Building a home ventilation programme: population, equipment, delivery and cost

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ABSTRACT
Home mechanical ventilation (HMV) improves quality of life and survival in patients with neuromuscular disorders (NMD). Developing countries may benefit from published evidence regarding the prevalence, cost of equipment, technical issues and organisation of HMV in NMD, facilitating the development of local turn-key HMV programmes. Unfortunately, such evidence is scattered in the existing literature. We searched Medline for publications in English and French from 2005 to 2020. This narrative review analyses 24 international programmes of HMV. The estimated prevalence (min–max) of HMV is ±7.3/100 000 population (1.2–47), all disorders combined. The prevalence of HMV is associated with the gross domestic product per capita in these 24 countries. The prevalence of NMD is about 30/100 000 population, of which ±10% would use HMV. Nocturnal (8/24 hour), discontinuous (8–16/24 hours) and continuous (>16/24 hours) ventilation is likely to concern about 60%, 20% and 20% of NMD patients using HMV. A minimal budget of about 168€/patient/year (504€/100 000 population), including the cost of equipment solely, should address the cost of HMV equipment in low-income countries. When services and maintenance are included, the budget can drastically increase up to between 3232 and 5760€/patient/year. Emerging programmes of HMV in developing countries reveal the positive impact of international cooperation. Today, at least 12 new middle, and low-income countries are developing HMV programmes. This review with updated data on prevalence, technical issues, cost of equipment and services for HMV should trigger objective dialogues between the stakeholders (patient associations, healthcare professionals and politicians); potentially leading to the production of workable strategies for the development of HMV in patients with NMD living in developing countries.

INTRODUCTION
Hypercapnic respiratory failure due to alveolar hypoventilation is a common complication of severe neuromuscular disorders (NMD), obesity hypoventilation syndromes (OHS), chronic obstructive pulmonary diseases (COPD) and restrictive thoracic diseases (RTD).1 Home mechanical ventilation (HMV) is effective treating chronic hypercapnic respiratory failure in the long term.2 HMV via positive pressure was introduced in the 1980s, initially for patients with poliomyelitis, NMD and RTD.3 There is accumulating evidence supporting improvement of gas exchange, quality of life and prolongation of survival by HMV in patients with hypercapnic respiratory failure.4 In 2005, the estimated prevalence of HMV in Europe was 6.6 per 100 000 people.5 To date, little is known regarding the use of HMV in developing countries.

Developing countries interested in using HMV may benefit from published evidence regarding the organisation of HMV. They should be aware of which patients are eligible for HMV and understand: number, type, cost of equipment needed for HMV and which ventilation approach is desired.6 Unfortunately, such information is scattered in the existing medical literature. The present authors suggest that collating the above-mentioned information is likely to facilitate the development of local turn-key HMV programmes.

This review discusses basic evidence with regards to HMV, with a focus on patients affected by NMD. Basic evidence includes the prevalence of disorders eligible for HMV, the prevalence of both HMV in general and within disorders and the technicalities and cost of equipment for HMV. This review also provides an original algorithm to calculate the cost of HMV equipment in accordance with local financial resources. This review aims to provide consistent evidence about existing HMV programmes, which will trigger an ongoing dialogue between patient associations, healthcare professionals and politicians. Informed dialogue should help to develop a workable strategy for the development of HMV in patients with NMD living in developing countries.

PREVALENCE
A search of Medline/PubMed for HMV articles published between 2005 and 2020 was performed. The search items included: neuromuscular diseases, HMV, domiciliary ventilation, prolonged ventilation, long-term ventilation and non-invasive ventilation. To determine the prevalence of HMV, we selected original articles that included comprehensive national or regional data on HMV. We excluded studies on any or all of the following: reporting the use of continuous positive airway pressure (CPAP) devices or mixing data from CPAP and assisted ventilation, using HMV in the hospital, conducted in a single centre, selecting a limited number of disorders, covering a limited range of age of HMV users or reporting the use of invasive techniques solely. Prevalence data were standardised by 100 000 inhabitants.

