

# Home Oxygen Therapy in Japan: Clinical application and considerations for practical implementation

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## Abstract

Twenty six years has passed since the home oxygen therapy (HOT) was approved for coverage under the public health insurance program in Japan, and now over 150,000 patients receive this therapy. Originally introduced from Europe and the USA, our own efforts have successfully added unique characteristics to HOT. The problem of prolonged hospitalization of patients suffering from chronic respiratory failure was resolved by the efforts of the specialty academic societies and Respiratory Failure Research Group of the Ministry of Health, Labour and Welfare. Their success can be also attributed to the concurrent progress in the development of medical equipment and monitoring devices. In other words, it was a success of the collaboration of industry and academia. In the mean time, a new type of comprehensive pulmonary rehabilitation has been developed, supported by the advancement of multidisciplinary medical teams. The quality of respiratory care is increasingly becoming a focus of the discussion in community healthcare.

It is also worth noting that HOT has had an impact not only on COPD, but on healthcare of the elderly people. However, the treatment standards for HOT, which were set up over 30 years ago, are not necessarily consistent with today's healthcare development. The current HOT standards have many issues to consider, and must be revised to meet the needs of various cardiopulmonary or neuromuscular diseases as well as the desire of end-stage patients to live at home.

**Key words** Home oxygen therapy (HOT), Home treatment, Standard of healthcare coverage, COPD

## Introduction

Home treatment has expanded rapidly in Japan since the 1980s. This can be attributed to the increase in the elderly population, the resulting rise in the number of chronically ill patients, and sharp climb in medical expenditure in the nation. In addition, the focus of medicine has been shifting away from the hospital-based medical care especially acute care that became the norm after World War II and moving toward a quality of life (QOL) at home. Home oxygen therapy (HOT; also known as long-term oxygen therapy, LTOT; or domiciliary oxygen therapy) has made it pos-

sible for patients at home to easily receive the long-term oxygen treatment, which had previously been available only in a hospital setting. This change was also encouraged by technological advances. Currently, HOT has developed into Japan's most typical home treatment and saved many patients with chronic respiratory failure. But this achievement also led to many spillover effects, including making machine use at home possible in treating the elderly, encouraging the development of medical care system by a team of multi-disciplinary specialists and professionals, intensifying the debate over the quality of respiratory care, and advancing comprehensive

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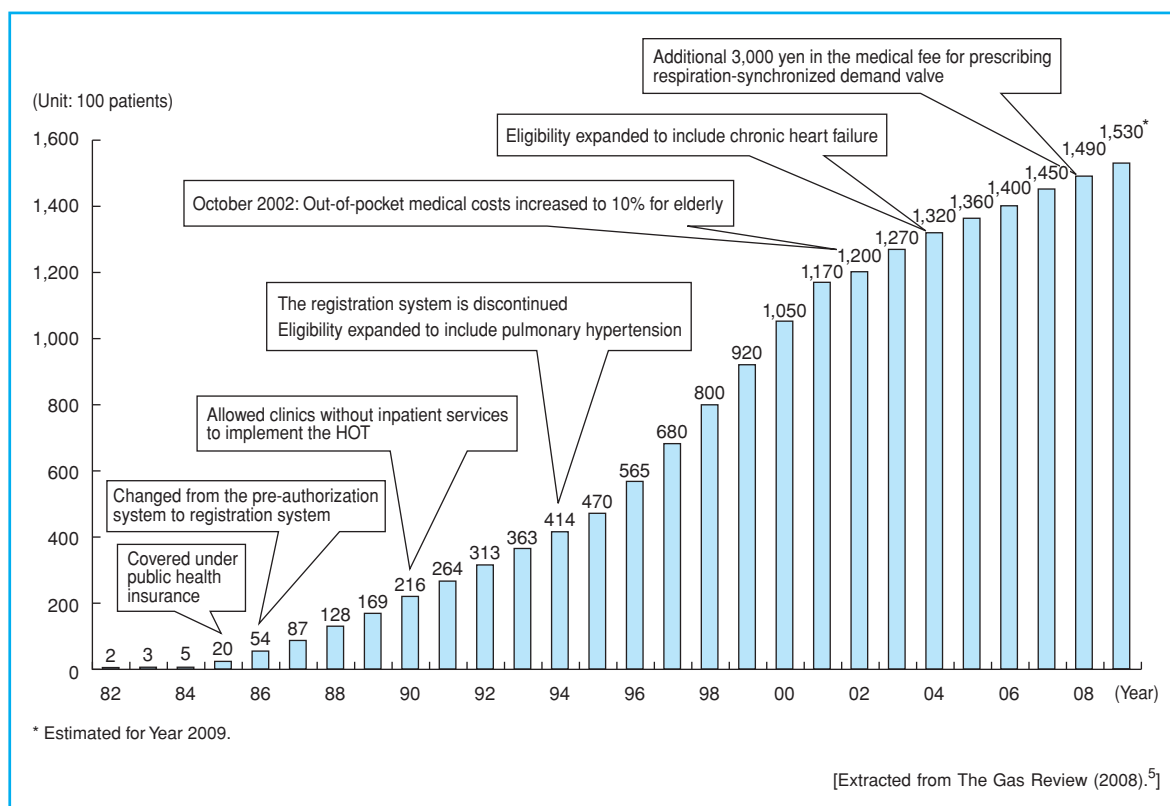


