# CIS: Where Are We Going and What Should We Demand From Industry?

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**Clinical information systems designed for use in the critical care setting have been available for many years. Yet, despite significant evidence that these systems contribute to patient safety and efficiency of care, they have not achieved widespread use. This paper examines some of the factors responsible for the slow growth in use of clinical information systems in the intensive care unit. We further examine the elements that will be necessary to support widespread adoption of future clinical information systems. We give an outline of functionalities, processes, and standards that users will demand from industry as they develop the information systems of the future.**


DESPITE GREAT AND continuing strides in computing science, bringing the power of computing to bear on the care of the individual patient lags far behind the adoption of automation in other parts of our society. Although clinical information systems (CISs), as we know them, have been in existence for decades, a very small proportion of hospitals and health care providers have adopted them to aid in the care of the patient. Although, nearly every US hospital has automated billing and laboratory services to some extent, more than 85% of US hospitals still communicate about and document the majority of care of critically ill patients on 18 lb., crisp, white, ruled paper.[1]

Paper is a difficult medium to improve on from a resolution standpoint. Screen by screen the pixilated world of clinical information systems can't hold a candle to the amount of information a determined micrographic clinician can squeeze into the space provided by an 8 ½ x 11 in piece of paper. Unfortunately, resolution is not the only part of the equation that is important. Paper presents a number of inherent failings that seem to advocate in favor of a basic change in how we view, communicate about and document patient care. First, the paper record represents the only copy of the communications and documentation included within. The paper record can be viewed by only one clinician at a time. The information contained within the paper record consists mostly of a linear recording of clinician observations and documentation. This record cannot be easily abstracted or summarized. The paper record does not inherently have an ability to provide a hierarchy of patient information beyond simple chart tabs. Thus, the paper record can, and often does, contain important patient information that is buried in the expanse of other documentation that makes up today's medical record. The paper record cannot provide patient context–specific expert advice to clinicians such as direct access to evidence-based practice guidelines related to the patient's underlying disease or access to knowledge bases containing current literature related to the patient's condition. The paper record requires significant additional manpower to extract patient-specific acuity and outcome information.

In contrast to the difficulties related to the paper record, the quality benefits of clinical information systems and related resources have been well documented. The introduction of a CIS has variously been associated with improvements in the quality and completeness of documentation and the decreased incidence of errors related to medication administration.[2-5]

Cooperation among professionals in highly technical fields, such as aviation, forms the basis for safety. The aviation industry recognizes the vital importance of crew cross-checking in preventing accidents. This strategy requires crew members who are not the "pilot flying" continually to check instruments against the expected plan for flight. In a recent review of human error flight accidents, the National Transportation Safety Board (NTSB) has identified a lack of adequate "cross checking/challenging" present in 84% of the air accidents studied.[3,4]

Research in medical simulation has demon-

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strated similar communication difficulties between team members in operating rooms.[5] Intensive care unit (ICU) care, in particular, lends itself to such cross-checking and challenging. In the ICU, this is accomplished by the process of rounds and daily sign out of patients. During each of these exchanges, the current course of care is reviewed and cross-checked and challenged. This process of cross-checking is enhanced by the concurrent availability of the patient record in a CIS.

Despite the well documented patient care benefits of implementing a CIS there are those who believe that widespread acceptance of CIS is years away.[6]

## THE PRESENT

### Why Has Medicine Been so Slow to Adopt the Advantages of Clinical Information Systems?

*Leadership.* Medicine has been slow to adopt automation in documentation and patient care for many reasons. Initiating change in medical care with its age-old traditions is fraught with difficulty. It has been suggested that there is a lack of the leadership within medicine necessary to support effective change.[7,8] Given the gradual introduction of information technology into daily life in our society, it seems likely that the medical establishment's interest for information technology growth into the healthcare sector will gain more widespread support over time.

Some have suggested that insertion of technology into the care of patients might interfere with the human contact so necessary for good medical care. The converse, however, has been shown to be true.[9] In a recent study in Critical Care Medicine, Dr. David Wong and colleagues documented an average 52 minute time savings during an 8-hour shift with CIS documentation. This could clearly allow an increase in the time ICU nurses spend with patients after the introduction of a CIS.