Prevalence of NMDs
The development of HMV programmes presupposes the identification of disorders potentially eligible for HMV initiation. Eligible disorders for
HMV are classically categorised in four groups: NMD, OHS, COPD and RTD. NMD include amyotrophic lateral sclerosis, bilateral diaphragm paralysis, post-polio syndrome, spinal muscular atrophies, type 1 myotonic dystrophy, myopathies, muscular dystrophies, chronic polyradiculoneuritis and multiple sclerosis. Although the incidence of patients with NMD is stable, the prevalence rises slightly due to improved outcomes in this patient group. In France (2012), the number of people affected by NMD was estimated to be between 20 and 25,000 cases for 65.5 million inhabitants, corresponding to a prevalence of about 30/100,000 inhabitants.

Prevalence of HMV

The largest survey describing the use of HMV was conducted by Lloyd-Owen et al. The estimated prevalence of HMV in East European countries, all disorders combined, was as low as 0.1 per 100,000 inhabitants as compared with 6.6 in Western and Central European countries. Figure 1 depicts the most recently reported prevalence from 24 national HMV programmes between 2005 and 2020. Available prevalence, ranging 1.2–47/100,000 inhabitants, was highly variable across countries. Northern European countries reported the most recently published and highest prevalence of HMV. Large differences are reported across regions within the same country, despite a homogeneous national healthcare system and similar indications for treatment. For example, the prevalence of HMV varies between 1.2 and 4.0 among 16 regions in Poland, between 4.3 and 13.0 among eight states and territories in Australia and between 0.4 and 15.5 among nine territories in Canada. Different reasons can explain such large variations within countries. Garner et al found that HMV prescribing patterns depend on each centre's location, size and experience. They found that the more densely populated Australian states have the highest prevalence of HMV. Dybwick et al found that an uneven distribution of the 'enthusiasm' among hospitals was a major factor impacting the geographical distribution of HMV in Norway. This finding from a high-income country suggests that the access to HMV would not solely be affected by objective parameters such as the level of healthcare development. Subjective aspects such as the variable interest of professionals and bureaucrats in specific healthcare domains may play a significant role in the local development of HMV.

Prevalence of HMV in NMDs

As previously stated, the prevalence of HMV in NMDs is reported as stable or slowly increasing over time. Table 1 reports a prevalence of NMDs using HMV at 2.9/100,000 inhabitants, which is in line with France in 2013 (3/100,000), and Belgium

Box 1

In 2005, the prevalence of home mechanical ventilation (HMV) in Europe was 6.6/100,000 inhabitants. According to international HMV programmes (figure 1, data from 24 countries), the prevalence of HMV ranges 1.2–47/100,000 inhabitants. The prevalence of HMV varies between different regions of the same countries despite a homogeneous healthcare system. Uneven distribution of the 'enthusiasm' between hospitals impacts the distribution of HMV.

Figure 1 Most recently estimated national prevalence of HMV in 24 countries. Prevalence by date of published reference: Austria, Denmark, Ireland, Italy, Portugal, Spain, France, Germany, UK, Poland, USA, Australia, New Zealand, Canada, South Korea, Chile, Greece, Hungary, Belgium, Czech Republic, Norway, Sweden, Finland, Netherlands. HMV, home mechanical ventilation.
in 2019 (2.6/100 000).19 Current prevalence data suggest that about 10% of all NMDS would use HMV.

Today, the reimbursement of HMV in NMDs is consistent across West-Europe but varies widely in other areas. Central Europe is a good example. In 2008, the National Health Authorities in Serbia recommended full reimbursement of respiratory equipment for NMDs.25 According to the information from the Russian Duchenne websites, as much as 20% DMD and 8% SMA patients would use HMV in Russia. Reimbursement policies may be totally lacking in countries neighbouring Russia such as Ukraine, where the prevalence of HMV is estimated to be as low as 0.2% of all patients with DMD (http://dmd.org.ua/).

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Prevalence of HMV according to nation wealth

It can be hypothesised that the development of HMV correlates with the economic development of a given country. Figures 2 and 3 present the correlation between the prevalence of HMV and markers of both wealth and development of countries, such as the gross domestic product (GDP, figure 2) and the human development index (HDI, figure 3). The GDP is the monetary value of all finished goods and services produced in a country. GDP is considered as a key tool to guide policymakers in strategic decision-making. The HDI, from 0 to 100 points, assesses the development of a country through three dimensions: the life expectancy, the level of education and the standard of living. Values of GDP and HDI were collected using the Development Programme of the United Nations.26 Values of GDP and HDI reported in figures 2 and 3 correspond to the year of reported prevalence of HMV in 24 countries.

