Prevalence and variability of use of home mechanical ventilators, positive airway pressure and oxygen devices in the Lombardy region, Italy

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Abstract

Few studies have analyzed the prevalence and accessibility of home mechanical ventilation (HMV) in Italy. We aimed to investigate the prevalence and prescription variability of HMV as well as of long-term oxygen therapy (LTOT) and continuous positive airway pressure (CPAP), in the Lombardy Region. Prescribing rates of HMV (both non-invasive and tracheostomies), CPAP (auto-CPAP, CPAP/other sleep machines) and LTOT (liquid-O_2, O_2-gas, concentrators) in the 15 Local Healthcare districts of Lombardy were gathered from billing data for 2012 and compared. Crude rates (per 100,000 population) and rates for the different healthcare districts were calculated. In 2012, 6325 patients were on HMV (crude prescription rate: 63/100,000) with a high variation across districts (8/100,000 in Milano 1 *vs* 150/100,000 in Pavia). There were 14,237 patients on CPAP (crude prescription rate: 142/100,000; CPAP/other sleep machines 95.3% *vs* auto-CPAP 4.7%) with also high intra-regional variation (56/100,000 in Mantova vs. 260/100,000 in Pavia). There were 21,826 patients on LTOT (prescription rate: 217/100,000 rate; liquid-O_2 94%, O_2-gas 2.08%, O_2-concentrators 3.8%), with again high intra-regional variation (100/100,000 in Bergamo *vs* 410/100,000 in Valle Camonica). The crude rate of HMV prescriptions in Lombardy is very high, with a high intra-regional variability in prescribing HMV, LTOT and CPAP which is partly explainable by the accessibility to specialist centers with HMV/sleep-study facilities. Analysis of administrative data and variability mapping can help identify areas of reduced access for an improved standardization of services. An audit among Health Payer and prescribers to interpret the described huge variability could be welcomed.

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Keywords: Chronic respiratory failure; noninvasive ventilation; chronic care; home care, oxygen prescription; continuous positive airway pressure.

Contributions: MV, LB, literature search, study design, data analysis, manuscript preparation. All Authors contributed to data collection, manuscript critical evaluation for intellectual content, and revised and approved the final version of the manuscript.

Conflict of interests: The Authors declare that they have no conflict of interests.

Funding: This work was supported by Institutional funding.

Acknowledgements: We thank Alma Lisa Rivolta of Lombardy Data Inspection Board, all the Lombardy Health district Directors for the precious data and information obtained from their Administrative units. We thank Laura Comini for critical revision and editing assistance, and Rosemary Allpress for the English revision.

Received for publication: 16 August 2017
Accepted for publication: 17 December 2017

Tipografia PI-ME Editrice, Italy
Monaldi Archives for Chest Disease 2018; 88:882
doi: 10.4081/monaldi.2018.882

Introduction

Long-term home mechanical ventilation (HMV) is increasingly being prescribed for people with chronic respiratory failure (CRF) arising from the advanced state of diseases such as chronic obstructive pulmonary disease (COPD), restrictive thoracic disease (RTD) and neuromuscular diseases (NMD). The last reported prevalence (though probably underestimated) of European patients requiring HMV is 6.6/100,000 population [1]. Although HMV has been shown to reduce patients' symptoms, improve health-related quality of life (HRQL) and, in many cases, reduce mortality and hospitalizations [2,3] there are problems connected with providing HMV, such as inadequate patient/caregiver training and lack of compliance, dis-homogeneous reimbursement policies and insufficient resources [4]. Differences in the availability of HMV, and in reimbursement regarding evidence-based medical policies/indications, may also lead to wide variations in the prevalence and the patterns of HMV provision throughout Europe [1,5]. The number of respiratory units and specialists available in a particular area can also account for the variability in prescription, as has been observed in other respiratory therapies such as home oxygen therapy [6]. Despite the growing practice of HMV, few studies have analyzed the prevalence of home respiratory devices prescription, *e.g.* ventilators, long-term oxygen therapy (LTOT), and continuous positive airway pressure (CPAP) devices.

