CHAPTER V

TECHNOLOGY DEVELOPMENT, STANDARDIZATION, AND EVALUATION IN PULMONARY MEDICINE

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Pulmonary Technology Task Force Report

- State of Technology
- Needs and Recommendations

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TECHNOLOGY DEVELOPMENT, STANDARDIZATION, AND EVALUATION IN PULMONARY MEDICINE

OVERVIEW

Technology is playing an ever increasing role in the practice of medicine. This is especially true in neurological, cardiovascular, and pulmonary function assessment. New technologies such as imaging techniques with computed tomography, sophisticated measurements of hemodynamic and respiratory function, along with a better understanding of the pathophysiology of pulmonary disease, provide a firmer scientific base on which to make clinical judgments. With technological developments, there is additional scientific knowledge gained which can aid in diagnosis, prognosis, and treatment of patients. The application of computers to assist in the correlation and utilization of this data is attractive for 2 reasons; first, the wealth of medical knowledge is rapidly expanding, making it difficult to consider all of the complexities and factors involved in patient treatment decisions, and second, the state-of-the-art of computer technology is advancing rapidly, providing increased performance at greatly reduced cost. The trends in both the discovery of new medical knowledge and the increase in performance-to-price ratio of computer technology are likely to continue over the next several decades.

The report of this task group covers a wide variety of subject material from recommendations on instrumentation to an expression of the need for development of general methods for evaluation of technology. Overall, the task group determined that 1) a great need exists for development of management methodology for neonates and children; 2) computers could be better utilized to acquire, process, store, and utilize data for medical decision making; 3) the Intensive Care Unit and Anesthesiology locations could be advanced by development of better instrumentation and alarm techniques; 4) computers could significantly aid in the evaluation of medical images; and 5) the development of reasonable "standards" could be a real aid in the development of technology. In addition, it was felt that a cooperative relationship should be established between government, industry, and clinical users so that innovative technology could be developed and applied promptly. Finally, the task group suggests that not only must new technology be evaluated, but the methodology for performing the evaluation also needs to be further developed.

TECHNOLOGY NEEDS OF FETAL, NEONATAL, AND PEDIATRIC AGE GROUPS

INTRODUCTION

There are three major considerations that make pulmonary data acquisition special in pediatric, and particularly neonatal patients. These are:

1. Special biological considerations: For example, the very flexible chest wall may allow phase differences which make ventilation inefficient, especially with high airway resistance or with decreased muscle tone (e.g., REM sleep results in a very flexible chest).

2. Technical difficulties related to patient size: For example, the difficulties and hazards of maintaining arterial catheters in infants makes other methods of measuring end tidal CO_2 desirable. Many methodologies common to the management of respiratory failure in adults cannot be used to treat critically ill neonates and infants.

3. Problems caused by inability to acquire patient cooperation: The single most useful pulmonary function test in adult pulmonary medicine is the forced expiratory spirogram. From this, ventilatory parameters, such as maximal midexpiratory flow and timed expiratory volumes, can be derived. Unfortunately, few small children and no infants can perform the necessary maneuvers. A substitute procedure, which is better than a crying vital capacity, is needed. Outlined below are some of the more important, and unfulfilled specific technical needs in pediatric pulmonology.

STATE OF KNOWLEDGE AND TECHNOLOGY

I
Minimally Invasive Monitoring to Determine Adequacy of Gas Exchange

Transcutaneous PO_2 and PCO_2 Measurements. The value of this technique in assessment of the well perfused neonate is now established. However, the limits of its application, particularly in regard to age and cardiovascular status, are not fully delineated despite the large number of instruments now commercially available. It appears that more research on the basic physiology of gas delivery to, and transport through, the skin is needed. In addition, this technology still needs more research and development in the area of instrument design. Problems of size, stability, and speed of response need to be resolved.

End Tidal CO_2 Monitoring. Although many clinicians and investigators have attempted to use this monitoring modality, new instrumentation with very small volume sample cells and recent theoretical analyses of catheter sampling systems have put this technology on a more firm foundation for use in infants. Empirical studies designed to explore limitations of use are now probably worthwhile.

Ear Oximetry. This method has a great advantage over the transcutaneous PO_2 electrode because of its very rapid response time. It may also have advantages in low blood flow states. A practical instrument for use on neonates is definitely needed.

Mixed Venous Blood Oxygen Sensor. There is a need for a mixed venous blood oxygen sensor to bring pediatric monitoring up to the current capability of adult monitoring.

II
Measurement of Tidal Volume

The measurement of tidal volume in infants on mechanical ventilators or during natural breathing is difficult. There are two methods currently used: 1) measurement of changes in chest dimensions, and 2) direct meas-

urement of expired gas flow or volume. The former method, which uses magnetometers, suffers from the fact that, at various times, the same infant may move different parts of its chest or diaphragm to achieve ventilation. For example, during REM sleep, the upper chest often decreases in volume during inspiration. This problem is compounded in disease where the time constants for gas flow may vary widely over the chest. A new device, consisting of an easily distensible, close fitting jacket, changes inductance with chest expansion and may sample over a wide enough area of the thorax to be practical, but it has not been fully tested. It is possible that such a device might be improved if fitted with multiple sensors and if appropriate data processing were used.

Measuring flow by using a face mask with a screen pneumotachometer has the disadvantage that it has several milliliters of dead space, and is very sensitive to the condensation of water. Most other flow measurement devices are either larger or have insufficient dynamic range. The recent development of an ultrasonic flowmeter may have application in infants. A method which is of some use is to introduce a constant gas flow under the mask to sweep out the dead space. This bias flow is then subtracted electronically. A technology which is totally noninvasive and which is potentially accurate in infants is the "barometric method" (1-3). However, the limits of its applicability require further evaluation. An easy-to-use, easy-to-calibrate, noninvasive method for measuring flow or volume in infants is still lacking.

There is greater hope for development of a device for use when an endotracheal tube is already in place. However, there are two remaining problems. First, there is the problem of estimating the size of the leak around the endotracheal tube as cuffed tubes are not generally used in infants. Second, there is the problem of "compressible volume." During inspiration, with a mechanical ventilator, gas is compressed in the tubing. The compliance of this tubing varies from 0.5 to 5.0 ml/cm H_2O in practical ventilators. In most, if not all, commercially available ventilators, the gas exiting via the exhalation valve contains true expired gas along with the gas compressed within the system during inspiration. Thus, the expired gas is diluted by a large amount of gas of inspiratory composition. This impacts on several areas of interest aside from measurement of tidal volume including: 1) disconnect alarms for infant ventilators and anesthesia machines, and 2) high frequency ventilation in infants. Modeling studies have shown that the volume loss due to compression in the tubing occurs primarily during the start-of-inspiration, and thus, this phenomenon is most prominent when inspiratory times are very short and would be of extraordinary importance during high frequency ventilation.

III
Measurement of Fatigue of Respiratory Muscles

There has been a great deal of recent work using the power spectrum of the diaphragmatic electromyogram (EMG) as an indicator of respiratory muscle fatigue. This is important as muscle fatigue is often the limiting factor precipitating frank ventilatory insufficiency and failure. The use of this method in small children and infants has many unsolved problems, including optimum electrode placement, noise rejection, and data processing. Moreover, there is insufficient understanding of its physiologic basis.

IV
Measurement of Fetal Breathing

Several groups of investigators have found that the absence of fetal breathing is a good indicator of fetal distress. This is of considerable importance from the standpoint of offering a reliable clinical diagnostic tool, and also because it may be fetal breathing which, by physically affecting venous return, causes short-term heart rate variability. The latter is currently used in fetal monitoring. The real-time ultrasonic B-scan is used to visualize chest wall motion. Work is needed to develop practical instrumentation and to determine the effect of fetal breathing on blood flow.

V
Measurement of Pulmonary Blood Flow and Shunts

The potential clinical benefit of measuring pulmonary blood flow in infants makes study of new and better techniques necessary.

VI
Predictors for SIDS

Many of the proposed predictors for SIDS are really attributes of populations postulated to be at increased risk for SIDS. These include siblings of infants who have died of SIDS and "near miss" infants, who have had a severe episode of apnea. Such infants have been shown to have abnormal heart rates, ventilation, and sleep patterns which might be useful as predictors for SIDS.

VII
Fiberoptic Devices

Fiberoptic devices of adequate resolution and of sufficiently small dimensions are commercially available for visualization of the infant's upper and lower airways. The problem is that manufacturers have been unable to combine the small size and necessary resolution with an adequate channel for suctioning so that in practical situations the view becomes obscured by airway secretions.

