



Agency for Healthcare Research and Quality Laboratory Exchange Meeting

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Final Report

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I. INTRODUCTION

Health information exchange (HIE) initiatives are being developed in communities and regions across the country. These initiatives are intended to enhance connectivity of healthcare information to improve the quality of health care. These exchanges are essential requirements for health care transformation. Without the availability of the appropriate information at the time care is delivered, some improvements in the quality of care are not possible. In ambulatory care settings, the availability of medication histories and current clinical laboratory data are especially important. Both are central areas of activity of the U.S. Department of Health and Human Services' American Health Information Community (HHS AHIC) and rate-limiting steps to realization of truly interoperable and connected health care information systems. The lack of such standardized approaches also diminishes the ability to care for evacuees from natural disasters and inhibit the creation of a bio-surveillance network to protect the American public.

Recognizing the critical role laboratory information plays in patient care and understanding the technical, legal, business, and policy impediments to more effective transmission and use of clinical laboratory information, the Agency for Healthcare Research and Quality (AHRQ) convened a meeting of representatives from major national data exchange initiatives, clinical laboratories, vendors, and other interested parties to examine means of accelerating the realization of a widespread, standardized approach to access and use of laboratory information in clinical settings.

A number of challenges have been identified:

- Standardized ways of representing requests for laboratory tests are not widely used.
- Standardized means of reporting laboratory information are not adopted; lack of standards is evident both in the format of message and in the widespread variation in naming of common laboratory tests.
- Standardized approaches to associating laboratory information with the correct patient have not been widely implemented and pose potential risks to patient safety.
- Although collected for the care of an individual, laboratory information is also used appropriately in some public health and quality improvement settings, but potential misuse of such data leads to confidentiality and privacy concerns.
- Regulatory barriers—for example the Health Insurance Portability and Accountability Act (HIPAA), Clinical Laboratory Improvement Amendments (CLIA), and State law—make it difficult for appropriate expanded use of clinical laboratory information.

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- Transforming proprietary business and technical approaches will be expensive and take time even if more standardized uses are agreed upon.
- Lab results integration into electronic health records (EHR) is difficult and expensive.

To address this wide range of challenges, AHRQ convened a 2-day meeting of industry leaders on June 8-9, 2006, to explore approaches to communicating, using, and aggregating patient laboratory information from disparate sources. AHRQ's portfolio of State and Regional demonstration (SRD) projects and DHHS' National Health Information Network (NHIN) prototypes were considered possible vehicles for experimenting with new, simple, low-cost, and effective means to exchange laboratory results in clinical settings. The conclusions from the meeting largely support recent recommendations made to the American Health Information Community.¹

II. OVERVIEW OF MEETING

The AHRQ Laboratory meeting was convened to bring together a representative set of key industry leaders from AHRQ's SRD projects, the HHS' National Health Information Network (HHS NHIN) Prototype contractors, national laboratories, providers, professional groups, and information system vendors to discuss the various technical architectures of lab information exchange and to explore approaches to aggregating patient lab information from disparate sources. The meeting emphasized means of addressing those barriers to exchange of laboratory information similar to the many issues identified in a recent AHRQ-funded report.²

The meeting was organized around three different models of lab information exchange already under discussion through the HHS AHIC process and in other venues. They are: direct reporting from laboratory to ordering provider with subsequent exchange (the provider-focused model); creation of an intermediate exchange where those with rights of access can receive information without proceeding through the primary provider (the aggregated model); and peer-to-peer communication of laboratory information through a decentralized exchange of laboratory information among EHRs or other electronic medical record systems (the peer-to-peer model). Each of these models strives to evolve from a provider-focused perspective to a patient-focused perspective, but each takes a different approach in striving toward this goal. The participants discussed the range of technical, policy, business, legal, and regulatory issues that would have to be addressed to

¹ Draft recommendations from the AHIC EHR group dated July 17, 2006 and accessed July 20, 2006 at: <http://www.hhs.gov/healthit/ahic/materials/meeting04/ehr/EHRDraftRecs.doc>.

² Shekelle PG, Morton SC, Keeler EB. Costs and Benefits of Health Information Technology, Evidence Report/Technology Assessment No. 132 (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-02-0003.) AHRQ Publication No. 06-E006. Rockville, MD: Agency for Healthcare Research and Quality. April 2006.

successfully implement each model and discussed the implications to data exchange initiatives and regional health information organizations (RHIOs).

III. PURPOSE AND OBJECTIVES

The purpose of this 2-day meeting was to explore each of the three models, understand their strengths and weaknesses, discuss general issues, and identify the barriers to realizing a patient-centered approach to using laboratory information. The meeting was not intended to identify the optimal model from a clinical, technical, or business perspective but instead to frame the issues so that decisionmakers would have a better understanding of the challenges they would face in adopting any specific approach as a standard.

