Heliyon 5 (2019) e03034

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Research article

Critical failures in the use of home ventilation medical equipment

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ARTICLE INFO

Keywords:
Safety engineering
Biomedical engineering
Failure analysis
Quality in health service
Risk assessment and management
Swiss cheese model
Home ventilation
Home care

ABSTRACT

Home ventilation involves the use of medical devices at patient's home by personnel who are not healthcare practitioners. This implies new potential risks not fully addressed by current standards and guidelines. A methodological approach to investigate potential failures and define improvement actions to address the dangerous potential situations in HV is required.

A multidisciplinary team performed an extended version of Failure Mode, Effect and Criticality Analysis (FMECA) to analyse the home ventilation service provided by the Local Healthcare Unit of Naples (ASL NA1) that assisted 60 homebound ventilator dependent patients. The failures were identified in three risk areas: device, electrical system & fire hazard, and indoor air quality. The corrective actions were formulated with two extra steps: identification of critical failures with a threshold applied to the risk priority number and analysis of causes by means of contributory factors (Organization, Technology, Information, and Structure) based on Reason's theory of failures.

22 of 86 potential failures were identified as critical. Specific corrective actions were addressed and proposed through contributory factors to improve the overall quality of home ventilation service.

The use of this systemic approach oriented the improvements to reduce the harms caused by vulnerabilities in high-risk care service as life support home ventilation.

1. Introduction

Home care is increasingly developing as an alternative to the conventional hospitalisation of chronic patients because of the indisputable benefits in terms of a patient quality life and cost saving [1, 2]. In particular patients affected by chronic respiratory and neuromuscular diseases can be successfully discharged and assisted for very long periods with home ventilation treatment [2]. This requires that lung ventilators, oxygen cylinders and other auxiliary medical devices, such as suction machines or uninterruptible power supply (UPS), are installed at the patient's home and used by patient itself and/or their careers. Actually, these devices are usually not designed to be daily used in a non-clinical environment [3] and by personnel who are not healthcare practitioners [3, 4, 5]. Furthermore, the interaction of different technologies and systems (e.g. medical devices – MDs, home electrical system, heating ventilation and air conditioning systems) causes a complex scenario and introduce new potential risks for the patients that can invalidate the quality of the service and the safety of the patient [6, 7].

Although the spread of home ventilation, there are currently very few guidelines, qualitative reports, and surveys related to global patient safety in home. Actually, different studies reports risk and hazard analysis in home ventilations limited to singular aspects. Particularly studies are related to the clinical practice [8], ventilator malfunctioning [5, 9], risks associated with medical equipment [10] and alarms [11]. The aim of this study is to provide a comprehensive, analysis related to the risks introduced in life support home ventilation due to the use of medical and non-medical technologies, devices, and materials in a non-clinical environment to be devoted to intensive and critical care.

Over recent years, professionals and managers of healthcare sectors have looked at methods and techniques to identify the risks that can lead patient harms. Proactive methodologies for risk assessment have the advantage to prevent harms, instead of reactively taking action after an

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https://doi.org/10.1016/j.heliyon.2019.e03034
Received 24 July 2018; Received in revised form 20 June 2019; Accepted 10 December 2019

accident has occurred [12, 13, 14]. Examples of proactive methodologies are Failure Mode and Effect Analysis (FMEA) [15] and the Failure Mode Effect and Criticality Analysis (FMECA) [16, 17, 18, 19]. Particularly FMECA is widely used for the prevention of medical errors and, in 2001, the Joint Commission on Accreditation of Health Care Organization (JCAHO) recommended the use of FMECA for the analysis of risks in the homecare sector [20].

As the combination of different failure and cause analysis tools revealed to be a valid approach to identify healthcare process vulnerabilities [10, 21], in this study the risk analysis was carried out by using an extended version of the FMECA methodology. In particular, it was enriched by new criteria for the identification of causes and corrective actions able to specifically address the causes of each critical failure based on Reason's hazard model.

In the paper the Method section introduces the basic concept of FMECA and Reason's model; Material section describes the application of the extended FMECA; Results section is dedicated to the description and characterisation of recognised critical failures; Discussion section describes and analyses the value of the approach in home ventilation and the improvements suggested by the proposed methodology. A focus on the Limitations of the study is reported before the Conclusion section.

2. Methods

2.1. FMECA

Generally speaking, retrospective and deductive methods are the most useful approach to risk assessment. As a matter of fact, their application requires the analysis of an amount of data on failures and adverse events after their occurrence.

As home ventilation is a quite new service, poor are studies reporting adverse events related to failures due to the use of medical and non-medical device and materials in non-clinical environment. Therefore, proactive methods are useful to cope this limit.

