Northern New England Society for Healthcare Risk Management

A Safety Management System for Returning Trustworthiness to Healthcare …. and Reducing Risk

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Thank you.

Presentation Objectives

- Define trustworthiness and its significance in healthcare
- Explore safety management systems and system safety approaches
- Highlight strategies for fostering transparency and clinician trust
- Discuss leveraging technology and leadership for safer care

I HAVE BEEN IN HEALTHCARE SINCE 1977

MY WHY

GOALS FOR TODAY'S PRESENTATION

Healthcare has morphed from the sacred doctor patient relationship into a complex ecosystem where death from healthcare associated error is the third leading cause of death in the United States… and we are losing that sacred trust in healthcare

The complexities that we see in healthcare right now are unparalleled.

- Uncertainty about upcoming changes
- Reimbursement on may levels
- Medicaid which impacts our ability to provide care
- Changes the lens through which our patient population is choosing to get seek care
- Rural care programs
- Shift from routine care to emergency care increasing the burden on ED and EMS

- Systems are increasing in complexity
- Pushing AI and other IT technologies
- Tariffs
- Supply chain
  - Tariffs
  - Product integrity
- Workforce
- Social destabilization
- Environmental destabilization
- Civil destabilization

How do we as healthcare partners create a trustworthy and resilient system in the face of complexity and uncertainty ?

What is trustworthiness?

- What makes you trust someone or something?
- What do you trust in Healthcare?
- What don't you trust?
- How do we decide what to trust or not ?

Do we trust the healthcare system?

- Why?
- Why not?
- What factors lead us one way or another?
- How do we make healthcare safer?

Why Trust Matters to Clinicians

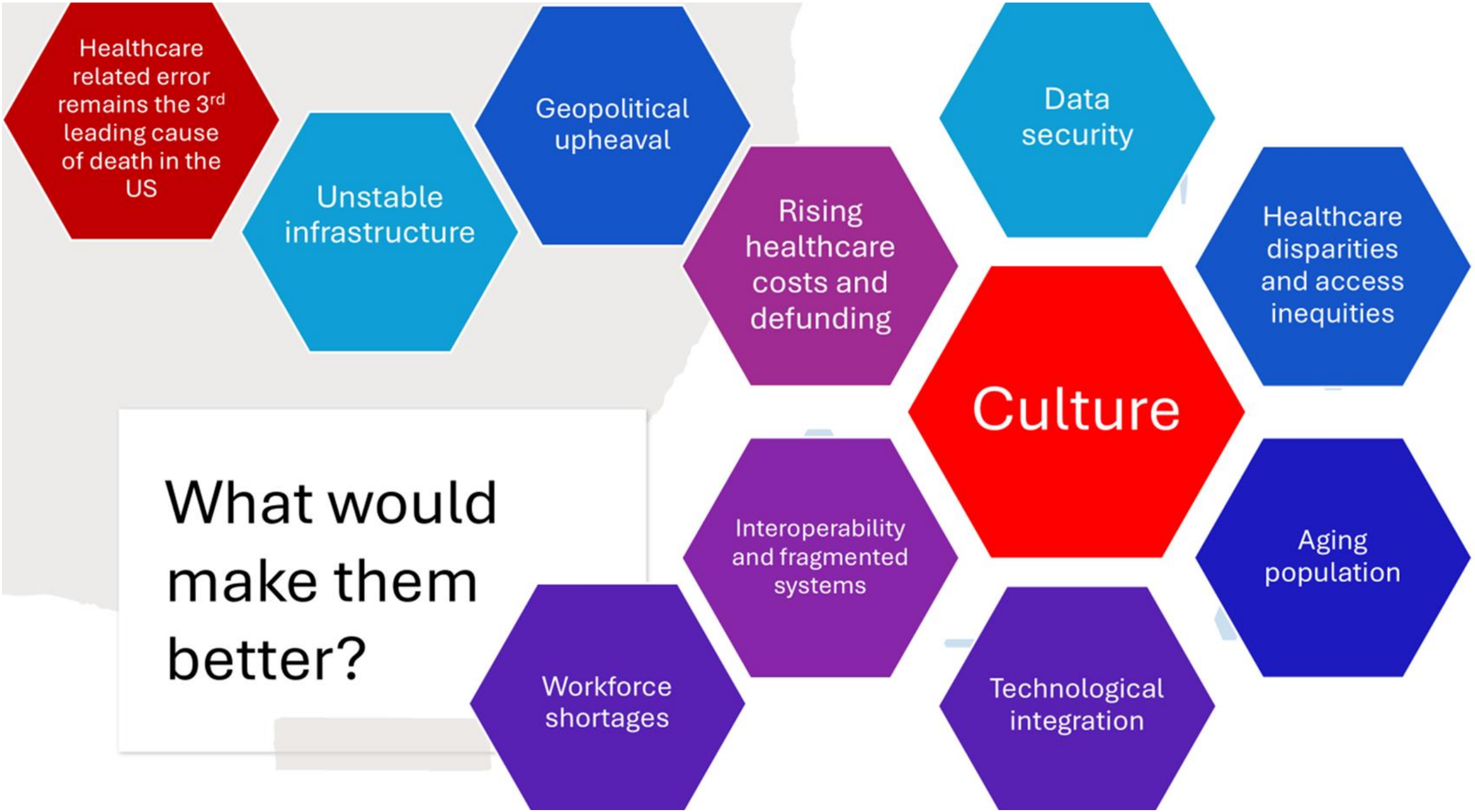
Trust drives patient adherence, satisfaction, and outcomes.

