Memorial Sloan Kettering Cancer Center

# MIT STAMP Workshop 2022:

# "Introducing STPA to Interventional Radiology within a Large Hospital"

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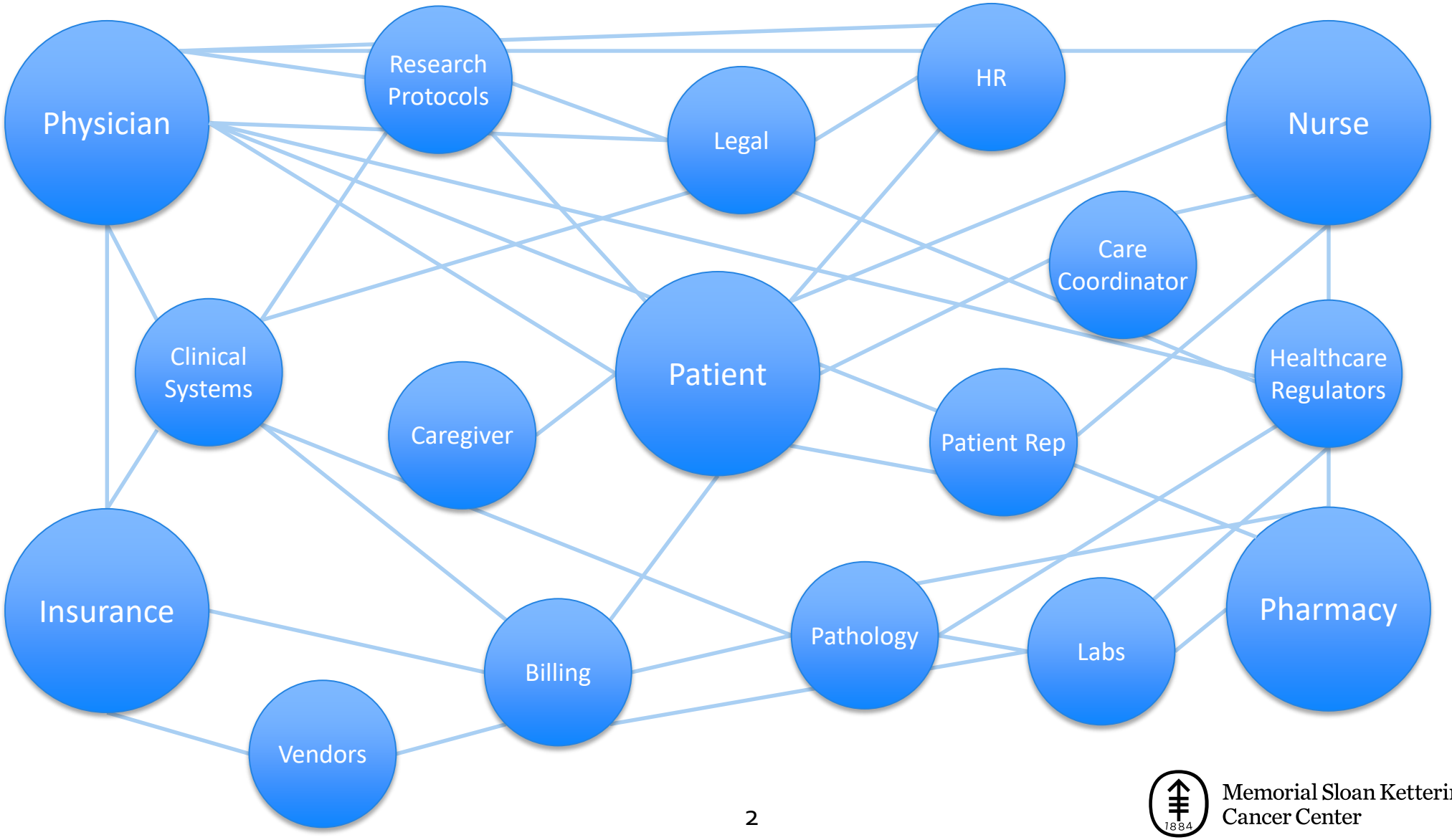
www.MSKCC.org

