HEALTH CARE IS GROWING INCREASINGLY COMPLEX, AND MOST CLINICAL RESEARCH FOCUSES ON NEW APPROACHES TO DIAGNOSIS AND TREATMENT. IN CONTRAST, RELATIVELY LITTLE EFFORT HAS BEEN TARGETED AT THE PERFECTION OF OPERATIONAL SYSTEMS, WHICH ARE PARTLY RESPONSIBLE FOR THE WELL-DOCUMENTED PROBLEMS WITH MEDICAL SAFETY.1 IF MEDICINE IS TO ACHIEVE MAJOR GAINS IN QUALITY, IT MUST BE TRANSFORMED, AND INFORMATION TECHNOLOGY WILL PLAY A KEY PART,2 ESPECIALLY WITH RESPECT TO SAFETY.

IN OTHER INDUSTRIES, INFORMATION TECHNOLOGY HAS MADE POSSIBLE WHAT HAS BEEN CALLED "MASS CUSTOMIZATION" — THE EFFICIENT AND RELIABLE PRODUCTION OF GOODS AND SERVICES ACCORDING TO THE HIGHLY PERSONALIZED NEEDS OF INDIVIDUAL CUSTOMERS.2 COMPUTER RETAILERS, FOR EXAMPLE, NOW USE THEIR WEB SITES TO ALLOW PEOPLE TO PURCHASE COMPUTERS BUILT TO THEIR EXACT SPECIFICATIONS, WHICH CAN BE SHIPPED WITHIN TWO DAYS. MEDICAL CARE IS, OF COURSE, ORDERS OF MAGNITUDE MORE COMPLEX THAN SELLING PERSONAL COMPUTERS, AND CLINICIANS HAVE ALWAYS STRIVED TO PROVIDE CAREFULLY INDIVIDUALIZED CARE. HOWEVER, SAFE CARE NOW REQUIRES A DEGREE OF INDIVIDUALIZATION THAT IS BECOMING UNIMAGINABLE WITHOUT COMPUTERIZED DECISION SUPPORT. FOR EXAMPLE, COMPUTER SYSTEMS CAN INSTANTANEOUSLY IDENTIFY INTERACTIONS AMONG A PATIENT’S MEDICATIONS. EVEN TODAY, MORE THAN 600 DRUGS REQUIRE ADJUSTMENT OF DOSES FOR MULTIPLE LEVELS OF RENAL DYSFUNCTION, A TASK THAT IS POORLY PERFORMED BY HUMAN PRESCRIBERS WITHOUT ASSISTANCE BUT CAN BE DONE ACCURATELY BY COMPUTERS.3 MULTIPLE STUDIES NOW DEMONSTRATE THAT COMPUTER-BASED DECISION SUPPORT CAN IMPROVE PHYSICIANS’ PERFORMANCE AND, IN SOME INSTANCES, PATIENT OUTCOMES.3-6

IN THE PAST DECADE, THE RISK OF HARM CAUSED BY MEDICAL CARE HAS RECEIVED INCREASING SCRUTINY:1 THE GROWING SOPHISTICATION OF COMPUTERS AND SOFTWARE SHOULD ALLOW INFORMATION TECHNOLOGY TO PLAY A VITAL PART IN REDUCING THAT RISK — BY STREAMLINING CARE, CATCHING AND CORRECTING ERRORS, ASSISTING WITH DECISIONS, AND PROVIDING FEEDBACK ON PERFORMANCE. GIVEN THE LARGE POTENTIAL RISKS AND BENEFITS AS WELL AS THE COSTS INVOLVED, IN THIS ARTICLE WE ANALYZE WHAT IS KNOWN ABOUT THE ROLE AND EFFECT OF INFORMATION TECHNOLOGY WITH RESPECT TO SAFETY AND CONSIDER THE IMPLICATIONS FOR MEDICAL CARE, RESEARCH, AND POLICY.