Although, there were positive relationships between both the prevalence of HMV and the GDP per capita (R²=0.4359), and between the prevalence and the HDI (R²=0.3475), the dispersion of the prevalence seems less pronounced in countries with the lowest GDP. This suggests that GDP is not the only determinant of NIV prevalence. This result should, therefore, be interpreted with caution. However, the wealthiest and more developed countries have the highest prevalence of HMV. It is, therefore, not surprising that new HMV programmes currently developing are in high-income countries such as Singapore,27 Taiwan28 and Saudi Arabia.29 Despite the high prevalence of non-invasive ventilation in high-income countries, it should be borne in mind that large disparities in access to care may persist in these countries.

Next to high-income countries, low to middle-income countries (LMICs) with developing healthcare systems have made efforts to develop HMV. In these countries, HMV is often developed in single centres, and studies do not report comprehensive data. These countries were, therefore, not included in figures 2 and 3. By decreasing order of GDP per capita, middle and low-income countries developing HMV include Thailand,30 China,31
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Brazil, Iran, South Africa, Tunisia, Malaysia, Turkey, Argentina, Serbia, India and Pakistan.

Evolution of the prevalence of HMV

Figure 4 illustrates the evolution over time of HMV in 15 areas, where estimates of prevalence of HMV were available at different periods. The number of HMV users were constantly rising, with rapid progression in some countries, and slow progression in others. The progression of HMV in high-income industrialised countries is explained by a drastically increasing prevalence and evolving evidence regarding the benefits of HMV in OHS, but even more so in COPD, leading to a change in the pattern of prescribing of HMV. The populations treated have persistent smoking habits and are ageing, comorbid and frequently obese. The region of Vaud, Switzerland, is an example of this phenomenon, with a prevalence of HMV increased 2.5-fold since 2000, reaching 37.9 per 100 000 inhabitants in 2020.

TECHNICALITIES AND COSTS OF HMV

Technical aspects of HMV

Depending on the time period of ventilator use per 24 hours, three categories of HMV users can be defined: nocturnal (8/24 hour), discontinuous (8–16/24 hours) and continuous (>16/24 hours,
life support) ventilation. Those categories include both non-invasive and invasive techniques of HMV. In Hungary, 74% of HMV users receive HMV at night, 15% between 8 hours and 16 hours and 10% use HMV for more than 16/24 hours. This is in line with Switzerland (2020), where 9% of NMDs use ventilation for more than 16 hours. In Belgium (2019), 58%, 17% and 25% of NMDs received nocturnal, discontinuous and continuous ventilation, respectively. Based on those results and on the opinion of the current authors, nocturnal, discontinuous and continuous HMV would roughly affect about 60%, 20% and 20% of patients using HMV. Equipment requirements increase according to the dependence on mechanical ventilation. Bilevel devices may not necessarily be equipped with batteries and provide pressure-cycled ventilation solely. They operate via 110–220 volts electricity and are designed for nocturnal use in bed. By contrast, life-support ventilators provide multiple modes of ventilation, such as volume-cycled ventilation, pressure-cycled ventilation or a mix between volume and pressure modes. They are equipped with internal and external batteries, and alarms aiming at providing secure continuous HMV in all circumstances.

Nocturnal ventilation (8 hour)
In this category, patients require ventilation for up to 8/24 hours. The ventilator is used solely at night during sleep. An internal battery is not mandatory, with exceptions for those patients living very far from their reference centre for HMV or living in an environment with inconsistent electrical infrastructure. Bilevel positive airway pressure devices are less expensive than life-support ventilators, and they are effective for nocturnal respiratory support.

Discontinuous ventilation (8–16 hour)
Patients receiving discontinuous ventilation require HMV between 8 hours and 16/24 hours. The ventilator is used at night during sleep, plus a few hours during the daytime. Ventilators, equipped with an internal battery, are ideal but bilevel positive pressure devices can be used. When ventilatory support is used on a wheelchair, the availability of an external battery is desirable.

