



System Safety within Laboratory Data Exchanges Report: Over-the-Counter and Point-of-Care Testing

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A System-Theoretic Process Analysis (STPA) of Over-the-Counter and Point-of-Care Testing in the U.S. Diagnostic Laboratory Data Safety Management System

Summary

This study extends the work of the System Safety within Laboratory Data Exchanges Report (clinical laboratories report) [1] to laboratory data from over-the-counter (OTC) point-of-care (POC) and in vitro diagnostic (IVD) test data. As in the clinical laboratories report, the OTC and POC systems were analyzed using System-Theoretic Process Analysis (STPA), an analysis technique based on system theory that can identify scenarios leading to adverse events in the design of complex, adaptive, and human-intensive systems.

The same losses are considered in both reports: loss of life or injury to patients and loss of reputation or trust in the laboratory ecosystem. These losses were associated with the following two hazards: (1) patients receive less than the acceptable standard of care, and (2) laboratory ecosystem stakeholders lose trust in the laboratory data being collected, shared, analyzed, and reported.

To understand how these hazards could arise with OTC and POC testing, models of the OTC and POC testing systems were developed using information derived from additional stakeholder interviews. These models were then analyzed to identify ways the current system design may lead to the losses considered.

Analyses of the two new models identified the same unsafe control actions (UCAs) and associated causal scenarios as in the clinical laboratories report. Many new UCAs and loss scenarios were identified; however, to reduce redundancy, duplicated UCAs and loss scenarios are mostly excluded from this report.

Overall, it was found that OTC and POC IVD test data is undercollected and underutilized. The lack of consistent, quality data negatively impacts the ability of regulatory agency personnel to make informed decisions, delays treatment decisions (or makes them more difficult), and reduces the information available to monitor the performance of the devices themselves. The controls used in traditional laboratory settings are inadequate to ensure the safety of OTC/POC testing.

Several systemic factors were identified that contribute to potential losses across the entire system. Many of these systemic factors were also identified in our clinical laboratories report, but some are unique to OTC/POC testing. In the list below, the factors that were also present in our clinical laboratories report are marked with an asterisk (*). To improve the OTC and POC data safety management systems, recommendations were identified for each systemic factor.

- ***Decentralized and Missing Oversight****

Different components of OTC/POC testing are controlled by different regulatory agencies. In addition, many components and system behaviors have no controls or are inadequately controlled. Several government agencies and organizations have developed tools to improve the flow of safe, complete data throughout the system. However, the disparate approaches and tools do not work as well together or on particular components as planned or intended.

Recommendation 1: Assign responsibility for addressing the regulatory gap in the certification of POC IVD devices and their operation in CLIA-compliant environments.

Recommendation 2: Consolidate and coordinate responsibilities for managing OTC test data collection.

- ***Framework for OTC and POC Testing Oversight Lacks Operational Specificity***

OTC and POC testing occur in many different contexts and environments. The regulatory framework controlling the tests, however, is not sufficiently tailored to the specific challenges of all of those environments. These challenges are particularly common when testing occurs outside of traditional patient care facilities.

Recommendation 3: Ensure that regulatory requirements and incentives regarding OTC/POC testing data are tailored to the needs of different users of the testing data and the specific challenges of the type of testing facility.

Recommendation 4: Study the usage of OTC tests outside of controlled laboratory settings (both testing and reporting behaviors).

- ***Flawed Communication and Coordination****

Creating appropriate controls and regulations on the OTC/POC system relies on correct identification of the problems to be solved. When problems are either not discovered or not reported to the manufacturers or the regulatory authorities, safe and effective decision-making is difficult. OTC and POC testing present unique challenges in both identifying and communicating problems when they arise.

Recommendation 5: Incentivize the use of POC devices that upload test results automatically to EHRs.

Recommendation 6: Facilitate the creation of a single platform where all OTC data can be sent to appropriate stakeholders based on data needs and incentivize or require reporting to that platform where possible.

- ***Inadequacies and Gaps in Laboratory Data Standards and their Usage****

OTC and POC systems are impacted by the same challenges involving standards as the clinical laboratory system, such as difficulties with inconsistent mapping across facilities and incentive structures that do not encourage standard usage across all system components. Additional challenges can occur (1) when data cannot be shared with the necessary stakeholders (like public health agencies) due to a lack of common standard usage, or (2) when data from OTC/POC tests and traditional tests are indistinguishable to decision-makers.

Recommendation 7: Develop requirements regarding the appropriate processing, storage, and display of POC data in safety-related certification criteria for health IT (HIT) systems.

Recommendation 8: Identify potential incentives or requirements to increase the adoption of data standards for OTC and POC testing.

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A System-Theoretic Process Analysis (STPA) of Over-the-Counter and Point-of-Care Testing in the U.S. Diagnostic Laboratory Data Safety Management System

Abstract

This report details the results of research conducted for the FDA by Synensys and researchers at MIT to expand the investigation of the causes of adverse events in the U.S. diagnostic laboratory data ecosystem to over-the-counter (OTC) and point-of-care (POC) testing. The same approach to modeling and analyzing complex, adaptive systems was used to identify scenarios in the OTC/POC laboratory system design that can lead to adverse events. The method used is based on system theory and uses an analysis technique called System-Theoretic Process Analysis (STPA). Causal factors that lead to adverse events were identified; some were present in the clinical laboratory system, but others were unique to the OTC/POC system design. The causal factors drove the development of recommendations to mitigate the systemic factors and reduce losses throughout the system.

1. The Problem and Research Goals

OTC and POC testing became an important component of the COVID-19 response across the United States. During the COVID-19 pandemic, POC drive-through sites were established in many urban and suburban areas across the U.S. to reduce the spread of infection, increase disease surveillance, and improve patient outcomes through early detection [2]. At the same time, OTC testing devices that required patients to administer tests and interpret the results independently became more widespread as the pandemic evolved [3].

Laboratory test results from either traditional clinical laboratories or POC testing affect 60-70% of all clinical decisions [4], and results from OTC tests are starting to be accepted for making care decisions like COVID treatments or insulin dosages. The quality of the data produced from these non-traditional test settings can directly impact the quality of treatment decisions: if OTC/POC testing data is to be used more broadly for making treatment decisions, it is imperative to identify and mitigate the hazards that can contribute to patient harm.

This report is an addendum to the original “System Safety within Laboratory Data Exchanges” report published in September 2023 [1], referred to herein as the “clinical laboratories report.” The additional research in this addendum started in January 2024. Interviews were conducted with 25 experts from several groups within the OTC/POC testing system in order to understand how the system works today. Formal models of the OTC and POC safety management systems were constructed, and STPA was used to analyze this model and identify scenarios that can lead to adverse events due to problems involving OTC and POC data.

The losses this analysis focused on were the loss of life or injury of patients and the loss of trust in the laboratory data system. STPA is a relatively new and powerful technique being used for hazard analysis of today’s most complex sociotechnical systems [5]. A detailed introduction to system theory and the modeling and analysis method used to obtain the results is available in the original report and is not included here.

The next section presents a short overview of the OTC/POC testing system today. Section 3 presents the results of the analysis, including specific scenarios that could lead to adverse events. Section 4 presents general systemic flaws in the overall laboratory system design leading to adverse events and associated final recommendations to improve the safety management system for OTC/POC testing in the U.S.

2. The OTC/POC Safety Management System Today

POC testing refers to any test whose result can be obtained at the patient’s immediate location without requiring the sample to be sent to a dedicated laboratory facility. POC tests are used in hospitals, clinics, urgent care centers, physician offices, long-term care facilities, retail pharmacies, schools, community health settings, and workplaces. POC tests can accelerate clinical decision-making as they usually have faster turnaround times than traditional clinical laboratory testing [6]. POC testing results are usually shared with patients either formally or informally. Tests administered in traditional care facilities (like urgent care centers or hospitals) usually upload results to the patient’s electronic health record (EHR), but data from other locations may never make it into a patient’s EHR.

OTC testing usually involves a patient, family member, or other non-professional caregiver administering the test, usually at home, and interpreting the results independently. OTC tests are often used for patient screening of a health condition (i.e., COVID, pregnancy, etc.) or for monitoring a known health condition (i.e., blood glucose monitoring for diabetic patients). Typically, data collected by patients during OTC tests at home are not systematically transmitted to the patient’s EHR.

All facilities in the U.S. that perform POC laboratory testing are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Some CLIA tests have reduced requirements for use and are called “waived tests.” Waived tests include, but are not limited to, test systems cleared by the FDA for home use (OTC). Waived tests are generally believed to have lower risk to patient outcomes than moderate or high-risk testing, which cannot be waived by CLIA. OTC tests are generally not covered by CLIA unless they are administered or reported by a medical practitioner [7].

At the same time, the Food and Drug Administration (FDA) is responsible for regulatory oversight of in vitro diagnostic (IVD) devices and test kits used in the U.S. to perform diagnostic tests, including OTC and POC devices. During the pandemic, the FDA issued emergency use authorizations (EUA) for 19 OTC COVID test kits for at-home testing, as well as many IVDs for POC and traditional clinical laboratory testing [8]. The FDA relies on real-world data (RWD) from IVD manufacturers to ensure the devices and test kits are safe and effective. Real-world data was especially important for monitoring devices approved through the EUAs. Before the pandemic, EUAs were not frequently used to approve diagnostic medical devices.

3. Research Method

In engineering, it is common to build models of the system being created or studied and to analyze those models to obtain important insights about the system. This approach has been particularly beneficial for complex systems, which can display unexpected behaviors or interactions that might not be readily foreseen or understood without the aid of a model. When the system is a physical or natural system, the models typically are composed of mathematical equations, often using differential calculus. The modeling and analysis of human or social systems, such as the diagnostic data safety management system in this report, uses a different type of engineering model and analysis method based on systems theory or systems thinking. The goal is to identify how the system could operate in a way that leads to adverse events. This information is then used to design or redesign the system to eliminate such events.

An introduction to systems theory and to the systems-theoretic approach used in this research can be found in the clinical laboratories report [1]. In summary, the systems analysis technique used to analyze the safety of OTC/POC testing here is called System-Theoretic Process Analysis (STPA). STPA consists of four steps. First, the basic purpose of the analysis and the boundary of the system being analyzed are determined. Next, a control structure model of the system is created. In the third step, unsafe control actions (UCAs) are identified by determining how each control action that is available to a controller in the system may become unsafe if performed in certain contexts. Finally, the fourth step identifies events that can lead to UCAs, which are called the *loss scenarios*. These loss scenarios can be used to determine how to redesign the system as a whole to eliminate them from the design or to minimize their impact if elimination is not feasible.

To create the models used in this research, interviews were conducted with 25 key stakeholders across the system. Like the clinical laboratory data system, the OTC/POC testing system in the United States is sociotechnical. Interviewees (subject matter experts labeled “key informants”) included regulatory personnel, medical practitioners, laboratory technicians, standard developers, payors, health information technology (HIT) professionals, health informaticists, and beyond. Some of the key informants were the same as those interviewed for the original report, while others were new. A list of key informants is included in Appendix A.

The STPA process in this research started with the losses and hazards identified in the original report, as well as the detailed control structure built over the course of the first year of the project. As the OTC/POC interviews progressed, the control structure was adapted to highlight the differences between OTC/POC testing and traditional clinical laboratory testing. Ultimately, two separate control structures were built to represent OTC and POC testing.

The scenarios were generated from the list of UCAs. Each scenario was constructed from discussions with the key informants, as well as a review of relevant literature. After being generated, scenarios were validated by the key informants. Some scenarios were augmented with real-world examples uncovered through parallel efforts of the SHIELD (Systemic Harmonization and Interoperability Enhancement for Laboratory Data) collaboration.

The steps are explained further in the next section of this report, which presents the results of the laboratory data system research performed for this part of the contract.

4. Research Results

The first step of STPA involves identifying the losses and hazards of interest to the system stakeholders. The OTC/POC testing stakeholders are the same as those in the clinical laboratory testing system. Therefore, the same losses and hazards from the original report are used here:

4.1 Losses and Hazards

Table 1. Losses and Hazards for the OTC/POC Testing System

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

4.2 OTC Testing Results

4.2.1 OTC Testing Control Structure

The OTC testing system consists of patients who acquire tests, carry them out, and interpret their results with or without guidance from practitioners. It also includes data consumers, including device manufacturers, public health agencies, and regulators who use OTC test data for decision-making. The model in Figure 1 highlights the control structure that exists between components of the OTC testing safety management system.

One critical feature of the model in Figure 1 is that there is no clinical laboratory, and involvement of medical practitioners and care facilities is limited. The patient is responsible for much more in the OTC system than in the clinical laboratory system or the POC system. For OTC testing, patients are responsible for obtaining the sample, running and interpreting the test, reporting results, and more. However, there are relatively few controls on the patients themselves.

The model in Figure 1 only explicitly shows the interactions relevant to the defined scope of the analysis. Complete descriptions of all controllers listed in Figure 1 are located in Appendix B. Table 2 contains descriptions and clarifications regarding certain terms used in the control structure that are unique to OTC testing.

Table 2. Clarifications on Key Terms Used in Figure 1

Term	Explanation
Test Vendor	The test vendor is the organization that sells or gives the OTC tests to the patient. Vendors are often brick-and-mortar pharmacies but can also include online retailers, government programs, and others.
OTC Test Result Hubs	These hubs (like Report Stream and AIMS) interface between OTC data and public health agencies (PHAs). They can be run by government agencies or private organizations.
IVD Companion App	IVD companion apps are any applications (mobile or web-based) that patients use to collect, store, and share test result data. The data may be transmitted automatically or through manual data entry from OTC tests. Companion apps may interpret test results for the patient, while others simply store data. The apps may or may not transmit data to others in the system, such as PHAs, through data hubs or EHRs.

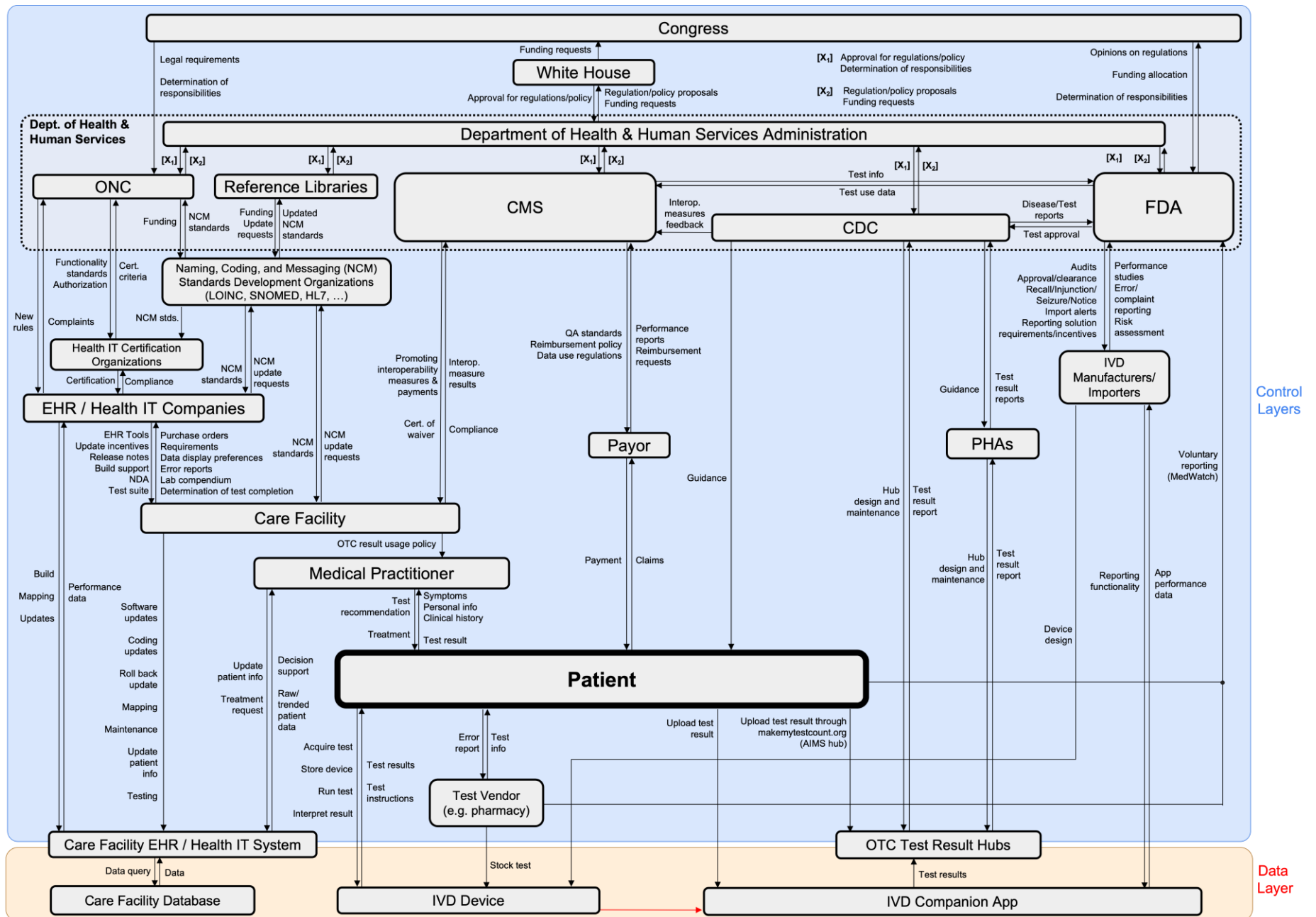


Figure 1. Detailed control structure for OTC testing safety management system

4.2.2 OTC Testing UCAs

Several hundred UCAs were identified across the OTC testing system. Table 3 lists the UCAs analyzed for the identification of causal scenarios. Note that some results presented here overlap with the results already documented in the clinical laboratory report [1]. Each UCA-scenario pair presented in this addendum fits into one of the following categories:

- Both the UCA and the scenario were already documented in the original report
- The UCA was already documented in the original report, but the scenario is unique to OTC testing and was not in the original report
- Both the UCA and the scenario are unique to OTC testing and were not in the original report

To avoid repetition, the UCA-scenario pairs that were already documented in the original report are not included in full in this addendum. The UCAs shown in Table 3 below includes only the UCAs used to generate new scenarios.

Because many of the UCAs identified by STPA share contributing factors and originate from the same (or very similar) scenarios, a detailed discussion of all UCAs is not included. The nine UCAs listed in Table 3 were selected based on those leading to the most distinct, unique, and helpful scenarios. These UCAs either came up frequently or were emphasized as important or urgent during key informant interviews. UCAs that generated scenarios or recommendations that were already generated by other UCAs were excluded to reduce redundancy. The sharing of causal factors across multiple UCAs means that analysis of one UCA can generate recommendations that preclude or mitigate the risk of several others.

Each UCA is traceable to one or both of the hazards identified in Table 1. Some UCAs are directly traceable to the hazard of a patient receiving less than the acceptable standard of care (e.g., a medical practitioner providing inappropriate treatment), while other UCAs are further removed from the patient but are still traceable to the same hazard (e.g., a manufacturer not recalling an OTC device).

Neither this list nor the longer list available in Appendix C is an exhaustive set of unsafe actions that may lead to the identified hazards. However, the ones shown below provide insight into the most important design problems identified in the OTC testing system.

Table 3. Consolidated List of Unsafe Control Actions for OTC Testing

ID	Controller	Control Action	UCA	Hazard
OTC-1	CDC/PHAs	Provide guidance	CDC/PHAs do not provide guidance in time to limit disease outbreak.	H-1, H-2
OTC-2	Medical Practitioner	Provide treatment	Medical practitioner does not provide treatment when patient needs treatment to avoid harm.	H-1
OTC-3	Medical Practitioner	Provide treatment	Medical practitioner provides treatment too late to avoid patient harm.	H-1
OTC-4	FDA	Approve OTC test	FDA approves an OTC test that does not facilitate data reporting by test users when that data is needed to inform public health decisions or test decisions.	H-1, H-2
OTC-5	FDA	Approve OTC test	FDA does not approve an OTC test when that test would enable better patient care decisions.	H-1
OTC-6	FDA	Issue corrective action to IVD manufacturer	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device.	H-1, H-2
OTC-7	Patient	Seek medical treatment	Patient does not seek medical treatment when treatment is needed to avoid harm.	H-1
OTC-8	IVD Manufacturer	Provide data collection mechanism	IVD manufacturer does not provide data collection mechanism when data is needed to inform regulatory or public health guidance.	H-1, H-2
OTC-9	Standards Development Organizations	Create new data messaging standards	SDO does not create a new data messaging standard format when the current standard format is insufficient to capture results from new OTC tests.	H-1, H-2

4.2.3 OTC Testing Causal Scenarios

From the nine UCAs listed in Table 3, approximately fifty causal scenarios were developed. Scenarios describe why a controller may reasonably make an action that is unsafe given the current system design. While scenarios describe controllers’ decisions and behaviors, assigning blame is not the goal of STPA. Instead, the goal is to understand why a controller might reasonably choose an action that is not safe. As in the original report, these scenarios illuminated numerous systemic causal factors that can lead to the UCAs and hazards.

A complete list of generated scenarios for OTC testing is available in Appendix D. This list includes causal scenarios from the broader diagnostic healthcare ecosystem that were discovered during the interview process, even if they do not reflect problems specific to laboratory data quality and interoperability. Though these scenarios are outside the scope of this work and are not discussed in detail, they are included in the list for completeness. They may be used in future studies to improve the safety of the system even further.

As in the original report, to aid with scoping and clarity, the causal scenarios have been subdivided into three categories, denoted A, B, and C. This categorization is based on how closely related the scenarios are to the direct scope of this study. These categories are outlined in **Error! Reference source not found.** below. For a more detailed description of what categories A, B, and C mean, see section 4.5 of the original report [1].

Table 2. Scenario Categorization Scheme

Category	Description
A	In-scope, directly related to issues of laboratory data, high explanatory power
B	Generally in-scope, contain data-related contributions but are primarily driven by out-of-scope elements, data-related components likely addressed in recommendations for mitigating A-level scenarios
C	Out of research scope, do not contain data-related contributions, but worth a mention for research completeness

The following subsections present two examples (Table 5 and Table 6) of A-level scenarios from different controllers at different hierarchical levels of the control structure for OTC testing. These two scenarios were selected because of their high explanatory power, and because they highlight the kind of analysis that was performed for the other scenarios in Appendix D. Additionally, the systemic recommendations generated from these scenarios may preclude or mitigate not only them, but several other scenarios as well. Alongside the two selected A-level scenarios is a visualization (Figure 2 and Figure 3) that traces the path of the scenario through the control structure and highlights the contributions of several controllers.

