1 What Is the Electronic Health Record?

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Reports of using computers to support clinical data management activities date back to the late 1950s. Over the years systems have been designed that support most major activities related to health care business practices and clinical processes. The most common systems are listed below (Table 1-1).

Until recently, hospitals have led the way in the development of clinical information systems. This was owing, in part, to several factors: 1) the cost of these systems (including personnel) made information technology too expensive for smaller entities, and 2) hospitals had greater need of meeting regulatory and financial requirements. Hospital information systems (HIS) usually have, as their central component, an Admission, Discharge, and Transfer (ADT) system that manages census and patient demographic information. Billing and accounting packages are also frequently included as core components. In many community hospitals, financial and ADT systems, along with Laboratory Information Systems (LIS), comprised the complete HIS package until recently. In the past fifteen years, most hospitals, regardless of size, have begun to create information systems solutions via integration of departmental systems with the core HIS, although almost 20% still do not have electronic implementations of all major ancillary systems (1,2).

Departmental systems, especially those for pharmacy, radiology, and laboratory, have evolved from a focus on administrative tasks (scheduling, order entry, billing) to more clinically oriented functions. For example, modern pharmacy systems commonly provide drug interactions, allergy alerts, and drug monographs as part of their standard feature set. When looking at the evolution of clinical information systems, it is instructive to consider how the end-user has changed over the years. Departmental systems were designed primarily for use by workers within those departments, not health

Table 1-1

HOSPITAL INFORMATION TECHNOLOGY APPLICATIONS

System Type	Function
Master patient index	Registration and assignment of unique identifiers for all systems within a hospital or integrated delivery network.
Pharmacy information system	Medication dispensing, inventory, billing, drug information, and interactions.
Radiology information system	Scheduling, billing, and results reporting.
Picture archiving system	Storage and presentation of radiological images.
Nursing information system	Storage and collection of nursing documentation, care planning, and administrative information.
Hospital information systems	Core system manages hospital census (admission, discharge, transfer) and billing. Most often linked to departmental systems (pharmacy, laboratory, etc.).
Chart management/medical records systems	Assists in the management of paper records and aids with required statistical reporting. Used by medical records personnel.
Practice management system	Outpatient system for managing business-related information. May contain some clinical information (CPT, ICD).
Laboratory information system	Orders for lab tests and results reporting. Covers blood bank, pathology, microbiology, etc.

care providers. Thus drug interaction information was available only to pharmacists and their staffs, not directly to doctors and nurses. Clinical information systems were labeled as such because they were utilized in areas that supported clinical activities, not because they were intended for use primarily by clinicians. Of all the systems that fall under the rubric of clinical information systems, only a few are designed primarily for use by health care providers: intensive care unit systems (ICU), picture archiving and communications systems (PACS), computerized physician order entry systems (CPOE), and the EHR.

The modern era of clinical information systems is being driven by concerns of quality, patient safety, and cost, in addition to secondary business and operational issues (3). Today emphasis has shifted toward providing information systems that support providers during the process of care, resulting in the advent of CPOE systems and a much higher profile for EHRs (4).

CPOE systems provide an integrated view of orders and results (medications, radiology, laboratory) along with decision support functions (drug interactions, duplicate requests, clinical protocols, etc.) and are most often seen in hospital settings. These are complex provider-centric applications and constitute one of the fundamental building blocks of a hospital-based EHR. However, they have not yet achieved wide acceptance: fewer than 7% of American hospitals have fully functioning CPOE systems (1,5).

The EHR is the goal towards which clinical information systems have been evolving since their inception. Even so, EHR systems remain uncommon in many practice settings. Fewer than 3% of American hospitals have robust EHR systems (1), while fewer than 15% of physicians use EHRs on a regular basis (6,7).

