

Using Computers for Intensive Care Unit Research

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A computerized clinical information system (CIS) is potentially a very important information tool for research and improving health care processes as well as for optimizing data management and thereby minimizing health care costs. The newest CISs automatically collect patient data from various sources, including monitors, the laboratory, radiology, and patient notes, and make the data highly organized and readily accessible. In the future CISs may be able to conduct signal analysis, assist in care decisions, provide advanced graphical data presentation, and generate warnings to clinicians. Most CIS systems include large databases, and the advent of relational databases has improved data retrieval and manipulation and thus made the data a powerful tool in outcomes research. On the whole CISs collect more frequent and more accurate data than do clinicians using paper-based data collection systems, but research continues on how accurate CIS data is, how to improve that accuracy, and how much data checking and correction is needed. At my institution we have used CIS data to study changes in patients' code status and to evaluate a protocol for arterial blood gas (ABG) testing. The primary challenges to optimizing a CIS are ensuring accurate data entry, learning to query the data so as to avoid misleading conclusions, and to administer and maintain the hardware and software so as to minimize the chance of data loss and system down time. CISs are in a relatively early stage of their development, and engineering improvements will eventually make CIS data highly accurate and easily accessible and queryable so that CISs become even more valuable for research. *Key words: computers, information management, research, data processing, data collection, research methodology, research techniques.* [Respir Care 2004;49(5):518–522. © 2004 Daedalus Enterprises]

Introduction

Computers are becoming an increasingly large part of the practice of critical care medicine. They are now an integral part of all aspects of intensive care unit (ICU) care

and monitoring, from ventilators to medication orders to charting. Over the last decade many elements of comput-

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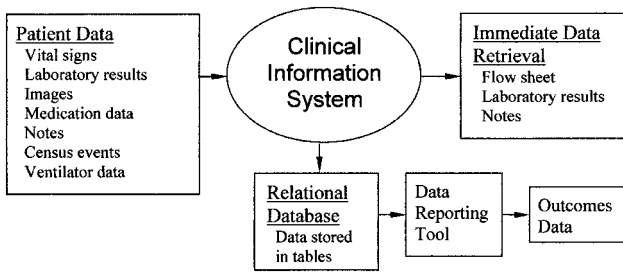


Fig. 1. Schematic of a clinical information system with a relational database.

erized patient data have been linked into *clinical information systems* (CISs). The term CIS, however, is still nebulous. Currently, it is used to describe a diverse array of computer hardware and software that aid in the care of patients. Generally these systems are able to record patient data, either directly, through links with monitoring equipment, or indirectly. A state-of-the-art CIS gets patient data from various sources, such as vital-signs monitors, laboratory data, radiology, and patient care notes, and incorporates those data into a format that is readily accessible and well organized (Fig. 1). These qualities have made CISs increasingly popular in intensive care units, where large amounts of data are generated.

Most CISs today also have features that make them more than just electronic patient charts. A CIS can also incorporate elements such as signal analysis,¹ decision analysis,^{2,3} advanced graphical data presentation,⁴ and computer-generated warnings that further aid in patient care. In addition, most systems today have large databases. The advent of relational databases has made data retrieval and manipulation much easier. It is the addition of these databases that have made the CIS a potentially powerful tool in outcomes research. An investigator can, theoretically, search for, collect, cross-reference, and analyze tremendous amounts of patient data very quickly.

CIS for Electronic Data Retrieval

One obvious way in which computers can potentially improve research is through gathering, recording, and presenting the tremendous amounts of data generated on patients. This can be a daunting task in the modern ICU where, every minute, data are generated by patient monitors. The ICU also uses laboratory and imaging services more frequently than do other departments. The shortcomings of hand-written patient charts are well documented.⁵ The most commonly cited problems with paper charts have been missing records, poor documentation, and illegible writing. A CIS can eliminate handwriting-legibility problems and automatically gather and store all pertinent clin-

ical information, such as medications, vital signs, test results, and narrative notes. Many commercially available CISs today have those abilities.