4.2.4 Example OTC Scenario 1

Table 5. Scenario OTC-6-2

Category	Scenario Information
Related UCA	FDA issues corrective action, like a recall, to an OTC test manufacturer too late following a series of inappropriate results from OTC devices
Controllers involved	<ul style="list-style-type: none"> • IVD manufacturer • FDA
Scenario	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device because they did not receive adequate post-market data from tests. It is difficult to get data from patients after they take an OTC test, even in a study environment. Because there is no way for the FDA or the IVD companies to require that patients report their results there are limitations to the amount of available post-market data. The IVD companies may not get notification of problems as patients may not always

	<p>be able to determine if the test worked or not. The FDA might require post-market data collection if they were concerned, with reason, for a certain performance aspect of the test. However, it may be difficult to detect when post-market data is necessary because when data is reported, it may not always be attached to a unique device identifier that would allow regulators to identify problems with a specific device, or specific lot of a device. Post market surveillance may only occur regularly when IVDs want to expand the population of individuals who are approved to use the test (i.e., children).</p>
Causal Factors	<ul style="list-style-type: none"> • Flawed communication and coordination • Framework for OTC and POC Testing Oversight that Lacks Operational Specificity

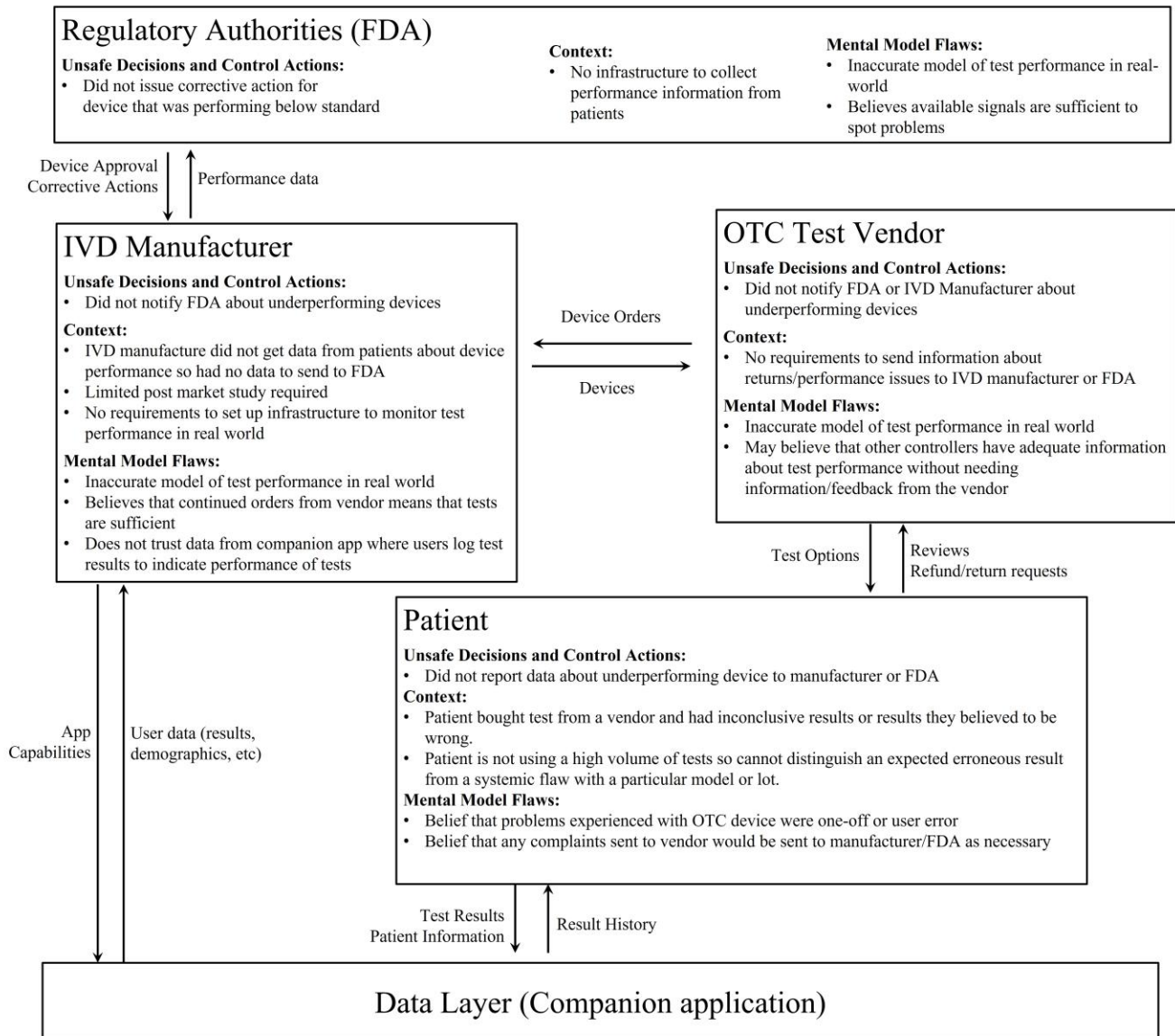


Figure 2 Visualization of Scenario OTC 6-2

4.2.5 Example OTC Scenario 2

Table 6. Scenario OTC-1-4

Category	Scenario Information
Related UCA	PHA does not provide guidance in time to limit disease outbreak
Controllers involved	<ul style="list-style-type: none"> • PHA • IVD manufacturer • FDA • HIT companies
Scenario	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have data to track disease outbreaks. OTC test devices may have the ability to transmit data to a database, for example a companion app, but that data may not be available beyond the patient/IVD company. Transmitting the data may take time and money and there may not be a direct benefit to the company to transmit that data. The cost may be high because different states and PHAs have different needs and uses for data. Because there is high variance across the nation, it would be difficult for OTC test manufacturers to ensure their product complied with the requests from the 64 different jurisdictions in the United States.</p> <p>There may be an option to send test results to a “data hub” like CDC’s ReportStream or APHL’s AIMS. These data hubs are able to transfer data to the appropriate PHAs in the requested format and frequency.</p> <p>The AIMS data hub is connected to all PHA jurisdictions in the U.S. However, AIMS is privately run and costs money to use. Government funding is available to ensure that AIMS can be used by OTC test manufacturers to report COVID data for free, but the funding is time limited and may not be extended.</p> <p>ReportStream is free to use but only accepts data from certain OTC tests (Flu, Monkey Pox, and COVID). It also is not yet connected to all PHAs.</p> <p>Additionally, OTC test manufacturers may not report data through the data hubs at all because there is no longer a requirement for IVD manufacturers to send data to PHAs. During the COVID EUA period, there was a requirement for FDA approved OTC COVID tests to have plans to send data, but that requirement has lapsed. Furthermore, this requirement only applied to COVID tests so manufacturers of other tests never had any incentive to set up reporting systems.</p>
Causal Factors	<ul style="list-style-type: none"> • Flawed communication and coordination • Decentralized and Missing Oversight

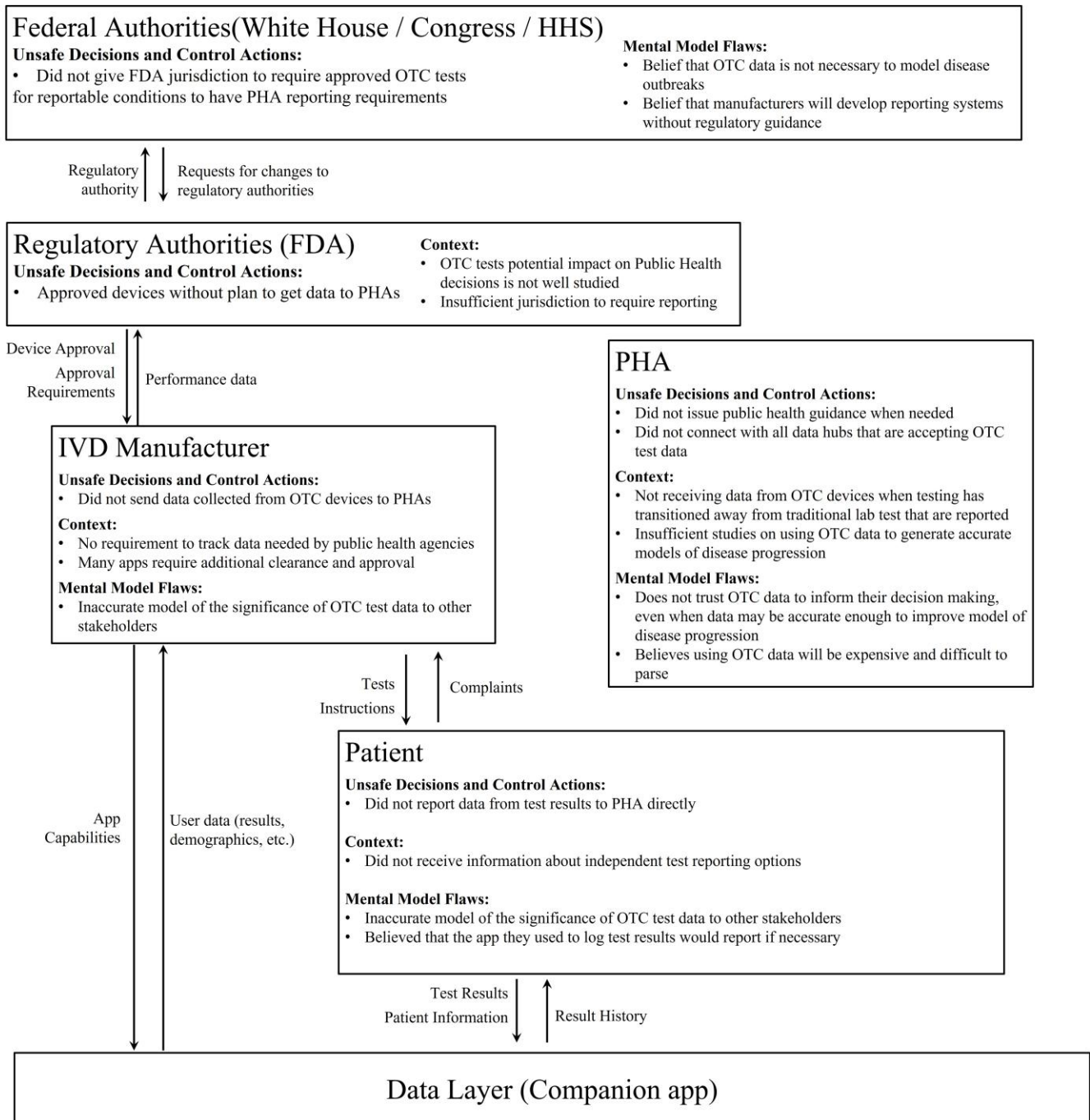


Figure 3. Visualization of Scenario OTC-1-4

4.3 POC Testing Results

4.3.1 POC Testing Control Structure

The POC testing system consists of patients that undergo testing without samples having to be sent to laboratories, practitioners who order and conduct these tests, and data consumers who use test data for decision-making, including public health agencies, regulators, accreditors, payors, information technology vendors, data standards professionals, and IT system support personnel. The model in Figure 4 shows the interactions between components in the POC testing safety management system.

The main differences from the OTC model are that the tests are conducted and ordered by medical practitioners, and the results can be directly added to the patients' EHR. Complete descriptions of all controllers listed in Figure 4 are located in Appendix B. Table 7 below contains descriptions and clarifications regarding the terms used in the control structure that are unique to POC testing.

Table 7. Clarifications on Key Terms Used in Figure 4

Term	Explanation
Ordering/Treating Practitioner	The medical professionals (e.g., clinicians or nurses) who place orders for POC tests, interpret the test results, and provide treatment/care.
Testing Practitioner	The medical professionals (e.g., clinicians or nurses) who collect patient specimens at the point of care, carry out the diagnostic tests, and communicate the results to the ordering practitioner. They may or may not be the same person as the ordering practitioner.

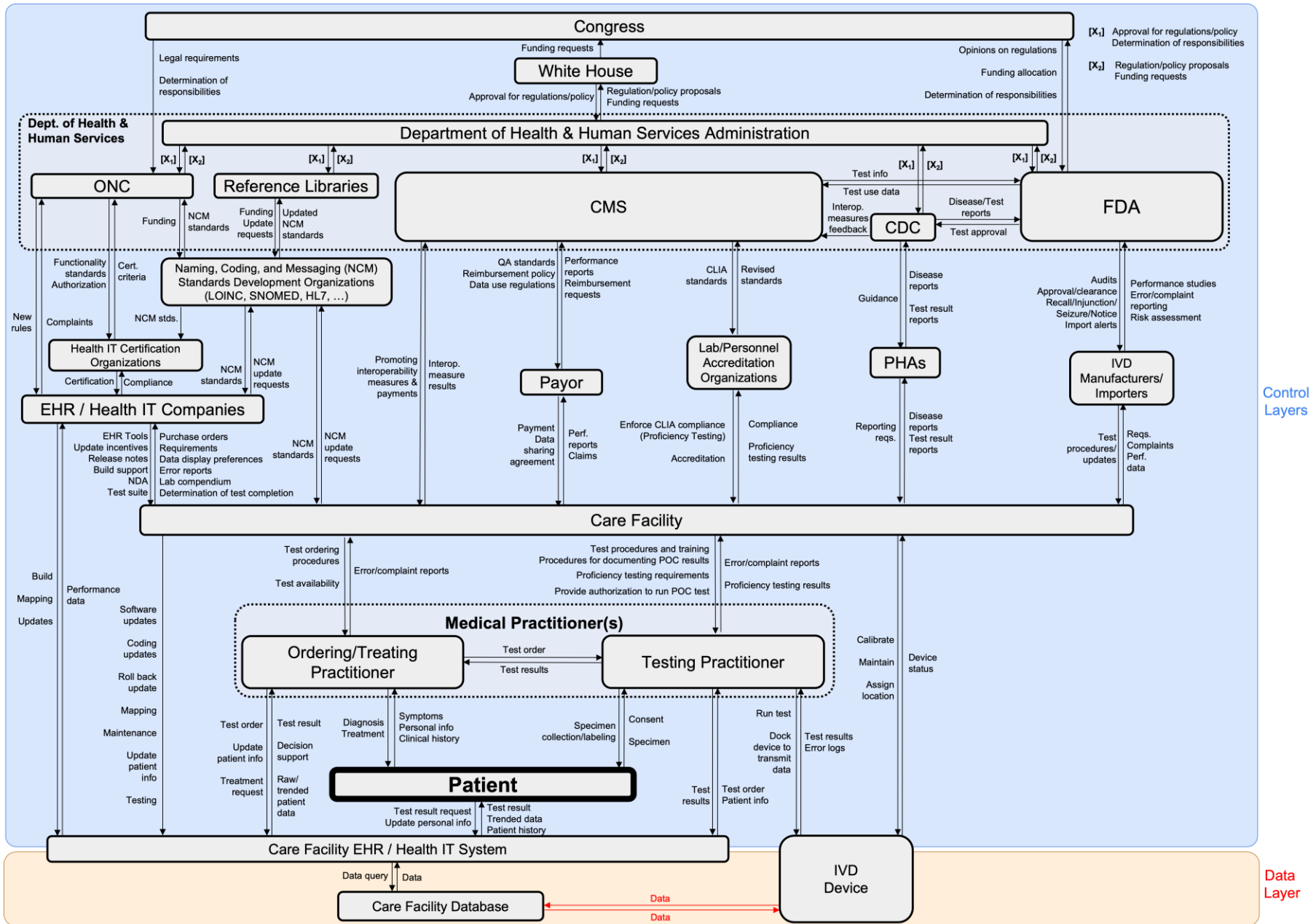


Figure 4. Detailed control structure for POC testing safety management system

4.4 POC Testing UCAs

Several hundred UCAs and scenarios were identified across the POC testing system. Table 8 lists the UCAs that were analyzed by STPA for POC testing. As with Table 3, Table 8 includes only the UCAs that are either entirely new or have new scenarios generated for them.

Once again, neither this list nor the list available in Appendix C can be considered an exhaustive set of unsafe actions that may lead to the hazards. However, those shown do provide insight into important design problems in the POC testing system.

Table 8. Consolidated List of Unsafe Control Actions for POC Testing

	Controller	Control Action	UCA	Hazard
POC-1	Medical Practitioner	Provide treatment to patient	Medical practitioner provides treatment that does not match the patient's condition.	H-1
POC-2	Medical Practitioner	Provide treatment to patient	Medical practitioner provides treatment too late to avoid patient harm.	H-1
POC-3	Medical Practitioner	Run laboratory test	Medical practitioner runs laboratory test that is not the best/most appropriate test to diagnose a disorder/disease.	H-1
POC-4	Care Facility	Provide medical practitioner authorization to perform POC test	Care facility does not provide authorization for a medical practitioner to perform POC test when practitioner needs to perform test to inform immediate patient care.	H-1
POC-5	Care Facility	Acquire POC test	Care facility does not acquire POC test that could improve clinical decision-making.	H-1
POC-6	CMS + Laboratory/ Personnel Accreditation Organizations	Provide care facility/ laboratory authorization to perform test	CMS does not provide authorization for a care facility/laboratory to perform test when test is needed to inform patient care.	H-1
POC-7	IVD Manufacturer	Release POC IVD device update	IVD manufacturer does not release POC IVD device update when device does not perform to expected performance levels.	H-1
POC-8	IVD Manufacturer	Provide connectivity functionality between POC device and HIT system	IVD manufacturer does not provide connectivity functionality between POC IVD device and HIT system when device's results need to be repeatedly accessible after they are generated.	H-1
POC-9	IVD Manufacturer	Provide connectivity functionality between POC IVD device and HIT system	IVD manufacturer provides connectivity functionality between POC IVD device and HIT system using data standard that is not compatible with other systems/devices.	H-1

POC-10	FDA	Issue corrective action to IVD manufacturer	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from POC IVD device	H-1
POC-11	Payor	Require prior authorization for coverage/reimbursement of test	Payor requires prior authorization for coverage/reimbursement of POC test that would be helpful to inform immediate patient care	H-1
POC-12	CDC/PHAs	Provide healthcare guidance	CDC/PHAs provide inappropriate healthcare guidance	H-1, H-2

4.4.1 POC Testing Causal Scenarios

From the 12 POC testing UCAs listed in Table 8, approximately 40 causal scenarios were generated. The full list of generated scenarios for POC testing is available in Appendix D. Once again, this list includes causal scenarios that were identified in the broader diagnostic healthcare ecosystem, even if they do not reflect problems specific to laboratory data quality and interoperability. Appendix D also indicates the scenarios already documented in the clinical laboratory report [1] that are also relevant to POC testing.

The POC testing scenarios have also been subdivided into the A, B, and C categories, explained in Table 4. The following subsections present three example A-level scenarios from different controllers at different hierarchical levels of the control structure for POC testing (Table 9, Table 10, and Table 11). Like the example OTC scenarios, these three scenarios were selected because of their high explanatory power. Alongside the scenarios is a visualization that traces their path through the control structure (Figure 5 and Figure 6).

4.4.2 Example POC Scenario 1

Table 9. Scenario POC-I-2

Category	Scenario Information
Related UCA	Medical practitioner provides treatment that does not match the patient’s condition
Controllers involved	<ul style="list-style-type: none"> • Medical practitioner • Care facility • IVD manufacturer • FDA • CMS
Scenario	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they had insufficient diagnostic information available to inform their process model of the patient’s condition. That may occur if the interpretation of a POC test result depends on additional contextual information that is not automatically conveyed to the practitioner alongside the test result.</p> <p>For example, a laboratory and a POC test used for the same purpose (e.g., measuring blood calcium) may not provide the same type of data and may not possess the same reference range (e.g., POC test only measures ionized calcium, not serum calcium levels). If there is no connectivity between a POC device and the care facility EHR, the medical practitioner may not have access to the appropriate reference range at the point of care, which would be available if the result were shared from a laboratory and visible in the EHR. An abnormal result that is outside the reference range may therefore not be flagged from a POC result.</p> <p>Many POC devices may have the ability to integrate with EHRs, but the underlying complexity and cost of doing so is outweighed by the low volume of POC testing that is occurring. Additionally, many IVD manufacturers may provide proprietary options for connectivity that use standards that are incompatible with devices provided by other manufacturers, meaning care facilities need to invest in separate, individual interfaces between each POC device and their EHR.</p> <p>Regulatory or statutory incentives to ensure connectivity between POC devices and HIT systems are scarce. Customers may also have the ability to opt in or out of delivering data from the POC device into a data platform (EHR), and only a small proportion of customers may opt in.</p>
Causal Factors	<ul style="list-style-type: none"> • Decentralized and missing oversight • Flawed communication and coordination