WAYS THAT INFORMATION TECHNOLOGY CAN REDUCE ERRORS

Information technology can reduce the rate of errors in three ways: by preventing errors and adverse events, by facilitating a more rapid response after an adverse event has occurred, and by tracking and providing feedback about adverse events. Data now show that information technology can reduce the frequency of errors of different types and probably the frequency of associated adverse events.7-18 THE MAIN CLASSES OF STRATEGIES FOR PREVENTING ERRORS AND ADVERSE EVENTS INCLUDE TOOLS THAT CAN IMPROVE COMMUNICATION, MAKE KNOWLEDGE MORE READILY ACCESSIBLE, REQUIRE KEY PIECES OF INFORMATION (SUCH AS THE DOSE OF A DRUG), ASSIST WITH CALCULATIONS, PERFORM CHECKS IN REAL TIME, ASSIST WITH MONITORING, AND PROVIDE DECISION SUPPORT.
Failures of communication, particularly those that result from inadequate “handoffs” between clinicians, remain among the most common factors contributing to the occurrence of adverse events.19-21 In one study, cross-coverage of medical inpatients was associated with an increase by a factor of 5.2 in the risk of an adverse event.22 A new generation of technology — including computerized coverage systems for signing out, hand-held personal digital assistants (Fig. 1), and wireless access to electronic medical records — may improve the exchange of information, especially if links between various applications and a common clinical data base are in place, since many errors result from inadequate access to clinical data. In the study mentioned above, the implementation of a “coverage list” application, which standardized the information exchanged among clinicians, eliminated the excess risk resulting from cross-coverage.16

Also, many serious laboratory abnormalities — for example, hypokalemia and a decreasing hematocrit — require urgent action but occur relatively infrequently, often when a clinician is not at hand, and such results can be buried amid less critical data. Information systems can identify and rapidly communicate these problems to clinicians automatically (Fig. 1), unlike traditional systems in which such results are communicated to a clerk for the unit.12-15 In one controlled trial, this approach reduced the time to the administration of appropriate treatment by 11 percent and reduced the duration of dangerous conditions in patients by 29 percent.23

Another key to improving safety will be improving access to reference information. A wide range of textbooks, references on drugs, and tools for managing infectious disease, as well as access to the Medline data base, are already available for desktop and even hand-held computers (e.g., through http://www.epocrates.com and http://www.unboundmedicine.com). Ease and rapidity of use at the point of care were initially problematic but appear to be improving, and hand-held devices are now widely used, especially for drug-reference information.24

One of the main benefits of using computers for clinical tasks that is often overlooked is that it makes it possible to implement “forcing functions” — features that restrict the way in which tasks may be performed. For example, prescriptions written on a computer can be forced to be legible and complete. Similarly, applications can require constraints on clinicians’ choices regarding the dose or route of

Figure 1. Notification about a Critical Laboratory Result.
This is an example of the combination of a hand-held device and a cellular telephone (Sprint) to allow rapid communication about an important abnormality (in this case, a potassium level of 2.5 mg per deciliter) and to offer the clinician the option to take one of several actions immediately.
administration of a potentially dangerous medication. Thus, a dose that is 10 times as large as it should be will be ordered much less frequently if it is not one of the options on a menu (Fig. 2). Indeed, forcing functions have been found to be one of the primary ways in which computerized order entry by physicians reduces the rate of errors. The usefulness of forcing functions may also apply to other types of information technology. For example, bar-coded patient-identification bracelets designed to prevent accidents, such as the performance in one patient of a procedure intended for another patient, function in this way. Similarly, many actions imply that another should be taken; these dependent actions have been termed “corollary orders” by Overhage et al. For example, prescribing bed rest for a patient would trigger the suggestion that the physician consider initiating prophylaxis against deep venous thrombosis. This approach — which essentially targets errors of omission — has resulted in a change in behavior in 46 percent of cases in the intervention group, as compared with 22 percent of cases in the control group, with regard to a broad range of actions.

The use of computers can also reduce the frequency of errors of calculation, a common human failing. Such tools can be used on demand — for example, by a nurse in the calculation of an infusion rate.

Monitoring is inherently boring and is not performed well by humans. Moreover, so many data are collected now that it can be hard to sift through them to detect problems. However, if the monitoring of information is computerized, applications can perform this task, looking for relations and trends and highlighting them, which can permit clinicians to intervene before an adverse outcome occurs. For example, “smart” monitors can look for and highlight signals that suggest the occurrence of decompensation in a patient — signals that a human observer would often fail to detect (Fig. 3).

A related approach that appears to be beneficial on the basis of early data is technology-enabled remote monitoring of intensive care. In one study, remote monitoring in a 10-bed intensive care unit was associated with a reduction in mortality of 68 percent and 46 percent as compared with two different base-line periods, and the average length of stay in the intensive care unit and related costs each decreased by about a third. Such monitoring is especially attractive in the intensive care unit because there is a national shortage of intensivists.

