

Decision Support in Medicine: Examples from the HELP System

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Computerized health information systems can contribute to the care received by patients in a number of ways. Not the least of these is through interactions with health care providers to modify diagnostic and therapeutic decisions. Since its beginnings, developers have used the HELP hospital information system to explore computerized interventions into the medical decision making process. By their nature these interventions imply a computer-directed interaction with the physicians, nurses, and therapists involved in delivering care. In this paper we describe four different approaches to this intervention. These include: (1) processes that respond to the appearance of certain types of clinical data by issuing an *alert* informing caregivers of these data's presence and import, (2) programs that *critique* new orders and propose changes in those orders when appropriate, (3) programs that *suggest* new orders and procedures in response to patient data suggesting their need, and (4) applications that function by summarizing patient care data and that attempt to retrospectively assess the average or typical quality of medical decisions and therapeutic interventions made by health care providers. These approaches are illustrated with experience from the HELP system.

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INTRODUCTION

As the United States explores new approaches to the delivery of medical care, the quality of that care is a topic that elicits much interest and concern. One of the central questions in the field of medical computing is how to use computer systems to maximize quality at a time when costs must be managed. This topic covers a broad range of possible computer-based interventions, from the use of programs in the home to help patients assess the need for professional care to the development of national data bases to evaluate the costs and benefits of the often widely varying approaches to diagnosis and treatment practiced in different parts of the country.

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A survey of all real or potential computerized interventions is beyond the scope of this paper. Instead, we will focus on a limited group of computer-oriented techniques for altering care. The emphasis will be on techniques that have been tested as a part of the development of the HELP Hospital Information System (*I*). This system provides a number of well-studied examples of computerized medical assistance. We will focus specifically on approaches that involve intervention in the decision-making behavior of the physicians and nurses primarily responsible for patient care.

The HELP system is the product of research and development by the Department of Medical Informatics at the University of Utah and the LDS Hospital in Salt Lake City. It has been the hypothesis of these researchers that computers can contribute both to an improvement in the quality of medical care and to an enhancement in the efficiency of care delivery. This expectation is shared with scientific investigators across the country and indeed around the world. Below we will discuss some of the evidence from our experience that supports this view. The accumulating evidence adds credence to the claim that future medical care will be best delivered with the active aid of clinical computer systems.

Several services provided by medical information systems have proven to be of value in a hospital setting. These fall into the major categories of electronic documentation, data review, and expert systems functions. This paper focuses on experience with the expert systems technologies embedded in the HELP system. The HELP system has been involved in the delivery of care since 1975. A number of experimental subsystems that have evolved within this hospital information system have lent themselves to formal evaluation. The more successful of these can be shown to enhance care and reduce costs.

While the value of expert systems technologies in the medical setting is the central theme of this document, it is clear that other technologies have played a vital role in the successful implementations described below. These include the proper use of interfacing techniques, appropriate procedures for the introduction of computerized tools, effective training of future users, and continuing maintenance of medical software. Moreover, the foundation for a system that can analyze clinical data and produce suggestions for care is a data base with two specific characteristics. It is integrated, in the sense that data from a variety of sources can be retrieved using a rapid and uniform interface, and it is as comprehensive as possible. The development of this sort of data base has been a central focus during the creation of the HELP system.

THE HELP SYSTEM

The HELP system, in its incarnation as a comprehensive medical information system, represents more than 20 years of development and testing. It currently runs on hardware provided by the Tandem computer company and communicates with users and developers through approximately 1200 terminals and more than 150 printers. It is interfaced to a variety of other computer systems,

including a billing system, a laboratory system, an electrocardiography system, a medical records system, and a collection of local area networks (LANs) used by a variety of departments for local research and departmental management functions.

The software that forms the foundation of the HELP system provides tools to support the three basic functions that define an advanced information system. These are data acquisition, data interpretation, and data review. While each of these functions has its own set of challenges and requires its own set of enabling technologies, our focus in this paper will be on tools for data interpretation and decision support. We will concentrate on the application of these tools to enhance the delivery of care in a hospital setting.

To simplify our discussion, these applications are broken into four categories. This classification captures the idea that different models of computerized assistance apply to different types of clinical problems. The applications discussed and illustrated below will be (1) processes that respond to clinical data by issuing an *alert*; the purpose of the alert is to inform appropriated care providers of the presence and import of this data; (2) programs that respond to decisions to alter care (typically new orders) by *critiquing* the decision and proposing alterations as appropriate; (3) applications that respond to a request by the decision maker by *suggesting* a set of diagnostic or therapeutic maneuvers fitted to the patient's needs; and (4) *retrospective* quality assurance applications that abstract clinical data and decisions from the records of patients. These typically provide summary information bearing on the quality of the decisions and therapies adopted by one or more caregivers. Each of these is discussed and illustrated below.

ALERTING SYSTEMS

Alerting processes are programs that function continuously behind the scenes to monitor clinical data as it is placed in each patient's record. They are designed to test specific types of data against predefined criteria. If the data meet the criteria, the alerting applications inform the proper medical personnel. The timing and character of this message vary with the alerting goals.

Below are two examples from the HELP system that illustrate an approach to computerized data alerting. The first deals with a system developed to monitor common laboratory results and to detect and alert for potentially life-threatening abnormalities in commonly acquired data. The second is an application devoted to identifying patients scheduled for surgery who require preoperative antibiotics. It functions by intervening to remind clinical staff to give preoperative antibiotics appropriately.

Example 1: The Computerized Laboratory Alerting System

The HELP system captures results from the clinical laboratory through an interface to a dedicated laboratory information system (LIS). Once laboratory tests have been ordered, this system manages their execution. The results are collected and returned to the HELP system for storage in the clinical record.

