Selection and Standardization of Respiratory Monitoring Equipment

Reed M Gardner PhD and Terry P Clemmer MD

Introduction

The selection and standardization of patient monitoring equipment present a multifaceted problem. There is very little standardization in this field of medical practice. The use of complex monitoring is only 25 years old, and the routine use of monitors in clinical practice is not yet mature enough to support standardization. The growth of monitoring technology has far outstripped our ability to measure the effectiveness of the monitoring tools we have developed. Confirmation of this is found in the recent consensus conference on intensive care sponsored by the National Institutes of Health (NIH).[1] The complexity and time-critical nature of the care of the critically ill has further stressed our ability to manage these patients.

Dr Gardner is Professor of Medical Biophysics and Computing, University of Utah, Salt Lake City, Utah, and Co-Director of Medical Computing, LDS Hospital, Salt Lake City. Dr Clemmer is Director of Critical Care Medicine, LDS Hospital, and Associate Professor of Medicine, University of Utah, Salt Lake City. A version of this paper was presented by Dr Gardner on November 9, 1984, during the Conference on Monitoring of Critically Ill Patients held in Puerto Vallarta, Mexico, and sponsored by the American Association for Respiratory Therapy and its scientific journal, RESPIRATORY CARE.

Reprints: Reed M Gardner PhD, Department of Biophysics, LDS Hospital, 325 8th Avenue, Salt Lake City UT 84143.

Equipment-Selection Criteria

A review of the fundamental components of a monitoring system should help us in the equipment selection process. Figure 1 is a block diagram showing the essential elements of a monitoring system.

The sensor that must be attached to the patient may be as simple as an electrocardiograph electrode or as complex as a fiberoptic catheter inserted into a pulmonary artery. Sensor technology has been rather slow to develop. For example, respiratory gas flow is still best estimated with a Fleisch pneumotachograph, which was developed more than 60 years ago.[2] There have been some recent additions to the respiratory flow measurement technology,[3,4] but the problems involved in making this measurement are still awaiting reliable and convenient solutions.

Many factors enter into determining which monitoring equipment to buy. These factors include (1) The capital cost of the equipment. (2) The cost of the disposables used with the equipment. It has become common practice for vendors to provide free monitors or transducers if the buyer will sign a contract to purchase their disposables. Clearly, the cost of disposables far exceeds the cost of monitors, especially when one considers the accumulated cost over the life of the monitor. (3) The accuracy and quality of the data derived from the monitor. It may be possible to purchase a system with adequate accuracy for clinical determinations at a fraction of the cost of a research-quality machine. (4) Convenience of use. (5) The amount of time and effort

required to train people in the use of the equipment. The training costs may be one of the largest costs in implementing some monitoring functions. (6) The decision about whether to make measurements with an invasive or noninvasive technique. Recently a large number of noninvasive devices in the respiratory monitoring field have been developed.[5-8] Many of these devices display values continuously and have alarm capabilities. (7) How frequently the variable can be monitored. The current trend is toward more frequent and accurate measurements.[9]

Display Technology

Monitoring display technology has advanced rapidly in the last two decades. Early monitors had only the 3-inch 'bouncing-ball' oscilloscope display of the ECG. If one was looking at the right time and light conditions were just right, one might be able to detect an arrhythmia. More recently, computer technology has made available the continuous and simultaneous display of multiple signals. Indeed, these signals can be stored and recalled in electronic form much as we previously used paper-strip recorders. The cathode ray tube (CRT) is still the most common bedside monitor display device. A simple CRT, or oscilloscope, as it is more commonly called, will display on its screen the physiological signal, and then the signal will quickly fade away—the so-called bouncing ball display. Recently, displays have been developed that are known as 'bright' or storage displays. These displays keep the patient's physiological signal scrolling across the screen for a period of 5 to 10 seconds. Because the signals are stored in digital memory, they can be 'frozen,' or stopped, for more careful review.

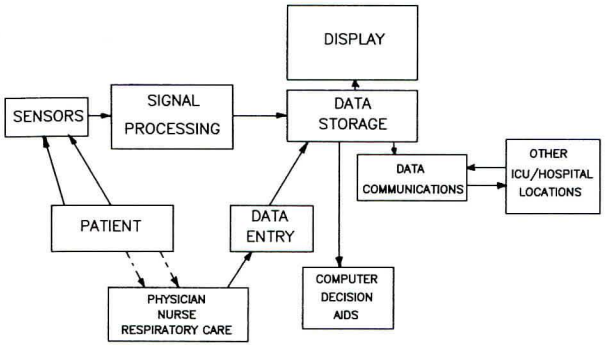

Fig. 1. Block diagram showing the essential elements of a patient monitoring system. Data are derived from the patient through sensors, observations by health care personnel, and samples or films delivered to other hospital facilities. Communication between many hospital facilities is crucial to optimal patient care.

Two general technologies are used to display data on monitor CRTs: (1) Raster-scanning technology, used in the television industry and in personal computer systems, has the advantage of being relatively inexpensive and providing a flicker-free display. It has the disadvantage of limited resolution, which becomes a major problem when information such as the electrocardiogram (ECG) and systemic and pulmonary artery pressures is being displayed. Unless special steps are taken, the signal displayed by raster scanning will have a "stair-step" look. (2) The technology of stroke-written display is also used in patient monitors. Its advantage is that it enables physiological waveforms to be beautifully displayed by connecting lines between sample points. Its major disadvantage is that it requires special-purpose hardware and may be slightly more expensive than the raster-scan technology. Either of these CRT technologies can be used to display alphabetic and numeric information. In recent years light-emitting diodes (LED) and liquid-crystal displays (LCD) have become attractive for monitoring devices. The red LED displays are frequently seen on ventilators and bedside monitors, and the LCDs used where their low power consumption is an advantage (eg, on portable oxygen analyzers). Plasma displays, which allow a 'flat screen' with characteristics much like a raster-scan CRT, are now being built into some of the more sophisticated personal computers.

