Experiences with STPA in Radiation Therapy

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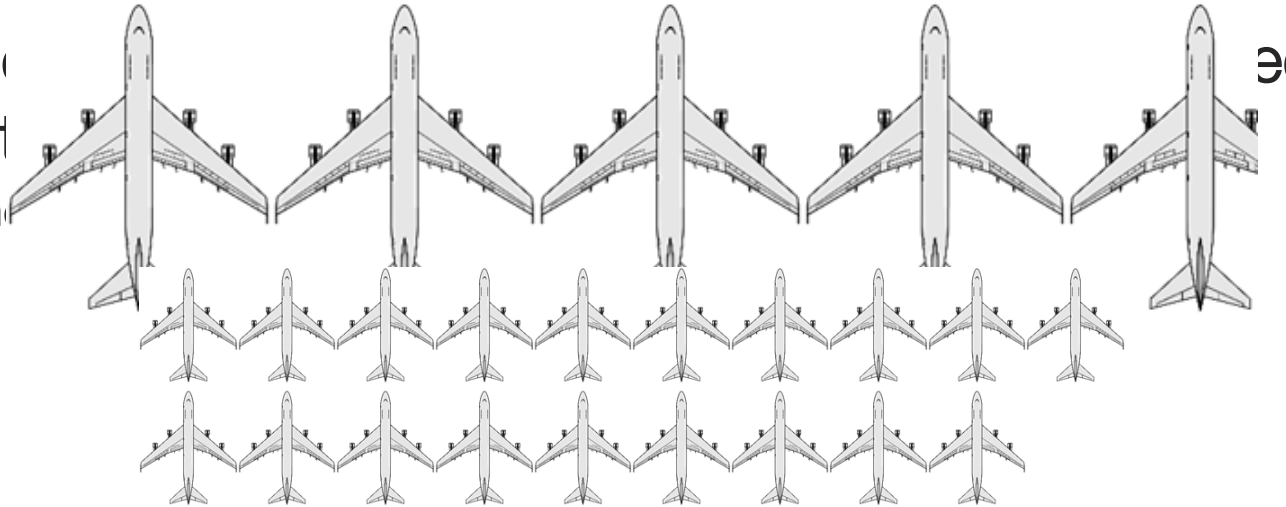
The Healthcare Safety Problem

- "98,000 people die in hospitals each year…"
  - Institute of Medicine (1999). To err is human: building a safer health system.
- "…tru ed at more t
  - Jam



The New York Times

Radiation Therapy Accident

Occurred: 2007

Reported: 2010

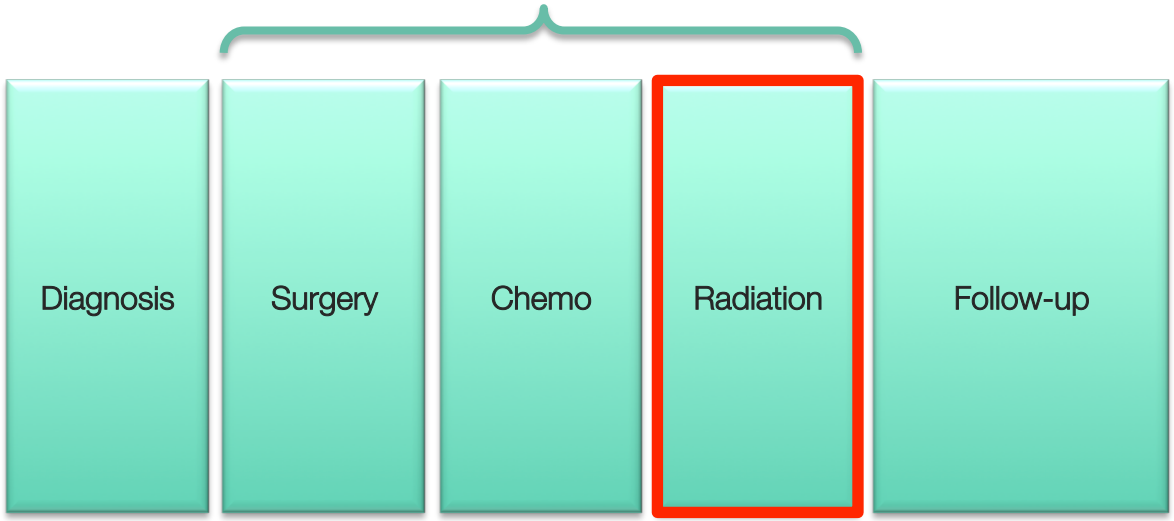
Scott Jerome-Parks, with his wife, Carmen, was 43 when he died in 2007 from a radiation overdose.