# Complexity of Health Systems



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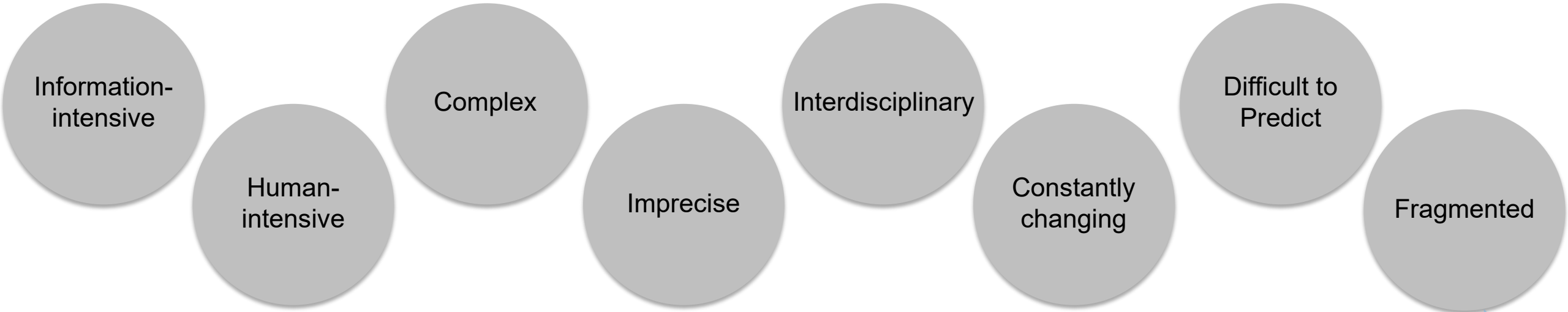
# Health Systems Safety Today

**Characteristics of Health Systems:**




| Safety I | Safety II | Safety III |
|---|---|---|
| Reactive Approach | Proactive Approach | Systems Approach |
| Respond to an accident or near miss | Continuously try to anticipate developments and events | Concentrate on ***preventing hazards*** while ***continuously learning*** from accidents, near misses, and trends |

Adapted from [1]

# Joint Commission Healthcare Standards

- **JC's Patient Safety Standards [2]:**

**LD.03.09.01:**

Having an organization-wide***, integrated patient safety program*** within performance improvement activities

**LD.03.09.01, EP 3:**

Requires leaders to provide and encourage the use of systems for ***blame-free reporting of a system or process failure*** or the results of proactive risk assessments

**LD.03.09.01, EP 7:**

Requires hospitals to select one high-risk process and conduct a ***proactive risk assessment*** at least every 18 months

- **A *Learning* Organization:**

One in which people ***learn continuously***, thereby enhancing their capabilities to create and innovate. [2]

Team learning

Shared mental model

Individual commitment to lifelong learning

Shared visions and goals

Systems thinking

# Problem Statement

| | |
|---|---|
| Complex patient pathway through therapeutic interventional radiology (IR) | • Radioembolization for hepatocellular carcinoma using Yttrium-90 microspheres (Y-90) |
| Substantial risk and consequence of error due to the radioactive material involved | • Risks to patient safety and staff involved |
| Current methods of accident analysis used in healthcare: | • Linear; Focus on a ***singular*** root cause of an accident<br>• Retrospective |

**Objective:** Apply an analysis method that considers the ***complexity and criticality*** of the system to systematically ***identify, quantify, and track*** the potential for risk in an IR procedure based on the ***design*** of the ***system***

# Project Goals

Improve ***patient safety*** in all Y-90 procedures

Improve ***safety culture*** and offer ***systematic solutions*** to hazards

Test the application of ***prospective systems analysis*** including ***Human Factors*** in complex patient safety systems

