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Quality control of equipment in home mechanical ventilation: a European survey

R. Farre*, S.J. Lloyd-Owen#, N. Ambrosino¶, G. Donaldson#, J. Escarrabill+, B. Fauroux§, D. Robertƒ, B. Schoenhofer, A. Simonds## and J.A. Wedzicha#**

ABSTRACT: Quality control of the equipment used in home mechanical ventilation is necessary in order to ensure that patients safely and accurately receive the prescribed ventilatory support. The aim of this study was to carry out a survey on the quality-control procedures in different centres and countries.

The survey was carried out in the context of a European Commission Concerted Action covering 16 European countries. The study was extensive and detailed, involving 326 centres, which provided home ventilation to >20,000 patients.

The survey showed that: 1) ventilator servicing was mainly carried out by external companies (62% of centres), with a servicing frequency ranging 3–12 months; 2) interaction between servicing companies and prescribers was limited (only 61% of centres were always informed of major incidents); 3) participation of centres in equipment quality control was poor (only 56% of centres assessed that patients/caregivers correctly cleaned/maintained the ventilator); and 4) centres were insufficiently aware of vigilance systems (only 23% of centres). Moreover, the data showed considerable inter- and intra-country differences. The size of the centre was an important determinant of many of these quality-control aspects.

This survey provides information that will enable the European Commission Concerted Action to formulate recommendations on procedures for home-ventilator quality control.

KEYWORDS: Chronic respiratory failure, healthcare assessment, home-care monitoring, home therapy, noninvasive ventilation

Home mechanical ventilation (HMV) is used to treat patients with chronic respiratory failure caused by lung and airway pathologies, thoracic cage abnormalities and neuromuscular diseases. Long-term HMV improves survival and quality of life, and reduces direct health costs, mainly by decreasing hospital stays. Initially, the application of HMV was limited because almost all patients were ventilated through tracheostomy [1]. However, the widespread use of noninvasive ventilation, in the 1980s, facilitated extension of this therapy [2–5]. The number of patients currently treated with HMV in Europe is expected to increase progressively, given the improvement in the survival of patients with chronic respiratory disease, the ageing of the population and the widespread use of noninvasive techniques.

The criteria and guidelines currently employed by the various prescribers to practically implement HMV are not fully standardised [6]. This is probably due to the lack of studies providing evidence about the best HMV procedures for the different patient groups; the fact that the logistics of HMV prescription, supply and follow-up are complex; and the limited experience in the application of this relatively new therapy in a large number of centres. One of the nonstandardised procedures in HMV practice is quality control of ventilators. This issue is relevant in terms of outcome because the core of HMV therapy is the equipment providing ventilatory support to the patient. A suitable quality assessment of ventilator performance at home is required in order to ensure that the patient is safely and adequately treated according to the prescribed ventilatory parameters. Recent data from a pilot study on quality control [7] indicate that, during HMV, some patients are not treated with the prescribed ventilatory support. Uncontrolled ventilation, under-/overassistance or ventilator–patient asynchrony could result in low treatment compliance or unexplained poor clinical outcome.

The aim of the present study was to undertake an extensive and detailed survey of the HMV quality-control procedures employed at the prescribing centres of 16 European countries. The

AFFILIATIONS
*Unitat Biofisica i Bioenginyeria, Facultat Medicina, Universitat Barcelona, Institut d'Investigacions Biomediques August Pi Sunyer, Barcelona, and
+Unitat Funcional Interdisciplinaria Sociosanitaria Respiratoria, Hospital Universitari Bellvitge, L'Hospitalet de Llobregat, Spain.
#Academic Unit of Respiratory Medicine, St Bartholomew's and the Royal London School of Medicine and Dentistry, and
##Royal Brompton and Harefield National Health Service Trust, London, UK.
¶University Hospital, Pisa, Italy.
§Hôpital Armand Trousseau, Paris, and
ƒAssociation Lyonnaise de Logistique Hospitaliere, Lyon, France.
**Oststadtkrankenhaus, Klinikum Hannover, Hannover, Germany.

CORRESPONDENCE
J.A. Wedzicha
Academic Unit of Respiratory Medicine
Dominion House
St Bartholomew's Hospital
West Smithfield
London EC1A 7BE
UK
Fax: 44 2076018616
E-mail: J.A.Wedzicha@qmul.ac.uk

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survey was carried out within the framework of the Concerted Action ''The role of home ventilators in the management of chronic respiratory failure'' funded by the European Commission (Brussels, Belgium) [8].

METHODS

For the purposes of the present survey, HMV was defined as noninvasive ventilation or ventilation *via* a tracheostomy for a period of $\geqslant$3 months on a daily basis, and carried out mostly in the patient's home or at another long-term care facility (not in an intensive care unit). The survey did not include patients with obstructive sleep apnoea alone, even if they were treated with bilevel positive pressure, nor patients with a tracheostomy not requiring mechanical ventilation. Centres prescribing HMV were defined as any hospital or outpatient unit that initiated or prescribed HMV and/or coordinated HMV services.

The content and questions of the survey on HMV quality control were defined and written by the authors of the present report, who are the members of the Steering Committee of the European Concerted Action. Moreover, one national representative per country (as detailed in the *Participants* section) contributed to the writing of the final version in order to ensure that the survey accurately collected data on the HMV practices in each country. The final survey questions (see *Results* section) were identical for each country and were translated by the relevant national representative.

