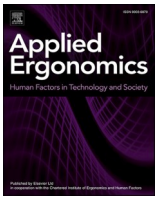
Applied Ergonomics 98 (2022) 103544



Contents lists available at ScienceDirect

Applied Ergonomics

journal homepage: www.elsevier.com/locate/apergo





Causes of use errors in ventilation devices - Systematic review

Beatrice Coldewey [a,*], Annette Diruf [b], Rainer Röhrig [a,b], Myriam Lipprandt [a,b]

[a] Institute of Medical Informatics, Medical Faculty, RWTH Aachen University, 52074 Aachen, Germany
[b] Division for Medical Informatics, Faculty VI - Medicine and Health Sciences, Carl von Ossietzky University of Oldenburg, 26129 Oldenburg, Germany

ARTICLE INFO

Keywords:
Mechanical ventilators
User centered design
Patient safety

ABSTRACT

A systematic review according to the PRISMA reporting standard was performed to identify causes of use errors in mechanical ventilators described in the literature. The PubMed search resulted in the inclusion of 16 papers. The errors described were systematically analyzed with regard to their causes and categorized in an adapted cause-and-effect diagram. The causes of use errors were related to specific usability issues and to the general condition that medical staff often work with different ventilators. When many devices are used, the different user interfaces are a source of use errors, since, for example, the same ventilation modes have different names. In order to avoid the identified causes for use errors in the future, this work offers manufacturers of ventilation devices design recommendations and the possibility to include the results in their risk management. In addition, standardizing user interface content across all ventilators, as in ISO 19223, can help reduce use errors.

1. Introduction

Mechanical ventilation provides life-saving support to patients in various environments such as anaesthesia, emergency medicine, intensive care units and intensive home care. The interventions are safety-critical for patients dependent on ventilation. Ventilation parameters and modes must be adapted to the patient's status in order not to further endanger his or her health. In case of health deterioration, a rapid intervention by the health care provider is necessary. (Pham et al., 2017; Windisch et al., 2017)

Several studies have investigated incidents related to mechanical ventilation (Cassidy et al., 2011; Cooper et al., 1978; Kamio and Masamune, 2018; Pham et al., 2016). Causes for avoidable incidents were e.g. assigned to human error or equipment malfunction. Mechanical ventilators are part of a complex socio-technical system together with the working environment, the users and the patients (Backhaus, 2010). According to the Swiss Cheese Model, hazardous situations occur due to an unfavorable sequence of several errors and contributing factors caused by holes in different securing layers (Reason, 2000). Human performance is not constant and errors are to be expected (St.Pierre and Hofinger, 2014; Kohn et al., 2000). Therefore, when hazardous situations occur, it should not be searched for a culprit, but rather analyzed why and how the system or the existing security layers have failed (Reason, 2000; St.Pierre and Hofinger, 2014).

Depending on the intended use context, there is a wide range of modern ventilators available on the market, which differ in the scope and implementation of their functionality (Kacmarek, 2011; L'Her et al., 2014). Despite the use of approved equipment, (serious) incidents[1] may occur. Use errors can lead to hazardous situations with adverse outcome for the patient (Mattox, 2012; Harrington, 2019; ISO 62366–1). The design of the user interface and its adaptation to the intended context of use can contribute to the avoidance of use errors and enables an effective, efficient and satisfying use (Fairbanks and Caplan, 2004; ISO 62366-1, 2015; Wiklund et al., 2016). Due to technological progress in the medical field, more and more functionalities of mechanical ventilators lead to an increase in complexity, which is reflected in the user interface (Chatburn et al., 2014; Kacmarek, 2011). In numerous studies, usability problems have been described as determining factors for the performance and avoidance of use errors (Gonzalez-Bermejo et al., 2006; Marjanovic et al., 2017; Spaeth et al., 2017). Especially in emergency situations under stress, fatigue or lack of experience, usability becomes a critical factor in the process of care (ISO 62366–1).

Known use errors and their causes should be taken into account for the improvement of existing techniques and the development of new user interfaces. Individual problems are addressed in various publications, but there is no comprehensive overview of problem areas to be considered. The aim of this work is to identify and provide an overview of published causes of use errors in mechanical ventilation devices.

* Corresponding author. Institute of Medical Informatics, Uniklinik RWTH Aachen, Pauwelsstr. 30, 52074 Aachen, Germany.
E-mail address: bcoldewey@ukaachen.de (B. Coldewey).

[1] For detailed information on the terminology used, see Glossary in Appendix A.

https://doi.org/10.1016/j.apergo.2021.103544
Received 14 August 2020; Received in revised form 15 July 2021; Accepted 25 July 2021
Available online 27 August 2021
0003-6870/© 2021 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

2. Methods

A systematic review was conducted to identify usability issues and contributing factors that can lead to use errors. The literature search was performed via PubMed using a combination of the keywords "mechanical ventilation", "usability" and "risk". Since the terms are used rather diversified, corresponding Medical Subject Heading terms (MeSH terms) and text words (e.g. human-computer interaction and user friendliness) were included for each to get a comprehensive search string. The search includes all entries published in English or German language and was not restricted with regard to the publication period. The exact search string and filters are provided in Appendix B.

The selection of eligible publications was carried out according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) (Page et al., 2021). Articles were first screened based on titles and abstracts. Articles were excluded if they contained research where the keywords, especially mechanical ventilation, were not used according to the focus of our study or as a subsidiary factor. These are, for example, studies on respiratory protective equipment, air conditioning or descriptions of medical procedures (see Fig. 1). In addition, technological progress in this field has led to the exclusion of papers that are no longer relevant. In a further step, the full-text of the remaining articles were assessed. Articles were eligible for inclusion if detailed information on usability issues and contributing factors as cause for reported incidents or use errors in mechanical ventilation devices was given.

The selected articles were qualitatively analyzed with regards to the causes that can lead to use errors. The findings were systematically listed in a cause-and-effect diagram by the occurring main categories. Two reviewers (computer scientists) independently assessed the articles. The analysis of the relevant content was supported by another computer scientist and a medical doctor. All conflicts were resolved by consensus.

