

Human-centered Design for a Chronic Disease Management System: An Explorative Case for Cystic Fibrosis

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Abstract— Background: Consistent self-management can improve symptoms and increase the quality of life of persons with cystic fibrosis (CF) who require daily care through following complex, time-consuming, and frequently changing self-management routines. However, it is challenging for many persons with CF to adhere to their self-management routines. Mobile health (mHealth) applications can support patients following and documenting daily treatment routines and medical history. **Objective:** This research aims to exploratively use the human-centered design approach (HCD) to identify needs and requirements to design an mHealth software concept for the disease management of persons with CF that includes secure data storage and communication with health care providers (HCP). **Methods:** The HCD process, as defined in ISO 9241-210, was used. Semi-structured interviews and a focus group interview were conducted with three adult persons living with CF, and two experienced CF nurses to explore the needs, challenges, and requirements for daily CF routines, nursing, and therapies. The interview transcripts were qualitatively assessed by thematic analysis, and the results were validated against previously published studies. The identified requirements were then used to design a technical software concept. **Results:** Participants expressed a need for patient-centered documentation that supports treatment adherence, enhances communication with their healthcare provider team, supports recalling their medical history, and overall enhances patient empowerment. The proposed features of the concept rely on daily documentation between clinic appointments, reminders and adherence checklists, a secure and direct communication channel with the healthcare provider team, medical summary reports, and customizing the application to individual user needs. This input made it possible to describe a user workflow and software functionalities using low-fidelity mockups. Based on the user workflow, a secure software architecture was developed. Prominent features are an in-person authentication process to define a trusted, secure, and direct communication channel between the self-management and HCP system. Furthermore, a clear separation of data storage and access is proposed, where the patient has full sovereignty to decide which data should be shared. **Conclusion:** We found that the HCD approach, particularly the use of stakeholder interviews, represents a feasible way to support the design of an mHealth software architecture in the context of CF. Further research in this domain is encouraged.

Keywords— telemedicine; cystic fibrosis; self-management; human-centered design; patient-centered care; software design

I. INTRODUCTION

Cystic fibrosis (CF) is a genetic, life-limiting multi-organ disease where a buildup of viscous secretion primarily effects the lungs, the digestive system, and the pancreas [1]. Pulmonary exacerbations, decreased lung function, and being underweight are some of the symptoms that reduce quality of life (QoL) and increase morbidity and mortality [2]. The life expectancy of persons with CF has increased over the last decades. Newborns diagnosed with CF as of 2009 are now estimated to reach their 50s [3]. This leads to an increased patient population and a shift in the age structure from mainly children and teenagers to a majority adult population living with CF [3, 4]. The increase in life expectancy and patient population emphasizes the strong need to improve and support self-management, driven by the lack of primary care support in the community [3].

To prevent disease progression, persons with CF need to follow a rigorous and time-consuming self-management routine lasting on average two hours a day, consisting of airway clearance, nebulized and oral medications, physiotherapy, exercise, and nutritional supplements. The condition can be positively influenced, and symptoms can be decreased through daily and consistent therapy [5]. However, numerous studies have shown that CF patients face many barriers to self-manage effectively, such as disease progression, mental wellbeing, fears of side effects, the complexity of the treatment, the treatment duration and unstructured days [5–7]. Non-compliance to self-management routines result in increased hospitalizations, time off school or work, and poor morale. Therefore, there is a need to provide tools to support efficient self-management and treatment adherence [5]. Self-management intends to help patients with chronic disease to understand their medical condition and cope with their treatment regimens better. It aims to decrease pulmonary exacerbations and hospitalization, which

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inevitably increases life expectancy, QoL and reduces health care costs [8–10].

Several reviews have observed a positive effect of digital self-management approaches, especially mobile health (mHealth) applications that allow collecting, monitoring, and reporting symptoms on the move. These mHealth applications can positively affect patients' lives, support self-management for chronic conditions, and reduce hospital (re)admissions [11, 12]. mHealth applications could lead to more patient-centric approaches and provide unique communication channels using telemedical applications [13]. Therefore, designing suitable mHealth applications that support individual regimens and adapt to user needs as well as changes in context are necessary [14]. This is especially important for diseases with complex and ever-changing self-management routines, such as CF [15].

However, previous mHealth solutions for CF self-management have faced adoption issues or have not accounted appropriately for user needs [13, 16]. mHealth designers and developers often assume the needs of their target population, which biases the results and often leads to "one-size fits all" solutions that do not fulfill user requirements [17]. Therefore, user involvement e.g., in form of the human-centered design (HCD) approach, is highly recommended and expected at the level of best practice for designing digital health applications [18–20]. A user-centered approach is essential to involve participants in the design and development process to maximize long-term engagement with the application [21].