The survey on HMV quality control aimed to collect information on five different aspects: 1) the servicing of the ventilators at home (who is in charge, and when and how the ventilator is serviced); 2) the information that the prescriber receives about the ventilator servicing; 3) the role played by the patient as regards ventilator servicing; 4) the part played by the prescriber in ventilator quality control; and 5) whether the prescriber was aware of the existence of adverse incident centres managing information regarding ventilator malfunctions, and patient associations playing a potential role in HMV quality control.

Each national representative identified the maximum possible number of HMV prescribing centres in their country. Various methods were used for this centre identification process, depending on the situation in each country. Complete registers of HMV centres and the number of users were available in some countries (Sweden, Denmark, the Netherlands and Belgium). Other national representatives used information from previous surveys and personal knowledge. Unless the list of centres and user numbers was complete and accurate, national representatives conducted a preliminary centre identification survey using a one-page questionnaire, which was sent to all potential centres covering the spectrum of respiratory, intensive care, neurology and paediatric specialities. This questionnaire asked whether the centre had any HMV users, and, if so, how many. They were asked whether they would be willing to complete a full survey regarding the users. In some countries, ventilator companies provided details of centres that were known to have purchased home ventilators in the past.

Of a total of 483 identified centres providing HMV, 329 responded to the survey questionnaire during the period September 2001–June 2002. These 329 centres were treating 21,526 patients with HMV. Three of these centres did not answer the quality-control survey section. The country distribution of centres providing quality-control data was as follows: Austria (n=7); Belgium (n=17); Denmark (n=2); Finland (n=16); France (n=58); Germany (n=22); Greece (n=5); Ireland (n=14); Italy (n=44); the Netherlands (n=9); Norway (n=17); Poland (n=15); Portugal (n=20); Spain (n=15); Sweden (n=17); and the UK (n=46). As explained in detail elsewhere [8], the median number of HMV patients per centre was 21 (interquartile range 8–58). On average, 34.4% of the patients suffered from lung and airway problems, 31.2% had thoracic cage abnormalities and 34.4% suffered from neuromuscular diseases [8]. These patients on HMV were treated with pre-set pressure (70.6%) and volume (29.4%) ventilators [8].

The data from the survey were recorded and summarised. All data on centres and users were made anonymous and kept strictly confidential. Mann–Whitney rank-sum tests were used to assess the relationship between prescriber centre size (as defined by the number of HMV users) and the different answers to the quality-control survey.

RESULTS

Servicing of home ventilators

Figure 1a, showing the pooled data obtained from all the prescribers in the 16 European countries, demonstrates that regular servicing of the home ventilators (including maintenance, repair and delivery of spare parts) was mainly undertaken by an external company (62% of the centres). In 24% of the centres, the servicing was carried out by a hospital department (technical or other). Figure 1b shows the percentage of centres whose ventilators were serviced by an external company by country. Although, in the European context, ventilator servicing by an external company was the most frequent procedure, there were considerable differences between countries (ranging from 0% in Sweden to 100% in Spain). In 70.3% of the centres, the ventilators were routinely serviced. Larger prescriber centre size was significantly related to routine servicing ($p<0.001$). However, the servicing was also performed at the request of the physician (33.4%) or the patient (47.5%). Servicing was also carried out depending on ventilator type (28.4%) and usage time (25.6%). The routine servicing was carried out with a periodicity ranging 3–12 months. Figure 1c shows the median periodicity of servicing for the prescriber centres by country. Tables 1 and 2 give the answers provided by all centres when asked about what ventilator functions were checked during the regular servicing to verify that: 1) the settings were as prescribed (table 1), and 2) the machine responded to the settings appropriately (table 2). The answers were similar for both questions. A remarkable feature of tables 1 and 2 is that the percentage of centres not answering these questions (ranging 17–25%) was much greater than that of those not answering the other quality-control questions (3%). Larger prescriber centre size was significantly ($p<0.001$) related to checking whether the ventilator settings were as prescribed and that the machine responded to the settings appropriately ($p<0.005$ in all cases). Moreover, in large prescriber centres, it was less likely that these questions remained unanswered ($p<0.005$).

