Requirements for a System Supporting Patient Communication in Intensive Care in Germany

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Abstract—Weaning from the mechanical ventilation poses substantial physical and psychical stress to the patients which is intensified by the obstruction of verbal communication. Hence, during the weaning phase, ICU patients often cannot impart their basic needs adequately. A prolonged healing process, delirium, and complications are possible consequences. The research project ACTIVATE aims to develop an interactive system to support communication and re-orientation in weaning patients and to allow them early autonomous control of ambient devices. The system will include an innovative ball-shaped interactive rehabilitation device (BIRDY), designed for weaning patients bound to the bed to control the proposed system.

As a result of the development process including two studies, several workshops and a comprehensive user and context analysis, non-functional and functional requirements for the overall system, consisting of BIRDY, the system's architecture and human-machine interfaces were determined.

The target group requires a particular focus on usability aspects addressing patients' cognitive and physical impairments. To save nursing staff time resources, the system should function as automatically as possible. Besides, safety and security by design, meeting infection control regulations, multilingual system dialogues and a multimodal presentation of information are crucial aspects.

Keywords — Intensive Care Unit, Mechanical Ventilation, Weaning, Human-Computer Interaction, Ambient Computing, Human Centered Design, Augmentative and Alternative Communication

I. Introduction

To treat the most critically ill patients, an intensive care unit (ICU) is staffed with experienced personnel and characterized by a high nurse-patient ratio. A common intervention for patients with life-threatening conditions is mechanical ventilation and hence, those patients represent a large and highly vulnerable patient group in intensive care. In 2016 about 425,000 of the 2.1 million reported cases of intensive care treatment in Germany were mechanically ventilated [1].

When the medical staff decides to remove the mechanical ventilation to have a patient breathe independently again, the first step performed is a reduction of the sedation. This initializes the weaning process where the human body has to re-adapt to breathing independently from mechanical support. To facilitate this re-adaption, the ventilation is gradually decreased.

During weaning from mechanical ventilation patients perceive substantial physical and psychical stress. The patients' serious conditions, the influence of sedating medication and the endotracheal intubation renders the patients temporarily voiceless. This obstruction of verbal communication potentially intensifies the stress. Adequate communication of even basic needs can be a major challenge to respective ICU patients. Possible consequences are a prolonged healing process, delirium, and complications. Patients lacking communication ability are facing a higher risk of poorer treatment [2]. Insufficiently treated pain [3], physical symptom burden, fear as well as feelings of unfamiliarity and identity loss [4] [5] are often reported strains among mechanically ventilated patients.

On the other hand, effective communication with ventilated patients has been linked to positive nursing care outcomes [6]. Regular and successful communication between patients and ICU staff is therefore of paramount importance to foster patients' recovery from the critical health conditions and must be established as early as possible. However, although this need for early and continuous communication is well-acknowledged by health professionals, effective methods are lacking to support this communication and in many reported cases, the interaction with mechanically ventilated patients is perceived as onerous [4]. Thus, novel and easy-to-use tools are required to facilitate communication between health professionals and non-vocal ICU patients from the very beginning of the weaning phase.

Information and communication technology (ICT) underwent a rapid evolvement in recent decades. Especially, the health technology sector has seen immense innovation in the past few years. Based on these trends, we aim to develop an interactive system to support communication and re-orientation in weaning patients and to allow them early autonomous control of ambient devices. The system's design and features are inspired by methods of augmentative and alternative communication (AAC) and the concept of successive information. Our approach involves providing the correct amount of information at the correct time to prevent overburdening the patient. The ACTIVATE system will make use of an innovative ball-shaped interactive rehabilitation device (BIRDY), designed for weaning patients bound to the bed to control the proposed system. The system's concept is inspired by the paradigm of ambient computing. We combine several smart devices to create a device ensemble that suits the users and serves specific use cases. A proposal for the usage of the ACTIVATE system can be seen in Figure 1.

In this article, we present key requirements for the ACTIVATE system. A human-centered design (HCD) approach including two studies, several workshops and a comprehensive user and context analysis was applied to gather these requirements.

II. Related Work

Different approaches for AAC strategies to support patient communication of the voiceless were already summarized [7]. Findings show various low- and high-tech approaches to overcome the communication barrier.