The Electronic Health Record Concept

The growing interest in EHRs has been paralleled by an increase in the number of attempts at defining what they are. When perusing publications concerned with EHRs and associated technologies, one is quickly struck by the number of terms used to describe them. Over the years EHRs have been referred to by a number of terms: electronic medical record, electronic patient record, electronic health record, computer-stored patient record, ambulatory medical record, and computer-based medical record. Unfortunately, the definitions are conceptual and do little in the way of providing a technical, engineering, or scientific view of EHRs that could be used for either designing systems or reviewing products.

In 1991 the Institute of Medicine (IOM) published a landmark report, "The Computer-Based Patient Record: An Essential Technology for Health Care" (8), which focused attention on important EHR concepts. One of its more valuable contributions was in the area of terminology. It defines the computer-based patient record (CPR) as an "electronic patient record that resides in a system designed to support users through availability of complete and accurate data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids" (8).

Further amplification was later provided by one of the report's editors, Richard Dick, PhD, who describes the CPR as "a representation of all of a patient's data that one would find in the paper-based record, but in a coded and structured, machined-readable form." Dick further notes that, "Clinical documentation is completed via computer and is coded within the patient's CPR. Stored data are indexed with sufficient detail to support retrieval for patient care delivery, management, and analysis" (9). Regarding the features of EHRs and EPRs, Dick writes:

> The EMR and EPR, which are in fact reasonably synonymous, are electronic, machine-readable versions of much of the data found in paper-based records, comprising both structured and unstructured patient data from disparate, computerized ancillary systems and document-imaging systems. Clinical documentation may originate in either paper records or computerized data;

> however, the data are not comprehensively coded. One might consider the EMR or EPR as transitional between the paper-based record and the CPR. (9)

The perspective offered by Dick relates the CPR, EPR, and EMR along a continuum based on, among other factors, the level of granularity of stored data. A true CPR requires that every data item be uniquely coded and individually searchable; an EPR/EMR does not. EPR/EMR systems only require that the data be in electronic form.

The CPR report, while providing a conceptual framework for discussion of electronic record systems, proved to be less useful when evaluating real world products. That task fell to "Key Capabilities of EHR Systems," a report published by the Institute of Medicine in 2003 (10). Building on the work of the 1991 report, it offered a more practical definition of EHRs. The report states:

> An EHR system includes: 1) longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or a health care provider to an individual; 2) immediate electronic access to person- and population-level information by authorized, and only authorized, users; 3) provision of knowledge and decision-support that enhances the quality, safety, and efficiency of patient care; and 4) support for efficient processes for health care delivery.

This definition of an EHR system encompasses all of the concepts and functionality proposed originally for the CPR; thus, we will use "EHR system" (EHR) as the official term for this text.

The 2003 report identified eight core areas for which EHR systems should provide supporting features/functions (Table 1-2) while recognizing four basic types of EHR care settings (hospitals, nursing homes, ambulatory care, community-personal health record). The functionalities identified to support

Table 1-2

CORE FUNCTIONAL AREAS IDENTIFIED BY THE 2003 IOM REPORT

- Health information and data
- Patient support
- Results management
- Electronic communication and connectivity
- Decision-support management
- Reporting and population health
- Order entry/management
- Administrative processes

these eight core areas were further expanded and developed by Health Level 7 organization (HL7) into a standard by which commercially available products could be evaluated and eventually certified by the Certification Commission for Health Information Technology (CCHIT) (11). The 2003 report acknowledges that EHR technology develops incrementally and that for a given setting or a particular product, EHR features and functions will vary over time. Therefore, many products will have advanced features in some areas while being relatively deficient in others: today's EHR products are seen as the progenitors of tomorrow's comprehensive EHR systems.

Introduction to Electronic Health Record Systems

Early efforts at building what became EHRs began in the 1960s with the COSTAR system, developed by Barnett at the Laboratory of Computer Science at Massachusetts General Hospital (12). Subsequent efforts at Duke University (13) and the Regenstrief Institute at Indiana University Medical Center (14) have all given rise to robust EHR systems that contain data for thousands of patients. While there is no formal model or standard architecture for EHR systems, these pioneering systems provided a basic model for current hospital-based and ambulatory EHR systems that has been emulated by current products.