TABLE 1
ALERTS FOR WHICH COMPUTERIZED ALERTING LOGIC WAS CREATED

Alerting condition	Criteria
Hyponatremia (NAL)	$\text{Na}^+ < 120$ meq/liter
Falling sodium (NAF)	Na^+ fallen 15+ meq/liter in 24 hr and $\text{Na}^+ < 130$ meq/liter
Hypernatremia (NAH)	$\text{Na}^+ > 155$ meq/liter
Hypokalemia (KL)	$\text{K}^+ < 2.7$ meq/liter
Falling potassium (KLF)	K^+ fallen 1+ meq/liter in 24 hr and $\text{K}^+ < 3.2$ meq/liter
Hypokalemia, patient on digoxin (KLD)	$\text{K}^+ < 3.3$ meq/liter and patient on digoxin
Hyperkalemia (KH)	$\text{K}^+ > 6.0$ meq/liter
Metabolic acidosis (CO_2L)	$\text{CO}_2 < 15$ and $\text{BUN} < 50$ or $\text{CO}_2 < 18$ and $\text{BUN} < 50$ or $\text{CO}_2 < 18$ (BUN unknown) or CO_2 fallen 10+ in 24 hr and $\text{CO}_2 < 25$
Hypoglycemia (GL)	Glucose < 45 mg%
Hyperglycemia (GH)	Glucose > 500 mg%

Laboratory results are reviewed by personnel engaged in patient care both through terminals connected to the HELP system and through a variety of special and general purpose printouts. The times when the data are reviewed have only a loose relationship to the times when they become available. Instead, the principal determinant is typically the work schedules of the physicians and nurses involved with the patient. The doctor, for instance, may visit the hospital twice a day and review patient data only at those times unless some aspect of the patient's condition prompts a more aggressive approach.

Under these circumstances abnormalities in laboratory results, especially those that are unexpected, may not receive the timely attention that they deserve. In particular, serious laboratory abnormalities may go unseen for hours until a nurse or physician reviews them during her/his routine activities. Or, as some authors have noted, they may be missed entirely (2, 3). As a response to this disparity, Bradshaw *et al.* have described an experiment with a Computerized Laboratory Alerting System (CLAS) designed to bring potentially life-threatening conditions to the attention of caregivers (4, 5). This system was constructed by reducing a set of 60 alerts used in a previous experimental system (6) to the 10 alerts felt to be the most important (Table 1). Six medical experts from the disciplines of surgery, cardiology, internal medicine, and critical care participated in the development of these alerts and the system used to deliver them. The alerts chosen were translated into computer logic and tested to determine that the logic functioned properly. Data from previously admitted patients were used to refine the logic.

Once the logic was deemed acceptable, an experiment was designed to evaluate the effect of the system on several measures of intermediate outcome. Two approaches were tested for delivering the alerts. The first of these techniques was tested in a single nursing division to determine its acceptability. A flashing yellow light was installed in the division and whenever an alert was generated for a patient in that division the light was activated. It continued to flash until

TABLE 2
 APPROPRIATENESS OF TREATMENT BEFORE AND AFTER CLAS
 WAS IMPLEMENTED

Type of alert	Baseline period ^a	CLAS in use ^a
Na ⁺ , K ⁺ , or glucose	45/66 (68.1)	57/68 (83.8)*
Metabolic acidosis	20/62 (32.3)	18/52 (34.6)
Total	65/128 (50.8)	75/120 (62.5)*

^a Patients treated appropriately/total patients (%)

* *P* of difference <0.05.

the alert was reviewed and acknowledged on a terminal. The second approach was less aggressive but proved more acceptable to nursing staff. Whenever anyone entered the program used to review a patient's laboratory results, any unacknowledged alerts for that patient were immediately displayed along with the data that had triggered them.

A set of parameters was chosen to measure the effect of this intervention. The clinical parameters collected included appropriateness of treatment, time spent in the life-threatening condition, and length of stay. These outcome measures were evaluated before clinical implementation in a group of patients who would have triggered alerts and after clinical implementation in a group who had alerting conditions identified. Patients in intensive care settings were excluded based on a previous study that suggested that alerts had no effect on their care. The results are summarized in Tables 2-4.

The study was carried out during 1986 and 1987. Baseline data were collected for patients retrospectively. Then CLAS was implemented clinically and prospective data were collected. Appropriateness of treatment was assessed by a physician who reviewed these patients' charts and evaluated the clinicians' response to the abnormalities for which the alerts were generated. Care was considered appropriate if specific guidelines were met.

Alerts for metabolic acidosis were seen most frequently and were evaluated

TABLE 3
 TIME SPENT IN A LIFE-THREATENING CONDITION BEFORE
 AND AFTER CLAS WAS IMPLEMENTED

Type of alert	Baseline period ^a	CLAS in use ^a
Na ⁺ , K ⁺ , or glucose	30.4/6	15.7*/6
Metabolic acidosis	44.3/20	26.5*/10

^a Hours spent in LTS/number of patients in LTS at discharge.

* *P* of difference <0.05.

TABLE 4
LENGTH OF STAY BEFORE AND AFTER IMPLEMENTING CLAS

Type of alert	Baseline period	CLAS in use
Na ⁺ , K ⁺ , or glucose		
Mean length of stay (all patients)	14.6 days	8.8 days*
Mean length of stay (no deaths)	14.2 days	6.9 days*
Mortality	6 of 61	8 of 54
Metabolic acidosis		
Mean length of stay (all patients)	14.9 days	11.2 days
Mean length of stay (no deaths)	15.4 days	10.9 days
Mortality	11 of 62	4 of 52

* *P* of difference <0.05.

separately. Alerts for abnormalities of sodium, potassium, and glucose were seen less frequently and were grouped for analysis.

Overall results showed a 12% increase in the proportion of the patients who received appropriate therapy after CLAS was implemented (Table 2). The principal contributor to this result was the sodium, potassium, and glucose alerting group, where a greater than 15% increase was seen.

Length of time spent (LTS) in the life-threatening condition was also reviewed. In both subgroups LTS dropped after CLAS was implemented. LTS dropped from 30.4 hr to 15.7 hr in the group with sodium, potassium, or glucose abnormalities and from 44.3 to 26.5 hr in the group with metabolic acidosis (Table 3). A total of 42 patients remained in the state that had caused the alert at the time they left the hospital.

