Medical Informatics

The Benefits and Challenges of an Electronic Medical Record: Much More than a "Word-Processed" Patient Chart

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The electronic medical record (EMR) will constitute the core of a computerized health care system in the near future. The electronic storage of clinical information will create the potential for computer-based tools to help clinicians significantly enhance the quality of medical care and increase the efficiency of medical practice. These tools may include reminder systems that identify patients who are due for preventative care interventions, alerting systems that detect contraindications among prescribed medications, and coding systems that facilitate the selection of correct billing codes for patient encounters. Numerous other "decision-support" tools have been developed and may soon facilitate the practice of clinical medicine. The potential of such tools will not be realized, however, if the EMR is just a set of textual documents stored in a computer, i.e. a "word-processed" patient chart. To support intelligent and useful tools, the EMR must have a systematic internal model of the information it contains and must support the efficient capture of clinical information in a manner consistent with this model. Although commercially available EMR systems that have such features are appearing, the builders and the buyers of EMR systems must continue to focus on the proper design of these systems if the benefits of computerization are to be fully realized.

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It is all but a truism today that health care is among the Last major industries to "computerize," and that the "computerization" of health care is an inevitable trend, driven by the need to improve productivity, assure and demonstrate quality, integrate organizations, facilitate research, and better manage the health-care process.¹ However, there is much less agreement on what exactly computerization means in the context of health care and what a computerized health-care world will look like. This lack of clarity is especially true with respect to the primary medical record, i.e. "the chart." The primary medical record constitutes the source and core of the clinical information to be computerized, and the nature of its rendition in a computer-processible form will influence, more than any other factor, the benefits or the headaches of a computerized health-care system.2

The potential benefits of computerization to individual clinicians and to healthcare organizations are considerable: Computer-based systems can generate reports of patients due for mammography, cholesterol screening, and many other preventative measures; programs can quickly identify patients taking medications that

have been recalled or for which monitoring procedures have changed; alerting systems can immediately notify clinicians when laboratory or other test results indicate adverse conditions in a patient that require prompt attention; computerized practice guidelines can help clinicians plan diagnostic and treatment strategies in accordance with selected guidelines, or warn clinicians when their interventions are straying from a guideline; drugmonitoring programs can identify contraindications based on drug-drug interactions and therapeutic overlap with existing medications; computerized coding systems can suggest the most appropriate billing codes for encounters based on the scope and nature of clinical documentation; researchers can analyze large sets of electronic patient data to quickly and cost-effectively conduct retrospective clinical studies.

All of the computer-enabled functionalities listed above have been demonstrated in medical-computing research settings, but very few exist in routine clinical settings. One important reason for this lack of wide-spread adoption is the absence or inappropriate representation of the primary medical record in a computer-

processible form. This article describes numerous computer programs in use today that effectively and unobtrusively assist in clinical decision making by analyzing electronic medical records (EMRs). The article also discusses the features of EMRs that such programs require and why these features are uncommon. The next section reviews several types of computer programs that have proven clinically effective and that depend on appropriate representations of clinical data in EMR systems. The following section briefly describes the characteristics of effective EMR systems and one of the technical challenges that impedes the widespread availability of such systems.

Clinical Computer Tools that Require Electronic Medical Records

Several clinical institutions around the country have sophisticated electronic medical record systems. These include (though are not limited to) Columbia Presbyterian Medical Center in New York, The Latter-Day Saints Hospital in Salt Lake City, The Regenstrief Institute in Indianapolis, and several Harvard teaching hospitals in Boston. These institutions and others have deployed a variety of useful computer-based tools that are integrated with and depend on clinical data stored in their EMRs. There are several classes of such tools.

Clinical Event Monitors.