Continuous ventilation (>16 hour)
In this category, patients need ventilation for more than 16/24 hour. Such patients are at risk of suffocating if mechanical ventilation is interrupted. In this context, patients ideally benefit from two life-support ventilators (or a bilevel at night plus a life-support ventilator for daytime use), equipped with disconnection alarms, an internal battery, and an additional external battery. If no internal battery is available, external supply of electricity is mandatory.

Accessories for HMV
Patients are generally offered HMV via non-invasive interfaces such as nasal or oronasal masks. Invasive ventilation is not discussed in this review. The delivery of a circuit and mask two times annually is a minimum—the replaced items can be retained as backup equipment. The provision of a simple resuscitation bag is advisable for each of the three categories, but it is crucial for continuously ventilated patients to ensure ventilatory support in case of ventilator or power failure. The availability of a resuscitation bag also aims to support secretion management by lung volume recruitment prior to coughing, or to improve lung function of patients with NMDs, as illustrated in a low-income country. Mechanical insufflation exsufflation devices alternate positive and negative pressure. Such devices are able to recruit volume, assist cough and clear secretions out of the bronchial tree with minimal participation of respiratory muscles.

Services for HMV
Service delivery involves both the provision of technical implementation and education at the initiation of treatment, including a follow-up service at home. The organisation of technical assistance (24/24 hours in case of continuous HMV) via a dedicated respiratory support call centre is critical to minimise the risk for patients. Service delivery also includes the cost of homecare and maintenance of equipment. Given the large variation in the organisation and financing of local healthcare systems across the world, we do not discuss the cost of care and service delivery in this review. We focus on the cost of supplying HMV equipment, which includes the ventilators and accessories.
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Cost for HMV equipment

Ventilators

The purchase of ventilators represents the largest costs related to HMV. In the Czech Republic, an affordable bilevel ventilator and related accessories cost 2,400€. Bilevel devices are cheaper (<4,000€) than life-support ventilators (>6,500€). Considering the bilevel lifespan over 7 years based on the authors’ experience, 1 year of treatment costs 630€, which includes accessory changes 1x/year.9 In Asia, inexpensive bilevel devices between 350€ and 600€ were developed to make HMV possible at low cost. A backup power supply unit can be provided for 160€ to support 24-hour ventilation at home in India.40

Accessories

In general, tubing is available at low prices (5–20€). Nasal masks (35–180€) are less expensive than oronasal masks (90–300€). Usually, accessories are cheaper in developing than in developed countries. Differences in the rate of replacement and reimbursement of accessories across countries impact on the cost for HMV equipment.55

Cost for HMV equipment in NMDs

Figure 5 provides an original algorithm to calculate an annual workable budget for HMV in patients with NMDs, per 100,000 inhabitants. It considers the prevalence of the three categories, nocturnal, discontinuous and continuous NIV. This algorithm aims to provide a rough estimation of the annual cost for HMV equipment according to low versus high budget allocated to HMV. Obviously, many combinations of equipment and cost exist between the low and high budgets in figure 5.

The calculation considers a minimum of 6-year amortisation of HMV equipment and includes the provision of two masks and tubing/year. As suggested in figure 5, patients with NMD can be offered HMV from around 504€/year/100,000 population when using inexpensive bilevel devices. This corresponds to ±168€/patient with NMD/year. Such low costs, corresponding to 10% of that in high-income countries, highlights why LMICs may find it possible to provide low-cost HMV.

The high budget suggests offering HMV from ±5,040€/year/100,000 population, corresponding to ±1,680€/patient with NMD/year. However, services, maintenance, reparations, delivery of humidification systems, suction units and chin straps (if needed), filters, resuscitation bag, additional external batteries and other accessories are not included in this budget. When considering all services and equipment, the reimbursement of HMV leads to greater costs. For example, reimbursement of nocturnal ventilation may reach 3,232€, 5,037€ and 5,760€/patient/year in France, Belgium and South Korea, respectively.15 56 57

Factors influencing the success of HMV development

There is a considerable number of interacting factors affecting the success of HMV development.