In the context of CF, Hilliard et al. [22] and Floch et al. [23] used an HCD approach to identify needs and requirements from persons with CF, respectively additionally care takers and health care providers (HCP). They reported a lack of mHealth applications explicitly tailored to CF and their participants expressed the wish that all relevant functionalities are represented in a single application. Rutland et al. [24] used an HCD approach to identify if the Swedish Genia app [25] is applicable for a US target group. They showed the importance of identifying user needs for the adoption of existing mHealth systems to a new target group in a different country by identifying missing functionalities and reporting issues regarding translatability to the local clinical environment [24].

A recent study by Martinez-Millana et al. [13] analyzed and categorized twelve CF applications listed on the myhealthapps.net directory [26]. Their results showed that most applications focused on education; some provided medication reminders and tracking of disease management aspects in a health diary. Applications rarely targeted communication with HCPs [13]. In a pre-search, we found that three out of the four applications targeting health diaries for persons with CF had not been updated in years or were no longer available. Other problems with existing apps are that they often require a country-specific registration or national Appstore access, limiting broad usage. Vagg et al. [27, 28] built a smartphone application allowing Irish persons with CF to track basic aspects of their disease, mainly targeting to document data collected and discussed during clinical appointments. Other studies in contrast highlighted a need for daily health diary applications [22, 23]. It is evident that much work is still needed to understand how to drive adoption and long-term engagement with CF health diary applications, that persons with CF are willing to use on a daily basis.

Health-related information is regarded as particularly personal and sensitive data according to the European General Data Protection Regulation (GDPR) [29]. A recent study indicates that most participants had concerns about their privacy using mHealth applications. They also stated that a lack of security features, costs of applications, and providing personal information for testing the application were barriers adopting mHealth applications [30]. Nurgalieva et al. [31] concluded their scoping review: *"Despite increasing awareness and research activity addressing the security and privacy of digital health interventions in recent years, there are still substantial gaps in the field."* Hence, the software concept presented in this study uses state-of-the-art security features and focuses on trustful communication.

This research aims to exploratively use the HCD approach to identify user needs and requirements to design an mHealth software concept for the disease management of persons with CF that focuses on secure data storage and communication with their HCP. The elaborated concept relies on daily patient-centered documentation to provide a medical history to CF nurses and physicians. Combining qualitative research with a technical concept in one mHealth publication is rarely presented. Still, it highlights the potential of using an HCD process for designing a chronic disease management system (CDMS) for CF nicely.

II. METHODS

A. Study design:

The HCD approach, as defined in ISO 9241-210, was used to involve the potential users, in this case, persons with CF and CF nurses, in the development and design process of the system [32]. The potential users were involved in the first two HCD phases *"understanding the user context"* and *"specifying the user requirements"*, which led to a technical concept meeting the user requirements. This research used a qualitative study design employing semi-structured interviews with CF patients and a focus group interview with CF nurses, which were conducted in June 2019 in Ireland.

B. Recruitment and sample:

A clinical microbiologist identified candidates to be invited to participate in this study. Participation was voluntary and could be discontinued at any time. Interviews were audio-recorded, transcribed, and anonymized. The interview topic guides were informed by previous research [22, 23, 33] and finalized in consultation with a clinical microbiologist and an experienced qualitative researcher. For the semi-structured interviews, the inclusion criteria were adults with a confirmed CF diagnosis.

C. Procedure:

The standardized measure of health status EQ-5D-5L questionnaire, consisting of a descriptive system and a visual analogue scale (EQ-VAS), was used to quantify the well-being and current health situation of the participating persons with CF. The latter EQ-VAS measures the best possible well-being subjectively on a scale from 0 to 100 [34]. Due to the risk of cross-infection, all participants were interviewed separately. Two experienced CF nurses participated in a focus group interview. They were chosen to represent the HCP side as they are the communication link between patients and the interdisciplinary HCP team in Irish CF centers.

To conduct the semi-structured interviews, an interview topic guide was created to explore their self-management routines, disease challenges, needs, and system requirements. An excerpt of the topics is shown in *Table 1*. The focus group explored ideas regarding a patient-centered CDMS and a telemedical application to connect patients with their HCPs. It was also essential to understand the treatment and self-management challenges from an HCPs perspective. An extract of the key topics from the used interview topic guide is shown in *Table 2*.

D. Data-analysis:

The patient and focus group interviews lasted between 60 and 90 minutes. They were audio-recorded with Audacity® recording and editing software [35] and were transcribed verbatim and anonymized by the first author. The patient interviews were thematically analyzed following the methodology introduced by Braun et al. [36], which is a qualitative analytic method used to find related topics and themes in the interviews. This approach entailed reading each transcript multiple times to become familiar with the data, identifying emergent patterns, coding the data with unique labels and generating themes and sub-themes [36]. Recurring topics in the transcripts were highlighted and coded in two rounds until saturation of themes was achieved that resulted in the final codebook [37]. Due to the small number of interview participants, the findings were intensively compared to previous studies to consider a wider target group, different healthcare systems and to ensure comparable results.