We explicitly looked for the causes of use errors. These issues are of a qualitative nature. Even a single occurrence of a use error provides information about possible causes to be avoided. To ensure the validity of the usability issues, we defined the following quality metrics for the included articles:

- peer-reviewed journal
- suitable study design for usability evaluation and/or identification of use errors
- use of the device within its intended purpose
- the description of the use error has to give an indication of the cause of the issue.

In addition to the quality of the studies themselves, the limitations on the outcome of the review due to limitations in the studies are considered.

3. Results

3.1. Study selection

The search strategy in PubMed resulted in 692 papers listed until the end of February 2021. The titles and abstracts were assessed based on the inclusion and exclusion criteria leaving 44 studies for the full-text screening. After reading the remaining articles, 28 papers were excluded due to refined criteria. 16 studies remained for inclusion in our review (precision 2,3%). The process of systematic search is depicted in Fig. 1.

3.2. Characteristics of included studies

The sixteen studies included contain detailed information on

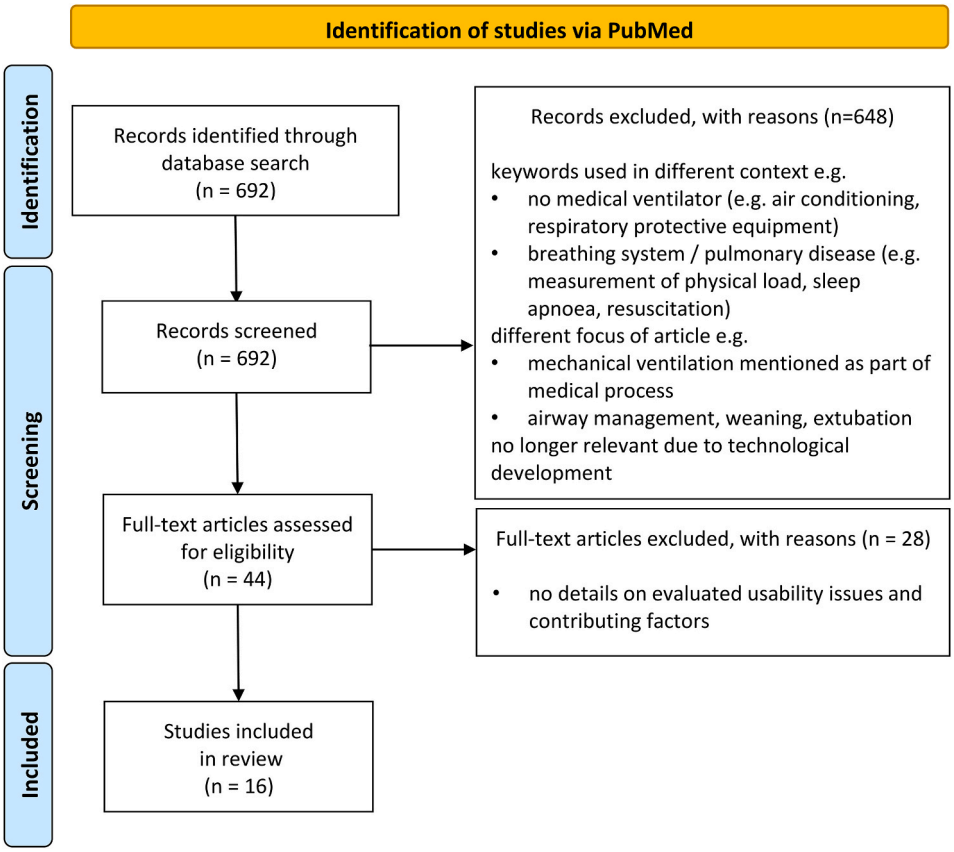


Fig. 1. PRISMA Flow Diagram with inclusion and exclusion criteria of study selection.

usability issues and contributing factors that can lead to use errors in mechanical ventilation devices. The studies were published between 2004 and 2020 in Canada, China, France, Germany, Japan, Sweden, Switzerland, United Kingdom or the USA. Table 1 in the Supplementary Data (Appendix C) gives an overview of the content of the included studies.

In terms of study design, fifteen of the sixteen studies are usability evaluation studies with task-based scenarios that were conducted in clinical simulation environments (Jiang et al., 2020, 2018b,a; L'Her and Roy, 2011; Vignaux et al., 2009; Uzawa et al., 2008; Gonzalez-Bermejo et al., 2006; Liu and Osvalder, 2004; Marjanovic et al., 2017; Marjanovic and L'Her, 2016; Maruyama et al., 2014; Morita et al., 2016; Spaeth et al., 2017; Templier et al., 2007; Wachter et al., 2006). Twelve of the fifteen compared mechanical ventilation devices (emergency and transport ventilators (Marjanovic and L'Her, 2016; Templier et al., 2007; L'Her and Roy, 2011), anaesthesia ventilators (Spaeth et al., 2017), critical care/intensive care unit ventilators (Jiang et al., 2020, 2018b,a; Vignaux et al., 2009; Uzawa et al., 2008; Marjanovic et al., 2017; Morita et al., 2016) and home care ventilators (Gonzalez-Bermejo et al., 2006)). Three of the fifteen evaluated the usability of prototypes with innovative graphical displays (Liu and Osvalder, 2004; Maruyama et al., 2014; Wachter et al., 2006). Several different quantitative methods were used to assess the ventilators and interface designs. All of the studies have investigated efficiency and effectiveness (e.g. task failure rate, processing time, the occurrence of errors or unnecessary treatments). For the investigation of subjective usability attributes like "ease of use" and "satisfaction", the twelve studies comparing the mechanical ventilation devices used several different questionnaires (USE (Jiang et al., 2018b), SUS (Marjanovic et al., 2017; Spaeth et al., 2017), PSSUQ (Morita et al., 2016), individual (Jiang et al., 2020, 2018a; Marjanovic and L'Her, 2016; Templier et al., 2007; L'Her and Roy, 2011; Vignaux et al., 2009; Uzawa et al., 2008; Gonzalez-Bermejo et al., 2006)). Additionally to the NASA-Task Load Index (NASA-TLX) method for measuring the subjective estimation of mental workload used in six of the fifteen studies (Jiang et al., 2020, 2018b; Marjanovic et al., 2017; Marjanovic and L'Her, 2016; Morita et al., 2016; Wachter et al., 2006), user's workload was investigated with the measurement and analysis of objective indicators like physical or psycho-physical parameters, e.g. heart and respiratory rate (Marjanovic et al., 2017) or changes of eye motion (Jiang et al., 2020, 2018b,a; Marjanovic et al., 2017).