Clinical event monitors are computer programs that look for combinations of clinical data that indicate the presence of adverse and noteworthy clinical situations.³ The situations are typically ones that busy caregivers might otherwise overlook or discover only after an inappropriate delay. For example, several hours might pass in a busy hospital between the time a low serum potassium value is reported for a patient on digoxin and the time a clinician reviews the laboratory results. Clinical event monitors can recognize such combinations of data immediately and at any time (for example, right after a lab value is electronically reported). When the programs detect adverse situations, they generate and dispatch alert messages to appropriate personnel, apprising them of the problem and possibly suggesting ameliorative actions. The method of dispatching a message depends on the urgency of the alert; for example, a covering physician might be paged in response to a critical lab value. A number of studies have shown that clinical event-monitoring systems can be effective in improving patient care in hospital settings.4-7

It is obvious that clinical event monitors require access to clinical data of various kinds, such as vital signs, laboratory results, radiology reports, current medications, problem lists, and past medical histories. The electronic medical record is the most comprehensive repository of such data, but the data must be organized and structured in such a way that the event monitors can identify the clinical situations of interest reliably and efficiently. Poorly structured representations of the med-

ical record, such as those found in "word-processed" patient charts, result in false-positive and false-negative clinical alerts. At a certain threshold, the rate of false positive and negative alerts becomes unacceptable and clinicians perceive the event monitors as annoyances, at best, and incompetent, at worst.

Preventative Care Recommendations.

Related to clinical event monitors, preventative care recommendation systems identify patients who are eligible and due for various preventative care interventions, such as screening tests, vaccinations, and patient counseling. Such systems are valuable, particularly in outpatient settings, where individual clinicians may be responsible for hundreds of patients, many of whom infrequently seek care. Recommendation systems can also help clinicians stay abreast of frequent changes and variations in the preventative care guidelines published by authoritative sources, such as the American Heart Association and American Cancer Society. The systems can help clinicians select the desired guidelines and identify patients who fit those guidelines. At least one study has shown that physician compliance with certain guidelines increases through the use of a preventative care prompting system integrated with an electronic medical record.

The criteria for preventative interventions usually include demographic data such as age and gender, the existence of risk factors, the absence of exclusionary criteria, and the time interval since previous interventions. These data are usually available in the paper chart, and should be included in a structured form in the EMR. As with clinical alerts, preventative care recommendation systems must identify relevant criteria with sufficient accuracy to prevent false-positive and false-negative recommendations. An appropriate internal model of clinical data is essential to this objective.

Diagnostic Decision Support Programs.

Diagnostic decision-support programs generate differential diagnoses based on clinical findings and medical knowledge bases. The findings, which may include historical, physical, and laboratory findings, are typically entered by the users of such systems. The knowledge bases relate findings to diseases, usually in some probabilistic fashion, and rank the set of diseases suggested by a constellation of findings. Among the most prominent of these systems are programs that provide diagnostic assistance in the fields of infectious disease9 and general internal medicine. 10-12 The diagnostic acumen of these programs has been studied and the systems have proven most useful in suggesting relevant diagnoses that clinicians would have otherwise failed to consider (rather than in ranking diagnoses more effectively than clinicians).¹³ Most of the programs allow users to inspect the knowledge bases and thereby learn which findings they should pursue to rule in or rule out the (presumably less common) additional diagnoses. These capabilities unto themselves can be very

useful to primary care physicians, who are increasingly asked to manage a broader set of medical conditions and patient presentations. ¹⁴ For example, many primary care physicians confronted with an intensely pruritic lower-extremity rash may overlook the possibility of cutaneous larva migrans (CLM) and fail to elicit the appropriate travel history needed to suggest or rule out this rare but uncomfortable infection. ¹⁵ In a recent study, 58% of Canadian patients with CLM eventually referred to a tropical disease unit were misdiagnosed and ineffectively treated prior to seeking specialty care. ¹⁶ Diagnostic decision-support systems could assist non-specialist clinicians in such cases.

Although diagnostic decision-support programs have been shown to be useful and effective, very few are in common use today. One significant reason for this is the extra effort required to consult such a system at the time it is needed. Given current medical record systems, the clinician still must manually enter the set of findings for each patient into the system, although she has already documented the same findings in the patient record. Without an internal model of clinical data, including a model of all relevant findings, there is no way to effectively "link" the patient record to diagnostic decisionsupport programs such that onerous and redundant data entry is avoided. Although researchers have integrated decision-support programs with electronic medical record systems in a few settings, 17,18 until such links are widely established and decision-support is widely enabled with the single click of a button, it is unlikely that busy clinicians will avail themselves of the benefits of diagnostic decision-support programs.

Automated Practice Guidelines.

