

ONC Data Brief ■ No. 13 ■ February 2014

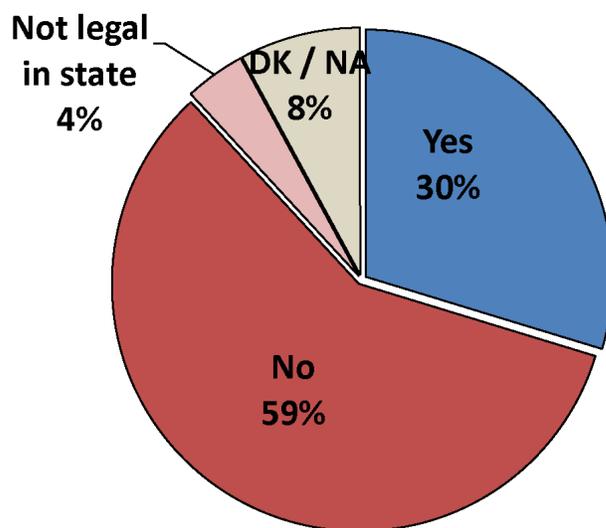
Patient Access to Test Results among Clinical Laboratories

Matthew Swain, MPH & Vaishali Patel, PhD MPH

Research demonstrates that providing patients or their caregivers with access to clinical information empowers them to better manage their health.^{1,2,3} Recognizing the importance of patient access to clinical information, the Department of Health and Human Services (HHS) has amended the Clinical Laboratory Improvement Amendments of 1998 (CLIA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to increase patients’ⁱ direct access to their test results from laboratories.⁴ Using data from a survey commissioned by the Office of the National Coordinator for Health IT, this brief describes the levels of direct patient access to test results allowed by clinical laboratories in 2012.

Three in ten laboratories allowed patients or their legal representatives direct access to clinical test results, either electronically or on paper.

Figure 1: Percent of clinical laboratories that allowed patients direct access to clinical test results: 2012



NOTES: Estimates based on long form survey respondents. Results may not add to 100 percent due to rounding. “DK/NA” accounts for respondents selecting “don’t know” and item non-response.

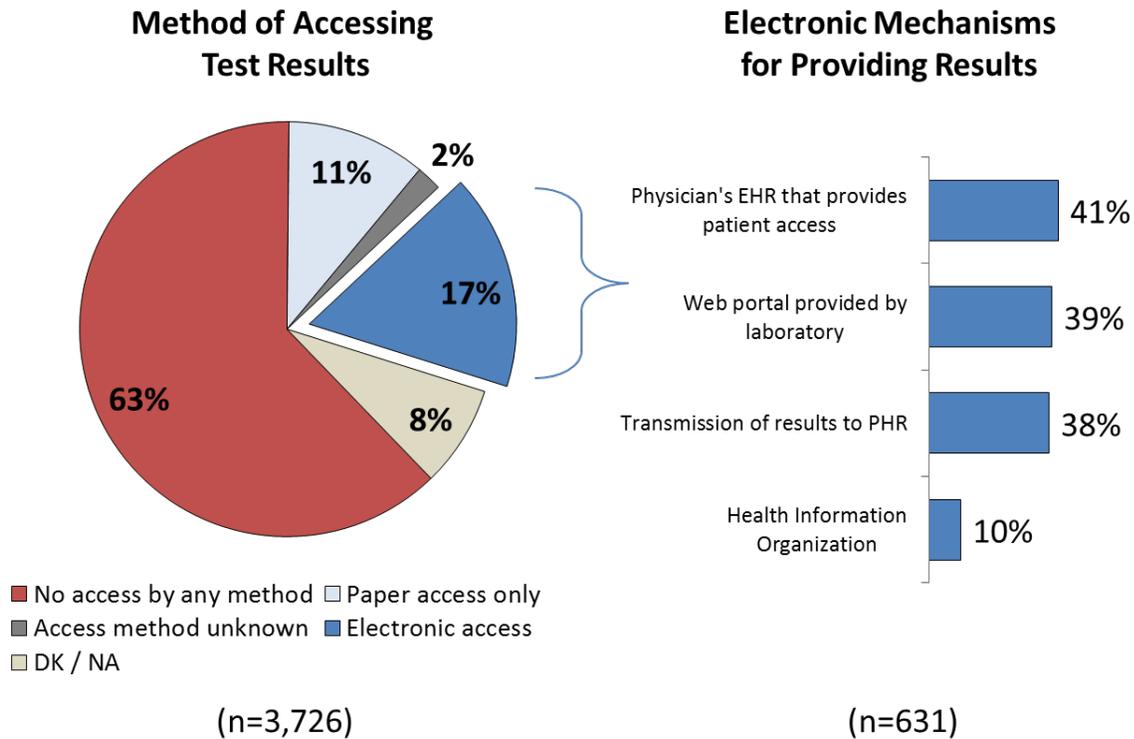
SOURCE: ONC analysis of data from National Survey on Health Information Exchange in Clinical Laboratories, 2012

- ★ Approximately thirty percent of clinical laboratories allowed patients or their legal representatives to have direct access to their clinical test results in 2012. A small minority (4%) reported that it was not legal in their state to provide these results directly to patients (Figure 1).

