

Clinical Information Systems in Intensive Care

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ABSTRACT

Objective: *To review the requirements and functions of clinical information systems for the critical care environment.*

Data sources: *Peer reviewed studies and articles reported from 1990-1998, identified through MEDLINE search and subsequent article references.*

Summary of review: *Clinical information systems (CIS) utilise information technologies to improve and add value to information management, and critical care areas have provided clinical leadership in their development and implementation. Expectations for these systems are high, yet certain basic requirements must be fulfilled. Bedside charting functions of CIS are highly developed and successful. Clinical record keeping has been more challenging, particularly the requirement for electronic storage of a medico-legal record. Decision support ranges in its extent and requires further development. Successful integration with other hospital systems is highly desirable but may be made more difficult by the lack of rigorous technical standards in healthcare computing.*

The CIS clinical database is fundamental to the quality improvement, research and business reporting functions. The huge amount of data, the lack of common minimal and extensive data sets, and the technical challenges of software development, all combine to make this a resource expensive venture requiring on site customisation. Purchasing and implementing a CIS is costly in human and material resources.

Conclusion: *A high performance CIS is not yet available as an 'off the shelf' product. Close collaboration between the industry and clinicians is important for successful implementation. Clinical awareness of these issues will encourage product development and suitable purchasing strategies.*

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Key words: Clinical information system, patient data management system, health informatics

THE REQUIREMENTS OF A CLINICAL INFORMATION SYSTEM

The most widely used information systems in intensive care are still the paper based medical records which underpin clinical practice in almost all environments. These have developed over the years to include the large bedside flow charts, often found in ICU's, and the highly ordered and categorised patient records seen in most Australian teaching hospitals.

Established standards of record keeping encourage separation of laboratory results from clinical notes. Clinical notes are separated into inpatient admissions, outpatient and emergency department notes, correspondence and summaries. We have become accustomed to seeking the patient demographics and admission/dis-

charge/transfer information from the 'front sheet' of any episode of care.

These developments reflect attempts to improve the management of clinical information. However, over the last 15 years 'clinical information systems' (CIS), also known as 'patient data management systems' (PDMS), have come to imply certain characteristics:

1. The system will be computer based.
2. Information will be entered directly into the system using keyboards and interfaces with other computers and electronic systems.
3. That the storage and retrieval of information will be by electronic means, at least in the short term.

Following on from these basic assumptions it is expected that:

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1. Data collection will be more precise, comprehensive and complete.
2. Interfaces with other similar systems will enhance the utility of the system for information capture and exchange.
3. The system will lend itself to the rapid and sophisticated queries that we expect from computer based systems.

However, despite the complex and sometimes mystifying technology of CIS, they seek to fulfil many of the same expectations as a paper based system.

These include:

1. The record must be available, for a wide range of clinical and administrative purposes, often in different geographical locations over a short time course.
2. The record should contain accurate and timely recording of clinical events and decisions in order to exchange information with other practitioners and also to provide a historical record. Those contributing to the record will include nursing and allied health clinicians.
3. The historical record must be suitable for medico-legal purposes – it should be clear, interpretable, comprehensive and attributable.
4. The system should bring together information from the diverse sources present in the clinical environment – administrative and demographic systems, the results of a wide range of investigations ranging from laboratory and radiological tests to more interventional procedures.
5. Each episode of care and each patient record should lend itself to retrospective audit and research and should, wherever possible, be adaptable enough to facilitate prospective research requirements.

Over the last 10 years the critical care areas of many hospitals, particularly in North America and Europe, have provided a leadership role in the implementation of clinical information systems.¹⁻⁴ The extensive use of physiological monitoring and organ support systems in critical care ensure that these areas are already technologically rich environments. This leads to a higher likelihood of acceptance of new information technology and ease in its implementation that reduces the inherent risk of information technology projects.

Critical care's emphasis on teamwork and a multi-disciplinary environment also supports the introduction of new information management systems, especially if they are perceived as offering wide spread benefits.² The nature of critical care practice engenders a demand for the rapid provision of accurate results and the simultaneous tracking of multiple complex therapeutic systems such as ventilators, drug prescriptions, and

intravenous infusions. Finally, the need to accurately record the consultations and contributions of many clinicians who move through the often chaotic physical environment places a premium on recording therapeutic assessments, plans and procedures to optimise patient care.

