COMPUTERIZATION AND QUALITY CONTROL OF MONITORING TECHNIQUES

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Webster defines quality as: "The degree of excellence which a thing possesses."[1] Demming, a pioneer in producing high quality products who helped the Japanese become world leaders in producing quality products, points out that "Reliable service reduces costs. Delays and mistakes raise costs."[2] Berwick tells us that "Real improvement in quality depends, according to the Theory of Continuous Quality Improvement, on understanding and revising the production process on the basis of data about the processes themselves. Every process produces information on the basis of which the process can be improved."[3] In a monograph written for the American Hospital Association, James tells us that quality is roughly equivalent to medical outcomes.[4] He further states that quality is "one of those things that is very difficult to define, but that anyone can recognize—I know it when I see it." These and others have shown that medicine, like any other "process," can be improved and that among other things the transfer of information is a key to improving the health care system. In about 1770 the great English writer Samuel Johnson said "Men more frequently need to be reminded than informed."

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Recently in the *New York Times* (January 13, 1991), Glenn Rifkin pointed out what quality means in terms of some everyday examples (Fig. 1).[5] It is interesting to compare the performance of different elements of our society. Not of much surprise, and in fact almost to our delight, we see that tax advice by telephone from the Internal Revenue Service is very error prone—about 15% of the time! The average company has approximately a 1% error rate, while

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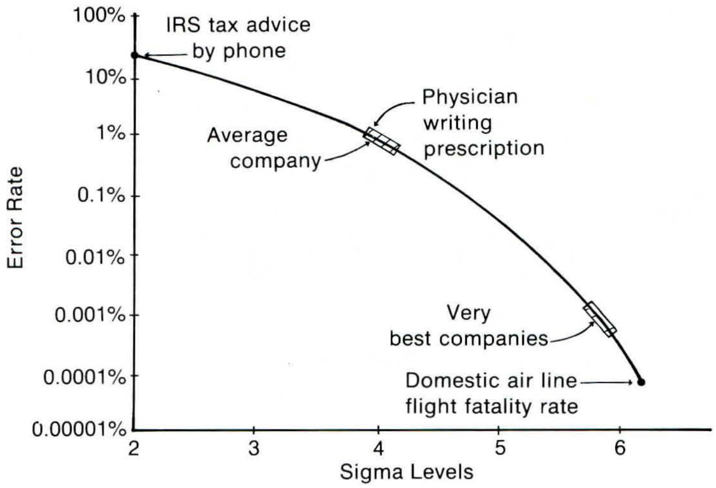

FIGURE 1 Error rates for some everyday tasks. Sigma levels = standard deviations from mean. Adapted from Rifkin G: Pursuing zero defects under the six sigma banner. The New York Times, January 13, 1991, p. 9. With permission.

the least error-prone have an error rate of less than 0.001%. Note that physicians writing prescriptions have close to a 1% error rate, the same as the average company. Domestic airlines have the lowest error rate.

Brennan and Leape and their colleagues have recently outlined the incidence of adverse events in hospitals.[6,7] They found what others have also found, namely, that errors in medical practice are common.[7] The researchers found that many factors increase the risk that a patient will have an adverse event during hospitalization and that a major determinant is the complexity of the disease or treatment. Complex patients are more likely to have adverse events. Clearly, patients in the Intensive Care Unit (ICU) are the most ill and have the most procedures performed on them of any patients in the hospital. Therefore, it is not surprising that the need for high quality care with the fewest errors should be the goal of everyone caring for patients in the ICU. How can this be achieved? Leape et al. state that "As knowledge increases, in theory more adverse events will become preventable" and that "Automatic 'fail-safe' systems—such as a computerized system that makes it impossible to order or dispense a drug to a patient with a known sensitivity—are likely to have an increasing role."[7] McDonald has stated that most adverse events are preventable, particularly those due to errors or negligence.[8] As noted in Figure 1, the airline industry has made dramatic progress in minimizing the number of errors and, consequently, deaths. The "flight recorder" has been one of the contributors to this achievement and shows that at-

