Interoperability in the 21st Century: Cost Effective Solutions and Guidelines for Interoperable Electronic Health Records

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Abstract

This paper describes the use of standards to enhance the capability of creating semantically interoperable documents and messages. Over the past few years, many information exchange formats have been created. While the health industry continues to develop new formats that attempt to simplify or modernize interoperability across healthcare, it is continually challenged by the difficulty of current applications to exchange documents that can be interpreted by the receiver of the document. Given the variety of standard formats, a framework should be developed that can bridge across multiple exchanged formats/syntax and semantics. It should reference the business content in a consistent way that represents clinical best practices and connects to the clinical workflow that triggers information exchange. This paper describes the use of model-driven development to bring balance to the art of data exchange by supporting semantic interoperability for design and runtime. The proposed model-based approach to mapping addresses the semantic challenges and allows sending systems to first specify the meaning of their data by relating it to a defined common data dictionary of business data elements thus making it independent of other datasets.

The resulting architecture proposes two sets of open-source components intended to provide a clear separation of concerns throughout the development process between design and run-time. SAMHSA is using this approach in its Information Exchange Hub (IExHub), the transformation/interface engine supporting both behavioral health and physical health interoperability for health information exchange network (HIEs).

Keywords

Semantic Interoperability; Electronic Health Records; Behavioral Health; Clinical Document Architecture; Consolidated CDA; Fast Healthcare Interoperability Resources; Semantic Mapping; HL7 Version 2; Model-Driven Interoperability; Model-Driven Health Tools; Information Exchange Hub; IExHub; CDA; C-CDA; MDMI; MDHT; FHIR; MDI; MDR

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1 Background

Information exchange has existed since the dawn of man. While the human mind can make inferences when information is missing or presented poorly, such inferences can be wrong due to missing, incorrect, or poorly presented information. When exchanging information human to human or augmented by minimal technology such as phone or FAX, the format and content of the information are often not very rigorous. This presents issues when exchanging information electronically.

Health information such as narrative descriptions are often exchanged between providers using a generic electronic format such as PDF and HTML. This is only marginally better than FAX and heavily reliant on human interpretation of the information received with little to no computeraided processing or analysis. A human must refer to and interpret the electronic document anytime the information can be used in the treatment of a patient. As information exchange relies on both the sending and receiving clinicians to interpret it in the same way, the semantic modifiers such as "resolved," "major," "critical," or "severe" that are associated with clinical information may be contextual. Thus, better interoperability requires semantic clarity that goes beyond human decoding of narrative information and requires machine processing of free-text and structured data. Similarly, it is important to convey such information as: "the patient does not report any allergies," "we have no information about allergies," or "tests reveal no allergies."

Over the past decades, many information exchange formats have been created to exchange messages and documents. While the intent of these formats and approaches is to simplify interoperability, it has presented a very complex interoperability landscape for implementers to navigate. As a Standards Development Organization (SDO), Health Level Seven International (HL7) has developed several file formats for exchanging information. These include HL7 Version 2.x, HL7 Version 3, Clinical Document Architecture (CDA), and Fast Healthcare Interoperability Resources (FHIR). All have been attempts to create machine-understandable structures with flexible semantic content, subject to implementation-specific clarifications. For standards to augment and improve interoperability, they must be associated with specific use cases. All HL7 standards have to be constrained (or extended) and combined with clinical terminology to create an implementable guide that attempts to eliminate ambiguity.

There are other content standards defined in the United States, such as the National Information Exchange Model (NIEM) and The Accredited Standards Committee X12 known as ASC X12 or simply X12. Layered below the content standards referenced above, there are transport protocols such as SOAP, REST, NwHIN DIRECT, and NwHIN CONNECT which are often tied to a particular information exchange standard and ignore semantic clarity. Figure 1 illustrates the complexity faced by EHR systems expected to convey business information using Meaningful Use standards such as C-CDA, HL7 V2, QRDA, or HQMF, or emerging standards such as FHIR.

2 Problem

Healthcare interoperability requires information to be semantically precise to ensure that its meaning is interpreted in the same way by both the sending and receiving systems. The challenge posed by semantic consistency increases exponentially when information is exchanged across multiple senders and receivers (many-to-many) across a nationwide network.

In the US, the current state of the health care delivery system is fragmented with many poorly implemented health IT systems still lagging in data (semantic) interoperability despite the billions of dollars spent to certify electronic health record (EHR) systems and launching health information exchange (HIE) solutions to integrate community-based providers.