ⁱ Includes patients and/or an individual or individuals identified by the patient to receive the results, identified in the regulation as “authorized individuals or their representatives.”

Fewer than two in ten laboratories allowed patients or their legal representatives electronic access to their clinical test results.

Figure 2: Percent of clinical laboratories that used electronic and non-electronic methods to deliver test results directly to patients: 2012



NOTES: Estimates based on long form survey respondents only. Results in the pie chart may not add to 100 percent due to rounding. The category “no access by any method” includes respondents that answered “no” or “not legal in state” in Figure 1. “DK/NA” accounts for respondents selecting “don’t know” and item non-response. The categories “paper access only,” “access method unknown,” and “electronic access” comprise the 30 percent of clinical laboratories providing patients or their legal representatives direct access to their clinical test results in Figure 1. Respondents were allowed to select more than one electronic mechanism.
 SOURCE: ONC analysis of data from National Survey on Health Information Exchange in Clinical Laboratories, 2012

- ★ Seventeen percent of laboratories shared test results electronically with patients or their legal representatives (Figure 2).
- ★ Among laboratories providing electronic access to patients, mechanisms for sharing test results included web portals provided by laboratories (41 percent), physician’s EHR that provides patient access (39 percent), transmission of results to a personal health record (38 percent), and through a health information organization (10 percent).



The percent of clinical laboratories that allowed patients or representatives direct access to clinical test results varied significantly from the national average in some states.

Table 1: Percent of clinical laboratories that allowed patients direct access to clinical test results by state and territory: 2012

State	Direct Access, %	n(N)	State	Direct Access, %	n(N)
United States	30%	3,726 (11,601)	Montana	40%	38(78)
Alabama	21%	72(219)	Nebraska	41%	63(126)
Alaska	51%	17(39)	Nevada	51%	20(80)
Arizona	28%	68(187)	New Hampshire	20%*	20(46)
Arkansas	26%	45(140)	New Jersey	27%	43(178)
California	23%§	308(1,074)	New Mexico	35%	25(79)
Colorado	24%	81(174)	New York	11%§	138(415)
Connecticut	37%	45(149)	North Carolina	23%	70(315)
Delaware	26%*	8(26)	North Dakota	30%*	24(57)
District of Columbia	13%*	8(27)	Ohio	33%	136(378)
Florida	16%§	172(678)	Oklahoma	44%†	76(191)
Georgia	11%*	84(295)	Oregon	47%†	55(149)
Hawaii	10%*	8(49)	Pennsylvania	33%	126(414)
Idaho	41%	29(64)	Puerto Rico	63%†	253(703)
Illinois	23%	118(376)	Rhode Island	14%*	6(36)
Indiana	44%†	81(254)	South Carolina	16%*	35(135)
Iowa	33%	75(159)	South Dakota	52%†	41(88)
Kansas	27%	84(201)	Tennessee	9%*	83(269)
Kentucky	17%§	68(181)	Texas	26%	257(1,037)
Louisiana	15%§	70(296)	Utah	60%†	29(94)
Maine	44%	18(57)	Vermont	14%*	7(25)
Maryland	24%	50(176)	Virginia	41%	55(203)
Massachusetts	29%	91(276)	Washington	30%	84(240)
Michigan	37%	118(263)	West Virginia	37%	27(74)
Minnesota	43%†	79(183)	Wisconsin	37%	86(195)
Mississippi	17%*	35(166)	Wyoming	11%*	23(47)
Missouri	47%†	73(240)			

NOTES: Estimates based on long form survey respondents. n = survey respondents; N = laboratories sampled. More information on sampling criteria can be found below in the Data Source and Methods.

