Patient Safety in Radiation Therapy:

A History of Errors & A Methodology to Prevent Them

About the speaker:

About the speaker:

- Tobin Hyman, MS, DABR
  - BS, Health Physics, Francis Marion College, 1992
  - MS, Health Physics, University of Florida, 1994
  - Senior Medical Physicist, MRMC
    - Practicing MP since 1995
  - Physics surveyor for the ROPA program of the ACR

Disclosures

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- sole proprietor of Carolina Physics, LLC

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- Presentation and discussion of these incidents are provided to establish a “burning platform” for change within clinical practice, and to highlight the use of the P-FMEA

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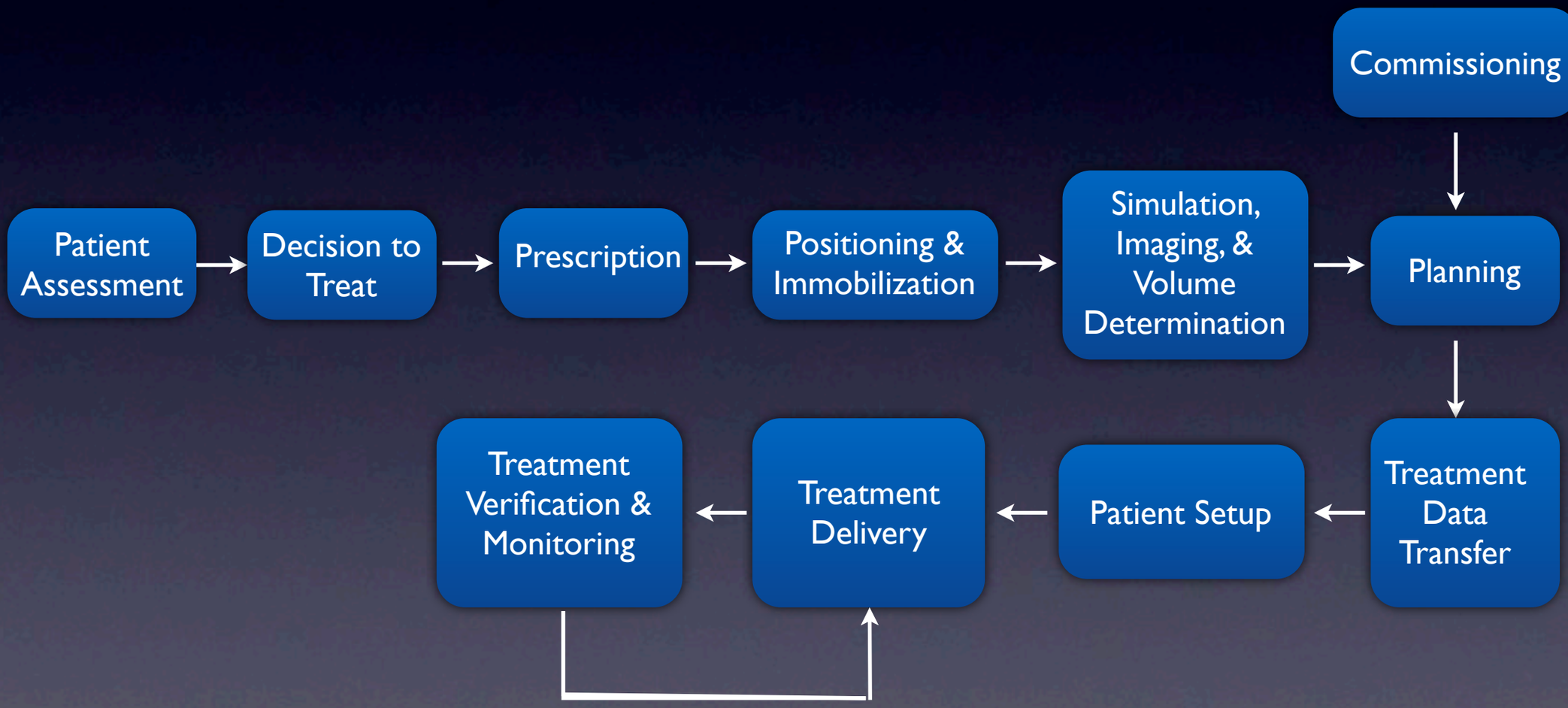
- Future Applications of the P-FMEA

The Radiation Therapy Process - Global View



How Many Errors are Occurring in Radiation Therapy?