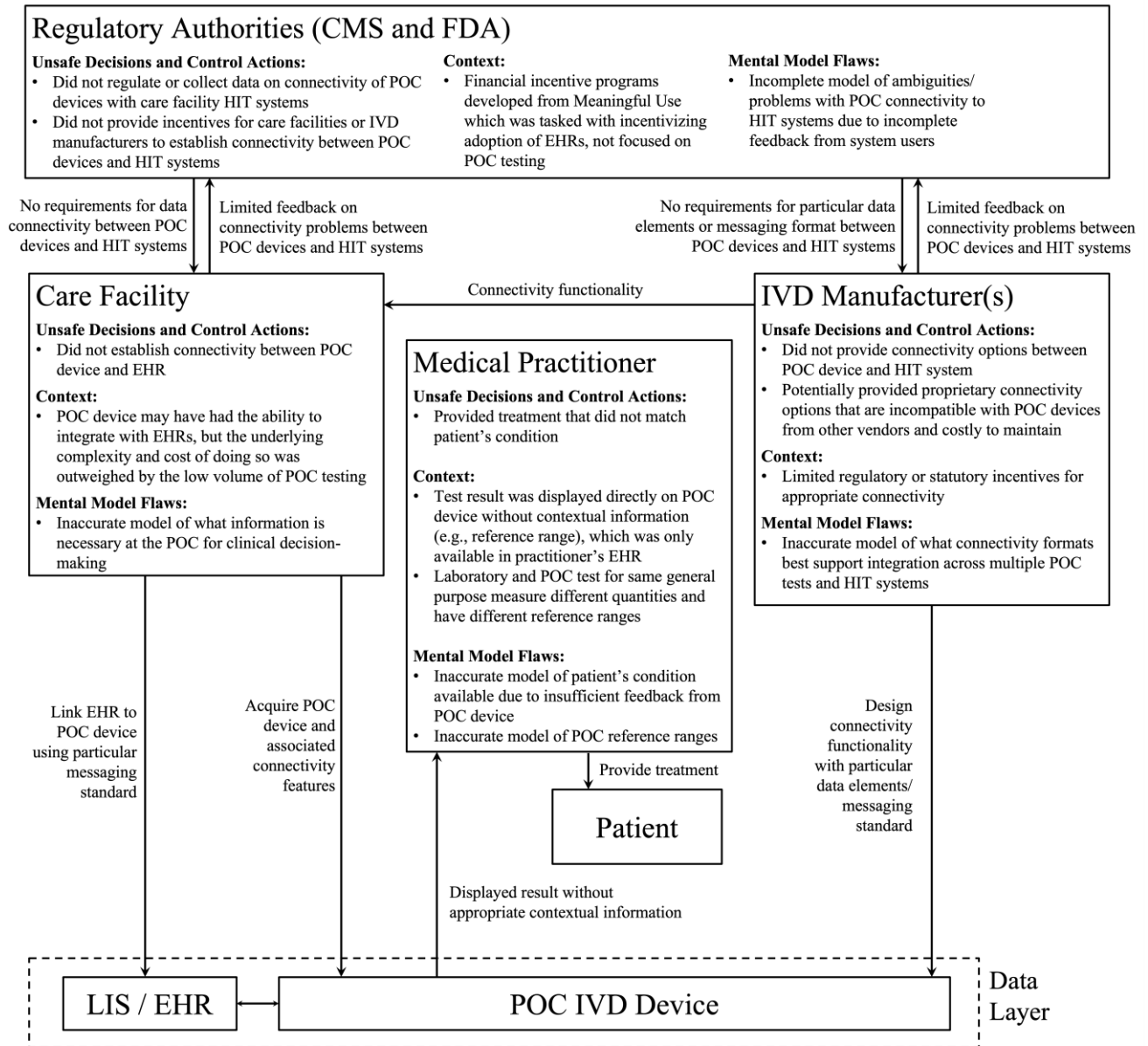


Figure 5. Visualization of Scenario POC-1-2

4.4.3 Example POC Scenario 2

Table 10. Scenario POC-7-1

Category	Scenario Information
Related UCA	IVD manufacturer does not update POC IVD device when device does not perform to expected performance levels
Controllers involved	<ul style="list-style-type: none"> • Medical practitioner • Care facility • IVD manufacturer • FDA
Scenario	<p>An IVD manufacturer may not update a POC IVD device when device does not perform to expected performance levels (UCA). One contributing factor may be that a POC IVD malfunction may not lead to a safety signal that is detectable or actionable by the IVD manufacturer.</p> <p>The IVD manufacturer may have received a report of a problem with an IVD device, but the user (care facility) may not have sent the device to the manufacturer, opting instead to perform internal testing. The IVD manufacturer may acknowledge the complaint but be unable to comment on the device if it was not sent to them for review.</p> <p>The IVD manufacturer may also not be getting all reports from care facilities about invalid or inaccurate results, since this reporting is voluntary and considered passive surveillance. The manufacturer may not be aware that the few reports they do get are indicative of a larger trend involving a device.</p> <p>The IVD manufacturer may have a perception that any problems reported with their devices are the result of flaws in quality control, and if no quality control metrics were flagged, they may not believe an actual problem existed with the device. IVD manufacturers may not be used to receiving reports from medical practitioners of design-related problems with devices, as opposed to quality control problems like manufacturing defects. There may be no formal venue where POC device users can engage in conversation regarding the design of IVD devices, either through the FDA or through the manufacturers.</p> <p>The IVD manufacturer may not have been issued any corrective actions by the FDA, because the FDA are not consistently receiving reports from the manufacturer or from care facilities about invalid or inaccurate results, since this reporting is voluntary and considered passive surveillance.</p>
Causal Factors	<ul style="list-style-type: none"> • Decentralized and missing oversight • Flawed communication and coordination

4.4.4 Example POC Scenario 3

Table 11. Scenario POC-7-2

Category	Scenario Information
Related UCA	IVD manufacturer does not update POC IVD device when device does not perform to expected performance levels
Controllers involved	<ul style="list-style-type: none"> • Medical practitioner • Care facility • IVD manufacturer • FDA
Scenario	<p>An IVD manufacturer may not update a POC IVD device when the device does not perform to expected performance levels (UCA). One contributing factor may be that a POC IVD malfunction may not lead to a safety signal that is detectable by the device user.</p> <p>The POC device may not be integrated with the care facility’s EHR system, meaning most of the results obtained from that device are only documented in unstructured free-text notes rather than mapped to fields in the EHR. The absence of structured data can make it challenging to aggregate results from many tests using the same device and identify abnormal trends. The care facility management may therefore not have enough information to detect that a device is not performing to expected levels and may not report the device to the manufacturer.</p>
Causal Factors	<ul style="list-style-type: none"> • Decentralized and missing oversight • Flawed communication and coordination

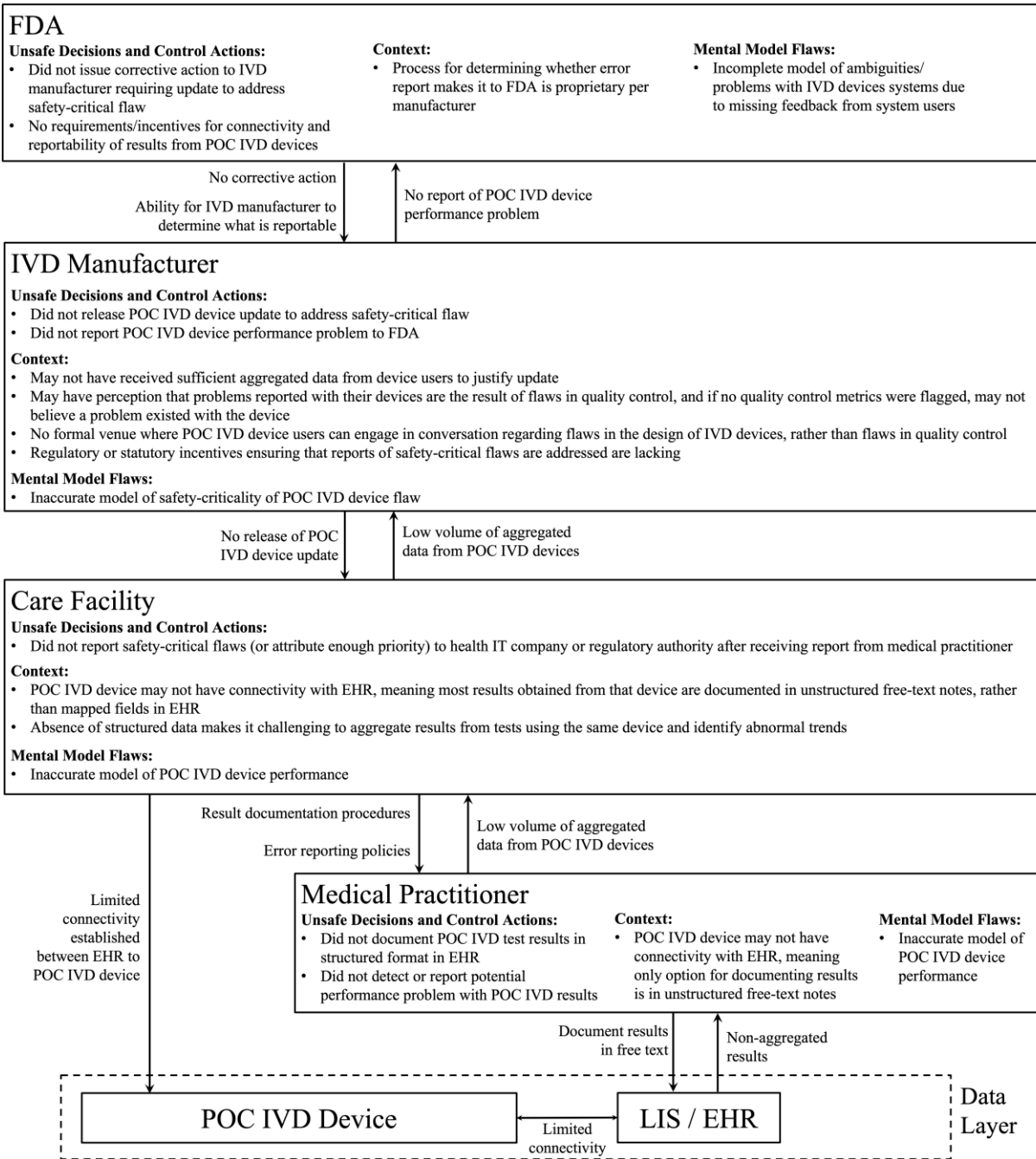


Figure 6. Combined Visualization of Scenarios POC-7-1 and POC-7-2

The next section identifies and discusses the adverse event causal factors identified for OTC/POC testing.

5. Discussion and Recommendations

5.1 Decentralized and Missing Oversight

Decentralized oversight of different components of the laboratory data system is a systemic factor discussed in the clinical laboratories report that can lead to adverse events. When examining the causal scenarios related to OTC and POC testing data, decentralized oversight once again played a significant role, albeit in distinct ways.

The FDA regulates the functionality and safety of IVD devices for OTC and POC tests. However, CMS has jurisdiction over the operation of POC devices at individual care facilities through the Clinical Laboratory Improvement Amendments (CLIA). CLIA regulations do not govern OTC device usage unless used in a POC context. For example, a rapid testing center may purchase and use OTC tests, but if they are administered by medical practitioners they are regulated under CLIA as POC tests.

The FDA and CMS communicate with each other and attempt to coordinate their regulatory requirements. However, the decentralization of authority can make it challenging for certain system elements to comply with their own requirements when other system elements are not subject to corresponding requirements.

As an example, consider Scenario POC-1-2, which involves a medical practitioner providing treatment that does not match a patient's condition because the treatment was based on a POC test result whose correct interpretation required additional information not available to the practitioner (e.g., a reference range). CLIA requires any facility performing non-waived testing (including POC testing) to document and share data elements like reference ranges and units of measure alongside each test result. Traditional clinical laboratories typically have controls in place to ensure these data elements are shared, and the practitioner usually accesses the test results through an EHR interface that displays these data elements.

However, at the point of care, the result may be read directly from the IVD device and used to inform immediate treatment. Particularly in cases like scenario POC-1-2, where the POC device does not have connectivity to the care facility's EHR, additional information that contextualizes the POC test result may not be immediately available to the practitioner and may require manual consultation. An abnormal result that is outside the reference range may, therefore, not be flagged from the POC test. If the result is eventually logged in the EHR, the appropriate reference range, units of measure, or critical values may not be logged with it, meaning a practitioner needing to access this result in the future may not have access to that information [9].

The FDA's approval process for POC testing devices does not include direct requirements or incentives for bidirectional connectivity between POC devices and HIT systems. Therefore, despite strong CLIA requirements on what data elements must be communicated with a lab result, many POC devices may simply not have the functionality to document any test result data to EHRs automatically. The result is a system in which individual regulatory control loops that are usually strong are weakened by other control loops that are not appropriately harmonized. As a result, the system collectively becomes weakly regulated.

As in the clinical laboratory system [1], there are also very few regulations for POC testing that meaningfully address interactions among system components. Despite no regulatory incentives for connectivity between POC testing devices and EHRs, many devices do have connective capabilities, as they are an attractive selling point for IVD manufacturers. However, connectivity features are unregulated, and there are limited incentives for manufacturers, care facilities, and HIT vendors to standardize communication between devices and HIT systems. Though standards for transmitting POC testing data do exist, like the Clinical & Laboratory Standards Institute's (CLSI) POCT-1A standard [10], usage of these standards is limited.

Not only are there no regulatory incentives for IVD manufacturers to increase the connectivity of their devices, but there are also no incentives for manufacturers to make the connectivity compatible with the POCT-1A standard. Additionally, there are no incentives for care facilities to utilize connective features or for the interfaces built to use the POCT-1A standard when transmitting data. A common consequence of weak controls on connectivity is delineated in scenario POC-1-10. Here, a POC device that can originally transmit test results directly into an EHR gets updated, and the data sharing format is changed; for example, results that used to be a numerical "5" are updated to the string "<5" instead. As a result of the format change, the test result may no longer be directly transmitted through the interface into the patient's medical record, may be transmitted in a format that charts differently, or may be transmitted in a format that does not trigger clinical decision support. It is often up to the care facility to detect such problems and repair the interface. The interface may be particularly prone to breaking when the manufacturer or HIT vendor changes their data storage or transmission format. These updates can be particularly difficult for smaller facilities without large IT teams or facilities with homegrown HIT systems [11].

The lack of regulatory incentives for standardization also often leads IVD manufacturers to provide proprietary connectivity options or interfaces that are incompatible with devices provided by other manufacturers [12], [13]. The proprietary interfaces may not be suitable for certain care facilities' particular data management needs [11].

The underlying complexity and cost of establishing a separate, individual interface for each POC device that a care facility owns is often outweighed by the low volume or low perceived criticality of POC testing data. The result is that many care facilities choose to rely on manual data entry to document POC test results. Such manual data entry is often error-prone, as demonstrated in many studies [14], [15], [16]. Some care facilities choose to acquire vendor-neutral middleware solutions to establish connectivity [17], but these intermediary systems are also not subject to controls on how they collect, store, and share POC testing data.

Recommendation 1: Assign responsibility for addressing the regulatory gap in the certification of POC IVD devices and their operation in CLIA-compliant environments.

A regulatory authority (or a partnership between regulatory authorities) should be assigned the responsibility of ensuring that the regulation surrounding the capabilities of POC IVD devices is aligned with and supports compliance with the regulation surrounding the operation of POC testing in different environments.

Any data elements generated by POC IVD devices that an end user needs for clinical decision-making, regulatory compliance, post-market surveillance reporting, or public health reporting must be preserved. Similar to the recommendations in the clinical laboratories report [1], the regulatory agencies that oversee different parts of the process for transmitting test data to and from devices, EHRs, and other databases must ensure that the controls enacted on each component of the system complement and do not negate other controls.

To meet the CLIA requirement that non-waived test results reliably get documented alongside their associated reference ranges, units of measure, and other important data elements, many care facilities may currently rely on laborious manual processes for documentation and verification. However, ways to establish robust, standardized connectivity between POC IVD devices and HIT systems do exist. Regulatory authorities should coordinate to ensure IVD manufacturers and HIT vendors have requirements or incentives regarding interface capabilities and use of POC testing data standards (like POCT-1A and LOINC®) that actively complement the CLIA requirements that care facilities need to follow.

To ensure standardized communication of POC testing data, regulatory authorities will need to provide requirements and incentives across the healthcare system rather than a limited number of individual components. For instance, IVD manufacturers could be incentivized to introduce standardized interface capabilities into their devices and HIT vendors could be incentivized to ensure their systems can receive and process data in those standardized formats. Once manufacturers and vendors have had time to adapt to the incentives, appropriate POC devices with HIT connectivity functionality should be included as a requirement in the device approval and EHR certification processes. Care facilities should also be incentivized to procure POC devices and HIT systems that are capable of bi-directionally interfacing with each other. Existing advisory programs like the *CMS Promoting Interoperability* guidance could be expanded to include standardized, electronic documentation of POC test results as a requirement for maintaining funding.

Once again, as described in the clinical laboratories report, regulatory agencies should ensure that any new regulations proposed are compatible with those of other agencies. As POC testing expands to more safety-critical decision-making, regulatory agencies must be aware of other agencies' planned updates so that regulations are compatible with future rules as well as current ones.

The OTC regulatory landscape is similarly convoluted and distributed. During the COVID-19 pandemic, numerous agencies, companies, and organizations created new ways to both increase the public's usage of OTC tests and to improve the data captured by patients using at-home tests. Before COVID, there were few large-scale attempts to collect OTC data from patients directly. Public Health Agencies (PHAs) mostly relied on data from clinical laboratories to track disease outbreaks. However, once OTC tests became widely available, they became more popular than clinical laboratory tests [18]. Therefore, it was much more difficult for PHAs to gather the data they needed to understand disease transmission in the U.S. To address this data gap, several government agencies under HHS developed tools to facilitate the transfer of OTC data to regulatory agencies and PHAs. However, the disparate approaches do not work as well together as may be expected.

When the FDA approved OTC COVID tests under an EUA (Emergency Use Authorization), the OTC manufacturers were required to develop methods for reporting patient test data from consumers to PHAs. However, reporting to PHAs is not a simple task. There are over 60 different public health jurisdictions throughout the U.S.

at the local, state, tribal, and federal levels. PHAs across the country vary widely in what data they want, when they want it, and for what diseases. To simplify the process of transmitting data to the appropriate PHAs, tools called data hubs are used. There are currently two main data hubs that are used: ReportStream, run by the CDC [19], and the AIMS (APHL Informatics Messaging Services), run by the Association of Public Health Laboratories [20].

NIH, through the RADx program, created data standards that can be used to transmit OTC test results from OTC companion applications to PHAs through these data hubs [21]. They also created validation tools that, when used, ensure the data sent to the data hubs is complete and usable [21]. However, companies do not always use the standards or the validation tools. For example, as in Scenario OTC-1-7, if a company's connection to the data company breaks due to an update, missing data or data fields may not be caught by the sending or receiving party promptly. Despite the availability of validation tools, companies are not incentivized to validate their data before uploading it.

Furthermore, both data hubs have limitations. ReportStream is a newer data hub created during the pandemic. It has yet to set up connections with all U.S. PHA jurisdictions, though it plans to do so in the coming year. Furthermore, ReportStream currently only accepts reports for Flu, Monkey Pox, and COVID tests.

AIMS, on the other hand, is fully connected to all PHAs and can report more types of test results, but it costs money to use. To encourage reporting and increase usage of the OTC data standards, NIH created a program where companies that used their data standards could have their AIMS fees waived. By the time the AIMS funding ends, Report Stream is intended to be connected to all PHA jurisdictions [22].

These data hubs ease the process of reporting to appropriate PHAs, however they only work when IVD manufacturers send test result data. Now that the EUA period is over, IVD manufacturers are no longer required to report data to PHAs. Therefore, manufacturers have no requirements or incentives to create ways to collect and report data, nor was there ever a requirement for IVD tests for other conditions or metrics to report data. As with POC devices, many companies create companion applications that collect patient data even without specific regulatory requirements as they can use it as a competitive advantage. However, there are no requirements that these applications use standards or report data to PHAs.

One of the reasons there are no controls that enforce or monitor data collection from OTC devices is that the FDA does not regulate "software functions" that allow patients to upload data from devices to electronic data systems [23]. However, there are no other authorities that do have control or influence over these functions.

Without any guidance, incentives, or requirements to collect data from OTC devices, few IVD manufacturers have robust data reporting systems in place.

Additionally, the data hubs that are available to collect patient data en masse are designed for public health reporting. Therefore, they are not well set up to collect data that would help the FDA assess overall OTC test device performance. Problems like these are highlighted in Scenario OTC-6-2, where the FDA is unable to take timely corrective action against a company producing a defective OTC device due to a lack of comprehensive post-market data. The FDA must wait for reports of problems from consumers and the device manufacturers. These signals often lag behind the problem, which means that action is only taken months or years after the problem may have started.

Recommendation 2: Consolidate and coordinate responsibilities for managing OTC test data collection.

The responsibilities across the HHS system for collecting OTC data should be consolidated and coordinated to ensure that regulations and tools developed do not conflict with each other. Furthermore, opportunities to enhance coordination to improve the impact of existing programs should be considered. For example, while reporting tools like ReportStream have been developed, without coordination with the FDA or other regulatory authorities, it is difficult to ensure that OTC test manufacturers will send any data to that hub.

Similarly, although OTC data standards have been developed, without incentives or requirements for OTC test manufacturers to use those standards, there will be limited adoption of standards. Without widespread usage, standards will have a limited impact on system interoperability.

One potential incentive is to incentivize OTC test manufacturers to develop companion applications that facilitate automatic data reporting. Many OTC companies already have applications that allow patients to record and store test results. But studies have shown that if patients use an application and are given the option of reporting data, the majority of patients will opt in [24]. However, there is no longer any requirement or incentive for this data to be reported to public health or other regulatory authorities.

Consolidation and coordination are particularly critical as the COVID emergency wanes. In order to ensure our systems are robust for any future emergencies, the tools developed under COVID emergency

conditions should be refined and improved. Without intentional focus and coordination, critical programs may receive less use and therefore attention and resources now that the emergency measures are no longer active.

5.2 The Framework for OTC and POC Testing Oversight Lacks Operational Specificity

Another important causal factor observed across multiple causal scenarios is that OTC and POC testing occurs in a diverse range of environments, but oversight of the different system components is often not tailored to the specific operations being controlled.

POC testing has traditionally occurred in environments like urgent care centers, physicians' offices, emergency departments, and emergency medical service (EMS) operations. The COVID-19 pandemic expanded this range to include environments like nursing homes, pharmacies, workplaces, and universities, among others. As mentioned earlier, any kind of diagnostic testing carried out by a medical practitioner in the U.S. is subject to CLIA regulations, but CLIA does not differentiate between tests carried out in clinical laboratories or in the POC setting. Therefore, it is commonly challenging for POC test settings to comply with certain regulatory requirements even in traditional POC test settings.

At the same time, other safety-critical elements of POC testing are weakly controlled. Consider, for instance, Scenario POC-2-7, where a medical practitioner provides treatment too late to avoid patient harm because the care facility's authorization to carry out a POC test has been revoked due to the potential for CLIA non-compliance. For non-waived testing, if a test result is above a certain critical threshold, CLIA requires the result to be communicated to a licensed provider and acknowledged, often by phone. A Laboratory Information System (LIS) in a traditional clinical laboratory may be set up to flag the critical value and prevent the technician from continuing their workflow without notifying the ordering practitioner. However, in a POC environment, the same systems may not be in place to stop the practitioner from proceeding with treatment without documenting and reporting the critical value.

Because POC testing is often done in time-sensitive situations, it does not make sense to hinder practitioners with lengthy manual reporting requirements. Today, if this documentation does not occur, it may result in a CLIA violation that results in the removal of authorization to carry out that test not just at the POC location but at the care facility's main laboratory as well. Even when communication of critical values are documented, the data is typically difficult to access, audit, or accurately transmit because it may have been manually stored in several different locations within the EHR. The difficulty in maintaining compliance within POC settings of CLIA accreditation requirements designed for clinical laboratories has also been documented in the literature [9], [16], [25].

Other unique challenges arise when POC testing occurs outside traditional care facilities, particularly when data-related safety controls are not tailored to those unique settings. For example, scenarios POC-1-6 and POC-1-7 highlight potential adverse events stemming from the lack of integration of POC testing data from EMS systems with care facility EHRs. Test results shared in EMS run reports typically come in unstructured formats like free-text notes or PDFs [26], which are sufficient to satisfy CLIA requirements. However, without appropriate association with fields in an EHR, unstructured data can be difficult to parse into data that the EHR can use to trigger a care facility's clinical decision support functionality. The problem of unstructured test results was already discussed in our clinical laboratories report [1] and is not unique to EMS, but is exacerbated by the unique circumstances of POC testing in the EMS environment. Controls or incentives that may be sufficient to increase structured data sharing in traditional care facility settings may not be sufficient in POC settings like EMS.

A majority of the incentives for adopting particular data standards for communicating data are focused on traditional EHRs and not on providing support across decentralized clinical environments like EMS [27]. For instance, the financial incentives care facilities can receive through CMS's Promoting Interoperability Program do not focus on structured sharing of EMS data (which in many cases includes POC testing data). Standards do exist for transmitting EMS data, like those used for the National EMS Information System (NEMSIS). However, these standards often have limited use cases (e.g., providing data to a national repository but not to a hospital EHR) and are not harmonized with other data-sharing standards like HL7 v2, v3, or FHIR.

Additionally, the use of particular POC standards is not required by any regulatory authority. Care facilities are often reluctant to adopt new standards out of fear of disrupting existing workflows. The controls and incentives that are effective in changing behavior in certain POC settings are not effective in others and need to be adjusted.