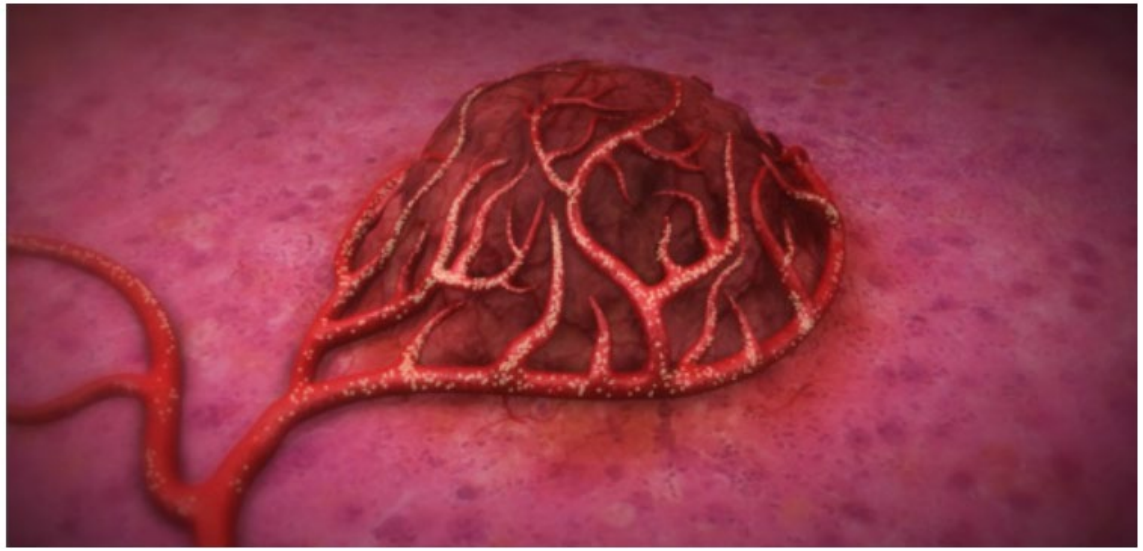
# Y-90 Background

**System in Focus:**

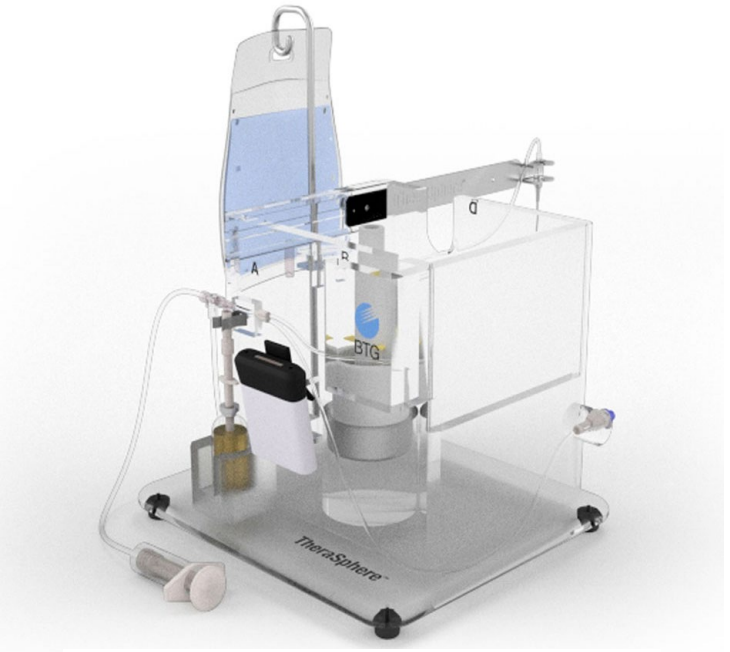
Radioembolization for hepatocellular carcinoma using Yttrium-90 microspheres (Y-90)

**Description:**

Glass beads or resin spheres containing Yttrium-90 deliver targeted radiation directly to the liver tumors through the tumor's main blood supply, via catheter



**Microspheres in Tumor Blood Supply [3]**




**Y-90 Administration Set [3]**

# Systems Theoretic Process Analysis (STPA)

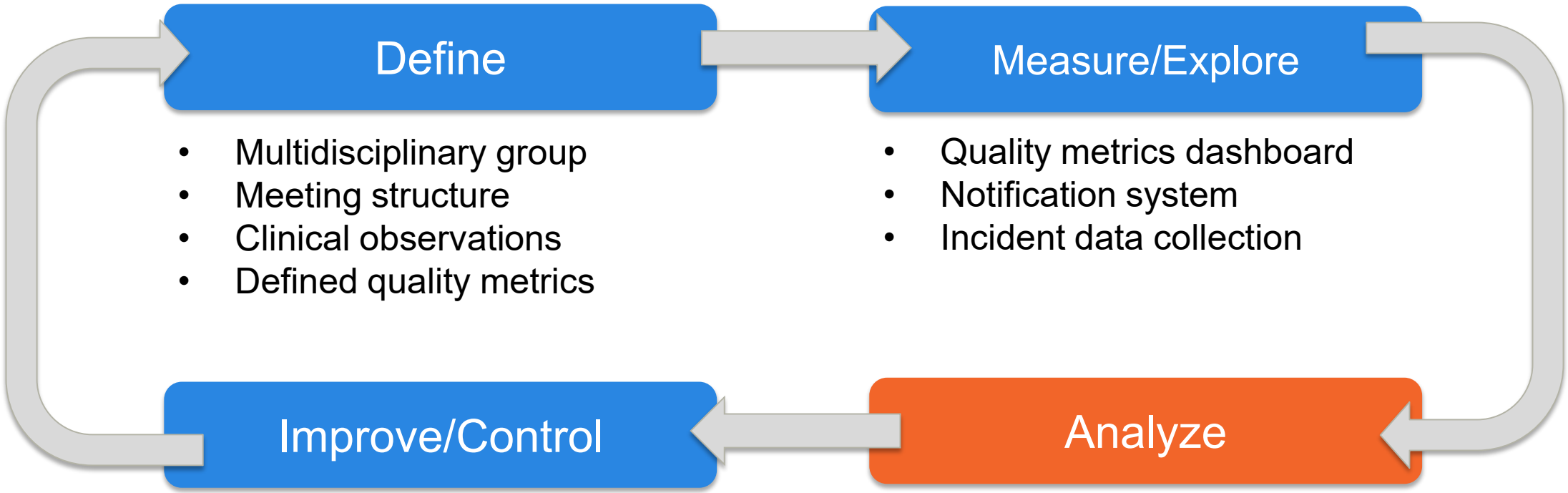
**Systems-Theoretic Process Analysis (STPA)**

Finds inadequate control in design of a system & identifies potential hazards

| | | |
|---|---|---|
| Non-linear | Multiple causal factors | Mitigates bias & blame |
| Handles Complexity | Identifies inadequate control | External factors |

Used in ***high-risk industries***: Aviation, Nuclear, Automation, IT, Health Systems, etc.

