ORIGINAL RESEARCH

HEALTH FAILURE MODE AND EFFECTS ANALYSIS APPLIED TO HOME MECHANICAL VENTILATION

Ondřej Gajdoš, Martin Rožánek, Vojtěch Kamenský, Ivana Kubátová

Department of Biomedical Technology, Faculty of Biomedical Engineering,
Czech Technical University in Prague, Kladno, Czech Republic

Abstract

To use home mechanical ventilation, it is necessary to choose the right target group that can benefit from moving to home care. Moving a patient to home care with home mechanical ventilation involves a number of risks. The aim of this study was to use Health Failure Mode and Effects Analysis (HFMEA) to analyse health risks at a time when a patient is just preparing to move to home care, and a nursing plan is being drawn up. HFMEA was used to analyse health risks. The expert team divided the process of nursing care into 7 parts with other own subprocess, which are 18 in total. Altogether, 41 risks were identified, of which 14 failures were analysed after HFMEA application, potential causes were defined, and their follow-up proposed. According to the results of the method used and the analysis of individual risks, it is necessary to focus on detailed setting of the nursing plan with thorough education of informal caregivers who play an important role in it. The education should be regularly repeated and the check of care itself should be supported by created checklists to confirm the individual steps.

Keywords

Health Failure Mode and Effects Analysis, HFMEA, home mechanical ventilation, risk analysis

Background

Mechanical ventilation is used when spontaneous ventilation is inadequate, and hypercapnia or hypoxemia occurs. Despite considerable developments in mechanical ventilation, patient mortality remains relatively high, particularly in Acute Respiratory Distress Syndrome (ARDS), etc. [1, 2]. It is the ventilation setup and management that is potentially associated with a number of risks that, even in the critical care setting, may be related to poor ventilation setup or poor monitoring [3]. Automated ventilation modes are a modern trend that minimizes ventilator error and can be a good alternative for home mechanical ventilation where a significant portion of the potential risks are transferred to an informal caregiver [4].

Moving a patient to home care with home mechanical ventilation (HMV) involves a number of risks. An overview of the risks was obtained based on an analysis of studies [5–16]. These risks can be divided into risks directly related to the patient's health, informal caregiver, technical equipment and nursing plan settings. Risks based on the nature of the disease affect the subsequent course of the disease. It is necessary to take these risks into account, although it is often not possible to completely avoid them [14]. The risks associated with informal caregivers are often of a psychosocial nature. The risk associated with frustration of the care providers can then reduce the effectiveness of the therapy [11]. Other mentioned risks are related to technical security, which in case of its failure can endanger life in some cases [5–9]. Setting up a nursing plan also entails certain risks that must be taken into account. An inherent risk is also a human factor, as almost all HMV users depend to a greater or lesser extent on the assistance of another person [8–10].

Risks are influenced by various factors, such as daily use of the lung ventilator, general health, nature of diagnosis, patient's age, and caregiver's experience. Risk analysis methods in the field of healthcare aim to provide prevention and eventual resolution of conditions causing adverse reactions that may endanger the patient's health or cause death [17].

One of the frequently used methods for risk assessment is Failure Mode and Effect Analysis (FMEA). This method was developed by National Aeronautics and Space Administration (NASA) and over the years has further expanded into various sectors. It has been used in the healthcare sector since 1999 [17]. It was also used to assess the technical risks of HMV [18]. However, a more suitable Health Failure Mode and Effects Analysis (HFMEA) was chosen to assess health risks, which was specifically designed for the health sector by

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

National Center for Patient Safety (NCPS) [19]. In 2003, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) selected HFMEA as the official standard for the analysis of high-risk processes in healthcare [17].

The aim of this study is to use HFMEA to analyse health risks at a time when a patient is just preparing to move to home care, and a nursing plan is being drawn up.

Methods

HFMEA is a prospective analysis that consists of 5 basic steps and combines elements of several different methods. This analysis should also include the introduction of measures and their subsequent evaluation [20].