Information systems can assist in the flow of care in many important ways by making available such
key information on patients as laboratory values, by calculating weight-based doses of medications, or by red-flagging patients for whom an order for imaging with intravenous contrast material may be inappropriate. A longer-term benefit will occur as more sophisticated tools — such as computerized algorithms and neural networks — become integrated with the provision of health care. Neural-network decision aids allow many factors to be considered simultaneously in order to predict a specific outcome. These tools have been developed in order to reduce diagnostic and treatment errors in numerous clinical settings, including the assessment of abdominal pain, chest pain, and psychiatric emergencies and the interpretation of radiologic images and tissue specimens. Controlled trials have demonstrated improvement in clinical accuracy with the use of such technical tools, including their use in the diagnosis of myocardial infarction, the detection of breast cancer on screening mammograms, and the finding of cervical neoplasia on Papanicolaou smears. However, of these practices, only neural-network-assisted cervical screening has had substantial use, and little of that use has been in the United States. Nonetheless, more widespread use of electronic medical records could lead to an expanded role for these applications and make it easier to integrate them into routine care.

Computerized tools can also be used with electronic medical records to identify, intervene early in, and track the frequency of adverse events — a major

**Figure 3. “Smart” Monitoring in an Intensive Care Unit.**

This screen highlights physiological changes that are occurring (in this case, a rapid pulse and a trend toward increasing pulse and decreasing blood pressure [BP]); such monitoring can help clinicians to detect and respond to such changes before an adverse event occurs. The heart-rate (HR) limit alert is triggered when the heart rate crosses a high (H) or low (L) limit, which are determined according to the patient’s active medical conditions. Patient 5 (thick arrow) has had surgery and is at risk for perioperative coronary events. The limit value is given in brackets, followed by the patient’s current value. The heart-rate or blood-pressure trend alert is triggered if the heart rate or blood pressure changes substantially over a period of several hours. Patient 4 (thin arrows) has an increasing heart rate and a decreasing blood pressure; on evaluation, this patient was found to have hypovolemia. The base-line value is given in brackets, followed by the current value. Screen courtesy of Michael Breslow, M.D., Visicu, Baltimore.
gap in the current safety-related armamentarium — since, to improve processes, it is important to be able to measure outcomes. Classen et al. pioneered an approach for combing clinical data bases to detect signals that suggest the presence of an adverse drug event in hospitalized patients, such as the use of an antidote; this approach identified 81 times as many events as did spontaneous reporting, which is the standard technique used today. Others have built applications that allow the detection of nosocomial infections in inpatients and adverse drug events in outpatients.40

Such tools may be useful both for the improvement of care and for research. Together with Indiana University, we are conducting a controlled trial to evaluate computerized prescribing for outpatients. In the first year of this study, we built a computerized monitor for adverse drug events, which goes through the electronic medical record to detect signals (such as high serum drug levels) that suggest that an adverse drug event may have occurred (Table 1). This approach inexpensively identifies large numbers of adverse drug events that are not routinely detected. We are now using the rates of events to assess the effect of computerized prescribing, first with simple and then with more advanced decision support.

Table 1. Results of Screening for Drug-Related Adverse Events with the Use of Electronic Medical Records for Outpatients.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Brigham and Women’s Hospital</th>
<th>Wishard Memorial Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>33,202</td>
<td>19,426</td>
</tr>
<tr>
<td>No. of visits</td>
<td>54,679</td>
<td>38,736</td>
</tr>
<tr>
<td>No. of signals</td>
<td>2,169</td>
<td>5,846</td>
</tr>
<tr>
<td>No. of signals per 1000 patients</td>
<td>65.3</td>
<td>300.9</td>
</tr>
<tr>
<td>No. of drug-related adverse events</td>
<td>220</td>
<td>647</td>
</tr>
<tr>
<td>No. of drug-related adverse events/1000 patients</td>
<td>6.6</td>
<td>33.3</td>
</tr>
<tr>
<td>No. of drug-related adverse events/100 signals</td>
<td>10.1</td>
<td>11.1</td>
</tr>
</tbody>
</table>

Data represent the findings of an ongoing trial and come from four months of outpatient visits at clinics affiliated with two large institutions. Examples of signals are the use of an antidote or a high serum drug level. This table illustrates the power of using computerized information to identify very large numbers of safety-related problems that would not be routinely detected with paper systems. Although the rate of drug-related adverse events appears to be much higher at Wishard Memorial Hospital (Indianapolis) than at Brigham and Women’s Hospital (Boston), there are differences between the populations of patients, and detection of drug-related adverse events appears to be better at Wishard Memorial, which has more extensive computerized information (data not shown).

