Clinical Informatics in Critical Care

G. Daniel Martich, MD*
Carl S. Waldmann, MA, MB, BChir, FRCA, EDIC†
Michael Imhoff, MD, PhD‡

Health care information systems have the potential to enable better care of patients in much the same manner as the widespread use of the automobile and telephone did in the early 20th century. The car and phone were rapidly accepted and embraced throughout the world when these breakthroughs occurred. However, the automation of health care with use of computerized information systems has not been as widely accepted and implemented as computer technology use in all other sectors of the global economy. In this article, the authors examine the need, risks, and rewards of clinical informatics in health care as well as its specific relationship to critical care medicine.

Key words: electronic medical record, electronic health record, clinical information systems, clinical decision support, computerized physician order entry, health care informatics, critical care information systems, leapfrog, Institute of Medicine, medical errors, clinical decision support, return on investment

The New York Stock Exchange developed its first automated quotation system in 1953, electronic ticker display boards in 1966, and by 1996, it had a fully integrated technology network with wireless data system. Stock markets throughout the world have similarly relied on electronic transaction systems for years. Banks and mutual fund companies do not balance their books at the end of the day using paper and pen, but rather through electronic spreadsheets with linked databases. The airline industry, too often used as a benchmark for the health care industry, could not fly the thousands of flights with disparate equipment to all corners of the globe without electronic tracking and reservation systems. Each of these industries can rightfully claim that efficiencies, greater productivity, increased revenues, and improved customer satisfaction have been a direct result of automation. Still, hospitals are at least as complex as banks, airlines, or steel plants. Even without an electronic patient record, a 300-bed hospital in the United Kingdom will generate 500,000 transactions every day; about the same number of transactions as a 180-branch bank network in the same time. In the United Kingdom, intensive care costs about £1.5 billion ($2.35 billion) annually. Can you name another multimillion-pound business that runs without computerization?

We in health care have fallen woefully behind other industries in automation of many processes.

• Is there a need for clinical information systems (CIS) in critical care?
• What should a CIS do for critical care?
• Why is there a reluctance to embrace information technology in health care?
• Can clinical decision support improved care?
• What is the return on investment for CIS?

In this article, we will address the above questions and discuss the state of the art of health care informatics.

Is There a Need for CIS in Critical Care?

Perhaps the most gripping reason for development of CIS comes from the reports of the Institute of Medicine (IOM). The IOM, part of the National Academy of Sciences, is an adviser on scientific and technological matters to the US government. In June 1998, the IOM Quality of Health Care in America Committee was formed and ultimately concluded in their report "To Err Is Human" that as many as 98,000 Americans die each year from preventable medical mistakes they experience during hospitalizations [1]. The report goes on to indicate that there are more deaths in hospitals each year from preventable medical mistakes than there are from motor vehicle accidents, breast cancer, or AIDS.
The single leading type of error is the medication error. Estimates range from 4% to 20% of all hospitalized patients encountering medication errors [2,3]. These errors result in increased charges of $2900 to $9000 per error, save litigation costs [4-6]. One of the oft-repeated recommendations from this IOM report is that information systems could reduce these mistakes considerably.

Information Overload at the Point of Care

An intensive care unit (ICU) is a data-rich environment. When so many data elements need to be turned into information and knowledge, errors occur because of sheer volume. A physician may be confronted with more than 200 variables during typical morning rounds [7]. However, even an experienced physician is often not able to develop a systematic response to any problem involving more than 7 variables [8]. Moreover, humans are limited in their ability to estimate the degree of relatedness between only 2 variables [9]. This problem is most pronounced in the evaluation of the measurable effect of a therapeutic intervention. Personal bias, experience, and a certain expectation toward the respective intervention may distort an objective judgment [10].

While the first IOM report did not focus on care in ICUs, the report does suggest that critically ill patients are at a particularly high risk for adverse events. That ICU risk, as high as 17.7% for death or disability and nearly 46% for any type of adverse event, was highlighted in “To Err Is Human” [11].