The current standard implementations have not matured sufficiently to remove ambiguity from the exchange standards or ensure consistent semantics across communities. There are no required implementation standards for HIE organizations, the key entities that facilitate electronic health information exchange between providers. Additionally, HIEs have demonstrated poor business model sustainability. These issues directly affect the interoperability landscape, especially for specialty providers such as cardiology and behavioral health. Simply validating the structure of a document or message does not ensure the information contained will either be sufficient or be interpreted in the same way for decision support and treatment. The current state of interoperability allows different systems to process and interpret information differently even though the underlying standard structure is valid and includes all the relevant business data elements.

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) is currently exploring ways to reduce the complexity of information sharing across the HIE without compromising patient privacy and confidentiality and supporting national regulations such as 42 CFR Part 2 [1]. SAMHSA is also creating opportunities for behavioral health clients in particular, and patients in general, to have greater control of their health information through standard-based solutions that ensure semantics interoperability across the continuum of care.

Achieving interoperability across the continuum of care requires that all systems must have a common understanding of the information shared regardless of the payload structure or transport. To bridge the differences among systems, a common, standards-based canonical definition of information meaning can help translate from one format to another while maintaining semantic precision. The goal is to allow EHRs and Health Information Exchanges (HIEs) to share information using standard structures (i.e. messages, documents, resources) and terminology as well as leverage standards-based knowledge models using standard terminology systems.

This paper describes how interoperability would be enhanced by model-driven architecture principles to add the science of semantic data definition and mapping to the art of standardsbased information exchange.

2.1 Why Mapping Fails

Throughout this paper, we emphasize the importance of semantic mapping and the use of profiles to constrain standards for precise implementation and transformation. Past attempts to map HL7 Version 2.x message elements to HL7 Version 3 classes have shown the futility of a map that relates an ambiguous concept (e.g., Observation class in V3 to an OBX segment in V2). In most cases, the structure can be constrained into a profile to exchange a certain type of information (e.g., V3 Observation to CDA Problem or V2 OBX to a device-reported bloodpressure measurement). Clearly, attempting to map an unconstrained standard structure to another unconstrained standard structure is not useful or reusable. Semantic

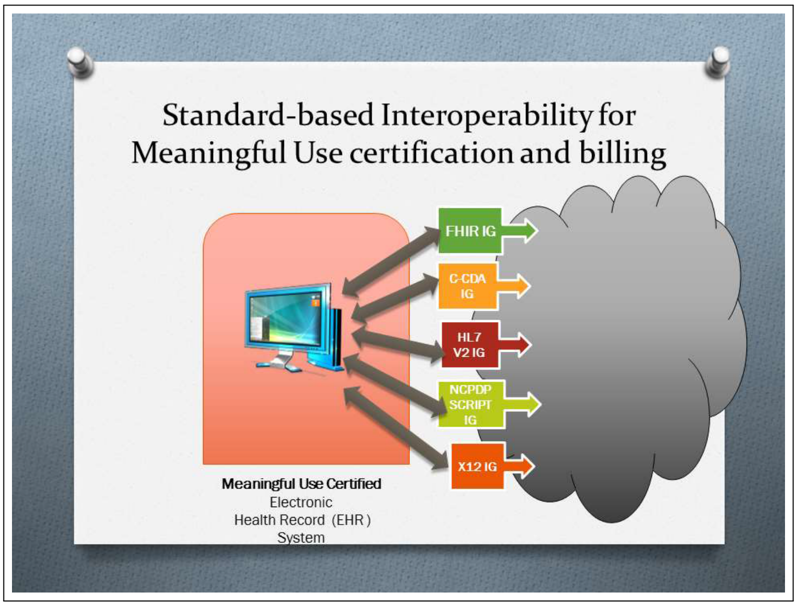

Figure 1: Standard-based Specifications required Meaningful Use certification and billing.

mappings, in contrast, are reusable. They document how business data elements are represented in a structure, for example, how a vital sign is represented in either V2 or V3—the same content but in two syntactical representations.

Semantic mapping also requires semantic clarity. Through semantic mapping we can distinguish between the dates (1) when a problem was recorded, (2) was observed, or (3) the year or age when a problem or symptom started. While dates appear trivial, certain qualifiers can clarify the meaning of a business data element and facilitate the creation of profiles and maps. Similarly semantic mapping includes mapping coded data by identifying equivalent concepts and relating local codes to standards (e.g., SNOMED CT, ICD-10, LOINC, RxNorm, etc.).