HFMEA topic definition

For the area of HMV itself and its nursing plan, HFMEA has been applied by its nature. Nursing care is an integral part of the therapy of people with HMV and potential risks can be expected. A nursing plan is drawn up within the framework of nursing care, which has the general principles for most patients, but is prepared individually for each HMV patient. The analysis was performed from the perspective of the patient's health risks. Patients may be expected to worsen their health based on the course of the disease, but the risks involved are often beyond our control. The analysis is therefore aimed at situations that are unexpected and not directly related to the diagnosis.

Team of experts

The team of experts consisted of the head of follow-up intensive care and long-term intensive nursing care of the Motol University Hospital and a nurse from the same department. Among other things, the nurse represented an informal caregiver who should be included in the entire risk analysis. Their role has a great weight in deciding on the severity and probability of potential risks. These measures can thus be tailored to specific members, both patients and caregivers, participating in the entire HMV therapy delivery process. Another member of the Motol University Hospital team was a professor at the Department of Anaesthesiology and Resuscitation. Furthermore, coordinator of the civic association “Dech života”, who also has considerable practical experience in the field of nursing care, was a member of the team as well.

Graphical representation of the process

In the case of this analysis, the graphical representation was made in such a way that it could be used by most people using HMV. The nursing plan may vary from patient to patient, as well as the subsequent graphical representation of the home care process. For this reason, the graphic design was made to decide whether the management of the invasive inputs is part of the nursing plan or not.

Healthcare Failure Mode Effects and Analysis

It was necessary to define severity rate of HFMEA by the expert team according to the impact on patients. Individual severity values are described in Table 1. Furthermore, probability values have been defined by the expert team based on the rate of potential occurrence of each failure. These values are defined in Table 2. Based on the Hazard Scoring Matrix, which was again compiled by the team of experts and shown in Table 3, the Hazard Score was determined. This value is calculated by multiplying the severity value by the probability value. The critical risk threshold is set at 8 based on the method procedure [20].

Table 1: Defining the severity rating of HFMEA [20].

Severity	Description	Classification
minor	without health problems, health will not deteriorate	1
moderate	temporary health problems that do not require professional medical intervention	2
major	health problems that may require professional medical intervention and may lead to long-term deterioration	3
catastrophic	difficulties leading to permanent consequences or risk of death	4

The decision tree (Fig. 1) is used to determine if a further action is required for a given failure. Thus, the HFMEA decision tree is a process whose individual steps determine how to resolve each failure. The decision tree serves as a tool to identify those areas that the expert team may consider less critical, or where failure is readily detectable, or where effective control measures have already been implemented. Based on the results from the decision tree, the potential causes of the selected failures were determined [20].

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

Table 2: Defining the probability rate of HFMEA [20].

Probability	Description	Classification
remote	in most cases it can occur within 5–30 years	1
uncommon	in most cases it can occur within 2–5 years	2
occasional	in most cases it can occur 1–2 times a year	3
frequent	in most cases it can occur several times a year	4

Table 3: Hazard scoring matrix.

probability	frequent	4	8	12	16
	occasional	3	6	9	12
	uncommon	2	4	6	8
	remote	1	2	3	4
		minor	moderate	major	catastrophic
	severity				

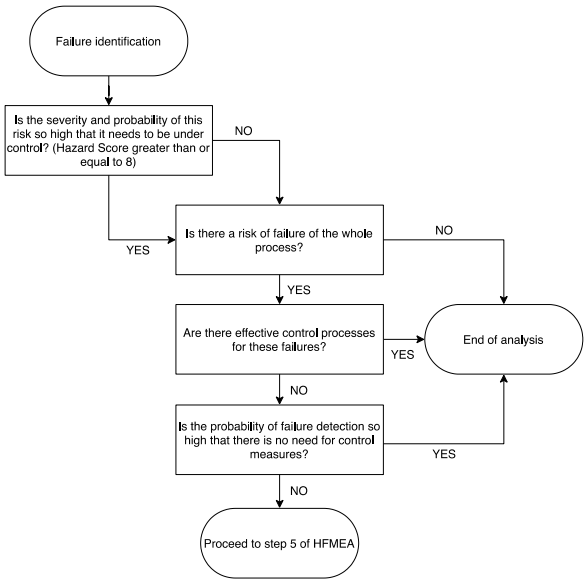

Fig. 1: Decision tree HFMEA [20].