# DMAIC Framework




- Multidisciplinary group
- Meeting structure
- Clinical observations
- Defined quality metrics

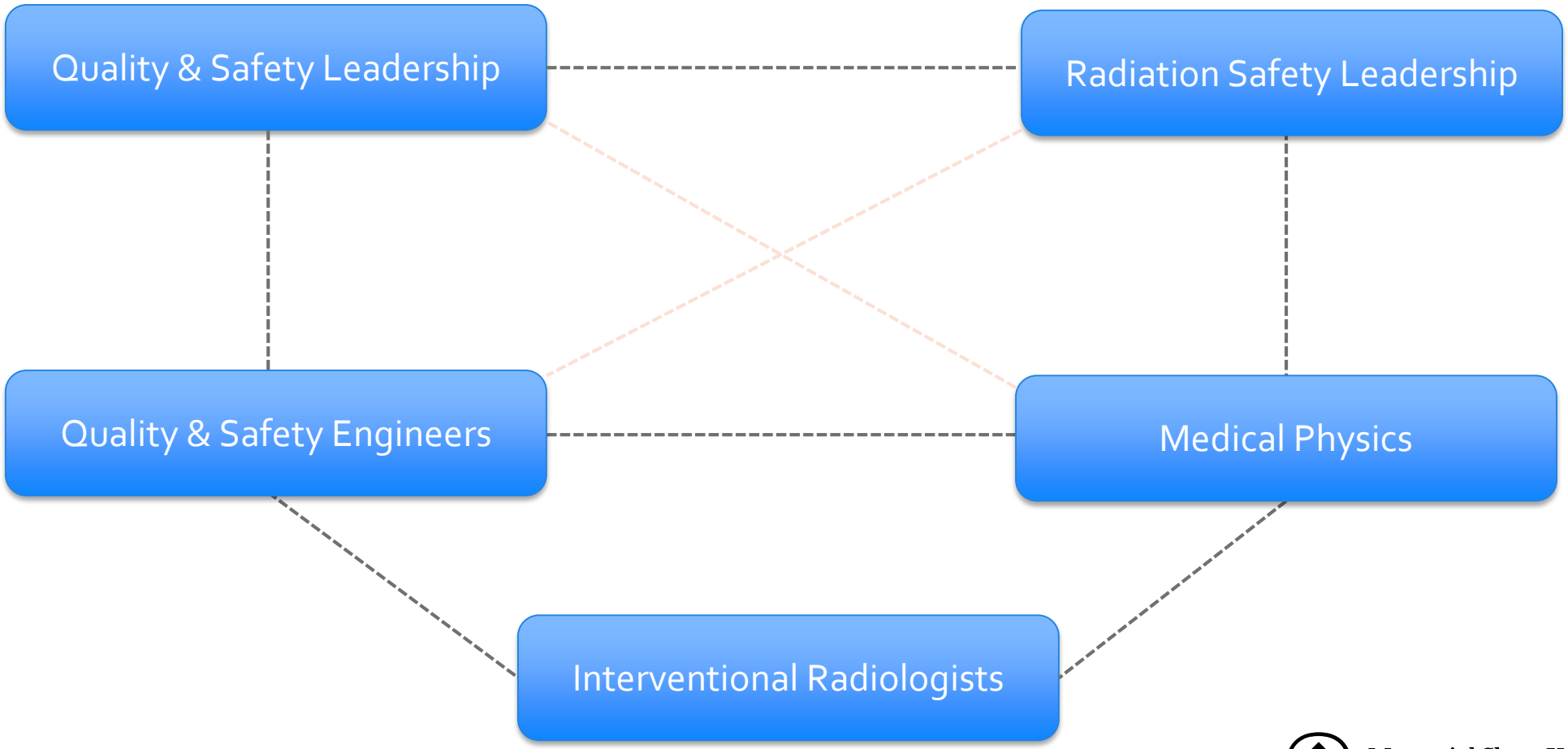
- Quality metrics dashboard
- Notification system
- Incident data collection

- Propose Solutions/ Recommendations
- Identify Leading Indicators of Hazards
- Track outcomes of analysis