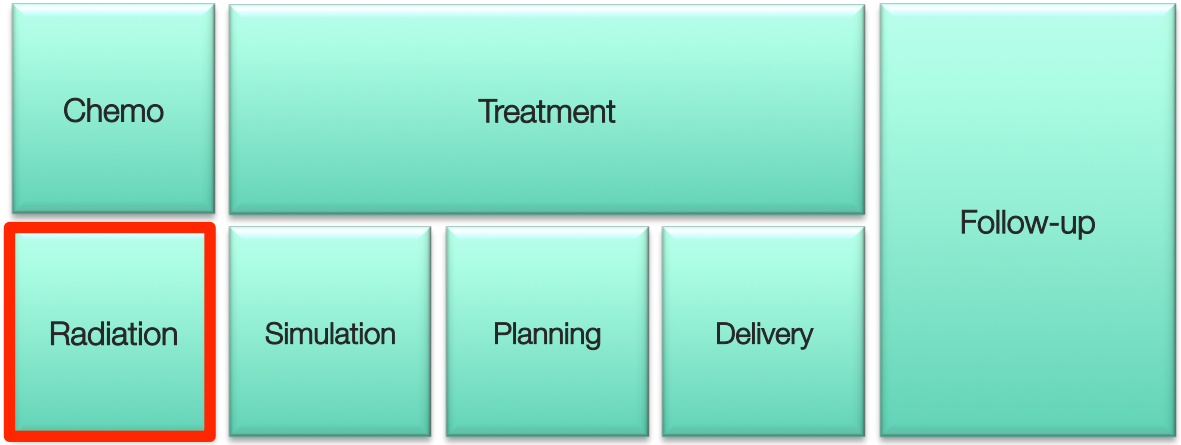
For his last Christmas, Scott Jerome-Parks rested his feet in buckets of sand his friends had sent from a childhood beach.

Outline

- What is radiation therapy?
- Initial experience with STPA
- Using STPA to change clinical practice
- Some future directions

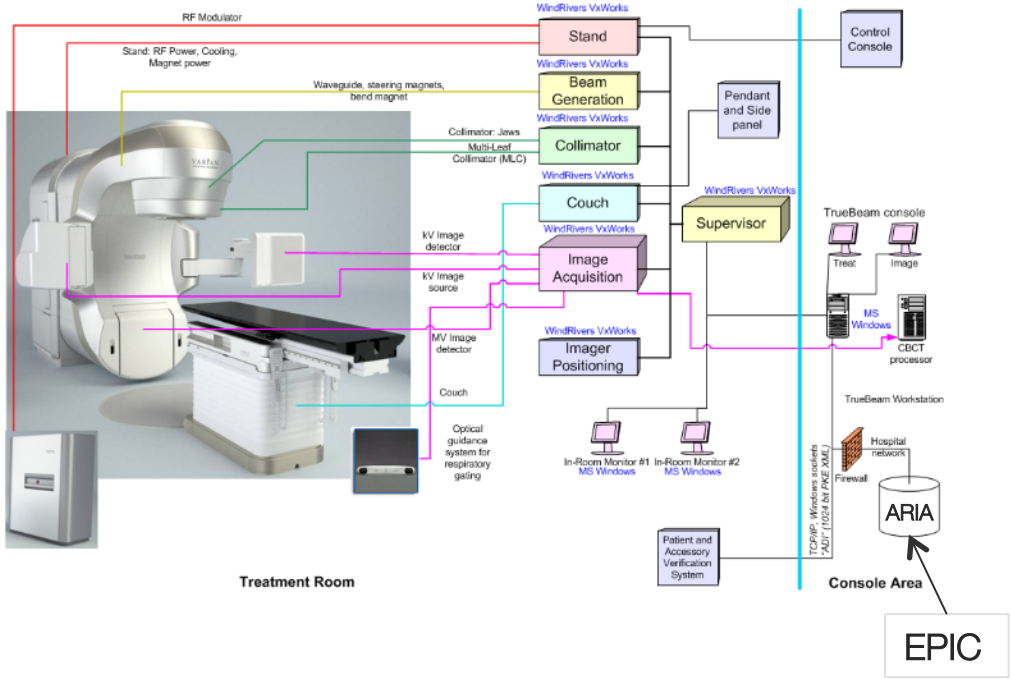
Cancer Treatment Options




Chemo
Treatment
Follow-up
Radiation
Simulation
Planning
Delivery

Teletherapy

"Therapy at a distance"
Linear Accelerator
(X-rays and electrons)



Brachytherapy

"Close therapy"
Radioactive sources (γ-rays)
placed within a tumor

An Investigation of the Therac-25 Accidents

Nancy G. Leveson, University of Washington

Clark S. Turner, University of California, Irvine

IEEE Computer, July 1993.