Besides the evaluation studies, one study dealing with the analysis of reported incidents was eligible for inclusion (Cassidy et al., 2011). Here, the reported incidents recorded in the database used were systematically analyzed with regard to potential risks and opportunities to improve patient safety.

Use errors and their causes were described in all studies but were not the primary outcome. All included usability problems fulfill the established quality criteria. There are some limitations regarding the generalizability and scope of the results of this review.

The included usability studies deal with the use of the mechanical ventilation devices and design prototypes in a simulated environment and quantitative measurement of their usability. Potential causes of use errors are given as examples as explanations for the quantitative results in the discussion. In the usability studies only certain tasks, certain devices and certain user groups were tested. These studies do not cover all devices, user groups and scenarios.

The limited results of the included incident analysis study are due to the lack of identification and description of usability errors in the data.

3.3. Usability issues and contributing factors

In total, 51 text passages with descriptions of use errors and underlying causes identified in the context of usability studies and the analysis of critical events with different ventilators were analyzed. The identified issues were grouped into 15 subcategories based on similarity. The subcategories describe the issues in abstract terms. The issues were systematically listed in a cause-and-effect diagram by the occurring main categories (Fig. 2). Deviating from widespread categorizations, e.g. the 6 M method (man, machine, method, milieu, materials, management) (Canham et al., 2018; Wilken et al., 2017), the main influencing factors were adopted to best match the aspects found. The main categories (root cause areas) cover different aspects of the design of the user interface and the context of use. Table 2 in the Supplementary Data (Appendix C) gives an overview of the relevant text passages from the included articles containing information about possible usability problems as well as the categorization of the findings.

3.3.1. Interface Elements (Soft- and/or hardware)

The category "Interface Elements" lists all problems found that are related to the design of the user interface elements, e.g. how the functions were made available and how the individual elements are designed and located. Depending on the design of the device, there are software elements for control and information elements available via a (touch) display, e.g. status bars and buttons, as well as hardware elements such as control knobs and switches:

Some aspects apply across soft- and hardware elements. Use errors and long processing times due to unclear or misleading labeling of buttons and functions were mentioned in several studies (Gonzalez-Bermejo et al., 2006; Marjanovic and L'Her, 2016; Spaeth et al., 2017; Templier et al., 2007; Uzawa et al., 2008). For example, the soft key provided for quitting alarms was not pressed, but the "Alarms" touchscreen-button which intended use is the opening of the menu for setting alarm limits (Spaeth et al., 2017). Regarding the choice of interaction elements, the use of a combination of hard- and software elements was not detrimental (Spaeth et al., 2017). However, the use of a touchpad enables the clear distribution of functions and parameters on individual screens, while the use of only hardware elements often requires several different types of controls for adjusting settings (Marjanovic and L'Her, 2016; Templier et al., 2007). Additionally, the use of a combination of mechanical and software controls, e.g. to start ventilation or set a parameter, was stated as the cause for inefficient interaction or even task failure as the operators did not expect an additional activation step (Spaeth et al., 2017).

Considering the issues regarding the software elements, a good recognizability and readability of the presented content, e.g. alarm messages and additional instructions, was named as a factor relevant to good performance (Jiang et al., 2018b; Marjanovic and L'Her, 2016; Spaeth et al., 2017; Templier et al., 2007). For example, a notification pointing to special interaction steps to start ventilation was overlooked during operation which considerably affected the execution of the task (Spaeth et al., 2017). The use of touchscreen offers new possibilities for information and interaction elements if they are used properly. Here, the design of a button that did not meet the user's expectations was described as an obstacle to setting the ventilation mode for one device. On the one hand, it served as the display of the current mode, on the other hand, it also served as a button for opening underlying functions, whereby the button was not recognizable as such and was placed differently than the other buttons (Spaeth et al., 2017). In addition, several studies dealt with an alternative graphical representation of data in comparison to traditional representations to enable clinicians better decision support and recognition of adverse respiratory events (Liu and Osvalder, 2004; Maruyama et al., 2014; Wachter et al., 2006).

Regarding especially the hardware elements, for powering on the ventilators, the position of the power switch, e.g. on the back of the device or hidden behind a flap, was described as problematic (Jiang et al., 2018b; Marjanovic et al., 2017). While this was done for safety reasons, it inversely makes fast operation more difficult in time-critical situations if it cannot be found (Jiang et al., 2018b; Marjanovic et al., 2017; Vignaux et al., 2009). Furthermore, the lack of the sensitivity of the touchscreen of some devices was mentioned as a source of confusion and barrier for the completion of some tasks (Marjanovic et al., 2017; Morita et al., 2016).

