

Chapter 6

Mechanical Ventilation

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Mechanical Ventilation

INTRODUCTION

Mechanical ventilation is one of the major life-support systems of the 1980s. For patients suffering severe impairment or even complete failure of respiratory function, the ventilator (or “respirator,” as the device is better known) is literally the link between life and death. Its capacity to take over the vital role of the respiratory muscles, inducing rhythmic inflation and emptying of the lungs, is beyond debate. Experience with this technology provides clear evidence that, for a substantial and diagnostically diverse patient population, mechanical ventilation can effectively assist or replace normal spontaneous breathing. Its wide availability and usually safe application have enabled thousands of patients of all ages to survive life-threatening pulmonary, neuromuscular, and necrologic disorders, as well as high-risk surgical procedures.

But, like the other life-sustaining technologies considered in this report, mechanical ventilation is a mixed blessing. Its technical virtuosity and potential good are not always good enough. The ventilator has attained notoriety as the focus of ethical and legal dilemmas. For severely ill patients and their families, as well as many health professionals, decisions about the use of this technology are the source of considerable anguish. While offering hope of prolonged life, mechanical ventilation has drastic implications for the quality of that life. Furthermore, the costs associated with this technology are enormous, and the Federal Government bears a large proportion of these costs. Thus, in assessing this technology, the appropriate emphasis is not: does it work? but rather, under what circumstances is its use appropriate?

In the care of many acutely ill patients, mechanical ventilation lasting only hours or a few days is sufficient. For patients with reversible disease or injury to the chest wall and for some surgical patients, artificial ventilation can buy the time needed for definitive therapeutic interventions to take effect or for spontaneous improvement to

occur. In a short time, the ventilator can be removed and normal breathing resumes. Unfortunately, however, mechanical ventilation has never been shown to improve the underlying pathology of any disease (9). Thus, acutely ill patients whose underlying disease is chronic or irreversible can become, sometimes unexpectedly, chronically **ventilator dependent**. Their continuing need for mechanical ventilation may be total, i.e., 24-hours a day, or it may be limited, i.e., only during sleep or intermittently through the day.

For patients with chronic, irreversible, or degenerative diseases or paralysis affecting respiration, mechanical ventilation represents a last resort, a sign that preventive measures or cures were ineffective or unavailable. At the same time, for such patients, this technology offers a realistic possibility for prolonged life. Thousands of patients, or others acting on their behalf, have chosen ventilator dependence as the best alternative and, with it, many have managed to develop and maintain successful family relationships and even careers.

Ventilator patients who are successfully “weaned” as well as chronically ventilator-dependent persons who remain functionally able represent important technological successes. Unfortunately, however, not all individuals fall into these categories. Mortality among patients receiving mechanical ventilation is very high. Most reports have found survival of the initial hospital episode to be under 55 percent (27,75,87,98,128)129); and mortality is usually highest for elderly patients (75,83,85,87,88,95,129).

Furthermore, among those patients who become permanently ventilator dependent are some whose physical and/or mental functioning is severely and irreversibly impaired. Although patients who cannot be weaned are thought to rep-

¹Weaning is the step-by-step removal, over a period of days, weeks, or months, of ventilator equipment that the patient is dependent on, with restoration of adequate spontaneous respiration,

n w h n 5 p n p n
ngm h n n h
h m d u h hp
m n u n g m n nd
m m h m
Wh h p p n w b n m
m h n n m d dg
m O h w n d gn h b
b h d nd wh n n h h p n
p gn m m n h gh n n h p
d m m mb m n g w h

h d h phy M ph
nd h p n g
m n g w h h h Th h d
nm k ngp b mm d phy n
p m p h m p h gy
h g m nd w
O h 30 h m d n n
hn gy d n wh hno g
p b nd h ng n h n h
b gh h g n h pu p p p n
nd m h d p d ng Th



D g m m⁹ g^g C H

cus has shifted from the operating room, to long-term care, to intensive care, and, lately, back to long-term care, including home care.

Perhaps the most significant development has been the considerable expansion of the potential patient population (106). Prolonged mechanical ventilation first became a reality in the midst of the worldwide epidemics of poliomyelitis during the first half of this century. In Europe and the United States, thousands of polio victims who suffered respiratory paralysis were sustained for months or years with “iron lungs” and other early types of ventilators. Individuals who were part of this cohort of patients are distinguished from their successors by their relative good health and their youth at the time mechanical ventilation was instituted. These individuals and events stimulated by their plight, including the virtual eradication of polio in developed countries, continue to stand out as historical examples of medical technology at its best.

Now, however, recipients of mechanical ventilation include patients in their eighties or nineties with multiple life-threatening conditions;

patients whose presumed temporary loss of spontaneous breathing proves to be permanent; patients for whom it is known in advance that spontaneous breathing will never be restored; and patients who are demented, unconscious, or even brain dead. These patients are the source of new ethical and legal issues, intensified economic strains, and heightened public interest.

This chapter examines a variety of issues pertaining to decisions about the use of mechanical ventilation. Because the issues are exaggerated with longer use, the chapter generally focuses on acute ventilation that becomes prolonged or **chronic**. Definition of this concept is, however, problematic. Some authors regard ventilation lasting 48 hours as “prolonged” (e.g., 27,98), while others define prolonged ventilation as that which continues for 1, 3, or even 6 months. According to some authorities, patients who require mechanical ventilation for as long as 2 weeks are essentially the same patients who require it for a month or longer (21). In general, the discussion that follows refers to individuals who have become ventilator dependent and who are unlikely to regain spontaneous respiratory function.

DESCRIPTION OF MECHANICAL VENTILATION

Respiratory Failure: The Need for Mechanical Ventilation

Respiratory failure is a life-threatening condition in which the respiratory apparatus is unable to provide adequate oxygenation (delivery of oxygen to the blood) and/or ventilation [removal of carbon dioxide from the blood]. It is an unstable condition, and if untreated, further deterioration and eventual **respiratory arrest** (i.e., the complete cessation of effective breathing) are more likely than improvement (111). Respiratory failure and arrest can occur in individuals of any age. As a group, however, elderly people are at greater risk because of normal age-related declines in pulmonary function, as well as the higher prevalence of diseases associated with respiratory problems and higher prevalence of comorbidities in general.

Clinical evidence shows that, “with a normal aging process, the bronchopulmonary system should be adequate for about 90 years of contin-

uous functioning” (78). After age 25, however, healthy individuals experience a gradual decline in pulmonary function (72). Normal changes in pulmonary function are due to aging per se; to the cumulative effect of exposure to environmental pollutants; to residual effects of disease and allergies; and to reduced levels of physical activity. Changes may occur in lung volume and in all aspects of respiratory function. Probably the single most significant risk factor affecting healthy individuals is cigarette smoking (121).

Severely impaired respiratory function and eventual respiratory failure may result from airway obstruction, inadequacy of the ventilator muscles, lung disease, or chest injury, as well as from a variety of cardiac, neurological, and neuromuscular disorders. The most common causes—asthma and COPD—are primarily diseases of older people (see box 6-A). In addition, other conditions associated with the risk of respiratory failure, including pneumonia, sepsis, and pulmonary edema,

are more likely to result in respiratory failure when the victim is elderly (111). Diagnoses associated with respiratory failure and subsequent mechanical ventilation in adults are listed in table 6-1.

Box 6-1.—Chronic Obstructive Pulmonary Disease

COPD, also known as chronic obstructive lung disease, designates a group of diseases characterized by chronic airflow limitation, especially during expiration. Asthma, chronic bronchitis, and emphysema, as well as much less common diseases, such as bronchiectasis and cystic fibrosis, are examples. Diseases of the airway are characterized by excessive mucus secretion of the bronchopulmonary tree and chronic inflammatory changes in the nasal passages (in chronic bronchitis) or by structural enlargement of the alveoli and destructive changes in the alveolar walls, resulting in abnormal gas exchange (in emphysema). Chronic, productive cough and difficulty breathing are the main manifestations. COPD is progressive and thought to be irreversible (35). If severe, hypoxemia, cor pulmonale, congestive heart failure, and eventual respiratory arrest can result.

COPD is seldom symptomatic before the age of 35 or 40 (111). An estimated 4 million Americans suffer from some form of the disease (114). In 1984, COPD, bronchitis, and asthma, and pneumonia with pleurisy (International Group (ICD) 48, 49, and 50) were the 10th leading cause of the 10 most frequent ICDs for hospital discharges (14). Closely associated with cigarette smoking and workplace exposures (especially coal mining, asbestos, lead, and silica), emphysema is more common among men than women (35), and it is the fastest growing cause of death in the United States (30).

Treatment of COPD is directed toward reversing the abnormalities of the airway and their effects. Most patients are treated effectively with oxygen, bronchodilators, and other drugs, without resort to mechanical ventilation. As the disease progresses, however, severe ventilatory failure becomes chronic and mechanical ventilation may be the only treatment option.

Changes in pulmonary function associated with normal aging and changes due to disease are interrelated and difficult to distinguish. The confounding of normal and abnormal processes can lead to generalizations about elderly patients and to assumptions about reserve capacity that are incorrect in individual cases.

Table 6-1.—Diagnoses Associated With Risk of Respiratory Failure and Subsequent Mechanical Ventilation in Adults^a

Pulmonary diseases
Chronic obstructive pulmonary disease (COPD)
Asthma
Bronchitis
Emphysema
Chronic restrictive lung disease
Adult respiratory distress syndrome
Interstitial lung disease
Acute bronchial asthma
Pneumonia
Pulmonary edema
Pulmonary embolism
Tuberculosis
Lung cancer
Neuromuscular disorders
Amyotrophic lateral sclerosis (ALS)
Diaphragmatic paralysis
Guillain-Barre syndrome
Myasthenia gravis
Kyphoscoliosis and senile kyphosis
Multiple sclerosis
Muscular dystrophy
Poliomyelitis
Tetanus
Neurological disorders
Cerebrovascular accident (stroke)
Brain trauma
Status epilepticus
Drug overdose, poisoning
Coma resulting from metabolic disorders
Cardiac disorders
Cardiogenic shock
Cardiac arrest
Congestive heart failure
Severe dysrhythmias
Major surgery (with general anesthesia)
injury, trauma
Chest injuries, including trauma during cardiopulmonary resuscitation (CPR)
Spinal cord injuries
Hypothermia
Burns, smoke inhalation
Other
Metastatic cancer
Aspiration

^aDiseases associated with short- as well as long-term Ventilation are included because of the potential for the former to evolve into the latter.

SOURCE: Office of Technology Assessment, 1987.

The Ventilator Apparatus

The mechanical ventilators in use today range from the relatively simple and relatively inexpensive variations of machines developed in the 1920s to the highly complex and expensive state-of-the-art ventilators found in intensive care units (ICUs). The pressure gradient necessary to deliver air or a mixture of air and other gases (especially oxygen) to a patient may be produced either by negative pressure (i.e., below-atmospheric pressure) applied to the chest wall or by positive pressure (i.e., above-atmospheric pressure) applied to the airway. Frequently, ventilators are classified along this dimension.

Negative Pressure Ventilators

The first ventilators to receive wide use for patients requiring long-term ventilator support



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This patient breathes with the aid of a cuirass, the most widely used negative pressure ventilator today.

were negative pressure devices introduced during the epidemics of paralytic poliomyelitis from 1910 to the mid-1950s. Exemplified by the iron lung, these devices were, for the most part, chambers or cabinets in which the patient was placed, from neck to toes, and enabled to breathe by the force of alternating negative and positive pressure. A major problem with these "tank" or "body respirators" is that they render the patient inaccessible for medical and nursing care. Another major problem, recognized only after the technology improved, is that the ventilation provided by negative pressure devices is inadequate for many patients. A 1978 report estimated that only 350 tank respirators remained in use in the United States (126).

Modern negative pressure ventilators reduce the problem of access to the patient posed by the iron lung and are also more portable. The most widely used negative pressure ventilator today is the cuirass (120). This consists of a metal or plastic shell, resembling a shield, that covers the chest and/or abdomen, and that is connected by a flexible hose to a vacuum pump. Negative pressure is intermittently cycled in the space between the shell and the patient's body, causing passive excursion of the diaphragm and expansion of the lower rib cage.

Other negative pressure devices in use today include the Pulmowrap ("poncho"), the pneumobelt, and the rocking bed. The Pulmowrap is a cloth or plastic wrap that operates by the same principal as the cuirass, cycling negative pressure in the space created around the body. The pneumobelt is another wearable device that ventilates mainly the lower lobes of the lungs by its alternate inflation and deflation. The motion of the rocking bed causes passive excursion of the diaphragm and regulates both the volume of the breath and the breathing rate.

Negative pressure ventilators are used primarily in long-term care institutions and home care for medically stable patients who require ventilator assistance less than 24 hours per day. Most of these patients have chronic respiratory *insufficiency* due to neuromuscular disorders, polio, or spinal cord injuries. Negative pressure devices are rarely used in acute care hospitals, but the com-

placations associated with positive pressure ventilation and tracheotomy tubes (see “Outcomes of Mechanical Ventilation,” below) have created renewed interest in negative pressure equipment for some hospitalized patients (44). Also, preliminary reports suggest that nocturnal use of negative pressure ventilators to rest the respiratory muscles is beneficial for some patients (68).

Positive Pressure Ventilators

Positive pressure ventilation has been regarded since the mid-1950s as the superior technique for acutely ill patients and for most stabilized ventilator-dependent patients. Compared with negative pressure devices, positive pressure ventilators offer several advantages. Most important, the volume and delivery rate of the inspiratory gases can be carefully controlled, and receipt of these gases by the patient is rather certain. Thus, the likelihood is greater with positive than with negative pressure devices that a patient will be *optimally* ventilated. In addition, the patient receiving positive pressure ventilation is completely accessible to caregivers.

The functioning of positive pressure ventilators involves the application of above-atmospheric pressure to the patient’s airway. This produces an inspiratory driving pressure. The lung and chest wall provide elastic recoil, creating a driving pressure back up the airway. This same basic process can be accomplished by regulation of pressure, airflow, rate, or volume, and positive pressure ventilators are usually classified according to these parameters, any one of which can be preset to trigger the end of the inspiratory phase. The patient’s specific condition and expected duration of need for mechanical ventilation may indicate one type of ventilator over another (71), but volume ventilators are most often chosen for long-term ventilator support or for complex care (68).

“Hospital ventilators” all resemble the model shown in the photograph on p. 212. The bulk of the apparatus is physically removed from the patient, usually positioned at the bedside. The dials used to set the prescribed volume, rate, breathing pattern, etc., as well as the display of monitored functions are visible and accessible to the patient or the patient’s attendants. State-of-the-art

hospital ventilators are complex, microprocessor-based units that permit continuous measurement of about a dozen patient parameters; the results may be displayed digitally, with lights, on CRT monitors (74), or may even be transmitted by computer modem and telephone lines to a remote central station (21). The monitoring system on most ventilators is tied to an alarm system. Unacceptable levels in monitored functions trigger a visible or audible alarm (74).