Patients trust individual clinicians more than institutions.

System safety protects patients and providers.

- Clinicians need to trust the system
- Data interoperability
- Use of AI
- Clinical decision support tools (CDSS)
- Things that have already been automated (CPOE for example)


We must answer
2 questions.....
What are our
biggest pain
points?


Healthcare related error remains the 3rd leading cause of death in the US
Unstable infrastructure
Geopolitical upheaval
Data security
Rising healthcare costs and defunding
Healthcare disparities and access inequities
Culture
What would make them better?
Interoperability and fragmented systems
Aging population
Workforce shortages
Technological integration

We Need to Create Order from Chaos

#1 Need to understand the healthcare ecosystem

#2 Look at how healthcare related error is a symptom of an unbalanced ecosystem

#3 Create a trustworthy ecosystem for our caregivers and our patients

Progress in Reducing Preventable Healthcare Errors

- Enhanced safety protocols have lowered error incidence rates in recent years.
- Implementation of Safety Management Systems contributes to proactive risk mitigation.
- Clinician engagement and training improve error recognition and prevention.
- Technology adoption, such as electronic health records, reduces documentation errors.
- Continuous monitoring and feedback loops facilitate ongoing improvements in care quality.

Common System Failures Undermining Healthcare Trust

1. Risks of Dismissing Patient, Family, and Caregiver Concerns
2. Insufficient Governance of Artificial Intelligence in Healthcare
3. The Wide Availability and Viral Spread of Medical Misinformation: Empowering Patients through Health Literacy
4. Medical Error and Delay in Care Resulting from Cybersecurity Breaches
5. Unique Healthcare Challenges in Caring for Veterans
6. The Growing Threat of Substandard and Falsified Drugs
7. Diagnostic Error: The Big Three—Cancers, Major Vascular Events, and Infections
8. Persistence of Healthcare-Associated Infections in Long-Term Care Facilities
9. Inadequate Communication and Coordination during Discharge
10. Deteriorating Community Pharmacy Working Conditions Contribute to Medication Errors and Compromise Patient and Staff Safety

Trustworthiness in healthcare ….

