



Electronic Test Order and Result Capabilities

Survey Findings

May 2021

Background

Electronic Test Orders and Results (ETOR) can significantly improve efficiencies within the laboratory and reduce turnaround times. This past year, the burden on public health laboratories (PHLs) and their clinical partners has been immense, and ETOR is a critically important tool that public health systems must have as they look ahead in preparation for the next pandemic.

Methods

This landscape analysis, completed by PHLs at both the state and local level, captures the current state of ETOR capability, including clinical testing, pandemic response, and newborn screening (NBS). It also covers the variety of methods in use, and the challenges inherent in each.

The APHL ETOR Taskforce, under the charge of the APHL Informatics Committee, began convening in August 2020 to determine the best method for documenting the current state of ETOR capability across state and local PHLs. The Taskforce recommended the modified use of the APHL Lab Informatics Self-Assessment Tool¹ to capture data specific to ETOR as well as supplemental assessments for Pandemic Response and Newborn Screening (NBS) capabilities. Each assessment was made into a fillable PDF that could be completed by a PHL and returned via email.

A summary of the capability areas in the ETOR, Pandemic Response and NBS self-assessments is shown in the tables below.

To analyze survey results, rankings of 1 to 3 were broadly categorized as fully capable, somewhat capable, and not capable. The numeric responses associated with individual capabilities in the survey instrument, however, were specific to each question. Categorization of numeric responses into capability level allows for general comparison between capability statements and capability areas, however, we are unable to identify specific associations or interdependencies.

The above identified gaps in methodology are both an opportunity for more in-depth follow-up with PHLs and continued refinement of the survey instruments going forward.

ID	Capability Area	Description
CA1	Laboratory Test Request and Sample Receiving	Informatics capabilities related to the business processes associated with the electronic receipt of the initial test sample request.
CA2	Test Preparation, LIMS Processing, Test Results Recording and Verification	Focusing on elements that are foundational to a full ETOR implementation.

CA3	Report Preparation and Distribution	Electronic report preparation, electronic submission of test results, and auxiliary data report format and content, transport and distribution, and tracking.
CA4	Interoperability and Data Exchange	This area focuses on systematically addressing electronic interoperability and data exchange.
CA5	Informatics and IT Resource Management	Training, education and resource management activities for laboratory informatics and associated IT staff.
CA6	Core IT Services: Hardware, Software and Services	This area addresses the breadth and maturity of laboratory information systems including informatics, interoperability, information and communications technology hardware, software and services.
CA7	Policies and Procedures, including Budgeting and Funding	This area addresses informatics-related policies and procedures, management of information systems and the funding of data exchange initiatives within the laboratory.

Table 1: Description of Capability Areas in the ETOR Assessment Tool and the NBS-focused ETOR Assessment Tool

ID	Capability Area	Description
CA1	Test Preparation, LIMS Processing, Test Results Recording and Verification (Part 2)	Test preparation, LIMS processing, test results recording and verification and interoperability.
CA2	Core IT Services, Hardware, Software and Services (Part 2)	Capabilities of a lab's core IT services as they relate to the response to a pandemic scenario.
CA3	Laboratory Test Scheduling	Prioritizing and processing the test workload for samples received, including the addition and prioritization of test requests and removal of completed requests.
CA4	Prescheduled Testing	Informatics capabilities related to receipt of prescheduled samples in an efficient and timely manner to help with workload management.
CA5	Reagents and Inventory	Informatics capabilities related to the use of electronic and real-time management of all inventory-related activities within the laboratory.
CA6	Laboratory Mutual Assistance and Disaster Recovery	Informatics capabilities, plans and agreements for laboratory mutual assistance, emergency preparedness, surge management and disaster recovery, assurance of continuity of operations, and related policies.

Table 2: Description of Capability Areas in the Informatics-focused Pandemic Response Assessment Tool

Assessments were piloted by PHLs in Texas, Missouri, and the District of Columbia and edits were made to the assessments based on user feedback. Assessments were then disseminated to the wider PHL community through APHL communications with Lab Directors and various Programs and Committees, and through the National Association of County and City Health Officials (NACCHO). PHLs were asked to complete the main ETOR assessment as well as any of the supplemental assessments that applied to their laboratory.

Data from the pilot sites were normalized in order to be analyzed along with the other PHL responses. For each type of assessment, results were combined, and scores were averaged for each capability statement.

Gaps in Survey Methodology

Survey content and structure were designed to establish a baseline of ETOR capability across public health laboratories. While this was accomplished, several gaps in the survey methodology were identified. The current survey language asks laboratories to identify their general ability to perform certain functions or tasks by ranking themselves on a scale of 1 to 3 or, in some cases, as a yes/no response. In some cases, these questions do not capture the extent of their abilities. For example, the survey respondent may rate their ability to consume HL7 orders as capable, however, the number of current messaging partners is not collected nor is the capability identified as day-to-day activity or a more intermittent function. Survey respondents indicated that for yes/no questions, the survey should have collected information on a more nuanced middle ground. Finally, the surveys do not currently collect information on the length of implementation or level of effort to become capable in each area. The considerable time and expense of informatics projects, and ETOR implementations specifically, would make this valuable information to collect in a standardized way going forward.

Findings

Clinical Survey Results

Respondents

Between March 1 and March 31, 2021, 46 ETOR assessments were completed and submitted. State public health laboratories comprised the majority of respondents with 78% (n= 36). The remaining 22% were submitted by local public health labs/university labs (n=9) and federal labs (n= 1).

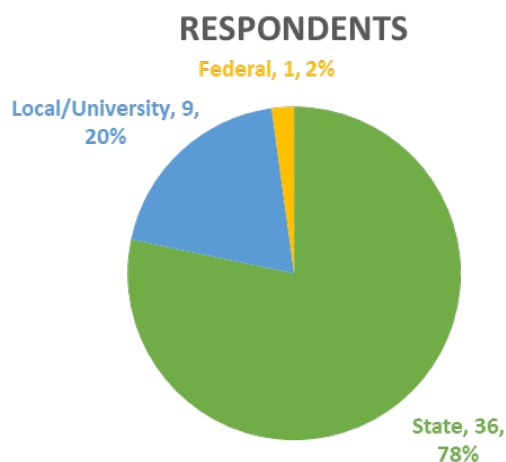


Figure 1: Representation of federal, state, and local entities responding to the clinical ETOR survey.

Laboratory Informatics Management Systems

Respondent's report utilizing LIMS from a variety of vendors, with StarLIMS comprising half of identified LIMS (n=18, 39%) and the other half fairly equally split between OpenELIS (n=3, 6%), Orchard (n=4, 9%), Horizon (n=4, 9%) and LabWare (n=5, 11%). 26% percent of respondents reported LIMS from another vendor or did not specify LIMS vendor.

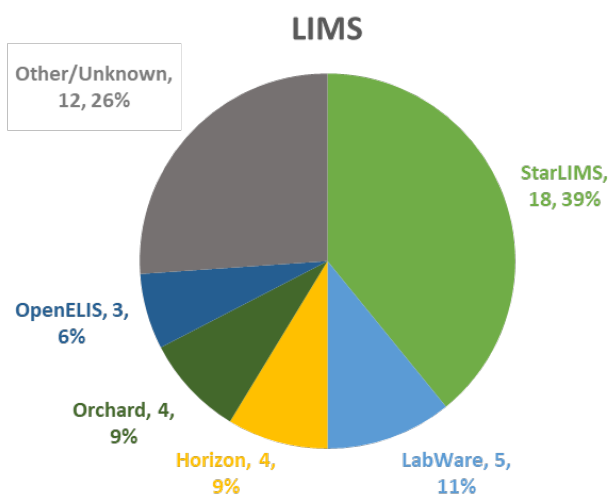


Figure 2: Representation of LIMS Vendors across clinical ETOR survey respondents.

Highest Rated Capabilities

Capability Area 3 (Report Preparation and Distribution) was the highest rated across all labs with an average score of 2.6 out of 3.0; 65% of responses indicated fully capability.

