The Need for Standards of Performance

The report by Epstein in this issue, describing the characteristics of triggering devices of ventilators used in intensive respiratory care, focuses attention on an area relatively neglected by investigators in the past. Very little about sensitivity and response times of ventilatory assistors can be found either in the manufacturers' literature or in the most comprehensive text on the subject of ventilators. Reports of the general characteristics and functions of the various ventilators have appeared sporadically in journals. The methods used to test ventilators have varied, as have the levels of expertise. Epstein's method of testing sensitivity and response times of ventilatory assistors is well suited to the evaluation of the comparative efficiency of the six devices tested. This model could well be used to evaluate the patient triggering characteristics of other ventilators in general use. The study itself raises a number of questions about the assist mode of ventilators. For example, Epstein tested one model each of six ventilators, all of which were "new or had been recently reconditioned by factory-authorized service facilities." It would be interesting to know the variation of sensitivity and response times among the different models of the same ventilator as well as among different examples of the same model. Also, what changes in the characteristics of the assist mode occur in ventilators which have been in clinical use for a long time? Another unknown is the effect of the currently-popular continuous positive-pressure ventilation on the triggering characteristics of various ventilators. Positive end-expiratory pressure in the ventilator system may radically change the characteristics of the patient triggering mode.

Epstein's report clearly demonstrates the need for uniform standards of ventilator performance. For example, one ventilator tested was found to have unsatisfactory patient triggering characteristics at respiratory rates higher than 9. Another ventilator required internal adjustment of the sensitivity controls before satisfactory triggering could take place. These findings bring up the question of the minimum standard of performance to which a ventilator must conform to be acceptable for use in clinical practice. At present there are no generally accepted standards of performance for medical devices in general and ventilators in particular. There has been considerable debate on the topic of regulation of medical devices by the federal government recently. Proponents of federal laws regulating medical devices cite the malfunctions, accidents and deaths which occur due to their use. Opponents of such laws claim that governmental regulations of and standards for medical devices stifle innovation. The answer would seem to be somewhere between the "laissez-faire" situation we have at present and an FDA for medical devices. If all manufacturers of ventilatory equipment could agree on certain basic standards which a ventilator must meet for clinical use, the problem would be soluble without the need for governmental intervention.

Voluntary standards to which all manufacturers will agree are difficult to formulate, as the anesthesiologists representing the American Society of Anesthesiologists on the Z-79 Committee of the American National Standards Institute will attest. This committee, sponsored by the ASA, AMA, and American College of Chest Physicians, is made up of representatives of industry and the medical profession. It has been trying to draft industry-wide standards for ventilators since 1966. The proposed standards are currently undergoing their fifth revision. They pertain to, among other things, ventilator performance, fittings, accuracy of controls and consistency of gas delivery. A lung model is proposed for testing the ventilator over a period of several hundred hours. Ventilator responses to these tests are to be made available to prospective purchasers. Proposed standards should contain limits for a minimum level of performance. With standardized testing, a knowledgeable physician could draw his own conclusions from the data, and would not have to wait until an independent investigator became interested in critical testing of the ventilator. These standards would be voluntary, however, and there is no law other than economics to force manufacturers of ventilatory equipment to conform to the basic standards of the American National Standards Institute. There is an international
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precendent for standards of performance for ventilatory apparatus. In France, there are now stringent regulations controlling standards and a testing scheme for ventilators which is binding on the manufacturer.

The next problem which Epstein’s study brings up is the placement of responsibility in correcting potential hazards inherent in a piece of equipment. It is the responsibility of an automobile manufacturer to notify owners and recall the cars for repair when a hazardous design problem is identified. The Food and Drug Administration requires drug manufacturers to warn physicians of all possible adverse effects in the package inserts. Furthermore, the drug makers must keep physicians abreast of new information about harmful side-effects of their products by direct mail. If medical devices were controlled like drugs and automobiles, the manufacturer of one of the ventilators tested by Epstein would have to notify physicians and institutions who had purchased its machine that it is not adequate as a pediatric assist because of its excessively long response time. At present, however, and in spite of federal legislation introduced as early as 1967, there are no laws governing such medical devices. While some manufacturers of ventilators have been extremely conscientious about notifying the users of their equipment about hazards and modifying the equipment, others have tended to take the attitude of “let the buyer beware.” This attitude will force the enactment of laws regulating medical devices. Such laws will no doubt evoke many problems similar to those we now face as a consequence of federal drug control.

The adage that unsafe drivers cause more accidents than unsafe automobiles also has application here. The best ventilator available can be a lethal instrument in the hands of unskilled personnel. Ventilators must be properly maintained and properly cleaned. Patients undergoing continuous artificial ventilation must be under constant, expert supervision. Standards for ventilators will improve patient care, but we should not lose sight of the fact that the most important factors in the care of the patient who needs continuous artificial ventilation are a knowledgeable physician and the continuous presence of well-trained respiratory therapists and nurses.

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References


Anesthesia

BOWEL-GAS EXPLOSION An explosion of gas in the large bowel ignited by electrosurgery led to the death of a patient undergoing elective colonic interposition for esophageal stricture. Various factors leading to the accumulation of explosive gases in the bowel include: fermentation; a milk-rich diet with production of hydrogen; a legume-rich diet with production of methane. Nitrous oxide anesthesia may have contributed to the considerable distention of the bowel noted prior to the explosion. (Hussey, J. L., and Poise, A. J.: Bowel-gas Explosion: An Unusual Surgical Complication, Amer. J. Surg. 120: 103 (July) 1970.) ABSTRACTER’S COMMENT: Although the nitrous oxide anesthesia (actually nitrous oxide, halothane and oxygen) may have been partially responsible for the distention of the bowel, the increased concentration of oxygen available in the bowel lumen because of the 60/40 ratio of nitrous oxide/oxygen anesthetic mixture being administered may have increased the risk of explosion.