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Real time data acquisition: recommendations for the Medical Information Bus (MIB)*

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Abstract

Care of the acutely ill patient requires rapid acquisition, recording and communications of data. In the modern hospital it is not unusual for a patient to be connected to several monitoring and recording devices simultaneously. Each of these devices is typically made by a different manufacturer who may specialize in one sort of measurement, for example, pulse oximetry. Most of the modern monitoring and recording devices are micro-processor based and have communication capabilities. Unfortunately, there is no operable standard communication technology available from all devices. In addition different clinical staff (physicians, nurses, or repiratory therapists) may be responsible for collecting data. As a result there is a need to develop methods, standards, and strategies for timely and automatic collection of data from these monitoring and recording devices. We report on more than 5 years of clinical experience of automated ICU data collection using a prototype of the Medical Information Bus (MIB).

Introduction

Communication is one of the most important tasks performed by health care professionals. Data underlie every medical decision, and except for the personal observations made by and acted upon by physicians at the bedside, should be communicated. Ofttimes, the data are communicated through several people and via electronic strips, hand-written notes, computer displays, and computer printouts before getting to the medical decision-maker. Each step in the process, especially if it involves people and hand written records, can result in delays and errors.

For patients in Intensive Care Units (ICU) and those undergoing anesthesia and surgery this need is especially urgent [1]. Information in the medical record should be easily retrievable and reviewable in a temporal relationship with other associated data. Records having these characteristics would facilitate the routine processing of data required for medical decisions. The HELP system uses an integrated data base and has decision making capability [2, 3]. Traditional manually recorded medical records lack these attributes. In the modern ICU it is not unusual for a patient to be connected to several computerized monitoring devices (see Fig. 1) [2].

With the 'on-line bedside monitoring situation, historically each supplier of monitoring equipment 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

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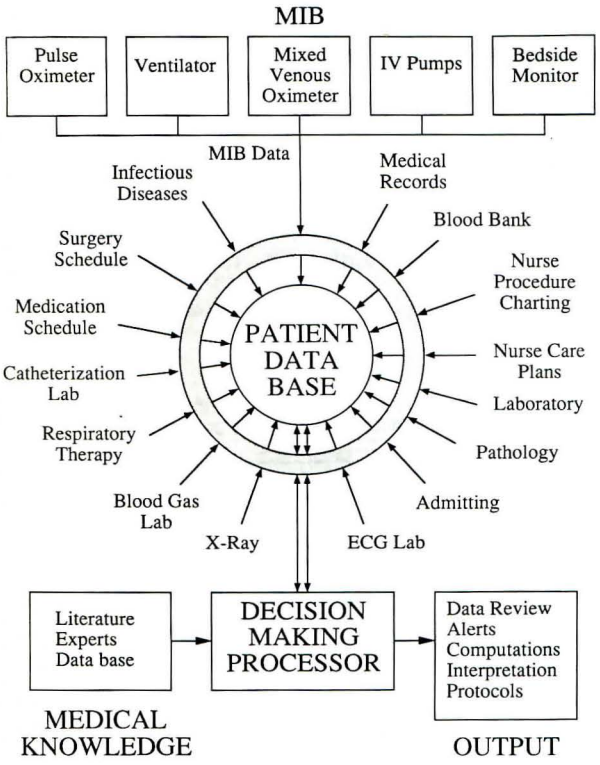

Fig. 1. Diagram of a computerized intensive care unit data collection system.

data flowing from bedside devices. Bedside monitoring devices today are being designed with micro-processors as the principal tool to solve the complex measurement tasks. For example, microprocessor based, small, portable, infra-red sensor based devices are now 'shined' onto the ear drum for quick, non-invasive, and accurate measurement of patient temperature. 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 physiological devices located at the bedside, we have integrated data flowing from these devices using the Medical Information Bus (MIB). Devices such as Bedside Monitors, Infusion Pumps, Pulse Oximeters, Venous Oximeters, 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 [4].