Signal Processing

Once a physiological signal has been obtained from a patient via a transducer, the signal must be 'processed.' Signal-processing technology is developing quickly as a result of the recent development of small, powerful, and inexpensive microcomputers.[10] Almost all bedside monitors or ventilators marketed today have at least one microcomputer in them. Most have several! These powerful microcomputers, with their attendant memory, present several new opportunities: (1) They allow the use of sensor technology that was inadequate in the past because of nonlinear data, difficulty of calibration, and

interference by other signals. (2) They allow patterns in the signals to be recognized, much as a human observer does, which can be useful in eliminating artifact. In the past, most monitoring equipment used only analog computing technology, which had virtually no memory. As a result it was impossible for such a system to 'learn' a pattern. The recent use of 'templates' in ECG-rhythm processing in bedside monitors is the best example of how microcomputers can use waveform memory to compare and better classify complex physiological signals. (3) They allow signals to be processed in 'real time,' thus enabling one to have information promptly. Major innovations in monitoring technology will come from the use of microcomputers in bedside monitors.

Signal processing has become an important feature of patient monitors. Signal processing is used to linearize, filter, and time-correct the signal and to combine it with other signals so that monitors can more accurately display waveforms and measure physiological variables. With the recent proliferation of microcomputers in bedside monitors, nearly all signal processing is done with digital computer techniques. Once the monitor learns patterns, it is able to recognize them much the same as humans do. ECG-rhythm-pattern recognition is a task that is becoming more reliably performed by computer. Waveform templates comprising several patterns (eg, normal sinus rhythm and preventricular depolarization) are matched with the current ECG complex. Microcomputer monitors are also now much better able to eliminate artifact and minimize false data logging. The range and quality of the signal can be checked as the data are processed, which allows signal quality to be enhanced, making the derived data more reliable. Finally, a major advance in the development of microcomputer-based monitors is that the algorithms can be upgraded with software changes rather than new hardware. Most software is stored in Read Only Memory (ROM) and can quickly be exchanged in this field. Therefore, new monitors should now have a longer useful life and be capable of growth in power and capability with time.

Data Communications

The need for data-communication capabilities in the intensive care unit (ICU) cannot be overemphasized. A recent study at our hospital showed that communication is one of the most important aspects of a critical care monitoring system.[11] Figure 2 shows by percentages the data used for decision making in teaching rounds. It is clear that many of the data come from outside the ICU, and that all the data must be integrated for patient care.

Communication of waveform and derived information from the bedside to other hospital locations is a frequently used feature of monitoring equipment. For example, it may not be possible to have a strip-chart recorder at each bedside, but one can be placed at a central location and shared by several beds. In some situations, the requirement that medical personnel stand at the bedside to watch waveforms may not allow the patient to relax or personnel to discuss the patient's problems in depth. Therefore, most monitoring systems now have the capability of transmitting waveforms and data. Until very recently, data transmission was done by sending analog signals over multiple-wire cables. However, with bedside monitors now microcomputer-based, it is possible to transmit the signals in a digital format. Because digital signals can be sent with error-free transmission techniques, the observer at the receiving display is assured that waveforms and data are correct.

There are a variety of digital-communication networks available with monitors. Unfortunately, there currently is no common communication protocol standard for bedside monitors. With the advent of 'networks' of personal computers, it is likely that local area networks (LAN) will develop that will allow the average user to connect into bedside monitors via a personal computer.[12] With LAN technology in use it will be possible to interrogate bedside monitors and even control them from a remote location. All this leads to the possibility of "closed-loop" control of devices at the bedside.[13]

A data exchange and communication problem has been noted in our computerized ICU environment. Most bedside devices, such as I.V. pumps, ventilators, oximeters, and physiological monitors, are microcomputer-based. However, each has its own display, and because each comes from a different manufacturer, each has been designed to 'stand alone.' As a result, it is common for a nurse or therapist to have to read data on a computer display and enter the data through a terminal into another computer to get the data integration function needed for optimum patient care. The need to develop an

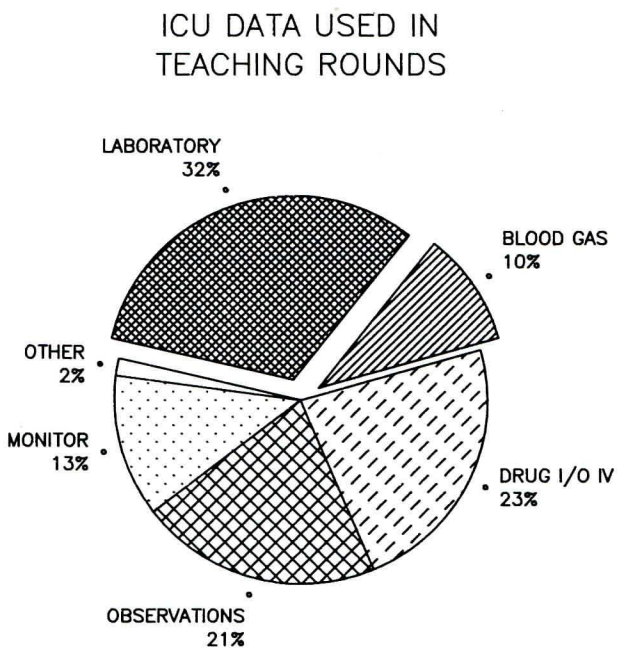

Fig. 2. Pie chart of patient data used by clinicians for decision-making in an ICU. Note that much of the data used in patient treatment decision making comes from outside the ICU (Laboratory & Blood Gas account for 42% of the data used.) (From reference 11, with permission)

integrated patient 'information bus' is apparent. Recently a committee was organized to write the standards for a medical information bus (MIB).[14] The MIB communications system will permit connection of up to 255 devices to a network and enable communication with each of these devices at least once per second. The technology now developing will allow the connection of a variety of such bedside devices as ventilators, physiological monitors, noninvasive blood pressure systems, infusion pumps, urine and drainage measuring devices, and oximeters—with their data recorded almost continuously. The potential for more accurate and timely data acquisition, as well as for labor savings, is enticing.

