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Toward Greater Health Information Interoperability in the United States Health System

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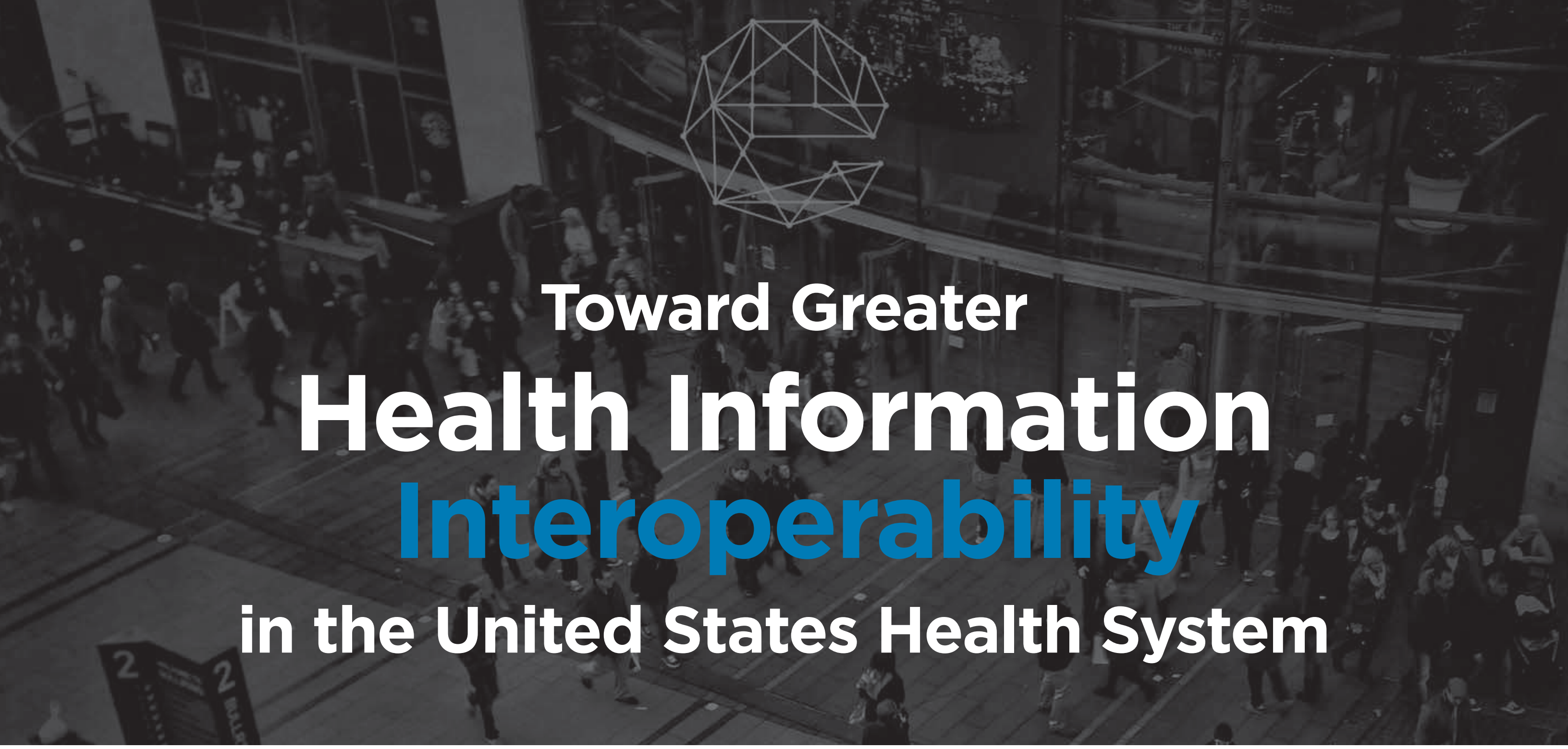

Toward Greater Health Information Interoperability in the United States Health System

EXECUTIVE SUMMARY

Health information interoperability—the ability to capture, review, share, and reuse electronic health data (EHD) seamlessly across the health system—has potential benefits for all stakeholders in the United States health care ecosystem. Despite significant health information infrastructure investments in recent years, however, the flow of information needed to achieve true learning health systems is still early in its development. Notably, there is a critical need to integrate existing technical standards with evolving health care processes in ways that will promote a culture of interoperability.

To achieve interoperability, EHR and other health information technology (IT) systems must have a common way to connect across the 4 distinct levels, or "layers" of interoperability: 1) process, 2) semantic, 3) syntactic, and 4) technical. There are more than 75 health IT standards in use today, most of which support the technical, syntactic, and semantic layers of interoperability. By comparison, only two standards in use today directly address process interoperability, which enables health data producers and users to integrate technology, workflows, and processes in meaningful ways that improve information exchange, outcomes, efficiency, and cost effectiveness.

This brief addresses three specific opportunities to enable greater process interoperability: 1) better integrating EHRs and other new forms of health IT into clinical workflows, 2) creating the right market incentives for health information interoperability, and 3) ensuring the security and privacy of health information as it flows through and between health IT systems.

Many stakeholders in the United States health care system agree that greater health IT interoperability is critical to system transformation and to improving health. In turn, achieving greater health information interoperability will require more "systems-level" thinking to better align technology use with the processes, workflows, tools, and policies within the United States health system. A critical next step for all stakeholders is to optimize the use of current standards for EHRs and other health IT in alignment with the social and cultural factors that most directly influence interoperability within the health system.

