338 - 59, and 77300 x 7 (	31:00.0	XXX	41:00.9	XXX	31:00.4	0	3		1	3	0			
26	120	XXXXX	7	0-10940-10941-10945		Charge capture of G6015, 77014, 77427, and 77336 correct.	44:56.0	XXX	48:53.7	XXX	44:56.7	0	3		1	3	0			
27	121	XXXXX	7	0-10940-10941-10945		Charge capture of G6015 and 77014 correct. Billing departm	49:41.0	XXX	52:28.8	XXX	49:41.7	0	3		1	3	0			
28	122	XXXXX	7	0-10940-10941-10945		Charge capture of G6015, 77014, 77427, and 77336 correct.	54:10.0	XXX	55:35.3	XXX	54:10.7	0	3		1	3	0			
29	123	XXXXX	7	0-10940-10941-10945		Charge capture of G6015 and 77014 correct. Billing departm	01:23.0	XXX	02:49.8	XXX	01:24.0	0	3		1	3	0			
30	124	XXXXX	7	0-10940-10941-10945		Charge capture of G6015 and 77014 correct. Billing departm	04:43.0	XXX	05:46.2	XXX	04:43.7	0	3		1	3	0			
31	125	XXXXX	7	0-10940-10941-10945		Charge capture of G6015 and 77014 correct. Billing departm	06:17.0	XXX	07:34.0	XXX	06:17.4	0	3		1	3	0			
32	126	XXXXX	7	0-10940-10941-10945		Charge capture of G6015, 77014, 77427, and 77336 correct.	14:29.0	XXX	15:45.7	XXX	14:29.2	0	3		1	3	0			
33	127	XXXXX	7	0-10940-10941-10945		Charge capture of G6015 and 77014 correct. Billing departm	17:30.0	XXX	18:23.2	XXX	17:30.3	0	3		1	3	0			
34	128	XXXXX	7	0-10940-10941-10945		Charge capture of 77014 correct on DOS January 28th, 2019	21:34.0	XXX	24:45.7	XXX	21:35.0	0	3		1	3	0			
35	129	SYS_QA	7	0-9-11667-12533		Physicist review/approval of CT simulator daily QA checks nc	41:52.5	XXX	48:00.2	XXX	41:52.5	0	3		0	0	2			
36	130	SYS_QA	7	0-9-11667-12533		Physicist review/approval of linac treatment machine daily (	51:32.5	XXX	52:36.0	XXX	51:32.5	0	3		0	0	2			
37	131	SYS_QA	7	0-9-11667-12542	Fraction Numbers incor	The number of fractions on the patient's weekly Physics Che	37:55.5	XXX	59:12.1	XXX	37:55.5	0	1		0	0	2			
38	132	XXXXX	7	0-10282-10283-12220	Contours Changed	PTV contours changed during planning process. Sigmoid and	22:16.7	XXX	30:51.1	XXX	22:16.7	0	3		1	3	0			
39	133	XXXXX	7	0-10282-10283-12220	Contours Changed	PTV contours changed a second time during planning proces	32:43.2	XXX	34:29.8	XXX	32:43.2	0	3		1	3	0			
40	134	SYS_QA	7	0-9-11667-12531		Weekly physics note in Chart QA missing, so cumulative dos(	56:57.3	XXX	58:10.9	XXX	56:57.3	0	1		0	0	2			
41	135	SYS_QA	7	0-9-11667-12531		Patient weekly physics chart check is incorrect. Date entere	09:52.6	XXX	13:14.2	XXX	09:52.6	0	1		0	0	2			
42	136	XXXXX	7	0-11466-11468-12780	Age Incorrect on Treatm	Age Incorrect on Treatment Summary. Dr. Good notified and	21:18.1	XXX	21:59.2	abartholomew	21:18.1	0	1		1	3	0			
43	137	XXXXX	7	0-10940-10941-10949		When patient's boost QA was completed, the number of 773	47:16.5	XXX	48:34.4	abartholomew	47:16.5	0	3		1	3	0			
44	138	SYS_QA	7	0-9-11589-12493	Dose integration board	Varian service engineer replaced the iX dose integration boa	33:27.0	XXX	45:20.1	ekline	33:27.6	0	3		0	0	2			

Step #2 – Construct a Reference Timeline

A Partial Timeline of the Different Stages in the Radiation Oncology Process



Step #3 – Determine When the Error Occurred & When Was it Detected at Check Points
Step #4 – Develop a Statistical Model

Step #3

Level-1 Model → **Detection Lag Time**

Level-1 Category	Check 1	Check 2	Neither
Patient Docs/Notes	2.4%	9.6%	88.0%
CT Simulation (Orders)	5.5%	19.0%	75.5%
Quality Assurance	5.7%	19.5%	74.8%
Scheduling (Appointments)	36.0%	39.8%	24.2%
Registration (Attending)	80.8%	15.1%	4.1%
Radiation Safety (Reviews)	100.0%	0.0%	0.0%
Computer Tx Planning	2.3%	9.3%	88.4%
Dose Calculations	5.3%	18.4%	76.3%
Billing (Codes)	6.9%	22.2%	70.9%
R & V (Treatment Field Definition)	0.0%	0.0%	100.0%
R & V (Tx Plan)	1.0%	4.5%	94.5%
Portal Images (Electronic Imager)	2.1%	8.7%	89.2%
Treatment Delivery (Patient Setup)	3.0%	11.8%	85.2%
In-Room Tx Setup	6.5%	21.5%	72.0%
Misc level1	16.4%	35.8%	47.8%

