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Chapter

Designing Heterogeneous-mHealth Apps for Cystic Fibrosis Adults

Tamara Vagg, Cathy Shortt, Claire Fleming, Mairead McCarthy, Sabin Tabirca and Barry J. Plant

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Abstract

In this chapter, we will discuss the design and development of a patient passport mHealth application for Cystic Fibrosis adults from ideation to app-store release. By allowing the patients access to their own unique data, it is anticipated that it will be of benefit when travelling abroad and between CF centres. The design process followed a pipeline we developed that is informed by patient and healthcare professional input. The app structure resembles an Irish patient file and is divided into three categories: "My CF Info", "My Medical History", and "My Clinical Appointments". My CF Info allows the patient to store personal information such genotype, medical team contact information, physiotherapy, allergies, and medications. My Medical History allows the user to record information such as CF renal disease, CF diabetes, and the insertion/removal of a portacath/gastrostomy tube. My Clinical Appointments allows the user to record the type of appointment (annual assessment, clinic, other) and all information that would ordinarily be inserted into a patient file such as weight, height, spirometry and other comments. Weight and lung function are also displayed in a plot graph. The app has undergone pilot testing with five CF adults before being rolled out onto the Google Play Store.

Keywords: cystic fibrosis, patient passport, mHealth, digital health, self-management

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1. Introduction

Cystic Fibrosis (CF) is the most common life limiting genetic disease affecting Caucasians. Patients must adhere to rigorous therapies in order to manage their condition. Such therapies include airway clearance physiotherapy, medications, diet, and exercise.

Ireland has the highest prevalence of CF worldwide, with 1 in 19 people being carriers for the CF gene [1]. Despite this, the life expectancy of patients with CF is rising. A child born with CF in 2009 is now predicted to live into their 50s [4, 5], compared to children born in 1950, of which half would live to the age of 16 and only 3% to 25 years old [2, 3]. However, this increase in life expectancy comes with an increase in patient population. There are now more adult CF patients than pediatric patients in Ireland [6]. It is projected that the pediatric service will need to grow by 25% and the adult service by 75% by 2025 [7]. This growth in adult population and the advent of ICT technologies in the medical space has led to mobile health applications (mHealth apps) being identified as potential powerful

tools to assist the growing and ageing CF population in the management of their condition. However, any mHealth app developed in this way must be fully personalisable in order to fit the heterogeneous nature of the treatment and management of CF.

In this chapter we will discuss the design and development of a patient passport mHealth app for CF adults; from ideation to app-store release. This chapter will first begin by introducing the CF unit responsible for its development, before discussing patient passports. Following this, the chapter will introduce the development of this mHealth app which follows the mHealth Design Pipeline as presented by Vagg et al. [8].

1.1 Cork CF multidisciplinary team

CF clinical care is driven by a multidisciplinary team approach. The CF Multidisciplinary Team (MDT) comprises of a mixture of healthcare professionals with varied skill sets to support this multisystem condition. This includes a CF nurse specialist (designated and working full time in CF care), CF physiotherapist (designated and working full time in CF care), and CF dietician (designated and working full time in CF care). The team is supported by a respiratory technician (with a commitment to CF) and psychologist. The MDT is medically-lead by a respiratory specialist with an interest in CF. The respiratory physician/specialist is also supported by a lung-disease research/specialist registrar [9].

The CF MDT at the Cork University Hospital includes: three CF nurse specialists (>30 years collective full time experience in CF care), one dietician (>10 years full time experience in adult and pediatric CF care) one senior physiotherapist (>5 years full time experience CF care), one respiratory technician (>20 years full time experience), and one CF consultant with 10 years as the director of the Cork unit and 10 years' experience in other leading centers both nationally and internationally.

This multidisciplinary team supports the second largest CF center in Ireland with over 180 adult CF patients. The Cork CF multidisciplinary team also lead CFMATTERS; an international multicenter consortium exploring antibiotic therapies in CF [10]. In addition to this, the research team includes a dedicated medical-multimedia research specialist who works directly with the MDT.

1.2 Patient passports definition and review

A patient passport is described by the National Quality Forum (NQF) and Health Service Executive (HSE) as a paper-based system which provides immediate and important information regarding a patient's health or condition to medical professionals [11, 12]. This passport system is implemented for a number of reasons, such as improved patient experience, improving the speed that care is delivered, and as a solution for those patients with learning disabilities [11, 12].