Length of stay was also reduced for the group of patients with sodium, potassium, or glucose abnormalities detected by CLAS (Table 4). Overall, in this group, length of stay decreased from 14.6 days to 8.8 days. However, six of the patients during the baseline period and eight of the patients during the CLAS study period died. When these patients are excluded the decrease in length of stay is from 14.2 days to 6.9 days. The length of stay also appeared to decrease for the group with metabolic acidosis; however, the degree of decrease was less striking and was not statistically significant.

With the increase in the severity of illness in hospitalized patients, unexpected abnormalities in clinical data can be expected to become more frequent. This study suggests that an intervention as simple as drawing attention to new abnormalities in laboratory data can significantly alter care and improve outcomes. Recent efforts have been directed toward refining the users' interface with the computer. A system in which the computer contacts nurses using the hospital pager system is now under investigation (7).

The system described above is dependent on a process called data-driving. The HELP system contains general-purpose tools for triggering processes (like those that produced the alerts described above) when prespecified data are

ANTIBIOTIC PROPHYLAXIS GUIDELINE

- () A parenteral prophylactic antibiotic is generally indicated for this patient's surgery. If given, prophylactic antibiotics should be started 1-2 hours before surgery and discontinued within 24 hours after surgery.

- () Prophylactic antibiotics are generally of unproven benefit for this patient's surgery but may be indicated in the presence of certain risk factors.

FIG. 1. Preoperative reminder sticker designed to be placed on the chart of surgery patients identified by the computer.

added to the clinical data base. When the specified data are stored, sets of programs that can write reports, collect additional data, or communicate with specific terminals such as those near a patient are activated. This type of tool greatly simplifies the construction of programs designed to respond in a timely manner to evidence of clinical abnormalities.

Example 2: Preoperative Antibiotic Alerting

Another set of applications that use an alerting process to provide clinically important feedback is part of a system called the Computerized Infectious Disease Monitor (CIDM) (8). This system uses data from HELP's integrated data base to (1) recognize the presence of nosocomial infections, (2) report unusual antibiotic sensitivity patterns, (3) alert in cases in which an infection is receiving inappropriate antibiotic therapy, (4) detect cases of reportable disease, and (5) alert in situations in which the delivery of perioperative antibiotics does not meet accepted guidelines. Several of these functions have been studied and shown to be of value (9). Here we will describe the processes that monitor prophylactic use of antibiotics in surgery and, through an alerting mechanism, attempt to modify the care of the patient.

Postoperative infections can lengthen hospital stays, cause serious medical complications, and increase patient mortality. For some types of surgery, preoperative antibiotic therapy has been demonstrated to reduce postoperative infections (10, 11). Guidelines for antibiotic use in these situations have been developed (12). Unfortunately, an important component of these guidelines, the delivery of the antibiotics in the preoperative period (defined as the 2 hr prior to surgical incision), is often neglected. One component of the CIDM is a subsystem that identifies patients who are scheduled for surgery. The system then determines whether the surgery involved is one for which preoperative antibiotics are recommended and generates reminders prompting the use of preoperative antibiotics when appropriate (Fig. 1).

The effect of this system was studied during two 6-month periods in 1985 and 1986 (13). First, the level of compliance with accepted behavior was determined without computerized intervention. Then the system described above was in-

TABLE 5
SUMMARY STATISTICS FOR PATIENTS RECEIVING PERIOPERATIVE
ANTIBIOTICS

Computer's suggestion	Baseline period (1985)	System installed (1986)
Prophylaxis indicated	1621	1830
Patient received antibiotic	1276 (79%)	1493 (82%)
More than 2 hr prior to incision	193 (12%)	176 (10%)*
2 hr before time of incision	638 (40%)	1070 (58%)**
After the time of incision	445 (27%)	247 (14%)**
Did not receive antibiotics	345 (21%)	337 (18%)

* $P < 0.02$.

** $P < 0.001$.

stalled and the effect of routine suggestions for preoperative antibiotics was assessed.

After excluding patients with short stay or outpatient surgery, emergency surgery, prolonged preoperative hospital course, multiple surgeries, and contaminated or dirty surgery, 3263 patients were available in the group collected in the June through November time frame in 1985. From the intervention group collected between June and November in 1986, 3568 patients were available. Tables 5 and 6 summarize the outcome of this study.

In 1985 the computer system identified 1621 patients for whom antibiotic prophylaxis was indicated. Of these, 1276 (79%) received antibiotics. Forty percent of the antibiotics were begun during the recommended 2-hr interval prior to the incision. In 1986, during the period when the computer's suggestions were fed back to the physician, 1830 patients were identified as appropriate for

TABLE 6
FREQUENCY OF WOUND INFECTIONS BEFORE AND AFTER COMPUTERIZED REMINDERS

Computer's suggestion	Baseline period (1985)		System installed (1986)	
	Wound infections	Percentage	Wound infections	Percentage
Prophylaxis indicated	28/1621	1.8%	16/1830	0.9%*
Patient received antibiotic	24/1276	1.9%	14/1493	0.9%*
More than 2 hr prior to incision	7/193	3.6%	4/176	2.3%
2 hr before time of incision	5/638	0.8%	7/1070	0.7%
After the time of incision	12/445	2.7%	3/247	1.2%
Did not receive antibiotics	4/345	1.2%	2/337	0.6%

* $P < 0.05$.

presurgical antibiotics. Of them, 1493 (82%) received antibiotics on the day of surgery. Fifty-eight percent of these patients were treated appropriately during the 2 hr preceding surgical incision.

This represented a significant ($P < 0.001$) improvement in adherence to proper use of these antibiotics. Both the patients receiving antibiotics more than 2 hr before surgery and those receiving antibiotics after surgery had begun were significantly reduced from the control period. The effect of this improvement is suggested by the information summarized in Table 6. The principal outcome that preoperative antibiotics effect is postoperative wound infections. During the period when alerts were issued, no significant change was noted in the wound infection rates in those patients for whom the computer system did not recommend antibiotics. In the group for which the computer suggested that prophylaxis was indicated, the overall rate of wound infections dropped from 1.8 to 0.9% (significant at $P < 0.05$). This decrease occurred in the group that received the antibiotics and appeared to be related to the larger proportion of these patients receiving antibiotics during the 2-hr preoperative period recommended by the computer.

