Usability-driven design of medical device APPs for telemonitoring of chronic patients

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***Abstract*—Telemonitoring systems, including devices, APPs, and Medical Device Software, provide an irreplaceable technological solution for the prevention of acute episodes in chronic pathologies such as heart failure. Nevertheless, the benefits are often compromised by complex designs which hinder their adoption and their seamless integration into the patient's daily life. In this work, we propose a user-centered design methodology to translate the specific requirements of chronic patients into suitable technical specifications for telemonitoring APPs.**

***Keywords*—Medical Device Software, Medical APPs, Usability Engineering, Telemonitoring.**

I. Introduction

The management of chronic diseases has improved significantly with telemonitoring systems, which include devices, patient-facing APPs, and medical device software (MDS) for continuous health care. These systems are often aimed at individuals affected by multiple chronic comorbidities [1][2]. Complex designs can hinder the adoption of telemonitoring technologies and limit their benefits, particularly in the elderly population [3]. To overcome these issues, it is essential to apply usability engineering principles in designing MDS APPs to make them intuitive and accessible for users. This ensures the highest adoption and adherence to the monitoring protocol. Moreover, usability is a key factor for risk analysis and to achieve compliance with the Medical Device Regulation 745/2017 and obtain the CE mark. This work presents a case study of usability-driven design for the telemonitoring of chronic heart failure patients, focusing on developing an APP tailored to these patients, usually elderly people with comorbidities. The goal is to propose a user-centered design methodology to translate the specific requirements of the target population into suitable technical specifications.

II. Case Study: Telemonitoring of Heart Failure

Heart Failure (HF) is a chronic condition affecting 1-2% of the global population [4], which necessitates effective home monitoring as a critical strategy to prevent acute episodes and reduce hospitalizations [5]. Regular follow-up is essential for thoroughly assessing the patient's status of compensation and requires consistent engagement from healthcare professionals. While clinical assessments provide valuable insights, daily data collection through home monitoring devices is essential to ensure early detection of an upcoming acute episode [6][7]. This approach allows patients and their caregivers to manage health conditions more effectively and clinicians to obtain more data to support decision-making during follow-up visits. Remote monitoring systems for chronic conditions such as HF typically include three components: 1) one or more monitoring devices to be used by the patient for daily data collection; 2) a patient-dedicated APP to provide direct feedback and communicate with the clinician; 3) a clinician-dedicated software for data visualization and to support decision making. The functionalities embedded in the two MDS components, as well as the user interfaces, are explicitly designed to address the unique needs of their users seamlessly.

III. From User Requirements to App Functionalities

Ease of use and well-organized information visualization are the key design requirements: users should be able to access what they need when they need it. User-centered software design was driven by a thorough analysis of the user requirements and the clinical processes, object of a previous work [8]. In the Process Modeling phase, we highlighted what role technology has in the clinical processes, and we translated it into software functionalities. Figure 1 presents the Use Case Diagram of the two MDS, namely the patient-dedicated APP and the clinician-dedicated software.

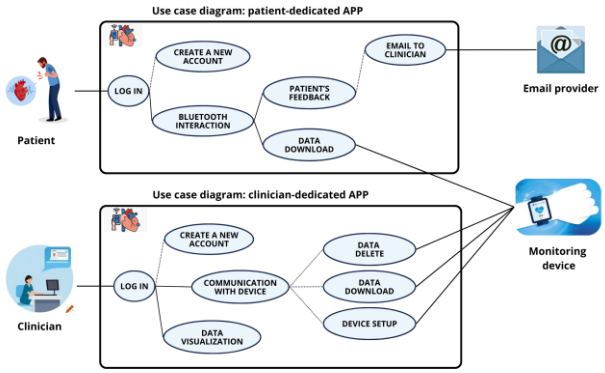

Fig. 1. Use Case Diagram of the system including a patient-dedicated app and a clinician-dedictated software.

A. Patient APP

The APP's design was guided by the need for an accessible tool that integrates into daily life. It was designed for smartphones ensuring compatibility with commonly used devices. Key requirements include user-friendly interfaces paired with precise step-by-step instructions that simplify a) wireless connection to the device, even for users with minimal technical skills; b) easy interpretation of the data monitored, ensuring clarity even in the case of users with limited experience. Additionally, the APP must include a functionality for secure communication with clinicians.