*Estimate does not meet standards of reliability

†Significantly higher than national average (p < 0.05)

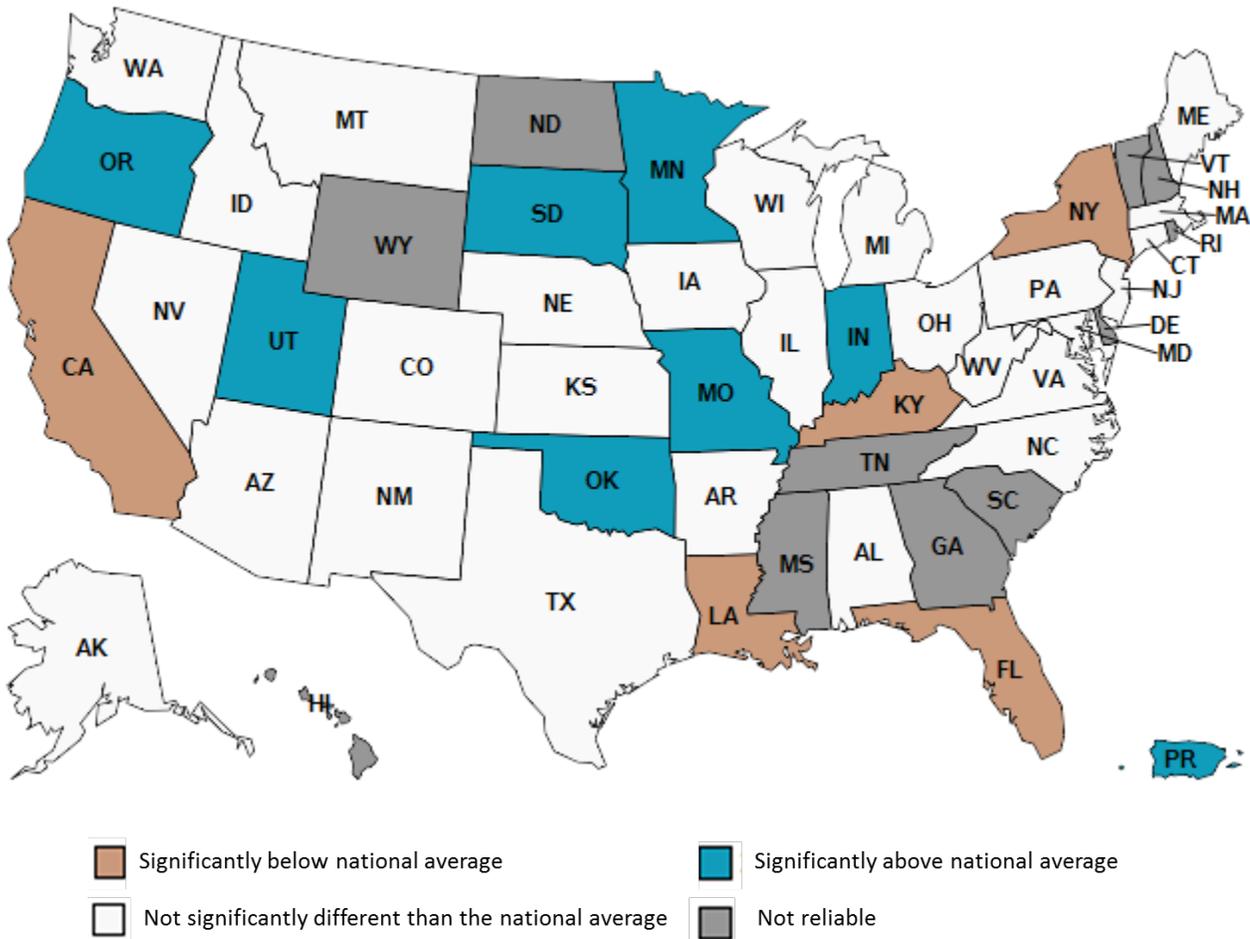
§Significantly lower than national average (p < 0.05)

SOURCE: ONC analysis of data from National Survey on Health Information Exchange in Clinical Laboratories, 2012

★ The proportion of clinical laboratories providing direct access to patient test results at the state level ranged from 11 percent (New York) to 63 percent (Puerto Rico) (Table 1).

The proportion of patients given direct access to test results by clinical laboratories was significantly higher than the national average in eight states and territories.

