

Rethinking Electronic Health Records to Better Achieve Quality and Safety Goals

William W. Stead

Departments of Medicine and Biomedical Informatics, Vanderbilt University Medical Center, Nashville, Tennessee 37203; email: bill.stead@vanderbilt.edu

Ann. Rev. Med. 2007. 58:35–47

First published online as a Review in Advance on September 20, 2006

The *Annual Review of Medicine* is online at <http://med.annualreviews.org>

This article's doi:
10.1146/annurev.med.58.061705.144942

Copyright © 2007 by Annual Reviews.
All rights reserved

0066-4219/07/0218-0035\$20.00

Key Words

health care information technology, biomedical informatics, clinical adoption, unintended consequences, patient engagement

Abstract

Health care information technology changes the ecosystem of a practice. Human roles, process work flow, and technology infrastructure are tightly interrelated. Medical errors may increase if a change in one is not accommodated by a change in the others. Introduction of information technology should be approached as an iterative process of care improvement rather than as a one-time insertion of an information system into established practice. Information technology supports a family of technological approaches, each with distinct mechanisms of action, benefits, and side effects. By matching technological approach to task and staging introduction into practice, initial benefit can be obtained more quickly, at reduced cost, while managing risk of a misfit. A staged approach to turning direct access by patients to their health information into more effective care is presented as an example of this strategy.

INTRODUCTION

Electronic health records are not a new idea. Pioneers began writing computer programs to store and retrieve patient records in 1958 (1). Controlled trials documented improvements in care with use of clinical information systems in use in the 1970s (2). The Institute of Medicine identified the computer-based patient record as “an essential technology for healthcare” in 1991 (3). However, a 2005 survey of medical group practices in the United States found <15% reporting use of an electronic medical record system (4). Recent scientific reports include examples of unintended adverse clinical consequences in health care settings using such systems (5) because of the mismatch between health care work and information system design or implementation (6).

Three bodies of literature come together to suggest a mismatch between today’s approach to health care information technology (IT) and the drive to rapidly implement electronic health records. The health care problem is one of cognitive overload. While it is intuitive that clinical information systems are needed, the documented improvements in performance are not impressive and unintended adverse consequences often occur. The mismatch stems from trying to solve a cognitive problem requiring a new approach to practice by inserting data processing and automation into old practice processes.

In general, whereas IT facilitates communication and access to information, data processing is helpful to “back-office” functions but not for customer-facing applications. I suggest we can do better in health care by taking advantage of the full range of technical approaches. I provide a schematic framework for comparing the mechanism of action of technology approaches, their effectiveness and their side effects, much as we compare pharmaceuticals. I suggest a medical practice use a mix of technological approaches, with each matched to task. This strategy allows the practice to stage health care IT implementation as a journey of iterative processes in

care improvement. Costs are reduced, benefits come earlier, and risks are minimized. I use a staged approach to engage the patients in their care as an example.

Healthcare IT is one aspect of creating a new practice ecosystem to deliver quality care safely. People’s roles and distribution, care process, and technology infrastructure all evolve together. The practice ecosystem is too important to be left to technologists alone. It calls for physician understanding and leadership.

HEALTH CARE PROBLEMS THAT CALL FOR INFORMATION TECHNOLOGY SOLUTIONS

Recent studies show that the U.S. health care system is failing to produce the quality or cost-effectiveness we expect. The problems result from underuse, overuse, and misuse. McGlynn’s random sample of adults living in 12 metropolitan areas showed that they received only 54.9% of recommended care (7). This problem of failing to deliver accepted best practice occurred across a spectrum of 30 acute, chronic, and preventive conditions. Fisher’s analysis of a representative sample drawn from the Medicare Beneficiary Survey showed a 60% variation in amount of care provided per patient between high-utilization and low-utilization regions of the country (8). This is a problem of doing more than needs to be done because the variation was not explained by baseline health status, and increased quantity of care did not translate into increased access to care or improvement on quality indicators. In addition, the Institute of Medicine estimated that between 44,000 and 98,000 Americans die each year from preventable medical errors (9).

These problems result from the same rapid advances in bioscience and technology that make medicine more effective when the care system executes properly. The information load on individual providers exceeds their cognitive capacity to respond reliably.

The effort by providers and patients alike to work around the fragmentation of specialized health care increases both the cognitive load and the chance for missteps. These challenges are compounded by administrative and regulatory constraints imposed on health care from the outside in response to the rate of cost increase and growing awareness of quality and safety problems. Health care IT is one key to reversing this spiral.

EVIDENCE OF EFFECTIVENESS OF HEALTH CARE IT

Health care IT improves quality and safety by supplying information when and where it is needed to help people make better decisions, by eliminating communication and process errors, and by analyzing information about the patient in combination with biomedical knowledge to make patient-specific recommendations. It improves efficiency by connecting information across health care transitions, and eliminating steps and rework. These improvements are difficult to quantify in a practice while changing people's roles, process, and technology at the same time. Most measures have an immediate impact on process whereas many of the expected benefits are in long-term clinical outcomes.

