

Health Information Technology Oversight Council

Oregon Laboratory Exchange Progress Report¹ November 2012

Executive Summary

The purpose of this Oregon Laboratory Exchange Progress Report is to provide the Oregon Health Information Technology Oversight Council (HITOC) and the Oregon Office of Health IT (OHIT) with an update on the status of electronic lab exchange in Oregon, implementation of the Lab Exchange Plan (approved by HITOC in September 2011), and plans/recommendations for continued lab exchange and interoperability improvement efforts in 2013.

Background

The Office of the National Coordinator for Health Information Technology (ONC) has identified the electronic exchange of structured clinical laboratory data between laboratories, Eligible Professionals (EPs) and Eligible Hospitals (EHs) as a high priority service for health information exchange (HIE).

In the second directive to State HIE Cooperative Agreement grantees (ONC-PIN-HIE-002), the ONC requires states "to collect data from all hospital and independent labs in their state to facilitate outreach, build partnerships, and to set goals and track progress on the following program measures: % of labs sending electronic lab results to providers in a structured format; % of labs sending electronic lab results to providers using LOINC."

Since the most recent status report to HITOC, we have conducted two meetings of the Oregon Laboratory Stakeholders Group. The first, on July 6, 2011, presented the findings of the first "environmental scan" survey of Oregon laboratories. The second meeting, held on November 14, 2011, reviewed the 2011 Oregon Lab Exchange Plan and addressed ways to increase electronic lab result delivery in Oregon.

On August 31, 2011, we finalized the Oregon Lab Exchange Plan. The plan was informed by communications from the ONC, the strategic and tactical goals of HITOC, the input of our stakeholders, the findings from our lab survey, and information gleaned from our participation in national groups convened by ONC (the Standards & Interoperability (S&I) Lab Results Interface (LRI) Initiative and the Health Information Technology Research Center (HITRC) Lab Community of Practice.)

¹ Report prepared by James McCormack, MT(ASCP), The Robertson Group LLC for the Health Information Technology Oversight Council (HITOC) and the Oregon Office of Health IT (OHIT).

In the plan, we identified five priorities:

1. *Increase the number of laboratory results being incorporated into electronic health records (EHRs) as structured data*
2. *Increase the capability of laboratories to submit reportable test results to Public Health agencies through the Electronic Laboratory Reporting (ELR) system*
3. *Incorporate Direct Project messaging into laboratory exchange as a means to deliver results to EHRs*
4. *Understand and bear in mind the business considerations of participating in electronic results exchange for commercial and non-commercial laboratories*
5. *Invite national labs (e.g., Quest, LabCorp) to participate in OHIT's efforts*

Progress

To date, we have made modest progress on each of the five priority areas identified in our 2011 Lab Exchange Plan.

Increase the number of laboratory results being incorporated into electronic health records (EHRs) as structured data

The priority has showed the least progress. Because laboratories themselves do not have specific Meaningful Use requirements under the Stage 1 Criteria, our experience getting clinical laboratories engaged in HIE has been difficult. Judging by the other participants in the HITRC lab community, our experience in Oregon mirrors that of other states and represents a major challenge to broader HIE goals that rely on lab data (e.g., continuity of care, use of clinical decision support, and the calculation of quality measures to name a few).

Increase the capability of laboratories to submit reportable test results to Public Health agencies through the Electronic Laboratory Reporting (ELR) system

There are two main reasons why progress has been slow on this priority. First, Oregon has been very aggressive in connecting clinical laboratories for public health over many years and we are starting at a very high adoption level. Second, the resources involved to set up system interfaces for electronic public lab reporting in the remaining labs are scarce.

Incorporate Direct Project messaging into laboratory exchange as a means to deliver results to EHRs

This priority leverages Oregon's state HIE, CareAccord, to exchange lab results using Direct Messaging. CareAccord has only recently been turned on, but has huge potential as a route for electronic lab exchange. What remains to be seen is whether labs will find commercial value from HIE-mediated access to new customers via Direct rather than point-to-point interfaces or other methods of report delivery.

Understand and bear in mind the business considerations of participating in electronic results exchange for commercial and non-commercial laboratories

In this priority we acknowledged the importance of business factors in driving lab participation in HIE. Oregon labs perform a substantial proportion of commercial testing for providers in the state. As a result, labs have developed private interoperability capabilities through direct system interfaces to client-providers and through dedicated online portals for orders and results. Our stakeholders and

the HITRC lab community have helped us understand that without clear value propositions or policy levers, labs are poorly motivated to participate in health information exchange.