As described in a recent article in this series, clinical practice guidelines have enormous potential to improve quality and accountability in health care, but their deployment and use remains sufficiently difficult as to limit their effectiveness.¹⁹ Specifically, current paperbased practice guidelines and paper-based medical records require that clinicians find the appropriate guideline(s) that apply to their patients and determine if the clinical conditions required to trigger diagnostic and treatment actions in those guideline(s) are present. Given the multitude and complexity of guidelines, both of these steps are time consuming, information intensive, and, for many clinicians, prohibitive. Automated practice guidelines are distinct from paper-based guidelines in that they are represented as computer programs and they are linked to EMR systems.²⁰⁻²² These features may allow clinicians more easily to select the guidelines they wish to use, access the information in those guidelines, determine if the guidelines apply to their patients, and determine what actions the guidelines recommend for their patients.

The advantages of automated practice guidelines rely on the electronic representation of clinical data that the guidelines need. For example, recommendations regarding cardiac revascularization for patients with unstable angina are conditioned on symptom severity, physical signs, response to prior medical treatment, the presence of comorbidities, and the results of cardiac catheterization, echocardiography, and electrocardiography.²³ All of these data, which are typically recorded in the paper record, must be completely and precisely represented in the electronic medical record to support "automation" of practice guidelines.

Drug-prescription Assistance.

One of the most mature areas of computerized decision support in health care is drug-prescription assistance. Several commercial systems exist that can detect drugdrug, drug-allergy, drug-disease, and drug-lab test interactions based on prescription information and other clinical data.²⁴⁻²⁶ Certain of these systems can also assist in appropriately dosing medications, identifying therapeutically overlapping medications, and detecting patient non-compliance. Drug-prescription assistance may be one of the most important areas of computerized decision support, in terms of clinical and economic outcomes. A recent study estimated that the morbidity and mortality related to medication problems cost over \$76 billion per year in the ambulatory setting in the United States, roughly 8% of total health care spending.²⁷ The study also estimated that up to half of the medication problems, which include adverse drug reactions, inappropriate drug selections, inappropriate dosing, and patient non-compliance, are preventable.

Currently, most drug-prescription assistance programs are used by pharmacists. In the outpatient setting, however, community pharmacists have limited access to the data that drive drug-prescription assistance, such as patients' existing medications, diagnoses, and allergic histories. Because these data are typically documented in the medical record, the optimal location of drug-prescription assistance systems may be in the physician's office, as integrated parts of clinical information systems. Such information systems would include an electronic medical record, an order-entry capability to capture drug prescriptions, and a drug-prescription assistance component. To support the requisite links between the drug-prescription component and the EMR component, a sufficient internal model of the relevant medication, diagnosis, and allergy information in the EMR is required.

Billing Codes.

A common annoyance for clinicians and administrators in the ambulatory setting is the need to assign appropriate billing codes for each outpatient encounter. These codes, which specify diagnoses, interventions, and the general scope of an encounter, are required by the Health Care Financing Administration, Medicaid, and most private insurers. Not only is the assignment of billing codes a time-consuming and mundane task, but it is often done incorrectly, which may needlessly reduce or delay reimbursements or trigger audits by payers. Many individual clinicians and certain organi-

zations have developed flow sheets or rules to assist in the task of assigning billing codes based on the clinical elements of an encounter. For example, a billing rule may specify that a Level-3 encounter should be billed for a new patient if at least four components in the history-of-present-illness are documented, between two and nine systems are reviewed, and an extended exam of the affected body area or organ system is performed. Another rule may specify that the ICD-9 diagnosis code "443.9" (Intermittent Claudication) may be used if there is pain and weakness of the affected limb during use, but NOT if the cause of the symptoms is known to be atherosclerosis, in which case the diagnosis code "440.20" (Atherosclerosis of the Extremities) should be used.

As with practice guidelines, matching such rules to the specifics of an individual patient may be time consuming and information intensive. Given that the bulk of information driving these rules is directly available in the clinical record, computer-based tools can facilitate the selection of appropriate billing codes. One study found that a computer-based coding tool integrated with an EMR increased the accuracy of diagnosis coding by 31% and reduced coding time by 50%.²⁸ It is not surprising that the ability of such tools to improve coding and save time depends on the appropriate modeling of information in the electronic medical record. Until the EMR contains systematically structured clinical data. tools to streamline and improve the coding process will have limited utility.

Bibliographic Retrieval Systems.