In the last decade, new kinds of positive pressure ventilators have been developed specifically for use outside the hospital, where portability, ease of use, and low cost are essential. These “home ventilators” are smaller and lighter than hospital ventilators, but have many of the same capabilities, including a range of volume, pressure, and breathing rates; monitoring of patient pressure and power supply; emergency alarms and standby power. Under the direction of a physician, nurse, or respiratory therapist, home ventilators can be operated by patients themselves, by family members or other nonprofessional caregivers. Some models of positive pressure home ventilators can operate on a 12-volt automobile-type battery, enabling patients to travel by wheelchair, car, or plane. Some patients can walk, carrying or pushing the ventilator on a small wagon. Stationary (or console) ventilators are also used in home care (21).²

Positive pressure ventilation requires a physical link between the ventilator and the patient. This physical link is accomplished by the insertion of flexible, sterile tubing leading from the ventilator into the patient’s airway, through the nose, mouth, or directly into the trachea. To ensure that the patient receives the full prescribed breath and the proper proportion of oxygen, an inflatable balloon cuff at the patient’s end of the tube maybe used to reduce the possibility of leakage.

The method of *incubation* depends initially on the urgency of the situation, expected duration of ventilator support, whether or not the patient is alert, medical details, and available personnel.

²Some physicians limit the use of portable ventilators to 4- to 5-hour periods or to daytime use, recommending the more reliable console machines for nighttime and when caregivers may be less available or less alert to problems (44).



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This patient indicates her tracheotomy, the surgically created opening through which tubing for mechanical ventilation can be inserted.

Each method has distinct characteristics in terms of patient comfort, needed care, and risk of complications.

Unless the need for mechanical ventilation is certain to be prolonged, endotracheal incubation is the preferred technique. In this method, the tube is inserted through the natural opening of the trachea, either through the patient's mouth (i.e., orotracheal incubation) or through the nose (i.e., nasotracheal incubation). Because the duration of ventilation is usually difficult to predict, most patients undergo endotracheal incubation at the start of their treatment. There is some disagreement about how long endotracheal incubation can be maintained, but most sources put the limit at 1 to 2 weeks (112).

Patients requiring ventilator support of longer duration must undergo a surgical procedure

known as a tracheotomy, to produce an opening into the trachea, through the neck. This opening, the **tracheotomy**, allows the insertion of a tracheotomy tube. This method of incubation maximizes patient comfort and facilitates removal of secretions from the airway, via **suctioning (7 I)**. However, tracheotomy is associated with numerous serious complications (see '(Outcomes of Mechanical Ventilation, ' below).

All methods of incubation interrupt important natural functions of the upper airway, including the natural processes of humidification, filtration, and warming of inspired gases, and each interferes with normal cough and gag reflexes. The ventilator support system must compensate for these lost functions. A humidifier is used to prevent dryness of the respiratory mucous membrane. Filters prevent foreign material from reaching the lungs, and heat controls prevent loss of body heat. Because most ventilator patients are unable to cough effectively, suctioning is an important component of care (73).

The ventilation equipment and the patient are literally tied into a common system that must be adjusted to a perfect balance. The patient respiratory drive, whether normal or abnormal, and the rhythm of the ventilator must be synchronized, so that "competition" or "interference" does not detract from the optimal functioning of either. The ventilator's operating **mode** denotes the degree of control the machine has over the patient's breathing. In the mode called "control ventilation," for example, the ventilator provides total support, cycling independently of the patient breathing effort or response. This mode is used for unconscious patients and for those whose spontaneous ventilation is significantly depressed. In the acute care setting, interference from the patient sometimes is managed by the administration of heavy sedatives or paralyzing agents to permit optimal functioning of the ventilator (20).

Safety and Reliability of Ventilation Equipment

Like any mechanical device, ventilators can malfunction or fail. Problems maybe due to the ventilator itself; to other components of the system, especially the tubing, oxygen supply, or power

source; or to human error. Appropriately scheduled and correctly performed maintenance are essential.

Mechanical ventilators are subject to regulation by the Food and Drug Administration (FDA). FDA's Medical Device Reporting regulation, implemented in December 1984, requires manufacturers of medical devices to report any deaths or serious injuries associated with their products. Between December 1984 and March 1987, FDA received approximately 2,800 reports of problems with positive pressure mechanical ventilators (hospital and home models).³ During the same period, FDA also received approximately 700 reports on positive pressure ventilators under the voluntary Medical Device and Laboratory Product Problem Reporting Program (100). Although fault has not been determined in all reported incidents, concern about the safety and reliability of these ventilators is understandable.

FDA has designated positive pressure ventilators for hospital and home use as Class II medical devices (i.e., devices for which general controls are deemed inadequate to ensure safety and efficacy, and for which sufficient information exists or could be developed to establish performance standards). They were among the very few Class II medical devices for which, in 1986, FDA initiated the process of developing a regulatory performance standard (17). However, FDA's invitation for offers to submit or develop a standard (51 FR 11516) brought no acceptable responses, and the agency has since withdrawn plans to develop a regulatory standard. Instead, FDA will attempt to solve the reported problems with ventilator equipment by other, less costly means (17).

Hospital ventilators used in critical care and anesthesia are subject to voluntary standards such as the performance standard developed in 1976 by the American National Standards Institute (5). That standard is currently being revised by the American Society of Testing and Materials. A standard developed by the International Stand-

ards Organization also applies to hospital ventilators (8).

The American Society of Testing and Materials, in response to numerous reported problems with home positive pressure ventilators, is also developing a voluntary performance standard for these devices. (FDA is participating in the process.) In addition, a subcommittee of the American Society of Testing and Materials has been formed to develop standards of *practice* for home ventilation (8).

Because problems with ventilation equipment may be life-threatening, whether in the hospital or elsewhere, a backup power supply (battery or generator) and backup ventilator are usually needed. Emergency equipment for resuscitation is also needed in the event that machine or power failure leads to respiratory arrest. Even in the home, a simple device for resuscitation, usually an ambu-bag (see ch. 5), should be available for

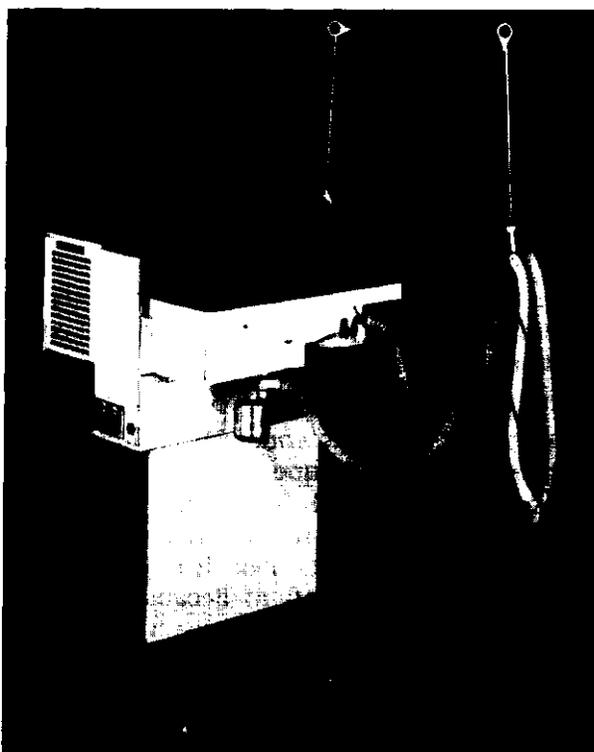


Photo credit: Puritan-Bennett Corp.

The Bennett 7200a is a microprocessor-controlled volume ventilator typical of the positive pressure ventilators used in hospitals today.

³In January 1986, FDA initiated a civil suit against one major manufacturer, whose home ventilators had been linked to 7 deaths, 9 serious injuries, and as many as 663 malfunctions (28). Equipment problems, however, are not unique to any one manufacturer or model (44).

all ventilator-dependent patients. In some communities, power companies, police and fire departments maintain registries of individuals who have life-support equipment in their home, providing an additional measure of safety.

Treatment Settings

Mechanical ventilation is usually initiated in an emergency room or ICU. Many ventilator patients who have been stabilized, however, do not need to remain in an ICU and may not need to remain in the acute care hospital at all. Patients requiring long-term ventilator support have been successfully treated in regular medical units of acute care hospitals, special step-down and rehabilitation units, chronic and rehabilitation hospitals, nursing homes, group homes, and their own homes. The various settings in which mechanical ventilation is provided imply widely different levels of care, cost, and patient responsibility, and they have considerable impact on the patient's quality of life.

Acute Care Hospitals

For patients who are medically unstable or at high risk and for whom aggressive life-sustaining treatment is desirable, the appropriate setting for the provision of mechanical ventilation is the ICU. The sophisticated equipment and skills available in the ICU, and the high staff-to-patient ratio, are needed to provide round-the-clock monitoring and care. In addition to ventilation, nutritional support, and any other treatments that may be necessary can be rapidly initiated and simultaneously managed. However, the ICU is by far the most restrictive and, almost always, the most expensive setting in which mechanical ventilation is provided.

Some ventilator patients remain in acute care hospitals long after they are medically stabilized (2). This situation may be due to the shortage of options in the community, caregivers' lack of awareness of the options, or reimbursement considerations (see below). The inappropriate use of ICU and other acute care beds increases costs, reduces the patient's quality of life, and may create a shortage of ICU beds. Moreover, some observers suggest that physicians and other health

professionals who trained and practice in acute care hospitals lack the experience and special expertise required to provide good quality care to patients who are chronically ventilator dependent (21).

The feasibility of caring for a ventilator-dependent patient outside an acute care hospital depends on factors such as the patient's physiological stability, comorbidity, and mental status; complexity of the prescribed ventilator and regimen; extent of the patient's need for medical attention and nursing care; the patient's prognosis; and minimum acceptable quality of life. Other major considerations are institutional policies; the existence of options in the community; admission criteria and available space in other facilities; distance of alternate facilities from family; the patient's personal financial resources; available reimbursement; and the ability of family members to provide social support.

Nursing Homes and Other Institutional Settings

Historically, very few nursing homes have accepted ventilator-dependent patients or kept patients who became dependent on this technology. The majority of physicians and institutions assumed, as many still do, that safe care of ventilator-dependent persons required staff and technological resources that are neither available nor feasible to provide in a nursing home. In the last few years, interest in containing hospital costs and in reducing length of hospital stay has given impetus to creation of special ventilator units within some skilled nursing facilities (14). Despite this change, however, the number of nursing homes that now care for ventilator-dependent patients is still small (115).

Nursing homes that do accept ventilator-dependent patients may provide long-term placement, transitional placement to permit training and preparation of patients who will eventually return home, and/or short-term respite for family caregivers. one of the first such programs in a nursing home opened in January 1983 at Care **Centers** of Michigan. This program offers comprehensive, long-term care for patients of all ages. Patients are said to enjoy improved quality of life, with

a broader range of rehabilitative services and environmental options, at approximately half the cost of hospital care (25).

Other options for some stabilized patients who remain ventilator dependent are chronic care and rehabilitation hospitals. Nationwide, there are a few hospitals whose major mission is pulmonary rehabilitation. In these special facilities, many patients, including some elderly patients who could not be weaned in acute care hospitals, are successfully weaned from mechanical ventilation, or their dependence is reduced (21).

Demand for skilled nursing and other kinds of long-term care facilities for ventilator-dependent patients appears to exceed availability. In a national survey of hospital discharge planners, the availability of beds and need for complex services including ventilator care was identified as the second most serious barrier to nursing home placement (119). The Goldwater Memorial Hospital in New York City, with a respiratory rehabilitation program for 46 ventilator patients, has a normal waiting list of 50 to 75 ventilator-dependent patients ready to be discharged from acute care hospitals in the New York metropolitan area (21). The Oak Forest Hospital in LaGrange, Illinois, has a 25-bed ventilator ward and a waiting list of 75 (40).

The Patient's Home

Mechanical ventilation at home is a realistic option only for a minority of patients, whatever their age. To date, the number of elderly patients who have been discharged to their own homes on a ventilator is very small. However, home care is an option that deserves consideration because the potential benefits for patients and the potential cost-savings are great. Care within one's own home can provide the highest quality of life and, for some patients whose prognosis is bleak, improved quality of death. In their own homes, patients retain the maximum degree of control over their health care and other aspects of their life. Patients of all ages have made successful adaptations to ventilator dependence at home, and some observers believe the feasibility of home care is underestimated (70,103).

Clearly, however, home care of a ventilator patient is not a decision to be taken lightly. The pa-

tient's readiness to go home and the family's readiness to receive the patient must be carefully assessed; extensive planning and education of both patient and family are necessary. Resources for care outside the hospital must be identified and evaluated. Also prior to discharge from the hospital, reimbursement for home care must be assured. Problems related to financial and social support for families providing home care are severe, whatever the age of the patient. The feasibility of home care for ventilator-dependent patients who are elderly is reduced by the decreased likelihood that they have a spouse or other family members capable of meeting the considerable challenges home ventilator care presents.

Barriers to home ventilator care for patients of all ages include the fact that the equipment and techniques for management of ventilation in the home (and alternate community sites) are relatively new; many physicians are unaware of the home care option; and most medical centers lack the experienced personnel and resources to coordinate the transition from hospital to home. Still, some observers predict that the number of home ventilator patients will increase rapidly (118), and this prediction has led to expressions of concern that the acquisition of necessary skills and the establishment of support networks will not keep pace with the expanded number of patients (51, 66).

Another alternative to institutionalization, with benefits that parallel those of home care, is congregate housing. The goal is to provide residents the relative independence of a private apartment rather than the controlled environment of a bed in a hospital or nursing home. Congregate housing can be designed to provide both personal and medical support services to enhance independence and reduce costs (21).

Linkages Among Treatment Settings

Some ventilator patients are moved back and forth among the various treatment settings. Such moves are often necessitated by changes in the patient's medical condition. Thus, for example, a COPD patient may be weaned from the ventilator, or partially weaned, over and over again, necessitating transfers in and out of an ICU. Or, a

patient who is at home maybe transferred back to the hospital in the event of an acute episode. In other cases, the reasons for moving a patient are strictly non-medical. For example, a patient cared for at home may be moved to a nursing home or hospital because the physical, emotional, and/or financial strain of providing care has become too great for the family.

Continuity of care requires good linkages among the various treatment settings and service providers. To increase the options for ventilator patients they are ready to discharge, many hospitals are developing their own nursing homes or contracting with existing nursing homes for a certain number of beds (12). Hospitals that discharge ventilator-dependent patients to nursing homes or to their own homes must be prepared to provide ongoing and emergency service for these patients. Other necessary community resources for nonhospital care are reliable companies to lease and maintain equipment, registries of nurses, attendants and/or health aides, and financial assistance. Some observers believe that the best way to ensure good care and efficient use of resources is to provide quality-assurance and case-management through a system of regional centers of expertise like those that existed during the polio years⁴ (21).

Caregivers

Ventilator patients in ICUs are in the care of a large and diverse group of highly skilled professionals that typically includes the attending and various consulting physicians, registered nurses, respiratory therapists and technicians, and dietitians. It may also include physical therapists, social workers, and others. The attending physician (who is likely to be a specialist in pulmonary medicine, anesthesiology, or critical care) has primary responsibility for determining whether or not mechanical ventilation is needed and prescribing the specific regimen. Registered nurses, often special-

ists in respiratory care or critical care nursing, have the most contact with the patient. If a decision about withholding or withdrawing treatment is considered, various members of the health care team may participate, along with the patient and/or family members.