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tention to systematic causes and consequences of errors has been worthwhile. The United States Army has developed a procedure to study and reduce human errors known to be the largest cause of aircraft accidents[9]; they call it the 3W approach. 3W stands for *What* happened?, *What* was the cause?, and *What* you do about it? Medicine should look at this procedure to determine how helpful it would be in preventing unwanted incidents and deaths.[6,7,9] Computers might be able to help in this process. The remainder of this chapter will deal with experience in using computers to improve the process of care.

HOW CAN COMPUTERS HELP?

Several areas where computers are being used to improve the quality of patient care are discussed below.

DATA ACQUISITION

The use of microcomputers in bedside monitors has revolutionized the acquisition, display, and processing of physiological data. Few bedside monitors or ventilators are marketed today that do not use at least one microcomputer. Sensors convert biological signals (such as pressure, flow, or mechanical movement) into electrical signals, while some biological signals, such as the electrocardiogram (ECG) are already in electrical form. These signals are "digitized" and processed to extract features from the waveforms; for example, determining heart rate from an ECG or arterial pressure pulse or deriving systolic, diastolic, and mean pressure from an arterial pressure waveform. These same computers can monitor the signal qualify of the waveforms and alert nurses or physicians when there is poor skin contact with an ECG lead or poor signal quality from a finger or ear probe of a pulse oximeter (see Fig. 3). As a consequence, alarms in bedside monitors are now much "smarter" and raise fewer false alarms. Automated data acquisition now allows nurses and physicians to have data almost continuously.

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DATA ANALYSIS

Increased sophistication of pulmonary, hemodynamic, and renal monitoring has resulted in the need to calculate derived parameters. In many ICUs today, this task is performed by nurses using a pocket calculator or perhaps even a programmable calculator. Unfortunately, entry of data from multiple sources and reentry of data by hand into the calculators results in delays and errors. Clearly, a computer system could enhance this process by making the calculations automatically and without error.

DATA COMMUNICATIONS

Communication is one of the most important tasks of health care professionals.

Communication is one of the most important tasks of health care professionals. Data underlie every medical decision, and except for the personal observations made by and acted upon by physicians at the bedside, data must be communicated. Often, the data are communicated through several people and via several media before getting to the medical decision maker. Each step in the process, especially if it involves people and handwritten records, can result in delays and errors. Clearly, computers are fast and accurate at recording and communicating data. Using the computer's capabilities, multiple users can have access to the patient data from multiple locations presented in a format that is optimized for their use.

DATA INTEGRATION

In the modern ICU it is not unusual for a patient to be connected to several computerized monitoring devices (Fig. 2).[10] For some of these data sources, such as intake and output, data are manually entered into the computer; for others they are electronically transmitted from locations such as the clinical laboratory. Results from a study that evaluated data used by physicians in ICU teaching rounds illustrates that data from multiple sources are used in decision making.[11] Laboratory data made up 42% of the data used to make treatment decisions; infusions, medications, and intake-output data account for 22%, nurse observations 21%, data from the bedside monitor 13%, and data from other sources 2%. To be effective and complete, physicians must integrate data from many sources. Most past attempts at computerization of ICUs have attempted to only deal with data from the bedside monitors.