This report discusses some of the practical issues faced in developing an optimum 'real-time' data acquisition from bedside monitoring devices. Our report is based on 5 years experience at collecting data from several devices and integrating the data collection into medical and nursing clinical practice.

Methods

To assist the IEEE P1073 MIB committee in developing appropriate standards and solve some of its internal data acquisition problems, in 1985 we built a prototype MIB. Since that time, interfaces have been built and tested for the following devices: 1) Infusion Pumps, 2) Pulse Oximeters, 3) Mixed Venous Oximeters, 4) ECG and blood pressure monitors, including non-invasive blood pressure 'Dinamap' type devices, 5) Ventilators, 6) gastric pH monitors, 7) Urimeters, and 8) Blood gas machines. In the process of testing these devices several common issues continued to appear: A) The *complex electrical interfacing issues,* B) The *people issues* of integrating the MIB data flow into clinical practice, and C) The *data selection issues,* since most devices produced much more data than was being charted manually or than was desired and these signals currently contain considerable 'noise'.

Since there is much in common for all devices interfaced, this report will summarize some of the findings for all devices interfaced. Also presented are specific issues for each device to illustrate the nature of the problems that must be solved.

Results

Complex electrical interfacing issues

Shabot stated the problem most clearly in his 1989 article [4]. 'The absence of interface standards for bedside medical devices has precluded the connection of most bedside devices to patient monitoring computer systems and alarm networks.' Even though most bedside instruments provide 'data' interfaces they come in a variety of forms, e.g., RS-232, TTL-Level serial bit streams, 20 ma cur-

rent loop, 4 bit BCD with synchronization pulses, full or half-duplex just to name a few. Although some devices do not have any software or hardware capability to check for transmission errors, others have their own proprietary data checking protocols. As a result of this circumstance, and in cooperation with IVAC corporation, we developed a microprocessor based Device Communications Controller (DCC) designed to allow interfacing of most bedside devices [5, 6].

Figure 2 is a block diagram of the prototype MIB system we constructed. The system was built such that each DCC could plug into 'standard' connectors on a wall connector box in the patient's room. Each patient room will likely have a variable number and mixture of devices. For example, we have had patients with 12 Infusion Pumps connected as well as a bedside monitor, a ventilator, pulse oximeter, and a mixed venous oximeter connected.

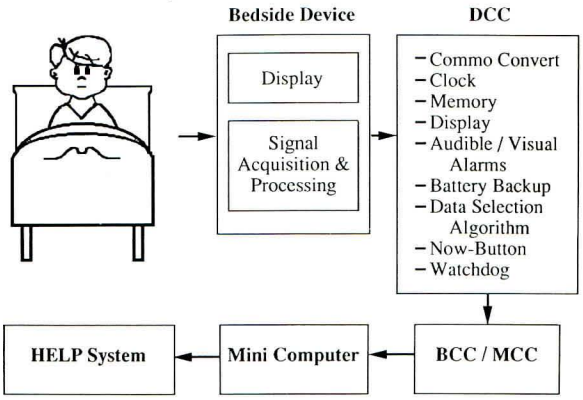

Fig. 2. MIB Block Diagram, where: DCC = Device Communications Controller, BCC = Bedside Communications Controller, MCC = Master Communications Controller.

People issues involved in integrating the MIB into clinical practice

Experience gained during the implementation of the prototype MIB system pointed out the need to have flexible software in the DCC. We found, as others have, that systems were most easily integrated into 'clinical' applications that required minimal changes in the user's environment [7]. If the MIB data gathering scheme does not allow a user to correct or change a procedural mistake simply, the user will revert to manual methods. After our experience with implementing the MIB for Infusion Pumps, Pulse Oximeters, ECG and Blood Pressure Monitors, and Ventilators [8], we have become much more aware of the need to integrate the functionality of MIB into nursing and clinical care practices. With Infusion Pumps we are now using the MIB routinely with excellent nurse acceptance. For example, many nurses put 'keep open' IVs on the MIB because it is an easier and more consistent way to chart. Bedside ECG and Blood Pressure monitors automatically collect data every 15 minutes in our ICUs and every 5 minutes in surgical suites with excellent physician and nurse acceptance [9]. A rigid system is least likely to be embraced by the users independent of its sophistication or perceived benefit.