There is previous work focusing on approaches that don't require ICT, like pen and paper [8] or illustrated communication material [9] for instance. Furthermore, one approach relies on nurse training with low-tech AAC, electronic AAC, and low-tech tools [10]. Some authors describe the application of AAC software on standard PCs with eye trackers and touch screens [11], the use of computers controlled by eye blinking and/or hand or finger movement [12], the use of tablets with AAC specialized content and speech synthesis [13–15] as well as the operation of tablet computers with programmable speech [16] [17].

The more advanced work is focusing on tablets or tablet-like devices that are inspired by basic talkers known in AAC and enhance this basic functionality using modern user interfaces like gaze control or touch. However, no systems specifically designed for the ICU context are presented in these publications, particularly no approaches based on an ambient system to fulfill the task.

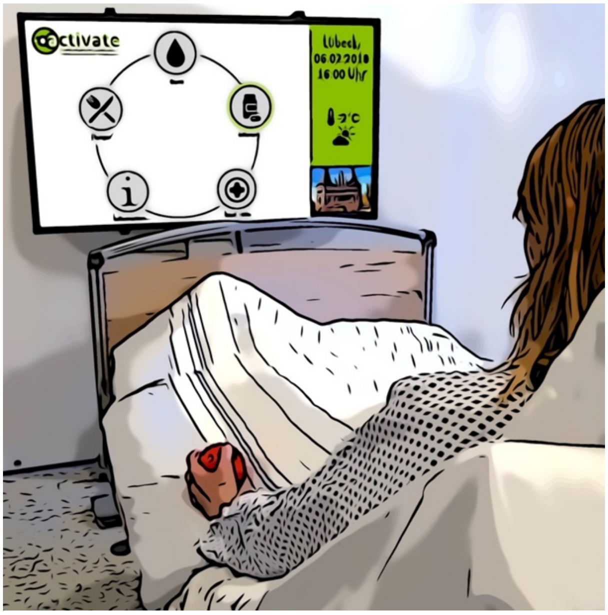

Figure 1. A possible setup where a patient interacts with the ACTIVATE system using BIRDY.

Several requirements for systems supporting patient communication in intensive care have already been reported [18]. Recently, based on these insights, an interaction device and a communication system controlled by the device was developed [19]. This device can be adapted to the patients' physical deficits and impairments and uses a vibration motor to provide feedback. Domain-specific requirements such as infection control, simple design, suitable content, and limited motor skills in ICU patients were taken into account by the design of this device. We adapted requirements for the ambient system for patient information, communication, and control targeted by the ACTIVATE project from these findings. Nevertheless, they do not cover all aspects relevant to this system.

III. Method – Human-Centered Design

The ACTIVATE system is planned to be deployed in clinical practice. Consequently, it is going to be evaluated under realistic conditions in a clinical study to prove its usability and to examine its impact on the target groups. To achieve the acceptance by potential users, namely patients, relatives and nursing staff, all of their needs must already be considered in the development process. Additionally, usability factors should be in focus during the development. As a consequence, we closely adhere to the HCD process as specified in DIN EN ISO 9241-210 [20] (Figure 2) at each stage of the development process.

Understanding and specifying the context of use and the users' needs and requirements plays a major role in the development process of interactive systems and particularly within the HCD process. These requirements are used to develop design solutions that are formatively evaluated within the process. Development is finished as soon as the solution meets the requirements in a summative evaluation. At this point, the ACTIVATE system can be tested in a clinical study.

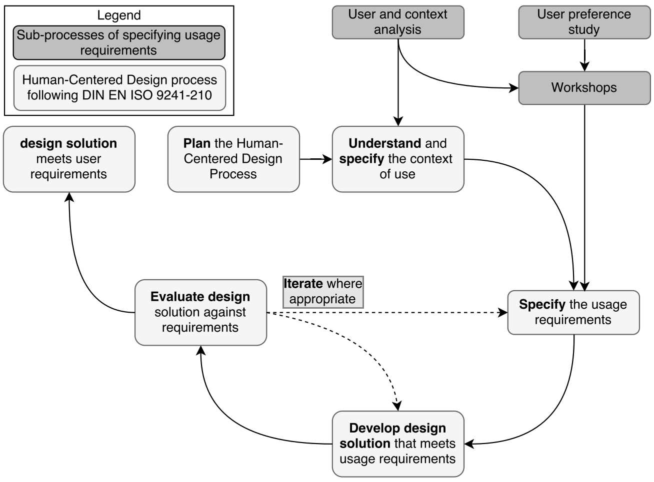

Figure 2. The Human-Centered Design process according to DIN EN ISO 9241-210.