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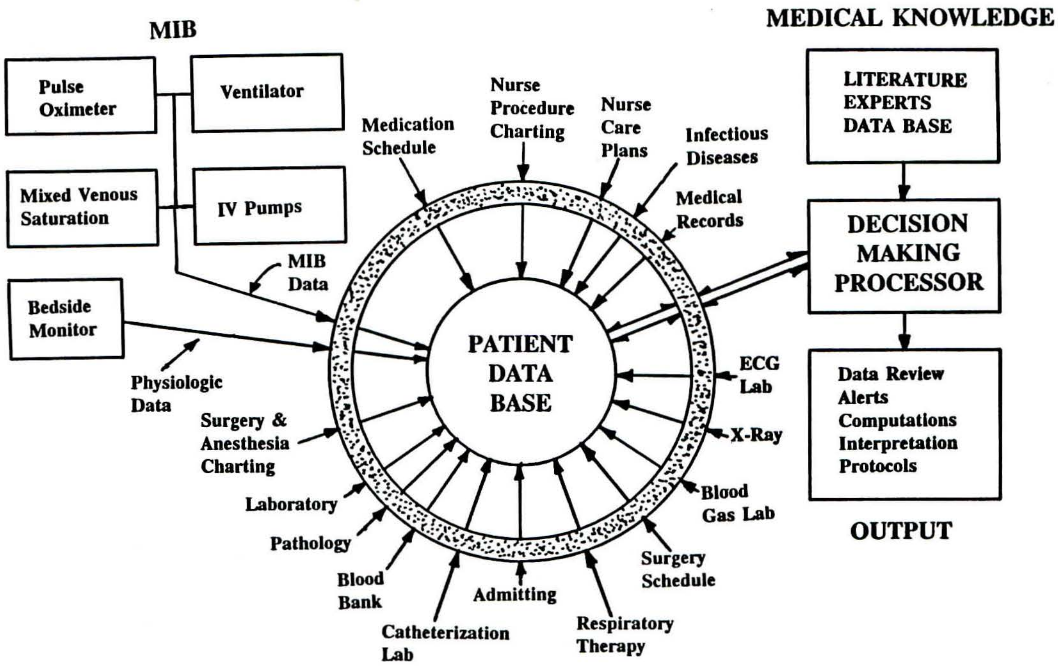

FIGURE 2 Diagram of a computerized intensive care unit data collection system. MIB = Medical Information Bus. Adapted from Gardner RM, Bradshaw KE, Hollingsworth KW: Computerizing the intensive care unit: current status and future directions. J Cardiovasc Nurs 4:68, 1989. With permission.

sources are available in the ICU. Delays are avoided, transcription errors are eliminated, and time can be saved.

DECISION MAKING ASSISTANCE

Medical decision making has traditionally been considered a scientific, as well as intuitive, process. In recent years, however, formal methods for decision making have been applied to medical problem solving and computer-assisted medical decision making has gained wider acceptance. Indeed, discussion of artificial intelligence (AI) is commonplace in medicine today (see the following chapter entitled *Use of Monitoring Information in Decision Making*). Computers can be used to interpret data, for example, interpretation of ventilatory status based on blood gas reports. Computers can also be used to alert physicians, nurses, or therapists when a medication may be contraindicated or a laboratory result is a threat to life.[13,14] As noted by Morris, computers can also be used guide patient treatment using protocols.[12,15–17]

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COMPUTER-BASED CHARTING

The patient record remains the principal instrument for ensuring the continuity of care.

The patient record remains the principal instrument for ensuring the continuity of care.[10] The medical record for every patient is a document that begs to be computerized.[18,19] For patients in ICU, and those undergoing anesthesia and surgery, this need is especially urgent. Information in the medical record should be easily retrievable and reviewable in a temporal relationship to associated data. Records having these characteristics would facilitate the routine processing of data required for medical decisions. Traditional manually recorded medical records lack these attributes.[19] Therefore, many investigators have attempted to computerize the medical record and make it "paperless." However, the hospital medical record has been difficult to computerize—far more difficult than either bank records or airline reservations.

With the "on-line" bedside monitoring situation, historically each supplier of monitoring equipment has wanted to "do it all." Each vendor wanted to provide *every* monitoring device for *every* bedside. Unfortunately, none of the vendors are large enough, flexible enough, or innovative enough to invent *all* the new monitoring devices. As a result, there is a veritable "Tower of Babel" situation with data flowing from bedside devices.