The increase in compliance with recommended preoperative antibiotic therapy to 58% was ascribed to the alerting processes described above. To further increase compliance with this protocol, the LDS Hospital infectious disease department has also developed computerized reminders for the surgical nursing staff. These include printed reminders provided as a part of a general purpose checklist for surgical patients and a computer program that displays upon demand those patients requiring preoperative antibiotics.

The cumulative effect of all of these interventions is evident in subsequent compliance with the antibiotic prophylaxis guidelines. In the first quarter of 1991 the frequency with which antibiotics were given during the 2 hr prior to incision was reviewed. The compliance rate at that time was 96% (14). Unfortunately, because of changes in surgical practice during the intervening years, the wound infection rates in 1991 cannot be compared directly to those in 1985 and 1986. However, the data that are available indicate that infection rates have continued to decline as conformity with these protocols improves.

The processes described above are not the only ones that monitor perioperative antibiotic usage. A complementary system alerts when prophylactic antibiotics are continued beyond the recommended 48 hr. These processes have also been shown to be effective in reducing the inappropriate use of antibiotics in the surgical patient (15).

During the busy hours prior to surgery it is not unusual for physicians with the best of intentions to neglect a step as simple as issuing orders for preoperative antibiotics. The study discussed above suggests that alerting functions can be effectively used for presenting reminders prompting well-accepted standards of care and that the result of these reminders is improved patient outcomes.

CRITIQUING SYSTEMS

In the alerting examples described above, the computer system responds to elements of data as they enter into the data base by prompting those caring for the patient to intervene. In contrast, critiquing processes begin functioning

when an order for a medical intervention is entered into the information system. They typically respond by evaluating that order and either pointing out disparities between the order and an internal definition of proper care or by proposing an alternative therapeutic approach.

Below, two applications that use critiquing to intervene in patient care are described. The first example examines orders for drug therapy and evaluates them against computerized knowledge of adverse interactions both between two or more drugs and between drugs and other aspects of the patient's clinical status. The second application is a critiquing subsystem specifically targeting orders for blood products. It is embedded in a system for ordering these therapies.

Example 1: Computerized Medication Monitoring

The computerized medication monitoring system is one of the oldest and most popular decision-support applications on the HELP system. It has been in operation since 1975 and, in surveys of the LDS Hospital medical staff, has consistently been rated as one of the most beneficial programs. The system is designed to monitor all drug orders as they are entered into the computer and to present a message to the user if potential problems are detected involving drug-drug, drug-allergy, drug-lab, drug-disease, drug-diet, drug-dose, or drug-interval interactions. This monitoring system is embedded in the medication ordering software and is used by pharmacists and nurses as they enter drug orders into the system.

The knowledge that underlies this system is routinely reviewed by physicians, pharmacists, and pharmacologists and is altered as necessary to reflect changes in the hospital formulary, experience with the system, experience with drug interactions in clinical practice, and the literature concerning these interactions. Messages returned by the system include both informational alerts and action alerts. The pharmacist is responsible for reviewing messages, determining which are valid and which require action, and for those that require action, communicating the message to the physician. The response of the physician is recorded and is used to help review the accuracy and effectiveness of the system.

Medication alert reports can be produced summarizing the behavior of the system. Table 7 contains a sample of this report from March 1988.

The system may run multiple times for any hospital inpatient. In one 16-month study (16), 88,505 medication orders were entered for 13,727 patients. Of these, 690 orders resulted in messages (0.8%). These were spread across 5% of the patients.

Because of the extensive experience with this system, it is possible to evaluate the effect of continuous review and updating of the logic combined with growing physician familiarity with and confidence in its workings. The effect is manifested as increasing acceptance of the system's messages. Figure 2 demonstrates the increasing compliance with the system's suggested actions over 12 years. The process of review and revision of this successful critiquing system continues in the current version of HELP.

TABLE 7
PHARMACY MEDICATION CRITIQUE REPORT

	March 1988	Year to date (1988)
Total number of valid messages	183	774
Total number of action messages	113	399
Total number of information messages	70	375
Compliance with action messages	99.1%	99.2%
Total number of drug-allergy messages	14	67
Total number of drug-drug messages	79	356
Total number of drug-lab messages	90	351
Different modules of computer logic triggered	45	—

Evaluation of the benefits of an alerting system of this sort are difficult. In an attempt to do a benefit/cost analysis of the medication monitoring system, Gardner *et al.* used a modified Delphi approach to assign a dollar cost to each alert the system was capable of sending (17). The dollar costs of treating potential adverse drug effects and the expected frequency and severity of these events in patients who had alerts were used in the calculations.

The result was an estimate of the benefits (measured purely in additional costs for patient care avoided) of each alert. This value was combined with the frequency of the individual alerts to give an overall estimate of the benefits in a 2-year period. Estimated charges of 35 cents per patient day for this service allowed an approximation of the cost of providing this service. Based on more than 53,000 patients, monitored for over 246,000 patient days, the cost was

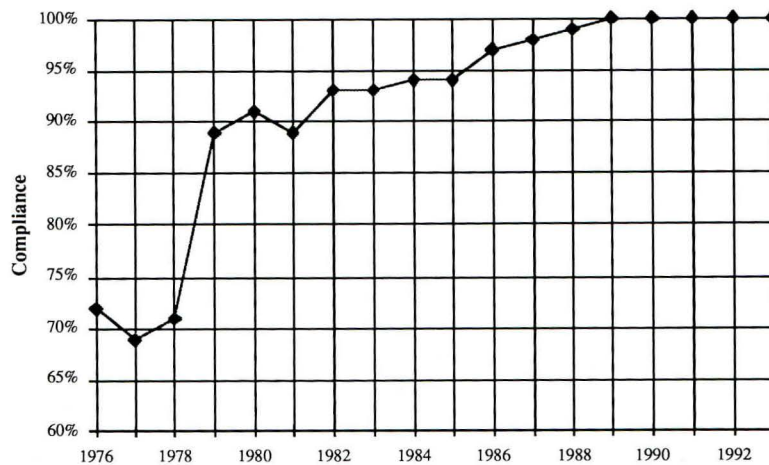


FIG. 2. Changes in compliance with critiques from the drug monitoring system between 1976 and 1992.