VIII
Alarm Systems Development for Infant Ventilators and Anesthesia Machines

Expired CO_2 monitoring is particularly difficult in infants. There are two types of CO_2 monitors. The first has a "flow through" cell in line with the endotracheal tube. This method has several advantages; however, its large volume precludes its use with small infants because of dead space considerations. The second method samples gas constantly from the airway and the measurement is done in a remote transducer. The problem with the second method is that if a sample flow rate is low enough not to deplete the expired gas, the response time may be too slow to permit breath by breath analysis. Modeling studies have shown that this is a significant problem with CO_2 measurements in small infants. Thus often, the measured CO_2 is not equal to the expired CO_2.

For the foreseeable future, the development of disconnect alarms for infants, especially if one wishes in addition, an assessment of the adequacy of ventilation, is so complex that a combination of methods is needed. Measurements of pressure, flow, and gas composition may all be needed, along with innovative data processing and display. The anesthesia circuit itself should be reevaluated as it complicates making all of these measurements. The solution may lie not in the development of a single instrument, but in the redesign of anesthesia machines.

NEEDS AND RECOMMENDATIONS

I

The development of minimally invasive measurement technologies, particularly for measurement of tidal volume and ventilatory patterns, should be continued.

II

Develop reliable reference methods for this group of patients against which less invasive, and more complex devices or technologies can be compared.

III

The development of better alarm systems for ventilators and anesthesia machines should be encouraged.

IV

The development of measuring systems, small in size with very low compliance to allow quantitative study of tidal volume and expired gas composition in infants during mechanical ventilation and anesthesia should be fostered.

V

Reliable methods for the measurement of pulmonary blood flow and pulmonary shunting should be developed.

VI

Further efforts should be made to improve fiberoptic instrumentation for use in infants.

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COMPUTER APPLICATIONS IN PULMONARY MEDICINE

INTRODUCTION

Computers can assist in improving human productivity. At the same time, the capability of computers in terms of computational speed, memory costs, and general overall costs has decreased rapidly as the technology has developed. Integrated circuit technology, especially with the recent innovations in large-scale integration which allows for the development of low-cost microprocessors with their associated peripheral equipment, has had a dramatic effect on the entire computing field. It is now possible to place in a bedside monitoring module a microprocessor, which facilitates computations and noise rejection, which several years ago would have required a large computer to implement. Computers are becoming more and more important in the following areas of pulmonary medicine.

Data Acquisition. By allowing the computer to acquire data from nonlinear devices, check data for quality, develop waveform recognition techniques, and sharing of data between multiple processors, data can be better validated and integrated.

Data Integration. Utilization of computers for data integration to solve the current problem of correlating data from multiple diverse sources such as laboratories, ICU's, etc., will permit more prompt and effective treatment of patients.

Data Communications. Utilizing computers to communicate data will help solve the problems of slow, unreliable communication which currently exist in hospitals.

One of the major problems remaining to be solved with use of computers in clinical medicine is the man/machine interface. A computer interface, which will allow for simple interaction with minimal training, has not yet been optimized for use by health care professionals. Computer terminals and computer software have been simplified to make them "user friendly" which is a partial solution to the problem. However, the problem still remains a major challenge for computer scientists applying computers to medicine. In the next 5 to 10 years, it is anticipated that this problem will be solved and data capture for clinical, as well as accounting purposes will provide entire clinical and administrative patient data bases. Once the data are entered into a computer, it serves not only the medical-legal requirements of the medical record, but it can also be used for computerized clinical decision-making and provide data for hospital administrative functions such as billing, productivity analysis, etc.

There is a need to establish computer data bases to answer specific questions in pulmonary medicine. Limited use of these data bases to date has provided valuable insight into types of patient populations. Epidemiological studies, for example, require large data bases which need to be standardized so that data can be shared between investigators looking for effects of environmental factors. Data bases on hazardous occupational locations would be very valuable to determine the effects of various environmental health hazards. Thus, the establishment

of 1) standard techniques, 2) standard equipment (specification), 3) standard data collection methods, and 4) softward documentation, should be given high priority.

STATE OF KNOWLEDGE AND TECHNOLOGY

I
Intensive Care Medicine

See the next section on Technology Needs of Intensive Care and Anesthesiology.

II
Data Base Development

The paralyzing effect of excessive amounts of raw data, particularly in the ICU, is becoming increasingly apparent, while the potential for use of automation to assist in compressing and evaluating data is great. This potential can only be met if available data are used to develop acceptable algorithms to interpret data, and suggest treatments.

The breadth of data which can be usefully shared for developing such decision making algorithms is unlimited. Both long-range outcomes and short-term ICU care outcomes are needed. For example, in patients with carcinoma of the lung, pooled data on the criteria for resectability--the useful predictors of cardiopulmonary function and their effect on operative and late mortality--would improve the treatment of this disease. Criteria for control of ventilator therapy in ICU patients of various primary disease categories, i.e., post-cardiac surgery, post-pulmonary resection, etc., would reduce complications, reduce cost, and shorten time spent in the ICU.

To evaluate decision making criteria, outcome goals and data bases must be defined. Data bases could then be used to test algorithms during their development. Finally, multi-institutional prospective controlled trials could be instituted to evaluate the usefulness of algorithms using a common data base to control the decision logic and assess how well outcome criteria have been met.

In the near future, data base sharing and decision algorithm sharing will depend on direct cooperation between medical scientists. For more general data base and decision making algorithm sharing, data base content and outcome criteria will need standardization. Until now, there has been no such standardization. It may be feasible to develop limited common data base contents, and outcome criteria which would allow useful data sharing. Until such an agreement is reached, sharing will be of limited value. Without such sharing, progress toward development of acceptable interpretive and decision algorithms will be slow. The utility of modern technology using the capabilities of automation will not be realized until such algorithms have been agreed upon, tested, and made generally available.

In addition to data base development for ICU use, there is a great need to develop data bases for other areas of the practice of pulmonary medicine. These include:

1. The establishment of reference or "normal" values for pulmonary function tests which can be used on a national basis. This will require standardization of measurement techniques and generation of reference values to take into consideration not only the size and age of an individual but also race.

2. Data bases which will aid in the development of a more rational determination of the severity of pulmonary disease would be useful. For example, the recent work of Epler and associates on the determination of severity of impairment from lung disease forms a quantitative basis for estimation of disability. Data should be collected which will encourage and enhance the ability to quantitate and predict the time course of degenerative lung disease.

3. Data bases of the natural course of pulmonary function parameters in a longitudinal study would aid in understanding the pathophysiology of aging of the normal lung and, perhaps, provide insight into the effect of environmental factors.

4. Data bases should be developed and shared which will help describe the effects of environmental factors on pulmonary function.

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III
Computerized Medical Decision Making

There is need to develop quantitative methods for medical decision making, so that computers and computational equipment can be better integrated with clinical medicine. Evaluation and management of a patient in left ventricular failure is an example of a situation requiring integration of data from many sources, including the intensive care unit (physiologic hemodynamic monitoring), the blood gas laboratory, the clinical laboratory, the x-ray department, etc. To make the most logical and rational decision in the treatment of a patient, all of this data, along with history and physical findings, must be integrated. To get computers to assist in this kind of decision process, there is a necessity to establish quantitative methods and develop algorithms for patient treatment. The development of medical decision logic is currently poorly organized and represents one of the greatest opportunities and challenges for the years to come in the application of computer technology to medicine. It is surprising how nonquantitative the practice of medicine is. There needs to be developed a mechanism for exchanging information on quantitative diagnosis/interpretive methods which will facilitate establishment of computer-derived alerting and treatment protocols.

For example, patient care in the Surgical ICU is becoming increasingly complex, both because more difficult operative procedures are being attempted, and because the therapeutic armamentarium is enlarging.

Therefore, the volume and complexity of data to be interpreted have increased. The new complexity is further aggravated by a shortage of physicians and nurses trained in critical care. To date, computer systems have done little to alleviate these problems; in fact, at times, they have compounded them by facilitating the collection of increasing amounts of data for which medical and nursing teams are ill prepared to use.

On the positive side, however, computer systems have the potential to greatly enhance the safety of critical care. The focus of ICU computer systems must shift beyond data collection and crisis alarms. Limited automated data interpretations have been attempted, but they have typically required users to enter information before any interpretations were made. Thus, instead of prompting action, they have been passive responders.

ICU computers should automatically acquire data for ICU personnel, i.e., laboratory data from laboratory information systems, vital signs and other pertinent hemodynamic data from bedside instruments, and pulmonary function data from tests and bedside monitors. Not all data can be directly acquired; fluids and drugs may require entry by the nurse.

With such data, a national cooperative effort should start to develop computer consultation and therapeutic control logic to automatically provide appropriate advice when data indicate a significant change in patient status. While the ultimate goal might be to provide closed loop therapy, initially this step is not essential. Useful open loop logic can be converted to closed loop after appropriate clinical trials, if controllable output devices are available.