Garg et al. recently updated the systematic review of controlled trials assessing the effects of clinical decision support systems (2). These systems match characteristics of individual patients to a knowledge base and then use algorithms to generate patient-specific recommendations. One hundred studies met their criteria for methodological rigor. Systems improved provider performance in 62 of 97 studies, including 4 of 10 providing a diagnosis, 16 of 21 providing reminders of steps to take, 23 of 37 disease management systems, and 19 of 29 prescribing or dosing systems. Results improved if the prompts were automatic instead of requiring activation by the provider and if the developers of the software were involved in the study. Although many of the systems improved provider performance, the in-

fluence on patient outcome was unstudied or inconsistent.

Wang et al. modeled financial cost and savings of electronic medical record systems in ambulatory care from the perspective of the health care organization (10). The comparison was to the paper medical record and the outcome was cost or saving per primary care physician over a five-year period. The estimated net savings ranged from \$8400 to \$140,100 per physician. Estimated savings accrue primarily from reductions in drug, radiology, transcription, and clerical expenditures; reductions in adverse drug events; and improved charge capture. The model showed capitation increased savings over fee-for-service. Costs include system acquisition and implementation as well as loss of productivity during implementation.

CHALLENGES TO USING HEALTH CARE INFORMATION TECHNOLOGY IN PRACTICE

The challenges to using health care IT in practice fall into two categories: ones that relate to the fit among people's roles, process, and the technology; and ones that relate to the fit between the practice's infrastructure and aspects of the national health system outside its control. The former include unintended consequences, human-computer interface, and data correctness and completeness. Although better IT design can minimize the chance of misfit, practitioners are responsible for managing the internal interrelationships of their people-process-technology system to get the outcomes they desire. The time horizon for change on the national scale is such that health care providers can make decisions based on factors within their control, assuming the rest will move in the right direction more gradually.

Unintended Consequences

Quality improvement and error reduction are two of the justifications for health care IT.

Paradoxically, researchers evaluating the introduction of clinical information systems often find situations where they appear to cause errors instead of preventing them. To better understand the cause of this paradox, Ash et al. reviewed the literature and a series of qualitative research studies in the United States, the Netherlands, and Australia designed to evaluate the impact of computer physician order entry systems, i.e., systems that capture orders for care directly from physicians without physicians writing orders on paper (11). This analysis suggested that the problem lay in “the nature of health care work, the role of information and information technology, and the risks of an improper interrelationship between the information system and health care work.” Health care work involves managing several problems per patient and many patients at once, under the pressures of life and death and uncertainty, while interacting with many professionals. Information systems are often designed for one person working alone at one task at a time. If practice workflow does not adapt to reflect information system constraints or vice versa, new cognitive and communication errors occur. Examples from the Ash study include the following: entering orders for the wrong patient when interrupted; picking the wrong item from a list when similar items are close together; losing track of the overview of the patient because of data fragmentation and excessive detail; not recognizing when information entry does not result in effective communication; and missing checks because of going around the system to get something done. Miller & Gardner analyzed the suitability of FDA premarket review processes for clinical software quality assurance (12). This position paper makes the point that software intended to help people make the right decisions at the right point in their work flow cannot be evaluated except in combination with the decision maker, the work process, and other systems that touch on that process. It recommended limiting FDA regulation to systems that result in action without human intervention, such as in dose calcu-

lation for radiation therapy. Otherwise, local software oversight committees were recommended to monitor software use in practice to insure that the combination of the people, processes, and technology delivered the desired outcome.

Human-Computer Interface

A clinical information system can improve quality and safety by reducing the cognitive and communication burden on the medical team. In practice, however, such systems often increase these burdens. Walsh’s review suggests that this failure results from attempts to formalize the medical record as a collection of structured codes or phrases picked from lists (13). Although this structured approach eases reuse of the medical record for automatic decision support, research, and administrative purposes, these gains come at a cognitive cost. Walsh reminds us that story-telling is an effective way of helping another person to quickly understand an idea. The medical encounter is a series of stories. Each clinician uses his or her expertise to add and discard facts and reach conclusions about what is important. Effective communication involves a conversation, where one person says something followed by the listener saying what he heard to see if his understanding is correct. Walsh proposes that voice recording, drawings, and narrative text be accommodated in the electronic record. Similarly, displays need to present a picture of the patient instead of requiring the clinician to assemble that picture from a set of disconnected facts.

Data Correctness and Completeness

An electronic health record can eliminate rework by capturing data once at the source and presenting it for reuse as needed downstream. This approach assumes an accurate record, which is rarely achieved in practice. Hogan & Wagner’s systematic literature review summarizes studies evaluating both correctness (the proportion of entries that

represent the true state of the patient) and completeness (the proportion of observations made about the patient that are included in the record) (14). The rates of correctness and completeness showed high variability, even within data types. The range for correctness was 44%–100% and for completeness 27%–100%. Common causes for data inaccuracy include placing a question in the wrong person's work flow; not allowing for clinically relevant answers; reflecting what the physician ordered but not what the patient did; and gaps in information about care by providers who are not using the system.

