Improving Homecare Risk Management and Patient Safety

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ABSTRACT

Background: Risk management in the domiciliary healthcare setting is a harder challenge than in a hospital environment. Many, not always predictable, variables related to the patient, the caregiver, the health professionals and the home environment make it impossible to guarantee complete safety in homecare. The first aim of the study was to verify that the Electrical Medical Devices (EMD) and medical Consumables Supplies (CS) provided to mechanically ventilated and artificially fed patients at home comply with requirements for safe homecare.
Methods: We conducted a Failure Modes, Effects and Criticality Analysis (FMECA) on two processes, mechanical ventilation and artificial feeding at home, and defined a local institutional list of the requirements for safe home healthcare; a checklist containing all the items in the list was administered to ventilated and artificially fed patients at home.
Results: The checklist was used for 92 home patients, sex M/F=52/40, mean age 59,8±22 years (range 2÷102 years). Many failures were highlighted when the checklist was applied and problems affecting AMBU resuscitator bags, tracheostomy tubes, ventilators in patients being mechanically ventilated around-the-clock and ventilator circuits were identified as the most critical potential vulnerabilities for homecare patients.
Conclusion: The checklist is a simple and valid tool for implementing proactive clinical risk management initiatives in homecare. Although it is impossible to guarantee complete safety in any healthcare environment, scheduling periodic checks with checklists to assess the quantitative and qualitative adequacy of EMD and CS provided to the patient could contribute to the homecare risk reduction.

Key words: Healthcare Failure Mode and Effect Analysis HFMEA, Checklist, Home Care, Mechanical Ventilation, Health Risk Assessment

INTRODUCTION

Home care represents a complex challenge for patient safety and the higher the patient frailty the greater the effort to be made.

The risk management of artificially-fed and/or mechanically ventilated patients at home needs to consider many aspects; although it is impossible to guarantee complete safety, even in a hospital setting, strategies for safe home care should include at least a structured discharge plan with formal training programme for patients and caregivers - in particular how to deal with unexpected or emergency situations; procedures for checking standard home equipment requirements and information on (who-

does-what) the roles of different health professionals involved in home care including technicians and their external service companies [1, 2]

The *"electrical medical devices"* (EMD: i.e. ventilators, suction machines, feeding pumps) and "consumable supplies" (CS: i.e. tracheostomy tubes, ventilator circuits, catheter mounts, gastrostomy tubes) are factors that play an important role in determining safety in home healthcare as well as the presence of a trained caregiver [1, 3-5].

Mc Graw C. and co-authors [5] tried to define the conditions of safe and unsafe medication-related practice in home care settings and proposed a framework of factors influencing such an activity; interestingly among the "Work environment factors" they identified Functionality and Availability of equipment/supplies as one of the conditions to be checked in order to promote safe care.

In 2012 the Joint Commission International [6] defined a list of patient safety goals that home care organizations have to implement in order to achieve international accreditation, including standards for Medical Equipment (chapter MSE -Management and Safety of the Environment- section 5): *"When the home care organization supplies medical equipment in the home, the organization plans and implements a program for inspecting, testing, and maintaining medical equipment and for documenting the results"*.

Failure mode and effect analysis (FMEA) is a team-based, systematic, proactive, and reasoned-based technique that involves identifying and eliminating process failures for the purpose of preventing an undesirable event [7, 8].

The application of FMEA is often the result of two sub-analyses: the Failure Modes and Effects Analysis (FMEA) and the Criticality Analysis (CA). This is the reason why FMEA is often extended to FMECA, to indicate that criticality analysis is performed too [9].

Proactive Risk Assessment models include Healthcare Failure Mode and Effect Analysis (HFMEA™) and Failure Mode Effect Analysis (FMEA) [10].

HFMEA™ has been successfully used to several healthcare processes in hospital settings [11-13]; although both methodologies can be applied to assess the riskiness of each procedure of the home healthcare, when evaluating health care accessories and consumables and electrical devices, conducting a traditional FMEA is the recommended proactive risk assessment method [14].

The domiciliary setting represents a complex environment where, according to A. Gawande [15, 16], the operators have to deal with two main difficulties in order to avoid errors: the fallibility of human memory and attention; and the custom of skipping steps of procedures of the daily care activities because they are considered pointless most of the time. Gawande A. considers the checklists a valuable tool to overcome failure.

The first aim of our study was to verify that the EMD and CS provided to mechanically ventilated and artificially fed patients at home comply with requirements for safe homecare.

We conducted a Failure Modes, Effects and Criticality Analysis (FMECA) on two processes of home care (mechanical ventilation and artificial feeding) with the aim of defining a local institutional list of the requirements for safe homecare regarding the availability and functionality of the EMD and of the CS; then we made a checklist containing all the items in the list; finally we tested the checklist in the *real world* of frail patients with complex needs cared for at home in a region of southern Italy.