Variability in the clinical practice regarding HMV is widely recognized and has been the object of study for over 30 years [7]. Decision-making is a complex issue, and clinical practice is established taking into account not only scientific evidence but also local circumstances, professional skills and, above all, patient values [8]. The magnitude of

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variability must be studied in order to introduce specific actions for improvement, and to guarantee equal access to effective treatments. A systematic study of variability can be done through disease registers over time, in order to observe trends, or by dedicated surveys addressed to health teams involved in this field. Another possibility is to collect information from national or regional healthcare administrative databases.

HMV started in an important Italian Region (Lombardy) riding between the 80s and 90s being home care management a new and pioneering approach for chronic ventilated patients (80% obstructive and 20% restrictive/neuromuscular patients) [9]. During the last 3 decades, HMV is dramatically increase also in this Region with inevitable changes in technology, habits, number of prescribers, diseases prescription and costs.

To this end, a dedicated Task Force comprising pulmonologists and healthcare administration staff based in an important Italian Region (Lombardy) carried out such a search of administrative data of the Local Health Authorities in Lombardy in order to characterize the prevalence of HMV, CPAP and LTOT and the variability in prescriptions in Lombardy.

Materials and Methods

As only administrative data were involved, no ethical approval was required. A web-based observational database was reviewed. This study compared the HMV prescription rates in the different Local Health Authority districts of Lombardy (Italy) active at the time of the survey. Patients were identified using the Lombardy Health Service billing database selecting all cases in which HMV was invoiced for the year 2012. The data collected were anonymous. Cases were assigned to each geographical area according to each patient's healthcare zone of residence. The denominators were calculated using population data from the Lombardy bureau of statistics (ISTAT Lombardia) central registry of whole population. The analysis included all 15 healthcare districts where health promotion, disease prevention, public health and social-healthcare activities are provided and coordinated at the primary care and specialist level. Cases were assigned to each geographical area according to each patient's healthcare zone of residence at the time of the billing data in 2012. Use of the Lombardy register of prescriptions data for this study was approved by the Lombardy Data Inspection Board.

Statistical analysis

A descriptive analysis was conducted using the Point Prevalence (PP) rate (per 100,000 inhabitants) of HMV prescription (both noninvasive and tracheostomies), CPAP prescription (auto-CPAP%, CPAP/others sleep machines %) and LTOT prescription (liquid O_2%, oxygen gas% and concentrators%) in the 15 Local Health Authorities districts of Lombardy defined on the basis of billing data in 2012. For each kind of prescription (HMV, CPAP, LTOT) we defined the coefficient of variation (CV), *i.e.* a standardized measure of dispersion of a probability distribution expressed as a percentage, and we showed the districts of residence that were below the 5th (P5) and above the 95th percentile (P95) of each distribution. Data analysis and processing were performed using Prism 4, Graph Pad Software. Normality of the data was checked by Shapiro-Wilk test and correlations were performed using Pearson's correlation analysis. A p value <0.05 was considered statistically significant.

Results

Lombardy is an Italian Region with a varied geographical terrain comprising mountains (40.4%), hills (12.4%) and lowlands (47.1%). It has a population of 10 million, ranging from 1,600,000 in the Local Health Authority of Milan to 183,000 in the Sondrio health district. Ten percent of the population is aged 0 to 14 years. Table 1 shows Lombardy's characteristics in terms of number of residents and number of specialized respiratory units and sleep centers (Prescrition centers were for the 21.8% University or Research Center Hospitals *vs* 78.2% non-university hospitals and 64% public hospitals *vs* 36% private hospitals) [10-12].

Table 1. Number of dedicated hospital units (respiratory wards and sleep centers) and inhabitants for each Local Health Authority district in the Lombardy Region.

Health districts	Respiratory wards, n	Sleep centers, n	Inhabitants, n	Inhabitants/ respiratory wards	Inhabitants/ slee centers
Milano	24	9	1,677,000	69,613	185,637
Milano 1	5	3	955,000	238,782	318,377
Milano 2	4	1	630,000	126,000	630,000
Mantova	5	1	415,000	85,201	426,005
Como	5	3	595,000	118,860	198,100
Varese	10	2	883,000	88,773	443,865
Sondrio	2	1	183,000	91,584	183,169
Brescia	8	4	1,155,000	146,296	292,593
Valle Camonica	1	1	101,600	107,039	107,039
Bergamo	6	2	1,098,000	183,123	549,370
Cremona	3	2	363,000	121,184	181,777
Pavia	9	3	548,000	59,518	178,555
Lodi	2	2	227,000	120,808	120,808
Monza	4	2	849,000	212,409	424,818
Lecco	4	2	340,000	85,485	170,971

In all Local Health Authorities, there is at least 1 respiratory ward (RW) and 1. sleep center (SC) available (range 1-24 for RW and range 1-9 for SC) [10-12]. But, as can be seen from table 1, the number of specialist units available varies greatly across the Lombardy territory and is not matched to the needs of the population. The ratio of differences between districts are 1:4 for RW and 1:6 SC.