Inpatient EHR Systems

Whereas EHR systems offer similar features and functions across care settings, they differ significantly in how that functionality is assembled.

EHR systems that support hospitals and integrated delivery systems are virtual systems created by pooling and sharing data between many component systems (15,16). Outpatient systems are usually self-contained applications in which all functions are built on top of a single, shared database. The ability of an EHR system to support advanced features such as decision support, sophisticated reporting, and coded data entry is determined by the level of integration of its component systems. Two levels of integration are common: presentation and data level (15,17,18).

System Integration

Presentation Integration

At the presentation level, users are able to view data from all connected systems through a common interface (15,17,18). The user may access a single terminal to review patient information. Systems like this are quite useful, but they are limited when users wish to do more that simple data retrieval. These systems only seem to be one coherent system because a single interface is required to interact with all of its components. Much of the enthusiasm for Intranets and Web browsers are due to their ability to support, with relative ease, presentation-level system integration (19,20).

A major downside to presentation-level integration is the lack of query capability across all systems. For example, it would not be possible to ask a question such as "find all patients with a diagnosis of congestive heart failure who are not taking an ACE inhibitor" because the patients' problem lists and medication records reside on two different computer systems. The billing system may hold the diagnosis codes, while the pharmacy system holds the medication profile. For a system to qualify as an EHR, some degree of data-level integration must be present.

Data Integration

Data integration is required for true EHR functionality and is more difficult to attain (21-23). Each component system may have its own data model and naming conventions for data elements. Data-level integration requires that all system components use a consistent scheme for coding data elements and that a mechanism be present for movement of data between systems (from components to the central system). In the case of a hospital or integrated delivery network (IDN), the central system is usually a large database called a clinical data repository (CDR) (15,16,24).

The CDR acts as the major information source for the entire EHR system (Chapter 4). The simplest CDR implementations rely solely on laboratory, radiology, pharmacy, ADT, and other standard department systems as information sources (1,2). Achieving true EHR functionality requires adding to this basic CDR environment CPOE, advanced reporting, PACS, clinical documentation, clinical decision support capability, and other provider-centric information technologies (1,2).

The goal of the CDR is to provide a common pool of data that all applications can access. The most frequently used method for populating the CDR is through the use of interfaces to link each component system. Interfaces are special software programs that move data between systems. Data that reside in component systems designed by different vendors use proprietary data models; therefore, similarly named data elements from different systems may have characteristics that prevent them from being interchangeable. Simple messaging interfaces alone cannot resolve the deeper semantic problems present by data from disparate systems (25,26). The problems that arise in reconciling terms, data elements, and data formats between component systems require additional applications, such as clinical data dictionaries, in order to provide true data-level integration. The costs and issues associated with implementating interoperability between systems, such as the lack of widely accepted data standards, create major barriers to EHR adoption for many hospitals (2,27).

Legacy systems (older systems currently in place) represent a special problem for EHR implementation for hospitals and IDNs. These older systems often cannot be easily replaced and so must become part of newer systems, thereby hampering data-level integration. In many instances, presentation-level integration is all that is possible for legacy systems.

A second approach to providing a common data pool is through the use of an integrated system that relies on a single, shared database that is used for storage by all components and applications (see Unified Database section, below).

The EHR is one instance in which ambulatory practice sites are in a much better position to implement new technologies than their often wealthier inpatient cousins. Ambulatory care sites are simpler work environments with fewer specialized information management needs. Integration issues are usually limited to practice management systems, laboratory interfaces, and office machines (e.g., EKG).