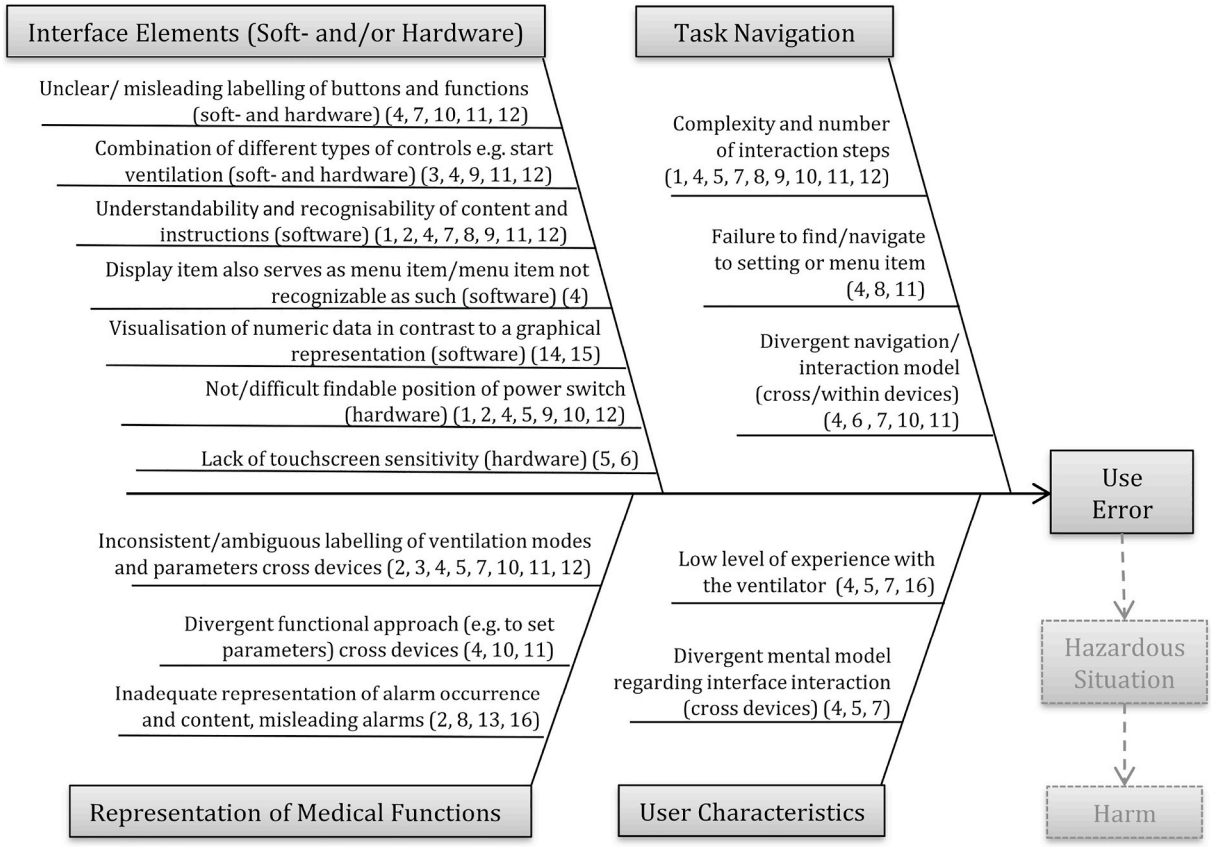


Fig. 2. Usability issues and contributing factors that can lead to use errors in mechanical ventilation devices and potential patient harm (1: Jiang et al. (2020), 2: Jiang et al. (2018b), 3: Jiang et al. (2018a), 4: Spaeth et al. (2017), 5: Marjanovic et al. (2017), 6: Morita et al. (2016), 7: Marjanovic and L'Her (2016), 8: L'Her and Roy (2011), 9: Vignaux et al. (2009), 10: Uzawa et al. (2008), 11: Templier et al. (2007), 12: Gonzalez-Bermejo et al. (2006), 13: Maruyama et al. (2014)), 14: Wachter et al. (2006), 15: Liu and Osvalder (2004), 16: Cassidy et al. (2011)).

3.3.2. *Task Navigation*

The category "Task Navigation" contains problems regarding the concepts behind the surface in terms of how to interact with the system:

The large number of functionalities offered due to the technical progress leads to a multitude of interaction steps with possibilities for use errors compared to simpler devices with only limited functionalities (Marjanovic and L'Her, 2016). While task performance was sometimes limited due to number of steps needed to perform the tasks, some tasks could not be executed because the user was not able to find the menu item or navigate to the setting, e.g. if they were placed in a submenu (Spaeth et al., 2017; Templier et al., 2007). It was also found that the efficient execution of some tasks was impaired by intra-machine or inter-machine inconsistencies in navigation (Morita et al., 2016; Spaeth et al., 2017). Especially the comparison of the task performance between the devices indicates that the choice of the interaction model interferes with task completion (Morita et al., 2016; Spaeth et al., 2017).

3.3.3. *Representation of Medical Functions*

The category "Representation of Medical Functions" names the problems that have arisen due to the underlying assumptions about the medical domain. These domain-specific issues are independent of the actual implementation of the design of the interface elements. The key issue here is the conceptual implementation of the domain-specific requirements that medical professionals demand of ventilators:

In performing tasks such as selecting and identifying ventilation modes, parameter settings and monitoring values several studies describe as a major problem the heterogeneous terminology used (Jiang et al., 2018b; Marjanovic et al., 2017; Marjanovic and L'Her, 2016; Spaeth et al., 2017; Templier et al., 2007). The various ventilator manufacturers use different labels for the same functions (e.g. "Tplat", "TIP:TINSP" and "Tpause"), which leads to unnecessary confusion, additional workload and operational failures (Jiang et al., 2018b; Spaeth et al., 2017). Likewise, the language-specific use of the french acronyms led to confusion and inadequate ventilation due to their similarity (Marjanovic and L'Her, 2016; Templier et al., 2007). On the contrary, elements that were labeled in an internationally conform manner (e.g. PEEP, ventilation frequency, tidal volume) enabled the shortest processing times and the fewest assistance (Spaeth et al., 2017). Use errors could also be observed in relation to a divergent functional approach to set parameters and their calculation (e.g. the ratio of inspiratory-to-expiratory time set as "I:E-ratio" or via the selection of the absolute inspiration time on the ventilators labeled "TINSP" or "Ti") (Spaeth et al., 2017; Templier et al., 2007). While e.g. the setting of the inspiratory pressure as pressure amplitude above PEEP, is physiological reasonable, it is still cause of confusion despite the corresponding labeling of the respective button (PC above PEEP) (Spaeth et al., 2017). Furthermore, some studies mention the need for a more suitable presentation of alarms as essential for the handling of these (Cassidy et al., 2011; Jiang et al., 2018b; Maruyama et al., 2014). The user must be able to quickly recognize the occurrence of the alarm and understand the alarm content (Jiang et al., 2018b; Maruyama et al., 2014) and not be misled by the information given (Cassidy et al., 2011). In addition to an easy to perceive presentation, e.g. auditory and visual, more detailed information on the alarm should enable fast response with less workload (Maruyama et al., 2014).

