

## EXPERT PANEL RECOMMENDATIONS: LAB DATA INTEGRATION FOR DIABETES CARE IMPROVEMENT

### INTRODUCTION

Integrating lab results with other sources of data, such as claims and other contextual, clinical patient health information, has the potential to significantly increase the data's usefulness with regard to decision-support and care management improvement, and performance and population health management. Such integration could allow for better care planning and management, and produce useful feedback for physicians to improve care. Additionally, payers could be better able to incentivize high-quality, cost-efficient care<sup>1</sup> if information on intermediate outcomes, such as lab results, were available electronically.

The growing adoption of health information technology (IT) in the care delivery setting can help ensure that electronic lab data from all sources, such as lab service providers and hospital systems, are available and accessible – and could have a significant impact on clinical decision support and care quality gaps.

Currently, many performance measurement and quality improvement efforts targeting intermediate outcomes for diabetes care rely on claims data supplemented by resource-intensive manual abstraction of medical records. For example, the widely-used Healthcare

### High-Value Health Care Project

Consistent information about health care is needed so that better decisions can be made. Such information about the performance of doctors, hospitals and other health care providers, and health care results can help individuals, providers, and payers better evaluate and choose where to get care, how to improve it, and how to pay for it. The High-Value Health Care Project is working to make valid, timely, and consistent information about the quality and cost of health care widely available in the United States. The Project is supported by the Robert Wood Johnson Foundation and directed by the Engelberg Center for Health Care Reform at Brookings.

Effectiveness Data and Information Set (HEDIS) measures for diabetes care control require that lab results are generally collected through supplemental chart abstraction (hybrid method) to determine cholesterol and HbA1c lab values. With the American Clinical Laboratory Association estimating that more than 70 percent of clinical decision-making is based on or assisted by lab results,<sup>2</sup> it is critical to make such information electronically accessible across care settings.

## IMPROVING PERFORMANCE MEASURE RESULTS

In a 21<sup>st</sup> century health care system, health information should follow the patient, and privacy-protected, secure information exchange should cross business and institutional boundaries. This will help ensure that patients receive and providers render the best care – using all available health information – at the right time. The Quality Alliance Steering Committee is working to achieve this by promoting performance measure results that rely on laboratory data that can be collected electronically.

## DATA INTEGRATION CHALLENGES

The High-Value Health Care Project – supported by the Robert Wood Johnson Foundation and directed by the Engelberg Center for Health Care Reform at Brookings – is working to make valid, timely, and consistent information about the quality and cost of health care widely available in the United States. One aspect of the project is a focus on integrating diabetes lab data to improve care, an effort which sought to identify the existing challenges and barriers to effective retrieval and integration of lab data electronically and to propose feasible recommendations for overcoming them. Staff conducted a short survey of current efforts by organizations to collect and integrate lab results with administrative data; results showed moderate success and progress towards collecting lab data electronically. However, despite efforts to develop needed terminology and data exchange standards for electronic exchange of lab results, the widespread availability of data is lacking.

To address this issue, the Engelberg Center convened a panel of key stakeholder experts – representing physicians, payers, health IT vendors, laboratory vendors, policy makers, regulators, and academics – to develop recommendations for overcoming key barriers and challenges to the collection and integration of electronic lab data through practical and replicable solutions. Panel members were asked to identify specific solutions and recommendations for overcoming regulatory, technical, and financial obstacles in making electronic lab data available and accessible to support care decisions and coordination, as well as to support secondary uses, including performance measurement and reporting.

## REGULATORY CHALLENGES

### Clinical Laboratory Improvement Amendments

The Clinical Laboratory Improvement Amendments (CLIA) – passed by Congress to establish quality standards for ensuring accurate, reliable, and timely patient test results, regardless of where a test is performed – currently support limited electronic exchange of lab data. First, CLIA provides that test results must be released only to “authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.”<sup>3</sup> By deferring to State law, CLIA’s definition of an “authorized person”<sup>4</sup> is narrow and can restrict the reporting of lab data to other (non-ordering) providers, intermediaries such as health information exchanges (HIEs), and other third parties, including health plans and disease management companies. Furthermore, the

“individual responsible for using the test results” is not defined in either the CLIA regulations or the CLIA Interpretive Guidelines, and most laboratories interpret it as referring to the ordering provider.