Identification of actions and results

For those failures that have emerged as the most risky, further procedures should be developed to eliminate or reduce the chance of such events occurring.

Results

The expert team divided the process of nursing care into 7 parts with other own subprocess, which are 18 in total. Its graphical representation is shown in Fig. 2.

The risk analysis was performed to identify possible failures, that could present some health risks. A total of 41 potential risks were identified by a team of experts. Hazard Score was determined after assigning severity and probability values. Based on this value, 6 critical failures were identified. If the risk value was evaluated as 8 or more, it was not necessary to address these failures as to whether they represent a threat to the process as a whole. The risk of failure of the whole process in this analysis is the inability to continue HMV.

Following the HFMEA decision tree procedure, the next procedure for each failure was selected. Based on the decision tree, 14 failures were evaluated for which potential causes had to be defined and their follow-up addressed. Once the potential causes were identified, the severity and probability rates were again determined in the same way, the risk matrix and the HFMEA decision tree were used. The identification of actions and results for the 14 failures analysed are given in the following text (see in Supplementary materials).

Failure 2A

The first step was to check the tracheostomy cuff. In this step, cuff pressure failures have been identified that may be either excessive or insufficient. Excessive pressure in this case is a more serious failure due to the compression of the trachea walls and the potential for the cuff rupture. The expert team identified two possible causes of this failure. The first reason was insufficient experience of the informal caregiver, the second was insufficient equipment. The inexperience of the informal caregiver can be reduced by regularly checking the level of education of informal caregiver. This check could be performed by a formal nurse from a home care agency. Reduction of the risk associated with the impossibility of measuring the cuff pressure would be possible when a suitable pressure gauge is obtained.

Failure 2C

Another failure in the first step was insufficient disinfection of the cannula during its cleaning. Here, the cause has already been identified in the form of a human factor, where the caregiver does not know how to properly disinfect or does not do it properly due to negligence. A partial solution may be to provide information on the subject in the form of a guideline or training.

Failure 2D

Another failure is the possibility of decannulating or shifting the tracheostomy cannula to the wrong position. The first cause is the human factor, which often cannot be completely eliminated. However, by using the correct, already mentioned, regular control of patient education, these risks can be partially minimized. If inappropriate equipment is the cause, it is possible to reduce the possibility of failure through a request for a new type of equipment.

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

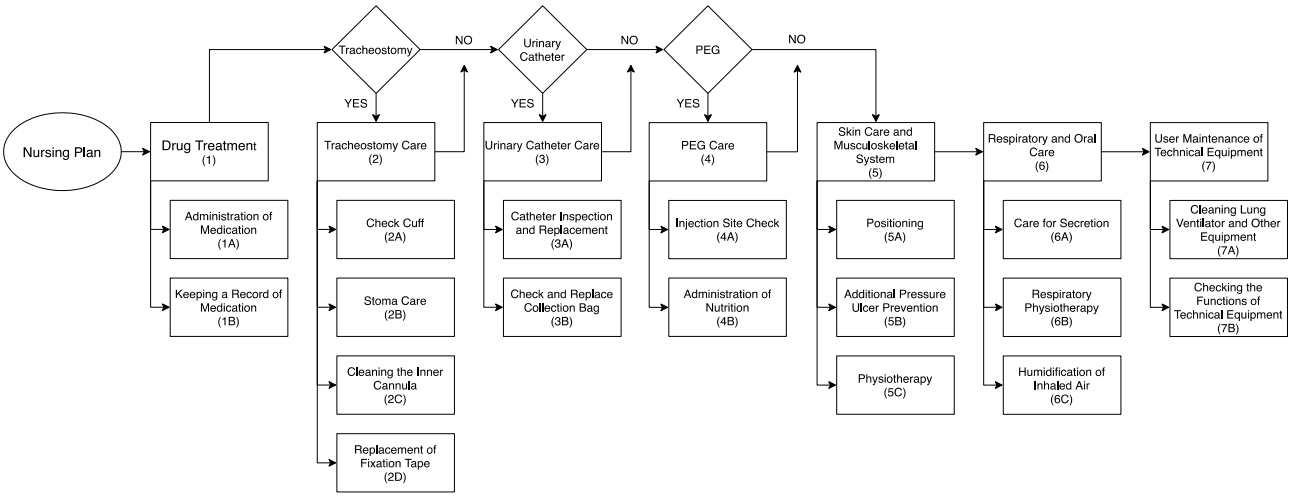

Fig. 2: Nursing plan process.

