National Institutes of Health
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Electronic Health Records Overview

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Accelerating and Enhancing Research From Basic Discovery to Improved Patient Care

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Applying Systems Engineering and Advanced Technology to Critical National Problems

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1. Introduction

This report provides an overview of the features and functions of major commercial electronic health records (EHR) and reviews how they are being used in academic medical centers (AMC). AMCs were among the pioneers in developing automated EHRs, and many AMCs are now faced with deciding whether or not to upgrade or replace their EHR systems. Commercial-off-the shelf (COTS) systems may be an attractive and cost-effective solution. COTS systems have defined some necessary data structures, vocabularies and interfaces appropriate for clinical trial research, and using COTS in AMC settings may improve data collection and sharing in ways that promote better clinical trials management and scientific discovery. But some AMCs continue to believe that custom-built EHRs are a better fit than COTS EHRs.

1.1 Definition of Electronic Health Records

This report uses the Health Information Management Systems Society's (HIMSS) definition of EHRs. It reads:

> "The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter, as well as supporting other care-related activities directly or indirectly via interface—including evidence-based decision support, quality management, and outcomes reporting."[1]

It is important to note that an EHR is generated and maintained *within an institution*, such as a hospital, integrated delivery network, clinic, or physician office. An EHR is not a longitudinal record of all care provided to the patient in all venues over time. Longitudinal records may be kept in a nationwide or regional health information system. Therefore, EHRs that are custom-designed or reside in other health care delivery venues are not reviewed in this document. The scope of this report focuses on COTS EHRs that may be appropriate for AMCs.

1.2 History of EHRs

The first known medical record was developed by Hippocrates, in the fifth century B.C. He prescribed two goals:

- A medical record should accurately reflect the course of disease.
- A medical record should indicate the probable cause of disease.[2]

These goals are still appropriate, but electronic health records systems can also provide additional functionality, such as interactive alerts to clinicians, interactive flow sheets, and tailored order sets, all of which can not be done be done with paper-based systems.

The first EHRs began to appear in the 1960s. "By 1965, Summerfield and Empey reported that at least 73 hospitals and clinical information projects and 28 projects for storage and retrieval of medical documents and other clinically-relevant information were underway."[3]

Many of today's EHRs are based on the pioneering work done in AMCs and for major government clinical care organizations. Notable early projects include:

- COSTAR (the Computer Stored Ambulatory Record), Barnett, et al., developed Harvard, placed in the public domain in 1975 and implemented in hundreds of sites worldwide.
- HELP (Health Evaluation through Logical Processing), Warner, et al., developed at Latter-Day Saints Hospital at the University of Utah (brought to market by the 3M Corporation). HELP is notable for its pioneering decision support features.
- TMR (The Medical Record), Stead and Hammond, Duke University Medical Center.
- THERESA, Walker, at Grady Memorial Hospital, Emory University, notable for its success in encouraging direct physician data entry.[4]
- CHCS (Composite Health Care System), the Department of Defense's (DoD) clinical care patient record system used worldwide.
- DHCP (De-Centralized Hospital Computer Program), developed by the Veteran's Administration and used nationwide.
- TDS, developed by Lockheed in the 1960s and 1970s.

These early projects had significant technical and programmatic issues, including non-standard vocabularies and system interfaces, which remain implementation challenges today. But they lead the way, and many of the ideas they pioneered (and some of the technology, such as the MUMPS language) are still used today.

1.3 Value of EHRs to Academic Medicine

1.3.1 AMCs Are Complex Enterprises

An AMC is actually multiple organizations within one. Many AMCs have multiple healthcare facilities, such as affiliated hospitals and clinics, numerous specialty diagnostic and treatment centers, laboratories associated with training and research, and complex business operations to manage all of these components. Because AMCs are providing tertiary medical care and are doing research, they often have more complex and more niche information systems to support new diagnostic and treatment modalities than a community hospital would have. For example, MedStar Health is a $2.7 billion healthcare organization, with seven hospitals in the Baltimore-Washington area. Georgetown University Hospital is only one of the research-conducting facilities within the network. One of the MedStar hospitals, Washington Hospital Center, audited the clinical systems within that facility alone and found that there were 300 distinct systems collecting clinical data—each with its own interfaces, maintenance costs, hardware requirements, etc.[5]

1.3.2 EHRs Respond to the Complex AMC Environments

The major value of integrated clinical systems is that they enable the capture of clinical data as a part of the overall workflow. An EHR enables the administrator to obtain data for billing, the physician to see trends in the effectiveness of treatments, a nurse to report an adverse reaction, and a researcher to analyze the efficacy of medications in patients with co-morbidities. If each of these professionals works from a data silo, each will have an incomplete picture of the patient's condition. An EHR integrates data to serve different needs. The goal is to collect data once, then use it multiple times.

EHRs are used in complex clinical environments. Features and interfaces that are very appropriate for one medical specialty, such as pediatrics, may be frustratingly unusable in another (such as the intensive care unit). The data presented, the format, the level of detail, and the order of presentation may be remarkably different, depending on the service venue and the role of the user. Scot M. Silverstein, MD, of Drexel University, stated "Clinical IT projects are complex social endeavors in unforgiving clinical settings that happen to involve computers, as opposed to IT projects that happen to involve doctors."[6]

1.4 Components of an EHR—Overview

An electronic record may be created for each service a patient receives from an ancillary department, such as radiology, laboratory, or pharmacy, or as a result of an administrative action (e.g., creating a claim). Some AMCs' clinical systems also allow electronic capture of physiological signals (e.g., electrocardiography), nursing notes, physician orders, etc. Often, these electronic records are not integrated, they are captured—and remain—in silo systems, which each have their own user log-ins and their own patient identification systems. Figure 1 illustrates a set of silos.