Real-World Electronic Health Record Models

Interfaced Systems: Best-of-Breed

The classic architecture for inpatient EHRs is based on the use of interfaces and is often referred to as the best-of-breed approach (so named because departmental managers bought the best component system that they could afford at the time) (28-30). Best-of-breed (Fig. 1-1) is the natural growth path to EHR functionality for most hospitals because it makes use of whatever component systems the hospital has in place. Most hospitals begin the

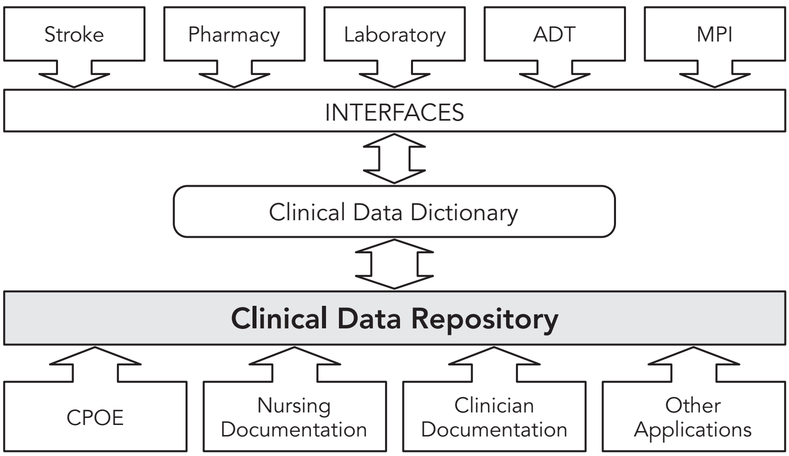

Figure 1-1 Best-of-Breed (interfaced) EHR.

journey to EHR functionality with the presence of a CDR that integrates data from departmental systems (laboratory, radiology and medication) and allows providers to access information from a single workstation (results viewing). Populating the clinical data repository, and by extension the EHR, using the best-of-breed approach results in the data integration issues discussed previously (Table 1-3). Once this foundation has been laid, advanced functionality is added over time in the form of CPOE, clinical documentation, electronic medication administration, and PACS (1,2).

Integrated Systems: Unified Database

At the other end of the spectrum are fully integrated, unified database systems (17,21,29,30). The term "unified database" will be used to denote systems that share a single underlying database to avoid confusion with the term "single source," which indicates that all systems were purchased from the same vendor. Systems from the same vendor do not necessarily share the same underlying database. Thus, single source does not automatically imply that systems are fully integrated at the data level.

Unified database systems are labeled as such because all components share a single (unified) database (Figure 1-2), eliminating the need for a separate CDR. This approach to EHR design minimizes or potentially eliminates the need for interfaces by providing true data-level integration. Unified database systems may be deployed using fewer hardware resources and simpler configurations than best-of-breed systems, making it less dif-

Table 1-3

EHR INTEGRATION MODELS

	Best-of-Breed: Interfaced	Hybrid	Unified Database: Integrated
Advantages	Build system "as-you-go". Select from best products available.	Build system "as-you-go". Fewer vendors than best-of-breed. Data integration less costly than best-of breed. Back-up/availability better.	Single vendor. No interfaces required (or very few). Complete data integration. Back-up/availability best.
Disadvantages	Costly to get good data integration. Many interfaces required. Manage multiple vendors. Back-up/availability more difficult.	Multiple interfaces required. Manage multiple vendors.	Tied to one vendor (may have less desirable applications in some areas).

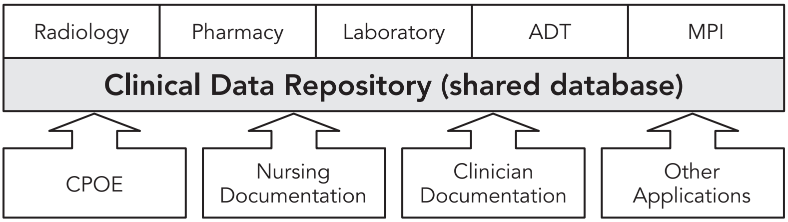

Figure 1-2 Unified Database (integrated) EHR.

ficult to provide high-availability deployments (less time spent with the system unavailable to users) that are easier to set up, maintain, and back up. The unified database approach to achieving EHR functionality is growing in inpatient environments, although it is the norm in physician offices (Figure 1-3).