Bedside monitoring devices today are being designed with microprocessors as the principal tool to solve the complex measurement tasks. Even small, portable infrared sensor-based devices "shined" into the eardrum to quickly, noninvasively, and accurately measure patient temperature are microprocessor based. Thus, the challenge is to acquire, store, report and use this data for diagnostic and therapeutic decision making. To facilitate automatic data acquisition from the multitude of devices located at the bedside, the medical, nursing, respiratory therapy, and medical informatics staffs at LDS Hospital in Salt Lake City have integrated data flowing from bedside physiological monitors using the Medical Information Bus (MIB) (See Fig. 2). Devices such as infusion pumps, pulse oximeters, mixed venous saturation monitors, and ventilators have been interfaced to the MIB. The MIB is being standardized by the Institute of Electrical and Electronic Engineers (IEEE) with their MIB standards committee IEEE P1073 established in 1984.[20]

Recently at LDS Hospital, computers have replaced manual charting for respiratory therapy.[21] To be effective, such systems must provide easy methods for data entry and review, give accurate and descriptive documentation, automate several functions with a single input (billing, reporting, valid data checks, alerting). The system is now used routinely in ICU, and throughout the hospital.[22–25] Each day more than 18,000 data items are entered into the computer system. Very few (< 1%) of the data items entered give cause for alarm or immediate action.

QUALITY IMPROVEMENT

Quality assurance, measurement of outcomes, and documentation of performance are growing requirements for modern hospitals. Because of the low incidence yet potentially fatal consequences of missing or not acting on potentially life-threatening events, computers are becoming indispensable in care of the acutely ill.[3,4,25,26] Currently, our respiratory care quality assurance program uses the enhanced capabilities of our integrated computerized database.[26] Data from the blood gas laboratory, microbiology laboratory, clinical chemistry laboratory, the Admit Discharge, Transfer module, and the respiratory therapy charting are used.[25,26] Manual chart review is by necessity retrospective and usually performed on "samples" of patient charts. As a consequence, it may take weeks to discover errors in treatment with the result that little can be done to correct errors.

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To fill this need, a Medical Director's ALERT report is generated each day just before morning rounds. Nine different events for each patient receiving respiratory care are reviewed each day.[26] Table 1 shows some recent results from the ALERT report.

A similar analysis was made for the blood gas laboratory data. Each month approximately 4,000 blood gas tests are run. Table 2 shows that nearly 99% of the results are not life-threatening. Thus, only about 48 analyses (1.2%) each month require immediate action and follow up.

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TABLE 1 Medical Director's ALERTs

	Percentage
F_IO_2 ≥60% (ICU)	50%
PEEP >10 cm H_2O	20%
Cuff pressure >27 cm H_2O	14%
Peak pressure >60 cm H_2O	6%
Temperature >39°C	6%
F_IO_2 ≥60% (Non-ICU)	4%

TABLE 2 Blood Gas ALERTs (Approximately 4,000 Blood Gas Analyses Per Month)

	n	%
Blood gases OK	3,952	98.8%
Blood gases results life-threatening	48	1.2%
pH <7.30	20	0.50%
PO_2 <55 mmHg	17	0.43%
pH >7.54	9	0.23%
CoHb >5%	2	0.05%