National Issues

An electronic health record can connect patients and their health information across specialties, geography, and time. However, the structure of the U.S. health care system presents barriers to data exchange. We do not have a national approach to authenticating patients to provide a nonambiguous link between patient and record. People have honest disagreements about the proper balance between protection of privacy and access to information to improve care or public health. Standards for representing the information content of medical data or computable knowledge are insufficient. Reimbursement mechanisms do not align where benefits accrue with costs. Anti-kickback regulations discourage cooperation among providers, and patient data sharing raises liability concerns. The 2003 Medicare Modernization Act established the federal Commission on Systemic Interoperability to develop a comprehensive strategy for adoption and implementation of health care IT standards. The Commission's report puts a public face on the need for connecting patients and their health information with electronic records by presenting stories of the burden patients and their families face when forced to shuttle information among their providers (15). It reviews the recommendations from 20 predecessor panels charged with examining related issues since 1973. It

makes 14 interlocking recommendations for increasing adoption by providers and patients of electronic health records and for achieving technical interoperability and culturally acceptable connectivity of the records. In a viewpoint paper looking for achievable steps toward such a national health information infrastructure, I suggested it "will serve more as an enabler that facilitates the convergence of information with security and privacy, rather than an information system itself, or even a federation of information systems" (16). Demonstration and test-bed projects are under way at both federal and state levels. Such efforts are experiments. They need to be completed before conclusions can be drawn about which approaches might best generalize.

MISMATCH: QUALITY AND SAFETY GOALS VERSUS TODAY'S APPROACH TO HEALTH CARE INFORMATION TECHNOLOGY

Today's predominant approach to implementing electronic medical records in a practice involves purchasing an information system to automate, or script, its care processes. These information systems are based upon data processing techniques. The vendor may provide a "starter set" but commonly the practice has to build its lists to support data capture, its decision or communication support logic, etc. In parts of the practice that use the system, the electronic medical record is created "for free" as a byproduct of using the automated care process (17). If care takes place in areas that are not automated, the record catches up through "after-the-fact" data entry. The vendors often seek to increase the coverage of the record by providing a suite of applications that work together supported by a common database. Data elements are mapped into standard formats, such as HL7, for exchange with parts of the vendor's suite that are not well integrated into the database or products from other vendors. Much of that mapping is repeated practice by practice because exchange

standards clarify what the data element is, such as a drug orderable, but not what it means, such as its chemical substance, dose form, and route.

This data-processing approach works if the practice is largely self-contained, if it can afford IT staff to handle the setup and data mapping, and if it has clinical process expertise to adapt practice and systems to avoid unintended consequences. Even when all of those conditions fall into place, the practice does not obtain the quality and safety benefits of electronic records until the automation of the practice is complete enough to fill out the record. Such complete clinical automation rarely happens because of conflict between sequential processes suitable for scripting and multitasking clinical work. Where process automation does work, the system makes the process rigid, providing a barrier to rapid changes over time as biomedical science advances.

A FRESH APPROACH TO HEALTH CARE INFORMATION TECHNOLOGY

I provide a framework for looking beyond information systems based on data-processing approaches to support efforts to improve quality and safety. Data processing regularizes relatively simple data sets and manipulates them over the course of sequential tasks. Data processing provides an important function for health care. However, health care's clinical information base is complex and ever-changing, and clinical work is multitasking. Other IT approaches are better suited to many clinical tasks.

Matching Technology Approach and Task

Outside of health care, the IT industry has succeeded in bringing computer processing, telecommunications and media together to work as one technology. Today's cell phone functions as a digital camera, a web browser,

and a calculator, and it combines voice and text messaging. A parent can ask a child to send a time-stamped picture to verify where the child is calling from. This merged technology lets people work together differently than they could with just the cell phone or the digital camera. Yet the request, the information capture, and the exchange of the two can happen without anyone preprogramming the sequence.

Inside health care, biomedical informatics has matured as a scientific discipline providing techniques to structure, discover, visualize, and reason with information content (18). For example, informatics makes possible the "mining" of an answer from data, text, or image instead of requiring a person to "enter" it. Use of Google's search algorithms to answer a question with information garnered from documents originally created for other purposes is an example of the approach. The human genome and related scientific efforts are possible because disparate, high-dimensional data can be submitted by scientists from around the world, aggregated, and mined to identify new relationships.