*False starts.* There have been many false starts on the road to a Clinical Information System that meets all of the needs of patients and clinicians. This road is littered with promises of functionality and interoperability that have not become realities.

Interoperability is a promise that each manufacturer makes in the sale of a new CIS. Semantic interoperability has been described by Benson as the ability of diverse systems to communicate using a common language.[10] The ability of systems to exchange and understand each other's data is a necessary prerequisite to widespread penetration of CISs. Most presently available CISs offer the promise of interoperability with other hospital systems via adherence to some widely accepted standard for exchange of clinical information. A common example of such a promise is HL7–based communication compatibility. HL7 is a messaging standard that is intended to allow healthcare applications to exchange important clinical and administrative data. HL7 is intended to provide a standard for data exchange across all aspects of the healthcare environment[11]. The reality of such a promise is unfortunately not so straightforward. First, HL7 is an evolving standard. There are presently several versions of the HL7 standard to which a vendor might build compatibility. Once a vendor's communication engine is complete, there is often a lag in updating to new standards as they are released. Therefore, the ability to exchange clinical information via HL7 does not necessarily assure interoperability between clinical systems. This shortfall of seemingly reasonable expectations represents a significant false start for many clinical information systems which depend so much on interoperability.

*Unfulfilled expectations.* Clinicians have, for their part, often expected more functionality than was actually deliverable from mainstream Clinical Information Systems. A well-known example of an expectation not yet matched by reality is the promise of voice recognition. Present voice recognition systems are capable of producing relatively accurate (~95% accurate recognition) renditions of the spoken word. However, this is presently implemented with the following caveats. The successful voice recognition session must occur in a quiet environment, consist of a relatively circumscribed specialized vocabulary, and be preceded by significant investment of time in "training" the system and user in the nuances of the voice recognition software. The average ICU environment presents none of the prerequisite requirements for a successful voice recognition session. Therefore, even though several manufacturers purport to have voice recognition capabilities within their CISs, none can control the environment necessary for success within this realm. The net result of offering

the presently relatively unrealistic application of voice recognition within the noisy and varied environment of the ICU is one such unfulfilled expectation.

## Communication Between Clinicians and Manufacturers During the Research & Development Process

Much of the disconnect between expectations and reality in CISs has been due to a lack of communication at the basic product-development level between manufacturers and clinicians. Sullivan describes the process of software development in his book *Under Pressure and On Time.*[12] Most CIS manufacturers follow a complex process of definition, specification, testing, and internal validation to bring a product to market. In the Research and Development (R&D) process, input from clinical users is typically sought first at the Beta Trial stage. Unfortunately, the release of software for Beta Trial is one of the last steps in the development process. While this strategy works well with software development for application areas where the need and functionality is well defined and accepted such as office productivity suites, the development of soundly-based complex systems such as CISs requires user input from the first stages of the development process. The disconnect between software development, implementation, and clinical reality has been implicated as one of the main reasons for some significant failures in clinical implementation of information systems in the recent past.[13,14]

## Cost

Cost for initial implementation of a CIS is a major impediment to widespread acceptance. A recent survey of healthcare IT executives conducted by the Medical Records Institute found that the major barrier to implementation of an electronic medical record was a lack of adequate funds to accomplish the task.[15] Return on investment (ROI) for CISs has always been difficult to predict and measure.[16] Sarv et al point out in their analysis of ROI in technology improvements that the benefits of technology investment may take place over significant time periods and thus may not be amenable to one-time analysis; the benefits of such investment may be better measured over a longer time period.[17] Improvements in efficiency of care and safety produced by introduction of CISs will continue to need documentation. In addition, as attention to non-monetary improvements which accompany the introduction of a CIS such as patient satisfaction and safety increase there may be new dimensions by which we measure ROI which move to the forefront.

## Lack of Standards for Integration

Up to this point, there have been few meaningful universally accepted standards for CIS design, interoperability, or functionality. It is clear that widespread use of such standards would mitigate much of the difficulty currently experienced by hospitals and health care agencies currently endure in attempting to integrate CISs with other hospital information sources. There has been significant recent progress toward the goal of standards for CISs, which may fuel progress toward the goal of interoperability and integration.