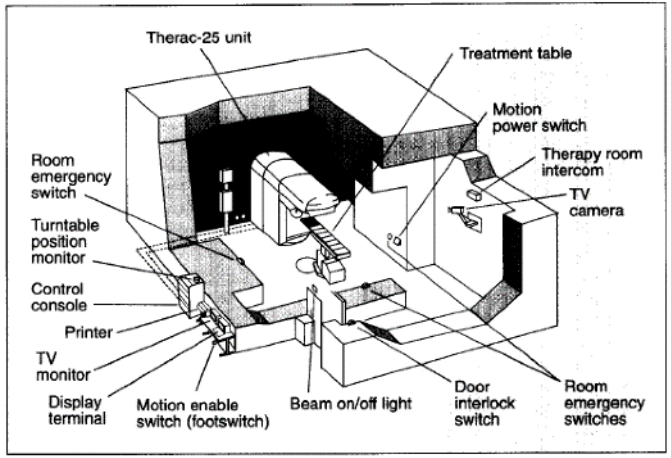
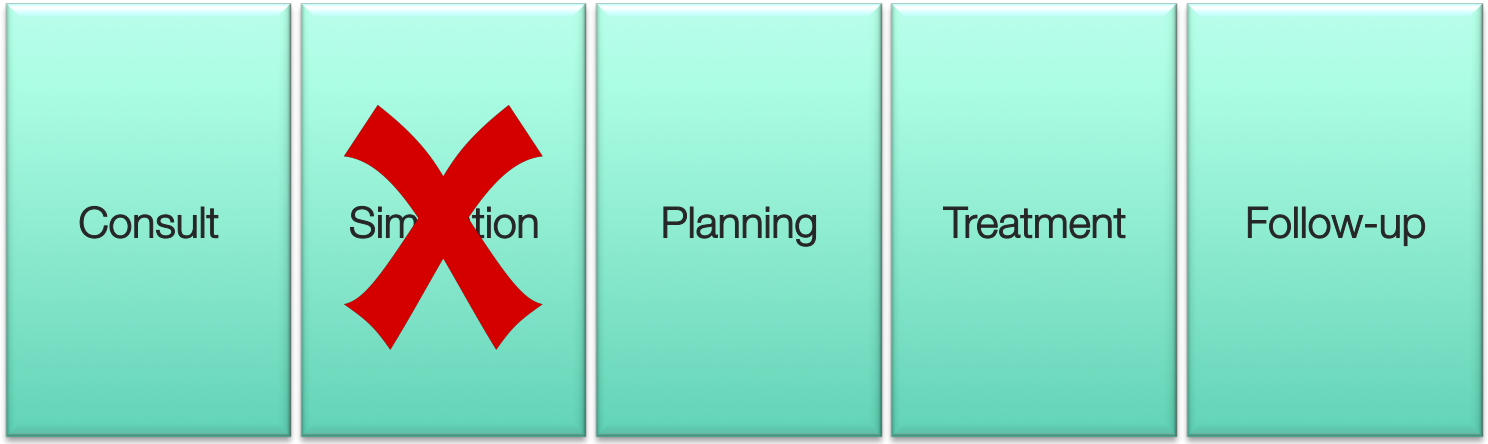


Figure 1. Typical Therac-25 facility.