DATA AND METHODS

Study Design

We conducted an observational study to test the effectiveness of a checklist in highlighting weaknesses relating to the availability and functionality of the electrical medical devices (EMD) and of the consumable supplies (CS) for ventilator-assisted individuals living at home.

Among barriers to home transition and risks in the home stay we identified this topic as a priority for the safe homecare setting.

The checklist was developed after conducting a FMECA of mechanical ventilation and artificial feeding at home; the Working Group (WG) followed the standard FMEA/FMECA steps in Table 1.

For the purpose of the study, *'failure mode'* was considered to be any possible failure (errors or defects) that could affect the processes of home ventilation and nutrition of frail and complex patients; and in particular the failures regarding the availability and functionality of the electrical devices and the accessories and consumables needed for the two activities.

Setting

Drawing up a checklist was the final result of a proactive approach to identify deficits and/or malfunctions regarding the EMD and CS provided to mechanically ventilated and artificially fed patients at home. When we started this work (which was carried out from February to December 2015), at the Department of Primary and Intermediate Care (DAPI) of the Local Health Agency in Bari (ASL Bari- Italy), there was no local encoded control procedure active; however the suppliers of medical equipment were expected to carry out periodic checks on mechanical ventilators and yet no regular formal verification was made by the ASL Bari.

Participants

The WG was made up of four physicians and six nurses engaged in the home care of ventilator dependent

TABLE 1. FMEA/FMECA steps [17, 18]

1) Defining the Topic	Home ventilation and nutrition of frail and complex patients.
2) Assembling the multidisciplinary team	The Working Group (WG) was made up of four physicians and six nurses engaged in the home care of ventilator dependent and artificially fed patients, a clinical engineer and a physician with expertise in risk management.
3) Mapping the process, targeting and listing the possible failure modes	After mapping all the activities associated with mechanical ventilation and artificial nutrition at home, the WG identified failure modes associated with the availability and functionality of the electrical medical devices (EMD) and the accessories and consumables (CS) provided to ventilator dependent patients requiring artificial nutrition at home.
4) Prioritization of the failure modes	The WG Calculated the risk priority number (RPN).
5) Development of action plans	The WG defined a local institutional list of the requirements for safe homecare regarding the availability and functionality of the EMD and of the CS and drew up a control checklist to enable the effective monitoring of the EMD/CS availability and functionality.

and artificially fed patients, a clinical engineer and a physician with expertise in Risk Management.

Over the course of six meetings default scenarios of mechanical ventilation and enteral artificial nutrition at home were defined; the objectives were to identify failure modes associated with, and to plan an effective strategy to manage the risks connected to, those home care activities.

The subjects under observational investigation were the cohort of 102 patients with a score 0 on the Barthel Index scale [19]; all the subjects were invasive mechanically ventilated through tracheostomy and could be artificially-fed through gastrostomy at home in the community of the Local Health Agency in Bari, Italy.

Variables

After mapping all the activities associated with mechanical ventilation and artificial nutrition at home, the WG identified the potential failure modes, their causes and consequences for each activity (*'What failure could occur?' 'How a failure could happen?' 'What happens when this failure occurs?'*); then made a proactive risk assessment assuming default scenarios of those activities and calculating the Risk Priority Number (RPN) for each activity failure mode. The indices that make up the RPN are "severity" (S), "probability" (P) and "detectability" (D); each factor is a numerical subjective estimate made by the WG operators of how severe they perceived the effect of a failure (S), of how likely it is that the agent of a failure mode will occur (P) and of how effectively the measures to detect the cause of failure mode will operate (D); these scores are expressed with a number ranging from 0 to 10 so that the single RPN value, resulting from the product S x P x D, ranges from 0 (absolute best score) to 1000 (absolute worst score).

Furthermore the WG assumed strategies for preventing deficits and/or malfunctioning of the electrical equipment and consumable supplies provided to the patients for home healthcare and drew up a control checklist to enable the effective monitoring of their availability and functionality.

After defining local institutional lists of the EMD and CS as well as the related requirements for safe homecare the WG composed a checklist containing all the items in the list (see tables 2/A, 2/B, 3); regarding the amount of accessories and consumables, the Working Group considered the provision supplied by the ASL Bari for a month as the minimum safety threshold; for tracheostomy and gastrostomy tubes the availability of two tubes was considered to be the minimum safe quantity (table 3).

The checklist consisted of two sections (see table 3):

- assessment of the accessories and consumables (Consumable Supplies - CS);
- assessment of the electrical medical devices (EMD).