TABLE 1 INTERVIEW TOPIC GUIDE PERSONS WITH CF – EXTRACT OF KEY TOPICS

Categories	Topics
Demographics	Gender; age; profession; employment status; proficiency with the use of technology and mobile devices
Experience with cystic fibrosis	Personal experience with illness; regular therapies; daily self-management routines; changes in health; and self-management routines over time
Healthcare experience	Treatment experience; relationship and communication with their HCPs
Information management	Which information is documented; how information is recorded; daily symptom and treatment tracking; digital recording of information
Feature requirements	Sharing health information with HCP; thoughts and ideas on a telemedical CDMS; system requirements and features; motivation to use a CDMS

TABLE 2 FOCUS GROUP INTERVIEW TOPIC GUIDE CF NURSES – EXTRACT OF KEY TOPICS

Categories	Topics
Demographics	Gender; age; experience as a nurse working with CF patients
Ideas on a CDMS	Important aspects and ideas for a self-management system for patients; items a patient needs to document; perspective on patient recorded data; a medical summary report with health events; challenges of patients self-management
Ideas on a tele-medical application	Medical data documentation; reasons why patients seek contact; requirements and needs for such a system; clinical workflow; interaction and communication through a telemedical application; providing information; motivation to use a CDMS
Aspects from patient interviews	Control of shared data; patient empowerment; communication; adherence; customization

III. RESULTS

All interview participants had extensive experience with their condition and their self-management routines. Two females (F1 in her 30s; F2 in her 40s) and one male (M1 in his 40s) with CF were interviewed. All participants were Irish. The spectrum of the disease was represented by different severity stages of CF, ranging from a stable controlled disease to post lung transplantation for end stage lung disease. The results of the QoL questionnaire resulted in overall positive well-being scores of twice 85 and one 93 on the EQ-VAS score. Only one participant mentioned slight problems with usual activities and slight pain or discomfort. They were experienced in using smartphones. The CF nurses were very experienced working with CF patients for more than 18 years and could contribute with extensive knowledge.

A. User Needs and Requirements

The user needs and requirements identified from the interviews are presented in *Figure 1*, which resulted from a further synthesis of the identified topics of the thematic analysis.

1) Persons with CF expressed a need for:

- a. Improving and facilitating adherence to treatment and self-management routines.

“There were times in college I was busy and might have skipped a nebulizer. Sometimes I got really annoyed about myself, because I got bad in doing things, so I made a list for myself and put it on my board and make myself tick off, what I was doing and have a compliance percentage I had to meet, e.g. I had to be 80% compliant.” [F1]

“Oh yeah reminders for your medicines, I have a lot of alarms on all of my phones!” [F1]

- b. Personal daily patient-centered documentation to track treatments, health events, and medical measures and note information provided during appointments.

“I kept track of my lung function, my C-reactive protein (...), so I keep track of what they were, so I be able to tell doctors what I am up to really quickly. What was important to me was to keep track of side effects and antibiotics, because I could tell them what antibiotics I was on in the past and if they work or not.” [F1]

- c. Increasing memory recall during appointments regarding their medical history, recent health events, and treatment-related aspects.

“It is helpful to record things for memory recall. Let’s say I had a lung bleeding in the recent past, the longer from the event the less you remember about it. So, if the medics ask relevant questions around that event, your memory of the event gets more faded.” [M1]

- d. Patient empowerment and shared decision-making by increasing treatment participation and knowledge of their disease.

“We should work as a team and it is me who lives with CF and it should be me who needs to make the decision, as right or wrong they are, but he (my

physician) has given good advice, even he has not always agreed with how I did things.” [F2]

“I am an expert with my CF!” [F2]

- e. Improved communication with HCPs and sharing information through a direct channel, especially to CF nurses.

“Every time they (CF nurses) are the first port to call. You talk to them before seeing or talking to a doctor. It is consistently the same nurses whereas you don’t necessarily see the same doctors.” [F2]

“Depends what the data is, I would not be comfortable with them just accessing a whole range of parameters (...), I rather would like to have some control on the data I provide to them, so I can control what I sent to them.” [M1]

- f. Non-functional aspects like safe storage of medical and personal data, time efficiency, user-friendliness, a visual user interface (UI), and restricted access for HCPs.

“It has to be easy, it can’t be anyway like work. Simple, easy, and telling Siri to do it would be good.” [F2]

2) CF nurses expressed a need for:

- a. Digital support for administrative tasks like scheduling appointments, sending prescriptions to pharmacies, and providing work, college, or travel certificates.

“In between visits, the obviously first one would be if they were sick, so if someone would be acutely unwell. (...) Then we have patients ringing us for prescriptions, so they all have to be organized through us. (...) It could be to write a letter to support them to get into housing or social welfare. health insurance letters, doctor’s certs, work certs and sick certs for work.” [N1]

- b. A direct communication channel to address specialists directly.

“A system could maybe link up to different specialties and not coming through the CF-nurses for everything within the team. They come through us if they want something from their dietitian, about their dietary intake or if there is a problem with their medications or say diabetes.” [N1]

- c. Tracking of treatment goals, adherence, and relevant information for memory recall.