The Computer as a Decision-Making Aid

An aspect of bedside-monitor technology that is gaining much attention is the microcomputer's role in assisting decision making. These decisions can range from simple sensor-failure prompts, such as "Right Arm Lead Disconnected," to data interpretations and therapeutic suggestions. Each computer-based decision is derived from knowledge learned in the clinical setting. High- and low-heart-rate alarms are routinely provided in bedside monitors but result in a large number of false alarms. Although no manufacturer has yet provided a device that can simultaneously determine heart rate from ECG and blood pressure signals or pulse oximetry, such systems are now under development. Our experience has shown that the arterial pulse waveform is generally more reliable than the ECG for use in deriving heart rate. The ECG and arterial pressure signals should be used synergistically to improve the quality of heart rate determination. If the ECG signal is noisy, the blood pressure signal can be used to derive heart rate, whereas if a blood sample is being drawn from the arterial line and no pulsatile signal is available, the ECG signal should become the primary heart rate signal.

Patient-dependent alarm settings will soon be developed. The default settings for bedside-monitor alarms are established quite arbitrarily and are usually given a wide range by designers so that they will fit a wide variety of patients. Newer monitoring systems will tailor their alarms to patient conditions existing at the time the alarms are set.

The computer is now being used as a decision aid in ICUs. The computer is able to assist physicians, nurses, and therapists (1) by interpreting data,[15] (2) by alerting to life-threatening situations,[16] (3) recently, by suggesting some simple therapeutic interventions, and (4) by providing closed-loop control of some physiological variables.[13]

Data interpretation is a new feature that will likely be included in monitoring equipment. It is possible to interpret blood gas data when the ventilator and respiratory values are known.[17] Computerized interpretation of hemodynamic data combined with blood gas data is practical and clinically helpful. It is unlikely that a computer tool will outperform an 'expert'; however, the expert's knowledge contained in the monitoring system may prevent errors by others and may even help the expert who is tired or focusing on another problem or who may be otherwise distracted.[18]

Standards for Patient Monitoring Equipment—Developing a Methodology

The medical community must now begin to establish criteria and standards for medical monitoring

equipment. The Association for the Advancement of Medical Instrumentation (AAMI) has developed several standards for medical instrumentation. Using a voluntary consensus mechanism to get manufacturers and clinicians together, this organization has developed standards for medical instrumentation that include blood pressure transducers, cardiac defibrillators, ECG connectors, disposable ECG electrodes, heart rate and cardiac monitors, intracranial pressure monitoring, safe levels of current, and automated sphygmomanometer systems.[19]

The development of standards for medical monitoring equipment is complex and tedious. It is not unusual for a standardization task to take from 2 to 5 years. Experience in the establishing of other medical standards has shown that the following steps should be taken by any group involved in standards development:

1. The procedure or measurement to be standardized is well-enough developed that it can and should be standardized. It is not wise to standardize too early in a technology's development, because it may slow research progress and inhibit innovation. On the other hand, several tests and procedures used in clinical monitoring are widely used but are performed differently and, as a consequence, give different results. These well-accepted procedures should be standardized.
2. Obtain from a small group of knowledgeable experts a preliminary written standard based on the best information available to them through personal knowledge and from the literature. Points on which there is a lack of knowledge should be identified. Where there is a lack of knowledge, the experts might propose a standard based on their best judgment. However, the best approach is to have them design experiments to derive the needed data. When a preliminary document is prepared, it must include at least the following: recommended standard expressed in clear and, if possible, quantitative terms; rationale for establishment of the standard, with appropriate literature references and comments from experts; and a methodology for verifying (testing) that the device or procedure meets the standard.
3. Circulate the preliminary standard document to a group of other recognized experts (10-20 persons), and get their written comments.
4. Modify the preliminary document in response to the written comments of the experts. Prepare an agenda for a joint conference with the experts to further refine the standards document.
5. Hold a consensus conference to discuss points about which there is substantial disagreement. Try to resolve the areas of disagreement by presentation of data and by working through the problems. If there are still not enough data to set standards, then priorities must be established for experimental work that must be done.
6. Once the experiments have been completed, present the data in written form and circulate them to each consensus conference participant. The data thus obtained can then be used as rationale for establishing a standard.
7. Prepare the standards document for public review and request comments. After the standards document is made public, it should also be presented for public discussion at an appropriate medical/scientific meeting. Comments from this meeting should be taken into consideration in preparing the final standard.
8. As the final step in the preparation of the standard, obtain approval and publication of the document by a recognized national medical/professional organization.
9. Update the standards at least every 5 years so that innovation is not stymied nor new knowledge ignored.

Experience with the American Thoracic Society's standardization of spirometry showed that the above methodology can work for the good of the patient and the medical community.[20]

It is clear from the standardization of certain aspects of medical practice that the task should be a cooperative effort of physicians, manufacturers, engineers, and allied health professionals. The medical community must take an active leadership role in such standards work, or some manufacturers will continue to sell what they can, with little regard for the real needs of the medical profession. If the medical profession does not take an active part, we will continue to get monitors and devices with a lot of 'bells and whistles' that have no beneficial function. Clearly, we must develop testing methodologies that will allow us to establish the costs and benefits of the new technologies we develop. Performing randomized clinical trials is expensive, complex, time-

consuming, and frustrating. Thus, we will most likely have to join our expertise and patient populations in some common protocols to demonstrate the effectiveness of new developments.[21]

What To Measure?