TABLE 2/A. List of the accessories and consumables (consumable supplies - CS)

- Tracheostomy Tubes
- AMBU Resuscitator bag
- Ventilator circuit
- Catheter Mount
- Endotracheal suction catheter
- HME Filter or Chamber Humidifier
- Dust filters for mechanical ventilators
- Tracheo-dressing
- Gastrostomy Tube
- Feeding set for enteral nutrition through PEG
- Disposable syringe 50-60ml
- Pack/Bottle for enteral nutrition
- Hydrophobic Antibacterial Filter for Aspirator
- Silicone Connection tube

TABLE 2/B. List of the electrical medical devices (EMD)

- Mechanical Ventilators
- Aspirator working only on mains or alternatively on mains or on battery.
- Heated Humidifier
- Pulse Oximeter
- Enteral Feeding Pump
- Anti–Decubitus Mattress
- (Liquid) Oxygen Tank

The section *"assessment of electrical medical devices"* contained three subsections:

a. EMD availability,
b. electrical connections of the EMD (and connection between oxygen tank and ventilators),
c. operation test of the EMD.

Data sources/measurement

The checklist was tested in patients' homes. The ASL Bari database registering all the subjects on invasive mechanical ventilation and artificial nutrition was used to identify the eligible patients. Each item on the checklist was explored and the nurses that made the checks in patients' homes had three possible responses (outcomes of the check):

- the check is OK;
- the check highlights a failure;
- the check highlights a failure that could be solved by nurse.

If a failure was highlighted the nurse was asked to give a brief description.

The collected data from the compiled checklists were analyzed and evaluated with respect to RPN values. The results were expressed as percentages of the total number of responses to each of the checklist items.

RESULTS

Participants

One hundred and two patients registered in the database for invasive mechanically ventilated individuals were examined for eligibility; eight of them were excluded: four patients had died, two had been hospitalized for exacerbations of chronic disease, two had improved and had been ventilator independent for more than four weeks.

Ninety-four patients were confirmed eligible and

TABLE 3. Checklist items

ASSESSMENT OF THE CONSUMABLE SUPPLIES (CS): *AVAILABILITY*
1. Tracheostomy Tubes: at least 2 sealed packages available that have the same characteristics as the patient's tracheostomy tube (manufacturer's, OD, ID, fenestrated/non-fenestrated).
2. AMBU Resuscitator bag with expiratory valve present at home and immediately available.
3. Ventilator circuit: at least 2 circuits (double circuit or single circuit with expiratory valve and with water traps).
4. Catheter Mount: at least 30 pieces available.
5. Endotracheal suction catheter: at least 200 pieces available.
6. HME Filter: at least 30 pieces available OR Chamber humidifier for Heated Humidifier: at least 1 pieces available.
7. Dust filters for mechanical ventilators (when supplied): at least 1 piece available.
8. Tracheo-dressing: at least 30 pieces available and Tracheostomy Necktape: at least 6 pieces available.
9. Gastrostomy Tube: at least 2 tubes that have the same characteristics as the patient's gastrostomy tube (manufacturer's, diameter Fr o Ch).
10. Feeding set for enteral nutrition through PEG: at least 30 pieces available.
11. Disposable syringe 50-60ml: at least 30 pieces available.
12. Pack/Bottle for enteral nutrition: at least the amount required for 30-day feeding.
13. Hydrophobic Antibacterial Filter for Aspirator: at least 1 piece available.
14. Silicone Connection tube: at least 1 piece available.
ASSESSMENT OF THE ELECTRICAL MEDICAL DEVICES (EMD):   ***A) EMD AVAILABILITY***
15. VENTILATED PATIENT 24/7: Ventilators: present in the patient's home two identical automatic ventilators..
15 bis. NOT CONTINUOUSLY VENTILATED PATIENT: Ventilators: present in the patient's home one automatic ventilator at least (if present 2 ventilators, the ventilators must be identical).
16. Aspirator: 2 aspirators are present in the patient's home; one of them works alternatively on mains or on battery.
17. Heated Humidifier.
18. Pulse Oximeter operating at power supply and battery.
19. Enteral Feeding Pump operating at power supply and battery.
20. Anti–Decubitus Mattress.
21. (Liquid) Oxygen Tank: if prescribed it must be present in the patient's home.
ASSESSMENT OF THE ELECTRICAL MEDICAL DEVICES (EMD):   ***B) ELECTRICAL CONNECTIONS OF THE EMD*** and connection between oxygen tank and ventilators
22. Check the general good condition of cables and sockets;the presence of power supply and external battery ventilator correctly positioned.
23. Ventilators both connected to the mains.
24. Aspirators both connected to the mains.
25. Heated Humidifier connected to the mains.
26. Enteral Feeding Pump connected to the mains.
27. Anti-Decubitus Mattress connected to the mains.
28. Correct connection between (Liquid) Oxygen Tank and Ventilator (in particular verify that it is not interposed humidification chamber).
ASSESSMENT OF THE ELECTRICAL MEDICAL DEVICES (EMD):   ***C) OPERATION TEST OF THE EMD***
29. Ventilators: the two automatic ventilators have the same identical set of ventilation modes and secondary parameters, and they work normally.
30. Aspirators: the two aspirators are working normally (one of them works alternatively on mains or on battery).
31. Ventilator circuit (double circuit or single circuit with expiratory valve and with water traps) is correctly positioned.
32. Heated Humidifier functioning normally.
33. Pulse Oximetry functioning normally.
34. Enteral Feeding Pump functioning normally.
35. Anti-Decubitus Mattress functioning normally.
36. Verify the effective dispensing of the flow of oxygen through the tube that goes from the (Liquid) Oxygen tank to the ventilator or to the patient.