CLINICAL ETOR SUMMARY

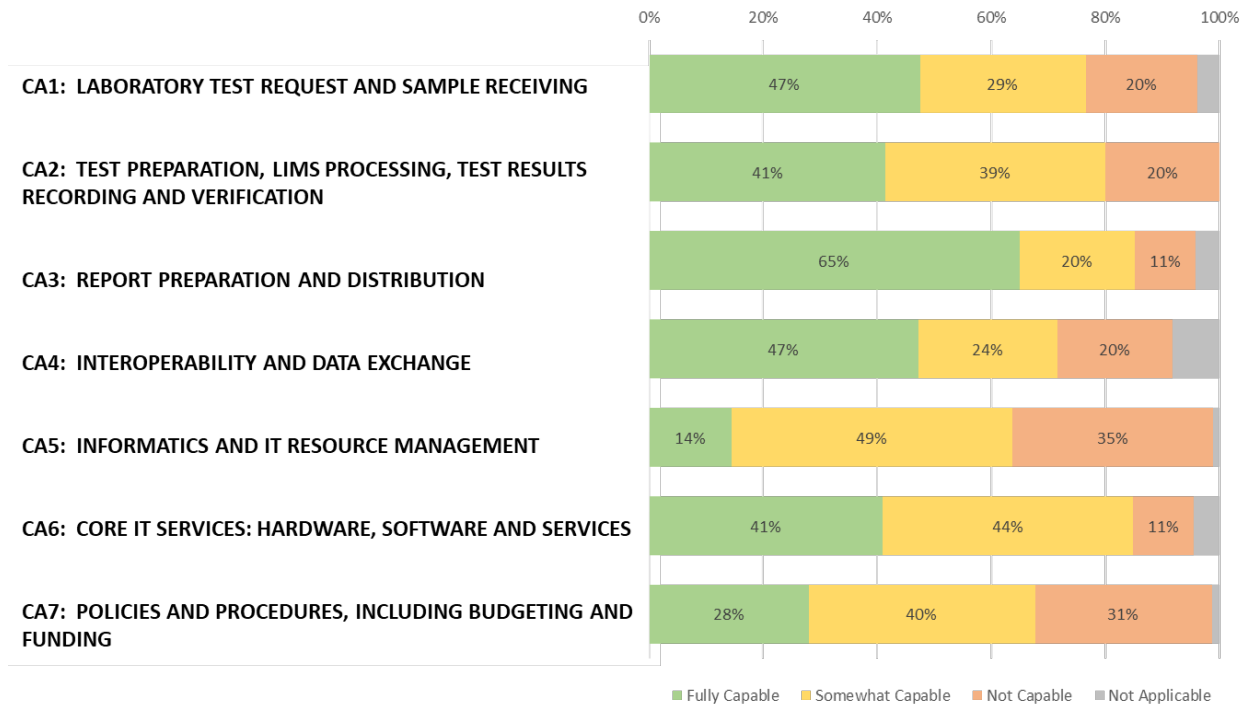


Figure 3: Percentage of responses identifying as fully capable, somewhat capable, and not capable across all jurisdictions and all capability areas.

Lowest Rated Capabilities

The lowest rated capabilities appear to be associated with functions that, historically, may not have been deemed as essential for the day-to-day operations of the laboratory or those for which public health laboratories have struggled in the past. This includes exchange of transactional data (CA4.7), informatics training and resource development (CA5.5 and CA5.6) and budget (CA7.8).

Capability Area 5 (Informatics and IT Resource Management) was the lowest rated across all respondents with an average score of 1.8 out of a possible 3.0. Only 14% of responses indicated the laboratory was fully competent within that capability area.

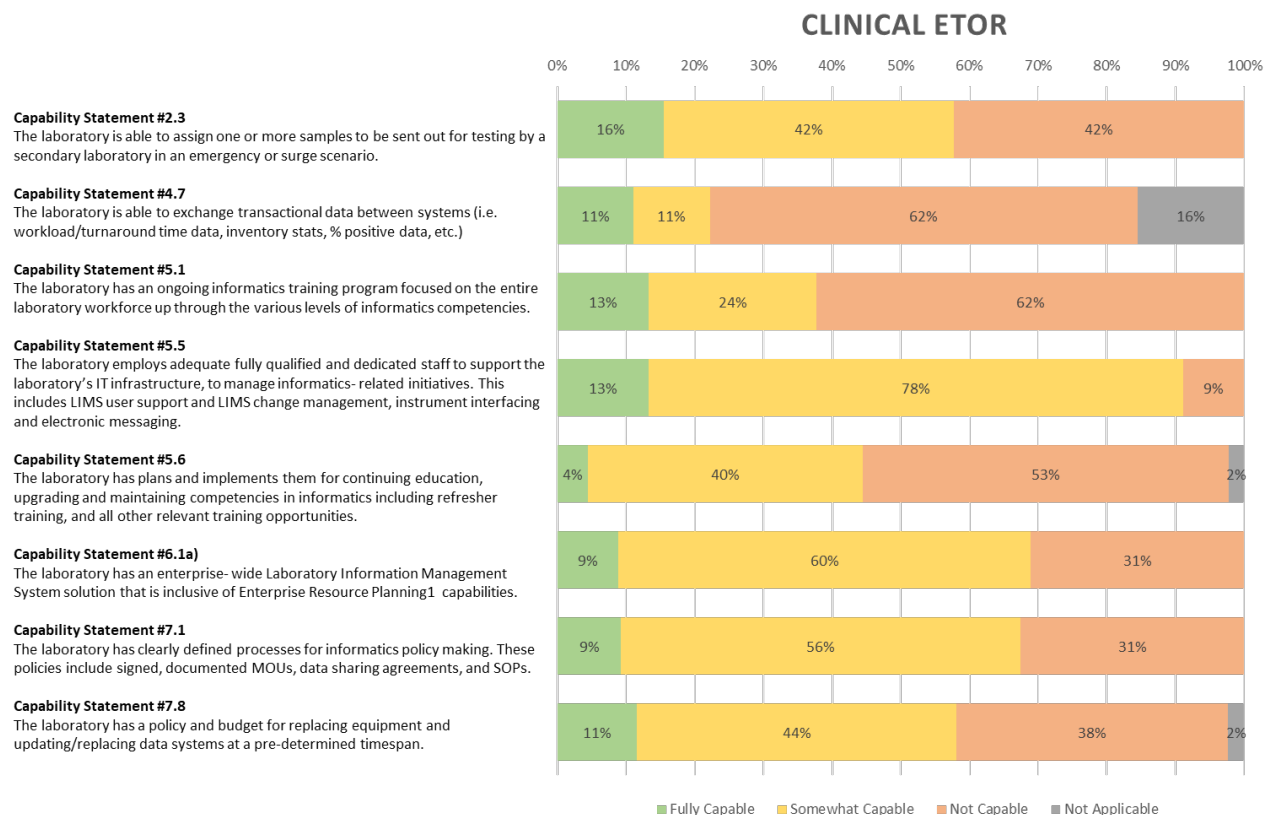


Figure 4: Lowest rated capabilities within the clinical ETOR survey results.

3.1.4 Other Trends and Observations

In general, state and local survey responses were not significantly different. Discrepancies between state and local scores for capability areas 5 and 6 were noticeable, however, a breakdown of the specific capabilities within those respective groups did not show any significant differences. In addition, there did not appear to be significant variability between LIMS vendors.

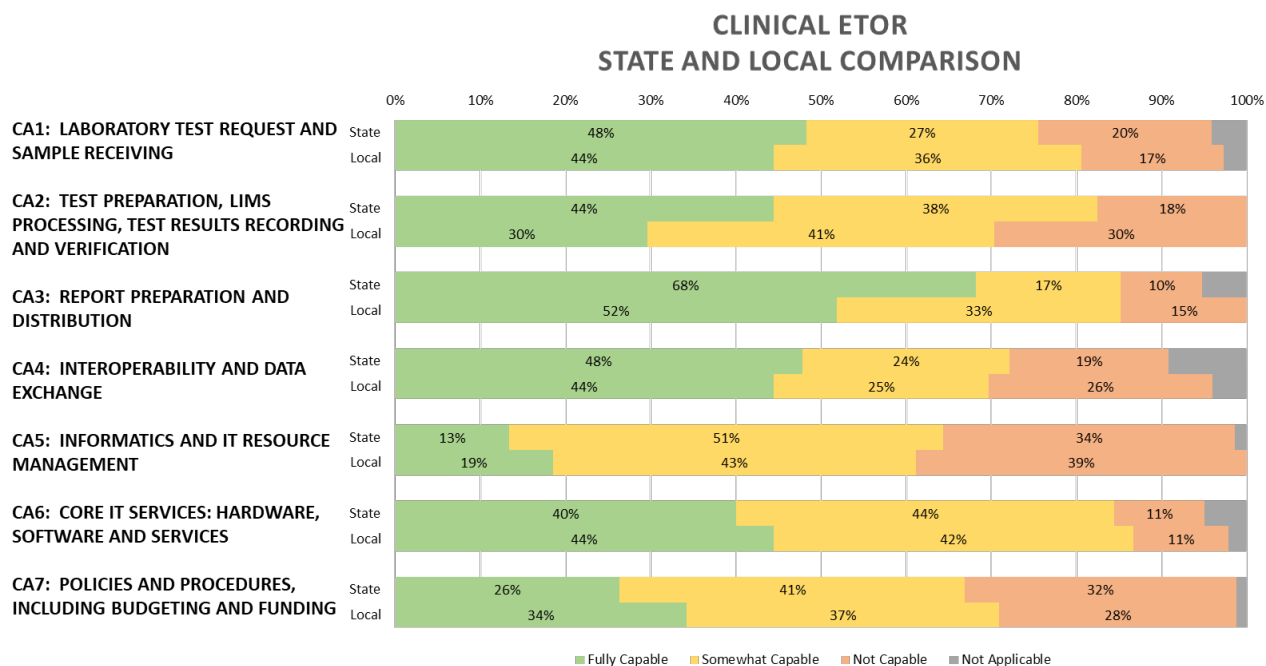


Figure 5: Comparison of state and local responses across capability areas.

Within Capability Area 4, Interoperability and Data Exchange, 83% of respondents indicated that they were compliant with HL7 LOI and LRI standards (CA 4.3), however, under half (46%) were able to generate that message directly without conversion (CA 4.4). Current data exchange appears focused on results reporting with only 11% of responses indicating proficiency in sending transactional data (CA 4.7). Web Portal adoption appears to be less prevalent than HL7, with only about a quarter of respondents indicating they were fully capable of receiving orders using this method (CA 4.9a) and only 39% indicating an ability to provide access to results (CA 4.9b).