The issues involved in deciding what variables should be measured in an ICU patient are many and complex. In some ICU patients it is necessary to monitor only the ECG for heart rate and rhythm, with other vital signs and measures needed only occasionally. On the other hand, some ICU patients may require several monitoring transducers and measurements almost continuously. This conference has addressed the issue[22] and we were queried for our opinions. Several recent reviews have also addressed this issue but have given only general statements.[23–26]

How Often To Measure?

The issue of how often a variable should be measured is just as elusive as the issue of what should be measured. On reading the most recent literature reviewing cardiopulmonary monitoring,[23–26] one is overwhelmed with how often purposely vague words and phrases like the following occur: "frequently," "when changes occur," "appropriate attention," "close monitoring," "routine," "on occasion," "attention to detail," "trends," "one needs to monitor," "monitor," "at least hourly," "checked daily," "continuous monitoring," "frequent sampling," "repeated analysis," "intermittent sampling," "breath-by-breath." Except for a few precise statements, most reporting in the literature is nonquantitative and indicates that the frequency of measurement is probably variable and patient-dependent. A recent thoughtful guest editorial by Stafford, entitled "Whither Monitoring?" provides some framework by which to determine "how often."[9]

If one were an engineer looking at the patient and being asked how often a certain variable should be sampled and recorded, the answer would be simple: Sample at the Nyquist frequency, which was determined by Nyquist in 1937 to be a frequency twice the highest frequency contained in the signal.[27] If we assume for the purpose of example that a patient has a single-lead ECG monitor connected (Fig. 3) and that the ECG contains frequencies from 0 to 100 hertz (Hz), the Nyquist sampling rate requires that we sample the ECG 200 times per second. A reasonable resolution of 8 bits (1 part in 256) is required. Thus, every 5 milliseconds (1/200 sec), 8 bits, or 1 byte, of data will be generated. Therefore, for each second, 200 bytes of data (1,600 bits) will be produced. With 86,400 seconds in a day, this translates into 17,280,000 bytes of data per day. A complete Webster's Collegiate Dictionary contains about that many bytes (characters of information)! It quickly becomes clear that we cannot afford to collect every 'bit' of information that is generated by a patient. Also, it is clear that no human being will be likely to review all these data. As a result, bedside monitors process the raw ECG data and derive variables, such as heart rate.

The maximum heart rate for an adult is about 240 beats per minute (4 per second). If the heart rate for every beat is stored in one byte (range 0 to 255 beats per minute), then 4 bytes per second are generated, and a 50-fold data reduction has been effected. If the heart rate display is updated only every 3 seconds, inasmuch as it is impossible for a human being to follow beat-to-beat heart rate changes, a further 12-fold reduction can be realized (1/3 byte per second). This data rate is still high and would result in 28,800 bytes of heart rate data per day. If we decide to record the heart rate at only 1-minute intervals, the data are further reduced 20-fold (1,440

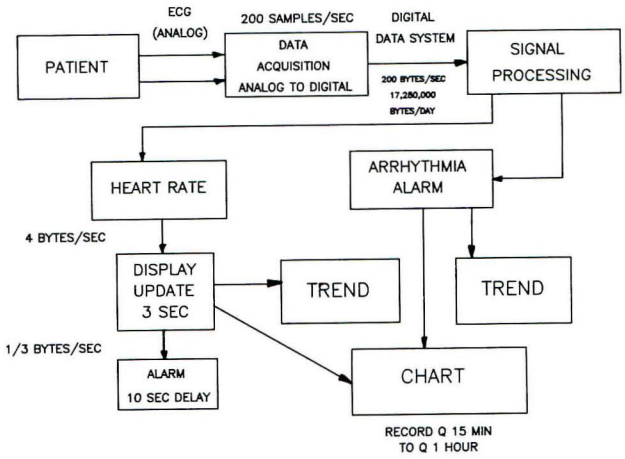

Fig. 3. Data flow diagram showing how the enormous amount of raw data from a patient is reduced to a level that is meaningful to clinicians. See text for discussion.

bytes per day). But what happens if the patient has a cardiac arrest? Monitoring equipment is purchased to log such events, and physicians typically want to focus on what happened just before the arrest. Therefore, most monitoring systems catch representative samples of data and take snapshots of data just before an alarm condition. This methodology lets us be much more efficient with data-logging functions, conserves data storage space, and minimizes complex numerical or graphical reporting. Preprocessing, whether done by computer or by medical staff, is a required task.

How does the above discussion relate to the physiological factors we are accustomed to looking at? Do we need to store each measurement to be assured that we are getting all the necessary information? Still other questions can be asked: How long is it after a variable changes dramatically before there is an irreversible medical change? If a dramatic change is detected, can or should we do anything about it? These challenging questions, which have not been addressed to any great depth in the monitoring literature, should be addressed by medical experts and monitor manufacturers so that directions will be provided for development of better and more cost-effective monitoring systems.

The problems of deciding what to measure and how often to measure are not related just to engineering considerations. Stafford points out that the physician is under the twin pressures of accepted clinical practice and legal security to collect more data and collect them more frequently.[9] Stafford also points out that knowledge of what to display and how to present the data once acquired is at least 10 years behind measurement capabilities.