For acutely ill, hospitalized ventilator patients, the staff-to-patient ratio is necessarily high. One hospital in Pittsburgh reports that its 16-bed surgical ICU has 7 physicians and 67 registered nurses (48). Staffing patterns vary in different institutions, however, and a more typical case is a 16-patient acute respiratory ward staffed by 2 physicians, 10 registered nurses, 2 practical nurses, 12 nurse aides, and a clerk (21). In the general medical unit of an acute care hospital, the ratio of staff (especially nurses) to patients is sharply reduced and the roles of various personnel are changed. Respiratory and physical therapists often have expanded roles. When weaning from the ventilator and/or discharge from the hospital can be considered, social workers, psychologists, psychiatrists, and rehabilitation experts become increasingly important.

In nursing homes and other institutions that care for stabilized ventilator patients, staffing needs are much simpler, though the needs of individual patients vary greatly. Care may be coordinated by a staff physician and the medical director, who may not be continuously available. This is the pattern at Care Centers of Michigan, where specially trained professional nurses, nurses aides, respiratory therapists, and rehabilitation assistants provide ongoing care. The ventilation unit at the nursing home has 1 professional nurse and 1 respiratory therapist for every 6 patients (24).

In the patient's home, there is substantial reliance on the ability of family members and the patient to provide basic care and to perform routine procedures. Respiratory therapists, nurses, aides, and attendants—under the auspices of hospitals, home care equipment companies, nursing homes, and home health care agencies—can be enlisted to assist the primary caregiver. Home care of ventilator patients raises important questions about the training and supervision of family members and other lay caregivers. Within some centers of expertise, model programs have been developed for patient and family education (39).

⁴Regional centers of expertise were established in this country to provide comprehensive services to polio victims who required ventilator support. As the incidence of polio fell, most of these centers closed. In France and England, comprehensive, government-funded programs currently provide a full range of services, including acute care hospitals, intermediate care facilities and organizations to provide service, equipment, and personnel in the home. These programs provide needed care, care-monitoring and quality-assurance, as well as cost savings via mass purchasing (2, 1,42,43).

UTILIZATION AND COST OF MECHANICAL VENTILATION

Utilization of Mechanical Ventilation

Available data on the utilization of mechanical ventilation are highly inadequate. Health statistics maintained and published by Federal agencies, notably the Health Care Financing Administration (HCFA) and the National Center for Health Statistics (NCHS), include no overall estimates for this technology. Moreover, the coding systems on which Federal data are based would make technology-specific analyses difficult to do and difficult to interpret.

Other potential sources of information regarding the utilization of mechanical ventilation are the manufacturers and the providers of equipment and/or services for home ventilation. A survey of over 50 national organizations concerned with health care, aging, home care, health care financing, or respiratory diseases found that equipment vendors and home health care providers were the only organizations that maintained any information about the utilization or cost of mechanical ventilation (21). Unfortunately, data from private companies are generally regarded as proprietary. In addition, the markets they describe are scattered and overlapping.

Table 6-2 presents estimates of long-term ventilator utilization nationwide, from all available sources. Data from a survey conducted for OTA

^aThere is currently no single DRG for mechanical ventilation but, instead, approximately 30 different DRGs that are sometimes, but not always, associated with this technology. (However, creation of two new DRGs for cases involving mechanical ventilation is proposed in HCFA's 1988 prospective payment classification changes (113).) Thus, one cannot use HCFA's data for Medicare Part A (hospital insurance) to deduce either the number of patients who receive mechanical ventilation or the associated costs. Data on procedures pertinent to mechanical ventilation, e.g., tracheotomy, endotracheal intubation, and continuous positive pressure ventilation, are coded in claims for Medicare Part B (Supplementary Medical Insurance), and these can be extracted from HCFA records. However, such data would yield very misleading estimates of the numbers of ventilator patients because the specificity of procedure codes and HCFA's requirement to code only the principal procedure (with up to two additional surgical procedures) result in a mismatch between the number of patients who have a relevant procedure and those who receive mechanical ventilation. To use the procedure codes for estimating utilization and cost would omit patients who do not have Part B insurance and double-count many who do. Similarly, procedure codes used by NCHS in its regular surveys of hospital discharges would produce a combination of double-counting and undercounting that could not be sorted out.

Table 6.2.—Estimated Utilization of Long-Term Mechanical Ventilation Nationwide

	Total number of patients	Hospital patients	Home care patients	Other patients
AARC	Min. 3,771 ^a incl. 1,236 over age 65	2,379 ^b (63%)	1,279 ^a ^b (34%)	113 ^c (3%)
Mass. Thoracic Soc. & Am. Lung Assoc. of Mass.	6,575 ^c incl. 2,200 over age 70	4,077 (62%)	920 (14%)	1,578 (24%)
Travenol . .	N.A. ^d	N.A.	5,500	N.A.
CBO	N.A.	N.A.	4,000	N.A.
Sivak.	N.A.	N.A.	2,500 to 4,000	N.A.

^aPatients identified in the 37 States responding to AARC survey, as reported by Care for Life (see text for identification of 37 States)

^bIn this study, the estimate of home ventilator patients includes patients in nursing homes, as well as the patient's home.

^cThis is a nationwide projection based on data collected in Massachusetts (see text for discussion)

^dN A = Not available

SOURCES: AARC: AARC survey reported in Care for Life, "Prolonged Mechanical Ventilation," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985. Massachusetts Thoracic Society and American Lung Association: Massachusetts: reported in B. Make, S. Dayno, and P. Gertman, "Prevalence of Chronic Ventilator Dependency," *American Review of Respiratory Diseases*, part 2, April 1986. Travenol: J. L. Retel, Manager of Marketing, Travenol, Deerfield, IL, personal communication, Dec 4, 1985. CBO: Congressional Budget Office, U.S. Congress, Cost estimate for draft legislation regarding Medicare and Medicare coverage for certain ventilator-dependent patients, communicated in letter from R. B. Penner to Senator Robert Packwood, Committee on Finance, Washington, DC, Aug 13, 1984. Sivak: E. O. Sivak, "Long-Term Ventilation: Where Are We Going?" presented at a postgraduate course at Rancho Los Amigos Hospital, Downey, CA, May 1985.

in 1985, under contract to Care for Life (21), are the closest thing available to national primary data on the utilization of long-term mechanical ventilation. The researchers attempted to collect data on all individuals who were receiving mechanical ventilation during a specified week and who had been ventilator dependent for more than 14 days. Data were obtained for 37 States, by their respective representatives to the American Association for Respiratory Care (AARC).⁷ A total of 3,771 long-term ventilator patients of all ages were found in these States. About one-third (1,236) of these individuals were over the age of 65. Based

⁷The 37 States providing data were: Alabama, Arizona, Arkansas, California, Connecticut, Florida, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Maryland/DC, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

⁸Prior to 1985, the name of this organization was American Association for Respiratory Therapy (AART).

on the combined elderly populations of the responding States, the researchers estimated that nationally the prevalence of ventilator dependency in the elderly is approximately 5.3 per 100,000 elderly persons. (However, regional differences were also noted.)

Illustrative statewide data on ventilator use come from a 1983 study conducted by the Massachusetts Thoracic Society and the American Lung Association of Massachusetts. Surveying all institutions serving ventilator-dependent patients in Massachusetts, the researchers estimated that a total of 162 persons in the State required positive pressure ventilation for 3 weeks or longer. This is equivalent to a statewide prevalence rate of 2.8 ventilator-dependent persons of all ages per 100,000 population. Approximately one-third of the 162 ventilator-dependent patients were under age 54, one-third were age 54 to 69, and one-third were age 70 or older. If the same total rate and age distribution were assumed to exist nationwide, there would be approximately 6,575 ventilator-dependent persons in the United States (69), including approximately 2,200 persons over age 70.

Estimates from other sources suggest that the utilization of long-term ventilation may be much higher. Travenol Laboratories told OTA, based on experience of its home respiratory program for the first part of 1985, that there were approximately 5,500 ventilator users, of all ages, nationwide in *nonhospital settings alone* (i.e., nursing homes, group homes, and patients' homes) (93). (The apparent discrepancy between the AARC survey and Travenol's data is at least partially explained by the fact that Travenol's data depict utilization over a longer data collection period.) Similarly, the Congressional Budget Office (CBO) estimated that in 1984 there were approximately 4,000 Americans of all ages at home on ventilators (118). CBO'S estimate is not inconsistent with an independent estimate that there are between 2,500 and 4,000 ventilator-dependent persons at home nationwide (101).

In interpreting data on the utilization of mechanical ventilation, it is important to recognize the distinction between incidence data (i.e., data related to the frequency of *new* cases in a defined population in a specified time period), and prevalence data (i.e., data related to the number of cases

existing in a defined population at a given time). Each of the figures reported in table 6-2 describes the prevalence of ventilator use at the time the data were collected. Patients who recovered or died previous to the data collection and those who required ventilator support subsequent to that time are not counted. In other words, the number of patients and other persons affected are considerably higher than these data suggest.

One point on which all available sources of data agree is that utilization rates are higher for elderly people than for the population as a whole. Since the prevalence of most conditions leading to respiratory failure increases with age, this is what one would expect.

Estimates of the proportion of ventilator-dependent patients who are elderly and in various treatment settings are shown in table 6-3. Although the figures are incomplete, they suggest that elderly individuals constitute a very large share (43 percent) of all patients who are ventilated long-term in hospitals and a smaller proportion of patients in nonhospital settings. For home care, estimates of the proportion of patients who are over 65 range from 17 to 33 percent. The high estimate is based on CBO'S report that one-third of all home ventilator patients were eligible for Medicare (118). The intermediate estimate that 27 percent of home ventilator patients are 65 or older is from Travenol (93). The low estimate is from the 37-State survey reported by Care for Life (21). Only 17 percent (220) of all non-hospitalized ventilator patients in that survey were age 65 or older (see table 6-4).

Table 6-3.—Estimated Percentage of Ventilator Patients Who Are Elderly, by Setting

	Hospital	Nursing home	Home
AARC	43%	N.A. ^a	17% ^a
Travenol	N.A. ^b	N.A.	27% ^c
CBO	N.A.	N.A.	33% ^c

^aIn this study the estimate of home ventilator patients includes patients in nursing homes, as well as the patient's home.

^bN.A. = Not available.

SOURCES: AARC: AARC survey reported in Care for Life, "Prolonged Mechanical Ventilation," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985. Travenol: J.L. Retel, Manager of Marketing, Travenol, Deerfield, IL, personal communication, Dec. 4, 1985. CBO: Congressional Budget Office, U.S. Congress, Cost estimate for draft legislation regarding Medicare and Medicare coverage for certain ventilator-dependent patients, communicated in letter from R.B. Penner to Senator Robert Packwood, Committee on Finance, Washington, DC, Aug. 13, 1984.

Table 6-4.—Distribution of Long-Term Ventilator Patients by Age and Setting for 37 States^a

Age	Hospital		Home		Other setting		All settings combined
	Number	Percent	Number	Percent	Number	Percent	
Under 18	445	19%	245	19%	N.A.	^b N.A.	690
18 to 64	916	38	787	62	N.A.	N.A.	1,703
65 and older	1,016	43	220	17	N.A.	N.A.	1,236
Age not determined	2	0	27	2	113	100%	142
All ages combined	2,379	100%	1,279	100%	113	100%	3,771

^aAlabama, Arizona, Arkansas, California, Connecticut, Florida, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Maryland/DC, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

^bN.A. = Not available.

SOURCE: AARC survey in 37 States, reported in Care for Life, "Prolonged Mechanical Ventilation," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985

Table 6-4 provides more detail about treatment settings for ventilator patients of different ages. While these data describe patients in only 37 States, and the age breaks are crude, they are the most complete available data of this type. The figures clearly show that, in contrast to children under age 18 and adults ages 18 to 64, more older persons receive mechanical ventilation and more of them are treated in hospitals.

Indicators of the duration of mechanical ventilation come from a survey of institutions and two case studies conducted for OTA by Care for Life (21). Eleven hospitals across the United States and Canada⁸ supplied data for all current elderly patients who had been treated with mechanical ventilation for at least 14 days and for at least 4 hours per day. Almost one-third of the elderly patients in those institutions had been ventilated for more than 6 months, and most of those had been ventilated for more than a year. Case studies of ventilator-dependent patients in hospitals, nursing homes, and rehabilitation institutes in Chicago and in New York City found, similarly, that between 25 and 40 percent of the elderly patients who required mechanical ventilation for at least 2 weeks needed treatment for 6 months or longer. In New York, one-third of the patients had been ventilated for 21 to 30 days and 20 percent for 30 to 90 days.

⁸The institutions surveyed were: Boston University Hospital (Boston, MA); Gaylord Hospital (Wallingford, CT); Meriden-Wallingford Hospital (Wallingford, CT); Goldwater Memorial Hospital (New York, NY); Bethesda Lutheran Hospital (Minneapolis, MN); Rancho Los Amigos (Downey, CA); Creighton University Hospital (Omaha, NE); Texas Institute for Research and Rehabilitation (Houston, TX); Emory University Hospital (Atlanta, GA); University of Wisconsin Hospital (Madison, WI); and St. Michael's Hospital (Toronto, Ontario).

Cost of Mechanical Ventilation

Information about the cost of maintaining a patient on a ventilator comes mostly from the reports of individual hospitals and other providers describing cost experience for the patients they serve. The dissimilar requirements of different patients, the nonrepresentative samples, and other methodological problems account for considerable variation in reported costs. For all these reasons, generalizations about cost and comparisons of alternate cost estimates must be made very cautiously.

There is considerable confusion in the literature regarding how to define the cost of mechanical ventilation and, especially, whose *costs* are at issue. Distinctions are seldom made among "costs," "expenditures," and "charges," i.e., costs incurred by the hospital or other provider, paid by the insurer or patient, and billed by the provider. Many studies label as "cost" whatever dollar figures were available.

For hospitalized patients, the cost of mechanical ventilation may be defined narrowly as the costs specifically associated with ventilator care, or it may be defined broadly to include other costs associated with treatment (notably, the hospital daily rate). Similarly, for home care patients, cost may be defined narrowly as only the costs for ventilation equipment and professional services, or it may be defined to include costs of supportive equipment and services (e.g., backup equipment, wheelchairs, architectural modifications, and the services of attendants, drivers, and housekeepers). Lost income or productivity of the ventilator patient or, more likely in the case of elderly patients,

family caregivers, has not been computed in any published cost estimates, but this is often a significant component of the family's cost experience.

Charges for Mechanical Ventilation in the Hospital

A 1983 survey by the AARC (2) found the average annual hospital charge for a ventilator-dependent patient (based on the mean daily hospital charge for respiratory plus nonrespiratory care) to be \$270,830 (equivalent to \$22,569 per month or \$742 per day). Data from the AARC's 1985 survey reported by Care for Life (21) indicate that the average annual hospital charge had risen 11 percent to \$300,760 (equivalent to \$25,063 per month or \$853 per day). As shown in table 6-5, published monthly hospital charges ranged from \$12,300 in 1975 to \$32,800 in 1982. In the surgical ICU of Pittsburgh's Presbyterian-University Hospital, the charges for critically ill ventilator patients currently exceed \$2,000 per day (48). This includes all care in the surgical ICU except fees charged by private physicians.