One impediment to having a unified database EHR is that all components must be purchased from the same vendor. Because most hospitals start with a few ancillary systems and build from there, in many settings going with a unified database architecture would require getting rid of many current systems. As a result, most hospitals develop hybrid architectures that exist along a continuum between best-of-breed and unified database (see Table 1-3). The marketplace reflects the newness of the unified database product in that no vendors currently offer an inpatient EHR on a unified database platform that includes all required components.

Electronic Health Record Advanced Features and Functions

Computerized Physician Order Entry and Decision Support

Computerized physician order entry (CPOE) is an application that allows physicians to enter orders for medications, laboratory tests, procedures, and imaging studies (31,32). CPOE is usually the next major component added

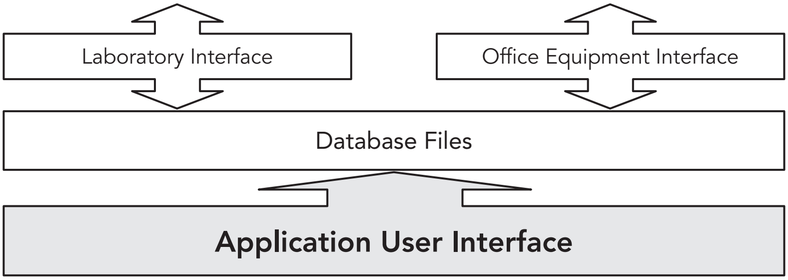

Figure 1-3 Office-Based EHR.

to inpatient EHRs once the CDR is fully functional. Decision support is a key component of CPOE functionality. Basic decision support is usually implemented as alerts and reminders such as drug interactions or warnings for order duplications (e.g., ordering a chest x-ray when a current one is extant) and is usually implemented in stages. Advanced decision support features include support for protocols, advanced drug-related alerts, and aid in drug selection.

Clinical Documentation

Full charting capabilities for nurses and clinicians are a major advancement for inpatient EHRs. Documentation runs the gamut from vital signs and basic nursing assessments to advanced systems that support structured data entry for clinicians. Nursing information systems have been around for quite a while but have not always been fully integrated with other systems. Clinician documentation functionality remains uncommon in most hospitals (1,2).

Picture Archiving and Communications Systems

Radiology information systems provide access to reports of imaging studies. Gaining access to the actual image requires access to picture archiving and communications systems (PACS) functionality. PACS began as standalone applications that were available either to radiologists or to limited areas of the hospital. Through the CDR, PACS functionality is made accessible as part of the EHR. PACS may be integrated at any stage of EHR evolution (33,34).

Electronic Medication Administration Records

Ensuring that the correct patient receives the proper medication is a major safety issue. Electronic medication administration records (eMAR) applications use wrist bands with bar codes to identify patients and to check the medication to be administered against the information in pharmacy records. This helps to prevent errors related to patient identity as well as to ensure that the proper dosage and drug are administered. eMAR is often integrated with CPOE in advanced EHR environments (35,36).

Ambulatory Electronic Health Record Systems

EHR systems designed for physicians' offices represent the simplest architecture consisting of three basic components: the database management system, user interface, and external interfaces (Figure 1-3). All are contained in one (unified) database and accessed through a common interface. Care must be taken when reviewing products to avoid systems that simply replicate the functions and content of paper-based records. This design is still seen in products that rely mainly on document imaging for storage of key chart documents (e.g., progress notes, lab reports). The ultimate value of an EHR requires, as emphasized by the IOM, discrete data that can be used for analysis or by other components of the EHR to support patient care and decision-making. EHRs offering the required level of functionality are evidenced by data formats that permit laboratory results, problem lists, medication lists and other common record data to exist as coded data elements. Ambulatory EHR products have begun to differentiate themselves based on ancillary components that support advanced population health features, as well as improved data exchange/interoperability features.