Fig. 1 Annual changes in the number of HOT patients in Japan

respiratory rehabilitation.

The current standards for introduction of HOT are based primarily on the results of clinical trials conducted about 30 years ago in the USA<sup>1</sup> and the UK.<sup>2</sup> These data are not necessarily sufficient, and multi-center study is being conducted in many institutions in the USA. Moreover, given the advances in the concepts of respiratory rehabilitation and successful results of combined treatment of HOT and exercise therapy in recent years, the approach to HOT is in flux.

This paper will primarily discuss the problems with the clinical application and implementation of HOT in Japan.

### History of HOT in Japan

Home treatment under public health insurance coverage in Japan considerably grew during the 1980's. Self-injection of insulin for diabetes was made eligible for health insurance benefits in 1981, the Public Aid for the Aged Act went into

effect in 1983, continuous ambulatory peritoneal dialysis (CAPD) gained eligibility in 1984, and HOT was also made eligible in 1985. In the past, patients with chronic respiratory failure due to pulmonary tuberculosis sequelae were forced to stay in the hospital for more than a year, sadly producing many suicides among them. HOT was made available after this dismal period, primarily due to advances in medical technology. The principles behind Mr. Takuo Aoyagi's accidental discovery of the principle of pulse oximetry (patent application filed in 1974) led to the subsequent development and sale of many measuring instruments. In the field of oxygen supply equipment, the development of domestically-manufactured oxygen concentrators using polymer membranes advanced, which ultimately resulted in the development of lightweight, portable cylinders that could be used outside of the hospital.

The second factor that contributed the dawn of HOT was the scholarly evidence for chronic respiratory failure. The research teams of the