BEDSIDE CHARTING

The most successfully realised goal for information systems has been the area of bedside charting.³ Intensive care units are noted for either the size of the paper bedside charting tool, or the multiplicity of fold out A4 pages required as an alternative - both present significant challenges in interpretation and storage. The spreadsheet functions of available CIS perform these functions ably, although some are limited by restrictions on the viewing of multiple windows simultaneously. Arithmetical errors in fluid balance summaries are completely eliminated. There are major operational advantages obtained for most units in being able to simultaneously access bedside information from multiple sites, including conducting clinical meetings, clinical audit and research.

Most systems permit a large amount of customisation, known as 'configuration', which allows different institutions and units to determine the layout of the spreadsheets. Interfacing bedside physiological monitoring is also a standard feature that dramatically reduces transcription errors, although some combinations of monitors and systems can still prove to be problematic.

There is some divergence of opinion over how best to filter physiological variables, however most systems include a manual validation step.^{1,3,5-8} This ensures that wildly erroneous values (e.g. arterial pressure during sampling from the same line) can be discarded. The accuracy of a CIS, together with some methods of data filtering, may in fact result in higher severity scores being recorded than by manual systems.⁹

Integration with other bedside equipment may be more challenging. Although some standards for electronic transmission of information from medical equipment are emerging, it is usual for a decoder and an interface to be required for ventilators, dialysis machines, infusion pumps, etc. Commercial imperatives dictate the speed and breadth of development and hence interfaces may be difficult to obtain for less common items of equipment.¹ In particular, the standards and regulatory requirements of the FDA have contributed to the slow development of feedback and controller systems for infusion pumps.

CLINICAL RECORD KEEPING

One of the difficulties in the development of CIS

technology has been the need to address the requirements of medical record keeping. There is a burgeoning industry, particularly in North America, providing solutions for the hospital-wide electronic medical record (EMR). Integrated systems throughout an institution are an obvious requirement, while systems that extend across a geographical area to include general practitioners, private specialists, allied health services and even community agencies are being considered. However, those applications are often underdeveloped for the requirements of critical care areas.

Most CIS include some provision for clinical record keeping with appropriate electronic password security and audit trails that note any subsequent changes to the record.^{1,3} However, the note keeping facilities of the critical care information systems have been slower to develop,³ perhaps because the CIS is run in parallel with a hospital wide EMR in many North American institutions.

It is not at all uncommon for otherwise sophisticated installations to print all information to paper at the time of patient discharge, as several systems have offered limited storage capacity and duration.² Similarly the provisions for the prescription of drugs and fluids may be somewhat rudimentary as North American institutions may use the CIS for recording administration, and have a separate hospital wide pharmacy system for prescriptions, which may remain paper based.

Utilisation of a CIS for clinical record keeping raises the issues of a medico-legal record and this aspect of the systems certainly produces a degree of caution amongst the product vendors. In most legal environments there is a growing acceptance of the electronic record. There are many advantages including maintaining a legible and attributable record, often with superior security through electronic restriction of access. The ability to prevent or record subsequent alteration of the record however is tantamount to its acceptance as a legal document. Such electronic document management systems are available and in use, although the construction of integrated operating systems requires additional resources.

There are a variety of appropriate storage media, which offer very efficient archival functions and also offer the opportunity to create multiple and off-site back up copies. Vendors may still be reluctant to certify systems as having achieved a medico-legal standard. However, achieving this outcome is important in achieving the benefits of a CIS and preventing the consumption of additional paper and space, for which the printing out of computer based information is renowned.

DECISION SUPPORT

Decision support seeks to provide additional value

from the CIS by providing pertinent reminders and guidance, based upon primary information entered into the system. Definitions and expectations of decision support vary between vendors and clinical consumers. Simple but valuable decision support displays may assist decision making by combining the appropriate information in a clear single screen display.^{1,8} More complex forms of decision support utilise sophisticated algorithms to suggest appropriate antibiotic choices, calculate parenteral nutrition requirements or advise on haemodynamic management.^{2,10}

Complex decision support remains underdeveloped in a number of systems. To perform these functions reliably presents the greatest series of programming challenges to all systems.^{3,7} Moreover, a change in the clinical environment, from say North America to Australia, may render invalid a number of basic protocol assumptions. While some commentators feel that this is where the ultimate benefit for a CIS resides, others emphasise the more basic CIS features and forms of decision support.