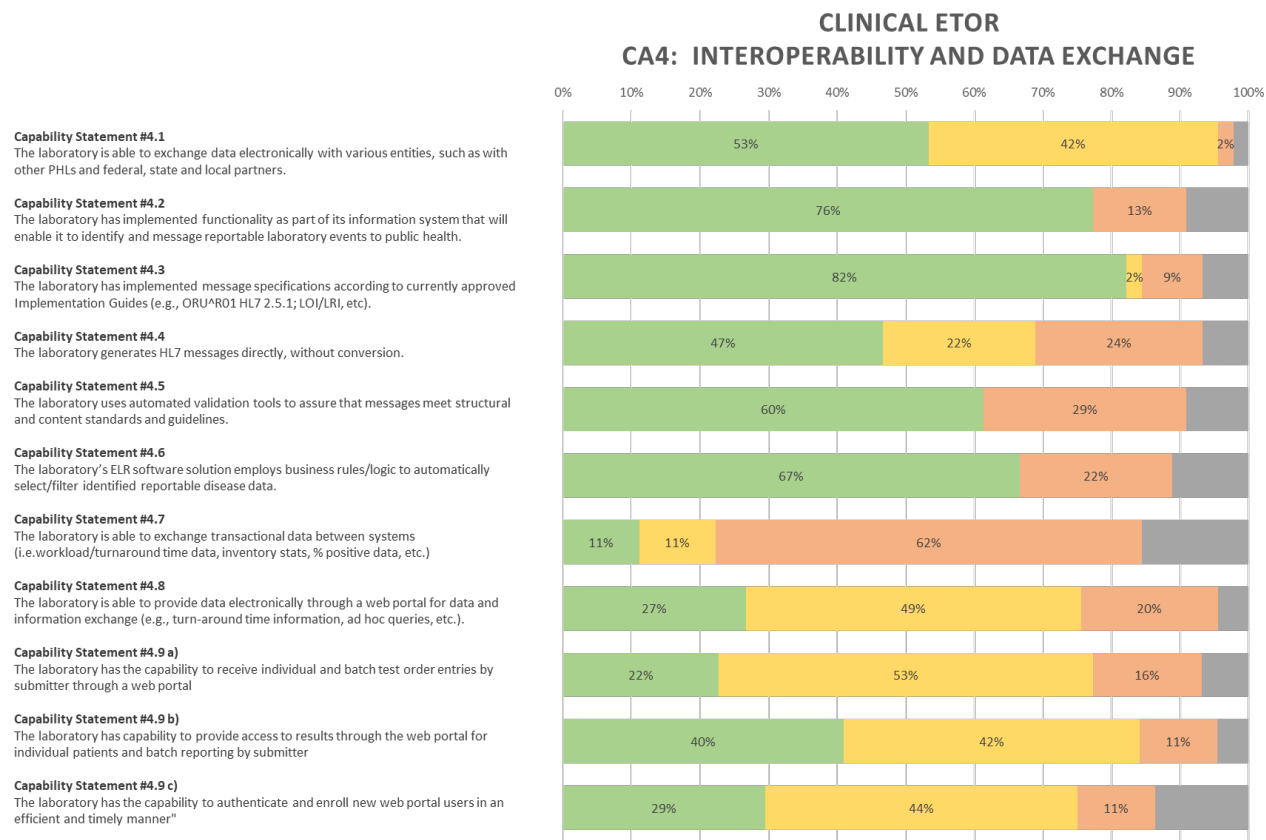


Figure 6: Percentages of responses indicating fully capable, somewhat capable, not capable, or not applicable within area 4, Interoperability and Data Exchange.

3.2 Newborn Screening Survey Results

3.2.1 Metadata

22 NBS-focused assessments were completed and submitted. State PHLs comprised all but one of the respondents.

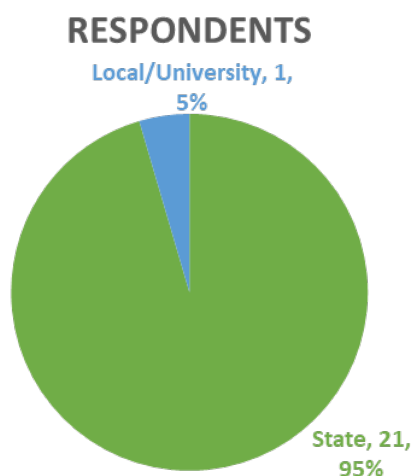


Figure 7: Representation of state and local/university entities responding to the NBS ETOR survey.

Respondents report utilizing LIMS from a variety of vendors, with Neometrics comprising half of all reported LIMS (n=6, 27%).

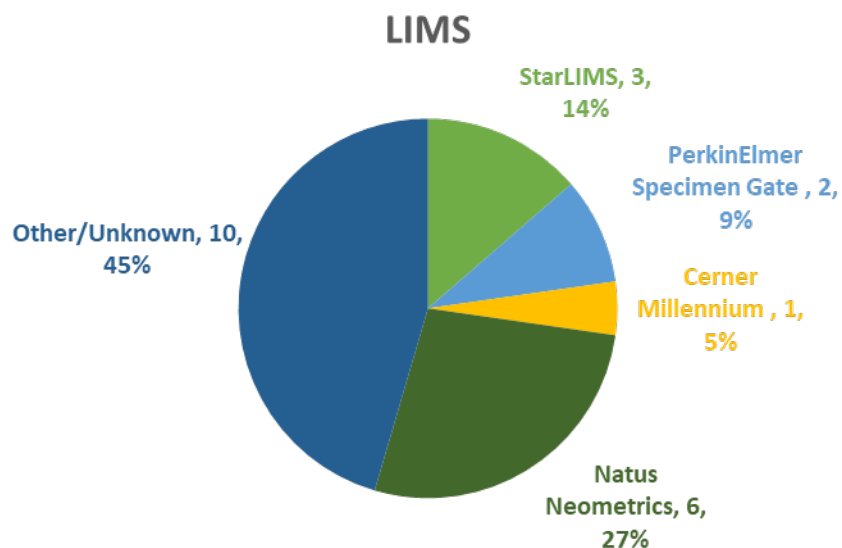


Figure 8: Representation of LIMS Vendors across NBS survey respondents.

There was a wide range of responses across capability areas with 45% of respondents indicating they are fully capable within the laboratory test request and sample receiving area, and only 11% reporting they are fully capable within the informatics and IT resource management area.

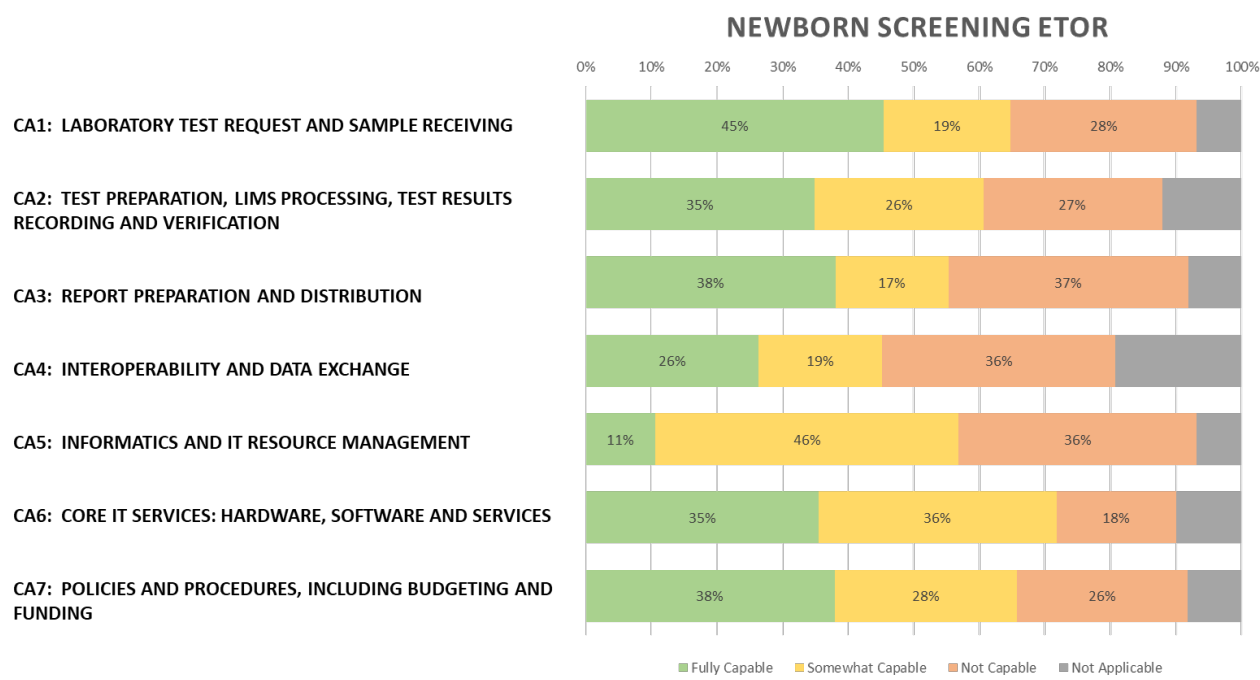


Figure 9: Percentage of survey responses indicating fully capable, somewhat capable, not capable, and not applicable across all jurisdictions and all capability areas included in the NBS-focused ETOR survey.

3.2 2 Comparison of NBS and Clinical ETOR Responses

Like the clinical survey results, Capability Area 5 (Informatics and IT Resource Management) was the lowest rated across all respondents with only 11 % of responses indicating the laboratory was fully capable within that area. When compared to the clinical ETOR survey, NBS matched the general trend in each capability area but consistently ranked lower. This is particularly evident for capability areas 3 and 4. Only 38% of responses indicated full capability in report preparation and distribution compared with 65% of clinical ETOR responses. Similarly, 26% of NBS responses indicated full capability within the interoperability and data exchange area. This compares to 47% of clinical ETOR responses.