HMV prescription

In 2012, 6325 patients were on HMV. The crude rate of HMV prescriptions was 63/100,000, with a high variation across districts (from 8/100,000 in Milano 1 to 150/100,000 in Pavia) (Figure 1A). The systematic coefficient of variation (CV) methods, which measure variation not due to chance, showed a high variation in HMV [CV = 0.5187; 5-95% confidence interval (CI) = 47.12-88.16; mean 148.91; standard deviation (SD) = 77.24]. Some districts were above (Varese, Milano 2, Pavia) and some below (Milano 1, Bergamo, Valle Camonica) the area defined by the CI, corresponding to overuse or underuse of HMV with respect to the average of all the districts, respectively.

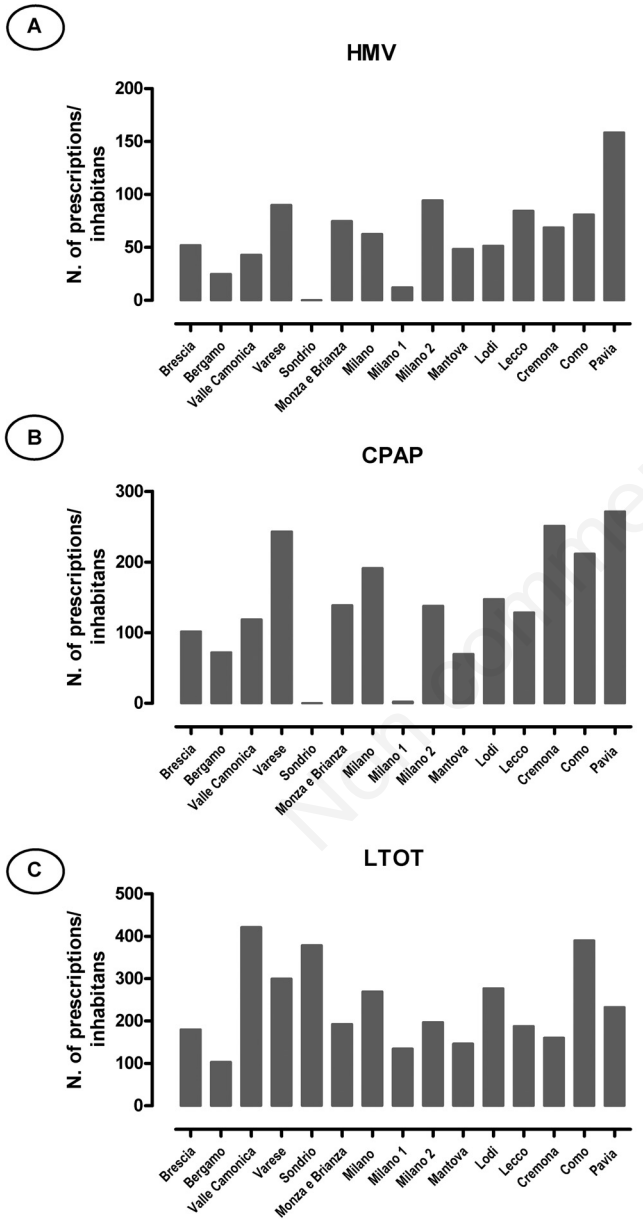

Figure 1. Prescription rate (per 100,000 inhabitants) for HMV (A), CPAP (B) and O_2 (C) in the Lombardy Local Health Authority districts. HMV, home mechanical ventilation; CPAP, continuous positive airway pressure; LTOT, long-term oxygen therapy.