During the routine course of clinical care, many questions arise regarding the proper management of patients. What is the predictive value of the test I am ordering? What is the latest treatment for this condition? Can any of the patient's medications be causing this new symptom? Studies have shown that most of these questions go unanswered at the time management decisions are made, and that the sources of information for the answered questions are usually colleagues rather than definitive references, such as text books and journals.^{29,30} At the same time, bibliographic retrieval systems that allow searching of the medical literature, such as Medline, and bibliographic retrieval systems that provide full-text access to journal articles, such as BRS Online, are becoming increasingly common and affordable. Although the medical literature is not the appropriate resource for all clinical questions, studies have shown that searching the literature from clinical settings is feasible and does affect clinical decision making. 31,32 Nevertheless, physicians cite bibliographic retrieval systems as the least desirable sources of information in clinical settings, largely because the systems are perceived as time consuming, difficult to use, and bereft of clinically relevant information.³⁰ This perception is not surprising given that inexperienced Medline users miss many relevant citations and search inefficiently compared to expert users.31

Several researchers have attempted to address the incongruence between the usefulness and the use of bibliographic retrieval systems by facilitating bibliographic searching through intelligent computer-based tools linked to EMRs. One such tool maps patients' diagnosis and procedure codes from a hospital information system to the Medical Subject Heading (MeSH) terms used to index Medline citations.³³ The tool uses the generated MeSH terms, along with one of several general information requests that the user has selected, to automatically formulate and submit a Medline search that is specific to the patient and the clinician's information need. This smooth integration of the Medline search capability with an electronic medical record relieves the clinician from remembering how to connect to Medline and how to formulate a potentially complex search request. These gaps in computer skills, and the attendant discomfort they cause, may well be the impediments standing between many information needs and the resources already available to meet them. As electronic medical records are extended to include a greater variety of structured clinical information (in addition to diagnoses and procedures), bibliographic retrieval tools will likely become more powerful, easy to use, and widely accepted.

Clinical Research Tools.

Most retrospective clinical research is still conducted today through laborious manual chart reviews done by medical students, research assistants, and office staff. This method of research is necessary because most clinical data are still locked in reams of paper charts. It is obvious that a rigorously modeled and well structured EMR could change this situation dramatically. Instead of poring over chart after chart, researchers could write programs to search and statistically analyze electronic databases of patient records without ever leaving their offices. The "word-processed" patient chart does not support this model of research, however, because the clinical information within it is not consistently represented and therefore not amenable to automated aggregation, comparison, and statistical analysis. The data in "word-processed" patient charts still must be extracted and abstracted into a normalized form before one can use the data for research. The internal model of a true EMR, however, already represents clinical data in a normalized form and can directly support clinical research.

Investigators have exploited this property of true EMRs to conduct several interesting studies with relatively minimal effort and expense. Tierney, et. al., used routine data from a comprehensive EMR system to identify predictors of mortality among patients with reactive airway disease (RAD).³⁴ Out of 90 potentially predictive variables recorded in the EMR, the study identified eight statistically significant predictors of death among RAD patients (the most strongly predictive was concomitant heart failure). The authors suggest that knowledge of grave risk factors among RAD patients can help practitioners direct healthcare resources, such as referrals to

pulmonary subspecialists, close monitoring, and aggressive preventative care measures, toward the patients at highest risk, thereby improving the average outcome for this population. Evans, et al, conducted a similar study at a different institution to identify risk factors for nosocomial infections among hospitalized patients.³⁵ These studies underscore the feasibility of conducting clinical research based on data in EMR systems and the value of carefully coding and structuring clinical data to support such research.

Effective Representations for the Electronic Medical Record

Researchers have demonstrated the effectiveness of clinical decision-support tools in settings where clinical data is available in electronic databases. The mere storage of clinical documents in a computer, however, is not sufficient to enable decision-support tools. To provide a "data substrate" for reliable and efficient decision-support tools, the electronic representation of primary clinical data must conform to certain specific design criteria, which together define a "true" electronic medical record.