Failure 3A

It was also necessary to address the failure associated with catheter control and replacement. One of the causes of failure during catheter inspection and replacement is failure to observe hygienic principles. This is primarily due to the human factor. It can be eliminated by rigorous staff control, by setting internal regulations or by training staff on the importance of the issue. Reducing the probability of failure of this risk is also associated with the education of informal caregivers after the first 6-12 months.

Failure 4A

Failures associated with inadequate injection site control in percutaneous endoscopic gastrostomy (PEG) care usually consist of the cause of non-compliance with the hygiene rules (4A1) and failure to recognize the infection (4A2). Failure to recognize the infection may then be related to either missing or insufficient education and may be due to insufficient attention. This risk can be prevented, in particular, by allocating HMV tasks between formal and informal caregivers and by setting up a schedule for the treatment plan. Non-observance of hygienic principles requires that informal caregivers be thoroughly educated to minimize this risk. For example, guidelines or training on the importance of the problem and how to deal with the situation can help.

Failure 5A

In the area of skin care and musculoskeletal system, the risk of patient positioning failure, which consists of several partial risks, was analysed. These are insufficient positioning frequency, patient fall during positioning and decannulation of the tracheostomy cannula. Insufficient positioning frequency may be due to time consumption or neglect of the caregiver. Here, it is clearly necessary to thoroughly train the informal caregiver again, further it is possible to partially eliminate this risk by purchasing an anti-decubitus mattress or adjustable bed. Another recommendation to eliminate this risk is to set up a regular evaluation of pressure ulcers assessment according to the standard scale for assessing pressure ulcers. The risk of falling of the patient during positioning may be associated with insufficient bed security or caregiver exhaustion. This risk can be reduced by proper control of the treatment plan, as well as by consistent communication between formal and informal caregiver of the patient. It is also possible to at least partially eliminate this risk by purchasing a hoist or a more suitable bed. Another risk associated with mishandling in positioning is the decannulation of the tracheostomy cannula, which may be due to inattention of the caregiver or the selection of an unsuitable cannula type. This risk can be partially eliminated by thorough training and consultation with a physician on the suitability of the cannula size.

Failure 6A

In the care of the respiratory tract and the oral cavity, sterility of the suction device or irritation of the trachea by the suction device may be impaired when taking care of secretion. The sterilization of the suction device can be given from the manufacturer. Indeed, the risk from the manufacturer's point of view should be minimal given the surveillance of the medical device market in the Czech Republic. Therefore, the highest risk associated with this failure is again related to the human factor. This can be eliminated by thorough training, communication between formal and informal caregivers and regular education. Trachea irritation can be caused by several ways. These are uncomfortable suction, inappropriate equipment and excessive intensity of the suction device. All these risks relate to the suitability of the equipment, the modification or the malfunction of the suction device. If necessary, this risk can be reduced by training and consultation with the technician of the company from which the suction device is purchased. Furthermore, it is necessary to

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

thoroughly communicate with the patient in order to avoid any adverse events.

Failure 6D

The risk associated with air humidification in respiratory and oral care is mainly related to the accumulation of water in the circuit. This may in turn lead to a higher bacterial fraction going to the inspiratory filter, circuit malfunction and emerging alarms on the lung ventilator. This risk can arise both from insufficient education of the informal caregiver and from insufficient control of accessories. This can be partially eliminated by regular breathing circuit checks, which should be part of the nursing plan.

Failure 7A

The last step in the nursing plan is the user maintenance of the equipment, in which the cleaning of the lung ventilator and other equipment may be another source of possible failures. This can be linked to two factors, the lack of cleaning frequency or lack of care. Both of these factors can be caused by a human failure, mainly due to poor or inconsistent education and poorly set up activities among individuals involved in the treatment of the patient. Again, these risks can be eliminated primarily by thorough training and effective setting of the nursing plan.