Invite national labs (e.g., Quest, LabCorp) to participate in OHIT's efforts

This priority seeks to engage the large national commercial laboratories that have a significant market share in Oregon. The most successful approach has been to interact with Quest and LabCorp as part of the HITRC Community of Practice rather than approaching them one state (and region) at a time. For example, we are following Quest's use of Direct Messaging in Florida as a potential model for result delivery using CareAccord in Oregon.

Current State of Lab Exchange in Oregon

Between May and June 2012, we conducted a state-wide census of hospital and independent laboratories in Oregon per the ONC's request in ONC-PIN-HIE-002. We mailed a census questionnaire to 179 labs (108 hospital labs and 71 independent labs) and gathered 52 responses for a total response rate of 29%. Below is the conclusion from our census report.²

[Excerpted from 2012 Lab Census] Our census found that just over half of the hospital and independent laboratories currently send structured electronic results to providers. Of concern, however, is the limited use and awareness of existing standards (HL7, LOINC) and best practices for electronic result exchange (S&I).

We interpret the census to suggest that our hospital and independent laboratories' capabilities for standardized exchange of test results in Oregon are not yet sufficient to provide electronic structured reports to all providers who want them. This finding raises concerns that clinical laboratory data needed for effective use of EHRs and cross-organizational information exchange may constrain adoption and meaningful use by Oregon providers.

Issues

Barriers and Dependencies

Through our activities in the last year and a half, we have identified several issues slowing the expansion of electronic laboratory results reporting to providers and to Public Health in Oregon. These barriers fall into three categories: technical, regulatory and policy, and incentives.

Technical Issues

While great progress has been made by the S&I Initiative to provide a clear and feasible implementation guide for sending electronic lab results in a structured (HL7 2.5 plus ELINCS) and standardized (the use of LOINC and SNOMED) form, our census showed that very few labs have yet adopted (or are even aware of) these national efforts. Despite a high percentage of labs having the capability to exchange results through their existing Laboratory Information Systems, few are distributing reports outside of their organization or customer-base in an electronic form.

Regulatory and Policy Issues

Laboratories regulated under the Clinical Laboratory Improvement Amendments (CLIA) continue to have concerns that distributing results to unaffiliated providers may violate CLIA or HIPAA

² See Appendix 1 for the complete 2012 State Census of Oregon Clinical Labs report.

rules, and expose their organizations to risk. The ONC has worked with national stakeholders and regulators to clarify these rules, but updated official guidance has been slow to reach individual labs.

Issues of Incentive

Incentives for HIE has thus been the focused so far on the recipients (providers and hospitals with EHRs) and not the senders of lab data. Because laboratories are not directly rewarded or penalized under Stage 1 Meaningful Use (aside from Public Health reporting), a value proposition remains elusive for labs to participate in HIE.

Next Steps and Direction

Our goal to expand the availability of structured and standardized electronic lab results to all hospitals and providers that need them depends on overcoming the three issues described above.

Overcoming Technical Barriers

- Oregon labs must be made aware of the state and national efforts to streamline electronic exchange. This includes the updated technical standards and best practices for applying LOINC and SNOMED strategically to reduce the burden on the lab.
- To effectively take advantage of CareAccord's infrastructure for Direct Messaging, laboratory systems vendors will need to provide built-in capabilities to integrate Direct result reporting into their products. Unless this form of reporting is at least as efficient as faxing, labs will be unlikely to use Direct for reporting test results.

Overcoming Regulatory Barriers

- Concerns regarding CLIA and HIPAA constraints on result reporting are being dealt with on a national level, but word must get out to Oregon laboratories from an official source; otherwise, labs will continue to be understandably cautious about sending results to outside providers.

Overcoming Incentive Issues

- The recent addition of the menu item for reporting of hospital laboratory results to outside providers in Stage 2 Meaningful Use provides a useful policy lever to expand electronic reporting.
- With CareAccord up and running, labs now have the option to distribute test results (and other communications) through secure Direct Messaging. To create an incentive to use these services, however, will require a combination of potential customers (providers with CareAccord or another Direct address) and operational efficiencies (at least as efficient as fax).
- Provider demand for structured electronic laboratory results, via Direct Messaging or other means, will be critical to achieve wide availability throughout the state.