As another example, consider scenario POC-12-1, which involves the data sharing capabilities of facilities carrying out POC testing. In this scenario, the CDC and PHAs cannot provide appropriate public health guidance to the general public because the data they receive from POC testing facilities is not of sufficient quality to inform the CDC's or PHAs' analyses. Our clinical laboratories report [1] discusses how regulatory agencies sometimes need information from system components outside their regulatory scope. Ensuring that agencies have access to the data they need for appropriate decision-making can be challenging. In an effort to increase the volume of test result

reports received by CDC/PHAs, the Federal Government may impose blanket regulatory requirements that mandate result reporting from all facilities carrying out testing, as was the case with the CARES Act during the COVID-19 pandemic. However, the diversity of the POC testing landscape means that some tests will be carried out in experienced facilities while others will occur in settings like nursing homes and pharmacies. These facilities may not possess large-scale EHRs and may not be equipped to store or disseminate data in formats that would be meaningful to the data's intended users.

Facilities are even less likely to have built robust data storage and reporting mechanisms in cases where only CLIA-waived POC testing occurs, which doesn't traditionally require any controls beyond ensuring that the testing practitioner follows the IVD manufacturer instructions. While CMS or its approved accreditation organizations may be able to enforce CLIA compliance (including appropriate reporting) in non-waived environments, the agencies are not staffed to broadly enforce compliance in waived environments. Nor have any other agencies been allocated sufficient resources to broadly support non-traditional facilities in establishing robust and standardized data collection and reporting systems.

Even if POC testing sites are able to establish reporting mechanisms, the results reported may not be easily aggregable and usable by their intended recipients because of a lack of standardization in how POC tests are to be reported for public health purposes [28]. A study by the ONC [29] found that structured result reporting from non-traditional POC settings is not just a problem for public health but also for individual patient care: Only 9% of hospitals reported that they consistently receive structured results from providers like pharmacies and "pop-up" testing sites. Data hubs like AIMS and ReportStream have functionality that would allow POC testing sites to report data to PHAs, but there may be insufficient controls that encourage POC testing sites to set up this functionality.

OTC tests are also used in a wide variety of contexts. They can be used by individuals monitoring a specific disease continuously, like diabetes, or on a one-off basis, like an individual who takes a COVID test every few months. However, the same controls and feedback mechanisms generally apply to all OTC tests.

Currently, there are few approaches to OTC data collection that acknowledge the wide variety of patients in the OTC system. For example, different patient populations may not all have the same need to have their data added to their health records. Patients who take an occasional one-off test may not benefit from having that result added to their health record. However, patients who have chronic conditions that require continual monitoring (e.g. diabetes, etc.) may benefit from the ability to upload OTC results to their EHR and for their physicians to reimbursable time to review these results.

One of the challenges in collecting more OTC test data is that stakeholders in the healthcare system do not trust data coming from OTC devices to inform any critical decision-making. Because the controls available in traditional clinical laboratory testing settings, including patient identification measures in healthcare facilities and stringent CLIA quality control measures, no longer apply, developing the appropriate amount of trust to place in data from OTC devices is difficult.

OTC tests do have fewer avenues for control than traditional clinical laboratory testing. However, there is insufficient research to verify or contradict a distrust of all OTC data. During the COVID-19 pandemic, new types of OTC testing were released that were previously considered to be too high risk for consumers to use at home, such as nasal swab tests. Some clinical studies have found that self-collected specimens result in slightly less sensitivity for rapid covid tests [30]. However, the results of different studies varied wildly. Several studies of self-collected nasal swabs found that self-collected samples were sufficient for accurate testing [31], [32], [33], [34]. Another study showed close agreement with clinical PCR tests and OTC tests but relied on trained staff to collect the sample [35] while other studies found that patients were more likely to get a false negative with self-collected samples [36], [37]. It was noted that the OTC tests were highly dependent on viral load and patients may need to take multiple tests in a series to get a clearer result [35], [36], [37]. Additional studies have shown that patients are reliably able to interpret COVID test results [33].

Assessing the correct level of trust for OTC data is critical as OTC test usage increases. While PHAs and other stakeholders have been able to rely on traditional clinical laboratory mandatory reporting to get high-quality data on disease spread, if more tests are taken at home, the traditional clinical laboratory reporting mechanisms will become less useful [18].

In addition to public health considerations, not having the ability for patients to share OTC tests with their medical practitioners can lead to unsafe outcomes as well. For example, in scenario OTC-2-3, medical practitioners may miss critical information about trends in a patient's health metric if their OTC data is only reported or recorded through free-form notes in their EHR. The patient may assume that because they shared the information, the doctor will be able to see previous results. However, the doctor may not remember that the information was added nor be able to locate it quickly. In scenario OTC-2-4, a patient does not receive necessary care because their physician is unable to utilize the patient's OTC test results to make treatment decisions or to develop an accurate picture of the

patient's health in a longitudinal time scale. Not all patients may be able to make lab appointments frequently, which can make it difficult for physicians to develop an accurate understanding of the patient's health or treatment progress.

Additionally, as in scenario OTC-3-1, a care decision can be delayed unnecessarily when a patient needs a critical OTC result to be confirmed in a traditional clinical laboratory test before care decisions can be made. Currently, there are some programs, like the HHS Test-to-Treat program [38], that allow treatments to be prescribed based on OTC test results. However, most physicians are not able or do not want to make decisions based on patient-generated OTC test data. While not utilizing patient-generated data may make sense in the current system, where there are few OTC tests and few controls on the data, investigation is needed to understand when patient-generated data should be used to inform care decisions and what controls could be used to reduce potential harm.

Recommendation 3: Ensure that regulatory requirements and incentives regarding OTC/POC testing data are tailored to the needs of different users of the testing data and the specific challenges of the type of testing facility.

Ensuring that all stakeholders in the OTC/POC testing system can perform their assigned tasks involves ensuring that they receive the necessary data and that this data is usable. One agency should be assigned the task of coordinating to ensure that different types of OTC/POC testing sites can provide the data elements needed by the users of OTC/POC data. This coordination will likely require that regulatory requirements or incentives on data-sharing capabilities be tailored to each specific type of testing site.

Care facilities using OTC/POC testing data to inform patient treatment decisions have different data-related needs than regulatory agencies assessing post-market performance of devices or tracking disease outbreaks. At the same time, non-traditional testing facilities like pharmacies or EMS have different capabilities and face different barriers to data storage and transmission compared to large-scale hospital systems. A single authority should be tasked with assessing the needs of each user of OTC/POC testing data. That same authority should also be tasked with establishing requirements or incentives regarding data sharing that are cognizant of the challenges faced by each type of OTC/POC testing site.

Existing regulatory frameworks (e.g., CLIA) or accreditation programs (e.g., CAP accreditation) could be expanded and diversified to address the specific challenges of non-traditional testing sites. The U.S. aviation industry, for instance, has different certification criteria for not only the different types of aircraft that are designed (e.g., large transport aircraft, business jets, helicopters, etc.) but also for the different operational profiles of each aircraft type (e.g., domestic passenger operation, charter flights, rotorcraft with or without external loads, etc.). Regulation of the operation of OTC/POC testing sites could also be tailored to ensure the specific data-related risks of each setting are adequately addressed.

It is important to note that if immediately required to implement costly interfaces and adopt particular standards, POC testing sites may simply choose to discontinue offering the test at the POC and instead choose to send it to a traditional clinical laboratory. Such a decision may be the most cost-effective from a management perspective. Therefore, agencies within HHS should support POC testing sites in establishing standardized data-sharing mechanisms. In fact, an ONC report on pharmacy interoperability has already recommended that ONC collaborate with pharmacies and other provider communities, as well as HIT vendors, to establish appropriate POC test reporting mechanisms directly from pharmacies to care facilities and vice versa [39].

In addition to technical support, financial incentives can be provided through existing programs that already encourage the use of digital solutions, like the *CMS Promoting Interoperability* programs. Eligibility to participate in these programs could be expanded to include facilities like pharmacies. Private institutions like professional societies and payors could also encourage the adoption of particular standards for sharing OTC/POC data.

One opportunity for OTC reporting incentivization is to enable patients to add results to their EHR. If OTC results can be added to EHRs, there may be even more benefits than improving patient treatment decision-making. For example, there may be a greater ability to collect and report device performance data from a broader range of users to both inform IVD manufacturers' device improvements/updates and FDA regulatory actions. Patients individually may not be able to recognize trends in device performance, but if the data is collected centrally, problems may be able to be identified more quickly.

Recommendation 4: Study the usage of OTC tests outside of controlled laboratory settings (both testing and reporting behaviors).

To determine the appropriate level of trust in OTC data, research is needed to understand how patients interact with the OTC tests themselves and with reporting mechanisms. With OTC tests, the only person who can initiate reporting is the patient. Because setting up any control that directly forces a patient to report a test result would be difficult and presumably quite unpopular, research should be done to identify barriers and opportunities to increase reporting.

Additional studies that track usage of OTC tests outside of controlled laboratory settings are needed, including behaviors in performing the test, interpreting the test, and taking actions like treatment or reporting. A better understanding of OTC-related patient behavior would help improve the quality of regulatory decisions and potentially improve the design of the devices and associated instructions/packaging. Without robust information about consumer behavior and the trustworthiness of patient-generated data, it will be difficult to set appropriate risk thresholds when approving or rejecting new OTC devices.

In the OTC system, there is hesitancy in expanding the range of OTC testing modalities or taking advantage of the data generated by such devices. While the concerns of misuse of medical tests are valid, so too is the harm created by limiting the accessibility of OTC testing.

Many patients do not have regular access to medical labs or clinics due to limited mobility, geographic distance, financial constraints, or other concerns. OTC test approvals are concerned with risks to patients who may make errors during test collection or interpretation. However, the risk to patients who may not get any health information if no OTC tests are available should not be overlooked. Furthermore, during health emergencies, individuals who do not experience severe symptoms can test at home, which may reduce the burden of testing in clinical labs and emergency rooms.

By developing a more robust understanding of patient behavior with OTC tests, we may be able to expand the degree to which the data the tests generate can be utilized to inform individual patient care decisions, public health models, and regulatory decisions regarding the devices themselves.

5.3 Flawed Communication and Coordination

Another causal factor observed in the traditional clinical laboratory safety management system, which is also highly prevalent in the OTC/POC system, is the lack of formal communication and coordination channels between controllers. Regulators, manufacturers, and operators often lack the necessary information to change or update their rules, infrastructure, or procedures.

Issuing the appropriate control actions to address problems with IVD devices requires first identifying the problems and then being able to appropriately report them to controllers with the authority to fix them. POC testing makes each of these steps more challenging due to common flaws in the infrastructure and mechanisms for providing feedback. For example, scenario POC-7-2 describes a situation in which an IVD manufacturer does not provide an update to a POC device that does not perform to the expected performance levels. An update may not be provided because the device's malfunction does not generate any feedback that is detectable by the device's users.

As described earlier, many POC devices may not have connectivity with a care facility's EHR system, meaning a majority of the results obtained from those devices get documented in unstructured, free-text notes rather than mapped fields in the EHR. Even if the results get documented in mapped fields, the necessary context needed to interpret the test result correctly may not be documented alongside it, including the test date, a unique device identifier, the device's lot number, its expiration date, and more. Particularly if a care facility uses multiple POC devices for the same type of test, the absence of structured data can make it challenging for the facility to aggregate results and identify abnormal trends. Therefore, the care facility management may not have enough information to detect that a device is not performing to expected levels and may not report the device to its manufacturer. Literature on quality assurance and the use of key performance indicators for POC testing corroborates the finding that poor connectivity hinders the ability to monitor the performance of POC devices and procedures [40], [41].

Even when the manufacturers receive reports from care facilities, they may not appropriately address them if the reports do not fall into the specific categories they are accustomed to receiving and are, therefore, set up to process. In scenario POC-7-1, the IVD manufacturer does receive reports from a care facility but thought that any problems reported would result from flaws in quality control, as opposed to the design of the IVD device. Because no quality control metrics are flagged, the manufacturer does not believe an actual problem exists with the device.

Typically, there are limited formal avenues through which POC device users can engage with manufacturers and provide feedback regarding design flaws or limitations of IVD devices.

The limited feedback pathways between device users and manufacturers can result in limited actionable signals to regulators of problems with POC IVD devices. Existing databases like the FDA's Manufacturer and User Facility Device Experience (MAUDE) database are largely populated by reports from manufacturers, which may have been triaged by the manufacturers through methods that are not publicly released [42]. It is likely that cases where a manufacturer determines that the device was built to specifications and functioned as designed are not reported to MAUDE. Poor data retention and categorization capabilities on the part of care facilities then make it challenging for the FDA to monitor and quickly detect anomalies with regulated medical devices.

Recommendation 5: Incentivize the use of POC devices that upload test results automatically to EHRs.

Automatic POC test result uploading increases patient safety in numerous ways. Connectivity would make it easier to store contextual information that would take too much time for practitioner who ran the test to type out every time. For example, automatic test logging could easily record the device identifier alongside the results. Reducing the time needed to record data would make it easier for POC locations to comply with CLIA documentation requirements. Additionally, EHRs with automatically uploaded and well mapped results can easily flag critical values. Additionally, well documented results enable for medical practitioners to find the data in the future and use it to understand the trend of the patient's treatment progress.

Having all POC test data stored in mapped fields that are less subject to manual data entry errors makes it easier to spot problems with specific devices earlier. Furthermore, regulatory authorities and manufacturers could obtain better models of device performance in the real world if incentivizing the use of POC devices could be paired with requirements to report de-identified device result data to regulators and manufacturers which would enable better monitoring of the safety and performance of the devices.

In most OTC use cases, there are no requirements for any data to be reported regardless of test results or problems experienced with the OTC test. Neither the patient nor the vendor is required to report problems to the FDA if they arise. Patients who purchase a test and experience problems may not consider reaching out to the manufacturer or the FDA and may instead go to the vendor, especially if looking for a refund. Furthermore, the only person who can initiate reporting of OTC test results is the patient, whereas, in clinical labs, certain test results are required to be reported to PHAs.

There are efforts to collect test results directly from patients in a public health context. The website *Make My Test Count* is one effort to collect OTC test result data from patients [43]. This website is managed by NIH and allows patients to report their results directly to public health authorities. This program currently only accepts COVID and Flu test results but plans to add other OTC tests that are relevant to public health in the future. Unfortunately, during COVID, awareness and use of this platform among patients was limited. There are efforts to allow organizations to embed the reporting mechanism into other websites and applications, which could help increase the number of patients who are aware of and use *Make My Test Count*.

To get patients to report their data voluntarily, patients need to see the benefits of sharing their results. Currently, patients have few incentives to self-report. In Scenario OTC-1-1, PHAs may be unable to provide timely guidance if patients are unaware of a reporting mechanism or do not trust the security of the reporting platforms. In Scenario OTC-1-2, patients do not report their results because they do not perceive any direct benefit to them in doing so. Patient test reporting solutions like *Make My Test Count* currently have limited benefits for patients. There is some ability to track results over time, but it is limited to a user's device and cannot distinguish between results from different people in a household using the same device/browser. The site, therefore, adds little value to the patient and does not encourage patients to continue to upload results.

One obstacle for OTC data reporting is that patients need to understand how their data is being used. The full data set requested by PHAs in a traditional clinical laboratory report may seem onerous or invasive to individuals using at-home tests. NIH recommends a set of information from OTC data collectors that includes 19 different fields [44]. While only nine fields are required (including type of test, age, zip code, and date of test), the full set of information requested may be daunting to patients. Information like name, street address, phone number, and email may concern patients about where that information will be stored and how it will be used. Concerns may be especially high for diseases where diagnoses may have associated stigmas or impacts on the ability of the patient to go to work/school/etc. While these pieces of information are optional, patients may not submit any data if these

questions are asked. More research is needed to identify patient concerns when reporting data from OTC tests and to identify best practices for collecting the best quality data while respecting privacy concerns.

Finally, data collection solely for public health concerns limits the amount of data that can be collected from patients. For example, the *Make My Test Count* platform does not allow patients to report problems encountered with the tests themselves, which makes it insufficient as a one-stop shop for all test feedback. In addition, to reduce the double counting of test results, *Make My Test Count* discourages users from reporting results that they have already entered in a companion app. However, not all companion apps report results as the regulatory directives to do so have lapsed as described above.

Recommendation 6: Facilitate the creation of a single platform where all OTC data can be sent to appropriate stakeholders based on data needs and incentivize or require reporting to that platform where possible.

Currently, if companies or individuals want to report OTC data, there is no one place where data can be reported to be used by regulatory and public health agencies. To ensure that the real-world performance of OTC devices is adequately tracked and controlled, greater data collection from patients using these products and devices needs to be considered. Because there are fewer ways to require reporting (compared to traditional clinical laboratory testing), additional pathways for feedback should be considered.

Currently, the options to report OTC data centrally are all focused on public health, like *Make My Test Count*. While public health is incredibly important, not having data reporting on all OTC tests reduces the ability to spot problems with OTC tests focused on non-communicable diseases. Furthermore, *Make My Test Count* does not allow patients to submit problems or complaints with devices. Patients need to go to an FDA database (e.g., MedWatch) in order to submit problems with devices. Asking patients to both remember numerous reporting mechanisms and to follow through with using all of them will likely be difficult to do.

It would be significantly easier for the agencies that could benefit from OTC data to collaborate on ways to incentivize reporting to one platform compared to trying to get patients to report results to numerous locations. If time and resources are expended to create a patient test result reporting portal, as much data as possible should be collected through one centralized platform.

As shown in scenario OTC-1-2, many patients will not report their test results to PHAs without awareness of existing reporting mechanisms. They may also not report if there are few perceived incentives or benefits associated with such reporting. Incentives could include information about or connection to care and treatment options. For example, the test-to-treat program was a government program that connected patients with COVID treatments based on POC or OTC results. It is unclear if the OTC test results from this program were reported, but similar programs could incorporate reporting requirements in the future. Of course, care should be taken not to incentivize needless testing or result manipulation.

5.4 Inadequacies and Gaps in Laboratory Data Standards and their Usage

Inadequacies and gaps in the standards used to store and exchange laboratory data were a key focus of our clinical laboratories report [1]. Most of the findings for laboratory data relating to the use of loosely constrained, outdated, and ambiguous standards are also applicable to OTC/POC testing data. However, a few new challenges arise when considering the use of standards in OTC/POC data. One significant risk is when OTC/POC test results are indistinguishable from test results that came from a clinical laboratory. It is in these types of situations that even POC tests/devices that have been directly connected to EHRs can still pose risks to patient safety.

One example is scenario POC-1-16, in which a medical practitioner provides inappropriate treatment because they interpret a POC test result as a laboratory test result. Certain POC testing devices may have been developed to monitor patients in very specific conditions and may only be reliable for a limited range of results (e.g., if a result is above 4, it should be seen as unreliable). In the example scenario, the output of a POC device is mapped to the same reference terminology (i.e., LOINC code) as the equivalent laboratory test. As a consequence, the POC test result is not differentiated in the EHR from a laboratory result, and a practitioner without additional information would be susceptible to interpreting an unreliable POC test result as a reliable laboratory result.

The reasons why a POC test and a laboratory test may be mapped to the same LOINC code are similar to the reasons why *any* two tests may be inappropriately mapped. These reasons include that standards are intentionally loosely constrained to cater to different implementers, that care facilities do not update reference terminologies in a timely manner, and that the developers of implementation and mapping guidelines are unable to anticipate every way a user may need to use the terminology.

Some care facilities may have individual controls to prevent this type of scenario, such as attaching prefixes like “POC–” to test names to differentiate them appropriately, but there is no requirement that they actually do so. As described in our clinical laboratory report, the EHR certification criteria from the ONC do not include strong controls over the methods by which test result data are aggregated and shown to the medical practitioner. In addition, the way a certified EHR is implemented or used at individual care facilities is not regulated.

Recommendation 7: Develop requirements regarding the appropriate processing, storage, and display of POC data in safety-related certification criteria for HIT systems.

The clinical laboratories report [1] recommended that the ONC be assigned additional regulatory authority regarding oversight of HIT safety, including the explicit directive to create and enforce safety-related certification criteria for HIT systems. To address the potential for incomplete or misleading documentation of POC testing data, these criteria should include specific requirements on how that data should be processed, stored, and displayed to medical practitioners for use in clinical decision-making.

As they exist right now, reference terminology formats like LOINC® are not designed to explicitly differentiate between tests carried out in a traditional clinical laboratory or within a POC setting. Therefore, the controls to ensure that POC testing data are represented appropriately in HIT systems typically come from individual care facilities with support from HIT vendors, IVD manufacturers, and middleware companies.

Determining what specific format should be used to represent POC data in HIT systems is beyond the scope of this study and should be done in consultation with medical practitioners, laboratorians, terminologists, and health informaticists who are knowledgeable about the clinical implications of different representations of test results.

On the OTC side, the NIH's RADx program developed standards for OTC test results. However, these standards are targeted towards reporting to PHAs rather than EHRs. PHAs tend to use HL7 V2, while EHRs certified by the ONC use FHIR. Because of this, the data format for most OTC data is not readily compatible with future integration with EHRs. While work is underway to create FHIR-compatible data formats that are accepted by data hubs, that development has yet to be published.

Once standards are developed, there are additional challenges to their universal adoption. While the FDA encourages medical device developers to use recognized consensus standards, they do not enforce the use of any particular standards [37]. This limitation means that no one regulatory entity currently has the authority to ensure that data is collected or logged in any particular format. There are also no incentive programs to encourage OTC test manufacturers who collect test data to use the standards developed by NIH or others. The low rate of OTC data collection is currently a small problem, as few patients need to share their results with their medical practitioners. However, as the number of OTC tests continues to grow, it will become more difficult to enforce standards especially during a future health emergency.

Recommendation 8: Identify potential incentives or requirements to increase the adoption of data standards in the OTC and POC testing systems.

While standards for OTC and POC test data exist, there are few incentives or requirements for their use by care facilities, medical devices, OTC companion apps, or others. Without incentives or requirements to use any particular standards, it becomes difficult to ensure that test result data from different parts of the system will be interoperable and usable after the test is conducted.

Furthermore, as the OTC and POC industries expand and new tests are introduced, it will be crucial to continue to develop and refine the standards so that future data remains accessible and usable by relevant stakeholders. Investment in the continual improvement and refinement of OTC and POC data standards will make it easier for users to adopt them. However, without incentives to use these standards, it will be difficult to justify the resources needed to keep them updated. Therefore, it is critical that efforts are made to encourage the use of specific standards.

6. Conclusions

This study applied a system-theoretic approach to model and analyze the integration of over-the-counter (OTC) and point-of-care (POC) testing within the broader U.S. diagnostic laboratory data ecosystem. Unlike other research that is focused specifically on data coding, interoperability, or individual technologies, this study employed a holistic view that modeled and analyzed many different kinds of interactions throughout the entire socio-technical system.