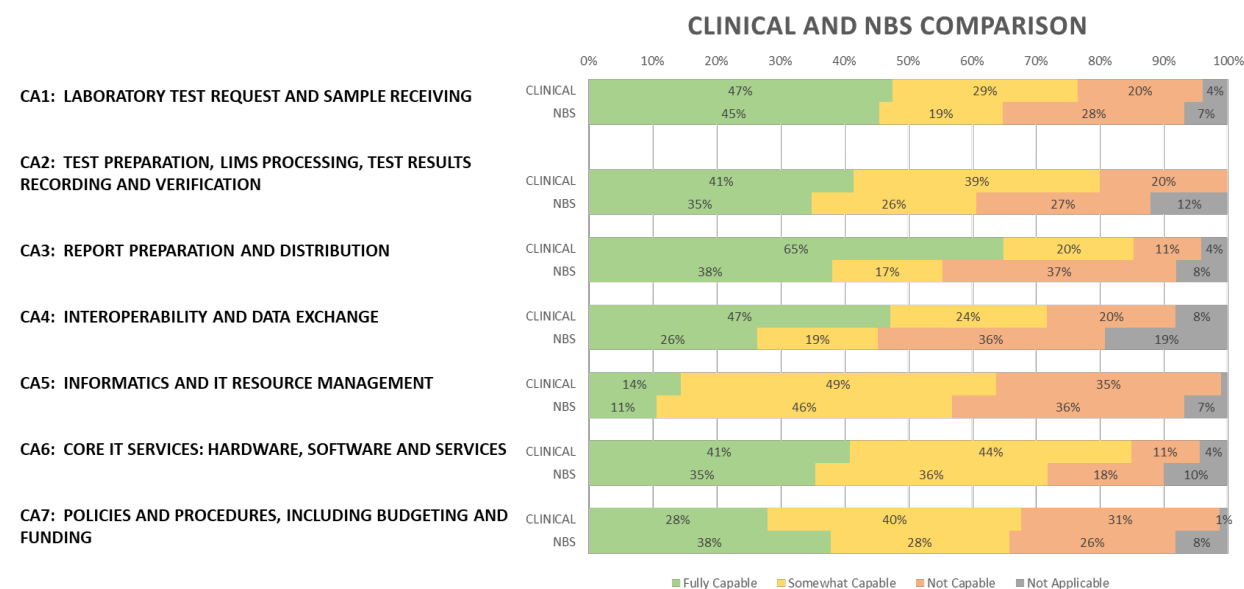


Figure 10: Comparison of clinical and NBS-focused survey results across all capability areas.

Within the area of report preparation and distribution, about half as many NBS responses as clinical ETOR responses report full capability for generating electronic results messages (CA3.2 and CA3.3). Only 18% of NBS responses, compared with

51% of clinical ETOR responses, indicate the laboratory can maintain unique data exchange formats for different receivers (CA3.7) and only 23% of NBS responses indicate an ability to route electronic results to additional requestors other than the original submitter (CA3.5).

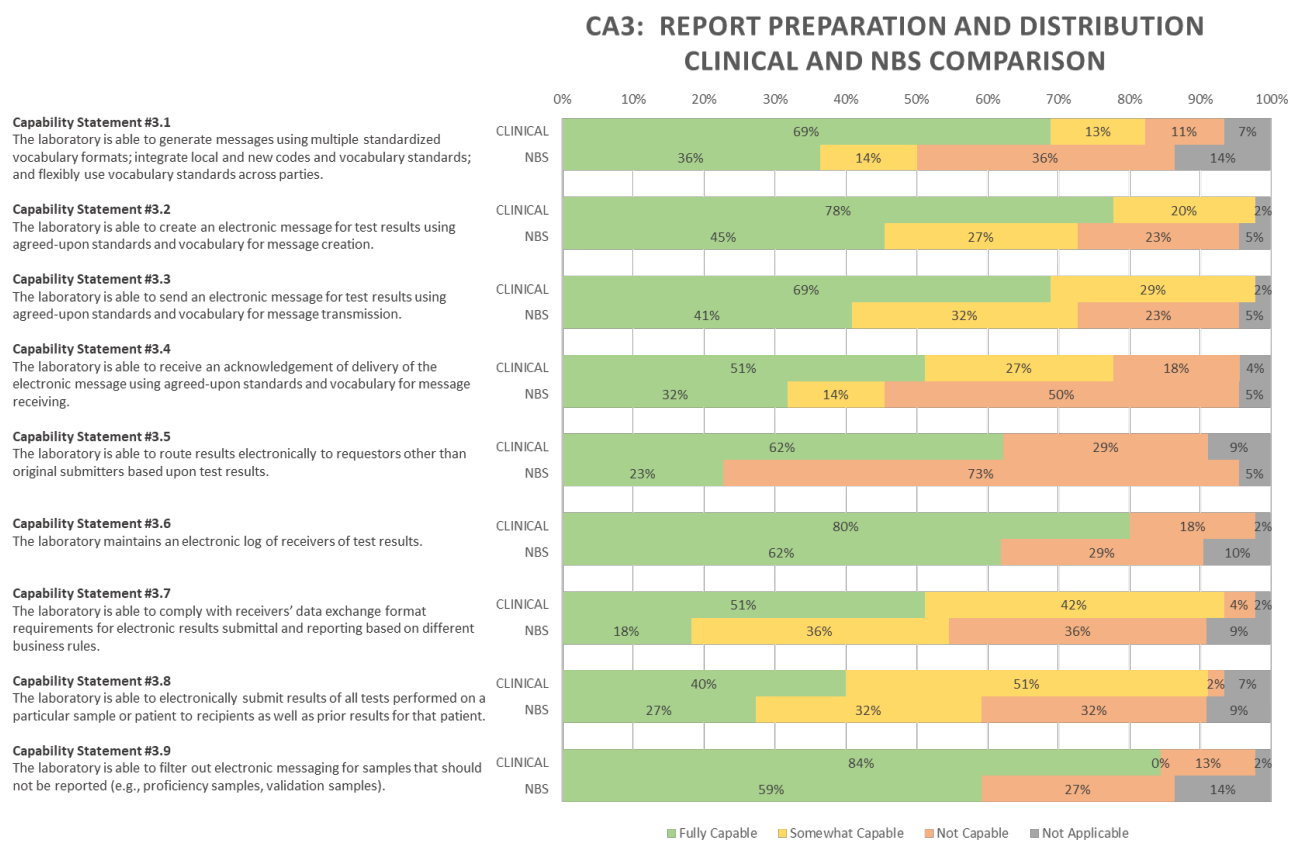


Figure 11: Comparison of clinical and NBS-focused survey results within capability area 3, Report Preparation and Distribution

Within Capability Area 4, NBS laboratories were significantly less able to send data electronically (CA4.1), use standardized HL7 formats (CA4.3) and use automated validation tooling (CA4.5).

CA4: INTEROPERABILITY AND DATA EXCHANGE CLINICAL AND NBS COMPARISON

Capability Statement #4.1

The laboratory is able to exchange data electronically with various entities, such as with other PHLs and federal, state and local partners.

Capability Statement #4.2

The laboratory has implemented functionality as part of its information system that will enable it to identify and message reportable laboratory events to public health.

Capability Statement #4.3

The laboratory has implemented message specifications according to currently approved Implementation Guides (e.g., ORU^R01 HL7 2.5.1; LOI/LRI, etc).

Capability Statement #4.4

The laboratory generates HL7 messages directly, without conversion.

Capability Statement #4.5

The laboratory uses automated validation tools to assure that messages meet structural and content standards and guidelines.

Capability Statement #4.6

The laboratory's ELR software solution employs business rules/logic to automatically select/filter identified reportable disease data.

Capability Statement #4.7

The laboratory is able to exchange transactional data between systems (i.e. workload/turnaround time data, inventory stats, % positive data, etc.)

Capability Statement #4.8

The laboratory is able to provide data electronically through a web portal for data and information exchange (e.g., turn-around time information, ad hoc queries, etc.).

Capability Statement #4.9 a)

The laboratory has the capability to receive individual and batch test order entries by submitter through a web portal

Capability Statement #4.9 b)

The laboratory has capability to provide access to results through the web portal for individual patients and batch reporting by submitter

Capability Statement #4.9 c)

The laboratory has the capability to authenticate and enroll new web portal users in an efficient and timely manner"

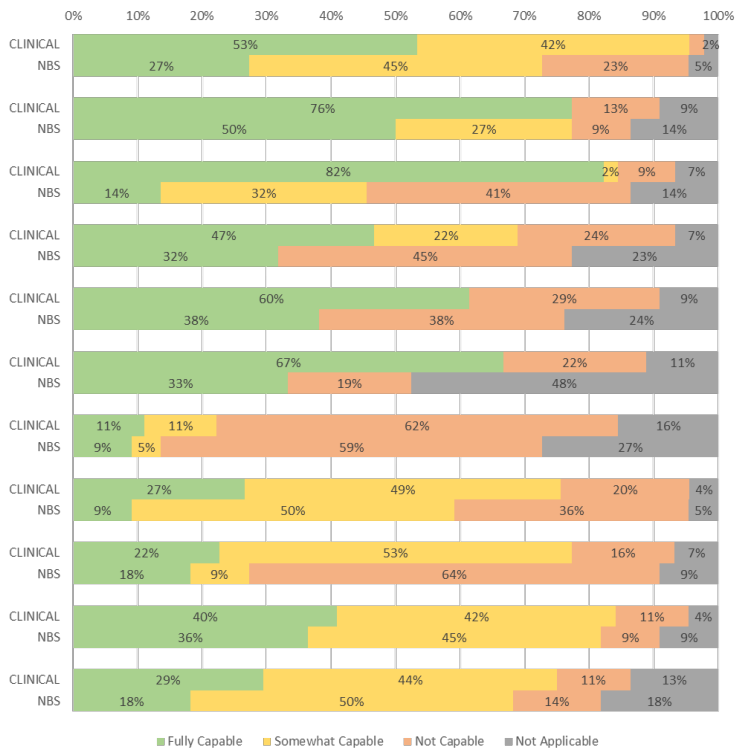


Figure 12: Comparison of clinical and NBS-focused survey responses within capability area 4, Interoperability and Data Exchange.