“We see compliance or non-compliance as a huge issue. We find that a good majority of the patients don’t take their medications, nebulizers, they don’t do their physiotherapy treatments.” [N1]

“I don’t think it’s in some cases deliberate non-compliance, but I think in a lot of times it is a lack of self-awareness of how compliant they can be.” [N2]

- d. Electronic patient-centered documentation due to challenges with paper documentation in the hospital, e.g., information that is hard to find, sometimes misplaced, and the absence of any data summary or visualization.

“If we order the chart, like it’s not unusual for folders to run to 17 folders, so trying to get the newest or accurate data or data that goes back two or three folders is very hard. There are no summary sheets and there is no handover from folder to folder to say this happened on these dates or look here for this information.” [N2]

As depicted in Figure 1, the needs of persons with CF and CF nurses resulted in requirements for the technical concept of a telemedical CDMS. These requirements are presented from the perspective of the persons living with CF and are listed in Table 3.

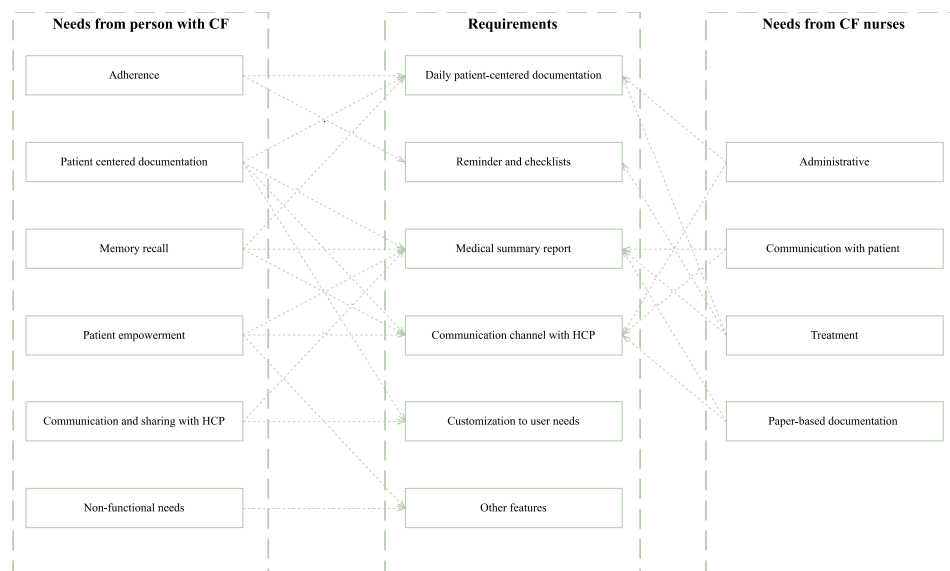


Figure 1 User needs from persons with CF (left) and user needs from CF nurses (right) transferred into requirements for the self-management application (middle). The requirements evolved from the user needs which are presented by the arrows. Cystic fibrosis (CF), Healthcare provider (HCP)

TABLE 3. IDENTIFIED REQUIREMENTS FOR A TELEMEDICAL CDMS:
HIGHLIGHTING SOLUTIONS FOR UNMET NEEDS FROM A SELF-MANAGEMENT APPLICATION PERSPECTIVE

Requirement	Requirement description	Unmet need addressed
1. Documentation <i>a. Documentation input</i> <i>b. Visualization</i> <i>c. Up-to-date medication list</i>	<i>a)</i> Subdivided into general CF information, appointment documentation, and daily treatment and symptom tracking. The user can provide documentation input for the health diary that is used for visualization. - General CF information: Information relating to the CF disease that changes seldom - Appointment section: Document health measures, goals, and notes communicated during an appointment - Treatment section: Document daily treatments, health measures, and health events, such as symptoms, general well-being, exhaustion, etc. <i>b)</i> The measures and health events are visualized in graphs and timelines to show trends and compare good and bad episodes. <i>c)</i> The user can keep track of their current medications.	1b) Daily patient-centered documentation to keep track of medical history, self-management routines, current medications. 1c) Improve recalling medical history through visualization of medical data that shows disease progression trends. 2a/c) Improve administrative and treatment related workflow in hospitals.
2. Reminder <i>a. Reminder/ Checklist for adherence</i> <i>b. Dashboard</i>	<i>a)</i> The user can set reminders for treatments, appointments, and prescriptions to support treatment adherence. The reminders are highly customizable for specific times, repetitions, and alarm patterns; notes can be added. <i>b)</i> All reminders and treatment tasks for a day, week, or month are presented in a dashboard as a checklist.	1a) Improving daily self-management and treatment adherence.
3. Medical Summary <i>a. Generation</i> <i>b. Visualization</i> <i>c. Share and print</i>	<i>a-b)</i> The user can generate a customized medical summary report, which visualizes the documented information for a chosen timeframe to provide an overview of their health status. <i>c)</i> The documents can be printed and brought to an appointment or shared with an HCP through the built-in secure communication channel or via e-mail.	1c/e) Improve memory recall and communication during hospital appointment. 1d, 2b/c) Strengthens patient empowerment by shared decision making through keeping own medical record. 2d) Improves treatment and reduces mistakes by targeting issues with paper-based hospital documentation.
4. Communication with HCP <i>a. Direct and secure communication channel</i> <i>b. Share selectively</i> <i>c. Request prescription</i>	<i>a)</i> A direct communication channel to the HCP can be initiated through an in-person authentication process, ensuring secure, transparent, and encrypted communication. <i>b)</i> The person with CF has full control over the shared information. The HCPs can only access the information shared with them through the communication channel. <i>c)</i> The user can request new prescriptions by transmitting their medication and pharmacy details.	1e, 2b) Improve communication during hospital appointments. 2c) Sharing medical summaries to improve therapy decisions. 2a) Streamline administrative requests, e.g., prescription, certificates, and appointments.
5. Customization to user needs <i>a. Reminders</i> <i>b. Medical summary</i> <i>c. Documentation modules</i>	<i>a-c)</i> The user can customize reminders, their medical summary report, and which documentation modules they need. They can select the documentation modules, e.g., a diabetes module, a communication module, or a transplantation module, according to their specific needs and disease progression.	1b/e) Adapt application to individual documentation needs, regarding demographics, disease progression, well-being, medical conditions. 1f) Simplify UI, easy and fast documentation workflow.
6. Other requirements <i>a. Backup, synchronization, export</i> <i>b. Data autonomy</i>	<i>a)</i> All information is synchronized and backed up encrypted through the internet and can be synchronized to different devices. <i>b)</i> The person with CF is in charge of their health-related documentation. HCPs do not have direct access to the data stored on the patient system.	1f) Synchronization and backups to access medical data on different devices. 1d) Person with CF decides which data is shared. Full control over recorded medical data.