I suggest thinking about clinical IT as a rich array of alternative approaches, in much the same way as medicine thinks of its pharmaceutical options. Each is suitable for some but not all purposes. Each has a mechanism of action, and proper use involves the right balance between good and adverse effects. **Table 1** is a schematic of such a view of IT approaches. It lists the potential purposes, mechanisms, or techniques appropriate for each purpose, an estimate of the balance between the effort required by humans and by technology for each mechanism, and an indication of the impact of each mechanism on the process it is supporting in terms of reproducibility and adaptability. For example, automation, using data-processing mechanisms, is largely a human task. The human operator seems to work for the system, not the other way around. Data processing results in moderate process reproducibility and some loss of process

Table 1 Information technology tool kit

Purpose ^a	Mechanism ^a	Balance between human and technology efforts ^b	Impact on process ^c	
			Reproducibility	Adaptability
Information	Aggregation	T	↑	↑↑↑
Access	Data mining	T/T	↑↑	↑↑↑
	Visualization	T/T/T	↑↑↑	↑↑↑
Work flow	Communication work lists	H/T	↑↑	↑↑
	Context-sensitive decision aids	H/H/T	↑↑	↑
Automation	Data processing and knowledge management	H/H/H	↑↑	↓↓
	Open process control	H/T	↑↑	↓↓
	Robotics	T/T/T	↑↑↑	↓↓↓

^a“Purpose” is what the technology approach does within a process; “mechanism” is how it does it.

^bT, the work is done by technology; H, by a human being; H/T, by both. Number of letters indicates task complexity.

^cNumber of arrows indicates relative increase or decrease.

adaptability. The majority of today’s purchasable clinical information systems are examples. Full automation of a task through robotics, such as a dispensing robot in a pharmacy, results in high process reproducibility and little process adaptability. Open process control falls somewhere in between; measures of system performance are used to identify when a nonrobotic system falls out of control, thereby permitting proactive problem resolution.

At the other end of the spectrum, information access using data aggregation techniques is a straightforward technological task, resulting in low-level process reproducibility by helping people involved in the process to be better informed. Making discharge summaries accessible on a file server is an example. Data mining is a mechanism requiring a higher-level technology and increasing process reproducibility by selectively showing the operators what they need to see. Google is an example. Visualization is the highest-level technology mechanism suitable for increasing information access. It increases process reproducibility by presenting the information in a

format or image that a person can easily assimilate. The CT scanner is an example. None of these approaches limits process adaptability because the human user remains free to choose what to do.

Work flow support falls in the middle of the spectrum. Communication work lists are added to an information access capacity to support tasks such as notification, handoff, and escalation. This mechanism is a mixed human and technological task resulting in moderate process reproducibility and moderate process adaptability. Context-sensitive decision aids require greater human effort during design of the decision support content and are usually implemented with the intent of reducing process adaptability.

I do not present this framework to argue for one approach over another. Instead, I clarify the differences relevant to how they might best be used. They are most effective when used together, with each matched to its purpose, instead of using one approach both where it works and where it doesn’t. To continue the analogy to pharmaceuticals, a diuretic and an ACE inhibitor control certain

cases of hypertension that neither controls alone. Automation works well for the subset of clinical processes that involve well-defined sequential tasks. In the process, it records a subset of data in a database from which the information can be accessed. Other approaches to supporting information access offer less expensive and less labor-intensive means to get other data where it can be viewed. Combining the approaches avoids the common pitfall of forcing the multitasking parts of the practice into an automated process just to get the data together.

Staging Implementation to Match Benefit and Cost

Freeing the practice from having to automate all of its clinical processes as the means of assembling electronic medical records creates flexibility in sequencing IT implementation. **Figure 1** shows use of this flexibility to ease adoption by the clinical team. The key idea is implementing the change in stages that provide more benefit than disruption in clinical work flow. IT is most helpful when easing access to data and most disruptive when data entry is required. This rule of thumb suggests a first step of using information aggregation techniques to assemble a record including images, scanned paper, word processing files from transcription, and text reports from data processing systems. The clinical team's first experience is access to the aggregate record

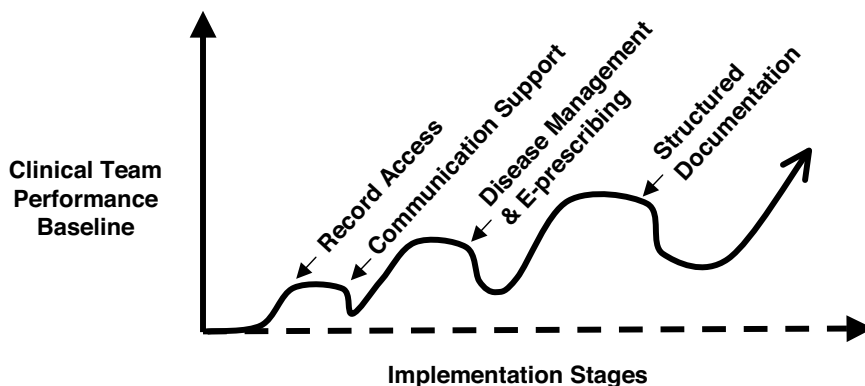
via a web browser when and where needed without the downside of change in the rest of the work flow.

