Technology Assessment and Support of Life-sustaining Devices in Home Care*

The Home Care Physician Perspective

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Practicing physicians are increasingly using life-sustaining devices in the home setting for patients with long-term needs due to chronic conditions. At the same time, public policy focus on technology assessment has broadened from narrow medical concerns about safety and efficacy to considerations of effectiveness, quality of life, patient preferences, and cost/benefit. Around the world high-technology home care (HTHC) features a number of ways to evaluate outcomes. One category of HTHC that requires initial and on-going technology assessment is home mechanical ventilation (HMV). Home MV has developed in nations with a variety of healthcare finance systems: England (national health system), France (national health insurance), and the United States (regulated/market-economy). Approaches to technology assessment differ among nations according to organizational design and evolution. Physician behavior is a major determinant in the application of medical technologies. There are new physician roles that can influence what, when, and how technology is appropriately used in the home—initially and over time. For this reason, it is crucial to consider the role of the practicing physician in home care technology assessment.

(Chest 1994; 105:1448-53)

FDA = Food and Drug Administration; HMV = home mechanical ventilation; HTHC = high-technology home care

As nations battle the rising burden of expenditures for healthcare and social services, they face new demands from growing numbers of people with chronic conditions. This population sector includes survivors of life-threatening illness of all ages who have benefited from modern medical progress in acute care, some of whom depend on the prolonged use of life-sustaining technologies. More efforts are needed to determine the size of the segment requiring long-term care. The transfer of these patients from institutions to community alternative care settings may result in cost savings and improved health outcomes.

The assessment of medical technology and its relation to cost and quality management concerns many groups: healthcare professionals, engineers, physical and social scientists, public policy analysts, government officials, business coalitions, and consumer organizations. These groups have broadened the scope of technology assessment from concerns about safety and efficacy to considerations of effectiveness, quality of life, patient preference, and cost/benefit. The application of new technologies and overuse of existing ones account for up to 50 percent of the rise in healthcare costs.3,4

Many technologies are now applicable in the home.5 Although home healthcare is not a new concept,6 the use of life-sustaining technologies in the home has a more recent history.7,8 It is essential that groups concerned about technology assessment have a better understanding of the home use of life-sustaining devices. High-technology designed for home use must be assessed before introduction and reassessed with experience for efficacy and safety as well as outcome and appropriateness.

The following observations review several nations' approaches to high-technology home care (HTHC) in the form of home mechanical ventilation (HMV). They will consider the evolution of programs from the poliomyelitis era to modern day and focus on how each country has or has not evaluated performance of devices used in the home. They will attempt to determine if a systems approach is feasible, necessary, and whether it makes a difference. They will describe technology assessment for home care physicians—physicians who consider the home as an appropriate setting for care.

**History of Home Mechanical Ventilation**

The poliomyelitis pandemic of the 1950s represented a global healthcare crisis affecting the lives of countless children and young adults. The most remembered achievement of that period was the successful application of research leading to the
polio vaccine. The medical community, however, also made major advances in life-supportive medical technologies. For example, the prototype of the modern positive pressure ventilator\(^7\) and its application via tracheostomy reduced mortality due to acute respiratory failure from 90 percent to 20 percent.\(^10\) A less-recognized technological advance was the adaptation of mechanical ventilators for home use by physicians working with engineers and polio survivors. These survivors with residual respiratory impairment required prolonged mechanical assistance and desired to leave the institution and return to their families. According to Gini Laurie, continuing home care was an integral part of the whole system. . . . The centers and home care resulted in tremendous financial savings and a greater degree of independence and self-sufficiency than was ever dreamed possible for people so severely disabled. . . . The average hospital time was cut from more than a year to seven months. The home care costs were one-tenth to one-fourth hospital costs.\(^11\)

The polioymelitis experience represented the first generation of ventilar-assisted individuals to use HTHC. An international network of designated polio respiratory centers arose, making technological progress possible.\(^12\) Physicians, engineers, and manufacturers met and directly communicated their needs and perspectives.\(^13\) Physicians played a vital role with others in establishing a well-defined mechanism for designing equipment, evaluating experience, and tracking device performance.

After the poliomyelitis era, the new technical capabilities of long-term mechanical ventilation via tracheostomy provided the life-sustaining means to maintain and improve the lives of patients with other categories of chronic respiratory insufficiency. Some physicians who had participated in interdisciplinary teams established to meet the complex needs of polio patients became the first leaders of neonatology, critical care, and rehabilitation medicine. As a result of advances in these modern interdisciplinary practices, patients were saved with many varieties of previously fatal life-threatening medical and surgical conditions. A few survivors who benefited from this progress, however, still maintained a degree of respiratory impairment that required prolonged support of medical technology.