A. Software Concept

A technical concept for a telemedical system divided into three subsystems was developed based on the presented requirements. The self-management system for persons with CF, the HCP system, and the communication system are presented in *Figure 3*. The self-management and HCP systems are strictly separated regarding user access and data storage. Information can be exchanged securely and encrypted between the self-management and the HCP systems through a clearly defined communication channel, which requires an in-person authentication. This architecture concept focuses on the self-management system, which is fully functional as a stand-alone app, and the secure communication channel to the HCP system. Therefore, the high-level architecture abstracts the HCP system to the needed interfaces and concentrates on securely storing and exchanging the health-related documentation with the self-management system.

1) Self-management system for persons with CF

The self-management system consists of a smartphone application and a web application server to synchronize between devices and backup the information. Users need to authenticate themselves with a username and login password combination when starting the application. The encryption and decryption of the medical documentation only takes place on the smartphone with an additional master password, chosen by the user. The smartphone is considered a trusted boundary since it is a personal belonging of a user. The web server only stores encrypted information; therefore, the data is not accessible without the encryption keys. The application synchronizes the encrypted data with the server through a secure communication protocol when the device is connected to the internet.

The server connected to the app is considered a trusted boundary that uses a classical three-tier architecture containing a web server, an application server, a database [38],

and an additional user- and key-management for storing the encryption keys. Information within the entire application is separated into encryption keys and medical data (MDAT). All information stored on the server is encrypted and cannot be decrypted by the server itself or by a not authorized person who gains access. The storage of the encryption keys is separated from the MDAT storage to ensure the defense of depth paradigm [39]. If an attacker gains access to one storage, they still do not have access to the second storage and the user's master password.

2) HCP system

The HCP system uses the same architecture as the self-management system. However, users can access the web application through a browser that could run on a (shared) computer in a hospital, a CF center, or a private practice. Those computers should not be considered trusted and secure devices since, in general, computers in a hospital are shared by many people. Therefore, all the encryption keys and MDAT get removed from the browser cache when the HCP logs out or is logged out by the system after inactivity.

3) Communication system

An in-person authentication process is proposed to set up an encrypted and direct communication channel between a person with CF and an HCP. This process ensures that both parties know each other before communicating and sharing information, developing trust on both sides. During the authorization process, each party's shared communication key and profile information are exchanged through a quick response code (QR-code) in person. A shared communication key is necessary to encrypt and decrypt the data sent in messages on both systems and ensure that a third party cannot read the transmitted information.

4) In-person authentication process:

- The HCP generates a QR-code in their web application containing a communication identifier (ID), a communication key (shared secret), and profile information.
- The person with CF starts their application and uses their smartphone camera to scan the QR-code. Now the self-management application receives the HCP's profile information, the communication ID, and the communication key (shared secret) for encryption.

- The person with CF and the HCP need to confirm the opposite participant's details to store the communication key in both key management systems.
- The self-management application sends a message to the communication server, which contains the profile information of the person with CF that has been encrypted with the shared communication key.
- The HCP system pulls the messages from the communication server, where they are saved temporarily, and decrypts the message with the communication key. After downloading the message, the communication server receives a confirmation and deletes the message.

As a result, both parties can exchange messages with each other through a secure communication channel.

