ELECTRONIC HEALTH RECORD

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1. ELECTRONIC HEALTH RECORD

The term electronic health record (EHR) refers to the complete set of information that resides in electronic form and is related to the past, present, and future health status or health care provided to a subject of care. The primary purpose of EHRs is the documentation, retrieval, transmission, linking, and processing of multimedia information to legitimate users for the delivery of knowledge and decision support that enhance efficient and secure health-related services, regardless of the health care model applied. Secondary uses of EHRs are related to policy development, education, research, quality management, and disease surveillance via pseudonymized or anonymized datasets requiring, in most of the cases, explicit consent on behalf of the subject of care.

Important characteristics of an EHR that stem from the above definition are:

- its patient-centered notion, as it is related to a single subject of care;
- its longitudinal spanning, possibly from conception until the end of one's life;
- its breadth, as it includes content from disparate in nature sources; and
- its association with not only previously recorded and currently available information, but also to prospective health status information.

EHRs usually contain, without being limited to, observations, opinions, and care plans, and, as a whole, act as a long-term accumulator of information about what has happened to or for the subject of care. EHRs have the potential to significantly improve quality of care and health outcomes. Anticipated benefits of an EHR include:

- around-the-clock availability of key health information, regardless of where the subject requiring care happens to be;
- more effective and efficient treatment and planning;
- reduction of mistakes because of lack of information;
- less health risks because of the reduction of redundant procedures and improved subject of care safety;
- empowerment of individuals to exercise greater control over their own health by enabling them to make informed choices about options available to them; and finally
- improved quality of care, as a result of the formulation of relevant health-care policies, by means of collectively anonymized information contained within individual EHRs.

2. BACKGROUND

The term EHR has undergone substantial changes throughout recent years. Terms like CPR, CMR, PHR, EMR, and EPR have been used in the past, and although the EHR has turned out to represent the most generic term, each one of them represents a different concept in the current understanding of EHR (1).

The term computer-based patient record (CPR) was used by the Institute of Medicine report (2) to denote the computer-stored collection of comprehensive health information about one patient (i.e., a representation of all patient data that one would find in a coded and structured, machine-readable form).

The term patient-carried medical record (sometimes abbreviated as PCR) appeared in the mid-1980s to denote longitudinal patient information stored in an intermittently connected device such as a smart card.

The term computerized medical record (CMR), although sometimes promoted as a form of the EHR, in reality refers to document imaging-based systems. It is directly linked to the scanning of traditional paper-based documents into computer systems and appropriately indexing them for instant multiuser access.

The term electronic patient record (EPR) is similar to the CPR, with the exception that it focuses only on relevant information for specific medical problem episodes. Up until recently, it was considered a synonym for CPR, and its usage is still often inconsistent in many places.

The term digital medical record (DMR) refers to a web-based patient record, maintained by a health-care provider or health plan, to be accessed by health-care practitioners.

The term electronic medical record (EMR) refers to an information system managing patient information within an enterprise (e.g., hospital, clinic, primary health-care center). It is medically focused, includes full interoperability required to cover all computer-based services provided within an enterprise (e.g., order entry, results status notification, follow-up scheduling), and can be used as a stepping stone toward an EPR, DMR, or EHR.

The term personal health record (PHR) introduces the notion of patient empowerment through personal management and sharing of personal health information, and that of others for whom they are authorized. An important prerequisite for effective use of personal health records (PHRs) is the understanding of their content (at least in general terms) by individuals.

Finally, the recently introduced term of continuity of care record (CCR) refers to a transportable set of basic information about a patient's health care (e.g., allergies, medication, history of present illness) to be shared between both clinicians and the patient. CCR addresses more directly the issue of patient data summaries used for transfers, referrals, and discharges, and is created by a health-care provider at the end of an encounter or at the end of an episode of care.

Today, EHR has turned out to be the favored nomenclature for a sophisticated, generic term covering all concepts described above. In contrast to CPR, it consists

of components implemented according to measurable and realistic benefits, including PHR information. It is not limited to scanned documents only, like CMR, and includes wellness information and nontraditional links to external knowledge, like guidelines, protocols, and genetic information, contrasting both CPR and EPR. It integrates legacy systems (in contrast to DMR), extends beyond the boundaries set by a single health-care organization (in contrast to EMR), and is primarily created and managed by health-care professionals (in contrast to PHR).