To meet these challenges, we recommend that OHIT and/or HITOC focus on the following priorities for 2013:

- Continue to participate in lab HIE communities of interest, compare experiences with other states, and maintain awareness of national efforts to streamline exchange and clarify regulation.
- Closely follow pilots in other states using Direct Messaging (or other means) to transport electronic test results (e.g., the joint project with Quest and Harris Corps. in Florida).
- Build on the contacts made with stakeholders and labs over the last year, and through the census. For example, interviews with different types of labs might provide a deeper understanding of the challenges identified above.
- Look for opportunities to leverage CareAccord to create a value proposition for laboratories. For example, uses other than primary result delivery (secure communication for orders or client service requests) might prove an attractive way to get labs signed up with a Direct address.
- Partner with the Public Health Division to create and implement a plan to connect the remaining labs for electronic notifications of reportable diseases. While leveraging CareAccord for this purpose is ideal, other mechanisms may be needed to achieve a goal of 100% electronic lab reporting in Oregon.

2012

State Census of Oregon Clinical Labs

**Prepared for the Oregon Health Information Technology Oversight
Council (HITOC)**

Released: August 5, 2012

Updated: September 6, 2012

EXECUTIVE SUMMARY

Our census found that just over half of the Oregon hospital and independent laboratories that responded to the census currently send structured electronic results to providers. Of concern, however, is the limited use and awareness of existing standards (HL7, LOINC) and recent practices for electronic result exchange from the Standards and Interoperability Framework working groups.

We interpret this census to suggest that our laboratories' capabilities for standardized exchange of test results in Oregon are not yet sufficient to provide standards-based electronic structured reports to all providers who need them – especially those practicing outside of large health systems. This finding raises concerns that clinical laboratory data needed for effective use of electronic health records and cross-organizational information exchange may constrain adoption and meaningful use by independent Oregon providers.

INTRODUCTION

This census of the electronic reporting capabilities of hospital and independent clinical laboratories in Oregon was requested by the Office of the National Coordinator for Health IT (ONC) in a Program Information Notice (ONC PIN-HIE-002). In the notice, the ONC asked states granted a State HIE Cooperative Agreement: "to track the progress of their health information exchange-enabling efforts in key priority areas." One of these priority areas is electronic exchange of structured laboratory data.

To collect and analyze this information, Oregon's Office of Health Information Technology requested a lab census focusing, per ONC request, on the "percent of labs sending electronic lab results to providers in a structured format", and the "percent of labs sending results using LOINC codes."

We also took the opportunity to learn more about: how hospital and independent labs in our state distribute their test reports (on paper, fax, or electronically); relative test volumes; and firsthand demographic information for later use in our outreach and education efforts.

In this report, we describe the methods and results of the Oregon state lab census conducted between March and June, 2012. We discuss the implications of these data for providers wishing to receive structured electronic results, and briefly compare these results with our first lab survey conducted in May of 2011.

METHODS

To describe the current capabilities of Oregon labs to send structured electronic test results, we mailed questionnaires to 108 hospital and 71 independent labs. Per ONC recommendations (*Conducting a state census of clinical labs*, ONC 2012) our recipients were drawn from the Online Survey, Certification and Reporting database (OSCAR) maintained by the Center for Medicare and Medicaid Services in compliance with the Clinical Laboratory Improvement Act (CLIA). Out of 2,526 CLIA registered laboratories (Appendix B), we selected

those identified as hospital and independent labs (179) as the major sources of laboratory data in the state.

Census data were collected on two paper questionnaires: one for hospital and one for independent labs (see Appendix C1 and C2). We based our questions on the census examples provided in the May ONC Guidance. The mailings were professionally printed on Oregon State letterhead, and mailed with a cover letter from our state's coordinator of Health IT (Carol Robinson) on April 9, 2012. A local Health IT graduate student was recruited to assist with the planning, delivery, and analysis of the census.

In addition to mailing the questionnaires, we designed an online survey form using Survey Monkey (www.SurveyMonkey.com). This form and database served two purposes: first, our research assistant used the website to enter and validate returned paper questionnaires and second, we wanted to have an electronic option available to our recipients.

We tried to maximize our response rate in three ways: first, by providing a "hotline" with access to our subject matter expert; second, by conducting telephone reminders; and third, by targeting key laboratory contacts known to the research team. We had no calls to our hotline, and over seventy hours were spent attempting to contact non-responders by phone or email.