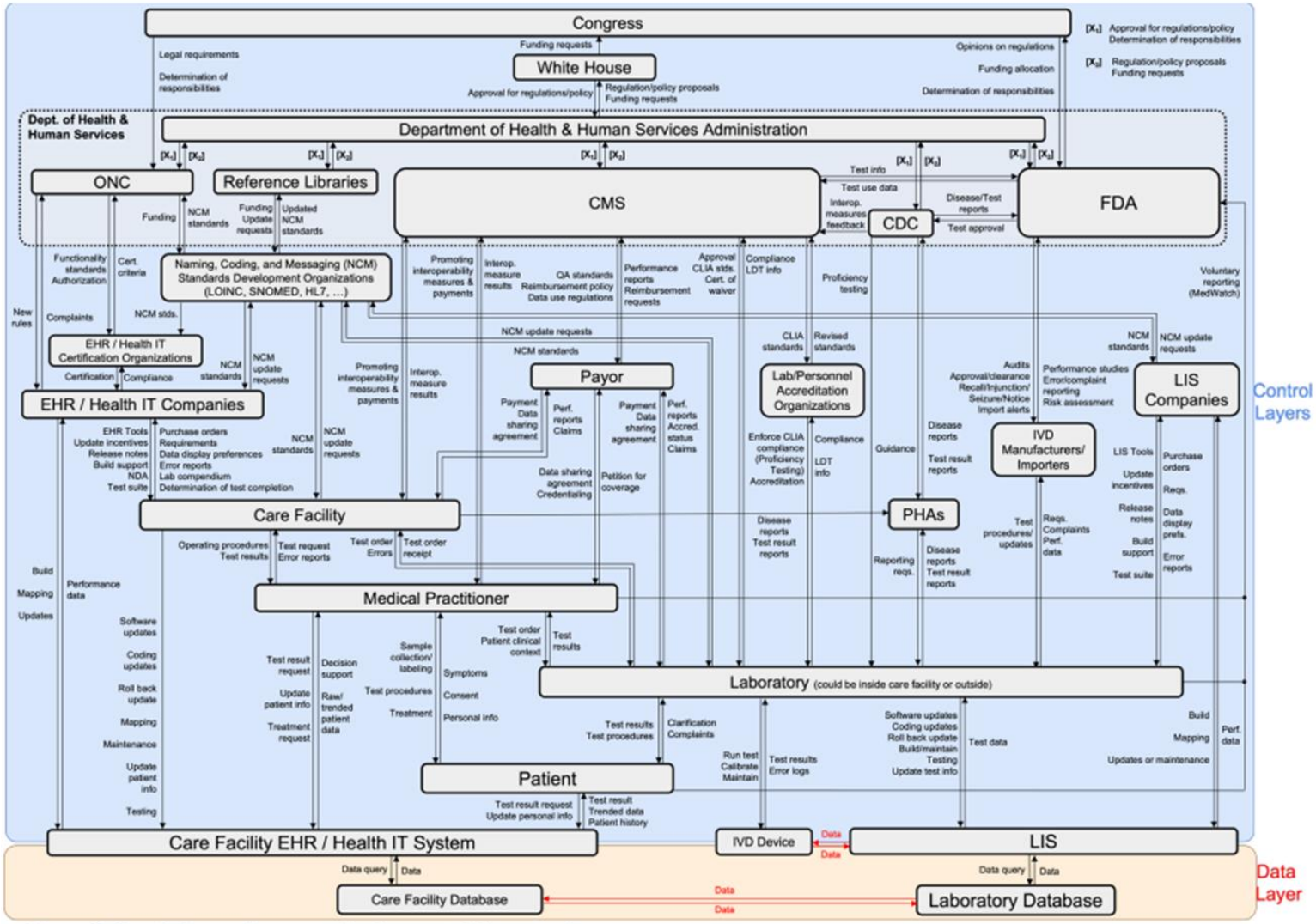


Figure 5. Detailed control structure for diagnostic laboratory data ecosystem

Hinges on effective information management systems essential for patient safety, which integrate safety science, human factors, and computer engineering to reduce adverse events.

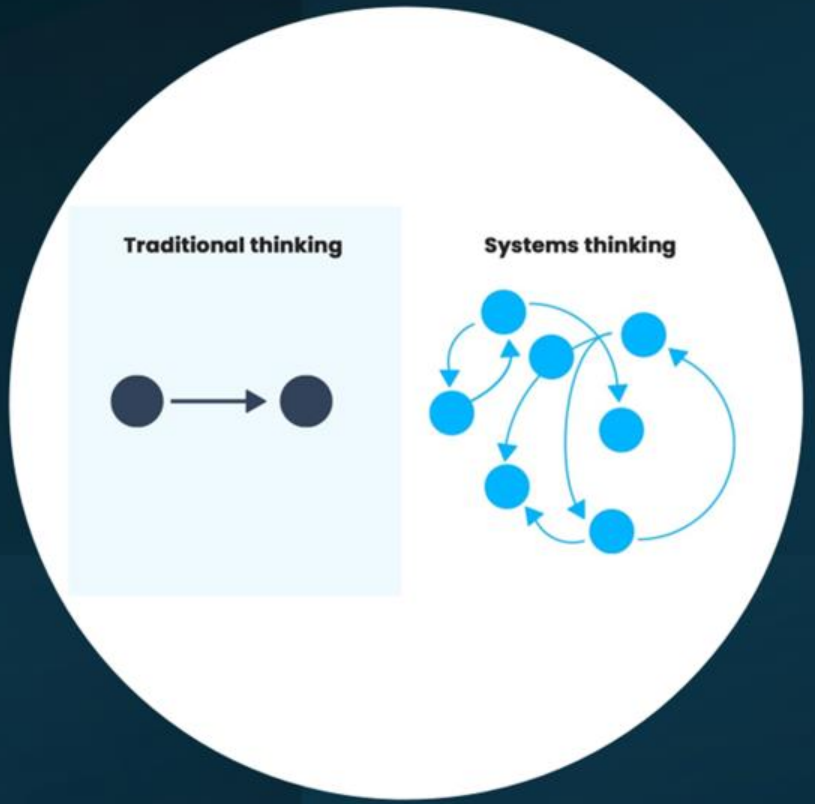
System Safety within Laboratory Data Exchanges Report September 25, 2023

Current Tools for Analysis of Adverse Events

- **Causal Analysis (RCA, ACA, CCA)**
- **Failure Mode and Effects Analysis (FMEA)**
- **Global Trigger Tools**
- **Other?????**

- How well are these tools working?
- What are the challenges and limitations?

Advancing Healthcare Safety Through a Safety Management System Lens



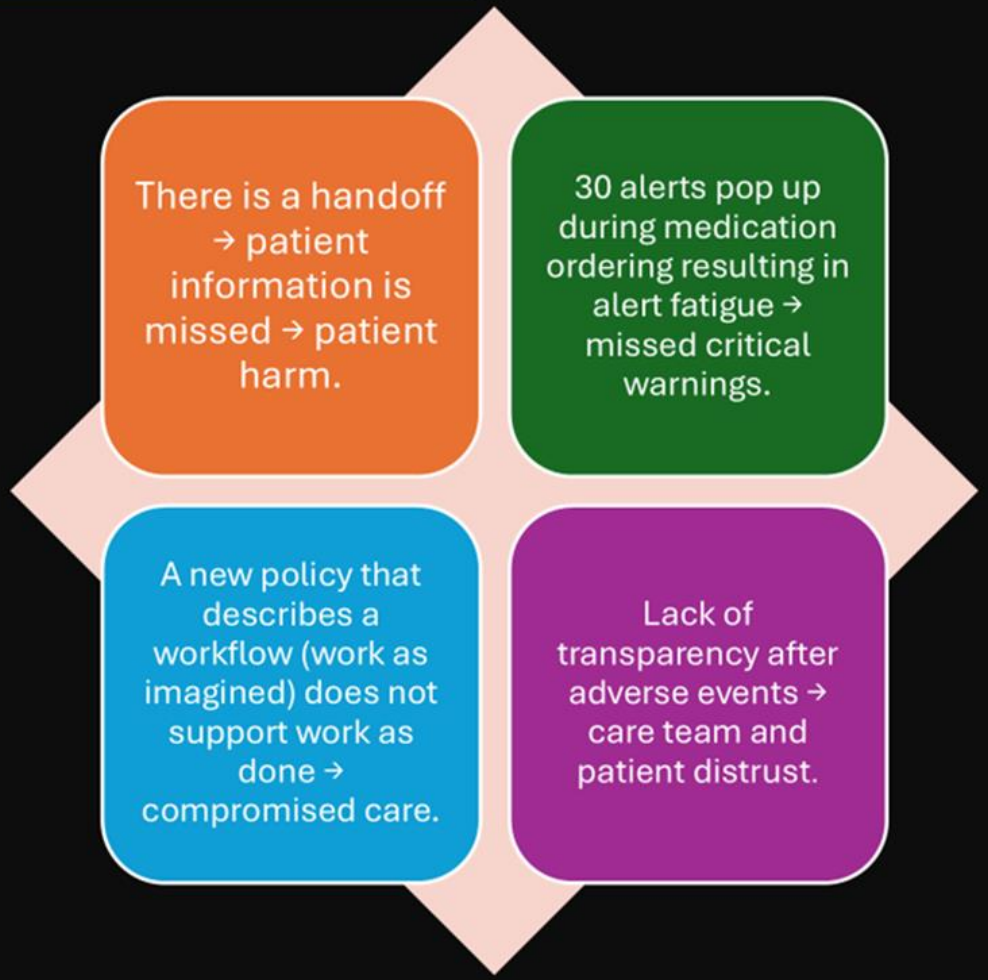
What Is a Safety Management System (SMS)?