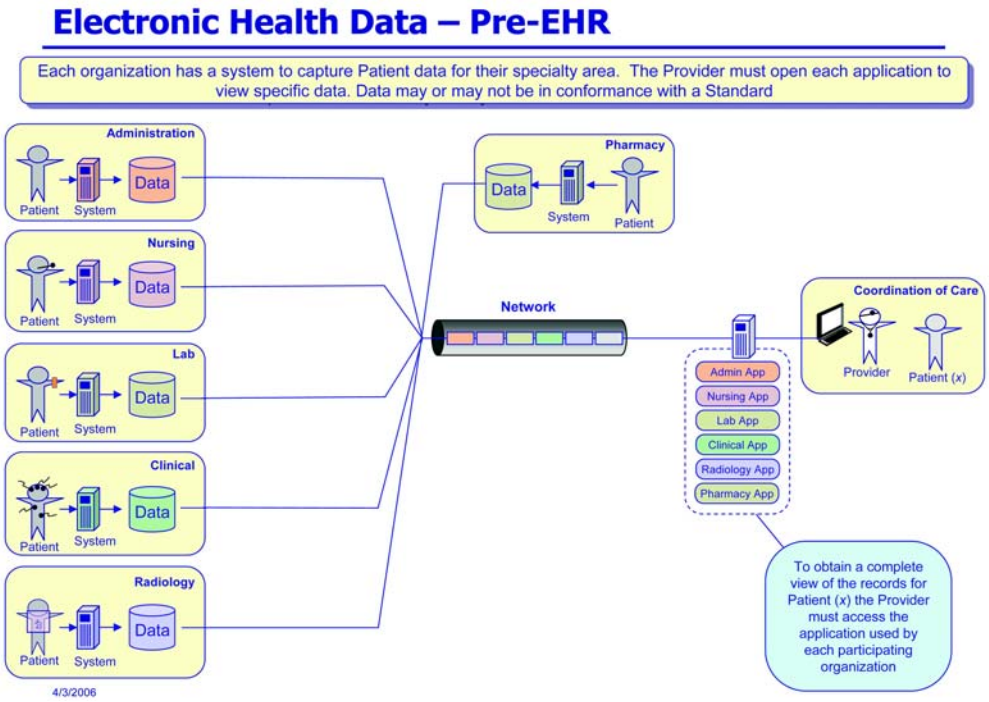

Figure 1. Electronic Health Data—Pre EHR

Siloed vendors may use different standards for vocabularies, user identification, and patient identification and there is no unified access to the silos. A clinical user would have to open a series of applications, log in, and then find the patient record within each application before seeing the patient's complete record. In practice, what often happens is that the electronic data gets faxed or printed and inserted into a paper record at the inpatient setting. If new results are available electronically, old results can be corrected, or new alerts (e.g., allergies) can be added, but the clinician on the units might not be notified unless they logged into the ancillary system. Furthermore, the disparate data cannot be aggregated into integrated displays, such as flow sheets for clinical analysis.

If a clinician has integrated access to the semantic content of the data, then the system will be able to show, for example, all cases in which patients were diagnosed with leucopenia integrated with all cases diagnosed as "low white count" because the two could be coded as synonymous terms. The system could resolve many vocabulary variations that currently make it difficult to find or track cases across multiple investigators. In order to resolve the vocabulary variations, a structured vocabulary system must be used, as described below, and the data must be captured in such a way that the system can recognize the appropriate terms and place them in the proper context. Data may be entered in free text (such as progress notes), in a structured form via a drop-down pick list, as images, or as digitized signals with associated meta data (e.g., electrocardiograms). Even if the system collects data via drop-down pick lists, though, there is no guarantee that the values in the pick lists will be compatible with those of other systems in use at the AMC.

The more structured the data coding demanded by the system, the more knowledge and discipline are required from the provider entering the data, and the more efforts within the organization are required to manage the structure and code vocabulary/nomenclature being used. The old information technology maxim of "garbage in–garbage out" applies here. Structured data that uses concepts or vocabularies not appropriate for the domain will not produce valid results.

An integrated architecture can be created to allow sharing of data across systems. Each system in Figure 2 stores its own data locally. To share patient information, a system (or system user) must allow another system to access its files, or it must transmit a copy of the file to the other system. Once the file is identified for sharing, it can be integrated with other files, depending upon the level of interoperability between the integrating systems.

The EHR in Figure 2 depicts the integration of healthcare data from a participating collection of systems for a single patient encounter.