3. TECHNICAL CHALLENGES

As a result of the fact that health care is delivered by many health-care providers, through one's lifetime, several episodes of care occur, having as a consequence the production of distributed segments of one's EHR. Data populating the EHR reside in a variety of highly heterogeneous, autonomous, and decentralized information systems. Therefore, a basis for the efficient correlation and linkage of EHR segments (and not necessarily their physical integration) among multiple organizations seems to be needed. Effectively, what is required is an approach where individual information providers for the EHR (i.e., the various EHR systems) are self-contained and autonomous, but together form part of a wider picture (3). It is foreseen that in the future one EHR system will directly communicate with other EHR systems. What is still missing is the ability to transparently locate those other systems that have pertinent information and directly access it on an as-needed basis.

A successful EHR realization requires, from a technological point of view, the existence of certain supporting features. Those features impose specific requirements that ought to be met in order to achieve user acceptance and meet the foreseen benefits. Certain technological requirements, imposed by end-user needs or expectations, as documented by the Professionals and Citizens Network for Integrated Care (PICNIC) (4) project, are listed below:

- Around-the-clock availability;
- Provision of fast responses even at high workload periods;
- Restricted access to information;
- Maintainability;
- Low usage cost;
- Role-based access to information;
- Secure communication of information;
- Activity monitoring;
- Access to reliable and up-to-date information;
- Support for native user interface;
- Support direct access to multimedia clinical data communication;
- Scalability;
- Support for standardized reference vocabularies;
- Functional and customizable user interfaces; and
- High availability.

Central issues related to any approach toward the adoption of the EHR are related to subject of care identification and access to the actual EHR information (5). In order for the EHR to deliver the longitudinal collection of information related to one's health, it must be in a position to resolve difficult indexing, location, and meaning issues. Access to all types of information related to the EHR must be provided for accessing, without being limited to, text and numeric values; structured and unstructured documents; multimedia information like waveforms, sound, and image files; or even analyzed Deoxyribonucleic Acid (DNA) sequences.

4. EHR ARCHITECTURE

The exact EHR content is dictated by the context upon which it is instantiated, and therefore in order to be in a position to support all possible domains of application, while at the same time facilitate the integration of all available autonomous EHR systems (i.e., systems for recording, retrieving, and manipulating information in EHRs (6,7) in a standardized manner, a general framework and an overall EHR Architecture (EHRA) must be in place.

This EHRA provides the generic structural components from which all EHRs are defined, in terms of a standardized or commonly agreed logical information model, totally independent of EHR systems that manage only subsets of one's EHR. In other words, the EHRA provides the generic structural components from which all EHRs are built, defined in terms of an information model.

The EHRA does not prescribe or dictate what is stored inside individual health-care records, nor does it prescribe or dictate how any EHR system is implemented. It also places no restrictions on the types of data that can appear in the record.

A standardized EHRA enables the whole or parts of the EHR to be shared and exchanged between authorized members of a multidisciplinary care team, including the subject of care, independently of any particular EHR system. EHR information conforming to a standardized EHRA should be capable of being accepted, processed, and presented by an EHR system that uses the EHRA irrespective of implementation.

Therefore, the purpose of an EHRA is

- to provide and enable interoperability (among EHR systems through the promotion of open standards);
- to adopt modularity (i.e., to facilitate the development, maintenance, and evolution of scaleable, secure, effective, and affordable EHR systems); and
- to support incremental evolution by building upon existing systems and functionalities while adding new capabilities as they become available.

Any architecture is usually represented by means of an architecture model. Example of such an architecture model is the Reference Model for Open Distributed Processing (RM-ODP) (8–11), which defines the standard reference model for open distributed processing systems. The RM-ODP framework for system specification consists of four fundamental elements:

– an object modeling approach to system specification;
– the specification of a system in terms of separate but interrelated viewpoint specifications;
– the definition of a system infrastructure providing distribution transparencies for system applications; and
– a framework for assessing system conformance.