Among the possible renditions of the primary medical record in a computerized form, one can imagine, at one extreme, a system in which all clinical information continues to be recorded on paper and maintained in record rooms, but the individual sheets of paper are scanned (i.e. digitally photographed) into a computer database and indexed by patient name, medical record number, and so forth. During routine care, clinicians use a computer to access these "pictures" of the medical record, instead of accessing the physical paper chart. New information is handwritten or typed on paper sheets, which are subsequently scanned into the database and ultimately filed in the paper chart. The rendition of the medical record as a set of scanned images in a computer database is useful because it minimizes the chance that the record will be unavailable, allows multiple parties to access the record concurrently, and facilitates the transmission of the record to various locations, all without requiring clinicians to change their current charting behavior. Systems such as this exist today, ^{36,37} but are they true EMRs?

The "word-processed" patient chart.

A natural enhancement to the medical record system just described entails that clinical information is not only stored but also *captured* using a computer. Clinical notes, orders, problem lists, and discharge summaries are directly typed by clinicians or transcribed from dictations into the computer database, circumventing the scanning step. This enhancement not only reduces the time before the clinical information is available in the database, but allows text-based searching tools to locate words and phrases of interest in the medical record (such as "family history of CAD"). The electronic capture of clinical information as collections of organized and indexed textual documents results in a "word-

processed" patient chart, because such a rendition of the medical record is similar to that generated using a word processor. Most commercially available computer-based patient record systems today provide this rendition, but is this a true electronic medical record?

There is a growing realization that the wordprocessed patient chart is not a true electronic medical record. It is not an electronic medical record, in general, because it cannot support the needs that are driving computerization in health care, namely improving productivity, assuring and demonstrating quality, integrating organizations, and facilitating research. Specifically, the word-processed patient chart cannot support these needs because it lacks a comprehensive internal model of the clinical information that it contains. In the vernacular of medicine, there are many ways to express the same meaning with respect to terminology and the grammatical construction of phrases and sentences (e.g. "dyspnea" versus "SOB," and "no splenomegaly" versus "splenomegaly not appreciated" versus "spleen normal," and so forth). In addition, the same words or phrases may express different meanings, depending on their context ("erythromycin" appearing in the "Allergies" section of a clinical note has a dramatically different meaning than "erythromycin" appearing in the "Prescription" section). In the word-processed patient chart, the complete universe of medical utterances may appear, and no consistent internal model exists of how clinical information is represented. This method of documentation makes it exceedingly difficult for computerbased tools to monitor, search, analyze, and compare clinical data with intelligence or reliability. In short, computer-based tools cannot understand clinical information in the absence of an internal model, and without an understanding, the tools cannot produce results that we consider sensible, useful, and trustworthy.

Internal Models of Clinical Information.

What constitutes an internal model of clinical information that computers can "understand?" (*internal* refers to the level at which information is stored inside the computer, not necessarily the level at which information is seen by users of the computer). There are two important elements to such a model:

Internal representations of data that are *concept based*, not word based

Internal representations of the *contexts* in which data are recorded

Concept-based representation means that medical concepts are stored as unique codes or identifiers that have no intrinsic meanings, but which are assigned agreed-upon conceptual meanings. For example, the code "F20040" may be assigned the conceptual meaning "the symptom of dyspnea." This code provides a unique representation of the concept "symptom of dyspnea" that is independent of the actual textual representation(s) that may be used to enter or display that concept. The textual representation seen by users of the computer may, in fact, be "dyspnea," "dyspneic,"

"SOB," or "shortness of breath" (or any other textual representation that has been registered as a synonym for the concept "F20040"). Concept-based representation allows a computer program that must know if a patient reported dyspnea to search the medical record only for the code "F20040." Word-based representation, on the other hand, provides no agreed-upon code or text that uniquely represents the meaning "symptom of dyspnea." Hence, a computer program must search the medical record for numerous possible words or phrases that may represent the concept "dyspnea." There is no guarantee that the program will anticipate all of the possible ways the concept may be represented (e.g. "dysp."). Furthermore, the computer program must be smart enough to exclude target words that appear in negation phrases such as "no dyspnea" or "patient denies dyspnea," a notably difficult task.38 Lastly, computer programs that search for words in documents rather than for codes in databases are much less efficient and much slower.³⁹

The internal models of effective EMR systems must represent not only individual clinical concepts, but also the contexts in which those concepts are recorded. Context representation is necessary to fully and correctly capture the intended meaning of documented clinical information. For example, the clinical concept "reactive airway disease" documented in the context of "Family History" has a different meaning and implies different diagnostic and therapeutic strategies than the same concept documented in the context of "Assessment." It is obviously important for computer programs that automate clinical guidelines, double check drug prescriptions, or suggest appropriate billing codes to distinguish the two meanings. Sophisticated EMR systems have extensive models of contexts that are relevant to the capture of clinical information. 40,41