This emphasizes the critical role of requirements in the whole development process, the part presented within this article.

The requirements for the total system were gathered in three parallel sub-processes, namely a user and context analysis (including qualitative interview studies as well as the creation of personas and problem scenarios), user preference studies, and finally, workshops with stakeholders to discuss insights and derive the detailed requirements. These sub-processes are described in the following.

A. User and Context Analysis

For a better understanding of the user groups, their needs and the general context of use, we conducted a user and the context analysis. First, a comprehensive literature search was performed to identify similar work in the field and gather the corresponding key insights. The search was focused on socio-technical systems to support patient communication in intensive care. Results confirm the need for AAC and emphasize the demand for novel solutions for patient communication during the weaning phase. Besides, the search revealed that there is only limited work on this topic (refer to Related Work).

Another systematic literature search was carried out to identify patients' perceptions and experiences recalled by themselves from the weaning process. The searches yielded one meta-synthesis [21] underscoring the weaning patients' largely unsatisfied communication needs, particularly with regard to possibilities to express their feelings and symptoms and to receive information about their situation. Further literature [22] was included to get additional information about the context which were complemented and reflected by discussions with domain experts.

Furthermore, a qualitative study comprising individual interviews with 16 patients, 16 relatives and 6 medical doctors as well as three focus group interviews with 26 nurses and other health professionals was conducted. This study allowed an in-depth analysis of the patients' needs from their own and nursing staffs' perspective as well as exploration of the staff's and relatives' own needs in the care for weaning patients. Besides, facilitating factors and potential barriers for the use of the planned system were identified.

Results of these various information sources were used to create data-driven personas that represent our target user groups. They were carefully designed according to chosen key characteristics, namely (un-)planned hospitalization, degree of physical, cognitive and behavioral impairments and disturbances, medical discipline and native speaker-status (German or other language). Additionally, we modeled a typical weaning process and used it for the creation of persona-based problem and solution scenarios.

At the final stage, our procedure resulted in an elaborated user analysis, a detailed organization analysis, and a task analysis. The user analysis includes descriptions of user groups along with their characteristics and personas of different types, namely primary, negative, served and customer personas. The organization and the task analysis provided valuable insights into the daily clinical routine.

B. User Preference Study

To identify key characteristics (namely shape, size, weight, surface properties and deformability) of BIRDY, the interaction device designed to control the ACTIVATE system, we conducted a user study to identify future users' preferences regarding different device properties. First, 30 commercially available objects having design characteristic attributes being potentially suitable for BIRDY were evaluated by 12 participants in a preliminary study resulting in eight preferred objects included in our main study.

For the main study, a setting that resembles realistic conditions in a hospital was created. The participants wore special gloves simulating swollen hands and reducing hand mobility. Additionally, they laid in a hospital bed, with the upper body being elevated by 30° [23]. 40 participants of two different age groups (20 each), the first group ranging from 18 to 40 years (M=23.45, SD=3.03, 11 females) and the second group ranging from 58 to 84 years (M=67.25, S=6.6, 12 females), chose their object preferences and told how they would interact with their favorite object. After a pair-wise comparison, they ranked their favorite objects regarding predefined characteristics, namely size, weight, shape surface properties and deformability, and their overall favorite object regardless of a fixed characteristic. We created several rankings based on the pair-wise comparison, preferences regarding fixed characteristics, and the overall favorite object.

An analysis of the choice and the reason for the decision [24] as well as an analysis of the first impulse in spontaneous interaction [25], both with the favored object, were already published.

C. Workshops

All previous results were discussed and refined in joint workshops of our project members. The team consists of experts of various disciplines, namely nursing research, ICU nursing practice, hospital IT, hardware engineering, software engineering, psychology, usability, and AAC. The workshops were conducted to determine concrete requirements and pave the way for further development.