In March of 2003 the Federal government Department of Defense, Veterans Administration and the Department of Health and Human services announced the adoption of the first set of standards for the exchange of clinical information. The standards adopted by these agencies include HL7, National Council on Prescription Drug Programs (NCDCP) standards for retail pharmacies, the Electrical and Electronics Engineers 1073 (IEEE1073) for medical device interfaces, the Digital Imaging Communications in Medicine (DICOM) standards for image communication, and Logical Observation Identifier Name Codes (LOINC) for uniform naming of clinical laboratory results.[18] Progress on development and adoption of standards in CISs received another boost in July 2003 when HHS reached an agreement with the College of American Pathologists to license the college's Medical Vocabulary system (SNOMED) to allow it to be made available free of charge in the U.S. During the same time period, HHS charged the Institute of Medicine to define the components of a standardized health record.[19]

The adoption of these standards by the Federal government will bring us closer to the goal of true interoperability between medical information systems. At least from this time forward, manufacturers will have a firm starting point when defining the data standards on which to build new information systems.

## THE FUTURE

### Where Are We Headed and Why?

In order to overcome the present difficulties in integrating CISs into routine patient care there will need to be a concerted effort on the part of clinicians and industry to bring new functionality and ease of integration to the CISs of tomorrow. The information needs of clinicians have been well described.[20] Currently-available CISs already meet some of these needs, but many have yet to reach the radar screens of CIS system architects. Some of the needed functionalities are discussed below. While some of the individual features described below are currently available within highly "evolved" in-house developed systems and mainstream commercial applications, there may be some time before the full array of necessary functionalities begin to appear in mainstream "off the shelf" commercial applications. Many of the functionalities that will characterize the CIS of the future are either individually available today or will be in the very near term. This is very good news for the late adopters of this technology, which includes most of us in the United States. Some of these features are described in more detail below.

### Data Capture, Review, and Alerting

There is ample evidence that humans are imminently distractible while managing concurrent tasks. A study undertaken by Dismukes et al at NASA's Ames Research Center examined the problem of managing concurrent tasks in general aviation. The researchers found that flight crews often neglected to complete deferred tasks because of concurrent task demands. The study also noted that the most commonly neglected tasks were those involving routine "monitoring" of flight operations followed by forgetting to perform previously deferred tasks. The ICU environment is a parallel world of deferred tasks and distractions. In this environment, the clinician is often presented with waves of raw patient data that must be sifted through and prioritized. This continual process of data acquisition, filtering and prioritizing creates many deferred tasks in the course of the clinician's day. In the ICU, as in the air, these concurrent processing demands often lead to neglect of the important tasks of monitoring patient condition and completing deferred tasks. The CIS of the future will provide the necessary filtering and intelligent pre-processing to allow clinicians to concentrate on the tasks that require immediate attention and to defer tasks that may be safely delayed. Some functionalities that will be required to support these needs are shown in Table 1.

**Table 1. Data Capture and Alerting Functions**

| |
|---|
| Capture and display vital sign data |
| Capture and display bedside device data |
| Capture and display laboratory data |
| Filter raw patient data and present important data to the care team in an organized easy to understand way |
| Provide data views to enable rapid complex decision-making |
| Provide "intelligent" clinical alerts |
| Context management |
| Smart symptom and syndrome identification |

### Reporting

The CIS users of the future need to demand ownership over data collected by their CISs. Some currently available information systems provide access to data only through arcane user interfaces that require specialized knowledge to operate or through a set of pre-defined reports. In order for the CISs of the future effectively to empower the users with their own information, the data that is collected must be readily accessible to authorized users. One of the measures of this accessibility will be the capability for users to run *ad hoc* queries against their data set. In order to produce the right capabilities in reporting tools, industry will need to work closely with clinicians, managers and administrators. The resultant set of reporting tools available in the CIS of the future will be easy to use and intuitive, providing clinicians and managers with the capability to fulfill their Continuous Quality Improvement (CQI), Benchmarking and Regulatory reporting needs. Some of the functionalities that will be required to support these needs are shown in Table 2.