The option of mechanical ventilation at home currently exists in several nations.\(^14-16\) In England, France, and the United States, special centers originally designated for polio provided the models for a second experience in HMV. Critical care and respiratory rehabilitation units developed home care programs to permit the option of life in the community for a new generation of ventilator-assisted individuals. The organizational structure in each nation reflected political, economic, social, and cultural realities as determined by national, regional, and local influences.\(^17-19\) Each nation’s technological achievements, product support, and device surveillance mechanisms stemmed from the experiences, perspectives, and backgrounds of the physicians who helped design the home care programs. The architects of the original programs included physicians from a variety of professional disciplines (ie, neonatology, anesthesiology, critical care, pulmonology, cardiology, surgery, rehabilitation medicine) and other healthcare professionals (ie, nursing, respiratory care, social work, physical therapy).

Ventilator-assisted individuals do not always have the same HMV option. Where they do, the quality of their program and safety at home varies greatly by location. Current life-sustaining technology used at home also varies in terms of availability and performance evaluation. In many situations where HMV has been available for several decades, the original technology initially designed for home or hospital application is still in use. This technology has been used for prolonged periods with or without assessment over time. Although the equipment may have originally met patient needs, most early technologies predate the rigor of current device standards and premarketing/clinical application approval processes.

In general, devices are used either on an individual or collective basis with variable tracking of location, use record, repair experiences, and maintenance history. Older technologies are used interchangeably and/or modified. More modern products specifically designed and manufactured for home use may have been subject to an initial technology assessment. There have been few attempts at reassessment, however, since there is no formal system in place to make involved actors aware of device failure or inadequacies during a product life-cycle.\(^5\)

Patient safety, quality determination, medical necessity, cost control, and risk management demand technology assessment to evaluate the medical appropriateness and performance of technology after prolonged application in the home. The following remarks will show this need and update previous communications about approaches to these concerns in three nations where HMV has evolved in different healthcare finance systems: England (national health system), France (national health insurance), and the United States (market-oriented).\(^14-20\)

**MULTINATIONAL COMPARISON OF HOME MECHANICAL VENTILATION**

**England**

The “Responaut Program,” England’s unique hos-
hospital-based HMV program, has served over 500 patients for more than 20 years. As with most regional HMV programs of this magnitude, it began with the need to send home polio survivors with chronic respiratory insufficiency. When these patients were incorporated into the first ICU in England at St. Thomas Hospital, they considered themselves “Responauts,” risking to enter the “unknown” — their community — despite prolonged need for mechanical ventilation. This program, based now in the Baroness Lane Fox unit, continues to actively serve about 250 persons at home. The majority of Responauts have neuromuscular diseases and reside with their families all over the United Kingdom. Those Responauts with complex medical needs and no family members can benefit from HMV with care from personal attendants as a result of recommendations of the Responaut Study.

The devices used at home by the Responaut Program include positive pressure “respirators” featuring simple “bicycle technology” and “alligator” iron lungs, which open to provide ready access and permit rotation for physical therapy. This innovative technology, specially designed for the original polio survivors, has a history of simplicity for instruction, adaptability for use, proven reliability, and ease of maintenance and repair.

Hospital-based technicians track the performance of all original equipment. These experts make monthly/bimonthly visits to the homes for routine maintenance and surveillance of the well-being of the Responauts, as well as emergency repair calls at any time of day or night. They replace original equipment with a loaner when they must perform more extensive repair in the hospital-based workshop. In the past when modern devices were imported, they were proven to be costlier to purchase and maintain. Manufacturers of imported technology had not established repair facilities in England, and returning them abroad required one-third to one-fourth the cost of the original machine and up to 4 months (G. Spencer, personal communication, 1990). Modern portable ventilators for home care are now manufactured in England. Examples include The Nippy portable positive pressure ventilator (Thomas Respiratory Systems, London, England) and the Brompton PAC assistor-controlled ventilator (Pneumo Pac, Luton Beds, England).

The Responaut Program is directed by an expert home care physician, who remains personally involved in technology assessment for each patient. All Responauts at home have direct telephone access to the hospital base-unit and this physician. Professional team members representing multiple disciplines (i.e., nursing, physical/respiratory therapy, social work) schedule regular home visits to each ventilator-user and their equipment. The physician and team members always remain immediately available to support technical, medical, social, and financial needs. The physician communicates with manufacturers providing direct feedback regarding equipment performance and design modification.