- A structured framework for managing safety risks in complex systems
- Includes hazard identification, risk assessment, mitigation, and continuous improvement
- Widely used in aviation, nuclear power, and critical infrastructure
- Relies on tools that do not see events in a linear fashion
- Provides the ability to understand how preventable events can occur .... *EVEN IF EACH PART OF THE SYSTEM IS DOING EXACTLY WHAT IT WAS DESIGNED TO DO.*

What Is a Safety Management System Approach?

Systems Safety 101 – the world is all about control structures and feedback loops	A proactive view of the hazards and losses within the system	Focuses on:	Create resilient systems that support safe, trustworthy and efficient care
Identify the missing control structures or feedback loops and you can identify causes of preventable error and fix the problem.	Only works once you understand the entire system A shift from blaming individuals to understanding system-level contributors to harm.	Focuses on systems, not individuals. Integrates human factors, workflows, and technology. Interdisciplinary collaboration Continuous learning and adaptation	If you understand the ecosystem, you can thoughtfully make changes without creating the potential for harm.

Any of these sound familiar?



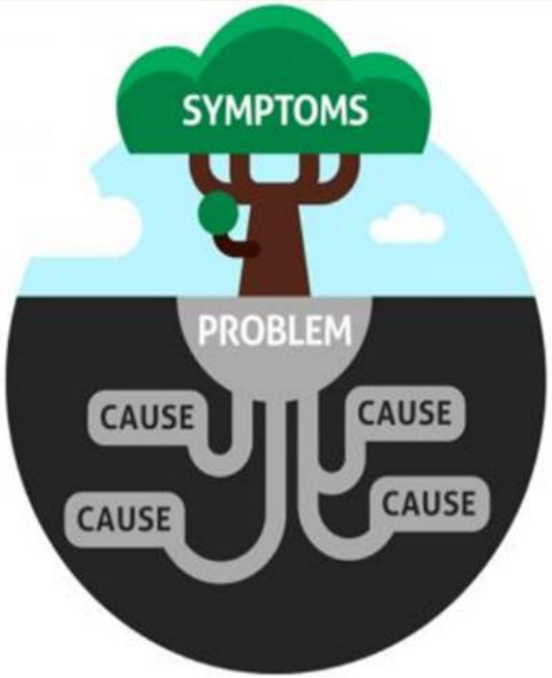
We focus on reliability……

- If something is reliable then it is safe – right?
- In science we look at the reproducibility of a study or parameter…..
- What is trustworthy?

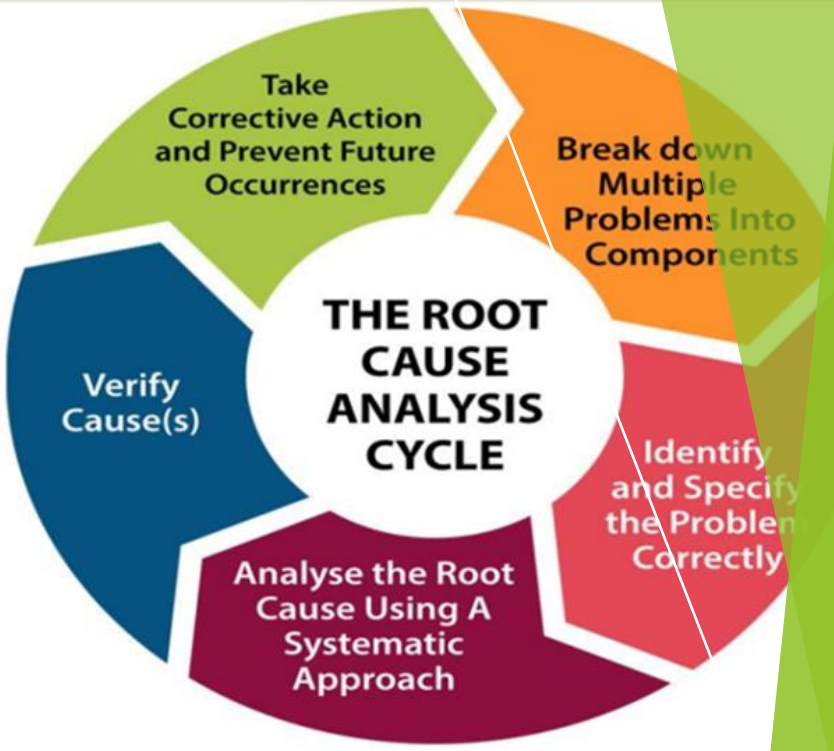
You cannot really fix what you do not understand