TABLE 8

SIMPLIFIED CRITERIA FOR ORDERING RED BLOOD CELLS

Hemoglobin <12 g/dl or hematocrit <35% if age \geq 35 years
Hemoglobin <10 g/dl or hematocrit <30% if age <35 years
Oxygen saturation (SaO ₂) <95%
Active bleeding
Blood loss >500 ml
Systolic blood pressure <100 mm Hg or heart rate >100 bpm
Adult respiratory distress syndrome (ARDS)

estimated to be over \$86,000 to deliver this service for 2 years. The estimated benefit exceeded \$339,000, resulting in a benefit/cost ratio of 3.94.

Example 2: Critiquing Orders for Blood Products

In recent years it has become increasingly apparent that the transfusion of blood products is at once an important, often life-saving therapy and that these same blood products must be ordered and administered with care. Not only are there significant reasons for anxiety concerning diseases that can be transmitted during transfusions, but also the limited supply and short shelf life of blood products make them a scarce resource to be used sparingly. In 1987 the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) released a document outlining nine steps to be taken in the review of institutional blood usage (18). Central to this document was a requirement to set institutional criteria for the use of blood products and to carefully monitor compliance with these criteria.

At the LDS Hospital the response to this document was to develop a computer system designed specifically to manage the ordering of transfusions and to assist in ensuring compliance with criteria for proper use of blood products (19, 20). A central premise of this system is that all orders will be entered into the computer and that nurses and physicians will do all of the blood ordering.

Embedded into the blood ordering program is a critiquing tool designed to ascertain the reason for every transfusion and to compare this reason to a set of criteria. The approach used provides information specific to the type of transfusion planned. For instance, when an order is made for packed red blood cells, the criteria in Table 8 are used to critique the order.

The process of entering an order into this system includes several points at which information bearing on the propriety of giving blood products is displayed. As a first step, the physician is shown the blood products ordered in the last 24 hr. This is followed by a display of the applicable laboratory data. Then the user chooses the specific blood products required along with the number of units and the priority (stat, routine, etc.). At this point the user is asked to document the reason for the order. A list of reasons, specific to the blood product chosen, is displayed and the user chooses the appropriate rationale for

the intervention. The computer then applies the stored criteria and determines whether the order meets the hospital's guidelines.

If the guidelines are met, the order is logged and the blood bank and nursing division are informed via computer printout. If the criteria are not met, the user is presented with a message stating the applicable criteria and relevant patient data. The physician or nurse may optionally decide to place the order, but he or she is required to enter (as free text) the reasons for the decision to override the system.

The criteria used are the result of an effort by the LDS Hospital medical staff. They developed the criteria primarily using published guidelines but with some adaptations for local conditions. The criteria are subject to modification based on experience.

One way of measuring the effectiveness of the system's various informational messages is to examine the frequency with which the process of ordering blood products is terminated because of them. During a 6-month period the ordering program was entered and then exited without an order 677 times. This is 12.9% of the total uses. We estimate that one-half of these exits represent decisions not to order blood products based on feedback from the program.

The process described fulfills the requirement of the JCAHO for ordering blood products. Because the quality assurance department need follow-up cases only in which the physician or nurse overrode the criteria, the task of monitoring compliance with the established guidelines has been made much easier. During 1989 when 13,833 orders were placed for 49,916 units of blood products, 2627 orders (19%) required review by quality assurance nurses. Sixty-two (0.45%) were considered true exceptions and were referred to the individual physician's department for further review.

Recent efforts to extend this work have focused on evaluating its effectiveness in preventing both over- and undertransfusions (21) and on experiments with a version that would propose therapy rather than simply critiquing physicians' orders (22). The blood ordering package has demonstrated the ability of computers to intervene in the medical decision making process to standardize and optimize therapy.

This program relies heavily on the integrated clinical data base in the HELP system. It accesses data from (1) the admitting department, (2) the clinical laboratory, (3) surgical scheduling, (4) the blood bank, and of course (5) the orders entered by nurses and physicians.

The drug and blood ordering programs described above contain processes that support computerized critiquing. Both respond to interventions chosen by the physician by analyzing the order and, if appropriate, suggesting reasons to alter the therapeutic plan. The process used by the blood ordering program is more sophisticated in that it involves a dialog with the user. As a result, it can provide a series of informational responses designed to ensure that the user is fully aware of the status of the patient as well as of accepted guidelines governing blood product usage. Unfortunately, physician use of generalized computerized order entry programs is limited. Doctors actively avoid inputting orders through

interactive computer systems. As order entry programs are designed to better encourage their use by physicians, opportunities for a constructive interaction between the computer and the clinician will grow.

SUGGESTION SYSTEMS

The third category of computer applications designed to support medical decision-making is, in some ways, the most promising. This group of processes is designed to react to requests (either direct or implied) for assistance. They respond by making concrete suggestions concerning which actions to take next.

Unlike alerts, messages from these systems are expected. A clinician would typically wait for suggestions from these systems before instituting a new therapy. Unlike critiquing systems, the physician need not commit to an order before the program applies its stored medical logic. Instead, the program conducts an interaction with the user, during which either explicitly or implicitly the user requests a suggestion concerning a specific therapeutic decision. The system then reviews relevant data, frequently including data that it has requested from the user, and formulates a suggestion for therapy based on the medical knowledge stored in its knowledge base.

The example below is in many ways typical of suggestion systems. It functions in the realm of ventilator therapy and has been implemented in increasingly sophisticated forms in intensive care settings as the LDS Hospital since 1987.

Example: Computer Protocols for Ventilator Management

As a tertiary care setting, the LDS Hospital sees a large number of patients with problems leading to respiratory failure. One of the most severe of these problems is that of adult respiratory distress syndrome (ARDS). This syndrome can be associated with a number of other conditions, including trauma, infectious disease, and shock. The usual therapy includes respiratory support while the underlying pulmonary injury heals. Unfortunately, overall mortality for ARDS has remained at about 50% for many years. For the subset of ARDS patients who manifest severe hypoxemia, the mortality is approximately 90%.