included in the study in July 2015; however by November 2015 one of these had died and another had been hospitalized so the checklists were administered to ninety-two patients.

Figure A shows the above data in a flow diagram.

Descriptive data

The WG made lists of EMD and CS provided to patients on invasive mechanical ventilation and artificial nutrition at home (see tables 2/A and 2/B) reaching a consensus agreement about the definition of the minimum quantities, conditions, settings and operating modes required for safe homecare (see table 3); the resulting checklists were used for ninety-two home ventilator-assisted patients, sex M/F=52/40, mean age 59,8±22 years (range 2÷102 years); their main underlying diseases are summarized in table 4.

Among the ninety-two ventilated patients thirty-five patients were not artificially fed; four were fed through a nasogastric tube; fifty-three were fed through a gastrostomy feeding tube; consequently the data reported in table 3 related to the EMD and CS for artificial feeding were less than the total ninety-two patients; furthermore only thirteen subjects used a heated humidifier, seventy-nine used an anti–decubitus mattress, ninety had a prescription for O_2.

Main results

The Risk Priority Number (RPN) calculation for each of the activities correlated with the EMD and CS in the use of the home ventilated and artificially fed patients are shown in Figure B.

WG addressed the highest rated failure modes and identified some key issues in the field of home care risk management as critical potential vulnerabilities: problems affecting AMBU resuscitator bag (RPN=400; S=10, P=5, D=8), tracheostomy tubes (RPN=245; S=7, P=7, D=5), ventilator in patient mechanically ventilated around-the-clock (RPN=60; S=10, P=2, D=3) and ventilator circuit (RPN=60; S=10, P=2, D=3).

The results of the checklists are reported in tables 5 and 6.

With regard to critical vulnerabilities; the checklists revealed 11 failures (one immediately solved), 12%, regarding the AMBU bag; 27 failures (one immediately solved), 29%, regarding the tracheostomy tube; 7 failures (8%) regarding the ventilator circuits; with regard to ventilators, the assessment of the EMD availability revealed 1 failure (2%) in a ventilator-dependent patient for 24 hours a day; the assessment of electrical connections of the EMD revealed 11 failures (one immediately solved), 11%; the operation test revealed 7 failures (three immediately solved), 8%.

Of the 10 AMBU bag failures highlighted, 6 concerned the absence and 4 the not immediate availability (kept in a different room outside the house) of the device; of the

