Application of STPA to the U.S. Diagnostic Laboratory Data Ecosystem

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Addressing the Patient Safety Challenge

- Preventable medical errors are the **3rd leading cause of death** in the U.S. (Makary & Daniel, 2016)
- **Diagnostic errors** account for **6-17% of all adverse patient events** occurring in hospitals, resulting in **most** of the paid medical malpractice claims and preventable patient deaths (National Academy of Sciences, 2015)
- An estimated **800,000 Americans are seriously injured or die each year** across multiple care settings **due to misdiagnosis** of dangerous diseases (Newman-Toker et al., 2023)
- Study of closed claim malpractice data found that **92% of diagnostic errors within the EHR occurred during laboratory testing** (Krevat et al., 2023)
- Up to **70% of all medical decisions** are reportedly **predicated on laboratory test results** (Raymond et al., 2020)
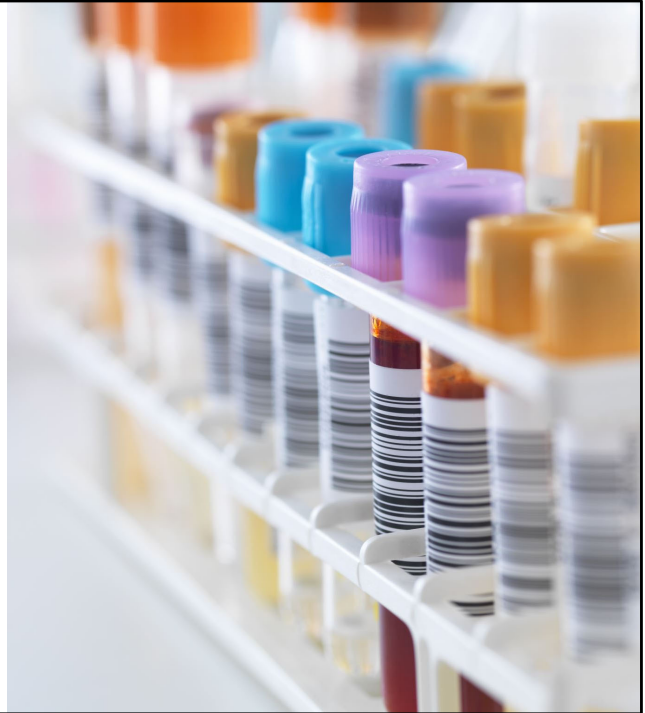
Numerous studies inform the need to improve the quality of laboratory data for better patient outcomes and patient safety.
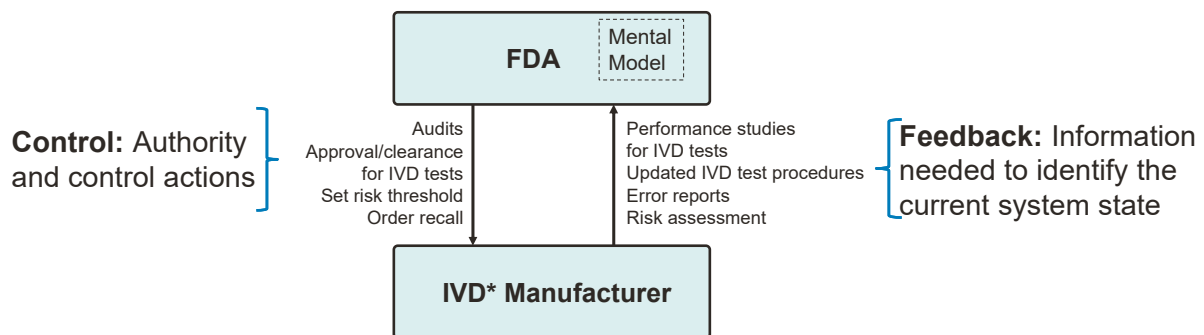
Setting the Goals of our System Analysis

Losses	Hazards
L-1: Loss of life or injury to patient	**H-1:** Patients receive less than acceptable standard of care
L-2: Loss of reputation or trust in the laboratory ecosystem	**H-2:** Laboratory ecosystem stakeholders, including patients, lose trust in the laboratory data being collected, shared, analyzed and reported

The first step in system analysis is to establish the analysis goals. What are we trying to understand, improve, and avoid? This is a proactive system safety analysis.

Method: Treat quality and safety as a control problem

Use engineering modeling and formal analysis based on systems theory to analyze the existing quality management system

FDA — Mental Model

Control: Authority and control actions
Audits
Approval/clearance for IVD tests
Set risk threshold
Order recall

Performance studies for IVD tests
Updated IVD test procedures
Error reports
Risk assessment

Feedback: Information needed to identify the current system state

IVD* Manufacturer

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Systems-theoretic Process Analysis (STPA) treats quality and safety as a control problem. The largest impact on quality and safety is through the design of the control (management) structure.