First, the created personas and problem scenarios were enhanced and used for potential use cases as well as the discussion of possible approaches that resulted in solution-based scenarios describing situations where the system can be used and promises positive impact on the user groups. Both of these tools were used for further considerations finally resulting in requirements.

We conducted several workshops with stakeholders to define requirements addressing (non-)functional aspects, technical details as well as design options. Results of previous work were shared; unresolved aspects were clarified, and the feasibility of different design options was verified. In total, 20 experts were involved in the workshops. We had one workshop focusing on the HCD process, eight workshops on technical details, scenarios and personas, three workshops to consider preliminary requirements, two workshops to realize safety and security by design, and one workshop to analyze state of the art devices for AAC. Additionally, we had seven telephone conferences to finalize technical details and requirements with our hardware engineers *CogniMed GmbH*, who will realize the interaction device BIRDY. Finally, we found a consensus among all stakeholders and had our design choices confirmed by the team.

IV. Results

We identified several barriers and enablers for the use of systems supporting patient communication in intensive care. On the barrier side, required time and expertise for the installation and use as well as a slow system performance were determined. Other risks are seen in a high effort resulting in possibly only little benefit and a potentially negative stance towards digital communication. On the enabler side, an intuitive and natural operation, stability, and simple usage were named. A fast and easy assembly and installation, an uncomplicated preparation for a change of patients and a possibly high acceptance based on good experiences are seen as chances.

Our process resulted in non-functional and functional requirements for the overall system, consisting of BIRDY, the system's architecture, and human-machine interfaces, were determined. Firstly, we describe the non-functional requirements (NFR).

The fact that weaning patients cannot be expected to learn complex interactions reinforces the need for an intuitive design, especially since we are planning an application at an early stage. Short awareness phases of the target patient group, as well as potentially lacking experience in controlling smart devices, demand that interaction and its effect must be immediately clear (NFR-1). Hence, typical interaction patterns of the target groups should be taken into account, particularly for the development of BIRDY. This applies also to other interaction possibilities, which should be provided to maintain controllability despite various impairments of possible users due to critical health conditions, age or intervention. Since the system is intended to not cause additional nursing resource use and the staff is not always present, patients should be instructed by the system itself most of the time (NFR-2). The usage of the system must not cause any injuries, posing special restrictions to possible interaction devices, BIRDY included (NFR-3).

The target group requires a special focus on usability aspects to address cognitive and physical impairments. Hence, in our development process we follow the seven general ergonomic principles that are described within DIN ISO 9241 part 110. Firstly, to maintain suitability for the task, cognitive and physical impairments should be regarded (NFR-4). Users should not be overstrained and interaction alternatives (for instance AAC) should be provided to guarantee controllability despite possible impairments. Displays and audio messages should be appropriate for patients in such conditions, also requiring text with large characters and alternative modalities, particularly for vision- and hearing-impaired patients. Additionally, reduced manual force should be taken into account when designing or selecting interaction devices. Next, a wake-up mode and tutorials should be implemented to ensure the suitability for learning (NFR-5). Suitability for individualization (NFR-6) is corresponded by allowing nursing and other healthcare staff to configure the system's interaction interfaces according to the patient's and their own needs. Considered configuration options include specific messages, individual music therapy modes and BIRDY's vibration or light intensity. To address user expectations, changes in interaction possibilities should be avoided or kept minimal, for instance when an interaction option becomes unusable, perhaps due to a deterioration of the medical condition. On this matter, self-descriptiveness should be provided, not only for the human-computer dialogue but for all system components and ambient devices (NFR-7). Finally, the system must be error tolerant (NFR-8), particularly due to the target group and the context of use.

