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

2024 STAMP Workshop

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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 while 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)
## Setting the Goals of our System Analysis

<table>
<thead>
<tr>
<th>Losses</th>
<th>Hazards</th>
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<tbody>
<tr>
<td><strong>L-1:</strong> Loss of life or injury to patient</td>
<td><strong>H-1:</strong> Patients receive less than acceptable standard of care</td>
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<td><strong>L-2:</strong> Loss of reputation or trust in the laboratory ecosystem</td>
<td><strong>H-2:</strong> Laboratory ecosystem stakeholders including patients lose trust in the laboratory data being collected, shared, analyzed and reported</td>
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Using interviews to understand current system

50 Stakeholders interviewed
Detailed Control Structure
No reporting of terminology related problems

Insufficient evidence to justify new directives

Inappropriate treatment

Non-comparable test results in same field

No formal feedback channels for mapping guidelines

No reporting of terminology related problems

No reporting of terminology related problems

No reporting of terminology related problems

No reporting of terminology related problems

Data Layer (EHR and LIS)
Inappropriate treatment
Non-comparable test results in same field

No control loop for updating reference terminologies in HIT systems
No control loop for proactively identifying unintended consequences of updates

No control loop for ensuring consistent mapping guidelines
No control loop for following mapping/implementation guidelines
No control loop for proactively identifying unintended consequences of updates
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 SHIELD

Addressable by the rest of the ecosystem
<table>
<thead>
<tr>
<th>Systemic Factor</th>
<th>Recommendation</th>
<th>Action Item(s)</th>
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<tbody>
<tr>
<td>Decentralized and missing oversight</td>
<td>1: Assign responsibility for addressing gaps in the regulatory oversight of laboratory data exchanges between system components that are regulated by different agencies.</td>
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<td>2: Identify the data and standards needs of regulatory agencies and ensure they have the ability to use them appropriately.</td>
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<td>3: Encourage the identification of regulatory gaps in other areas of the laboratory ecosystem through additional systems-theory-based analyses.</td>
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<td>Inadequacies and gaps in laboratory data standards</td>
<td>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.</td>
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<td>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.</td>
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<td>6: SDOs must continuously support users by identifying and eliminating ambiguities in implementation guides for HIT standards.</td>
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<td>Inaccurate perceptions of data and HIT risks</td>
<td><strong>7: Proactively and retroactively investigate systemic sources of diagnostic error.</strong></td>
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<td><strong>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.”</strong></td>
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<td>Lack of a systems view by system participants</td>
<td><strong>9: Educate the healthcare community on systems engineering and systemic approaches for solving problems, including tools to accomplish this goal.</strong></td>
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<td><strong>10: Establish appropriate control loops for updates to standards and HIT.</strong></td>
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<td>Inadequate regulatory emphasis on HIT safety</td>
<td>11: 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.</td>
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<td>12: Establish incentives for using certified HIT throughout the entire healthcare ecosystem.</td>
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<td>Flawed communication and coordination</td>
<td>13: Develop formal processes for inclusion of laboratorians in the multidisciplinary teams responsible for decisions about laboratory data needs, representations, and interfaces at care facilities.</td>
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Conclusion
Acknowledgments

- FDA SHIELD Program
- SHIELD collaborative community
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Questions, Comments, Observations, Discussions, Feedback, Follow-up