There are additional factors that affect mapping one healthcare format to another. Using the earlier example, there can be many problems observed by a healthcare professional for a patient. In each observation, data elements for the date, the type of specific problem, the severity of the problem, and who authored the observation are all recorded data elements. For this information to be used correctly later, all of the specific data elements for the observation must be bound together. Therefore, the semantics of a format are not simply represented by the semantics of a specific data element, but rather the semantic clarity of the data element is influenced by how the data elements are organized or structured (i.e., hierarchy). There are additional factors that can have an impact on semantic mapping such as relationships and values of other data elements (e.g., moodCode in CDA and the relationship between OBX-3 and OBX-5 in HL7 V2) and these must be understood to achieve a precise meaning and precise structure.

Therefore, strictly syntactic mappings fail and are generally expensive to implement for a variety of reasons:

- Lack of semantic understanding between data elements
- Lack of semantic clarity for data elements
- Complexity introduced by format structures and relationships between different data elements.

The use of a model-based mapping helps avoid the pitfalls of syntax-based mapping, driving interoperability towards semantic consistency across systems and applications.

3 Semantic Consistency across the Continuum of Care

The proposed semantic mapping approach is intended to add semantic consistency across systems using widely-adopted model-driven architecture principles, similar to the HL7 Services- Aware Enterprise Architecture Framework (SAIF). It adds the semantic versus syntax model separation introduced by the Open Management Group's Model-Driven Message Interoperability (MDMI) [2] specification as a technical approach to model-driven semantic interoperability. To address the complexity of healthcare information exchange, the canonical data elements are described using the ISO 11179 metadata registry (MDR) [6]. The canonical data are then reused to establish semantic equivalence across systems, across syntactic models (e.g. HL7 V2, CDA, FHIR, etc.), across knowledge models (e.g. Detailed Clinical Models, CIMI clinical models, OpenEHR clinical models/archetypes) and even across diverse clinical coding systems (e.g., SNOMED CT vs ICD, local system to standard systems). The maps rely on a common "model of meaning", which is a logical representation of payloads that consist of data elements organized into a well-defined registry or "Referent Index". Similar to other standards products, the Referent Index would derive its authority from a consensus-based change management process organized by a SDO.

Using this approach, each side of the exchange must first map its own data to a common data element (i.e., vital sign result). A second map ensures that the standard syntactical structure (e.g. FHIR Observation, HL7 V2 OBX segment, CDA Observation) is used consistently to represent its data element (i.e. Vital Sign Result). This approach may map not only across standard-based syntactic models (e.g., CDA, V3, V3, and FHIR), but also across models of clinical knowledge and requirements such as Detailed Clinical Models, Open EHR Archetypes, and the Clinical Information Modeling Initiative (CIMI).

The software architecture required bringing these concepts to life, ensuring that semantic mapping provided a clear separation between data semantics and syntax/representation. This promotes the development of reusable maps for well-defined implementation specifications. The success of semantic mapping relies on a community of interest and an SDO that can maintain the data elements which make up the Referent Index.

The architecture must also provide a means of executing semantic maps at runtime and requires a sustaining effort to develop a reusable registry of data elements. SAMHSA has created the Information Exchange Hub (IExHub) project to build the transformation/interface engine supporting both behavioral health and physical health interoperability for HIEs. [3]

4 Benefits of Runtime Model-Driven Interoperability

Previous standards-based mapping projects aimed to facilitate transition from one standard sy and syntax to another (e.g., HL7 Version 2 ASCII Encoded messages mapped to HL7 Version 3 XML messages). These projects attempted to map the entire standard to its newer version without considering that both versions required additional refinements and constraints for realworld implementations.

Due to the unconstrained definitions or specified optionality of the base standards, mapping an entire standard from one format to another has proven to be unreliable. In programmatic terms, the mapping of one base class to another base class while ignoring that each class must be further specialized prior to instantiation cannot guarantee semantic interoperability. This mapping approach fails to align semantically equivalent data elements because the interoperability standards contain generic concepts and optionality intended for adaptability to a multitude of implementations. Therefore, mapping of base standards is inherently imprecise, requiring instead a semantics-driven solution.