The proactive risk analysis methodologies uses expert opinions based on empirical data, comparison with similar phenomena and standard source from comparable fields. There are different methods each one has its own procedure that is more or less suitable for a specific application domain [4, 12, 13, 15].

Particularly FMECA (a logical extension of FMEA – Failure Mode Effect Analysis) and HFMEA ™ – Healthcare Failure Mode and Effect Analysis) are among the most popular proactive methods in health care [10]. FMECA methodolgy is mainly used in manufacturing [13] and it has been recently demonstrated that is a valid risk assessment tool to analyse process involving medical devices [22], risk assessment of medical device [11, 23] also in home ventilation [10]. On the contrary, HFMEA ™ is more oriented to the analysis of clinical processes (such as nursing and other clinical aspects) [4, 10, 21].

For the reasons explained before, FMECA can be retained useful in assessing and managing the failure modes related to the technologies (devices and plants) in the home environment.

FMECA is based on a failure identification and a successive ranking process accomplished by a multidisciplinary team. The level of criticality of each failure is expressed in a Risk Priority Number (RPN) [13, 14] that categorises the failures through to the seriousness of their possible effect (severity - S), the measure of the frequency of their occurrence (probability - P) and the ability to identify the failure before it may occur (detectability – D) [24]. These three factors are firstly evaluated with qualitative expressions and then correlated to numerical values through evaluation scales adapted to the context [25]. The RPN numerical value is the product of these factors (RPN = S x P x D).

In practical terms, the FMECA methodology is articulated in five consecutive steps described in details in the Material section:

a. definition of multidisciplinary team,
b. identification of sub-processes and main activities,
c. identification of failures,
d. scoring of the failures,
e. Suggestions of corrective actions.

2.2. The Reason's model

Considering the quality improvement of a process in healthcare systems, of interest are the description, the classification, and the correction of the main causing factors that may contribute to the quality and safety of the process under evaluation. Because of these factors point to the areas of intervention towards which improvements must be addressed, their identification has become a fundamental in the analysis of processes [26]. Therefore several frameworks study the latent conditions and contributory factors that take part in incident in healthcare setting [27].

As from [28], there are two approach to analyse the problem of fallibility: the person and the systemic approach. The person perspective focuses on the unsafe actions performed by people that are responsible for errors and the countermeasures are directed mainly to address human behaviours. In the systemic approach, failures or accident sources are to be found within main areas (foundations) of the healthcare system [29]. These are in correlation with barriers intercepting and blocking adverse events generating real accidents [29, 30, 31]. Particularly, Reason's theory depicts the barriers of healthcare organization as the slices of a Swiss cheese where the holes in each slice represent the unintended weaknesses and opportunities caused by latent conditions [31]. This model is used with the aim to identify and analyse latent conditions and providing an indication of the current state of safety. It has become the dominant paradigm for analysing medical errors and patient safety incidents that occur in a complex system and supports system analysis to identify the factors which may affect patient safety within the healthcare system [32].

From the risk analysis point of view, the Reason's model is applied to conceptualize with a systemic approach the barriers to accidents [29]. Of course, all technologies and medical devices have barriers and safeguards. When an adverse event occurs in a quality improvement oriented organization it is important to define how and why the defences fail and thus improve them. Using a systemic approach, the goal is not so much to prevent isolated failures, but to have model for robust system design [28].

Thus, even if it was originally developed for accident investigation, Reason's model can be used to identify the foundations in which failures originate in order to address them into solutions to reinforce barriers [29, 31].

As said, the current interpretation of the Reason's model defines the slices of Swiss cheese as barriers which have some holes caused by active failures or latent conditions. The active failures are unsafe system elements while latent conditions are pre-existing conditions that can lie dormant in the system and they may not have immediate safety consequences [27]. When the holes in each slice momentarily align, an active failure “passes” through them and becomes an accident [31]. In adopting this model it is suggested [33] the use of a taxonomy of contributory factors, defined according to Reason's model, as barriers to the occurrence of real harm. In this paper, the slices of Reason's model are the elements that represent the foundations of the healthcare delivery system, such as physical and technological means of support, communication and information, physical structure, etc. [29].

3. Materials

This section details the implementation phases of the above described methodology. An extended version of FMECA is applied to study risks associated to the use of medical and non-medical technologies in home ventilation. Since proactive studies are not based on patient's data, any experiment has been conducted on patient and the study did not require the approval by ethic committee.