Discussion

The risk analysis shows that it is necessary to set up a detailed nursing plan and focus on the consistent education of informal caregivers, including their support through checklists and regular check-ups.

The transition of a patient with mechanical ventilation to the home is a current topic in the world. In all developed countries this issue is discussed and more or less supported [21]. We used a HFMEA methodology to analyse the transition to home ventilation and establish guidelines to mitigate the inherent risks.

The Czech Republic is currently in a state which is below the European average in the number of people that use HMV [21]. In order for the Czech Republic to be able to cope with other European countries, active cooperation is needed between all stakeholders involved in HMV issues. The ideal situation, when all participating subjects will be fully satisfied with the state of the discussed issue, can be achieved only by clearly presenting objective results of the overall benefit of this method.

Given the nature of HMV itself, the incidence of potential risks arising from the transfer of the patient and the provision of this method of treatment is also an indisputable factor. These risks can be assessed from different perspectives. First, the perspective of the patient himself. The associated risks are characterized by a close association with the person's health status and can be considered the most serious. There may be risks arising from the diagnosis itself and the subsequent course of the disease [14]. Another possible group is the risks associated with technical equipment and its potential failure [9]. The severity of these risks increases as the patient is more dependent on specific equipment. Equipment failure, which for one patient only means a reduction in standard comfort, can have fatal consequences for another patient [7]. A number of risks also arise not only from the equipment failure, but also from insufficient quality or inadequate quantity [22].

Another possible perspective is the risks of informal carers, most often family members. These persons in most cases become a provider of continuous nursing care of the patient at home. This situation is undoubtedly very demanding and can have negative psychosocial effects on all parties involved and consequently lead to a reduction in the effectiveness of the care provided, thus affecting the patient himself [11].

To ensure an appropriate process for the entire treatment, it is necessary to try to identify the widest possible spectrum of potential risks and to develop measures that reduce the chance of these failures. A number of risk analyses are currently being used worldwide to improve processes in various areas, including the health sector [17].

In the classical FMEA analysis, the main problem compared to HFMEA is the risk assessment for very serious and at the same time unlikely failures. These situations can be fatal to the patient. Due to their low probability of occurrence, they could be assessed as less risky by FMEA and failure would not be addressed as a priority. Therefore, classical FMEA is not appropriate for the identification of health risks, as confirmed by G. Faiella [17]. The above-mentioned fact was confirmed in the study, for example, in the tracheostomy cuff failure. Excessive pressure can cause damage and result in rupture, which would be a very serious situation on the one hand, but very unlikely on the other. So, if measures were taken, they would not pay attention to this failure.

A common cause of a failure to endanger the patient's health may be the human factor. It may be insufficient education of informal nurses or decrease of quality of provided care due to mental and physical exhaustion. It is therefore necessary to ensure sufficient controls and education as described by A.K. Simonds [23]. The lack of suitable equipment is another common risk that threatens the smooth running of the entire home care process. This is confirmed by R. Gershonem et al [22].

The nursing plan is not the only area that should be evaluated in terms of risks when introducing HMV. The possibility to cover all the risks from all of the aforementioned HMV-related perspectives is to create a model that combines other complementary methods. The use of a combination of several analyses was discussed by Shaqdan [24].

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

The risk assessment model for HMV could be the HFMEA for health risk assessment addressed in this study, the FMEA for technical risks and the retrospective Root Cause Analysis (RCA) method to serve as a retrospective assessment of the root causes of patient rehospitalization. The Fault Tree Analysis (FTA) based on the results of the HFMEA and FMEA methods, would be used to deepen the analysis of high-risk failures. This model was introduced by the authors in 2018 [25].

Conclusions

In the study, the HMV nursing plan was evaluated in terms of risks using HFMEA. Altogether, 41 risks were identified, of which 14 failures were analysed after HFMEA application, potential causes were defined, and their follow-up proposed. According to the results of the method used and the analysis of individual risks, it is necessary to focus on detailed setting of the nursing plan with thorough education of informal nurses who play an important role in it. The education should be regularly repeated and the check of care itself should be supported by created checklists to check the individual steps.