In addition to the major costs associated with high staff-to-patient ratios and inpatient care in general, hospital charges reflect the high capital costs associated with mechanical ventilation. The most popular ventilators in the hospital market ranged in price, in 1984, from approximately \$15,000 to \$18,000 per unit (13). Expensive accessories needed to provide mechanical ventila-

tion in the hospital include oxygen delivery systems and concentrators, blood gas monitors, and pulmonary analysis equipment.

Charges for Mechanical Ventilation in the Patient's Home

Presumed economy is one of the main reasons for current interest in home ventilator care; however, there is considerable variation and disagreement regarding home care charges. AARC's 1985 data indicate that charges for home ventilator care averaged \$1,853 per month (\$22,236 per patient per year) (21). Other investigators have reported monthly bills for home ventilation as low as \$350 per month (for a patient requiring a ventilator only at night) (34) to over \$16,000 per month (for patients requiring continuous ventilation, oxygen, and round-the-clock care by registered nurses) (108). Costs tend to be highest when the patient is first sent home, particularly if equipment is purchased.

Whether home care for ventilator patients is more economical than care in the hospital or nursing home, and the magnitude of potential savings, depends on characteristics of the particular case. The type of ventilator required, whether the equipment is purchased or rented, the amount of oxygen required, and method of oxygen delivery are key factors. Most important is the ability of the patient or family members to provide care versus the need for professional nursing services.

Table 6-5.—Reported Monthly Charges for Hospitalized Ventilator Patients

	Date	Location	No. of patients	Patient's ages	Charges ^a
Davis, et al.,	,1975 -76	St. Louis, MO	100	Avg. 67	\$12,300
Sivak, et al.	,1978	Cleveland, OH	N.A. ^b	N.A.	\$15,600
Feldman & Tuteur	,1981	St. Louis, MO	2	Avg. 57	\$17,500
Splaingard, et al.	,1982	Houston, TX	N.A.	N.A.	\$15,000
Banaszak, et al.	,N.A.	Milwaukee, WI	2	Avg. 61	\$15,469
Giovannoni	,1982	Madison, WI	5	N.A.	\$32,800
AARC	,1985	37 States	3,771	All	\$25,063

^aReported charges are not adjusted for inflation

^bN A = Not available.

- SOURCES: 1. I.D. Davis, III, S.S. Lefrak, D. Miller, et al., "Prolonged Mechanically Assisted Ventilation: An Analysis of Outcome and Charges," *Journal of the American Medical Association* **243(1):43-45**, 1960.
 2. E.D. Sivak, E.M. Cordasco, W.T. Gipson, et al., "Clinical Considerations in the Implementation of Home Care Ventilation Observations in 24 Patients," *Cleveland Clinic Quarterly* **50:219-225**, summer 1983.
 3. J. Feldman, and P.G. Tuteur, "Mechanical Ventilation: From Hospital Intensive Care to Home," *Heart and Lung* **11(2):162-165**, 1982.
 4. M.L. Splaingard, R.C. Frates, Jr., G.M. Harrison, et al., "Home Positive Pressure Ventilation: Twenty Years Experience," *Chest* **84:376-382**, 1983.
 5. E.F. Banaszak, H. Travers, M. Frazier, et al., "Home Ventilator Care," *Respiratory Care* **26(12):1262-1268**, 1961.
 6. R. Giovannoni, "Chronic Ventilator Care: From Hospital to Home," *Respiratory Therapy* **14:29-33**, 1964.
 7. AARC survey in 37 States, reported in Care for Life, "Prolonged Mechanical Ventilation," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985.

The total cost of initial purchases necessary for a home ventilator program, in 1984, has been estimated to range from \$8,000 to \$15,000 (41,77). Prices for popular home ventilators in 1985 were between \$5,000 and \$7,000. Patient circuits, hoses, valves, filters, and other needed accessories ranged in price from about \$5 for a 4-inch tapered flextube to \$650 for a humidifier (64). Other essential supplies, such as sterilizing agents, sold for \$1.25 to \$9.00 per month (79). Home ventilator patients usually must keep on hand at least a 1-month inventory of essential supplies and spare parts for their equipment (68). When equipment is rented, charges for equipment and disposable supplies range from about \$825 to almost \$3)600 per month, averaging \$1,500 (93).

Another major expense for home ventilator patients is for extra equipment—needed as backup in the event of equipment failure; for portability; and to provide the different kinds of ventilator support that may be needed in different circumstances (55,86). For the estimated 2,500 home respiratory patients in the United States in 1978, there were approximately 5,000 pieces of equipment in use (126). The equipment needs of one home ventilator patient are illustrated by the following comment:

In 1949, when a sophomore in high school, I was completely paralyzed from polio and placed in an iron lung. . . . Now . . . I use, during a 24-hour period, a rocking bed and a pneumobelt powered by a Bantam portable respirator for sitting in a wheelchair. When in bed but not rocking, I use a Zephyr positive pressure blower, complete with cascade, via long hose and mouthpiece. In addition, I use emergency and maintenance frog breathing and have an extra Bantam portable for traveling (125).

For home care patients, charges for regular maintenance and repair of ventilation equipment may also be significant. For rented equipment, the

“Frog” or glossopharyngeal breathing is a substitute method of breathing that can produce adequate ventilation for short periods, even when there is total paralysis of the respiratory muscles. It uses the tongue and pharyngeal muscles to force air by repeated swallowing into the trachea and lungs. The muscles of the tongue, soft palate, fauces, pharynx, and larynx must be functional, and considerable instruction and practice are needed to learn this technique. Frog breathing may be used for emergencies, transference, chest stretching and coughing, and to permit time off the ventilator (63).

cost of maintenance and repair is included in the monthly rental rate, and service is the responsibility of the vendor. For purchased equipment in the home, patients are responsible for repair and maintenance, which can amount to anywhere from \$1,500 to \$2)500 per year (93). Some patients who use negative pressure ventilators, or their caregivers, can perform maintenance and repairs themselves, finding that “the average [negative pressure] home respirator is no more complicated than a washing machine” (26). With positive pressure ventilators, however, especially as those manufactured for home use have become increasingly sophisticated (44), self-maintenance is usually not feasible (102).

Securing and paying for proper equipment maintenance are significant problems for some home ventilator patients. Reimbursement provisions (under Medicare and private insurance) generally do not consider required maintenance, some durable medical equipment dealers are not trained to service the devices they distribute, and most repairs and recalls necessitate sending the ventilator to the manufacturer in order to maintain the warranty and prevent liability (44).

Reimbursement for Mechanical Ventilation

Reimbursement for Hospital Care

Under Medicare’s Part A prospective payment system (see ch. 2), Medicare pays hospitals a fixed amount that depends on the patient’s DRG, rather than on the number or type of services he or she receives. Since approximately 30 DRGs are potentially associated with mechanical ventilation, and the patient may or may not qualify as an “outliner,” Medicare payments for ventilator patients vary widely. Often, hospital costs substantially exceed Medicare’s payment for patients requiring long-term mechanical ventilation (127). This is particularly likely if the hospital stay is very long or if treatment includes a long stay in the ICU (18). Medicare will not reimburse hospitals for “administratively necessary days” (i.e., days during which inpatient care is no longer necessary but lower level care is not immediately available) unless the patient is already an outlier based on length of stay (53).

At the same time, elderly patients who require prolonged mechanical ventilation may exhaust their Medicare hospital benefits for a given episode, and they may exhaust their lifetime benefits as well. Moreover, a patient's personal obligation toward the cost of care (a deductible per admission, a portion of the daily rate for days 61 through 90, and a portion of the daily rate for each day of the 60 day maximum lifetime benefit) may exceed his or her personal or family resources. For some ventilator patients, total bills are lower at home than they would be in the hospital, but the patient's out-of-pocket expenses may remain very high and, indeed, may be higher than the unreimbursed components of hospital care. Elderly patients who deplete their personal resources or whose income is below specified limits may qualify for benefits simultaneously from Medicare and Medicaid. Medicare policy allows hospitals to bill other payers, including Medicaid, for services Medicare does not cover."¹⁰

CBO (117) estimated that in fiscal year 1985, combined Federal and State Medicaid expenditures for a hospitalized ventilator-dependent patient (of unspecified age) averaged \$98,000 per year (equivalent to \$8,167 per month or \$268 per day), not including additional payments for physician charges (118).

Reimbursement for Nursing Home **Care**

Medicare coverage in skilled nursing facilities, for patients who qualify, is limited to 100 days. Individual nursing homes have tried, so far unsuccessfully, to workout special agreements with Medicare for more flexible reimbursement for ventilator-dependent patients (24).

Some ventilator-dependent patients require "subacute" care (i.e., care that is less intense than that provided in a hospital but more intense than that typically provided in a nursing home). Medicare and Federal Medicaid legislation do not provide subacute care benefits, however, approxi-

¹⁰For patients who are eligible for both Medicare and Medicaid, some hospitals have sought payment for "administratively necessary days" from Medicaid, under Medicaid provisions for subacute care. In most States, these attempts have been unsuccessful, but they illustrate the confusion regarding responsibility for payment (53).

mately one-third of States' Medicaid programs now include provisions to address these higher costs. Under Wisconsin's "Skilled Care Reimbursement Supplement" and Illinois' "Exceptional Nursing Care" provision, for example, ventilator-dependent patients in those States are now eligible for supplemental Medicaid funds. In both, because the number of patients applying for these benefits is still very small, the rates have been negotiated by nursing homes on an individual basis (40). Some States, California for example, have provisions for extra skilled care based on preset rates (53). Some observers are concerned that even when this reimbursement is available, the rates maybe too low to permit adequate staffing and quality of care (44).

Reimbursement for Home Care

Third-party reimbursement for respiratory care in the home is partial and undependable. Medicare and major for-profit health insurance companies have approved reimbursement in individual cases, (89) but the patient's out-of-pocket expenses often remain high.

Many chronic ventilator-dependent patients qualify for Medicaid, but the regular Medicaid programs of most States cover few of the expensive services (e.g., daily nursing) many of these patients need. The home and community-based waiver gives States the option to offer (but most do not) some special services to subgroups of their Medicaid patients, including ventilator-dependent patients. Under the waiver, Medicaid will cover care in the home so long as the average per capita expenditure does not exceed that for institutional care (92).

The 1985 Consolidated Omnibus Budget Reconciliation Act (COBRA, Sec. 9504) made respiratory care services for ventilator-dependent individuals an option that States can offer under their regular Medicaid programs. States can choose to extend this coverage to those patients who require mechanical ventilation at least 6 hours per day, were ventilated at least 30 consecutive days in a hospital or other institution, would need to remain institutionalized if home respiratory care were not reimbursed and would have been eligible for Medicaid inpatient benefits, want to go

home, and have adequate social support services to do so. ”

Under the provisions of Medicare Part B (Supplementary Medical Insurance), durable medical equipment (DME) is covered in the home when it is supplied directly by a DME vendor. Medicare pays 80 percent of reasonable charges, and the remaining 20 percent is the patient’s responsibility. Prior to changes in Medicare regulations that

“There had been several earlier proposals in Congress to extend respiratory care services to the home. The “ventilator bills” proposed in 1985 (H.R. 2703 and S. 1249) would have provided mandatory coverage under both Medicaid and Medicare. Supporters of these bills projected annual savings of \$20 million to Medicaid and no increase to Medicare (3). In contrast, CBO estimated that these provisions would be cost neutral for Medicaid but add \$18 million to Medicare costs in fiscal year 1986, largely due to the projected number of new elderly patients (17).

went into effect in February 1985, almost all durable medical equipment for mechanical ventilation was rented. Medicare currently requires purchase of all items costing less than \$120 and provides a purchase option for more expensive equipment whose expected rental cost over time would exceed the purchase price.

Effect of Reimbursement on Choice of Treatment Setting

For at least some ventilator patients, the availability or lack of reimbursement is a major influence on the choice of treatment setting. At times, the setting whose use is encouraged by reimbursement policy is not the most economical or the least restrictive. According to a representative of AARC,



Photo credit: Foster Medical Corp

Some elderly patients make successful adjustment to chronic ventilator dependence. Supportive family members and caregivers are essential.

“there are literally hundreds of people—young and old—around the nation who are needlessly confined to their hospital beds by current reimbursement policy” (2). Based on their 1985 survey, AARC reports that 34 percent (813) of all hospitalized chronic ventilator patients identified in 37 States, including 349 ventilator patients over age 65, would have been able to leave the hospital if reimbursement had been available for ventilator support in the home (21). In addition, some home ventilator patients have had to return to the hospital in order to reduce their out-of-pocket costs (21). The hospitalization of ventilator patients who could be safely cared for at home, AARC argues, not only subjects patients to unnecessary institutionalization, but also wastes up to \$278,524 per patient per year, much of which is taxpayers’ money.

The availability and level of reimbursement also affects health care institutions’ capacity to provide care. Hospitals facing high unrecoverable costs under Medicare’s prospective payment system have strong incentives to limit access to ICUs, to discharge patients earlier, or to transfer patients to other facilities. Some observers fear that community, acute care hospitals will no longer be willing or able to care for Medicare patients who require prolonged mechanical ventilation (127). Also,

¹²This figure represents the difference between annual hospital charges (\$300,760) and annual home care charges (\$22,236). Although this calculation probably overstates the potential savings to payers by assuming that hospital charges are fully reimbursed, the potential savings do appear to be substantial (21).

OUTCOMES OF MECHANICAL VENTILATION

The outcomes of mechanical ventilation reflect the wide variability in patients’ physiological reserve, mental capacity, social resources, and will. Across and within each age group, patients’ life expectancy and ability to cope with this technology vary greatly and often cannot be predicted. The following cases illustrate the extremes of patients and outcomes:

senator Jacob Javits was told he had amyotrophic lateral sclerosis (ALS) in 1979, at age 75. Within 2 years, the progressive muscle weakness had confined the avid tennis player to a wheel-

acute care hospitals’ incentives to discharge patients earlier increase the pressure on other kinds of facilities to admit them. Currently, available reimbursement for nursing homes provides only limited incentive to develop facilities for ventilator-dependent patients (115).

In States where Medicaid reimbursement is available, nursing home care is now a real alternative for ventilator-dependent patients. In some cases, however, this development has unwanted results. In at least one case in Illinois, a family was forced to move a ventilator-dependent child from home to a nursing home in order to reduce the cost to Medicaid (44).

CBO estimated that if coverage for respiratory therapy were available in the home, an additional 200 elderly COPD patients would be discharged home with a ventilator each year (117). Some observers caution that extending coverage for home care would give impetus to the use of mechanical ventilation for new categories of patients and could lead to a repeat of the “Pandora’s box” phenomenon exemplified by Medicare’s End-Stage Renal Disease program (see ch. 7). Those who dismiss this warning argue that no change in reimbursement will change the medical indications for home mechanical ventilation. Moreover, the American College of Chest Physicians’ clinical guidelines for home care indicate that most COPD patients, because of the complex medical management they require, are unlikely candidates for long-term mechanical ventilation at home (44,86,102).

chair; then an episode of pneumonia and respiratory failure necessitated a tracheostomy for the initiation of mechanical ventilation. Thanks to excellent health care, a supportive family, and a portable ventilator, he was able to return to his own home. For 2 years, he maintained a busy teaching and lecturing schedule,¹³ then returned to an active private law practice, making frequent trips around the country and numerous public appear-

¹³Unlike victims of the more serious (i.e., bulbar) form of ALS, which attacks the muscles responsible for swallowing, speech, and breathing, Senator Javits retained his ability to speak (54).

ances. Despite his physical deterioration, his intellect and his will to live were undiminished. Near total paralysis necessitated round-the-clock nursing and assistance in virtually all physical activities. Still, he remained energetic and outspoken, trying to set an example for less fortunate patients and advocating more funding for medical research. Until his death at age 81, Senator Jacob Javits continued to serve as an effective public citizen, claiming he was "too busy to despair" (54).