FIGURA A. Participants' Flow Diagram

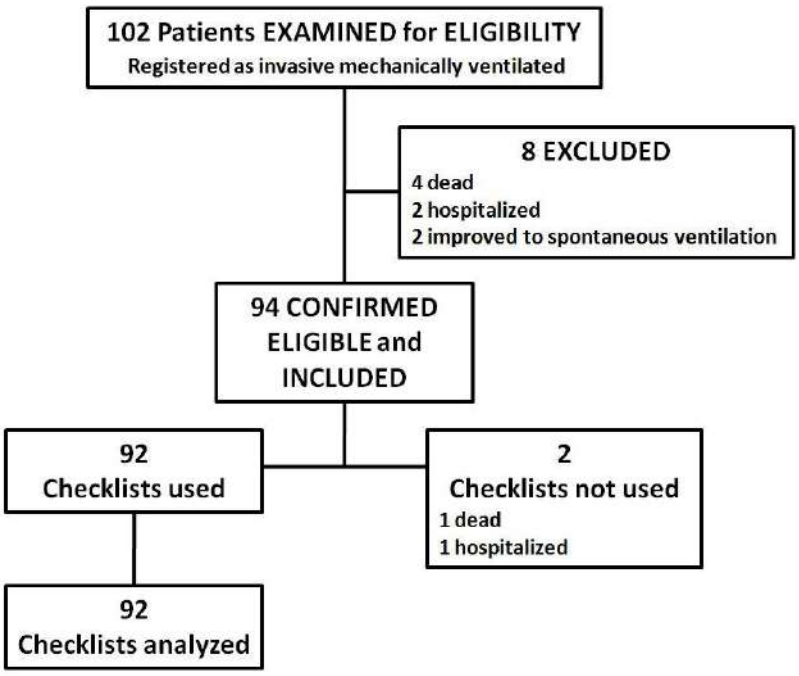
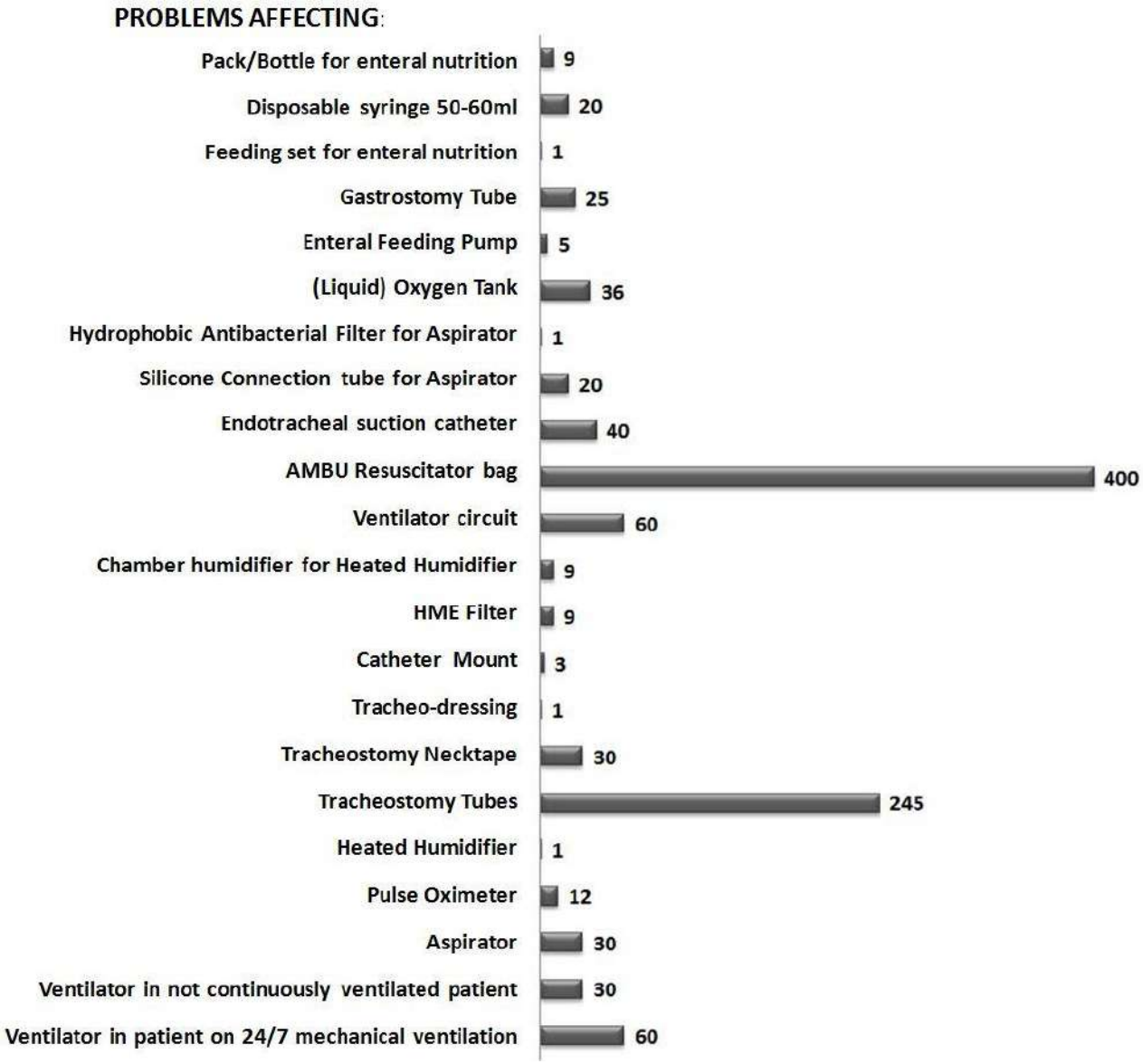


TABLE 4. Main underlying disorders of patients requiring invasive mechanical ventilation

Neurologic/Neuromuscular diseases	73
ALS (Amyotrophic Lateral Sclerosis)	36
SMA (Spinal Muscular Atrophy)	7
Others	30
Pulmonary diseases	18
Cardiologic diseases	1

FIGURE B. Results of the Risk Priority Number (RPN) calculation



27 tracheostomy tube failures highlighted, 20 concerned the availability of a single tube instead of the two pieces required, 5 concerned the absence of the spare device and 1 the presence of a single tube different from that prescribed; the 7 ventilator circuit failures highlighted concerned the presence of a single circuit instead of the two pieces required.