Use of OTC and POC tests has increased significantly over the last few years, especially during COVID [3]. With more tests available and more people using them, the data they generate could be invaluable to decision-making throughout the healthcare system. The FDA would benefit from an increased understanding of OTC/POC device performance and usage in the real world. PHAs would benefit from tracking disease progress. Patients and their medical practitioners would benefit from being able to track health metrics without the cost of frequent trips to laboratories. However, very little OTC and POC data is available for decision-making. The strong control loops and feedback channels in the traditional clinical laboratory system are missing and have not been created in OTC/POC settings. Furthermore, the weak control/feedback loops from the previous study are also present for OTC tests. The scenarios revealed patterns of systemic factors that reduced the amount of usable data from the OTC environment.

The conclusions drawn highlight the benefits of using a systems approach across the diagnostic testing landscape:

- **A Total System Perspective:** The systemic approach created the means for a comprehensive analysis of the interactions and interdependencies between technology, people, and processes involved in diagnostic testing. This led to a deeper understanding of the weaknesses and opportunities for improvement that are often overlooked when focusing solely on individual pieces.
- **Enhanced Risk Identification:** By modeling the larger socio-technical system, this study identified not only technological risks but also procedural and human factors contributions to system vulnerabilities. This broader perspective is crucial for developing more effective strategies that address the root causes rather than just symptoms like technical interoperability and data coding issues.
- **More Regulatory and Operational Insights:** The systems approach analysis provided key insights into the adequacy of current regulatory frameworks and operational practices. It highlighted the need for regulatory adjustments that are better aligned with the complexities of modern diagnostic testing environments, particularly in accommodating the rapid pace of advances in OTC and POC testing.
- **Broader Recommendations:** This study produced targeted recommendations to strengthen safety beyond technological solutions and standards compliance. The recommendations include enhanced reporting and feedback for decision-makers, addressing gaps in policies and practices, improved integration of OTC/POC testing into different contexts, and establishing better coordination and communication across all stakeholders.

This report's findings demonstrate the power of using system-theoretic approaches in health system research. Future studies should focus on other proposed adaptations of the system as new technologies emerge and regulatory landscapes evolve, ensuring that the laboratory data system remains resilient against both existing and emergent challenges.

As OTC and POC testing continue to evolve, there are tremendous opportunities to adapt the safety management structure to prevent losses and prepare the system for future testing modalities. By considering the socio-technical system as a whole, rather than each part in isolation, system stakeholders can achieve a safe and more efficient diagnostic environment, ultimately leading to better patient outcomes and enhanced public health surveillance.

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Appendix A - List of Key Informants

We would like to thank the regulators, laboratorians, medical practitioners, health IT analysts, terminologists, payors, medical device industry subject matter experts, patients, and accrediting agency representatives who have participated in this research, including, but not limited to:

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Appendix B - Controller Descriptions

This appendix provides descriptions of the roles and responsibilities of controllers in the safety management system for OTC/POC testing data. The controllers included here are only those that were not already described in the clinical laboratories report, or those whose responsibilities change when it comes to OTC/POC testing as compared to traditional clinical laboratory testing.

OTC Testing

- **Test Vendor:** Test vendors are retailers who market and sell OTC test devices directly to patients. They are typically pharmacies, but may be online retailers as well. Test vendors acquire IVD devices from manufacturers or distributors and stock the devices for patients to purchase. Test vendors may occasionally receive reports from patients of defects or problems encountered with OTC devices, and may voluntarily transmit those reports to the FDA through the MedWatch program.
- **FDA:** The Food and Drug Administration (FDA) is an operating division of HHS that regulates foods, drugs, biologics, medical devices, electronic products that give off radiation, cosmetics, veterinary products, and tobacco products [45]. The FDA approves OTC test devices through the De Novo classification process or the 510(k) clearance process before manufacturers can sell them in the U.S. [46], [47]. The FDA also specifically regulates the labeling of OTC devices, as well as certain software functions of OTC devices, including those that analyze or interpret medical device data. The FDA monitors the ongoing safety and efficacy of OTC devices in use primarily through MedWatch, the FDA Safety Information and Adverse Event Reporting Program [48].
- **CDC:** The Centers for Disease Control and Prevention (CDC) is an operating division of HHS that fights disease and supports communities and citizens in doing the same. In the OTC space, the CDC maintains one of two OTC test result “hubs,” which receive test result data from OTC devices and transmit that data directly to the CDC and the appropriate public health agency for each state. The other OTC test result “hub,” with similar functionality, is maintained by the Association of Public Health Laboratories (APHL)

POC Testing

- **Medical Practitioner:** Medical practitioners (e.g., clinicians) interact directly with patients in the form of consultations, ordering and interpreting diagnostic tests, collecting test samples, and providing treatment/care.
 - **Ordering Practitioner:** The term “ordering practitioner” is used in this report to refer to the medical practitioner who orders a POC test to be carried out for a patient. The ordering practitioner receives information about a patient from the patient themselves, from other medical practitioners, or from patient data stored in a care facility’s EHR/HIT system. The ordering practitioner may then issue POC test orders verbally or through the EHR/HIT system interface. The ordering practitioner is subject to the care facility’s policies on how POC tests can be ordered. Upon receiving an order from the ordering practitioner, the testing practitioner then interprets the order and carries out the test. The ordering practitioner may then receive the test result from the testing practitioner and provide treatment to the patient based on that result.
 - **Testing Practitioner:** The term “testing practitioner” is used in this report to refer to the medical practitioner who collects a patient sample and runs the associated POC test. The testing practitioner receives an order from the ordering practitioner, either verbally or through the care facility’s EHR/HIT system. The testing practitioner then communicates the POC test results back to the ordering practitioner, logs the test result in the patient’s record in the EHR/HIT system, and may directly provide treatment to the patient. In certain cases, the testing practitioner may be authorized to carry out a test without a formal order, and an order may be automatically created in the EHR/HIT system when the results are uploaded.
- **Care Facility:** Care facilities are the institutions (e.g., hospitals or clinics) where patients go to receive medical care. Care facilities performing POC testing acquire and maintain POC IVD devices, as well as the interfaces that allow these devices to automatically communicate with the care facility’s EHR/HIT systems. Care facilities performing any kind of diagnostic testing are also required to possess a CLIA certificate. Care facilities that possess clinical laboratories may conduct their POC testing under the same CLIA certificate as the laboratory conducts their traditional tests or may have separate certificates for the laboratory and the POC testing site. Therefore, care facilities are subject to the regulatory controls of the CMS (through CLIA) and of external accreditation organizations like CAP. Care facilities also provide practitioners with infrastructure and policies for ordering POC tests and documenting, using, and sharing POC test results. Care facilities also provide authorization for individual medical practitioners to carry out POC tests, and may revoke these authorizations if they observe noncompliance with regulatory requirements or care facility policy.

Appendix C - Complete list of UCAs

This list of unsafe control actions includes all UCAs identified during the course of this study. The 9 UCAs shown in 4.4 POC Testing UCAs

Several hundred UCAs and scenarios were identified across the POC testing system. Table are indicated with a number, an asterisk, and are highlighted.

OTC Testing

Controller: Medical Practitioner

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Prescribe/ recommend OTC test to patient	UCA: Medical practitioner does not prescribe/ recommend an OTC test when the test is available and continuous monitoring improves patient care decisions, and patient cannot access traditional clinical laboratory testing	UCA: Medical Practitioner prescribes/recommends traditional clinical laboratory test that is inaccessible to patient (costs, location) when OTC tests are available and accessible to patient UCA: Medical practitioners prescribes/recommends test that is inappropriate to monitor patient's condition	UCA: Medical practitioner prescribes/recommends test too late to impact care decisions	UCA: Medical practitioner stops prescribing/ recommending or monitoring tests too soon to observe trend in patient condition
Provide treatment to patient	OTC-UCA-2*: Medical practitioner does not provide treatment when patient needs treatment to avoid harm	UCA: Medical practitioner provides treatment when patient does not need any treatment UCA: Medical practitioner provides treatment that does not match the patient's condition	OTC-UCA-3*: Medical practitioner provides treatment too late to avoid patient harm UCA: Medical practitioner provides treatment too early before patient condition has been identified	UCA: Medical practitioner stops providing treatment too early before patient condition has been resolved UCA: Medical practitioner provides treatment for too long after patient condition has been resolved

Controller: Care Facility

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Provide OTC result response policies	<p>UCA: Care facility does not provide policies for making care decisions based on OTC results when patients are reporting OTC results</p> <p>UCA: Care facility does not provide updated procedures/policies to medical practitioners following change in OTC test availability or protocol (ref. ranges, etc.)</p>	<p>UCA: Care facility provides policies for making care decisions based on OTC results that allow decisions to be made on misleading data</p> <p>UCA: Care facility provides policies for making care decisions based on OTC results that prevent treatment starting promptly from reliable results</p> <p>UCA: Care facility provides incomplete OTC policies to medical practitioners following a change in OTC test availability/ protocol</p>	<p>UCA: Care facility provides procedures/ guidelines to medical practitioners too late after OTC test results are shared by patients</p>	N/A

Controller: HIT Company (medical device app, EHR, LIS, etc)

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Select data standards to implement in HIT system	<p>UCA: HIT company does not select data standards to implement in HIT system when data needs to be shared with external groups</p>	<p>UCA: HIT company selects data standard that is not compatible with data standards used in HIT systems from competitors or other stakeholders</p>	N/A	N/A

Controller: ONC

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Set certification standards	ONC does not set certification standards that ensure that data from OTC devices could be included in patients EHRs when doctors need that information to make decisions	ONC sets certification standards that block the ability for patients to add OTC results to EHRs when doctors need that information to make decisions	N/A	N/A

Controller: FDA

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Approve OTC device	OTC-UCA-5*: FDA does not approve an OTC test when that test would enable better patient care decisions.	OTC-UCA-4*: FDA approves an OTC test that does not facilitate data reporting by test users when that data is needed to inform public health decisions or test decisions.	FDA approves an OTC device too late to get critical data during a health emergency	N/A
Issue Corrective action to IVD manufacturer	UCA: FDA does not issue corrective action to IVD manufacturer following a series of inappropriate results from IVD device	UCA: FDA issues corrective action to IVD manufacturer whose device is performing according to regulation	OTC-UCA-6*: FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device	UCA: FDA issues corrective action to IVD manufacturer for too long following the resolution of a problem with an IVD device

Controller: IVD Manufacturer/Importer

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
<p>Release OTC device and instructions</p>	<p>UCA: IVD manufacturer does not release OTC test for which there is no adequate replacement in the market</p>	<p>UCA: IVD manufacturer releases OTC device that has been insufficiently tested on particular demographics (e.g., children)</p> <p>UCA: IVD manufacturer releases OTC device that was approved with inadequate validation data</p> <p>UCA: IVD manufacturer releases OTC device without accessible device usage instructions</p>	<p>UCA: IVD manufacturer releases OTC device too soon before sufficient testing has been performed on particular demographics (e.g., children)</p>	<p>N/A</p>
<p>Provide data collection mechanism</p>	<p>OTC-UCA-8*: IVD manufacturer does not provide data collection mechanism when data is needed to inform regulatory or public health guidance</p>	<p>UCA: IVD manufacturer provides data collection mechanism that does not collect sufficient data to be used by PHAs or regulatory agencies</p> <p>IVD manufacturer provides data collection mechanism that patients are not willing to use</p>	<p>N/A</p>	<p>N/A</p>

Controller: Test Vendor (to consumer)

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Stock OTC tests	UCA: Test vendor does not stock particular OTC tests when patients served by the vendor have no adequate replacement for it	UCA: Test vendor stocks OTC test that does not perform to expected performance levels UCA: Test vendor stocks OTC test without accessible instructions for when to purchase OTC test	UCA: Test vendor stocks OTC test too late after its results become valuable to inform patient care	UCA: Test vendor keeps stocking OTC test for too long after it is known that test does not perform to expected performance levels
Sell medication	UCA: Vendor does not sell treatment to patient based off of OTC results that do not reflect the patient’s condition	UCA: Vendor sells treatment to patient based off of OTC results that do not reflect the patient’s condition	N/A	N/A

Controller: Naming/Coding/Messaging Standards Development Organizations & Reference Libraries

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Create new data messaging standards	OTC-UCA-9*: SDO does not create a new data messaging standard format when the current standard format is insufficient to capture results from new OTC tests	UCA: SDO creates additional data messaging standard formats when the current standard format is sufficient to capture results from OTC tests UCA: SDO creates additional data messaging standard formats when	UCA: SDO creates a new data messaging standard format too late after safety-critical changes in the laboratory data ecosystem are released	N/A

		<p>a different SDO has already created a sufficient standard</p> <p>UCA: SDO creates a data messaging standard formats that does not capture necessary components of OTC data</p> <p>UCA: SDO creates a data messaging standard formats that requires the capture of data that OTC results do not have.</p>		
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Controller: Patient

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Acquire OTC test	UCA: Patient does not acquire OTC test when test would be helpful to inform patient decision-making	<p>UCA: Patient acquires OTC test that is not the best/most appropriate test to diagnose a disorder/disease</p> <p>UCA: Patient acquires OTC test that does not perform to expected performance levels</p>	<p>UCA: Patient acquires OTC test too soon before learning what test can help inform their decision-making</p> <p>UCA: Patient acquires OTC test too late after test would be needed to inform patient decision-making</p>	N/A
Follow OTC pre-test instructions or test procedures	UCA: Patient does not follow OTC pre-test instructions or test procedures when procedures are necessary for validity of test results	<p>UCA: Patient follows OTC pre-test instructions or test procedures incorrectly when procedures are necessary for validity of test results</p> <p>UCA: Patient follows OTC pre-test instructions or test procedures when those procedures can harm their health</p>	<p>UCA: Patient follows OTC pre-test instructions or test procedures too soon before test is to be conducted, when timing of procedures is crucial for validity of test results</p> <p>UCA: Patient follows OTC pre-test instructions or test procedures too late before test is to be conducted, when timing of procedures is crucial for validity of test results</p>	UCA: Patient stops following OTC pre-test instructions or test procedures too soon before test is to be conducted, when timing of procedures is crucial for validity of test results

<p>Interpret test results</p>	<p>UCA: Patient does not interpret OTC test results when interpretation of results is necessary to inform patient’s decision-making</p>	<p>UCA: Patient interprets OTC test result as invalid when test result was valid UCA: Patient interprets OTC test result as valid when test result was invalid UCA: Patient misinterprets OTC test result (units, measured quantity, etc.) when correct interpretation of results is necessary to inform patient’s decision-making</p>	<p>UCA: Patient interprets OTC test result before the test result is available/ready UCA: Patient interprets OTC test result too late after test accuracy window has ended</p>	
<p>Enter personal data into OTC companion app</p>	<p>UCA: Patient does not enter personal data into OTC companion app when data is necessary to inform patient care UCA: Patient does not enter new personal data into OTC companion app when patient condition has changed</p>	<p>UCA: Patient enters incorrect personal data into OTC companion app when data is necessary to inform patient care UCA: Patient enters incomplete personal data into OTC companion app when data is necessary to inform patient care UCA: Patient enters other patient’s personal data into OTC companion app</p>	<p>UCA: Patient enters personal data into OTC companion app too late after data is needed to inform patient care</p>	<p>N/A</p>
<p>Seek Medical treatment</p>	<p>OTC-UCA-7*: Patient does not seek medical treatment when treatment is needed to avoid harm</p>	<p>Patient seeks medical treatment when treatment will cause harm</p>	<p>N/A</p>	<p>N/A</p>

Controller: CDC/PHAs

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
<p>Set standards for reporting of OTC data</p>	<p>UCA: CDC/PHAs do not set standards for reporting OTC data when data needs to be aggregated for use by the agencies</p>	<p>UCA: CDC/PHAs set standards for reporting of OTC data that patients or providers are unable to comply with</p> <p>UCA: CDC and different PHAs set conflicting standards for reporting of OTC data</p>	<p>UCA: CDC/PHAs set standards for reporting diagnostic data too late after providers or device manufacturers have already implemented other standards</p>	<p>N/A</p>
<p>Provide healthcare guidance</p>	<p>UCA: CDC/PHAs do not provide healthcare guidance that may provide value to patients' cases</p>	<p>UCA: CDC/PHAs provide healthcare guidance that conflicts with current/previous guidance</p> <p>UCA: CDC/PHAs provide health guidance that is too stringent for institutions or individuals to follow</p>	<p>OTC-UCA-1*: CDC/PHAs do not provide guidance in time to limit disease outbreak</p> <p>UCA: CDC/PHAs do provide healthcare guidance too early before sufficient data is received</p>	<p>UCA: CDC/PHAs remove healthcare guidance when the guidance is still relevant for patient safety outcomes</p> <p>UCA: CDC/PHAs maintain healthcare guidance when it is no longer relevant for patient safety outcomes</p>

Controller: HHS

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Provide prescription guidance	HHS does not provide guidance to allow pharmacies to prescribe medication based on OTC results when patients do not have other care options	HHS provides a program that allows for treatments to be prescribed based on OTC results when treatment may harm patients who received the necessary result for treatment	N/A	N/A

POC Testing

Controller: Medical Practitioner (ordering or testing practitioner)

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Provide treatment to patient	UCA: Medical practitioner does not provide treatment when patient needs treatment to avoid harm	UCA: Medical practitioner provides treatment when patient does not need any treatment POC-UCA-1*: Medical practitioner provides treatment that does not match the patient's condition	POC-UCA-2*: Medical practitioner provides treatment too late to avoid patient harm UCA: Medical practitioner provides treatment too early before patient condition has been identified	UCA: Medical practitioner stops providing treatment too early before patient condition has been resolved UCA: Medical practitioner provides treatment for too long after patient condition has been resolved
Collect POC test specimen	UCA: Medical practitioner does not collect POC test specimen that is needed for a test	UCA: Medical practitioner collects incorrect POC test specimen that is needed for a test	UCA: Medical practitioner collects POC test specimen too soon before test needs to be run	UCA: Medical practitioner stops collecting POC test specimen too soon before full specimen has been collected

		<p>UCA: Medical practitioner collects specimen from incorrect patient</p> <p>UCA: Medical practitioner follows incorrect procedure in collecting POC test specimen</p> <p>UCA: Medical practitioner collects POC test specimen when patient has not followed test requirements</p> <p>UCA: Medical practitioner harms patient during POC test specimen collection</p>	<p>UCA: Medical practitioner collects POC test specimen too late after sample was requested</p> <p>UCA: Medical practitioner collects POC test sample too late after patient conditions change</p> <p>UCA: Medical practitioner collects POC test specimen too early before patient conditions change</p>	<p>UCA: Medical practitioner continues collecting POC test specimen for too long after full specimen has been collected</p>
Label POC test specimen	<p>UCA: Medical practitioner does not label POC test specimen that is needed for a test</p>	<p>UCA: Medical practitioner labels POC test specimen with incorrect description of sample</p> <p>UCA: Medical practitioner labels POC test specimen with one patient's name when sample belongs to another patient</p> <p>UCA: Medical practitioner labels POC test specimen without following proper labeling procedure</p>	<p>UCA: Medical practitioner labels POC test specimen too late after specimen has been collected</p>	N/A
Enter POC test result into HIT system	<p>UCA: Medical practitioner does not enter POC test result into HIT system when</p>	<p>UCA: Medical practitioner enters incorrect POC test result into HIT system</p>	<p>UCA: Medical practitioner enters POC test result into HIT system too late after</p>	<p>UCA: Medical practitioner stops POC test result in HIT</p>

	<p>result is needed to inform future treatment</p> <p>UCA: Medical practitioner does not update POC test result in HIT system when result has changed</p>	<p>UCA: Medical practitioner enters incomplete POC test result into HIT system</p> <p>UCA: Medical practitioner enters POC test result into HIT system under one patient's name when data belongs to another patient</p>	<p>data has to be used to inform treatment</p>	<p>system too soon before full set of data has been entered</p>
<p>Run POC test</p>	<p>UCA: Medical practitioner does not run POC test when patient needs that test to diagnose/monitor a condition</p>	<p>UCA: Medical practitioner runs POC test when patient does not need that test to diagnose/monitor a condition</p> <p>POC-UCA-3*: Medical practitioner runs POC test that is not the best/most appropriate test to diagnose a disorder/disease</p> <p>UCA: Medical practitioner runs POC test that is not covered by patient's health insurance</p>	<p>UCA: Medical practitioner runs POC test too late after it is determined that patient needs that test to diagnose/monitor a condition</p> <p>UCA: Medical practitioner runs POC test too early before it is determined that patient needs that test to diagnose/monitor a condition</p>	<p>UCA: Medical practitioner stops running POC test too soon before test result has been obtained</p>

Controller: Care Facility

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
<p>Provide medical practitioner authorization to perform POC test</p>	<p>POC-UCA-4*: Care facility does not provide authorization for a medical practitioner to perform POC test when practitioner needs to perform test to inform immediate patient care</p>	<p>UCA: Care provides authorization for medical practitioner to perform POC test when practitioner has not met requirements to perform test</p> <p>UCA: Care provides authorization for wrong medical practitioner to perform POC test</p>	<p>UCA: Care provides authorization for medical practitioner to perform POC test too late after practitioner needs to perform test to inform patient care</p>	<p>UCA: Care provides authorization for medical practitioner to perform POC test for too long after practitioner no longer meets requirements to perform test</p>
<p>Acquire POC test</p>	<p>POC-UCA-5*: Care facility does not acquire POC test when POC test can improve clinical decision-making</p>	<p>UCA: Care facility acquires POC test that does not improve clinical decision-making</p>	<p>UCA: Care facility acquires POC test too soon before interface between POC testing device and EHR is set up</p>	<p>N/A</p>

Controller: CMS + Laboratory/Personnel Accreditation Organizations

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Provide care facility/ laboratory authorization to perform POC test	<p>POC-UCA-6*: CMS does not provide authorization for a care facility/laboratory to perform test when test is needed to inform patient care</p> <p>UCA: CMS does not provide authorization for a care facility/laboratory to perform test when care facility/ laboratory has met requirements to perform test</p>	<p>UCA: CMS provides authorization for care facility/laboratory to perform POC test when care facility/laboratory has not met requirements to perform test</p>	<p>UCA: Care provides authorization for care facility/laboratory to perform POC test too late after care facility/laboratory needs to perform test to inform patient care</p>	<p>UCA: Care provides authorization for care facility/laboratory to perform POC test for too long after care facility/laboratory no longer meets requirements to perform test</p>

Controller: IVD Manufacturer

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Release POC IVD device update	<p>POC-UCA-7*: IVD manufacturer does not release POC IVD device update when device does not perform to expected performance levels</p> <p>UCA: IVD manufacturer does not update POC IVD</p>	<p>UCA: IVD manufacturer releases POC IVD device update that does not sufficiently address error reports from customers</p>	<p>UCA: IVD manufacturer releases POC IVD device update too late after receiving error reports from customers</p>	N/A

	<p>device when safety-critical reference terminology/messaging standard update is released.</p>	<p>UCA: IVD manufacturer releases POC IVD device update without providing sufficient support/ communication to customers</p> <p>UCA: IVD manufacturer releases POC IVD device update without informing customers of the implications of updating or not updating</p>		
<p>Provide connectivity functionality between POC device and HIT system</p>	<p>UCA: IVD manufacturer does not provide connectivity functionality between POC IVD device and HIT system when functionality is needed for appropriate interpretation of test results</p> <p>POC-UCA-8*: IVD manufacturer does not provide connectivity functionality between POC device and HIT system when device's results need to be repeatedly accessible after they are generated</p>	<p>POC-UCA-9*: IVD manufacturer provides connectivity functionality between POC IVD device and HIT system using data standard that is not compatible with other systems/devices</p>	<p>UCA: IVD manufacturer provides connectivity functionality between POC IVD device and HIT system too late after data standard is no longer in use</p>	<p>UCA: IVD manufacturer stops providing connectivity functionality between POC IVD device while device is still in use</p>

Controller: FDA

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Issue corrective action to IVD manufacturer	UCA: FDA does not issue corrective action to IVD manufacturer following a series of inappropriate results from POC IVD device	UCA: FDA issues corrective action to IVD manufacturer whose device is performing according to regulation	POC-UCA-10*: FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from POC IVD device	UCA: FDA issues corrective action to IVD manufacturer for too long following the resolution of a problem with a POC IVD device

Controller: Payor

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
Require prior authorization for coverage/reimbursement of test	N/A	POC-UCA-11*: Payor requires prior authorization for coverage/reimbursement of POC test that would be helpful to inform immediate patient care	N/A	UCA: Payor requires prior authorization for coverage/reimbursement of POC test for too long after it is determined that test is helpful to inform immediate patient care

Controller: CDC/PHAs

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order	Stopped too soon, applied too long
<p>Provide healthcare guidance</p>	<p>UCA: CDC/PHAs do not provide healthcare guidance that may provide value to patients' cases</p>	<p>POC-UCA-12*: CDC/PHAs provide inappropriate healthcare guidance</p> <p>UCA: CDC/PHAs provide health guidance that is too stringent for institutions or individuals to follow</p>	<p>UCA: CDC/PHAs do provide healthcare guidance too late after data is received</p> <p>UCA: CDC/PHAs do provide healthcare guidance too early before sufficient data is received</p>	<p>UCA: CDC/PHAs remove healthcare guidance when the guidance is still relevant for patient safety outcomes</p> <p>UCA: CDC/PHAs maintain healthcare guidance when it is no longer relevant for patient safety outcomes</p>

Appendix D – Complete list of Loss Scenarios

This list of loss scenarios is categorized as A, B, and C, and are color-coded as follows:

Category	Explanation
A*	In scope, directly related to issues of laboratory data, high explanatory power, worth a deep dive
B	Generally in scope, contain data-related contributions but are primarily driven by out-of-scope elements, data-related components likely addressed in recommendations for mitigating A-level scenarios
C	Out of research scope, do not contain data-related contributions, but worth a mention for research completeness

*Some A-level scenarios include a visualization that traces the path of the scenario through the control structure and highlights the contributions of several controllers.