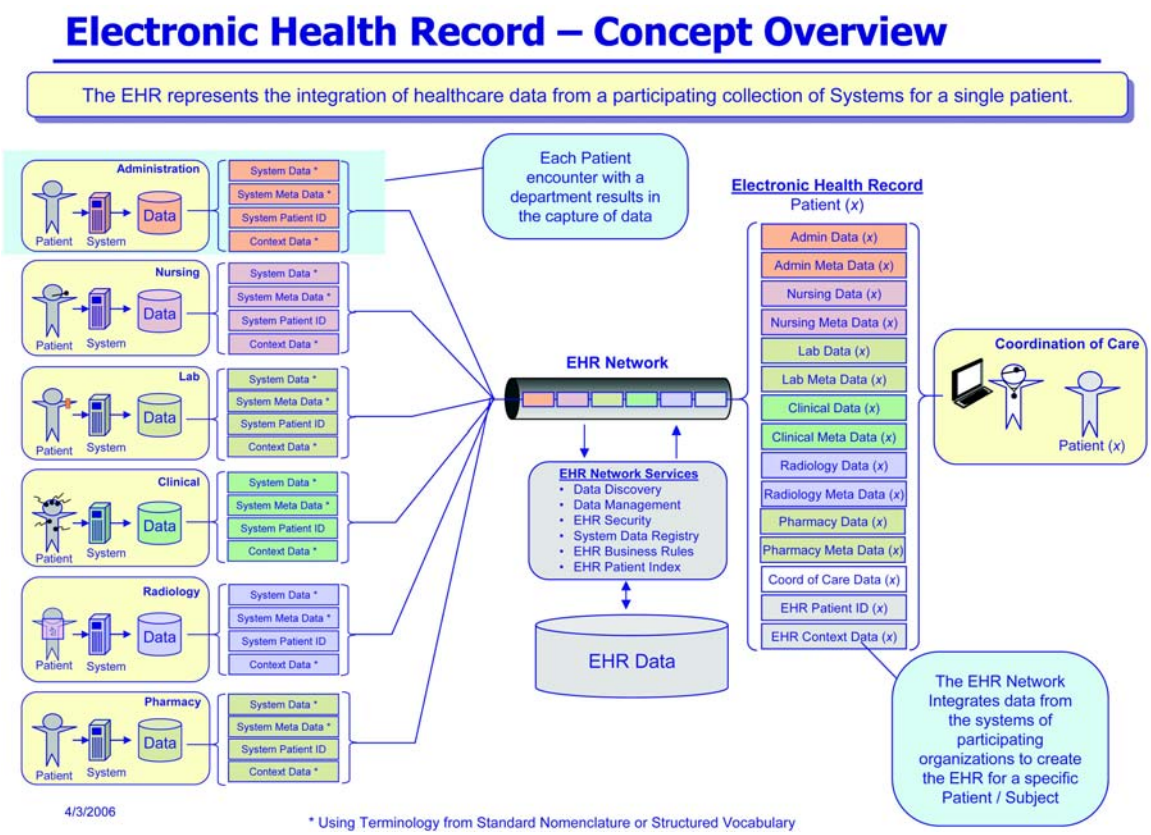

Figure 2 EHR Concept Overview

2. Key Components of Electronic Health Records

Most commercial EHRs are designed to combine data from the large ancillary services, such as pharmacy, laboratory, and radiology, with various clinical care components (such as nursing plans, medication administration records [MAR], and physician orders). The number of integrated components and features involved in any given AMC is dependent upon the data structures and systems implemented by the technical teams. AMCs may have a number of ancillary system vendors that are not necessarily integrated into the EHR. The EHR, therefore, may import data from the ancillary systems via a custom interface or may provide interfaces that allow clinicians to access the silo systems through a portal. Or, the EHR may incorporate only a few ancillaries.

2.1 Administrative System Components

Registration, admissions, discharge, and transfer (RADT) data are key components of EHRs. These data include vital information for accurate patient identification and assessment, including, but not necessarily limited to, name, demographics, next of kin, employer information, chief complaint, patient disposition, etc. The registration portion of an EHR contains a unique patient identifier, usually consisting of a numeric or alphanumeric sequence that is unidentifiable outside the organization or institution in which it serves. RADT data allows an individual's health information to be aggregated for use in clinical analysis and research.

This unique patient identifier is the core of an EHR and links all clinical observations, tests, procedures, complaints, evaluations, and diagnoses to the patient. The identifier is sometimes referred to as the medical record number or master patient index (MPI). Advances in automated information systems have made it possible for organizations or institutions to use MPIs enterprise wide, called enterprise-wide master patient indices.[7]

2.2 Laboratory System Components

Laboratory systems generally are standalone systems that are interfaced to EHRs. Typically, there are laboratory information systems (LIS) that are used as hubs to integrate orders, results from laboratory instruments, schedules, billing, and other administrative information. Laboratory data is integrated entirely with the EHR only infrequently. Even when the LIS is made by the same vendor as the EHR, many machines and analyzers are used in the diagnostic laboratory process that are not easily integrated within the EHR. For example, the Cerner LIS interfaces with over 400 different laboratory instruments. Cerner, a major vendor of both LIS and EHR systems, reported that 60 percent of its LIS installations were standalone (not integrated with EHRs).[8] Some EHRs are implemented in a federated model, which allows the user to access the LIS from a link within the EHR interface.

2.3 Radiology System Components

Radiology information systems (RIS) are used by radiology departments to tie together patient radiology data (e.g., orders, interpretations, patient identification information) and images. The typical RIS will include patient tracking, scheduling, results reporting, and image tracking functions. RIS systems are usually used in conjunction with picture archiving communications

systems (PACS), which manage digital radiography studies.[9] The RIS market is considered to be mature by industry analysts, with 80 percent market penetration by 2001. This means that most AMCs have RIS systems.[10] However, it does not guarantee that the RIS systems are integrated with the EHRs.

2.4 Pharmacy System Components

Pharmacies are highly automated in AMCs and in other large hospitals as well. But, again, these are islands of automation, such as pharmacy robots for filling prescriptions or payer formularies, that typically are not integrated with EHRs. Ondo, et al, report, in 2005, that "in inpatient settings, an average of 31 percent of all [electronic] pharmacy orders … are re-entered in a pharmacy system. While re-entry is not desirable, this is a 35 percent improvement overall since 2003, and a 14 percent improvement from that reported in 2004."[11]

2.5 Computerized Physician Order Entry

Computerized physician order entry (CPOE) permits clinical providers to electronically order laboratory, pharmacy, and radiology services. CPOE systems offer a range of functionality, from pharmacy ordering capabilities alone to more sophisticated systems such as complete ancillary service ordering, alerting, customized order sets, and result reporting.

According to Klas Enterprises, a data provider for the hospital informatics industry, only four percent of U.S. hospitals reported that they are using CPOE systems.[12] Ondo, et al, report that 113,000 physicians are using CPOE regularly and 75,000 of these physicians are using CPOE in teaching hospitals.[13] Forty teaching hospitals reported in 2005 that 100 percent of their physicians were using CPOE for placing orders, an increase from eight teaching hospitals in 2004. The uptake among teaching hospitals may be happening because, Ondo reports, "…teaching sites typically have employed—as opposed to privileged—physicians as well as a significant number of residents and interns, it's easier to gain physician buy-in for the system."

This slow dissemination rate may be partially due to clinician skepticism about the value of CPOE and clinical decision support. There have been some major CPOE successes and some notable failures. Handler, et al, in an overview article concerning CPOE and clinical decision support systems, stated "that CPOE has been well demonstrated to reduce medication-related errors. However, CPOE and dosing calculators do not entirely eliminate error and may introduce new types of error. It has been shown that weight-based drug dosing calculators are faster for complex calculations and may be more accurate than hand calculations. Many CPOE systems have dosing calculators. However, the net effect of CPOE can be to slow clinicians."[14]

2.6 Clinical Documentation

Electronic clinical documentation systems enhance the value of EHRs by providing electronic capture of clinical notes; patient assessments; and clinical reports, such as medication administration records (MAR). As with CPOE components, successful implementation of a clinical documentation system must coincide with a workflow redesign and buy-in from all the stakeholders in order realize clinical benefits, which may be substantial—as much as 24 percent of a nurse's time can be saved.[15]

Examples of clinical documentation that can be automated include:

- Physician, nurse, and other clinician notes
- Flow sheets (vital signs, input and output, problem lists, MARs)
- Peri-operative notes
- Discharge summaries
- Transcription document management
- Medical records abstracts
- Advance directives or living wills
- Durable powers of attorney for healthcare decisions
- Consents (procedural)
- Medical record/chart tracking
- Releases of information (including authorizations)
- Staff credentialing/staff qualification and appointments documentation
- Chart deficiency tracking
- Utilization management

Medical devices can also be integrated into the flow of clinical information and used to generate real time alerts as the patient's status changes. Haugh reports that "At Cedars-Sinai Medical Center, Los Angeles, for example, intravenous medication pumps connected to the clinical information system provide automatic dosage verification and documentation for medication management. All of Cedars-Sinai's physiologic monitoring systems are networked, and data on patients is viewable on other clinical information systems in the hospital. From his office, Michael Shabot, M.D., can monitor patient EKGs using a Web-based viewing system created at Cedars-Sinai that incorporates a vendor product that provides live waveforms from ICU and monitored bedsides."[16]

3. Consideration of Standards

3.1 Definition

A "standard" is "established by consensus and approved by a recognized body that provides rules, guidelines, or characteristics for activities."[17] Standards are created for many technical and clinical domains, as described below. EHRs use both technical and clinical standards.