Is there a risk of presenting too much data to human observers and as a consequence having an information overload? Data from medicine, anesthesiology, and the aerospace and nuclear power industries suggest that indeed this is a possibility.[28,29]

Direct Blood Pressure Measurement— A Technique in Need of Standardization

There are two primary reasons for inserting a systemic or pulmonary artery catheter: for the measurement of intravascular pressure and for the withdrawal of blood samples for blood gas analysis and other laboratory tests. The components of a pressure-measuring system include a catheter, stopcocks, connecting tubing, continuous-flush device, pressure transducer, and bedside monitor with display. Because information obtained from the monitoring of systemic and pulmonary artery pressure can be crucial to medical decision making, it is imperative that these measurements be made correctly. The major problems in making blood pressure measurements with catheter systems are associated with the mechanical characteristics of these systems.[30] These problems fall into four categories: (1) improper zeroing, (2) inadequate dynamic response of the system, (3) improper transducer/monitor calibration, and (4) improper extraction of derived data from the available pressure signals. Dr Marini discussed some of the problems at this conference,[31] and a recent publication has outlined the incidence of technical problems.[32]

Zeroing

Zeroing the pressure-amplifier-display system is the single most important step to be taken when a pressure monitoring system is being set up. One should zero the system by opening an appropriate stopcock to the atmosphere and aligning the fluid-air contact point with the mid-axillary line. Although several other procedures have been published, many can lead to important errors, especially when one is measuring pulmonary artery pressure.

Inadequate Dynamic Response

The catheter-tubing-transducer (plumbing) systems used in the ICU can cause distortion of the pressure signal.[30] Merely viewing the pressure waveform on the bedside monitor display is seldom sufficient to determine that the system has adequate dynamic response fidelity. One must activate the plumbing system by use of a "fast flush" test to assure that the waveforms recorded and values derived therefrom are accurate.

Figure 4A shows an 'ideal' arterial pulse waveform (recorded with a catheter-tipped transducer). Three other waveforms obtained with typical catheter plumbing systems attached to the same patient are also shown. Figure 4B shows a waveform from a plumbing system that is 'overdamped.' Of note is the fact that the fast-flush waveform is slow to return