Electronic tools designed to identify a broad array of adverse events in a variety of settings seem promising. Often, these signals may permit earlier intervention; for example, Raschke et al. found that 44 percent of the alerts generated by a tool that they built had not been identified by the team of clinicians.5

**MEDICATION SAFETY AND THE PREVENTION OF ERRORS**

After anesthesia, medication safety has perhaps been the most closely studied domain in patient safety. Efforts to reduce the rate of medication errors have involved all the strategies discussed above. Nearly half of serious medication errors have been found to result from the fact that clinicians have insufficient information about the patient and the drug. Other common factors include a failure to provide sufficient specificity in an order, illegibility of handwritten orders, errors of calculation, and errors in transcription.7 In one controlled trial involving inpatients, the implementation of a computerized application for order entry by physicians — which improves communication, makes knowledge accessible, includes appropriate constraints on choices of drugs, routes, frequencies, and doses, helps with calculations, performs real-time checks, and assists with monitoring — resulted in a 55 percent reduction in serious medication-related errors.8 In a further study, which evaluated serial improvements to this application with the addition of higher levels of support for clinical decisions (e.g., more comprehensive checking for drug allergies and drug–drug interactions), there was an 83 percent reduction in the overall rate of medication errors.9 The use of decision support for clinical decisions can also result in major reductions in the rate of complications associated with antibiotics, and can decrease costs and the rate of nosocomial infections.10 Other technological tools with substantial potential but less solid evidence of effectiveness include the bar coding of medications and the use of automated drug-delivery devices for both oral and intravenous medications.11

**SUMMARY OF APPROACHES TO PREVENTION**

To date, studies have generally been conducted only in individual facilities and rarely in the outpatient setting; moreover, only a few types of technology...
have been well tested. However, the large benefits found in the improvement of fundamental aspects of patient care\(^8,12,13,16-18\) indicate that information technology can be an important tool for improving safety in many clinical settings.

Tools that can improve communication, make knowledge more accessible, require key information, and assist with calculations and clinical decision making are available today and should provide substantial benefit. More research is needed on such questions as how best to perform checks, how best to assist in monitoring, and especially, how to provide decision support most effectively in complex situations. In today’s systems, many important warnings are ignored,\(^42\) and there are too many unimportant warnings. Approaches have been developed to highlight more serious warnings — for instance, by displaying a skull and crossbones — when a clinician tries to order a drug that has previously caused an anaphylactic reaction in the patient (Fig. 4). However, many efforts directed at complex targets such as the management of hypertension\(^44\) or congestive heart failure\(^45\) have failed. Overcoming these difficulties will require bringing cognitive engineers and techniques for assessing and accommodating human factors, such as usability testing, into the design of medical processes.

Figure 4. Warning Displayed for a Drug Allergy.

When warnings are displayed in current systems, even important messages are often overridden, most likely because too many unimportant warnings are displayed. Principles of design that take into account human factors suggest that it is important to make warnings that are more serious look different from those that are less serious,\(^43\) as in this case, in which the screen displays a skull and crossbones to warn that the patient has previously had anaphylaxis. Whether or not such a design would result in increased attention to important warnings has not been tested.
Despite the substantial opportunities for improvement in patient safety, the development, testing, and adoption of information technology remain limited. Numerous barriers exist, although some approaches to overcoming them are at hand.

**Financial Barriers**
The development of medical applications of information technology has largely been commercially funded, and reimbursement has rewarded excellent billing rather than outstanding clinical care. As a result, the focus has been more on products to improve the “back-office” functions related to clinical practice than on those that might improve clinical practice itself. Since they depend on new capital, research and development efforts for clinical tools have had relatively limited funding. When companies have produced useful technological tools, their spending on clinical testing has been negligible, particularly in comparison with what is spent on the testing of medical devices or drugs. Furthermore, even for proven applications, such as computerized order entry for physicians, vendors do not have ready-made products. For clinicians and institutions seeking to adopt technological tools, the investment costs can be high, and the quality of the decision support that comes along with these applications remains highly variable.