EHR vendors have been implementing some standards, but have had a great deal of variation in their implementation methods, which results in systems that cannot interoperate. "Electronic patient records today are highly idiosyncratic, vendor-specific realizations of patient record subsets. They adopt few, if any, health information standards, and very rarely accommodate controlled terminologies where they might be sensible. The reason for this epidemic of incompatible data has more to do with the limitations of available information standards and machineable vocabularies than with any fundamental unwillingness to adopt standards. A compelling business case, for system vendors or patient providers, simply has not emerged to foster standards adoption and systems integration."[18]

The use of standard clinical vocabularies and structured data organization (ontologies) greatly enhances the ability of clinical systems to interoperate in a meaningful way and for EHR data to be used in clinical trials.

3.2 Key Standards

To create interoperable EHRs, standards are needed for:

- Clinical vocabularies
- Healthcare message exchanges, in which one system exchanges messages with another
- EHR ontologies (i.e., content and structure of the data entities in relation to each other)

In addition, EHR systems must follow appropriate privacy and security standards, especially as they relate to HIPAA regulations.

Three main organizations create standards related to EHRs: Health Level Seven (HL7), Comite Europeen de Normalization – Technical Committee (CEN TC) 215, and the American Society for Testing and Materials (ASTM) E31. HL7, which operates in the United States, develops the most widely used healthcare-related electronic data exchange standards in North America. CEN TC 215, which operates in 19 European member states, is the preeminent healthcare IT standards developing organization in Europe. Both HL7 and CEN collaborate with the ASTM, which operates in the United States and is mainly used by commercial laboratory vendors.

3.2.1 Clinical Vocabularies

Vocabularies play a strategic role in providing access to computerized health information because clinicians use a variety of terms for the same concept. For example, either "leukopenia" or "low white count" might be written in a patient record—usually these are synonyms. Without a structured vocabulary, an automated system will not recognize these terms as being equivalent.

Standard vocabularies are a means of encoding data for exchange, comparison, or aggregation among systems.[19] Specifically, they are used to:

- Search knowledge resources (e.g., key word searches, tagging)
- Identify the correct guidelines, critical paths, and reminders to be used in prompting high-quality patient care
- Support practice analysis, quality improvement, and outcomes research
- Provide data for clinical epidemiological analyses

Vocabularies are absolutely essential for data interchange and analyses within and across institutional domains. They are required for all secondary uses of clinical data and for functions such as generating flow sheets.

When a clinician evaluates a patient, the documentation usually captures free text or unstructured information, such as history and physical findings. As the clinician evaluation process continues, the unstructured data is transformed (often by a clinical coding specialist) into more structured data that is often linked to payment processing and reimbursement. These claims-related structured data sets (which are different from clinical vocabularies) include Current Procedure Terminology (CPT) codes, International Classification of Diseases (ICD), and Diagnosis Related Groups (DRG). These data sets are primarily used for structured billing and are not designed to capture clinical details that would be most useful for research purposes.

Implementing standardized clinical vocabularies and disease ontologies into clinical data capture systems can alleviate terminology inconsistencies when data is captured at the point of care. Logical Observation Identifiers, Names and Codes (LOINC) for ordering lab tests and Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT) for recording test results, along with many other existing vocabularies, provide well-defined meanings for specific terms that can be standardized across applications. These vocabularies lend themselves to much more detailed and relevant clinical analyses, especially when measuring outcomes for clinical research support, but only when they are implemented in a uniform way.

The DoD has developed an integrated vocabulary for its worldwide automated medical record system. The DoD found that there were numerous synonyms and conceptual differences across clinical user communities that had to be reconciled. '"Total cholesterol' had 11 different ways of being spelled and defined. The word 'cold' might mean the patient has a runny nose, is cool to the touch, or that he's got a lung disease. There's a logic built into the [new] system that gives everyone a common language of care."[20]

3.2.1.1 International Classification of Disease

The ninth revision of ICD is the most commonly used version (the tenth edition is slowly being adopted). It is published by the World Health Organization (WHO). The ICD-9-CM (Clinical Modification) was developed by the National Center for Health Statistics for use in the United States. For an online version, see http://www.eicd.com/EICDMain.htm. The ICD is primarily used to code data for billing purposes to identify the disease or problem for which the patient was treated.

3.2.1.2 Systematized Nomenclature of Medicine (SNOMED)

SNOMED is developed by SNOMED International—a division of the College of American Pathologists (CAP). SNOMED is designed to be a comprehensive, multi-axial, controlled terminology, created for the indexing of the entire medical record. The new version is called SNOMED-RT (Reference Terminology).

SNOMED-CT (Clinical Terms) is aimed at specifying the core file structure of SNOMED Clinical Terms. This new collaborative terminology is being developed jointly by the National Health Service in the United Kingdom and the CAP, integrating the British system of Read Codes and SNOMED-RT.

3.2.1.3 Logical Observation Identifiers, Names, and Codes (LOINC)

LOINC codes are used to identify individual laboratory results (e.g. hemoglobin values), clinical observations (e.g., discharge diagnosis), and diagnostic study observations (e.g., chest x-ray impression). LOINC is most widely used in laboratory systems.

3.2.1.4 Health Level 7 (HL7)

HL7 is a messaging standard that is widely used in messaging across health care applications. That is, it is used to send structured, encoded, data from one application (such as the laboratory system) to another (such as the EHR). There are two major versions of HL7 in use today. One is HL7 v. 2x, which is commonly used by the existing COTS applications and the other is HL7 v. 3, the Reference Information Model (RIM) which provides a much more robust ability to represent complex relationships. While the RIM is not yet implemented by many COTS EHRs, it can potentially be used for representation of translational research data in a form that can be exchanged with EHRs in the future. The web page shown here: http://www.hl7.org/EHR/ describes the ways in which HL7 is working to improve EHR messaging.