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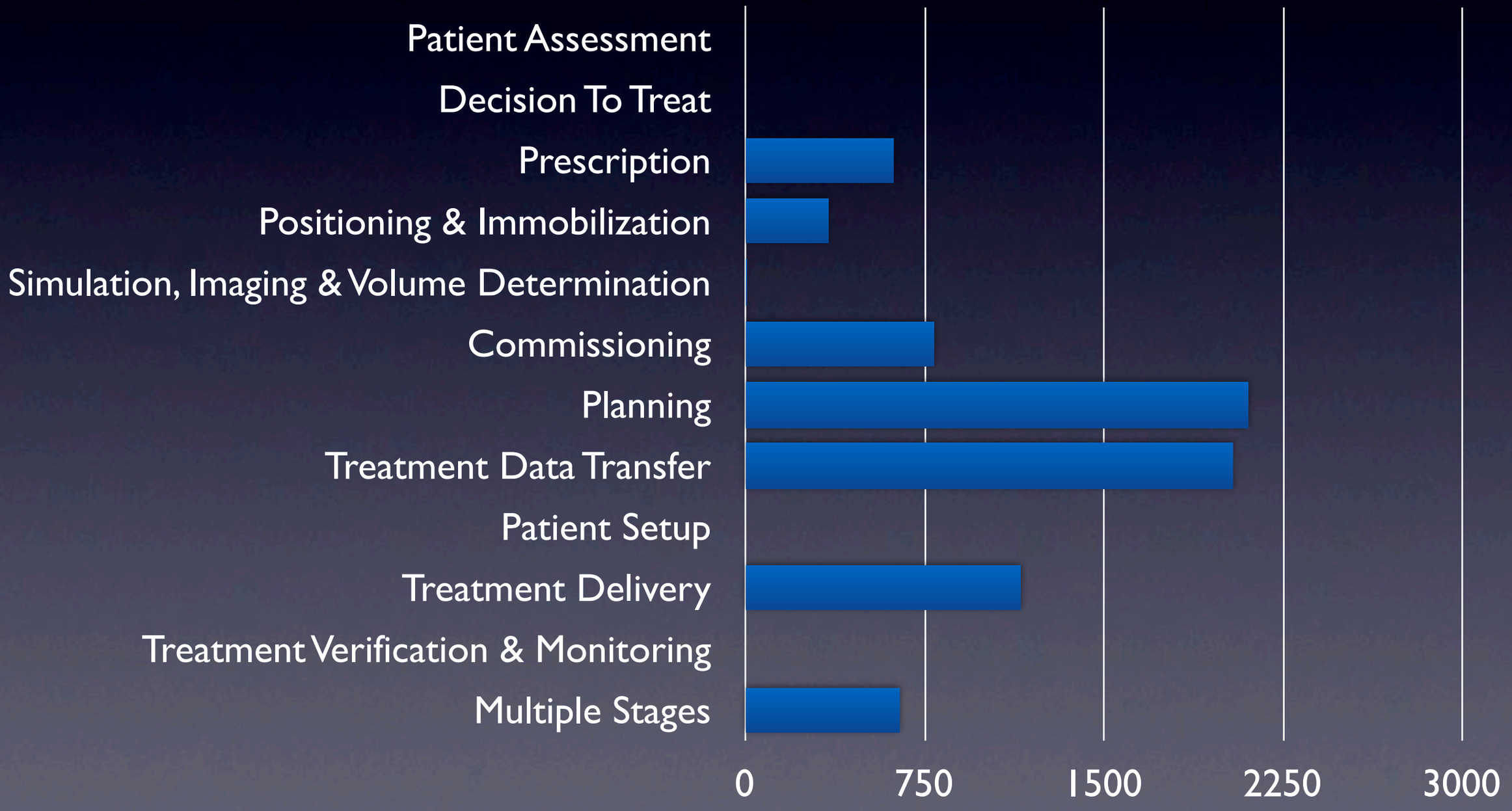
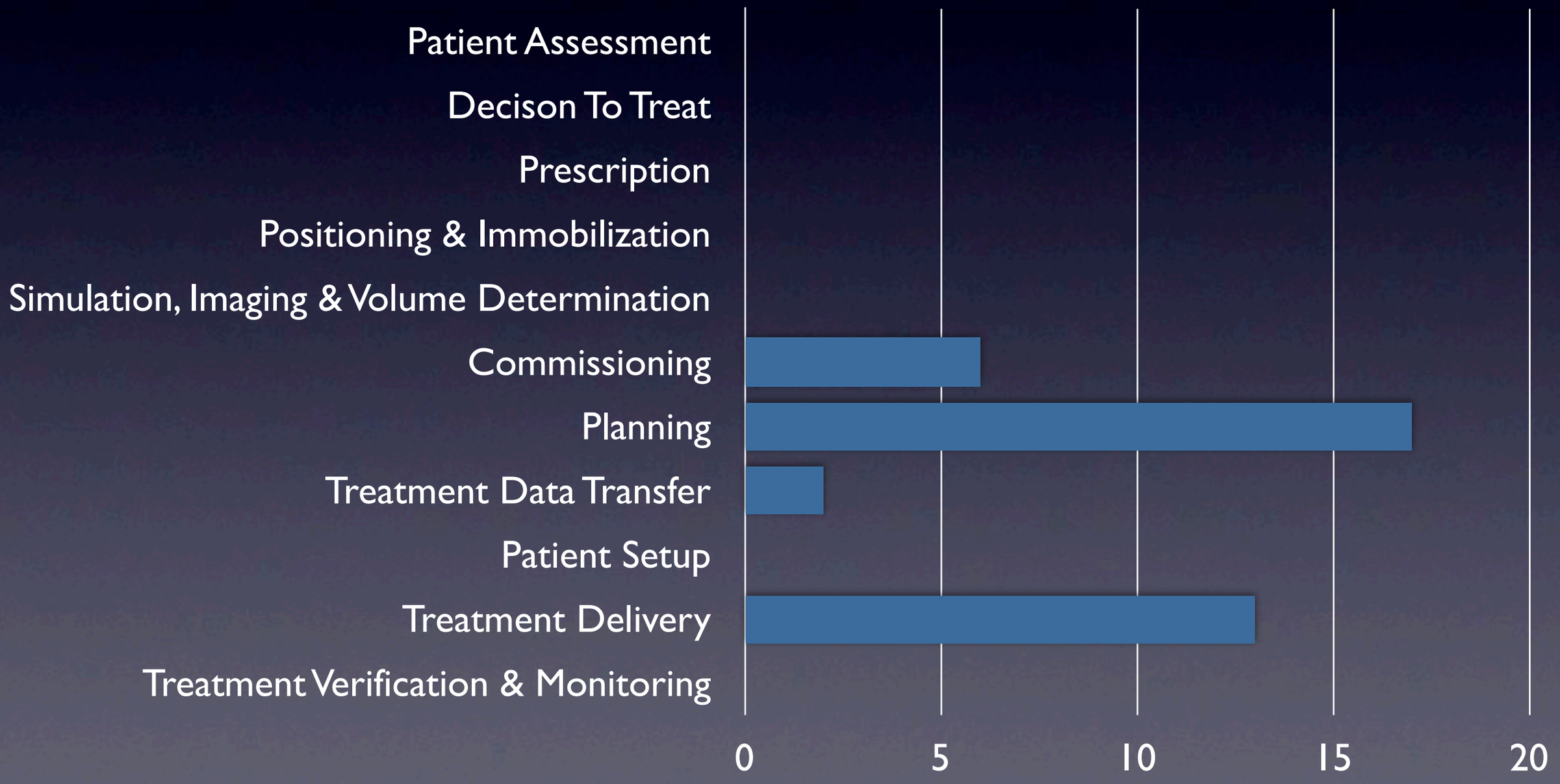
- 2008 World Health Organization (WHO) published the "Radiotherapy Risk Profile"
- retrospective review of 30 years of reported radiation therapy incidents
- findings included:
  - from 1976 to 2007, 3125 patients were reported to be affected by radiotherapy incidents that led to adverse events (38 reported fatalities; differs from the 53 reported in this presentation)
  - from 1992 to 2007, 4616 "near misses" (incident that did not cause harm) were reported
  - Total of 7741 "events"
  - weaknesses/flaws? result of investigations of major events, relates mainly to developed countries

