Hospital Technology at Home

Portable Oxygen Therapy in COPD

SUMMARY

AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Québec

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Report prepared for AETMIS
by Susan Law and Pascale Lehoux

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MISSION

The mission of the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) is to contribute to improving the Québec health-care system and to participate in the implementation of the Québec government's scientific policy. To accomplish this, the Agency advises and supports the Minister of Health and Social Services as well as the decision-makers in the health care system, in matters concerning the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for disabled persons, as well as the modes of providing and organizing services. The assessments take into account many factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic implications.

FOREWORD

HOSPITAL TECHNOLOGY AT HOME: PORTABLE OXYGEN THERAPY IN COPD

People with chronic obstructive pulmonary disease (COPD) associated with moderate to severe hypoxaemia need long-term oxygen therapy for between 15 and 24 hours a day. Long-term oxygen therapy (LTOT) has proven to be an effective and cost-effective treatment that contributes to increasing patients' life expectancy. Introduced in the 1980s, portable oxygen systems for home use were designed to help patients comply with their prescribed treatment (i.e., dose and daily hours of use) and to improve their quality of life. The use of this equipment spread throughout the world even before solid scientific evidence had been obtained about its benefits for patients and its cost implications.

Québec's *Ministère de la Santé et des Services sociaux* (MSSS) therefore asked the *Agence d'évaluation des techniques et modes d'intervention en santé* (AETMIS) to summarize the available scientific evidence about the efficacy, safety, cost effectiveness and use of portable oxygen equipment and to evaluate its social, legal and ethical implications.

There is very limited evidence about the clinical efficacy or cost effectiveness of portable oxygen therapy. To date, only one controlled trial (completed in Québec in 2003) has been conducted with these issues in mind. According to that study, portable oxygen equipment apparently offers no benefits in terms of quality of life, compliance with treatment or exercise tolerance. It should be pointed out, however, that the sample size in this trial was too small to generalize the results to all patients.

Although the indications for long-term oxygen therapy are generally well recognized, there are no commonly accepted clinical or social indicators for prescribing portable oxygen therapy. Both the utilization of portable systems and the organizational models for health-care delivery vary considerably from one country to the next and even from one region to the next. There are no reliable data on the number of patients who actually use or who might benefit from using portable oxygen equipment. There are also widely differing views among professionals and the public on what constitutes appropriate access to portable oxygen therapy.

In light of these findings, AETMIS recommends that the MSSS should 1) define indications for each type of portable oxygen equipment; 2) develop a standardized assessment tool and standard procedures for the prescription and coverage of portable oxygen equipment; 3) set up the infrastructure for a coherent home oxygen therapy program that would include portable oxygen equipment; and 4) consider establishing a central patient registry. The MSSS is also encouraged to work in partnership with health professionals and research groups to implement a care program that is effective, efficient and fair for all patients requiring home oxygen therapy in Québec.

In submitting this report, AETMIS hopes to provide decision makers in Québec with the information they need to guide their policies and actions with respect to portable oxygen therapy.

Dr. Luc Deschênes
Chairman and Chief Executive Officer

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Any criticisms or errors remain the responsibility of the authors.

EXECUTIVE SUMMARY

Given the results of clinical trials conducted in the 1980s, long-term oxygen therapy (LTOT) has been proven to be an effective and cost-effective treatment for chronic obstructive pulmonary disease (COPD) with hypoxaemia. Oxygen therapy has been shown to increase the life expectancy of patients with moderate to severe hypoxaemia ($\leq$ 55 mm Hg saturation level) who receive oxygen from between 15 and 24 hours a day. Clinical trial results regarding the impact of LTOT on patients' quality of life, however, are inconclusive and difficult to interpret, owing to disease progression and problems associated with therapeutic compliance on the part of both health professionals and patients. Indications for long-term oxygen therapy are based on the criteria that were established for these trials and these criteria have since been adopted almost universally. Introduced in the 1980s, portable oxygen systems for home use were designed to increase patients' compliance with treatment and to improve their quality of life. The use of portable oxygen therapy spread throughout the world even before solid scientific evidence had been obtained about its benefits and cost implications.