According to RM-ODP, a viewpoint is a subdivision of the specification of a complete system, established to bring together those particular pieces of information relevant to some particular area of concern. RM-ODP is used actively by industry in the domain of health care, and the EHR is perceived from all five viewpoints defined by the standard, which complement each other and allow for a thorough and complete description of it. These five viewpoints are:

– the enterprise viewpoint, focusing on EHR purpose, scope, and policies;
– the information viewpoint, focusing on the semantics of the information and information processing performed;
– the computational viewpoint, enabling distribution through the functional decomposition into objects that interact at interfaces;
– the engineering viewpoint, focusing on the mechanisms and functions required to support distributed interaction between objects; and
– the technology viewpoint, focusing on the choice of technology.

EHRA levels can also be classified using the Health Informatics Profiling Framework (HIPF) (12) that provides a consistent method for describing and classifying "artefacts" within the domain of health informatics standards. Figure 1 shows the HIPF classification matrix with levels of specificity and types of perspective identified. Types of perspective are the basic questions that can be reviewed for any model or standard in order to address coordination, communication, and compatibility, whereas levels of specificity provide differentiation of the different aspects as one move from abstract to exact implementation specifications.

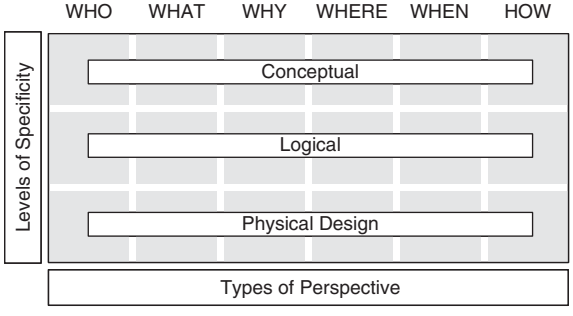

Figure 1. Health informatics profiling framework classification matrix. The conceptual level contains shared fundamental meanings. The logical level contains generalized models or standards without technological constraints (tactical and operational perspectives). The physical design level contains models and protocol definitions within technological constraints (operational perspective).

5. EHR CONTENT

In order to enable EHR system interoperability, adequate answers must be provided in dealing with semantic-level issues, which further requires an analysis on how terminologies and domain ontologies are currently embedded in these systems. In particular, attention must be given to what parts of the semantics are explicitly conveyed by means of the architecture of EHR systems, and what parts are only implicitly addressed and are in fact hidden in the user interface or in the pragmatic ways human users work with these applications.

Content of EHRs may include, without being limited to, information regarding subject of care identification, demographics, health history, clinical summaries, problem lists and diagnoses, diagnostic values and interpretation, care plans and decision support, treatments, consent, vital signs and alerts, provider identification, clinical documentation for chronic diseases, encounters, immunizations, primary care and community care, and quality and safety information. In order to use and interpret this information in a clinical relevant context, certain requirements are considered to be of great priority, including contextual information related to encounters and clinical decisions, privacy and confidentiality of information, disclosure law and logs, service agency directories, and information on current legislation.

Today, EHR systems cover ephemeral needs through clearly specified domain models, populated by means of controlled vocabularies, whereas certain needs for external communications have to be provided through well-defined interfaces. An attempt is being made to separate the level of knowledge from the level of information through the creation of clinical documents, which are based on a reference model and describe a domain concept. These documents, called archetypes (13), are the business entities represented in the EHR systems. Furthermore, the adopted domain reference model is based on relevant work of international standardization bodies and contains a limited and constant number of entities (see Fig. 2). In other words, if sufficiently generic and granular models in the commonly agreed ontology of structures can be created, then any health-care application's domain model can be mapped into (and out of) that particular reference model.