CPAP prescription

In 2012, 14,237 patients were on CPAP with a crude prescription rate of 142/100,000. A high variation in Local Health Authorities districts (from 56/100,000 in Mantova to 260/100,000 in Pavia) was observed (Figure 1B). High variation in CPAP (CV = 0.60; 5-95% CI 2.09-251.13; Mean 139; SD 83.77). Some districts were above (Cremona and Pavia) and others below (Milano 1 and Sondrio) the area defined by the confidence interval. CPAP devices were prescribed in 95.23% of cases (range 90-99.1) while auto-CPAP in 4.77% of cases (range 0.18-10).

LTOT prescription

In 2012, 21,826 patients were on LTOT with a crude prescription rate of 217/100,000. A high variation in Local Health Authorities districts (from 100/100,000 in Bergamo to 410/100,000 in Valle Camonica) was observed (Figure 1C). Also for LTOT, a high intra-regional variation was observed (CV = 0.41; 5-95% CI 183.85-292.84; mean 238; SD 98). Some districts were above (Valle Camonica, Como, Sondrio) and others below (Milano 1, Bergamo, Brescia and Varese) the area defined by the confidence interval. Liquid oxygen was prescribed in 94% of cases (range 52-99.2), oxygen concentrators only in 3.8% (range 0-17.85), while in the other cases gaseous oxygen was prescribed (2.08% as mean with a range 0-47.7).

Figure 2 shows the negative correlation between HMV (Panel A), CPAP (Panel B) and LTOT (Panel C) prescriptions and the inhabitants/respiratory wards ratio. Table 2 shows a highly significant correlation between HMV prescription and Respiratory wards, CPAP prescriptions and LTOT prescriptions showing a strong relation between supply and patients' demand and among all respiratory prescription opportunities.

Discussion

Few reports have described the prevalence and variability of HMV, CPAP and LTOT prescription. To the best of our knowledge, this is the first survey evaluating these issues in a major Region of Italy. The aim of this study was to analyze the variability in the prescription of different ventilators, CPAP and oxygen devices based on administrative data available from the public health service financial records. Variability in the clinical practice regarding HMV, CPAP and oxygen devices prescription ratio occurred across all Local Health Authorities districts. The high variation identified between districts could be explained by different factors related to supply and demand for the service.

Studies (Table 3) showing variability in the prescription of HMV in Europe have been published for over 20 years [13]. The Eurovent Survey found that HMV variability concerned both the number of prescriptions and the profile of patients for whom this treatment was prescribed, neither of which was related to the characteristics of the healthcare system or the economic situation in the country involved [1]. The national Swedish HMV register also highlighted variability in prescription within the country itself, despite a similar level of healthcare coverage [14,15]. In Denmark, there are only 2 centers that pre-

scribe HMV; in this country, the prevalence of HMV is low, and the therapy is usually indicated in younger patients with neuromuscular diseases [14]. A recent study on the variability of HMV in Australia and New Zealand suggested that, in addition to variability in prevalence, HMV was more likely to be started in obese patients in New Zealand than in Australia [16].

In England [17] evidence of variability and difficulty of access to treatment led to calls for the creation of a register, and for the indications to be standardized by means of clinical practice guidelines. A crude rate of HMV prescriptions of 23/100,000 was observed in Catalonia (Spain) [18]. Compared to other countries and to Italy as a whole [19], HMV prescription in Lombardy (63/100,000) seems to be the highest ratio published so far in the literature (Table 3). The first reason for this high ratio is that the present data were obtained from crude and sure administrative data not coming from doctors' or hospitals' surveys. Although HMV is not technically complex, decision-making and resolving complications require high skills that justify concentrating the prescription in respiratory centers [18,21] widely distributed among all health Lombardy districts. Another factor that may explain a high variability is the absence of objective evidence-based criteria for starting HMV, especially in obese or COPD patients [18]. On the other hand, the wide variety of diagnoses or patients potentially in need of HMV could also explain the variations observed. The attitude of physicians to ventilation seems in fact to be one of the most important factors behind the variability [18,22]. The high number of prescriptions in Lombardy could be related to the number of prescribing centers and their characteristics (presence of a respiratory specialist) (Table 2). We have confirmed previous data in Catalonia [18] that districts with a high number of Hospitals with a respiratory medicine unit were associated with a greater number of cases (Table 2) while the high variability in prescribing HMV in Lombardy has demonstrated inhomogeneity in the HMV care program.