This meeting was part of a broader set of gatherings required of AHRQ-funded SRD contractors. These contractors are required to demonstrate an exchange of laboratory information as part of their work. Similarly, the HHS NHIN Prototype contractors face the same challenges both in their NHIN work and in other activities in which their businesses participate. Clinical laboratories likewise are deluged with competing requests for access to clinical laboratory information and seek means to ensure that they meet the needs of patient care as well as those of their businesses. Professional organizations, plans, consumer groups, and others likewise have a compelling interest to understand the complexity of the project. Key objectives of the meeting were to:

- Identify the technical, policy, legal, business, and privacy barriers related to achieving interoperability.
- Explore each of the three models for exchanging clinical laboratory data between laboratories and health care organizations.
- Determine the prevalence of each of the models and means by which these models may be implemented and evolve toward a fully patient-focused approach to laboratory information access.
- Propose solutions and formulate strategies for achieving some short-term interoperability with respect to laboratory data – solutions that are realistic over a 12- to 24-month timeframe.

Key assumptions of the meeting included:

- There will be no “big bang” approach to transforming the exchange of laboratory information. Such a transformation will require time, funding, leadership, regulatory changes, and ongoing guidance.

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- Organizations and regions differ in their current capabilities to exchange and integrate laboratory information into hospital and ambulatory health care information systems. Information exchange will be occurring in a heterogeneous environment that consists of different business entities using different information systems.
- Information exchange will support a “patient-centric” view of medical data, i.e., a view oriented toward individual patients regardless of the site of care or source of data.

IV. MEETING PARTICIPANTS

Over the 3-day period of deliberation, 42 participants attended the meeting. Included were representatives from the six SRDs, AHRQ and its National Resource Center, Quest, LabCorp, Laboratory and EHR vendors, NHIN contractors (CSC, Northrup Grummon, and IBM), the American Clinical Laboratories Association, American Public Health Laboratories, the Office of the National Coordinator, Centers for Medicare & Medicaid Services (CMS), and the American College of Physicians. A list of attendees is included in the Appendix.

V. MEETING FRAMEWORK

a. The current State and three “future state” models

There are two common models for collecting laboratory information in an ambulatory care setting. The first is to perform a laboratory test within the office practice setting or a counter-top machine (and billing through conventional billing systems). If the test is actually conducted in the office practice setting, little common identifier information is needed because the results can be immediately recorded in the medical record (usually a paper chart). The second is to order the laboratory test from the office practice setting and obtain the specimen either in this setting or at a clinical laboratory. In this case, the clinical laboratory reports the information back to the provider ordering the test. Billing and reporting are performed either by the laboratory, by the provider, or by both parties.

In general, these devices are not connected to more systematic means of transmitting laboratory data in digital form. When laboratory tests are performed by a third-party clinical laboratory, identification information often is only sufficient to match the patient to the chart in the office of the provider and not sufficient to merge the data without provider information. For example, the identifier may be a simple code and name that is unique within the practice setting but not sufficiently unique to ensure proper integration without the addition of more unique demographic information from the provider. Even if

a laboratory transmitted such information to another clinical setting, it could not reliably be associated with the appropriate individual without additional information from the provider who initially requested the test.

To explore the underlying issues, the group defined three models that were similar to models proposed in AHIC and other meetings. Each model is paired with a set of assumptions or requirements that allows it to function effectively. The groups used the following operational definitions:

Provider-centric model – This model is based on the initial ordering of a laboratory test from a specific provider and reporting the result back to that provider. Such a transaction may have limited patient identification and a method of transmission that is idiosyncratic. The model could be expanded by identifying means by which information can be supplemented with sufficient standardized identifier information and business rules in a way that would allow for a more patient-centric approach (through either a RHIO or other means). This is consistent with AHIC’s recommendation for an evolutionary approach and such an expansion would require that (1) the RHIO or other body make data available in a format that EHRs can access and import and (2) that EHRs have the capacity to import and integrate data made available by the RHIO with other existing data. It may also require that EHRs be able to “publish” certain clinical data to the RHIO, thereby making the data available to other EHRs.

Aggregated model (Shared view of historical data) – This model makes no requirement that the initial provider be the first recipient of the laboratory result; instead, it assumes that sufficient business and confidentiality rules, standards, and patient identification methods exist such that the result can be placed into a centralized or decentralized “historical view” database that would allow those with appropriate rights to access the data from a single source. To do so, this model requires that data be physically or logically consolidated from multiple sources and labs into a format that all parties deem beneficial to patient, legal, policy, and business interests. There are many ways to implement this model and, in essence, the implementations represent the “end state” infrastructure of an evolution from a provider-centric to a patient-centric model. Such a model assumes ultimate access by consumers and other groups, but such uses and issues were outside the scope of the group’s deliberations.