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Interoperability: The Key to Unlocking the Potential of Big Health Data?

The health care community has long recognized the potential for health information technology (IT) systems—electronic health records (EHRs) systems in particular—to improve clinical care and health while reducing costs.[1,2] The ability to electronically capture, review, share, and reuse electronic health data (EHD) has potential benefits for all stakeholders in the health care ecosystem, and is an important component of efforts to redesign health care—to pay for the value, rather than volume, of services. Ideally, EHD can be used to continuously improve health systems through ongoing analysis and quality improvement—a goal many refer to as achieving a *continuously learning health system* (LHS).[3]

One major challenge to the development and execution of strategies to transform the delivery system is managing the sheer volume, distinct formats, and complexity of EHD in EHR systems. A typical EHR, for example, contains data from a range of different domains (e.g., patient demographics, clinical information, and administrative and payment information) in a number of different formats; within these domains, there are also several distinct data elements—including race and ethnicity, medication history, chief complaint for current visit, vital signs, and insurance providers (Figure 1). In parallel, the number of health IT standards has proliferated to keep pace with the intricacies and uses of health data. These challenges will only expand as patient-generated, patient-reported, and community level data[4] become even more important components of assessing health.

Adding to this complexity is the variety of EHR vendors and products. As of March 2015, 179 vendors offer EHR systems that have been certified by the United States Office of the National Coordinator for Health IT (ONC), with the top 10 EHR vendors providing the primary EHR for more than 9 out of 10 hospitals.[5] At the same time, most EHRs are built on top of legacy systems and are highly tailored to meet the needs of a particular provider group or hospital, resulting in numerous variations of architecture and organizational processes.

It has long been recognized that the capacity to share information across systems—e.g., health information exchange (HIE) enabled by health IT—is critical to improving care and health. Yet, the rise in the number of technology products and their diverse implementation in practice have created challenges for the interoperability of health information—that is, the ability of health systems or products to exchange and use information with and from other systems or products. This interoperable flow of information is necessary to ensure that health information moves fluidly across care settings within a health system (e.g., from local outpatient clinic to surgical unit at a hospital), between IT systems within a hospital (e.g., from physician order entry to pharmacy), as well as across health systems in the United States and internationally (e.g., allowing a provider to view a traveler's patient records).

Across the care continuum, this flow of health information has implications for continuity of care that have an impact on patient safety and quality. And while meaningful HIE and interoperability are relatively easy to describe in principle, there are significant challenges to implementing effective health IT in practice. Notably, there is a need to build upon current standards to integrate existing technical standards with health care processes and workflows in order to promote a culture of interoperability. This brief reviews key interoperability concepts and related standards, and discusses major social and cultural challenges of implementing health IT that must be considered in order to achieve the goals of an LHS.

Figure 1. Examples of Diverse Sources of Health Information*

ADMINISTRATIVE INFORMATION	PATIENT INFORMATION	CLINICAL INFORMATION
Billing codes	Name	Medications
Payments	Sex	Medication allergies
Insurance provider	Date of birth	Problems
Admission and discharge dates	Race	Lab tests and results (including text and images)
Admission and discharge locations	Ethnicity	Care plan
	Preferred language	Immunizations
	Home address	Smoking status
	Phone numbers	Procedures
	Patient ID numbers	Vital signs
		Diagnoses
		Discharge instructions
		Cognitive status
		Functional status

Note: *Examples come primarily from the Meaningful Use Common Data Set; for more information visit http://www.healthit.gov/sites/default/files/c-cda_and_meaningfulusecertification.pdf

Aligning Standards and the Layers of Interoperability

To successfully execute interoperable exchange of health information, separate EHR systems need a common way to connect, and this connection must be enabled at four distinct levels—or "layers": process, semantic, syntactic, and technical[6] (Table 2). Components within each of these layers must be integrated with and supportive of the others to facilitate meaningful HIE. For example, meaningful HIE must ensure that each system can read *both* the structure of the data (syntactic interoperability) and what the resulting information means (semantic interoperability) in context. One principal obstacle to achieving a fully interoperable United States health system is the need to synchronize all the components within the four layers in a way that will best facilitate the flow of health information.

Supporting each interoperability layer is a set of technical standards or shared specifications that underlie how systems manage, format, and share health information. However, due to the way that EHR technology and systems have evolved, coupled with a high degree of local customization for specific organizations and use cases, there are numerous and sometimes redundant standards in use across the health system.

In its final *Shared Nationwide Interoperability Roadmap*,[7] ONC provides a set of definitions to help stakeholders to better understand the proliferation of standards by sorting them into distinct categories:

1. vocabulary and code sets (semantics);
2. format, content, and structure (syntax);
3. transport;
4. security; and
5. services.

Because standards are an important tool to improve interoperability between technologies and systems, it is useful to understand how the layers of interoperability align with the ONC's standards classification. Figure 2 demonstrates how each layer of interoperability maps to the categories of standards and offers examples of standards within each layer.