An example of such a passport can be seen for asthma management in the research conducted by Newell et al. [13]. The paper-based passport as presented in this research is developed to store pertinent medical information that an asthmatic would require to receive care on entering an emergency room. Newell et al. found that patients would often experience more fear and stress in this situation as responding medical professionals may ask the patient to repeatedly speak to gain an understanding of this patient's condition, or leave the patient alone so that they can source the information. The paper passport solution is designed to be small and convenient to carry (the size of a credit card) and can provide medical professionals

the medical data needed to treat the patient immediately [13]. Another example of these paper-based passports can be seen in the research carried out by Barber et al. [14]. This passport was developed as a medication aid and allowed geriatric patients to record and review their medications and dosages. The researchers found that this system empowered patients to be more in control of their medication and also acted as a mechanism for the patient to communicate and discuss their medications more confidently with their medical team [14].

Patient passports have also been created for other long-term conditions, such as diabetes. Similar to other chronic conditions, diabetic patients must meet with various members of the multidisciplinary healthcare team. For diabetic patients, passports can be beneficial as they allow the patient to record medical data received from each member of the diabetes multidisciplinary team [15]. In this way, passports bridge a communication gap between patients and these various multidisciplinary members [15].

When researching "CF Patient Passports", only two bodies of work were found. The first was a book titled "The Cystic Fibrosis Passport" by Fitzgerald, which aims to aid family members in understanding the needs of children with cystic fibrosis, and to serve as a practical guide to those who care for these children [16]. The second was a quality improvement initiative taken by the Stanford CF Center, which presented a paper-based system that used a passport-sized document containing instructions on how to care for a patient with CF [17]. The document could be presented by a CF patient to a hospital or clinic to ensure the correct measures are taken to avoid potential issues with infection and cross-contamination. Although both passports are important for the care of CF, they do not include features common to long term condition passports as they do not facilitate self-reported medical data that is accessible to patients at all times.

In addition to paper-based CF passports, a search was performed for digital CF patient passports on both the Google Play and iOS mobile App Stores. From this search, only one app was found that allows CF patients to record their medical data, similar to a passport; "CF View" [18]. CFView is an app which was created by "CF Ireland", a CF charity in the Republic of Ireland. The app allows patients to view medical data that has been collected regarding their condition; however, it does not allow patients to enter or save data. In addition to this, CF patients can only use this app if they are part of a CF registry in Ireland, Denmark or Slovenia, and have been issued with an account by that registry. From the findings of the paper based and digital based search, it would appear that there is no freely or publicly available CF patient passport system that allows patients to record basic medical data. Considering the benefits of a patient passport, it can be stipulated that such a tool would be beneficial to adult CF patients.

1.3 Possible issues with patient passports

The previous section outlines cases where patient passports have been used advantageously for patients; asthma patient information, diabetic patient information, medication aid. However, patient passports can also present other challenges which may lead to low adoption rates and minimal impact on patient experience. To investigate this further, Dijkstra et al. interviewed diabetic patients and medical professionals to understand their experience of implementing the passport into their current care system [19]. Concerns expressed by the patients were predominantly focused on security, forgetting the passport, being over encumbered, and need for additional time to enter information into the passport. For security, patients were concerned of the ramifications of losing the passport and the threat

this may have on identity theft. Furthermore, some paper passports can be the size of a small A5 copy and cannot fit into a pocket easily. For this reason, patients expressed concerns with forgetting to bring the passport to clinical appointments and also friends or work colleagues seeing or finding the passport. As for time, patients felt that entering information into the passport could often take away from the valuable time they had with their healthcare team [19].

When interviewing medical professionals Dijkstra et al. found that often there was no clear agenda for the passport and how it would be of benefit to patient self-management. Consequently, it was unclear at which stage a passport should be introduced formally to a patient to ensure they know how to use it sufficiently. Moreover, there are discrepancies over who is responsible to manage the passport, if it is of benefit to medical professionals, and how this passport can be implemented seamlessly to the current healthcare system [19].

2. Patient mHealth survey

The General mHealth Design Pipeline [8] first suggests gathering insights from key stakeholders to mHealth applications (patients and medical professionals). As such a survey is conducted with CF adult patients from the Cork University Hospital to include their insights before developing a written report with medical professionals. To evaluate if CF adults would find an mHealth app beneficial and to determine what aspect of patient education and patient management that is of interest to CF adult patients, an 18-part multiple choice survey was created and validated over a series of three formal meetings with the Cork CF multidisciplinary (see appendix). Participation in this survey was voluntary, and the inclusion criteria for this survey were that participants were 18 years old or older and owned a smartphone. Surveys were offered to all patients attending their designated outpatient appointment over a 4 week period at the CF Day Ward in Cork University Hospital. Ethical approval for this survey is obtained via the Clinical Research Ethics Committee in University College Cork. During the study period, 49 eligible patients completed the survey; no patients opted-not to complete the survey. The collected survey data was anonymized, and the only clinical information collected in this survey was that the participants have CF and are attending the Cork CF center.