Acknowledgement

Authors affiliated to the Department of Biomedical technology, Faculty of Biomedical Engineering, Czech Technical University in Prague were supported by the internal student grant No. SGS19/087/OHK5/1T/17 and No. SGS20/086/OHK5/1T/17. Authors acknowledge the service technicians for providing the data and information, as well as Martin Chlouba for their work on data processing.

Supplementary materials

Evaluation of failure in the process of nursing plan

Risk analysis									Identification of actions and results	
Step in the process	Failure	Potential cause	Hazard score	Risk of Process Failure?	Effective review process?	Sufficient detect-ability?	Continue?	Further action	Description of the action	Evaluation of results
Cuff Control (2A)	Excessive cuff pressure (2A1)	Inexperience of caregivers (2A1a)	3	Yes	No	No	Yes	Control	Regular check of sufficient level of education	Checking the education of informal caregivers after the first 6 and 12 months
		Insufficient equipment – manometer (2A1b)	12	→	No	No	Yes	Eliminate	Submitting an application for a manometer to be provided by an insurance company	Determina-tion of the insurance company on the application results
Internal Cannula Cleaning (2C)	Insufficient disinfecttion (2C2)	Human Factor (2C2a)	8	→	No	No	Yes	Control	Guidelines, training on the importance of the issue	Checking the education of informal caregivers after the first 6 and 12 months

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

Fixation Tape Replace-ment (2D)	Decannu-lation or displace-ment of the tracheo-stomy cannula (2D2)	Human Factor (2D2a)	8	→	No	No	Yes	Control	Regular check of sufficient level of education	Checking the education of informal caregivers after the first 6 and 12 months
		Unsuitable cannula / tape type (2D2b)	6	Yes	No	No	Yes	Eliminate	Apply for a new kind of equipment	Medical opinion
Catheter Inspection and Replace-ment (3A)	Failure to observe hygienic principles (3A1)	Human Factor (3A1a)	8	→	No	No	Yes	Control	Guidelines, training on the importance of the issue	Checking the education of informal caregivers after the first 6 and 12 months
Injection site control (4A)	Failure to observe hygienic principles (4A1)	Human Factor (4A1a)	8	→	No	No	Yes	Control	Guidelines, training on the importance of the issue	Checking the education of informal caregivers after the first 6 and 12 months
	Failure to detect infection (4A2)	Insufficient Education (4A2a)	4	Yes	Yes	-	No			
		Lack of attention (4A2b)	8	→	No	No	Yes	Control	Appropriate allocation of tasks between formal and informal caregivers, cooperation of both members	Check the schedule of the treatment plan
Psitioning (5A)	Frequency Insuffi-ciency (5A1)	Time Consuming and Negligence (5A1a)	9	→	No	No	Yes	Eliminate	Apply for an anti-decubitus mattress	Regularly, according to the scale for assessing pressure ulcers evaluation
	Patient drop during handling (5A3)	Insufficient bed security (5A3a)	9	→	No	No	Yes	Eliminate	Provide suitable equipment, bed	-

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

		Caregiver exhaustion (5A3b)	9	→	No	No	Yes	Control	Appropriate allocation of tasks between formal and informal caregivers, cooperation of both members	Check the schedule of the treatment plan
	Tracheo-stomy Cannula Decannu-lation (5A6)	Human Factor (5A6a)	3	Yes	No	No	Yes	Accept	-	-
		Incorrect Cannula Type (5A6b)	6	Yes	No	No	Yes	Eliminate	Ask for more suitable equipment after consulting a doctor	Medical opinion
Secretion Care (6A)	Non-sterile aspirator (6A2)	Human Factor (6A2a)	6	Yes	No	No	Yes	Control	Guidelines, training on the importance of the issue	Checking the education of informal caregivers after the first 6 and 12 months
	Trachea irritation by aspirator (6A3)	Rough Suction (6A3a)	6	Yes	No	Yes	No			
		Inappropriate Equipment (6A3b)	3	Yes	No	No	Yes	Eliminate	Apply for a new kind of equipment	Subjective evaluation by the patient
		Excessive suction devices intensity (6A3c)	6	Yes	No	No	Yes	Control	Adjusting the suction device settings	Subjective evaluation by the patient
Inhalation air humidi-fication (6D)	Water Accumu-lation in Circuit (6D1)	Poor accessory check (6D1a)	3	Yes	No	No	Yes	Control	Establish a regular circuit check	Checklist with task layout
		Insufficient Education (6D1b)	3	Yes	Yes	-	No			