Understanding the Evolution of Systems and Standards

Many EHRs evolved as separate, stand-alone systems that use their own internal protocols and definitions, some of which were developed and coded in-house by clinical informatics experts.[8] Likewise, long-standing EHR products are often heavily customized versions of a vendor's existing product. Both evolutionary paths have led to systems that are primarily suited to meet individual organizations' needs such as local workflows. The result is that communication *between* different systems—and even among products from the same vendor or developer—is not always possible.

Like many of the key technologies in use today, foundational work on EHRs dates back to the late 1960s and 1970s.[9,10] One consequence of this relatively lengthy evolution is that many systems were designed and implemented with insufficient input from end users. In great part this is because many EHR systems were developed before the wider community of stakeholders was able to help define, create, and adopt a set of common technical standards.

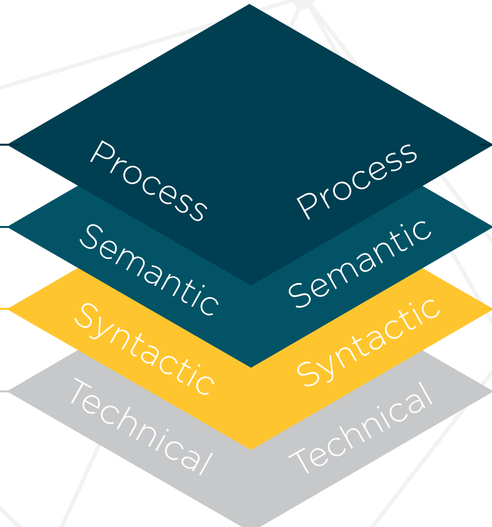
Despite efforts aimed at standards coordination and harmonization by a number of stakeholders over the last several years—including ONC, ANSI, HITSP, and others—there are still numerous health IT standards from a number of standards development organizations (SDOs). These range from widely used standards generated or coordinated by organizations such as Health Level Seven International (HL7), Integrating the Healthcare Enterprise (IHE), and the National Library of Medicine,[11] to domain specific standards that may support only one department in one location.

Gaps and Opportunities for Standards to Support the Layers of Interoperability

Appendix A maps the layers of interoperability to a number of important standards drawn from ONC's *2016 Interoperability Standards Advisory*[12] and elsewhere. The *Interoperability Standards Advisory*, published annually, uses a public process that engages with all health related stakeholders to identify the best available standards and implementation specifications so that developers and others could know which ones to use for specific interoperability needs.

Appendix A describes the general functions of each standard in the context of the layers of

Figure 2. Mapping the Layers of Interoperability to Categories of Health IT Standards



CATEGORIES OF HEALTH IT STANDARDS	EXAMPLES OF STANDARDS SUPPORTING EACH LAYER
Incorporates all categories of Health IT standards to ensure successful implementation, adoption, and use.	Audit Trail and Node Authentication (ATNA), Basic Patient Privacy Consents (BPPC)
1. Vocabulary and terminology	SNOMED, LOINC, RxNORM, ICD-9, HL7, Fast Healthcare Interoperability Resources (FHIR)
2. Content format	XML, C-CDA, Structured Data, Capture (SDC)
3. Transport 4. Security 5. Standards for Services	TCP/IP, SMTP, S/MIME, HTTPS, X.509, DNS+LDAP

Process
The ability for health data users (e.g. care providers, patients, EHR vendors, technology companies) to integrate technology, workflows, and processes in meaningful ways that improve information exchange, outcomes, efficiency, and cost effectiveness.

Semantic
The ability of two systems to communicate and exchange information so that the data is read and interpreted the same on both ends.

Syntactic
The ability to transfer data between two systems so that it can be read at the machine-level and structured or formatted appropriately without any deeper interpretation.

Technical
This layer includes all the protocols by which a connection between two systems or devices is established to enable data exchange.

interoperability and ONC's categories, and it demonstrates the large number of standards presently supporting EHRs and interoperability efforts. This array of standards options underscores the range of choices faced by entrepreneurs and developers working in health IT who may not know which standard to adopt for a given purpose. While Appendix A is not an exhaustive overview of ***all*** health IT standards, it helps to illustrate the breadth and complexity of the landscape of standards facing those working to implement interoperable health IT systems today.

The appendix also highlights potential gaps in standards or process guidance. For example, the vast majority of standards or specifications in Appendix A are intended to ensure that health IT systems can exchange electronic health data in a secure, reliable, and meaningful way. This is not particularly surprising given the primary importance of developing standards to support the technical aspects of data exchange.

By comparison, only two standards or specifications in the appendix address *process interoperability*. As noted in Table 2, "process interoperability" is "the ability for health data users (e.g., care providers, patients, EHR vendors, technology companies) to integrate technology, workflows, and processes in meaningful ways that improve information exchange, outcomes, efficiency, and cost-effectiveness."

Despite the great importance of process interoperability in developing functional, useful EHR systems and other health IT, there are several likely reasons for a limited focus on standards and standardized approaches to achieve process interoperability thus far. The first is that policies over the last few years have appropriately focused on increasing EHR adoption rates and the use of basic technical standards. The result is that it is taking time to "turn on the tap" and get electronic health data flowing freely. Second, it is probable that developing process standards is simply more difficult given the variation in local clinical workflows. Third, more standardized efforts to promote process interoperability will likely disrupt local practice and workflow. At least in some settings, this potential for disruption will necessitate additional effort by vendors and local institutions to accommodate new, more standardized processes. As discussed in the next section, these types of social and cultural challenges are significant and will take time and effort to resolve.