5) Key management: Encryption and decryption

The key management on the self-management server and the local smartphone storage stores the MDAT encryption key and the shared communication keys encrypted. This allows the synchronization of the encryption keys between devices to decrypt the MDAT and communication enquiries on the smartphone itself. All encryption keys get encrypted and decrypted with the user's master password to ensure that the data is only decrypted on the smartphone itself and never on the server. The decryption process is presented in *Figure 2*. MDAT and new communication messages get encrypted on the smartphone by following the procedure in reverse.

This decryption process in *Figure 2* is mainly comparable to the decryption process used by the HCP system. Instead of the smartphone, the de- and encryption occurs in the web browser on a shared computer. The HCP user logs into the application with their username and login password. Through this authorization, the user management provides access to user specific MDAT and communication keys from the key management system. The encryption keys are only decrypted in the browser application with the user's master password. This allows local decryption of the MDAT and the communication messages with the associated keys. The keys are stored securely in the session cache of the browser and are terminated after logging out. New messages and changes are encrypted in the browser and are securely transmitted to the server.

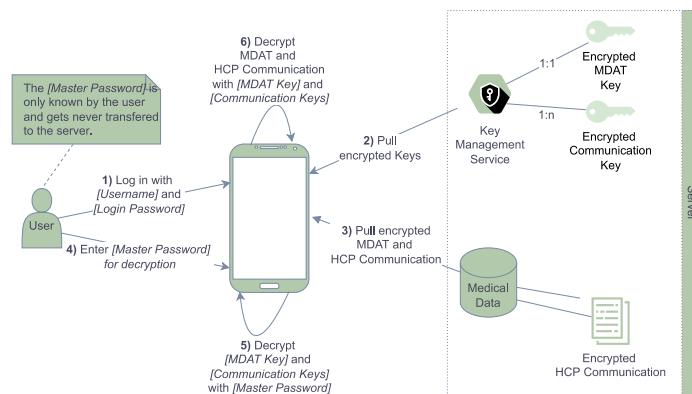


Figure 2 Decryption process and key management of the self-management application. Medical data (MDAT), Healthcare provider (HCP)