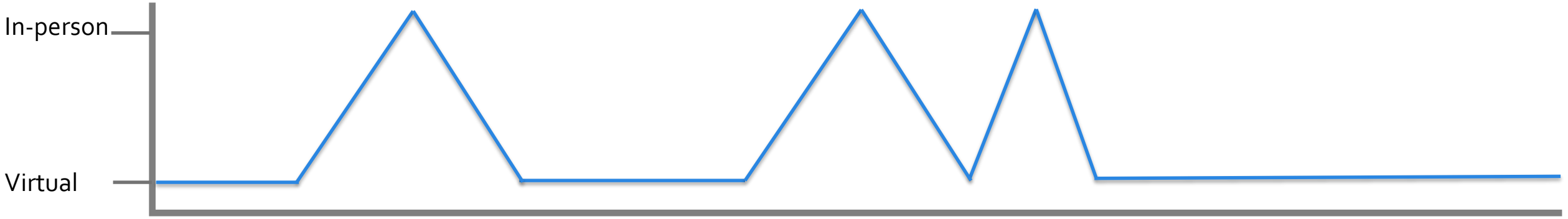
- Incorporate incident data
- Incorporate public data (i.e. NRC)
- Review of industry standards & regulations
- Apply safety analysis (STPA)

# Key Stakeholders

**Interdepartmental communication**



# Strategy




## In-Person

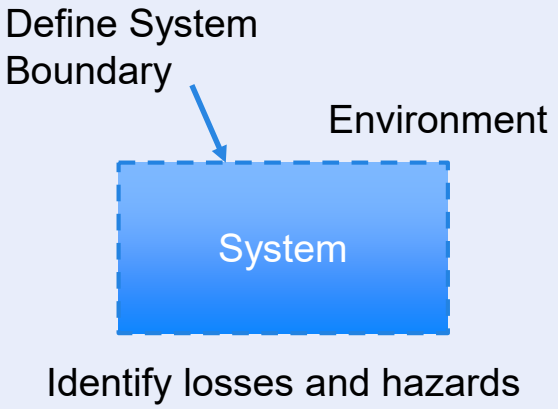
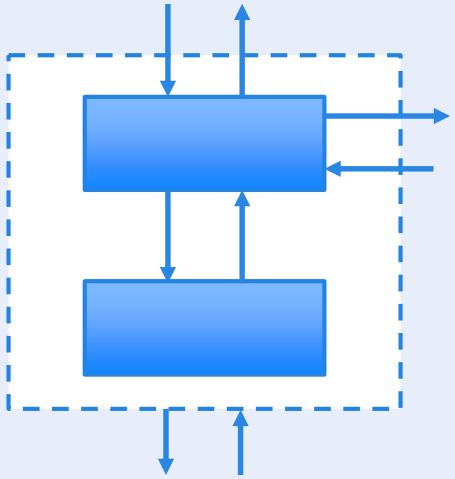
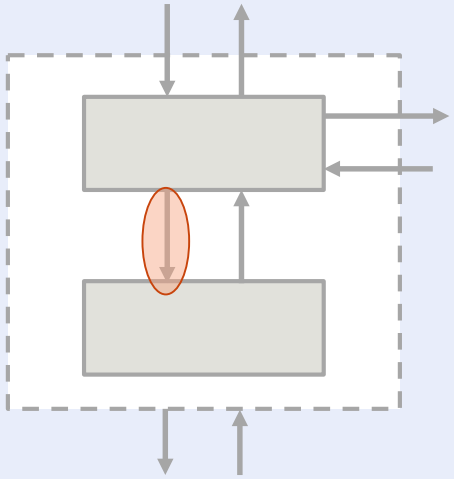
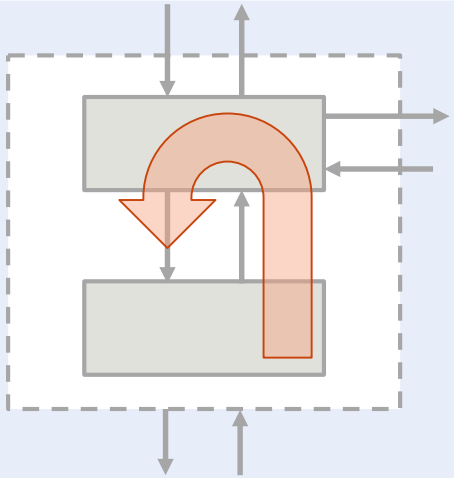
- Clinical observations
- Staff interviews

## Virtual

- Introductory meetings
- Structured bi-monthly meetings during analysis
  - i.e. UCAs & Causal Scenarios
- Ad-hoc meetings
- Offline feedback
- Centralized communication platform on MS Teams

# STPA

## General Steps

| 1) Define the Purpose of the Analysis | 2) Model the Control Structure | 3) Identify Unsafe Control Actions (UCA) | 4) Identify Causal Scenarios |
|---|---|---|---|
| System definition of boundaries, losses, hazards, and existing safety constraints | A functional model of system composed of feedback control loops | An unsafe action that, in a particular context and worst-case environment, will lead to a hazard | Scenarios where multiple causal factors that can lead to the UCA and eventually a hazard |
|  |  |  |  |