The goal is to create a system where quality and safety are effectively controlled.

Problems are not due to "failures" of the individual (who is trying to do the right thing) but instead due to the poor design of the controls and the quality control system. We used engineering modeling and formal analysis to model and analyze the current system.

This slide shows what engineers call a feedback-control loop. Effective decision-making also requires correct mental models of the current state of the system.
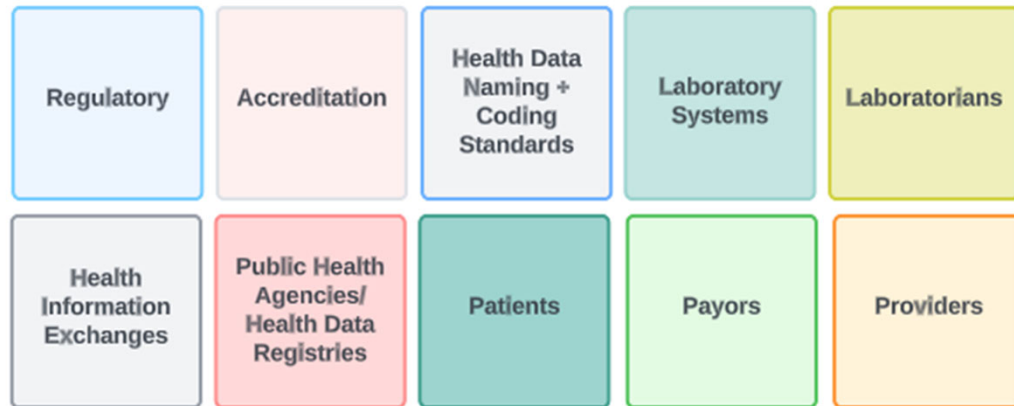
Feedback is needed to update mental models to ensure that decision-making is informed.

Decision-making can be ineffective if mental models are flawed.

To make effective decisions and changes (and avoid unintended consequences), the mental model must include the state of entire system, not just the individually controlled process.

*Note: IVD = In vitro diagnostic test

Using interviews to understand current system

Regulatory	Accreditation	Health Data Naming + Coding Standards	Laboratory Systems	Laboratorians
Health Information Exchanges	Public Health Agencies/ Health Data Registries	Patients	Payors	Providers

50 Stakeholders interviewed

We conducted interviews with dozens of stakeholders across the ecosystem to gather data.

Detailed Control Structure
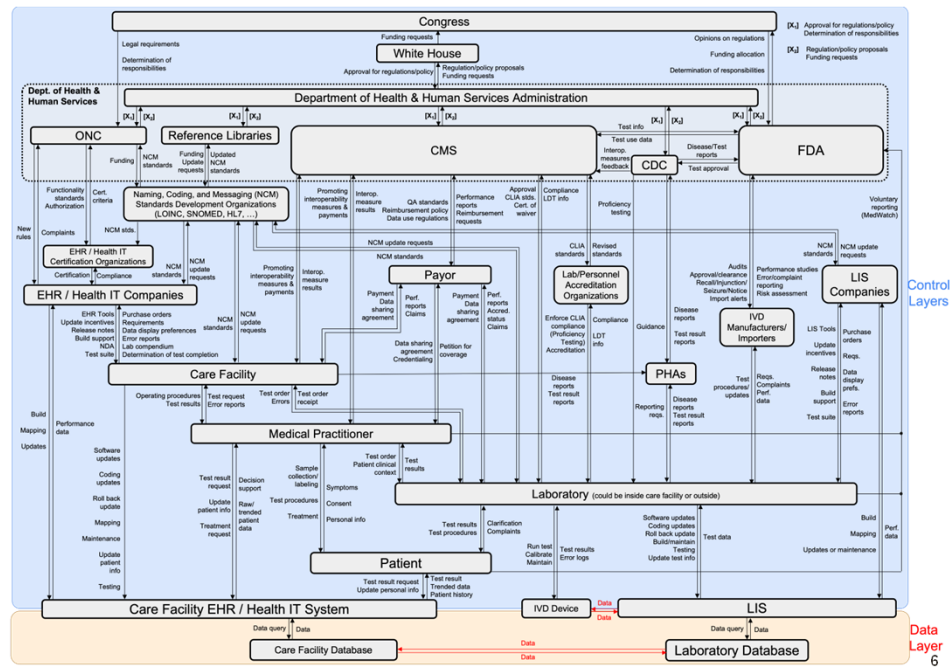
We developed a *control structure* to understand how the system operates as a whole. This is a very complex diagram, which is part of the problem. Many of the safety problems arise when gaps or inadequacies in the control relationships between groups arise.