Peer-to-peer model - This model envisions EHRs or other systems exchanging lab data directly with each other without an intermediate system. Such communication requires that EHRs be able to import and export lab data using formats known to other EHRs and that appropriate mechanisms are in place to transmit lab data from one EHR to another with appropriate business rules to ensure reliable and confidential access. It represents one instance of an end state “aggregated” model and was discussed because of the unique technical aspects of peer-to-peer communications.

b. Addressing the models and their implications

The meeting participants formed three workgroups, each focusing on one of the three models. Each group spent a session defining their model and identifying key challenges to lab data exchange and then reported back to the group. Then they spent two subsequent cycles of work on individual models and discussion among the groups to bring forth a final set of observations and recommendations.

All three models attempt to create a more effective means of creating a patient-centric view of laboratory information. Logically, they share in common some means of creating a peer-to-peer or more centralized intermediary function where laboratory data can be uniquely associated with an individual and made available on the basis of appropriate business and confidentiality principles. Most of the pressing issues identified were common to the three models.

VI. OBSTACLES TO REALIZING EFFECTIVE LABORATORY HIE

The meeting reinforced some of the obstacles to the creation of a patient-focused laboratory infrastructure identified as part of the AHIC deliberations and the prior experience of AHRQ SRD and NHIN contractors. These include:

- Business and financial constraints that inhibit the evolution from a provider-centric to a patient-centric model.
- Regulatory impediments, especially to CLIA, HIPAA and State laws.
- Technical and policy issues addressing the security, privacy, and confidentiality of patient data collected from disparate sources and used in a broader range of settings.
- Technical challenges to achieving effective and uniform interoperable vocabulary, messaging, and implementation standards for laboratory results and data exchange.
- Technical challenges to ensuring correct linkage of data from disparate sources and accurate transmission of information to appropriate care settings.
- Ongoing research and communication of best practices derived through the experience of early adopters of proposed standards.

VII. OBSTACLES AND PROPOSED SOLUTIONS

The groups identified both obstacles and possible means of overcoming these obstacles. The groups compared and contrasted the extent to which the three proposed models accommodated these changes, and, in some instances, they identified next steps to resolution.

a. Business and Financial

Patient-centric laboratory data approaches may lead to a perceived “commoditization” of lab services. Laboratory tests are part of a broader range of services provided to patients and providers. Each provider has developed operational models, workflow methods, ordering approaches, and access systems that differentiate them. Although pressure for standardization is high, there remains a belief that an “open” market for laboratory data will jeopardize current relationships between clinical laboratories and those who pay for services. If such services are identified (many feel erroneously) with data silos instead of overall levels of quality and service, such transparency would remove the advantage of incumbents, create more competition, and possibly lower prices. Such a scenario requires one to assume that it is the technology and not the overall level of quality and service that dictate price. Many dispute these assumptions and further argue that standardization and differentiation on non-technical issues like service and quality are inevitable.

Although there was no immediate solution to these issues, they must be addressed if the nation is to realize a patient-centered approach to the use of clinical laboratory information. In order to mitigate business risks, the group identified new value-added services and business opportunities associated with a comprehensive infrastructure but not with a more fragmented approach. These approaches would afford the labs the opportunity to differentiate themselves from their competitors on the basis of service and outcome, not on possession of data. For example, the ability to retrieve data more efficiently and identify newer, near “real-time” means of communicating laboratory data may allow laboratories to provide additional tests on an initial sample without requiring the patient to return for a second sample. This savings in time and convenience provides value to all without reducing revenues. In addition, tighter linkage of laboratory data with clinical decision support allows laboratories to claim that they are in part responsible for the overall improvements in performance and quality upon which future health care payment schemes may be based.

Laboratories achieve at best only limited cost savings and incur significant costs. To achieve standardization, laboratories, vendors, and all others involved in the chain of data transmission must incur costs to change their systems. Such costs are not reimbursed directly; hence, it is unreasonable from a business perspective to incur such costs. However, the current “Tower of Babel” created by growing demand for health

information data by patients and their providers, coupled with the explosion in the growth of health information technology in care settings, makes such a transformation inevitable. Hence, options to address this need include a more detailed determination of the costs and benefits of such transformation (and to which parties) and to compare these costs and benefits to an illusory static world where such evolution does not take place. The extent to which various parties benefit from such a transformation may in turn determine how such transformations are financed since it is reasonable to assume the long-term beneficiaries should somehow assume a cost in proportion to their benefit.

Incentives to standardize and provide patient-centered laboratory information are not necessarily aligned with those who will incur the costs of transformation. Patient-focused laboratory information provides new opportunities for clinical decision support both from a clinical and administrative perspective. Although administrative issues were not formally included in the discussions, the ability to obtain pre-authorization for some tests as well as the avoidance of duplicate or redundant tests is a significant opportunity for payers. In the case of duplicates, however, reduction results in a loss of revenue to the laboratory if payment is sufficient to offset costs. Non-laboratory providers and payers seem to be the beneficiaries in this scenario and their benefit should factor into financing. Since laboratory data can be critical to improving quality, pay-for-performance approaches should provide additional revenue with respect to more appropriate use and less inappropriate (redundant) use.

b. Regulatory

The existing CLIA regulations were identified as the major issue in this category. It formed a central theme of the discussions in all three workgroups.