Our data were analyzed from the Survey Monkey database, which was downloaded, reformatted, and reviewed as a Microsoft Excel spreadsheet. For each laboratory that responded, we collected basic demographics, yes/no responses, numeric ranges, and free-text "other" responses.

We did not attempt statistical analyses beyond totals and response frequencies, choosing to handle this project as a census and not a formal scientific survey. We also lacked enough information on the recipients to conduct a meaningful comparison of responders versus non-responders.

After tabulating the responses, our team reviewed the results looking for patterns, trends, and anomalies. We attempted to verify any inconsistent responses with the recipient by phone or email. A draft of this report was distributed to a selected group of laboratory stakeholders for comments before being reviewed by HITOC.

As a check on validity, we informally compared the findings from a similar lab survey we conducted in May 2011, and present this comparison in the results section below.

RESULTS

Data for the results below were collected from two census forms (see Appendix C1 and C2), one for hospitals and one for independent labs. Because not all questions were answered by all respondents, we present the numerator and denominators (nn/nn) along with the percentages where appropriate. Please see the tables in the Appendix A for a complete tabulation.

From a total of 179 Oregon hospital and independent laboratories listed in the OSCAR database, we received responses from 44/108 (41%) and 8/71 (11%) respectively. Our total response rate was 52/179 (29%). Of that total, 14 labs completed the census online, 33 mailed their response, and six provided answers over the phone during a reminder call.

The majority of hospital labs (36/44) are affiliated with hospitals or health systems versus either academic medical centers (2/44) or "other" (6/44). Of the independent labs, only one response out of eight represented an in-state affiliate of a national laboratory.

Most of the hospital labs reported volumes of less than 100,000 billable tests per year (22/44), followed by up to 1 million billable tests (17/44), and only five laboratories with over 1 million (5/44). Of the independent labs, most were small (5/8 under 100,000 billable tests), and two reported over 1 million tests.

About half of the responding (23/44) hospitals and independent labs (4/8) reported that they currently send structured electronic test results to ambulatory providers -- either within or

outside of their organizations. Of the hospital labs, 91% (21/23) send electronic results outside of their organization, one does not, and one was unsure.

Provider access to lab results through a web portal is provided by less than half of the hospital labs (12/22) and three of four of the responding independent labs (one did not know).

Only two hospitals and one independent lab say they are using the LRI implementation guide from the S&I Framework. The vast majority did not use the S&I framework (24/44, hospitals; 4/7 independent) or did know (18/44, hospitals; 2/7, independent).

Less than half of the hospital (16/42) and independent labs (3/7) currently support HL7 2.3x; version 2.5.1 is supported by 17% (7/42) and 43% (3/7) respectively. None reported using Clinical Documents (CDA, CCD, etc.) for reporting electronic test results.

Finally, 16% (7/44) of hospitals and 25% (2/8) of independent labs reported using LOINC codes to identify lab tests; the rest did not or were unsure.

DISCUSSION

This census provides an important measure of the current electronic reporting capabilities of a small proportion of Oregon laboratories. Our response rate remained fairly low (a total of 29%), despite our use of a professional mailing and considerable resources devoted to telephone follow-up with non-responders.

The present results are consistent with a similar survey we conducted in May, 2011, which also used CLIA labs as a source of recipients. In 2011, with a 29% response rate we found that 41% (12/26) of labs electronically reported results to outside providers, 38% (10/26) offered web portals, 46% (10/22) used HL7 2.3, 46% (10/22) HL7 2.5.1, and 58% (11/19) identified tests with LOINC codes.

CONCLUSION

Our census found that just over half of the hospital and independent laboratories currently send structured electronic results to providers. Of concern, however, is the limited use and awareness of existing standards (HL7, LOINC) and best practices for electronic result exchange (S&I).

We interpret this census to suggest that our hospital and independent laboratories' capabilities for standardized exchange of test results in Oregon are not yet sufficient to provide electronic structured reports to all providers who want them. This finding raises concerns that clinical laboratory data needed for effective use of electronic health records and cross-organizational information exchange may constrain Oregon providers' ability to demonstrate Meaningful Use.

LIMITATIONS

Our census has several limitations. First, the census was limited to hospital and independent labs, self-identified in the OSCAR database. This excludes other sources of lab data, including ambulatory clinics and group practices.

Second, we lacked responses from three large independent laboratories with sizeable markets in Oregon: LabCorp, Quest Diagnostics, and PAML (Spokane, WA).