Note that HL7 adherence is claimed by many COTS vendors, but that does not necessarily mean that their applications are easy to interface with other COTS vendors claiming that they adhere to HL7 as well. To address this issue, the vendor and user communities have formed the Certification Commission for Healthcare Information (CCHIT, http://www.cchit.org/) to certify that vendors have implemented HL7 and other standards in such a way that the resulting applications can exchange data with a minimum of customization.

3.2.1.5 Ontologies

An ontology, for the purposes of automated knowledge navigation, is a "…specification of a representational vocabulary for a shared domain of discourse—definitions of classes, relations, functions, and other objects…"[21] Ontologies are used by people, databases, and applications that need to share domain information.[22] Ontologies are structured in such a way as to have computer-usable definitions of basic concepts in the domain together with their relationships. They encode knowledge in a domain and also knowledge that spans domains, which makes this knowledge very reusable.

Generally, ontologies are used to specify descriptions for the three following concepts:

- Classes (things) in the many domains of interest
- The relationships that can exist among things

- The properties (or attributes) those things may have

Different ontologies may model the same concepts in different ways. While shared ontologies and ontology extensions allow a certain degree of interoperability among different organizations and domains, there often are cases in which there are multiple ways to model the same information. In order for machines to be able to integrate information into different ontologies, there need to be primitives (core relationships and definitions) that allow ontologies to map terms to their equivalents in other ontologies.

Translational research programs can significantly benefit from data interchange among healthcare institutions, AMCs, and medical research institutions. The HL7 version 3 Reference Information Model (RIM) provides an object model of clinical data that can be extended readily to cover other biomedical models (such as genomics). This is not without controversy; some reviewers have had difficulty implementing RIM. Also, a given ontology may work well for one specialty area (e.g., pathology) but may not be useful for other clinical users who need different views of the same data (internists). Thus, tools are needed to navigate across ontologies and to validate their utility as they cross clinical domains.

3.3 Trends

Institutions implementing EHRs have reported immediate rewards, intervening pain, and successes[23] The implementation model reported by the Medical Records Institute has the following phases:

- **Rewards:** Virtually any current EHR application can support more efficient and accurate collection, storage, analysis, and distribution of data than current manual operations. Eliminating the need for managing paper files provides immediate efficiency benefits.
- **Pain:** At present, available EHR applications rarely allow a seamless flow of data to a common database where multiple users—physicians, researchers, administrators, patients, and nursing stations—can convert data to information using a shared set of tools. As more EHR systems are implemented, chief information officers' departments will be forced to find ways to interface existing ancillary systems (such as pharmacy) to respond to pressing needs for integrated data views and analyses. Some have investigated buying all components of their clinical automation tools from one vendor, but have discovered that these vendors have recently bought series of smaller vendors and have not yet had a chance to integrate disparate applications themselves. Also, specialty physicians often resist using the solution provided by a "mega-vendor," preferring to use a more specialized vendor that they consider "best of breed."
- **Success:** Discussion of EHRs at the national level begins to impose expectations that any new technology must be compatible with a data-driven medical enterprise. New data, communication, and visual technologies (e.g., "endo-cams," digital camera views of the intestine uploaded to a hip-mounted data collection device), for example, will need to be integrated into the automated clinical records systems. More systems will be designed to allow data collection to become a by-product of the process—administration of a medication to a patient could be integrated with billing, inventory, and MAR systems. This improvement will come as the systems mature and as the clinical users become more involved in the design of systems and associated process changes.[24]

4. Workflow Implications

4.1 Physicians, Nurses, and Other Clinicians

EHR workflow implications for healthcare clinicians (physicians, nurses, dentists, nurse practitioners, etc.) may vary by type of patient care facility and professional responsibility. However, the most cited changes EHRs foster involve increased efficiencies, improved accuracy, timeliness, availability, and productivity (See references 1, 8, and 9 in the References section).

Clinicians in environments with EHRs spend less time updating static data, such as demographic and prior health history, because these data are populated throughout the record and generally remain constant. Clinicians also have much greater access to other automated information (regarding diseases, etc.), improved organization tools, and alert screens. Alerts are a significant capacity of EHRs because they identify medication allergies and other needed reminders. For clinical researchers, alerts can be established to assist with recruitment efforts by identifying eligible research participants.

Challenges that EHRs may present to workflow processes include: increased documentation time (slow system response, system crashes, multiple screens, etc.), decreased interdisciplinary communication, and impaired critical thinking through the overuse of checkboxes and other automated documentation. System crashes are particularly problematic because clinicians, particularly at in-patient facilities, will not know what treatments are needed or if medications are due.

Interestingly, the national attention and rapid adoption of EHRs come at a time when the nursing industry is experiencing a substantial *decrease* in workforce and an *increase* in workload. To help compensate for this workforce discrepancy, EHR implementations must coincide with workflow redesigns to ensure increased efficiencies, to generate improvements in quality of care, and to realize the maximum benefits of an automated environment.

5. EHR Dissemination Across Academic Medical Centers

EHRs are very complex to install, and they often are rolled out gradually across the multiple facilities that are part of the typical AMC. Figure 3 shows the distribution of density of EHR functionality across 220 AMCs, as represented in the HIMSS/KLAS database. This chart was generated by selecting all institutions that were classified as AMCs and looking at the EHR-related functions that were shown as actually having been automated (versus planned to be automated) at the time of the survey. These functions included items such as clinical data repositories, master patient indices, CPOEs, and MARs. Ancillary functions, such as those provided by laboratory, radiology, or pharmacy, and specialty services, such as obstetrics and emergency departments, were not included.

Ultimately, Figure 3 shows that most of the AMCs have at least six automated functions installed that support the ultimate vision of the EHR; the rest of the AMCs are in the process of building their function sets.