Subsequent stages are more difficult because each involves change in clinical work itself. **Figure 1** depicts a drop in performance during the learning curve followed by first gradual and then steeper improvement until a new plateau is reached. The goal is to scope each stage so that team performance never falls below baseline and to time the next stage to start after a period of plateau. Again continuing the analogy to pharmaceuticals, this staging is like step control of hypertension. In practice, this goal is hard because each new plateau resets the clinical team's expectations. This moving baseline is offset to a degree because their willingness to tolerate steeper learning curves grows each time they experience such a dip resulting in improvement.

The best sequence for stages of role-process-technology change will vary by practice, reflecting clinical priorities, workflow problems that present opportunities for early wins, and prerequisite resources. Common prerequisites are access to data to carry out a task, connectivity to people who participate in the task, and suitable hardware. Early stages should have as few prerequisites as possible while putting in place resources needed for subsequent steps. **Figure 1** reflects the sequence adopted at Vanderbilt for our outpatient practices through a diffusion

Figure 1

Impact of staged implementation on clinical team performance. Arrows indicate the start of roll-out of a stage.



theory process (19). The second stage supported communication among the clinical team, including notification of new information on their patients as it appeared in the aggregate record, means to note action, and management of handoffs. The third stage added panel displays and alerts on disease management. Provider-patient messaging and E-prescribing came next. Capture of ancillary orders and structured data entry were not part of the early critical path because these require more work from the clinical team without providing significant benefit to their work flow.

Manage to Clinical and Process Outcomes

A staged approach that matches technology to task lets the practice turn implementation of health care IT into a journey of iterative cycles of care improvement. The first step is to pick the destination. If the goal is improved quality and safety outcomes, start by measuring or approximating the gap to be closed: for example, the rate at which important results are overlooked, acted on too slowly, or not communicated to others who need to know. Consider which changes in people's roles, process, and support technology might make a big enough difference to close the gap. Remember that a change in one affects the others. This focus on what it takes to achieve an outcome mitigates the tendency to implement a change too broadly and thereby reduces both cost and unintended consequences.

Given this vision of what might work, the next step is for the practice to pick the smallest first step to deliver immediate benefit. Keep that step small enough to be completed in 3–6 months. If that step works as expected, book the benefit and move on to the next step. If not, rethink the vision, redesign the first step, and try again. The big vision increases the chance that a step will be important if it works. The small steps let failure occur but minimize the repercussions.

ENGAGING THE PATIENT THROUGH ELECTRONIC HEALTH RECORDS

In telephone interviews with a nationally representative sample of 914 adults living in the continental United States, the Pew Internet & American Life Project found that 59% of American adults had Internet access in 2005. Of these users 79% have used the Internet to search for information on health topics, 66% searched for a specific disease, 51% for a specific treatment or procedure, 28% for a particular doctor or hospital, and 23% for experimental treatments (20). This section shows how a practice can turn patients' direct access to health information into more effective care. The complete effort would be a four-stage process. The first two or three steps can be accomplished without a clinical information system by matching technology to task.

Stage 1: Guiding the Patient to Trusted Information

The National Library of Medicine's mission includes making health information accessible to the public. Their health information page, <http://www.nlm.nih.gov/hinfo.html>, provides several Web-accessible resources for patients. For example, MedlinePlus includes information on >700 health topics. This "consumer information" is automatically linked to a prepopulated PubMed/Medline search for people who want to cross over to the biomedical literature. The American College of Physicians is working with the Library to help physicians use this resource with patients (21). Among physicians involved in a pilot, 42% reported that MedlinePlus helped them explain complex conditions to patients. Among patients, 65% reported that it helped them understand their conditions.

Stage 2: Personal Health Records

The personal health record is a concept in evolution (22). In essence, personal health

records are the information people need to have about their health status and care to understand how they are progressing and to give their history to a new provider. It includes information on their health care providers, current and past medical problems, procedures, current and past medications, allergies, and key test results. It includes information not necessarily found in their medical records, such as use of complementary and alternative medicine and logs of information they are tracking themselves, such as weight and blood pressure.

A practice can begin by coaching patients on the value of keeping such a record and what they should be tracking themselves. Ask them to bring it with them to the clinic and give them copies of significant results. A Harris Interactive online survey of a nationwide cross-section of adults found that 42% keep personal health records. Of these records, 86% are a paper file of copies of reports, 15% a formal journal, 13% a file on a personal computer, and 1% a website such as MyDocOnLine™ (23). Of the patients using paper instead of electronic personal health records, 60% indicated they would not use an electronic version, the majority because of privacy concerns.