3.3.4. *User Characteristics*

The category "User Characteristics" summarizes problems that refer

to the properties of the user. "User" refers to the users who use the devices for the treatment of patients in a clinical environment. We distance ourselves from a user-centered shame and blame culture. As part of the socio-technical system, the known user characteristics are to be taken into account as a basis within the development process in order to avoid potential use errors:

For medical devices, there are regulations that request manufacturer training (Morita et al., 2016; Spaeth et al., 2017). However, Templier et al. (2007) pointed out that "some physicians have few opportunities to use ventilators and may therefore forget some of their initial training" (Templier et al., 2007) and "in theory, physicians should receive training before using a new ventilator. In practice, however, training may be cursory" (Templier et al., 2007). Spaeth et al. (2017) additionally mention that in time-critical situations and at a high level of stress the cognitive processing and performance of trained operators can be impaired to a comparable degree of naive operators. The influence of experience with certain ventilators, corresponding mental models and individual preferences becomes particularly clear when different devices are used (Marjanovic et al., 2017; Marjanovic and L'Her, 2016; Spaeth et al., 2017). In addition, larger deviations in the performance indicate different user characteristics, so that probably not every concept is equally suitable for every user (Spaeth et al., 2017).

4. Discussion

4.1. Principal results

Possible causes of use errors were identified in this systematic review. The causes of use errors described in the 16 included papers could be grouped into 15 subcategories. These in turn could be categorized into four root cause areas in the cause-and-effect diagram (Fig. 2). On the one hand, the use errors refer to the direct interaction with the ventilator. On the other hand, there are also use errors due to the use of many different devices (annotated cross device in the diagram). The findings presented show only a selection of possible causes for use errors, but include the main problems mentioned in the literature. Due to the safety-critical area of application, even the single occurrence of an error must be taken seriously.

The cause or contributing factor for the use errors in the direct device interaction was either a violation of design guidelines or an insufficient or incorrect use requirement. The identified problems "Unclear or misleading labeling of buttons and functions" and "Inadequate representation of alarm occurrence and content", for example, are indications of weaknesses in self-descriptiveness and suitability for the user's tasks. "Combination of different types of controls" and "Display item also serves as menu item/menu item not recognizable as such" lack of conformity with user expectations. The aspect "understandability and recognizability of content and instructions" violates the principles of dialog design detectability and unambiguous interpretability. "Complexity and number of interaction steps" and "Failure to find/navigate to setting or menu item" can be reduced by faster accessibility of the most frequently used functions and by flatter hierarchies. In general, it can be said that adherence to design guidelines (e.g., ISO 9241–110; ISO 9241–112; ISO 9241–125) and heuristics (Nielsen, 1994; Nielsen and Mack, 1994) contribute to error prevention and good design. Furthermore, the underlying needs and user requirements must be correctly identified. An analysis of the medical context is therefore indispensable.

In contrast to problems that affect the human-machine interaction between a user and a concrete device, some problems only occur when a user has to work with several devices (cross-device interaction). This is caused by manufacturer-specific use concepts, which differ from each other in a relevant way but are not always directly recognizable to the user. Ventilation modes are one example. The number of ventilation modes has increased with technological progress (Mireles-Cabodevila et al., 2013; Chatburn et al., 2014). These ventilation modes have different names for the same mode depending on the manufacturer and, conversely, different modes are hidden behind the same names. Furthermore, activated features with parameterization lead to new ventilation modes that are not assigned a name. This situation makes familiarization with new devices time-consuming and, above all, switching between different devices and their operation a risk to patient safety. For patient safety, it is essential that all available ventilation modes are understood to avoid adverse events (Barnes et al., 2010). To address this problem across devices, Chatburn et al. (2014) propose a standardized glossary with a taxonomy that leads to harmonization of ventilation modes regardless of manufacturer. The ISO 19223 standard adopts this approach and defines a standardized vocabulary adapted to the context of use, which use should limit the potential for incorrect use.

Risk management should anticipate use errors at an early stage in the development process and avoid them by means of suitable usability tests. An example of a risk minimization measure according to ISO 14971 is the design of the power switch. Here, there is a tension between accidently turning off the ventilator which must be avoided at all costs and finding the power switch quickly and easily (Jiang et al., 2018b; Spaeth et al., 2017; Marjanovic et al., 2017; Vignaux et al., 2009). Design decisions based on risk minimization may therefore be perceived as usability errors by the user. In this case, medical staff must be instructed separately on the criticality of the controls. But is training sufficient when the challenge is to overcome confusion, for example, in selecting ventilation modes or setting parameters when use is infrequent and stress levels are high? User expectations and experiences, and associated mental models regarding interaction through previous experience, can compound problems. Due to lack of standardization and commercialization issues, the ventilator is a "black box" in many cases. Advanced training in technical issues beyond that of individual devices is required for the user (Dellaca' et al., 2017). Organizational workarounds such as providing training and lists/overviews for reference can support the user. However, such measures should not relieve manufacturers of their responsibility.

In summary, it can be said that the qualitatively listed usability issues could all be sorted into differentiated cause categories. This made it possible to identify solution options for the use errors. In the context of a systematic error analysis (Vincent et al., 2000) the causes are multicausal. The manufacturer is responsible for designing the user interface in such a way that patient safety is not compromised. Here, risk management and requirements analysis as well as usability testing during manufacturing play a significant role. This work offers manufacturers and users the opportunity to take a multi-perceptual look at the causes of errors. The analysis offers the possibility to include frequent error causes in the checklists for avoidance.

4.2. Strengths and weaknesses of the study

In the review process, only a few studies could be found that dealt with concrete causes of use errors with ventilators. The methodology used and the results of the review are subject to some limitations. Despite these limitations, some descriptions of usability problems could be identified. For our qualitative analysis, a single mention of an error and a description of its cause was sufficient. A detailed analysis of the quality of the paper was therefore not significant. Additionally, the nature of the findings does not allow any statement to be made about their relevance and the associated risk. However, due to the generalized categorization, the results nevertheless provide a useable overview for the reduction of use-related risks.