Figure 3: Percent of clinical laboratories that allowed patients direct access to their clinical test results by state and territory, compared to the national average (30 percent): 2012



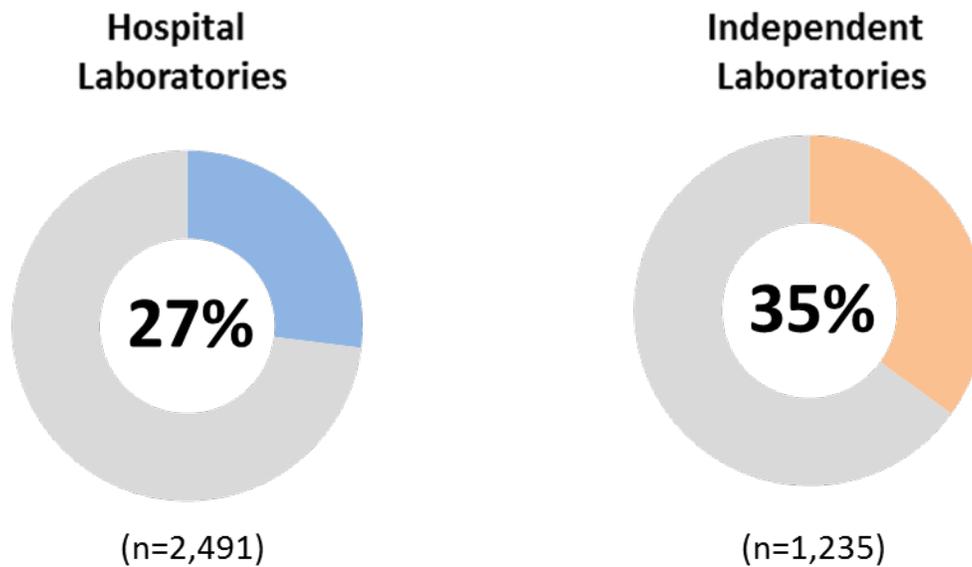
NOTES: Estimates based on long form survey respondents.
 SOURCE: ONC analysis of data from National Survey on Health Information Exchange in Clinical Laboratories, 2012

- ★ The proportion of patients given direct access to test results by clinical laboratories was significantly higher than the national average in Indiana, Minnesota, Missouri, Oregon, Oklahoma, Puerto Rico, South Dakota, and Utah (Figure 3).
- ★ The proportion of patients given direct access to test results by clinical laboratories was significantly lower than the national average in California, Florida, Kentucky, Louisiana, and New York.



A significantly higher proportion of independent laboratories allowed patients direct access to their clinical tests, compared with hospital laboratories.

Figure 4: Percent of clinical laboratories that allowed patients direct access to their clinical test results by laboratory type: 2012



NOTES: Estimates based on long form survey respondents.

SOURCE: ONC analysis of data from National Survey on Health Information Exchange in Clinical Laboratories, 2012

- ★ More than one-third (35%) of independent laboratories allowed patients or their representatives to directly access their clinical test results (Figure 4).
- ★ Approximately one-quarter (27%) of hospital laboratories allowed patients or their representatives to directly access their clinical test results.



Summary

The National Survey on Health Information Exchange in Clinical Laboratories included survey items to describe baseline rates of clinical laboratories providing patient access to their test results. In 2012, only three in ten laboratories allowed patients or their legal representatives with access to their test results. Independent laboratories had higher rates of allowing patients direct access to their test results compared to hospital laboratories; however, access among these laboratories was still limited.

Less than one in five clinical laboratories shared results electronically with patients (17 percent). Among clinical laboratories that did share results with patients electronically, the three most common mechanisms for sharing test results with patients included physician's EHR that provides patient access (41 percent), web portals provided by laboratories (39 percent), and transmission of results to a personal health record (38 percent).

The proportion of clinical laboratories allowing patients or representatives with direct access to clinical test results varied significantly by state. State level rates of clinical laboratories providing direct access to patient test results ranged from 11 percent to 63 percent. Patient access to test results was significantly higher than the national average in Indiana, Minnesota, Missouri, Oregon, Oklahoma, Puerto Rico, South Dakota, and Utah.

The changes to the CLIA and HIPAA Privacy Rule in 2014 will enable increased patient access to their laboratory results. The 2012 rates of patients' allowed access their test results by clinical laboratories reported from this national survey have the potential to increase due to these proposed changes. Additionally, rates of patients being able to electronically view their test results electronically have the potential to increase as providers that are participants in the Centers for Medicare & Medicaid Services (CMS) EHR Incentive Programs will be required to provide patients the ability to electronically view, download and transmit their health information.⁵



Definitions

Clinical laboratory: Includes hospital and independent laboratories processing test results for clinical purposes and located within the 50 states, the District of Columbia, and Puerto Rico. Laboratories conducting tests of minimal complexity were ineligible for the survey. In-scope laboratories were identified from the CMS Online Survey, Certification and Reporting (OSCAR) database based on laboratory type, laboratory type description, and state.