The study of computer protocols in this area was driven by research into the effectiveness of a new therapeutic intervention. In the early 1980s research began to suggest that devices that bypassed the lungs to remove carbon dioxide (CO₂) directly from a patient's body might improve survival in the most severely ill of the ARDS patients. Physicians at the LDS Hospital wanted to study this new approach in a rigorously controlled setting. They chose to do an experiment with a test group who would receive the treatment and a control group who would not. However, the researchers were aware that the management of ARDS differed from patient to patient depending on the course the disease followed and the training and previous experience of the physicians and staff caring for the patient. For this reason, they decided to standardize care by strict adherence to predetermined treatment protocols.

They began by developing a set of paper protocols. As the protocols became

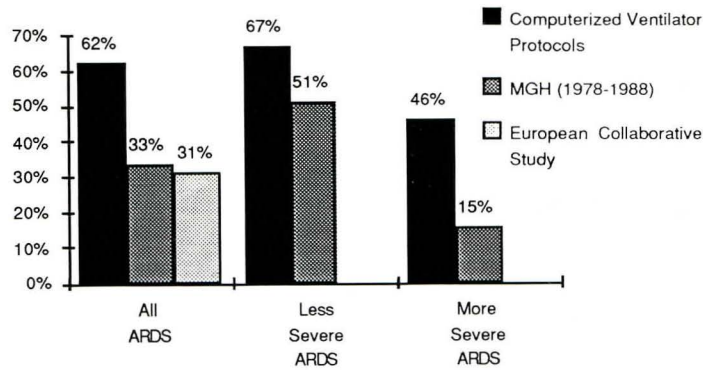


FIG. 3. Comparative results for groups managing ARDS patients. Percentages shown are the survival rates of ARDS patients.

more complex, it became clear that they would be difficult to follow manually. Therefore, it was decided to computerize them. The result was a set of computerized rules that were designed to direct, in detail, the management of patients in both the test and the control branches of a study of extracorporeal CO₂ removal (ECCO₂R)(23-26). While the rules were designed initially for this research, they were found to be acceptable for management of all ARDS patients.

The protocols were created by a group of physicians, nurses, respiratory therapists, and medical informaticists. The initial work of this study group spanned a period of 18 months. Subsequent development has concentrated on first eliminating errors in protocol logic and extending its scope and second in reworking behavioral patterns in the intensive care setting so that the protocols could be effectively implemented.

The system devised was used successfully during the ECCO₂R study. The study was terminated after 40 patients were treated, 21 with ECCO₂R and 19 with conventional therapy. At that time there were 8 survivors in the conventional therapy group (42%) and 7 in the ECCO₂R group (33%) (27). The researchers concluded that there was no significant difference between ECCO₂R and conventional treatment of severe ARDS. However, the 42% survival in the control group was unexpected. Reported survival in these severely ill patients is 0 to 15%. The results led the researchers to suspect that the quality and uniformity of care provided through the use of computerized protocols had resulted in a significant improvement in patient outcomes.

As a consequence, development and study of these protocols has continued. Figure 3 summarizes the results of their use in the 111 LDS Hospital patients studied to date and compares these results to those of two other groups (Massachusetts General Hospital (MGH) and the collaborative ARDS studies carried out in Europe).

In ARDS patients and in two subgroups (more and less severe ARDS pa-

tients), it appears that patients cared for using the ventilator protocols show a higher survival than those cared for using conventional therapy delivered without computer assistance. This finding is consistent with historical comparisons of LDS Hospital patients treated before the development of this system and those treated using these protocols.

Development and testing of this approach to delivering care in the intensive care setting is continuing. As a part of this effort the protocol development group has continued to refine the protocol logic (28) and to monitor compliance with protocol suggestions (29) and the success of this computer-aided intervention (30).

In this section we have focused the definition of systems for suggesting therapeutic interventions quite narrowly. We have limited our examples to systems that respond with a suggestion when the clinician has explicitly or implicitly requested one and plans to base his or her own decision upon the system's response. This is an area in which we are continuing to explore better ways to interact with clinicians and better ways to capture and encode protocol knowledge.

COMPUTERS IN RETROSPECTIVE QUALITY ASSURANCE

A final form of computerized intervention that may be useful in influencing the quality of care is that of retrospective review. This approach emphasizes the computer's ability to collect and make available a variety of information bearing on the effectiveness of care delivery. In this case, the computer functions to facilitate review of information used as a measure of the clinician's behavior. Feedback can be based on individual actions or on an overview of actions taken over multiple patients and thought to represent a behavioral pattern.

One example of intervention based on individual actions identified by the computer is provided by the computerized blood ordering system described above. In this system it is possible to place an order for a blood product that does not meet the criteria in the system's critiquing rules. The system was not designed to ration blood use and all orders are accepted. However, when the rules fail to support a specific order, the physician is required to enter an "override" reason. These orders are stored as exceptions in the order log and are reviewed individually by a quality assurance nurse within 24 hr of the order.

The blood ordering system supports this review by providing a printout of essential information at the time the quality assurance is done. Figure 4 is an example of two exceptions. During the first 2½ years of its use, 18% of the orders required quality review. The subset that proved to be true exceptions (less than 0.5% of all blood orders) were referred to the appropriate medical committee.