Achieving Process Interoperability: Addressing Workflow, Market Incentives, and Privacy

Perhaps the greatest challenges to interoperability are those most closely linked with process interoperability. Below we discuss three critical challenges to process interoperability: (1) integrating EHRs and other new forms of health IT into clinical workflow, (2) creating the right market incentives for interoperability, and (3) ensuring the security and privacy of health data as it flows through and between health IT systems.

Implementing EHRs into Clinical Workflow

Infrastructure investments from the American Recovery and Reinvestment Act of 2009 (ARRA), Health Information Technology for Economic and Clinical Health Act (HITECH), and other sources, have better enabled United States providers to realize the benefits of useful information sharing such as improved care coordination;[13,14] increased feedback and shared decision-making with patients;[15] and patient real-time surveillance and reporting.[16] However, we now know that simply having technology infrastructure in place only gets us so far.[17] EHR developers and users must also recognize the role of human factors and the importance of workflows in the successful implementation and use of EHR systems and other health IT, including clinical decision support. Analyzing, understanding, and adapting clinical workflows and procedures within and across care providers to achieve greater interoperability, HIE, and improved outcomes are still major challenges.[18]

As one illustration of the importance of workflow, in 2014 the National Institute for Standards and Technology (NIST) issued a paper with recommendations regarding human factors and best practices for incorporating EHRs into clinical workflow.[19] The NIST report focuses on activities such as managing physician order sets and summarizing laboratory results, which require more relevant and flexible workflows. In the paper, NIST also offers recommendations for EHR developers to ensure that health IT improves clinical workflow, including the ability to prepopulate certain physician orders and design in order to enable physicians to maintain eye contact with a patient while interacting with the EHR.

A recent ***eGEMs*** paper[20] builds on NIST's 2014 recommendations and offers lessons based on efforts to implement the recommendations in a Veteran's Health Administration innovation (VHAi) project. The VHAi program described was designed to improve workflow at all four stages of a patient visit: (1) before the visit, (2) during the visit, (3) the patient discharge, and (4) visit documentation. Among other features, the prototype generates dynamic, patient-specific draft order sets for a physician during a clinical encounter and produces more standardized educational materials such as a one-page, patient-specific visit summary. The implementation pilot demonstrates the practicality of the NIST recommendations as well as next steps needed to study process interoperability.

An important caveat to the NIST recommendations is to consider the size and maturity of a given care organization. For example, large care provider organizations may be better prepared to absorb or offset the costs and effort associated with EHR implementation and workflow changes. However, smaller providers who may have purchased stand-alone, off-the-shelf EHR systems may not see the return on investment in adapting their systems, workflows, and processes for greater interoperability and health information sharing. These are considerations that will require further review and innovation to address.

Aligning Market Incentives for Interoperability

As noted recently by Edmunds et al.,[21] the financial incentives in the United States health care system "are not aligned in ways that encourage the sharing of health data between and across physicians, hospitals, plans, payers, researchers and patients." One consequence is that market incentives for broader, nationwide HIE and interoperability do not currently exist in the United States. The inherently competitive nature of the health care system—among vendors, technology companies, and even providers (for patients and staff alike)—is itself often a major disincentive to greater information sharing.

For this reason, among others, the Health IT Policy Committee's Clinical, Technical, Organizational and Financial Barriers to Interoperability Task Force recently offered recommendations[22,23] in a draft report for Congress aimed at accelerating payment incentives for interoperability. Overall, the task force notes that moving "interoperability up the priority list" for providers and vendors will likely take financial incentives that are more targeted than the Centers for Medicare and Medicaid Services (CMS)'s broader shift from fee-for-service to paying-for-value. As a result the task force's draft guidance includes specific recommendation for CMS to promote or require (1) specific HIE-sensitive payment incentives for vendors and care providers that incorporate performance measure criteria, and (2) a timeline for implementing payment incentives.

Ensuring the Security and Privacy of Health Data

Despite consensus regarding the critical importance of health information privacy and security,[24] there are numerous impediments to data sharing that must be addressed by patients and organizations to facilitate effective HIE. Interpreting the Health Insurance Portability and Accountability Act (HIPAA) has itself become a limiting factor for interoperability[25] and HIE since many organizations focus on efforts to maintain the privacy and security of personal health data—which may come into direct conflict with efforts to promote information sharing. Given the number of high-profile data breaches involving electronic health data in 2015,[26] these concerns are understandable; however, there remains a need to consider the balance of risk between privacy breaches and enabling beneficial uses (and reuses) of greater data sharing.

Among efforts to facilitate understanding and awareness of health IT implementation strategies, ONC, the Federal Communications Commission (FCC), and the United States Food and Drug Administration (FDA) recently issued a joint report[27] offering a strategy and recommendations for a risk-based regulatory framework pertaining to health IT, including mobile medical applications. The framework seeks to promote innovation, protect patient safety, and minimize regulatory duplication.

The report offers a number of recommendations related to interoperability, standards, and best practices and contains an appreciation of process interoperability challenges. Importantly, the report recognizes that

> [H]ealth IT products and technologies are not used in isolation. Rather, they are part of a larger sociotechnical system that includes people (e.g., patients and healthcare providers), healthcare organizations, health IT developers and vendors, processes (actions and procedures performed during the delivery of health care), and the environment of use.[28]

A new report from ProPublica conveys similar themes, emphasizing the harms of small-scale breaches that are often the result of health personnel who disclose personal health information because they are driven by "personal animus, jealousy or a desire for retribution."[29] While such breaches may be facilitated by electronic access to personal health information, the breaches are the result of human behaviors rather than technology, underscoring the need to manage privacy (and organizational processes) at all levels, with stiff consequences for violating health privacy.