Understand your organization's culture

"To address this mistake we must use root-cause analysis. I'll begin by saying it's not my fault."



Follow the process.....



Understand your ecosystem

Understanding your Ecosystem

STPA (Systems-Theoretic Process Analysis) is a hazard analysis method used in healthcare to identify potential accidents by focusing on unsafe control actions within a system, rather than solely on component failures.

STPA is applied to complex, socio-technical systems like medical device interactions or patient monitoring, recognizing that hazards can arise from flaws in design, human behavior, and organizational factors, not just technical malfunctions.

Why should be adopted by Healthcare?

- Complex Systems: Modern healthcare involves intricate systems with interactions between technical components, human operators, and organizational factors, making STPA particularly relevant.
- Beyond Component Failures: Unlike traditional methods that focus on component failures, STPA addresses hazards arising from faulty interactions, flawed design, or complex human errors.
- Proactive Risk Management: STPA is a proactive approach that seeks to prevent accidents by identifying potential unsafe control actions and causal factors before they lead to adverse events.

Core Principles of STPA in Healthcare

STPA is built on the idea that accidents and safety incidents are not just the result of equipment malfunctions, but of inadequate control over a system. In a hospital, a "system" includes the relationships between:

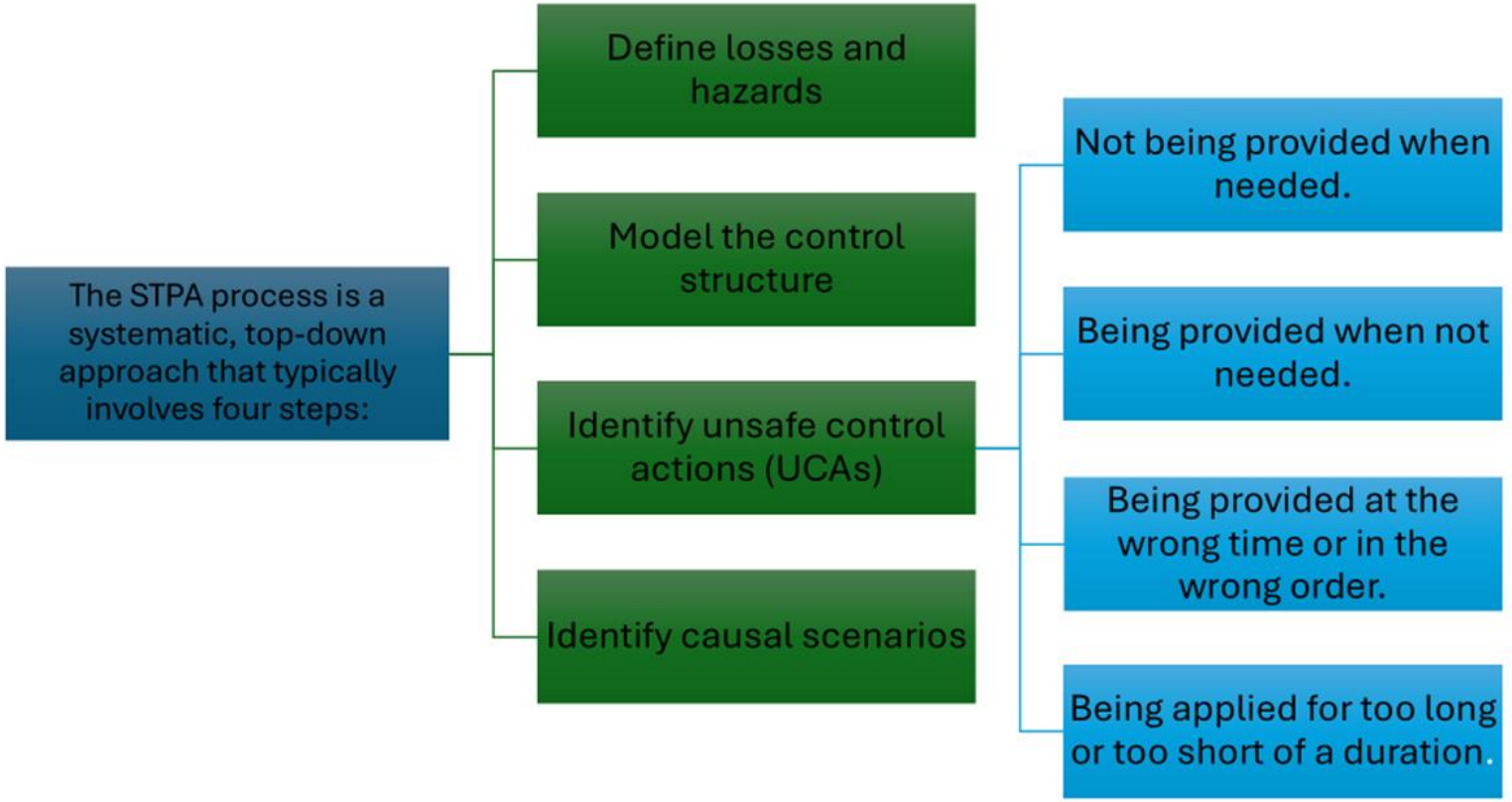
Human controllers, such as doctors, nurses, and administrators.