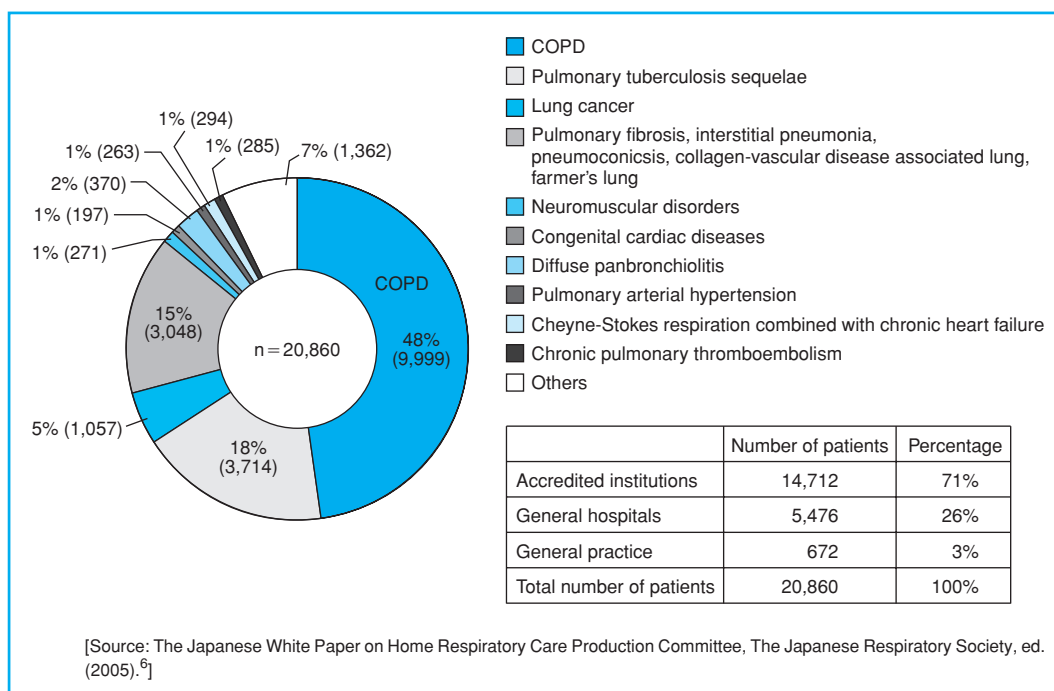


Fig. 2 The number of patients receiving HOT by facility, and the breakdown of patients by disease

US National Institutes of Health conducted clinical trials comparing a group of COPD patients with chronic respiratory failure who received oxygen therapy for 12 hours at night to a control group that received no treatment.<sup>1</sup> In the UK, the British Medical Research Council's team held clinical trials that compared a group inhaling oxygen night and day to a control group.<sup>2</sup> These clinical trials both found that life expectancy was significantly extended for the treatment group.

In Japan, the Respiratory Failure Research Group of the former Ministry of Health and Welfare (current Ministry of Health, Labour and Welfare, MHLW) pursued its own research. In particular, a national study on the patients suffering COPD or pulmonary tuberculosis sequelae reported that life expectancy was extended for the groups that received either oxygen therapy or oxygen inhalation treatment. This report significantly substantiated the medical benefits of oxygen therapy. In 2006, the Japanese Respiratory Society (JRS) issued guidelines for the implementation of oxygen therapy, in which the problems commonly experienced in implementing oxygen therapy are discussed.<sup>4</sup>

## Status of Home Oxygen Therapy in Japan

From the late 1980s through the 1990s, environment surrounding HOT improved. The implementation of HOT changed from the pre-authorization system to the registration system to the authorities. The prescription and management of HOT were extended to clinics without inpatient services, and then the registration system was abolished. The insurance coverage was expanded to include pulmonary hypertension. These changes contributed to the steady increase of the number of HOT patients. But in 2002, the elderly (generally 75 years of age or older) became responsible for 10% of their healthcare costs as an out-of-pocket expense. Since, the increased costs borne by the many elderly who needed HOT impeded its spread. It is now difficult to ascertain the exact statistics of HOT users in Japan since the registration system was abolished, but it is estimated that about 150,000 people used HOT as of 2009. **Figure 1<sup>5</sup>** shows the annual changes in the number of HOT patients.

In 2005, JRS published *Japanese White Paper*

**Table 1 Eligibility standards for public health insurance coverage of HOT**

<ol style="list-style-type: none"> <li>1. Cyanotic congenital heart disease</li> <li>2. Cases of advanced chronic respiratory failure Patients with arterial oxygen tension of 55 mmHg or less while using HOT, or patients with arterial oxygen tension of 60 mmHg who experience severe hypoxemia when sleeping or exercising whose doctors determine that HOT is necessary.</li> <li>3. Pulmonary hypertension</li> <li>4. Chronic heart failure Based on a doctor's diagnosis; patients are classified as NYHA III or higher and exhibit Cheyne-Stokes respiration when sleeping, and an apnea/hypopnea index (an index of the number of complete cessations and partial obstructions of breathing occurring per hour of sleep) of 20 or higher is confirmed using polysomnography.</li> </ol>
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[Extracted from Ministry of Health, Labour and Welfare, Japan (2008).<sup>7]</sup>