Major Ancillary Components of Outpatient Systems

Disease Registries and Preventive Medicine

Taking care of patients with chronic illnesses requires managing data from a wide variety of sources over a period of years. Disease registry features that support managing a select population such as specialized recall functions, disease-based templates, flowsheets, and specialized reporting functions are becoming more common in outpatient EHRs (37,38).

Data formats that support discrete elements along with more sophisticated report writers are being added to systems due to pressures from quality concerns such as pay-for-performance programs (39). These new features encourage "systems" thinking on the part of clinicians who use these tools to review the efficacy with which they manage their patients at the population level. They provide the analyzable data required to be able to audit the practice's adherence to internal and external clinical policies and guidelines.

Two-Way Laboratory Interfaces

Downloads of laboratory results have been available for a while. Second-generation systems are now extending their external interface features with uplinks to clinical labs as well. Removal of the need for paper when ordering labs aids in practice efficiency, reduces costs, and paves the way for additional decision support functionality.

E-Prescribing

Typical EHR medication features include medication lists and prescription writers with automatic checks for allergies and drug interactions and drug information. E-prescribing promises to add new features that promote patient safety and practice efficiency. E-prescribing services may be embedded in an EHR or provided as a stand-alone product. The most important advance of e-prescribing over previous electronic prescription writing applications is the presence of a mechanism for standardized electronic data interchange (40). With an accepted standard, all EHR and e-prescribing vendors can create applications that can share and use the same data. This makes it possible to have access to formularies from third-party payers, share medication histories between providers, and securely submit prescriptions to any pharmacy that participates. These features are making their way into second-generation EHRs systems but not without a few glitches. A national study conducted in 2006 found on-going problems with e-prescribing services (41).

Electronic Health Record Supporting Technologies

Databases

Databases are the key technology underlying all EHR systems. Databases can store data in large blocks (documents or images) or as discrete items (numbers or single words). Modern database systems may hold billions of data items and manage thousands of transactions per second. A database may reside on a single computer (the server) or multiple computers. Data repositories, warehouses, and EHRs are special types of database programs (see Chapter 4). Database management systems are software programs that provide the functions required to manipulate the information stored in databases (e.g., database creation, reporting, design). The internal structure or organization of a database is referred to as a "schema." There are no standards for schema design for EHRs; consequently, EHR products built using the same database management systems may have different schemas. This creates difficulties when attempting to move from one EHR product to another. The CCHIT certification process focuses on functional issues (whether features are present and work appropriately); they do not address database-related matters.

Delivery Models

Most EHRs are deployed on computers that reside in physicians' practices and use a central computer (server) to house the main database, which is accessed using workstations (client): this is referred to as a client/server model. Using this model, practices must have access to technical expertise (e.g., systems administrators) to maintain their computer systems. Over the last 3 years, with the rise of the Internet and high-speed connections, the "application service provider" (ASP) model for EHR deployments has become more popular. In the ASP model, the EHR resides on a central computer housed by a hosting company (usually the EHR vendor) and is accessed via the Internet. The ASP model is less expensive to deploy because the practice does not have to buy a server and maintain it. The advantages of each deployment model are listed in Table 1-4.

Data Input Technologies

Data entry is a major EHR implementation issue. The traditional means of interacting with computers, the keyboard, is not the most efficient method for many EHR users. The two alternatives that have received the most attention are pen- and voice-based input.

Pen-based input relies on a device that may be used primarily like a mouse as a pointing device, or it may be used to "write" on the computer screen much like a real pen. In the latter case, what is written may be captured as "electronic ink" and look like a handwritten note or the computer may attempt to interpret what has been written (handwriting recognition) and covert it to typed text prior to storing it in the EHR. Success with handwriting recognition is limited when large amounts of data are to be entered.