Automated controllers, such as software and smart medical devices.

Controlled processes, which include everything from a patient's physiological state to a clinical workflow.

Control actions and feedback, which are the commands and information flowing between these elements.

How STPA is applied in healthcare



Applications of STPA in Healthcare

Medical devices: STPA has been used to assess the safety of automated external defibrillators (AEDs) and to anticipate hazards related to user error and software flaws.

Sepsis treatment: One study applied STPA to the neonatal sepsis treatment process to develop numerous safety recommendations targeting human, technological, and organizational factors.

Electronic health records (EHRs): STPA can be used to improve the safety and interoperability of health IT systems by identifying flawed or missing requirements that could lead to medical errors.

Medication administration: STPA has been used to analyze the complex system of hospital medication administration and identify safety management deficiencies.

Remote patient monitoring: It can be adapted to analyze the safety of monitoring and tracking chronic conditions like diabetes, where multiple human and technical factors are involved.

How does this help us reduce healthcare harm and get to zero?

In healthcare, Causal Analysis based on Systems Theory (CAST) is a more advanced method than traditional Root Cause Analysis (RCA). Instead of finding ***a single "root cause"*** for an adverse event, CAST examines the ***complex system factors***, including human behaviors, technology, and management decisions, that lead to accidents.

Why healthcare is moving from RCA toward CAST

- Complex failures: Modern healthcare systems are complex and dynamic, and accidents need to be investigated in a way that matches this complexity, unlike the oversimplified, linear cause-and-effect model of traditional RCA.
- Systemic solutions: By revealing underlying issues in a system's design and management, CAST helps organizations develop more sustainable and robust interventions.
- Focus on learning: CAST is built on a model of causation called STAMP (System-Theoretic Accident Model and Process), which is more aligned with creating a robust learning system.

Aspect	Traditional RCAs	CAST
Model of Causality	Linear; focuses on a single "root cause" and a temporal sequence of events.	Systemic; views accidents as the result of complex interactions between technology, people, and organizational processes.
Scope of Analysis	Often looks at individual actions and immediate contributing factors, which can oversimplify complex events.	Broadens the scope to include design flaws, inadequate procedures, human decision-making, and safety culture.
Focus	Retrospective analysis of what went wrong.	Retrospective analysis of what went wrong, but with a focus on system redesign and proactive risk control.
Blame	Can result in a culture of blame despite a "no-blame" rhetoric, as it often identifies human error rather than systemic flaws.	Emphasizes system-level defects rather than individual actions, which fosters a more constructive "just culture".
Output	Tends to generate weaker, less sustainable recommendations, such as reminders, education, and re-training.	Identifies systemic causes that enable the redesign of the system itself, leading to stronger, more effective interventions.
Expertise	Often conducted by local teams with inconsistent training in accident investigation or human factors.	Requires specialized knowledge in systems theory and safety science, with training available to healthcare teams.

How CAST analysis is applied in healthcare

Frame the event

Investigate the control structure

- Control actions: Was there an unsafe or missing control action?
- Controller: What were the goals, knowledge, and process models of the involved humans and automation?
- Design: Were there design flaws in the equipment or user interfaces?
- Management: Were there organizational factors, such as flawed policies or inadequate safety culture, that enabled the unsafe control action?