CLIA regulations make laboratories responsible for the accuracy and manner of displaying laboratory information in electronic medical records. CMS' CLIA regulations place the responsibility of accurate reporting of laboratory information on the laboratories performing the tests.³ Originating from an era of a paper-based approach to health information management, these regulations impede streamlined lab data reporting because labs must certify every single recipient, interface, and EHR that receives a particular lab result. It is largely for this reason that clinical laboratories originally developed interfaces through their own systems and now face increasing pressures as the number of EHR systems in use requesting access grows rapidly. In the context of a RHIO, results would be sent to a central 'switch' and this information would then get routed to multiple end points. This creates a risk situation for the labs because they will not be aware of all uses and displays of data and hence must trust another organization to

³ The CMS home page for CLIA may be accessed at: <http://www.cms.hhs.gov/CLIA>.

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certify final display. Such an approach places too much risk on the laboratories and will require regulatory changes.

A re-examination and consistent interpretation of CLIA regulations are essential for development of a patient-centered approach to laboratory information no matter what technical or organizational model is employed. One way of doing this is to formally incorporate CLIA displaying requirements into certification criteria for EHRs and to remove certain liabilities from laboratories if they are communicating with certified vendor systems. Where other intermediaries and health information exchanges are concerned, the liability concerns would have to be transitive so that an intermediary can be shown not to alter the data in ways that affect the ultimate display. In this circumstance, responsibility for accuracy is appropriately distributed among clinical laboratory, intermediary, and vendor at the point of care.

The patchwork of State laboratory regulations makes standardization difficult at the national level. Although CLIA is a Federal regulation, some argue that its interpretation varies from state to state much as HIPAA is interpreted differently. In addition, states have a larger set of confidentiality and data use limitation regulations, policies, and laws that must be examined from the context of laboratory information exchange. There are cases where the law is silent, so that HHS can issue guidance, and there may be cases where the law needs to be changed. Identifying the list of changes and clarifications that need to be made is a critical next step.

c. Data security, privacy, and confidentiality

Variations in confidentiality, privacy, and security practices impede a national approach to electronic lab data exchange. These variations are being explored in the context of broader policy investigations by AHRQ and ONC's NHIN contractors in the course of their work, as well as under AHRQ's contract with RTI International: Privacy and Security Solutions for Interoperable Health Information Exchange (the Privacy Contract), which is co-managed with ONC. Many of the SRDs are participating in the research under the Privacy Contract through RTI's HISPC subcontracts with 34 jurisdictions across the country. The SRDs can promote resolution of the issues identified in the lab context in a manner consistent with privacy and security issue resolution in the broader context of the Privacy Contract work and any follow-on activities. Policies and procedures around the use of laboratory information must be developed for AHRQ contractors to achieve their milestones. Similar consideration of laboratory data should be pursued in the Privacy Contract and other regional, state, or national discussions surrounding patient confidentiality, patient privacy, and data security.

d. Technical

Messaging standards either are not yet fully developed or not widely adopted. The ability for labs and other clinical data to be moved from one care setting to another is critical to the business case. A single patient's health care spans many decades and may involve a plethora of different providers that need to know that patient's medical history. In addition, payers are now requesting that labs be attached to the bill as a claims attachment. Direct data transfer, either through an EHR-to-EHR model or through a personal health record model, would support data exchange whether a RHIO were present or not.

To promote EHR-EHR data transfer, considerable work needs to be done to support standard messaging interfaces for EHR vendors. The Health Information Standards Technology Panel (HISTP) appears to be well positioned to further this agenda. The SRDs may also provide a good test-bed for testing of interoperability standards. The three workgroups identified a number of common standards-related issues that pertained to all three models. Key topics of discussion included messaging standards, LOINC®, and some of the limitations within the current ELINCS specification.⁴

Current messaging and vocabulary standards are not uniformly implemented and are not sufficiently constrained. Standards like LOINC and HL7 allow great flexibility in representation and transmission. This flexibility both in ordering and reporting can ease adoption but make comparison more difficult. In all instances, the existence of a standard is not sufficient to ensure successful exchange; the standards must be implemented uniformly so that data can be compared and exchanged reliably. Some steps that can address these problems include:

- Develop sufficiently constrained implementation guides.
- Promote implementation guides that can actually be implemented in the short term.
- The current standards activity may benefit from SRDs and other implementing RHIOs. This will ensure that there is more practical input from the field to inform the discussion and drive standards.

Some standards like LOINC do not translate easily into the manner in which clinicians order and review laboratory tests. Although LOINC is an appropriate terminology for the labs and their coding, this does not translate well for the providers. Today there is no standard vocabulary for providers that maps unambiguously to LOINC.

⁴ The Markle Foundation's Connecting for Health Initiative provides a concise summary of some of these issues at: http://www.connectingforhealth.org/commonframework/docs/T4_Labs.pdf

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These deficiencies are most apparent if LOINC is used to order laboratory tests, because in some instances a provider may by default identify one highly detailed method of testing for a value when the laboratory employs another, equally valid and clinically similar method. If the ordering and reporting methods are used and compared, the order and the results will not be identified as part of the same transaction.