### Business Functions

The ANSI X12N and ICD-9-CM and ICD-10-CM code sets have been identified as part of the Transactions and Code Sets Rule put forth by HIPAA. In response, the CIS of the future will need to provide compliant billing and charge capture tools for the clinician. The CIS user of the

**Table 2. Reporting Functions**

| |
|---|
| Capture and display patient acuity data |
| Capture report CQI data |
| Capture and report benchmarking data |
| Capture and report regulatory data |
| Methods to map individual data concepts to standardized naming schema |
| Standardized nomenclature within and across systems |
| *Ad hoc* reporting tools |
| Simple, user-friendly reporting tools |

future will demand that these tools be integrated into the workflow of the clinician and provide "intelligence" to the process of rendering professional charges that are consistent with the data contained within the associated documentation. The tools provided by industry will need to be easy to use and intuitive to gain widespread acceptance. The functionalities that will be required to support these needs are shown in Table 3.

## User Interface/Human Factors

As previously mentioned, user interface features such as speech and writing recognition will continue to be of significant interest to many CISs users. It is clear that user pressure to develop speech recognition technology that is usable in the noisy ICU environment will continue to influence industry for the foreseeable future. Current speech recognition systems separate speech sounds into basic units called phonemes. These phonemes are then compared a database of phonemes and a statistical probability of a match is derived. The most probable word match is then entered into text. Other speech recognition systems are based on grammatical understanding of the spoken word. These systems parse sentences into their grammatical components to discern the underlying meaning and increase the possibility of accurate translation into text. Yet, other systems link large sets of sentence fragments with their individual contexts to improve "understanding."[21] Another approach to improving accuracy of speech recognition systems, especially within noisy environments, uses a

**Table 3. Business Functions**

| |
|---|
| Physician billing/charge capture tools |
| Physician billing reporting tools |
| Support for X12N data standards |
| Diagnosis coding tools |

**Table 4. User Interface/Human Factors**

| |
|---|
| Speech recognition |
| Writing recognition |

combination of audio and visual recognition of the spoken word. These systems record simultaneous audio and visual input to help discern the details of spoken language in much the same way we tend to concentrate on the face and mouth of a speaker when attempting to communicate in a crowded train station or noisy ICU.[22] It seems very likely that systems utilizing a combination of grammatical knowledge, phoneme matching, context intelligence and visual data will bring increased accuracy to speech recognition in the near future. Once speech recognition software reaches a critical threshold of accuracy (~95%-98%) when used in the ICU, user adoption of this technology will be rapid (Table 4).

Writing recognition is developing on a parallel but faster track than its sister technology, speech recognition. Inclusion of writing recognition technology into mainstream operating systems such as Windows XP (Microsoft, Redmond, WA) will likely bring this technology to the mainstream ICU CIS in the near term.

# INTEGRATION AND IMPLEMENTATION

The CIS of the future will provide significant improvements in the ease of integration with existing hospital information systems. In addition, the CIS of the future will provide easy to use tools, standard content, standard data structures and data mapping to standard terminology. These enhancements will speed implementation and will limit implementation cost.

## Integration

Despite the progress in developing standards to help guide the development of future CISs, there remain significant impediments to easy integration of CISs into existing Hospital Information Systems (HIS). Users and purchasers of information systems need to demand that manufacturers provide transparency to the processes involved in integration of new systems with existing systems. Hospitals and clinicians should be able to fully understand and have direct input into the process by which information flows to and from the CIS.

Communication engines of the CIS of the future will comply tightly with at least one version of the HL7 standard. In addition, the users of the CIS of the future will demand easy to use integration tools that will allow local operators to configure interfaces between the CIS and other hospital systems.

The CIS of the future will provide easy to use tools to integrate with any hospital's user authentication system. At present, this would include the ability to utilize access permissions provided by Windows NT 4.0 and MS Active Directory services. This list of access compatibilities will expand as HIS authentication technology progresses. Industry system architects will need to be committed to keeping pace with user authentication technology within off-the-shelf CISs.