2008 WHO Report - All Incidents



2008 WHO Report - Fatalities



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- New York Times reported:
  - between 2001-2008, 621 events were reported in New York State
  - most were minor, however...
    - 133 reported incidents of devices being left out or wrongly positioned (causation of 2 fatalities and a third incident of over-dose)
    - 284 reported incidents were geometric miss

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- in 2005, Eric Klein, et. al., (Washington University, St. Louis, MO) reported:
  - 103 "events" in 3964 (2.5% incidence rate per course) courses of therapy initiated (over a 30-month period)
    - stratified each error type in terms of frequency, longevity, and dosimetric impact (low, medium, high)
    - 76 of the 103 (74%) were categorized as >/= medium in terms of dosimetric impact
  - Was this the "first" FMEA in the Radiotherapy Arena?

Errors in Radiation Therapy - Handicaps

Errors in Radiation Therapy - Handicaps

- Lack of a national database
- Voluntary reporting
- Lack of reporting structure for incidents and near misses
- Dissemination of events/data to other parties
- “Knee-jerk” response to errors - not resolving the “root cause” - we all jump to box 5

SCDHEC Misadministration - defined

- South Carolina Department of Health and Environmental Control defines a therapy "Misadministration" as (RHB 9.153):
  - Radiation delivered to the wrong patient
  - Radiation delivered to the wrong site
  - Radiation delivered with the wrong mode of treatment

SCDHEC Misadministration - defined

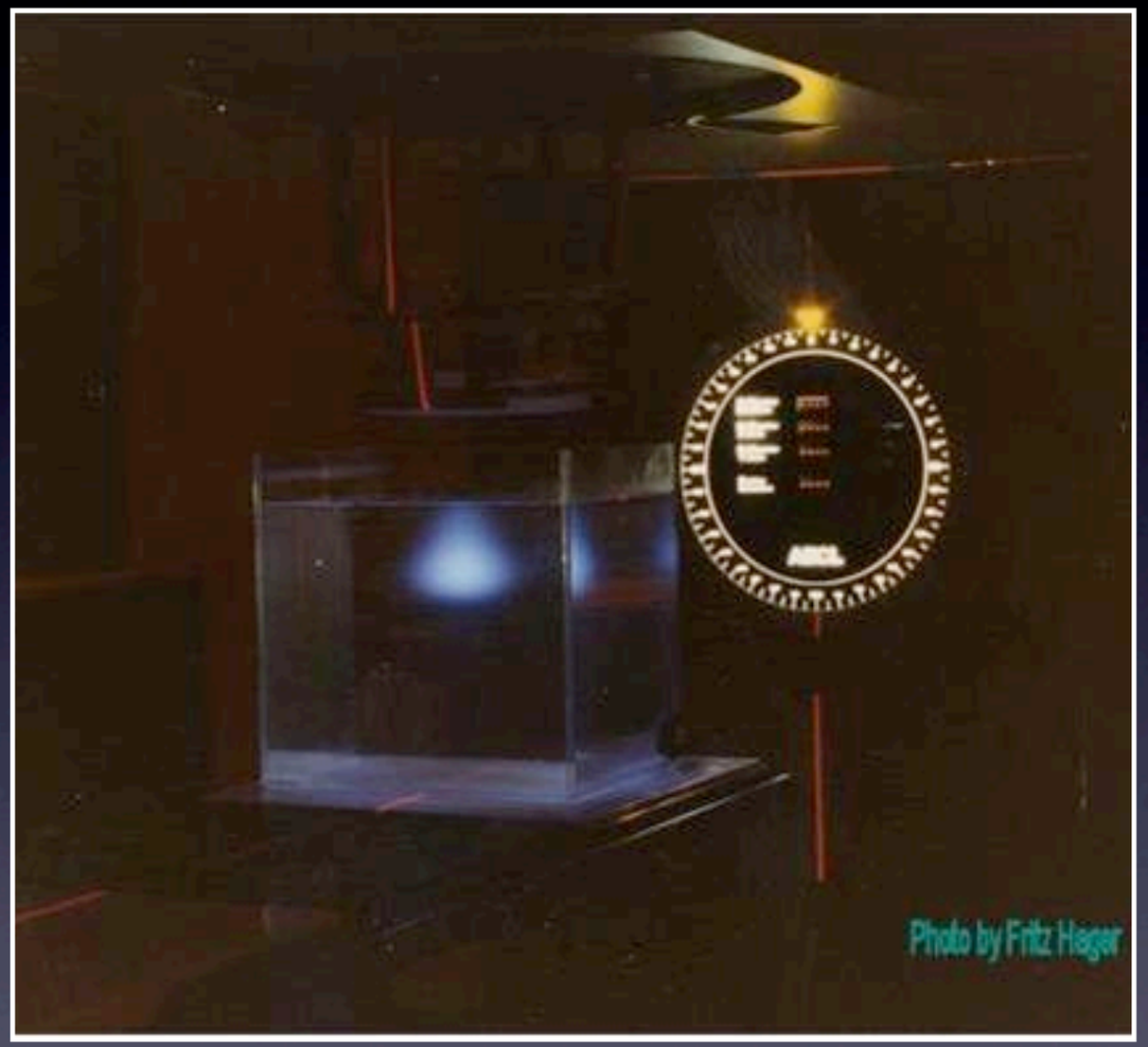
- Performance of a therapeutic procedure other than that ordered by the prescribing physician
- Error in calibration, time of exposure, or treatment geometry that results in a calculated total dose > the total prescribed treatment dose by more than 20%
  - 3 fractions or less > 10%
  - Weekly treatment dose exceeds weekly prescribed dose by 30% or more