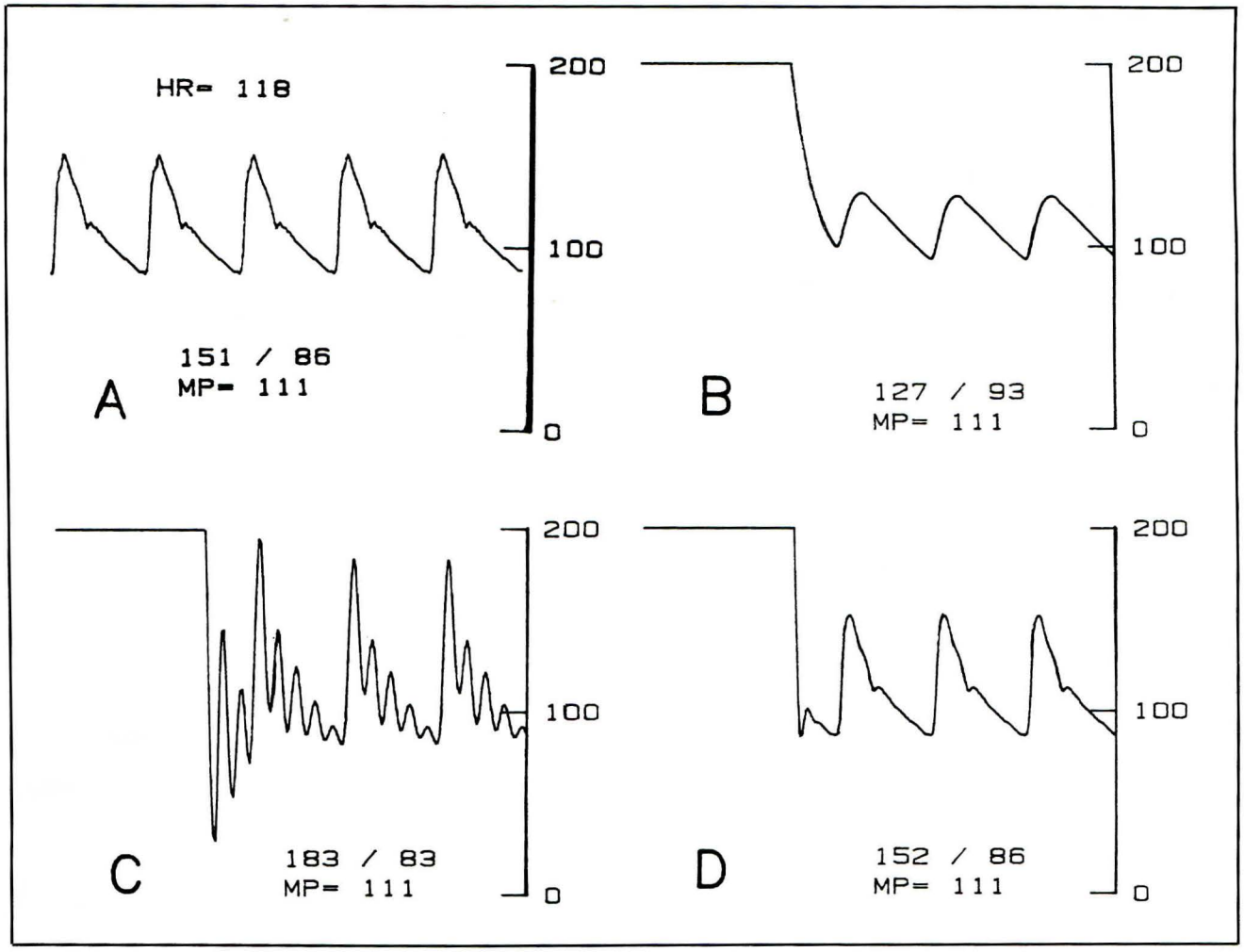

Fig. 4. Four arterial pressure waveforms obtained from the same patient (heart rate 118 beats per minute).
Figure 4A shows the patient's actual arterial pressure waveform recorded with a catheter-tipped device. The systolic pressure is 151 torr, the diastolic pressure is 86 torr, and the mean pressure is 111 torr.
Figure 4B shows the same patient's arterial pressure waveform recorded with an 'overdamped' system. Note that the 'flush' signal (upper left) returns slowly to the patient waveform. Systolic pressure is underestimated (127 torr), diastolic pressure is overestimated (93 torr), and mean pressure is correct.
Figure 4C shows an 'underdamped' condition. After the 'flush,' the pressure signal oscillates rapidly (rings). Systolic pressure is overestimated (183 torr), diastolic pressure is slightly underestimated (83 torr), and mean pressure is correct.
Figure 4D shows an ideally damped system. The undershoot after the 'flush' is small, and the original patient waveform is reproduced (systolic pressure, 152 torr; diastolic pressure, 86 torr; and mean pressure, 111 torr).

to the actual patient waveform. The systolic pressure is diminished and the diastolic pressure is elevated, while the mean pressure is unchanged. Figure 4C shows a waveform from a plumbing system that is 'underdamped' (damping coefficient less than 1.0) and has a low natural frequency (less than 20 Hz). It should be noted that the fast-flush signal oscillates rapidly (rings) and takes considerable time to stabilize to the patient's pressure waveform. With this system, systolic pressure is overestimated, diastolic pressure is slightly underestimated, and the mean pressure is unchanged. Figure 4D shows a waveform from a plumbing system that has an adequate dynamic response. The fast-flush signal quickly returns to the patient's pressure signal. The measured pressures are close to the true pressure shown in Figure 4A.

Transducer-Monitor Calibration

Most bedside monitors currently available allow adjustment of the pressure channel sensitivity. The

monitor sensitivity adjustment allows compensation for imperfections in transducer standardization. Unfortunately, most of the pressure checks on the monitors are only internal checks of the amplifier and display system and do not test the transducer. Transducer standards are being prepared that will eventually do away with the calibration step in the setting up of a pressure monitoring system. Recently, a variety of single-use (disposable) pressure transducers that are rugged, small, and remarkably stable have become available.[33] These devices will revolutionize the way pressure monitoring is done and simplify the process.

Extracting Data from the Pressure Signal

Deriving numerical data from patient pressure waveforms requires the use of signal processing technology described earlier. With current monitors, compensation is seldom made for known physiological artifacts.[34,35] Thus, the numerical values presented to the nurse or physician at bedside can be wrong and can lead to inappropriate therapy.

Direct blood pressure monitoring is widely used in the modern ICU, but the accuracy of the data derived from the signals is uncertain. Standards should be written that assure that each of the error sources outlined above is understood, can be tested, and is compensated for in the clinical setting. Standards need to be established for measurement of pressures during episodes of patient arrhythmia and respiratory variation.

Conclusion

Although there are few standards to guide us in the selection of monitoring equipment, the state of the art of monitoring equipment is progressing rapidly. In the era of prospective reimbursement and the public's expectation of 'perfection' in the delivery of health care, all health care providers must deal with complex issues. Evaluation of the cost effectiveness of any process in health care is complex. As a consequence, studies in the field, especially as they relate to monitoring, are limited. Therefore, it is incumbent on the medical profession to be as introspective as possible, while at the same time not stifling innovation. Development of standards by the medical community is essential if we are to maintain the high level of trust and confidence in our community that the public now has. If we refuse to take up this challenge, it will be forced on us by those who see that we have not been sensitive to the responsibilities entrusted to us.

REFERENCES

1. Ayers SM (panel chairman). Critical care medicine—NIH consensus conference. JAMA 1983;250:798-804.
2. Fleisch A. Der Pneumotachograph—ein Apparat zur Geshwindigkersregistrierung der Atemluf Pflugers. Arch Gas Physiol 1925;209:713.
3. Osborn JJ. A flowmeter for respiratory monitoring. Crit Care Med 1978;6:349-351.
4. Westenskow DR, Tucker SM. Evaluation of a ventilation monitor. Crit Care Med 1981;9:64-66.
5. Burki NK, Albert RK. Noninvasive monitoring of arterial blood gases. A report of the ACCP Section on Respiratory Pathophysiology. Chest 1983;83:666-670.
6. Rebuck AS, Chapman KR, D'Urzo A. Accuracy and response characteristics of a simplified ear oximeter. Chest 1983;83:860-864.
7. Mihm FFG, Halperin BD. Noninvasive detection of profound arterial desaturation using a pulse oximeter device. Anesthesiology 1985;62:85-87.
8. Yelderman M, New W Jr. Evaluation of pulse oximetry. Anesthesiology 1983;59:349-352.
9. Stafford TJ. Whither monitoring? (editorial). Crit Care Med 1982;10:792-795.
10. Toong HD, Gupta A. Personal computers. Scientific American 1982 (Dec);244:87.
11. Bradshaw KE, Gardner RM, Clemmer TP, Orme JF Jr, Thomas F, West BJ. Patient data usage in a computerized ICU—An evaluation. Int J Clin Monitor and Comput 1984;1:81-91.
12. Durr M. Networking IBM PCs: A practical guide. Indianapolis IN: Que Corp, 1984.
13. Sheppard LC. Computer control of the infusion of vasoactive drugs. Ann Biomed Eng 1980;8:431-444.
14. Gardner RM, Hawley WL. Standardizing communications and networks in the ICU. Proceedings AAMI Patient Monitoring and Data Management Conference, Philadelphia PA, Dec 1984. Arlington VA: Assoc for Advancement of Medical Instrumentation, 1985; (in press).
15. Gardner RM, Cannon GH, Morris AH, Olsen KR, Price WG. Computerized blood gas interpretation and reporting system. Computer 1975;(Jan)8:39-45.
16. Johnson DJ, Ranzenberger J, Herbert RD, Gardner RM, Clemmer TP. A computerized alert program for acutely ill patients. J Nurs Adm 1980;10:26-35.
17. Gardner RM, West BJ, Pryor TA, Computer-based ICU data acquisition as an aid to clinical decision making. Crit Care Med 1982;10:823-830.
18. McDonald CJ. Protocol-based computer reminders, the quality of care and the non-perfectibility of man. N Engl J Med 1976;295:1351-1355.
19. AAMI standards and recommended practices—1985 reference