Despite stakeholders' growing awareness of the need for improvement, much work remains for regulators, clinical leaders, researchers, payers, purchasers, and other stakeholders to better address process interoperability in support of HIE and broader health system transformation.

Systems-Level Thinking Is Key to Achieving Interoperability

Many stakeholders in the United States health care system—including patients, care providers, regulators, and vendors—agree that greater HIE and health IT system interoperability are critical to system transformation and to improving health.

To achieve these goals, systems thinking—which examines linkages and interactions between the components of a system—can help create a culture of interoperability that aligns the uses of technology with clinical and administrative processes, workflows, tools, and policies.

One exemplar of systems thinking applied to health care delivery comes from researchers at Geisinger Health System, who identify[30] nine key components of a framework for operationalizing an LHS. The framework proposes that the system integrate data and analytics, people and partnerships, patient and family engagement, ethics and oversight, evaluation and methodology, funding, organization, prioritization, and deliverables. Notable are the critical dependencies between all components of the framework—with an emphasis on the context in which the system generates and uses data and technology to achieve a common aim, such as improving patient safety and quality.

Many components within the operational framework that Geisinger is pursuing address culture and organizational processes; critically, they do not focus solely on technology or technical issues. The authors note the importance of understanding all dimensions of the "knowledge enterprise" within a system, from the people and partnerships that drive the system to the ethical considerations that underlie decisions about how health data are used for clinical practice and research. Awareness of these system factors, and pragmatic efforts to outline and address each, indicate progress toward integrating the standards and processes within the layers of interoperability using a systems approach.

The development and implementation of "live" LHSs is generating new lessons about ways to transform the health system so that we reward high value care rather than volume of care. Building on recent investments in EHR infrastructure and data analytics is a significant opportunity to accelerate progress toward a nationwide LHS that pays for value. As indicated by the new Senate draft discussion bill designed to address interoperability,[31] there are significant opportunities to define the key aspects of interoperability in health IT as part of the EHR certification process. In addition, the bill proposes a set of priority setting activities that may articulate key aspects of process interoperability where further standardization is needed.

A critical next step for all stakeholders is to consider the social and cultural factors that most directly influence process interoperability in health IT, while working to align the use of current standards. The EDM Forum will continue working with communities and stakeholders to identify and address the challenges to achieving functional interoperability, while supporting innovative, collaborative approaches that promote effective and secure HIE. In sum, efforts to integrate technology standards with organizational processes are now within our grasp. Working together, we can develop systems approaches that ensure that EHRs and other health IT systems are developed, implemented, and used in ways that best support health system transformation and improve health.

Acknowledgments

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About the EDM Forum

Started in 2010 with a cooperative agreement between the Agency for Healthcare Research and Quality (AHRQ) and AcademyHealth, the EDM Forum drives rapid collaboration between the diverse stakeholders who create the data, methods, and evidence to shape the next generation of health systems. The EDM Forum aims to identify and address the shared challenges experienced by those using electronic health data, with an emphasis on disseminating the methods and results of patient-centered outcomes research (PCOR) and developing collaborative approaches to move these innovations into practice.

For more information on the EDM Forum's work, and for access to more than 350 resources developed by the community to address shared challenges and to share innovative approaches using electronic health data, please visit www.edm-forum.org.

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Appendix A

Mapping Interoperability in Health IT: Layers, Standards, and Categories

INTEROPERABILITY LAYER	SDO OR COORDINATOR	STANDARD OR SPECIFICATION	DESCRIPTION	ONC INTEROPERABILITY ROADMAP STANDARDS CATEGORY
PROCESS	IHE	Audit Trail and Node Authentication (ATNA)	Profile establishes security measures that provide patient information confidentiality, data integrity, and user accountability. Limits network access between nodes and limits access to each node to authorized users.	Security
PROCESS	IHE	Basic Patient Privacy Consents (BPPC)	BPPC provides a mechanism to record the patient privacy consents and a method for Content Consumers to use to enforce the privacy consent appropriate to the use.	Security
SEMANTIC	HITSP/ANSI	C80	Defines the vocabulary for either document-based or message-based HITSP constructs such as CDA documents, HL7 V2 messages, etc. to support the interoperable transmission of information.	Vocabulary and terminology
SEMANTIC	HITSP/ANSI	C154	A library of Healthcare Information Technology Standards Panel (HITSP) defined data elements that are used for mapping to data elements from the HITSP selected standards. It defines data elements that have been constrained or used in other HITSP documents (such as Components, Transactions, Transaction Packages) and facilitates the consistent use of these data elements across the various HITSP selected standards.	Vocabulary and terminology
SEMANTIC	NCI	caDSR	The need to maintain and share data about data, or metadata, became the basis for the NCI's repository of CDEs, metadata and data standards—what is now known as the caDSR.	Vocabulary and terminology
SEMANTIC	CDISC	CDASH	CDASH defines a common minimum data set for data capture across all clinical research protocols in accordance with global regulatory requirements.	Vocabulary and terminology
SEMANTIC	CIMI	CIMI	An international collaboration dedicated to providing a common format for detailed specifications for the representation of health information content.	Vocabulary and terminology
SEMANTIC	ADA	Code on Dental Procedures and Nomenclature (CDT)	The purpose of the CDT Code is to achieve uniformity, consistency, and specificity in accurately documenting dental treatment. One use of the CDT Code is to provide for the efficient processing of dental claims, and another is to populate an Electronic Health Record (EHR).	Vocabulary and terminology
SEMANTIC	AHRQ	Common Formats	The term "Common Formats" refers to the common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events.	Vocabulary and terminology
SEMANTIC	AMA	CPT	Current Procedural Terminology (CPT) numeric code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers.	Vocabulary and terminology