Reimbursement policies and network

Adequate reimbursement policies as well as an organised and functional network are essential for HMV implementation.25 The lack of full reimbursement hampers the development of HMV in most LMICs, however, during the past few years, the situation has improved in Europe.58 There may be either no reimbursement at all (Ukraine, Bosnia and Hercegovina) or partial reimbursement such as in children (Bulgaria), in NMD (Serbia, Romania) or in the case where invasive ventilation is used as interface (Czech Republic). In Russia, candidates for HMV initially relied either on charitable foundations or on the patients and families themselves. In 2019, the Russian Ministry of Health introduced a system where the purchase and delivery of HMV equipment are made by state hospitals. In Poland (2004), the National Health Fund reimbursed HMV through public health funding. Since then, a rapid increase in HMV prevalence was observed, indicating the importance of public funding.23

To achieve a satisfying life, patients with HMV require help from a variety of health and social care services, community services as well as care from the family.59 Centres for HMV ensure the selection of the right patients, the timely initiation of adequate ventilation and monitoring during regular long-term follow-up.60 The network should facilitate the distribution of the responsibilities at different levels: the social work department for home discharge, the providers of HMV equipment delivery, the HMV specialists for long-term follow-up, the personal support worker at home and the availability of contacts in case of technical or medical emergencies.61

Dedicated centres for HMV
Centralisation of care in few dedicated centres for HMV, concentrating the experience of HMV, is desirable.25 In the historical survey by Lloyd-Owen et al, as few as 65 HMV users on average were followed up per centre.5 In order to maximise the effectiveness and minimise costs for centres for HMV, Denmark and the Netherlands have limited the number of centres providing HMV.46 In the Netherlands, patients were split into four national centres: each centre covering a general population of 4.3 million. Comparatively, in 2005, there were 4.4x, 6x, 12.6x, and 31x more centres in Poland, Belgium, Portugal, and Sweden, respectively.5 The largest and least inhabited countries accounted for many centres, each concentrating on fewer HMV users.13

Role of international cooperation
Examples of emerging programmes of HMV in developing countries demonstrate the positive impact of international cooperation, such as between Serbia and France in 2005,25 and between Chile and Germany in 2006.16 After donations of second-hand ventilators, a successful programme for HMV was established and subsequently subsidised by local health authorities, highlighting the importance of developing care and financing together. Such successful cooperation substantiates that second-hand devices, used in developed countries for 5 or 6 years but due for replacement, should be fit for use for an additional few years in LMICs.

Socioeconomic conditions
It is obvious that socioeconomic conditions impact the development of HMV. However, there are numerous studies from LMICs concluding that HMV can be initiated in developing countries. In South Africa, an LMIC, HMV was deemed as feasible despite difficult socioeconomic circumstances. Survival outcomes were comparable to high-income countries with HMV. An underlying medical condition was the only independent significant risk factor for mortality.29 In Poland (2010), the most important factors, which originally inhibited the development of HMV, were the omission of respiratory physicians in the process of qualification, the absence of any national guidelines and the sophisticated demands for HMV equipment.11 In Canada, important perceived barriers to HMV were the insufficient funding for paid caregivers and equipment for HMV.14 However, it is hard to differentiate the costs for the care of people with a disability in general from the supplemental care related to HMV. Again, the socioeconomic conditions do not appear to be the only parameter limiting the prevalence of HMV. Enthusiasm and willingness to develop HMV explain, in part, why high-income countries insufficiently develop HMV and why some LMICs make inspiring efforts to develop it.24

Requirements of local authorities
The initiation of HMV should meet the requirements of the local authorities regarding the equipment specifications for HMV. The initiation of a pilot programme of HMV in Ukraine in 2021, using 10 second-hand ventilators donated from abroad, met unexpected barriers.62 Quite logically, the Ministry of Health in Ukraine required an assurance (especially during the COVID-19 pandemic) that the manuals and guides for all ventilation equipment for HMV were available in Russian language (devices and accessories). On one hand, ventilators were not reimbursed, but, on the other hand, donation was challenging, suggesting that stringent regulations can prove, to some extent, a hindrance to the development of care.