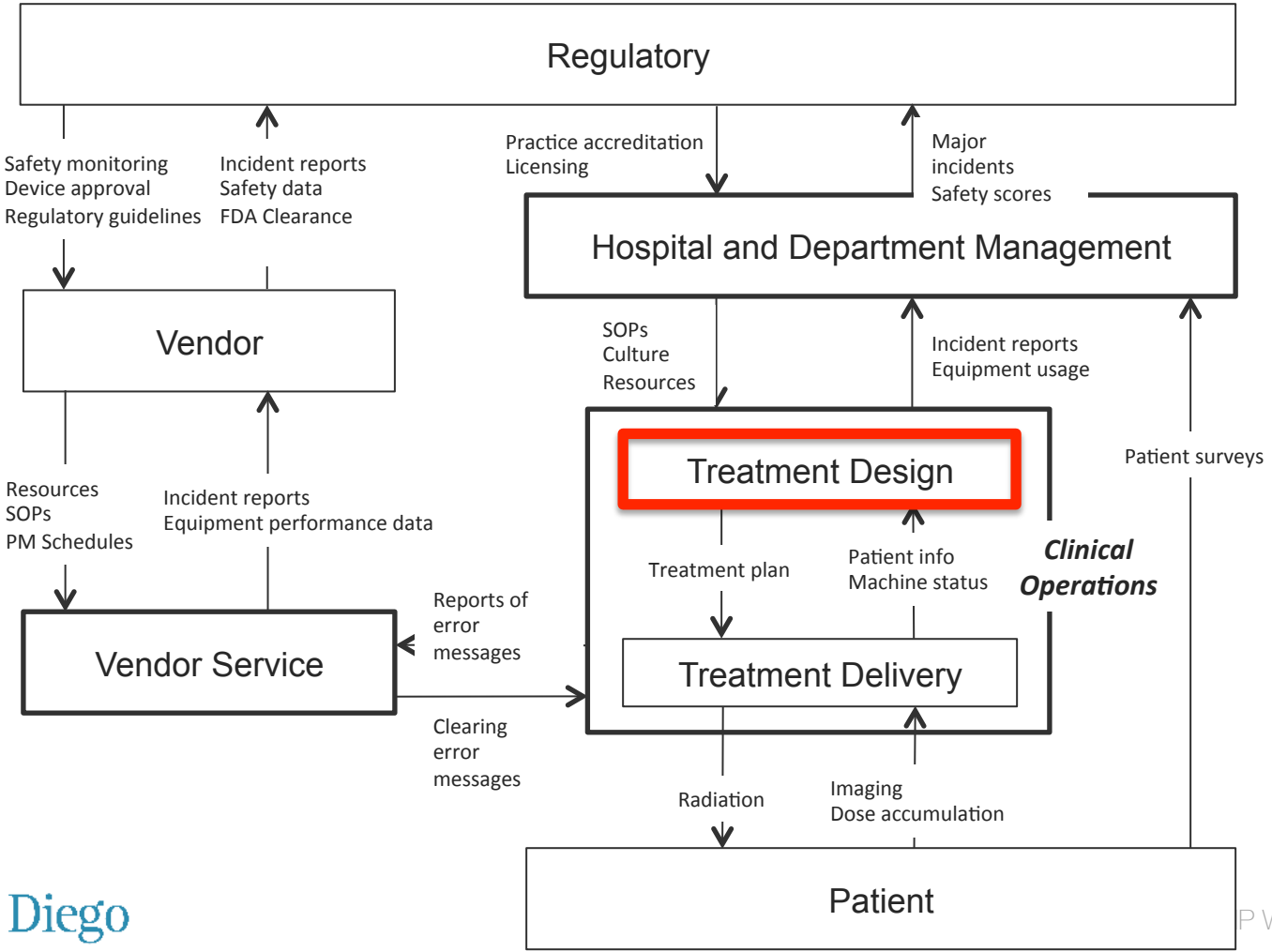
STPA in Radiation Therapy

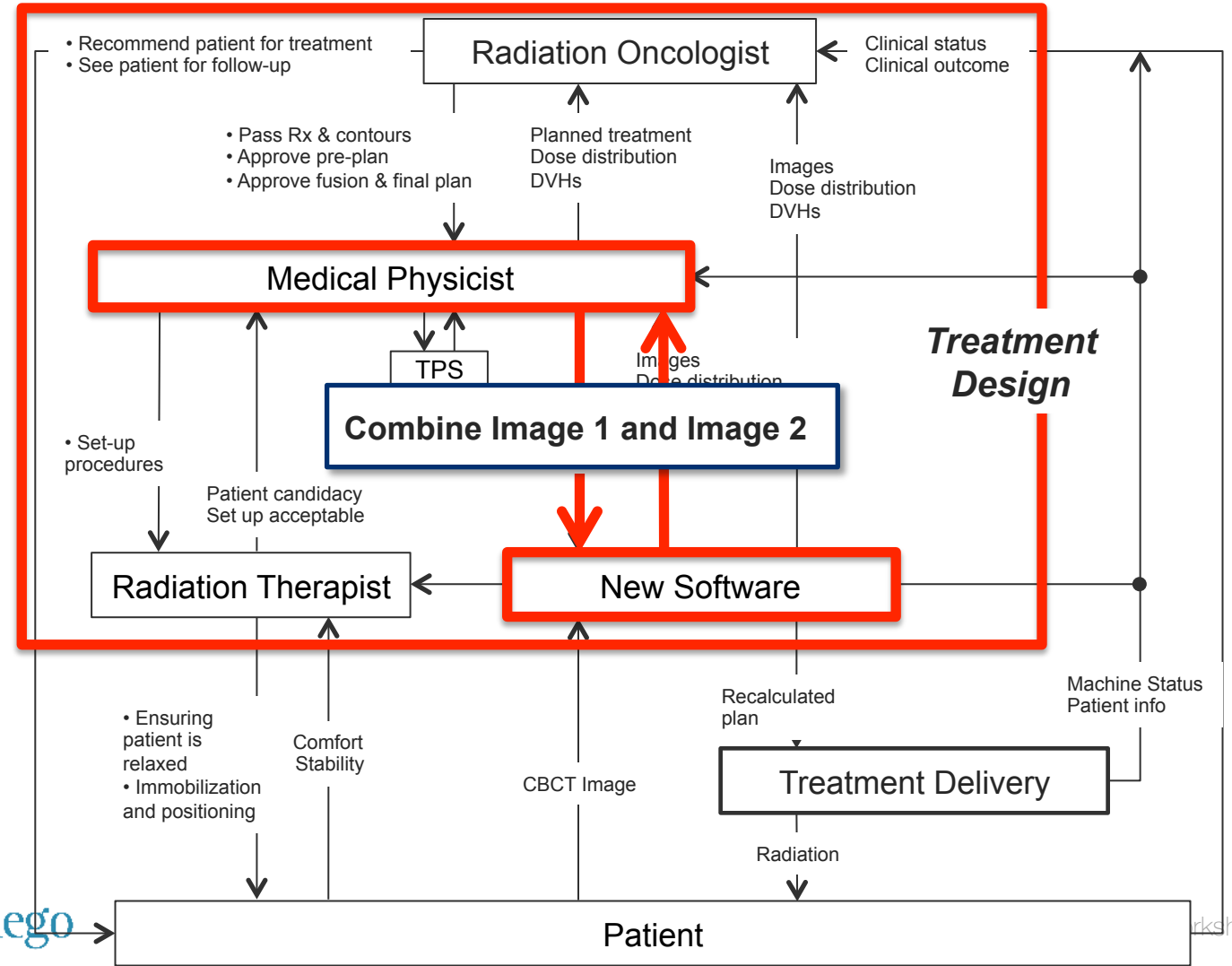


Accidents and Hazards

1. Patient injured or killed from radiation exposure
2. Staff injured or killed from radiation exposure
3. Physical injury to patient or staff during treatment (not from RT)
4. Damage to equipment
5. Damage to patient or staff satisfaction, or hospital reputation

1. Wrong dose, location, or patient
2. Staff is unexpectedly exposed to radiation
3. Persons are subjected to the possibility of non-radiological injury
4. Equipment is subject to unexpected stress
5. Workflow is subject to unexpected stress, delays in starting treatments


Regulatory
Safety monitoring
Device approval
Regulatory guidelines
Incident reports
Safety data
FDA Clearance
Practice accreditation
Licensing
Major
incidents
Safety scores
Hospital and Department Management
Vendor
SOPs
Culture
Resources
Incident reports
Equipment usage
Patient surveys
Treatment Design
Resources
SOPs
PM Schedules
Incident reports
Equipment performance data
Treatment plan
Patient info
Machine status
Clinical
Operations
Reports of
error
messages
Vendor Service
Treatment Delivery
Clearing
error
messages
Radiation
Imaging
Dose accumulation
Patient