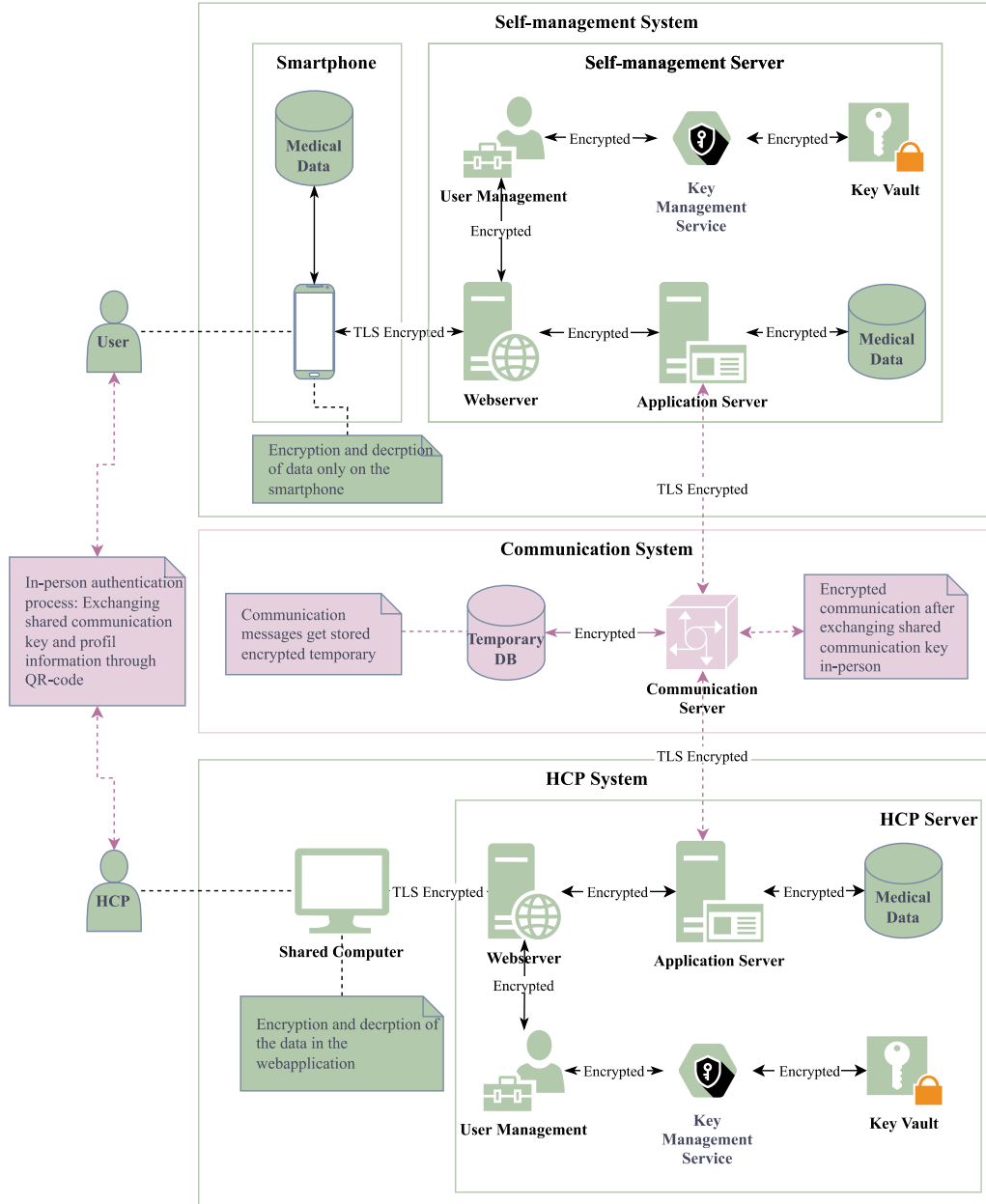


Figure 3 Architecture concept: Secure communication between the self-management system and the HCP system through the communication system. Healthcare provider (HCP), Transport Layer Security (TLS)

B. User Interface Concept

In the following, exemplary mockups are described to understand the application's features better. In Figure 4a, the QR-handshake is presented, which is required to exchange the communication key between the self-management and HCP systems. The communication between the patient and the HCP is shown in Figure 4b and Figure 4c. It is based on enquiries,

where an enquiry describes a case-based problem, question, or in general, a communication request. Enquiries can be opened by either the patient or the HCP and can be used to start a conversation. Each side can terminate and archive these to keep an overview over current and open enquiries. As shown in Figure 4d, a medical summary report can be added to an enquiry to provide related medical information.



Figure 4 Mockups: a) Connect to HCP app b) Communication: Overview of enquiries c) Communication: New enquiry d) Medical summary report

IV. DISCUSSION

This study aimed to identify the needs and requirements of persons with CF and CF nurses and proposes a technical concept of a patient-centered telemedical CDMS. Our findings provide direction for the future development of mHealth systems, especially ones that connect patients with their HCPs in a secure way. While this study addresses and focuses on the needs of persons with CF, it is likely that the presented ideas, requirements, and aspects of the technical concept are transferable to systems targeting other chronic diseases with complex self-management routines, e.g., asthma, diabetes, and cancer that share comparable treatment burdens [40].

1) User needs and requirements

The participants clearly stated a preference for a self-management application for CF, as previously shown by Hilliard et al. [22]. They saw a strong need for patient-centered documentation to keep track of daily treatments, health measures, and health events. The documentation is the center of the CDMS and supports all other features. In contrast to previously published concepts [28, 41], the focus of this application is to provide longitudinal daily documentation rather than documentation centered around hospital appointments. However, the participants also stated that documenting appointments was a vital need, mainly motivated by difficulties with paper-based documentation in hospitals.

Adherence to self-management routines is one of the biggest challenges for persons with CF. Therefore, documentation, checklists, and reminders were desired to aid treatment adherence [33, 42, 43]. The CF nurses emphasized the need to set and document treatment goals, visualize them for patients and follow up on them later as goals are often misinterpreted and consequently not achieved. Setiawan et al. [44] targeted this problem by providing a dedicated module in their mHealth application.

A critical challenge shown before and highlighted by participants in this study is memory recall [28, 41]. A medical summary report suggested in this research can highly benefit from recalling important aspects. All participants saw a need for stronger patient empowerment. These findings were equally emphasized in Floch et al. [23] and Hilliard et al. [22]. In our study, persons with CF

highlighted communication problems with their HCP team, which was partly explained due to physicians regularly changing departments. Providing personal documentation containing the most important health measures with a trend overview can enhance communication significantly [22, 28]. Generally, participants were willing to share data with their HCPs, as long as they maintained control over content and recipients, which is supported by Floch et al. [23]. Patients already used to telling HCPs about their behaviors were willing to share data more openly [45].

The participants were opposed to a system that would allow close monitoring and permanent access to the documentation for HCPs. CF nurses stated that they would not have the time to check weekly or monthly summaries regularly, which confirms previous findings by [22, 23]. Therefore, the patient should send medical summaries through the communication module in addition to a question or a concern. This differs from solutions with a strong telemedical focus, where a continuous data exchange and telemonitoring is targeted [25, 44, 46, 47].

Customizing the application to individual needs was an important requirement, as documentation needs change over time regarding the disease progression, especially when new symptoms occur [45]. To support this customization, a modular approach is contemplated, where required modules can be selected, and unnecessary ones can be deselected. This reduces documentation possibilities and simplifies the UI while still providing various documentation options in case of changing needs. The modular approach allows to adapt the application to other chronic diseases by developing specific modules. Vilarinho et al. [43] included context, age group, and user group (children with CF, parents, adults with CF) into their customization. Setiawan et al. [44] presented a modular approach that is adaptable by either the user or the HCP and incorporates customization for educational material.