CLIA requirements also appear to hold laboratories responsible for how an electronic health record (EHR) system displays lab results to physicians. CLIA requires laboratories to have an adequate system in place to ensure test results and other patient-specific data – whether interfaced or entered manually – are accurately and reliably sent from the point of data entry to final report destination in a timely manner.<sup>5</sup> While CLIA does not specify how this system must be maintained, laboratory personnel have interpreted it to mean they are required to visually inspect every terminal or transmitting EHR system for results consistent with reporting requirements.

***Recommendation: Clarify the interpretation of CLIA regulations.***

- The Centers for Medicare & Medicaid Services (CMS), with the assistance of the appropriate advisory panel, should develop and disseminate additional detailed CLIA Interpretive Guidelines. These guidelines should clarify the parties to whom a laboratory may release test results under 42 C.F.R. § 493.1291(f). Furthermore, guidelines should describe the verification methods that laboratories must use to ensure accurate and reliable transmission of test results to an EHR when electronic verification methods are not available.
- Application of CLIA regulations should be aligned with meaningful use requirements and target dates for achieving such

requirements. CMS should begin the regulatory process to amend the CLIA regulations accordingly.

**Health Insurance Portability and Accountability Act**

The Health Insurance Portability and Accountability Act (HIPAA) also discourages the electronic exchange of lab results. The current HIPAA “minimum necessary” rule,<sup>6</sup> interpreted as “for intended purpose,” has been taken to mean reporting of lab data to an authorized user. Additionally, some states have implemented more stringent laws that go beyond HIPAA regulations. These laws can have the unintended consequence of limiting the exchange of health information with non-traditional health care intermediaries, such as registries and HIEs, who are involved in facilitating patient care management through their support of small practice physician groups.

***Recommendation: Clarify application of HIPAA data transfer rules and varied state enactment of HIPAA privacy and security rules.***

- The U.S. Department of Health & Human Services (HHS) should develop interpretation guides to expand on the HIPAA definition of “intended purpose.” The expanded definition should include a recognition of the role of health care entities, HIEs, and other health care intermediaries, such as registries (as deemed appropriate) in supporting direct patient care management.
- State enactments of privacy and security measures that preempt HIPAA regulations should avoid limiting the exchange of information with health care entities, HIEs, and other health care intermediaries that are involved in direct patient care management.

## TECHNICAL CHALLENGES

### Technical Coding and Data Interchange Standards

Logical Observation Identifiers Names and Codes, also known as LOINC<sup>®</sup>, is a very detailed and specific coding system for more than 30,000 lab tests. This system is valued as a lab test terminology standard, as it can reduce the variability of lab test codes among lab vendors who frequently develop their own unique codes. Yet the widespread adoption – and perceived value overall – of LOINC<sup>®</sup> remains limited due to the complexity of the code set, as well as major financial and administrative resource investments needed to update legacy lab systems. There is also currently no non-proprietary mapping system between LOINC<sup>®</sup> and diverse code compendiums used by laboratories.

Recent feedback from the Standards committee hearing on electronic lab exchange<sup>7</sup> held by the Office of the National Coordinator for Health Information Technology (ONC) also indicated issues with technical specifications for electronic laboratory data developed by the Healthcare Information Technology Standards Panel. Specifically, exchange, management, and integration specifications – which are based on an HL7 standard – are highly complex and pose a barrier to broad adoption. A standard messaging format is needed to facilitate the communication and exchange of clinical data between HIEs.

#### ***Recommendation: Promote adoption and use of technical coding/terminology and lab data interchange standards.***

- A collaborative of public and private organizations is needed to identify a “starter set” of LOINC<sup>®</sup> codes for the top 200–300

lab test codes in use across the country and to promote its broad adoption and use.

- A large-scale collaboration between ONC, the National Library of Medicine, and private sector organizations should strongly encourage the adoption and use of standards, such as LOINC<sup>®</sup> and the EHR-Lab Interoperability and Connectivity Specification (ELINCS), that align with standards supporting health IT and meaningful use.
- Medicare and commercial contracts should make incentives available to lab vendors to adopt and use LOINC<sup>®</sup>.