In relation to the 19 mechanical-ventilator failures highlighted, they concerned:

- the presence of two different devices provided to 24-hour-a-day ventilated patients (one failure);
- damaged cables and sockets (two failures);

TABLE 5. Results of the checklists (for a legend of the items see table 3)

Item	Patients Data Available	OK (%)	Failure highlighted (%)	Failure solved	Total failure (%)
1	92	65 (71)	26 (28)	1	29
2	92	81 (88)	10 (11)	1	12
3	92	85 (92)	7 (8)	0	8
4	92	74 (80)	18 (20)	0	20
5	92	79 (86)	13 (14)	0	14
6	92	72 (78)	18 (20)	2	22
7	92	67 (73)	25 (27)	0	27
8	92	83 (90)	8 (9)	1	10
9	53	24 (45)	28 (53)	1	55
10	57	46 (81)	6 (11)	5	19
11	62	55 (89)	6 (10)	1	11
12	56	41 (73)	10 (18)	5	27
13	91	70 (77)	20 (22)	1	23
14	92	62 (67)	29 (32)	1	33
15	57	56 (98)	1 (2)	0	2
15.bis	35	34 (97)	1 (3)	0	3
16	92	81 (88)	11 (12)	0	12
17	13	8 (62)	0 (0)	5	38
18	92	78 (85)	11 (12)	3	15
19	59	56 (95)	0 (0)	3	5
20	79	79 (100)	0 (0)	0	0
21	90	86 (96)	4(4)	0	4
22	92	90 (98)	2 (2)	0	2
23	92	83 (90)	8 (9)	1	10
24	92	68 (74)	19 (21)	5	26
25	13	8 (62)	0 (0)	5	38
26	59	47 (80)	9 (15)	3	20
27	79	68 (86)	0 (0)	0	0
28	90	65 (72)	24 (27)	1	28
29	88	81 (92)	4 (5)	3	8
30	92	81 (88)	11 (12)	0	12
31	92	92 (100)	0 (0)	0	0
32	13	8 (62)	0 (0)	5	38
33	92	87 (95)	4 (4)	1	5
34	59	55 (93)	1 (2)	4	8
35	79	68 (86)	0 (0)	11	14
36	90	69 (77)	21 (23)	0	23

- back-up ventilators not connected to the mains (9 failures);
- different set of ventilation on the two ventilators (7 failures).

DISCUSSION

The WG has drawn up two lists on EMD and CS used by mechanically ventilated and artificially fed patients at home and has defined the minimum safe conditions for home care regarding the EMD and CS while also developing a checklist for periodic monitoring of the existence of the safe conditions.

The RPN calculation pointed out some critical potential vulnerabilities; among them the problems affecting the AMBU resuscitator bag gained the highest score: health care professionals and caregivers are not always aware

TABLE 6. Specification of failures highlighted by the checklist regarding the availability of accessories and consumables (A), the availability of electrical medical devices (B), the assessment of the electrical connections (C) and the operation test (D) of the EMD.

TABLE 6/A

ASSESSMENT OF THE ACCESSORIES AND CONSUMABLES (CS) AVAILABILITY
- **Tracheostomy Tubes**: 27 failures (20 concerned the availability of a single tube instead of the two pieces required, 5 concerned the absence of the spare device and 1 the presence of a single tube different from that prescribed).
- **AMBU Resuscitator bag**: 10 failures (6 concerned the absence and 4 the not immediate availability of the device).
- **Ventilator circuit**: 7 failures (availability of a single circuit instead of the two pieces required).
- **Catheter Mount**: 18 failures (availability of fewer than 30 pieces required).
- **Endotracheal suction catheter**: 13 failures (availability of fewer than 200 pieces required).
- **HME Filter/Chamber Humidifier**: 18 failures (availability of fewer than the pieces required).
- **Dust filters for mechanical ventilators**: 25 failures (absence of the spare device).
- **Tracheo-dressing**: 8 failures (availability of fewer than pieces required).
- **Gastrostomy Tube**: 28 failures (24 concerned the availability of a single tube instead of the two pieces required, 4 concerned the absence of the spare device).
- **Feeding set for enteral nutrition through PEG**: 6 failures (availability of fewer than 30 pieces required).
- **Disposable syringe 50-60ml**: 6 failures (availability of fewer than 30 pieces required).
- **Pack/Bottle for enteral nutrition**: 10 failures (availability of fewer than the amount required for 30-day feeding).
- **Hydrophobic Antibacterial Filter for Aspirator**: 20 failures (absence of the spare device).
- **Silicone Connection tube**: 29 failures (absence of the spare device).