A 72-year-old man with multiple myeloma and prostate cancer suffered a cardiac arrest while at his local bank. Cardiopulmonary resuscitation (CPR) was not begun until the rescue squad arrived some 10 to 15 minutes later. Finding no pulse or respirations, they provided CPR during the 8-minute ambulance ride back to the nearest hospital. In the emergency room, he was pulseless and apneic. Resuscitation was nevertheless successful, and he was transferred to the coronary care unit. There he was maintained on mechanical ventilation. He appeared to have severe anoxic brain damage, and exhibited no spontaneous neurological activity over the next 24 hours. On the 10th day, the family came forward with the request that he receive maximal support. Although the medical support team believed it was not appropriate, maximal support was started at the family's insistence. During the patient's subsequent rocky course, he never showed signs of cortical functioning. He died in the eighth week of hospitalization (109).

Because most causes of respiratory failure are either short-term and treatable or have a rapidly terminal course (7), most reports in the literature measure the outcomes of mechanical ventilation in the general terms of survival or, conversely, mortality. Few reports differentiate survival with successful weaning from survival with chronic ventilator dependence. The studies that have examined age-related differences in survival are few, and the studies that have focused on the social and psychological impact of prolonged mechanical ventilation describe, for the most part, younger patients or exceptional elderly patients who can return to their own homes. Prospective, randomized, controlled studies to test the outcomes of mechanical ventilation have not been performed, nor would they be ethically feasible (21).

Clinical Outcomes of Mechanical Ventilation

Survival of Respiratory Failure

There are serious problems in comparing survival data from available studies. None of the reported studies is based on a representative sample of ventilator patients, much less a representative sample of elderly ventilator patients. Rather, each of the available studies was conducted at a single hospital, with a unique patient population, resources, criteria for admission to the ICU, and criteria for instituting mechanical ventilation. Patients in different hospital studies may not have started with equal chances of survival.

In addition, methodological differences, such as how "survival" is defined, abound. Studies that measure survival of ventilator patients only in the short term (e.g., survival of the ventilation episode or survival until hospital discharge) probably overestimate the benefits of mechanical ventilation. On the other hand, the benefits of this technology may be underestimated if one attributes all mortality of ventilated patients to the ventilator. A mechanical ventilator cannot be expected to protect a patient from myocardial infarction or any of the numerous other dangerous conditions that threaten all critically ill patients and many healthy elderly individuals. Furthermore, mortality sometimes results from instituting mechanical ventilation too late (83).

OTA's review of the literature from 1973 to 1985 found eight clinical studies that examined survival rates among patients receiving mechanical ventilation in acute care hospitals. Despite problems of comparability and some dissimilar results, the available studies reveal a general consistency—i.e., mortality among critically ill ventilator patients is high, and it increases with increasing age. As shown in table 6-6, the five studies that reported survival rates for patients in ICUs, found survival rates ranging from 36 to 89 percent, with an average of 63 percent. In five of the six studies that reported survival of critically ill ventilator patients to hospital discharge, the survival rates were even lower, averaging 55 percent. In the months following hospital discharge, survival rates dropped even further.

Table 6-6.—Survival Rates for Patients Receiving Mechanical Ventilation in Acute Care Hospitals, All Ages

Study	date	Number of patients	Patients' ages	Minimum ventilation	Survival rate		
					In ICU	To hospital discharge	1 Year
Nunn, et al.	1970-74	100	0 to 75+	4 hr.	670/o	47 % ^a	N. A.=
Pierson, et al.	1971-72	113	70 to 95	1 hr	N.A.	51 %	N.A.
Petheram & Branthwaite	1972-77	91	3 to 75	N.A.	N.A.	54%	380/o
Zwillich, et al.	1972-73	314	15 to 95	1 hr.	640/o	N.A.	N.A.
Davis, et al.	1975-76	104	Mean 68.7	48 hr.	N.A.	44%	37%
Schmidt, et al.	1976-77	137	N.A.	48 hr.	360/o	N.A.	300/0
Witek, et al.	1980	100	17 to 70+	N.A.	600/0	50 % ^a	330/0
McLean, et al.	1982-83	1,010	14 to 95	N.A.	890/o	820/o	N.A.

^aN.A. = Not available.

SOURCES: 1. J.F. Nunn, J.S. Milledge, and J. Singaraya, "Survival of Patients Ventilated in an Intensive Therapy Unit," *British Medical Journal* 1(6177): 1525.1527, June 9, 1979.

2. D.J. Pierson, T.A. Neff, and T.L. Petty, "Ventilatory Management of the Elderly," *Geriatrics* 26(1 1): 66-95, 1973.

3. I.S. Petheram and M.A. Branthwaite, "Mechanical Ventilation for Pulmonary Disease." *Anesthesia* 35:467-473, 1980.

4. C.W. Zwillich, D.J. Pierson, C.E. Creagh, et al., "Complications of Assisted" Ventilation: A Prospective Study of 354 Consecutive Episodes," *American Journal of Medicine* 57:161-170, 1974.

5. H.D. Davis, III, S.S. Lefrak, D. Miller, et al., "Prolonged Mechanically Assisted Ventilation: An Analysis of Outcome and Charges," *Journal of the American Medical Association* 243(1):43-45, 1980.

6. C.D. Schmidt, C.G. Elliott, D. Carmelli, et al., "Prolonged Mechanical Ventilation for Respiratory Failure: A Cost-Benefit Analysis," *Critical Care Medicine* 11(6):407-411, 1983.

7. T.J. Witek, Jr., E.N. Schachter, N.L. Dean, et al., "Mechanically Assisted Ventilation in a Community Hospital: Immediate Outcome, Hospital Charges, and Follow-up of Patients," *Annals of Internal Medicine* 145:235-239, 1985.

8. R.F. McLean, J.D. McIntosh, G.Y. Kung, et al., "Outcome of Respiratory Intensive Care for the Elderly," *Critical Care Medicine* 13(8):625-629, 1985, © by Williams & Wilkins, 1985.

Published studies from Denver (85,87,88,129); Philadelphia (95); Toronto (75); and London (83) have consistently reported that mortality is highest for ventilator patients who are elderly. While noting that advanced age is an important predictor of survival, however, almost every author is quick to point out that age alone is not a good predictor. Other factors that bear on survival include primary disease process (21,81,98)128); number of failed systems (27,59); time to reversal of organ failure (21); and specific physiological values (98).

OTA found only two studies that specifically examined survival among *elderly* patients receiving mechanical ventilation in the hospital. The first study, by Pierson and colleagues (88), followed all 113 patients over age 70 who were treated with mechanical ventilation at either of two Denver hospitals between January 1971 and December 1972. The investigators found that survival to hospital discharge—51 percent overall—declined with increased patient age, but that differences among subgroups of elderly patients (i.e., 70 to 74, 75 to 79, and 80 to 95) were not statistically significant. The researchers concluded:

These data do not support the contention that mechanical ventilation in the elderly is inappropriate or usually unsuccessful. On the contrary, they

suggest that the potential gains from such treatment may be as great in this age group as in any other . . . (88).

The second study of elderly ventilator patients, by McLean and colleagues, was conducted in the respiratory ICU (RICU) of St. Michael's Hospital, an affiliate of the University of Toronto (75). Results of this study are displayed in tables 6-6 and 6-7. The first observation is that survival rates for each age group in this study are high relative to the survival rates in the other studies summarized in table 6-6. (This is explained by the RICU's pol-

Table 6-7.—Survival Rates for Patients Receiving Mechanical Ventilation in the St. Michael's Hospital Respiratory Intensive Care Unit, by Age

Age	Number of admissions ^a	Survival rate	
		To ICU discharge	To hospital discharge
14-19	4	1000/0	75% ^a
20-34	50	94	88
35-44	102	93	91
45-54	213	95	92
55-64	377	91	86
65-74	213	80	69
75-95	54	76	54
Total	1,013	890/o	82%

^aThere were eight repeat admissions and five patients of unknown age among 1,010 patients.

SOURCE: Adapted from R.F. McLean, J.D. McIntosh, G.Y. Kung, et al., "Outcome of Respiratory Intensive Care for the Elderly," *Critical Care Medicine* 13(8):625-629, 1985, © by Williams & Wilkins, 1985.

icy to admit only those patients with cardiorespiratory failure due to "potentially reversible causes"). Equally clear from the figures in table 6-7 is the decline in survival rates with increasing patient age. The researchers attributed this in part to the fact that more of the younger patients were in the RICU following elective cardiovascular surgery (19). Survival rates were significantly lower for patients over age 75 than for younger patients. However, no difference was found in survival rates between subgroups of patients 65 to 74 versus 75 and older. On followup of the St. Michael's patients conducted between 12 and 24 months after hospitalization, 18 of the 49 patients over age 75 were alive, and 14 of them were living in their own homes. The researchers concluded that some elderly patients can benefit from mechanical ventilation and that a patient's age alone does not have good prognostic value.

Chronic Ventilator Dependence

For many patients, especially those with chronic or degenerative diseases (e.g., muscular dystrophy, spinal cord injury or disease), medical stability with chronic ventilator dependence is the best realistic outcome. For others, chronic ventilator dependence is an unexpected, devastating outcome. For individual patients with irreversible disease processes, "failure to wean" is often impossible to predict prior to instituting mechanical ventilation (21). Some observers regard inability to wean as a "feared but rare complication" (34).

Although the risk of failure to wean is probably greatest for patients with conditions associated with advanced age (e.g., COPD), the patient's age is not the critical factor. Experience with 355 ventilator-dependent patients treated between 1980 and 1985 at the Prolonged Respiratory Care Unit of Minneapolis' Bethesda Lutheran Medical Center led investigators there to conclude that "age is not a deterrent to attempting the weaning process" (21). Difficult weaning and failure to wean are associated with a variety of factors that originate either in the patient, the ventilator system, or the artificial airway (50).

Physicians working in pulmonary rehabilitation hospitals have provided OTA the following information about patients at their institutions requiring prolonged ventilator support. At New York

City's Goldwater Memorial Hospital, most of the patients who require long-term mechanical ventilation are elderly persons with chronic lung disease or neuro-muscular-skeletal diseases. Although they must remain in the hospital with mechanical ventilation indefinitely, most of these patients are judged to have "quite favorable" prognoses. Most of them are said to remain mentally competent and to lead satisfying lives within the rehabilitation milieu of the hospital, for from 1 to 10 years (21).

The Prolonged Respiratory Care Unit at Minneapolis' Bethesda Lutheran Hospital is a regional center, serving ventilator-dependent patients from the entire upper Midwest. The majority of patients are over 60 years old, and nearly half of those individuals are over 70. Between August 1979 and April 1983, patients had lengths of stay ranging from 2 to 831 days, with an average stay of 148 days (52). Of the 86 patients admitted during the first 9 months of 1985, 73 percent survived and 71 percent of them were completely weaned (21).

Complications Associated With Positive Pressure Ventilation

The incidence of complications associated with positive pressure mechanical ventilation and incubation, especially in acute care, is high. Complications range from relatively minor conditions, such as elevated body temperature, to severe and potentially fatal complications including obstruction or displacement of the tracheotomy tube, pneumothorax, pulmonary emboli, and nosocomial pulmonary infections.

Above-atmospheric pressure during inspiration, never present in a spontaneously breathing individual, frequently results in decreased arterial blood pressure and decreased cardiac output, potentially causing inadequate blood return to the heart (99).

Controlled mandatory ventilation produces a "clinically important" decrease in renal function (110). In one study of 100 patients ventilated for a minimum of 48 hours, 18 suffered associated renal failure (27). Impaired renal function, in turn, often leads to increased retention of water and salt, which sometimes is associated with, among other things, respiratory problems.

One study reported 400 individual complications or potential complications in 354 episodes of acute mechanical ventilation (129). The above-cited study of patients who required ventilation for 48 hours or longer reported that 11 percent experienced life-threatening complications (27). A 1981 review cited one study in which serious complications were associated with long-term endotracheal incubation in 4 percent of patients and another in which serious complications accompanied 16 percent of tracheotomies (112). For adults, the risk of most complications is not affected by increased age (105), but even minor complications can lead to increased morbidity and mortality in patients who are already critically ill or severely debilitated. When complications are identified promptly, steps to prevent serious consequences can usually be taken (85).

Effects on Mental and Physical Functioning

Improved Mental Functioning

Many patients with even mild chronic respiratory insufficiency have chronically impaired mental function due to hypoxia (i.e., insufficient oxygen) or hypercarbia (i.e., an excess of carbon dioxide). Even in mild degree, these conditions are associated with fatigue, hypersomnolence, and decreased mental function (21). Patients in acute respiratory failure are frequently severely hypoxic and their level of consciousness may, as a result, “be grossly altered” (111). Mechanical ventilation with or without supplemental oxygen (or, for less serious cases, supplemental oxygen alone) can correct the exchange of oxygen and carbon dioxide and thus may improve a patient’s mental functioning, alertness, and clarity of thought (21).

Discomfort

Positive pressure ventilation imposes numerous stressful physical effects. These effects, which are at their most extreme for acutely ill patients, have been described not so much as “pain,” which can be relieved in most cases by morphine or other drugs, but as a multitude of relatively minor complaints that add up to what one survivor called a condition of being “chronically uncomfortable” or “just plain miserable.” Contributing to the pa-

tient discomfort are such things as “(the raw post-tonsillectomy feeling in one’s throat after a nasogastric tube has been in place for 31 straight days,” chest tubes reminding you every time you try to breathe or move, nausea, abdominal cramps and hiccoughs (related to swallowing of air and distension of hollow organs), feeling dirty, having a bad taste in your mouth, and fatigue (124). Other causes of discomfort related to the ventilator are ability to take only shallow breaths, potential hypoxia (resulting in restlessness, confusion, change in blood pressure, or tachycardia), heavy tubing, impaired ability to cough, inability to yawn or sigh, impaired ability to swallow, and overheated air (71).

Patients who are unable to move secretions from the lungs by an effective cough must routinely undergo “one of the most unpleasant experiences that a ventilator patient has” —suctioning (71). This technique for removal of secretions from the airway involves passage of a catheter through the trachea and into each mainstem bronchus, with the application of suction for 10 to 15 seconds.

Eating Difficulties

Ventilator patients who are intubated endotracheally, i.e., through their nose or mouth, can take no food or liquid by mouth. Those who require endotracheal incubation of more than 2 or 3 days (as well as those who are malnourished) require tube feeding or other forms of nutritional support (see ch. 8). Patients intubated by tracheotomy, on the other hand, can eat if they have normal swallowing ability.

Speech/Communication Problems

Inability or severe restriction in speech is a pervasive problem for patients receiving positive pressure ventilation. Those who are intubated endotracheally cannot speak. Tracheotomized patients can speak during ventilator-delivered inspirations if the tracheotomy cuff is partially deflated or if they have special “speaking-cuffed” tracheotomy tubes (45). These options are only feasible, however, for patients who are medically stable with stable respirations (68).