In only one capability area did NBS survey responses exceed clinical ETOR responses. 38% of NBS responses, compared with 28% of clinical lab responses, indicated they were fully capable in the area of policies and procedures (capability area 7). A breakout of this area shows significant discrepancies for CA7.7 and CA7.8, with NBS labs reporting higher access to non-grant operational resources and adequate budget for equipment updates/replacement, respectively.

CA7: POLICIES, PROCEDURES, BUDGETING AND FUNDING CLINICAL AND NBS COMPARISON

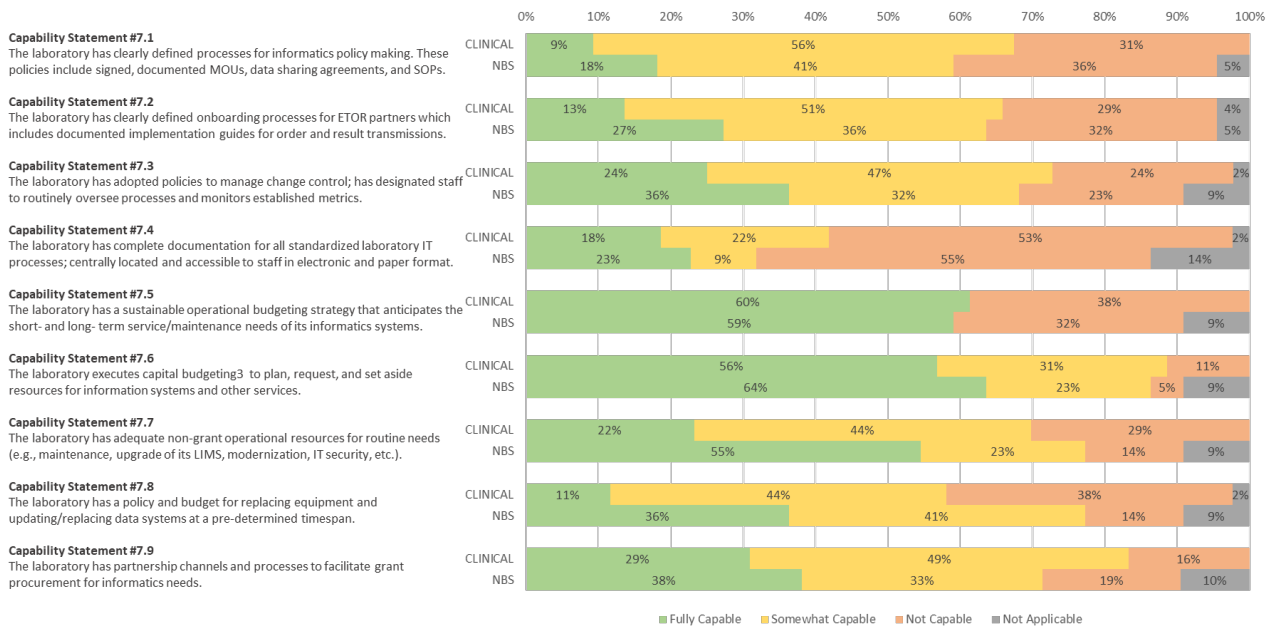


Figure 13: Comparison of clinical and NBS-focused survey responses within capability area 7, Policies, Procedure, Budgeting, and Funding.

3.2.3 NBS-focused Results

Several questions specific to the NBS workflow were included in the NBS survey only. Half of NBS responses indicate an ability to maintain local master patient index for tracking purposes (CA1.5), however, only 9% reported access to other public health registries, including Vital Records, to aid in that goal. Half of NBS responses indicated access to a

comprehensive case management system (CMS), however, only 14% allowed for effective communication with pediatric specialties and tracking of short term and long-term follow-up (4.2b and 4.2c).

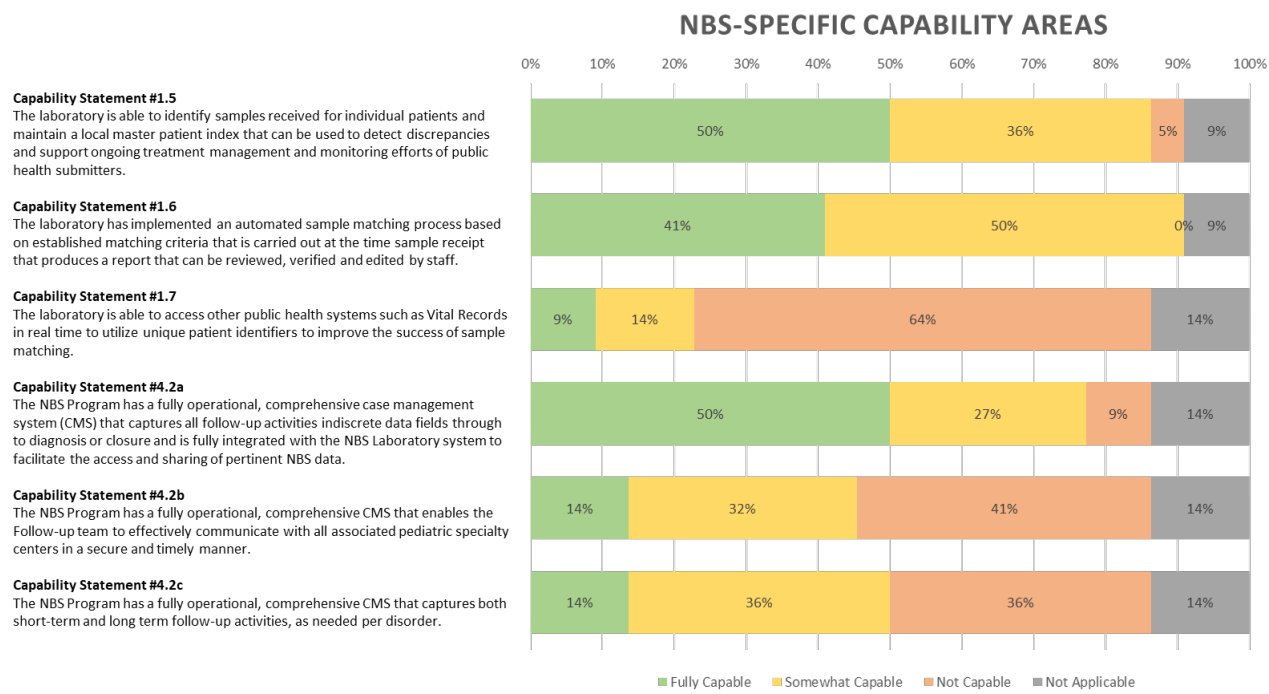


Figure 14: Summary of NBS-specific capabilities.

3.3 Pandemic Response Survey Results

3.3.1 Metadata

Overlap between clinical ETOR survey participation and Pandemic Response survey participation was good with almost every laboratory who filled out the main ETOR assessment also completing the Pandemic Response supplement.

3.3.2 Strong Negative and Positive Responses

Capability Area 5 (Reagents and Inventory) was the lowest rated across all respondents with an average score of 1.7 out of a possible 3.0. Only 11% of responses indicated the laboratory was fully capable within that capability area. Capability Area 4 (Prescheduled Testing) was next lowest with an average of 1.8 out of 3.0. 17% of responses indicated full capability.

Capability Area 2 (Core IT Services: Hardware, Software and Services) was the highest rated across all agencies with an average score of 2.5 out of 3.0. 62 % of responses indicated full capability.

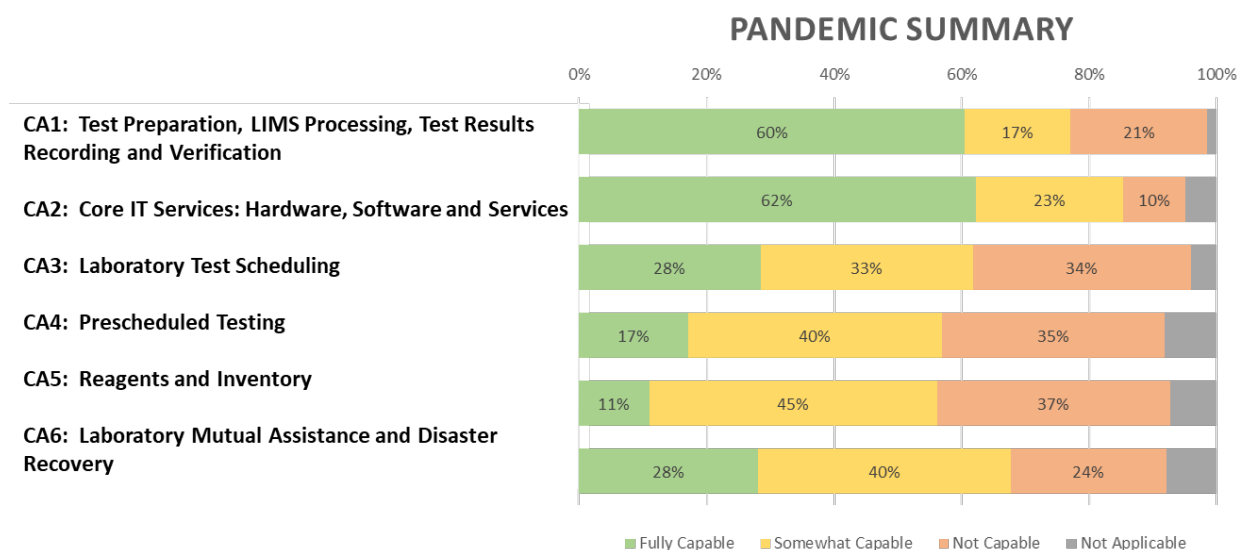


Figure 15: Percentage of responses identifying as fully capable, somewhat capable, and not capable across all respondents and capability areas.