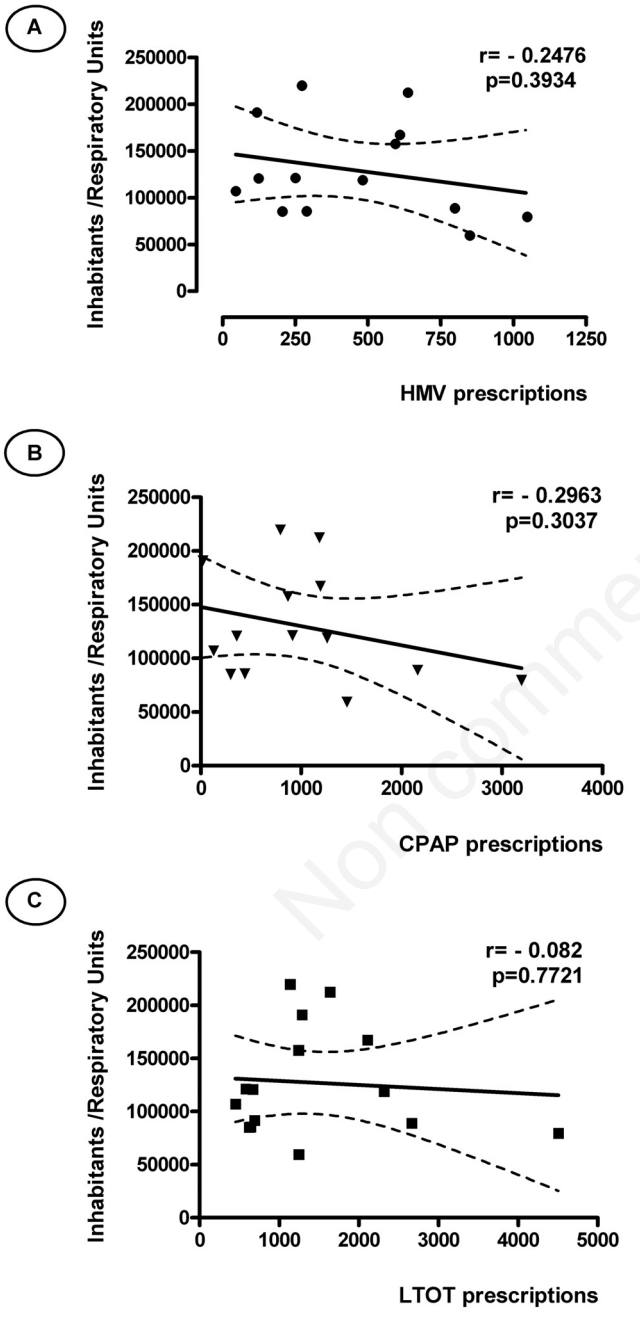

Figure 2. Correlations between number of inhabitants per Respiratory Unit and prescriptions for HMV (A), CPAP (B) and O_2 (C). HMV, home mechanical ventilation; CPAP, continuous positive airway pressure; LTOT, long-term oxygen therapy.

Data on the prevalence of CPAP treatment for sleep apnea in different countries around the world are not clear, probably due to the mixed supply from both private market (not clearly measurable) and the public health organizational system. Only 17 individuals out of 3300 respondents (weighted prevalence 0.73%) reported being prescribed CPAP in an Australian survey for people with OSAS [23]. In Ontario, Canada, the rate of new CPAP approvals ranged from 1.86/1000 residents in 2006 to 2.93/1000 in 2011, while the annual number of diagnostic polysomnograms continued to rise from 16.1/1000 in 2006 to 18.5/1000 in 2013 [24]. In Catalonia [25] the reported ratio for CPAP prescription is 54:100,000 inhabitants while the estimated number of CPAP prescriptions in Italy ranged from to 44:100,000 [19] to 33:100,000 inhabitants, 200,000 [26] being the estimated number of CPAP devices used. Variability in clinical practice was found in all Lombardy Local Health Authority districts also in terms of CPAP devices prescription ratio. The high percentage of CPAP prescriptions was linked to a high sensitivity to sleep diseases throughout the entire Lombardy Health System (GPs, specialists, health payer) and to the availability of respiratory units as well as to a high number of sleep centers (Tables 1 and 2). We are confident of the crude rate of CPAP devices in Lombardy because at the time of data collection no private market for CPAP was available and all the CPAP devices were censored.