The International Standards Organization (ISO) (14) EHR ad hoc Group classification (15) lists four key prerequisites necessary to achieve semantic interoperability of EHR information, with the first two being required for functional interoperability:

– a standardized EHR reference model (namely, the EHRA) between the senders (or sharers) and receivers of the information;
– standardized service interface models to provide interoperability between the EHR and other components such as demographics, terminology, access-

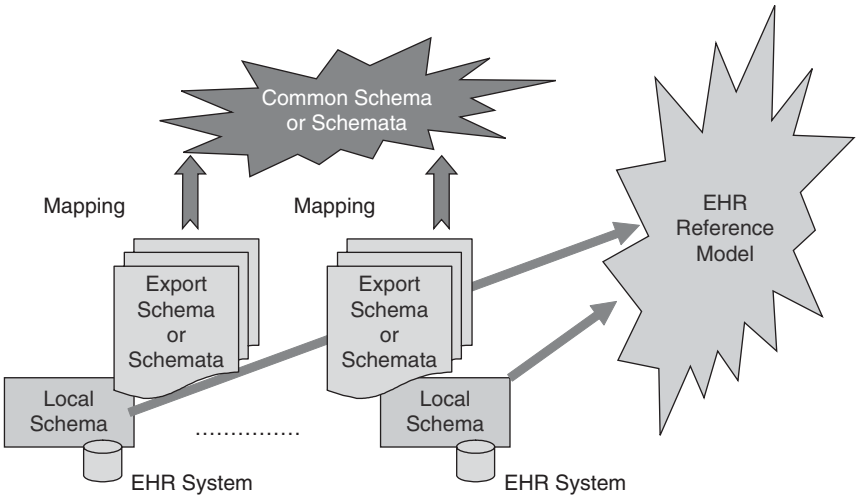

Figure 2. In order to make EHR information available outside the strict boundaries defined by each individual EHR system, the appropriate standardized interface that has to be defined must be based on a common domain model and a corresponding controlled common vocabulary. Subsequently, part (or the whole) of the schema of each EHR system must be mapped to that particular common, normalized schema. In order to achieve concept mapping in an efficient manner, a standardized EHR reference model must be in place to support standardized service interface models.

control, and security services in a comprehensive EHR system;
- a standardized set of domain-specific concept models, namely, archetypes and templates for clinical, demographic, and other domain-specific concepts; and
- standardized terminologies (which underpin the archetypes).

Rector (16) characterizes the problem of the interface of EHR and terminologies in terms of the notion of encapsulation (i.e., the amount and form of information in a terminological entity) and the choice between precoordinated and postcoordinated terms. The latter in particular is a serious problem because many concepts exist that are composites of more basic concepts, and the inclusion in a terminology in precoordinated form would vastly increase the size of the terminology, making it impossible to manage. The use of formal domain concept models provides a place for standardized postcoordination of terms, according to actual uses.

6. EHR MESSAGE HANDLING

In real life, content can be exchanged through messages. Messaging makes the exchange of form-based information such as prescriptions, laboratory results, referrals, and discharge summaries almost automatically possible between different health-care providers. When communicating clinical messages, a store-and-forward e-mail technique is often used providing the opportunity to communicate 24 h a day. As such messaging is suitable for standardization, national or regional standards make it possible to integrate clinical messages in Information Technology (IT) applications already in use.

Any given message supports a given process with a required dataset, which facilitates interoperability, both by supporting the propagation of information between internal computer systems in response to an "event" created by a process (unsolicited update), or through the movement of data in response to a "query" (solicited update). It is predicted that, in the future, information will not be sent or exchanged but rather posted and accessed, and authorized health-care professionals will be notified that they can access information.

7. SECURITY ISSUES

For communication between different information domains, a trusted end-to-end communication policy must be established. In general, access rights can be managed through:

- Authentication, being the process of ensuring that the communicating party is the one it claims to be
- Authorization, being the process of ensuring that the communicating party is eligible to request for a specific action

In addition, audit trails are needed to ensure accountability of actions of individual persons or entities, such as obtaining informed consent or breaching confidentiality. These records can be used to reconstruct, review, and examine transactions; track system usage; control authorized users; and detect and identify intruders.

The ISO Technical Committee 215 (ISO/TC 215) in its Technical Report (TR) 21089 (17) offers a guide to trusted end-to-end information flow for health (care) records and to the key trace points and audit events in the electronic entity/act record lifecycle (from point of record origination to each ultimate point of record access/use). It also offers recommendations regarding the trace/audit detail relevant to each.