on Home Respiratory Care.<sup>6</sup> The breakdown of HOT patients reported here is quite similar to the aforementioned report by the former Ministry of Health and Welfare; the most common disease is COPD occupying nearly half of the patients, followed by pulmonary tuberculosis sequelae (**Fig. 2**).<sup>6</sup> Over 70% of the cases were implemented through the facilities accredited by JRS. Although HOT can be provided through clinics that have no inpatient services, they account for only a few percentage points. Currently, respiratory specialists are taking the leading role in providing the therapy.

The points stated in *Japanese White Paper on Home Respiratory Care*<sup>6</sup> can be summarized as follows.

- (1) Team approach has been encouraged.
- (2) The social role of the specialists has been clarified.
- (3) The current health insurance coverage is insufficient, and the need to proactively encourage the revision of the medical fee points has been recognized.
- (4) The idea was suggested that the promoting medical care by a team of multi-disciplinary specialists and developing medical collaboration in communities would reduce the burden of the specialists.

### Standards for Adoption of HOT

The current eligibility standards in Japan that must be met to receive HOT under the public health insurance are shown in **Table 1**.<sup>7</sup> Previously, the HOT implementing facilities had to be hospitals (medical facilities with 20 or more beds). Since HOT became eligible for healthcare

coverage in 1985, the eligibility standards were extended to clinics without inpatient services, which promoted home treatment. Coverage has also been expanded to patients with congestive heart failure accompanied by sleep respiratory disorders. A study by Dr. Sasayama and others specifically provides data on the cases of congestive heart failure among Japanese people.<sup>8</sup> An examination of the effect of HOT given over 12 weeks to patients with NYHA II to III heart failure who has left ventricular ejection fraction (LVEF) of 45% or less showed improvements in the apnea/hypopnea index (AHI) at night and the oxygen desaturation index (ODI) and the increases in the amount of exercise and LVEF.

HOT in Japan is primarily based on the clinical trials data conducted in the USA<sup>1</sup> and the UK,<sup>2</sup> both of which had COPD patients as subjects. In Japan, however, HOT is used for an extremely wide range of diseases in order to encourage home treatment, and yet we lack clear evidence for other diseases. In addition to advanced hypoxemia, HOT is often used to ease respiratory distress. The survey result in the white paper by JRS<sup>6</sup> shows that HOT is provided in conditions that do not meet the implementation standards in about 30% of cases.

Patients with COPD may experience extreme hypoxemia during exertion and sleep at night, even if their arterial oxygen tension was preserved within the normal range when the patient is at rest. Accordingly, even if oxygen saturation at rest exceeds 93% on the pulse oximeter during an outpatient examination, the patient can still experience hypoxemia during exertion or sleep. Sustained hypoxemia could impede not only the respiratory system but also the circulatory

system, haematopoietic system, and higher central nerve system. Oxygen therapy is intended to prevent and treat these problems. Moreover, HOT improves exercise tolerability and activity of daily living (ADL), and reinforces exercise therapy since oxygen is administered during the exercise therapy. On the other hand, patients who receive portable oxygen therapy for hypoxemia during exertion do not show any improvement in QOL.<sup>9</sup>

Recently, the National Emphysema Treatment Trial (NETT) study conducted in the US, which targeted patients who had undergone lung volume reduction surgery, gave a general overview of the effects of HOT.<sup>10</sup> In the short term, oxygen administration improves hypoxemia, mitigates shortness of breath during exertion, and enhances exercise tolerance. At the same time, the long-term effects include a longer life expectancy for patients with advanced hypoxemia. As regards the impact of oxygen administration on lung hemodynamics, only minimal fluctuations were observed in pulmonary hypertension, but sustained oxygen administration showed a tendency of better improvement than intermittent administration. With respect to sleep respiratory disorders, the sustainability and quality of sleep was improved by administering oxygen to prevent oxygen saturation level from dropping at night, which is one of the main causes of respiratory problems during sleep. Consequently, oxygen therapy can be expected to prevent pulmonary hypertension, but the data that oxygen administration at night extends life expectancy is still insufficient.