The abundance of information generated during the process of critical care can now be captured and stored using CIS, which provide for complete medical documentation at the bedside. The clinical usefulness and efficiency of CIS have been shown repeatedly [12-15].

On the level of the hospital enterprise, information overload is an issue too. In addition to the administrative aspects of such a complex enterprise, new and much more complicated reimbursement and accounting policies lead to an unmatched complexity of data and information [16].

The volume of scientific literature is growing exponentially. As of 1993, the number of systematic reviews in medicine increased 500-fold during a 10-year period [17]. It is impossible for the individual health care professional to keep track of all relevant medical knowledge even in very narrow subspecialties.

Compliance With Accreditation Rules

The every-3-year assessment of hospitals in the United States by the Joint Committee on Accreditation of Healthcare Organizations (JCAHO) mandates compliance with certain standards. This year, the JCAHO has developed 6 new core competencies for all ICUs. These include the following [18]:

- ICU-1, ventilator-associated pneumonia (VAP; VAP prevention; patient positioning): numerator = number of ventilator days in which the patient’s head of bed is elevated equal to or greater than 30°; denominator = total number of ventilator days.
- ICU-2, stress ulcer disease (SUD) prophylaxis: numerator = number of ventilator days in which patients received SUD prophylaxis; denominator = total number of ventilator days.
- ICU-3, deep vein thrombosis (DVT) prophylaxis: numerator = number of ventilator days in which patients received DVT prophylaxis; denominator = total number of ventilator days.
- ICU-4, central line associated primary blood stream infection (BSI): numerator = number of central line–associated BSI by type of ICU; denominator = number of central line days by type of ICU.
- ICU-5, risk adjusted ICU length of stay by type of ICU: continuous variable statement = mean length of stay for ICU patients by type of ICU.
- ICU-6, risk-adjusted hospital mortality for ICU patients: numerator = total number of adult patients having had an ICU stay and whose hospital outcome is death; denominator = total number of adult patients having had a qualified ICU stay.

Each of these measures makes a strong case for capturing data electronically at the point of care. For instance, for the VAP core competency, the measurement needed by the JCAHO requires reporting the number of days that the head of the bed is tilted at least 30° upward in a mechanically ventilated patient (numerator) over the total number of ventilator days (denominator) for the patient. This would need to be done for all ventilated patients and would be a daunting task without electronic documentation by the bedside nurse, data capture, and database analysis tools.

In Germany, in conjunction with disease-related groups (DRGs) as the sole method for inpatient reimbursement, health care authorities will require hospitals to publish quality benchmarks and also accumulate accreditation data after 2005. This can realistically be captured only by means of an electronic patient record.

In the United Kingdom, a recent government initiative has set up the Modernisation Agency for Critical Care to try to ensure standardization of protocols for transfers and the introduction of care bundles for stress ulcer prophylaxis and DVT pro-
phylaxis with hopes to address other issues such as the management of head-injured patients not requiring neurosurgery in district general hospitals. Now that more than two-thirds of UK ICUs subscribe to the Intensive Care National Audit and Research Centre, it has been possible for ICUs to measure themselves on case-mix adjusted outcome against other units. Each of these initiatives, including data collection and standardization, lends itself perfectly to the use of CIS for the ICUs.

Shortage of Intensivists

It is well known, at least among intensivists, that in addition to national and global shortages of nurses, there are too few intensivists to staff ICUs across the United States and the world. While intensivist-led care teams demonstrate improved mortality, it would be impossible to physically provide each ICU with enough intensivists on site to demonstrate the better outcomes. Therefore, 1 possible solution using information technology (IT) in the ICU is to create an e-ICU. One commercial model for such a virtual ICU care team is that established by VISICU [19]. The VISICU model is dependent on 2 essential factors: technology at the bedside capable of capturing vital signs, medication administration, documentation, and laboratory information and hospital/physician practice change behavior to enable an off-site intensivist to lead the care team.