INTEGRATION WITH OTHER HOSPITAL SYSTEMS

This is one of the most technically challenging areas of CIS implementation. Although computerised laboratory results systems have a long history, there are a plethora of systems without standard means of communication, and often institutions individualise codes for particular pathology tests. There is also a diversity of hospital admission, discharge and transfer systems. However, a successful interface is highly desirable to ensure that patient demographics are correctly recorded and the laboratory interfaces are essential if maximum benefits are to be obtained from a CIS.^{1,3}

Significant resources are required to ensure a successful interface solution, often including resources from pathology and information technology departments. The term 'interface engine' is used to describe software and associated hardware that facilitates the creation of such complex interfaces. This is a specialised area in which the expertise of the CIS vendor may be limited.

Ongoing support costs to maintain and upgrade the interfaces should be anticipated. This is a particular issue as hospitals address the Y2K problem.

CLINICAL DATABASING

The clinical database is the 'mother lode' of the CIS, and often just as unattainable. There is obviously considerable incentive to exploit the opportunity to query the large amount of clinical data that already resides in an electronic format within a CIS. However,

as most current systems were not constructed primarily for database construction there are significant challenges in adapting them to this use.^{1-3,7}

The amount of data available on a daily basis is enormous and there is great temptation to preserve all of it for some future research purpose. Yet no matter how sophisticated the database and query tool is, there is always an ultimate trade off between the quantity of data retained and the speed and simplicity of subsequent queries. In addition, the quality and consistency of data collected is one of the primary attributes of a clinical database, and meeting the desired high standards may require re-engineering work practices and configurations.⁷ Even the most advanced systems cannot ‘see’ a central line being inserted. This information, with the required detail, must be entered into the system as part of an accurate and reliable routine. Similarly the diagnosis chosen by the clerk in the emergency department or your own unit at the time of admission may not be the one you wish to perform subsequent

searches on. It is critical to realise that free text searches are laborious, even for commercial standard software and hardware, and are fraught with difficulties relating to sensitivity and specificity.⁷

Many CIS research centres are proficient at producing attractive reports. These centres often benefit from additional institutional and vendor support that is not available to the purchasing institution. The industry is still struggling to produce a system for a clinical database that can be queried by the clinical end user – preferably one without an Oracle™ programming qualification!³

The most encouraging developments have occurred when the need for an additional intermediate sized database, often referred to as a ‘data warehouse’ or ‘subsidiary data repository’, has been recognised. Unfortunately even this engenders significant additional resources, as this is a specialised area of programming. Data warehouse design tends to be site specific and requires extensive collaboration with the end users to ensure that the design is appropriate for the rapidity and content of reports required.

Data warehousing is recognised by business users as being moderately high risk and requires some ongoing resources for administration and maintenance. The components of an integrated CIS are shown in figure 1.

“WHICH CIS?”