The proposed solution includes model-driven semantic maps that are directly executable by the IExHub runtime environment which supports the bi-directional exchange of business data and information independent of format:

- CDA R2 (using C-CDA templates)
- FHIR (resources/profiles)
- HL7 Version 2 (use case specific implementation guides)
- Other formats as identified (X12, NCPDP)

Additionally, the IExHub provides a number of connectors for specific transport protocol and envelope formats to support the exchange of standard-encoded messages and documents:

- REST
- SOAP (IHE ITI Integration Profiles, NwHIN Connect/eHealth Exchange)
- S/MIME (NwHIN Direct)
- HL7 Minimal Lower Layer Protocol (MLLP)

5 Semantic Mapping Design for Model-Driven Interoperability

Semantic maps are created using an open-source Eclipse-based tool - the business analyst's "workbench" (i.e. MDI Workbench). It integrates existing open-source tools (e.g. MDHT MDMI, Art-Décor [7]) to put subject matter experts in charge of defining maps and creating model-based implementation guides for information exchange standards.

The workbench combines standards profiling and semantic mapping thus leveraging the work done by the Open Health Tools community to create the "CDA Tools" for template development and model-based validation. Consumers of CDA-based documents and implementers of CDA and C-CDA are able to generate run-time components from models of the implementation guides, thus accelerating and lowering the cost of adoption for this key standard required in Meaningful Use Stage 2 and Stage 3 (MU2/MU3) certification.

During our evaluation of standard profiling tools, the MDHT tools were used to create implementation specifications for information exchange formats beyond the CDA format such as FHIR profiles. The MDHT tool provides a model-driven framework for generating a Java runtime application program interface (API) that supports template conformance. The API enables construction of instances that conform to these templates, ensuring that documents conform to the relevant constraints. Since it is based on UML 2.0, MDHT can be used to contain any standard structure and provides built-in support for constraining a template/profile to add more specificity if required by an implementation.

For semantic data element mapping to be successful, the metadata registry [6] must be completed before a business analyst can create a semantic map. The metadata registry should be curated by an international Standards Development Organization (SDO). This insures that the resultant Referent Index describes the canonical definition of semantic business data elements. An international SDO is best suited to curate the Referent Index so that the semantic data elements are not corrupted from adding content that is not rigorously defined.

The MDI workbench allows an analyst to create or edit maps that relate local EHR/HIE source data to information exchange formats using the Referent Index. The map editor could also be applied to creating "standard" maps that specify how a canonical data element is represented.

This frees the semantic data elements from being bound to an exchange format until an implementation guide is defined based on a well-defined use case. A **logical payload** can then be developed, not bound to a syntax or representation but derived from concrete business requirements. This leads to standards-based implementation guides which satisfy, in a verifiable way, a need for semantic information sharing. The logical payload supported by an implementation guide consists of data elements defined in the Referent Index and provides implementers with the detailed knowledge to represent that logical payload in a standard-based syntactic structure (e.g. CDA document, V2 message, FHIR transaction) and terminology (e.g. LOINC value sets).

Figure 2 describes how using a model-driven semantic mapping uses two semantic mappings which allows a data element mapped to equivalent information exchange structures (syntax model) using a common semantic model. This approach can be extended and invoked to translate the EHR data to a variety of formats, for example, from C-CDA 1.1 to FHIR and HL7 Version 2.x implementation guides. To enable the adoption of standards, the Referent Index should be developed by the SDO to specify data elements semantically within an implementation guide. Interested stakeholders can reuse the maps at design-time and generate run-time specifications consistent with model-driven architecture principles.

At runtime, the map configured for specific endpoints is executed by dedicated software components.. Thus mapped, the EHR local data can then be represented correctly as an implementation guide-specific payload. A standard set of maps, which will be provided in the open source project, would describe how business data is represented in a specific CDA template, HL7 Version 2 profile, or FHIR profile (i.e., unit of exchange). As new implementation guides and profiles/templates are developed, the Business Elements could be referenced alongside each constraint applied to the standard.