What Should a CIS Do for Critical Care?

The Leapfrog Group

In addition to the reasons mentioned already, there are many other compelling initiatives that push for the development of CIS. The first of these ideas should be well known to intensivists around the world despite being a proposal by American companies to improve health care in the United States. This initiative, called Leapfrog, was presented on January 26, 2000, to the Senate committee of Health, Education, Labor and Pensions by Dr Arnie Milstein, the medical director of the Pacific Group on Health. A group of large employers, such as General Electric, International Business Machines, General Motors, and Boeing, who have also focused on the issue of medical errors from the payer's perspective, has explicitly defined 3 issues that will influence their choice of health care organizations for their respective companies' health plans. These 3 major goals would result in leaps forward for health care, with a 105% to 50% reduction in patient mortality. Attendant to these 3 aims was the explicit cost savings associated with better care to their employees both directly by decreasing the cost of the health insurance and indirectly by reducing lost days of work by the employee. The medical directors of many Fortune 500 companies determined these goals. The goals were chosen on the basis of likely impact on health care quality, attainability, and ease of explanation to large segments of the population. The initiatives can be found in Table 1, with the translation to the sixth grader next to the original goal.

Data Security and Confidentiality

Yet another requirement for pursuing CIS implementations in hospitals includes the Health Insurance Portability and Accountability Act (HIPAA) in the United States. This act demands that hospitals know which individuals have accessed patient-specific data. This daunting task cannot be done with paper charts. Only with electronic time, date, and person stamping will this degree of identification be in compliance with the law. Comparable rules and legislation apply in many other developed countries, where federal or state supervision of confidentiality of private data, including specifically patient data, has a long tradition.

Current State

Documentation in Critical Care

The patient record remains the principal instrument for ensuring continuity of care. The numerous drugs and devices for diagnostics, monitoring, and therapy combined with the steadily increasing acuity of our patients prompt a demand for an improvement of integration and acquisition of data [20,21]. The current methods for documentation are fraught with inefficiencies. The paper chart can be used by only one individual at a time. The paper chart can be in only one location at a time. The paper chart is fragmented (Fig 1) and does not allow for extraction of data across a defined popu-
The discordance between the mass of data and the capacity of paper-based documentation leads to major defects in information processing. As many as 30% to 50% of all interventions and observations are not recorded, especially in emergency situations [16,20,22].

Although many vendors offer CIS software systems for critical care, only a very small minority of ICUs inside and outside the United States are using paperless documentation. Despite its very small market penetration, CIS for critical care can be considered a mature product. In many instances, systems have been on the market today for more than 20 years.

Some ICUs have replaced the paper record at the bedside by a computerized patient record. Early studies reported optimistic figures for achievable time savings with electronic ICU documentation. Estimates of 30 to 90 minutes saved per shift per nurse with a CIS compared to manual documentation were reported [12,23,24]. In recent years, a more realistic evaluation of the potential of time saving from electronic documentation alone has prevailed. More recent studies suggest that only minor time savings are feasible but that adoption of an electronic flow sheet (Fig 2) significantly improves the quality of documentation and care [20,25].

It must be assumed that documentation alone, while definitely feasible with CIS, is not an end in and of itself. Electronic documentation at the bedside becomes extremely productive when the data are used for further analysis and processing (eg, charge capture, quality control) and for medical process control (eg, online decision support, electronic protocols). Electronic data capture with a CIS at the point of care is the indispensable prerequisite for any workflow automation and for any effective implementation of computerized physician order entry (CPOE).

Why Is There a Reluctance to Embrace IT in Health Care?