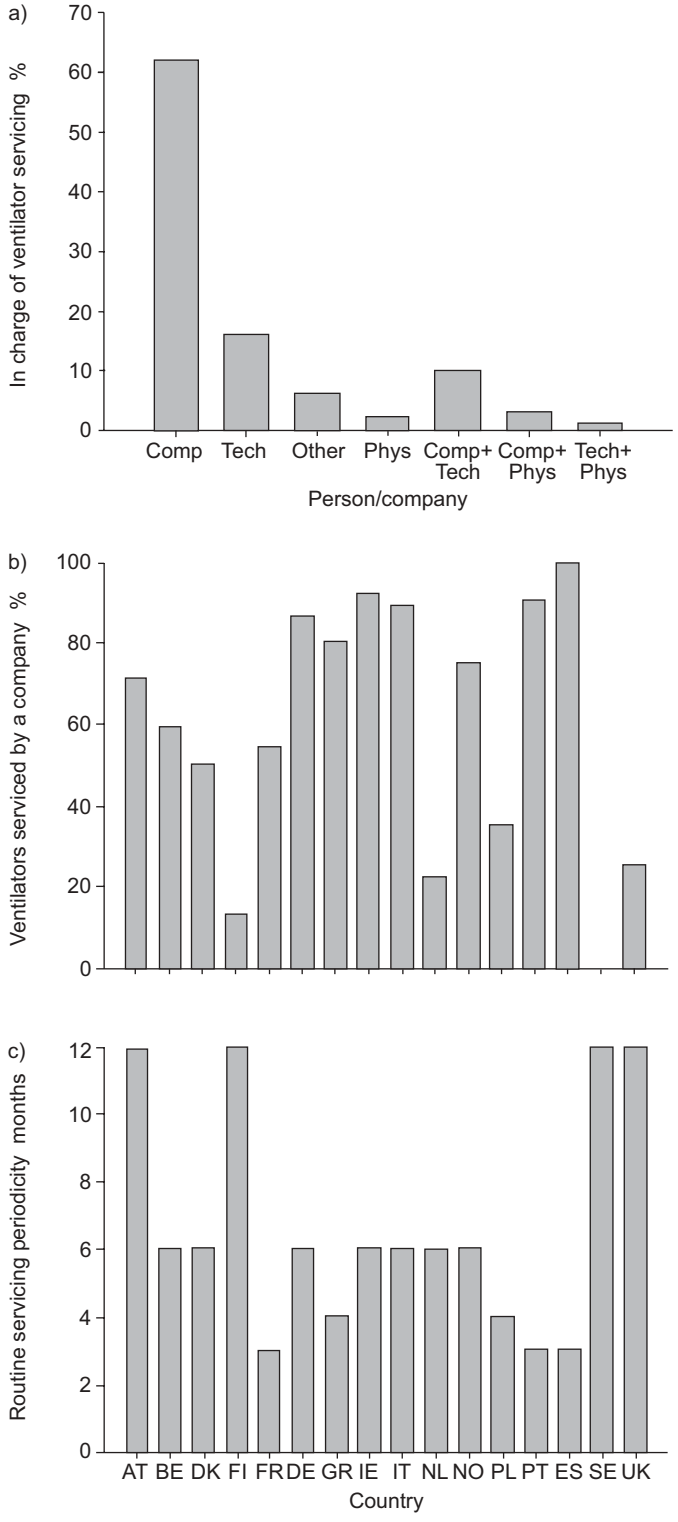

FIGURE 1. a) Answers to the question ''Who is in charge of the servicing and repair of ventilators in your centre?'', and b) centres answering that ventilator servicing was carried out by an external company, and c) answers to the question ''How often is your equipment routinely serviced?'' by country. Comp: ventilator company; Tech: hospital technical service; Other: other hospital department; Phys: physician in charge of patient; AT: Austria; BE: Belgium; DK: Denmark; FI: Finland; FR: France; DE: Germany; GR: Greece; IE: Ireland; IT: Italy; NL: the Netherlands; NO: Norway; PL: Poland; PT: Portugal; ES: Spain; SE: Sweden.

TABLE 1 Answers to the question ''During regular ventilator servicing, for which functions is it checked that the ventilator settings are as prescribed?''

	Yes %	No %	Not applicable %	No answer %
Alarms	72	4	7	17
Oxygen	55	10	14	21
Tidal volume	63	7	10	20
Minute volume	58	7	13	22
Inspiratory pressure	75	5	3	17
Expiratory pressure	72	6	4	18
Trigger sensitivity	67	8	7	18

Data are presented as percentages of centres.

TABLE 2 Answers to the question ''During regular ventilator servicing, for which ventilator functions is it checked that the machine responds to the settings appropriately?''

	Yes %	No %	Not applicable %	No answer %
Alarms	73	3	5	19
Oxygen	47	9	19	25
Tidal volume	63	4	10	23
Minute volume	58	4	13	25
Inspiratory pressure	72	2	5	21
Expiratory pressure	68	4	6	22
Trigger sensitivity	63	6	8	23

Data are presented as percentages of centres.

Prescriber information about ventilator servicing

On average, 72% of the centres answered affirmatively when asked whether the prescriber was regularly informed of any problems concerning the maintenance of the equipment. Figure 2a shows the variability in affirmative percentages by country (ranging from 41% in Norway to 100% in Denmark). The percentage of centres that answered affirmatively when asked whether they were regularly updated on the equipment servicing was 63%, on average, with marked differences between countries (ranging from 13% in Norway to 95% in Belgium), as shown in figure 2b. On average, in 12% of the centres, the model of ventilator could be changed without the agreement of the prescriber. As indicated in figure 2c, in seven countries, this change without agreement was not possible, but, in nine other countries, it was possible in up to 38% (Sweden) of centres. Table 3 shows the answers obtained when it was asked whether the prescriber received information about four specific issues during the normal process of HMV: 1) change of ventilator, 2) change of interface, 3) minor incidents (noise and vibration), and 4) major incidents (arrest and malfunctions). It should be noted that only 61% of the centres were always informed of major incidents. In large prescriber centres, it was less likely that they never received information