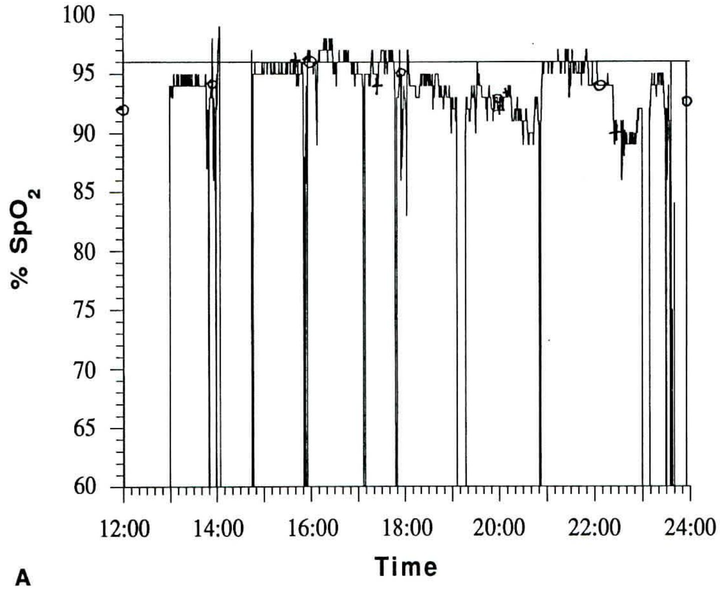
As a consequence, policy and procedure reviews have been strengthened to provide an overview of the performance of each staff member.[26] Thus, the goal of Continuous Quality Improvement is being accomplished.[3,4,26] In addition, some of the goals set forward by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and others recommending improvements in quality of care are being carried out with the aid of computers.[27–30]

COMPUTERIZED RESPIRATORY MONITORING

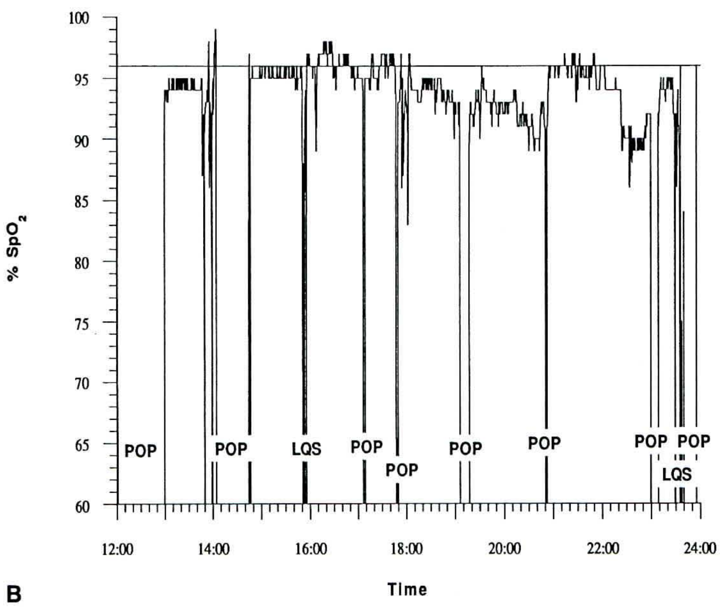
FUTURE CHALLENGES AND OPPORTUNITIES

Computerized bedside monitors, ventilators, pulse oximeters, and mixed venous oximeters have provided us with a flood of data. However, much like floods of water can overwhelm us, so can floods of data overwhelm computer storage capabilities and overload the computers and humans that must use the data for decision making. Artifacts and noise in the data stream continue to be a problem for automated and human data collection. The issue of data "ownership" and sharing also becomes a problem. For example, with pulse oximeters we find that saturations are independently stored in computer records by respiratory therapists, nurses, and blood gas technicians. All of these "non-computer" problems must be resolved before optimal data collection and decision making can be applied.

To illustrate these issues, we recently collected data for 12 hours from a patient on a ventilator. Figure 3 is a plot of the pulse oximeter oxygen saturation for this 12-hour period. Figure 3A shows the raw data available from the pulse oximeter at 30-second intervals, and Figure 3B illus-



A



B

FIGURE 3 Plot of oxygen saturation data coming from a pulse oximeter every 30 seconds for a 12-hour period obtained through the MIB. (A) Raw saturation data with data manually charted by nurses (○) and respiratory therapists (+). (B) Same data as (A) but with markings of POP and LQS. (*Figure continues.*)