We found that few people understood the entire system. As a result, there is redundancy and inefficiency, gaps, and incomplete controls. Many of the problems stem from inadequate feedback to decision-makers.

In the following three slides we outline a scenario where a medical practitioner provides treatment that does not match the patient's condition (an unsafe control action, "UCA") and how inadequate controls contributed to the unsafe outcome.

One contributing factor may be that their [medical practitioner] mental model of the patient's condition was informed by diagnostic information presented in a misleading way. That may occur if the EHR aggregated (e.g., placed in the same field) noncomparable test results that were derived using different methodologies that have not been harmonized to give comparable results.

That may occur if two different tests that use the same or similar approaches for different conditions are mapped to the same reference terminology (i.e., LOINC code, etc.). It may also occur if two tests that use different methodologies for the same condition are mapped to the same reference terminology.

This could happen because mapping different formats is a manual process, subject to the interpretation of the individual mapper, who may be an IT professional rather than a medical professional. It may also be the other way around, where a medical professional without reference terminology experience is tasked with mapping codes following an update.

Tests using different methodologies and producing noncomparable results may also be *appropriately* mapped to the same reference terminology, as the terminology structure may not support sufficient granularity to distinguish results performed on different noncomparable instrumentation. On the other hand, there can be multiple

appropriate codes for a given test, so different users may not always select the same code.

Implementation/mapping guidelines cannot anticipate every system and source data upon which the terminology or messaging standards would be implemented. Therefore, guidelines cannot provide specific mapping of proprietary data to standards. Inconsistent mapping is more likely to occur if implementers are unable to access support resources to clarify ambiguities in implementation/mapping guidelines or standards themselves.
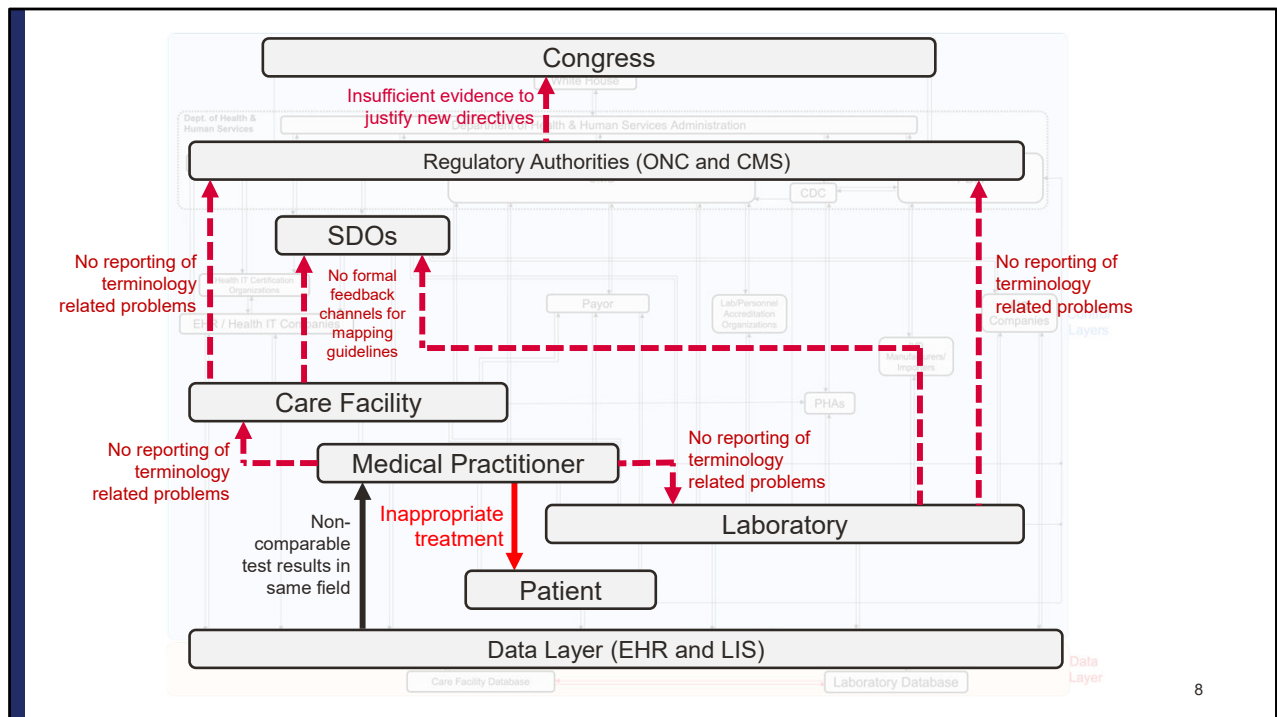
Many of the unsafe controls identified on the previous slide additionally have components of missing feedback.