Systems need to be developed based on decision logic which permits weighted evaluation of diverse interrelated information. Areas for the development of such logic include: 1) optimization of available oxygen; 2) warning of cardiac tamponade, pneumothorax, and ARDS; 3) adjustment of preload, afterload, and inotropic therapy; 4) optimization of CPAP and PEEP levels; 5) management of fluid therapy; and 6) assistance in acid-base and electrolyte management. Without some effective prompting, accidents of oversight or misinterpretation will continue. If the goals are defined, an automated watchdog of ever increasing capability should be able to assist the ICU staff in patient care by prompting timely and appropriate action.

Computerized medical decision making can also be of assistance to a general hospital population through simple, but important, decisions which can adequately be made by the computer such as interpretation of blood gas results, interpretation of screening pulmonary function tests, the evaluation of the effects of various modes of respiratory therapy, and generation of differential diagnosis lists.

To allow modifications to medical decision algorithms and to transfer this technology between laboratories, detailed software documentation is essential. Support for development of medical decision algorithms should include support for software documentation in a manner which is easily understood by other computer specialists.

IV
Use of Microcomputers in Pulmonary Medicine

A recent (October 17-19, 1979) NIH consensus development conference on "The use of microprocessor-based 'Intelligent' machines in patient care" was held to explore the opportunities resulting from the development of microcomputer (microcircuit) technology which allows tens of thousands of transistors and related electronic components to be fit on a one-fourth inch square silicon chip. The following is a brief summary of this conference.

1. The general effect of this technology on society will go far beyond its application to medicine alone.

2. Development and use of such devices could be slow and expensive because of the cost of software development and regulatory compliance.

3. Microcomputers could transfer some of the workload of physicians in their offices to allied health personnel. Pulmonary function testing is an example.

4. Use of the computer for the auditing of simple routine decisions, assisting in selected complex decisions, increasing access to medical data, and more rapidly communicating data were all felt to be major contributions.

5. Microcomputers will find increasing use in diagnostic and therapeutic instruments.

6. The need for standards development, quicker transfer of the technology into practice, and the concern about regulatory compliance were emphasized.

The terms "computer" and "microprocessor" are sometimes very confusing. From a programming standpoint, they are identical. That is, a person writing a program in Fortran, for instance, would proceed about the same whether the execution takes place on one commercial microprocessor or another. The differences are in the hardware. Microprocessors are usually smaller and slower. They are also considerably cheaper which lends them well to instruments that provide data which require calculation to yield the desired results. Although a typical processor chip may be purchased for $10, it may require $50,000 worth of program development, equipment, and man-years of time to write and debug the program. On a typical microprocessor system that might have 16K of memory, 8 parallel input/output ports, and all the necessary support chips, the hardware design time might be on the order of 1 week. The program to analyze an FEV curve with this system will take 1 man-year to develop. Although microprocessors have advanced to a point almost beyond belief in small size and low cost, little has been done to accelerate the software development process over the last decade.

V
People and Technologic Advances

Technologic developments will not likely replace people in patient care. The spectre of an unattended patient controlled and monitored by machines in closed loop array is not attractive. Technologic advances will, however, continue to allow people caring for patients to operate at a level which would not be attainable if they were unassisted by machines. One has only to consider the impact of blood gas analysis plus balloon tipped, flow directed pulmonary artery catheters upon the management of respiratory failure (failure of cellular respiration, tissue hypoxia). Whereas a short time ago, we were limited to nonquantitative clinical assessments, and subsequently could use arterial oxygenation (PaO_2) only as a guide, we now can assess overall function of heart, lungs, and blood and the efficiency of heart and lungs relative to metabolic demand - (mixed venous PO_2, arteriovenous O_2 content difference, and right to left shunt fraction). The patient care work load has not been reduced, but rather increased, per patient, but the medical deliberations occur on a much different and more sophisticated level. Questions now routinely addressed in some centers could not even be formulated 25 years ago. Future technical advances will likely provide better assessments of the state of regional tissue (cellular) oxygenation. Admittedly, the ultimate impact of these new technologies upon mortality and its impact upon the medical and general communities is not yet known.

NEEDS AND RECOMMENDATIONS

I

Standard techniques for data collection and equipment which meet minimum standards need to be established so that data can be exchanged between institutions and centers.

II

Data bases should be established for:

- Pulmonary function testing to allow validation and testing of various instruments and software algorithms (for example a library of representative FVC curves).
- Reference (normal) values for pulmonary function tests.
- Assessing new techniques for quantitating pulmonary dysfunction and disability.
- Following the "natural" course of pulmonary function in normal subjects and those exposed to adverse environmental conditions.

- Monitoring and treating the critically ill patient so that treatment algorithms could be validated and implemented in computer assisted form.

- Development and testing of better diagnostic and treatment protocols for patients with pulmonary disease.

TECHNOLOGY NEEDS OF INTENSIVE CARE AND ANESTHESIOLOGY

INTRODUCTION

The care of patients undergoing surgery and immediately following in the intensive care unit is one of the most demanding areas of medicine. Because there can be multiple organ failures and patients are so unstable, minute to minute measurements are often required which can quickly result in an overload of information for physicians and, in some cases, result in less than optimum care. Therefore, the ICU/surgical suite is an area where measurement, support, and computer technology may have the largest impact.

The complexity of the clinical care of ICU patients and the resulting intense pressure on personnel have led many institutions to acquire ICU computer systems in attempts to improve patient care and relieve some of the pressure on attending personnel. For these systems to serve their purpose requires three parallel developments: 1) the development of new sensors; 2) the development of new testing procedures suitable for the ICU; and 3) the interpretation of these procedures to provide diagnostic and therapeutic information. As more and more sophisticated technology is introduced into the ICU setting, the National Institutes of Health (NIH) clearly must assume an important role in evaluating that technology before its use becomes widespread. A fundamental problem for all of the automated testing techniques is that their development, and the advocacy of their use, continues without complete testing, let alone proof of their role in improving patient care.

STATE OF KNOWLEDGE AND TECHNOLOGY

I
Ventilation During Clinical Anesthesia

The automatic measuring or monitoring of ventilation and assurance of its adequacy is a very difficult and unsolved problem in anesthesiology. However, since a large proportion of anesthetic mishaps in healthy patients (American Society of Anesthesiologists (ASA) physical status 1) is due to airway and/or ventilation problems, this is an important area of concern. The concern here is with monitoring the anesthesia machine circuit, and which does not require devices attached to the patient (e.g., skin PO_2 electrodes). The most practical automatic monitors rely on sensing pressure within the tubing of the anesthesia machine. The majority merely sound an alarm if a period of time elapses without the pressure exceeding a user selected threshold. A few have additional alarms triggered by: 1) subatmospheric pressure; 2) pressure exceeding a preset threshold; or 3) absence of pressure oscillations, or pressure continuously above a preset threshold.

Although these latter criteria improve the safety, the large variety of anesthetic circuits, the many different clinical situations in which they are used, and the fact that all such methods detect pressure rather than ventilation itself, point to the need for additional instrumentation, as illustrated by the following:

1. The monitor should function during spontaneous as well as during mechanical ventilation. During spontaneous ventilation, there is little pressure fluctuation in the anesthetic circuit. Flow and/or expired gas concentration (CO_2) monitoring is probably needed.

2. The monitor should sound an alarm if the artificial airway (e.g., the endotracheal tube) is not positioned correctly. With placement in the esophagus, pressures and flows may appear reasonably normal, and sophisticated processing of such data and/or gas composition measurement may be needed.

3. The monitor should function in the presence of severe lung disease. In such situations, pressures, flows, and expired gas concentrations may be quite different from normal, despite "optimal" ventilation.

4. The monitor should function with a variety of anesthetic circuits or new anesthetic circuits should be devised which facilitate effective monitoring. If the latter course is chosen, the other requirements of anesthetic circuits should be considered. The wide variety of anesthetic circuits include:

   - Nonrebreathing systems, and systems in which there is CO_2 absorption with total or partial rebreathing of expired gases.
   - Systems with a wide variety of valves at many different positions as well as valveless systems.
   - In some systems there is continuous flow past the endotracheal tube connection; in others, there is only flow on the inspiratory side during inspiration and on the expiratory side during expiration.

5. Special considerations apply to small infants. For example, the tidal volume is so small that even in the absence of any ventilation due to obstruction of the airway, circuit flows and pressures during mechanical ventilation may appear normal. The compliance of the anesthesia circuit may be an order of magnitude greater than that of the infant. Monitoring expired gas concentration in the presence of very small tidal volumes also has severe limitations.