In terms of gathering physiologic data, a CIS offers 2 potential advantages over other methods. The first is that the CIS theoretically can provide more frequent and accurate data that are more easily stored. This aspect of a CIS seems initially to be nothing but a benefit. Computing and automatic data entry eliminate transcription errors, tabulation errors, and incomplete data, and save time, but, unfortunately, continuous or near-continuous physiologic data entry has some problems: as always, there is the potential for erroneous measurements (eg, when a blood pressure cuff is off the patient’s arm) and signal noise, as is common with electrocardiograms. To ensure data accuracy, it is frequently necessary to review data before accepting them into the record. Also, in physiologic data the range of extreme high and low values increases with the frequency of measurement, which can impact the calculation of disease-severity scores.⁶

Another potential advantage of a CIS is the possibility of adding secondary data to the primary data via complex signal analysis. An example of this that is familiar to many is the automatic interpretation of electrocardiogram signals. Many cardiac telemetry systems identify and record events such as ventricular tachycardia through signal analysis. A CIS could potentially record events such as shock and ventilatory failure and analyze them for known patterns by interpreting the primary data. That said, it is unlikely that automatic signal analysis and interpretation by CISs will play an important role in the near future, because the variables of human physiology are so complex.

The CIS Relational Database As a Tool for Research

Much of the current interest in computers for ICU research focuses on databases of clinical information collected during patients’ stays. In the early days of CISs the effective use of clinical databases was greatly limited by the technology. More than any other component of a CIS, the database requires a tremendous amount of computer memory. Furthermore, efficiently querying a large database requires a very fast computer. As computer memory and speed have rapidly improved, so have the utility of CIS databases.

The other development that made CISs powerful research tools was the invention of the relational database. A relational database essentially “tags” every piece of data as it is stored, much like a library card catalog. By way of those tags the program can quickly relate a piece of data to other similar types of data without searching the entire database (Fig. 2). A state-of-the-art CIS with a relational database can quickly search years of patient data and re-

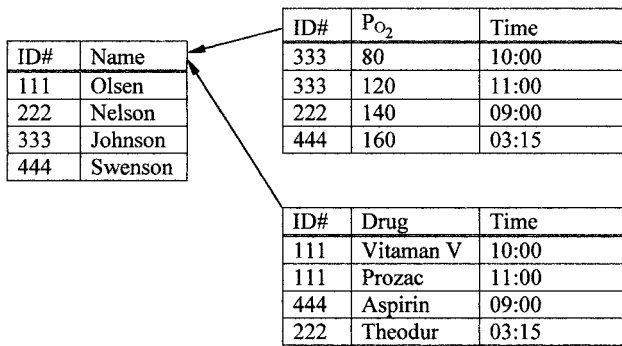


Fig. 2. A simplified example of a relational database showing links between data tables. The patient identification number (ID#) is the key to associating types of data. (Figure courtesy of Steven B Nelson MSc RRT FAARC.)

trieve specific data. Unfortunately, most commercially available CISs either do not have an archived database or have databases that are very difficult or too time consuming to query effectively.

There are 3 fundamental requirements for a database to be useful for outcomes research: accuracy, feasibility, and appropriateness.⁷ The problems with accuracy are discussed below. The feasibility of owning and accessing such a database is increasing because the systems are becoming less expensive. The ability to create a large clinical database on site—as is possible with the latest commercially available systems—makes them more appropriate for a given clinician or researcher than most outside databases. Furthermore, outcome data can be analyzed in context with resource utilization data from the same institution. Cowen and Matchett believe this to be perhaps the “greatest ability of a clinical database.”⁸ In any case, outcomes research on ICU patients should become much more comprehensive and faster to produce with the latest clinical databases.

Problems With Data Accuracy

The potential for data inaccuracy in a CIS is a problem that has not received much attention. Investigators have attempted to determine the accuracy of various commercial and noncommercial databases for measuring specific data such as medications,⁹ diagnoses,¹⁰ and patient physiologic data.¹¹ Wagner and Hogan reviewed 20 studies that compared CIS data accuracy¹² and found that CIS patient data was more accurate than other databases or paper charts. In reviewing this topic Hogan and Wagner helped elucidate the complexity of the problem with computer-based patient records. They divided the concept of accuracy into 2 components: completeness and correctness. Of the 20 studies they reviewed almost all measured only completeness, not correctness.

In addition to that problem most authors who have attempted to validate CIS data accuracy have compared CISs to paper charting. Multiple studies have documented the inaccuracies of handwritten medical records. Instead of being a standard by which to judge CIS data accuracy, handwritten records may be less accurate.¹² A better standard is needed by which to measure data accuracy, but that can be a complex task in a large, comprehensive system.