Communication problems can be a major source of frustration for ventilator patients as well as their

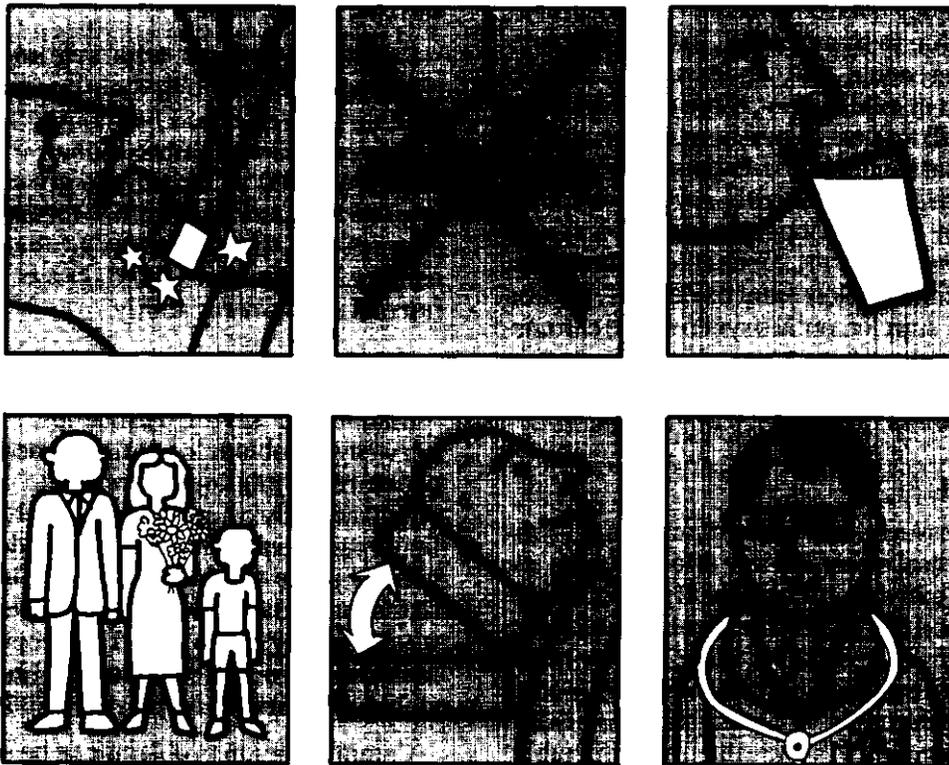
family members and caregivers. Patients' fears regarding their prognosis and the procedures and equipment to which they are subjected may make the need to communicate especially intense. Patients who are sufficiently alert may try to express themselves in writing. Computers and other much simpler devices (e.g., the "Speak and Spell" toy) may be used. Some patients are helped by provision of a poster or set of cards depicting things patients frequently want to express, such as "I'm thirsty," "I want to go to sleep," "I want my family," etc. (One communication aid of this type, "The Patient's ABSee," developed by Siemens, is shown in figure 6-1.) Other forms of nonverbal communication include hand-squeezing and other kinds of signals that might be established before the patient is intubated. Maximizing the patient's ability to communicate helps restore his or her sense of control and, sense of personal value (38). For acutely ill patients, nonverbal communication options are reduced by sedation, medication, confusion, and limited mobility.

In the nursing literature, ventilator patients' difficulty in communicating is regarded as probably the patients' most pressing problem (36). Communication problems may be not merely frustrating, but dangerous. One former ICU patient reported:

On two occasions, the janitor pulled the respirator plug out of the socket without realizing it, leaving me on a closed system with no movement of air. I am told that emergency alarms were supposed to go off, but my only memory was having to detach the respiratory tube from the tracheotomy myself in order to breathe room air (124).

The inability to call out for help is a source of great fear. Psychologists studying the matter have suggested that the inability to communicate triggers feelings of helplessness and despair that may negatively affect the course of the illness (94). Communication problems are made still worse by the fact that too few caregivers and visitors know how to talk to a person who is critically ill or appreciate how much these patients crave human contact.

Figure 6-1.—Patient's ABSees



SOURCE: Siemens-Elema AB, Ventilator Division, *The patients ABSees*.

It becomes a matter of routine for the staff to frequently check the ventilator and all the tubings, connections, etc. All too often this is all that is done—that is, we check the equipment but forget about the patient who is lying there worrying if everything is working correctly. A simple statement to the patient such as, “Everything checks out fine,” could go a long way to reassure the patient that not only is the equipment functioning, but that the staff is concerned enough to check the ventilator frequently and verify that it is working (36).

Decreased Mobility

Patients tethered to a stationary mechanical ventilator are partially or totally immobilized. Limited mobility brings physical discomfort, as well as the risk of developing embolism, phlebitis, and pressure sores. In addition, the loss of control over one’s physical movements is often experienced as a constant fear of falling (out of bed). Perhaps most serious is the physical “reconditioning” associated with remaining relatively still for an extended time and nonuse of the muscles of respiration (71). This is manifested by general weakness and, after about 3 days of continuous ventilation, specific reconditioning of the respiratory muscles that makes weaning from the ventilator more difficult after that time.

For ventilator patients who do not need to be confined to bed, portable ventilators allow mobility and a variety of physical activities. Even with portable ventilators, however, logistical constraints remain. Furthermore, portable ventilators can only be used as the primary device for selected patients.

Psychological Outcomes of Mechanical Ventilation

A patient experience of severe respiratory impairment and treatment with mechanical ventilation, as with other life-threatening illness and treatment, is a function of a variety of personal and environmental factors. Among the most important are the patient’s personality, prognosis, level of consciousness, social support, the quality and sensitivity of care received, and treatment setting. Individual patients cope better or worse with the physical, psychological, and social stresses to which they are subjected.

These topics are addressed to some extent in the nursing literature and in a handful of articles by former or chronic ventilator patients; the scant attention to these topics in the medical literature is conspicuous except for some interest in patients’ psychological reactions to ICUs in general. In one study of the psychological effects of ventilation, the dissimilar perspectives of patients and their family members, on the one hand, and nurses and physicians, on the other, was singled out by the researchers as their most striking finding (94).

Initial Reactions to Mechanical Ventilation

Acutely ill ventilator patients experience many of the significant psychological outcomes of mechanical ventilation that are characteristic of critical illness, institutionalization in general, and the ICU environment in particular. Intense physical problems, sleep deprivation, and medication interact to produce psychological problems that may include depression, confusion, disorientation to time and place, anxiety, and acute delirium, along with fears of permanent dependency and preoccupation with death. These effects are particularly disturbing to acutely ill patients who are self-aware. One former ventilator patient described his ‘(psychotic thinking” and loss of emotional control as frightening and embarrassing. He feared that he might recover physically but not mentally, and worried about his ability to resume his career, family roles, etc. (124). Difficulties in communicating, as described above, and the lack of privacy typical in hospitals may exacerbate these problems.

Initially, for many patients experiencing the difficult breathing that is characteristic of respiratory distress, the assistance offered by the ventilator provides a great sense of relief (71). Often, however, this relief is subsequently replaced by a sense of lost autonomy and lost control.

The patient . . . being mechanically ventilated is expected to trustingly permit others to manipulate his physical and psychological self, his environment, and his significant others. A formerly independent, self-reliant human being must breathe artificially and be fed intravenously; he is dressed and undressed, bathed, pulled, pushed, and moved about without much control over his keepers or himself. Finally, he finds his physical

and psychological nakedness exposed to strangers who have varying levels of empathy (71).

Psychological discomfort can be minimized by skillful caregivers and visitors. The sources of psychological distress include inadequate information about why the ventilator is needed, its reliability and alarm system, lack of confidence in the caregivers, difficulty communicating, lack of privacy, loss of sleep, sensory deprivation or overstimulation, and loss of power and control.

Conscious adult patients on mechanical ventilation may experience what have been identified as “the problem of threat)” “(the problem of loss)” and “the problem of meaning” (38). According to this analysis, in the early phases of treatment, ventilator dependent patients exhibit a pervasive anxiety about their survival. Feelings of being threatened are reflected in fear of mechanical failure of the equipment and in a love-hate relationship to it. Many patients display a “hostile gratitude,” toward the ventilator and the caregivers on whom they are dependent. According to one formerly ventilator-dependent patient, “It was the enemy. How dare a mass of steel and dials and tubing take control of my life?” (38). In contrast, another ventilator patient described the life-sustaining devices as “friends. ”

Loss of spontaneous breathing is accompanied by loss of the ability to communicate, eat, and move. Illness and institutionalization bring loss of social roles within the community and family, loss of accustomed life style, loss of positive body image and self-image, loss of privacy, and general loss of independence. For elderly patients, ventilator-related losses come at a time when other serious losses—retirement, income, social status, friends, or spouse—are accumulating. Behavioral responses to this multitude of losses are said to resemble grief behavior, with a period of denial followed by a period of depression. The ventilator patient’s greatest psychological problem is the lack of control, the inability to do anything for oneself or for anyone else.

By the same analysis, the other most serious problem ventilator patients face is the need to re-assess or reorder their basic values, “to discover meaning in a drastically altered state of existence” (38). This is sometimes described as a religious

crisis, focused on the struggle between living and dying, and between meaning and despair.

Ironically, for patients who improve to the point where weaning from the ventilator can be attempted, independence from the ventilator can engender tremendous fear and anxiety (36), sometimes severe enough to impede the weaning process (61).

Adjustment to Chronic Ventilator Dependence

Available information about the psychological effects of chronic ventilator dependence pertains to patients who have been able to leave the hospital. These individuals are medically stable, have been through a period of rehabilitation designed to help them adjust to their new lifestyle, and have an established support system. To date, few elderly patients have been included in this exceptional group.

Survivors of the polio epidemics of the 1940s and 1950s constitute a special group of ventilator-dependent patients. Of an estimated 300,000 persons who survived polio with some degree of disability, there were, in 1959, 1,200 who were ventilator dependent (63). Some of these people have remained ventilator dependent ever since and now are approaching age 65.¹⁴ Despite more than 25 years of ventilator dependence, many of these patients have managed to maintain a positive outlook, as the following cases illustrate (62):

Statement by a 52-year-old respiratory polio quadriplegic, ventilator dependent since age 23: “By being disabled we do miss out on many things. Yet the kindness and consideration that we receive from others compensates in some small measure. . . . After several years at home with my husband and son, I ended up with pneumonia and a blocked lung and moved to Pearson.¹⁵ In the early 1970s I switched to positive pressure via trach full-time. . . . I knit with a mouthstick and enjoy reading and music. . . . I live one day at a time and look forward to tomorrow. ”

¹⁴Also, some polio survivors are experiencing the delayed respiratory problems typical of *post-polio syndrome* and face the possibility that mechanical ventilation will again become necessary (63).

¹⁵A long-term respiratory rehabilitation facility in Vancouver, British Columbia.

Statement by a 52-year-old respiratory polio quadriplegic, ventilator dependent since age 30: "I was living with my husband and seven children when I contracted polio. . . . This is certainly not the kind of life I would have chosen, but since it is the one I'm living—I'm going to live it."

OTA found no information describing the polio survivors or others whose psychological response to ventilator dependence was poor. However, one article, based on the author's personal experience, suggests that psychological problems among disabled people in general are great and that these problems have been ignored by the mental health professions (37). The author of that article estimates that at least one-third of spinal cord injured persons, many of whom are ventilator dependent; suffer serious anxiety or depression:

Morbid passivity is common. Drug and alcohol abuse levels are high. Between 12 and 50 percent of all deaths of spinal cord injured persons is by their own hand (37).

A significant aspect of adjustment to chronic ventilator dependence is actually adjustment to institutionalization or to an otherwise changed living environment. Initiation of mechanical ventilation always necessitates a period of institutionalization and is frequently, especially for elderly persons, the precursor to permanent institutionalization. A person who had been living in his or her own home must be transferred to the acute hospital and, subsequently, perhaps to a long-term care facility. For patients already in a nursing home, the need for ventilator support typically requires transfer to the acute hospital and may preclude return to the nursing home. Even home care may involve a major adjustment—especially if it requires the patient to move in with adult children or vice-versa.

Effects on the Patient's Family and Caregivers

As is any life-threatening, lingering, and costly illness, ventilator dependence is stressful not only for the patient, but for those around the patient. For the spouse and children, serious illness and hospitalization can be physically, emotionally, and financially exhausting. In addition to the strain of frequent trips to and from the hospital over

an extended period, the severity of the patient's condition puts the family "(through many emotional highs and lows" (77).

In the early days or weeks of mechanical ventilation, family members typically experience the same kinds of grief reactions that alert patients experience. Like patients, they need understanding and communicative professionals to help them cope with the changed situation of their relative, its impact on their own lifestyle and, perhaps, its spiritual meaning (38). The strain may be particularly great on the adult children of elderly ventilator patients. This "generation in the middle," often must, simultaneously, meet responsibilities to their (possibly several) elderly parents and their own children, as well as their spouse, work, etc. (15).

The effects on the family are perhaps greatest when a patient returns home and family members participate in their care. Certainly, home care offers a far greater sense of normalcy and the opportunity for the family to stay close. However, having the patient at home means the patient's family "will be solely responsible for a patient's life." According to one observer, the "very mention" of this fact "is overwhelming for the long-term ventilator-dependent patient and his family" (77) whose members must be responsible for routine patient care and equipment maintenance, recognizing signs of distress in the patient, and knowing how to handle emergencies. Caring for a ventilator-dependent person is a difficult, responsible, round-the-dock job. Its time demands alone, if not the economic and emotional drain, can drastically change a family's lifestyle; in a sense, the whole household becomes tied to the machine.

Often, the physical and psychological load on family caregivers is lightened if more people share the work. Also, if financial resources permit, the family's workload can be lightened by employment of nurses, attendants, and other helpers. For elderly patients, both the number of relatives who are available to help and the feasibility of purchasing assistance may be reduced.

Caring for critically, terminally, or chronically ill ventilator patients also takes a toll on physicians, nurses, and other professional caregivers. Unlike patients and family members, professional

caregivers, especially physicians and special respiratory personnel, are involved with illness and ventilator-dependent patients by choice. Still, caregivers who are constantly faced with dying pa-

tients, grieving families, and their own fallibility are under enormous stress, which can lead to personal problems, "burnout" and possible effects on the quality of care they can provide (see ch. 10).

MAKING DECISIONS ABOUT STARTING AND STOPPING MECHANICAL VENTILATION

Decisions about the use of mechanical ventilation for individual patients are highly specific and individualized, ideally focused on a comprehensive assessment of one patient's condition and prognosis and taking into account his or her personality and personal wishes. Such decisions occur within the context of the laws, ethics, and customs of the society, as well as the specific governmental, institutional, and professional policies that limit what is possible and what is permissible. Such decisions are also influenced by the diverse perspectives and objectives of the numerous parties involved in the decisionmaking process.