Resolution of these problems and the development of new instrumentation will require work along several lines. These include:

- Determination of the various ways in which ventilation can fail during anesthesia. Some information can be obtained from empirical clinical surveys, but difficulties in obtaining accurate reporting will make necessary the use of failure analysis and modeling.
- Determination of the ways various parameters (e.g., pressures) change during failures.

- Development of instrumentation, including sensors for flow and gas concentration, which are practical for routine use during clinical anesthesia, along with development and testing of appropriate algorithms and automatic computational procedures.

- System integration.

II
Alarms

Most ICU's utilize devices that fall into various categories, including ECG rhythm or arterial waveform monitoring (usually heart rate only, but occasionally rhythm information is also displayed), ventilatory support, and blood pressure monitoring. Devices currently available have a multiplicity of alarms with no standardization with respect to sound pitch, tonal quality, duration, or intensity. A standard recognizable audio code for specific categories of failure (blood pressure, rhythm, respirator disconnection, low tidal volume, etc.) is highly desirable. Synthesized voice alarms should also be investigated.

Usefulness of End-Tidal CO_2 as an Alarm

End-tidal CO_2 is being advocated as a generally useful method of monitoring patients in the ICU and operating room. Current evidence suggests that measurement of end-tidal CO_2 in the ICU has only limited usefulness. However, it may be an ideal parameter to monitor in the operating room to prevent anesthetic accidents. To date, most monitoring of cardiorespiratory function has focused on seriously to critically ill patients, i.e., those whose potential for recovery is limited (8,13,15). The young patient with a normal cardiopulmonary system requiring elective or simple emergent operative procedures has been neglected. As a result, fatal anesthetic accidents occur due to failure to provide adequate ventilation. A system is needed that assures, either directly or indirectly, that adequate ventilation is being provided at all times to support aerobic metabolism.

It has been suggested that a single mass spectrometer can be used to monitor a large number of patients simultaneously by "time sharing" the device. Monitoring of airway concentrations of CO_2 for cyclic variation of PCO_2, while at the same time monitoring inspired oxygen (F_IO_2), could assist in assuring adequate patient ventilation. The operating room environment lends itself to end-tidal CO_2 monitoring since all patients have some type of airway attachment.[2] The anesthetic agents now in use also make most patients entirely dependent on ventilatory support.

To function safely as monitors of ventilation and to prevent apnea of more than 60 seconds, the expired breath must be measured for a full respiratory cycle every 60 seconds. With conventional mass spectrometer time sharing systems, it is not possible to safely monitor more than 4 patients at one time. However, recent modifications to the sampling systems may allow gas "storage" in the tubing to reduce dwell time and increase sampling rates (14).

These are minimum requirements for the use of end-tidal CO_2 to monitor the presence of active ventilation. Monitoring systems which sound an alarm for lack of CO_2 excretion or safe inspired O_2 levels should be simple and easy to maintain and operate. If mass spectrometers are used, anesthetic gases as well as O_2 and CO_2 could be monitored. However, the primary goal must be to monitor all patients for the presence of cyclic changes in expired CO_2, and not to develop a complex, expensive system that cannot be used universally.

The national investment to develop facile, effective instruments for this type of patient protection is of critical importance. Despite the clear need for a form of monitoring to assure that anesthetized patients are being adequately ventilated, few such systems are in use in the United States - clear evidence that technologic development is needed.

The installation in the ICU of mass spectrometer systems to monitor end-tidal CO_2 is occurring at an accelerating rate. Yet, there have been few studies of the reliability of the equipment, or the usefulness of the measurements in this environment. Spending large amounts of money to purchase such systems is not justified until their efficacy has been demonstrated. As noted above, conventional mass spectrometer systems cannot be used to monitor ventilation and prevent apnea for more than 4 patients, since the time before return to each patient is too long for safe monitoring. Most systems installed in ICU's attempt to serve more than 4 patients, or are used only on selected patients in the ICU. They are not used as apnea monitors.

In most ICU systems, measurement of end-tidal CO_2 ($PetCO_2$) is used to predict $PaCO_2$ by averaging the expired CO_2 peak value from consecutive expired breaths. The accuracy of the estimation depends on: 1) a consistent breathing pattern with breaths of equal volume and uniform rate; and 2) no significant $(A-a)CO_2$ gradient. If the $(A-a)CO_2$ gradient is measured, then $PetCO_2$ could be used as a predictor of $PaCO_2$ if the $(A-a)CO_2$ remained constant.

With unsteady state respiration, the measurement of peak end-tidal CO_2 and averaging the measured values are not predictive of $PaCO_2$. With increasing use of intermittent mandatory ventilation (IMV), with an unsteady ventilatory rate and tidal volume, $PetCO_2$ is not likely to be useful. In addition, respiratory failure is characterized by a changing $(A-a)CO_2$ gradient, and no studies are yet available to show how one can interpret $PetCO_2$ under these conditions. Before further expenditures are made on this type of instrument, definitive studies of the usefulness of the equipment must be made. For example, measurements to weight the individual $PetCO_2$ values before averaging of end-tidal CO_2 may be more useful if combined with measurements of tidal volume.

III

Measurement of Cardiac Output

Acute respiratory insufficiency can result in pulmonary edema with a resulting intrapulmonary shunt. The survival of these patients is determined by their ability to deliver oxygen to peripheral tissues.

The amount of oxygen delivered to the tissues is the product of cardiac output and arterial oxygen content. Decreases in cardiac output directly lower oxygen delivery and indirectly lower pulmonary capillary O_2 content (CaO_2). With a significant intrapulmonary shunt, the level of CaO_2 is critically dependent on mixed venous oxygen content ($C\bar{v}O_2$). When cardiac output falls, oxygen extraction from blood increases and $C\bar{v}O_2$ falls, and with no change in shunt fraction, CaO_2 falls. $C(a-\bar{v})O_2$ is used as a measure of the ratio of cardiac output to metabolic rate. However, direct measurement of cardiac output is of critical importance in assessing the efficacy of therapeutic manipulations in patients with Adult Respiratory Distress Syndrome (ARDS). The importance of such measurements has been clearly documented in adults. Without technology for measurement of cardiac output in neonates and infants, this same knowledge cannot be used. Since placing catheters in the pulmonary arteries of neonates has resulted in thrombosis and other serious complications, the adult technology (cardiac output by thermal dilution) is not usable. For this reason, infants must be treated without knowledge of cardiac output. Development of a method of measuring cardiac output in neonates and small children could markedly enhance treatment of respiratory insufficiency in the neonatal period.

There are special problems with measuring cardiac output which might also make it less important in children than adults: 1) the lower incidence of myocardial disease and heart failure (in the absence of congenital heart defects), and 2) the difficulty of interpreting the output in the presence of shunts.

IV
Oxygen Toxicity

The primary and most commonly used form of treatment for patients with acute and chronic respiratory disease is administration of increased concentrations of oxygen. The dependence of life on oxygen is paradoxical since life is also threatened by oxygen's toxicity (1,3). This paradox has led to great interest in oxygen toxicity, and present studies indicate that the concentration of oxygen which can be toxic will not be absolutely definable.

Under certain circumstances, even a PO_2 of 150 mm Hg can be injurious. This problem is most apparent in studies of superoxides (O_2^-). Superoxides are produced in large quantities by granulocytes and provide one of the important factors in phagocytosis (9). At the same time, they cause damage to biological structures such as nucleic acids, lipids, and proteins. In addition to the role of superoxides, the SH enzymes in cells are extremely sensitive to oxygen. Superoxides can be lethal to cells if the concentration is too high to be controlled by intracellular enzymes, or if they are generated in the extracellular space. Superoxide dismutase is a major enzyme providing protection from superoxides, and under some circumstances, exposure to high concentrations of oxygen can increase the concentration of this enzyme and, thereby, increase the concentration of oxygen that can be tolerated. For example, rats exposed to F_IO_2 of 0.85 adapt so that F_IO_2 of 1.0 is tolerated, while an F_IO_2 of 1.0 is uniformly fatal to unconditioned rats. The adapted rats have an increased level of superoxide dismutase in their lungs.

Oxygen toxicity, as are all toxicities, is relative and varies between species and individuals within species as well as in an individual. A number of quetions need answering regarding the potential dangers versus benefits of the use of augmented concentrations of inspired oxygen. Does an elevated F_IO_2 1) increase the production of superoxides by granulocytes and, if so, does this increase injury to normal structures of the lung? 2) make the lung more susceptible to injury by superoxides when infection occurs and defense mechanisms are activated? and 3) to what extent can the sick lung adapt to protect itself from the toxic effects of oxygen? (For example, are reports of patients surviving after long periods (days to weeks) of F_IO_2 near 1.0 examples of patients who have adapted slowly by increasing enzymes to inactive superoxides or other destructive effects of hyperoxygenation?)