RT Errors - Historical

- Description of the incident
- Tobin's Taxonomy
- Equipment Design
- Process
- Human Error

RT Errors - Historical

- Therac-25 (TX, W, Canada)
- 1982-1990
- 3 fatalities; 4 others with severe or debilitating injuries
- treatment programming change resulted in electron beam at x-ray tube currents - dose > 40Gy
- manufacturers response was “slow”
- Taxonomy - Equipment Design
- photo courtesy of Fritz Hager



RT Errors - Historical

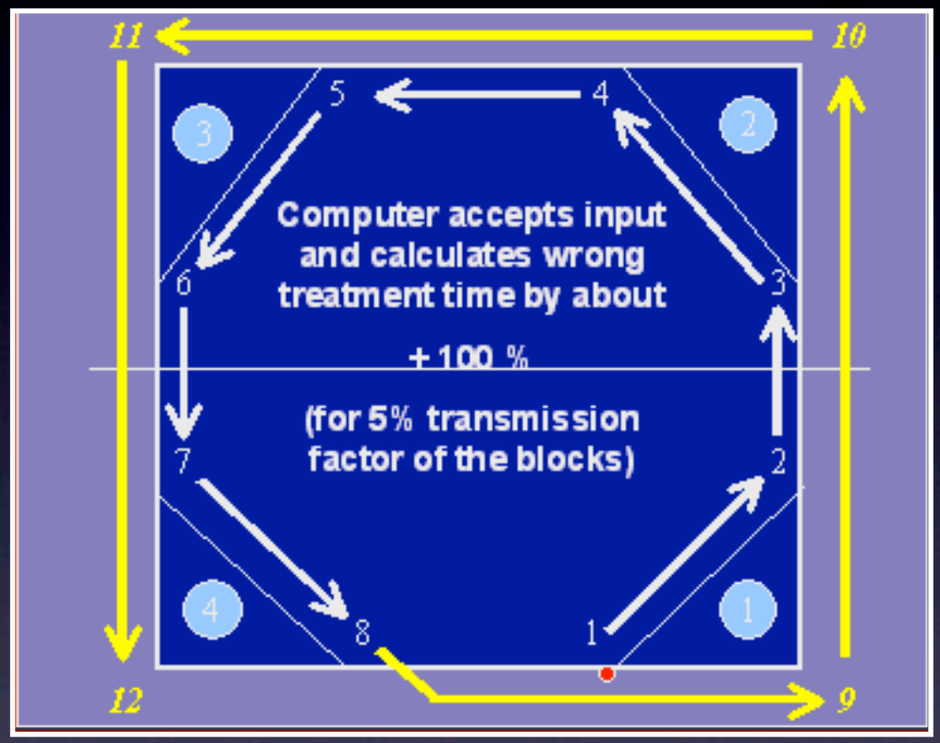
- Incorrect Linac Repair (Spain)
- 1990
- 15 fatalities (most within 1 year; lung & spinal cord injury)
- Repair of accelerator led to 36MeV electron beam delivery regardless of console input
- Physics did not verify operation after maintenance
- Taxonomy - Process, Human Error

RT Errors - Historical

- Error in the calculation of the dose rate of a Co-60 teletherapy unit (Costa Rica)
- 1996
- 13 fatalities (varies by report from 4-17)
- value of 0.3min interpreted as 30 seconds (rather than 18 seconds)
- 73% overdose (including patients from the children's hospital)
- side effects included ulceration, bleeding, epilation, and anemia
- Taxonomy - Process, Human Error