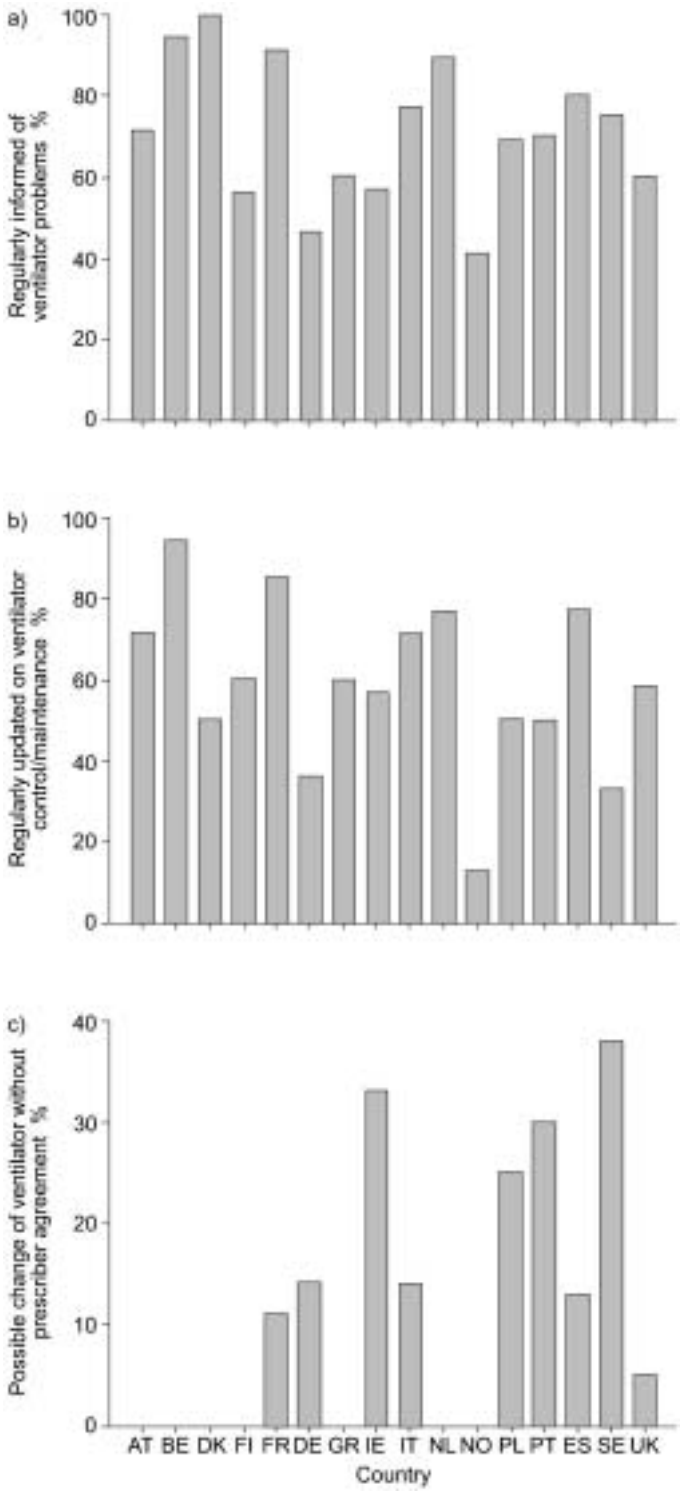

FIGURE 2. Answers to the questions: a) ''Are you regularly informed of any problems with HMV [home mechanical ventilation] by the person/company responsible for the maintenance of the equipment?''; b) ''Are you regularly updated on the specific control/maintenance of the equipment performed by the person/company responsible?''; and c) ''Can the person/company providing the ventilator change the model of ventilator without asking for your agreement?'' by country. AT: Austria; BE: Belgium; DK: Denmark; FI: Finland; FR: France; DE: Germany; GR: Greece; IE: Ireland; IT: Italy; NL: the Netherlands; NO: Norway; PL: Poland; PT: Portugal; ES: Spain; SE: Sweden.

TABLE 3 Answers to the question ''During the normal process of home ventilation, do you receive information on the following?''

	Always %	Often %	Sometimes %	Never %	No answer %
Change of ventilator	71	9	9	5	6
Change of interface	53	17	16	7	7
Minor incidents[#]	25	23	34	13	5
Major incidents[¶]	61	19	11	4	5

Data are presented as percentages of centres. [#]: noise, vibration; [¶]: arrest, malfunction.

on change of ventilator ($p=0.001$), change of interface ($p=0.009$) or major incidents ($p<0.001$).

Role of the patient in equipment maintenance

Figure 3a gives the answers obtained when the centres were asked whom the patients were told to notify of any detected or supposed ventilator malfunction. Larger prescriber centre size was significantly related to the patient reporting malfunctions to the company ($p<0.001$). On average, the physician (among others) was informed in 49% of the centres. Figure 3b gives the percentage of centres in each country where the patient was told to notify at least the physician in the case of suspected ventilator problems. The differences between countries ranged from 18% in Sweden to 100% in Greece. On average, in 60% of the centres, the patients had received written instructions on the cleaning and maintenance of the equipment. As indicated in figure 3c, this percentage varied between countries, from 20% in Greece to 100% in Denmark. Larger prescriber centre size was significantly related to centres having written instructions on the cleaning and maintenance of the equipment ($p<0.001$).

Role of the prescriber in equipment maintenance

In 21% of the centres, there was a written protocol for reporting the detection of equipment malfunction. Figure 4a shows that, in several countries, such a written protocol was implemented in no centres. In almost all (96%) of the centres, the prescriber was able to request an extraordinary equipment check (fig. 4b). On average, 56% of the centres assessed whether or not the patients or caregivers correctly cleaned/maintained the equipment. This percentage varied considerably between countries, from 23% in Ireland to 100% in Denmark (fig. 4c). The percentage of centres having a checklist with the different quality-control items concerning HMV for each patient was 21% on average (ranging from 0% in Greece to 100% in Denmark; fig. 4d). Larger prescriber centre size was significantly related to: 1) the existence of a written protocol for reporting the detection of equipment malfunction ($p<0.001$); 2) the prescriber being able to request an extraordinary equipment check ($p=0.003$); 3) the assessment by the centre of whether the patients or caregivers correctly cleaned/maintained the equipment ($p<0.001$); and 4) the centres having a checklist with the different quality-control items ($p<0.001$).