Examples From a Computerized ICU

At Rhode Island Hospital we have been using a commercially available CIS in our 18-bed medical ICU (MICU) for the last 6 years. In those years we have collected a tremendous amount of data and have used our relational database to answer some important clinical questions. We have also run into many problems. Two topics we have studied with our CIS data include code status and arterial blood gas testing.

Code Status

In order to better understand one end-of-life issue in our MICU, we studied the code status of admitted patients. For the study a row was added to the nursing flow sheet and the nurse was required to pick from a list of code statuses and input the patient’s code status at MICU admission (eg, do not resuscitate [DNR], do not intubate [DNI], or full code). On subsequent days, if the patient’s code status changed, the nurse was prompted to enter the new code status in the patient flow sheet. The database was queried to determine the numbers and percentages of patients with various code statuses at admission, code-status changes from initial status, and the time to change. The study considered data from a 6-month period. At admission 91.5% of our MICU patients had full code status (no restrictions on advanced cardiac life support or intubation), 4.6% were DNR/DNI, and 3.9% were in the category “other.” During MICU stay 25% of the patients’ code status changed: 7% to DNR, 11% to DNR/DNI, and 5% to comfort measures only. One percent whose original status was DNR were changed to full code status. Sixty percent of code-status changes were made within 48 hours of MICU admission. Figure 3 shows an example of that type of data.

Arterial Blood Gas Testing Protocol

To evaluate our practices and reduce unnecessary arterial blood gas (ABG) tests in our MICU, we instituted a protocol for ordering them. First we queried our database to determine the daily average number of ABG tests per mechanically ventilated patient. Then doctors and nurses were asked to limit ABG tests to only those situations indicated in the protocol. In the flow sheet the nurse was

Pitfalls of CIS Data

Admission Code Status		
	No.	%
Full Code	53	94.6
DNR/DNI	1	1.8
DNR	0	0
CMO	0	0

Change in Code Status				
No.	%	Percent Changed During		
		0-2 days	3-10 days	>10 days
0	0	NA	NA	NA
3	5.4	66.7	33.3	0.0
10	17.9	60.0	30.0	10.0
1	1.8	100	0	0.0

Fig. 3. Data generated by query of patient code status. DNR = do not resuscitate. DNI = do not intubate. CMO = comfort measures only. NA = not applicable.

prompted to choose from a list of reasons the ABG was done. If none of the reasons in the list applied, the clinician could input "other." At the end of the trial period we queried the database to compare ABG ordering before and after implementing the protocol. The protocol decreased the average number of ABG tests per patient per ventilator day from 4 to 2. However, we found that no reason was given (ie, "other" was selected) 92% of the time, indicating poor compliance with the protocol. After further education of the medical staff and eliminating the choice "other," we discovered that a new clinical intervention was the most common reason for conducting an ABG test. Table 1 summarizes the results.

Table 1. Reasons Given for Obtaining an Arterial Blood Gas Measurement After Adjustments

Reason	No.	Percent of Total*
No reason charted	2	> 0.01
Clinical intervention	2201	73.9
Assess P _{CO2}	54	1.8
New intubation	18	0.6
Other/unexplained	33	1.1
Patient deterioration	156	5.2
Study	89	3.0
Unable to obtain pulse oximeter reading	30	1.0
Ventilator setting change	396	13.3

* Because of rounding, percent values do not total 100%.

The 2 most common CIS problems are getting quality data into the system and querying the right data. As with any clinical study one must be careful how a question is asked or the resulting data can be inaccurate or confusing. In addition, given that much of the data entered into a CIS is entered or confirmed by human staff, there are limits to how much data can be entered accurately. It has been our experience that the more data entry is asked of the staff, the less accurate and complete the data will be. This makes choosing what data to ask for even more challenging, because quantity impacts quality.

Another major CIS pitfall is technical problems in the hardware and software. At times we have suffered major data losses from our system, from outages of the system and from loss of stored data. Good system administration is a vital component to doing research with a CIS, and the importance of system administration should be emphasized by any group considering implementing a CIS.

Summary

Information gathering via computerized systems is becoming a large part of modern ICUs. These systems offer many advantages over older data gathering systems, including more complete and accurate records. Relational databases enable the study of large volumes of data from various fields and can combine that data quickly and easily. In the future, additional computing capabilities, such as complex signal analysis, could make relational databases even more powerful tools, which should enhance ICU care. Concerns remain about the accuracy of CIS data but in the future the data will probably become consistently accurate enough to facilitate definitive studies.

