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A Lab-EMR Interoperability Profile as an eHealth Architecture Component for Resource-Constrained Settings

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Abstract

Implementation of computerized systems in resource-constrained settings have been gaining traction as a means of improving the delivery of health care, the use and reuse of information, and providing a standards-based capacity for assessing the process and impact of health care. In a resource-constrained environment, systems are often implemented as stand-alone entities focused on specific care activities (for example, delivering antiretroviral therapy). As such, in many countries, taking a generalized approach to linking electronic medical record systems with laboratory information systems (EMR-LIS) is an important area in which to achieve interoperability. In this paper we describe a scenario of use and information interaction interoperability profile based on our experience implementing EMR-LIS integration in two resource-constrained settings. Of significance, the profile emphasizes queued matching in order to avoid mutual dependence while achieving interoperability between systems.

Keywords:

Clinical laboratory information systems, Developing countries, Computerized medical record systems, Public health informatics, Systems integration

Introduction

In resource-constrained settings, both government and donor agencies are emphasizing implementation of computerized systems to improve the use and reuse of information, to improve the delivery of health care, and to assess the process and impact of that care. While operational efficiency, as well as internal and external goals in the distribution and reuse of data are motivations for using such systems, their implementation is a challenge. Identified barriers to implementation have included funding limitations, variety in health care data, the differing ways used to represent those data, and the variety of locations in which it is collected and stored.[1] In a resource-limited environment, how does one support the exchange of data required for effective use and reuse?

This paper proposes the use of interoperability profiles as one component of an eHealth architecture framework that integrates laboratory information systems (LIS) and electronic medical records (EMR) in resource-constrained environments. The goal of this interoperability profile is to enable point-to-point healthcare information exchanges between these two primary and heterogeneous health information systems.

Following background information regarding health architectures and the accepted protocols for creating and elaborating the components and steps of an information interaction profile, we describe a scenario of use and interoperability profile that enables LIS-EMR integration appropriate to the constraints of resource-constrained settings.

Background

There are a number of eHealth architecture initiatives currently funded through organizations such as the Rockefeller Foundation, the World Health Organization's Health Metrics Network (HMN), the International Development Research Center (IDRC), and the Centers for Disease Control and Prevention (CDC). These initiatives provide information to support three essential eHealth architecture goals:

- A framework into which stakeholders can easily place themselves and their systems;
- A way to identify dependent and interacting components and systems within a broad framework; and
- A description of common semantic, syntactic and interaction standards or guidelines that support interoperability.[2]

The goal of interoperability--i.e., the exchange of information between two or more systems or components and the use of the information that has been exchanged--has been identified as key in connecting systems to create more integrated views of health data in support of both individual and population care. This point was emphasized in the 2008 "Making the eHealth Connection" background paper in which Bailey, et al described different types of standards required to support interoperability including: identification standards; semantic

and syntactic standards; and standards of content, such as core data sets.[3] Other important types of standards are transport protocols; security standards; and operational standards (back-up/data reliability, training, service level agreements, etc.).

In a resource-constrained environment, systems are often implemented as stand-alone products focused on specific care activities (for example, delivering antiretroviral therapy). As such, in many countries, taking a generalized approach to linking EMRs with LISs is an important area in which to achieve interoperability. As important as data standards are, we propose that it is equally important to specify "interaction standards", or standards that describe the specific information flows between the dependent and interacting components and systems whose identification comprises the second goal of eHealth architecture. These standards are written around the business rules that govern the flow of information, and describe the constraints upon, and usage of, semantic, syntactic, and other standards to support specific transactions.

Here we propose a method that provides concrete implementation guidance with a scenario of use contextualized in a resource-constrained setting. This methodology is based on our work in the Integrating the Health Enterprise (IHE) Showcase [4] as well as in Haiti and Côte d'Ivoire where we have implemented two open-source projects—the iSante EMR [5] and OpenELIS system [6] in over 55 sites—experience which has provided an excellent testbed in which to explore generalized, standards-based interoperability between these two representative systems. In addition, our goal is to use this reference implementation for Lab-EMR interoperability to support more general interoperability between other systems, such as the Bika LIS[1] and OpenMRS EMR[2].