Stage 3: Patient–Provider Messaging

Electronic messaging between patients and their care providers enables a shift from encounter-based to continuous care, which is automatically documented. A practice can begin to move in this direction with Internet-based email. Such a solution, although simple and commonly used, is problematic. Internet email is rarely encrypted and should not include information that the patient would not want written on a postcard. Email is usually directed to a specific user's inbox; if the user is away or an irregular user of email, the message may sit unnoticed. An email message does not become a part of the medical record unless it is copied manually. The American Medical Informatics Association has published guide-

lines for use of clinical email, with steps to avoid these and other problems (24).

Web-based messaging is a better alternative, whereby patient and provider sign onto a secure portal designed for this purpose. Security is not compromised because the browser handles encryption during transmission over the Internet and the messages are stored on a secure server hosting the portal. Setup is more difficult because the practice needs a method of establishing user names and passwords for patient and provider. Stand-alone products are available for clinical web messaging or the functionality can be obtained as an add-on to an electronic medical record system. Liederman et al. analyzed the impact of a stand-alone product in practice (25). Retrospective analysis of six case and nine control physicians showed an 18.2% drop in case call volume; the volume of combined case messaging, by call and Web, was 13.7% lower than control call volume. The related survey of 5971 patients messaging with 267 providers had a response rate of 40.3% by patients and 61.4% by providers. Patients were overwhelmingly satisfied, and providers were generally satisfied.

Regardless of which technological approach is selected, the practice has to make decisions about how to adapt process and roles to insure that the combination improves the practice. For example, how are overload and cross-coverage handled if messages go directly to physicians? Conversely, how does the patient know when to sign on to the clinical portal where new messages are infrequent? At Vanderbilt, we created a shared medical group inbox to represent the staff point that would otherwise receive a call. A physician may elect to have all his messages automatically copied to his individual inbox, but one staff person is responsible for timely responses to all messages in the group inbox. Similarly, we send a message to the patient's general-purpose email when a new clinical message is waiting. This message comes into the patient's normal email work flow but poses no threat to privacy because it contains no clinical information.

Stage 4: Direct Patient Access to the Electronic Medical Record

The fourth stage is to enable patients to access their medical records directly. Ross & Lin conducted a systematic review of interventional and noninterventional studies to assess potential benefits and drawbacks of providing this type of access (26). Potential benefits include improvements in patients' understanding, adherence, self care, and satisfaction, as well as in doctor-patient communication and reassurance. Potential drawbacks include confusing or insulting notes that create anxiety and make demands on physician and staff time. Actual benefits appeared modest and risks minimal, but the studies were not of a quality or statistical power to yield definitive conclusions.

Before a practice enables direct medical record access by patients, a number of decisions are needed. What procedure is required to verify a patient's identity whenever a link is established between his user name and medical record? Should patients be allowed to delegate access to family members? If so, how will the practice handle changes in relationships and circumstances such as guardianship? What information is displayed? Is it displayed prior to review by the physician? At Vanderbilt, each of these questions has resulted in tiered answers matching benefit and risk. For example, we currently limit display to test results. Results judged to have low "information toxicity," such as glucose, are displayed immediately. Others, subject to possible misinterpretation, such as imaging results, are displayed after a time delay to provide opportunity for physician review and intervention. Still other results, such as HIV status, are never displayed.

ACKNOWLEDGMENTS

Taneya Y. Koonce, Blaine Danielson, and Nila Sathe performed a systematic search to identify the most significant publications. The review includes concepts I learned working with the Vanderbilt Informatics Center team: Drs. Randolph A. Miller on human-computer balance in

CONCLUSIONS AND RECOMMENDATIONS

The introduction of health care IT into a practice changes the practice's ecosystem. Human roles and distribution of responsibilities, process work flow and decision making, and technology infrastructure are tightly interrelated. A change in one requires change in the others. To support continuous improvement with advances in biomedical science and health services research, the people-process-technology systems of a practice need to be adaptable, include measurement of effectiveness, and have control processes to guide proactive correction.

IT is a tool kit of technologies and techniques. The maximum benefit at the lowest cost in both human effort and dollars comes by matching the technological approach to the task. A modular or component approach to IT, using technologies that plug and play, gives a practice's management the flexibility to carry out this mixing and matching.

Health care IT implementation is best managed as care process improvement projects. The goal is to reduce the cognitive load the care provider must carry to do the right thing. To achieve this reduction, the practice needs to invest cognitive energy in developing and maintaining its people-process-technology systems. Expertise in health, quality improvement, informatics, and finance may be required. The role of the health care IT vendor shifts from system provider to partner providing aspects of this expertise and supplier of required technology components.

The adoption of more systematic approaches to health care is a journey. Cost and risk are minimized through iterative improvement cycles.

decision support; Dario Giuse on aggregation of an electronic chart; Nancy Lorenzi on people and organization issues; and Jim Jirjis on multitasking work flow and the patient portal.