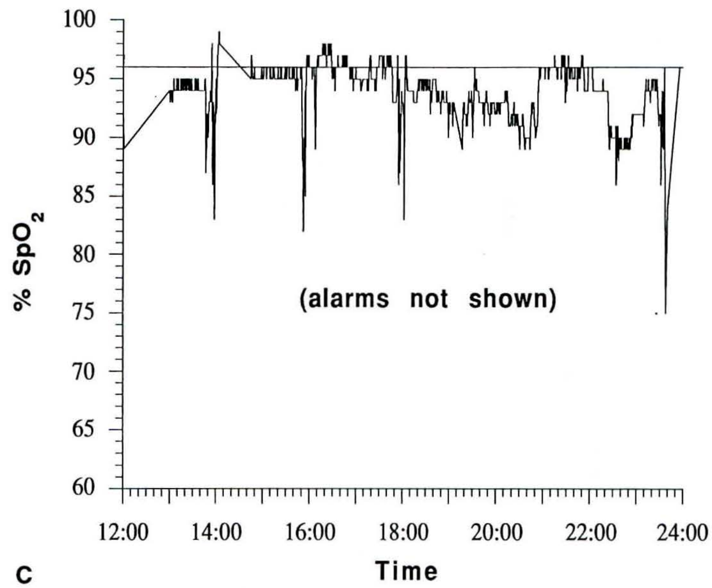


FIGURE 3 (*continued*) (C) Same data as in (A) but with time intervals with POP or LQS eliminated.

trates the times when the probe (on the ear) was either off the patient (POP = probe off patient) or had a low quality signal (LQS). Figure 3C illustrates how having knowledge about signal quality can minimize the noise or artifact in the information presented. Figure 4A is a plot of the raw pulse rate data obtained from the same pulse oximeter and Figure 4B is the data after taking into consideration the knowledge about signal quality. These data illustrate the problem of data overload, artifact, and ownership.

OVERLOAD: For the 12 hours of saturation and heart rate data flowing from the pulse oximeter registered every 30 seconds, there are about 60,000 bytes of data stored in the computer—approximately twice the number of characters presented in this chapter.

ARTIFACT: From Figure 3A and 4A it is clear that artifacts are the major problem that must be resolved.

OWNERSHIP: Figure 3A also shows by the + and O marks where therapists and nurses, respectively, have charted oxygen saturation data. The nurses charted at about a 2-hour interval and the therapist charted at more irregular time periods. Their measurements have a reasonable correspondence with the "true" value for the times noted.

Figure 5 is a plot of the spontaneous respiratory rate for the same patient for the same time interval as in Figures