It can be concluded, even without answers to these and many other questions regarding mechanisms by which, and levels at which, oxygen is toxic, that elevated levels of F_IO_2 are potentially dangerous. If this tenet is accepted, then an immediate aim of technology should be to develop techniques that limit to the maximum extent possible, patient exposure to elevated concentrations of oxygen.

V
Role of Airway Pressure and Flow Monitoring

Technology is presently available for facile measurement of tidal flow and airway pressures in intubated patients (7,10-12). The cost of devices to monitor flow and pressure is comparable to the cost of monitoring the ECG and two vascular pressures. Measurement of flow with presently available devices requires attention to the flow transducer to prevent fouling with secretions or condensed vapor. Flow transducers that are relatively simple to maintain have an absolute accuracy that is not much better than 5 percent and is typically nearer 10 percent. However, these transducers can monitor changes in flow with greater accuracy.

Measurements of airway flow and pressure are of little value if unprocessed, so useful devices must include some form of data processing. The most versatile and economic method of processing will be on-line digital microprocessors. Current pattern recognition, computation, and display algorithms need further development before standards are established.

Monitor Capability

At present, it would appear that the capability of the flow-pressure monitor should include:

- Stand-alone instruments that could be used for any intubated patient regardless of whether the patient is breathing spontaneously or attached to any of a number of different types of ventilators.

- The capability to measure, with an accuracy of ±5 percent, inspired and expired tidal volume, ventilatory rate, and minute ventilation.

- The ability of separating spontaneous from ventilator breaths when IMV is in use and, thus, measure spontaneous rate and tidal volume, and ventilator rate and volume, and thereby, calculate the contributions of each type of breathing to minute ventilation.

- The measurement of peak, mean, end-expiratory and end-inspiratory airway pressures, and the average of these over a 1-minute time interval.

- The use of pressure and flow measurements to calculate compliance, resistance, and work, preferably with an algorithm that predicts reliability of calculations. This type of data acquisition and computation will require special training of medical and nursing personnel.

- The capability of measuring transpulmonary rather than airway pressure if an intrathoracic pressure is available. The pressure manometer should be a differential manometer. This will allow calculation algorithms to measure compliance, resistance, and work, regardless of the mode of ventilation.

Monitor Evaluation

Monitors with these capabilities would permit design of clinical studies to evaluate how useful this information would be in the management of respiratory therapy. Major questions that need to be answered are:

- Does the ratio of spontaneous to ventilator tidal volume, respiratory rate, and minute ventilation predict effect of changes in level of ventilator support needed?

- Does knowledge from flow-pressure monitoring reduce the need for blood gas determinations, barotrauma, ventilator accidents, and duration of ventilator support?

- Is a flow and pressure sensor system an effective monitor for prevention of anesthetic apnea accidents? How effective is it compared to sensors with gas concentration measurement capabilities?

- Does knowledge of lung mechanics permit more precise control of the level of increased end-expiratory pressure, and ventilator tidal volume? Can it reduce barotrauma or depression of cardiac output?

- Is automated interpretation essential for effective use of the data?

This list must be considered a partial list of pertinent questions. The new technology is not the capability to measure flow and pressure, but the on-line processing of information from these sensors. The usefulness depends on the further technical and clinical applications of the potential of these capabilities. These simple measurements may prove to be some of the most useful signals for controlling ventilator therapy and preventing its complications. The studies will require coordinated evaluation of ventilation-perfusion distribution, cardiac output, and PaO_2.

Finally, studies of $PetCO_2$ when combined with simultaneous tidal volume may enhance the efficacy of $PetCO_2$ as a predictor of $PaCO_2$.

VI
Invasive and Noninvasive Blood Gas Measurements

There is no doubt that noninvasive, transcutaneous PO_2 electrodes are practical for use on infants, with several good instruments on the market. In the older age group (above 6 months), the circulation to the skin varies greatly with the clinical state so that oxygen may be consumed at such a high rate that transcutaneous PO_2 may be much lower than arterial PO_2. The sensors need to be effective when perfusion is poor, or provide a reliable warning that their signal is poor. Present sensors, including oximeters, are uncomfortable, unreliable, and expensive. Potential solutions to this problem include:

- Increase local skin perfusion. This is currently done with heat. Unfortunately, this may not be adequate in the older infant without risking an unacceptable burn. It may be worthwhile to investigate using pharmacologic methods.

- Decrease skin O_2 consumption. Again, pharmacologic methods should be tried.[2] Considerable basic research should be done, however, before clinical trials are conducted.

Invasive sensors for measuring arterial or mixed venous PO_2, PCO_2, and pH would be useful in certain critically ill patients. Their development should be encouraged, but cost and reliability must be scrutinized.

VII
Measurement of Vital Capabity

The measurement of vital capacity (VC) and its use in clinical decision making in critical care is not widespread, in spite of the fundamental role of VC in monitoring the state of many cardiopulmonary disorders. Decisions concerning the application or withdrawal of ventilatory assistance, the progress of pulmonary congestion due to left ventricular failure, and the progress of neuromuscular disorders affecting ventilation are frequently made more easily and rationally in light of a well-determined measurement of VC. The progress of patients with airflow obstruction (bronchitis, emphysema, asthma, etc.) is frequently only rationally assessed by measurement of the FEV_1 (or a substitute measurement of flow). Application has clearly lagged behind the availability of devices.

VIII
Detection of Pneumothorax

A large tension pneumothorax is life threatening and requires immediate specific therapy. Unfortunately, the therapy (aspiration of pleural air by needle or chest tube) is itself a potentially dangerous procedure and may itself cause a pneumothorax. X-ray diagnosis is potentially of extreme benefit and presents an acceptably low risk. Unfortunately, it is, in many practical clinical situations, far too time consuming. There is urgent need for a simple noninvasive and rapid procedure for determining the presence of pneumothorax. It is essential that the method define the side on which the pneumothorax is located.

ICU DATA TYPES AND FREQUENCY OF COLLECTION

To list data important to collect and frequency of required collection for intensive care will inevitably reflect the prejudice of authors and will be probably obsolete as soon as it is written. If these limitations are accepted, the following is a list of data that can be acquired in mid-1980 and which has proved useful for control of treatment in the intensive care environment (2,4-6).

	Acquired Data	Derived Variables	Frequency
1.	Arterial $PaCO_2$, pH, PaO_2, Hgb or Hct, F_IO_2	CaO_2, SaO_2 (estimated Q_s/Q_t and reliability evaluation), type acid-base derangement	Depends on patient status, rarely more than q1h
	In infants, transcutaneous PaO_2, $PaCO_2$		Continuous
	If reliable, comfortable, and reasonably priced continuous indwelling or surface monitors of $PaCO_2$, pH, or PaO_2 for adults become available, they should be substituted for blood sampling.		
2.	Mixed venous oxygen content (CvO_2)	with 1), A-V DO_2, with $\dot{V}O_2$, cardiac output	$Q_s/Q_t > 0.15$, CPAP or PEEP > 10, with changes in treatment, cardiac output, or clinical state
	If reliable catheter tip instrument becomes available to measure CvO_2, it should provide a near continuous monitor.		
3.	ECG	Heart rate, frequency of PVC, type of arrhythmia, asystole	Continuous
4.	Systemic arterial pressure	systolic, diastolic, mean pressure	Continous with cardiovascular instability
5.	Pulmonary artery and wedge pressure from Swan Ganz catheter or intraoperatively placed catheter	Systolic, diastolic, mean and wedge pressure, preferably coordinated with phase and type of respiration	In patients on CPAP > 10 and those with cardiovascular instability. Pulmonary artery pressure continuous. Wedge pressure q30min to 1h

ICU DATA TYPES AND FREQUENCY OF COLLECTION (continued)

	Acquired Data	Derived Variables	Frequency
6.	Cardiac Output	Cardiac index, pulmonary and systemic vascular resistance, left and right stroke work index. If CaO_2 and CvO_2 available, then $\dot{V}O_2$	In patients on CPAP or PEEP > 10 and/or those patients with cardiovascular instability, q1h or when therapy changed
7.	Airway flow and pressure	Spontaneous and ventilator tidal volume, rate, minute ventilation; mean, peak and end-expiratory pressure (compliance, resistance, and work if proven reliable)	q60-120min for testing. Continuous if used as apnea monitor. (For latter, expiratory flow and peak inspiratory pressure adequate.)
8.	Spirometry and functional residual capacity. Maximum airway pressures	Tidal volume, vital capability (VC), forced vital capacity (FVC), FEV_1, inspiratory and expiratory reserve volume	q12-24h or with change in ventilatory treatment or status
9.	Fluid electrolyte, blood products intake, output	Fluid, electrolyte, blood product net gains, losses. Hourly, daily, and cummulative	q1-3h, dependent on state of patient
10.	Serum Na, K, Cl, CO_2		K^+ when critical q1h. Otherwise q8h if good balance determinations available
	If indwelling sensors that are comfortable, reasonable in cost, and accurate are available, this information could be available constantly. This facility is of questionable value.		
11.	Urine Na, K, Cl	Use for electrolyte balance calculations	qd
12.	Lung water		
	Needs testing for usefulness evaluation		

NEEDS AND RECOMMENDATIONS

I

Methods should be developed and applied to evaluate technologies used in the care of critically ill patients of all ages.