**Adapted from [4]**

# STPA: Modeling the Control Structure

## 2.1 Identify and Define Controllers

1. Patient
2. Medical Heath Physicist
3. Medical Physicist Dosimetry Team
4. Authorized User (AU)
5. Interventional Radiology Doctor (IR MD)
6. Radiopharmacy (Nuclear Pharmacy)
7. SAIL Team
8. Radiology
9. Anesthesiologist
10. RNs
11. Interventional Radiology Technologist (IR Tech)
12. Interventional Radiology Care Coordinator (IR CC)
13. Hospital Leadership
14. Governing Bodies
15. Vendor

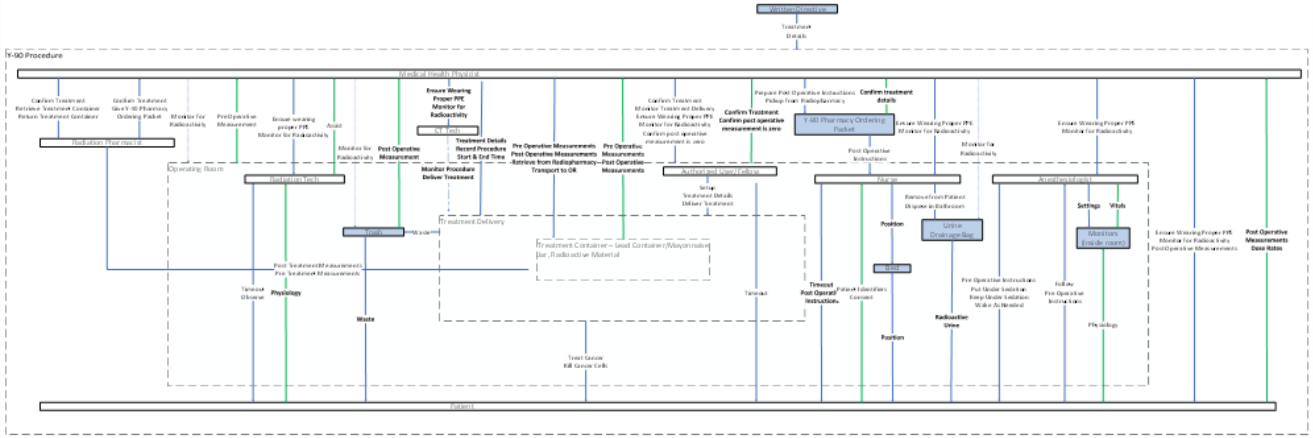
## 2.2 Define Controller Responsibilities

**Controller:** Medical Health Physicist

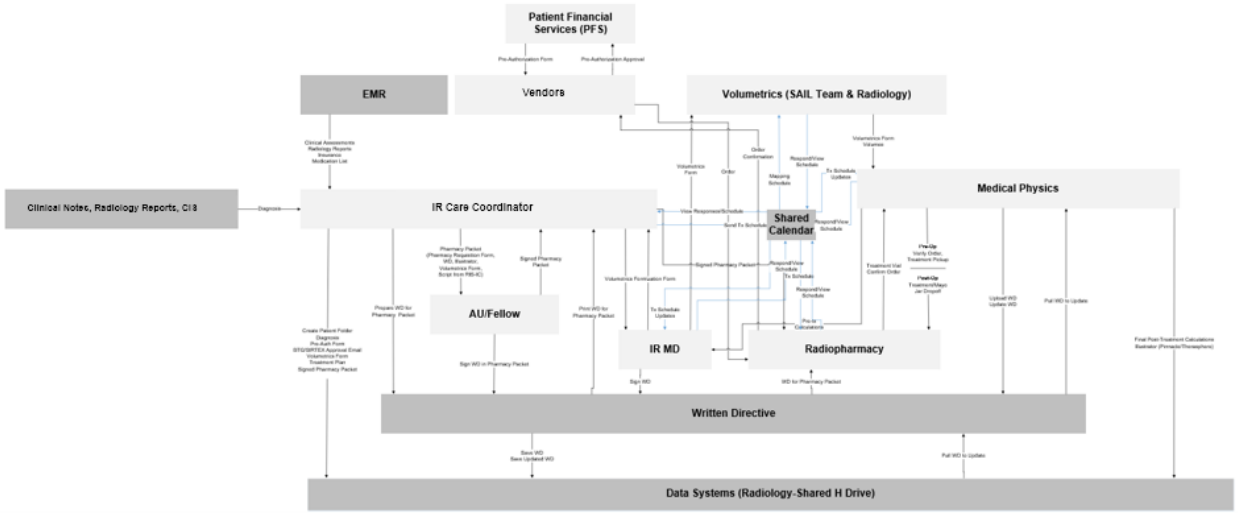
- Prepare dosimetry
- Dose vial delivery
- Monitor Patient Radiation
- Monitor/Survey OR & OR Staff Radiation
- Update written directive
- Coordinate treatment plan with IR MD
- Confirm treatment plan with IR MD & Radiopharmacy
- Prepare pre & post operative measurements