In recent years, comprehensive pulmonary rehabilitation approach, such as exercise therapy together with drug therapy, has been seen as more important. Pulmonary rehabilitation is effective in alleviating respiratory distress, improving exercise tolerance, and enhancing QOL.<sup>11,12</sup> Patients who experience hypoxemia on exertion are recommended to receive exercise therapy under oxygen therapy.<sup>13</sup> Oxygen administration during exercise therapy has the benefits of raising exercise performance, making rehabilitation more effective while enabling high-intensity exercise.<sup>14,15</sup>

HOT is implemented as a supportive measure in Japan in cases of interstitial pneumonia with hypoxemia on exertion. However, clinical trials conducted in many institutions in Italy were not able to prove its effectiveness such as extend-

ing longevity (personal communication by Dr. Zielinski, 2002). HOT has been shown to be effective in easing shortness of breath, but its academic significance must be reviewed in the future.

In the terminal stage of lung cancer, patients may experience respiratory difficulties due to a large volume of pleural fluid and/or lymphangitis carcinomatosa. Until now, HOT's use with lung cancer patients tended to focus on promoting home treatment to alleviate respiratory difficulties during the terminal stage. But there are reports that find oxygen administration had no effect in alleviating respiratory difficulties in lung cancer patients with mild or no hypoxemia.<sup>16</sup> Recently, exercise therapy (aerobic exercise), which is intended to restore physical function to address the decline in exercise tolerance resulting from lung cancer and cancer treatment, has been attracting more attention, too.<sup>17</sup>

As such, the effect of HOT differs depending on the diseases—just as the effect that can be expected from oxygen administration vary depending on the disease and condition, such as the mitigation of respiratory distress, an improvement to ADL, or prevention and improvement of secondary pulmonary hypertension. We have now reached the point where we must consider these expected effects in terms of each disease category and condition. Moreover, asthma death is common among the elderly, which can be avoided with the aggressive use of oxygen therapy.

### **Approach in the Stable Stage**

During the stable stage of HOT, the medical cost of HOT is processed under “the guidance and management fee” by hospitals and clinics. But MHLW does not specify the details of such guidance and management. In the case of COPD and interstitial pneumonia, early detection of exacerbations of the underlying disease and confirmation of the appropriate oxygen flow rate are essential. Accidents resulting from HOT pose a particular problem.

The quality of medical care related to HOT is not consistent; it varies among medical institutions and home respiratory equipment providers. When introducing HOT, the physicians must adequately evaluate its medical need and effect, determine an appropriate oxygen flow rate, and carefully instruct the patient and the family including emergency handling. There are also

certain social conditions that must be assessed, namely: (1) whether the patient and the family understand the need for HOT, (2) whether home treatment or care can be provided at home over the long term, (3) whether the patient can visit the implementing hospital/clinic regularly, (4) whether the patient can manage the equipment on a continuous basis, (5) whether the patient or the family can contact a medical facility in case of emergency, (6) whether the caregiver and the family understand the patient's current medical condition and will provide cooperation, and (7) whether the patient has completely quit smoking. In particular, households made up exclusively of elderly people should be instructed in detail.

Recently, there have been many cases of fire and burns involving elderly people that are

related to smoking. Considering that the physician's responsibility can be called into question for accidents caused by insufficient instruction to and management of the patient and the family, due caution is required when implementing and managing HOT.

## Conclusion

HOT is costly home therapy. Among COPD patients, HOT often fails to achieve sufficient result because it is used incorrectly or the oxygen prescription is inadequate. We must promote medical collaboration in communities in order to ensure the full result of HOT as effective home treatment for the elderly.

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