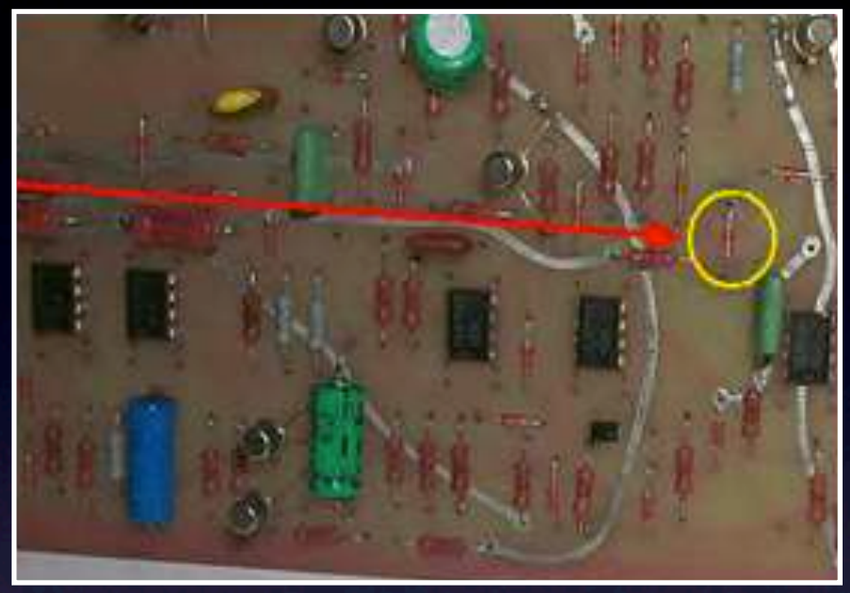
RT Errors - Historical

- TPS modification - block entry (Panama)
- 2000
- 17 fatalities from radiation overexposure
- limitations in the TPS with regards to block entry led to 20-100% overdose (treatment times calculated incorrectly)
- Taxonomy - Process, Human Error



RT Errors - Historical

- Machine Malfunction (Poland)
- 2001
- 5 reported overdoses
- Power outage led to a burned out fuse on a control board for the accelerator; failure of the interlock circuit governing this CB resulted in the dose rate increasing five-fold when returned to service; patients reported “itching and burning” of the skin following treatment prompting staff to cease use of the equipment



- 3 patients received 60 to 80 Gy
- Taxonomy - Process

Severe skin changes following a radiation burn

Local injury before reparative surgery

RT Errors - Historical

- Change from physical wedges to Dynamic Wedges (France)
- 2004
- 1 fatality; others with severe complications
- clinic moved from PW to DW; continued to calculate MU for physical wedges resulting in 20-30% overdose
- Taxonomy - Process

RT Errors - Historical

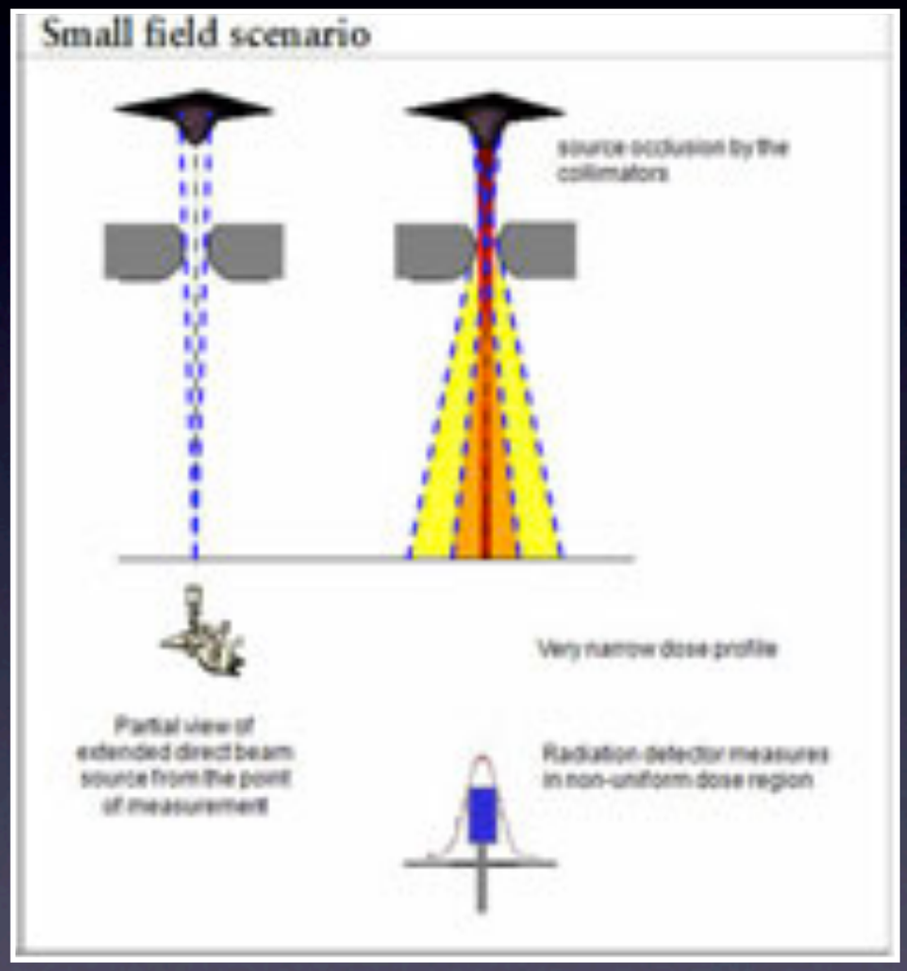
- Improper jaw size during SRS (France)
- 2004
- normal tissue irradiated; patient developed “fibrosis & oesotracheal fistula” requiring surgery; patient died from “brutal haemorrhage” a few days after surgery
- physicist instructed therapist to set a “40x40” field size, which the therapist interpreted as 40cmx40cm (40mmx40mm)
- Taxonomy - Process

RT Errors - Historical

- Procedure change (Scotland)
- 2005
- 15-year old patient undergoing whole CNS irradiation (brain + spine) received 67% overdose to whole brain due to calculation error
- Patient died 9 months post irradiation - recurrent tumor
- Taxonomy - Process

RT Errors - Historical

- Commissioning (mis)-measurements (France)
- 2007
- Large chamber used to make small field measurements for SRS
- 200% overdose for some patients
- Taxonomy - Human Error



RT Errors - Historical

The U.S. is not immune...