Referring to the previously described barriers, the system should function as automatically as possible to save nursing staff's time (NFR-9). Besides, safety and security by design (NFR-10), meeting sanitary regulations (NFR-11), providing multilingual system dialogues (NFR-12) and a multimodal presentation of information (NFR-13) are central factors. Particularly, unnecessary acoustical and optical noise should be avoided (NFR-14) and it should be possible to deactivate the system in situations where is it not appropriate (NFR-15). To meet infection control regulations, objects that are not directly in contact with the patient (e.g. more than 1.5 m away) must be designed in such a way that they can be disinfected by wiping and objects closer must be hermetically sealed (NFR-16). Following this regulation, all components that are in contact with the patient, namely BIRDY and potential other interaction devices, must be sealed. It should be noted that small objects are, although not required, often immersed into a disinfectant and should therefore be submergible. To allow for a continuous operation, replaceability of the components (NFR-17) should be ensured.

The ACTIVATE system is planned to be applied in German hospitals and thus, must conform European Union's General Data Protection Regulation (EU-GDPR). Hence, all data communication shall be encrypted (NFR-18) and the system shall be secured to be resistant against attacks (NFR-19). Besides, to maintain patient's privacy, personal information should be protected from prying eyes where possible (NFR-20). Yet, it should be noted, that insights by third persons cannot always be prevented, due to shared rooms and visits of relatives.

Functional requirements (FR) are described in the following. The system consists of a user interface (UI) for the patients and an UI for the staff, as well as a system architecture to integrate all components.

Patients should be able to send messages to the nursing staff (FR-1) notwithstanding their condition (smart nursing calling system). Furthermore, the system should provide application masks for AAC on different topics, like pain or breathing/mechanical ventilation for instance, also to support the nursing staff's assessment and information gathering of patient's problems (FR-2). To foster re-orientation, basic information about date, time, place, weather conditions, and if available the relevant nursing staff member(s), as well as possible further information about interventions (for instance mechanical ventilation) shall be given to the patient (FR-3). The basic information should be provided visually and during the wake-up phase acoustically (FR-4). Further information about interventions should be included in the audio message (FR-5). Besides, schematic information about future steps in treatment and process should be given (FR-6).

The wake-up mode should introduce patients to their current situation and the ACTIVATE system (FR-7). Hence, the wake-up mode should provide primarily information for the patient. To avoid overstraining the patient, the functionality should be reduced during this phase and it should be possible to unlock further functions according to the patient's condition. Particularly during this phase, but also at later stages, unintended input should be avoided (FR-8), e.g. by using a lock screen and appropriate tutorials for the wake-up phase and for later phases.

Due to the situation, feedback plays an important role in the ICU setting. Hence, acoustic and visual feedback should be used (FR-9a). Besides, BIRDY should provide tactile feedback (FR-9b), a function that should be used by the ACTIVATE system to address the patients.

The staff should be able to configure (FR-10) and control (FR-11) the patient system (the information given, intervals for audio messages, the wake-up mode and individual customizations of the application masks according to the patient's needs) and receive information about any interaction attempts of the patient with BIRDY and the system (FR-12). Furthermore, the staff should be informed about messages from patients (FR-13) by the application (smart nursing calling system, cf. FR-1).

The system architecture should allow for the integration of BIRDY, potential other interaction devices, smart room components controlled by the patient and output devices, like screens and audio devices (FR-14).

To enable patients to manage a feelgood atmosphere, they should be able to control room components (devices of the internet of things, like smart lights). This requires corresponding control possibilities in the patient UI (FR-15) as well as an integration of the components in the system (FR-16). Furthermore, the playback of media provided by relatives, like music files, photos, videos, or audio messages, should be possible and controlled by patients as well as the staff (FR-17).

V. Discussion

Gathered requirements provide valuable information for the development of the ACTIVATE system. They can be used to design and realize further systems for the support of mechanically ventilated ICU patients during the weaning phase.

During our qualitative study we faced limited capabilities of the participants to imagine possible sociotechnical solutions for the communication barrier. To handle this shortcoming, we implemented additional workshops with domain and engineering experts to find and discuss potential solutions in this team.

The conducted user preferences study was limited to acquirable objects and hence, decisions were made based on the physical characteristics of these objects and not based on a combination of single favored attributes. Nevertheless, results of our study addressing size, weight and first interaction pattern are comparable to those of other studies [26].

In the future, we plan to evaluate the ACTIVATE system in a clinical study in the care setting of interest (ICU hospital care) to examine the system's feasibility and potential impact on the target groups. Consequently, the next step is to realize the system with its components, including BIRDY, based on the specified requirements.

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