edition. Arlington VA: Assoc for Advancement of Medical Instrumentation, 1985.
20. Gardner RM, Chairman. ATS statement—Snowbird Workshop on Standardization of Spirometry. Am Rev Respir Dis 1979;119:831-838.
21. Weinstein MC, Stason WB. Foundations of cost-effectivenss analysis for health and medical practices. N Engl J Med 1977;296:716-721.
22. Neff TA. Monitoring alveolar ventilation and respiratory gas exchange. Respir Care 1985;30:413-421.
23. Goldenheim PD, Kazemi H. Cardiopulmonary monitoring of critically ill patients (Part 1). N Engl J Med 1984;311:717-720.
24. Goldenheim PD, Kazemi H. Cardiopulmonary monitoring of critically ill patients (Part 2). N Engl J Med 1984;311:776-780.
25. Wiedemann HP, Matthay MA, Matthay RA. Cardiovascular-pulmonary monitoring in the intensive care unit (Part 1). Chest 1984;85:537-549.
26. Wiedemann HP, Matthay MA, Matthay RA. Cardiovascular-pulmonary monitoring in the intensive care unit (Part 2). Chest 1984;85:656-668.
27. Schwartz M. Information transmission, modulation, and noise—A unified approach to communication systems. 2nd ed. New York: McGraw-Hill Book Co, 1970:119.
28. Arnell WJ, Schultz DG. Computers in anesthesiology—A look ahead. Med Instrum 1983:17:393-395.
29. Cooper JB, Newbower RS, Kitz RJ. An analysis of major errors and equipment failures in anesthesia management: Considerations for prevention and detection. Anesthesiology 1984;60:34-42.
30. Gardner RM. Direct blood pressure measurement—Dynamic response requirements. Anesthesiology 1981;54:227-236.
31. Marini JJ. Obtaining meaningful data from the Swan-Ganz catheter. Respir Care 1985;30:0000-0000.
32. Morris AH, Chapman RH, Gardner RM. The frequency of technical problems encountered in the measurement of pulmonary artery wedge pressure. Crit Care Med 1984;13:164-170.
33. Disposable pressure transducers—Evaluation. Health Devices 1984;13:268-290.
34. Cengiz M, Crapo RO, Gardner RM. The effect of ventilation on the accuracy of pulmonary artery and wedge pressure measurements. Crit Care Med 1983;11:502-507.
35. Ellis DM. Interpretation of beat-to-beat blood pressure values in the presence of ventilatory changes. J Clin Monitoring 1985;1:65-70.

Discussion

Dr Luce: I'm going to give you an example of a disturbing ICU scenario in which Dr Schlobohm and I were involved recently. We had a patient who was receiving intracranial pressure monitoring and was receiving therapy for presumed intracranial hypertension. One of our fellows investigated the tubing in the system and found it to be too long. Thus, we were treating an artificially elevated ICP by virtue of not knowing how to use our system. None of us—physicians, nurses, therapists—were aware of this. I would warrant that the majority of people in practice do not know how to distinguish a true waveform on a monitor. We are so imprecise in our ability to make these measurements, regardless of their physiological meaning, that we cannot leave their interpretation to a machine unless it can do better than we can. Because we are going to be programming that machine, it is hard to believe that such superiority is going to be possible.

Dr Gardner: We have nothing operational at our hospital that is closed-loop controlled. There are, at the moment, no devices commercially available that provide closed-loop control. Manufacturers are scared to death of closed-loop-control devices, with good reason. However, if you had a mechanism in a monitoring system to prompt you, as soon as you hooked up your pressure transducer, by saying "Flush the system to test dynamic response," it could easily evaluate the data and assess the adequacy of dynamic response. Perhaps the message would come back, "Dynamic response inadequate, eliminate air bubbles, shorten tubing," to guide you through the setup. Thus the computer could provide some good signal-quality-checking procedures so you could optimize the quality of data you gather. If you aren't trained to handle the sophistication of the monitoring techniques and methods, then you shouldn't use them. There is no substitute for training.[1] If the medical staff can't handle the complexity of invasive monitoring equipment, perhaps they should use simpler, noninvasive types of devices. If you can't handle the complexity of an invasive arterial pressure monitoring system, you are likely to make fewer errors with noninvasive methods, even with their limitations.

1. Ayers SM (panel chairman). Critical care medicine—NIH consensus conference. JAMA 1983;250:798-804.

Dr Luce: I agree with you entirely, but everywhere in the country monitoring is becoming more sophisticated rather than less. What bothers me is that the average hospital is gearing up to offer every new technological advance.

Dr Gardner: Waveform pattern recognition capabilities are coming. Computer monitoring systems will be able to provide insights into problems and help you solve them. Set-up procedures will be able to tell you how to set up for a procedure. Checklists like those that pilots routinely use will be provided for bedside computer monitoring equipment.

Dr Luce: Do you think that will facilitate our understanding of how all this works or merely allow us to avoid facing the issue?

Dr Gardner: Physicians really have to take the leadership role in what monitoring equipment should provide. Clinical people should tell manufacturers, "We want these things" and "We don't want those things." Manufacturers are currently providing what 'sells,' and they get their input from their sales force. The engineers designing the equipment may not have been in an ICU for 5 years. Physicians really need to have some input into what is being designed. There needs to be interaction between clinical staff and manufacturers. At the present time, manufacturers are decoupled from the clinical world.