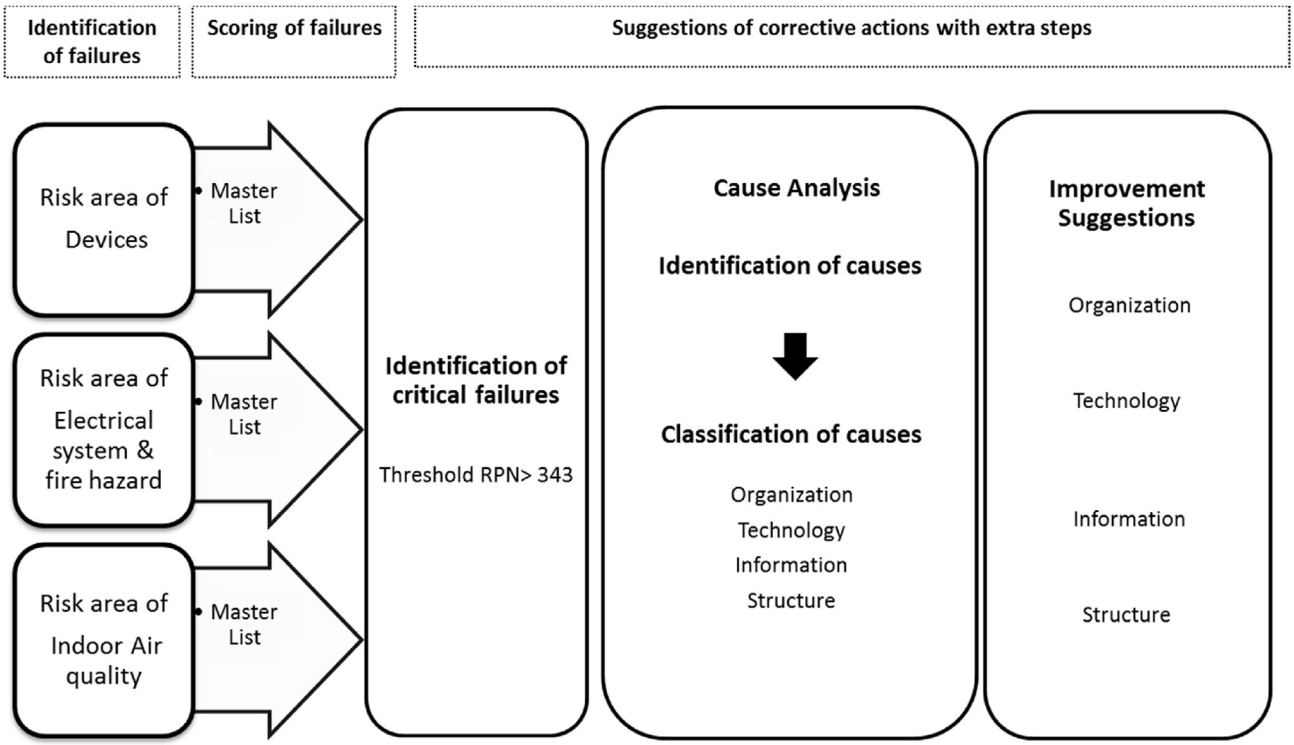

Figure 1. Methodological framework of extended FMECA.

Figure 1 shows the methodological framework described in the following sections.

The analysis was conducted at Local Healthcare Unit – Napoli 1 (ASL NA1) which assists one thousand housebound patients with different pathologies. At the time of the analyses, 60 patients were treated in home ventilation with life supporting ventilators due to the gravity of their pathologies (i.e. neuromuscular diseases such as amyotrophic lateral sclerosis, and chronic respiratory failures). The ventilator was used with ancillary equipment (such as suction machines, pulse oximeter, UPS, oxygen cylinders, etc.) and each patient received a back-up set composed of one ventilator, one suction machine and one UPS (according to regulation from regional health system, i.e. Regione Campania). A dedicated unit of ASL NA1 (Biotechnology Unit - BU), was in charge to assess the home environment through house inspections and assessment, manage the medical equipment and coordinate the technical staff involved.

BU coordinated the technical aspects from the beginning of home care process It supervised the global management (including preventive and corrective maintenance) of medical devices at home. This activity is toward the safety of patients, caregivers and medical practitioners.

3.1. Definition of multidisciplinary team

The FMECA multidisciplinary team was composed of six operators with different backgrounds. The team leader was the (i) responsible of the BU with twenty-five years' experience in clinical engineering, including experience in setting up the patient's dwelling so that the introduction of technologies takes place in compliance with the good practice and in line with technical standards for safety of medical environment. The other team members were (ii) one biomedical engineer, (MSc and PhD in health management) expert in proactive failure analysis; (iii) one biomedical engineer (MSc) with two years' experience at the BU in clinical engineering and safety use of medical devices including those used in home care; (iv) three biomedical engineers (BSc) each with one year's experience in the technical aspects of the home care service derived from clinical engineering training. The team consulted the intensivist (head of medical staff) involved in home ventilation and an informal caregiver.