Most health care institutions in the Western world have already implemented IT systems for business administration, billing, and accounting. Although these systems provide some of the IT infrastructure needed to support clinical systems, most of these
installations cannot handle the kind of medical information that is necessary to manage the process of care. Today there are only very few examples of robust, integrated hospital-based clinical information systems, notably most in the United States [26]. Only about 20 full CPOE systems are installed in US hospitals [27].

Moreover, investments into IT systems to improve the quality of care have to compete for funding with legally required changes, such as HIPAA in the United States or the introduction of DRGs in Germany. It is also noteworthy that about 70% of all medical IT projects do not fully succeed [27].

(Lack of) Process Control

Point-of-care CIS allows the broadest control over the process of care. Outstanding examples for the management of process control are computerized protocols, clinical pathways, and guidelines. Order entry and decision support systems offer a unique opportunity to dramatically improve the quality of care while reducing overall costs [28,29]. In the terminology of total quality management, an explicit method (e.g., a computerized protocol) is part of the stabilization of the process necessary to improve quality [30,31]. With the above background information, the major focus in health care informatics in the United States has been CPOE with or without electronic decision support systems. While endorsed by the Leapfrog Group and recommended by the IOM, many hospitals and vendors are struggling to implement these extremely complex systems. Physician order entry can be considered the key to medical process control. It is probably the most complex functionality in any CIS.

The major factor in the recent and remote failures of CPOE has been the lack of process control in hospitals [32-34]. Physicians have long been taught to “trust no one but yourself” and are in many ways independent practitioners of their trade despite being members of private group practices or academic departments. Therefore, when CIS and CPOE “force” the individual physician down a pathway that is not to his or her liking, he or she will rebel. That rebellion has stopped the implementation of CPOE efforts despite all of the hereto-

![Fig 2. Electronic data capture. A sample computerized spreadsheet with the patient’s noninvasive blood pressure highlighted with the detail of who, what, and when the data were entered on this test patient, automatically captured during the documentation process. Similar data capture occurs each time a patient’s record is accessed electronically.](image-url)
fore mentioned need at Cedars-Sinai Medical Center in Los Angeles [35].

This example shows how important it is that complex medical information systems fit into the clinician’s workflow. The importance of understanding medical workflows on a very detailed level before implementing medical information systems cannot be overstated [34,36].

### Time Is Money

Before process control manifests itself as an issue, however, physicians most often disdain new information systems because it costs them extra time. Unlike attorneys who bill quarter hours for even thinking about a case, intensivists in the United States can charge a 99291 code beginning at only the 31-minute threshold and up to 75 minutes for the time spent actually caring for the patient. The extra time required logging in to CIS or waiting for the processing of lab data, orders, and so forth results in frustration from simply waiting for computer screen flips. While realtors worldwide constantly speak the mantra of “location, location, location” when it comes to properties they wish to sell, physicians who are selling CIS deployments stress to our technology colleagues the need for “performance, performance, performance.” In other words, lack of speed kills when it comes to physician adoption of CIS. Early analysis of the extra time spent by medical residents at Regenstrief Institute found that it took an extra 5.5 minutes per patient per day to enter orders using CPOE versus handwriting orders [37]. When that is multiplied by an average ICU census of 12 critically ill patients, more than an hour will be added to the intensivist’s day in performing a function formerly done by unit clerks. Several investigators have found and supported what most of us feel when working with computers: speed is everything [38,39]. It has been shown that fast response times are what medical users value most in their IT systems. For CPOE and clinical decision support (CDS) systems, typical response times should be subsecond [36].

### Expensive

Experience shows that the largest investments are needed to provide the information infrastructure such as electronic patient records and physician order entry systems, while the cost of implementing and maintaining online CDS in these systems is moderate [39-41]. Depending on the kind of decision support and the level of standardization, even expensive systems have the potential to generate significant financial return on investment [16,42].