A model-driven approach promotes the reuse of the Referent Index as the canonical representation of all the data exchanged through any interoperability specifications. The importance of semantic business data when creating a new profile or template is evident in the way other open-source tools such as Art Décor begin the development of a new template by first creating a data model of required data and then applying the necessary constraints to the underlying standard structure to support the data set. The model-driven approach promotes the reuse of business data elements by:

- Helping applications clarify the semantics of their local data
- Helping profile developers clarify how a message or document would represent the Business Elements in an interoperable way, using standard constructs and syntax

Figure 3 illustrates the use of metadata based on clinical terminology. This ensures that the meanings of Referent Index Business Elements are not dependent on narrative descriptions but instead on a post-coordinated expression that combines the meaning of well-defined standard concepts (e.g. Allergy + observation + date/time). These computable expressions can be used to de-duplicate and navigate the Referent Index for precise mapping and predictive reasoning.

6 MDI Runtime Transformations

Semantic maps allow information systems to specify how their local format/syntax relates to the canonical data elements in Referent Index. To transform data between two syntactic models, a second map is required to specify how the canonical data elements are represented to a target representation. To facilitate reuse each implementation guide may have an associated map that represents the community consensus on how a specific data item (e.g. vital sign result) is represented in a standard syntax (e.g. the Observation value data element of the C-CDA template). This ensures that EHR systems can exchange health information in a manner that guarantees that the content of the information is understood across disparate systems, thereby allowing for semantic interoperability.

A **transformation** consists of two mapping operations: first from a source structure to a canonical data definition and a second from the canonical data definition to the target syntax specified by an implementation guide. The IExHub automatically executes the necessary map sequence based on the source and target format and implementation guides invoked at runtime.

MDI transformations allow EHR systems to (1) migrate selected interfaces to later versions of the standards, (2) adopt new information exchange formats, and (3) maintain backward compatibility with existing interfaces inside and outside the enterprise. The transformations also allow the systems to support more than one exchange syntax/format for a logical payload.

In addition to executing semantic maps, the IExHub can also act as an application gateway linking FHIR-based applications with existing SOAP-based HIEs. The IExHub can map not only data but system capabilities and behavior (e.g., the application invokes FHIR Patient

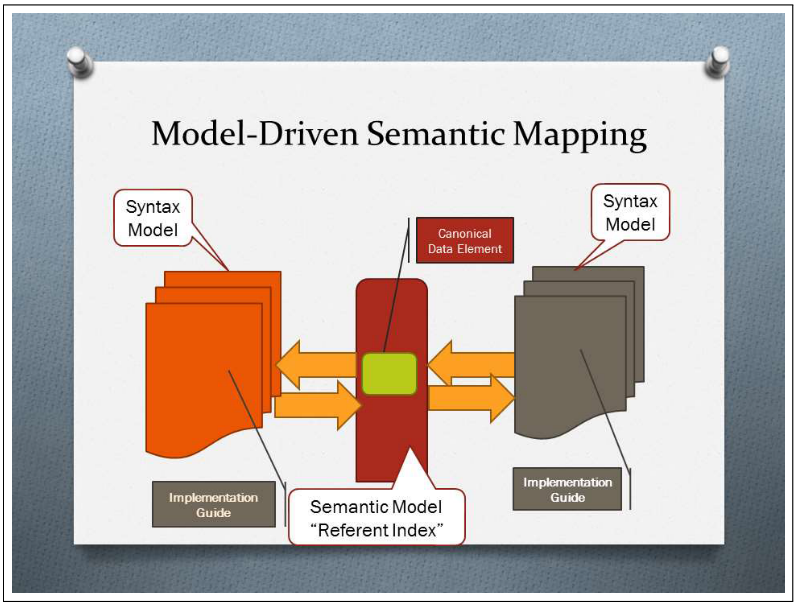

Figure 2: Model-Driven Interoperability using Semantic Mapping.