TABLE 6/B

ASSESSMENT OF THE EMD AVAILABILITY
- **Mechanical Ventilator** for around-the-clock Ventilated Patient: 1 failure (two different devices).
- **Mechanical Ventilator** for Not Continuously Ventilated Patient: 1 failure (two different devices).
- **Aspirator**: 11 failures (availability of a single device instead of the two aspirators required).
- **Heated Humidifier**: none.
- **Pulse Oximeter** operating at power supply and battery: 11 failures (devices not operating at power supply).
- **Enteral Feeding Pump** operating at power supply and battery: none.
- **Anti–Decubitus Mattress**: none.
- **(Liquid) Oxygen Tank**: 4 failures (absence of prescribed Oxygen Tank in the patient's home).

of the importance of this device in the management (with manual ventilation) of some severe failures related to home mechanical ventilation; furthermore the immediate availability and the caregivers' competence in its use are necessary for improving safety in home care.

The WG has also examined the conditions that must exist for a failure affecting any EMD or CS, which could lead to an adverse event to occur, and considered the

TABLE 6/C

ASSESSMENT OF THE ELECTRICAL CONNECTIONS OF THE EMD
- **Good condition of cables and sockets and the presence of power supply and external battery ventilator**: 2 failures (cables and sockets damaged).
- **Ventilators both connected to the mains**: 8 failures (back-up ventilators not connected to the mains).
- **Aspirators both connected to the mains**: 19 failures (back-up aspirators not connected to the mains).
- **Heated Humidifier connected to the mains**: none.
- **Enteral Feeding Pump connected to the mains**: 9 failures (pumps not connected to the mains).
- **Anti–Decubitus Mattress connected to the mains**: none.
- **Correct connection between (Liquid) Oxygen Tank and Ventilator**: 24 failures (humidification chambers interposed between Oxygen Tank and Mechanical Ventilator)

TABLE 6/D

OPERATION TEST OF THE EMD
- **Ventilators**: the two automatic ventilators have the same identical set of ventilation modes and secondary parameters, and they work normally: 4 failures (the two ventilators did not have the same identical set of ventilation).
- **Aspirators**: the two aspirators are working normally (one of them works alternatively on mains or on battery): 11 failures (low vacuum or battery would not charge).
- **Ventilator circuit** (double circuit or single circuit with expiratory valve and with water traps) is correctly positioned: none.
- **Heated Humidifier** functioning normally: none.
- **Pulse Oximeter** functioning normally: 4 failures (battery would not charge).
- **Enteral Feeding Pump** functioning normally: 1 failure (battery would not charge).
- **Anti-Decubitus Mattress** functioning normally: none.
- **Verify the effective dispensing of the flow of oxygen through the tube that goes from the (Liquid) Oxygen tank to the ventilator or to the patient**: 4 failures (no oxygen flow to the patient).

preventive strategies; the strongest agreement was reached on the two main conditions necessary for safe home care: adequate training of caregivers and assessment of the existence of the minimum safe conditions at home made by the case manager before discharging the patient.

There are no specific recommendations for the quantitative and qualitative characteristics of EMD and CS associated with the best home care safety; therefore, ours is the first local attempt to formalize a list, subject to changes, containing conditions considered safety standards.

The first administration of the checklist highlighted several deficiencies that required corrective actions; applying the checklist periodically throughout the home care period could represent a useful tool for verifying the persistence of the safety standard. The use of the checklist could be one of the criteria to be satisfied before discharging the patient from hospital (or from an intermediate residential care setting) to home care.

When compared with hospital care, home care is a less structured setting [4] *"because each home is, in essence, a 'worksite'"* and consequently risk management is especially problematic in the latter environment [20]; with the activities described in the present work we tackled just one of the several potential tasks towards the goal of safer home healthcare for artificially-fed and/or mechanically ventilated patients: to enable effective monitoring of and

prevent failures related to the availability and functionality of EMD and of CS. We chose that specific field as a subject of our investigation being aware that the analysis would bring out many avoidable failures, most of them related to human fallibility.

In 1975 Gorovitz S. and MacIntyre A. published a paper [21] where they discussed the nature of human fallibility in many fields (i.e. medicine, law, finance, business); besides the necessary fallibility due to our human physical and mental limits they pointed out two further reasons for failure: *" … all scientific error will arise either from the limitation of the present state of natural science – i.e. ignorance - or from the willfulness of negligence of the natural scientist - i.e. ineptitude -"*.