The implementation costs for CIS can be staggering, in the range of $5 to $20 million for a single hospital. Therefore, it comes as no surprise that CPOE is not widely implemented in US hospitals or around the rest of the world. Hospital operating margins in the United States average less than 3%; indeed, many hospitals are hemorrhaging red ink.

In the United Kingdom, the National Health Service has experienced embarrassment following massive investment in computer systems. The most recent fiasco concerned the information system introduced for dealing with calls by the London Ambulance Service. The system reportedly resulted in ambulances being sent to wrong addresses and delay in care resulting in several deaths [43]. It is no wonder, then, that hospital administrators and boards of directors are often fearful of implementing an unfamiliar technology such as CIS. With no clear-cut vendor-provided electronic health record system leading the marketplace and the bursting of the dotcom balloon, hospital’s capital-improvement dollars are more often spent on bricks and mortar than on picks and clicks on a computer screen.

### Further Problems

Also, significant technological hurdles have still to be overcome. Most decision support applications and any kind of qualified data analysis require consistent and standardized medical vocabularies, which are still lacking in all developed countries despite the formidable efforts of international and national organizations [44].
But there may be even more daring challenges to the implementation of IT to reduce medical errors [3]:

- The successful implementation of medical information technology often requires changes in the way health care professionals think and act. These may include, among other issues, the standardization of care, the abandonment of personal style, and development of trust in computer systems.
- The small number of fully evidence-based guidelines and pathways indicates the need for substantiation and validation of medical guidelines and common practices in a timely and cost-efficient manner.

Can CDS Improve Care?

Assuming that physicians and hospital organizations buy into the notion of process and change control as well as acceptance of evidence-based medicine in their daily practice, then the implementation of CIS, CPOE, and, perhaps most important, CDS is possible. The goal of CDS is to supply the best recommendation under all circumstances [45]. In its 2001 report, the IOM strongly recommended the use of sophisticated electronic CDS systems for radically improving safety and quality of care [12]. Clinical information systems that generate CDS-driven electronic reminders and CDS-assisted CPOE have been shown to improve both quality and cost-effectiveness of care [4,20]. Electronic reminders can significantly improve physicians' compliance with guidelines, reduce the rate of human errors, and make physicians more responsive to specific clinical events [6,46].

The most detailed and explicit algorithms in clinical decision making use rule-based computer systems [27,47]. Using data from one of the most comprehensive clinical data repositories in the world (LDS Hospital, Salt Lake City, Utah), the group of Morris developed a rule-based CDS for the mechanical ventilation of the critically ill [48]. Their CDS generates, on the basis of actual patient data, explicit, executable, and reproducible instructions or recommendations for the next therapeutic step. Their study found that it was possible to control more than 95% of the ventilation times with these protocols, while intermediate and final clinical outcomes showed a beneficial effect [30].

Another tangible benefit of a CDS system is evident in the example of a large institution in which the CDS checked all doctors' orders for drug interactions and approximately 400 of 15,000 orders were changed daily. Most of these CDS-recommended changes were to avert potential adverse drug events [49].

What Is the Return on Investment for CIS?

The increasing pressure on health care expenditures and cost-effectiveness of care has made return on investment (ROI) analysis more important for the health care professional [13,29,45]. In other industries, the scope of ROI most often is very clear. It is typically analyzed from only the perspective of the investor, which in most cases is also the company benefiting from this investment. Normally, this perspective is the only applicable one.

In health care, there may be many different perspectives to assess ROI. We need also to keep in mind that investor and beneficiary are not always the same. Therefore, we need to define which perspective we address before we engage in an ROI analysis. Different perspectives in health care may include

- the individual care provider (eg, the primary care provider, surgeon, nurse, dietician),
- the health care organization (eg, a hospital, clinic, nursing home),
- a health maintenance organization,
- an entire health care system (ie, the public purse, Medicare),
- the employer of the patient, or
- the individual patient.