The crude rate of LTOT prescription ranges from 3.28/100,000 in USA [27] to 36/100,000 in Italy [19], 48.1/100,000 in Denmark [28] and 90/100,000 in France [29] The number of respiratory units and specialists available in a particular area could cause variability in prescription, as has been observed with other respiratory therapies such as home oxygen therapy [6]. However, this phenomenon does not explain the variations within the 15 Lombardy areas, where access is easy and a large number of specialists are available. The high rate of LTOT prescription (217/100,000 inhabitants in Lombardy) is also tied to the regional funding approach which favors a prescriptive option for border-line chronic respiratory failure (night-time and during exercise). In some areas of Lombardy, the prescriptive oxygen option may have replaced that for CPAP or HMV due to the lesser number of specialized units available.

A strength of this study is the type of analysis performed, based on available administrative data, which provides a good complement to

clinical experience and cross-sectional studies, giving a comprehensive view of the devices' prescription problem.

The greatest limitation of this study is the lack of access to diagnoses and clinical data with the difficulty to explain the dramatic differences in prevalence of HMV between different districts and the possibility to compare present data with other reports of literature in which diagnosis was present. Nevertheless, we have previously discussed that the use of administrative data (the case of this paper) only allowed access, for reasons of data confidentiality, to the type of treatment subsidized by the public health system and zone of residence. Moreover, obtaining information from the prescribing center with a survey (which would give more detailed information on diagnosis and the technical characteristics of the treatment) might not necessarily give an idea of the population impact (a center may prescribe ventilation to patients from various geographical districts).

Unfortunately our data coming from "crude administrative data" are aggregate data according to single Health District Zone: for this reason we have not access to single center data allowing specific and details correlation between center and level of HMV prescription.

As further limitation of the study, it is important to remember that Hospitals did not begin to prescribe HMV and CPAP simultaneously. Supply companies can influence the variability of respiratory devices prescription. However, given the characteristics of the funding system, with very stringent limits on increases in prescriptions, it is unlikely that these companies have a direct effect on such prescriptions [18]. Another possible confounding factor is that some people may migrate from their district to another one to receive support and prescription.

Conclusions

The crude rate of HMV prescriptions in Lombardy is very high. The high variability found among the Lombardy Local Health Authority districts in prescribing HMV, CPAP and LTOT can be explained, in part, by the attitude of professionals toward treatment and the high availability of specialist centers with a respiratory unit dedicated to HMV and sleep study. The wide differences observed can help to identify areas characterized from a reduced availability of instruments and structure for diagnosis and therapy of respiratory diseases requiring home mechanical ventilation. The rate of HMV prescription described in the literature is probably underestimated. Analysis of administrative data and variability mapping can help identify unexplained variations, *i.e.* areas of reduced access, so leading to an improved standardization of healthcare services. The expected action coming from the Health Payer is to propose an Audit among prescribers to interpret the described huge variability.

Table 2. Correlations between respiratory units and HMV, CPAP and LTOT prescriptions.

	HMV prescription, n	CPAP prescription, n	LTOT prescription, n
Respiratory units, n			
Pearson r	0.8023	0.8916	0.8987
95% confidence interval	0.4731 to 0.9349	0.6850 to 0.9655	0.7162 to 0.9662
P value (two-tailed)	**0.0006**	**P<0.0001**	**P<0.0001**
HMV prescription, n			
Pearson r		0.9120	0.8002
95% confidence interval		0.7390 to 0.9722	0.4684 to 0.9342
P value (two-tailed)		**P<0.0001**	**0.0006**
CPAP prescription, n			
Pearson r			0.9048
95% confidence interval			0.7197 to 0.9698
p value (two-tailed)			**P<0.0001**

HMV, home mechanical ventilation; CPAP, continuous positive airway pressure; LTOT, long-term oxygen therapy.

Table 3. Comparison of the crude rate of HMV prescription (per 100,000 inhabitants) in Lombardy Region, Italy. Comparison with available international data.

	Year of survey	HMV prescriptions/100,000
Lombardy (this study)	2012	63
Italy [19]	2010	20
EU [1]	2004	6.6
Catalonia (Spain) [18]	2011	23
France [20]	2009	32
Canada [21]	2014	12.9
New Zealand [16]	2012	12
Australia [16]	2012	9.9
Denmark [14]	1996	5.5
Sweden [14,15]	1996	6.1

HMV, home mechanical ventilation.

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