		SDO OR COORDINATOR	STANDARD OR SPECIFICATION	DESCRIPTION	ONC INTEROPERABILITY ROADMAP STANDARDS CATEGORY
INTEROPERABILITY LAYER	SEMANTIC	HL7	CQL	Clinical Quality Language (CQL) Specification defines a representation for the expression of clinical knowledge that can be used within both the Clinical Decision Support (CDS) and Clinical Quality Measurement (CQM) domains.	Vocabulary and terminology
		CDC	CVX	The CDC's National Center of Immunization and Respiratory Diseases (NCIRD) developed and maintains HL7 Table 0292, Vaccine Administered (CVX).	Vocabulary and terminology
		IHE	Data Element Exchange (DEX)	DEX leverages the concept of a metadata registry to add mapping metadata to an annotated data capture form at the point of form design instead of the exchange of data instances.	Vocabulary and terminology
		FHA, ONC	The Federal Health Interoperability Model (FHIM)	FHIM is a project under a larger program called the Federal Health Interoperability Modeling and Standards (FHIMS), which is an initiative of the Federal Health Architecture (FHA). FHIM is a logical information model of information required for exchange in MU.	Vocabulary and terminology
		HL7	FHIR (Fast Healthcare Interoperability Resources)	FHIR is a standard for exchanging health care information electronically, leveraging the latest web standards, and applying a tight focus on implementability.	Vocabulary and terminology
		CMS	HCPCS	Healthcare Common Procedure Coding System (HCPCS) consists of CPT (Level I) and is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services, medical equipment, and prosthetics (Level II).	Vocabulary and terminology
	SYNTAX	ONC [?]	Applicability Statement for Secure Health Transport (DIRECT)	Applicability Statement for Secure Health Transport is intended to provide constrained conformance guidance on the interoperable use of a set of RFCs describing methods for achieving security, privacy, data integrity, authentication of sender and receiver, and confirmation of delivery consistent with the data transport needs for health information exchange (HIE).	Content format
		HL7	C-CDA	A streamlined version of CDA that is based on HL7 CDA Release 2. It consolidates multiple Implementation Guides (IGs) to support exchange of common types of clinical documentation and to provide a comprehensive library of reusable data elements.	Content format
		HITSP	CAP 135	This Capability addresses interoperability requirements to support the upload of specific captured data (e.g., public health surveillance reportable conditions, health care associated infection reporting) to Public Health Monitoring Systems and Quality Organizations Systems.	Content format
		HL7	CDA R2	First ANSI-accredited, XML-based standard in health care industry. It has human-interpretative text (without requiring additional software) and structured content. Part of the HL7 version 3 standard, and based on the Reference Information Model (RIM).	Content format
		HL7	CTS2	Common Terminology Services 2.0 (CTS2) details the behavioral requirements that specify how a proposed system will process and handle information.	Content format

		SDO OR COORDINATOR	STANDARD OR SPECIFICATION	DESCRIPTION	ONC INTEROPERABILITY ROADMAP STANDARDS CATEGORY
INTEROPERABILITY LAYER	SEMANTIC	HL7	HL7 Version 3 Clinical Document Architecture (CDA)	The HL7 Version 3 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between health care providers and patients.	Vocabulary and terminology
		HL7	HQMF	The Health Quality Measures Format (HQMF) is a standards-based representation of quality measures as electronic documents.	Vocabulary and terminology
		CDC/CMS	ICD-9-CM	Clinical Modification (CM) is the official system for diagnostic classification of morbidity data associated with United States hospitals. Typically, 3 digits in format.	Vocabulary and terminology
		CDC/CMS	ICD-10-CM	Clinical Modification (CM) is the official system for diagnostic classification of morbidity data associated with United States hospitals. Typically, 3 digits in format.	Vocabulary and terminology
		WHO	ICD-10-PCS	Procedure Coding System (PCS) used in the United States for medical classification of procedural codes. Typically, its format uses a letter followed by 2 digits.	Vocabulary and terminology
		WHO	International Classification of Diseases (ICD) 10	ICD-10 is the standard diagnostic tool for epidemiology, health management and clinical purposes.	Vocabulary and terminology
		Regenstrief Institute	LOINC	Logical Observation Identifiers Names and Codes (LOINC) is a common language (set of identifiers, names, and codes) for clinical and laboratory observations.	Vocabulary and terminology
		Medicomp Systems	MEDCIN	Provides integrated physician and nursing documentation, clinical decision support, and patient management, mapped to reference terminology standards. It's a proprietary, standard system of medical vocabulary that is point-of-care terminology intended for EHR use.	Vocabulary and terminology
		Northrop Grumman/ICH/IFPMA	MedDRA	A clinically validated, international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry throughout the entire regulatory process—from premarketing to postmarketing activities; and for data entry, retrieval, evaluation, and presentation.	Vocabulary and terminology
		First DataBank	Multilex DDF	The United Kingdom's most comprehensive and widely used drug databases—and it is integrated into clinical systems across the whole health care community.	Vocabulary and terminology
		CDC	MVX	The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) developed and maintains HL7 Table 0227, Manufacturers of Vaccines (MVX), which includes both active and inactive manufacturers of vaccines in the United States.	Vocabulary and terminology
		NCPDP	National Council for Prescription Drug Programs Formulary and Benefits v3.0	Provides a standard means for pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to prescribers via technology vendor systems.	Vocabulary and terminology