Some immediate next steps identified by the participants included:

- A pressing need exists for a non-proprietary mapping between LOINC codes and terms used by clinicians. Current exchange efforts have identified an enormous variability in the way common tests are named (e.g., “Serum Sodium,” “NA_S”) and each exchange effort must laboriously map each term from each laboratory to an appropriate LOINC code. Many individuals who have taken this work on have found that mapping to the very granular codes is difficult and time consuming. Further, many EHR vendors find that their clients prefer coarser categories for displays. In particular, many users are not concerned about the measurement method that was used to obtain the result (e.g., ion-specific electrode versus flame photometry). LOINC has responded to this need by creating codes that are not specific to the measurement methods.
- Another long-standing need that had been identified was for codes for test batteries. A complete blood count or CBC, for example, consists of a white blood cell count, a hemoglobin concentration, a platelet count, and any of dozens of other measurements. Each of these may be measured using a variety of methods. LOINC has created a large number of batteries using common patterns from across a large number of healthcare delivery systems. Even with this large number though, not every local pattern is represented. The LOINC codes that don’t specify methods may also be appropriate to use for ordering where the provider doesn’t know or doesn’t care what method is used. A common example might be a serum calcium where they are comfortable with whatever method the laboratory uses.
- All instrument vendors, including bench-top laboratory devices used in small practice settings, should ultimately be incorporated into data exchanges using LOINC mapping.
- The full potential and implementation of LOINC is often not fully appreciated, even in some health care information technology settings. Technical and clinical professionals must be educated on the value and use of LOINC.

ELINCS is an appropriate vehicle for the evolution of laboratory information for patient-centered use of laboratory data and acceleration of its development and

adoption. The current ELINCS standard emphasizes hospital-based laboratory use but a revised version of ELINCS has been introduced to standards bodies for consideration.

The groups identified several issues for further work:

- The current ELINCS specification should include better coverage for non-electronic orders.
- There must be a determination on whether a need exists to modify the current ELINCS specification to accommodate getting historical labs back into EHRs.
- ELINCS must add electronic ordering messages with ordering codes.

New means must be developed to represent data sets that are exchanged directly among EHRs or other end-user systems. It is definitely possible to use more than one messaging standard provided adequate translation occurs. Standards evolve and take time for dissemination and adoption. The RHIOs and SRDs are ideally positioned to be a test-bed for format conversion. Currently the HL7 SIG and the X12 groups are revising laboratory and other attachments within X12 messages and doing it using CDA V2, producing HL7 CDA messages that will have a user friendly, human readable format as well as structured version. They are using the concept of a 'clinical statement' where there will be no difference between the attachment and a separate HL7 message. This activity is being boot-strapped by Integrating the Healthcare Enterprise (IHE).

EHRs must be consistent with CLIA standards. Some EHR systems today do not display data consistent with CLIA requirements because they have been designed to display a clean and compact report. In the model where EHRs will exchange information with other EHRs, the need to capture and transmit all the CLIA data becomes increasingly important. Examples of such data would include where the test was performed and the methods used. This data preservation allows one to always determine the source of the lab regardless of the number of transitions that data made en route to the final system.

EHRs must consistently manage changes and addenda to laboratory data reports. In current medical practice it is not uncommon for labs to be updated after a medical summary is sent, particularly among Emergency Department patients. This would require EHR systems to implement a method to update as well as track when results get updated. This must be done in a way that maintains an audit of what information was available when a decision was made (i.e., an amendment to a data item cannot be a simple replacement because it will then give a false impression of the information available for care prior to the amendment) and ensure that future decisions are made on the basis of the most current reports and data items.

EHRs must retain source information data. Because lab summaries include information from multiple sources there is a perceived need to distinguish between primary tests ordered by a physician and lab data that has been obtained from other sources. This is more than a matter of preference. Each source may have different normal values and the knowledge of the source of a data item will become increasingly relevant as a wider array of data sources are incorporated into decision-making. Examples include table-top laboratory instruments in small practice settings and glucometer readings and other data obtained directly from patients and possibly present in personal health records.

Data integrity is also critical both for decision-making and regulatory compliance. Appropriate quality assurance and auditing techniques must be developed and implemented systematically to ensure the reliable transmission of clinical laboratory information. Some proposed solutions include the use of a digital signature to individual data objects so that there is some assurance that they have not been altered.

No medical record is entirely complete. No single medical record has all of the information pertaining to one's health. Completeness is a matter of degree and the match between medical need and pragmatic collection and display. Different care providers and others in the health care delivery system have different needs for information. The completeness of a record is critical and must be incorporated into the use of clinical laboratory information. Clearly, professional judgment is the most important factor and no medical record—no matter how allegedly complete—should substitute for a thorough medical history. HISTP has a role to play in assisting the industry set standards to address the above issues. This would ultimately be incorporated into the criteria used by CCHIT in their certification process for EHRs. Significant work in the standards space would need to occur before CCHIT involvement was considered.

e. Patient identification and matching

Patient identification and matching is a core challenge to the patient-centric use of laboratory information and to health information exchange in general.