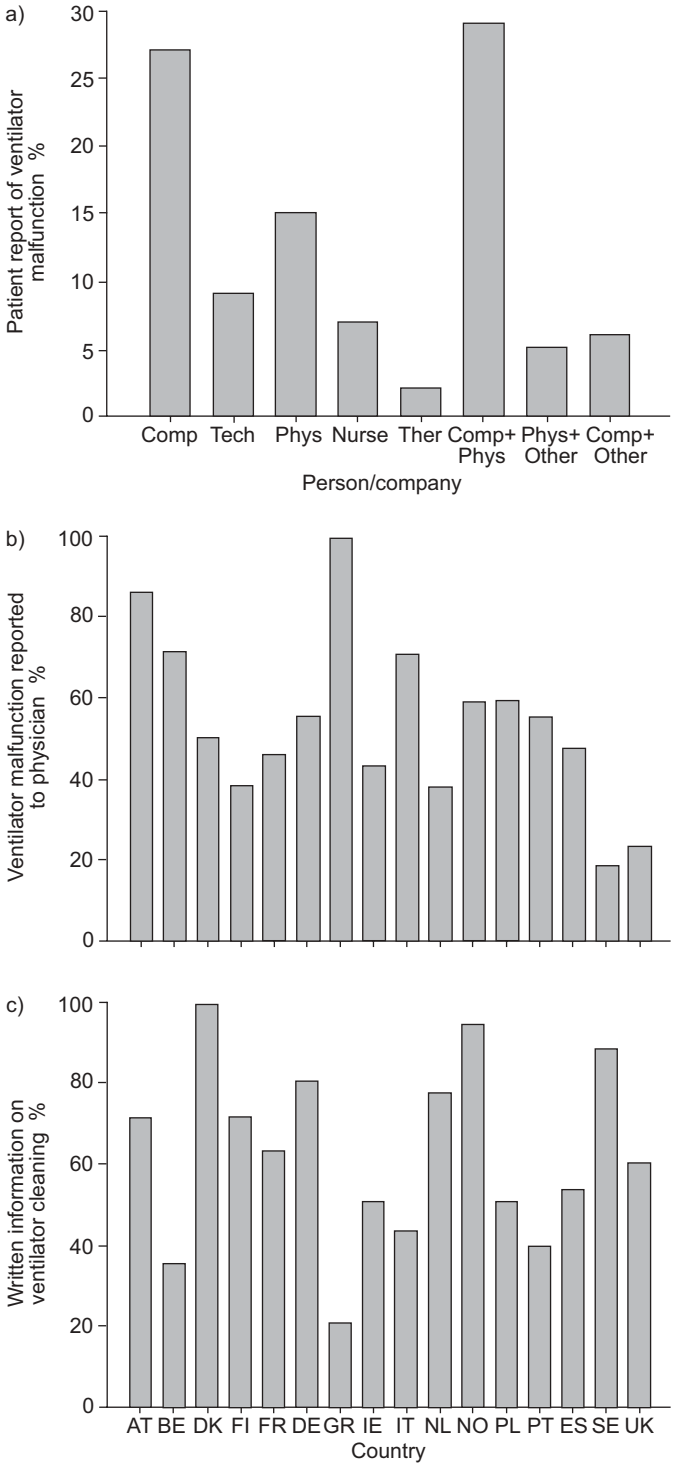

FIGURE 3. a) Answers to the question ''In the case that the patient detects or supposes a ventilator malfunction, to whom are they told to report it'', and b) centres answering that the patient is told to inform at least the physician in the case of supposed ventilator malfunction, and c) answers to the question ''Have the patients written information about the cleaning and maintenance protocol of the equipment?''. Comp: ventilator company; Tech: hospital technical service; Phys: physician in charge of patient; Ther: respiratory therapist; Other: other hospital department; AT: Austria; BE: Belgium; DK: Denmark; FI: Finland; FR: France; DE: Germany; GR: Greece; IE: Ireland; IT: Italy; NL: the Netherlands; NO: Norway; PL: Poland; PT: Portugal; ES: Spain; SE: Sweden.

Adverse incident centres and patient associations

When the prescribing centres were asked whether or not there was some kind of adverse incident centre for HMV, 52% answered negatively, 23% affirmatively and 24% indicated no knowledge of such a centre (1% did not answer). Only 25% (6% of the total) of the prescribers that were aware of the existence of adverse incident centres routinely received information from such centres. Larger prescriber centre size was significantly related to awareness of adverse incident centres ($p<0.001$) and to receiving information from them ($p<0.001$). Knowledge of adverse incident centres on the part of the prescribers depended on the country, as shown in figure 5a. Figure 5b gives the percentage of centres that were aware of any consumer association of HMV patients (21.5% on average). Only 24% (5% of the total) of these centres answered affirmatively when asked whether these patient associations participated at any level in the quality control of HMV.

DISCUSSION

The survey on quality control of home ventilators provided extensive up-to-date information, yielding four main results. First, the quality-control procedures of HMV showed considerable inter- and intra-country variability, which was consistent with the lack of standardised protocols. Secondly, there is poor exchange of information and feedback between the prescribing centres and the external companies performing the ventilator servicing. Thirdly, a minority of centres actively participate in aspects related to equipment quality control. Fourthly, only a few centres are aware of the procedures of vigilance of medical devices, and only a few knew about the existence of associations of HMV patients. Moreover, the data strongly suggest that large prescriber centres have improved HMV quality-control procedures.