		SDO OR COORDINATOR	STANDARD OR SPECIFICATION	DESCRIPTION	ONC INTEROPERABILITY ROADMAP STANDARDS CATEGORY
INTEROPERABILITY LAYER	SEMANTIC	CMS	National Provider Identifier Standard (NPI)	NPI is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard that facilitates a unique identification number for covered health care providers.	Vocabulary and terminology
		FDA	NDC	National Drug Code (NDC) is a unique 10-digit, 3-segment numeric identifier used in the United States for drugs intended for human use.	Vocabulary and terminology
		CDC	PHIN-VADS	A web-based enterprise vocabulary system for accessing, searching, and distributing vocabularies used within the Public Health Information Network (PHIN). PHIN Vocabulary Standards is a key component in supporting the development and deployment of standards-based public health information systems.	Vocabulary and terminology
		HL7	QICore	QICore FHIR profiles define the Quality Information and Clinical Knowledge (QUICK) logical model. The QUICK model, derived from Quality Improvement Core (QICore), provides a uniform way for clinical decision support and quality measures to refer to clinical data.	Vocabulary and terminology
		NIH	RxNORM	Provides a normalized naming system for generic and branded drugs, and is a tool for supporting semantic interoperation between drug terminologies and pharmacy knowledge base systems.	Vocabulary and terminology
		NLM	RxNorm	RxNorm is a standardized nomenclature for clinical drugs.	Vocabulary and terminology
		IHTSDO	SNOMED-CT	Machine-readable collection of structured medical terminology and used internationally (multilingual).	Vocabulary and terminology
		IHTSDO, NLM	SNOMED-CT	SNOMED-CT, a comprehensive clinical terminology, is one of a suite of designated standards for use in U.S. federal government systems for the electronic exchange of clinical health information.	Vocabulary and terminology
		Regenstrief Institute	UCUM	The Unified Code for Units of Measure (UCUM) system is intended to include all units of measures. The purpose is to facilitate unambiguous electronic communication of quantities together with their units.	Vocabulary and terminology
		NLM	UMLS	A set of files and software that combines health- and biomedical vocabularies and standards to enable interoperability by enabling linking of information (e.g., medical terms, drug names, and billing codes) across different systems.	Vocabulary and terminology
	SYNTAX	Medical Imaging & Technology Alliance	Digital Imaging and Communications in Medicine (DICOM)	Digital Imaging and Communications in Medicine (DICOM) is the standard for the communication and management of medical imaging information and related data.	Content format
		W3C	Extensible Markup Language (XML)	XML is a simple, flexible text format derived from SGML (ISO 8879). Originally designed to meet the challenges of large-scale electronic publishing, XML is also playing an increasingly important role in the exchange of a wide variety of data on the Web and elsewhere.	Content format

		SDO OR COORDINATOR	STANDARD OR SPECIFICATION	DESCRIPTION	ONC INTEROPERABILITY ROADMAP STANDARDS CATEGORY
INTEROPERABILITY LAYER	SYNTAX	HL7	Healthcare Privacy and Security Classification System	Explains how to tag sensitive data with metadata indicating privacy and security classification, permissible purposes of use, and obligations and refrains, thereby enabling sending and receiving systems to comply with regulatory requirements.	Security
		HL7	HL7 Implementation Guide for CDA, Release 2: Consent Directives, Release 1	Describes constraints on the CDA R2 header and body elements used to express Privacy Consent Directive documents. The CDA IG for Consent Directives is intended to provide multiple representations for expressing privacy preferences and for exchanging privacy policies.	Security
		HL7	HL7 Implementation Guide for CDA Release 2.0: Form Definition Document, Release 1	This project will define a specification for the structured representation of a Form Definition and Questionnaire Response documents focusing initially on the requirements presented by the Continua Health Alliance Questionnaire Use Case and leverage HL7 CDA base standard and derived implementation guides.	Security
		HL7	HL7 V2.x	Defines a series of electronic messages to support administrative, logistical, financial, and clinical processes. Messaging standard that supports human readable, non-XML electronic messages based on segments (lines) and one-character delimiters.	Content format
		HL7	HL7 V3	HL7's Version 3 (V3) Normative Edition is a suite of specifications based on HL7's Reference Information Model (RIM) that provides a single source that allows implementers of V3 specifications to work with the full set of messages, data types, and terminologies needed to build a complete implementation.	Content format
		HL7	ICSR	The Individual Case Safety Report (ICSR) is a Health Level Seven standard for the capture of the information needed to support the reporting of adverse events, product problems, or consumer complaints associated with the use of FDA-regulated products.	Content format
		ISO, NIH/NLM	ISO/IEC 11179	ISO/IEC 11179 specifies the kind and quality of metadata necessary to describe data, and also specifies the management and administration of that metadata in a metadata registry (MDR).	Content format
		ISO	ISO/IEC 19763	The primary purpose of the multipart standard ISO/IEC 19763 is to specify a metamodel framework for interoperability. This part of ISO/IEC 19763 specifies a metamodel for registering forms.	Content format
		Netscape/ Mozilla	Javascript	An interpreted computer-programming language originally implemented as part of web browsers so that client-side scripts could interact with the user, control the browser, communicate asynchronously, and alter the document content that was displayed.	Content format
		OMG	MDMI	General purpose specification, written in UML, that lets financial institutions map legacy financial data correctly to ISO 20022 compliant formats.	Content format