Lekar a technika – Clinician and Technology 2020, vol. 50(3), pp. 85–94, DOI: 10.14311/CTJ.2020.3.02
ISSN 0301-5491 (Print), ISSN 2336-5552 (Online)

Ventilator and Other Equipment Cleaning (7A)	Frequency Insuffi-ciency (7A1)	Insufficient Education (7A1a)	3	Yes	Yes	-	No			
		Unclear allocation of tasks among caregivers (7A1b)	6	Yes	No	No	Yes	Control	Regular checks of the responsi-bilities of the nursing plan	Checklist of tasks
	Insuffi-cient care (7A2)	Human Factor (7A2a)	6	Yes	No	No	Yes	Control	Guidelines, training on the importance of the issue	Checking the education of informal caregivers after the first 6 and 12 months

References

[1] Bellani G, Laffey JG, Pham T, Fan E, Brochard L, Esteban A, et al. Epidemiology, patterns of care, and mortality for patients with acute respiratory distress syndrome in intensive care units in 50 countries. J Am Med Assoc. 2016;315(8):788–800. DOI: 10.1001/jama.2016.0291

[2] Wang CY, Calfee CS, Paul DW, Janz DR, May AK, Zhuo H, et al. One-year mortality and predictors of death among hospital survivors of acute respiratory distress syndrome. Intensive Care Med. 2014;40(3):388–96. DOI: 10.1007/s00134-013-3186-3

[3] Amato MBP, Meade MO, Slutsky AS, Brochard L, Costa ELV, Schoenfeld DA, et al. Driving pressure and survival in the acute respiratory distress syndrome. N Engl J Med. 2014;372(8):747–55. DOI: 10.1056/NEJMsa1410639

[4] Branson RD. Automation of Mechanical Ventilation. Crit Care Clin. 2018;34(3):383–94. DOI: 10.1016/j.ccc.2018.03.012

[5] Piper A. Discharge planning and management for patients with chronic respiratory failure using home mechanical ventilation. 2010;6(4):323–33. DOI: 10.1183/18106838.0604.322

[6] Tuggey JM, Delmastro M, Elliott MW. The effect of mouth leak and humidification during nasal non-invasive ventilation. Respir Med. 2007;1874–9. DOI: 10.1016/j.rmed.2007.05.005

[7] Lechtzin N, Weiner CM, Clawson L. A Fatal Complication of Noninvasive Ventilation. N Engl J Med. 2001;344(7):533. DOI: 10.1056/NEJM200102153440718

[8] Srinivasan S, Doty SM, White TR, Segura VH, Jansen MT, Ward SLD, et al. Frequency, Causes, and Outcome of Home Ventilator Failure Chest. 1998;114(5):1363–7. DOI: 10.1378/chest.114.5.1363

[9] Chatwin M, Heather S, Hanak A, Polkey MI, Simonds AK. Analysis of home support and ventilator malfunction in 1,211 ventilator-dependent patients. Eur Respir J. 2010;35(2):310–6. DOI: 10.1183/09031936.00073409

[10] González-Moro JMR, Vivero GA, Díez JDM, Martín SL, Sánchez C, Alonso JLI, et al. Bacterial Colonization and Home Mechanical Ventilation: Prevalence and Risk Factors. Arch Bronconeumol. 2004;40(9):392–6. DOI: 10.1016/S1579-2129(06)60341-8

[11] Kesteren RG van, Velthuis B, Leyden LW van. Psychosocial Problems Arising from Home Ventilation. Am J Phys Med Rehabil. 2001;6(80). DOI: 10.1097/00002060-200106000-00011

[12] Gajic O, Frutos-Vivar F, Esteban A, Hubmayr RD, Anzueto A. Ventilator settings as a risk factor for acute respiratory distress syndrome in mechanically ventilated patients Risk. Intensive Care Med. 2005;5(31):922–6. DOI: 10.1007/s00134-005-2625-1

[13] Reiter K, Pernath N, Pagel P, Hiedi S, Hoffmann F, Schoen C, et al. Risk Factors for Morbidity and Mortality in Pediatric Home Mechanical Ventilation. Clin Pediatr (Phila). 2011; 50(3):237–43. DOI: 10.1177/0009922810388508

[14] Alharbi HHO, Roy SS, Astird OA. Predictors of 1-Year Mortality inpatients with Non-invasive Home Mechanical Ventilation. Int J Sci Eng Res. 2016;7(8):885–9.