The software and technology for critical care CIS

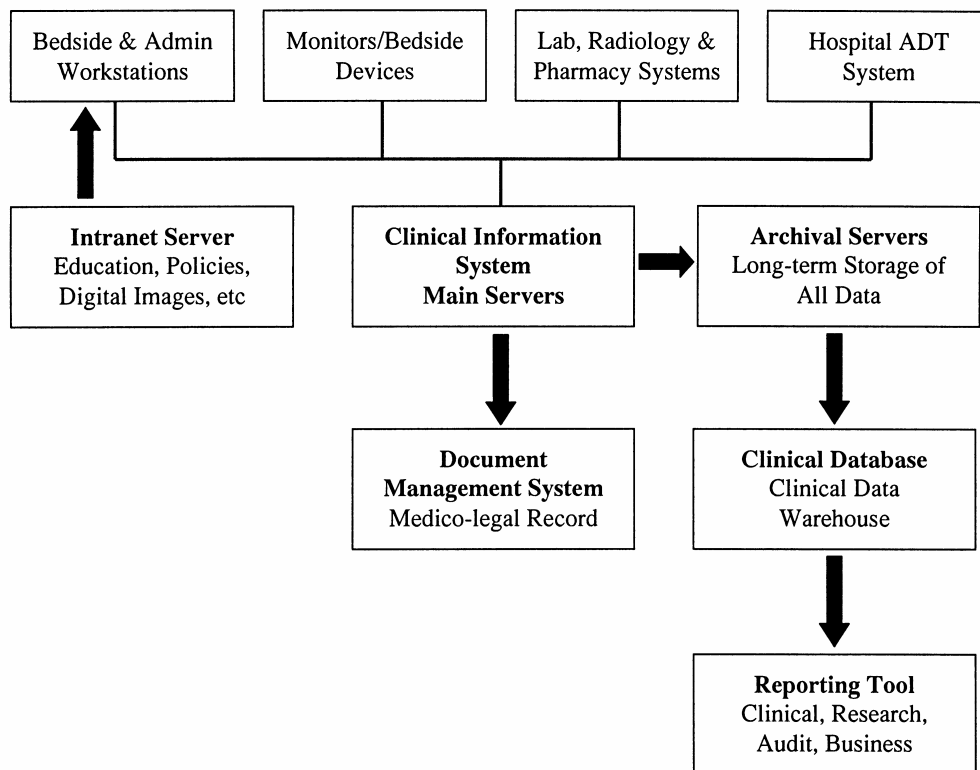


Figure 1. Components of an integrated Clinical Information System

was initiated by a small number of enthusiastic programmers familiar with the health environment. However, its subsequent development has been fostered by the more entrepreneurial interests of the medical equipment companies, particularly those with a strong interest in monitoring and the ability to develop substantial software systems.^{1,3,4} The central stations available in most monitoring systems seemed like a logical starting point for developing an integrated information system.

The ability of a monitoring company to offer even the future option of developing a centralised monitoring system into a CIS conferred significant leverage on clinical purchasers at the time of purchasing decisions. More recently, major computing hardware companies have sought the benefits of introducing information systems as a means of entering the medical market place with their servers, PC's and ancillary products. In addition, the dominance of the North American market has produced regulatory restrictions on clinical software development through the FDA, to which numerous delays in the implementation of new developments are often attributed.

The choices of software platform available to developers a decade ago were significantly more restricted than the current Windows enchanted, Internet impassioned and browser enabled systems that so many personal computer users are familiar with today. The UNIX platform was the most common and pragmatic choice, as it offered robust performance ensuring data integrity and safety with minimal downtime for so called 'mission critical' tasks in healthcare. Some observers suggest that the reliability standards of these systems are yet to be matched by more recent platforms such as Microsoft's NT system. However, these early developments in UNIX required programming in a software script such as C++, and modifications to these programs remains a super-specialised programming task, which hinders development and customisation of these programs.

The other consequences of the dominance of the UNIX system were expense, as decentralised work stations were more costly than personal computers, and limitations on flexibility, as the development of local area networks emphasised the benefits of distributed applications such as word processors, educational resources, and eventually intranets. Some of these limitations have been overcome by developing a 'PC client' or 'front end' that is still storing and distributing information on a UNIX server but is also able to offer additional familiar applications, educational resources and intranets.

One of the consequences of commercially led development is that the clinical contributions have been

limited and are often in the hands of those of our colleagues who are technology habitués. The frequent use of jargon and acronyms may disenfranchise other clinicians with a strong professional interest in improving the management of information flow in their workplace. The marketing arms of the corporations require showcase or beta-test sites, in which significant additional resources contribute to the overall ability and success of the installation, but are often not openly acknowledged. The vendors that have established themselves as global market leaders are still having difficulties in resolving some of these basic clinical and technology issues. Newer venture and niche market developers are the current pace-setters, although currently without the reputation, distribution and support abilities of the larger companies.

IMPLEMENTATION OF A CLINICAL INFORMATION SYSTEM – COSTS, BENEFITS AND OUTCOMES

The delivery of health care in most countries in the developed world is influenced by the tide of economic rationalism, although this may now be on the ebb. This has created the expectation that innovation must deliver cost-savings, either in absolute terms or in terms of efficiencies. Medical bureaucracies may expect that many improvements should be self funded from such savings. This requires clinicians to perform as business men and women in order to present, justify and implement new proposals. The 'business case' expresses in economic terms, any subsequent improvements in clinical outcome or service. While this encourages professionalism in project planning and implementation, the preparation of business cases and economic evaluations may also present a significant hurdle, particularly for a justification that is based upon quality of care.