		SDO OR COORDINATOR	STANDARD OR SPECIFICATION	DESCRIPTION	ONC INTEROPERABILITY ROADMAP STANDARDS CATEGORY
INTEROPERABILITY LAYER	SYNTAX	CDISC	ODM	Operational Data Model (ODM) is a vendor-neutral, platform-independent format for interchange and archiving of clinical study data; the model includes the clinical data along with its associated metadata, administrative data, reference data and audit information.	Content format
		HL7	QRDA	Quality Reporting Document Architecture (QRDA) is a document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data.	Content format
		HL7	QUICK	The QUICK data model is an initiative of the Clinical Quality Information (CQI) and Clinical Decision Support (CDS) HL7 Work Groups. This data model is autogenerated from the HL7 Quality Improvement Core (QICore) FHIR Profiles.	Content format
		IETF	RFC 5646	RFC 5646 describes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object.	Content format
		IHE	RFD	Retrieve Form for Data Capture provides a method for gathering data within a user's current application to meet the requirements of an external system—supporting the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.	Content format
		IHE	RPE	Retrieve Protocol for Execution (RPE) enables a health care provider to access a process definition such as a research protocol, and to execute automated activities, without leaving an EMR session.	Content format
		OASIS	SAML	Security Assertion Markup Language (SAML) is an XML-based framework for communicating user authentication, entitlement, and attribute information between security domains, that is, between an identity provider (producer of assertions) and service provider (consumer of assertions).	Security
		HL7	vMR	vMR (for CDS or GELLO) describes a data model for representing data from clinical information systems to be analyzed or produced by clinical decision support engines.	Content format
		IHE	XD*	XD* Metadata has three objects—submission set, document entry, and folder—that are represented in XML.	Content format
		ONC [?]	XDR and XDM for Direct Messaging	This specification addresses use of XDR and XDM zipped packages in email in the context of directed messaging to fulfill the key user stories of the Direct Project.	Content format
		OMG	XMI	Object Management Group (OMG) standard for exchanging metadata information via XML.	Content format
		IHE	XUA	Cross-Enterprise User Assertion Profile (XUA) provides a means to communicate claims about the identity of an authenticated principal (user, application, system, etc.) in transactions that cross enterprise boundaries.	Content format

		SDO OR COORDINATOR	STANDARD OR SPECIFICATION	DESCRIPTION	ONC INTEROPERABILITY ROADMAP STANDARDS CATEGORY
INTEROPERABILITY LAYER	TECHNICAL	ONC	Direct	The Direct Project develops specifications for a secure, scalable, standards-based way to establish universal health addressing and transport for participants (including providers, laboratories, hospitals, pharmacies and patients) to send encrypted health information directly to known, trusted recipients over the Internet.	Transport
		ONC	esMD Author of Record Level 1 Implementation Guide	Addresses the replacement of wet signatures with a digital signature, and covers both the use of digital signatures on document bundles and delegation of rights artifacts.	Security
		IETF	HTTPS	Hypertext Transfer Protocol Secure is a communications protocol for secure communication over a computer network, with especially wide deployment on the Internet.	Security
		OASIS	OASIS XAdES	Defines one abstract profile of the OASIS DSS protocols for the purpose of creating and verifying XML- or CMS-based Advanced Electronic Signatures. It also defines two concrete subprofiles: one for creating and verifying XML Advanced Electronic Signatures, and the other for creating and verifying CMS-based Advanced Electronic Signatures.	Security
		OMG	REST	Representational State Transfer (REST) is a style of software architecture for distributed systems. REST exemplifies how the Web's architecture emerged by characterizing and constraining the macro-interactions of the four components of the Web—namely origin servers, gateways, proxies and clients—without imposing limitations on the individual participants.	Transport
		W3C	SOAP	Simple Object Access Protocol (SOAP) is an XML-based protocol messaging specification for exchange of structured information with three major characteristics: Extensibility, Neutrality, and Independence.	Transport
			TCP/IP (Transmission Control Protocol/ Internet Protocol)	TCP/IP is the basic communication language or protocol of the Internet. It can also be used as a communications protocol in a private network (either an intranet or an extranet).	Transport
		IETF	TLS	Transport Layer Security (TLS) and its predecessor, Secure Sockets Layer (SSL), are cryptographic protocols that provide communication security over the Internet.	Security
		OASIS	XACML	Defines a declarative access-control policy language implemented in XML and a processing model describing how to evaluate authorization requests according to the rules defined in policies.	Security

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