RT Errors - Historical

- Failure to follow accepted practice/protocol (USA)
- March 2005
- Detailed in NY Times article ("Radiation Boom" series by Walt Bogdanich)
- Plan change after treatment initiation was not "QA'd" in a timely fashion; patient received IMRT MU with NO mlc-modulation (jaws were wide open), resulting in a brutal overdose for 3 fractions
- After suffering from swelling of the brain, loss of sight, loss of hearing, inability to swallow, and finally, difficulty breathing, the patient died of his overdose in 2007
- Same error (mlc retracted) occurred several months later; patient received 6x prescribed dose, but caught after 1 fraction!!!!
- Taxonomy - Process & Human Error at the Physics and Therapist level

RT Errors - Historical

- Failure to implement treatment plan (USA)
- April 2005 (significance with previous case; state inspectors had reinforced need to ensure proper accelerator programming)
- Detailed in NY Times article ("Radiation Boom" series by Walt Bogdanich)
- Physical wedge was either incorrectly positioned or left out entirely, resulting in tissue damage/necrosis of soft tissue, rib, and lung; the resulting burn required a skin/tissue graft and hyperbaric treatment for necrosis; condition lasted for over a year; the patient died several months after the damage from the radiation healed
- Taxonomy - Process & Human Error at the Physics and Therapist level

RT Errors - Historical

- other incidents within New York State reported by the NYT:
  - 14-year old girl received double the prescribed dose for 10 treatments (faulty calc, failure to verify)
  - 2 prostate cancer patient irradiated to the wrong location 32 of 38 treatments and 19 of 38 treatments (equipment not tested following repairs)
  - 31-year old vaginal cancer patient over-dosed by 80%; risk of fistula formation between rectum and vagina (inexperienced team performing IMRT)
  - 63-year old patient received >10x the prescribed dose in one location and 1/10th of the prescribed dose in another location
  - wrong patient irradiated
  - other cases reported in NYT series of articles

RT Errors - Historical

- SRS unit mis-calibrated (Florida, USA)
- 2005
- 77 brain cancer patients over-dosed by >50% (from 2004 to 2005); disposition of most of the patients was grave due to the disease
- discovered by independent audit by RPC
- Taxonomy - Human Error

RT Errors - Historical

- SRS unit - leakage outside of conical applicator due to incorrect field size (Illinois, USA) - Toulouse, France anyone?
- 2009
- 4 patients over-dosed to regions of the brain that were not intended to be treated
- 50-year old mother of 3 converted to an invalid (currently in a nursing home, unable to communicate other than “blinking her eyes and squeezing her husband’s hand”) after treatment for a benign condition (TriN)
- After procedure, patient #1 experienced vomiting, burning in her throat, weight loss, and swatches of hair falling out; patient #2 experienced irregular heartbeat, weakness, changes in mental status; patient #3 experienced nausea, vomiting and dehydration (classic ARS of the CNS)
- Taxonomy - Human Error

RT Errors - Historical

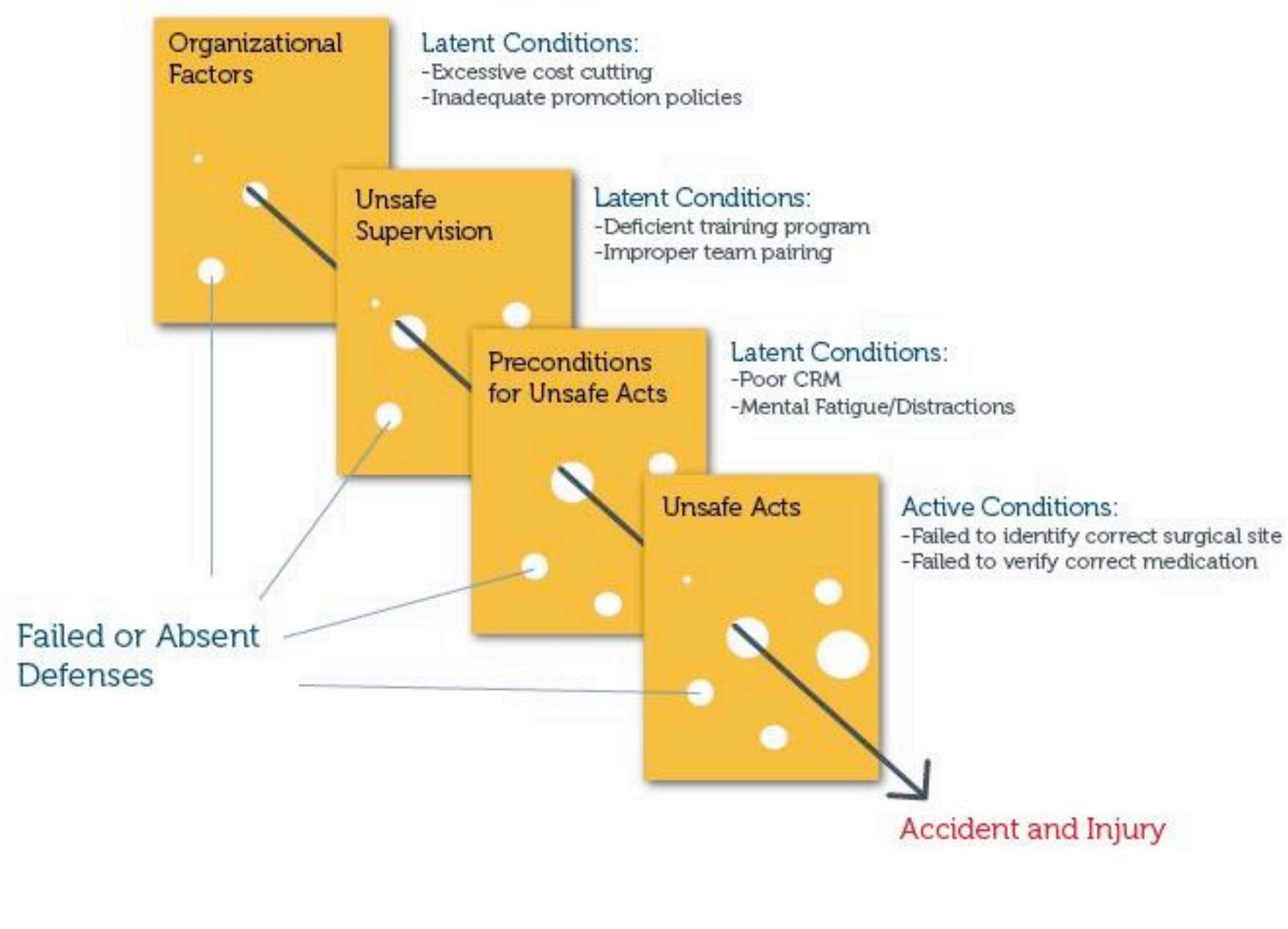
- SRS unit - improperly calibrated using an ion chamber "too large" for the purpose of the measurements (sound familiar, France?)
- 2004-2009
- 76 patients over-dosed by >25-100% (right location, wrong dose)
- results of over-dose varied from facial spasms to balance and memory problems (issues that were reported)