OTC Testing

Controller: Public Health Agencies (PHAs)

Control Action:	Provide public health guidance
UCA Type:	Too Early, too late, out of order
UCA:	PHA does not provide guidance in time to limit disease outbreak
Scenario OTC-1-1:	A PHA may not provide guidance in time to limit a disease outbreak because the PHAs may not have sufficient data to track the disease outbreak. Patients may be taking OTC tests instead of traditional clinical laboratory tests that have mandatory reporting. Patients may not report OTC test results to public health databases if they do not know who will have access to the data or do not trust that the data is secure. OTC test platforms may not be held to the same security standards that EHRs and LISs are. OTC tests and their associated products are not necessarily covered by HIPPA and patients may not have control over who has access to their records once they report their data. Patients may not know how their data will be used or how anonymized their data will be. Patients may be concerned that their test results may be used against them. For example, their access to public spaces may be limited if they report a positive test result.
Scenario OTC-1-2:	A PHA may not provide guidance in time to limit a disease outbreak because the PHAs may not have sufficient data to track the disease outbreak. Patients may not report their data because they are unaware of the importance or benefit of reporting OTC results. Patients may not know that there is an avenue for reporting to public health agencies if there is no information about it in the informational packets, on the box, or in public spaces. Furthermore, there is no direct incentive or benefit to the patient to report their data. Furthermore, some state/local PHAs want information on only positive cases while others (including federal) receive all test data. However, patients often believe it is more important to report positives than negatives which biases complete data collection efforts. The PHA may not have the ability to understand trends in a disease outbreak because there has been insufficient investment into how limited OTC data can be used to model disease progression.

<p>Scenario OTC-1-3:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. Patients may be taking OTC tests instead of traditional clinical laboratory tests that have mandatory reporting. No regulatory authority has the authority to require that OTC test results are reported to anyone because CLIA only applies to laboratories not individuals. The data coming from traditional clinical laboratories may not reflect the population as a whole if only the sickest individuals end up testing at traditional or POC facilities.</p>
<p>Scenario OTC-1-4:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have data to track disease outbreaks. OTC test devices may have the ability to transmit data to a database, for example a companion app, but that data may not be available beyond the patient/IVD company. Transmitting the data may take time and money and there may not be a direct benefit to the company to transmit that data. The cost may be high because different states and PHAs have different needs and uses for data. Because there is high variance across the nation, it would be difficult for OTC test manufacturers to ensure their product complied with the requests from the 64 different jurisdictions in the United States.</p> <p>There may be an option to send test results to a “data hub” like CDC’s ReportStream or APHL’s AIMS. These data hubs are able to transfer data to the appropriate PHAs in the requested format and frequency.</p> <p>The AIMS data hub is connected to all PHA jurisdictions in the U.S. However, AIMS is privately run and costs money to use. Government funding is available to ensure that AIMS can be used by OTC test manufacturers to report COVID data for free but the funding is time limited and may not be extended.</p> <p>ReportStream is free to use but only accepts data from certain OTC tests (Flu, Monkey Pox, and COVID). It also is not yet connected to all PHAs.</p> <p>Additionally, OTC test manufacturers may not report data through the data hubs at all because there is no longer a requirement for IVD manufacturers to send data to PHAs. During the COVID EUA period, there was a requirement for FDA approved OTC COVID tests to have plans to send data, but that requirement has lapsed. Furthermore, this requirement only applied to COVID tests so manufacturers of other tests never had any incentive to set up reporting systems.</p>
<p>Scenario OTC-1-5:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. This may occur if the patient does not know where to self-report data. There may be infrastructure set up for patients to self-report results but the package inserts or the test vendors do not direct patients to those tools in a consistent manner. This is because it is not required that instructions contain information about test reporting and there is no standard way that this information is presented if it is presented at all. Additionally, self-report infrastructure may only exist during public health emergencies and may not exist for health problems that are reportable to PHAs in non-emergency situations as well (for example STD testing). Furthermore, not all tests results are requested at all times. PHAs change what diseases are reportable depending on disease trends. Consumers may not be aware that the disease they are testing for is now reportable and IVD manufactures may have limited ability to update packaging or guidance based on state or municipal requests.</p>
<p>Scenario OTC-1-6:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. While many PHAs set minimum data elements for reporting, they may not receive all elements for all cases. Additionally, data may be entered into the reporting systems incorrectly or not reported at all if patient reported data is missing, or incorrect. Data that is supplied is voluntarily provided by patients who may not feel comfortable reporting all data that is requested. Patients may not fill out all fields but may also not submit any data if a field they do not feel comfortable reporting is required.</p>
<p>Scenario OTC-1-7:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. Test data may not be captured because there is</p>

	<p>no longer any regulatory requirement for OTC test companies to encourage data reporting. During COVID, The FDA required EUA approved devices to send data to PHAs after a certain number of months. However, there was no requirement that any particular format be used. Specifications were created by NIH but were not used by all manufacturers. NIH did incentivize companies to use their specifications, however, this program may not be utilized if there is no incentive for the IVD companies to report data in the first place (WHO). Furthermore, these incentives only applied to COVID tests and did not affect other OTC tests.</p>
<p>Scenario OTC-1-8:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. This may occur if not all data that is generated by patients and uploaded to databases is transmitted successfully to public health databases. For example, if data is sent to a hub like HHS Protect, collection of OTC test data may stop if the OTC test software is updated and breaks the connection. There may be tools available to validate data (like those developed by NIST) but not all data going into the hub uses those checks as there is no incentive to do so. Once data is in a database like HHS Protect it is difficult, if not impossible to replace missing data fields because identifying and contacting the patient from anonymized data is not possible.</p>
<p>Scenario OTC-1-9:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. There may already be OTC tests to detect an emergent disease outbreak. However, because there is no capacity for reporting data during non-emergencies, there is no way to quickly access that data when emergencies emerge. By the time reporting structures get set up, they may have missed critical results.</p>
<p>Scenario OTC-1-10:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. The IVD manufacturer may have set up an application to collect data from OTC tests that automatically sends results to PHAs. However, as the public becomes more comfortable using OTC tests, their reliance on instructions and willingness to use companion apps may decrease. Patients may not be aware that the data from their OTC is useful to PHAs and may not report using government mechanisms like <i>Make My Test Count</i>.</p>
<p>Scenario OTC-1-11:</p>	<p>A PHA may not provide guidance in time to limit disease outbreaks because the PHAs may not have sufficient data to track disease outbreaks. PHAs may have OTC test results available but do not use it to inform their decision making because they do not have the bandwidth to analyze it or believe it is unusable because it was generated in a non-controlled laboratory setting. PHAs may not have sufficient methods to rigorously evaluate OTC data to use it to model disease outbreaks or there may not be sufficient data to draw actionable conclusions from. There have been few studies about the reliability of using user-generated OTC lab data for public health matters which may limit the degree to which PHAs are confident in using OTC data.</p>

The following scenarios from the clinical laboratory report are also applicable in this case: Scenarios: 36-1, 36-2.

Controller: Medical Practitioner

<p>Control Action:</p>	<p>Provide treatment</p>
<p>UCA Type:</p>	<p>Not providing causes hazard</p>
<p>UCA:</p>	<p>Medical practitioner does not provide treatment when the patient needs treatment to avoid harm</p>

<p>Scenario OTC-2-1:</p>	<p>A medical practitioner may not provide treatment when the patient needs treatment to avoid harm. This may occur if the medical practitioner requires a traditional clinical laboratory test to provide treatment but the patient is unable to access a traditional clinical laboratory test. The patient may have an OTC test result that is positive, but the healthcare facility may have a policy against using OTC data to make treatment decisions. The care facility may be concerned that if the OTC test result was inaccurate or misleading that they will be held liable for incorrect treatment decisions made based on the flawed data. Furthermore, the care facility gets paid for conducting and reviewing lab data from clinical laboratories. The medical practitioner may not be able to get paid for time reviewing OTC data which further disincentives its use.</p>
<p>Scenario OTC-2-2:</p>	<p>A medical practitioner may not provide treatment when the patient needs treatment to avoid harm. This may occur if the patient does not get a diagnosis from a traditional clinical laboratory test. The patient may have taken a point-of-care test and believed the result to be negative either through misuse or misinterpretation when the result should have been positive. The patient may not seek further care if they receive a false negative.</p>
<p>Scenario OTC-2-3:</p>	<p>A medical practitioner may not provide treatment when the patient needs treatment to avoid harm because their OTC test results were hidden in their EHR in a note. The data may not be coded into the patient’s chart because there is no way for the patient to write data to their EHR record and the only way the result can be reported is through a message (digitally or by phone). The patient may not come in to receive confirmatory testing and their test result may not be seen in future visits when the result could have informed care decisions or recommendations to get follow up testing. The patient may assume that the medical practitioner is aware of the result because they had previously mentioned it and had seen it documented in their care notes.</p> <p>An implementation guide to standardize OTC results in EHRs is available but may not be used because the care facility does not want data that is uncontrolled (sample could be taken improperly, wrong person) in official test records. Additionally, implementing OTC data would require development support from EHR companies which may be costly.</p>
<p>Scenario OTC-2-4:</p>	<p>Medical practitioner does not provide treatment when the patient needs treatment to avoid harm because the doctor is only able to use data from tests in lab. The medical practitioner may develop an inaccurate mental model of the patient’s condition. Tests like blood sugar or cortisol may naturally go up and down throughout the day and over time so doctors may not be able to detect an accurate model of the patient’s condition with only infrequent traditional clinical laboratory tests. The patient may go in for annual checkups during periods that are outliers (during the holidays, for example) and the trends seen in the EHR may not match the patient’s typical condition. There may be applications that could collect data and interface it with the patient’s medical record, but the care facilities may not always accept OTC data.</p>

<p>Control Action:</p>	<p>Provide treatment</p>
<p>UCA Type:</p>	<p>Too Early, too late, out of order</p>
<p>UCA:</p>	<p>Medical practitioner provides care too late to avoid patient harm</p>
<p>Scenario OTC-3-1:</p>	<p>Medical practitioner may provide care too late too late to avoid harm because the physician needed to run a traditional clinical laboratory test to confirm the diagnosis. The patient may have taken an OTC test with the same results, but the physician may not be able to use that to inform their care decisions. Data from OTC tests may not be accepted into the medical record because physicians and care facilities do not want to be liable for patient-generated health data that health professionals were not controlling. Furthermore, doctors may also be uncompensated for the time it takes to review patient generated data.</p>

Scenario OTC-3-2:	<p>Medical practitioner may provide care too late to avoid harm because the hospital is overwhelmed with people taking POC or traditional clinical laboratory tests. Doctors may have less time and resources to spend on patients in the hospital for other care purposes. Patients who need care may also be exposed to sick individuals who are only in the hospital for testing which may reduce the patients willingness to go to a hospital to get traditional clinical laboratory testing. The patients coming in for traditional clinical laboratory tests may not have the ability to test at home because there is no test that meets the approved criteria for complexity of procedures.</p>
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The following scenarios from the clinical laboratory report are also applicable in this case, particularly in contexts where OTC test results are able to be added to an EHR: 1-2, 1-5, 1-6, 1-7, 1-8, 1-9, 1-10, 1-11, 1-12, 1-14, 1-16, 1-17, 1-23, 1-24, 1-26, 1-27, 2-3, 2-4, 2-9, 2-11, 2-14, 2-15, 5-3.

Controller: FDA

Control Action:	Approve OTC test
UCA Type:	Providing causes hazard
UCA:	FDA approves an OTC test that does not facilitate data reporting by test users when that data is needed to inform public health or corrective action decisions.
Scenario OTC-4-1:	<p>FDA approves an OTC test that does not facilitate data reporting by test users. The FDA may approve a device that does not facilitate data reporting because during times when there is no Emergency Use Authorization process in place, the FDA is unable to regulate most data storing and communication features. Without additional regulatory authority they do not have the authority to require that OTC manufacturers provide ways for patients to report data. There are government provided websites (<i>Make My Test Count</i>) where patients can report their data independently, but the tests may not include information about reporting or why it may be beneficial to the patient. The FDA may not have the ability to require that information about reporting be included in the test instructions. Additionally, the options available for patient self-reporting may not include all FDA approved OTC tests or all the fields needed to monitor device performance. The FDA may not have the resources to develop and monitor systems that would track device performance independently from the data received from the OTC test manufacturers.</p>

Control Action:	Approve OTC test
UCA Type:	Not providing causes hazard
UCA:	FDA does not approve an OTC test when that test would enable better patient care decisions
Scenario OTC-5-1:	<p>FDA may not approve an OTC test when that test would enable better patient care decisions. They may not approve this test if there is concern about patients using the device incorrectly. They may not have a full picture of the risks because there have been few studies into patient behavior and risks of OTC tests in a real-world setting. FDA may certify an OTC test for prescription use only in order to control risks, but this may reduce access without substantially increasing safety.</p>

Control Action:	Issue corrective action to IVD manufacturer
UCA Type:	Too Early, too late, out of order
UCA:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device.
Scenario OTC-6-1:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device. This may occur if patients who experience harms or difficulties with OTC tests may not know who to report to. They may report the problems to the vendor of the test in order to get refunded but that vendor may not elevate that report to the FDA or the IVDM. Reporting pathways like MedSun are known to healthcare communities but not to many patient communities.
Scenario OTC-6-2:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device because they did not receive adequate post-market data from tests. It is difficult to get data from patients after they take an OTC test, even in a study environment. Because there is no way for the FDA or the IVD companies to require that patients report their results there are limitations to the amount of available post-market data. The IVD companies may not get notification of problems as patients may not always be able to determine if the test worked or not. The FDA might require post-market data collection if they were concerned, with reason, for a certain performance aspect of the test. However, it may be difficult to detect when post-market data is necessary because when data is reported, it may not always be attached to a unique device identifier that would allow regulators to identify problems with a specific device, or specific lot of a device. Post market surveillance may only occur regularly when IVDMs want to expand the population of individuals who are approved to use the test (i.e., children).s
Scenario OTC-6-3:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device because they did not receive adequate post-market data from tests. Data may be unstandardized because there is no requirement for data collection on the IVD companies from the FDA. The FDA cannot fund any products they regulate so they cannot work with manufacturers to develop solutions. Other agencies may work with companies to develop data reporting solutions, but these are not required and may not be used by all OTC tests.
Scenario OTC-6-4:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device because they filtered out a lot of reports of problematic test behaviors. There may be heavy filters in place to prevent rival companies from poisoning data sets with false reporting. However, this may make it more difficult to sense other problems on the market. Data may also be filtered if it does not contain sufficient information to identify the product.
Scenario OTC-6-5:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device. This may occur because the signals tracked by the FDA can take months or longer to emerge clearly. The FDA needs thousands of results to determine whether or not there are critical problems worthy of recall. With OTC devices reporting is more sporadic and random which means that tools like statistical analysis of report frequencies are less helpful at determining aberrations. During the EUA test manufacturers supposed to report all instances of problems, especially when they lead to death or serious injury, but not all data was reported.

Scenario OTC-6-6:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device. The inappropriate results may be a result of systemic misuse of the test due to missed concerns during usability testing. The FDA does require usability studies before device approval, but the population studied may not reflect the population or the environment that the test will be used in. The usability studies may also be done with healthy individuals as opposed to individuals currently experiencing impairments from the disease being tested.
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The following scenarios from the clinical laboratory report are also applicable in this case: 24-1, 24-2, 25-2, 25-3.

Controller: Patient

Control Action:	Seek medical treatment
UCA Type:	Not providing causes hazard
UCA:	Patient may not seek medical treatment when treatment is needed to avoid harm
Scenario OTC-7-1:	Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. The test result may have been inaccurate if the patient taking the test is not part of the population the test was approved for. Tests are approved based on pretest probabilities and prevalence. The patient may not have realized that being outside of the testing population would impact result accuracy or may not realize that they are not in the approved demographic. For example, a parent may use a test on a child when it was only cleared for use on adults.
Scenario OTC-7-2:	Patient may not seek medical treatment when treatment is needed to avoid harm. This may occur if the patient does not get a diagnosis from a traditional clinical laboratory test. The patient may have taken a point-of-care test and believed the result to be negative either through misuse or misinterpretation when the result should have been positive. The patient may not seek further care if they receive a false negative.
Scenario OTC-7-3:	Patient may not seek medical treatment when treatment is needed to avoid harm. The patient may not seek additional treatment if they received misleading instructions from their OTC test. The test result may have been correct, but the patient may have mis-entered the information from the device into a reporting system that used that information to recommend treatment or follow up care. The patient may not have understood the raw result data and may not have recognized their error.
Scenario OTC-7-4:	Patient may not seek medical treatment when treatment is needed to avoid harm because they believe their test is negative. The OTC test may have an accompanying app that helps the patient interpret the test results using photos of their test. The photo of the test may not be interpreted correctly by the app if the app was not calibrated or tested in the environmental conditions of the patient’s photo (lighting, etc.). The patient may not know how to interpret the test on their own and may not recognize the interpretation error.
Scenario OTC-7-5:	Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. The patient may believe their result was negative because they did the test according to their belief of how the test was supposed to work. They may have ignored instructions in the test because it required an app, the instructions looked too long, or they felt like it looked simple enough. The patient may have made incorrect assumptions about

	<p>how the test was supposed to work and made an error that rendered the result invalid without their knowledge.</p>
<p>Scenario OTC-7-6:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they believe their test was negative when it was actually positive. The patient may have taken this test before in the past having read the instructions and memorized the procedures. However, there may have been an update to the procedures that the patient did not know about. The updated procedures may have changed critical steps of the process that resulted in the patient obtaining a false negative.</p>
<p>Scenario OTC-7-7:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm because their first test was negative. However, this test may have required a series of tests over a set time period for full accuracy and sensitivity. The patient may not understand the necessity of testing sequences or have sufficient OTC tests available to conduct repeat tests. There may not be clear ways of communicating to the patient when to take a follow up test, especially if the recommendations change over the course of a season or disease outbreak. Apps may be available to remind patients to take additional tests at set intervals, but patients may not use apps for all OTC tests.</p>
<p>Scenario OTC-7-8:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. Patient may not seek appropriate care or laboratory testing because the patient did not want any outside entity to know the result of the test. Additionally, the patient may not get a traditional clinical laboratory test done because they do not believe that they are a high risk for a certain condition or thought the traditional clinical laboratory test was too invasive for the perceived benefit. The patient may have been willing to test using an OTC option. However, if there is no OTC test available the patient cannot access that diagnostic information. The decision to allow a particular test to be offered in an OTC context may be based on patients with regular access to a quality healthcare system. However, this may not represent all patients in the healthcare system.</p>
<p>Scenario OTC-7-9:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. Patient may not seek appropriate care. The patient may have received the correct test result but not have known what to do after receiving the test result. Because there is difficult to share OTC test data with care providers, the patient may not contact their provider to determine the next steps.</p>
<p>Scenario OTC-7-10:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they do not understand their OTC test result. The patient may use a test that does not give specific results. For example, the test may show positive for individuals who currently have a disease or who have had a disease in the past. The patient may not understand that they need additional testing to determine care steps.</p>
<p>Scenario OTC-7-11:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. The sample for the OTC test may be taken at home but analyzed at a traditional clinical laboratory. The patient may not have taken the sample correctly or the sample may have been handled improperly. The results may accurately reflect the sample that was sent but not the conditions of the patient, the testing laboratory may have limited ability to detect problems with the sample.</p>
<p>Scenario OTC-7-12:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an invalid OTC test result but believed it was valid. The patient may use an OTC test that is unable to display error messages for all ways the result may become invalid. The device may not be technologically capable of showing all potential error messages such as insufficient</p>

	<p>sample, wrong sample type, out of date, etc. Furthermore, the patient may interpret the error message as the test result itself if they are not expecting an error as a possible test outcome.</p>
<p>Scenario OTC-7-13:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they believe their test is more specific and accurate than it is. The patient may believe that their test is regulated by the FDA but the test may not be one of the tests covered by the FDA’s purview. The vendor may not make it easy to distinguish regulated versus unregulated tests and the patient may not realize that not all OTC tests are regulated. Furthermore, there may be counterfeit tests on the market that may be difficult for manufacturers and patients to identify.</p>
<p>Scenario OTC-7-14:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm. This may occur if patients believe the treatment for a particular condition will be useful to them regardless of their test result. The patient may intentionally misconstrue test results to access care (like medications). Patients may also misconstrue/misinterpret test results if there are significant social ramifications to a positive or a negative.</p>
<p>Scenario OTC-7-15:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. Patient may conduct the OTC test incorrectly because they are ill when conducting the test. The test may be for an illness that has symptoms such as nausea/headache/fatigue/motor control difficulties which could make it more difficult for a patient to read and follow instructions. The usability tests may be conducted on individuals with no impairments and may overestimate the ease of use for impacted individuals.</p>
<p>Scenario OTC-7-16:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. The result may be incorrect if the patients did not follow all directions of an OTC test correctly. For example, a refrigerated component may need to be set out for an hour. The patient may not realize how significant each step is on the test accuracy and may skip or not finish certain steps to finish the test quickly. The patient may also try to find workarounds to complete long or difficult steps faster (like heating the test component) that could negatively affect results.</p>
<p>Scenario OTC-7-17:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they receive an incorrect OTC test result. The result may be incorrect if the patient uses a test that is expired. The patient may not realize the test has expired because they bought it recently or did not realize that the tests expire. The patient may not think that the expiration date is significant as other consumer products have different kinds of expiration dates (best by vs do not use after) and different brands may have substantially different shelf-lives. There may be no information from the vendor that alerts the patient to the significance or existence of expiration dates. There may be no controls about how long before an expiration date a vendor can sell the tests to the patient.</p>
<p>Scenario OTC-7-18:</p>	<p>Patient may not seek medical treatment when treatment is needed to avoid harm if they do not conduct an OTC test at all. Patients may not run the test if they are unable to access the test due to financial reasons. Some OTC tests like continuous glucose monitors may be considered medically necessary and will be covered and paid for by insurers. However, for tests that are not considered medically necessary or do not have the option of being prescribed, the patients may not find the benefits to be worth the price. It may also take time for a new OTC test to be considered fit for continual monitoring and be considered medically necessary in order to be covered by insurance plans.</p>

The following scenarios from the clinical laboratory report are also applicable in this case: 33-2, 33-3, 34-7.