DISCLOSURE STATEMENT

W.S. is Director of Healthstream, an internet training company, and of Netsilica, a private internet security company. Under Vanderbilt University's technology policy, W.S. has an inventor interest in the computer physician order entry system licensed by Vanderbilt to McKesson (which markets it as Horizon Expeo Orders), and also in the electronic patient chart licensed by Vanderbilt to Informatics Corporation of America.

LITERATURE CITED

1. Stead WW. 1989. A quarter-century of computer-based medical records. *M. D. Comput.* 6(2):75–81
2. Garg AX, Adhikari NKJ, McDonald H, et al. 2005. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes. *JAMA* 293(10):1223
3. Dick RS, Steen EB. 1991. The computer-based patient record. *Inst. Med. Rep.* Washington, DC: Natl. Acad. Press
4. Gans D, Kralewski J, Hammons T, et al. 2005. Medical groups' adoption of electronic health records and information systems. *Health Aff.* 24(5):1323–33
5. Han YY, Carcillo JA, Venkataraman ST, et al. 2006. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. *Pediatrics* 116:1506–12
6. Rosenbloom ST, Harrel FE, Lehmann CU, et al. 2006. Perceived increase in mortality after process and policy changes implemented with computerized physician order entry. *Pediatrics* 117:1452–55
7. McGlynn EA, Asch SM, Adams J, et al. 2003. The quality of health care delivered to adults in the United States. *N. Engl. J. Med.* 348:2635–45
8. Fisher ES, Wennberg DE, Stukel TA, et al. 2003. The implications of regional variations in medicare spending. part 1: the content, quality, and accessibility of care. *Ann. Intern. Med.* 138:273–87
9. Kuhn L, Corrigan J, Donaldson M. 2000. To err is human: building a safer health system. *Inst. Med. Rep.* Washington, DC: Natl. Acad. Press
10. Wang SJ, Middleton B, Prosses LA, et al. 2003. A cost-benefit analysis of electronic medical records in primary care. *Am. J. Med.* 114:397–403
11. Ash JS, Berg M, Coiera E. 2004. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *J. Am. Med. Inform. Assoc.* 11:104–12
12. Miller RA, Gardner RM. 1997. Recommendations for responsible monitoring and regulation of clinical software systems. *J. Am. Med. Inform. Assoc.* 4:442–57
13. Walsh SH. 2004. The clinician's perspective on electronic health records and how they can affect patient care. *BMJ* 328:1184–87
14. Hogan WR, Wagner MM. 1997. Accuracy of data in computer-based patient records. *J. Am. Med. Inform. Assoc.* 5:342–55
15. Ending the document game: connecting and transforming your healthcare through information technology. 2005. *Comm. Syst. Interoper. Rep.* Washington, DC: US GPO

16. Stead WW, Kelly BJ, Kolodner RM. 2005. Achievable steps toward building a national health information infrastructure in the United States. *J. Am. Med. Inform. Assoc.* 12:113–20
17. Stead WW, Hammond WE. 1988. Computer-based medical records the centerpiece of TMR. *M.D. Comput.* 5(5):48–62
18. Stead WW, Miller RA, Musen MA, et al. 2000. Integration and beyond: linking information from disparate sources and into workflow. *J. Am. Med. Inform. Assoc.* 7:135–45
19. Jirjis J, Patel NR, Aronsky D, et al. 2003. Seeing stars: the creation of a core clinical support informatics product. *Int. J. Healthcare Technol. Manag.* 5(3/4/5):284–95
20. Fox S. 2005. Eight in ten internet users have looked for health information online, with increased interest in diet, fitness, drugs, health insurance, experimental treatments, and particular doctors and hospitals. *Pew Internet*. <http://www.pewinternet.org>
21. Information Rx Project: a joint project of the ACP Foundation and the National Library of Medicine. 2006. *Am. Coll. Physicians*. <http://foundation.acponline.org>
22. Tang PC, Ash JS, Bates DW, et al. 2006. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. *J. Am. Med. Inform. Assoc.* 13:121–26
23. *Harris Interact*. 2004. Two in five adults keep personal or family health records and almost everybody thinks this is a good idea. <http://www.info@harrisinteractive.com>
24. Kane B, Sands D. 1998. Guidelines for the clinical use of electronic mail with patients. *J. Am. Med. Inform. Assoc.* 5:104–11
25. Liederman EM, Lee JC, Baquero VH, et al. 2005. Patient-physician Web messaging: the impact on message volume and satisfaction. *J. Gen. Intern. Med.* 20:52–57
26. Ross SE, Lin CT. 2003. The effects of promoting patient access to medical records: a review. *J. Am. Med. Inform. Assoc.* 10:129–38