This type of approach provides feedback to physicians after they make their blood ordering decision. The computer assists by expediting a thorough review of each individual order. An alternate approach is to focus on behavior that is


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1 PATIENT NAME NO: 20716668 AGE: 74 SEX: F E714 28-NOV-07:58
PRODUCT: PACKED CELLS UNITS: 1 STAT WRITTEN ORDER
REASON: NO REASON GIVEN
DOCTOR: MILLAR, XXX ENTERED BY: BOWEN, SHELLY G
PLATELETS: 91 K HCT: 35.7 HGB: 11.4 TIME: 28-NOV-03:58
VIT-HR: 118 VIT-SP: 112 TIME: 28-NOV-07:45
SA-O2: 86 TIME: 28-NOV-05:10
PROGRAM EXECUTION TIME: 1 MINUTE
EXCEPTION: UNCLASSIFIED
1 UNIT ISSUED FIRST ISSUED: 28-NOV-16:30 LAST ISSUED: 28-NOV-16:30
.
.
1 PATIENT NAME NO: 10725273 AGE: 60 SEX: M E847 28-NOV-07:58
PRODUCT: LEUKOCYTE POOR CELLS UNITS: 4 ROUTINE WRITTEN ORDER
REASON: ANEMIA
DOCTOR: MAIR, XXX ENTERED BY:
OVERRIDE REASON: HCT = 22 AT MD OFFICE
PROGRAM EXECUTION TIME: 1 MINUTE
EXCEPTION: UNCLASSIFIED
1 UNIT ISSUED FIRST ISSUED: 28-NOV-16:30 LAST ISSUED: 28-NOV-16:30

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FIG. 4. Example of blood order exception list for use by quality assurance nurse in reviewing orders that do not meet criteria.

typical for a physician or group of physicians. In this case the computer's task is to collect and summarize data bearing on actions or decisions made by caregivers. Below we discuss two examples of this approach.

Example 1: Mammographic Screening

A great deal of research supports the use of routine mammography to help recognize and treat breast cancer early in its course. There is clear evidence that these malignancies can be detected by mammograms well before they are recognized through breast examination and that treating the tumors at this early stage greatly increases the opportunity for cure.

A number of computerized systems have been developed to manage the delivery of screening mammography. One of the early examples was built as a subsystem of the HELP system (31). The advantages of integrating this system into a general purpose medical information system were multiple. A principal advantage, however, was the ability to access outcome data in the form of the results of breast biopsies captured by the system. Using this information and the coded interpretations of the mammograms, we have been able to engage in feedback to the physicians concerning the accuracy of their interpretations.

A simple example of the type of information available is shown in Fig. 5. In a group of approximately 1500 patients with mammograms, 33 had biopsies showing cancer. Twenty-eight of these malignancies had been recognized on mammogram, while 5 of these patients had a normal mammography result.

This analysis is for the Radiology Department as a whole. However, it is straightforward to stratify the results by radiologist and to allow them to compare their individual accuracies with that of the group. An example of this kind of feedback is given next.

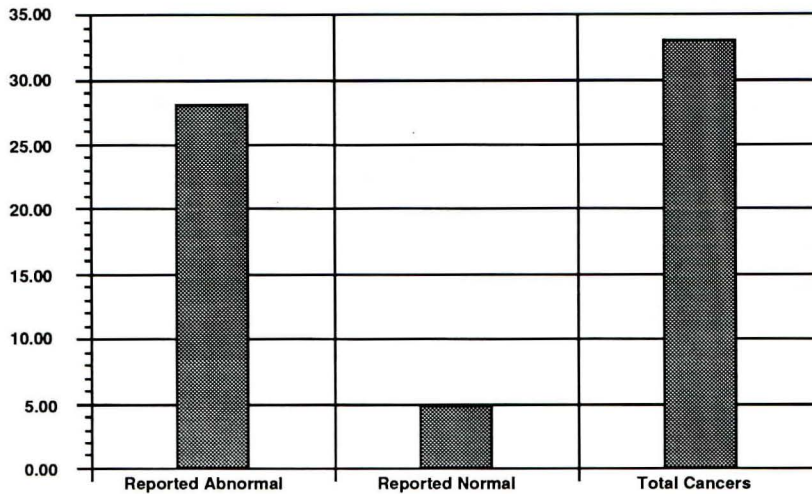


FIG. 5. Analysis of 33 biopsy-proven breast cancers. Twenty-eight were recognized on mammogram and 5 were missed.

Example 2: CQI in Obstetrics and Cardiac Surgery

A more formal approach to the process of retrospective quality assurance is exemplified by a study carried out recently in the Division of Thoracic Surgery and the Department of Obstetrics. This experiment had, as its focus, techniques from the discipline of continuous quality improvement. Continuous quality improvement (CQI) is an approach to organizational management popular in Japan for decades. It has recently been gaining advocates in American industry. In addition, there have been a number of calls to investigate its applicability to problems in medical care (32-34).

To try to understand the applicability of these techniques to physician behavior, researchers at the LDS Hospital tested their ability to provide CQI-based feedback to two groups of physicians and to measure a set of outcomes that might be affected by this feedback (35). Core goals of this experiment were (1) to determine whether the data necessary for this form of quality management could be derived from computerized patient records, (2) to involve physicians in the selection of the parameters that would be analyzed, (3) to determine the acceptability of blinded, graphical feedback of relevant data to the physicians, (4) to explore techniques for separating assignable variation in behavior from that due to random variation, and (5) to test the effects of this intervention, again using data from the medical computer system. Of these goals, 2 through 4 are among the precepts of CQI.

CQI begins by determining, in accord with the users, which data elements best represent the underlying process of medical care that is being examined. In the case of thoracic surgery, the decision was made to study coronary artery

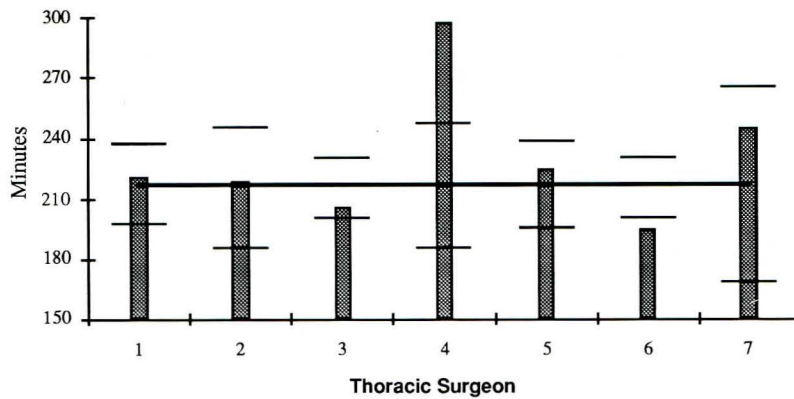


FIG. 6. An \bar{x} -bar plot of mean surgical coronary bypass surgery times for 7 thoracic surgeons. The boldface line is the group mean and the thinner lines are the upper and lower control limits.

bypass surgery. The agreed-upon measures included surgical time, total patient length of stay, postoperative length of stay, total patient hospital charges, and complications of surgery (i.e., atelectasis, thrombophlebitis, mortality, and intrathoracic hemorrhage necessitating return to the operating room). These data came from the HELP system except for patient charges, which came from an interconnected hospital billing system.