It could be argued that the information obtained in the present survey does not exactly reflect the situation as regards HMV quality control in Europe. The main potential source of bias is that, given its extent and complexity, the survey was only sent to prescribing centres and not to providers or patients. Although this limitation could partially influence the results, the present authors believe that the viewpoint of the prescribing centres is particularly relevant because of the central role that the prescribing physician plays in the clinical management and follow-up of patients on HMV. Another potential source of bias is that some centres (154 out of 483) did not answer the survey. However, bearing in mind the high response rate of the survey (68%) and the fact that the answers were collected from centres treating >20,000 patients, it is assumed that the results obtained are reasonably representative of the situation concerning HMV quality control in Europe.

In the present survey, selection of HMV machine was not considered since this is not included in the process of follow-up of ventilator performance. Nevertheless, selection of the best ventilator for each patient is an issue that may play a role in the success of HMV. From a legal point of view, any ventilator labelled with the Conformité Européene [European Conformity] (CE) mark can be used in Europe. However, it is well known that there is considerable variation in the performance of different commercially available devices, as has been largely demonstrated by laboratory [9–12] and

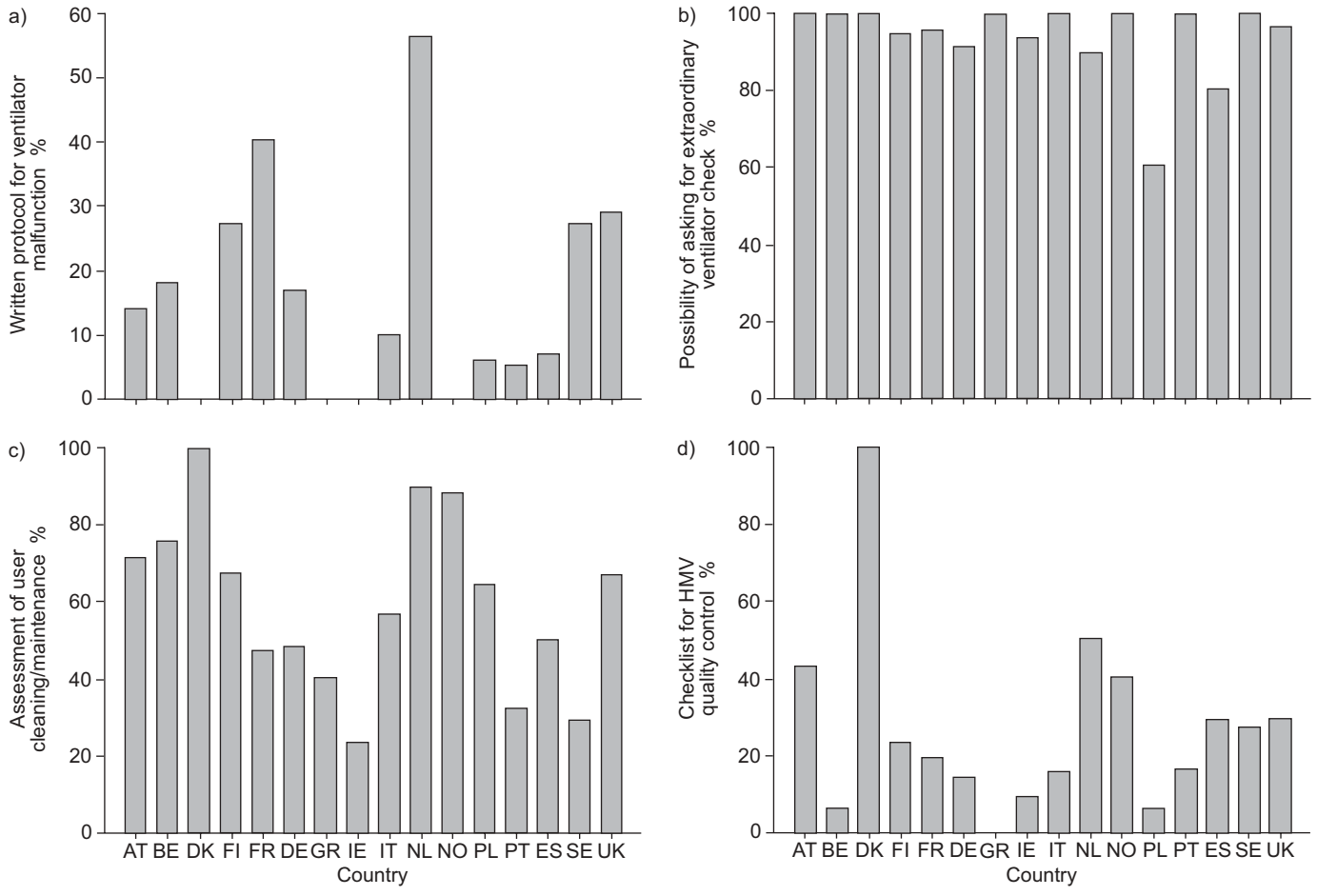

FIGURE 4. Answers to the questions: a) ''In the case of detecting a malfunction of the equipment, is there any written protocol to report this event?''; b) ''Are you able to ask the person/company responsible to perform an extraordinary check/control of the equipment?''; c) ''Do you assess that the patient or caregivers correctly follows the cleaning/maintenance of the equipment?''; and d) ''Is there a checklist with the different quality control items relating to HMV (home mechanical ventilation) for each patient?''. AT: Austria; BE: Belgium; DK: Denmark; FI: Finland; FR: France; DE: Germany; GR: Greece; IE: Ireland; IT: Italy; NL: the Netherlands; NO: Norway; PL: Poland; PT: Portugal; ES: Spain; SE: Sweden.