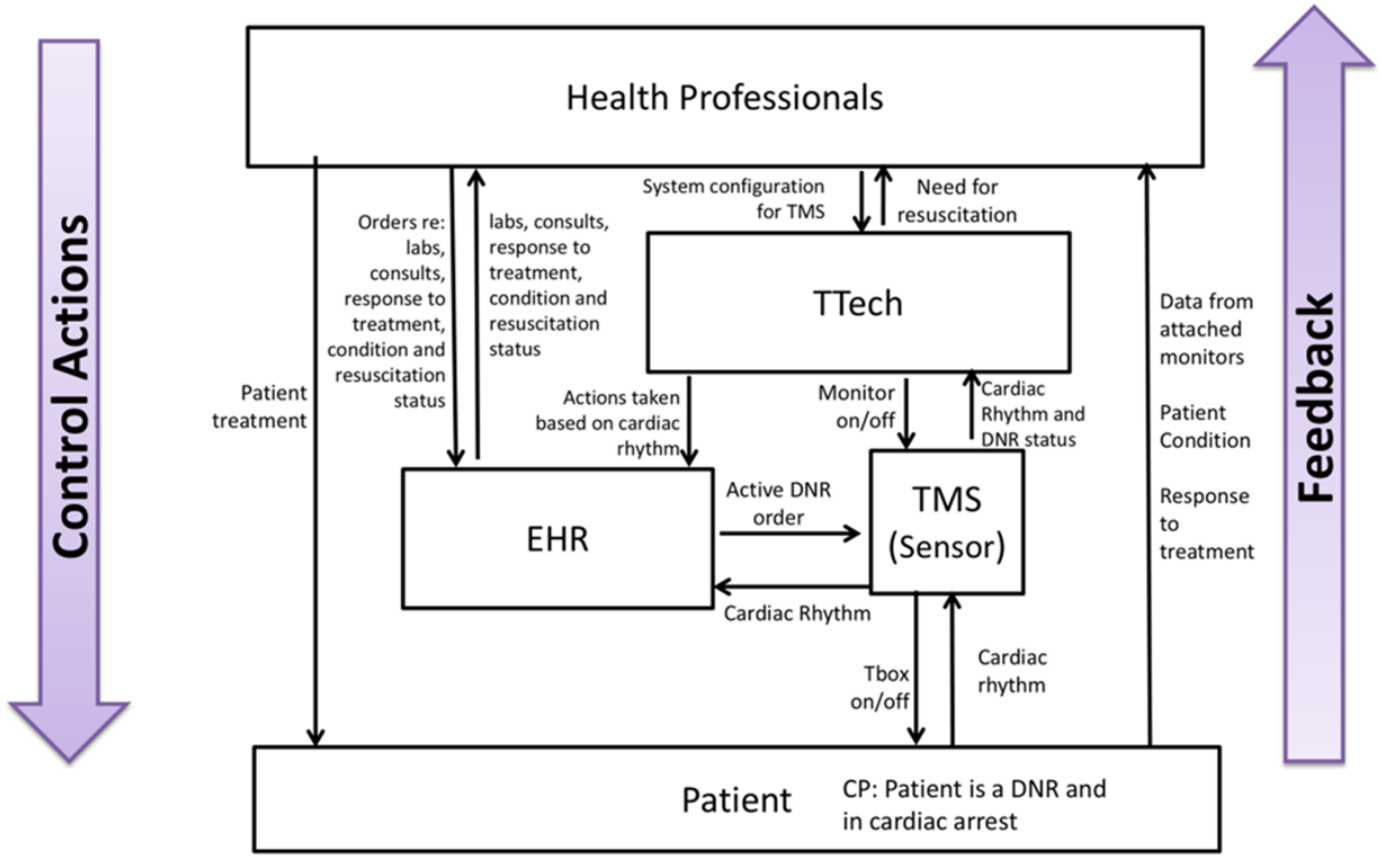
Identify systemic factors

Recommend interventions

An example

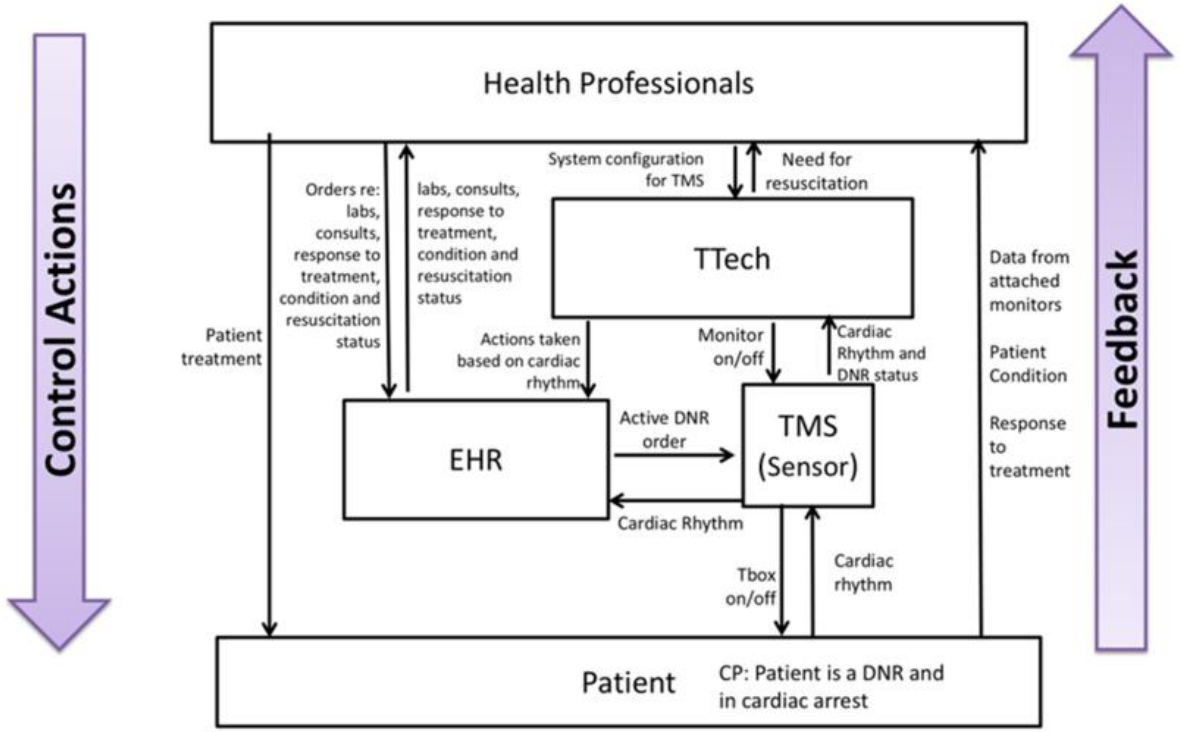
- Need to have a way to visualize the ecosystem at issue
- Draw the system

Model the Control Structure



Looks good – what could possibly go wrong?