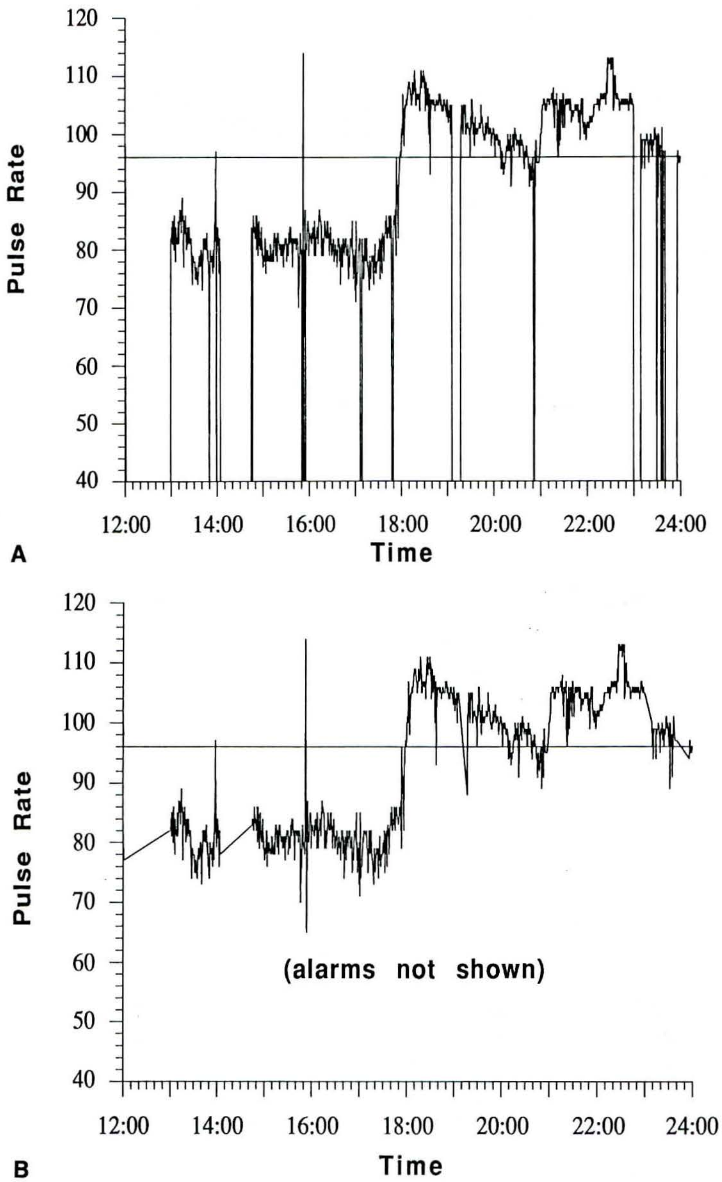


FIGURE 4 Plot of heart rate data coming from a pulse oximeter every 30 seconds for a 12-hour period obtained through the MIB. (A) Raw heart rate data. (B) Same data as in (A) but with time intervals with POP or LQS eliminated.