Table 1-4

ASP VS CLIENT/SERVER

	ASP	Client Server
Cost	Cheaper to start up Subscription: cost ongoing Maintenance included in subscription price	Large upfront expenditure Set price Maintenance is a separate fee
Hardware	Workstations with browsers	Workstation connected to server
Support Needs	For EHR system only Minimal need for information technology support staff	EHR and server hardware Requires greater information technology support staff
Access Method	Broadband connection (if connection is down, EHR is unavailable) Speed may be slow due to bad connection or many users accessing same server Secure remote access from anywhere	Local access (computers are directly connected) Server workload may affect response time Remote access to server may create security risk
Customization	Minimal customization possible	Customization possible
Security	Internet access risks Backups not under user control Vendor bankruptcy could result in data loss	Server security breachs possible Back-ups under user control Vendor bankruptcy results in unsupported system but no data loss

However, electronic ink is popular for drawing diagrams or other notations. The introduction of tablet PCs (computers designed to support pen-based input), which are supported by many EHR systems, are making pen-based input a workable solution (42).

Voice-recognition technology has progressed significantly over the past few years. Voice-recognition systems are now available that can handle continuous speech (no unnatural pauses between words) with relatively few errors. They are also much more affordable. Voice recognition has yet to be widely adopted as an EHR data entry mechanism. However, the technology is sufficiently mature to warrant an evaluation (43,44). In concert with templates or other structured entry formats, it can be very effective (see Chapter 3).

Networking

Local Area Networks (LAN) are groups of computers linked together to permit communication and sharing of resources. LAN technology makes computing more affordable because it permits a build-it-as-you-need-it approach to purchasing and installing both hardware and software. The main computer on a LAN is referred to as the server. Depending upon the amount of computing power required, a server may be a fast personal computer with extra memory or a special computer designed just for this purpose. In either case, a server for a small office can be purchased for a few thousand dollars.

Wireless computer capability is also changing the networking equation. Wireless networks rely on radio frequency transmissions to communicate. One great feature of using wireless technology is that users are not tied to one location. No more worrying about wiring schemes and which rooms should have terminals. The cost of wireless technology is decreasing while becoming more powerful. It is worthy of consideration when setting your networking strategy. One caveat: wireless networks may be security risks if not properly set up. Have your wireless network set up by a professional and then tested for security vulnerabilities.

Internet technologies also provide a cost-effective means for sharing applications. Applications designed for use with Internet protocols may be open to the public (Web site) or permit access only to a limited group of computers or people (intranet). Intranets are used to provide EHR applications (ASP), as well as common office applications such as word processors and spreadsheets, making intranet applications viable alternatives to LAN-based, client/server arrangements.

User Authentication

Maintaining the security of the information stored in an EHR is of the utmost importance. The standard mechanism in most EHRs for restricting access to sensitive information is passwords. Passwords can be quite effective if guarded properly. However, they can easily be forgotten or stolen. A newer approach to identifying users is via the use of biologic markers (45,46). Fingerprint and iris scanning technologies are already enjoying fairly widespread use in number of fields. Voice and face recognition systems are also available. Biometric identification is superior to passwords in two ways: they cannot be forgotten or stolen. Some laptops come with biometric access built in. The role of biometric identification for EHR security has yet to be fully determined (47).

Standardization

One of the most exciting developments in recent years is the drive to develop a set of national standards for EHRs and interoperability. HL7 published its initial EHR functional model, which contains nearly 1000 criteria organized into about 130 areas. A subset of this group is being used to define a "legal" EHR (48). The Healthcare Information Technology Standards Panel is tackling the issue of interoperability by defining formats for information exchange based on currently available standards. The work of this group may make the long-held dream of easily sharing health information between computer systems a reality (49). Only time will tell.

Summary

Over the past 40 to 50 years clinical systems have undergone significant evolution. The EHR is the ultimate goal of those who see the value of information systems in the care of patients. However, much remains to be done in the areas of data exchange/interoperability, data entry, user interfaces, database design, and security before the full benefits of EHRs can be realized.

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