II

Studies should be undertaken to delineate the efficacy of high frequency ventilation (HFV) and those conditions in which its use is recommended.

III

Equipment utilization at the bedside should be reviewed to define that instrumentation and support equipment essential to optimize patient care.

IV

Major emphasis should be placed on the development of methods which will detect and sound an alarm following ventilator and anesthesia machine disconnects.

V

Further development of noninvasive methods for measuring PO_2, PCO_2 and pH in adults, children, and patients with poor perfusion is needed.

VI

Development of noninvasive methods for measuring all important physiological parameters, such as pulmonary blood pressure, arterial pressure, PO_2, PCO_2, etc. would minimize risk to the patient and maximize data access for decision making.

VII

Further studies of the mechanisms of oxygen toxicity and its prevention should be encouraged.

VIII

Studies should be conducted to assess the benefit of airway flow and pressure measurements, and to determine in which patients this type of monitoring is warranted.

IX

Improve flow measurement technology so flows can be 1) accurately measured in the ICU patient environment where varying flows, temperatures, and plugging are major problems, and 2) measured for pulmonary function studies to an accuracy of better than ±3 percent.

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COMPUTER ANALYSIS OF MEDICAL IMAGES

INTRODUCTION

Recent advances in computer technology, with a corresponding reduction in computer costs, have made the application of image processing and enhancement techniques to medical problems more feasible. In addition, data are now more frequently in digital form such as data from computed tomography and digital radiograph systems. Operations which were once too time consuming to be practical are now possible through whole image operations with multiprocessor systems (11,13). Faster image processing will also significantly improve interactive image analysis. Digital processing methods may also result in lower radiation doses (15).

Epidemiological studies and medical surveillance programs frequently use chest radiographs as part of their medical protocol. With these usages, large numbers of mostly normal radiographs must be interpreted, and computerized analysis is particularly attractive because of the large number of interpretations which must be rendered, the relatively narrow range of diseases encountered, and the significantly larger interobserver reading variability. In addition, a computerized system may provide an increase in the sensitivity for the detection of low level radiographic changes which can occur with some occupational exposures.

In applying computerized analysis of radiographs to epidemiological and surveillance programs, accurate validation is most important. With proper validation, it is conceivable that a computerized system could outperform the human observer in a limited number of radiographic disease manifestations.

STATE OF KNOWLEDGE AND TECHNOLOGY

I
Image Resolution

The first consideration in computerized analysis of medical images is the spatial, temporal, and density resolutions needed. In general, higher resolutions require considerably more processing time and increase the cost of the system. Image acquisition technology is now reaching the level at which some comprehensive analysis of resolutuion requirements for CT scans are needed. For example, the need of increasing spatial resolutions beyond 0.4 mm should be reviewed.

II
Preprocessing Algorithms

After a medical image has been acquired, it must usually be preprocessed or enhanced. The preprocessing algorithm used is often very dependent on the origin of the image, i.e., a digitized radiograph or computed tomography system. Preprocessing can range from applying a reconstruction technique to a CT scan, to the use of spatial filtering and edge enhance-

ment to accentuate certain regions of the image for display. Image preprocessing techniques have also been used for normalization of a radiographic image to compensate for variations in film quality (5). While there is a need for more and better preprocessing algorithms, they must be considered within the context of the origin of the image.

III
Image Segmentation

One advantage of computerized analysis of medical images is the vast amount of quantitative information which is available in the digital image. However, for this information to be extracted, the image must first be segmented into regions of interest. Segmentation may be performed interactively or be completely automated. Once the region of pathology has been isolated, a number of quantitative measurements such as area, density histograms, and texture measurements can be computed. Thus, with computer assisted segmentation, the tedium of manual delineation of areas of interest is reduced and quantitative measurements are often more reproducible.

Quantitative information from CT systems has been used in the diagnosis of pulmonary nodules (1), demonstrating one future use of either automated or interactive image segmentation. Image segmentation algorithms have been used on skull CT scans (3,7) and similar techniques could be applied to CT scans of the lung. One method of stimulating the development of segmentation algorithms would be to establish a computer image data base of lung anatomic information. Then, various segmention algorithms could be developed, compared, and evaluated for possible inclusion in CT system software libraries.

Numerous applications of modern image processing techniques have been made to digitized chest radiographs (9). Much effort has been directed towards development of algorithms to outline the lungs and heart and extract measurements for automated determination of heart disease (6). Other efforts have examined the lung field for tumors (2) and detection of infiltrates (14) with particular emphasis on pneumoconioses (10). Work has also been done on locating the ribs (4) prior to any quantitative measurements. Although much work has been conducted on image analysis of chest radiographs, more work is needed to validate these methods on a large number of radiographs. Automated analysis of radiographs will be most useful in screening, epidemiological, and surveillance programs where a wide variation in film quality and disease patterns exist. As with CT data, the establishment of a well validated and representative computer image data base would be an important first step towards evaluating these algorithms. Such a data base would serve as a bridge between physicians and computer specialists.

IV
Display Technology

One of the limiting factors in the interpretation of an image is the mismatch between the observer and the image display system. Through the use of image processing and display techniques (such as pseudo color display) more efficient display of radiographic and CT images is possible.

More work is needed to optimize image display for decision making. In addition, work is needed to develop methods for the display of three-dimensional information.

V
Feature Extraction

Feature extraction is the reduction of the number of parameters in the original pattern space to a smaller subset of the most relevant features with respect to classifying an observation. For example, feature extraction techniques have been used in the analysis of chest radiographs to select the best measurements from the cardiac silhouette to classify heart disease (6), and to determine which texture measurements are the most useful in the diagnosis of interstitial fibrosis.

Feature extraction techniques have also been applied to respiratory data. For example, feature extraction has been applied to an analysis of flow volume curves to improve their sensitivity and provide an understanding of the information content of the flow volume curve (11).

Feature extraction and pattern recognition techniques can be applied to a variety of medical decision processes and are particularly useful when parameters are highly correlated or redundant. More effort is needed to apply these techniques to respiratory data, not only to develop decision making algorithms, but also to provide a basic understanding of the data.

NEEDS AND RECOMMENDATIONS

I

Studies specially designed to validate computerized analysis systems should be conducted.

II

The development of more efficient image display methods, especially for display of three-dimensional information, should be strongly encouraged.

III

The application of feature extraction algorithms to assist in medical decision making should be pursued.

IV

Establish evaluation criteria to determine the incremental increases which spatial and time resolutions give to each image methodology.

V

The establishment of a representative image data base to allow physicians and computer scientists to develop, test, and validate human and computer image extraction and analysis techniques should be fostered.

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STANDARDIZATION

INTRODUCTION

The National Heart, Lung, and Blood Institute is to be commended on its previous efforts in the standardization of data collection for epidemiological purposes. Standardization is also important for the routine clinical respiratory tests which are used at most medical facilities. The best approach to standardization is through the support of professional and technical societies which are interested in setting or recommending standards. An example is the recent American Thoracic Society (ATS) effort on spirometry standardization. Standardization for blood gas analysis, single breath diffusion, and exercise testing should be given high priority.

The establishment of equipment testing centers is not necessary if voluntary standards have been developed. Standards alone are often sufficient to encourage manufacturers to improve and evaluate their instruments. Until the medical community can agree on performance requirements, manufacturers will continue to guess at what is needed. Once performance requirements have been defined, manufacturers have generally been willing to conform to the standards and even test their devices to ensure that their specifications are accurate.

STATE OF KNOWLEDGE AND TECHNOLOGY

The Intermountain Thoracic Society, the California Thoracic Society, NHLBI's Division of Lung Diseases, and the American Thoracic Society have all made major strides in establishing standards for procedures and data interpretation (1-4). The development of standards for spirometry, which included instrumentation requirements, test procedure requirements, and data selection requirements, has had a positive effect on manufacturers and clinical users. These standards have developed methods so we can now generate and share interchangeable data. Standards for pulmonary medicine should be developed carefully, so as not to stifle innovation, nor slow the development of better, and more sensitive and specific, test methodologies. We should not, however, wait 130 years, as has been the case with spirometry, to develop meaningful and practical standards.