After collecting the chosen data, analysis began. At this point there were two goals. The first was to document the variability in the parameters chosen and to determine which part of that variability was due to natural variation and which could be attributed to the process of care managed by the physician. Variability occurs naturally due to a group of factors including differences in patients, differences in degrees of illness (number of involved vessels, etc.), and other factors beyond the physician's control. Assignable variability is that portion of the variability that is due to differences in the practice patterns of the physicians involved. A group of statistical tools has been developed to aid in the recognition and communication of these two forms of variability (36).

The communication of the concept of assignable variability is important because it is through communicating to the users data concerning assignable variation in their own practices that the CQI process has its effect. The tools used to communicate information concerning physician-related variability in the parameters described above were based on statistical process control (SPC) charts. These charts are designed to allow visualization of both the contribution to variation that is random and that which is assignable. Two forms of these charts were used. They are called \bar{x} -bar plots (used to analyze continuous data) and p -bar plots (used to analyze binary data). Figure 6 is an \bar{x} -bar plot depicting the variation among seven surgeons for surgical times.

The data for this chart come from a preliminary study of 196 surgical patients seen between September 1991 and January 1992. The chart shows the mean surgical time for each of the seven surgeons. In addition, a boldface line shows

TABLE 9
DIFFERENCES IN PARAMETERS BEFORE AND AFTER PRESENTATION OF CQI DATA TO
THORACIC SURGEONS

Parameter	Group mean	Standard deviation	Difference	2-way ANOVA <i>P</i> value
Surgery time				
Before	215.6 min	56.8 min	10.3 min	0.0456*
After	205.3 min	60.5 min		
Length of stay				
Before	9.35 days	3.43 days	0.34 day	0.5043
After	9.01 days	3.06 days		
Post-op stay				
Before	7.57 days	2.91 days	0.42 day	0.4106
After	7.14 days	2.37 days		
Charges				
Before	\$24,455	\$7,571	-\$1,395	0.1445
After	\$25,851	\$7,829		

* $P < 0.05$.

the group mean time of 215.6 min. The thinner lines placed in each surgeon's column are the upper and lower control limits (UCL and LCL). These represent the range of values within which each surgeon's mean time could fall and still be due entirely to random (unassignable) variation. Values outside of this range are considered to represent assignable variation (i.e., variation that can be attributed to the behavior of the physician). In this example, both surgeon 4 and surgeon 6 have fallen outside of the control limits.

The UCL and LCL are calculated using the group mean, a weighted standard deviation, and the number of cases seen by each surgeon. A correction for statistical bias is made. In this study the UCL and LCL were calculated in such a way that values would fall outside of them only 1% of the time by chance alone.

The data depicted in Fig. 6 and similar plots for total patient length of stay, postoperative length of stay, total patient hospital charges, and complications of surgery were presented to the Division of Thoracic Surgery during the second week in April 1992. A careful description of the process of acquiring the data was given and the meaning of the information was provided. A copy of the data along with their blinding codes was subsequently mailed to each physician. Anonymity of the individual physicians was maintained.

One goal of the project was to determine whether the feedback of these aspects of their practice patterns had any effect on the physicians. From April 15, 1992, to July 15, 1992, follow-up data were collected. Table 9 summarizes these data.

Following the intervention, one measure achieved statistical significance. The mean time spent in surgery dropped by 10.3 min.

TABLE 10
DIFFERENCES IN PARAMETERS BEFORE AND AFTER PRESENTATION OF
CQI DATA TO OBSTETRICIANS

Parameter	Pre-rate (%)	Post-rate (%)	χ^2 P value
Antibiotics in vaginal delivery	8.21	6.77	0.298
Antibiotics in cesarean section	54.17	64.60	0.092
Elective inductions	9.86	6.62	0.028*
Lacerations	10.30	9.57	0.823

* $P < 0.05$.

As a part of the same study, a similar process was undertaken in the Department of Obstetrics. The parameters chosen for analysis were antibiotic use in vaginal delivery, antibiotic use in cesarean sections, elective inductions, and cervical and peroneal lacerations. The process was similar. After a period of data analysis and refinement of the analytic method, the data were plotted and presented to the Department of Obstetrics. Since the data were all binary, p-bar plots were used. Copies were given to the physicians. Subsequently, a second copy of these data was mailed to the obstetricians.

During the first 3 months of 1992, postintervention data were collected. The group results are in Table 10. In this set of parameters, the change in elective induction rates changed significantly.

CQI has some characteristics that are at variance with the traditional view of medical quality assurance. One of the characteristics of the CQI approach is its lack of internal specification of the correct behavior. A central premise is that, through the process of reviewing the data and of discussing them with their peers, physicians will reach a conclusion about how they should respond to differences between their practices and the norm. This should be adequate motivation to change.

An aspect of CQI that is missing in the experiments described above is a sequence of repetitions of the process described. CQI is designed to be a cyclic process. Feedback of relevant information is repeated multiple times. This has the effect of reinforcing the message gleaned from the data and of allowing the user to witness the behavioral changes that occur during the CQI process.

CONCLUSION

The discussion above focuses on extensions of a medical information system designed to participate in the decision-making activity that defines the care given to patients. These applications borrow freely from the branch of computer science that studies artificial intelligence and expert systems. Systems of this type are capable of changing the way medical care is managed not only in the inpatient setting but also in the outpatient realm. While the impact is currently modest, this decade will see computer-assisted medical care spread throughout

American health care. Applications like those described above give us a glimpse of the computer-based tools that will help manage patients in the future.

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The HELP system has been a multiyear venture involving a host of researchers, students, administrators, physicians, pharmacists, nurses, and others. Too many have contributed to the work described to name here. The authors express their appreciation to all who have contributed to the studies summarized here and to additional important work whose description space would not allow.

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