### Configuration

The CIS of the future will have significant standard clinical content that can be configured easily by the users. Configuration tools will be user friendly and share graphical user interface characteristics with popular operating systems. Configuration of the CIS should be possible by non-technical, clinical personnel. The CIS of the future will allow configuration elements to be imported from like systems to allow rapid deployment in similar environments.

### Standard Data Structure

The CIS of the future will have at its heart a standard data structure. This data structure will encompass the tables containing the standard data elements of the CIS. Additional tables and views may be present to allow storage and extraction of specialized or additional data. The standard data tables may be the core data structure or exist as views onto the data present within other data structures.

### Standard Terminology

All data elements within the CIS of the future will be mapped to standard nomenclature. The inclusion of standardized nomenclature and table structure will allow cross-platform data collection. This will allow large-scale data collection for benchmarking and the development of evidence-based clinical decision support tools. Users of the CIS of the future will demand automation in the process of mapping local use names to standard terminology. The CIS of the future will provide easy to use tools that will make this process less of an implementation impediment than is currently the case. Integration and implementation tools expected are shown in Table 5.

**Table 5. Integration and Implementation**

| |
|---|
| Integration tools |
| Standard-compliant communication engine |
| User authentication tools |
| Standard content to limit initial configuration needs |
| Standard data structure or standard views of data |
| Mandatory mapping of data elements to standard terminology |

## HARDWARE/IT INFRASTRUCTURE

### On-line/Near On-line Data Availability

Improvements in computer capability/storage bring the promise of on-line access to historical data with few constraints. With the average cost of storage continuing to fall, it is likely that the CIS of the future should be able to store very large numbers of patient records in "live" data form or near-on-line in archived format. Access to historical patient data will be immediate regardless of the storage format.

### Wireless

Advances in wireless LAN standards have brought the prospect widespread availability of Wireless access closer to reality. With the recent acceptance of the 802.11g standard, high speed wireless connections with sufficient bandwidth are now possible and affordable for even the smallest of installations. However, wireless security remains the major impediment to widespread use within the hospital environment. While it is well known that the currently widely used Wired Equivalent Protocol (WEP) carries with it significant security risks, the 802.11i standard ratified in July of 2004 by the IEEE (Institute of Electrical and Electronic Engineers, Inc.) has added greatly to the strength of the security of wireless installations.[23,24] Wireless products using security technology based on the IEEE 802.11i standard are referred to as WPA2 compliant. In the final analysis, it seems likely that a combination of MAC filtering and WPA2 will provide adequate wireless security for the CIS of the future. These advancements in security, speed, and cost will almost cer-

tainly spur the development of mainstream CIS support for these technologies in the near future.

## Portability

The CIS users of the future will demand portability for all patient care applications. These applications will need to function equally well regardless of the platform on which they are run. Continued progress in the development of portable computing devices and their rapid adoption by the mobile medical professional will necessitate support in mainstream CIS applications in the very near future.

## Remote Access

The CIS of the future will provide secure remote access as part of the basic feature package. As remote access to corporate networks continues to become part of our lives, users of medical applications will insist on secure access regardless of their physical location. Hardware/IT infrastructure functionalities expected in the CIS of the future are shown in Table 6.

**Table 6. Hardware/IT Infrastructure**

| |
|---|
| On-line/near on-line data availability |
| Wireless |
| Portability |
| Remote access |

It is clear that the combination of necessity, external influences and advances in hardware and software technology will fuel continued development of CISs over the coming years. In addition, it seems likely that widely available technology such as wireless, remote access, and writing recognition will become part of mainstream off-the-shelf CISs in the very near future. These factors, and the continued refinement of Clinical Information and Decision Support Systems, will likely lead to significant increases in the use of these applications to help clinicians care for critically ill patients.

In order for CISs to become an everyday reality in ICUs of every description, R&D programs within the CIS industry will need to closely collaborate with clinicians, administrators, managers, and regulatory specialists. These collaborations will re-define the process by which medical software is created bringing clinical insight into the process very early in the development cycle. This re-definition will ensure that CISs of the future contain real-world relevance and functionality that will benefit the care of real-world patients.

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