Controller: IVD Manufacturer

Control Action:	Provide data collection mechanism
UCA Type:	Not providing causes hazard
UCA:	IVD manufacturer does not provide data collection mechanism when data is needed to inform regulatory or public health guidance.
Scenario OTC-8-1:	IVD manufacturer does not provide data collection mechanism when data is needed to inform regulatory or public health guidance. IVDM may not collect data from users because companies that develop apps that interpret or instruct users in testing protocols must recertify using the 510k process for each OTC test they add to the app. This may discourage IVD manufacturers from adding new OTC tests to apps which could limit data collection potential for post market testing. Apps may be an additional mechanism to control and track test reuse, lot numbers, expiration dates, etc. but if it is too expensive to certify for new OTC tests IVD manufacturers may not develop them.
Scenario OTC-8-2:	IVD manufacturer does not provide data collection mechanism when data is needed to inform regulatory or public health guidance. The IVD manufacturer may not provide a data collection mechanism if they do not see that increasing the profitability of their product and there are not always other incentives or requirements to do so. Furthermore, if a company wanted to collect data, public health agencies and EHRs use different data standards and require different information. For example, ONC requires certified EHRs to use FHIR but nothing requires PHAs to do the same. Neither care facilities nor PHAs incentivize IVD manufacturers to collect data in a standardized way. Care facilities may not be ready to accept OTC data if they are worried about taking on additional legal liabilities. PHAs may not prioritize incentivizing OTC reporting because there is insufficient guidance on how to use patient generated data to create disease tracking models. Without knowing how to best utilize OTC data, spending resources to incentivize reporting may not appear to be worthwhile, especially for smaller PHAs.
Scenario OTC-8-3:	IVD manufacturer does not provide data collection mechanism when data is needed to inform regulatory or public health guidance. The IVD manufacturer may have an interface that allows patients to track their result data, but the information may not be sufficient for use in public health or regulatory decisions. The data that each agency needs are distinct and there are no incentives for any of it to be collected from OTC devices. For example, PHAs may not care about device identifiers but the FDA does. PHAs may only want reporting on positive results, but the FDA may find positive and negative results useful to understand test performance.

The following scenarios from the clinical laboratory report are also applicable in this case:26-1, 26-2.

Controller: Standards Development Organizations

Control Action:	Develop Standards
UCA Type:	Not providing causes hazard
UCA:	SDOs may not develop standards that allow OTC test results to be shared and documented in HIT systems

<p>Scenario OTC-9-1:</p>	<p>SDOs may not develop standards that allow OTC test results to be shared and documented in HIT systems. One factor that makes developing OTC standards challenging is that lab tests results usually include the person who ordered the test and FHIR and other standards require that individual to be listed. OTC Tests do not always have a person who ordered the test associated with a result, so some systems would boot out any OTC test that was entered.</p>
<p>Scenario OTC-9-2:</p>	<p>SDOs may not develop standards that allow OTC tests to be shared in documented across different types of HIT systems. There are standards to allow OTC tests to be shared with PHAs, but PHAs and EHRs use different data standards. Because PHAs are requesting OTC data, but most care facilities do not yet want to add OTC results to patient portals, there is no pressure to create standards that work for EHRs.</p>

The following scenarios from the clinical laboratory report are also applicable in this case: 29-1, 30-1, 30-2, 31-1, 31-2, 32-1.

Controller: Care Facility

The following scenarios from the clinical laboratory report are also applicable in this case. These scenarios are particularly applicable in contexts where OTC test results are able to be added to an EHR::6-2, 6-3, 8-1, 9-2, 9-4, 10-1, 10-2, 11-3.

Controller: HIT company

The following scenarios from the clinical laboratory report are also applicable in this case. In the OTC system HIT companies could be developers of the companion apps for OTC tests or the developers of EHRs as in the clinical laboratory report: 13-1, 13-2, 14-2, 17-1.

Controller: CMS

The following scenarios from the clinical laboratory report are also applicable in this case: N/A.

Controller: ONC

The following scenarios from the clinical laboratory report are also applicable in this case: 21-2, 22-1, 22-2.

Controller: Payor

The following scenarios from the clinical laboratory report are also applicable in this case: 27-1.

Controller: HHS

The following scenarios from the clinical laboratory report are also applicable in this case:38-1, 38-2, 38-3, 38-4, 38-5, 38-6, 39-1, 39-2, 39-3.

Controller: Congress/White House

The following scenarios from the clinical laboratory report are also applicable in this case:40-1,41-1, 41-2, 41-3, 41-4, 41-5, 42-1, 42-2, 42-3.

POC Testing

Controller: Medical Practitioner

Control Action:	Provide treatment to patient
UCA Type:	Providing causes hazard
UCA:	Medical practitioner provides treatment that does not match the patient’s condition
Scenario POC-1-1:	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they had incorrect diagnostic information available to inform their working diagnosis (mental model) of the patient’s condition. That may occur if a POC test result was influenced by the procedure used to conduct the test.</p> <p>That may occur if the specimen was not collected or stored using the appropriate procedure/equipment (e.g., blood specimen for a potassium test was allowed to hemolyze). With a traditional clinical laboratory test, the medical practitioner may be accustomed to receiving a note from the laboratory if the specimen was hemolyzed, however that information may not be available for a POC test.</p> <p>If a laboratory result and a POC result are not differentiated in the EHR interface, the doctor may assume that the absence of a note means the sample was not hemolyzed, when instead the sample may have been hemolyzed, but this was a POC test and that information was not available/documented.</p>
Scenario POC-1-2:	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they had incorrect diagnostic information available to inform their working diagnosis (mental model) of the patient’s condition. That may occur if the POC test result was influenced by the procedure used to conduct the test, and that contextual information was not communicated alongside the POC test result.</p> <p>That may occur if the specimen was not collected or stored using the appropriate procedure/equipment (e.g., blood sample for a potassium test was allowed to hemolyze, or tourniquet was left for too long on the patient’s arm), but the POC test result interface does not allow for contextual information about the state of the patient/specimen to be stored and communicated alongside it in the EHR.</p>
Scenario POC-1-3:	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that important diagnostic information that would have helped to inform their working diagnosis (mental model) of the patient’s condition was not directly available to them. That may occur if the interpretation of a POC test result depends on additional contextual information that is not automatically conveyed to the practitioner alongside the test result.</p> <p>For example, a laboratory and a POC test used for the same purpose (e.g., measuring blood calcium) may not provide the same type of data and may not possess the same reference range (e.g., POC test only measures ionized calcium, not serum calcium levels). If there is no connectivity between a POC device and the care facility EHR, the medical practitioner may not have access to the appropriate reference range at the point-of-care, which would be available if the result were shared from a laboratory and visible in the EHR. An abnormal result that is outside the reference range may therefore not be flagged from a POC result.</p> <p>Many POC devices may have the ability to integrate with EHRs, but the underlying complexity and cost of doing so is outweighed by the low volume of POC testing that is occurring. Additionally, many IVD manufacturers may provide proprietary options for connectivity that use standards that are incompatible with devices provided by other</p>

	<p>manufacturers, meaning care facilities need to invest in separate, individual interfaces between each POC device and their EHR.</p> <p>Regulatory or statutory incentives to ensure connectivity between POC devices and HIT systems are scarce. Customers may also have the ability to opt in or out of delivering data from the POC device into a data platform (EHR), and only a small proportion of customers may opt in.</p>
<p>Scenario POC-1-3:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that important diagnostic information that would have helped to inform their working diagnosis (mental model) of the patient’s condition was not directly available to them. That may occur if the critical/panic value for a POC test result depends on additional contextual information that is not automatically conveyed to the practitioner alongside the test result.</p> <p>A POC device may not be able to bidirectionally interface with the care facility’s EHR, so the medical practitioner may not have access to additional information about the patient that influences the interpretation of the result (e.g., the patient presents with an elevated potassium level but it turns out the patient is on medications that elevate potassium, or the patient presents with low white blood count but it turns out they are on chemotherapy). Even if the POC device and EHR are interfaced, the design of the interface or the display of the POC device may preclude the availability of contextual information sometimes important in result interpretation. Contextual information may be important to interpreting test results, regardless of whether a test takes place in a laboratory or at the POC.</p>
<p>Scenario POC-1-4:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that important diagnostic information that would have helped to inform their working diagnosis (mental model) of the patient’s condition was not directly available to them. The diagnostic information may have been in the form of a POC test result that is displayed in a different window of the EHR as opposed to traditional clinical laboratory results.</p> <p>The medical practitioner may have developed a routine process to more easily access laboratory test results. That process may be a workaround to avoid multiple clicks or process steps that would be necessary to access the laboratory result. Because POC results are stored in a different window of the EHR, the practitioner’s workaround may only reveal the laboratory results, and not POC results.</p>
<p>Scenario POC-1-5:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they were not aware that diagnostic information was already available to inform their mental model of the patient’s condition. The POC test may have been ordered verbally, and no order was logged in the EHR.</p> <p>Without the order in the EHR, the practitioner may have no feedback on whether the order has been received, whether the test is being carried out, what step of the process the test is at, and whether there is a result available. The testing practitioner may not communicate the test result directly to the ordering practitioner, and without an order in the EHR the practitioner may not realize that a result was obtained that could inform treatment.</p>
<p>Scenario POC-1-6:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they did not have the diagnostic information to inform their working diagnosis (mental model) of the patient’s condition. The diagnostic information may not be observed by the medical practitioner if the practitioner only accesses laboratory results that documented in structured fields within the care facility’s EHR system (e.g., results that were mapped to a LOINC code or local code representation).</p>

	<p>In some cases, additional unmapped POC results are available in emergency medical services (EMS) run reports, which may not have been loaded into the EHR or may have been loaded as free text in a “notes” section as opposed to a structured field. EMS systems frequently have a different EHR system from the care facility and thus communication of important patient information may rely on verbal handoffs as well.</p> <p>Physicians who are not expecting and looking for the test results may not know to look for additional, unmapped information in a patient profile, particularly if the unmapped results were ordered by another physician.</p> <p>The results may have been shared as free text notes because the ambulance uses a separate EHR system that does not have a bidirectional interface set up with the EHR of the care facility, or has an interface that cannot appropriately transmit all the necessary data elements.</p>
<p>Scenario POC-1-7:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that important diagnostic information that would have helped to inform their working diagnosis (mental model) of the patient’s condition was not directly available to them. That may occur if POC test results for a patient are not transferred into that patient’s medical record.</p> <p>This may occur if the patient was unable to be associated with their medical record upon arrival at a care facility, such as if the patient is obtunded, cannot be identified, and a new medical record must be created for them. The patient’s POC results from the EMS or emergency room (ER) may be logged in a temporary record (e.g., under the name John/Jane Doe) that is not later merged with the patient’s permanent record. There may have been an attempt to merge the results with the permanent record, but certain results may have been lost in that process.</p>
<p>Scenario POC-1-8:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that important diagnostic information that would have helped to inform their working diagnosis (mental model) of the patient’s condition was not directly available to them. The diagnostic information may have been in the form of a POC test result that was not logged to the patient’s medical record.</p> <p>The medical practitioner carrying out the test may have had difficulty locating the patient’s wristband/barcode. Some POC devices may require scanning a patient’s wristband/barcode in order to perform the test, so the practitioner may have inserted a different patient record number (e.g., 1111111) to be able to carry out the test. The result is then not documented in the appropriate patient’s medical record.</p>
<p>Scenario POC-1-9:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they had incorrect diagnostic information available to inform their working diagnosis (mental model) of the patient’s condition. That may occur if the POC test result was entered manually into the EHR, and this was done incorrectly (e.g., typo, wrong patient, etc.).</p> <p>Care facilities may not want to invest in a separate interface between each POC device and their EHR due to financial constraints. Many POC devices may have the ability to integrate with EHRs, but the underlying complexity and cost of doing so is outweighed by the low volume of POC testing that is occurring.</p>
<p>Scenario POC-1-10:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that important diagnostic information that would have helped to inform their working diagnosis (mental model) of the patient’s condition was not directly available to them. The diagnostic information may have been in the form of a POC test result that is not appropriately documented in the patient’s medical record in the EHR.</p> <p>A POC device may originally be harmonized to transmit test results directly into the EHR, so the medical practitioner may anticipate that they will have access to the results after the test</p>

	<p>is carried out. However, the IVD manufacturer may have updated their system to change how the result is shared (e.g., used to report a numerical “5” and now report a string “<5”). The result may no longer be directly transmitted through the interface into the patient’s medical record, may be transmitted in a format that charts differently, or may be transmitted in a format that does not trigger clinical decision support.</p> <p>There may not have been appropriate communication from the IVD manufacturer that the update was occurring, or what the implications of the update would be. The IVD manufacturer may not have taken into consideration every possible software or hardware the IVD device system is expected to interact with, due to the high amount and variability of connections the system may have.</p>
<p>Scenario POC-1-11:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they had insufficient diagnostic information available to inform their process model of the patient’s condition. That may occur if POC test results for a patient are not transferred into that patient’s medical record.</p> <p>This may occur if the POC device was registered in a particular environment (e.g., an adult hospital) and was used and docked in a different environment (e.g., an affiliated children’s hospital). The device or the interface may not be set up to be able to transfer results from any docking station into the patient’s medical record.</p>
<p>Scenario POC-1-13:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they did not have the diagnostic information to inform their mental model of the patient’s condition. The diagnostic information may have been in the form of a POC test result that was not logged to the patient’s medical record.</p> <p>The medical practitioner carrying out the test may have scanned the patient’s wrong wristband/barcode. Some facilities that have associated pharmacies may have different wristbands/barcodes for laboratory results and for the pharmacy’s medication tracking system. The patient may have a different record number in each system, and if the practitioner scans the wrong code or enters the wrong number, the result may not be logged in the patient’s medical record.</p>
<p>Scenario POC-1-14:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that their working diagnosis (mental model) of the patient’s condition was informed by diagnostic information presented in a misleading way. The POC device may have produced an error code that was misinterpreted by the medical practitioner as a test result.</p> <p>The POC device may not have been harmonized with the EHR, such that the medical practitioner would receive a specific notification that the result is invalid. The practitioner may have needed to provide treatment quickly and did not realize the device’s display presented an error code instead of a result.</p>
<p>Scenario POC-1-15:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they had incorrect diagnostic information available to inform their working diagnosis (mental model) of the patient’s condition. The POC device may have produced an invalid result because the device/reagent was expired, and that information was not documented and shared with the practitioner.</p> <p>The POC device may not have been harmonized with the EHR and data elements like the device’s serial number, fabrication date, and expiration date may not have been automatically documented alongside the result and transmitted into the patient’s medical record.</p>

<p>Scenario POC-1-16:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that they had incorrect diagnostic information available to inform their working diagnosis (mental model) of the patient’s condition. A POC device may have been developed to monitor patients in a particular condition, and may therefore only perform well for a certain range of results (e.g., if the result is above 4, it should be treated as unreliable). A practitioner may have seen a POC result that should have been treated as unreliable, but interpreted the result as having come from the laboratory, and therefore believed the result was reliable.</p> <p>The POC device may have been coded to interface directly with the care facility’s EHR system, and the device’s output may be mapped to the same reference terminology (i.e., LOINC code, etc.) as the equivalent laboratory test that measures the same quantity. The POC result may therefore be displayed and charted in the EHR interface in the same field as results that came from the laboratory.</p> <p>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.</p> <p>Tests using different methodologies and producing noncomparable results may also be <i>appropriately</i> 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.</p> <p>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.</p>
<p>Scenario POC-1-17:</p>	<p>A medical practitioner may provide treatment that does not match the patient’s condition (UCA). One contributing factor may be that their working diagnosis (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.</p> <p>That may occur if two POC tests that use different methodologies or specimens for the same condition are mapped to the same reference terminology. This could happen if a particular reference terminology (e.g., a LOINC code) already exists for a POC test measuring a certain analyte (like blood glucose) and the developer of a new POC device that measures the same analyte from a different specimen type does not request that an SDO create a new reference terminology for that device.</p> <p>SDOs may not be aware of all new POC tests on the market and rely on others to request new reference terminology, as well as provide them with package insert information so they can make decisions on what terminology to create.</p>

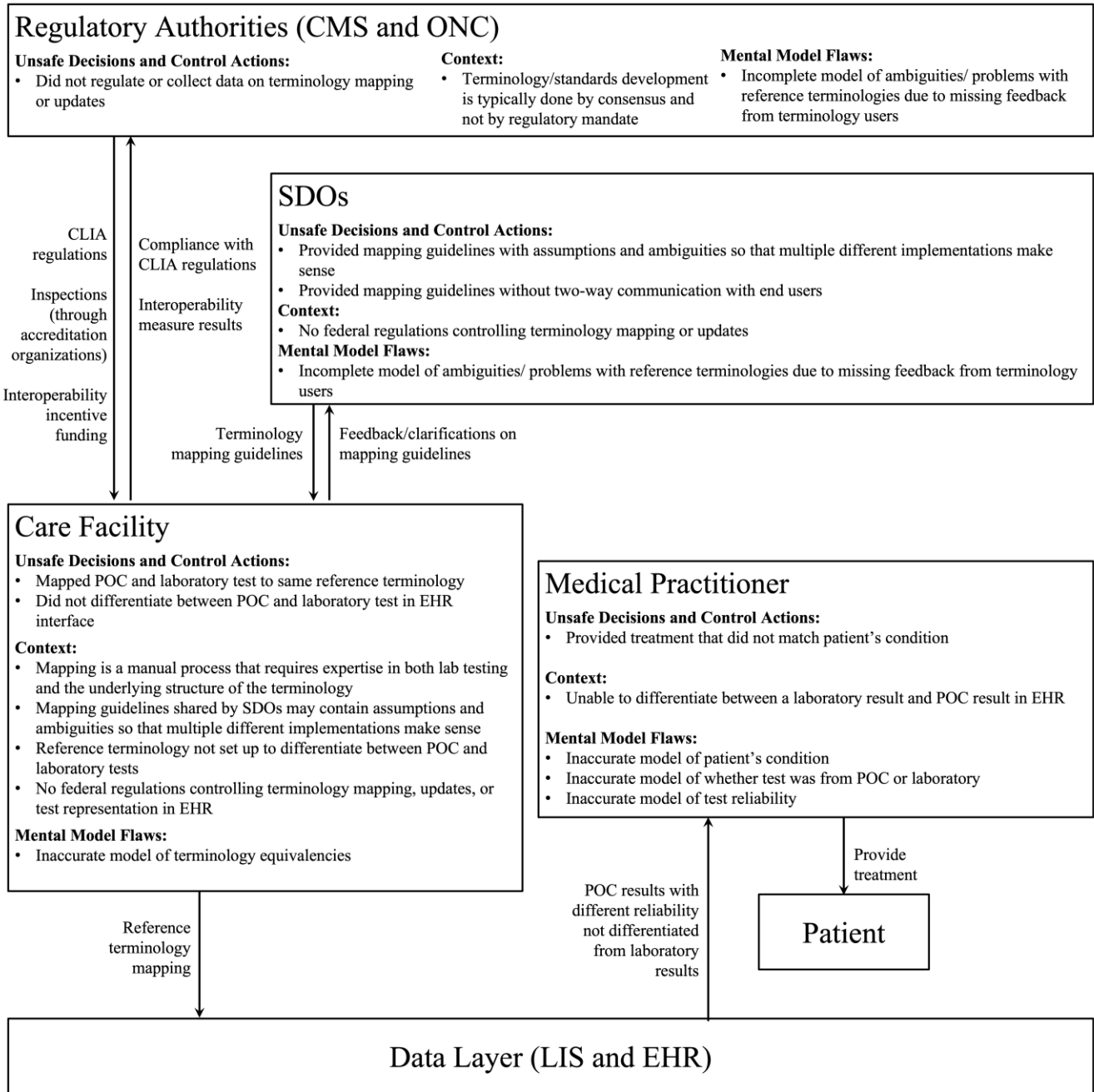


Figure 7. Visualization of Scenario POC-1-16

Control Action:	Provide treatment to patient
UCA Type:	Too early / too late / out of order
UCA:	Medical practitioner provides treatment too late to avoid patient harm
Scenario POC-2-1:	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that important diagnostic information that would have helped to inform their working diagnosis (mental model) of the patient’s condition was not directly available to them in a timely manner. That may occur if a medical practitioner intended to order a POC test, but a laboratory test was ordered instead.</p> <p>When the ordering practitioner orders the POC test verbally without properly communicating whether they want a POC or laboratory test, the testing practitioner may put in a formal order that gets sent to the laboratory and has a longer turnaround time, instead of directly carrying out the test. The ordering practitioner may not want to expend additional time to put in the POC order, so they issue a verbal order with language that is not standardized.</p>
Scenario POC-2-2:	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that there was a delay in obtaining diagnostic information to inform their working diagnosis (mental model) of the patient’s condition. The POC test may have required a control to be completed before the test could be run, and that control was not done, so the testing practitioner had to carry out the control before they were allowed to obtain actual results for the patient. If the patient is in critical condition, delaying care may lead to patient harm.</p>
Scenario POC-2-3:	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that important diagnostic information that helped to inform their working diagnosis (mental model) of the patient’s condition was lost and had to be reobtained. That may occur if POC test results for a patient are not appropriately transferred into that patient’s medical record.</p> <p>This may occur if the patient was unable to be associated with their medical record upon arrival at a care facility, such as if the patient is obtunded, cannot be identified, and a new medical record must be created for them. The patient’s POC results from the EMS or ER may be logged in a temporary record (e.g., under the name John/Jane Doe), and during the process of merging those results with the patient’s permanent record, some test results get lost and need to be redone.</p>
Scenario POC-2-4:	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unable to carry out the POC test in a timely manner. That may occur if the patient is in critical condition but has not been fully registered at the care facility and does not have a wristband/barcode.</p> <p>Some POC devices may require scanning a patient’s wristband/barcode in order to perform the test, so the practitioner may have to wait for the patient to be registered before they can obtain diagnostic information.</p>
Scenario POC-2-5:	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unable to carry out the POC test in a timely manner. That may occur if the patient is in critical condition but the practitioner has not</p>