## 2.3 Iterative Control Structure Modeling & Abstraction

### Detailed Control Structure of Y-90 Procedure

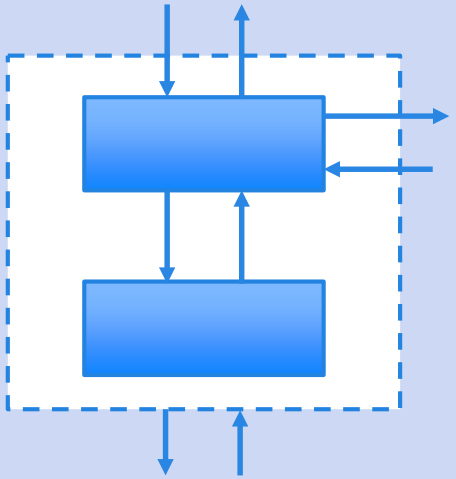
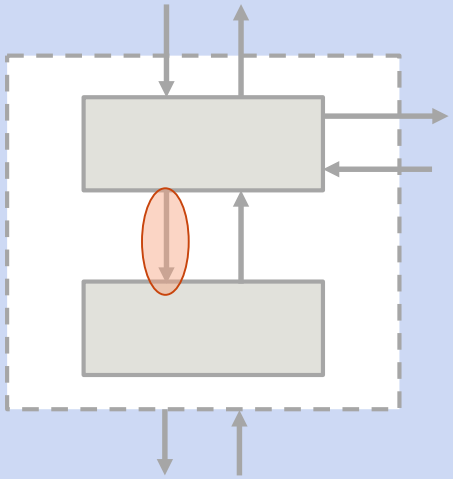