• Recommend patient for treatment
• See patient for follow-up
Radiation Oncologist
Clinical status
Clinical outcome
• Pass Rx & contours
• Approve pre-plan
• Approve fusion & final plan
Planned treatment
Dose distribution
DVHs
Images
Dose distribution
DVHs
Medical Physicist
TPS
Images
Dose distribution
Treatment Design
Combine Image 1 and Image 2
• Set-up procedures
Patient candidacy
Set up acceptable
Radiation Therapist
New Software
• Ensuring patient is relaxed
• Immobilization and positioning
Comfort
Stability
CBCT Image
Recalculated plan
Machine Status
Patient info
Treatment Delivery
Radiation
Patient

Results – STPA Tables

Control Action	Control action is not given	Control action is given incorrectly	Control action is given at wrong time or order	Control action is stopped to soon or applied too long
Combine Image 1 and Image 2				

Result – STPA Causal Scenarios

CA: **Combine image 1 and image 2**
UCA: **Combining the images takes too long [H1]**

- Example causal scenarios identified for this UCA
  - Medical physicist is distracted with other non-related clinical issues
  - Image 2 is not imported to the new software
    - Not automatically stored correctly or imported
  - Software crash that the medical physicist cannot recover from
    - Assumes if the software can be restarted again then all future operations will be safe

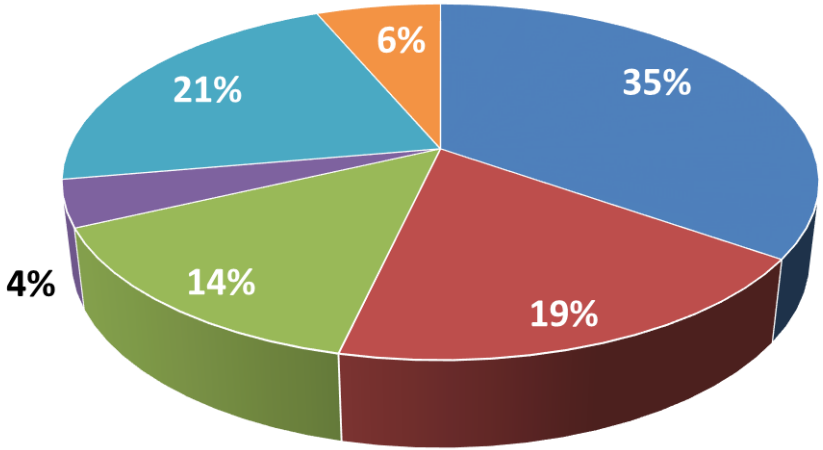
Results

- 10 Control Structures
  - 23 Control actions
  - 83 Unsafe control actions
  - 472 Causal scenarios

Application of systems and control theory-based hazard analysis to radiation oncology

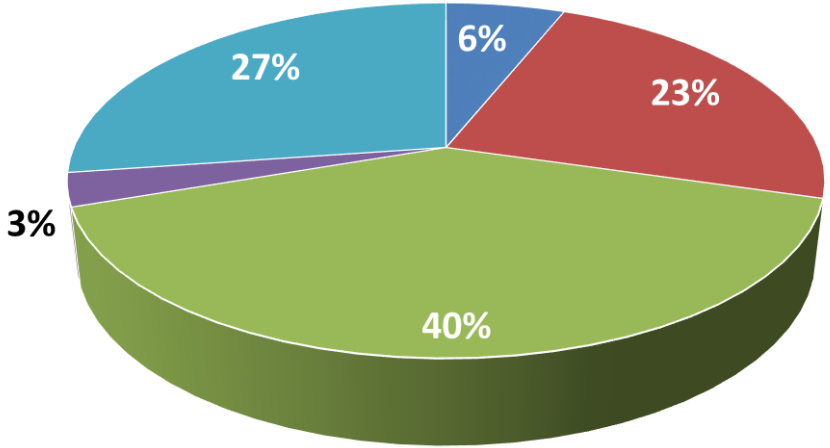
Todd Pawlicki, Aubrey Samost, Derek W. Brown, Ryan P. Manger, Gwe-Ya Kim, and Nancy G. Leveson

STPA (472)



- Organizational management
- Technical
- Human behavior of individual staff
- Patient-related circumstances
- Procedural issues
- Other

FMEA (132)



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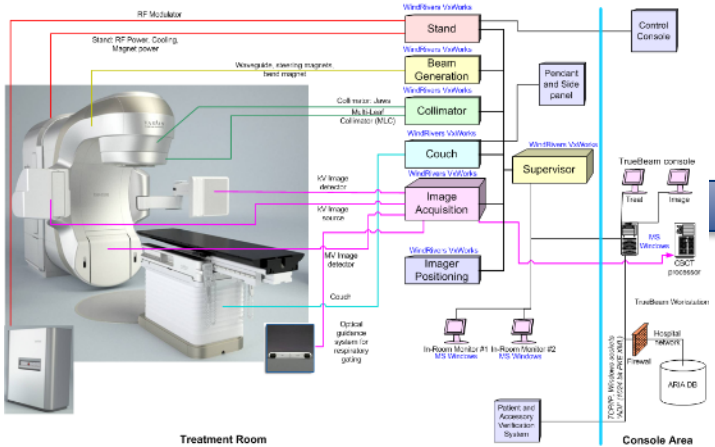
- Other