Gawande A. [15, 16] commented on the article by Gorovitz and MacIntyre: *" […] If the knowledge of the best thing to do in a given situation does not exist, we are happy to have people simply make their best effort. But if the knowledge exists and is not applied correctly, it is difficult not to be infuriated. […] Avoidable failures are common and persistent, not to mention demoralizing and frustrating, across many fields—from medicine to finance, business to government. And the reason is increasingly evident: the volume and complexity of what we know has exceeded our individual ability to deliver its benefits correctly, safely, or reliably. Knowledge has both saved us and burdened us. That means we need a different strategy for overcoming failure, one that builds on experience and takes advantage of the knowledge people have but somehow also makes up for our inevitable human inadequacies."*

Glouberman S. and Zimmerman B. [22] discussed the *"distinction between simple problems, complicated problems and complex ones"*; they identified health care systems as complex systems and stated that many health care experts describe complex problems as complicated ones and hence employ solutions that often prove to be inappropriate because they neglect many aspects of complexity.

Although we agreed with Simonds A.K. [1] that it is impossible to guarantee complete safety in the home care setting as well as in a hospital environment there are some initiatives that could be useful in minimizing risk; among them is the use of a checklist; nevertheless we consider it appropriate that the drafting and use of a checklist be preceded by other activities such as a FMEA to proactively assess the potential failures.

Furthermore the role of the caregivers (family members or friends) is crucial for best risk management in the home care setting; electrical medical equipment like ventilators can break down but such a failure is predictable and infrequent and associated with few adverse consequences for home patients [1]; an adverse event is more likely in the presence of an untrained caregiver or a caregiver unable to appropriately deal with emergencies such as the tracheostomy-related accidents or complications in a full-time ventilator dependent patient [1-4, 23]. The caregivers also need to be supported in their care activities considering that a link exists between caregiver and patient health and safety [3, 24]: caregivers frequently lack sleep as they provide day-and-night care and may suffer from fatigue, exhaustion, stress, poor health and all of them potentially resulting in a low quality of care for the patient and an increased safety risk. Healthcare organizations must include initiatives aimed at improving not only the training, the experience and the knowledge but also the health of the caregivers.

Finally the quality control procedures performed by the ventilator companies have an important role in preventing failures [1, 23, 25]: the clinical engineer in the WG provided certifications about the regular service and effective maintenance of home electrical equipment; in particular the planned preventative maintenance of ventilators is performed every 4 months by the ventilator companies and a 24 hour on call service is operative in case of malfunction of the EMD; all the 24-hour ventilator dependent patients had a back-up ventilator.

Study limitations

The first limitation of our work concerns the generalizability of the activities: in the absence of an international agreement on EMD and CS qualitative and quantitative requirements the checklist verified the existence of conditions that we decided locally to consider as a safety standard for the home care of frail and complex patients. A tentative list of equipment believed to be required by experts for children mechanically ventilated at home was made by Sterni L.M. and co-authors [23]; they identified as absolutely indispensable the ventilator, a back-up ventilator, batteries for the ventilator, self-inflating bag and mask, suctioning equipment, heated humidifier, supplemental oxygen for emergency use, nebulizer, and a pulse oximeter. We did not find any paper with a list for the accessories and consumables required for adults or children mechanically ventilated at home.

Another limitation of the study concerns the calculation of RPN: the context factors, such as the absence of regular formal checks at home and the presence of untrained caregivers, often elderly and contending with their own health challenges, affected the calculation of RPN; the severity rating (S), the probability rating (P) and the detectability rating (D) determinations were influenced by those factors and could get better as the training of caregivers improves or a safety standard is set down.

Furthermore, the checklists even if based on standards or on rigorous evidence are a weak tool; although they are a valuable aid to improving performance, in order to be successful, the checklists need to be coupled with actions aimed at understanding how home healthcare organizations work and removing barriers (technical,

social, political, psychological) which cause operators to ignore the evidence [26, 27].

CONCLUSION

Clinical risk management in the home care setting is a complex task. Being aware that it is impossible to guarantee complete safety in any healthcare environment and formalizing procedures for safe discharge could contribute to the reduction of home care risk. For example the identification of clinical criteria for discharging patients from hospital to an intermediate residential care setting or home care; the continuing education of health professionals and caregivers on issues relating to home care; the prior assessment of the appropriate training of caregivers who must be able to manage the EMD and CS, addressing the main problems associated with their use, appropriately responding to emergencies; the strategies for preventing the decline of caregivers' health related to the strenuous efforts required for patient care; scheduling periodic checks with checklists to assess the quantitative and qualitative adequacy of EMD and CS and periodic monitoring of the outcomes of maintenance of electrical equipment provided to the patient.

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