B. Clinician software

According to Process Modelling [8], three main tasks are expected to be carried out by the clinician: 1) at patient enrollment, setting up the device with the required patient data before handing it over to him/her for telemonitoring; 2)

during follow-up visits, download and review the data collected by the device during its usage, and decide about storing it in the patient's electronic health records or deleting it; 3) when a potential upcoming acute episode is detected, receive the relevant data from the patient APP and review them. The MDS should allow clinicians to inspect clinical parameters without a physical connection to the device.

IV. User-centered APP Interface Design

In the following, we focus on the patient APP because it provides a good case study for usability-driven design. The APP is designed to pursue minimalism. This design approach ensures that users can easily access essential information, without being distracted by items they cannot interpret. The interfaces require only a few clicks for navigation, which helps eliminate confusion. In the phase of wireless data transmission via Bluetooth (Fig. 2a and 2b), the interface design is driven by the need for guiding the elderly patient through the process: the interface summarizes the services to be enabled on the smartphone, and their status. For data visualization, to support clear interpretation of clinical information and avoid false alarms, the APP includes a color-coding system similar to traffic lights (Fig. 2c and 2d). Traffic-light information prevents the user from being misled by clinical data he/she cannot fully understand. The user is instructed on the action to be taken on each color. The same system is used to provide historical information about the last 5 recordings (Fig. 2e). The historical data interface ensures that the user can share the results of their previous recordings with a caregiver weekly and that no relevant alarm is missed. In the end, a significant challenge for elderly users is their ability to contact healthcare providers and send relevant data when issues arise. The APP addresses this challenge by enabling users to send a pre-written email to their designated physician with just two clicks. To avoid false alarms, this option is available only when the patient's clinical data indicates a need for professional attention (Fig. 2d). The APP uses the user's selected email client (Fig. 2f).

V. Conclusions

This study proposes usability-driven considerations about the design of MDS APPs for telemonitoring applications. The issue is presented through a case study regarding chronic heart failure, a condition that typically affects the elderly population, which makes the design of an easy-to-use system mandatory. The patient-facing APP provides an immediate solution for monitoring the results of clinical tests during home care. Its design prioritizes simplicity and minimalism, featuring a streamlined interface and intuitive guidance tailored to meet the specific needs of elderly users. A clinician-facing software complements this system for facilitating informed decision-making. Together, these tools address essential usability challenges in digital health, fostering a seamless connection between patients and clinicians while simplifying the complexities of managing chronic conditions. Future works will validate the usability of the designed system through beta testing and data collection.

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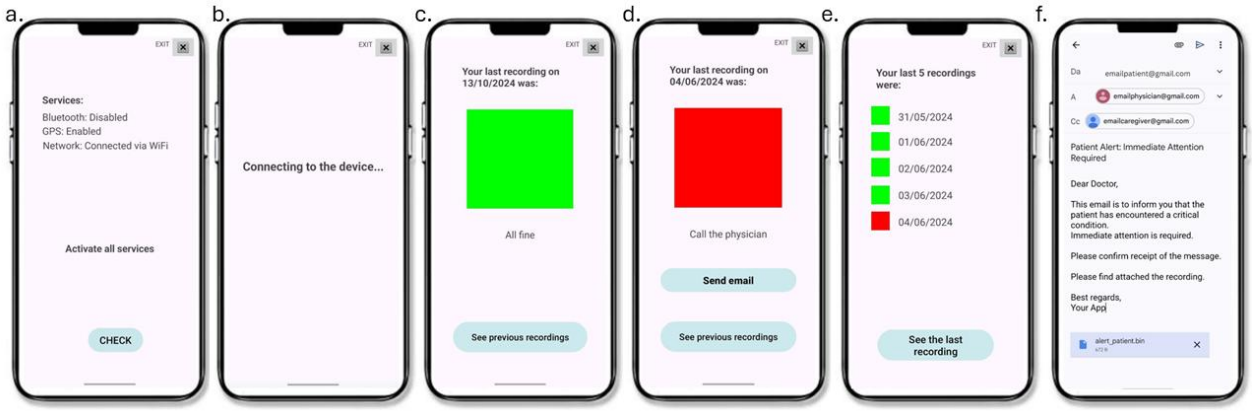

Fig. 2. Interfaces to check the habilitation of the necessary services (a) and the Bluetooth connection status (b); the status of the last recording, clinical status fine (c) or clinical status requires attention (d); the history of the status of previous recordings (e); and the pre-written e-mail to the clinician.