The most prevalent non-functional requirements were time efficiency and minimizing user burden, user-friendly design, and data security [22, 23, 43]. This application was developed from a patient-centered perspective, where also the interviewed CF nurses focused mainly on the self-management system for persons with CF. Therefore, an in-depth requirements analysis for the HCP system and

involvement of other HCP specialists needs to be carried out in the future.

2) *Software concept*

A patient-centered self-management application should be accessible for everyone and not limited to specific institutions or countries. Apart from the communication module with its secure communication channel, all functions are usable without the telemedical counter system on the HCP side. Integrating a new system into hospital environments is complex and requires changes in the treatment process [13]. Therefore, the focus of this research was on the self-management application for persons with CF.

All participants expressed the need for a secure communication channel, where the person with CF can decide which information they like to share with their HCPs. Designing a secure application including a secure communication channel was done by incorporating privacy by design and the CIAA security principles (confidentiality, integrity, availability, authenticity) [29]. This was achieved by using state-of-the-art security patterns and technologies, including user authentication, encrypted MDAT, secure communication protocols, trust boundaries, and an in-person authentication process to exchange the shared encryption key for a trustful communication [48–50]. Ensuring that sensitive health-related data is handled GDPR compliant should be considered in the design process [29–31]. Most mHealth users in the study of Zhou et al. [30] wished for explicit encryption for data stored on the smartphone as well as remote on a server. They also stated that the mHealth application should require specific user authorization [30] because many smartphone users do not use basic authentication features to secure their device [51].

Another aspect mentioned several times during the interviews was the need for a trustful relationship with their HCPs to strengthen patient empowerment and enable open communication. To incorporate trustful and transparent communication, an in-person authentication was proposed, so the communication partners can verify each other before opening the communication channel. This process was loosely inspired by the verification ceremony of encrypted messengers [52]. Scanning a QR-code is an easy and fast option to exchange encoded information. By exchanging a common encryption key in person, the risk of transmitting it through a non-secure channel is minimized, and the inconvenience of exchanging and entering a long key is removed [50]. While the keys are stored safely inside trusted boundaries, the communication is regarded secure, where only the intended users are able to encrypt and decrypt the messages. The key management stores the MDAT key and the communication keys, which makes it possible to access and decrypt the information from different devices and eliminates the risk of losing information in case of a lost or broken phone. The HCPs only have access to the communication messages and the attached medical summaries. This data is stored encrypted in the HCP system as well as in the self-management system.

3) *Summary of novel findings*

Persons with CF addressed an unmet need to document their daily treatment routines and medical history in a patient-centered longitudinal documentation, that provides medical summaries to improve recalling medical history during hospital appointments. CF patients often struggle

with adherence to their complex treatments and self-management routines, which could be improved through daily documentation and reminders.

Between hospital appointments the participants expressed the need for a direct and secure communication channel, that allows a trustful communication. This was highlighted through introducing an in-person authentication process to start an encrypted communication channel. The presented architecture concept focused on a loose telemedical coupling, an encrypted and clear separated data storage, and a secure communication channel. This novel design gives persons with CF full autonomy and control over their medical data, by allowing them to share their medical data selectively and secure with their HCPs.

4) *Limitations*

Due to the qualitative nature of this study and the low number of participants, confounding cannot be excluded. There is a reality to conducting qualitative research, funding constraints and difficulties recruiting participants are common issues. However, the participants of this study were male and female, had different levels of disease severity and complexity of treatments, and were actively involved in Irish CF patient organizations, highlighting their awareness of the needs of a broader CF patient population. After comparing the results of this study to previous studies, we conclude that the results presented here are representative of a larger proportion of the target population (persons with CF and CF nurses).

The interviews took place in Ireland, and all participants were Irish. Thus, there is a chance that the results may not be transferable to other healthcare systems and cohorts. There is the possibility of selection bias regarding the older, highly educated participants that had significant experience with their condition. Therefore, a younger, less experienced, or less educated cohort might have additional needs and requirements. As the participating CF nurses were very experienced and worked in the same hospital for a prolonged time, they might have difficulties imagining a new system or a different workflow.

For this study, we chose CF nurses to represent the HCPs, as in Ireland, they are the communication link between the patient and the hospital. Before developing the system, other HCPs from different specialties, such as physicians, physiotherapists, dietitians, etc., should be interviewed to understand their needs and requirements for the system. An evaluation of the proposed needs, requirements, mockups, and authentication process is planned with adults with CF and CF nurses.

V. CONCLUSION

We found that the HCD approach, particularly the use of stakeholder interviews, represents a feasible way to supplement the design of an mHealth software architecture in the context of CF. This study presents user needs, system requirements, and a technical concept for a patient-centered telemedical CDMS for persons with CF.

The user requirements emphasize patient-centered longitudinal documentation, a secure and direct communication channel with HCPs, a medical summary report, and application customization. Our study findings

confirmed previously reported user needs and requirements and highlighted potential improvements that could be achieved with a well-designed self-management application. The presented technical concept focused on a secure architecture design of a telemedical CDMS. Further research in this domain is strongly encouraged.

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