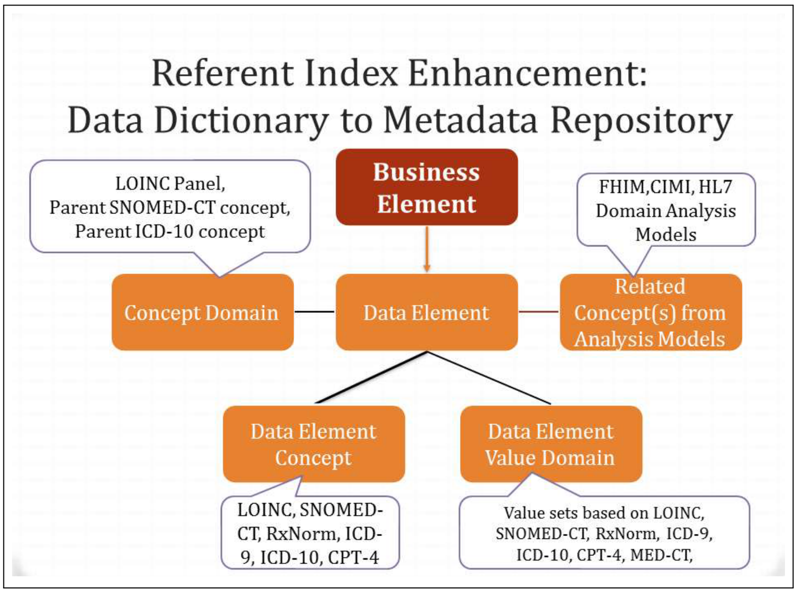

Figure 3: Data Element Metadata combined using ISO 11179.

"search" to transmit the IHE ITI-47 PDQV3 Query message supported by the HIE). The transformation includes mapping payloads and transport from FHIR over REST to HL7 V3 with ebXML over SOAP.

6.1 Transforming Atomic and Aggregate Data

Most of the transactions and message exchanges currently implemented using standards share three characteristics. They aggregate information corresponding to a specific focal structure:

- Messages (e.g. HL7 Version 2, X12, and NCPDP)
- Documents (e.g. CDA documents, FHIR resource, HQMF, and QRDA)
- Support simple interaction modes:
  - Unsolicited notifications (e.g. laboratory results reports)
  - Request/Response transaction (e.g. order request message/order response message)
  - HL7 FHIR adds support for atomic data objects

FHIR and CDA will coexist for the near future as they address complementary requirements.

- FHIR supports access to atomic elements while CDA provides access to aggregate objects containing both narrative text and structure.
- FHIR supports queries for discrete data elements while CDA supports only queries for documents or document sets.

Thus, CDA is ideal for large transactions containing a variety of sections and objects. In contrast, FHIR provide access to specific data elements (e.g. lab results, patient records, and provider records).

MDI allows the two standards (and other required interoperability standards) to co-exist and fulfill the requirements of various projects. The MDI approach supports transition from one standard or version of FHIR or CDA without affecting the business data content of resources or documents. Typically, a CDA document may be represented by two or more FHIR resources (e.g. Composition in a Bundle with dependencies).

FHIR allows systems to provide new capabilities to HIE repositories that persist aggregate messages/transaction or documents. For example, providers may create CDA documents to be sent to a data store such as an HIE, and others may make queries to the HIE and receive FHIR resources (created from data content in a CDA document) in response.

Not only is the document information mapped from one format to another, it is done with complete semantic integrity because the Referent Index data element represents the conical definition used by each template definition. Now we begin to see synergy between the different standard formats and convergence across the various areas of the health continuum for where the different formats provide the most value.

7 Model Driven Interoperability (MDI) Value Proposition

The MDI approach requires more upfront work by defining the content of semantic data elements. This approach facilitates the exchange of documents in one format or another much faster than waiting until a standard is defined to determine the semantic content required. MDI strives to ensure semantic consistency across EHR systems. Errors in data and clinical terminology transformations have caused serious safety problems by creating errors in systems attempting to decode the data. Mapping ambiguities can lead to medical treatment errors that require a systematic approach to later tackle the root cause of such errors.

Why is true interoperability so difficult to achieve? Often it's the result of focusing on strictly structural conformance to a standard syntax to the detriment of semantic validation. If the sending and receiving systems do not share a common model of meaning, then divergent semantic understandings may be derived even if they share valid structures.

MDI overcomes these data equivalence issues by promoting mappings to and from canonical business elements (e.g. LOINC encoded vital sign observation) rather than syntax node (e.g. OBX.5). A model-driven mapping approach frees implementers from the burden of dealing with syntax-based mapping and allowing for focus instead on precise semantics.

Another business benefit of MDI is managing changes in interoperability standards over time by allowing new standard maps to augment existing representations of data without requiring business analysts to redesign existing maps.

8 Model-driven Interoperability Solution for Behavioral Health Providers

Behavioral health providers are expected to adopt standard-based information exchanges without the benefit of financial incentives provided by the Centers for Medicare and Medicaid Services (CMS) to those providers who demonstrate Meaningful Use of EHR systems. Therefore, these providers require a cost-effective approach to interoperability that relies on open-source and standard-based software tools to leverage the collective investments of federal, state, and private sector stakeholders.