The study lasted six months. The team meetings were held during BU's daily activities devoted to the home ventilation. Particular aspects were handled individually by members and proposed to the team for their approval and/or revision.

3.2. Identification of sub-processes and main activities

The team identified 3 sub-processes and 12 main activities related to technical aspects:

(1) Use and maintenance of devices:
  (1.1) Use of ventilator.
  (1.2) Use of suction machine.
  (1.3) Use of UPS.
  (1.4) Maintenance of devices.
(2) Use of electrical systems and control of fire hazard:
  (2.1) Use of electrical system.
  (2.2) Use of protective devices.
  (2.3) Maintenance of electrical system and components.
  (2.4) Control of fire hazards.
(3) Control of indoor air quality:
  (3.1) Control of indoor air quality.
  (3.2) Control of volatile organic compounds emissions.
  (3.3) Control of moisture accumulation.
  (3.4) Control of temperature.

3.3. Identification of failures

During brainstorming sessions, the team identified the potential failures that could affect the previously identified activities (Figure 2). The questions that guided the session were “what could interfere with the activity under examination?”, “what could go wrong?”, “what could be the consequences of each failure (effects)?”. In order to answer these questions, the members of the team consulted literature (as from

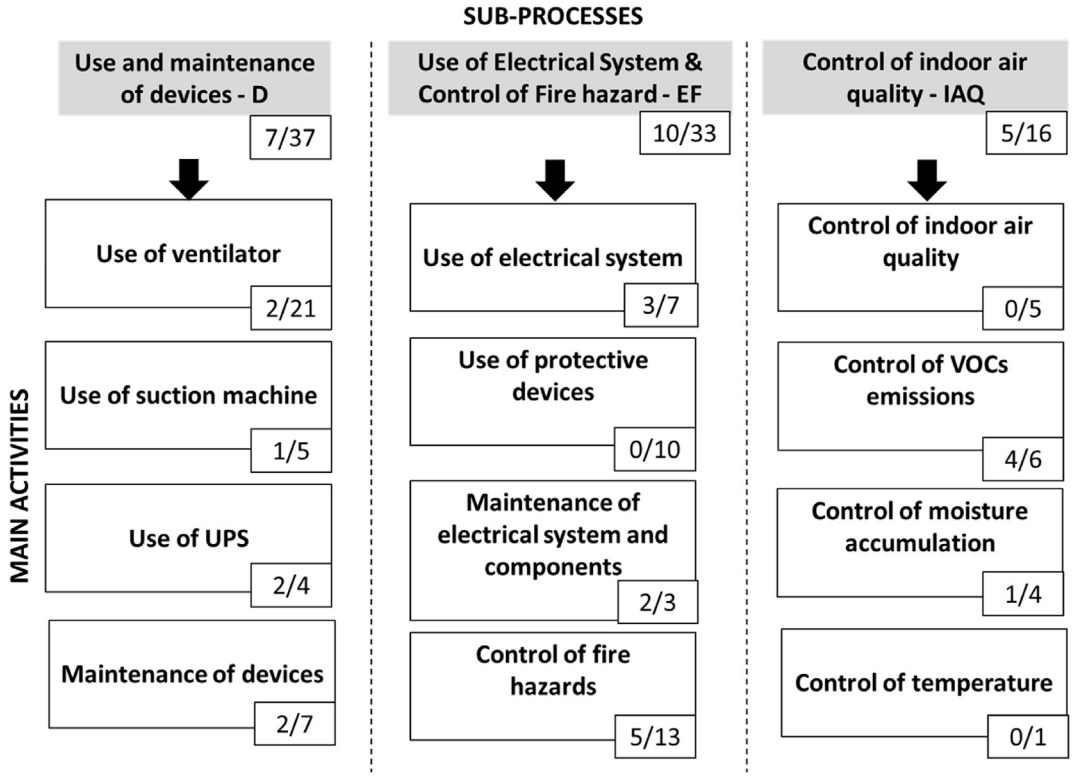

Figure 2. Sub-processes (grey boxes) and main activities (white boxes). In the corners of each box the ratios between the number of critical failures and total failures are reported.

introduction), technical standards, manuals, interviewed technicians of the BU (treated by (iv) team members) and data collected by BU during house inspections by (i) and (iii) team's members. All contributions were collected, compared and discussed in order to reach the consensus and identify the failures to be included. Finally, failures were classified into three risk areas corresponding to each sub-process. This phase was facilitated by (ii) team member due to his practical experience.