Every control action must be paired with sufficient information/feedback for the controller (the groups represented in the boxes) to appropriately adjust their mental model in order to select the right control action. When feedback is missing or inadequate, the control actions made do not match the actual state of the system.

In this system, we see a lot of voluntary or optional reporting, and also unclear reporting paths. This makes it difficult for care facility administrations, SDOs, Regulatory Authorities, and other controllers to make informed decisions.
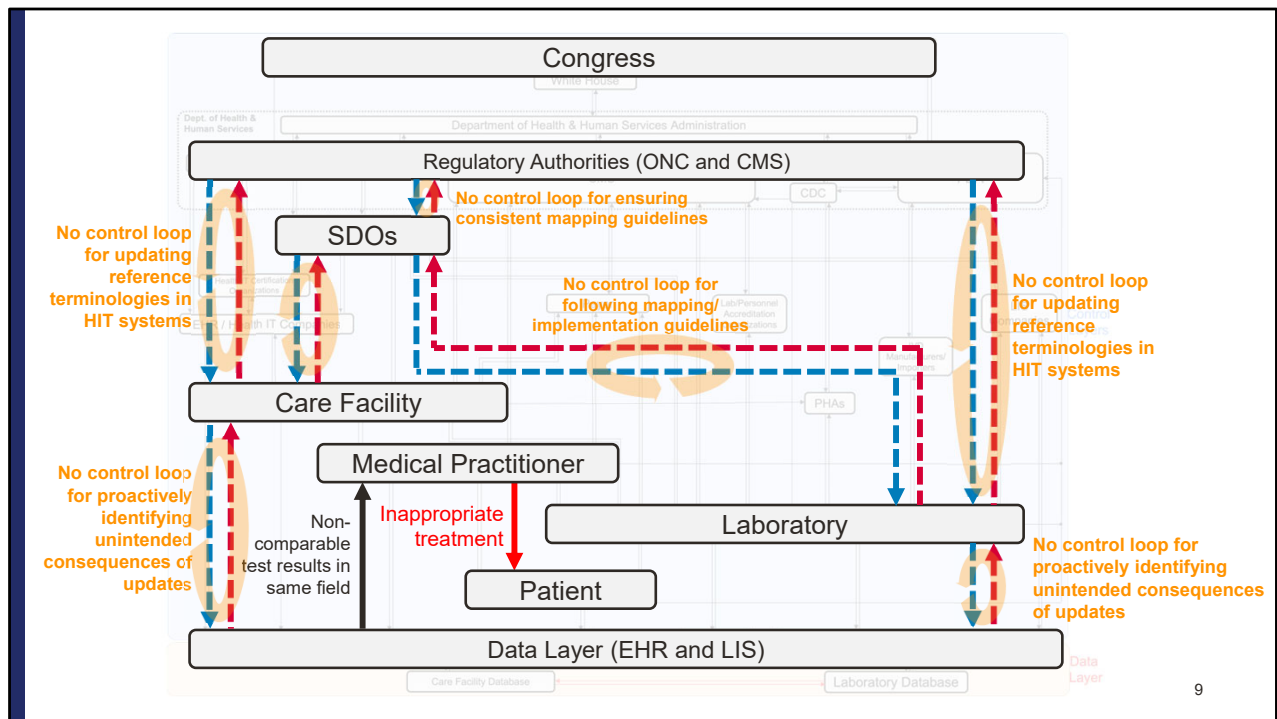
Finally, we observed missing control loops. These are places where there is neither control nor feedback between different groups.

Systemic Factors

Decentralized and missing oversight	Inadequacies and gaps in laboratory data standards	Inaccurate perceptions of data and HIT risks
Lack of a systems view by system participants	Inadequate regulatory emphasis on HIT safety	Flawed communication and coordination

Addressable by the rest of the ecosystem

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Our system analysis uncovered over 100 scenarios like this one. When we analyzed all of the scenarios together, we found that many scenarios involved the same six themes/ factors. Addressing these six factors will help prevent dozens of scenarios. Rather than trying to address each adverse event as they occur, taking a systems approach allows us to identify broader patterns that can be addressed.