To reduce the cost of interoperability, the Behavioral Health Interoperability demonstration initiated by the Substance Abuse and Mental Health Services Administration (SAMHSA) implemented software components and developed methodologies to reduce the high cost of healthcare interoperability for EHR systems that are sharing healthcare information using the standards and implementation guides required by the Meaningful Use certification. The certification criteria include adoption of C-CDA for document-based exchanges, HL7 Version 2.7.1 Profiles for Laboratory Results and Orders (LRI, LOI) in addition to Health Quality Measures Format (HQMF), Quality Reporting Document Architecture (QRDA), and the emerging implementation guides for FHIR.

A model-based, semantic mapping approach separates content from syntax to allow the exchange of business data consistently. Whether using FHIR, CDA, or HL7 V2, an EHR system is able send or process laboratory results. The laboratory result data content is the same.

For an implementer, the difficulty increases each time a new implementation guide or format is proposed for adoption. Each system must map local business data to a variety of formats (e.g. HL7 Version 2, CDA R2, and FHIR) based on the constraints and criteria defined by implementation guides (e.g. C-CDA, Laboratory Results Interface, and Health Quality Measure Format). The challenge for implementers is not only to understand the information exchange format, the implementation constraints, and implementation guidance, but also to create semantic relationships between local data elements and the stan-

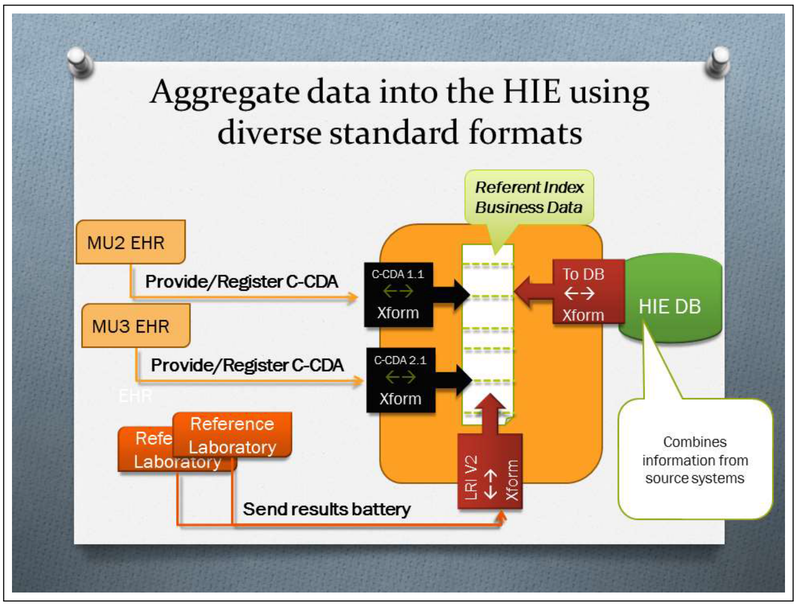

Figure 4: Aggregate Transactions and Domains Persisted by HIEs.

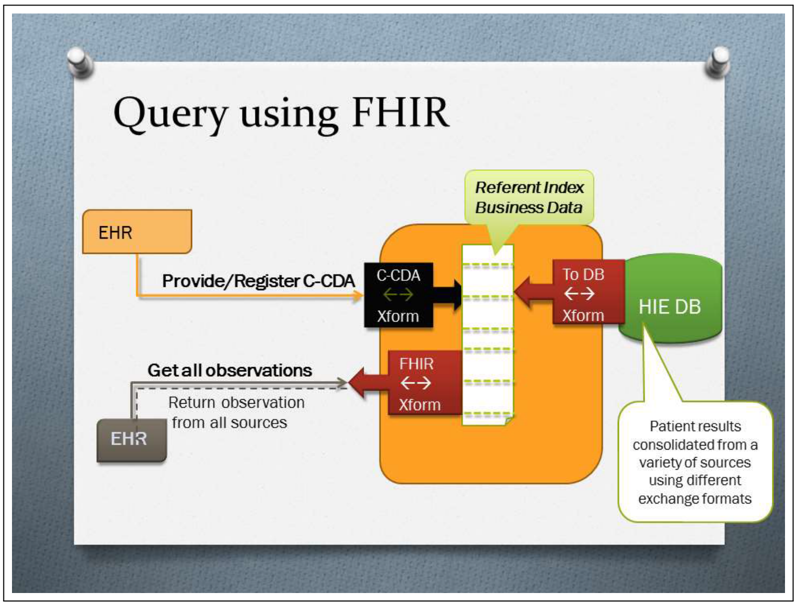

Figure 5: Retrieving Atomic Data from Aggregate HIE Database.