3.3.1. Devices (D)

This risk area, corresponding to the sub-process '(1) Use and maintenance of devices', included the failures regarding the devices malfunctioning, misuse or damage by users, bad maintenance and cleaning, maladjustment of ventilation settings and the inability to cope with emergency situations in the case of malfunctioning [6].

3.3.2. Electrical system and fire hazard (EF)

This risk area, corresponding to the sub-process '(2) Use of electrical systems and control of fire hazard', included the failures related to the compliance of the electrical system to national Italian standards. In particular, the failures are associated with protective devices (i.e. residual current devices or equipotential bonding bar if required). Moreover, the risk area considered the fire hazard caused by electrical defects and the presence of inflammable products (e.g. oxygen, drugs, towels, etc.) [34].

3.3.3. Indoor air quality (IAQ)

This risk area, corresponding to the sub-process '(3) Control of indoor air quality', included the aspects critical for ventilation dependent patients [35]. In particular, it considers the failures related to the control of indoor air quality, emissions of Volatile Organic Compounds (VOCs), the use of cleaning/maintenance products, and microclimate.

3.4. Scoring of failures

The team scored the failures using a 10-point scale, where 10 was the most severe outcome. The severity scale considered four levels of severity: catastrophic (10-9); critical (8-7); marginal (6-4) and minor (3-1). The probability scale considered four probabilities of occurrence, i.e. frequent, if it is expected to occur at least daily (10-9); possible, if it is expected to occur monthly (8-7); unlikely, if it is expected to occur annually (6-4); and rare, if it is expected to occur in a few years (3-1). The detectability scale had four levels, i.e. impossible (10-9); low (8-7); high (6-4) and sure (3-1).

The scores were assigned with the consensus of the whole team considering the critical health conditions of patients and their limited ability to move and react against dangers. Then the team globally evaluated the scores to avoid inconsistencies and sorted the RPN values in each risk area in descending order obtaining the so-called master lists.

3.5. Suggestions of corrective actions with extra steps

As said, the final step of FMECA is the suggestion of corrective actions and recommendations to solve the identified criticalities. In this study, this final step was extended with the introduction of two extra steps, i.e. the identification of critical failures and the cause analysis based on the Swiss cheese Reason's Model.

3.5.1. Identification of critical failures

The critical failures were identified when the RPN values exceed a threshold value equal to 343 ($7 \times 7 \times 7$) correspondent to high/extreme level of risk [36].

Table 1. Critical failures details (risk area, RPN, causes, and cause group).

Risk Area, Failure Mode, RPN	Cause(s)	Cause Group
D, Presence of electromagnetic interferences, 720	Presence of mobile phones, cordless telephone, walkie-talkie	**S**
	Lack of knowledge about safety distances from objects that can interfere with the equipment	**I**
EF, Lack of knowledge about fire safety and emergency procedures, 720	Absence or inadequate fire emergency procedures	**I**
D, Lack of communication about malfunctioning of equipment, 640	Misinformation about how to receive assistance and help about equipment malfunctioning	**I**
EF, Lack of communication about problems of electrical system, 640	Impossibility to contact the maintenance service provider or manufacturer	**O**
IAQ, Presence of humid air in patient room, 640	Absence of a system to control the humidity in patient room	**S**
IAQ, Improper use of sprays for dust, 640	Misinformation about the dangerous effects of the use of spray for dust	**I**
D, Incorrect autonomous fixing up and/or modifications of equipment, 576	Misinformation about the dangerous effects of the incorrect autonomous fixing up and/or improper modifications of equipment	**I**
	Absence of safety constraints applied to electrical system components	**S**
EF, Incorrect modifications and/or autonomous fixing up of electrical system, 576	Absence of instructions about the electrical system and components	**O**
	Misinformation about the tasks and responsibilities for the maintenance of electrical system	**I**
EF, Malfunctioning of fire extinguishers (when present), 560	Absence of fire extinguishers maintenance	**O**
IAQ, Presence of pollutants released by heat sources, 560	Presence of improper heat sources (e.g. gas stove, kerosene heater) in the patient room	**S**
	Not understanding/not reading the procedure to maintain the heat sources reported in the instructions	**I**
	Lack of knowledge about safety distances from heat sources	**I**
	Inadequate preventive maintenance of heat sources	**O**
	Malfunctioning of air-conditioning filters	**T**
D, Malfunctioning of reserve ventilator, 540	Damages to the batteries of reserve equipment	**T**
	Misinformation about the tasks and responsibilities for the maintenance of reserve equipment (e.g. functionality test)	**I**
D, Malfunctioning of reserve suction machine, 512	Inadequate environmental storage conditions of reserve equipment (e.g. high temperature, humidity)	**S**
EF, Improper maintenance of electrical system, 504	Absence of instructions of electrical system and components	**O**
	Not understanding/not reading the electrical system documentation	**I**
IAQ, Malfunctioning of air-conditioning filters, 504	Not understanding/not attending to the maintenance of air conditioning filters	**I**
EF, Absence of fire extinguishers (when not mandatory), 450	Absence of a tool/method to determine the fire loads in patient house (room)	**O**
	Presence of fire extinguisher(s) at home not mandatory	**O**
D, Presence of old and/or damaged UPS, 448	Absence of UPS maintenance	**O**
	Misinformation about the tasks and responsibilities for the maintenance of UPS	**I**
EF, Improper use of adapters, extension cables, 432	Misinformation about the dangerous effects of the improper use of sockets-plugs, adapters, multiple sockets, extension cables	**I**
	Absence of safety constraints applied to the electrical system components	**S**
	Inadequate number of sockets to connect all the equipment	**S**
D, Incorrect storage of oxygen tanks, 432	Not understanding/not attending to the instructions about the storage of oxygen tanks	**I**
	Absence of instructions about the storage of oxygen tanks	**O**
D, Presence of objects containing liquids above the UPS, 405	Caregiver misinformation about the dangerousness of objects containing liquid above the UPS	**I**
EF, Malfunctioning of emergency lights, 392	Absence of emergency lights maintenance	**O**
IAQ, Improper use of cleanliness products (not spray products), 384	Not understanding/not attending to the instructions about the use of cleanliness products	**I**
EF, Presence of voltages caused by metalwork, 378	Presence of metalwork (e.g. metallic pipes for water and gas) not connected to the ground (earth) or equipotential bonding bar	**S**