It is extremely important to have longitudinal and intergroup comparisons of epidemiological data. These would aid in the early detection of lung disease, provide clinical comparisons relating to individual diseases and the effects of drugs and therapy, and allow for fair and equal evaluation for disability. The current Snowbird (2) and epidemiological (1) standards that have been published are steps in the right direction; however, they might be made more readily available, perhaps, in a condensed form. These standards should probably be attached to all relevant research applications. There does not seem to be a great deal of concern for following these standards among the medical profession, and were it not for the leading manufacturers fighting it out through their advertising, these standards might never have been implemented. Industry has mixed feelings about the standards that have been published.

Obviously, if one firm meets all of the requirements with its equipment, it will support enforcement while those that fail question the validity of the standard. The larger companies can accept the expensive, and often hard to obtain, equipment necessary for accurate testing, while the smaller companies find it a financial burden. Most companies in the business of manufacturing instrumentation for pulmonary function have sales under $10 million per year and are more concerned with product development and marketing than with engineering, basic research, and physiologic problems. Too much enforcement could result in driving smaller companies out of business with only 2 or 3 of the larger ones surviving. Perhaps, the answer is the establishment of centers for instrument testing.

The other half of the problem is that pulmonary laboratories presently are not certified and often neither is the operator. How does one determine if the machine was properly calibrated or the test performed correctly? Registration? Regulations? There is little hard evidence that certification improves quality.

Problems of communication are common to groups both within and outside of government. The Federal agencies currently involved with health care suffer from a lack of coordinated action. The benefits of a coordinated government approach to health care and technology development are obvious. However, the deleterious effects of unilateral, uncoordinated actions are often less obvious. Frequently, the policies of one government agency, although fully in concert with its statutory authority, cause a ripple effect throughout the industry which manifests itself in ways completely unconsidered. The formation of an intragovernment health coordination group, similar to the Interagency Regulatory Liaison Group (IRLG) composed of representatives from various government agencies involved in health care (e.g., FDA, NIH, NCHCT, HCFA, HRA) may alleviate some of these problems. The coordinating group would meet periodically to keep appraised of the issues of concern to each group and the policies being considered for implementation. In this manner, policies could be evaluated for their effect, if any, on other groups before, rather than after, implementation. Unilateral policy often leads to confusion within the government and industry with the potential for economic loss. The problems of communication between groups outside of government are compounded by their diversity and distance. The basic problem, simply stated, is how to encourage communication between those people with a problem (e.g., the physician), and those people who may have a solution (e.g., the engineer or industry). Stimulation of this type of communication may require the establishment of some type of information exchange. A possible scenario might be the formation of a computerized data base, maintained by the Federal government, consisting of professional organizations and their areas of expertise. In this manner, periodic reports of health issues could be made publicly available to these groups for dissemination to their members. The data base would be maintained, updated, and coordinated by the Federal government. In this manner, unresolved problems could be brought to the attention of the widest possible audience, with the hope of identifying possible solutions.

Protocol definition and standardization of measurement techniques in both the pulmonary laboratory and the intensive care unit is highly desirable. Although standardization of spirometers and spirometric methodology, body plethysmography, and esophageal pressure measurements, have received much attention during the past 5 years and likely herald future major efforts towards standardization of many pulmonary laboratory techniques, major advances in critical care have occurred so rapidly that with the exception of electrical safety regulations, virtually no other effort towards standardization in the ICU has been made. The measurement of pulmonary artery wedge pressure (Pw), for example, is very difficult in many clinical settings, and is associated with major and clinically significant errors, the frequency of which is currently unknown. Techniques used for measuring Pw are quite variable from center to center. The techniques used for portable chest x-rays (i.e., exposure, focal spot to film distance, patient position, removal of monitoring leads, size of breath, etc.) are equally nonstandard with the result that portable chest x-ray quality varies from unacceptable to excellent. Specimens of blood for blood gas analysis, when hemoglobin concentration is included (required for O_2 content calculation), must be associated with a known and fixed dilution factor (due to anticoagulant volume) and must be adequately mixed (not a trivial problem with modern blood specimens contained in syringes without air bubbles or foreign bodies such as glass beads, metal wires, etc.) before analysis.

NEEDS AND RECOMMENDATIONS

I

The development of "flexible" standards for devices and methods which have reached maturity in the pulmonary area should be strongly encouraged. Examples are:

- Spirometry, including establishment of reference "normal" values
- Dilutional lung volume testing
- Pulmonary questionnaire
- Body plethysmography
- X-ray lung volume determination
- Criteria for interpretation of chest x-rays
- Blood gas analysis
- X-ray film quality
- Measurement of pulmonary artery wedge pressures, especially in patients with pulmonary disease

II

Encourage utilization of currently developed standards by having all government agencies and professional organizations adhere to a single standard (this has been accomplished with spirometry).

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TECHNOLOGY DEVELOPMENT

INTRODUCTION

On October 31, 1979, President Carter announced a program to encourage industrial innovation emphasizing the importance to the American economy of the development and commercialization of new products. The improvement of health care was one of the primary directions for this program (1). The application of medical technology to health care represents the final step in a long series of events consisting of inputs from both public and private sectors. At any stage in the developmental process, these inputs can exert either a constructive or destructive influence on technological progress.

STATE OF KNOWLEDGE AND TECHNOLOGY

An important factor in the development of medical technology is the role of the physician and the medical system. Physicians are keenly aware of those areas in medicine where new technical advances are needed or where developments are delayed. Physicians are continually presented with diagnostic and/or therapeutic challenges which must await the advent of new technological discoveries. The interaction between these physicians and the engineering community represents a basic link in the innovation process (2). However, this link often develops haphazardly, and the problem becomes one of how to fortify this link between the medical and engineering communities to elicit the development of needed products. The coordinated efforts of government agencies such as the National Institutes of Health which are heavily involved in the research and development of medical technology through both intramural research and extramural funding, the National Center for Health Care Technology (NCHCT) which is involved in the assessment of medical technology, the Food and Drug Administration (FDA) which evaluates the safety and effectiveness of new products, and the Health Care Finance Administration (HCFA) which provides reimbursement for medical expenses, can stimulate the development of needed technologies. Each of these agencies represents a part of the innovation process, and each may be constructive or destructive in that process.

The first part of the innovation process is the identification and funding of areas where research is needed. The National Institutes of Health currently has a mechanism for this purpose. Through task forces, areas of medicine are identified where additional clinical information would result in more effective treatment. Often, these areas are ones with little economic potential because of either the small market or the high cost of development relative to the potential return. There are two possible approaches to stimulating development in these areas. The first is to increase government funding of research. The second is for the government to bear the entire cost of development, relying on the private sector only for the production and commercialization of the product.

The passage of the Medical Device Amendments of 1976 gave the Food and Drug Administration the statutory authority to ensure the safety

and efficacy of medical devices. These amendments provide regulatory safeguards to address the potentially devastating effects of unsafe or inefficacious medical devices. While regulatory control was designed to protect the consumer, it has the potential to injure the medical device industry by delaying the development and commercialization of new devices. This deleterious effect of regulation can, however, be minimized by the development of a priority system under which innovative products with exceptional benefit would undergo an expedited clearance. Under this system, the Bureau of Medical Devices (BMD) would identify candidate devices from information submitted to the Bureau in response to regulatory requirements [e.g., investigational device exemption (IDE) applications; product development protocol (PDP)], from direct contact with device developers, from the professional literature, or from information provided by organizations currently funding device research and development (e.g., the National Institutes of Health). These candidate devices would then be evaluated according to a classification scheme. This scheme evaluates the devices on the basis of two factors; 1) the level of innovation over current technology, and 2) the diagnostic or therapeutic potential associated with the device. These two factors are then further subdivided, the truly new and unique device from the device without innovation and the device with an exceptional medical/social benefit from those with little or no medical/social benefit. Devices ranked high on this classification scheme would be candidates for expedited FDA review. Devices selected for expedited review would be encouraged to utilize the PDP process, which offers the greatest flexibility in expediting premarket clearance. Under this process, the Bureau in concert with the manufacturer and the appropriate device advisory panel would develop and agree upon a protocol for testing the device. Continuous review of the data generated during device testing would eliminate the serious delays caused by unproductive or inappropriate testing. Any problems arising during the course of testing can be immediately rectified without adding additional delays. An alternative approach to expediting the review of medical devices includes the use of the IDE/PMA (premarket approval) process. However, this process is less flexible than the PDP process due to statutory constraints. Devices rated high on the classification scheme would receive a high priority for Bureau review. If submitted early enough, deficiencies in the investigational protocol could be rectified in a manner similar to the PDP process. Furthermore, regulatory discretion in approving a device could be applied to a device rated high on the classification scheme, but which does not, as yet, meet all the statutory requirements for approval. In this manner, the device would be available to the public, contingent upon a subsequently successful completion of all statutory requirements.