Computer based systems have been in common usage for management, financial, administrative and laboratory information for many years. They are still relatively novel in the clinical environment where one might hope that the maximum impact on patient care would be achieved. Computer technology in other sectors of industry has been well accepted for administrative and financial systems and perhaps it is therefore not surprising that it's first applications in healthcare have been at this level.

Cost, opportunity, complexity and the inherent conservatism of clinical practitioners have made the clinical arena the last and greatest challenge for information technology in healthcare. Some hospital clinicians are reluctant to use keyboards for note writing and have little time to devote to managing a transition to a clinical information system. However, if they do not participate

in the change then they are even less likely to be comfortable with the outcome.¹

There is very little published literature on the virtues and benefits of a CIS in critical care. A similar deficiency in demonstrating health or financial outcomes is associated with many other information management systems in healthcare, although similar demands for justification or outcomes do not seem to be made upon administrators or business managers. It is often forgotten that a clinical information system is a means of delivering care, rather than a specific therapy in itself. Yet there are few aspects of the intensive care unit that impact so extensively upon its operation as the information management system used to plan, implement and document patient care.

The capital cost associated with these systems is large. A basic charting system may cost around \$25,000 per bed, however a system capable of archival storage, some decision support, and a clinical database facility may be expected to be in excess of \$50,000 per bed. The capital cost is therefore comparable to patient monitoring and ventilation technologies and some vendors have constructed leasing and activity based charging systems as methods of reducing the capital hurdle. However, in Australian hospitals at the present time recurrent expenditures may often be more difficult to establish and fund than capital expenses. Some recurrent costs are inevitable as part of a CIS.³ These should be anticipated and may be substantial, with software and hardware support contracts in the region of 10%-15% pa of the initial capital outlay. Systems implementation, management and development is a significant undertaking and for a 10-12 bed unit should be budgeted for with a middle level professional required for at least half a full-time equivalent.

Early marketing strategies from vendors attempted to emphasise potential savings achieved in nursing hours through reduced time spent in documentation.¹ These savings are not realisable³ and the associated industrial concerns previously threatened nursing support for CIS implementation. It is preferable to emphasise the efficiencies that may be achieved. At the Royal Brisbane Hospital the implementation of the CIS in one intensive care unit was associated with a substantial decrease in patient stay with a potential dollar value in excess of \$1 million per year. Nursing recruitment had previously been problematic and subsequently showed substantial improvements. The improved staff retention rate also had a cost saving of \$50,000 per annum.

The benefits of a CIS should be emphasised in terms of quality of care.¹⁻³ We have prospective unpublished data that demonstrates a greater than 50% decrease in medication administration and intravenous therapy incidents following the introduction of our CIS. While

there are some timesavings associated with charting these are translated into better and more comprehensive documentation of other tasks and time spent on patient care.

Medical note keeping emphasises keyboard skills, which is a diminishing problem, and is rewarded by legibility and more comprehensive records of problems and procedures. It is difficult to put a dollar value on, a) never having to search for the current case notes or, b) being able to have simultaneous access for multiple users. The rapid availability of laboratory results at the appropriate bedside is also a major quality improvement. Educational resources are also made available at the bedside, ranging from drug information and medical literature search tools to local policies, procedures and operational guidelines.

One of the important long-term goals for a clinical information system must include the provision of high quality clinical data for audit, research and unit management purposes.^{1,3} All Australian health departments have substantial investments in their financial management systems, however few have been able to achieve the nexus between clinical and financial activities embodied in clinical costing. Most intensive care practitioners, be they medical or nursing, have seen examples of 'data gone mad' with the inappropriate use of erroneous information. If we are to be in a position to direct the future development of our specialty then we must guide and participate in the collection of clinical business information.

There are many clinical functions that the available products achieve admirably and apparently effortlessly. However, there are also many additional requirements that are much more difficult to achieve and require additional resources. There is therefore no ideal CIS, and it is not possible to purchase an 'off the shelf' product that will fulfil all of a clinician's needs without further expenditure and development.² Increasing awareness of these issues by clinicians will provide the consumer demand and contributions to achieve the required improvements.

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