Systemic Factor	Recommendation	Action Item(s)
Decentralized and missing oversight	**1**: Assign responsibility for addressing gaps in the regulatory oversight of laboratory data exchanges between system components that are regulated by different agencies.	
	2: Identify the data and standards needs of regulatory agencies and ensure they have the ability to use them appropriately.	
	3: Encourage the identification of regulatory gaps in other areas of the laboratory ecosystem through additional systems-theory-based analyses.	
Inadequacies and gaps in laboratory data standards	**4**: Reference libraries must develop a knowledge base that establishes a ground truth for naming, coding, and mapping of reference terminologies to particular laboratory tests, and stakeholders must be incentivized to use it.	
	5: Appropriate groups must be assigned responsibility for identifying gaps and weaknesses in laboratory data standards and for establishing a reporting channel for problems related to them.	
	6: SDOs must continuously support users by identifying and eliminating ambiguities in implementation guides for HIT standards.	

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We have identified general recommendations to address the identified systemic factors. The Action Item(s) column is for coordinated and collaborative system redesign efforts across the laboratory data ecosystem to prevent local changes having unintended consequences in other parts of the control structure.

| Systemic Factor	Recommendation	Action Item(s)
Inaccurate perceptions of data and HIT risks	**7:** Proactively and retroactively investigate systemic sources of diagnostic error.	
	8: Create a consolidated national database for HIT safety reporting that can be used to identify trends and opportunities for improving patient safety outcomes. It should include information about HIT not behaving as users intended and allow understanding how features of HIT design may have contributed to "user errors."	
Lack of a systems view by system participants	**9**: Educate the healthcare community on systems engineering and systemic approaches for solving problems, including tools to accomplish this goal.	
	10: Establish appropriate control loops for updates to standards and HIT.	

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Systemic Factor	Recommendation	Action Item(s)
Inadequate regulatory emphasis on HIT safety	<u>11</u>: Assign regulatory oversight of HIT safety to ONC or another appropriate group. Include the explicit directive to develop and include safety-related certification criteria for HIT and the ability to limit the inclusion of "hold harmless" clauses in HIT contracts.	
	<u>12</u>: Establish incentives for using certified HIT throughout the entire healthcare ecosystem.	
Flawed communication and coordination	<u>13</u>: Develop formal processes for inclusion of laboratorians in the multidisciplinary teams responsible for decisions about laboratory data needs, representations, and interfaces at care facilities.	

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Conclusion
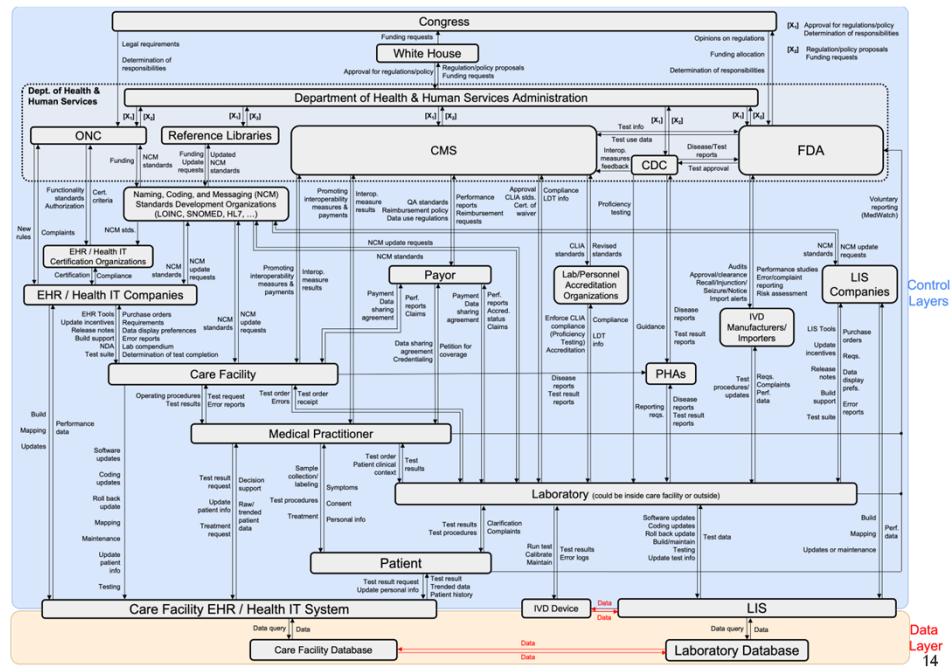
To improve quality and safety, the first step is to identify where the gaps, redundancy, and incompleteness exist in the current quality and safety control structure and then redesign responsibilities, authority, and accountability.

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This is not a complete list of key informants from the study due to requested privacy of their institutional involvement.

Questions, Comments, Observations, Discussions, Feedback, Follow-up