Using STPA to Change Clinical Cractice

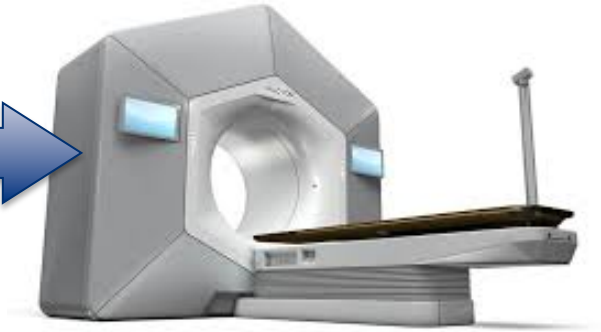
2010

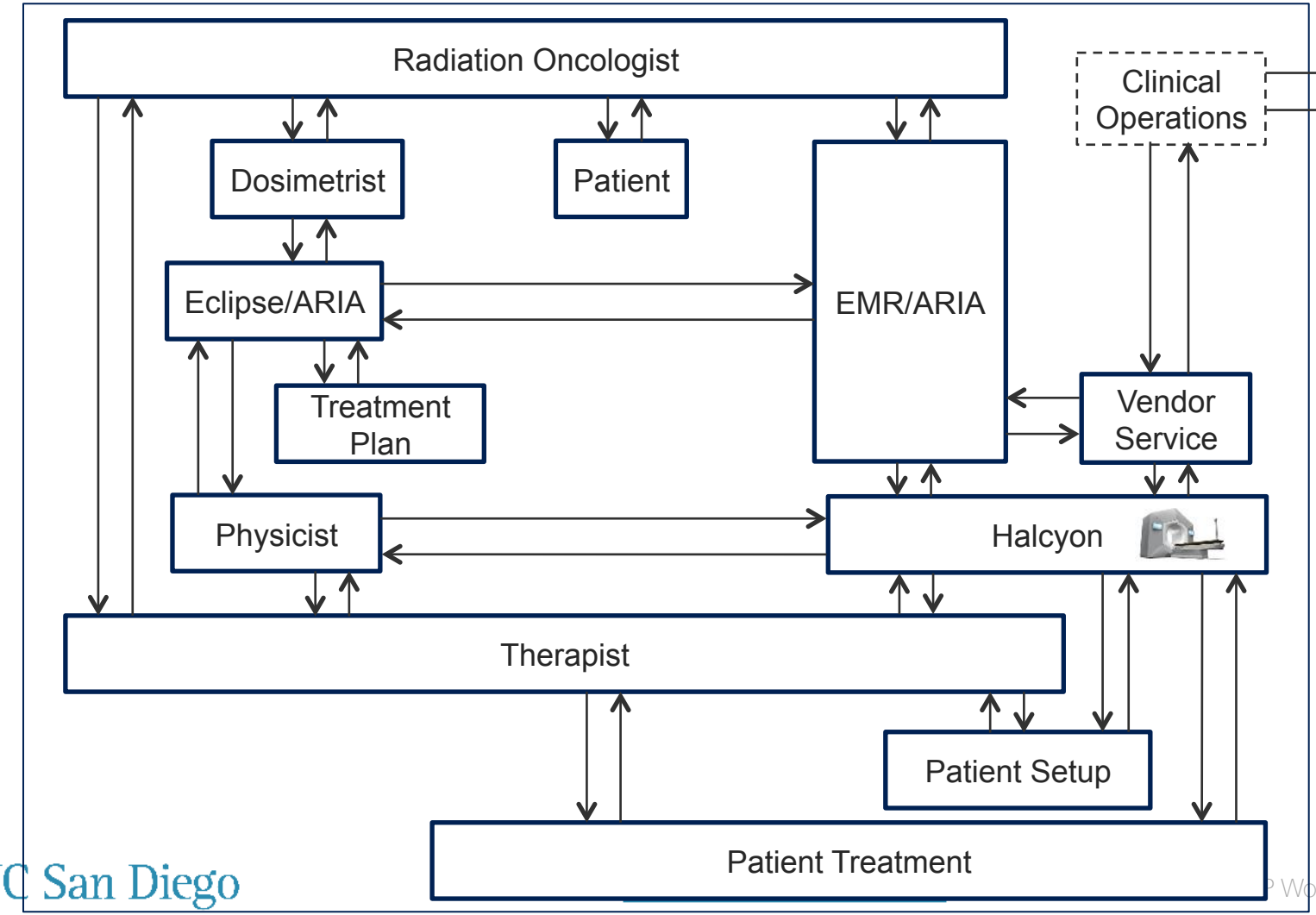


2018

Simplification

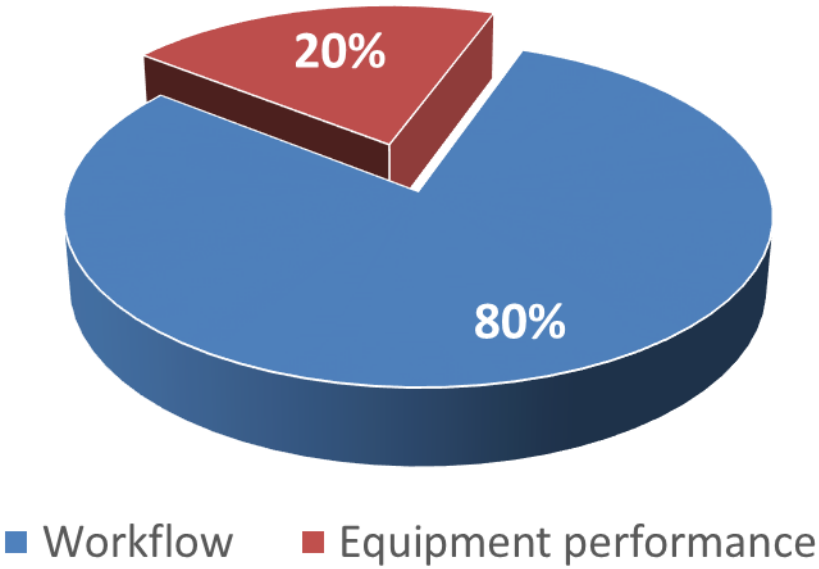
Automation




Radiation Oncologist
Clinical Operations
Department Leadership
Dosimetrist
Patient
Faculty and Staff
Eclipse/ARIA
EMR/ARIA
Treatment Plan
Vendor Service
Physicist
Halcyon
Therapist
Patient Setup
Patient Treatment