dard data element identified in the target implementation guide. If these semantic relationships are incorrect, the resulting CDA document or HL7 Version 2 message may pass validation and even certification but may carry the incorrect business data. These semantic errors may amplify when an HIE or another data aggregation system combines information received from multiple senders. Each semantic error further limits the ability of such systems to process the data pertaining to a patient of population.

The Behavioral Health Interoperability project used the model-based approach outlined in this paper to show that it can address the semantic challenge and financial limitations facing this domain. Our team showed that semantic mapping can be applied directly to application semantics to map local data to/from canonical data elements and then use a set of standard maps to represent the application data using the standard implementation guides mandated by national regulation.

9 Conclusions

The inherent complexities in adopting multiple information exchange syntax models and terminologies in interoperability scenarios are mitigated using a MDI approach. The principles and architecture outlined in this paper require a community of interest to maintain a clinically relevant Referent Index and contribute standard-

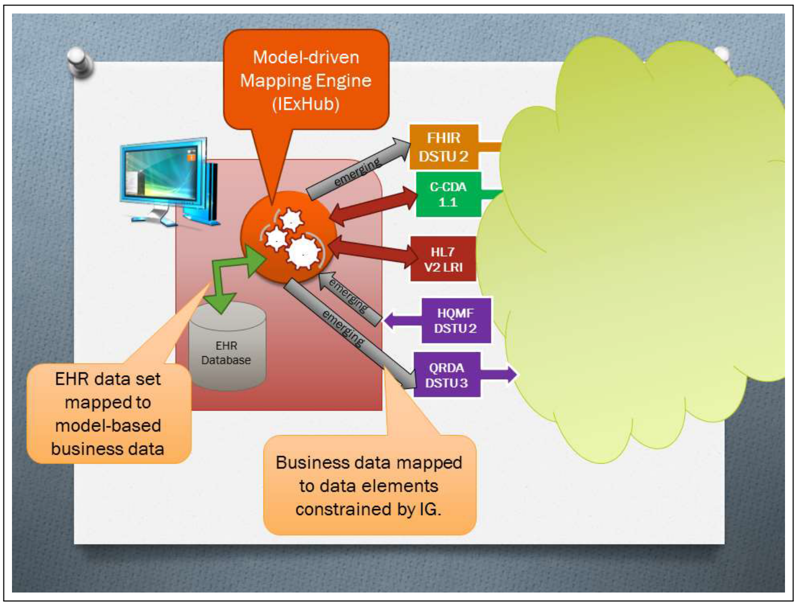

Figure 6: Semantic Mapping enables Meaningful Use standards adoption.

based maps for implementation guides rather than base standards. MDI also recognizes the need to support a variety of interoperability specifications and leverage clinician-designed knowledge and create a framework to support these standards without many-to-many syntax maps and relying instead of one-to-many semantic maps.

Key benefits of MDI include:

- Simplifying the process of mapping local EHR or other local data to standard semantic definitions using a canonical information representation, ensuring that information semantics rather than format drive any decision related to mapping data across systems and organizations.
- Create reusable open-source mapping definitions that enable diverse EHR or other systems to conform to common information exchange formats. A library of mapping/transformation models specific to an information exchange standard implementation guide (e.g. HL7 C-CDA 1.1, HL7 LRI, etc.) would ensure that meaning of business information is mapped identically across information exchanges.
- Promote mapping to implementation guides, not to a base information exchange Standard/format. This is an important principle that acknowledges that health information technology standards require explanation using additional constraints before a real-life implementation is possible. Therefore, by mapping to an implementation guide or a profile of a standard, we ensure that the business semantics are clearly addressed and have unambiguous or unique representations in the payload for each business data element. This principle also guarantees that the complexity of the "on the wire" representation of business data is isolated to a specific map and does not permeate into an application's own representation, thus separating concerns of application optimization from information exchange optimization.
- Promote model-based development of specifications for new profiles and templates traceable to the well-defined, consensus based business data dictionary leading to an implementation ready specification.

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