3.3.3 Comparison Between State and Local Respondents

A comparison of state and local survey responses showed larger discrepancies in the pandemic response survey than the clinical ETOR survey.

PANDEMIC **STATE AND LOCAL COMPARISON**

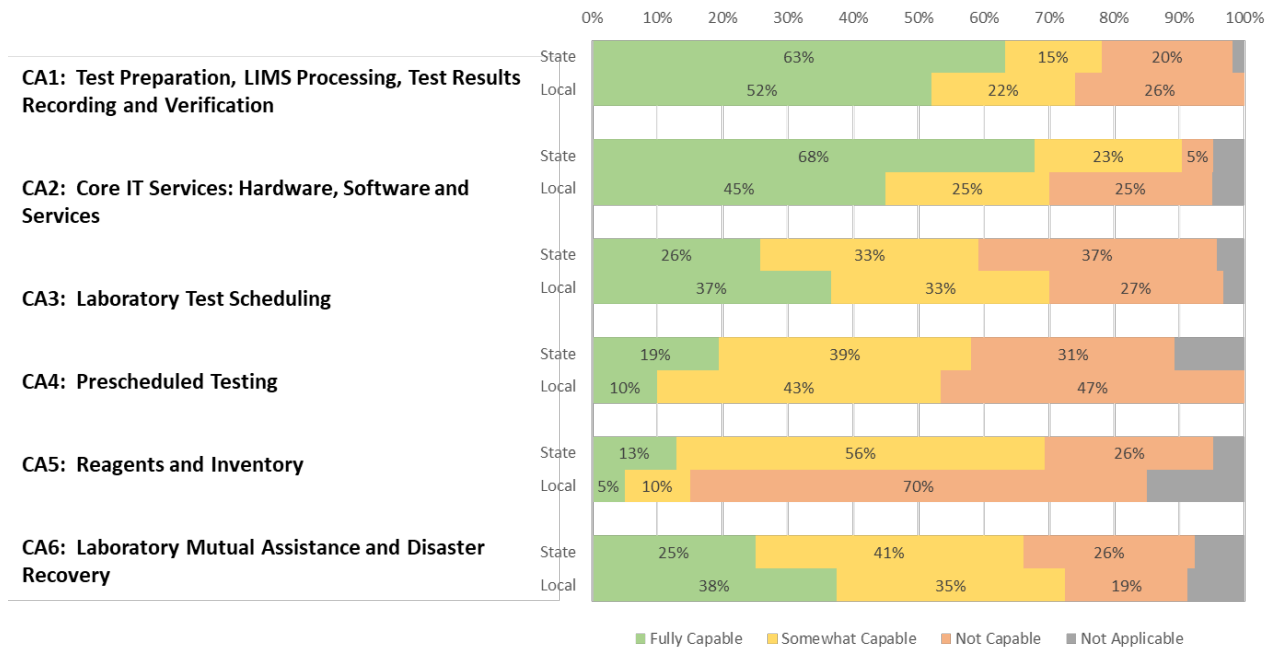


Figure 16: Comparison of state and local responses across all capability areas of the pandemic response survey.

The core IT group included only 2 additional capabilities, one of which specifies ability to collect and maintain audit records. High levels of compliance required by CLIA certification may contributed to the high average in this capability area.

PANDEMIC **CA2: CORE IT SERVICES: HARDWARE, SOFTWARE AND SERVICES** **STATE AND LOCAL COMPARISON**

Capability Statement #2.1

The laboratory is able to incorporate change management and follow a software development life cycle (SDLC), which includes defining functional requirements, and translating these into software development and configuration.

Capability Statement #2.2

The laboratory routinely collects and maintains detailed access and audit records on all its information systems and can review and sort these records to assure satisfaction of compliance metrics.

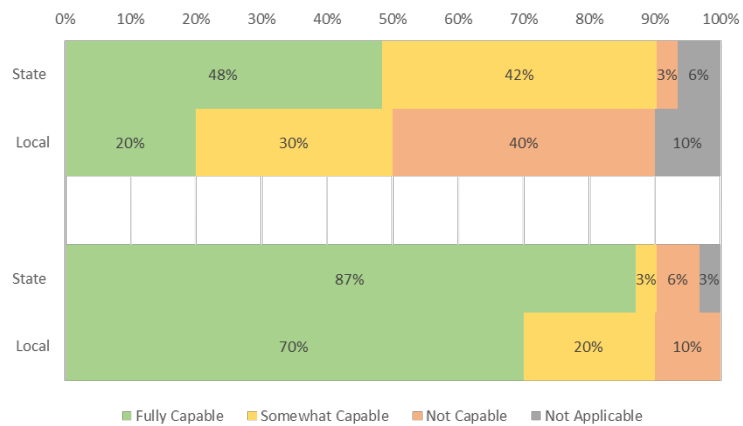


Figure 17: Comparison of state and local responses within capability area 2, Core IT Services.

Local responses indicated higher ability in the areas of laboratory test scheduling (CA3) and mutual assistance (CA6) possibly due to a more common need for local laboratories to send out testing to partners.

Capability Statement #3.1
The laboratory is able to electronically select tests for diversion to a mutual assistance laboratory and transmit metadata associated with tests/sample.

Capability Statement #3.2
The laboratory is able to electronically generate a real-time test schedule by calculating daily processing capacity and tracking test load; flag overdue test requests; and notify submitter through LIMS and/or integrated information systems.

Capability Statement #3.3
The laboratory is able to electronically a)capture specific data elements associated with process improvement indicators regarding test schedule; b)create reports of test processing time(by priority where applicable); and c)create test status reports such as pending lists and turnaround time.

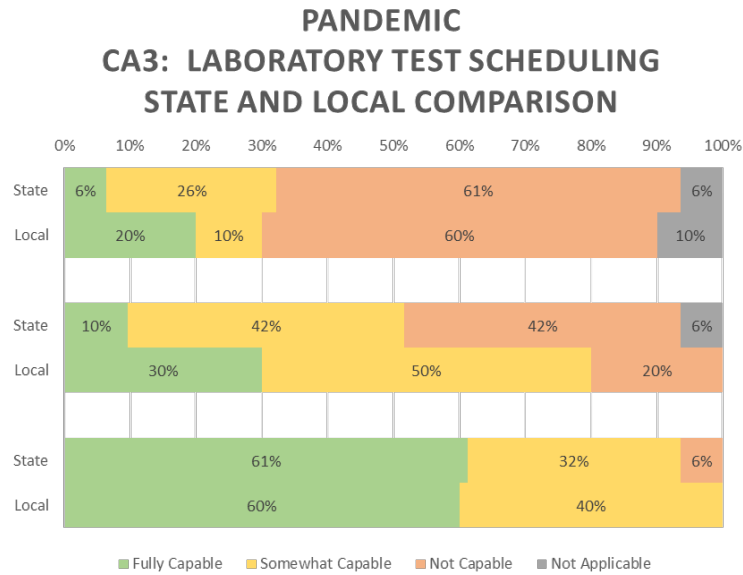


Figure 18: Comparison of state and local responses within capability area 3, Laboratory Test Scheduling.

Capability Statement #6.1
The laboratory has memoranda of agreement (MOA)/ memoranda of understanding (MOU)/service level agreements (SLAs) for all IT maintenance and support services.

Capability Statement #6.2
The laboratory has MOU/MOA, including data sharing agreements and SLAs, with outsourced IT services, and has processes/procedures to routinely monitor these services to ensure compliance with MOU/MOA.

Capability Statement #6.3
The laboratory has MOU with other laboratories for mutual assistance during emergency response and surge testing; data sharing agreements for secure electronic data exchange; and signed agreements to support putting these agreements into practice. All agreements are compliant with state and federal standards.

Capability Statement #6.4
The laboratory routinely conducts exercises and drills following a documented schedule, at least annually, to test the effectiveness of the MOA/ MOU and performs After Action Reviews (AARs) designed to improve the process.

Capability Statement #6.5
The laboratory has established policies, protocols, resources, and requirements for IT infrastructure and support services for emergency and disaster recovery operations with clearly documented duration and extent of required IT supports.

Capability Statement #6.6
The laboratory has defined policies and procedures for continuity of operations plan (COOP) to restore informatics support including IT services.

Capability Statement #6.7
The laboratory manages and routinely updates all documentation supporting existing agreements (i.e., MOU/MOA/SLAs) pertaining to disaster recovery and mutual assistance.

Capability Statement #6.8
The laboratory manages and routinely updates a catalogue of capacities and services offered by partners, and a documented schedule to test effectiveness of partners' capabilities in disaster recovery and emergency situations.