3.5.2. Cause analysis and improvement

The causes of critical failures were identified through a brainstorming session during which the team members had to describe the conditions in which each failure potentially may potentially occur answering two guide questions: "what are the causes of each failure?, "Are there any specific conditions that can generate the failure?".

Once the causes were identified, they were classified into four cause groups (or contributory factors) derived from [29, 30, 31].

In the following the cause groups definition are reported, together with few key words used as examples:

3.5.2.1. Organisation (O). The causes classified in this group regarded the process and the procedures that regulate the sequence of activities. Examples: the process of procurement, storage and maintenance (e.g., impossibility to contact the maintenance service provider or the manufacturer).

3.5.2.2. Technology (T). The causes classified in this group regarded the functioning of the technological equipment used by the actors involved in the process. Examples: the functioning of the equipment, power supply, accessories, changes in materials conditions (e.g., malfunctioning of air-conditioning filters).

3.5.2.3. Information (I). The causes classified in this group regarded the level of information and knowledge of the actors involved in the process. Examples: lack of knowledge or misinformation about procedures (e.g.,

lack of knowledge about safety distances to prevent interferences). With reference to [29] Information has been considered better than Communications using systemic approach as this includes personal relationship between stakeholders.

3.5.2.4. Structure (S). This group classified the causes with regard to the environmental requirements and the environmental control systems. Examples: the negative effects of environmental elements (e.g., presence of mobile phones, cordless telephone, walkie-talkie).

Both the identification of risk areas and the assignment of the causes of each failure was propose by (ii) team member and discussed by the whole team. Once the consensus was reached, the team suggested a set of recommendations/improvements to solve the critical failures starting from the causes. This required the consensus of all members too.

4. Results

4.1. Failure analysis

As in Figure 2, the total amount of failures was 86 and the total number of critical failures (i.e. with a RPN > 343) was 22, corresponding to 26% of the total. The sub-process 'Use and maintenance of devices', emerged to be the most vulnerable sub-process due to the amount of potential failures followed by the 'Use of electrical systems and control of fire hazard' sub-process. Focusing on the critical failures, the sub-process 'Use of electrical systems and control of fire hazard' had the major number of critical failures.

Table 1 reports the critical failures and their risk areas, sorted out by descending RPN value, detailed with their causes and respective cause groups.

Then the cause groups of critical failures were related to their risk areas using a matrix (Figure 3) where each element (named $a_{i,j;}$ i: [D, EF, IAQ], belonging to cause-group and j: [O, T, I, S]) represents the number of causes in the risk area.

The final row of the matrix contains the total amount of causes in each cause-group. This representation reveals that the most significant contributory factor was I (Information), followed by O (Organisation), S (Structure) and T (Technology). Moreover, the same considerations derive from the raw of the risk areas 'Device' and 'Indoor air quality', whereas the risk area 'Electrical system and fire hazard', is affected significantly by the contributory O (Organization) cause group.