Inconsistent and incomplete test-ordering processes impede correct association of results to orders/patients/providers in EHRs. Today, inconsistent and incomplete test-ordering processes impede correct association of results to orders, patients and providers in EHRs. To address this issue some actions that could be taken include:

- Promoting a minimum set of identifiers on test orders. Currently, there are no standards for this. The ELINCS specification does not include electronic ordering but it does include minimum data elements and this could potentially be a starting point. Despite the use of a minimum data set there will be some outlier cases.

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- Developing standard processes for heuristic patient matching when patient identifiers are not viable.
- Developing and promoting standard processes and formats for electronic ordering.

A patient-centric exchange will require all intermediate steps in the data transmission process to retain sufficient identifier information so as to allow results to be merged with the appropriate individual on a “stand alone” basis. Currently, the practice-centric approach retains only enough identifier information to allow unique matching at the level of the practice. Although this information is sufficient for this process, it is too idiosyncratic and incomplete if matching is attempted without the ordering intermediary. This requirement of mapping to the ordering system presents an extra technical step and, if the system is unavailable due to technical problems or natural disasters, incompletely identified laboratory information will be “orphaned” and of no clinical value.

Requiring doctors to collect the necessary set of minimum demographics takes time and currently there are no business incentives to do this. The group proposed pay-for-performance as a means to motivate providers to collect this information.

Identification formats are lengthy and difficult to process in current models incorporating direct exchange among EHRs. When relaying information from EHR to EHR the source or issuer of the patient identifier should itself be unique and accessible for subsequent audits or quality checks. Current identification (ID) formats are cumbersome and hard to process. One proposed solution would be the use of a global unique identifier (GUID). This unique identifier should contain some identification of relationship and may be a combination of a provider ID and a patient ID.

VIII. ROLES FOR GOVERNMENT AND THE PRIVATE SECTOR

Successful realization of a patient-centric approach to the use of clinical laboratory information will require a high degree of effort and coordination among the private sector and both Federal and State governments. The draft report from the American Health Information Community (AHIC) makes several recommendations in this regard with which the participants concur. Among the roles identified by AHIC and by the participants are the following:

a. Role for the Office of the National Coordinator

AHIC recommends that the Office of the National Coordinator for Health IT (ONC) ensure that laboratory data is transmissible in a patient-centric environment. In this capacity ONC must ensure that HITSP endorses the appropriate vocabulary, messaging,

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and implementation standards both for reporting and (the participants feel) the ordering of laboratory tests. These standards should ideally be included in the CCHIT interoperability certification and hence must be completed by September 2006.

ONC also should ensure that its NHIN prototype projects and other efforts strive to implement and explore these standards and policy issues in the course of their demonstration projects. Both ONC and HITSP must also consider CLIA and HIPAA regulatory requirements, and the same issues should be a part of the ONC State contracts to study policy, legal, and regulatory issues. Where the latter is concerned, pertinent case studies should be developed immediately if they are required.

ONC should clarify CLIA, HIPAA, and other regulatory issues and advise CMS so that the latter can publicize guidance to clarify the broad definition of authorized parties. At the same time, AHIC has recommended that ONC work through the National Governors Association and other state-based organizations (e.g., the Gulf States Task Force led by the Southern Governors Association) to resolve variations in policies and practices. One mentioned in particular by AHIC and confirmed by the findings of this report is the need for defining “authorized persons” and access rights to laboratory data.

In the view of the meeting participants, these access rights discussions are part of a broader policy debate that must include the private sector. One example of such an initiative highly relevant to the use of laboratory information is the Markle Foundation’s Connecting for Health Common Framework. These documents are a foundation for policy and technical architectures in some ONC- and AHRQ-funded data exchange initiatives. The support and leverage of these organizations will help resolve issues for authorization and authentication that are critical for public trust and ensure uniform means for individuals to “opt out” of the voluntary aspects of data exchange.

A similar argument for public-private sector collaboration can be made for the AHIC recommendation to include incentives to develop or endorse methodologies to match an individual patient to his or her information across multiple systems into the HITSP contract. These HITSP efforts should be based upon and be consistent with significant efforts already taking place among the NHIN prototypes, the AHRQ State and Regional Demonstration projects, efforts based on the Markle Connecting for Health Framework, and other private-sector initiatives.

b. Role for the Agency for Healthcare Research and Quality

The AHIC draft recommendations state two critical roles for the Agency for Healthcare Research and Quality:

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- AHRQ should develop a proposed study methodology to measure the extent and effectiveness of the adoption of the first stage of HITSP standards, as well as the adoption and utilization of aggregated patient-centric data as it becomes available. (Recommendation 5.0)
- AHRQ should research best practices in the implementation and utilization of patient-centric laboratory data stores and how to disseminate this knowledge. (Recommendation 5.1).