Even if all the other obstacles can be overcome, there are still subtle concerns about *data ownership* in an integrated computerized medical record, *timeliness* of data entry, and selection of *accurate* or *representative* data.

Data ownership. It is common practice for several health professionals to record the same data and not share it effectively. For example, at our institution, ventilator data e.g., FiO_2 is entered into the medical record by nurses, respiratory therapists, blood gas technicians and physicians. This would be acceptable if they 'shared' their data and stored it in a common place. Unfortunately the data is neither shared nor is it consistent. This inconsistency does not usually cause a problem for the 'manual' record, but it can clearly cause a problem for the care of the patient. If a physician asked what the FiO_2 on a patient were, they may ask 3 caretakers and get 3 different answers! In fact, we have documented that problem with our computerized ICU medical record. We found that the FiO_2 recorded in the computer record at the time a blood gas sample was drawn was correct only about 50% of the time!

Timely data recording. Manual records do not require timely data recording. What is 'timely' recording? To the engineer or computer scientist it is

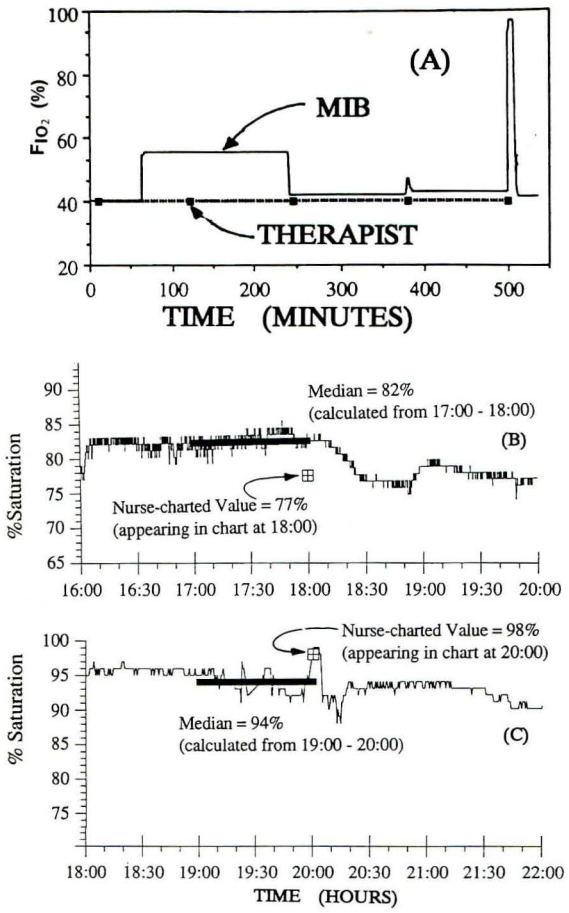

Fig. 3. A) Shows MIB and therapist charted FiO_2. B and C) Show MIB and nurse charted O_2 Saturations. B has a timeliness error and C an atypical data error.

data recording as it occurs. To the nurse or therapist it may mean recording data by the 'end of the shift'. Since most computerized systems allow data review by professionals from locations outside the unit, data entry must be timely. Timely 'external' review of patient data is 'foreign' to nurses and therapists who typically have only dealt with manual charting. They expect to provide verbal reports to physicians as they come into the unit for rounds or discuss the patient status via telephone. Thus, we have had to make a fundamental 'cultural' and philosophical change to improve the timely recording of data by nurses and therapists. These health care professionals must realize that they must enter data in a timely fashion much as personnel in the laboratory or radiology must do.

Entry of accurate and representative results. It is expected that human observers take all the important factors into consideration when they record observations at the bedside. For example, is the patient stable, is the physiological parameter stable and representative for the time period? Unfortunately, our observations made from MIB data collection experiments in which we have compared nurse or therapist manual data entry with on-line logging has shown more data logging errors than expected.