### High Level Control Structure of Data Systems



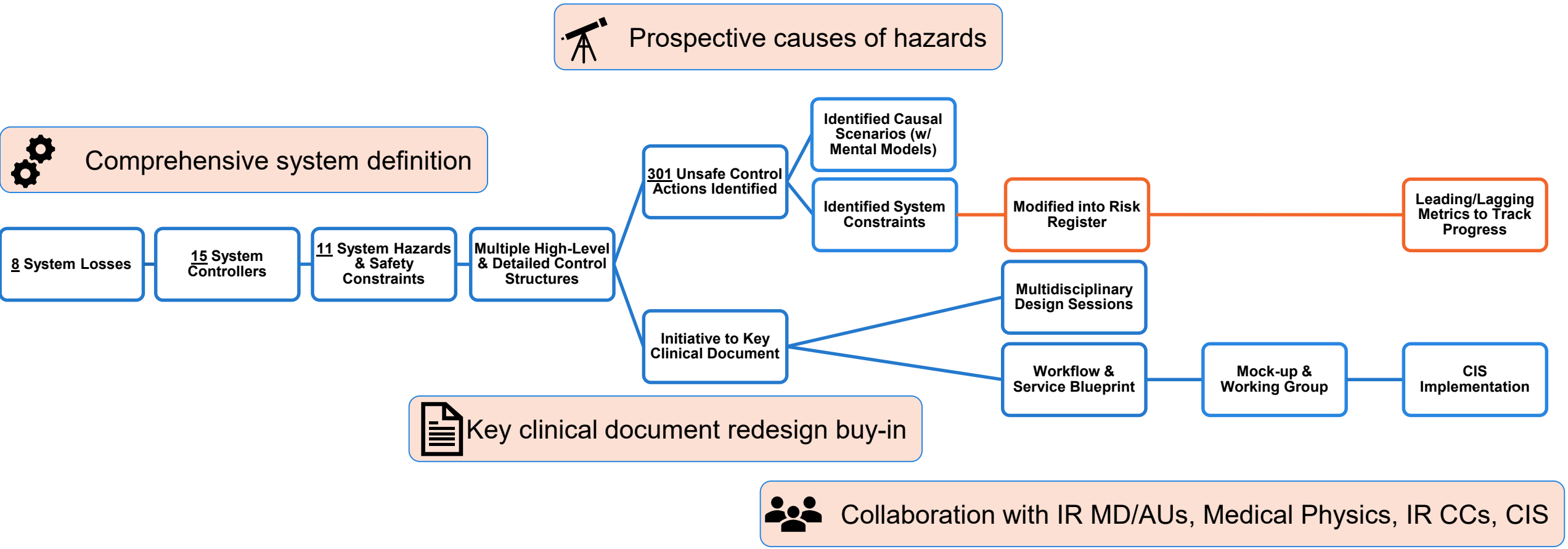
# STPA: Identifying Causal Scenarios

## Human Factors Element

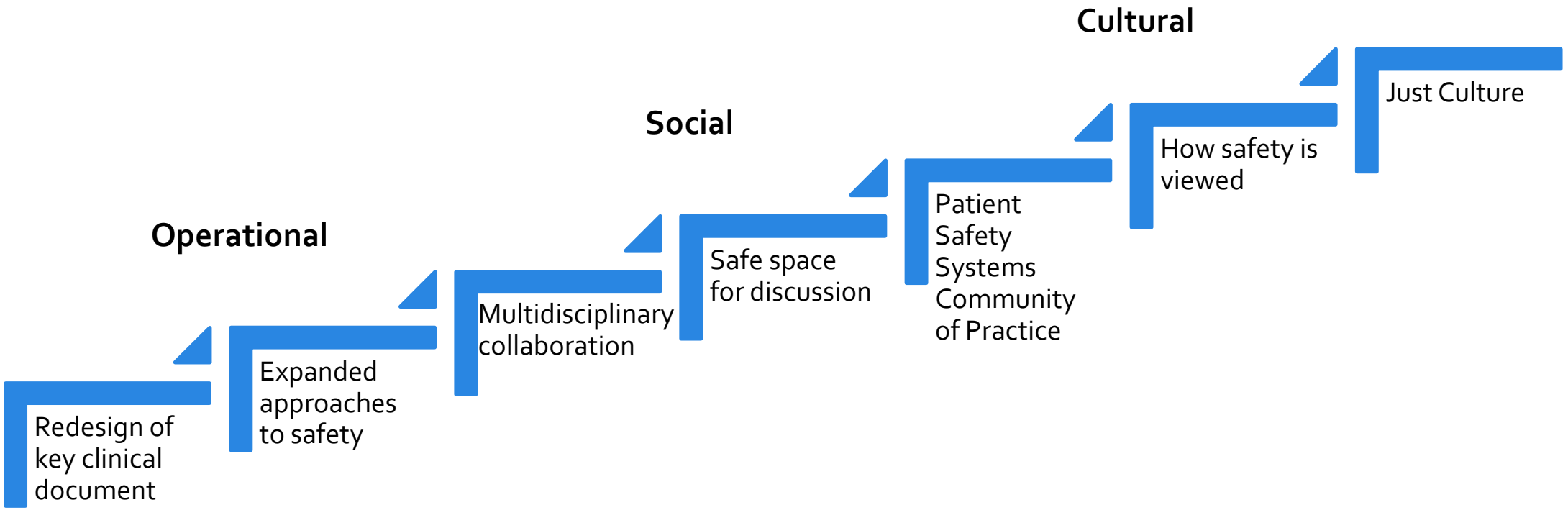
| 1) Define the Purpose of the Analysis | 2) Model the Control Structure | 3) Identify Unsafe Control Actions | 4) Identify Causal Scenarios |
|---|---|---|---|
| Define System Boundary<br>Environment<br>System<br>Identify losses and hazards |  |  |  |

**Adapted from [4]**

# Overview & Outcomes



# Impacts


Operational
Redesign of key clinical document
Expanded approaches to safety
Social
Multidisciplinary collaboration
Safe space for discussion
Cultural
Patient Safety Systems Community of Practice
How safety is viewed
Just Culture

# Lessons Learned

Organize a multidisciplinary team & ensure alignment

Communicate the value and approach in a minimally technical manner

Introductory meetings are worthwhile

Take your time learning the system in question

Read up on STAMP/STPA articles and presentations prior to applying

Emphasize applicability towards outcomes, culture, and harm prevention

# References


1. Leveson, N. & MIT Aeronautics and Astronautics Dept. (2020). Safety III: A Systems Approach to Safety and Resilience. MIT Aeronautics and Astronautics Dept. Published. http://sunnyday.mit.edu/safety-3.pdf
2. The Joint Commission. (2021, January). Patient Safety Systems (PS). https://www.jointcommission.org/-/media/tjc/documents/standards/ps-chapters/camlab_03a_ps_all_current.pdf
3. Boston Scientific. (2021). *TheraSphere Y-90 Glass Microspheres*. Www.Bostonscientific.Com. https://www.bostonscientific.com/en-US/products/cancer-therapies/therasphere-y90-glass-microspheres.html
4. Leveson, N. G., & Thomas, J. P. (2018). STPA Handbook. NANCY LEVESON AND JOHN THOMAS. http://psas.scripts.mit.edu/home/get_file.php?name=STPA_handbook.pdf

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# Thank You!