Currently, the most common technological tool to cover various security aspects is the public key infrastructure (PKI). PKI is used to describe the processes, policies, and standards that govern the issuance, maintenance, and revocation of the certificates, public, and private keys the encryption and signing operations require. PKI incorporates the necessary techniques to enable two entities that do not know each other to exchange information using an insecure network such as the Internet. PKI is based on asymmetric cryptography, and each entity (user,

information system, etc.) is provided with a pair of keys (a private and public one).

The public key security infrastructure comprises the following services:

- Certification authorities that control and manage the PKI, publish public key certificates, and impose policies in their domain of authority
- Registration authorities that act on behalf of the certification authorities to declare registered in the domain of authority the certification authority manages
- Certificates management systems for management of certificates during their entire duration of validity
- X.500 directories that store public key certificates and public information for the holders of certificates and are used for the verification of digital certificates
- The user certificate for each of the users, which is published by the certification authority and is stored together with the user's private key, in a microprocessor card.

To guarantee the authenticity of a set of input data, the same way a written signature verifies the authenticity of a paper document, PKI uses digital signatures. European Prestandard (ENV) 13729 (18) on Secure User Identification for Healthcare Strong Authentication Using Microprocessor Cards defines how certificates are used to support authentication. Because of its importance, ENV 13729 is expected to be reviewed and enhanced further in the future.

ENV 13608 (19–21) on Security for health-care communication specifies a methodology for defining, expressing, and selecting a communication protection profile specification (i.e., integrity, confidentiality, availability, and legal accountability); defines a standard way of securing health-care objects (so that they can be transported over open, unsecured networks, or stored in open unsecured repositories), and specifies services and methods for securing interactive communications used within health care (including preservation of data integrity, confidentiality with respect to the data being communicated, and accountability in terms of authentication of one or both communicating parties).

Building on the digital signature technology, the digital signing of clinical documents is a special instance in which the nature of the clinical workflow may require that each participant only sign that portion of the document for which he/she is responsible. Older standards for digital signatures do not provide the syntax for capturing this sort of high-granularity signature or mechanisms for expressing which portion a party wishes to sign.

ISO/TC 215 is going to create a new standard (22600) on Privilege Management and Access Control (PMAC) (22,23), including structural and functional roles (e.g., delegation policies), which is very important for accessing a complex multilingual and multimedial virtual distributed EHR system.

8. THE NEED FOR A HEALTH INFORMATION INFRASTRUCTURE

A regional/national health information infrastructure (HII) is fundamentally about bringing timely health information to, and aiding communication among, those making health decisions for themselves, their families, their patients, and their communities. Individuals, healthcare providers, and public health professionals are key HII stakeholders and users, and the applications that meet their respective needs are important components of the infrastructure.

The envisioned environment for the EHR provides a decentralized view of the patient medical record, by dynamically composing key information that resides in a variety of heterogeneous, self-consistent, EHR systems that have been optimized with respect to the requirements of different medical specialties and levels of care. The initial sets of essential HII services that have been identified as required (24) include the following:

- Identification services for identifying subject of care based on their demographic data and correlating their identities across different identification domains
- Security services (like for encryption, authentication, etc.) to counter all kinds of security threats
- Health resource services for identifying availability of related resources such as organizations, devices, or software and the means for accessing them
- EHR indexing services for locating segments of clinically significant health information maintained by different clinical information systems
- Clinical observation access services for direct access to the sources of clinically significant health information where the complete, original, valid health information is kept
- Update brokers for maintaining consistency between indexing services and the various EHR systems
- Terminology services for the association of existing coding schemes and to enable the transformation of information from one form or representation to another.

This type of multitier approach, which heavily depends on the existence of both generic and health-care-specific middleware services/components, imposes a level of common design that varies according to the actual composition of the overall platform. "Health-care-related" components are needed for the proper identification of the subjects of care, the exchange of EHR indexing and health data (using appropriate health-oriented protocols), health resource(s) location(s), collaboration between health-care professionals and patients/experts, authorization for accessing health-care-related resources, medical terminology, and so on, whereas "Generic" components are required to support low-level, essential, platform-dependent functionalities like concurrency control, directories, event handling/notification, licensing, security (authenti-

cation, encryption, auditing, etc.), timing, and transaction management.