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Discussion

MacIntyre: What are the HIPAA [Health Insurance Portability and Accountability Act] implications of searching these databases? I realize you're not going to publish patient information, but you are matching things about specific patients to other things without their permission. Are there HIPAA issues?

Ward: Yes, there are. You do need consent from these patients, and approval from your internal review board. Nowadays you're definitely going to need consent if you're going to prospectively collect data that include patient identifiers. If the data is collected only for quality assurance, you don't need consent, but you can't publish it. So that makes it that much harder. At a computer I used to be able in 15 minutes to collect enough data for a report. Now I have to go back and figure out if I need consent and otherwise address data security issues. It's becoming a lot more complicated.

Stewart: If you remove patient identifiers in your database, then you can query that information without it being a HIPAA violation and without needing to have an audit trail of who accessed the information. One thing we've done is to remove patient identifiers and send the clinical information to a central repository. If the data has any patient identifiers, then you have to go through the institutional review board process and have patients' permission to access that infor-

mation. However, most privacy notices, which patients sign at admission, indicate that the patient allows the use of some information, though the patient can check the restriction clause that reads: "Do not use my medical record for research." It depends on the institution's privacy notice. You can avoid HIPAA problems by having the privacy notice read, "Your clinical information may be used for research."

Pierson:* You touched on quality assurance, and your presentation very nicely showed how data that is primarily generated for one purpose, or maybe a couple of purposes, such as patient management and keeping track of things and billing, can be desirable to use for another purpose such as research. We're all required to do QA [quality assurance] activities and we're often interested in doing research as well.

A commonly done thing is to take this year's departmental QA plan and just write it up and submit it for publication and say, "Look at all this data." From an editor's perspective this has been very problematic. It gets back to exactly what you were saying: "Garbage in, garbage out." You have to design something to be of acceptable rigor for research at the front end before you collect any data if those data are going to be worth anything for research. So a QA activity *can* be valid research if it's designed as that from the beginning. But it's unlikely that if

you retrospectively go back to a QA project you've done, that you'll be able to get good enough data to answer the right questions with it to make it fill the needs for research.

Ward: That brings up an interesting point. CISs have been around for about 10 years, depending on where you want to draw the starting line. At the trade shows you hear these vendors describe these systems, and the first thought that pops into my mind is, why aren't researchers around the country cranking out reports on a daily basis if the system could quickly give you perfect data on, say, the rate of ventilator-associated pneumonia in people over 65 who have COPD? I think the fact that we don't see such reports is a tip-off that these systems are not as easy to operate as they are sometimes advertised to be, that the data is not as good as is needed, and that CISs are still in their clunky stage.

Nelson: Correlation does not equal causation. In this data-mining adventure that you described in several of your examples, do you think it's just coincidental that you found those results or was there more than just correlation? Were you able to find causation?

Ward: It depends on which of these things you're talking about. For example, there was a correlation between alcoholism and pneumonia, but that's just a correlation, although some other literature shows that same thing. People in alcohol withdrawal have a very high rate of respiratory failure from pneumonia. Regarding the other stuff

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I showed on accuracy, I don't know what to make of that data. I'd chosen 2 commonly used methods for collecting that data, and I compared them and showed there was a difference. And so the question is, which is more accurate? In a number of those cases I'd say my system is more accurate, though I know that's a value judgment. The reason why is that in a couple of those things—not so much with the diagnoses but definitely with things like medications—we are much closer to the point of care than these other systems are. Duration of ICU stay is another example: we're much closer to where the duration of stay decision is made in the hospital computer. So I can't prove that our duration-of-stay data is more accurate than some other institution's duration-of-stay data, but ours is collected by the team taking care of the patient. It's almost as good as if I had a research nurse in my ICU prospectively collecting that data.

Volsko: When you said that your system is more accurate than the hospital's system, especially with your reference to duration of stay, is it really a matter of *accuracy* or is it standardization? I encountered a similar problem when analyzing cystic fibrosis data. I captured my cystic fibrosis duration-of-stay data based on a 24-hour rolling calendar. I looked at date and time of admission, and date and time of discharge, in 24-hour increments. So if you were admitted at 2:00 in the afternoon on April 1, at 2:00 in the afternoon on April 2nd that was 24 hours, whereas the hospital looked at their data on the 24-hour rolling calendar based on the midnight census. Before that problem was corrected it caused disparities and an inability to compare baseline to care path outcomes when duration of stay was calculated. Wouldn't it behoove us to standardize those practices to capture the most accurate reflection of what our patients are doing, and so that we can compare that within and among institutions, to facilitate benchmarking?

