System Safety within Laboratory Data Exchanges

A System Theoretic Process Analysis (STPA) across the U.S. Laboratory Data Ecosystem

Focused on understanding how the laboratory data ecosystem works today, this project conducted a systems analysis to identify weaknesses and sources of adverse events in the laboratory ecosystem. Through interviews with 50 stakeholders, the research team developed a model of the ecosystem and analyzed it to identify the causal factors in common types of adverse events related to diagnostic laboratory data and provided recommendations for improvement and system redesign.

Causal Factors Addressable by the SHIELD* Collaborative Community

1 Decentralized & Missing Oversight

Recommendation 1: Assign responsibility for addressing gaps in the regulatory oversight of laboratory data exchanges between system components that are regulated by different agencies.
Recommendation 2: Identify the data and standards needs of regulatory agencies and ensure they have the ability to use them appropriately.
Recommendation 3: Identify regulatory gaps in other areas of the laboratory ecosystem through additional system analysis.

2 Inadequacies and Gaps in Laboratory Data Standards, including loosely constrained, ambiguous, and outdated standards.

Recommendation 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. Stakeholders must be incentivized to use it.
Recommendation 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.
Recommendation 6: SDOs must continuously support users by identifying and eliminating ambiguities in implementation guides for Health Information Technology (HIT) standards.

* Learn more about the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) Collaborative Community

Causal Factors to be addressed by *other* Components of the Data Ecosystem

Simply addressing the causal factors addressable by the SHIELD Collaborative Community is not enough to significantly reduce adverse events related to laboratory data. Causal factors in other parts of the system need to be addressed:

3 Inaccurate perceptions of risks with respect to both laboratory data and the use of health information technology (HIT)

Recommendation 7: Investigate systemic sources of diagnostic error both before and after adverse events.
Recommendation 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.”

4 Lack of a systems view by participants in the system

Recommendation 9: Educate the healthcare community on system safety engineering and systemic approaches for solving problems, including the use of tools to accomplish this goal.
Recommendation 10: Establish appropriate controls for updates to standards and HIT.

5 Inadequate regulatory emphasis on the safety involved in health system information technology

Recommendation 11: Assign regulatory oversight of HIT safety to ONC or appropriate group. Include explicit directive to develop and include safety-related certification criteria for HIT and ability to limit the inclusion of “hold harmless” clauses in HIT contracts.
Recommendation 12: Establish incentives for using certified HIT throughout the entire healthcare ecosystem.

6 Flawed communication and coordination.

Recommendation 13: Develop formal processes for including laboratorians in the multidisciplinary teams responsible for decisions about laboratory data needs, representations, and interfaces at care facilities.

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