Initial Results

- # of Control Structures = 23
- # of CAs = 54
- # of UCAs > 150 (so far)
  - and still working on causal scenarios



Research

UC San Diego
The Design Lab

Our research focuses on building a substantive body of theor
based insights to establish a scientific basis for design. We st
best practices in design, across a range of domains from heal
autonomous vehicles, to online education and civic engagem

Activity-Centered Visualization

Design-Driven Transformati

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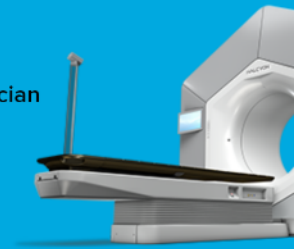
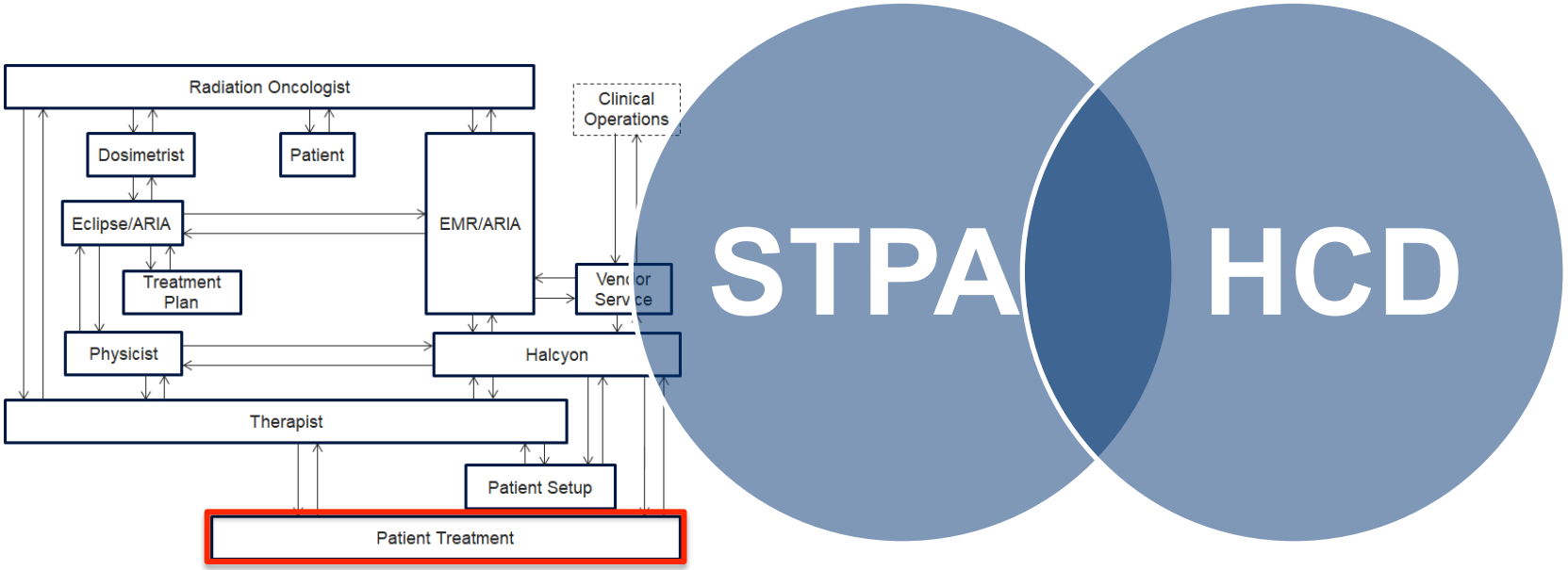


Oncology

Welcome, Healthcare Professionals.