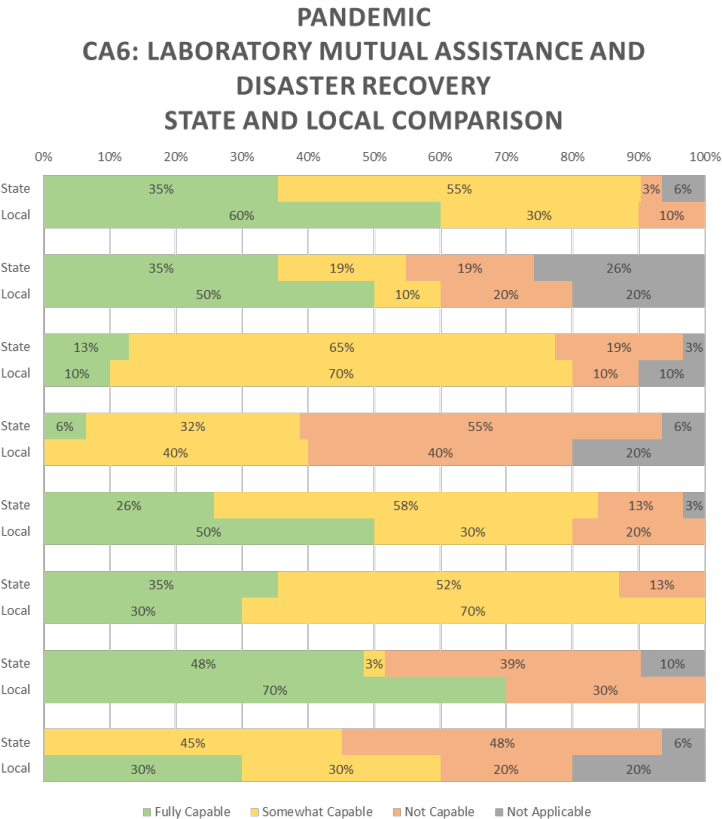


Figure 19: Comparison of state and local response within capability area 6, Laboratory Mutual Assistance and Disaster Recovery.

3Current State of ETOR

As described in the previous sections, no PHL scored 100% on their ETOR assessments. PHLs overall scores averaged around 70% with many in the 50-60% range. This indicates that ETOR capabilities are lacking across PHLs and that there are weaknesses in all PHLs when it comes to ETOR capabilities. This section outlines several of the projects that APHL and partners have undertaken in recent years to address ETOR challenges as well as current trends in ETOR exchange methods.

4.1 Current Initiatives

ETOR is quickly becoming standard protocol across clinical laboratories and the nation's PHLs and is a critical tool for a coordinated COVID-19 response. The APHL-sponsored **COVID-19 Lab Web Portal (LWP)**, developed by iConnect Consulting, is an ETOR solution featuring a secure web-based platform offering laboratory customers an intuitive, efficient, and paperless interface to order tests, track progress and review results. The COVID-19 LWP is easy to integrate with current testing workflows and LIMS and is accessible from any web-enabled device. Core features include an integrated dashboard, dynamic notifications, configurable Test Request Forms (TRF), batch order upload, EPI approval functionality, patient management, business analytics, and more. Currently, the COVID-19 LWP supports implementation of ETOR via batch upload of orders and automated result return, or via a StarLIMS bi-directional synchronization service.

The **Antimicrobial Resistance Laboratory Network (ARLN)** relies heavily on the timely and accurate exchange of electronic test orders and results between hospitals and public health laboratories to rapidly detect and respond to emerging antimicrobial-resistant threats. APHL and CDC have partnered with iConnect Consulting to implement the lab web portal (LWP) in every ARLN Regional Lab². Figure 20 below outlines the data flow from submitters to PHLs via the LWP. Going forward, an updated version of the LWP (LWPV2) will allow for batch uploads of orders and enhanced abilities to track patient and specimen information over time. LWPV2 also utilizes LIMSCoconnect with the regional PHLs, a smart data synchronization service that provides near-real time data flow between LWP and the LIMS. Several advantages of the LWP are that it is LIMS agnostic, accommodates multiple submission methods, and is available 24/7. LWP is hosted on the APHL Informatics Messaging Services (AIMS) Platform, which allows for more seamless exchange between state and federal partners. However, this may be a barrier for PHLs who are not able to utilize AIMS due to IT security restrictions or other constraints.

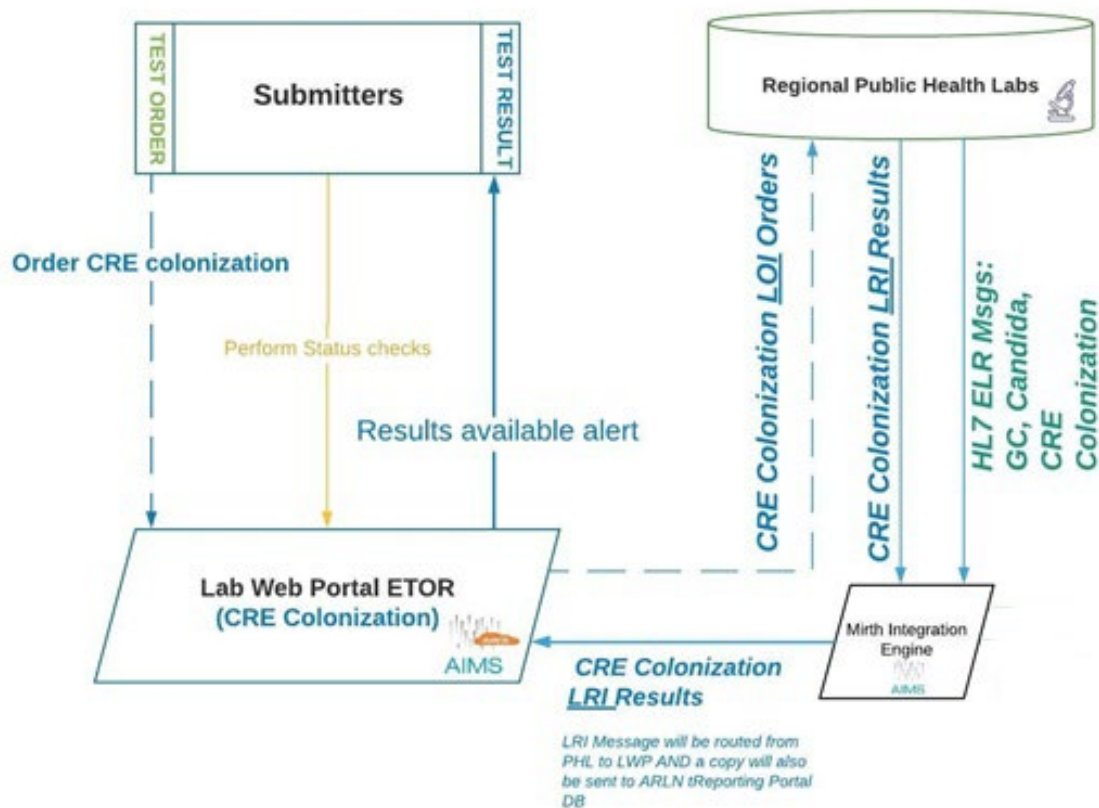


Figure 20: ARLN ETOR data flow using LWP

The **APHL TB ETOR** initiative was a collaboration between APHL, CDC, and the California Public Health Lab (Microbial Diseases Laboratory) to replace cumbersome email/fax processes by connecting the MDL with the AIMS based lab web portal (LWP). Submitting public health labs use the lab web portal to submit electronic orders for tuberculosis testing to the regional lab for drug susceptibility testing (DST) and pyrosequencing. LOI messages generated by the LWP are consumed by the lab. The outbound LRI message includes both an encapsulated pdf of the results report and discrete results. Recent project work looks to transition to LWPV2 and retire the HL7 messages, and implement LIMS Connect.

4.2 Trends in Data Exchange Methods

Currently, there are two general methods of order and result exchange for healthcare providers and organizations with PHLs.

1. Web-based individual orders and requests, where individual test orders are keyed into a user interface as part of an established workflow and results are provided through the same interface. The user may log onto a publicly available page published by the LIMS application or a third-party service that provides connectivity to the LIMS.
2. Larger organizations have the capability to generate requests from either their EMR system or an established integration engine. They typically submit HL7 order requests and receive HL7 result messages from the PHL. Due to security considerations, VPN tunnels between each sending and receiving facility is common. Another common approach is to use web services to exchange HL7 order and result messages. In this scenario, the lab provides a web service for submitting orders and querying for available results in the results repository.

A common trend is to utilize an integration engine to transform and transport requests from EMR Systems to the standard HL7 order and for labs to utilize integration engines to consume standard HL7 orders into LIMS readable format documents and in turn serve up the LIMS result in an HL7 message to be consumed.