Contents

The Drug Development Crisis: Efficiency and Safety <i>C. Thomas Caskey</i>	1
Idiosyncratic Toxicity: A Convergence of Risk Factors <i>Roger G. Ulrich</i>	17
Rethinking Electronic Health Records to Better Achieve Quality and Safety Goals <i>William W. Stead</i>	35
Schizophrenia: New Pathological Insights and Therapies <i>L. Fredrik Jarskog, Seiya Miyamoto, and Jeffrey A. Lieberman</i>	49
Cardiac Resynchronization Treatment of Heart Failure <i>Ayesha Hasan and William T. Abraham</i>	63
New Approaches in the Therapy of Cardiomyopathy in Muscular Dystrophy <i>Elizabeth M. McNally</i>	75
Acute Ischemic Stroke: Overview of Recent Therapeutic Developments <i>Nijasri Suwanwela and Walter J. Koroshetz</i>	89
Use of Stents to Treat Intracranial Cerebrovascular Disease <i>Philip M. Meyers, H. Christian Schumacher, Kurenai Tanji, Randall T. Higashida, and Louis R. Caplan</i>	107
Kidney Disease and Cardiovascular Risk <i>Marcello Tonelli and Marc A. Pfeffer</i>	123
Cardiovascular Risks of Antiretroviral Therapies <i>Kristin Mondy and Pablo Tebas</i>	141
Airway Surface Dehydration in Cystic Fibrosis: Pathogenesis and Therapy <i>Richard C. Boucher</i>	157

Toward a Comprehensive Set of Asthma Susceptibility Genes <i>Yohan Bossé and Thomas J. Hudson</i>	171
Does Anti-IgE Therapy Help in Asthma? Efficacy and Controversies <i>Pedro C. Avila</i>	185
Advances in the Treatment of Prostate Cancer <i>Mark Pomerantz and Philip Kantoff</i>	205
Immunotoxin Treatment of Cancer <i>Ira Pastan, Raffit Hassan, David J. Fitzgerald, and Robert J. Kreitman</i>	221
NSAIDs and Cancer Prevention: Targets Downstream of COX-2 <i>Yong I. Cha and Raymond N. DuBois</i>	239
The Multiple Endocrine Neoplasia Syndromes <i>Vipul T. Lakhani, Y. Nancy You, and Samuel A. Wells</i>	253
Cancer Stem Cells: Models and Concepts <i>Piero Dalerba, Robert W. Cho, and Michael F. Clarke</i>	267
Stem Cells and Chronic Lung Disease <i>Brigitte N. Gomperts and Robert M. Strieter</i>	285
Progress and Potential for Regenerative Medicine <i>Geoffrey C. Gurtner, Matthew J. Callaghan, and Michael T. Longaker</i>	299
The Leading Edge of Stem Cell Therapeutics <i>Ilyas Singec, Rabul Jandial, Andrew Crain, Guido Nikkhab, and Evan Y. Snyder</i>	313
New Reagents on the Horizon for Immune Tolerance <i>E. William St. Clair, Larry A. Turka, Andrew Saxon, Jeffrey B. Matthews, Mohamed H. Sayegh, George S. Eisenbarth, and Jeffrey Bluestone</i>	329
T Cell Costimulation: A Rational Target in the Therapeutic Armamentarium for Autoimmune Diseases and Transplantation <i>Flavio Vincenti and Michael Luggen</i>	347
A Human Monoclonal Antibody Cocktail as a Novel Component of Rabies Postexposure Prophylaxis <i>John de Kruif, Alexander B.H. Bakker, Wilfred E. Marissen, R. Arjen Kramer, Mark Throsby, Charles E. Rupprecht, and Jaap Goudsmit</i>	359
Why Hasn't Eliminating Acute Rejection Improved Graft Survival? <i>JogiRaju Tantravahi, Karl L. Womer, and Bruce Kaplan</i>	369
End-Stage Renal Disease Measures of Quality <i>Jonathan Himmelfarb and Alan S. Kliger</i>	387
Inflammatory Bowel Disease Genetics: Nod2 <i>Judy H. Cho and Clara Abraham</i>	401

New Therapeutic Approaches for Multiple Sclerosis <i>Philip L. De Jager and David A. Hafler</i>	417
Cytokine Therapy for Crohns Disease: Advances in Translational Research <i>Theresa T. Pizarro and Fabio Cominelli</i>	433
Chemokine Antagonists as Therapeutics: Focus on HIV-1 <i>Athe M.N. Tsibris and Daniel R. Kuritzkes</i>	445
Current Concepts in AIDS Pathogenesis: Insights from the SIV/Macaque Model <i>Andrew A. Lackner and Ronald S. Veazey</i>	461
Macular Degeneration <i>Edwin M. Stone</i>	477
Targeting VEGF-A to Treat Cancer and Age-Related Macular Degeneration <i>Napoleone Ferrara, Robert D. Mass, Claudio Campa, and Robert Kim</i>	491

Indexes

Cumulative Index of Contributing Authors, Volumes 54–58	505
Cumulative Index of Chapter Titles, Volumes 54–58	509

Errata

An online log of corrections to *Annual Review of Medicine* chapters (if any, 1997 to the present) may be found at <http://med.annualreviews.org/errata.shtml>