France

France has a system of 32 regional associations and one national organization that serves over 20,000 ventilator-assisted and/or oxygen-dependent persons. Its origin dates back to the 1960s when polio patients were discharged from respiratory centers, which had subsequently evolved into ICUs, to designated home care organizations in the community. At the end of the 1970s, the French government authorized a study evaluating the initial regional experiences with home mechanical ventilation. The study recommended a uniform national approach for both home mechanical ventilation and the growing demand for home oxygen. This resulted in the establishment of associations for chronic respiratory insufficiency in all regions of France and the creation of a national organization (Association National pour la Traité à Domicile de l’Insuffisance Respiratoire, ANTADIR).

Currently, HMV is available in every part of France from designated, not-for-profit regional associations that provide equipment, supplies, clinical oversight, and technological surveillance. The patient’s physician must prescribe devices for home use by a uniform national mechanism that guarantees full reimbursement for the technology and its essential support. After physicians from the regional association and social security review each initial prescription ANTADIR orders the appropriate equipment, which receives its own identification number. These prescriptions and a computerized database permit the system to track and evaluate the application of technology at home and the performance of devices from initial manufacture and delivery through all clinical use until obsolescence.

Regional associations do not provide primary caregivers; ventilator-assisted persons in France require care from a highly committed family. When events at home require supplemental caregivers, professionals and personal attendants are available on a limited basis from other organizations.

Home care physicians, along with nurses, respiratory/physical therapists, and technician specialists from regional associations do make intermittent home visits to ensure that equipment matches the need of each user and to evaluate technology performance. In most regional associations, clinical and technical information immediately enters a computerized database that permits national pooling of
information for review, analysis, and feedback to users and manufacturers. The information network provides physicians with access to instant notification by all regional associations of technological problems as discovered. An “info-alert” and/or tri-monthly bulletin disseminate news about relevant experiences and unusual occurrences. Additionally, expert physicians and technicians from regional associations share this information and conduct essential field trials and device re-evaluations at the Medical-Technology Commission of ANTADIR.

United States

In the United States, technology assessment is impeded by our complex system that has many gaps. It is true that the Food and Drug Administration (FDA) evaluates new respiratory care products before distribution. By FDA regulation, manufacturers must test new devices to establish safe and effective performance before release to consumers. However, market channels among manufacturers, distributors, professionals, and consumers breakdown thereafter. There is no established mechanism for multidirectional flow of safety information or use experience. Although the home care physician may have access to device reporting processes for life-threatening events, the fragmentation of our complex system hampers dissemination of isolated experiences of inadequate product performance. This leaves the physician, the HMV team members, and the ventilator user without a predetermined way to share their device experiences and inform both manufacturers and distributors. For the physician, this translates into isolation; the only way to learn about shared device performance experiences is through informal and irregular networking. The home care physician depends heavily on communication from the ventilator user, family members, and professionals in the home for information about technology performance. Personal attendants who may serve as acceptable alternate caregivers for ventilator-assisted individuals may be another source of observations for the physician.

The means of promoting product improvement through technology assessment and information exchange in our free market has been limited. In the past, funding for home care technology and its support has been discretionary and dependent on fragmented healthcare funding policies. Managed care organizations, commercial insurers, public payers, and self-insured employers have differed in their willingness to pay for such coverage. A growing number of patients have had either insufficient or nonexistent means to pay for technology surveillance. Only recently (1993) have Health Care Financing Administration rulings defined comprehensive home care requirements for health maintenance organizations and managed care organizations based on medical necessity without regard to cost or duration. As a result of past funding inadequacies, HTHC in the United States has featured inequities of access and allocation of resources. Without sufficient funding for technology and its support, the physician and management team cannot adequately address quality improvement, risk management, and cost control.

Recent initiatives have begun to raise consciousness about the need to disseminate information about home care technology. In 1986, the American College of Chest Physicians created guidelines for physicians about mechanical ventilation in the home or alternative community settings. In 1988, consensus conferences sponsored by The American Thoracic Society, The Food and Drug Administration, The American Association of Respiratory Care, and The Health Resources and Services Administration addressed HMV and equipment-related problems. Several committees of the American Society for Testing and Materials developed voluntary consensus standards, and the Joint Commission of Accreditation of Healthcare Organizations established quality management accreditation for home care organizations providing support services related to medical technology.