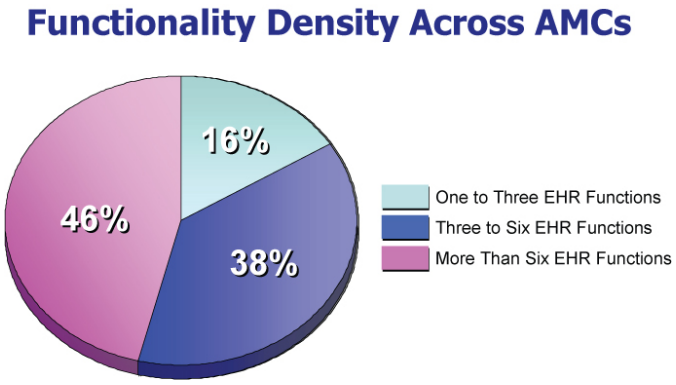

Figure 3. Functionality Density Across AMCs

Figure 4, below, is based on an American Hospital Association study of use of fifteen EHR-related clinical informatics functions by a sample of 903 hospitals.[25] It shows that EHR-related technologies are used by many more teaching hospitals than non-teaching hospitals. AMCs are leading the technology bandwagon.

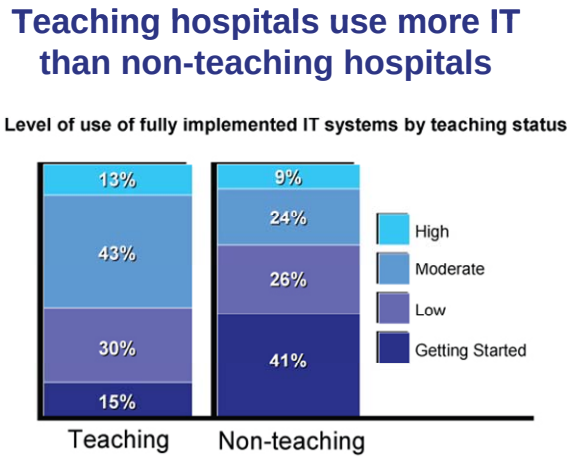

Figure 4. Level of EHR-Related Technology Used by Teaching Hospitals

6. Technical Trends

6.1 Ontology and Semantics

The field of computable ontologies, particularly clinical ontologies, is still in its infancy. In 2005, MITRE conducted an assessment of the semantic web vendors and ontology languages and methodologies to determine their maturity along a continuum between the state of the art and the state of the practice. The results of this assessment are shown in Figures 5 and 6 below. As illustrated, semantic web vendors are in the early commercialization phase, while the majority of ontology languages and related methodologies are emerging from applied research and beginning to enter early commercialization.

In the near term, the maturity of the semantic web will be led by the expanded use of extensible markup language (XML) and resource description framework (RDF) standards. The use of XML and RDF standards will result in a larger collection of structured data on the Web. This, in turn, will allow queries that yield richer and more relevant search results. Further maturity of the semantic web will require the emergence of an integrated framework of ontology tools that are capable of translating their output into non-native executable forms (knowledge compilation) which is necessary to support their use in Web services and semantic queries.

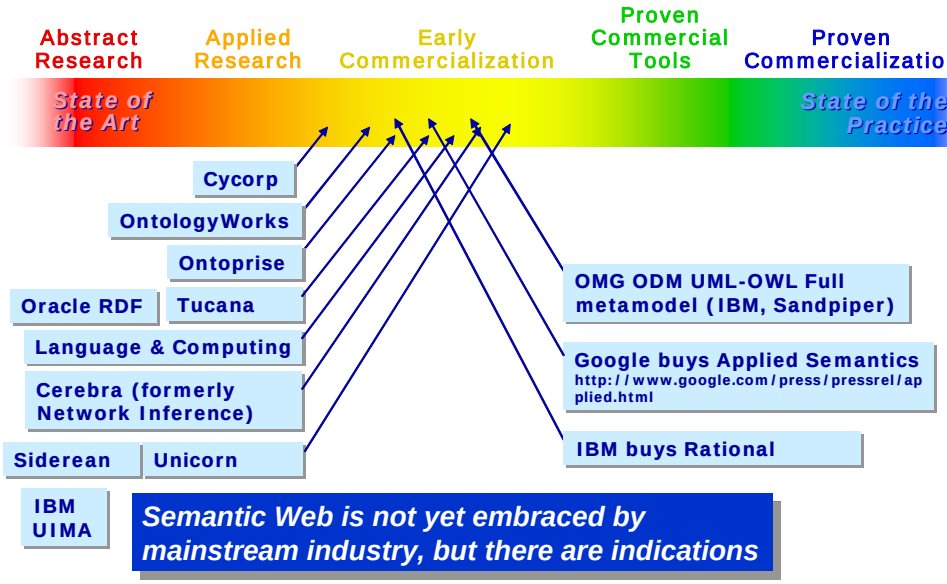

Figure 5. Semantic Web Vendors and Commercial Indicators

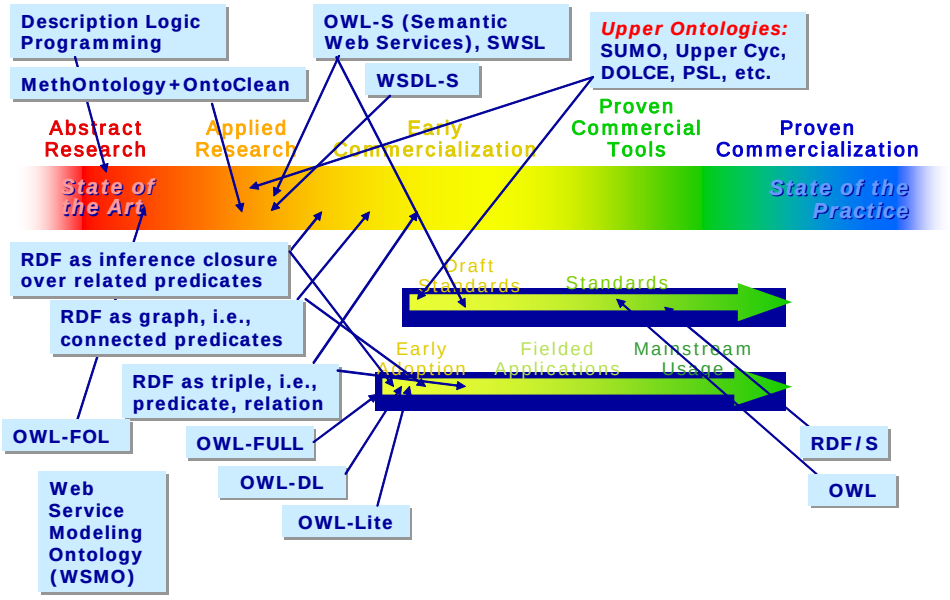

Figure 6. Languages, Ontologies, Methodologies

7. Business Trends

7.1 Consolidation of System Vendors

Consolidation is a standard phase in the life cycle of software in a cash-rich industry. It is apparent that EHR is rapidly approaching this phase; one of three in information revolutions, which include:

- **Initiation.** Small, entrepreneurial ventures, responding to recognized "pain" within an industry, focus on a specific niche (e.g., patient records, billing, etc.) and serve it with proprietary software. They attempt to respond to unique language, structure, and processes associated with an industry. As awareness of their products and their credibility grows, they leverage the knowledge they have gained serving their installed base of customers and apply increasing revenues to further the development of their "flagship" product and attempt to expand into other arenas of the industry.
- **Acquisition.** As their sales begin to validate the presence of a real need, entrepreneurs attract acquirers—larger companies that seek to exploit an emerging market and build upon their own capabilities and products (such as "compatible" software, data collection devices such as barcode readers, etc.). Acquirers' difficulty comes when they try to integrate disparate software that was created using different terminology, operating systems, and hardware platforms. It can take several years to establish a stable suite of products.[26]
- **Consolidation.** The final stage is consolidation, in which larger companies make decisions about remaining in the market or departing it, and in which a few surviving companies become "standards" for the industry.

EHRs are in the middle phase, with companies like GE, Siemens, and McKesson buying smaller vendors and bundling them with their own products. There also are companies such as IBM, Intel, Microsoft, and Accenture that lack established clinical record product lines and are investing in the development of EHR-related technology. But the health care industry is not necessarily the same as other industries. The rate of change for some ancillaries is much greater than others, and monolithic vendors may not be able to update the ancillary systems fast enough to suit the provider community's needs. In an AMC environment, this may lead to development of a federated architecture instead. This type of architecture would use standard messaging and vocabularies to integrate several systems into a unified view.

8. Cost and Return on Investment

Measuring return on investment (ROI) of IT systems is difficult for any industry. Most research has been focused on how to compute ROI for medical IT systems such as EHRs, but do not present the results of such studies. The qualitative benefits of EHRs are generally accepted and have been presented anecdotally throughout the literature. These include, but are certainly not limited to:

- Improved quality and patient care[27]
- More efficient tracking of patients and costs[28]
- Benefits to the business of healthcare[29]
- Better documentation and improved audit capabilities[30]
- Avoidance of repeating expensive tests and more time spent with patients[31]

Memorial Sloan Kettering, for example, did not base its ROI assessments on financial returns. Its CPOE system was judged as an overall success because it:

- Saved an average of one hour per shift in nursing staff time
- Improved the use of clinical order sets
- Improved workflow across the entire institution, especially because orders were complete when sent, were legible, and were entered immediately (versus at the end of rounds). This meant that workflow in the pharmacy was evened out, that nurses did not have to spend time filling in incomplete orders, and that medications could reach the floor more quickly.[32]

Implementation costs for a given AMC installation will vary considerably, depending on what is being implemented and what systems are already in place. Some AMCs are able to negotiate very favorable agreements with vendors who already provide large systems to their ancillary units (such as radiology). Essentially, the vendors add the EHR capabilities at a favorable rate in order to smooth integration and build customer commitment. But other installations can be extremely expensive, for example, the roll out of an EMR across the entire Kaiser Permanente network was reported to cost more than $1 billion.

A recent American Hospital Association survey found that "the median annual capital investment on IT was over $700,000 and represented 15 percent of all capital expenses. Operating expenses were much higher—$1.7 million, or 2 percent of all operating expenses. Those with more advanced systems—and especially advanced CPOE systems—spend even more."[33]

8.1 Make or Buy Decisions

Many factors go into the decision to buy an EHR from a COTS vendor, rather than develop a customized EHR within the AMC itself. Feied, et al.,[34] identify the tradeoffs as:

- Buying an EHR from a COTS vendor allows the AMC to distribute development and maintenance costs over many buyers.

- Design improvement ideas may be collected from multiple institutions, which may result in improved functionality (or may result in a system built on multiple compromises).
- The COTS systems are completed, tested, and implemented in many institutions, so the expertise of the installing teams has been increased, and lessons learned can be applied to new implementations. Test data suites are well developed, test cases are understood, and training materials are provided.
- The business model and workflow processes embedded in the COTS products are designed to meet the needs of as many potential buyers as possible. They often are generic and inflexible.
- The vendor develops new releases slowly, in response to market demands. The vendor is not necessarily going to prioritize the changes in the way that most benefits the clinical community.
- The technical environment is rapidly changing, but the major vendors have a hard time implementing these changes quickly. In fact, the more successful the vendor, the more difficult it is to make major changes because the needs of multiple hospitals must be considered. Backwards compatibility (the ability to upgrade without losing data or functionality) is desired, but the more complex the system, the more difficult it is to produce technical enhancements that meet the user community's needs.

Feied, et al., suggest that the best solution may be to buy certain components but to build an open standards, data centric model that integrates data into a user-accessible repository.

9. Implications for Clinical Research (NCRR Activities)

9.1 Implications for the National Center for Research Resources

Clinical Research

A major differentiator of an AMC in the medical community is its commitment to research.

Current EHR systems support some aspects of clinical research. According to an analysis by Forrester Research, the more an EHR incorporates the following characteristics, the more likely it is to be useful in supporting clinical trials:

- Richness or level of detail concerning each patient
- Relevance of the data collected to clinical trial work
- Reach or number of potential participants whose data is accessible through the EHR
- Freshness or currency of the data in the EHR
- Consistency of medical terms and codes, both within the EHR itself and also with the codes and terms used by clinical trial protocols
- Interoperability with the clinical trial management systems or data repositories
- Consent management features that support adherence to review board requirements[35]

EHR data can be used to support clinical trial recruitment, research collaboration, and retrospective studies. Capturing the data electronically can reduce duplicate data entry (with associated mistakes), improve longitudinal follow-up, and enhance the ability to conduct meta-analyses.[36] A survey reported by Glaser, et al., found that access to EHR data, particularly laboratory data, was among the highest information technology (IT) priorities at clinical research centers.[37] The rapid identification of potential research subjects before they undergo an intervention that will preclude their participation in a clinical trial also is important. Access to an EHR may be used for such rapid case findings.[38]

At present, EHRs are being integrated with research processes at some AMCs. Notable projects include:

- Clinical trial recruitment at the Cleveland Clinic[39]
- Feeding a dedicated research repository, such as the Stanford Translational Research Integrated Database Environment (STRIDE) project at Stanford University Medical School[40]
- The Mayo Clinic's integrated clinical and research data infrastructure, being developed with IBM.[41]

9.1.1 Availability of data

Increasing the use of standards will help make data more available for research sponsored by the NCRR. Clinical researchers with access to EHR data will be able to identify eligible clinical trial participants before they undergo therapies that might interfere with their eligibility. Researchers will be able to obtain a more complete clinical picture of the patients over time and

may be able to identify adverse events more rapidly (especially if there is a message to the clinical trial data center after each patient encounter, rather than the data center obtaining data only when the patient visits the principal investigator). Of course, there are many issues concerning patient confidentiality and security that will have to be managed as these integrated systems evolve.