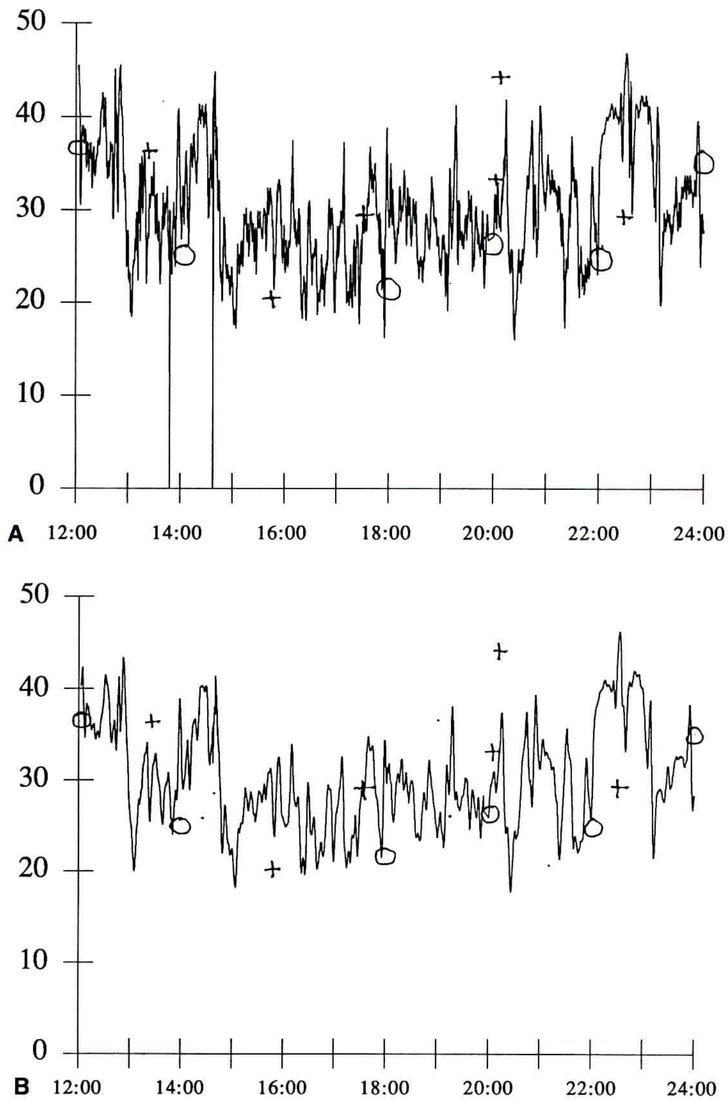


FIGURE 5 The spontaneous respiratory rate for the same patient as in Figs. 3 and 4 and obtained from the ventilator via MIB. These data were obtained every 10 seconds. (A) Plot of the raw data and those charted by respiratory therapists (+) and nurses (○). (B) Plot of a 3-minute average of the spontaneous respiratory rate. (*Figure continues.*)

3 and 4. The problems discussed above are further exacerbated with ventilator data.

OVERLOAD: The data space required to store the data from the ventilator with all its parameters is over 375,000 bytes of data for this 12-hour period.

ARTIFACT: The respiratory rate signal from the ventilator

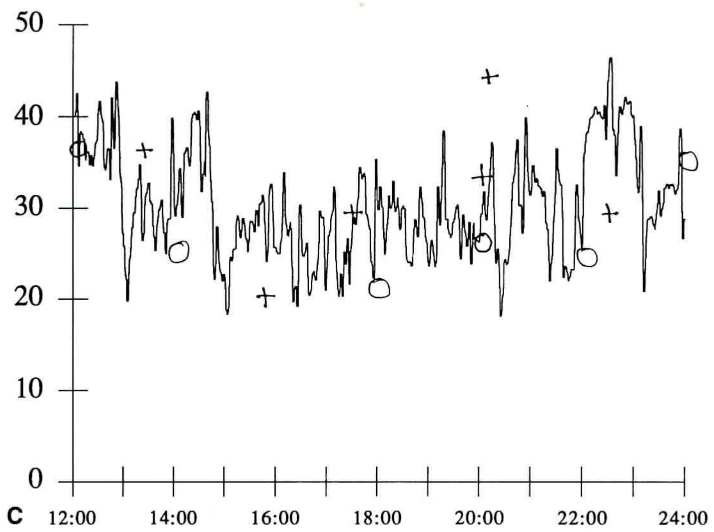


FIGURE 5 (*continued*) (C) Plot of a 3-minute median of the spontaneous respiratory rate.

clearly has considerable noise (Fig. 5A). Taking either a 3-minute mean (Fig. 5B) or a 3-minute median (Fig. 5C) of the respiratory rate smooths the data. However, note that the values selected and manually charted by the respiratory therapists and nurses appear to be taken as "instantaneous" observations and not based on watching for a minute or so and "averaging" the results. Based on this and other observations, concern arises about the quality of data recorded by human observers.

Concern arises about the quality of data recorded by human observers.

OWNERSHIP: With ventilator data, as with pulse oximeter data, nurses and therapists chart the information. Their observations, even when taken within similar time windows, seem to have large variability.

We have proven the basic premise of the MIB in clinical applications. However, sociological, physiological, data selection, artifact reduction, and medic-legal issues must still be addressed. For example, consider the emotional issue of taking something away when a process becomes automated. If an individual is charting data and must write it down, this process usually causes the individual to "think" about or process the data. By having the computer take over this task, is something lost? What data should be used? How should it be integrated and communicated?

With newer monitors, three or four devices may be giving the same information, such as heart rate. Which are correct and which should be logged? Despite the fact that people think that they are the most accurate "data loggers," evidence clearly indicates that humans do make data measurement and logging errors. Finally, the people factors and data selection strategies are more difficult than the engineering interface and computer science data acquisition requirements. These issues provide challenges and opportunities for making future progress in patient charting and patient care.

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