Third, many multi-site organizations have multiple CLIA registrations. We opted not to attempt to adjust the reported proportions, leading to some over-reporting by large health system labs receiving more than one questionnaire.

Finally, it is possible that the person completing the questionnaire for their organization may not have been aware of the technical details of their result delivery. Future studies may require contacts outside of the laboratory to ensure a complete and accurate landscape.

ACKNOWLEDGMENTS

We would like to thank our laboratory stakeholders group, Oregon HITOC, the Oregon Health Authority, and the OHA Shared services for their support in planning, distributing and completing this census.

DISCLOSURE

This report was prepared under State contract by Dave Witter and Associates in association with The Robertson Group LLC.

REVISIONS:

September 6, 2012 (JM): Corrected response rate for independent labs to 11.3%.

APPENDIX A

A. 2012 Lab Census Data Tables

Forty-four Hospital and eight independent labs responded to a specific census form and are analyzed separately. Some questions were skipped by recipients, and we report both the actual responses along with the percentage (Responses (%)).

A1. Census response rate

	Responses	Total Recipients	Response Rate
Independent Labs	8	71	11.27%
Hospital Labs	44	108	40.70%
All labs	52	179	29.10%

A2. Laboratory ownership or organizational affiliation

Organizational Affiliation or Ownership	Independent Labs
Independently Owned	5 (62.5%)
Clinic or Group Practice	2 (25%)
Affiliated with National Lab	1 (12.5%)
Other	0
Total Responses	8

Organizational Affiliation or Ownership	Hospital Labs
Affiliated with a University/Academic Center	2 (4.5%)
Hospital or Health System	36 (81.8%)
Non-academic affiliated laboratory	6 (13.6%)
Other	3 (6.8%)
Total Responses	44

A3. Billable tests per year received from ambulatory providers

Billable Tests per Year	Independent Labs	Hospital Labs
Fewer than 100,000 billable tests	5 (62.5%)	22 (50%)
100,000 - 499,999 billable tests	1 (12.5%)	13 (29.5%)
500,000 - 999,999 billable tests	0	4 (9.1%)
1,000,000 or more billable tests	2 (25%)	5 (11.4%)
Total Responses	8	44

A4. Currently send electronic lab results

Send electronic results	Independent Labs	Hospital Labs
Yes	4 (50%)	23 (52.3%)
No	3 (37.5%)	21 (47.7%)
Don't Know	1 (12.5%)	0
Total Responses	8	44

A5. Currently deliver electronic lab results to outside providers: Independent Labs

Independent Labs	None	Some or all	Unknown	Total Responses
Electronic delivery to EHR	0	3 (75%)	1 (25%)	4
Available on web portal	0	3 (75%)	1 (25%)	4
Other method	0	0	1 (100%)	1
Hospital Labs	None	Some or all	Unknown	Total Responses
Electronic delivery to EHR	1 (4.3%)	21 (91.3%)	1 (4.3%)	23
Available on web portal	8 (36.4%)	12 (54.5%)	2 (9.1%)	22
Other method	2 (33.3)	4 (66.7%)	0	6

A7. Currently use LOINC codes to identify lab tests

Use LOINC	None	Some or all	Unknown	Total Responses
Independent Labs	4 (50%)	2 (25%)	2 (25%)	8
Hospital Labs	27 (61.4%)	7 (15.9%)	10 (22.7)	44

A8. Have used the LRI Implementation Guide (S&I Framework)

Use LRI (S&I Framework)	Independent Labs	Hospital Labs
Yes	1 (14.4%)	2 (4.5%)
No	4 (57.0%)	24 (54.5%)
Don't Know	2 (28.6%)	18 (40.9%)
Total responses	7	44

A9. HL7 Standards currently in use

Independent Labs	Yes	No	Unknown	Total Responses
HL7 2.3.1	3 (42.9%)	2 (28.6%)	2 (28.6%)	7
HL7 2.5.1	3 (42.9%)	3 (42.9%)	1 (14.3%)	7
Other	0	1 (100%)	0	1
Hospital Labs	Yes	No	Unknown	Total Responses
HL7 2.3.1	16 (38.1%)	9 (21.4%)	17 (40.5%)	42
HL7 2.5.1	7 (16.7%)	17 (40.5%)	18 (42.9%)	42
Other	5 (28.4%)	3 (17.6%)	9 (52.9%)	17