Methods

The IHE Initiative[3] aims to improve interoperability of healthcare information systems by promoting the adoption and use of existing healthcare information technology (IT) standards. IHE provides a framework through which existing healthcare standards are applied in a structured and consistent way to address specific needs in healthcare operations, care and treatment, research, and public health. The Technical Framework presented by the organization is something similar to an integration guide describing interactions between systems. The IHEs Integration Profiles use this framework and expand it by identifying actors and transactions to address information needs that occur with specific use cases. While the IHE profiles support interoperability between a wide variety of sophisticated commercial systems, resource-constrained settings present different challenges and require an approach that addresses these challenges as presented below.

Fewer Clinical Systems and Number of Tests

In resource-constrained countries there are typically only a handful of different clinical information systems implemented and they tend to focus on specific populations, such as people living with AIDS. This presents both a benefit and a risk: the benefit is that there are fewer partners with whom one must interact to achieve develop consensus on interoperability, the risk is that partners face a constant temptation to build ad hoc linkages between the systems with which they work, rather than addressing interoperability in a more general way. We have found that we have to work conscientiously to engage other partners, and have set as a goal that our initial interoperability profile fits within the work processes and system architecture of at least two different EMRs communicating with at least two LISs.

Clinical laboratories in many resource-constrained countries have a narrower range of tests available than that which might be found in a US or European laboratory. For example, a third-party index intended to facilitate the interpretation of lab results commonly available through clinical laboratories in the USA lists over 1000 separate studies[4] yet our experience in Haiti suggests that a typical clinical lab in those settings may have a catalog of approximately 120 studies. This difference may be significant and affect the priorities when implementing interoperable systems.

Challenges in Implementing IHE Profiles

While IHE profiles are built on the real-world standards in use in health information systems which tend to be complex and use HL7 2.x messages; but the complexity of HL7, as well as the financial cost of joining the organization and accessing the standards, have limited utilization by developers working with limited resources. Since IHE profiles make use of the richness of HL7 and other standards, they inherit that complexity which presents an additional barrier to profile use in some settings.

In the laboratory domain, Logical Observation Identifiers Names and Codes (LOINC)[5] provides a semantic standard with a set of universal codes and names to identify laboratory and other clinical observations. LOINC is an open standard, however, the size and richness of LOINC may be daunting to some. Our observation has been that systems like Bluebird[6] tend to develop their own tailored specifications for exchanging data, often in XML, and often using locally developed code sets. Our experience has been similar; two large HIV observational cohort projects in which we are involved similarly use local code sets agreed upon by the participating institutions.

As mentioned in the Introduction, it is common to see stand-alone systems implemented in resource-constrained settings so linking EMRs with LISs is an important area in which to achieve interoperability—especially since the need for such linkages for reporting purposes is strong.

[1] www.bikalabs.com/
[2] openmrs.org/wiki/
[3] ihe.net/
[4] www.labtestsonline.org/map/aindex.html
[5] loinc.org
[6] www.bluebird.co.za

Documents or Messages

IHE offers both document- and message-based protocols. In the clinical domain, the former are based on variants of the HL7 Clinical Document Architecture (CDA), and include ways of exchanging medical summaries, lab results, immunization summaries, and other structured documents. Given ad hoc profiles often seem to be developed using short objects, structured using XML, we were initially tempted to use an IHE profile as the basis of our EMR-LIS interface. We explored XDS-Lab which we had used in other IHE demonstrations of public health capabilities [4] however, after consultation with other collaborators working on EMRs for resource-constrained settings, we elected to use a message model, using HL7 2.x as the syntactic standard.