### Standard Quality Reporting

Current EHR systems also lack appropriate functionality to report standardized lab data for use in performance measurement. Standardized data elements and an electronic data standard for exchange of patient-level quality measurement lab data between health care information systems are necessary for accurate and reliable collection, aggregation, and use in measure calculations. The National Quality Forum (NQF) has started addressing this substantial need with the development of the Quality Data Set (QDS), a template that defines clinical data elements that should be captured from patients’ EHR and used to enable comparable, effective, and comprehensive quality measurement.

#### ***Recommendation: Adopt standard quality reporting formats involving lab data from EHRs.***

- ONC and certification bodies for EHRs and other health information systems should require lab data to be EHR-exportable in the

Quality Reporting Document Architecture format or another federally-approved standard for a minimum set of measures.

- NQF and measure developers should promote the development and wide-scale adoption of QDS templates for quality measures requiring lab data.

## Patient Matching

There was general consensus that for broad application of integrated lab data – in particular where applications are focused on patient-centered care – a reliable method of patient matching using a patient identifier is needed. A number of solutions were suggested, from payer-led efforts to develop a more robust health plan member ID to a volunteer universal patient identifier relying on an “opt-in” model to support patient matching. Short of such automated matching solutions, efforts to avoid errors in manual patient identifier entry, such as check digits, would be necessary to ensure successful adoption and use in performance measurement and care coordination activities.

### ***Recommendation: Enable patient matching through management of patient identifiers.***

- Both the public and private sectors should support ongoing efforts by ONC and other groups to assure reliable matching of patient data.

## FINANCIAL CHALLENGES

### Economic and Business Practices

Building and maintaining multiple, customized information systems interfaces is costly, as are defining processes for exchanging lab data.

Meanwhile, the benefits of electronic lab data exchange are often realized by entities other than those covering the cost of building and refining such systems. Such financial barriers, combined with current business practices, limit seamless exchange of health information. If health information is to be made available when providers and patients need it to derive the best clinical decisions, then public and private initiatives must act in concert to incent the providers of health information (e.g., laboratories) to support seamless exchange. Furthermore, financial barriers can be mitigated by broader adoption of electronic data standards, and the cost and benefit of building an information exchange should be appropriately shared by the community of stakeholders.

### ***Recommendation: Incentivize providers of health information to directly support seamless exchange of health information.***

- Federal programs initiated through the Health Information Technology for Economic and Clinical Health (HITECH) Act should encourage the adoption of business practices that promote seamless exchange of health information across business boundaries to support provider and patient health information needs.
- Federal requirements for meaningful use of EHRs and development of HIEs should require adoption of lab data standards for terminology and exchange to reduce variability and the associated cost burden of current laboratory practices.

## CONCLUSION

The challenges of effectively collecting and integrating electronic lab data are substantial, but feasible solutions exist that could make data more available and accessible to care providers. Clarifying CLIA and HIPAA regulatory policies, promoting adoption and use of technical coding and quality reporting standards, and providing incentives to support seamless information exchange could all help promote better care planning and management, improved clinical decision support and care quality gaps. Ultimately, these activities could improve patient care.

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1. Gillette B. "Integrating Lab Results into Analytic Databases Can Yield Valuable Information." Managed Healthcare Executive. June 2005
  2. American Clinical Laboratory Association. Issues – The Value of Clinical Laboratory Services. (<http://www.clinical-labs.org/issues/value/index.html>)
  3. 42 C.F.R. §493.1291(f).
  4. 42 C.F.R. §493.2 defines "Authorized person" as an individual authorized under State law to order tests or receive test results, or both.
  5. 42 C.F.R. § 493.1291(a).
  6. The HIPAA Privacy Rule incorporates what it calls a "minimum necessary" standard when it comes to how much information should be disclosed. Doctors, hospitals, and others covered by the HIPAA Privacy Rule are required to limit the amount of information disclosed to others to the minimum necessary to accomplish the intended purpose. What amounts to the minimum is left up to the health care provider. Definition accessed from website: <http://www.privacyrights.org/fs/fs8a-hipaa.htm#4>
  7. Office of National Coordinator – HIT Standards Committee public hearing. Available at [http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_11673\\_909257\\_0\\_0\\_18/ChopralImplementationWGUpdate.ppt](http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_909257_0_0_18/ChopralImplementationWGUpdate.ppt)