The Challenge of Capturing Structured Information

Powerful EMR systems that store data for decision-support programs must represent clinical information in a systematically structured format. Because the clinician is the source of most information in the medical record, a requirement of powerful EMR systems is the ability to capture structured information directly from clinicians. However, this has proven very difficult. Capturing information in a structured format requires clinicians to select appropriate codes from a fixed set of coded clinical concepts and to place these codes in predefined clinical contexts. Most clinicians, however, are accustomed to generating clinical information by writing, typing, drawing, or dictating the observations that they wish to record. Relative to generating clinical narratives, selecting coded concepts requires more time because it entails a search through the set of all concepts for the desired observations. In the busy practice environments that characterize medicine today, delays and inefficiencies introduced by a technology will discourage the adoption

of that technology, regardless of the additional benefits that it may confer.⁴² Researchers in medical computing are addressing the problems of data capture by pursuing two distinct strategies: structured data entry and natural language processing.

Structured Entry.

Structured data entry entails the capture of information from the clinician directly in the coded format needed by the EMR. The proponents of structured data entry work to build well-designed and intelligent user interfaces that minimize the time and effort required to capture information in this way. Their strategies include using medical knowledge to anticipate the concepts that clinicians wish to record^{43,44} and designing input screens that allow clinicians to locate desired concepts quickly.45 For example, user interfaces that apply medical knowledge know to present additional options that record the dosage and frequency of the concept "Penicillin" when "Penicillin" is selected as a prescription, but to suppress these options when "Penicillin" is selected as a drug allergy. Other user-interface research has revealed that clinicians find specific concepts more quickly when those concepts appear consistently in the same position on the computer screen.45

Language Processing.

Natural language processing (NLP) is the alternative to structured data entry. NLP entails the capture of information from the clinician in an unstructured narrative format, and the subsequent extraction of structured clinical concepts by automated computer tools. The narrative text may be typed in by the clinician or it may be dictated and transcribed. The proponents of natural language processing work to build programs that can scan narrative documents and recognize relevant clinical concepts with high accuracy. Once such concepts are recognized, they are translated to concept-based codes and placed in their appropriate contexts in the EMR. Issues in building NLP programs include specifying sufficiently large vocabularies to recognize all of the terms, acronyms, and abbreviations typically used in clinical documents, and designing sufficiently powerful algorithms to recognize all of the grammatical forms in which positive and negative findings may be expressed in clinical documents. Natural language processing of medical narratives has demonstrated impressive performance for limited document types (such as radiology reports, surgical reports, and discharge summaries), providing upwards of 90% sensitivity and specificity of concept identification.⁴⁶⁻⁴⁸ However, no NLP systems have yet shown the ability to extract all clinically relevant information from all document types that may appear in the medical record. Although it is not clear whether structured data entry or natural language processing (or some hybrid of the two) is the superior strategy for capturing concept-based data in EMRs, it is likely that further research is needed before either method proves adequate.

Other Challenges.

This article has focused on the technical issues related to the capture and representation of clinical information in EMR systems. However, many non-technical issues also must be resolved before powerful EMR systems can become realities in our health care system. These include issues of patient privacy and confidentiality, physician acceptance of closer scrutiny by management, regulatory and medicolegal standards for electronic medical records, and cost-benefit justification for investments in EMR systems. All of these technical, cultural, and economic challenges must be met before the benefits offered by EMRs will be available widely.

Summary

Electronic medical record (EMR) systems have the potential to significantly improve the way that clinical information is handled and clinical medicine is practiced, to the point of constituting a revolutionary technology in health care. However, poorly designed "word-processed" EMRs will deliver on very few promises of a computerized health care system. Without well-designed internal models of the clinical information that they store, EMRs will lock patient data in electronic files, much the way that data are locked in paper charts today. Isolating clinical information from the computer-based tools that could monitor, search, analyze, compare, and aggregate it will deprive clinicians of most benefits that computer technology can confer. Recognizing this, the builders of EMR systems must continue to develop proper representations of clinical information and the consumers of EMR systems must continue to insist on products with the appropriate design and functionality.

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