Another area of FDA authority, similar in some aspects to PDP and PMA guidelines, is that of standards. Standardization can potentially encourage or discourage innovation. Rigid standards will undoubtedly deter technology development. The establishment of performance standards specifying only the required goal, rather than the means of achieving it, will stimulate the development of efficient, cost effective products. The adoption of acceptable reference standards against which a manufacturer can check his product eliminates costly testing and decreases regulatory

review time. The benefit derived from the standards process can only be achieved if there is widespread acceptance of a particular standard, which necessitates the coordination and involvement of users, government, and industry. A standard responsive only to the interests of a single group will inhibit, rather than promote, development.

The final aspect of the innovation process is the stimulus provided by government reimbursement agencies and other third-party payers. Certain areas of medicine (e.g., preventive medicine) exhibit little progress in the development and utilization of technology. The reason for this lack of progress may, in part, be due to the lack of third-party payment. Practitioners may be reluctant to utilize new technology when the cost may have to be borne by the patients themselves, especially if it is not clearly demonstrated to be clinically superior. But where the expense is covered by some form of health insurance, a demand for the technology can be generated, stimulating the market place to fill it. Reimbursement can be an effective tool for stimulating innovation, if it is appropriately managed and properly targeted.

Each of the elements - reimbursement, funding, standardization, and regulation, affect the climate for innovation. While no singular element is sufficient to stimulate innovation, each can stifle it. A program to truly encourage technological development requires a coordinated effort by the agencies and individuals who are responsible for overseeing these areas. Users, developers, and regulators of medical technology should identify areas of high priority for development and expedite the development process. Government is not the sole determinant of the process of technological development, but requires input from consumers and industry to encourage innovation. Some of the elements of this concerted effort are already in place, but without the remaining elements, the results fall far short of the desired goal.

Industrial Perspectives

The usual course of research in industry might have the following scenario. Someone has a basic science idea, follows it up with a research grant or support from a large company, and ends up with a basic science publication. This stimulates interest in applied science research leading to clinical research and a clinical publication. The end result is that information is generated to aid the person in charge of patient care and it may create a market for a product. All this falls down in bioengineering. First of all, the basic science is usually further removed from the clinical setting than is the case with drugs or chemistry. Secondly, publications of basic science or even applied science are unacceptable to medical journals where physicians could benefit, and when rarely accepted, are either incomprehensible to possible users or too simplified as to be of any use. The need for cooperation between bioengineers and medical people participating in multidisciplinary research is crucial for the health care field to be well served. In the medical research field, invention, development, testing, and publishing may serve the individual who has published; however, the medical public is not served until such devices prove financially practicable, are manufactured, and become readily available to the end user. The device or product must also provide a profit to the manufacturer.

NEEDS AND RECOMMENDATIONS

I

Encourage closer and more effective interaction between physicians, scientists, and engineers during the development of innovative technology. This could be enhanced by encouraging proposals from engineers in areas of technologic need and by recommending medical consultants to the engineers.

II

Develop funding incentives which will encourage the use of cost effective technologies.

III

Encourage the development of standards which will meet medical needs and at the same time stimulate industry to build better and more cost effective instruments. Assist industry with expedited product approval by the regulatory agency (FDA) for devices or products which have a high priority, such as those recommended by this task force.

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EVALUATION OF TECHNOLOGY

INTRODUCTION

It has only been in recent years that medicine has taken a careful look at evaluation of the effects of new methods and technologies. Development of methodologies for evaluating the effect of a new technology is severely lacking. Evaluations typically require complex experimental designs and raise ethical and moral questions. For example, if a new method is shown to be somewhat effective, is it ethically right to deny that technology or methodology to all patients? If one finds a study patient who may be severely compromised when conducting such an evaluation, is one justified in carrying on the experiment just for data collection reasons? Evaluation is a very important, yet very complex, procedure. Excellent quantitative and scientific help is needed to solve the problems of performing evaluation.

STATE OF KNOWLEDGE AND TECHNOLOGY

The number and complexity of test procedures for diagnosing pulmonary dysfunction and controlling therapy are rapidly increasing. Unfortunately, good studies to evaluate the usefulness of such tests are few. Drugs and other therapeutic modalities have legal requirements for efficacy testing and liberal support is available for such studies. Determination of the effectiveness of diagnostic tests should also be a requirement. The lack of such a requirement leads to a dual deficit: 1) the potential usefulness of the test may not be realized; and 2) it may be inappropriately used, placing patients at undue risk and discomfort and resulting in a wasting of resources. A requirement of all such studies should be a true cost analysis so that the providers and sponsors of health care can measure the usefulness against cost, not charges. Since the respiratory system has a relatively long time constant of change, such studies should also assess the optimum frequency for testing.

Several examples of the problems engendered by the lack of proper evaluation of cost effectiveness or cost-benefit analysis of testing patients with pulmonary disease will illustrate the problem. Routine admission examinations for most hospitalized patients include hematologic, urinary, and blood chemistry analyses, and in some instances, a chest x-ray. These tests are done regardless of indication. Yet, few hospitals carry out routine simple spirometry, even on high-risk patients who are to have major surgical procedures, despite the fact that unrecognized pulmonary disease results in a significant incidence of serious preventable postoperative pulmonary complications. Routine simple spirometry is not widely used because: 1) present technology with automation to simplify testing and interpretation has been underutilized; 2) charges have been set far above costs; and 3) physicians have not been educated to use this information.

In contrast, testing for staging carcinoma of the lung is a good example of overutilization. A number of studies have shown that routine radioisotope scanning procedures for determining tumor spread--bone, brain,

and liver scans--are of no value in asymptomatic patients (2,5). However, these tests are used routinely by many in all patients with carcinoma. Computed tomography is now being added to the tests without critical evaluation of its usefulness.

Detailed in the ICU/anesthesiology section of this chapter is the efficacy of the measurement of end-tidal CO_2. Its usefulness in the ICU, although very promising, is untested; yet, large sums of money are being spent for complex instrument systems to monitor airway CO_2 concentrations (1,6,7). These examples of monitoring, routine testing, and disease specific testing are cited to emphasize the fact that for all kinds of tests of pulmonary disease, objective studies of appropriateness are lacking. Definitive multi-institutional studies to determine test effectiveness will allow PSRO review to be more precise and protect those physicians not doing unnecessary tests from the risk of malpractice. It is now national policy to carry out institutional appropriateness review. It should be national policy to carry out technology appropriateness studies.

Other areas where evaluations are needed are outlined below.

Respiratory Gas Analysis

- The potential of mass spectrometers for measuring cardiac output noninvasively needs further evaluation. This evaluation should include assessment of the accuracy, reliability, and technical skill needed for making this measurement; in particular, the physiologic and clinical situations in which the measurement is unreliable need definition. A further aspect of this study is to assess the noninvasive measurement against that provided by Swan-Ganz catheterization. Does the added information (filling pressures, mixed venous samples) provided by the Swan-Ganz catheter outweigh the consideration of invasiveness?

- The incremental benefit of gas analysis over simple airflow and pressure monitoring needs to be studied.

- Instruments for continuously measuring oxygen consumption and carbon dioxide production are in the prototype stage. These instruments need to be evaluated not only for reliability, but more importantly, to assess the usefulness of these measurements in managing patients.

Respirators

- In spite of the advantages claimed for intermittent mandatory ventilation, controlled ventilation is still widely used. A systematic comparison of these two forms of ventilation should be performed.

- High frequency positive pressure ventilation (HFPPV, or jet ventilation) has been used in a limited way in Europe and in some centers in the United States. The use of this form of ventilation should be investigated, particularly in conditions where high levels of PEEP or CPAP are to be avoided, such as head injury. The effect of this form of therapy on traditional forms of respiratory monitoring will likewise need evaluation.

An area of medicine which has recently received much attention and evaluation is computed tomography (3). Methodologies have been developed using receiver operator curves (ROC) to help determine which competing diagnostic method is better (4). The ROC method works well if sufficient cases of proven positive and proven negative diagnoses are available and if a confirmatory "reference" diagnostic test is available. Methods for evaluating cost effectiveness are also becoming available (8).

NEEDS AND RECOMMENDATONS

I

Establish methodologies for conducting evaluations on various technologies. This has already begun but could be accelerated by long-term funding commitments through agencies such as the National Center for Health Care Technology.

II

Multi-institution studies should be conducted to assess the effectiveness of various technologies.

III

Though some applications of technology may be effective for one situation, they may be completely inappropriate for other uses. Therefore, it is important to outline the boundaries of appropriate technological development. A review of high cost technologies, whether because of high cost of a single test or multiple low cost tests, should be conducted.

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