There are significant differences between health care and other industries in how ROI can be generated [21,29]. Of course, from a monetary perspective, there are still only 2 basic approaches to improve ROI: increase revenue or reduce cost. The differences are how likely each of these approaches can be followed in health care compared to other industries.

In health care, the emphasis has been on cost reduction rather than on increasing revenue. The highest cost in health care is also the most limited resource: personnel. With that in mind, the greatest potential for cost reduction is associated with changing the process of care in a way that allows a reduction in personnel [17,50]. As alluded to above, CIS, CPOE, and CDS are possible (and potentially profitable) only if associated with large-scale acceptance of standardized process of care. However, the more complex the change in the processes of care, the more difficult it is to carry out an appropriate ROI analysis. Many analyses are
based on assumptions derived from studies in the literature. Whether these assumptions are actually justified is often questionable [51]. Differences in health care systems and the practice of medicine may render it impossible to extrapolate results from one country to another. For example, CPOE systems and CDS systems have been shown in US studies to reduce the rate of medical errors [4,20]. As medical errors are a problem in all developed countries and their underlying causes are comparable, it is probable that findings from these studies also apply to other countries. Nevertheless, the absolute ROI may be different because of different cost structures, ancillary workflows, and litigation practices.

ROI analysis is feasible even in the highly complex setting of a health care institution. It is necessary to justify the significant investments into medical information technology that will be needed in the upcoming years to cope with the problems of cost reduction, medical errors, and quality of care [21]. But even on a limited scope, ROI analysis is a formidable task that carries a high level of uncertainty.

Finally, ROI and cost-related issues may become moot as initiatives such as Leapfrog, the IOM reports, and especially the medical malpractice crisis in many US states mandate that CIS and CPOE be implemented. The only ROI justification needed may be that these information technologies are essential to fulfill requirements and permit hospitals to stay in business. Therefore, CIS and CPOE could become just part of the cost of doing (health care) business [52].

Discussion

Medical errors are without any doubt one issue of major public interest and concern. The IOM report “To Err Is Human” describes a situation that is intolerable in the United States. Although the report covers only the US health care situation, its findings also give a broad idea of how the situation is in other countries with advanced health care systems.

There are studies that make it very likely that the problem of medical errors is as grave in Europe as in the United States. Although the debate on medical errors has not fully started in Europe yet, the question is not whether it will become a high priority issue, but only when this will happen.

Information management, given its broadest meaning to include communication among caregivers, process control, and standardization to achieve efficiencies, is at the core of many efforts to reduce medical errors. Therefore, medical information management, with or without the help of computers, will play a decisive role in any solution posited for the growing concerns of quality in health care. The application of technology to the solution is a certainty given the complexity of the problem with the caveats of cost, timing, and acceptance.

Specific recommendations from many groups focus on point-of-care CIS with CPOE and CDS systems. For the development of medical IT systems, the implications are the following:

- The development of medical IT must be in point-of-care information systems integrated into the health care enterprise-wide information management approach.
- The integration of information and knowledge must be seamless along the continuum of care and across the entire health care enterprise.
- Clinical information systems, electronic order entry systems, CDS systems, medical knowledge bases, and ultimately the electronic patient record provide the most powerful solutions to the problem of medical errors. These systems may even become in part legally compulsory or may be enforced by major payer groups.

It is also clear that IT must reach a critical mass to be effective. For instance, payback from a physician order entry system can be expected only if it covers most of the continuum of care. This means that massive up-front investments are needed. Moreover, most advanced online CDS systems require comprehensive patient information in electronic format, which can be provided only by clinical information systems.

There is no doubt that medical information management is one answer to the problem of medical errors. Standardization of care, process control, physician order entry systems with online CDS, and the electronic patient record have the potential to make health care safer, improve quality of care, and reduce cost in the interest of all parties involved.

We do not know how long it will take nor how expensive it will be. But we know that action, investments, and commitment are needed now. And we know that the way we practice medicine will never be the same again.

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