Progress on this front is unlikely to occur without considerable investment — particularly public investment — in clinical information technology. Incentives could make an important difference. To increase capital investment, legislation has been introduced in the U.S. Senate to provide nearly $1 billion over a period of 10 years to hospitals and Medicare-supported nursing homes that implement technology that improves medication safety. Of concern, however, are measures that mandate the adoption of such technology without providing the funding for doing so. California, for example, has passed a law requiring, as a condition of licensure, that all nonrural hospitals implement technology such as, but not limited to, computerized order entry for physicians by January 1, 2005. Neither an increase in reimbursement nor capital grants were provided to help hospitals to meet this requirement. A piece of national legislation in this area — the Patient Safety Improvement Act of 2003 (H.R. 877) — was passed by the House of Representatives on March 12, 2003. This bill would provide $50 million in grants over a two-year period to institutions that implement information technology intended to improve patient safety. Forms of technology that are named include electronic communication of patient data, computerized order entry by physicians, bar coding, and data support technology. Although this is a positive development, these incentives are sufficiently limited that their effect would most likely be small.

**Lack of Standards**
We lack a single standard in the United States today for representation of most types of key clinical data, including conditions, procedures, medications, and laboratory data. The result has been that most applications do not communicate well, even within organizations, and the costs of interfaces are high. Another highly charged issue is that standards for some important types of data are privately held. Privately held standards are standards that are in general use but are licensed by a company or organization. Examples of privately held standards are diagnosis codes that are licensed by the College of American Pathologists and procedure codes that are licensed by the American Medical Association.

However, there are both short-term and longer-term opportunities in this area. The National Committee on Vital and Health Statistics recently released a report endorsing national standards for electronic data for key domains. The adoption of the Consolidated Health Informatics standards by the federal government on March 21, 2003, represents a major step forward. This initial set includes standards for messaging, images, and clinical laboratory tests. Such standardization will encourage innovation and the adoption of applications with relatively little cost to the government. Although standards are not fully developed for every important type of information, the identification of this area as a major priority should make it possible to do the additional work required, especially if federal funding to support it is provided. An important open question is whether any organization should be able to hold a national standard privately. We believe that one appropriate approach would be to require organizations to sell such classification systems for a fair price.

**Cultural Barriers**
There is also a tendency for clinicians and policymakers to see information technology as relatively unimportant for either research efforts or incorpor-
ration into medical practice. Academic centers are more apt to seek and reward faculty members who pursue research on a drug or a device that might lead to a reduction of 0.5 percent in the rate of death from myocardial infarction than those who develop a decision-support system that could result in a far greater reduction. Furthermore, clinicians have been reluctant to adopt information technology even when it has been shown to be effective.

This reluctance appears to have a number of causes. It is still a new concept in medicine that computerized tools can have powerful benefits in practice. When errors occur, physicians are no less likely than the public to see the clinicians involved, rather than the system, as the central problem.\(^2\) In addition, many physicians are still uncomfortable with computers. Some are concerned about depending on them, particularly for clinical decision making. With regard to certain technological tools, such as e-mail between physicians and patients and electronic medical records, clinicians are also concerned about legal issues, including privacy.

Not only the government but clinicians too, in their practices and relationships with colleagues and health care facilities, must recognize that most preventable adverse events result from failures of systems, not individual failures. Investment in and adoption of new forms of information technology must be understood as being as vital to good patient care as the adoption of new technological tools for diagnosis and treatment.

**CURRENT SITUATION**

Overall, few of the types of information technology that may improve safety are widely implemented. For example, few hospitals have adopted computerized order entry for physicians. However, the Leapfrog Group — a coalition of some of the nation’s largest employers, such as General Electric and General Motors — has identified it as one of three changes that they believe would most improve safety,\(^56\) and many hospitals are beginning on this path. Use of computer-assisted decision making in diagnosis and the planning of treatment remains rare. Furthermore, the quality of the clinical software applications that are currently being developed remains unclear. Especially given the absence of widely used standards, organizations have been reluctant to make large financial commitments, fearing that they will select a dead-end solution. Another pivotal issue is that information technology has been seen by many health care organizations as a commodity, like plumbing, rather than as a strategic resource that is vitally important to the delivery of care. Exceptions are institutions such as the health systems of the Department of Veterans Affairs and Kaiser, and reported data suggest these strategies have been successful.\(^57-59\)

**CONCLUSIONS**

The fundamental difficulty in modern medical care is execution. Providing reliable, efficient, individualized care requires a degree of mastery of data and coordination that will be achievable only with the increased use of information technology. Information technology can substantially improve the safety of medical care by structuring actions, catching errors, and bringing evidence-based, patient-centered decision support to the point of care to allow necessary customization. New approaches that improve customization and gather and sift through reams of data to identify key changes in status and then notify key persons should prove to be especially important.

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improving safety with information technology

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