What does this have to do with me?

- in the span of 22 months between 2007 and 2009, 6 events which required reporting to the state of SC occurred at MRMC (read "misadministration")
- No patients were injured, but they did not receive "optimal" care
- My platform is now burning...

Burning Platform

- 2 wrong patients (Tx Delivery)
- 3 wrong sites
- 2 instances where incorrect reference images were generated resulting in the patient being incorrectly setup/irradiated (Planning)
- 1 instance where a pretreatment shift was not performed to the correct area (Tx Delivery)
- 1 instance where a treatment block was incorrect, not detected for 17 fractions (Tx Delivery)


Organizational Factors
Latent Conditions:
-Excessive cost cutting
-Inadequate promotion policies
Unsafe Supervision
Latent Conditions:
-Deficient training program
-Improper team pairing
Preconditions for Unsafe Acts
Latent Conditions:
-Poor CRM
-Mental Fatigue/Distractions
Unsafe Acts
Active Conditions:
-Failed to identify correct surgical site
-Failed to verify correct medication
Failed or Absent Defenses
Accident and Injury

What do we do?

- engaging our colleagues within Operational Effectiveness (OE), we decided to use Lean principles to analyze the "gap" in our processes
- live by the mantra "we don't have bad people, just bad processes"
- OE suggested performing a Process-Failure Modes and Effects Analysis

P-FMEA

- we assembled a multidisciplinary team (physicists, dosimetrists, administrators, therapists, nurses), each with a stake in the process
- we mapped our current processes in as much detail as we could
- for each process step, we identified potential failure modes (91 total)
- each failure mode is scored for Occurrence, Detection, and Severity (scale of 1-10)

P-FMEA

- Occurrence = 1, rarely happens
- Occurrence = 10, happens all the time
- Detection = 1, easy to see
- Detection = 10, difficult/impossible to see
- Severity = 1, no impact to the patient (perhaps a delay)
- Severity = 10, death/misadministration (our designation)
- Take care to keep scoring “realistic” and “consistent”

P-FMEA

- for each failure mode, the product of the scores for Occurrence, Detection, and Severity is known as the RPN, or Risk Priority Number (1-1000)
- RPNs can then be sorted in terms of priority for problem solving

					Process Risk Profile Number =			
	Category	**Process Step**	**Failure Mode**	**Effect**	**Occurrence (1-10)**	**Detection (1-10)**	**Severity (1-10)**	**Risk Profile Number**
1	Prescription	Prescription Written by Oncologist	Orders Not Dated - Initial	Delay In Treatment	**3**	**1**	**1**	**3**
2	Prescription	Prescription Written by Oncologist	Illegible Prescription	Prescription Intent Not Carried Out	**7**	**5**	**10**	**350**
3	Prescription	Prescription Written by Oncologist	Unclear Prescription (Not enough info)	Wrong Treatment	**3**	**1**	**4**	**12**
4	Prescription	Prescription Written by Oncologist	No Written Orders	Wrong Treatment / Delay In Treatment	**3**	**1**	**2**	**6**
5	Prescription	Prescription Written by Oncologist	Unrecognized Changes In Prescription (Date)	Delay In Treatment	**4**	**3**	**4**	**48**
6	Diagnostic	Patient Diagnostic Studies	Pull Study For Incorrect Patient	Incorrect Site	**1**	**5**	**10**	**50**
7	Diagnostic	Patient Diagnostic Studies	No Access To Appropriate Study	Delay In Treatment	**2**	**1**	**3**	**6**
8	Diagnostic	Patient Diagnostic Studies	Delay In Access To Appropriate Study	Incorrect Volumes In Treatment	**4**	**2**	**4**	**32**
9	Immobilize / CT	Immobilization Initial Set-up	Inadequate Immobilization	Incorrect Treatment / Re-Image / Delay	**1**	**3**	**7**	**21**
10	Immobilize / CT	Immobilization Initial Set-up	Reproducibility Of Set-up	Incorrect Treatment / Re-Image / Delay	**2**	**3**	**5**	**30**
11	Immobilize / CT	Planning CT	Insufficient Data	Re-Image / Delay	**1**	**2**	**2**	**4**
12	Immobilize / CT	Planning CT	Inadequate Contrast Studies	Incorrect Treatment	**3**	**3**	**7**	**63**
13	Immobilize / CT	Planning CT	Nonstandard Patient Orientation	Incorrect Treatment / Incorrect Plan/Delay	**1**	**1**	**10**	**10**
14	Immobilize / CT	Planning CT	Missing Accessory	Re-Image / Delay	**1**	**2**	**7**	**14**
15	Immobilize / CT	Assign Patient	Limited Communication Regarding Patient	Incorrect Treatment / Delay	**4**	**3**	**9**	**108**
16	Immobilize / CT	Image Transfer / Patient Creation	Call Wrong CT Data Set	Incorrect Treatment (Big)	**2**	**9**	**10**	**180**
17	MD Contour	Chart To MD	Wrong Data Set Used	Incorrect Treatment / Delay In Treatment	**1**	**8**	**10**	**80**
18	MD Contour	Pull Diagnostic	Pull Wrong Data Set	Incorrect Treatment	**1**	**8**	**10**	**80**
19	MD Contour	Tumor & Targets	Inaccurate Volumes Set	Increased Side Effects / Delay In Treatment	**7**	**5**	**7**	**245**
20	MD Contour	Tumor & Targets	Lack Of Consistency	Delay In Treatment	**7**	**2**	**5**	**70**
21	MD Contour	Tumor & Targets	Lack Of Clarification	Incorrect Treatment / Delay In Treatment	**5**	**10**	**7**	**350**
22	MD Contour	Tumor & Targets	No Read back	Incorrect Treatment	**5**	**10**	**7**	**350**
23	Dosimetrist Contour	Contour Normal & Critical Structures	Contour Wrong Structure	Incorrect Treatment / Increased Side Effects	**2**	**10**	**10**	**200**
24	Dosimetrist Contour	Contour Normal & Critical Structures	Failure To Contour Critical Structure	Increased Patient Side Effect	**1**	**5**	**10**	**50**
25	Dosimetrist Contour	Expand MD's Contours	Unrealistic Expectations	Delay In Treatment	**6**	**1**	**3**	**18**
26	Dosimetrist Contour	Expand MD's Contours	Incorrect Margin On Volumes	Incorrect Treatment / Delay In Treatment	**1**	**8**	**3**	**24**