One should be inspired by trials to make low-cost ‘custom-made’, and easy-to-build non-invasive pressure support ventilators for hospital use, potentially leading to the development of equipment for HMV in LMICs, provided that such devices can obtain official recognition to be used at home.63

Developing expertise for NIV in acute care
Implementation of HMV is challenging when NIV is not used on regular basis in acute care units in LMICs, leading to the lack of equipment and skills of the medical staff.64 Usually in LMICs, only a few clinical centres with enthusiastic leaders use NIV to treat acute respiratory failure, whereas, for the majority of patients, acute NIV is not available. Without acute NIV, it is not easy to implement long-term NIV for home use, since most of eligible patients would be recruited after an acute episode. To bridge this gap, between 2016 and 2019, the Ministry of Health in Poland financed the development of beds in specialist wards providing acute NIV care across Poland. This highly cost-effective programme, reducing in-hospital mortality, could be adapted and introduced in other LMICs.65

Training of local medical staff
Knowledge about the pathophysiology of respiratory failure, principals of operation of HMV devices, circuits and interfaces should be shared in the training of involved medical staff.62 Since 2012, the Polish Society of Respiratory Diseases has run 2–3 days hand-on workshops for about 30–40 doctors and the same number of nurses.66 Three editions are running every year: basic, advanced and home NIV. To date, about 1000 professionals have been trained. Hence, efforts should be concentrated on assisting local leaders in NIV in adapting such educational programme in all LMICs. Assistance should cover preparation of presentations, and teaching materials and support by experts, in person during workshops.62 The creation of a guideline for HMV would be the pinnacle of success. The assistance and cooperation, with experts from developed countries, would be invaluable for leaders from LMICs.

The burdens of care and financial constraints for family members
The everyday care of disabled patients dependent on HMV is an even more demanding issue than providing and operating a ventilator. In LMICs, the social care is underdeveloped and this issue usually falls on family members who have to take responsibility themselves or hire a caregiver out of personal funds. In this scenario, families in LMICs have to assess whichever option is better for them. Public caregivers are available in most LMICs, but they can serve only a few hours a day, which does not enable full-time employment for the family member. If a family is not able to perform full-time care or afford hiring a...
CONCLUSIONS

This review reports updated prevalence data of HMV. The prevalence of HMV is estimated at 7.3/100 000 inhabitants, all diseases combined. The prevalence of NMDs is estimated about 30/100 000 inhabitants, of which 10% would use HMV. The group-specific prevalence of patients with NMD prescribed HMV is estimated about 3/100 000 population.

Our review clearly shows that a nation’s economy has a crucial impact on medical care. Since HMV is a method of treatment requiring sophisticated technology, the impact on this field seems to be even bigger, which contributes to large discrepancies in availability of HMV among countries, depending on their income. Thereupon, cooperation with developed countries may play an important role in accelerating the development of HMV in LMICs.

Our review concentrates on the technical needs of HMV. However, the provision of equipment does not meet all the needs of patients receiving HMV. Equally important is a system of care for these patients, with various needs and problems, which includes assessment of the timing of HMV, mode of initiation and long-term follow-up. The model of HMV differs from country to country, suggesting that none is perfect. That is why countries with HMV programme aspirations have a unique opportunity to benefit from experiences acquired by developed countries and thereby create their own, more comprehensive, patient-oriented and cost-effective system, in which we believe data presented in this article will be helpful.

This review proposes a method of calculation of the cost for equipment in NMDs per 100 000 inhabitants. Evidence from emerging countries suggest that a minimal budget of about 168€/patient with NMD per year, including the cost of equipment without any service, can address the cost of HMV equipment in LMICs. In high-income countries, a minimal budget of about 1680€/patient/year can address the cost of HMV. However, when the maintenance of equipment and services is included in the budget, it can increase between 3232 and 5760€/patient/year. There is a positive relationship between the prevalence of HMV and markers of wealth and development. Adequate reimbursement policies as well as an organised and functional network are essential for the implementation and development of HMV. However, the willingness of both healthcare professionals and patient associations can inspire health leaders who are equally concerned about the crucial importance of effective respiratory care of all health consumers in their jurisdiction.

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