Dr Schlobohm: I would just point out that the system showed on the last slide is at least 25 years old. We didn't have the appropriate peripheral information that would make it go at that time, and perhaps we don't now. I understand that is what your intention might have been. I don't know whether that assuages John's fears, but if we let the industry push us, then he has a justifiable fear.

Dr Ziment: Two things bother me. It reminds me of the old days when Bird and Bennett were fighting with each other to see who could get more dials and knobs on their machines, seeming to take us away from the basic purpose of the machines' being there. And similarly today, the manufacturers of monitoring equipment find it very easy to put in all sorts of computerized games, which are similar to the 'video' games that we have. If you get one of the manufacturers to show you his machine, it will probably take an hour or more just to go very quickly over everything that the machine can do. So, to train house staff and nurses you have an intensive training course to make them into machine specialists, and after they have that ability, they are going to spend a lot of their time playing around with the machine. I fear that we are seducing people with the machines and the things that they can do, rather than adding to our ability with some of these devices to do what we are trying to do—that is, to prevent the patient from getting into trouble, and reacting to the information in a sensible way. One of the real games that I see, and I wonder how you feel about it—perhaps I am looking at it in the wrong way—is this trend recording, where you can recall every event that happened over the last 8 or 24 hours, when by and large it really doesn't matter because you are looking at the patient now and must make decisions on what is going on now.

Dr Gardner: You are getting at the heart of the issue of what we should record, and how often we should record it. I agree with Dr Ziment that trending information—say PA pressure, taken without regard to the patient's position in relationship to the pressure transducer, or without considering ventilatory status—is not a good practice. However, the medical community has not said what it wants. The manufacturers are in the back room designing 'whistles and bells' and 'sexy' things to make their product attractive to you.

We went around this room yesterday and there was disagreement on just about everything we discussed. Manufacturers can't profitably make monitoring devices for each one of us individually. Therefore, they make their monitors do everything for everybody, which makes them much more complex and expensive.

As for video games, I think they have their place in patient monitors if they can teach people how to use the equipment and at the same time make it fun. The other day I happened to ride on a new Boeing 757 for the first time. There were only 20 people on board so I went up to the cabin before takeoff and peeked at the pilot's console. There I saw some of the most beautiful video displays. I asked, "Wow, can we play Pac Man or some other Star Wars game?" The pilots proudly said, "Oh yeah, we've got video games" and then they proceeded to show me an enjoyable and sophisticated vector-interceptor video game. So video games are not all bad.

Dr Dantzker: I am concerned that everyone alway wants the most computerized system available. When we come back 2 years later, no one is using it because it doesn't reduce work. Nurses will not use a system that does not relieve them of some burden, and many of these systems, in fact, increase the amount of work that they have to do. It is disconcerting that there is no regulation of the kinds of equipment that wind up in ICUs, especially because a share of the increased medical cost is tied up in this. In addition, while people invest a lot of money in equipment, they rarely invest in somebody to maintain it. What do you feel about having somebody in a hospital who is engineering oriented to be sure that the equipment is working up to its specifications?

Dr Gardner: Let me respond to your questions in a couple of ways. I hope the federal government does not come and regulate things at the level you suggest. In my opinion, that is not the best way to solve the problem. Instead, I would like to see a professional group similar to that assembled here say, "These are the things that are needed and this is what we want." Let's come up with some monitoring device standards that manufacturers can shoot for. Understand that if we do this, we don't want to block the guy working out there in his garage or in a hospital or a laboratory who says he can attach a device to my ear and measure blood flow to the brain or measure tidal volume. Let's not block innovation, but at the same time let us not have innovation just for innovation's sake.

As far as trending goes, I think that one of the biggest costs we are going to have with equipment is not just the capital costs and the costs of dispos-

ables, but we must invest in training the people to use the equipment. If we don't want sophisticated equipment, then professional groups like this should make recommendations on simplification, based on clinically based experimental data.

Dr Grossman: The work you have been doing with the standardization for spirometry and blood gas analysis may be appropriate in this regard. In principle, I oppose the federal regulation of laboratories; but it seems appropriate, given the cost of critical care monitoring, for the National Institutes of Health to convene a consensus conference or task force. The modest cost would be very small compared to the money saved on a national basis. I believe manufacturers would listen and generally comply.

Dr Gardner: Having been through several standards development procedures, my experience tells me that the type of meeting we are having here is not optimum for developing a consensus standard. To most efficiently develop standards, a different meeting format is required. First, a small group should isolate the major issues and, based on data in the literature, find out where there is a consensus and where there is controversy. Then a proposed standard outlining each issue should be prepared, with appropriate rationale for the proposed standard. Then the document should be circulated to a group of experts similar to those assembled here. After each expert has had a chance to respond to the proposed standard, the most important and controversial issues can be identified. The next step involves getting the experts together in a conference room to try to resolve the controversial issues or outline experiments that might resolve the controversial issues. My experience suggests that indeed manufacturers listen very carefully to professional community standards. Dr Clemmer is going to talk about computer applications in the ICU later. I agree that to write something down on a piece of paper and then go over and enter it into the computer is not efficient or wise. On the other hand, our experience with respiratory therapists entering their notes directly into the computer provides an efficient and effective tool. As a result of the clinical data's being directly entered into the computer, the procedure is documented, the patient is billed, management data are a byproduct, patient acuteness is modified, and data are immediately available to the entire health care team. Let's face it, the cost of computers is coming down dramatically and they are going to be used in the health care field. We had better be ready for them.

**Reprinted from RESPIRATORY CARE,
Vol. 30, No. 7, July 1985.**