4.2. Addressing corrective actions

The cause analysis revealed that the maintenance was particularly important for equipment (e.g. UPS), but also for electrical system components and air-conditioning filters. Thus, the process of maintenance of the device and the system by means of different modelling techniques was analysed [3]. This aspect clarified the responsibilities and the sequence of activities to properly address the correction actions.

The corrective actions (solutions) were designed into the cause groups. Using this systemic approach, the solutions were able to address multiple causes (Figure 4) reinforcing barriers.

The Organisational (O) causes were specifically addressed with the introduction of new procedures. It was delivered a new technical report to be used during the home assessment in the form of a checklist with strict deadlines, and new time based operative procedures. The checklist aimed at investigating the presence/absence of technical documents related to the equipment (e.g., manuals, maintenance diary), technical aspect of the electrical system (e.g., the presence of protective device components, quality certifications), presence/absence of fire extinguishers, presence of sources of interference (e.g. cell/cordless phones, heat sources). A second facility introduced to address risk was the implementation of a model to estimate the fire load in the patient house according to technical standards (e.g. NFPA - National Fire Protection Association). Data on most dangerous goods are collected in a database (spreadsheet) to have the personalized equivalent fire load to check the compliance with required limits. This introduced the need of a storehouse reorganizations to reduce potential risk of fire.

The Technological causes (T) were addressed with solutions aimed at encouraging the safe use of the equipment (i.e. preventive maintenance and training).

The team suggested addressing the Information (I) causes mainly by verifying the presence of equipment instructions, providing new simple written and verbal instructions, posting signs and labels. In particular, it was suggested to provide simple instructions (e.g. leaflets) to inform the caregivers about fire emergency procedures, cleaning practices, basic maintenance of equipment, electrical system components, fire extinguishers and air-conditioning accessories. The instructions had to improve the ability to address dangerous situations related to the malfunctioning of the equipment and the electrical system, inform on the safe use of plugs and multi-sockets and instruct on how to receive technical assistance. To cope with language barriers, it was suggested to support written instructions with conventional native languages, and/or pictograms.

Finally, the Structure causes (S) were addressed verifying the presence of structural problems in the patient room and promoting the introduction of preventive maintenance for non-medical devices (e.g. UPS, emergency lights, and fire extinguishers).

5. Discussion

A short comment is necessary before the discussion of the obtained results in this study. Generally speaking, prospective and proactive risk assessment methodologies, like FMECA, have been designed to anticipate or prevent harms rather than relying corrective actions after an accident have occurred [14, 21] and to generate guidelines and countermeasures to be implemented in a system [21, 24].

As the real value of proactive system analysis is to reveal system inadequacies [33], this research does not practically contribute with quantitative measures of the effectiveness of the proposed improvements.

RISK AREA	CAUSE-GROUP			
	Organization- O	Technology - T	Information- I	Structure -S
Device - D	3	1	7	3
Electrical System and Fire hazard - EF	7	0	5	3
Indoor Air Quality - IAQ	1	1	5	2
Tot.	11	2	17	8

Figure 3. Number of causes of critical failures reported in risk area-cause-group matrix.

SOLUTIONS	CAUSE-GROUP			
	Organization	Technology	Information	Structure
Technical Report	■		■	■
Fire Load calculator	■			
Maintenance Calendar	■		■	
Signposting *(correct use of devices ,prohibition)*			■	
Instructions *(maintenance, storage, cleaning)*			■	
Operative Procedure *(maintenance of electrical system and devices)*	■		■	
List of emergency numbers			■	
Preventive maintenance *(of non-medical devices)*	■	■		■
Training *(maintenance, cleaning, hazards)*	■	■	■	

Figure 4. Categories of solutions to address contributory factors (The adopted solutions are coloured in grey).

The reinforcement of barriers (O, T, I, S) recognised to be the foundations of the system, according to Reason's theory, reduces the generation of fails that can led to real patient arms due to system inadequacies.

However, such proactive and systemic study prodiced some practical recommendations and quality tools to be disseminated among the stakeholders [4].

Particularly regarding the HV setting, this paper aims to improve the quality of this new healthcare service. The patient's home is an environment that involves additional, specific risks compared to the hospital environment [29]. The home electrical system is not specifically designed to support a continuous, safe operating of medical equipment. The simultaneous use of therapeutic oxygen greatly increases the risk of fire. The air conditioning systems should ensure an appropriate temperature and air quality for the patients in mechanical ventilation.