The search for publications was complicated by the lack of established MeSH terms and the inconsistent use of the term "usability". Instead of the term usability, other terms (e.g. ease of use (Spaeth et al., 2017; Templier et al., 2007), ergonomic evaluation or ergonomics (Jiang et al., 2018b; Marjanovic and L'Her, 2016; Marjanovic et al., 2017), human factors or human factors study (Morita et al., 2016; Spaeth et al., 2017), self-explanatory interface (Spaeth et al., 2017) and

user experience (Jiang et al., 2018b; Morita et al., 2016)) are often used synonymously. Likewise, instead of use error, a variety of alternative terms were used. In addition to the terminology used, there may also be a misinterpretation of the causes of incidents, so that potential usability problems are not described as such. Therefore, despite the extensive search string, it is possible that studies containing usability problems and contributing factors were not found by the search strategy implemented. At the same time, the chosen search string led to numerous findings that did not meet the inclusion criteria. For better discoverability, for example, the MeSH term "user-centered design" introduced in 2021 is the first step. In addition to establishing suitable methods at the manufacturer, however, the user's awareness of usability and not the individual as the cause of errors must also be strengthened.

The focus of this review was on scientific publications on systematically analyzed usability problems. The search for these was done only via PubMed. An extension of the search in other publication databases could lead to further suitable publications. Moreover, incidents involving medical devices are primarily reported to the regulatory authorities, so there may be no separate publications on them. The analysis of entries in corresponding incident reporting systems such as the German Critical Incident Reporting System (CIRS) and reports to the Federal Institute for Drugs and Medical Devices (BfArM) could reveal further issues and enables an extension of the overview already created in this paper.

In fifteen of the studies, different ventilators and alternative displays were tested against each other. The studies measured and evaluated usability metrics such as effectiveness, efficiency and satisfaction. The measurement procedures used were limited to quantitative methods that offered information on performance. These provided a concrete result for the usability and comparability of the ventilators among themselves. The analysis of use errors and underlying usability problems was not the primary goal of the studies. The causes mentioned were only a secondary outcome and only given as examples to explain the quantitative results in the discussions. The amount of information and its level of detail was therefore sometimes very limited. For the detailed analysis of the underlying causes, the application of qualitative methods, such as video analysis and thinking aloud, is required to allow a more in-depth examination (Morita et al., 2016).

A large number of publications from the area of reported incidents and systematic reviews of these were excluded due to a lack of information about concrete usability problems. The structured analysis of reported incidents provided indications of existing problems in addition to quantitative results, e.g. on the severity of the incidents, but did not sufficiently analyze their causes. A lack of detail and understanding of what happened in reports often leads to poor data quality, so that the exact causes cannot be traced (Cassidy et al., 2011; Pham et al., 2016). In addition to a sufficient level of detail, suitable incident analysis methods are essential for the correct assignment of causes and the initiation of appropriate risk management methods (Lipprandt et al., 2020).

4.3. Conclusions and practical applications

This paper gives a systematic overview of the causes of use errors in mechanical ventilators. The issues could be divided into categories that allow a cause analysis. In addition to non-compliance with design guidelines and underlying requirements, the causes of use errors mainly concern the use of several devices in alternation. Very different interaction designs and inconsistent naming of ventilation modes are challenging for users. Efforts to standardize the user interface components may lead to a reduction in use errors and thus increase patient safety. In order to avoid the identified causes for use problems in the future, this work offers manufacturers of ventilation devices design recommendations and the possibility to include the results in their risk management.

Contribution of the authors

R.R. and M.L. conceived the original idea. B.C., R.R. and M.L. were involved in the conception and design of the work. B.C., A.D., R.R. and M.L. performed the data acquisition, analysis and interpretation.

B.C. took the lead in drafting of the work. R.R., A.D. and M.L. revised it critically for important intellectual content.

Declaration of competing interest

The authors declare the following financial interests/personal relationships, which may be considered as potential competing interests:

The article was conceived as part of the simpliVENT project funded by the Federal Ministry of Education and Research. The respirator manufacturer Löwenstein Medical Technology GmbH + Co KG functions as a project partner. However, they were not involved in this subtask and the creation of this article. The findings presented were examined regardless of assignment to specific ventilators and manufacturers.

Acknowledgments

This project is funded by the German Federal Ministry of Education and Research (BMBF) (simpliVENT FKZ: 13GW0262C).

Appendix A. Glossary

Harm: "injury or damage to the health of people, or damage to property or the environment" (ISO 14971).

Hazard: "potential source of harm" (ISO 14971).

Hazardous situation: "circumstance in which people, property or the environment is/are exposed to one or more hazards" (ISO 14971).

Usability: "characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment" (ISO 62366–1).

Use error: "user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user" (ISO 62366–1).

Normal use:"operation, including routine inspection and adjustments by any user, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those medical devices provided without instructions for use" (ISO 62366–1).

Incident: "means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect; " (MDR, 2017/745).

Serious incident: "means any incident that directly or indirectly led, might have led or might lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, a serious public health threat; " (MDR, 2017/745).

Appendix B. Search string and filters used via pubmed

(((respiration OR breathing OR ventilation) OR (respirator OR ventilator) OR "Respiration, Artificial"[Mesh] OR "Ventilators, Mechanical"[Mesh] OR "Respiratory Therapy"[Mesh]) AND (usability OR "user friendliness" OR ergonomics OR ergonomic OR "user experience" OR "User−centered design" OR "human factors" OR "user interface" OR "interaction design" OR "interface design" OR "human−computer interaction" OR "human−machine interaction" OR HMI OR HCI OR "User−Computer Interface"[Mesh] OR "Ergonomics"[Mesh] OR "User−Centered Design"[MeSH]) AND ((risk OR risks OR "risk"[Mesh]) OR (error OR errors) OR hazard OR incident OR mishaps OR "patient harm" OR "patient safety" OR "adverse event" OR "adverse effects" OR "critical incident" OR "Use Safety" OR "usability

problems" OR failure OR "Patient Harm"[Mesh] OR "Patient Safety"[Mesh] OR "Medical Errors"[Mesh] OR "Harm Reduction"[Mesh] OR "Near Miss, Healthcare"[Mesh])) AND (German[Language] OR English [Language])

Appendix C. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apergo.2021.103544.