Test results: A laboratory test that is (1) ordered by a provider; (2) performed on received specimens; and (3) finalized and results have been produced. The laboratory has incorporated and calculated reference data to produce the results referenced.

Health Information Exchange: The electronic movement of health-related information among organizations according to nationally recognized standards.

Health Information Organization: An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.

Portal: Hosted and maintained by a provider or payer organization, without transferring access and control and use of the information to the individual, are not considered PHRs based on this definition.



Data Source and Methods

Data are from The Office of the National Coordinator's (ONC) National Survey on Health Information Exchange in Clinical Laboratories. The survey was conducted by NORC at the University of Chicago as part of the evaluation of the State HIE Program.

The source for the sampling frame was the CMS Online Survey, Certification and Reporting (OSCAR) database, which contains information on over 225,000 laboratories in the United States, and contains 29 different categories of laboratories, of which two, hospital and independent, were in scope for this survey. Laboratories conducting tests of minimal complexity, that is, waived tests,ⁱⁱ were ineligible for the survey.

A stratified random sample design was utilized for the survey, with strata defined on the basis of state (50 states, D.C., Puerto Rico), category (hospital and independent laboratory), and, for independent laboratories, ownership (LabCorp, Quest, other). LabCorp and Quest laboratories were sampled with certainty given the large volume of tests conducted by these two organizations, and data collection for these laboratories was carried out through headquarters rather than through the individual laboratories. The strata were defined to support estimates and analyses at the state by category level and provide data collection efficiency for the large chain independent laboratories, LabCorp and Quest.

Respondents were directed to have the individual most knowledgeable about the laboratory's information exchange capacities complete the survey, which could include the lab director, the lab manager, laboratory information specialist, or IT staff. Non-respondents received follow-up mailings and phone calls to encourage response. The survey was fielded to 11,601 clinical laboratories from January through May 2013. The survey was administered through the mail, with an abridged eight-question survey administered via phone for non-responders. The items covered in this data brief were excluded from the phone survey.

The weighted response rate for clinical laboratories was 43.2%. Laboratories were weighted through a multiple step process which included the application of base weights (inverse of probability of selection), a nonresponse adjustment, and a ratio adjustment to population totals within stratum. Given the need for estimates related to proportion of laboratories with some characteristic and proportion of laboratory results that are handled in some manner, three sets of weights were derived for both for independent and hospital labs: one for use in estimating characteristics associated with laboratories, one for use in estimating characteristics associated with laboratory test results, and one for respondents to the mail survey, as opposed to the abridged phone survey.

Estimates considered unreliable had a relative standard error adjusted for finite populations greater than 0.30. Responses with missing values were assigned zero values. Significant differences were tested using $p < 0.05$ as the threshold. Robust standard errors are estimated using adjustments for survey design and the additional variance introduced by variable level imputation.

ⁱⁱ As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."



References

1. Holman H, Lorig K. Patients as partners in managing chronic disease. Partnership is a prerequisite for effective and efficient health care. *BMJ*. 2000;320(7234):526–7.
2. Hibbard J, Mahoney E, Stock R, Tusler M. Do increases in patient activation result in improved self-management behaviors? *Health Serv Res*. 2007;42(4):1443–63.
3. Mosen DM, Schmittiel J, Hibbard J, Sobel D, Remmers C, Bellows J. Is patient activation associated with outcomes of care for adults with chronic conditions? *J Ambul Care Manage*. 2007;30(1):21–9.
4. Department of Health and Human Services. Centers for Medicare & Medicaid Services. Final Rule: <https://www.federalregister.gov/articles/2014/02/06/2014-02280/patients-access-to-test-reports-clia-program-and-hipaa-privacy-rule>
5. Centers for Medicare & Medicaid Services. [Medicare and Medicaid] EHR Incentive Programs. Available form: <https://www.cms.gov/ehrincentiveprograms>

About the Authors

The authors are with the Office of the National Coordinator for Health Information Technology, Office of Economic Analysis, Evaluation and Modeling.

Acknowledgements

Felicia LeClere, Brad Parsell, Prashila Dullabh, Susan Schechter, Erin Tanenbaum, Fang Wang, Whitney Murphy, Susan Hinkins, and Lauren McNamara from NORC at the University of Chicago contributed to the development of the survey instrument, survey administration, and data analysis.

Suggested Citation

Swain M, Patel V. “Patient Access to Test Results among Clinical Laboratories.” *ONC Data Brief, no 13*. Washington, DC: Office of the National Coordinator for Health Information Technology. February 2014.