Some of the decisionmaking dilemmas that arise in the care of individual patients are illustrated by the following case:

A 55-year-old woman had suffered progressive muscle weakness finally diagnosed as myotonic lateral sclerosis. She had bilateral weakness was present and swallowing became difficult resulting in a 20-pound weight loss. She also presented with respiratory distress. The attending neurologist decided that a feeding gastrostomy was needed to avoid further weight loss. The gastrostomy was placed. . . . In the immediate postoperative period the patient was very weak and required a ventilator. . . . The next morning she was awake and able and an attempt at extubation was made. Within 2 hours the patient was disoriented and suffering anxiety and air hunger. She was restless, tachycardic and rested only with sedation. . . . Because of the feeding gastrostomy the use of the ventilator was discontinued but strength did not return. Decisions between the consulting respiratory care team and neurologist then began for the first time. Also the family sought discussions with the consulting respiratory care team. The possibility of a continuing "life" with ventilatory support had never occurred to either patient or family. Both the patient's daughter . . . and the patient herself became angry over

the "announcement" yet neither could face the reality of death. At the writing, the patient remains in a totally paralyzed state and on a mechanical ventilator (34).

The most fundamental decisions that must be made about mechanical ventilation are: 1) whether to initiate or withhold it, and 2) whether to continue or withdraw it. These decisions frequently are not end-points, but rather part of a *continuum of momentous decisions*. That is, decisions about mechanical ventilation are often preceded by decisions about diagnostic tests, admitting the patient to the hospital or to the ICU, and providing resuscitation. And, the decision to initiate mechanical ventilation is often followed by decisions concerning the transfer of a patient from one setting to another and the provision of other life-sustaining technologies in the event of complications or new illness. In making a decision about the use of mechanical ventilation for a particular patient, caregivers, patients, and family members must be prepared to make subsequent difficult choices, and policies must be broad enough to leave open all suitable options.

Complicating decisions about initiation of mechanical ventilation is the fact that the need for ventilation is sometimes unforeseen. In some situations, the diagnosis is known and the patient's eventual need for mechanical ventilation can be anticipated. For patients with progressive diseases like COPD and ALS, for example, eventual respiratory failure may be foreseen over a period of years. There is time for collection of data pertinent to the prognosis as well as the patient's wishes. In other situations, however, patients experience respiratory failure without warning. When a patient is in the throes of acute respiratory failure, there is no time to make a careful diagnosis, to determine his or her wishes, or to

inform the patient and gain consent for incubation and initiation of ventilation.

Patients in respiratory failure are typically unconscious or, at best, in a severely altered mental state due to hypercapnia, acidosis, and/or hypoxia. Even once ventilated, some patients remain in a compromised mental and emotional state that impairs or precludes their ability to participate in decisions about their treatment. For decisions about mechanical ventilation in these patients, caregivers and family members acting as surrogates frequently play a fundamental role (see ch. 3 and OTA background paper on surrogate decisionmaking by A. Buchanan, M. Gilfix, and D.W. Brock (16).

Decisions about the use of mechanical ventilation are also very difficult for the health professionals who are regularly involved in them. A recent workshop on “Withholding and Withdrawing Mechanical Ventilator Support,” sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and several professional organizations,¹⁶ provided valuable insights into the process of and problems in clinical decisionmaking (see app. E). Physicians expressed humility with respect to the difficult clinical decisions they must frequently make and particular trouble with the conflicts in their joint roles as patient advocate and hospital employee. This workshop was regarded by the invited experts as a historic event, signifying important change in clinicians’ attitudes about mechanical ventilation and, in particular, their widely held belief that the technology has come to be used too frequently in cases where the patient does not benefit. Perhaps, suggested one physician, if more attention had been paid 10 years ago to decisionmaking about initiating mechanical ventilation, a workshop on withholding and withdrawing would not have been needed (107).

Physicians have different views about their role in the decisionmaking process. Some physicians believe that decisions about ventilator support are entirely medical. The patient or surrogate must

give permission for the physician’s decision to be carried out; but patients should not be expected, perhaps not even allowed, to “shoulder the burden” of such a grave decision (58). Others find this view paternalistic and believe the physician’s role should be mainly to educate and advise patients regarding treatment options. Ultimately, the attending physician is responsible for the patient’s care and is legally liable for action taken or not; thus, the attending physician usually makes the final decision or reviews the decision of house staff. Increasingly, physicians view themselves as members of a decisionmaking team, whose role is to facilitate consensus of the, possibly disparate, perspectives represented by the patient, family members, consulting physicians, and other health professionals (see ch. 10).

Clinical Considerations

Clinical evaluation of a patient’s condition is the logical first component of the decision process. Details of a patient’s physiological condition are needed both for decisions about whether to initiate mechanical ventilation and about when to initiate it. Respiratory insufficiency or failure is not always apparent by clinical observation alone, particularly in elderly patients.

The clinical manifestations of acute respiratory failure . . . are nonspecific and seldom point directly to the lung; in the elderly they may be especially subtle. The most frequent signs—restlessness, confusion, and tachycardia—may be interpreted in the elderly patient as “sundowning,” “senility,” or just “cantankerousness,” and may not arouse concern until respiratory arrest or other serious complication occurs (87).

The clinical evaluation includes objective measurement and analysis of air volumes and pressures, blood gases, electrocardiogram, and changes in heart rate. Other important clinical observations include vital capacity, breathing rate, inspiratory capacity, tidal volume, and the degree of physical and mental exhaustion. Because of time limitations and variations in facilities, complete data may not be available.

For each of the measurable parameters, levels indicating adequate ventilation have been determined; for some parameters, however, there is

¹⁶Cosponsors were the American Association of Critical-Care Nurses, American Association for Respiratory Care, American College of Chest Physicians, American Thoracic Society, and the Puritan Bennett Foundation. The workshop was held in Washington, DC, Sept. 30 through Oct. 2, 1985.

a range of acceptable values. The patient's precipitating conditions and previous state must be taken into account; "absolute blood gas levels" are "difficult to assign" (1 11). Inpatients with established chronic respiratory insufficiency, interpretation of blood gases is particularly difficult (1 11). Thus, moving from physiological assessment to treatment decisions may still be very difficult. "Laboratory and clinical findings," according to the American Association of Critical-Care Nurses Procedure Manual, "*aid* [emphasis added] the decisionmaking process" (74).

Other clinical considerations focus on the patient's prognosis and judgments about whether or not mechanical ventilation will improve it. Prognostic uncertainty is the nemesis of clinical decisionmaking. Will the patient live or die? Will weaning be possible or will the patient be permanently ventilator dependent? What will be the quality of the life saved? For elderly patients, as any others, clinicians must be able to incorporate their knowledge and experience of previous patients into decisions without making unjustified generalizations about likely outcomes. Clinicians at the NHLBI workshop rejected chronological age as an independent predictor of the outcomes of mechanical ventilation and expressed great interest in prognostic tools currently being developed. The need for better means of predicting the outcome of mechanical ventilation is clearly reflected in the following comment:

We should accept that we really are only slightly wiser than the apes in regard to the science of living and dying and that we know very little about quality of life or the balance between a life of terror or a death of peace. When making an irrevocable decision for someone else, our actions should be guided by a notion of our fallibility and a surge of humility. . . . I have witnessed many instances where nature, in its greater wisdom, has taken the final step out of my hands and made my puny efforts at life-support impotent. In other words, when the end has come, it has come, and often there is not much for us to decide. The opposite may occur when, with great solemnity, we switch off the respirator, and the patient goes on living and may perhaps do even better than he had previously. . . . (11).

In deciding whether it is appropriate to continue or discontinue ventilation, caregivers consider

many of the same physiological parameters that were used to determine the need to initiate ventilation. Clinical evaluation of the appropriateness of continuing ventilation includes determination of the patient's basic condition, acute or chronic disease; whether the patient's need is for a breathing aid, for oxygen, or for airway patency;¹⁷ and the likelihood of the patient's ability to sustain spontaneous breathing.

Decisions to stop mechanical ventilation may take one of two dramatically different forms. On the one hand, there may be a decision to wean the patient from the equipment he or she has become dependent on, with the goal of restoring normal spontaneous breathing. Ventilator patients who are stabilized and able to breathe spontaneously for 10 minutes out of an hour are widely regarded as ready for weaning. The clinical evaluation of a patient's readiness for weaning also includes assessment of possible psychological dependency. For patients who are terminally ill, complete weaning from the ventilator is usually not feasible, but the possibility of temporary or partial weaning should still be considered. Since restoration of ventilator independence is the best possible outcome for the patient and, since it represents therapeutic success for caregivers, the decision to attempt weaning is relatively unproblematic.

In almost every case where the patient is ventilator dependent, the need eventually arises to determine whether continued ventilation is indicated or whether further treatment is futile. If the patient is terminally ill, and especially if the patient is in a permanent noncognitive state or brain dead, clinicians might recommend that ventilation be discontinued or withdrawn. In contrast to weaning, a decision to discontinue or withdraw mechanical ventilation signifies the removal of equipment without which the patient is not expected to survive. In such cases, some physicians advocate what they call "terminal weaning," i.e., the deliberate, gradual withdrawal of ventilation from a patient for whom further treatment is deemed

¹⁷Patients who have been successfully weaned from a ventilator may be unable to maintain a patent airway. Therefore, removal of the artificial airway may have to be delayed. Readiness for extubation is indicated by a vigorous cough capable of clearing secretions from the airway. Also, many patients who no longer require mechanical ventilation cannot be weaned from supplemental oxygen.

to be futile. Whereas simply “pulling the plug” can cause abrupt and painful dying, withdrawal of the ventilator over a period of hours usually permits the inevitable death to proceed peacefully (46).

Many of the physicians, nurses, and respiratory therapists at the NHLBI workshop expressed strong opinions that despite lawyers’ and ethicists’ claims to the contrary, (90) at-the bedside decisions to withdraw mechanical ventilation are entirely different from decisions to withhold it. For professional caregivers, the decision to withdraw a ventilator is an admission of failure or an admission that the initial decision to ventilate was wrong (80). Moreover, while patients sometimes participate in decisions to withhold treatment, the decision to withdraw a ventilator is almost always made by people other than the patient. All parties, i.e., family members, and the numerous caregivers who have become involved with the patient, must be prepared for this event. Workshop participants indicated that withdrawal of ventilators occurs much more frequently now than it did 5 years ago (some of this increase results from more frequent initiation) and that families are now more involved in the decision to stop treatment.

Ethical Considerations

The prolonged use of mechanical ventilation with patients of any age raises important ethical issues. These issues have to do primarily with how decisions should be made to initiate, withdraw, or withhold mechanical ventilation for a specific patient, with the balance of benefits and burdens this treatment brings, and with the distribution of technological resources. In the words of one leading pulmonologist:

... all who are seriously involved in respiratory care or intensive care in general recognize that a great deal of harm and suffering can be caused by the inappropriate or irresponsible use of mechanical ventilators in hopeless situations (84).

Some of the ethical quandaries involved in defining what constitutes “harm,” “suffering,” or a “hopeless” situation, and what is “appropriate” and “responsible” use of this technology are illustrated by the case of the 79-year-old widow outlined here (and detailed in ch. 4).

After short-term treatment with mechanical ventilation for her congestive heart failure and COPD, the patient said she “absolutely refused” to be intubated ever again. Upon subsequent re-Admission the hospital, she initially repeated this wish, but said she would accept basic CPR if she suffered cardiac arrest. Over a hospital stay of approximately 40 days, her condition worsened; her lucidity, and her conviction about what treatment she wanted wavered. When she was eventually reintubated, she made it clear that she wanted mechanical ventilation and maximal care. However, in a few days she had lapsed into a coma, and her physicians judged that her condition was irreversible. With the concurrence of her son, a DNR order was written, and she was allowed to die (65).

The ethical principles that are features of the decisions taken in this case are: respect for the patient as a person, yielding to the patient’s autonomous wishes, being of benefit to the patient, and avoiding harm through the extension of suffering. This case also illustrates some of the moral and practical difficulties in respecting patients’ wishes. By her wish to receive basic CPR but not to be intubated, the patient put her caregivers in a position that some people find illogical, i.e., to restore her circulation but not support her breathing. This indicates some of the difficulties in drawing lines between treatments that are part of a logical continuum, for example, between a full resuscitation code and a limited code (see ch. 5), or between mechanical ventilation and other life-sustaining treatments (23). The significant changes in this patient’s medical condition, in her wishes regarding treatment, and in her ability to express those wishes illustrate how, even if physicians are determined to carry out the patient’s wishes, it is not always possible for them to do so.

A case in which the patient family demanded maximum care provides an interesting contrast.

A 75-year-old married man was admitted to the intensive care unit of hospital in acute respiratory distress. He was anxious but fully alert and gasping for help. A retired laborer, Mr. Watkins had been suffering from a chronic pulmonary disease for the past 15 years. For the past 5 years he had become progressively debilitated.

Prior to admission he had been confined to his home and depended on his wife for the bulk of his care. . . . He had been a formerly healthy man and did not expect enduring medical problems. His wife and married son were usually dependent on him.

The diagnosis was bilateral pneumonia, and Mr. Watkins was given antibiotics and pain relief. A chest x-ray taken 2 weeks later appeared normal. Within 2 weeks the pneumonia had largely cleared and Sarah Radburn, the physician, began attempts to wean him from the respirator. Un fortunately, he had become "respirator dependent" as a result of a combination of poor nutrition, possible new damage to his large, weakened respiratory muscles, and fear of being left on his own. Despite a slow, cautious approach with much reassurance, the weaning attempts repeatedly failed. Mr. Watkins, short of breath and terrified, would demand to be placed back on the respirator.

Dr. Radburn rated the ultimate chance for successful weaning as "maybe 20 percent." The patient became more and more discouraged with his lack of progress and the frequent painful medical procedures. . . . After 3 weeks of unsuccessful efforts, Mr. Watkins refused to cooperate with further attempts at weaning. His wife and son became concerned that he had given up the "will to live." They begged the medical staff to "do something to save him." Although he had become less communicative, he remained alert and aware and, in the opinion of the staff, was fully competent. He told Dr. Radburn he wanted the respirator disconnected. "I want to die" he said (49).

The possibility of permanent ventilator dependence and the patient's view of this must be included in any comparisons of harms versus benefits in the decision to initiate ventilation in the first place. In the view of Mr. Watkins, dependence on a ventilator 24 hours per day had an overwhelming impact on his quality of life. He concluded that his quality of life on the ventilator was so unsatisfactory that death would be preferable. (The constancy of treatment also seems to put mechanical ventilation in a class by itself from the standpoint of caregivers and other observers. "Physicians seem to find it easier," for example, "to decide not to continue hemodialysis" (47).)

Mr. Watkins's expressed wish "to die" could be interpreted either as suicidal or the more neutral

wish to avoid mechanical ventilation. The former interpretation raises additional ethical questions which are of both philosophical and practical concern. Does, for example, the use of a life-sustaining technology sometimes actually facilitate suicide? If caregivers accede to a patient's wish to withdraw treatment, are they assisting suicide? (see ch. 4). Some observers have noted that before caregivers accede to a patient's request to disconnect a ventilator, they must determine whether this request results from conditions that are reversible, such as temporary depression, fear based on misperceptions or misinformation, or underlying problems between the family and patient.

The above case also highlights questions about the role of family members and the proper weight of their wishes. When, as in this case, the patient is alert and able to participate in treatment decisions, there is wide agreement that the family's wishes should always be secondary to the patient's. The family, after all, is not the physician's patient; nor in a case like this is a family member the patient's proxy (96).