References

Backhaus, C., 2010. Usability-Engineering in der Medizintechnik. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-00511-4.

Barnes, T.A., Gale, D.D., Kacmarek, R.M., Kageler, W.V., 2010. Competencies needed by graduate respiratory therapists in 2015 and beyond. Respir. Care 55, 601–616.

Canham, A., Jun, G.T., Waterson, P., Khalid, S., 2018. Integrating systemic accident analysis into patient safety incident investigation practices. Appl. Ergon. 72, 1–9. https://doi.org/10.1016/j.apergo.2018.04.012.

Cassidy, C.J., Smith, A., Arnot-Smith, J., 2011. Critical incident reports concerning anaesthetic equipment: analysis of the UK National Reporting and Learning System (NRLS) data from 2006–200. Anaesthesia 66, 879–888. https://doi.org/10.1111/j.1365-_2044.2011.06826.x.

Chatburn, R.L., El-Khatib, M., Mireles-Cabodevila, E., 2014. A taxonomy for mechanical ventilation: 10 fundamental maxims. Respir. Care 59, 1747–1763. https://doi.org/10.4187/respcare.03057.

Cooper, J.B., Newbower, R.S., Long, C.D., McPeek, B., 1978. Preventable anesthesia mishaps: a study of human factors. Anesthesiology 49, 399–406. https://doi.org/10.1097/00000542-197812000-00004.

Dellaca', R.L., Veneroni, C., Farre', R., 2017. Trends in mechanical ventilation: are we ventilating our patients in the best possible way? Breathe 13, 84–98. https://doi.org/10.1183/20734735.007817.

Fairbanks, R.J., Caplan, S., 2004. Poor interface design and lack of usability testing facilitate medical error. Joint Comm. J. Qual. Saf. 30, 579–584. https://doi.org/10.1016/s1549-_3741(04)30068-_7.

Gonzalez-Bermejo, J., Laplanche, V., Husseini, F.E., Duguet, A., Derenne, J.P., Similowski, T., 2006. Evaluation of the user-friendliness of 11 home mechanical ventilators. Eur. Respir. J. 27, 1236–1243. https://doi.org/10.1183/09031936.06.00078805.

Harrington, L., 2019. Use errors with health care technologies: an inconvenient truth. AACN Adv. Crit. Care 30, 12–15. https://doi.org/10.4037/aacnacc2019884.

ISO 14971, 2019. Medical Devices — Application of Risk Management to Medical Devices.

ISO 19223, 2019. Lung Ventilators and Related Equipment - Vocabulary and Semantics.

ISO 62366-1, 2015. Medical Devices — Part 1: Application of Usability Engineering to Medical Devices.

ISO 9241-110, 2020. Ergonomics of Human-System Interaction — Part 110: Interaction Principles.

ISO 9241-112, 2017. Ergonomics of Human-System Interaction — Part 112: Principles for the Presentation of Information.

ISO 9241-125, 2017. Ergonomics of Human-System Interaction — Part 125: Guidance on Visual Presentation of Information.

Jiang, M., Liu, S., Feng, Q., Gao, J., Zhang, Q., 2018a. Usability study of the user-interface of intensive care ventilators based on user test and eye-tracking signals. Med. Sci. Monit. 24, 6617–6629. https://doi.org/10.12659/MSM.909933.

Jiang, M., Liu, S., Gao, J., Feng, Q., Zhang, Q., 2018b. Comprehensive evaluation of user interface for ventilators based on respiratory therapists' performance, workload, and user experience. Med. Sci. Monit. 24, 9090–9101. https://doi.org/10.12659/MSM.911853.

Jiang, M., Sun, D., Li, Q., Wang, D., 2020. The usability of ventilator maintenance user interface: A comparative evaluation of user task performance, workload, and user experience. Sci. Prog. 103 https://doi.org/10.1177/0036850420962885.

Kacmarek, Robert M., 2011. The mechanical ventilator: Past, present, and future. Respir. Care 56, 1170–1180. https://doi.org/10.4187/respcare.01420.

Kamio, T., Masamune, K., 2018. Mechanical ventilation-related safety incidents in general care wards and ICU settings. Respir. Care 63, 1246–1252. https://doi.org/10.4187/respcare.06109.

Kohn, L.T., Corrigan, J.M., Donaldson, M.S. (Eds.), 2000. To Err is Human: Building a Safer Health System. National Academies Press, Washington DC. https://doi.org/10.17226/9728.

L'Her, E., Roy, A., 2011. Bench tests of simple, handy ventilators for pandemics: performance, autonomy, and ergonomy. Respir. Care 56, 751–760. https://doi.org/10.4187/respcare.00841.

L'Her, E., Roy, A., Marjanovic, N., 2014. Bench-test comparison of 26 emergency and transport ventilators. Crit. Care 18, 506. https://doi.org/10.1186/s13054-014-0506-0.

Lipprandt, M., Klausen, A., Alvarez-Castillo, C., Bosch, S., Weyland, A., Röhrig, R., 2020. Erweiterte systematische Fehleranalyse zweier CIRS-AINS Alert-Fälle: Vom Anwender- zum Anwendungsfehler. Anasthesiol. Intensivmed. 61, 76–84. https://doi.org/10.19224/ai2020.076.

Liu, Y., Osvalder, A.L., 2004. Usability evaluation of a GUI prototype for a ventilator machine. J. Clin. Monit. Comput. 18, 365–372. https://doi.org/10.1007/s10877-005-7997-9.

Marjanovic, N.S., de Simone, A., Jegou, G., L'Her, E., 2017. A new global and comprehensive model for ICU ventilator performances evaluation. Ann. Intensive Care 7, 68. https://doi.org/10.1186/s13613-017-0285-2.