Effectiveness of standards adoption

It can be argued that the AHRQ Health Information Technology Portfolio and broader initiatives are already pursuing this course. As part of their State and Regional Demonstration contracts first awarded in October 2004, AHRQ requires and emphasizes (1) the adoption of standards, (2) a critical examination of the impediments to achieving patient-centric laboratory data access, and (3) broader health information exchange efforts. Among the lessons already learned through these efforts is that standards adoption is timeline-driven and costly. Each institution starts from a different place and must evolve. High-level definitions (e.g., HL7) are not sufficient and must be complemented by detailed specifications and documentation.

Even where standards exist, means of implementing them become at times arbitrary and must be coordinated. Nowhere was this more apparent than in the use of LOINC.

Although all meeting participants believed LOINC was a critical factor in the evolution of laboratory data standards both alone and through the ELINCS 2.0 specifications, they also stressed the need for completing the standards and creating a set of application documents, toolkits, and a cadre of expert consultants was critical.

Legal and policy barriers have also been identified as critical roadblocks to laboratory data exchange and to health information exchange in general. Several of the states have formalized their efforts through a legal framework that addresses many of the concerns raised by the AHIC and the AHRQ sessions. Proactive measures among the public and private sectors – coordinated through the AHRQ National Resource Center – are being taken to disseminate these early lessons. AHRQ-funded projects have also played a critical role in identifying HIPAA, CLIA, and other regulatory impediments and both through their own initiative and through HHS-sponsored contracts, are bringing their considerable experience into play to accelerate change.

Best practices and dissemination

Workshop participants agreed with the AHIC recommendations that AHRQ should research best practices in implementing and utilizing patient-centric laboratory data stores and disseminating this knowledge. Along with many other AHRQ grantees and contractors, the SRD projects are charged with researching best practices, and the AHRQ

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National Resource Center is disseminating knowledge. The very purpose of the meeting described in this report was to identify how the AHRQ contractors and grantees, working with NHIN contractors and other public and private initiatives, could accelerate processes already under way.

The workshop identified the need for case studies of early adoption, qualitative arguments, formal research, and a cadre of professionals who can help accelerate the adoption of these standards and practices. One major challenge that AHRQ is addressing is to make clear to the public that the transformation of the current system into a patient-centric approach to medical information is as much a matter of policy and culture as it is technology. Through its wide range of activities, AHRQ is addressing this transformation from these perspectives.

Although the primary focus of the meetings was technical, the transformation to a patient-centered view of laboratory information presents fundamental challenges to the business interests of all parties involved. Transformation is associated with a cost and often the benefit of transformation is not accrued to those who incur the cost. Because so many parties have a great interest in skewing arguments according to their unique perspectives, AHRQ—as an independent entity dedicated to research in quality and safety—is in an ideal position to complement the cases made in the private sector and support decisions that must be made both in government and in industry.

IX. NEXT STEPS

a. Business and financial constraints

While sensitive to the business concerns of all involved, our discussions focused primarily on the technical and policy issues in an effort to support business decisions. The participants did not fully explore the business implications arising from each proposed approach. Despite the obvious business and technical challenges, most participants agreed that an evolution to a patient-centric view is inevitable. The initial phase of such a view is the association of unambiguous patient identification with every laboratory transaction. Even if this information is not routinely used and not initially included as a vehicle for changing business practices, the inclusion of such identification will be essential for vital public health, bioterrorism, and disaster responses. (As one example, provider-centric linkage was of no value when the providers were in areas affected by Hurricane Katrina and all information required for such linkages was lost.) There are many ways to achieve this without a national patient identifier, and there are means by which the privacy and security of transactions can be maintained. The group supports the AHIC recommendations to pursue such means aggressively and AHRQ's role in studying various approaches.

b. Regulatory Impediments

CLIA regulations must be changed to support electronic communication. Clinical laboratory organizations and other expert bodies have provided guidance on this topic. Although such alterations may seem formidable, they are no more so than the other alterations to policy required when one party assumes responsibility for the transmission of information from another. As is the case with many other aspects of the SRD projects, such changes require a legal and policy framework, a means of auditing, a means of oversight, and a high degree of public trust. Hence, CLIA regulatory changes can be placed in the context of an overall transformation of a health care infrastructure to a more consumer-centric and systemic approach.

c. Uniform interoperable vocabulary, messaging, and implementation standards

The group strongly recommends further work on the ELINCS 2.0 effort. The implementation guide for lab-result reporting based on HL7 being developed by the California Healthcare Foundation ELINCS project holds great promise for specifying the message standards to the rigorous degree necessary and for facilitating certification of conformance. This work must be extended to include microbiology and other non-numeric results, full coding of result values, and laboratory test ordering messages.