Radiation Oncologist
Clinical Operations
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Physicist
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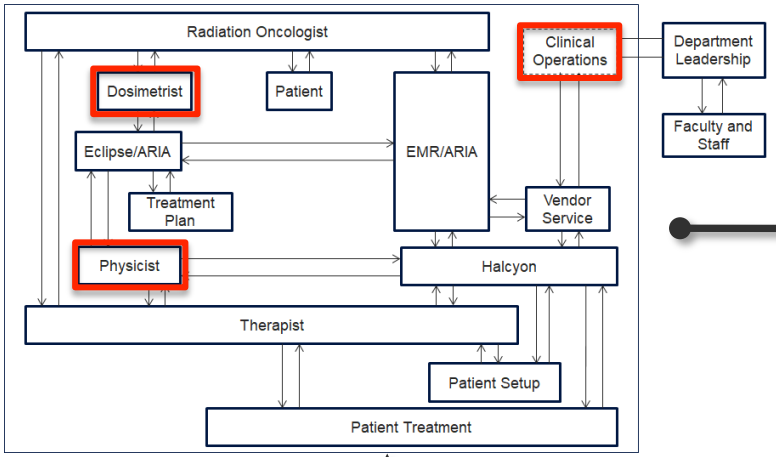
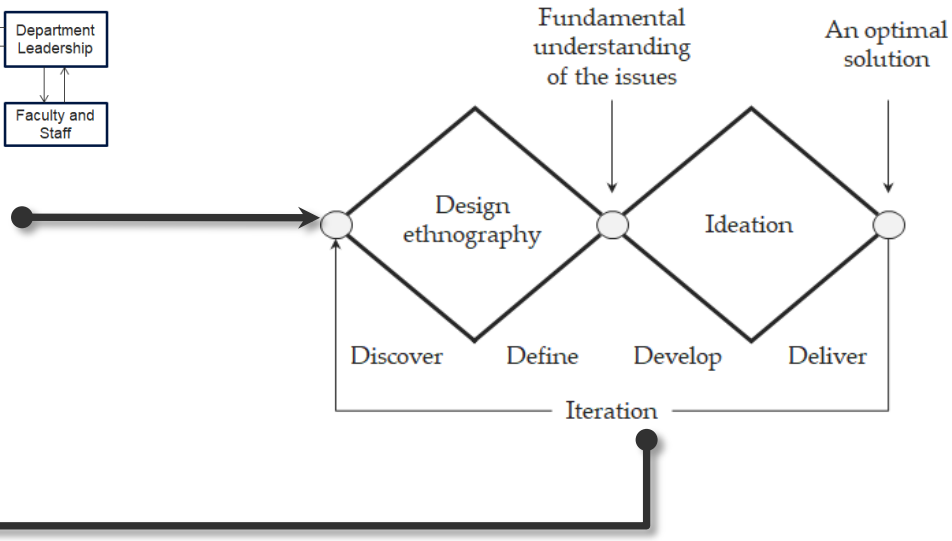
Therapist
Patient Setup
Patient Treatment
STPA
HCD

Clinical Research

STPA

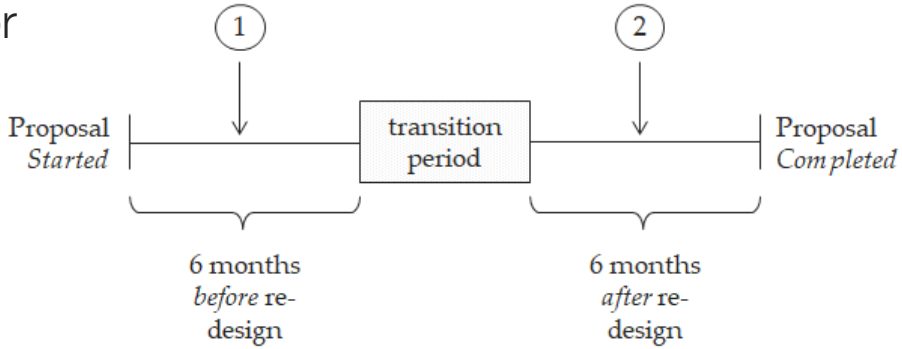


HCD



Evaluate Changes

- **Quality** → Radiation dose to the tumor
- **Safety** → Near-Miss Risk Index
- **Workload** → NASA Task Load Index

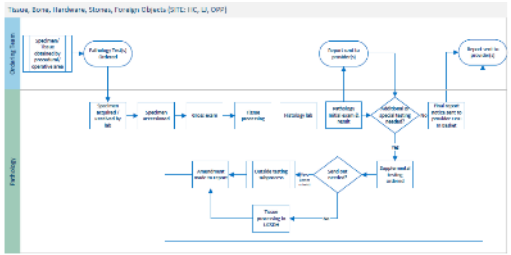


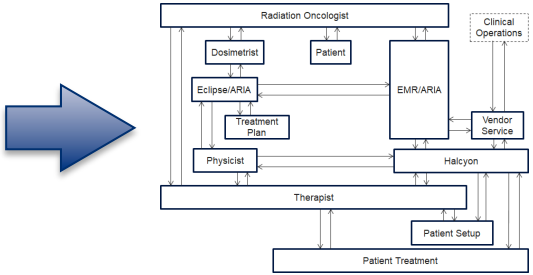
- **Efficiency** → Duration from Simulation to the Start of Treatment
- **Safety Culture** → AHRQ Safety Profile Assessment

Future Directions

- How to apply and disseminate to healthcare?

- Top down approach
  - Re-do hospital FMEA





- The Joint Commission

The Joint Commission Journal on Quality and Patient Safety

Future Directions in the Clinic

- After an accident or significant near-miss happens
  - You have to do something
  - You have limited time to identify and address the causes

- Bottom up approach
  - Is it possible (or useful) to do a quick STPA or CAST?
  - How to educate and train front-line staff?

Radiation Oncology Safety Course

how to create a safer radiotherapy environment

Discipline of Radiation Therapy, School of Medicine, Trinity College, Dublin, Ireland

Endorsed by ESTRO

21st – 24th August, 2017

- Perform a prospective safety assessment
  - Groups 1 – 2 use FMEA
  - Groups 3 – 4 use STPA
- Group discussion
  - Watch error video
  - Was your analysis effective?

Summary

- STPA is applicable to radiation therapy
  - Additional research pending
- Still need to disseminate to other specialties
- Engage and train front-line staff
  - Must work in LIMCs