9. EHR STANDARDS

The major purpose of EHR standards is to facilitate improvements regarding interoperability, security, reliability, efficiency, and communication. However, interoperability is the area most lacking in information management today. Any standard for the EHR should be defined as part of a family of standards that collectively represent the major services in a distributed health computing environment. This layering approach allows standards to be built incrementally and enhanced over time.

Three main standards bodies are currently active in international standards directly related to the EHR. These bodies are the ISO (14), the European Committee for Standardization (Comité Européen de Normalisation—CEN), and HL7 (25). Within the United States, many other standards development organizations are involved in the development of EHR-related standards, most notably, ASTM (26) and the Object Management Group (OMG) Health Domain Task Force (HDTF) (27). Digital Imaging and Communications in Medicine (DICOM) (28) is the peak international standards development organization for image storage and communication in health.

HL7 Version 3 (V3) is designed to take a structured definition of data and process and produce a standard message based on both the data required and the process being supported into a standard methodology giving semantic interoperability. HL7 Clinical Document Architecture (CDA) Release 2 (R2) (29) is now ready as a compliment to HL7 V3 to move electronic "documents" as well as "messages." HL7 V3 and CDA documents (defined to be complete information objects that can include text, images, sounds, and other multimedia content) are characterized by persistence, stewardship, potential for authentication, wholeness, and human readability. They seem to be the preferred vehicle for the movement of structured clinical information, and they are based on the HL7 American National Standards Institute (ANSI) (30) standard Reference Information Model (RIM), which is depicted in Fig. 3.

The American Society for Testing and Materials (ASTM) (26) Continuity of Care Record standard, based on HL7 V3 CDA, is considered today the strongest candidate for becoming the first ISO (14) standard regarding EHR content.

At the same time, HL7 has approved the EHR System (EHR-S) Functional Model to move forward as a Draft Standard for Trial Use (DSTU) (31) intending to provide a summary of understanding of functions that may be present in an EHR-S, from a user perspective, to enable consistent expression of system functionality. The HL7 EHR-S DSTU is expected to form the basis for the international (ISO) standard for EHR system functionality.

The CEN Technical Committee 251 (CEN/ TC 251) (32) has started revising ENV 13606 (Electronic Health Record Communication) (33–36) to provide a rigorous and durable information architecture for communicating EHR to support the interoperability of systems and components interacting with EHR services, by having adopted the OpenEHR (37) archetype methodology and by using ISO 18308 (7) as an EHRA standard. The revised CEN European Standard (EN) 13606 will be a five-part standard consisting of the "Reference Model," the "Archetype Interchange Specification," the "Reference Archetypes and Term Lists," the "Security Features," and the "Exchange Models." CEN EN 13606 will also include compliance with HL7 CDA R2 (29).

ISO/TC 215 in its technical report 20514 (EHR Definition, Scope, and Context) (38) and its technical specification 18308 (Requirements for an EHRA) (7) provides an EHR definition and delivers a consolidated set of EHR requirements for using, sharing, and exchanging EHRs, independently of technology and current organization structures.