Figure 3 shows examples of these errors. Figure 3A shows there was about a 3 hour (180 min) time interval when a patient was on a ventilator with 55% oxygen while the therapists record showed 40%. Even when the therapist made a data entry in the middle of the time interval they still logged 40%. Figure 3B shows that a nurse charted a 77% oxygen saturation from a pulse oximeter at 18:00 when the median saturation for the hour before was 82%. This data entry error was likely a 'timeliness' error. The nurse most likely measured the saturation at 18:20 and to fit the patient care order for making the observation at 18:00 decided that 'it was close enough'. Figure 3C shows that the patient's median saturation had been 94% and yet for an interval of less than 2 minutes the saturation was 98% – the nurse chose to chart the 98% data – *not* a representative or typical saturation for the time interval.

For effective computerized decision-support systems, data must be entered promptly and correctly. It is no longer adequate to have the 'chart' correct only at the time of shift change.

Data selection issues

Bedside monitoring devices such as heart rate meters, blood pressure monitors, pulse oximeters, ventilators, etc. generate a 'flood' of data. Up to 1.5 M Bytes per patient per day are produced every day if just heart rate data is recorded! Obviously this amount of data could quickly overwhelm storage and display capabilities of any clinical computer system. Thus, a better way must be developed to preserve a 'reasonable' data storage and display

strategy. Recently Gravenstein has suggested physiologically based methods for establishing data collection rates [10]. It appears that recording most physiological parameters recording parameters every minute is acceptable. Other parameters such as temperature can be recorded at longer intervals. If one decided to record data at 1, 5 or 15 minute intervals what should be recorded? Maximum value, minimum value, an average, a mathematical 'median', or some other time weighted function? Answers to these questions are not yet known for certain. Development of a 'consensus' by physicians, ethicists, nurses, therapists, medical informatics professionals with input from legal representatives will be necessary. During this process the need for data recording will come under close scrutiny and it is likely that there will be a better understanding the clinical importance of each of the measured parameters.

Figure 4 illustrates the problem of data selection for a patient on a ventilator. Plotted along the X axis is the time of day in hours. Along the Y axis is the Tidal Volume (TV) delivered by the ventilator in Liters. Tidal volume is but one of 33 parameters available from the modern ventilator every 10 seconds! Figure 4A shows ventilator data recorded at 10 second intervals. Figure 4B is illustrative of a 'moving average' filtering mechanism used to reduce the amount of data stored and presented. Figure 4C shows the same data recorded by a respiratory therapist at roughly 2 hour intervals.

Early experience with collecting data from our prototype MIB devices has shown that data collection and selection techniques have shown major flaws. These flaws occur with both the 'human' data recorder and the simpler computerized data selection technologies already applied. We have found it necessary to permit easy selection and collect of episodic data such as may occur when a thermodilution cardiac output and wedge pressures are measured. Other similar occasions occur when a patient is in a particular position or 'stable' condition. In these episodic situations a single button push allows the collection of these data easily and simply.

Based on our experience with selecting data from devices we have found the following: Infusion