Electronic Test Orders and Results (ETOR)

Technical Data Flow Diagram – Open

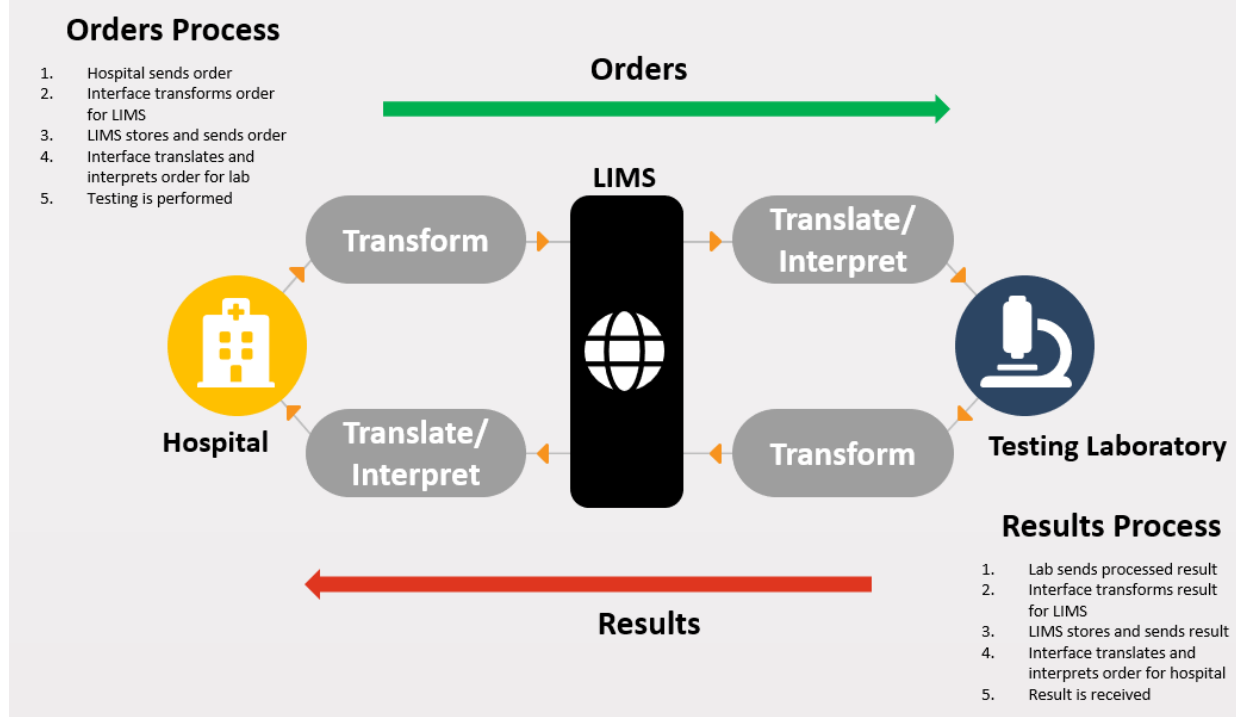


Figure 21: Common technical data flow of electronic lab orders and results.

Desired State of ETOR

The desired state of ETOR was determined based on responses to the assessments and in-depth discussion with PHLs during APHL Informatics Committee and ETOR Taskforce meetings. Topics are categorized into funding/resources, tools for implementation, and LIMS/IT infrastructure.

5.1 Funding and Resources

A common theme throughout the assessment responses and discussions is the need for continued annual funding to support infrastructure and skilled human resources for ETOR implementation and maintenance. Due to the COVID-19 pandemic, increased funding has become available to PHLs. However, without a guarantee that funding will remain available even after the pandemic, PHLs are hesitant to expand their workforce or begin years-long upgrade and improvement projects. One proposed solution to the lack of human resources is to have an increased workforce of APHL Technical Assistance staff, as well as CDC Informatics fellows, who could be deployed to work directly with PHLs on ETOR implementation and maintenance. This model has been used successfully on past data exchange projects, such as the Public Health Laboratory Interoperability Project (PHLIP).

Another desire expressed by many PHLs is a knowledge repository for exchanging resources and ideas and a place to get help from their colleagues across the country. Informatics Committee members described this as a knowledge base that anyone can contribute to and access for help, a place where staff members can get answers to commonly asked questions, and where colleagues can share new and innovative tools and processes that they have implemented in their lab.

5.2 Tools for Implementation

One of key takeaways when discussing ETOR implementation with lab informatics staff was that any tool developed by APHL for large-scale adoption must be scalable and reusable. With limited resources, informatics staff do not have the time

or resources for many one-off ETOR implementations or for having to “reinvent the wheel” with each new partner. Ideally, tools and solutions would work across PHLs and across submitter EHRs.

One of the ways to achieve this could be through a centralized translation service between PHL and submitter so that new submitters could be onboarded more quickly. PHLs also expressed the desire for centralized vocabulary and validation services that can be used with or without access to AIMS and with or without any other suite of ETOR tools developed by APHL.

5.3 LIMS and IT Infrastructure

In addition to funding, resources and tools for ETOR implementation, committee and taskforce members also discussed ways in which their overall LIMS and IT infrastructure could be improved. Several members mentioned the desire to set up instrument interfacing in their lab, reducing the need to document results on paper then re-enter them into the LIMS. While not directly related to ETOR, instrument interfacing would lead to increased speed and accuracy in getting results back to the submitter and other stakeholders.

During the pandemic, many PHLs worked with APHL to establish lab web portals for exchanging lab orders and results for COVID-19, influenza, and other respiratory pathogens. These PHLs have expressed a strong desire to expand the LWP for their full test catalog. Similarly, PHLs want to improve their LIMS and IT infrastructure to better support surge capabilities as both senders and receivers of lab orders and results. For example, while many PHLs have some capacity to receive an electronic lab order and send back a result, they are not able to electronically select tests for diversion to a mutual assistance laboratory and transmit metadata associated with tests and samples.

Gaps Identified Between Desired State and Current State

6.1 Financial Resources

Public health laboratories present a diversity of financial situations due to differences in government organizations and state specific legislation. However, on the whole, public health laboratories often contend with a feast or famine approach to funding. Previous challenges, including bioterrorism and the H1N1 pandemic, and the current fight against COVID-19, direct much needed funding toward public health laboratories and agencies. However, limits on funding timeline and allocation make it difficult to ensure that funds reach the most critical need and financial decisions are made with an eye toward future sustainability.

Success in public health ETOR requires adequate long-term funding be available to support the staff and information systems needed not only for implementation but for the long-term sustainability. Public health programs are often put in the position of securing grant funding for informatics projects. Ideally this funding would set aside as more permanent allocation in budgets for full time employees.

-“We have been able to add resources thanks to some recent grants to work on modernization of the applications which also includes new functionality and added capabilities and capacity.”

Providing guidance to public health laboratories on budgeting and staffing opportunities, particularly ideas and strategies for transitioning positions previously required for manual processing of test orders and results to informatics roles, would be beneficial.

6.2 Human Resources

Survey results clearly identify Informatics and IT Resource Management (Capability Area 5) as the lowest ranking capability in both the clinical and NBS surveys. Laboratories currently do not have sufficient resources to meet informatics needs. Additionally, staff currently in place often rely upon on-the-job training and are not able to keep pace with the constant changes presented by an expanding number of informatics initiatives.

Public health laboratories have expressed a desire for informatics training that would be available to support continuing education of existing staff and entry level education to train new employees. Of particular importance would be training that specializes in the unique requirements of public health data exchange.

-“Training opportunities and continue education heavily rely on funding resources and staff availability pending projects; hope to see an improvement in this area with courses and functionality being designed for virtual learning.”

-“No structured training plans. Are any plans available?”

-“Filling IT roles is difficult finding qualified, experienced team members. Bridging IT and Lab skill sets including retention for consistent builds with upgrades verification and maintenance is extremely hard.”

6.3 Difficulty of ETOR Implementation

ETOR implementation is often a long and difficult journey without a defined end point. Laboratories encounter a number of challenges – some small, many big – that can collectively slow or prevent success. Public Health Laboratories have provided feedback on the following barriers:

- Lack of project buy-in/investment from leadership, from either that of the laboratory and/or the messaging partner, often results in inadequate prioritization of resources and funding. Also, the lack of motivation and dedication needed to push ETOR implementations past speed bumps.
- Inability to build and maintain unique interfaces for each trading partner. Many LIMS lack the flexibility to accommodate data requirements and mappings specific to messaging partners. CA3.7 indicates that only about half of laboratories are fully capable in this area. Despite efforts to adhere to national standards, real-world implementation almost always requires at least a minimal level of specialization. This is often removed from the LIMS and handled via integration engines, which only displaces the burden by way of multiple messaging routes. Maintenance of unique configurations, either accomplished in the LIMS or by integration engine, is extremely difficult in the long term.
- Difficulty in upgrading systems and projects to keep current with changing standards: The 10-15 years have seen transitions from HL7 2.3.1 to 2.5.1 to LOI/LRI standards and finally FHIR. As mentioned in the above section on human resources, staff are often unprepared to participate in upgrade efforts and differences in versions between messaging partners can add another roadblock to implementation.
- Lack of reusability: New ETOR implementations can often feel like starting back at square one. Each new messaging partnership requires a requirements elicitation, gap analysis, and validation period. Without reusable tools, the process can be overwhelming. Unique business requirements will almost always necessitate some specialization; however, standardization of approach and tooling would make significant strides.
- Extended implementation periods can result in slowing of progress, eventual disinterest by stakeholders, and potential prioritization of other projects by either messaging partner.
- Lack of familiarity with the legal implications and requirements for exchanging patient information, can hamper implementation process. ETOR often requires laboratories to wade into uncharted legal waters. While legal requirements will vary by state, access to guidance and a sharing of collective experiences would be helpful.
- Restrictions imposed by IT security policies: Some PHLs are unable to access and utilize cloud-based data exchange solutions, such as AIMS, due to agency-wide security policies. These respondents expressed concern that with so many new tools and solutions being deployed using cloud services, their PHL would be left behind.

A future desired state would provide guidance, support, and technical assistance to Public Health Laboratories and agencies to overcome these challenges. Of particular importance is an organizing body to effectively document lessons learned, facilitate sharing of experiences, curate a knowledge repository, create reusable implementation tools and guide laboratories moving forward.

References

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