At first glance, message- and document-based systems appear to be substantially different, with messages tailored to convey a stream of events that must be assembled to reconstruct the current "state" of a patient and documents able to capture a rich "snapshot" of patients. However, this is more a function of the level of information traditionally included in the syntax standards commonly used for each of these modes, rather than innate characteristics. In essence, if one takes a message, and prints it out, it becomes a document, regardless of its content, with all of the attributes of that type of artifact. And if one takes a document and carries it across the room or from the clinic to the lab next door, it becomes a message.

Developing a Resource-Constrained Appropriate Profile

To develop the resource-constrained EMR-LIS profile, we first identified the important components (see Figure 1 for acronyms and definitions) and the order in which they are utilized. The "traditional" order is as follows:

1. Patient Identification: Based on the PIX and PDQ IHE profiles.
2. Order Transmission: Based on the LSWF IHE profile.
3. Results Transmission: Based on the LSWF IHE profile.

PIX - Patient Identifier Cross Referencing - cross-references patient identifiers between organizations

PDQ - Patient Demographics Query - allows for query of a central server for demographic and visit information on a patient

LSWF - Laboratory Scheduled Workflow - establishes the continuity and integrity of clinical laboratory testing and observation data throughout the healthcare enterprise.

XD*-LAB – Sharing Laboratory Reports - a clinical laboratory report as an electronic document,

XDS - Cross Enterprise Document Sharing – allows for registry and location of documents between organizations

Figure 1- IHE Profiles of interest [7]

However, in resource-constrained settings, the first two steps are often paper-based—therefore the value of a profile is concentrated in what is traditionally the final step, Results Transmission. Because labs have needs beyond the receipt of orders and delivery of results, including quality assurance, reporting of laboratory performance indicators, and communication of inventory for supply-chain management, we believe that laboratory needs are best addressed through implementation of a laboratory information system, interoperable with an EMR, rather than the extension of the EMR to include a "laboratory module". In addition, we wanted to develop a reference implementation for Lab-EMR interoperability and to use that implementation to support more general interoperability between systems.

To accommodate the reality of the environmental constraints, we addressed these components in the following order, reverse from the order in which they occur in a typical workflow:

1. Results Transmission Only
2. Order Transmission and Results Transmission
3. Identification of Patients in EMR, Order Transmission and Results Transmission

The information interactions required to support the three use cases were assigned to specific parts of the Laboratory Testing Workflow (LTW) as described in the IHE Laboratory Technical Framework, Vol. 1: Profiles.[7] Next, the specific "actors" in those use cases were assigned to either the EMR or LIS, a constraint that further simplified the IHE profiles. Finally, the message specifications were reviewed to determine if additional simplifications could be made.

Results

The context within which we composed the profile assumed the following scenario of use that we found to be common in our work in countries like Haiti and Côte d'Ivoire.

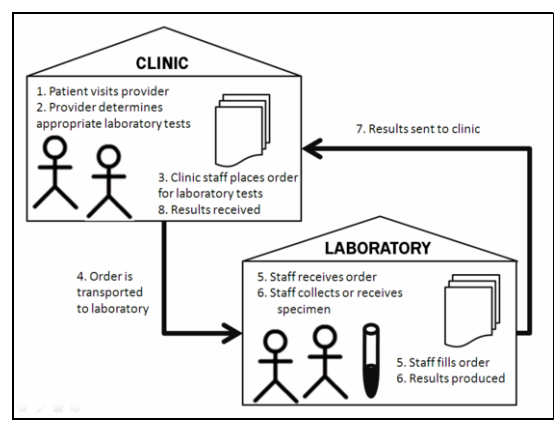

Figure 2- Lab-EMR integration scenario of use

In the clinic, a patient visits a provider, appropriate laboratory tests are identified and orders for the lab tests are placed. The order is transported to the laboratory. In the laboratory, staff receive an order, specimens are collected or received, tests are performed/orders are filled and results are produced and reported/sent to the clinic. Back in the clinic the results are received. Of note is that in the settings we are addressing, one, several, or none of these steps may involve electronic systems and when systems exists, connections may exist with similar inconsistency.