clinical studies [13–16]. The differences between ventilators stem from the fact that the CE mark simply denotes a formal statement by the manufacturer of compliance with the essential requirements of the European Medical Devices Directive (risk assessment and management; chemical, physical and biological characteristics; infection and microbiological contamination; *etc.*) [17]. In order to carry out the required conformity assessment procedure, the manufacturer can voluntarily comply with the corresponding Harmonised European Standards. Compliance with such standards provides a presumption of conformity with the relevant essential requirements of the directive. In the particular case of home ventilators, the standard defines only basic requirements for some of the fundamental variables (tidal volume, inspiratory pressure, *etc.*) [18]. Other important issues (such as inspiratory waveform, trigger sensitivity, *etc.*), which play an important role in the success of HMV, are not defined [18]. Indeed, some limitations and risks of currently available home ventilators have been reported [19–25]. It should be mentioned that the results of the quality-control survey indicate that, in several countries, the provider can change the ventilator type without prescriber agreement. This could be relevant because the quality of the HMV applied to the patient could be modified depending upon the specific ventilator replacement [24].

The most important issues in ventilator quality control are when and how the equipment is serviced. Like all electromechanical devices, ventilators can deteriorate with use. This risk is particularly enhanced in home ventilators, since they are used for a long time in a context that is not permanently supervised by health professionals [7, 26]. The results of the survey indicate that, on the whole, ventilator companies rather than prescribers are in charge of servicing the equipment (fig. 1a and b), with a frequency that ranges considerably, 3–12 months (median per country). Given that the distribution of the type of ventilator is probably similar between countries, such a great difference in servicing frequency could be due to economic/administrative or reimbursement rather than technical reasons. As regards quality control, the thoroughness of ventilator inspection (table 1) is as important as the frequency of servicing. The fact that a large number of centres did not answer the question about which ventilator functions were checked during regular servicing (table 1), and the data in

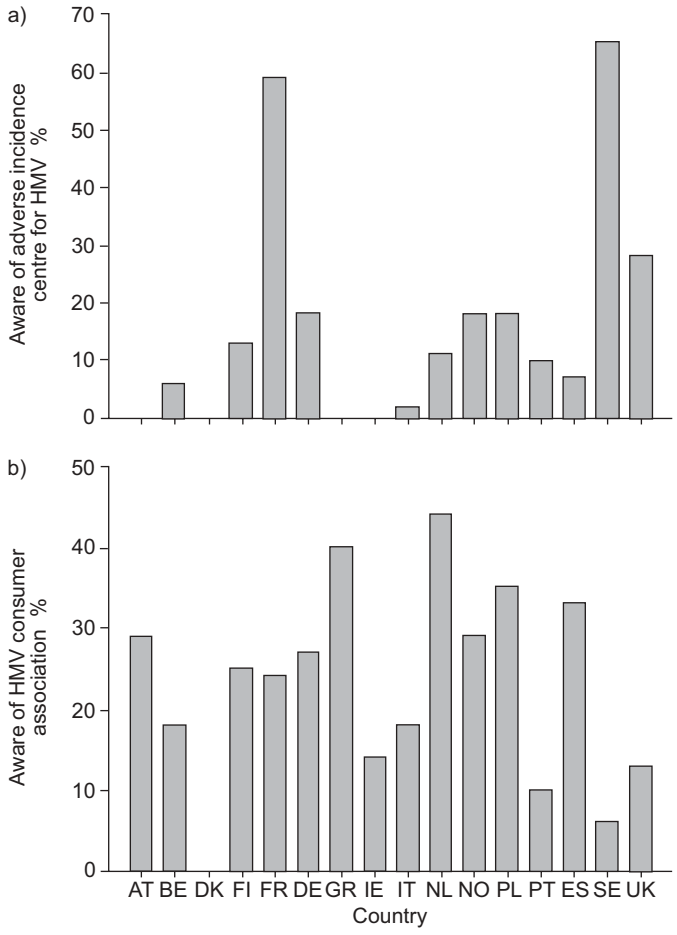

FIGURE 5. Answers to the questions: a) ''Is there any Adverse Incident Centre or similar (at the local, regional or national level) for collecting, analysing, classifying and reporting problems with HMV (home mechanical ventilation)?''; and b) ''Is there any HMV consumer association that you know of?''. AT: Austria; BE: Belgium; DK: Denmark; FI: Finland; FR: France; DE: Germany; GR: Greece; IE: Ireland; IT: Italy; NL: the Netherlands; NO: Norway; PL: Poland; PT: Portugal; ES: Spain; SE: Sweden.

figure 2a and b, probably reflects that a considerable number of centres are not informed about ventilator servicing. This finding can also be corroborated by the data indicating that in only 49% of the centres patients were told to inform the physician about possible malfunctions of the ventilator (fig. 3a and b). Other results of the survey indicate poor involvement of prescribers in issues related to ventilator quality control. As shown in figure 4a, few centres (21%) have a written protocol for reporting the detection of equipment malfunction. Moreover, only 56% of the centres assess the capacity of the patients/caregivers to maintain the equipment (fig. 4c). Furthermore, only a small percentage of centres have a checklist with the quality-control items related to HMV for each patient (fig. 4d).