Model the Control Structure



Measuring What Matters

Use metrics clinicians care about:

Time to resolve safety concerns	Staff perception of safety culture	Patient feedback on communication and respect	Integrate safety data into clinical dashboards—not buried in admin reports.

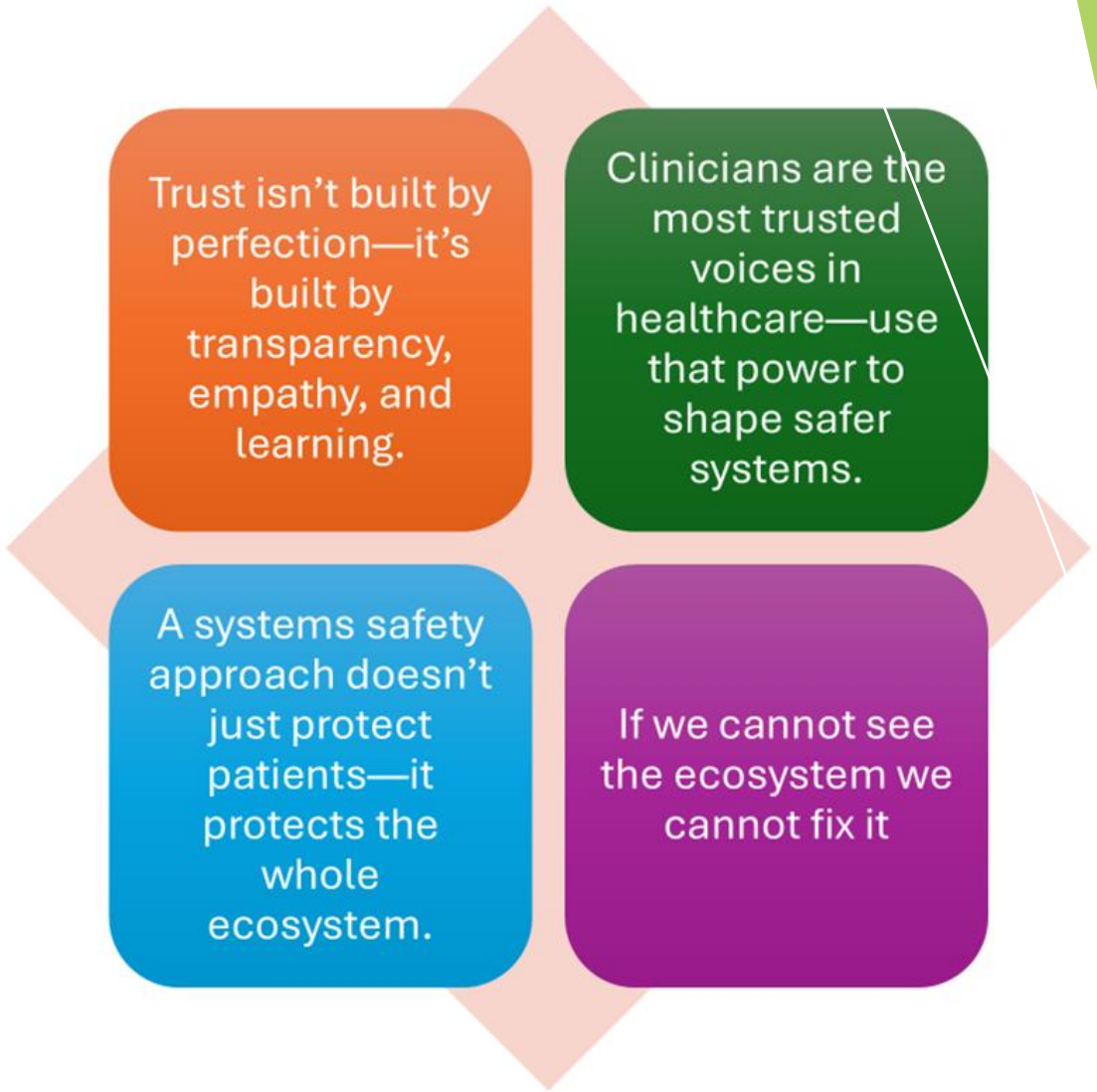
Sounds good but….. Would it surprise you to know that there is not a set of standard SAFETY measures?

What You Can Do Tomorrow ?

Start a micro-intervention: one change in your unit

- Be proactive and address near misses with the same academic rigor as serious harm events.
- Mentor others in systems thinking.
- Advocate for patient involvement in all aspects in care.
- Push for workflow redesigns that reflect clinical realities.
- Advocate for adoption of systems thinking.

Closing Thoughts



Returning Trustworthiness to Healthcare

Amid they current geopolitical disruption in healthcare, we need to strengthen out ability to understand and perfect our ecosystem to proactively plan for rapid pivots and unexpected disruptions in daily “routine” operations.

In identifying where changes can be made without additionally disrupting our healthcare ecosystem and making those changes in response to external changes and internal discoveries, we build resilience.

By harnessing the power of out understanding of our ecosystem we can make the necessary changes to achieve meaningful reduction in healthcare related harm events and restore trustworthiness to healthcare.