Figure 2 depicts this resource-constrained scenario of use. As stated, we are focusing first on the Results Transmission step (Step 7 in Figure 2), as the glue between an EMR and LIS. In this way, we are not only addressing the principal gap of interdependency between these two systems but we are also creating a business case for further development and funding to design and implement an LIS-EMR integrated system.

Use Case Actors and Workflow

IHE profiles define actors in terms of their roles, but in this profile, we can further assign the roles played by the use case actors to the two systems in use, with the EMR as the "Order Placer" and the LIS as the "Order Filler". The EMR also acts as the "Order Result Tracker".[7] We were able to tailor the representative workflow described in the IHE profile using both fewer potential actors as well as more limited information interactions, in order to support a more constrained set of workflows. This allowed us to limit the message types required for implementation.

The criteria used throughout this process ensured that the interactions described were part of the IHE document structure, could be referenced specifically to sections of those documents, and included only those elements of the profile which were needed to support interoperability using HL7 2.x messages between the two types of facility level systems, LIS and EMRs.

Final Profile and Scenario of Use

In the context of the LTW Profile, our resource-constrained scenario of use includes an order that is created by the laboratory and specimens which are assumed to be collected by the lab or ward, i.e.:

- Filler creates Order Filler Number
- Results transmitted post validation to the Order Result Tracker

We extended the case above to include transmission of orders, with demographics, from the EMR to the LIS. However, this does not include the ability for the LIS to query the EMR for demographics and resolve LIS patients to new or changed patients in the EMR. Therefore, we added the Patient Identification in the EMR component which both addresses this need and simplifies the cycle described. For this step, orders are placed with specimens identified by a third party and transmitted electronically. The result is that the LIS will gain the ability to query an EMR for patient demographic information, with the EMR playing the role of a Master Patient Index (MPI) component.

This profile encompasses demographics, orders and results, which are generalizable components of other information interactions. Related and potential extensions of this profile as tailored to a resource-constrained environment includes pharmacy, which is a very close match, as well as patient lookups for remote patient list management, remote sample entry, linkages to demographic surveillance systems, and other applications.

Discussion

The resource-constrained profile we present is limited in its focus primarily on transmission of results and in its assumptions. Although we believe that there is value in approaching this problem of integration stepwise, we also acknowledge the significance to all parts of the process, the issue of patient identifiers and patient matching. Patient identification presents challenges in any setting, for example there is no way for the lab to know for certain that the patient has been identified accurately. In this case, the EMR will need to be enhanced to both match on more than one identifier and to put questionable results in a queue for manual matching. Where connectivity between the LIS and EMR is intermittent, this scenario may occur fairly frequently.

We anticipate that developing an appropriate matching scheme in this case will likely need to be based on an exact match of the Patient Medical Record Number transmitted with the paper order or patient, in combination with some secondary identifiers as a double check (for example, last name, ordering facility/physician, age/Date of Birth, visit date, lab entry in the EMR). Some of the challenges of this case include: 1) There is no guarantee that a visit will have been entered in the EMR by the time the result comes back from the LIS; 2) Some (or many) patients may not be able to provide a date of birth; and 3) The ordering physician may not be part of the workflow for a particular site. For these reasons and others, it may be necessary to leave the choice of secondary identifiers for automated assignment of results in this profile to be determined on the institutional level. However, we believe that this queued matching is important in resource-constrained settings as even interoperable systems should avoid mutual dependence.

Alternatively, a purely manual system, with a strategy for catch-up when an interface is restored, must be developed. Direct entry of imperfect match results into the EMR would be a suitable strategy, and may be a reasonable alternative for manual matching and entry of results, as above.

Although insights into this interoperability profile have the benefit of being informed by our work in many resource-constrained countries, there is no way of knowing without a formal evaluation how generalizable a profile such as the one presented here would be to a wider set of EMR and LIS implementations. Future work includes such an evaluation, as well as a demonstration of this profile, in order to gather input from a wide audience of developers working in similar settings.

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