RPN #	Severity ≥ 7 & Detection ≥ 5	Severity ≥ 7 Occurence ≥ 5	Original #	Category	Process Step	Failure Mode	Effect
600			88	Treatment	Field Light / Accessory	Failure To Detect Error	Misadministration / Incorrect Treatment
540			81	Film	Field Check Form	Failure To Follow Standard Work	Misadministration / Incorrect Treatment
400			71	Physics	DRRs	Incorrect Plan	Sentinel Event / Misadministration / Delay In Treatment
400			72	Physics	DRRs	Incorrect Point	Sentinel Event / Misadministration / Delay In Treatment
350			2	Prescription	Prescription Written by Oncologist	Illegible Prescription	Prescription Intent Not Carried Out
350			21	MD Contour	Tumor & Targets	Lack Of Clarification	Incorrect Treatment / Delay In Treatment
350			22	MD Contour	Tumor & Targets	No Read back	Incorrect Treatment
300			91	Treatment Checks	MD Approval	Sign Off On Incorrect Plan / Film	Misadministration / Incorrect Treatment
270			30	Planning	Isocenter Placement	Wrong Placement	Sentinel Event / Misadministration / Delay In Treatment
270			58	Plan Output	DRRs To Impac	Incorrect Placement Iso	Misadministration / Incorrect Treatment / Delay In Treatment
270			59	Plan Output	DRRs To Impac	Incorrect Reference Image For MD	MD Approves Error - Non Detection
245			19	MD Contour	Tumor & Targets	Inaccurate Volumes Set	Increased Side Effects / Delay In Treatment
240			82	Film	MD Approval	Failure To Detect Error	Misadministration / Incorrect Treatment
216			80	Film	Iso Verification / Treatment Fields	Failure To Detect Error	Misadministration / Incorrect Treatment
200			23	Dosimetrist Contour	Contour Normal & Critical Structures	Contour Wrong Structure	Incorrect Treatment / Increased Side Effects
200			48	Plan Output	Print Plan	Source Data for iso pair does not match DRR	Misadministration/Sentinel Event
200			51	Plan Output	Send To Simulation	Send Incorrect Images	Misadministration / Incorrect Treatment / Delay In Treatment
200			53	Plan Output	Send To Impac	Send Incorrect Images	Misadministration / Incorrect Treatment / Delay In Treatment
200			56	Plan Output	DRRs To Impac	Send Incorrect Images	Misadministration / Incorrect Treatment / Delay In Treatment
200			74	Physics	Verify Iso Coordinates	False +	Sentinel Event / Misadministration / Delay In Treatment
180			16	Immobilize / CT	Image Transfer / Patient Creation	Call Wrong CT Data Set	Incorrect Treatment (Big)
180			52	Plan Output	Send To Simulation	Send Incorrect Plan	Misadministration / Incorrect Treatment / Delay In Treatment
180			77	Iso Verification	Set-up Marks	Incorrect Set-up Marks	Incorrect Treatment / Delay In Treatment
180			78	Iso Verification	Daily Shifts	Incorrect Shifts (sim)	Delay In Treatment
162			85	Treatment	SSDs	Failure To Set Correct SSDs	Incorrect Treatment
160			66	Physics	Rad Calc Check MU	False + Calculation	Patient Injury / Delay In Treatment
150			83	Treatment	Patient ID	Failure To ID Patient	Sentinel Event / Misadministration

Value of the Work/Data

- From February 2007 to April 2009, 6 misadministrations requiring reporting to the patient and the state
- From April 2009 to now, NO treatment events have been detected or reported (48 months)
- Tracking the perceived impact of process changes on patient safety

Lean Healthcare - A3 Thinking

- named for “A3” paper format for printing - seriously!
- logical extension of the scientific method
- box 1 - Reason for Action
- box 2 - As Is Condition
- box 3 - Desired State
- box 4 - Gap (define the reasons for difference between box 2 and box 3)
- box 5 - Solutions
- box 6 - Rapid Experiments
- box 7 - Completion Plan
- box 8 - Confirmed State
- box 9 - Insights