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Usability-Tests of Mechanical Ventilators: A Systematic Review

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Abstract. The usability of ventilators is critical for patient safety. This systematic review shows the methods used in usability studies on ventilators, if those are similar in methodology. Furthermore, the usability tasks are compared to the requirements for manufactures during approval. Results show that the methodology and procedure of the studies are similar, but only cover part of the primary operating functions from their corresponding ISO Norm. Therefor optimisation of aspects of the study design, e.g., scope of tested scenarios, is possible.

Keywords Mechanical Ventilators, Usability-Test, User-Centered Design, Systematic Review, Patient Safety

1. Introduction

While technical progress increases complexity in medical devices like ventilators, multimorbidity and rising numbers of elderly people lead to more people in need of those machines. Compounding to this situation are unforeseen pandemics like COVID-19.

This leads to a rising number of people requiring ventilation, increasing the need for usability testing of ventilators. To avoid hazards for patients, manufacturers are bound by the Medical Device Regulation (MDR) to comply with the general safety and performance requirements. Therefore, a usability engineering process must be carried out on the primary operating functions [1]. The goal is to ensure that use errors either do not occur or do not result in harm.

The aim of this systematic review is to compare methodological approaches in usability tests of ventilators for similarities, and an unwittingly used standardization. The results are also compared to the requirements for the approval of medical devices.

2. Methods

PubMed and Embase were searched with a string consisting of "mechanical ventilation", "usability" and suitable synonyms, limited to the last 20 years. In accordance with the

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Prisma standard [2], relevant studies were filtered out by two independent researchers using the software Rayyan [3]. These studies were examined for various criteria such as study design, qualification and number of participants, usability test procedure, the individual tasks, and methods used to measure the outcomes. In order to assess the quality of the studies, an assessment was carried out using QualSys [4].

3. Results

Of the 5463 articles found, 12 relevant articles were identified. All studies conducted a comparative evaluation of usability in form of a summative test. The number of participants varied from 6 to 48, and from 2 to 13 tested devices. The process leading to sample size was documented in only four studies. Between 5 and 20 tasks were tested, which differed in their granularity. For comparability, these were mapped to the primary operating functions of the associated standards, e.g. ISO 80601-2-12 [5]. Regarding the usability outcomes, effectiveness (success rate), efficiency (time) were measured and satisfaction were determined in most of the studies by means of questionnaires. Six of the studies also measured the (perceived) workload.

4. Discussion

The review identifies differences as well as shortcomings in the study design. The results show that the methodology and the procedure of the studies are similar, but improvable. Furthermore, they are only partly comparable to the primary operating functions. This adds to the non-standardized way of usability testing, that could be improved by aligning the tasks at least the given categories in the norms. In some studies, the description of the method did not allow any reproducibility. There were no publications by manufacturers themselves. In order to improve the quality of usability studies of ventilators, more focus could be placed on the optimisation of certain aspects regarding the study design, e.g. the scope of tested scenarios with regard to the main operating functions, hazard-related usage scenarios or the systematic collection of usage problems. The limiting factor to this study is the use of different terms and synonyms in usability and medicine, leading to possible missed studies.

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