Uniform use of laboratory terminology, coding, and vocabularies is essential to successful importing and merging of data from multiple sources. The Logical Observation Identifiers Names and Codes (LOINC®) system provides an appropriate framework and a good organizational structure for maintaining the database used to identify test values. More work is needed to promote the use of SNOMED® (the Systematized Nomenclature of Medicine) and SNOMED Clinical Terms® (SNOMED CT®) to encode test results, and to improve universal and uniform use of LOINC coding for laboratory test orders and results. There is an immediate need to refine the LOINC reporting methods, develop standardized approaches to definition, growing a cadre of professionals expert in such data transformations, and expanding the inquiry into the less mature use of LOINC as a means of order request.

d. Linkage of data and data accuracy

Each of the AHRQ and NHIN initiatives is working actively on means to link and report data accurately. Although the Markle Connecting for Health Framework is a dominant initial approach, it is silent on the appropriate technical means and algorithms to link patient data with a high degree of accuracy. Such linkage is essential if data are to be used in clinical care or clinical decision support. As is the case with an adverse drug event, the inappropriate linkage of laboratory data can be fatal. Further inquiry along the lines supported by AHRQ, ONC, and other groups, is essential. Dissemination of best

practices is equally vital given the growing activity in clinical information systems and data exchanges.

e. Security, privacy, and confidentiality

The group believes that the patient-centric approach to laboratory information is part of a broader security, privacy, and confidentiality framework already under development through a wide range of public-private initiatives. What is most important is that laboratory exchanges are included both as use cases and as test beds for research and implementations.

f. Ongoing research in best practices

In working with their communities and the public at large, all participants identified the significant effort required to maintain currency and relevance in the wide array of issues surrounding patient-centric use of laboratory information. Research and experience in these areas must be communicated quickly and in a way that is understandable to the public and to decision makers, as well as to the technical community. Increased efforts in this area are very consistent with the mission for AHRQ set forth by AHIC.

X. APPENDIX : LIST OF PARTICIPANTS

Adair, Jared; Director of Healthcare Strategies, Computer Sciences Corporation
Blair, John; President and CEO, Taconic IPA, Inc.
Bradford, Alicia; Program Analyst, Office of the National Coordinator of Health IT
Braithwaite, Bill; Chief Medical Officer, e-Health Initiative
Brewer, Donna; EDI Project Manager, Laboratory Corporation of America
Cain, Carol; Senior Portfolio Manager of Health IT, AHRQ
Christensen, Susan; Senior Advisor, AHRQ
Clancy, Carolyn; Director, Agency for Healthcare Research and Quality
Cusick, Kristin; Director of Government Affairs, Quest Diagnostics, Inc.
Davidson, Art; Project Director, Colorado SRD
Dolan-Branton, Lisa; Senior Advisor for Community-Based Health IT, AHRQ
Dubois, Jason; Vice President of Government Relations, American Clinical Laboratory Association
Dullabh, Prashila; Health IT Program Manager, NORC
Frisse, Mark; Director of Regional Informatics Programs, Vanderbilt Center for Better Health
Hennesey, Bob; Director of Systems, Laboratory Corporation of America
Hornsby, Roger; Manager of Physician Central Implementation, Quest Diagnostics, Inc.
Horton, Donald; Director of Public Policy and Advocacy, LabCorp
King, Janet; Technical Project Manager, Vanderbilt Center for Better Health
Lauraitis, John; Lead Project Manager, AllScripts
Lobenthal, Connie; Director of Medical Laboratory Evaluation Program, American College of Physicians
Madison, Matt; Project Manager, Colorado SRD
McCaslin, Ken; Manager of EAI Connectivity Strategies, Quest Diagnostics, Inc.
Megas, Laura; Senior Analyst, Northrop Grumman
Meigs, Michelle; Informatics Program Manager, Association of Public Health Laboratories
Overhage, Marc; President and CEO of Indiana Health Information Exchange, Senior Investigator at Regenstrief University
Parisot, Charles; Manager of Standards and Testing, GE Healthcare Information Technologies

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Peters, Rick; CEO, PatientChoiceRx

Ripp, Laura; Project Manager, Rhode Island SRD

Root, Jan; Assistant Executive Director, Utah Health Information Network

Ryan, Tim; Director of EAI Services, Quest Diagnostics, Inc.

Samarth, Anita; Program Director, eHealth Initiative

Sieber, Karen; Director of System Integration, Cerner

Sorace, James; Medical Officer, Center for Medicare and Medicaid Services

Stockdale, Holly; Principal Research Analyst, NORC

Sujansky, Walter; CEO, Sujansky and Associates

Wade, Geraldine; Senior Industry Expert, Computer Sciences Corporation

Welebob, Emily; Vice President of Program Delivery, eHealth Initiative

White, Jon; Senior Service Fellow for Healthcare IT, AHRQ

Young, Scott; Former Director for Health IT, AHRQ

Zimmerman, Amy; Project Director, Rhode Island SRD

Zuckerman, Alan; Director of Primary Care Informatics, Georgetown University