This context is complicated by the conditions of patients affected by severe disabling pathologies that prevent them to react quickly against dangers and assisted by unqualified personnel, as a family member, in charge to manage alarms or dangerous situations.

The very limited availability of information about the risks and the absence of reliable incident reports related to home care ventilation encouraged the use of a proactive method typically used in the industrial sector, FMECA, with the aim to predict failures before they cause harm to patients [29]. In addition, this study proposes an extension of the typical FMECA methodology using a specific threshold and a deep analysis of the causes using the Reason's latent failure theory [29, 31]. The adopted threshold allowed to set a critical value to discriminate the failure severity, in analogy to other risk assessment procedures (i.e. HACCP). The Reason's latent failure theory was useful to counteract the predisposing factors to failure by means of specific solutions that are able to build barriers into the domains of the healthcare system (i.e. Organisation, Technology, Information and Structure) [29].

The results of this approach revealed that the most failures are caused by Information (I) and Organization (O) contributory factors. Therefore, it will be of value in the design of home care service, to strictly define the sequence [3] of the activities of the people (clinical practitioners, technicians, care givers, etc.) involved in the process and providing them in advance information and knowledge about how to carry out specific tasks. In addition, when the service need to be activated specific procedures based on documents, checklists and evaluation tools can be used to support a preventive assessment of the patient's home environment in order to plan the continuous improvement process. The new procedures may become part of the daily activities of home care service. This operative strategy is in line with many international guidelines that suggest analysing the home environment before the patient transfer, to arrange in advance opportune modifications of the physical environment and introduce specific safety procedures [39]. The documents are drawn up as simple leaflets and guidelines booklets to facilitate their easy and intuitive use by patients and caregivers.

At end of this study, such materials were delivered to the personnel of the ASL NA1 and to people, including family members, involved in the home care service, which appreciated it the daily use. Moreover, the results of this study were presented as practice oriented solutions in some national workshops organized by the National Research Council (CNR) and the Italian Government Agency for the Insurance against Work-related Injuries (INAIL) and in a workshop on “Human factors for social innovation” organised in the framework of EXPO Milan 2015.

In addition to these outcomes, a second achievement of this paper is the proposal of an innovative failure analysis methodology applied to a new intensive health service provided outside standard medical setting. Indeed, the use of critical medical equipment outside clinical setting, as in the case of home ventilation, is rapidly increasing and new challenges must be faced. As first approach, healthcare services and technology providers are retrofitting and adopting methodologies derived from traditional hospital environment [39] and similar contexts [10]. Altough, this can be not optimal to solve new unique and complex system configuration [2], including risk analysis, in innovative care.

Thus, the adopted systemic approach is oriented towards the introduction of innovative quality tools in the in HV process [3, 7, 37, 38] and is generally applicable to other healthcare processes.

6. Limitations of the study

A first limitation of the study is that the FMECA multidisciplinary team did not include any patient or family members, however it included members with a deep knowledge of home care service and management of medical equipment so, the relevant experiences of people daily involved in the home care were anyway considered. A second limitation regards the absence of feedback about the corrective actions and the

impossibility to use an incident report, this because of a new procedures was established at local healthcare unit that required the hospitalisation of the patients in serious conditions. Therefore, the number of assisted patients decreased for a robust feedback evaluation.

The direction for future research regards the implementation of the study results in operative settings to evaluate, by means of objective measures, the benefits of these improvements [10, 34].

7. Conclusion

The home care treatment of patients affected by chronic respiratory failures implies new risks related to the use of medical and non-medical technologies at home. These failures are not fully addressed by current standards and guidelines. In this paper a specific risk analysis was presented. The analysis has been carried out by using the FMECA methodology enriched with the identification of critical failures and an additional analysis of failures causes. The extended FMECA methodology was useful to increase the level of details of the risk analysis and it provided a thorough knowledge of the most critical areas where technical risks may originate. Furthermore, the extended analysis supported the definition of proper countermeasures and actions designed to assess changes by means of a systemic approach that guarantees acceptable level of safety for patients and care givers when life support medical equipment are used.

Declarations

Author contribution statement

F. Clemente: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

G. Faiella: Conceived and designed the experiments; Performed the experiments; Facilitated FMECA, Analyzed and interpreted the data; Wrote the paper.

G. Rutoli: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data.

P. Bifulco: Analyzed and interpreted the data.

M. Romano: Analyzed and interpreted the data; Contributed materials, analysis tools or data; Wrote the paper.

M. Cesarelli: Conceived and designed the experiments.

Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Competing interest statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

Acknowledgements

The authors would like to thank all the team members for their help and contributions in the analysis and the experts that reviewed the results.

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