The objectives of this report are the following: 1) to summarize published data about *a*) the effectiveness and use of portable oxygen therapy in the treatment of patients with COPD associated with severe hypoxaemia, *b*) different health-care organization models, and *c*) the cost effectiveness and quality of the care provided to these patients; and to review the psychosocial, legal and ethical implications involved in the delivery of oxygen therapy services; 2) to present a broad outline of service delivery in Québec with respect to the different types of oxygen systems available and the questions they raise; 3) to present a comparative analysis of the two home-oxygen programs in Canada that have adopted LTOT organization and service-delivery models known to be efficient and effective (Ontario and Alberta); and 4) to draw conclusions and make recommendations serving to guide the development of policies and practices, and to direct research in Québec.

Patients who require LTOT are typically over the age of 65. They are people who have smoked most of their lives and are limited in their daily activities because of the restrictions imposed by severe COPD. They have a life expectancy of approximately five years. A large minority of patients on LTOT continue to smoke. Problems related to patients' non-compliance with prescribed LTOT and portable therapy are well documented. It is also known that many health professionals fail to comply with established guidelines for LTOT.

The use of portable oxygen therapy as a component of LTOT is highly variable from one region to the next and from one country to the next, which is likely the result of two factors. First, health professionals do not have conclusive scientific evidence to make informed decisions about patient selection and therapeutic prescription. Second, there are widely differing beliefs concerning the potential benefits of portable oxygen therapy in terms of survival and quality of life. Portable systems were introduced with the intent to increase patients' mobility and ability to participate in activities outside the home, which would apparently contribute to increasing their compliance with treatment. This would in turn improve their life expectancy and quality of life.

While it has been clearly shown that the use of LTOT prolongs the lives of patients with COPD, there is limited published evidence regarding the costs and benefits of portable oxygen therapy. Oxygen therapy (with pharmacotherapy) is one of the largest cost components in the management of severe COPD with hypoxaemia, and portable oxygen therapy is commonly considered an expensive part of LTOT even though there is little information on its actual marginal costs. Whereas the criteria for prescribing LTOT are almost universally accepted, none exist for portable oxygen therapy. The United States

and the United Kingdom, however, have adopted some guidelines. The very first controlled trial to assess the costs and benefits of portable oxygen therapy was conducted at Hôpital Laval in Québec and completed in the fall of 2003. Preliminary results seem to indicate that portable oxygen equipment does not improve patients' quality of life, compliance with treatment or exercise tolerance. The researchers conclude that portable oxygen therapy should not be prescribed routinely to all oxygen-dependent patients with COPD. Nevertheless, it is doubtful whether these findings can be generalized to all patients, given that the sample size was very small (n=22) and that the researchers had difficulty recruiting patients for this trial.

In Québec, the organization and delivery of home oxygen therapy has varied significantly from one region to the next since 1998 when the services offered by the *Office des personnes handicapées du Québec* (OPHQ) were decentralized. These services are now provided at various levels. Some are regionally centralized, while others are based at a hospital or CLSC, when they are not subcontracted outright to oxygen-equipment suppliers. No data have ever been systematically gathered on the use, cost, health outcomes or quality of care, permitting an analysis of the delivery of home oxygen therapy services. Reported use of portable oxygen therapy also varies widely, but there are no precise figures available. Coverage of portable systems is complex and inconsistent across the province. Most patients with COPD who are eligible for long-term oxygen therapy do not have private insurance.

Many of the people we interviewed stated that fewer people use portable systems in Québec than in other provinces and countries, while the burden of COPD is higher in Québec than in the rest of Canada.

Given the cost information provided by key informers, the marginal annual cost of a portable compressed gas system (provided to patients in addition to a fixed system at home) is estimated to range from $500 for a patient with limited activity to $2,000 for a very active patient. There are about 450 portable systems in use in the Montréal and Laval regions. Only one program has adopted formal criteria for the use of home oxygen equipment. In addition, there are widely differing views on the ideal candidate for home-based portable oxygen therapy.