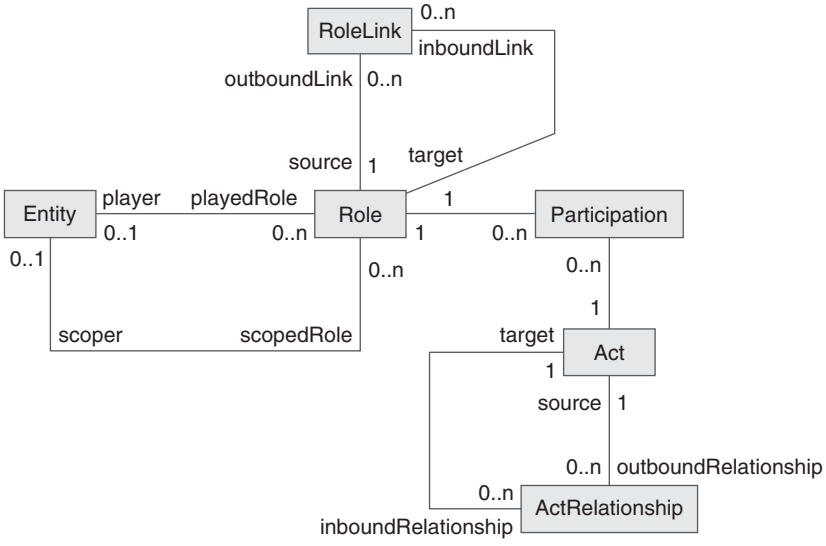

Figure 3. HL7 ANSI RIM links together an Entity (living subject, place, organization, or material), a Role (employee, access, licensed entity, or patient), Participation (managed participation), and an Act (patient encounter, control act, supply, working list, procedure, observation, context structure, device task, substance administration, financial contract, account, financial transaction, or invoice element).

The other main CEN EHR standard currently under development is CEN 12967 "Health Informatics—Service Architecture" (HISA), which is a major revision of the earlier ENV entitled "Healthcare Information Systems Architecture" (39). HISA is a high-level service-based architecture that is compatible with and "sits above" CEN 13606 and similar lower level standards such as HL7 CDA. The revised standard will consist of three parts that correspond to the first three viewpoints of ISO 10746 RM-ODP (8–11), i.e., "Enterprise viewpoint," "Information viewpoint," and "Computational viewpoint."

In parallel with the above efforts, the Integrating the Healthcare Enterprise (IHE) initiative (40) has introduced Cross-enterprise Document Sharing (XDS) as part of its IT Infrastructure Technical Framework (41,42), to support the sharing of electronic clinical documents among enterprises belonging to a "clinical affinity domain," contributing this way to the foundation of a shared EHR, through the sharing of clinical records in the forms of documents by specifying the appropriate metadata to facilitate document content discovery.

Although the IHE does not develop standards, it selects and provides detailed guidelines on how to use available standards to implement specific use cases to deliver simplified integration through sets of specifications that can be fully implemented.

10. DISCUSSION

EHR adoption will certainly require standards to facilitate interoperability. Although the approach will be decentralized, a HII of standards and privacy safeguards that restricts access only to authorized users will be required at some level. In addition, the issue of identifiers will need to be resolved so that significant health information can be connected at the subject of care level while ensuring individuals' privacy. At some level, an underlying HII of standards and privacy safeguards that supports a decentralized, federated architecture will be required to support electronic connectivity between health industry constituents. The issue of proper identification of the subject of care and comprehensive ability to locate individualized information will be paramount, requiring attention when demonstrations move from strictly local activities to regional (and ultimately national) interconnectivity.

Until now, the lack of a common HII has prevented health-care professionals from mining and analyzing disparate data sources. Similarly, the lack of a unifying architecture has proven to be a major roadblock for industry to develop interoperable and open solutions. In summary, today there is no unifying infrastructure or common standards for the technologies that most healthcare organizations need and use. As a result, health professionals cannot share their data or benefit from the innovative services that are developed by other healthcare professionals and organizations.

Because the delivery of a lifelong EHR is considered today a crucial factor in reducing medical errors (43), our ability to link unaffiliated sites to share patient data with each other (requiring the communication of complex and diverse forms of information between a variety of clinical and other settings) is expected to close the information gap that has traditionally impaired the delivery of the highest quality of care. A recent report by Kerr et al. (44) underscored the need to advance Health IT to disseminate knowledge and wisdom in health care. This study suggested that there is a huge disconnect between best practices and appropriate medical treatments and the clinical care that is actually delivered. Unfortunately the barriers to implement these technologies are high, and the immediate tangible benefits to health organizations remain indefinable.

Widespread adoption by physicians in their office practices will require the EHR system to make their professional lives easier, not more complex, and will need to provide a clear benefit to their clinical activities. At the same time, the development of comprehensive policies for privacy, consent management, and access to the EHR is required, together with the corresponding legislation. By having the entire EHR available, it will be far more possible to tailor medical care for each individual's clinical needs. Furthermore, Health IT will enable more effective disease management and prevention, leading to improved clinical outcomes. Genetic information is expected to become an essential part of EHRs and to help provide a basis for a new, personal, and proactive form of medicine to drive the delivery of individualized health care linking EHRs with clinical protocols and guidelines, while preventing thousands of diseases, by improving human knowledge.

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