[15] Stieglitz S, George S, Priegnitz C, Hagmeyer L, Randerath W. Frequency and management of respiratory incidents in invasive home ventilation. Chron Respir Dis. 2013;3(10):135–40. DOI: 10.1177/1479972313493099

[16] Edwards JD, Kun SS, Keens T. Outcomes and Causes of Death in Children on Home Mechanical Ventilation via Tracheostomy: An Institutional and Literature Review. J Pediatr. 2010;6(157):955–9. DOI: 10.1016/j.jpeds.2010.06.012

[17] Faiella G, Clemente F, Romano M, Bifulco P, Cesarelli M. FMECA and HFMEA of indoor air quality management in home mechanical ventilation. 2014 IEEE Int Symp Med Meas Appl. 2014; 1–. DOI: 10.1109/MeMeA.2014.6860116

[18] Gajdoš O, Kamenský V, Erfanyuková A, Rožánek M. Failure mode and effects analysis application on a home mechanical ventilation. 2019 7th E-Health Bioeng Conf EHB 2019. 2019; 31–4. DOI: 10.1109/EHB47216.2019.8970054

[19] Rah J-E, Manger RP, Yock AD, Kim G-Y. A comparison of two prospective risk analysis methods: Traditional FMEA and a modified healthcare FMEA. Med Phys. 2016 Nov;43(12): 6347–53. DOI: 10.1118/1.4966129

[20] Vélez-Díaz-Pallarés M, Delgado-Silveira E, Carretero-Accame ME, Bermejo-Vicedo T. Using Healthcare Failure Mode and Effect Analysis to reduce medication errors in the process of drug prescription, validation and dispensing in hospitalised patients. BMJ Qual Saf. 2013 Jan;22(1):42–52. DOI: 10.1136/bmjqs-2012-000983

[21] Lloyd-Owen SJ, Donaldson GC, Ambrosino N, Escarabill J, Farre R, Fauroux B, et al. Patterns of home mechanical ventilation use in Europe: results from the Eurovent survey. Eur Respir J. 2005 Jun;25(6):1025-31. DOI: 10.1183/09031936.05.00066704

[22] Gershon RR, Pogorzelska M, Qureshi KA, Stone PW, Canton AN, Samar SM, et al. Home Health Care Patients and Safety Hazards in the Home: Preliminary Findings. In: Advances in Patient Safety: New Directions and Alternative Approaches (Vol 1: Assessment). Rockville: Agency for Healthcare Research and Quality; 2008.

[23] Simonds AK. Risk management of the home ventilator dependent patient. Thorax. 2006;61(5):369–71. DOI: 10.1136/thx.2005.055566

[24] Shaqdan K, Aran S, Besheli LD, Abujudeh H. Root-Cause Analysis and Health Failure Mode and Effect Analysis: Two Leading Techniques in Health Care Quality Assessment. J Am Coll Radiol. 2014;11:572–9. DOI: 10.1016/j.jacr.2013.10.024

[25] Kubátová I, Chlouba M, Gajdoš O. Design Model for Risk Assessment for Home-Care Lung Ventilation. In: Lhotská L, et al., editors. IFMBE Proceedings: World Congress on Medical Physics and Biomedical Engineering 2018. Prague: Springer Nature Singapore Pte Ltd.; 2019. p. 391–7. DOI: 10.1007/978-981-10-9023-3_71

Ing. Ondřej Gajdoš
Department of Biomedical Technology
Faculty of Biomedical Engineering
Czech Technical University in Prague
nám. Sítná 3105, CZ-272 01 Kladno

E-mail: ondrej.gajdos@fbmi.cvut.cz
Phone: +420 604 256 983