Access to portable therapy is not uniform throughout Québec, which raises the issue of equity, not only with respect to the existing distribution of services but also with respect to the changes that should be proposed to help policy makers reach informed decisions, once evidence becomes available.

It is unlikely in the near future that conclusive scientific evidence regarding the clinical efficacy and cost effectiveness of portable oxygen therapy will be available to guide Québec policy in this area, although it is hoped that the results of the clinical trial will be a step in this direction. In the meantime, however, in order to build a system based on criteria such as transparency, efficiency (i.e., the rational use of existing resources) and equity, as well as on fair decision-making processes, it is proposed that any policies on the use of portable oxygen therapy in Québec take into account the priorities listed below, that is, it would seem advisable to:

1) Define, by clinical consensus and with the involvement of patients or their representatives, the indications and contra-indications for the use of the different portable oxygen systems as part of long-term oxygen therapy and to determine areas of clinical uncertainty regarding their use;
2) Develop a standardized instrument for the clinical assessment and prescription of portable oxygen equipment and for monitoring eligible patients (this could be a component of a tool developed specifically for home oxygen therapy services);
3) Establish standardized procedures for the prescription and coverage of portable oxygen equipment. Two possible options are **a)** to consider portable oxygen therapy an "exception treatment" (in line with the principle governing exception drugs) or one

intended for patients viewed as "exception patients." This would mean that the RAMQ would make case-by-case decisions about access to portable oxygen therapy in response to physicians' requests and in accordance with pre-determined indications; and/or **b)** to develop routine, systematic procedures for audit review and monitoring of prescription and use in accordance with established indications and procedures for prescribing this therapy. (This option could build on administrative procedures currently in effect in some regions for home oxygen services);

4) Set up a clear and transparent structure for LTOT in Québec with a central body or forum mandated to oversee the development of a coherent home oxygen program across the province. This would include a standardized coverage policy for home oxygen therapy, including portable therapy, which would be homogeneous across the province but which could be adapted to suit the specific characteristics of the region and to meet the particular needs of the local population. Information about available services could be disseminated to patients via patient associations; and
5) Consider establishing a central patient registry for home oxygen therapy that would include information about the prescription and utilization of portable systems and that could be used to monitor access, care delivery and patient outcomes.

The options described above could be the mandate of groups or networks already involved in the treatment or research of COPD (e.g., the Québec Association of Respirologists or the respiratory research network of the FRSQ). These groups would work in partnership with the MSSS and with the involvement of concerned groups of patients and health professionals.

DEFINITIONS

Long-term oxygen therapy (LTOT)

Long-term oxygen therapy refers to the provision of home-based oxygen therapy on a continuous basis (for at least 15 and up to 24 hours a day) and on a long-term basis (for more than three months) to correct chronic hypoxaemia appearing in chronic respiratory diseases.

Long-term oxygen therapy can be provided by a fixed (i.e., stationary) system of oxygen supply (oxygen concentrator or large cylinders of compressed or liquid gas) or by a combination of fixed and portable systems, as briefly described below.

In most countries, LTOT is prescribed by respirologists.[1] The involvement of general practitioners, paediatricians and other specialists varies from one region and country to the next.

Oxygen delivery systems

Most patients on LTOT receive oxygen through a continuous flow nasal cannula. Yet this form of delivery is highly inefficient because only about 17% of the gas participates in the actual gas exchange; the balance is wasted to environmental air [Tiep, 1990]. This inefficiency is only a concern when patients use liquid-oxygen or compressed-oxygen gas tanks. In the 1980s, three types of oxygen-conserving devices were developed: transtracheal catheters, reservoir cannulas and electronic-demand oxygen delivery devices. These systems reduce the amount of wasted oxygen, which helps decrease costs and increase the portability of the device since the oxygen in the reservoir lasts longer.

Portable oxygen therapy

In this report, portable oxygen therapy refers to the use of small oxygen cylinders (compressed gas or liquid) that patients can carry or push themselves (e.g., shoulder bags or small trolleys) during exercise and daily living activities (within or outside the home). Portable systems usually weigh under 4.5 kilograms (10 lbs). Small cylinders of compressed gas provide about two hours of use at 2 L/min oxygen flow rate.