A fundamental part of HMV quality control, as for any other treatment involving the use of medical devices, is the vigilance system. This is clearly regulated by the European Medical Devices Directive [17] and the corresponding legal transposition in each European Union country. A medical device vigilance system is set out nationally in order to ensure that any information regarding specific incidents involving medical devices is recorded and evaluated centrally [27]. The national vigilance systems are coordinated at European level to share the information received. Reinforcement of the national vigilance systems and improvement in their coordination have recently been recommended by the European Commission [28]. The results of the quality-control survey (fig. 5a) indicate poor knowledge of the existence of alert centres where the prescriber can: 1) report adverse incidents involving medical devices such as home ventilators, and 2) obtain information on quality-control procedures and dissemination of medical devices alerts related to HMV [29–34].

Patients and caregivers should play an active role in maintaining the quality of HMV. To this end, the provider should facilitate training and communication channels between the patient/caregiver and the HMV team [5]. The results of the present survey showed that the patients have written instructions on cleaning of the equipment in only 60% of the centres, with considerable variation between the different countries (fig. 3c). Moreover, figure 4c indicates that only 56% of the centres assess whether or not the patients/caregivers are able to correctly carry out the cleaning/maintenance of the equipment, again with marked differences between countries. Supplying the patient with more written information on cleaning/maintenance and assessing their abilities would contribute towards an improvement in the self-management of patients with chronic respiratory conditions [35, 36]. Such promotion of patient empowerment would probably also improve the quality of HMV. The role of the patients/caregivers in the improvement in the quality of HMV could be strengthened by their participation in consumer–patient associations. This participation affords technical support to facilitate compatibility of daily life activities with HMV, and psychosocial help to patients and caregivers [37, 38]. The involvement of patients/caregivers in these associations is increasingly being promoted by information and communication technologies [39]. A remarkable result of the present survey was that the prescriber centres have poor knowledge of the existence of such patient associations (21.5% of centres) and their potential role in quality control (5% of centres; fig. 5b).

HMV quality control is a complex process, given the involvement of several main partners: the prescriber, the patient, the provider of home ventilation and the agent paying for the treatment. The partner funding HMV (*e.g.* National Health Service, insurance company, *etc.*) plays an important role because it regulates: 1) the kind of ventilator that the physician can prescribe to each patient depending on their clinical status, and 2) the detailed procedures that the provider must follow for the servicing of the equipment. The prescriber and the provider should interact with the patient/caregiver in all issues concerning quality control (*e.g.* training in equipment maintenance, reporting incidents, *etc.*). Moreover, the provider and the prescriber should cooperate to ensure that the physician in charge of the patient is updated with regards to the application of HMV treatment (*e.g.* incidents, change of equipment, *etc.*). In addition, both the prescriber and the provider should be in contact with the corresponding vigilance institution to report incidents and be updated on HMV quality-control issues. As shown by the results of the present survey,

the distribution of the quality-control tasks among the different partners can vary between centres and countries. Given the complexity of HMV organisation, it should be stressed that what is relevant in terms of quality control is consistency of the whole process rather than the particular answer to each of the questions posed in the present survey. For instance, the key issue is not which partner detects and corrects a ventilator malfunction, but rather that the problem is promptly solved and the physician kept informed so that the potential clinical impact of the incident can be evaluated.

More detailed analysis of the extensive information provided by the survey will enable the European Commission Concerted Action to formulate recommendations on home mechanical ventilation quality control. In addition to the issues described in the present survey, these recommendations will also address the role that the modern technologies of information and communication could play in improving home mechanical ventilation quality control in the future, in particular, the manner in which these technologies could be used to: 1) remotely monitor ventilation variables using new-generation home ventilators incorporating data logging and telemetry functions [40], and 2) facilitate exchange of information on quality control between the different partners involved in home mechanical ventilation.

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Partners: N. Ambrosino, Pisa, Italy; J. Escarrabill, Barcelona, Spain; R. Farre, Barcelona, Spain; D. Robert, Lyon, France; and J.A. Wedzicha, London, UK.

Steering Committee: N. Ambrosino, Pisa, Italy; G. Donaldson, London, UK; J. Escarrabill, Barcelona, Spain; R. Farre, Barcelona, Spain; B. Fauroux, Paris, France; S. Lloyd-Owen, London, UK; D. Robert, Lyon, France; B. Schoenhofer, Grafschaft, Germany; A. Simonds, London, UK; and J.A. Wedzicha, London, UK.

National Representatives: T. Wanke, Vienna, Austria; D. Rodenstein, Brussels, Belgium; O. Nørregaard, Aarhus, Denmark; R. Pirtimaa-Kaitanen, Helsinki, Finland; J-F. Muir with A. Cuvelier, Rouen, France; G. Laier-Groeneveld, Hannover, Germany; N. Siafakas with M. Kilmathianaki, Heraklion, Greece; W. McNicholas with L. Doherty, Dublin, Ireland; A. Vianello, Padua, Italy; M. Kampelmacher, Utrecht, the Netherlands; S.O. Mollestad, Oslo, Norway; J. Zielinski, Warsaw, Poland; J.C. Winck, Porto, Portugal; F. Masa, Cáceres, Spain; B. Midgren, Lund, Sweden; and M. Elliott, Leeds, UK.

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