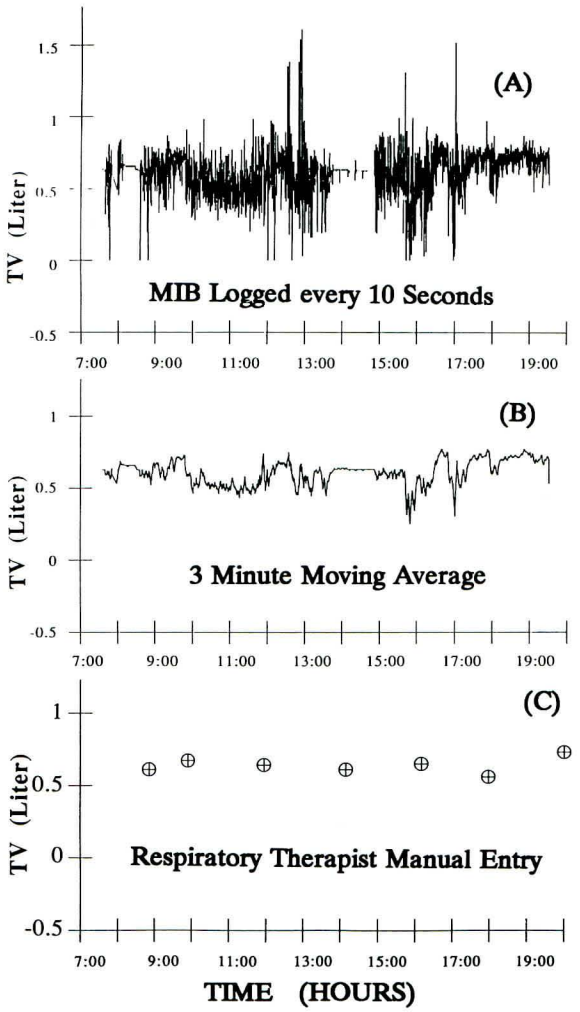

Fig. 4. A. Tidal volume (in liters) logged every 10 sec for a 12 h period. B. Tidal volume data obtained by using a 3 min moving average filter to get more 'representative' data for the same time period. C. Tidal volume recorded by a respiratory therapist for the same 12 h period.

Pumps – Flow rates charted when a new rate has been stable for 2 minutes and at 1 ml volume increments are adequate. Pulse Oximeters – Arterial Oxygen Saturation and Heart Rate can be determined reliably and nearly free of artifacts. Recording this data at 30 second intervals and storing median values every 15 minutes has resulted in an acceptable record. A competing strategy might be to record 'beat-to-beat' information. Such a strategy would result in a large amounts of artifact. Using

the manual recording alternative of logging data every few hours also seems inappropriate. Ventilators: With these devices one must record not only the 'delivered' volumes, oxygen concentrations, and rates, but also those set on the ventilator. The number of parameters we have chosen to store is large (20 with one ventilator as noted below) and the required interval of recording is about 3 minutes.

Recommendations

Monitoring manufacturers have NOT been careful to eliminate artifact and often transmit invalid data. A first and major effort must be undertaken by the manufacturers to eliminate known artifacts. In many cases, simple signal processing would dramatically reduce the false results presented as output [9].

Based on more than 5 years of experience in the clinical setting with data selection schemes, we make the following recommendations for data recording. These data selection strategies are not meant to replace the alarm functions built in bedside devices, but only to help in the data recording process. The data selection recommendations made below have only been tested in our ICUs and MUST receive the scrutiny of many other clinical and manufacturing institutions. We are certain that modifications will be made to these recommendations. However, we feel that presenting our recommendations as a target will elicit a movement to optimize these strategies.