In the United States, the term "ambulatory" often refers to therapy and services that are provided outside a hospital. In the case of oxygen therapy, a distinction is also made between *portable* systems that patients can transport in strollers or on pushcarts, and *ambulatory* oxygen systems that patients can carry or wear. Because the term "ambulatory" is potentially confusing, we have avoided it, except when it is explicitly defined. For the purposes of this report, the term "portable" refers to all non-fixed oxygen-delivery systems used by patients.

Supply systems

There are three stationary sources of oxygen supply available for home use: oxygen concentrators, compressed-gas cylinders and liquid-oxygen reservoirs. Portable oxygen systems are available for use with compressed gas or liquid oxygen. A brief description is provided below [Weg and Haas, 1998; Levasseur et al., 1998].

1. The meaning of the term "respirologist" used in this report includes all physicians with specialist training in respiratory/chest medicine, e.g., pulmonary or respiratory physicians, chest or lung specialists.

Oxygen concentrators

Concentrators are electrically powered molecular sieve beds that filter and concentrate oxygen molecules from ambient or room air, generating concentrations of 90-98% oxygen. Maximal flow rates are 3-5 L/min. They are the preferred source of home oxygen for patients on long-term continuous oxygen therapy because the supply is constant and total costs for these systems are lower than for those that use gas cylinders. Concentrators weigh between 18 to 27 kg on average and are about the size of a home humidifier. They can be used with several metres of oxygen tubing to provide some mobility within the home, although the concentration and flow diminish if the tube is too long. Concentrators generate some heat and emit a constant low rumbling sound when in operation. Patients usually have a medium-sized backup cylinder that they can use in the event of a power failure. The use of a concentrator slightly raises people's electricity bills.

Oxygen concentrators are currently the predominant form of oxygen supply for LTOT in Québec. Hydro-Québec maintains a list of patients who require a constant source of electricity for medical equipment; however, this information is provided at the patient's discretion.[2]

Compressed-oxygen cylinders

This form of oxygen supply is particularly useful in the absence of a reliable electrical source and for short-term therapy. The large cylinders (H size) weigh around 67.5 kg and can provide oxygen for about 57 hours at 2 L/min; flows can go up to 15 L/min. A mid-sized cylinder that weighs between 6 and 7.5 kg provides oxygen for about 5.5 hours at 2 L/min. This cylinder, however, requires a cart to wheel it around and is appropriate for patients who only occasionally leave their homes. Small lightweight aluminum cylinders of compressed oxygen can be carried in a shoulder bag but last only from between 1 to 3.5 hours at 2 L/min. All compressed-oxygen cylinders must be provided by authorized oxygen suppliers; patients cannot refill portable cylinders on their own because of the safety hazards involved in handling compressed gas.

Liquid-oxygen system

This system comprises a large cylinder of liquid oxygen (oxygen maintained in a liquid state at an extremely low temperature) that functions as a reservoir and fixed system and comes with lightweight portable tanks. The reservoir lasts from about five to seven days at 2 L/min. Valves occasionally freeze at high flows (8 L/min). When this system is not in use, the liquid oxygen gradually evaporates. Equipment and delivery costs are typically from three to four times higher than those of concentrators. Portable cylinders of liquid oxygen weigh from 2.5 to 4.5 kg (lighter than compressed-gas cylinders), and last 8 hours at 2 L/min (about four times as long as portable compressed-gas cylinders). Liquid-oxygen cylinders can deliver high flow rates for longer periods than gas cylinders. Portable tanks can be refilled from stationary reservoirs by patients/carers who have had the proper training.

Given its relatively high cost, liquid oxygen is covered by the public system in Québec only in exceptional cases (e.g., patients who spend considerable amounts of time outside the home for employment or leisure activities, or those requiring high flows). This does not prevent patients from making their own private arrangements with liquid-oxygen suppliers.

2. HMR has developed a standardized form to collect pertinent information to be submitted to Hydro-Québec.

Agence d'évaluation des technologies et des modes d'intervention en santé

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