Ward: That's exactly right. That form of error came in dramatically in the data for time on the ventilator. I had 2 systems for calculating time on the ventilator in terms of days, which is kind of loose, and they weren't standardized to each other. That *could* reflect some of the difference in duration of stay but, clearly, with differences up to 8 days or more. The point I *thought* you were going to make is that the hospital system is more accurate because the patient really *is* in the ICU for, say, 8 days. One could argue that, too.

Gardner: How did you get the data out of the CareVue [CIS] system into your [Microsoft] Access database?

Ward: All I have to do is launch Access and it accesses the CareVue database through some intermediary software. I have a lot of help with that part by people who understand the system better than I do.

Gardner: But did you do your database searches on a separate desktop computer that *wasn't* on the CareVue system, or *was* it on the CareVue system?

Ward: CareVue operates on desktop computer. The computer in the head nurse's office is configured with Access so that it plugs right into the CareVue database, which I guess is kept in the bowels of the hospital.

Gardner: The reason I ask is that part of the issue you're talking about is data mining and data structures. There would be things that you'd want to do in CareVue, such as you'd want data to come up quickly and have it organized in a different way than you'd want it for the database searches. Many people have 2 or more copies of the database—secondary databases that we call “datamarts.” Pharmacy data, for instance, would be in one datamart, data about ICD-9 [International Classification of Diseases, Ninth Revision] codes would be in another datamart, and

so on. We use that strategy because there are researchers who query the HELP system [Health Evaluation Through Logical Processes system, at LDS Hospital in Salt Lake City, Utah] and they look at 10 patients and find something interesting and then want to look at the data for last 10 years, which can dramatically impact the speed of the clinical data collection system. So generally you pull that data off to a datamart. I've heard the complaint about CareVue and other systems that the data are very hard to get out of the vendor system to pull off into datamarts.

Ward: There is some sort of datamart intermediary in between Access and the database.

Walker: It really caught my attention that not all of the ventilators interface with your CIS, which necessitates manual data entry. That dovetails into Rob Chatburn's discussion¹ about ventilator manufacturers. I'm not so sure that all the ventilator manufacturers have it as a high priority to interface their ventilators to CISs. At the technology meeting in Washington DC last week, I was assured that there are many standards being discussed and that the vendors are being included, but when I talked to the ventilator manufacturers, I got the impression that that's really not the case.

From a respiratory care standpoint my concern is that our devices might be somewhat left out while all the other devices are electronically interfaced with the CIS. However, at the same time, are we going to have to buy a whole new fleet of ventilators to electronically capture patient data? If we're going to improve our productivity by using these emerging technologies, I think that we have to get the manufacturers to work with us both with regard to the “front end” (the user interface) and the “back end,” so that the devices interface with CISs.

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Ward: I agree.

Gardner: There is an Institute of Electrical and Electronic Engineers [IEEE] standard, number 1073,¹⁻³ and we've been using versions of it for more than a decade. The whole industry, including vendors such as CareVue and manufacturers of bedside monitors and ventilator equipment,

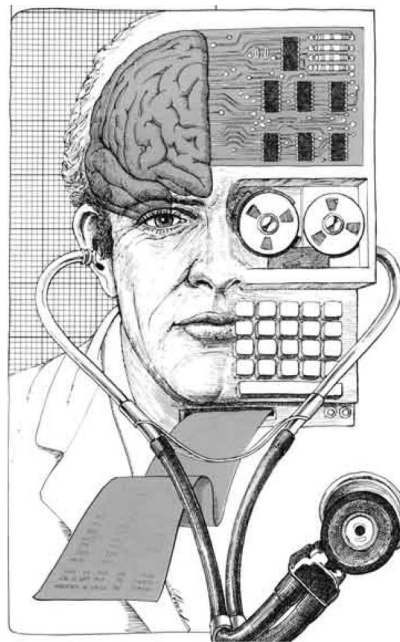
has to use it. The standards work, but we've got to get *all* vendors to use them.

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Walker: Dr Gardner, is that something you could have input into? You're on the leading edge and you make these devices work. Do you see that happening in the near future?

Gardner: Yes I do, and you can too, because the IEEE establishes standards with a consensus process. They're the people who came up with Ethernet and lots of other standards. There's a very active group, and I was involved in the standardization development process for about 10 years.



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Courtesy National Library of Medicine