Marjanovic, N., L'Her, E., 2016. A comprehensive approach for the ergonomic evaluation of 13 emergency and transport ventilators. Respir. Care 61, 632–639. https://doi.org/10.4187/respcare.04292.

Maruyama, K., Morohashi, S., Fukakura, Y., Takeuchi, H., Miyaji, T., Tsuji, T., Hasegawa, T., Eguchi, K., Usuda, Y., Andoh, T., 2014. Preliminary development and evaluation of the support system for care of mechanically ventilated patients. Br. J. Anaesth. 113, 491–500. https://doi.org/10.1093/bja/aeu097.

Mattox, E., 2012. Medical devices and patient safety. Crit. Care Nurse 32, 60–68. https://doi.org/10.4037/ccn2012925.

MDR 2017/745, 2017. Regulation (EU) 2017/745 of the european parliament and of the council of 5 april 2017 on medical devices, amending directive 2001/83/ec, regulation (ec) no 178/2002 and regulation (ec) no 1223/2009 and repealing council directives 90/385/eec and 93/42/eec (text with eea relevance.). https://eur-_lex.europa.eu/eli/reg/2017/745/oj.

Mireles-Cabodevila, E., Hatipoğlu, U., Chatburn, R.L., 2013. A rational framework for selecting modes of ventilation. Respir. Care 58, 348–366. https://doi.org/10.4187/respcare.01839.

Morita, P.P., Weinstein, P.B., Flewwelling, C.J., Bañez, C.A., Chiu, T.A., Iannuzzi, M., Patel, A.H., Shier, A.P., Cafazzo, J.A., 2016. The usability of ventilators: a comparative evaluation of use safety and user experience. Crit. Care 20, 263. https://doi.org/10.1186/s13054-016-1431-1.

Nielsen, J., 1994. Enhancing the explanatory power of usability heuristics. ACM CHI'94 152–158. https://doi.org/10.1145/191666.191729.

Nielsen, J., Mack, R., 1994. Heuristic Evaluation. Usability Inspection Methods. John Wiley & Sons, New York, NY.

Page, M.J., McKenzie, J.E., Bossuyt, P.M., Boutron, I., Hoffmann, T.C., Mulrow, C.D., Shamseer, L., Tetzlaff, J.M., Akl, E.A., Brennan, S.E., Chou, R., Glanville, J., Grimshaw, J.M., Hróbjartsson, A., Lalu, M.M., Li, T., Loder, E.W., Mayo-Wilson, E., McDonald, S., McGuinness, L.A., Stewart, L.A., Thomas, J., Tricco, A.C., Welch, V.A., Whiting, P., Moher, D., 2021. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 372. https://doi.org/10.1136/bmj.n71.

Pham, J.C., Williams, T.L., Sparnon, E.M., Cillie, T.K., Scharen, H.F., Marella, W.M., 2016. Ventilator-related adverse events: a taxonomy and findings from 3 incident reporting systems. Respir. Care 61, 621–631. https://doi.org/10.4187/respcare.04151.

Pham, T., Brochard, L.J., Slutsky, A.S., 2017. Mechanical ventilation: state of the art. Mayo Clin. Proc. 92, 1382–1400. https://doi.org/10.1016/j.mayocp.2017.05.004.

Reason, J., 2000. Human error: models and management. BMJ 320, 768–770. https://doi.org/10.1136/bmj.320.7237.768.

Spaeth, J., Schweizer, T., Schmutz, A., Buerkle, H., Schumann, S., 2017. Comparative usability of modern anaesthesia ventilators: a human factors study. Br. J. Anaesth. 119, 1000–1008. https://doi.org/10.1093/bja/aex226.

St.Pierre, M., Hofinger, G., 2014. Human Factors und Patientensicherheit in der Akutmedizin. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-55420-9.

Templier, F., Miroux, P., Dolveck, F., Descatha, A., Goddet, N.S., Jeleff, C., Baer, M., Chauvin, M., Brochard, L., Fletcher, D., 2007. Evaluation of the ventilator-user interface of 2 new advanced compact transport ventilators. Respir. Care 52, 1701–1709.

Uzawa, Y., Yamada, Y., Suzukawa, M., 2008. Evaluation of the user interface simplicity in the modern generation of mechanical ventilators. Respir. Care 53, 329–337.

Vignaux, L., Tassaux, D., Jolliet, P., 2009. Evaluation of the user-friendliness of seven new generation intensive care ventilators. Intensive Care Med. 35, 1687–1691. https://doi.org/10.1007/s00134-009-1580-7.

Vincent, C., Taylor-Adams, S., Chapman, E.J., Hewett, D., Prior, S., Strange, P., Tizzard, A., 2000. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. BMJ 320, 777–781. https://doi.org/10.1136/bmj.320.7237.777.

Wachter, S.B., Johnson, K., Albert, R., Syroid, N., Drews, F., Westenskow, D., 2006. The evaluation of a pulmonary display to detect adverse respiratory events using high resolution human simulator. J. Am. Med. Inf. Assoc. : JAMIA 13, 635–642. https://doi.org/10.1197/jamia.M2123.

Wiklund, M., Dwyer, A., Davis, E., 2016. Medical Device Use Error: Root Cause Analysis. CRC Press, Taylor & Francis Group, Boca Raton, FL.

Wilken, M., Hüske-Kraus, D., Klausen, A., Koch, C., Schlauch, W., Röhrig, R., 2017. Alarm Fatigue: Causes and Effects. Stud. Health Technol. Inf. 243, 107–111. https://doi.org/10.3233/978-1-61499-808-2-107.

Windisch, W., Dreher, M., Geiseler, J., Siemon, K., Brambring, J., Dellweg, D., Grolle, B., Hirschfeld, S., Köhnlein, T., Mellies, U., Rosseau, S., Schönhofer, B., Schucher, B., Schütz, A., Sitter, H., Stieglitz, S., Storre, J., Winterholler, M., Young, P., Walterspacher, S., 2017. Guidelines for non-invasive and invasive home mechanical ventilation for treatment of chronic respiratory failure - Update 2017. Pneumologie 71, 722–795. https://doi.org/10.1055/s-0043-118040.