The physician must remember that he has only one client—the patient. He is the advocate of the patient—not the family, nor the welfare agency, nor the kindly clergyman, squeamish at the sight of tracheotomy (32).

Finally, there is an important ethical issue related to when obligations to patients end. The initiation of mechanical ventilation for acute care often creates many long-term needs (e.g., for continuing professional services, reimbursement, social support). Indeed, mechanical ventilation itself (and not merely the disease or condition originally leading to its use) maybe the cause of a person's loss of spontaneous breathing. Prolonged use of mechanical ventilation can irreversibly suppress spontaneous breathing in some cases in which it might have resumed. Patients and professionals closely involved with this technology suggest there is a need to reconsider how the boundaries of this treatment have been defined (21). Do obligations to a patient end with discharge from an ICU or hospital, or do obligations stand as long as the patient is ventilator dependent? If the latter, reimbursement policies and inadequate community resources that commit some medically stable venti-

lator-dependent patients to ICUs and some to poverty are in clear need of revision.

Legal Considerations

Mechanical ventilation, as an arbiter of life and death, raises legal questions concerning suicide, assisted suicide, homicide, and medical malpractice. Decisions regarding the use of this technology are greatly influenced not only by laws and

court actions (see ch. 3 and OTA background paper on court decisions and legislative approaches, by G.J. Annas and L.H. Glantz (6)) but also by patients' and caregivers' perceptions and misperceptions of these (see OTA background paper on legal perceptions and medical decisionmaking, by M.B. Kapp and B. Lo (56)). Of the life-sustaining technologies that OTA studied, mechanical ventilation was the first to draw legal attention. Some of the recent court cases involving this technology are summarized in box 6-B.

Box 6-B.—Some Recent Legal Cases Involving Mechanical Ventilation

***Barber v. Superior Court of Los Angeles County* (10)**

In this case, decided October 12, 1983, a nursing supervisor brought criminal charges against two physicians for acceding to the request of a patient's relatives to discontinue life-support equipment and intravenous tubes. The court ruled that a competent adult patient has the legal right to refuse medical treatment; a physician has no duty to continue use of life-sustaining machinery after it has become futile in the opinion of qualified medical personnel; and there is no legal requirement of prior judicial approval before any decision to withdraw life support for terminally ill patients can be made. Charges against the physicians were dismissed.

***Satz v. Perlmutter* (97)**

Mr. Perlmutter was a 73-year-old man with a terminal illness, amyotrophic lateral sclerosis. After trying by himself, unsuccessfully, to remove the ventilator which was keeping him alive, Mr. Perlmutter petitioned the court to allow him to direct his own treatment and to have the ventilator removed. He was mentally competent, and his family approved his decision. The Florida court ruled: 1) he could decide to remove the ventilator; 2) the medical profession should not substitute its judgment for the patient's; and 3) the hospital would not be liable for the result of his decision.

***Elchner v. Dillon* (31)**

Brother Fox, an 83-year-old member of the Catholic Order of the Society of Mary had a heart attack during routine surgery. He fell into a coma with severe brain damage and was placed on a ventilator. Two neurosurgeons who examined him agreed that there was no reasonable possibility that he would regain consciousness. A long-time friend, Father Philip Elchner asked the hospital to disconnect the ventilator, but the hospital refused. In court, Father Elchner said Brother Fox had expressed his wish that "extraordinary" life support not be applied on his behalf. The court ruled that there was no reasonable possibility that Brother Fox would ever return to a "cognitive and sapient state," and that when he was competent, he had made clear he would not want this treatment. With the court's approval, mechanical ventilation was discontinued.

***Estate of Leach v. Shapers* (33)**

Following a cardiopulmonary arrest, the 70-year-old woman was successfully resuscitated, but she did not regain consciousness. She remained in a chronic vegetative state, on a mechanical ventilator for more than 5 months until a court order led to withdrawal of the ventilator. Her husband, who was her guardian, had petitioned the court after 2 months to terminate treatment, but his petition was denied. The family alleged that Mrs. Leach had been put on the ventilator and other life-support without her own or her family's consent, although she had expressly advised that she did not want to be kept alive by such machines. The trial court dismissed the case, but the Ohio Court of Appeals subsequently overruled the dismissal (4).

Informed Consent

A patient's legal right to make decisions about his or her health care is well established. Under the doctrine of informed consent, patients have the right to accept or to refuse treatment, as well as the right to request that treatment be withdrawn. Moreover, there are available legal provisions to specify treatment preferences in advance (see ch. 3). Highly publicized court cases have consistently upheld the right of decisionally capable patients to have mechanical ventilation withdrawn,

However, in practice, patient's choices regarding mechanical ventilation are not always known, knowable, or carried out. Exercising the right to direct one's own care requires a patient who is mentally competent, alert, and informed. In the case of respiratory insufficiency or failure, these conditions frequently do not obtain. Disease, medications, pain, and the urgency of the situation may render the patient incapable of participating in treatment decisions.

Informed consent for instituting mechanical ventilation is, at best, difficult to obtain. Participants at the NHLBI workshop emphasized the importance of ascertaining the patient's preferences early and documenting them in the medical record. (They also emphasized the difficulty for both physicians and patients in discussing these sensitive subjects.) Even if time, the patient condition, and the relationship between the patient and physician permit careful discussion, it may be impossible to fully inform a patient about mechanical ventilation. In fact, some physicians believe that ***no one can recognize the impact of being on a ventilator in advance (67)***. In a life-threatening emergency, consent is often "implied." When consent is explicitly obtained, it is most often verbal. Often, a patient silence is interpreted as consent.

If the patient is not decisionally capable, a surrogate decisionmaker or legal guardian, or a court order regarding treatment may be sought. (These mechanisms are reviewed in ch. 3 and analyzed in detail in a background paper to this report (16)). Other legal problems arise from the variation State to State, institution to institution, and physician to physician in how directives by patients or their surrogates are handled.

Because some caregivers are willing to override the patient's wish and because practice and theory are not the same, one respiratory therapist reported:

Elderly patients are often not active participants and . . . their preference is not an issue in the decision. Many patients are (or are perceived to be) unable to understand, poor communicators or historians, not "responsible" or capable of making decisions, and difficult to deal with. There is usually more involvement by the patient when the care is more long-term. . . . The goals of long-term ventilator management could never be accomplished in a patient who is not desirous of this form of therapy (21).

Advance Directives

By means of a formal advance directive—a living will or durable power of attorney for health care—or informal means, a patient attempts to ensure his or her participation in decisions regarding life-sustaining treatment in general or mechanical ventilation in particular. In some instances, advance directives specify ***particular treatments*** an individual does or does not wish ever to receive. A patient may, for example, indicate that he or she does want to receive nutritional support, but not mechanical ventilation.

In practice, caregivers do not always comply with a patient's advance directive to withhold life-sustaining treatment. Often there is simply no mechanism or time for discovering that a directive exists or to produce it. In an emergency, or with a decisionally incapable patient, even if the patient has an advance directive, it is unlikely the physician on the scene will know of it. Another reason caregivers sometimes do not comply with a patient's advance directive is that they feel that the directive is not sufficiently clear or that it does not serve the patient's best interest. Some people are skeptical about patients' ability in general to specify treatment preferences in advance. And, some are particularly skeptical about directives made prior to the—terrifying—experience of severe breathing difficulty. According to one physician, "patients who think they don't want to be ventilated change their mind when they are choking to death" (22).

Fear of the Law

The fear of legal liability remains a major issue for caregivers—especially when a patient is not decisionally capable, when the patient's wishes are not known, and when there is disagreement among the patient and family, caregivers, or between caregivers and their employing institution about what to do. Differences in State laws and precedents add to the confusion.

The fear of being sued for malpractice may at once encourage physicians to use all available life-sustaining technologies and discourage them from taking any action that is contrary to the patient's wishes. In practice, these two objectives may conflict, thus adding to caregivers' uncertainty about legally correct action. There has been no successful suit against any physician who followed the wishes of the patient, but there has been at least one case (*Barber v. Superior Court of Los Angeles* (10)) in which physicians were accused of criminal intent and murder despite carrying out the family's wishes. Physicians and other health professionals are acutely aware of the possibility of malpractice claims and fearful of what appear to be uncertain and shifting legal boundaries (56). (Malpractice and other legal questions are more fully discussed in ch. 3.)

professional and Institutional Guidelines

Standards and guidelines developed and promulgated by professional associations and institutions are other important factors in decisions about the use of life-sustaining technologies in general and mechanical ventilation in particular. They help to guide treatment decisions as well as procedures for making those decisions. Although these do not have the force of law, and their intent is usually to solve clinical and ethical dilemmas more than legal ones, they may be used in legal proceedings to determine whether or not acceptable care was provided. They may address a variety of issues, including who should make the treatment decision, where or by whom care should be provided, and when it should not be.

Standards of care (or standards of practice), as established formally or informally by professional associations provide some, limited, guidance in

decisions about mechanical ventilation. Although voluntary professional standards serve primarily to assure quality of care (and to protect professional interests), over time, they become the expected norm. In legal proceedings, particularly malpractice cases, health professionals and institutions may be held accountable to the standards of care in their community. Knowing this, health professionals have a keen interest in observing these voluntary guidelines,

One example of professional standards relevant to mechanical ventilation is the "Guidelines for Management in the Home and at Alternate Community Sites," published in 1986 by the American College of Chest Physicians (82). These guidelines identify factors that should be considered in the selection of ventilator-dependent patients for care at home or in other community settings. Another example is the standards of care for providing mechanical ventilation in nursing homes, developed jointly by the American Association for Respiratory Care and the American Health Care Association (1). Among other things, these standards address staffing, quality assurance, infection control, safety, and continuing education.

Such policies and standards may assist in legal proceedings or they may, at times, be the focus of the legal debate. For example, the point of contention in the 1986 case of *Tune v. Walter Reed Army Medical Hospital* was a policy of the Department of the Army precluding the withdrawal from any patient in an Army medical facility of life-support systems that have been put in place.

Many institutions now have policies that specify categories of patients who should not be resuscitated. DNR policies (see ch. 5), although usually meant to address only the question of resuscitation, may directly or indirectly resolve or preclude questions about the use of mechanical ventilation. The DNR policy of the Veterans Administration (VA), for example, explicitly states, "a DNR order is compatible with maximal therapeutic efforts short of resuscitation" (122). Patients for whom a DNR order has been written might still receive nutritional support, antibiotics, or mechanical ventilation that had been started; subsequently, however, withholding of resuscitation almost always precludes initiation of mechanical ventilation. In addition, some institutions have "disaggregated

DNR policies,” i.e., policies that distinguish Do Not Resuscitate from “Do Not Intubate” (DNI) (e.g., (76)). Patients coded DNI might be resuscitated but not receive mechanical ventilation. Disaggregation of the DNR order is thought by some observers to reduce uncertainty or the possibility that the directive will seem unclear. However, others argue that specifying what treatments should or should not be provided raises new questions about potential treatments that remain unspecified.

In addition to addressing substantive issues, standards of care and institutional policies may address decisionmaking procedures—e.g., documentation in patients’ charts, the role of surrogates, ethics committees, etc. In 1976, for example, the Joint Commission for the Accreditation of Hos-

pitals published standards for hospital respiratory therapy departments. These standards require that a physician’s order for services indicate the criteria for continuing or ending each therapeutic procedure prescribed. Another example is the VA’s requirement of written consent for a tracheotomy (123).

The level of activity surrounding the development of standards and guidelines suggests an awareness within the professions associated with mechanical ventilation that guidance is needed to improve treatment decisions and decisionmaking procedures. It also suggests that professionals are interested in developing these guidelines themselves.

FINDINGS AND IMPLICATIONS

A large proportion of patients who become candidates for mechanical ventilation—and a large proportion of patients whose need for ventilation becomes prolonged—are elderly. Some elderly individuals, although permanently ventilator dependent, manage an active life and maintain a strong will to live. Senator Jacob Javits was an example. Other individuals are severely debilitated and severely brain damaged with no prospect of recovery or rehabilitation. Clinical studies consistently show that mortality, which is high for mechanically ventilated patients in general, is highest for elderly patients. Advanced age alone, however, is an inadequate predictor of the outcomes of mechanical ventilation.

Survival, functional capacity, and an individual’s ability to cope with prolonged ventilator dependence are often difficult to predict at the time the decision to initiate mechanical ventilation is made. Many physicians and other health professionals involved in mechanical ventilation believe that this technology is frequently used when it should not be. The lack of definitive prognostic measures for patients with respiratory failure subjects some patients to needless suffering and precludes efficient use of health care resources. Research is needed to reduce prognostic uncertainties and to support improved decisionmaking. There has been practically no research focused on the clinical and be-

havioral aspects of mechanical ventilation with elderly patients.

In patients with chronic or progressive diseases affecting respiration, eventual respiratory failure can be anticipated. When a patient is in acute respiratory failure or unconscious, he or she cannot give informed consent to mechanical ventilation. This observation suggests the special importance of early and frank conversations between physicians and patients and between family members and patients regarding the potential need for mechanical ventilation, and the importance of advance directives that are clear and well-documented.

The decision to initiate mechanical ventilation is frequently only one of several very difficult decisions regarding this technology. As the patient’s condition and circumstances change, choices must be made about other medical treatments, and the benefits of continuing ventilation must be re-evaluated.

Despite ethical and legal pronouncements to the contrary, caregivers involved in providing mechanical ventilation argue that, at the patient’s bedside, the difference between withholding and withdrawing this life-sustaining treatment is vast. Needless suffering and expense could be reduced if there were provisions to make withdrawal of

ventilation less difficult when the treatment has proved to be futile or no longer wanted by the patient.

Mechanical ventilation is an extraordinarily expensive treatment, with a large share of the cost borne by Medicare and Medicaid. For hospitals, the cost of treating patients who require this technology sometimes far exceeds Medicare's current DRG-based payments. Thus, hospitals have financial incentives not to treat some seriously ill Medicare patients. In most States, however, limited Medicaid payments for ventilator-dependent patients favor the use of acute care hospitals over other treatment settings.

Interest in providing ventilator care for patients in their own homes and in skilled nursing facilities is strong. To date, however, few elderly ventilator patients have been discharged home, and few nursing homes are able to admit ventilator patients. Some observers warn that extension of Medicare and Medicaid coverage for home care of ventilator-dependent patients would stimulate an explosion of utilization and cost. Those who dismiss this warning argue that no change in reimbursement will change the medical indications for long-term ventilation, and that more liberal reim-

bursement for home ventilation would permit more efficient use of resources.

There is significant potential for prevention of the need for mechanical ventilation. The Surgeon General reports that COPD, the single greatest cause of respiratory failure, would almost disappear if Americans quit smoking. Moreover, the benefits of stopping smoking are significant, regardless of the individual's age and years of smoking.

Ventilator-dependent persons have ongoing needs for resources and services. These needs may be unforeseen or unavailable. In addition to medical care and equipment-related resources, many patients and families need facilities and services to help them cope with the social, emotional, and financial costs of ventilator dependence.

While the burden as well as the promise of mechanical ventilation for individual patients, family members, and caregivers are identifiable, it remains very difficult to assess the magnitude or urgency of societal problems associated with this technology. Data on utilization and cost are very inadequate, and there is no consensus on what constitutes appropriate usage or public expenditure.

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