Consumer organizations have begun to formalize their networks to share information, and manufacturers have established networks among professionals to describe product-related experiences. The National Center for Home Mechanical Ventilation, an independent nonprofit research organization supported by manufacturers, suppliers, healthcare professional associations and consumer organizations, encourages device performance tracking and information exchange among representatives of its constituency. These recent attempts, however, have not completely solved the systemic fragmentation of technology assessment and information dissemination.

Discussion and Recommendations

Home care technology use and assessment in England, France, and the United States show what can (or cannot) be accomplished in different nations because of (or despite) certain healthcare financial and delivery systems in place. In each country, healthcare professionals, consumers, and organizational leaders have achieved some awareness of the universal importance of a mechanism to evaluate and improve technology performance with use over time.

In England, The Responaut Program represents a unique model approach; it does not reflect a uniform national experience. Rather, it functions as a
regional program with a national outreach. This achieves technology assessment on a program level without a formal system and despite healthcare finance not necessarily geared for this purpose.

The French system shows a formal mechanism established to track and reassess home technology performance. Prior to application, a rigorous premarket evaluation process with strict device standards and protocols determines acceptability of technology for home use. The French system then determines whether continuous home use is appropriate, safe, and medically necessary. This mechanism conforms to healthcare financing and political, social, and cultural realities in France.19

The current inadequacy of technology tracking in the United States results from absence of a defined health policy and lack of success establishing an organized way to effectively link all involved actors. This is partly explained by our political history and market-based approach to the economy which encourages individual freedom, pluralism, and diversity as an acceptable way we approach issues.20 Rather than working together for a common purpose, professionals, service providers, manufacturers, suppliers, and consumers have pursued and lobbied their own interests. Our nation, however, also has a tradition of unity of purpose and action in times of crisis as shown during the poliomyelitis era. Now is such a crisis due to the impact of technology costs on overall healthcare spending. Technology assessment should involve all potential stakeholders of a system; they should also define the coordinated way to accomplish it.14 The absence of an effective systems approach will result in continued operational inefficiencies and requirements for additional costly safeguards (second ventilators, professional surveillance). Consequently, HTHC may become prohibitive for financial and risk concerns.

In the United States, there is a growing general interest in technology assessment to accomplish quality healthcare and cost containment.37 Evaluations of the Office of Technology Assessment found that only a minority (15 to 20 percent) of existing healthcare practices in 1978 were considered beneficial based on well-controlled trials.38 There is a strong case for regular reassessment of existing technology in use as well as the assessment of newer technology before introduction into the clinical setting and healthcare marketplace.5 Reassessment is especially important in view of high economic costs, burdens to patients and families, and risk of adverse outcomes to users of technology that may be inappropriately prescribed or continually used.

The scope of future technology assessment must be broad. Devices and procedures should be critically tested before routine clinical use, with the focus going beyond the biomedical perspective of safety and efficacy.39 The “new technology assessment” has to include a wide scope of perspectives representing multiple disciplines with an emphasis on outcome, efficiency, and medical appropriateness.40 The interplay of forces that determine the diffusion of technology in the marketplace is poorly understood.5 Physician attitude and behavior, however, determine to a large extent when and how technology will be applied in the clinical setting.5 Unfortunately, not much is known about the influences on physicians regarding how they obtain and apply practice-related information about use of technologies.40

In the United States, HTHC may evolve without input of physicians due to the lack of incentives for physician participation.41 Nevertheless, pediatric home care physicians surveyed unanimously agree that a physician must be directly involved.42 These physicians stated a need for access to information about home care technology to assume their responsibilities. Physicians also want mechanisms to report experiences as users of technology in the home. These experiences would provide invaluable information for technology reassessment.

A system that encourages physician participation in home care technology assessment should focus on what physicians value: quality care. Continuous quality improvement activities of practicing physicians should incorporate technology assessment. A system also ought to reflect how physicians work; a technology tracking mechanism should relate physicians to physicians and to other healthcare professional experts. Physicians who use home care technology have insights that might then be transmitted to others involved in technology assessment and technology tracking systems could integrate their experiences.

The United States can look to other nations that have created successful mechanisms for home care technology assessment. The experiences of these nations show that methods of technology evaluation exist regardless of the healthcare finance system in place. Each nation’s particular approach reflects their own culture, which determines what and how things are done. Physicians in each country recognize that technology assessment represents a component of quality, risk, and cost management that impacts patient care and safety. Technology assessment should incorporate physician experience as technology users in the home environment.

REFERENCES

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