	<p>completed the necessary competency checks to carry out that test. Some POC devices may require scanning a practitioner’s badge in order to perform the test, and the practitioner may not be able to do so if they have not completed their competency checks.</p> <p>The practitioner may not have completed the competency check for several reasons, such as the check being scheduled at a time that is not aligned with the practitioner’s work schedule. The practitioner may utilize another practitioner’s badge to carry out the test instead.</p>
<p>Scenario POC-2-6:</p>	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unable to carry out the POC test in a timely manner. That may occur if a nurse cannot carry out a particular POC test for a patient if the test was not ordered by a physician, and the physician either does not place the order or places it through a mechanism that is against care facility policy (e.g., sends it in a text instead of putting the order directly into the EHR).</p> <p>The physician may be busy treating other patients and may not see the value in adhering directly to care facility policy. The nurse may not want to violate policy and carry out the test, as they may face disciplinary action from care facility administration for doing so.</p>
<p>Scenario POC-2-7:</p>	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unable to obtain the diagnostic information they needed to treat the patient in a timely manner. That may occur if a practitioner cannot carry out a particular POC test for a patient, because the care facility’s authorization to carry out that test has been revoked.</p> <p>The care facility may lose authorization to carry out that test if they fail proficiency testing for the test, or if CLIA/CAP surveyors uncover other rule violations in the POC testing environment.</p> <p>For example, CLIA requires documentation of critical value communication (i.e., if a result was above a certain threshold, it needs to be communicated to a licensed provider and acknowledged). A LIS system in a traditional clinical laboratory may flag the critical value and prevent the technician from continuing their workflow without notifying the ordering practitioner, but in a POC environment the device may not be harmonized with the EHR and there may not be anything stopping the testing practitioner from proceeding without reporting the critical value. If this communication does not occur or is not documented, it may be a violation of CLIA requirements, which may result in removal of authorization to carry out that test.</p> <p>All POC testing occurs under a CLIA license, which in many cases may be the same license as the main laboratory at that care facility. Therefore, if the authorization to carry out a particular test is removed due to violations in a POC environment, the clinical laboratory may also be unable to perform those tests. However, the clinical laboratory may not have control over CLIA compliance in the POC environment.</p>
<p>Scenario POC-2-8:</p>	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unable to obtain the diagnostic information they needed to treat the patient in a timely manner. That may occur if a practitioner cannot carry out a particular POC test for a patient, because the care facility’s authorization to carry out that test has been revoked.</p> <p>POC testing is required to occur under a CLIA license, which in many cases may be the same license as the main laboratory at that care facility. The laboratory may revoke the care facility’s authorization to carry out that test if they suspect the care facility will fail proficiency testing for the test, or if they suspect there to be CLIA/CAP rule violations in the POC testing environment due to past performance issues.</p> <p>If the authorization to carry out a particular test is removed due to violations in a POC environment, the clinical laboratory may also be unable to perform those tests. Therefore, the</p>

	<p>clinical laboratory may remove the care facility’s authorization to use that POC test to minimize the risk of CLIA noncompliance in the POC environment.</p>
<p>Scenario POC-2-9:</p>	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unaware of critical diagnostic information that would be needed to inform immediate treatment of the patient. That may occur if a practitioner is not notified of a critical POC test result.</p> <p>A LIS system in a traditional clinical laboratory may flag a critical result and prevent the technician from continuing their workflow without notifying the ordering practitioner, but in a POC environment the device may not be harmonized with the EHR and there may not be anything forcing the testing practitioner to report the critical value to a physician. Though CLIA requires documentation of critical value communication, EHRs are not typically designed to require that to occur, and may not provide a single field in which this documentation can be stored.</p>
<p>Scenario POC-2-10:</p>	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unable to carry out the POC test in a timely manner. That may occur if the patient is not ambulatory and requires the POC test to be carried out at their home. A home health agency may not be willing to initiate the action of collecting a sample and carrying out a test without having received an order with confirmation that the test will be covered by the patient’s insurance.</p>
<p>Scenario POC-2-11:</p>	<p>A medical practitioner may provide treatment too late to avoid patient harm (UCA). One contributing factor may be that the practitioner was unable to obtain the diagnostic information they needed to treat the patient in a timely manner. That may occur if a practitioner cannot carry out a particular POC test for a patient, because the care facility’s authorization to carry out that test has been revoked.</p> <p>The care facility may lose authorization to carry out that test if the care facility cannot provide the laboratory with evidence of the appropriate use of each POC test made available to them.</p> <p>For example, a care facility may have originally ordered 25 POC tests of one type, and then may run out of tests while only having reported results for 10 of those tests. The other 15 tests may have been used by other departments of the care facility, may have been used off-label, or their results may simply not have been manually logged in the EHR. If the POC device is not harmonized with the EHR, it may be up to the individual medical practitioner carrying out the test to manually input the result in the system.</p> <p>All POC testing occurs under a CLIA license, which in many cases may be the same license as the main laboratory at that care facility. The laboratory may not want to risk losing the CLIA authorization to perform a particular test, and may therefore revoke the care facility’s authorization to carry it out at the point-of-care.</p>

<p>Control Action:</p>	<p>Run laboratory test</p>
<p>UCA Type:</p>	<p>Providing causes hazard</p>
<p>UCA:</p>	<p>Medical practitioner runs laboratory test that is not the best/most appropriate test to diagnose a disorder/disease</p>

Scenario POC-3-1:	A medical practitioner may not order the best/most appropriate lab test to diagnose a disorder/disease (UCA). One contributing factor may be that the positive predictive value of a test is influenced by contextual factors that are not available to the medical practitioner. If the pre-test probability of a particular condition is low in a certain patient population, the performance characteristics of the test may limit the test’s usefulness.
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The following scenarios from the clinical laboratory report are also applicable in this case: 1-3, 1-4, 1-5, 1-6, 1-7, 1-8, 1-21, 1-22, 1-24, 1-25, 1-27, 3-2, 3-3, 3-5.

Controller: Care Facility

Control Action:	Provide medical practitioner authorization to perform POC test
UCA Type:	Not providing causes hazard
UCA:	Care facility does not provide authorization for a medical practitioner to perform POC test when practitioner needs to perform test to inform immediate patient care
Scenario POC-4-1:	<p>A care facility may not provide authorization for a medical practitioner to perform POC test when the practitioner needs to perform the test to inform immediate patient care, if the practitioner’s qualifications have recently changed and the POC device has not been updated to include that practitioner among its approved users.</p> <p>Each POC device may have an individual database that stores the list of approved users for that device. The “lockout” feature that prevents practitioners from using a device may be independent from the care facility’s EHR, its email database, or its identity management tool. The care facility may be managing multiple systems in which they keep track of approved users, and it can be challenging to ensure that the appropriate permissions have been updated in each individual system.</p>
Scenario POC-4-2:	A care facility may not provide authorization for a medical practitioner to perform POC test when the practitioner needs to perform the test to inform immediate patient care, if the practitioner has not completed the necessary competency checks to carry out that test. The practitioner may not have completed the competency check for several reasons, such as the check being scheduled at a time that is not aligned with the practitioner’s work schedule. The practitioner may be forced to utilize another practitioner’s badge to carry out the test instead.

Control Action:	Acquire POC test
UCA Type:	Not providing causes hazard
UCA:	Care facility does not acquire POC test that could improve clinical decision-making
Scenario POC-5-1:	<p>A care facility may not acquire a POC test that could improve clinical decision-making (UCA). One contributing factor could be that a regulatory authority imposed a requirement that the care facility implement an interface and adopt a particular standard for sharing data between POC IVD devices and EHRs, which is too costly for the care facility to comply with.</p> <p>Many POC devices may have the ability to integrate with EHRs, but the underlying complexity and cost of doing so may be outweighed by the low volume of POC testing that is</p>

	occurring at the facility. The care facility may therefore choose to discontinue offering the test at the POC and may choose to send it to a traditional clinical laboratory instead, as it may be most cost effective from a management perspective.
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The following scenarios from the clinical laboratory report are also applicable in this case: 6-1, 6-2, 6-3, 6-4, 7-1, 7-2, 7-3, 8-1, 9-1, 9-2, 9-3, 9-4, 10-1, 10-2, 10-3, 11-1, 11-2, 11-3, 11-4.

Controller: HIT Company

The following scenarios from the clinical laboratory report are applicable in this case: 13-1, 13-2, 13-3, 14-1, 14-2, 14-3, 15-1, 16-1, 17-1.

Controller: CMS + Laboratory/Personnel Accreditation Organizations

Control Action:	Provide care facility/laboratory authorization to perform test
UCA Type:	Providing causes hazard
UCA:	CMS does not provide authorization for a care facility/laboratory to perform test when test is needed to inform patient care
Scenario POC-6-1:	<p>CMS may not provide authorization for a care facility/laboratory to perform test when test is needed to inform patient care, if authorization is contingent on CLIA compliance and the facility has not been able to remain compliant.</p> <p>The facility may not have been able to remain CLIA compliant if they fail proficiency testing for a POC test, or if CLIA/CAP surveyors uncover other rule violations in the POC testing environment.</p> <p>All POC testing occurs under a CLIA license, which in many cases may be the same license as the main laboratory at that care facility. Therefore, if the authorization to carry out a particular test is removed due to violations in a POC environment, the clinical laboratory may also be unable to perform those tests.</p>

The following scenarios from the clinical laboratory report are also applicable in this case: 18-1, 18-2, 18-3, 18-4, 18-5, 19-1, 19-2, 20-1, 37-1.

Controller: ONC

The following scenarios from the clinical laboratory report are applicable in this case: 21-1, 21-2, 22-1, 22-2, 23-1.

Controller: IVD Manufacturer

Control Action:	Release POC IVD device update
UCA Type:	Too Early, too late, out of order
UCA:	IVD manufacturer does not update POC IVD device when device does not perform to expected performance levels
Scenario POC-7-1:	An IVD manufacturer may not update a POC IVD device when device does not perform to expected performance levels (UCA). One contributing factor may be that a POC IVD malfunction may not lead to a safety signal that is detectable or actionable by the IVD manufacturer.

	<p>The IVD manufacturer may have received a report of a problem with an IVD device, but the user (care facility) may not have sent the device to the manufacturer, opting instead to perform internal testing. The IVD manufacturer may acknowledge the complaint but be unable to comment on the device if it was not sent to them for review.</p> <p>The IVD manufacturer may also not be getting all reports from care facilities about invalid or inaccurate results, since this reporting is voluntary and considered passive surveillance. The manufacturer may not be aware that the few reports they do get are indicative of a larger trend involving a device.</p> <p>The IVD manufacturer may have a perception that any problems reported with their devices are the result of flaws in quality control, and if no quality control metrics were flagged, they may not believe an actual problem existed with the device. IVD manufacturers may not be used to receiving reports from medical practitioners of design-related problems with devices, as opposed to quality control problems like manufacturing defects. There may be no formal venue where POC device users can engage in conversation regarding the design of IVD devices, either through the FDA or through the manufacturers.</p> <p>The IVD manufacturer may not have been issued any corrective actions by the FDA, because the FDA are not consistently receiving reports from the manufacturer or from care facilities about invalid or inaccurate results, since this reporting is voluntary and considered passive surveillance.</p>
Scenario POC-7-2:	<p>An IVD manufacturer may not update a POC IVD device when the device does not perform to expected performance levels (UCA). One contributing factor may be that a POC IVD malfunction may not lead to a safety signal that is detectable by the device user.</p> <p>The POC device may not be integrated with the care facility’s EHR system, meaning most of the results obtained from that device are only documented in unstructured free-text notes rather than mapped to fields in the EHR. The absence of structured data can make it challenging to aggregate results from many tests using the same device and identify abnormal trends. The care facility management may therefore not have enough information to detect that a device is not performing to expected levels and may not report the device to the manufacturer.</p>

Control Action:	Provide connectivity functionality between POC device and HIT system
UCA Type:	Not providing causes hazard
UCA:	IVD manufacturer does not provide connectivity functionality between POC device and HIT system when device’s results need to be repeatedly accessible after they are generated
Scenario POC-8-1:	<p>An IVD manufacturer may not provide connectivity functionality between POC device and HIT system (UCA). One contributing factor may be that there are insufficient incentives for the manufacturer to introduce this functionality into their devices.</p> <p>Regulatory or statutory incentives to ensure connectivity between POC devices and HIT systems are scarce. Customers may also have the ability to opt in or out of delivering data from the POC device into a data platform (EHR), and only a small proportion of customers may opt in.</p>

Control Action:	Provide connectivity functionality between POC device and HIT system
UCA Type:	Providing causes hazard

UCA:	IVD manufacturer provides connectivity functionality between POC IVD device and HIT system using data standard that is not compatible with other systems/devices
Scenario POC-9-1:	<p>An IVD manufacturer may provide connectivity functionality between a POC IVD device and an HIT system using a data standard that is not compatible with other systems/devices (UCA). One contributing factor may be that there regulatory and statutory requirements/incentives on what standard a manufacturer needs to use for transmission of data from POC IVD devices are lacking.</p> <p>The IVD manufacturer may also have an incentive to provide a proprietary connectivity solution that requires the care facility to hire the same manufacturer or an affiliated company to set up and maintain the interface.</p>

The following scenarios from the clinical laboratory report are also applicable in this case: 26-1, 26-2.

Controller: FDA

Control Action:	Issue corrective action to IVD manufacturer
UCA Type:	Too Early, too late, out of order
UCA:	FDA issues corrective action to IVD manufacturer too late following a series of inappropriate results from POC IVD device
Scenario POC-10-1:	<p>The FDA may issue corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device (UCA). One contributing factor may be that an IVD malfunction may not lead to a safety signal that is detectable or actionable by the FDA.</p> <p>This may occur because the FDA are not getting all reports from care facilities about invalid or inaccurate results, since a facility’s POC devices may not be integrated with the care facility’s EHR system, meaning a majority of the results obtained from that device are documented in unstructured free-text notes, rather than mapped fields in the EHR. The absence of structured data can make it challenging to aggregate results from many tests using the same device and identify abnormal trends. The care facility management may therefore not have enough information to detect that a device is not performing to expected levels and may not report the device to the FDA.</p>
Scenario POC-10-2:	<p>The FDA may issue corrective action to IVD manufacturer too late following a series of inappropriate results from IVD device (UCA). One contributing factor may be that an IVD malfunction may not lead to a safety signal that is detectable or actionable by the FDA.</p> <p>This may occur because the FDA are not getting all reports from IVD manufacturers about invalid or inaccurate results, as existing databases like the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database are largely populated by reports that have been triaged by the manufacturers through methods that are not publicly released [42]. A manufacturer may not choose to report a case to the MAUDE database if there was no direct patient harm involved (even though there may be potential for harm), the device was built to specifications, and the device functioned as designed.</p>

The following scenarios from the clinical laboratory report are applicable in this case: 24-1, 24-2, 25-1, 25-2, 25-3.

Controller: Payor

Control Action:	Require prior authorization for coverage/reimbursement of test
UCA Type:	Providing causes hazard
UCA:	Payor requires prior authorization for coverage/reimbursement of POC test that would be helpful to inform immediate patient care
Scenario POC-11-1:	<p>A payor may require prior authorization for coverage/reimbursement of POC test that would be helpful to inform immediate patient care if the POC test comes at a high financial cost (e.g., a pharmacogenomic test) and is only meant to be ordered on rare occasions but is ordered repeatedly by a practitioner.</p> <p>The test may be ordered repeatedly if the results from the original test were documented in unstructured formats like PDFs or clinical notes, because they pertained to a new or uncommon test whose format could not be represented in the standard fields available in the care facility’s EHR.</p>

The following scenarios from the clinical laboratory report are applicable in this case: 27-1, 28-1.

Controller: Naming, Coding, and Messaging Standards Development Organizations

The following scenarios from the clinical laboratory report are applicable in this case: 29-1, 30-1, 30-2, 31-1, 31-2, 32-1.

Controller: Patient

The following scenarios from the clinical laboratory report are applicable in this case: 33-1, 33-2, 33-3, 33-4, 33-5, 34-1, 34-2, 34-3, 34-4, 34-5, 34-7.

Controller: CDC/PHAs

Control Action:	Provide healthcare guidance
UCA Type:	Providing causes hazard
UCA:	CDC/PHAs provide inappropriate healthcare guidance
Scenario POC-12-1:	<p>CDC/PHAs may provide inappropriate healthcare guidance if they receive conflicting diagnostic data or had originally received insufficient diagnostic data from POC tests with which to provide guidance.</p> <p>This may be because the lack of good consistent data encoding of POC test results, where data availability could inform better care opportunities. POC devices in emergency rooms, urgent care centers, and physicians’ offices may not be harmonized with EHRs, meaning results are not automatically uploaded into each patient’s medical record and may need to be manually entered. If the results are not entered into the EHR, there is no ability for the results to be reported to CDC/PHAs.</p> <p>POC tests may also be carried out in facilities that do not traditionally possess large-scale EHRs (e.g., pharmacies or nursing homes). These facilities may not have the resources needed to develop robust data storage and reporting mechanisms.</p> <p>There is no regulatory authority on the part of the CDC/PHAs to require that facilities carrying out POC testing set up data collection and reporting mechanisms, and actually report particular data elements, so that CDC/PHAs may provide better guidance to medical practitioners. Currently, requiring that specific data elements get shared with CDC would require action from ONC and CMS as well. Most POC testing occurs in CLIA-waived</p>

environments, and CMS may not be staffed to broadly enforce compliance in CLIA-waived environments.

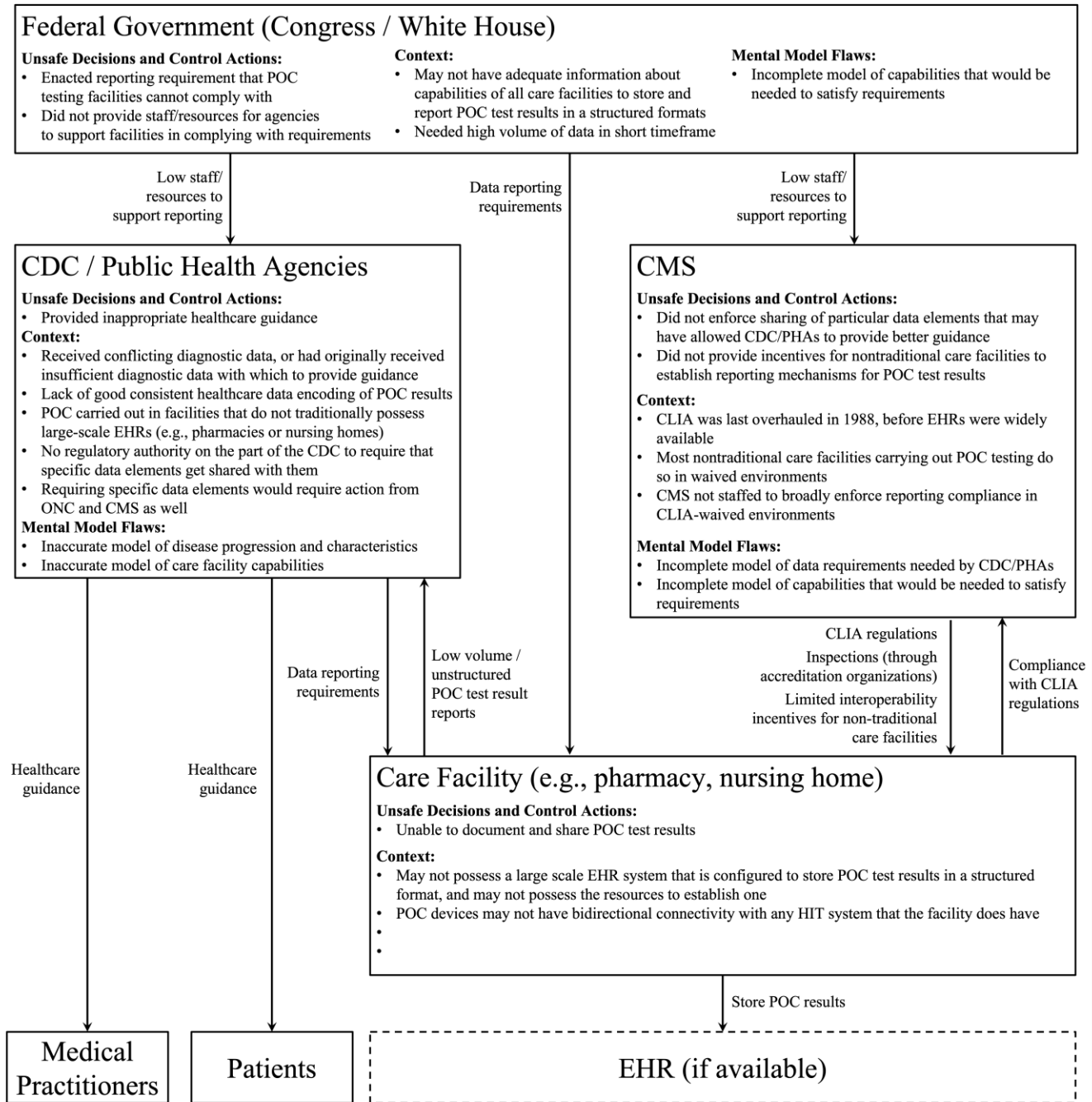


Figure 8.. Visualization of Scenario POC-13-1

The following scenarios from the clinical laboratory report are applicable in this case: 35-1, 35-2, 36-1, 36-2, 36-3.

Controller: HHS Administration

The following scenarios from the clinical laboratory report are applicable in this case: 38-1, 38-2, 38-3, 38-4, 38-5, 38-6, 39-1, 39-2, 39-3.

Controller: Congress/White House

The following scenarios from the clinical laboratory report are applicable in this case: 40-1, 41-1, 41-2, 41-3, 41-4, 41-5, 42-1, 42-2, 42-3.