9.1.2 Potential for supporting NCRR Grantees

NCRR can provide ways to guide and encourage Clinical and Translational Science Awards (CTSA) and Research Centers in Minority Institutions (RCMI) to become involved in informatics. NCRR can provide governance and planning guidance, as requested, to ensure research needs are considered and included in project planning. This is a very important focus activity. Most bioinformatics activities in AMCs are conducted within siloed centers—there is very little integration and even less integrated planning. In a recent report (summarized in the exhibit below), Glaser, et al., surveyed AMCs concerning their vision for research informatics. Glaser concluded that there is very little focus on an overall vision for integrated systems—indeed, for any systems at all. If this situation continues, EHRs will be much more fully developed, and the biomedical community will be forced to use whatever tools the EHR community selects, instead of defining its own needs.[42]

Exhibit # 1: Glaser, et al., Survey of AMC Informatics

- Most organizations do not have a formal strategic vision for IT and clinical research:
  - Not a written vision but more of a "spirit"
  - Vision for a specific clinical research area such as cancer care or AIDS, but not for all clinical research
  - Increased awareness, but nothing in writing
- Reasons for the lack of a formal vision:
  - Clinical research is de-centralized, consisting of independent centers of excellence
  - The formal vision is a work in progress—new administration or new focus area for current administration
  - Lack of good communication between research and IS to bring the pieces together
  - Focus on replacing aging clinical systems for now
- For those that do have a vision, some commonalities in the vision are:
  - Technology connecting all departments to promote collaboration of disparate groups, some using a portal approach
  - IT vision is linked to the clinical research strategic business plan requirements
  - IS supports centralized data from research efforts, the hospitals CIS (clinical information system), and tissue sample databases
  - Standard terminology and a data warehouse for central data capture is a key focus

9.1.3 Implications of Standards and Vocabulary Adoption

Once standards are widely used, clinical trials data can be imported from EHRs in a standard form, establishing comparability across studies and sites. This improvement will free data administrators from the need to validate data types and content and enable them to focus on other activities, such as data security. Correctly designed ontologies with appropriate meta-data can support much richer meta-studies because data will be collected and reported in standard ways. But without dedicated participation in standards development bodies, the clinical research community's needs will be unrecognized. This is a serious issue because the vendor community is seeking to standardize and certify adherence to those standards through the various activities sponsored by the Office of the National Coordinator for Health Care Information Technology (http://www.hhs.gov/healthit/).

9.2 Future Vision

The advent of the Nationwide Health Information Network envisioned by President Bush may be the ultimate means of integrating clinical and translational research information over large patient populations. Interoperability standards, tools, architectures, and vocabularies that are developed for this network might well be used to enhance interoperability across the AMCs as well. The leading EHR vendors are participating in developing technologies for the nationwide network that will be incorporated into their product base. If the translational community becomes involved in defining the requirements for these interactions from a research perspective, the vision shown below may become reality. Figure 7, below, shows such an integrated architectural vision.

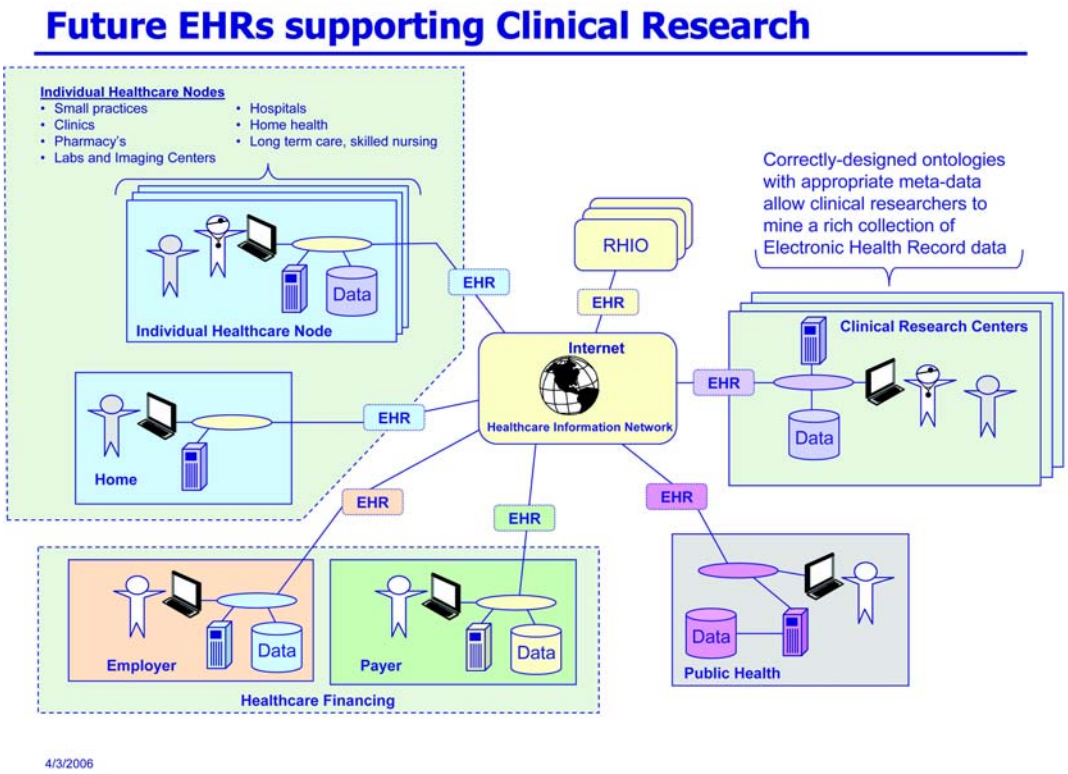

Figure 7. Future EHRs supporting Clinical Research

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