Level-2 Model → **Detection Lag Time**

Level-1 Category	Level-2 Category	Check 1	Check 2	Neither
Patient Docs/Notes	Misc Level-2	0.0%	0.0%	100.0%
Patient Docs/Notes	Simulation Notes (Default)	0.3%	0.7%	99.0%
Patient Docs/Notes	Default (Patient Docs/Notes)	4.8%	9.9%	85.3%
Scheduling (Appointments)	Appointments	89.0%	7.5%	3.5%
Registration (Attending)	Misc Level-2	65.4%	21.2%	13.4%
Radiation Safety (Reviews)	Misc Level-2	65.4%	21.2%	13.4%
Computer Tx Planning	Tx Plan	57.8%	24.6%	17.6%
Dose Calculations	Misc Level-2	0.0%	0.0%	100.0%
Dose Calculations	Computer Calculations	35.1%	29.7%	35.1%
Portal Images (Electronic Imager)	Electronic Imager	3.2%	6.9%	89.9%
Portal Images (Electronic Imager)	Misc Level-2	17.2%	24.2%	58.6%
Treatment Delivery (Patient Setup)	Tx Plan	12.2%	19.9%	67.9%
Treatment Delivery (Patient Setup)	Misc Level-2	19.2%	25.6%	55.2%
Treatment Delivery (Patient Setup)	Beam Modifiers	58.6%	24.2%	17.2%

Note: Detection Lag Time = Date of Occurrence - Date of Detection

Step #4

Statistical Error Propagation Model (ordinal regression model)

↓

Flag variables vs predictor/explanatory variables

↓

Fit hierarchical model using proportional odds logistic regression in 'R'

↓

Analyze risk patterns + proactively determine points of weakness

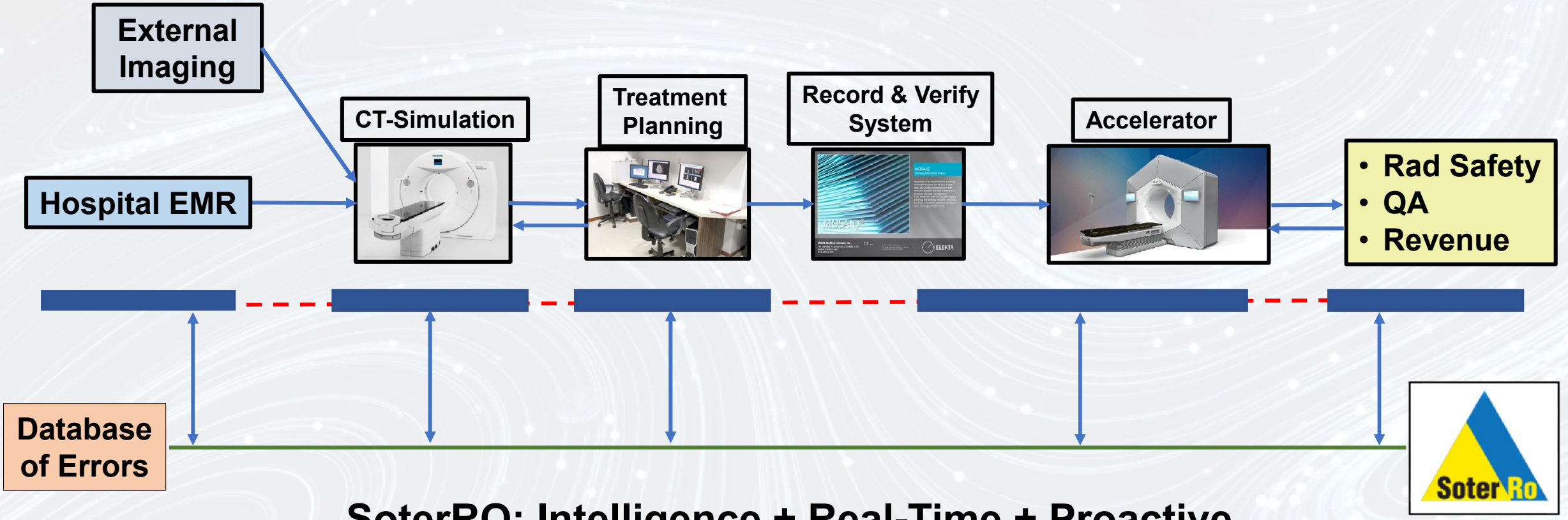
Step #5 - Show Which Errors Propagate Undetected

- From our Statistical Model
  - Errors related to patient documentation/notes were very unlikely to be detected by either the 1st or 2nd check
  - Similar patterns showed in Tx planning, imaging, and patient setup
  - On the other hand, errors related to patient scheduling, registration or radiation safety were very likely to be detected within the first 2 checks.

Step #6 - Determine Points of Weakness

- From our Statistical Model
  - Errors relating different clinical pathways pointed to weak points:
    - Errors in CT Sim Notes under patient documentation records
    - Errors in patient setup on machine at Tx delivery vs setup shown on Tx plan

Integrated Productivity (Error Reduction) System
Involving Silo'd Sub-systems



SoterRO: Intelligence + Real-Time + Proactive

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
- Our data shows most patients experienced an error of some type in their overall treatment pathways
- An algorithm was validated that allows for the use of predictive analytics of high-risk feature combinations
- SoterRO is the next step in creating a prototype of a highly-reliable, AI-driven system

Thank You!

Further Questions?

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