1. DEVICE – Heart Rate, ECG
   First priority heart rate signal. Collect data every 30 seconds and store a moving median every 15 minutes. If a 5 minute median has a greater than 5 beat per minute heart rate change, store that value.
2. DEVICE – Heart Rate, Direct Arterial Blood Pressure
   Second priority heart rate signal. Collect data every 30 seconds and store a moving median every 15 minutes. If a 5 minute median has a greater than 5 beat per minute heart rate change, store that value.
3. DEVICE – Heart Rate, Pulse Oximeter
   Third priority heart rate signal. Collect data every 30 seconds and store a moving median every 15 minutes. If a 5 minute median has a greater than 5 beat per minute heart rate change, store that value.
4. DEVICE – Blood Pressure, Arterial Blood Pressure
   Be certain that data selection algorithms for direct arterial blood pressure are built into the bedside monitor [9]. Collect systolic/diastolic and mean blood pressure every 30 seconds and store a moving median every 15 minutes. If a 5 minute median has a greater than 10 mmHg pressure change, store that value. If automated non-invasive blood pressure is measured it will be the second priority signal and finally manually (auscultatory) measured blood pressure will e the third priority blood pressure signal source.
5. DEVICE – Oxygen Saturation, Pulse Oximeter
   Collect data every 30 second and store a moving median every hour. If the 10 minute media has a greater than 4% saturation change in either direction, store that value.
6. DEVICE – Oxygen Saturation, Mixed Venous
   Collect data every 30 second and store a moving median every hour. If the 10 minute media has a greater than 4% saturation change in either direction, stored that value.
7. DEVICE – Mechanical Ventilator
   General: Collect data every 10 seconds and make the data selections based on the rules noted elow. Also any time a therapists, nurse or physician activates a 'data collection' button.
   Settings: Store every ventilator *setting* that lasts for more than 3 minutes. Ventilator setting recommended for collection are indicated below:
   1. Ventilation Mode
   2. Respiratory Rate (IMV Rate)
   3. Tidal Volume
   4. Inspiratory Flow
   5. Oxygen %
   6. Trigger Sensitivity
   7. PEEP
   8. Plateau Time or Percentage
   9. I/E Ratio
   10. Pressure Support or Control Level

11. Flow-by Support Level
12. Flow-by Sensitivity

Measured Parameters: Calculate a 3 minute moving median from the 10 second data collected. Store a moving median for each 1 hour time interval. In addition, store measured parameters where there is a change greater than the thresholds noted below that lasts for more than 3 minutes.

Ventilator *measured* parameters recommended for collection are indicated below:

1. Peak Airway Pressure > 10 cm H2O Change
2. Mean Airway Pressure > 5 cm H2O Change
3. Spontaneous Tidal Volume > 100 ml Change
4. Corrected Expired TV > 50 ml Change
5. Spontaneous Rate > 5 beat per minute Change
6. Machine Assisted Rate > 2 beat per minute Change
7. Plateau Pressure > Every Change
8. Measured I/E Ratio > 25% Change

8. DEVICE – IV Pump

Record volume infused to the nearest ml and record changes in flow rate once it has remained stable for at least 2 minutes.

It is not uncommon for a patient to be attached to 3 or 4 devices that derive heart rate. We have only indicated a priority for selecting the signal from which heart rate should be determined. In the future, there should be strategies developed to combine data from these multiple signals to establish representative heart rates.

Conclusions

The basic premise that the MIB can be used as an automated data collection and communications system has been proven in the clinical setting. However, MIB standards must be developed and accepted, artifacts present in the raw physiological signals must be reduced, consensus on what data to collect, how often to collect the data, how to select the data, data ownership, sociological, and medical-legal issues must still be addressed.

Physicians, nurses, medical informatics professionals, and manufacturers should unite and push forward and complete the MIB standard. Once a first standard is produced then there will be the impetus for the industry to move forward.

As stated earlier, monitor vendors must take a more careful look into their methods of artifact rejection and transmission of non-representative data. Eventually the MIB and data selection methodology should be built into every monitor.

The recommendations presented above are given as a starting point. These recommendations should be carefully tested and validated and where needed, better recommendations proposed and tested.

Data ownership and sociological issues will continue to be a problem, but must also be addressed. There is an emotional issue of losing something with automation. We have all been taught to write with a pencil on paper and are reluctant to have that 'security blanket' taken away from us. If one is charting data and must write it down, we surmise that this process will cause the observer (nurse, physician, therapist) to think about or process the data [11]. Despite what most people believe about their accuracy as data loggers, we have clear evidence that humans observers do not always record data accurately nor in a timely fashion.

Finally the medical-legal factors must also be considered. We feel that the factors that can be raised here are best solved by an open discussion and the development of a consensus of the data needs for optimum patient care.

The people factors and data selection strategies are likely to be more difficult to accomplish than the device engineering interface and computerized acquisition factors. For optimum care of our patients, we must make the major cultural and philosophical changes needed to achieve a consistent, timely and accurate, real-time computerized medical record.

Acknowledgement

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