2.1 Survey results

A total of 49 completed surveys were analyzed. Of the 49 participants, 55% of respondents use an Android smartphone and 40% use an iPhone. It was reported that 38% of participants have a mHealth app installed on their smartphone device such as exercise trackers or calorie counters; however, only 10% (n = 5) know of or are aware of an app which targets CF. Those CF focused mHealth apps identified by the participants are “CF MedCare”, “MyFitnessPal”, “CFMATTERS STUDY INFO”, and “CF View”. Two of the five participants reported having a CF app installed on their phone (CF View and CF MedCare). The remaining 44 participants who do not know of any CF apps or have a CF app installed were then asked to explain their answer. Of the 44 participants, 20 patients reported being unaware of the existence of CF apps; *“I don’t think there is one”,* and three advised that they are not interested in a CF app; *“Not Interested”.*

The participants are also given the option to choose multiple aspects of their CF that they would like targeted by a CF mHealth app. To note, the participants could choose as many of these options as applicable. It was found that “New

Research Developments" (55%), "Medication" (55%), and "Physiotherapy" (47.5%) are the areas of most interest to the participants, followed by "Diet" (42.50%), "Monitoring" (40%), "Social Networks" (40%), "Self-Psychological Help" (37.50%), "News" (32.50%), "Education" (27.50%), and "Management" (20%). One patient reported *"None"* for this question.

Further questions were presented regarding specific features within mHealth applications. 85% of participants agreed that they would like to receive notifications from the app, such as reminders to take medication or next clinical appointment. When asked would the participant play a game to support their CF, the results were more dispersed; 32.65% agreed they would play a game, 34.69% reported they would not and 30.61% were unsure. Ten of the 49 participants reported as being part of a clinical trial currently or in the past. Six of these 10 participants reported that an mHealth application would have been of use to this trial for data collection or self-reporting.

A series of questions regarding the collection of personal medical data was then presented. When asked if their CF medical information, such as genotype and medical history, is difficult to remember, 32.65% of participants regarded this information as difficult and 42% regarded this information as easy to remember. 26.5% of participants agreed they would record their medical information in a mHealth app. 46.9% agreed they would store this information if the mHealth app is password protected and 16% (n = 8) agreed they would if the mHealth app is password protected and does not have access to the internet. One participant reported being unsure to recording their medical data. Each participant was then given the option to further explain their reasoning for choosing their security preference. These results are listed below.

- *Yes: If password protected*
    - *"Security is priority"*
    - *"Only available to me and no online servers"*
    - *"Privacy Matters"*
    - *"As long as it is stored on a secure database"*
- *Yes: If password protected and does not connect to the internet*
    - *"It would be very helpful/useful to store the data for myself but I would be cautious about who else could access it "*
    - *"It is personal information and so it would need to be very secure "*
    - *"It is personal and private info "*
- *Unsure*
    - *"Security Issue"*

To note, two additional answers were submitted for "*Yes: If password protected*"; however, these answers were specific to the perceived usefulness of such

an mHealth application and not their rationale for their security preference and hence negated from the above list. The two submitted answers include: "*Handy if required when travelling/emergencies*" and "*It would help to track what might have been working at the time to maintain lung function (e.g. meds/physio)*". In a follow up question specific to the usefulness of such an application, 87.5% of participants reported that they would find it beneficial to have access to their medical data through an mHealth app. Of the 49 participants 67.35% agreed that an mHealth app that recorded their medical data would be useful and 61.22% confirmed they would use an app to record this data.

Two questions were also posed regarding travel and admission to the accident and emergency department in a hospital to determine scenarios in which the recording of medical information would be of benefit (similar to other passports as discussed earlier). 75.5% of participants reported having gone travelling outside of Ireland and only 12 participants have had to visit a hospital emergency room due their CF. When the participants were asked if they would use a CF mHealth app if created, 67.5% said yes; however, 27.5% were unsure.

Lastly, the participants were given the option to share what they felt a CF mHealth app should target. Twenty three participants suggested mHealth apps which can be categorized under three headings; Management, Support, and Information. Sixteen participants suggested management apps to track and store their medical information to aid in self-management of the condition. Examples of this category include *"Medication taken/taking"* and *"Medical Info i.e weight lung fx exercise + diet plans"*. Six participants suggested apps that can access medical information such as drug names and new treatments or research. An example of this category includes *"Proper medical names of meds"* and *"New treatments"*. Lastly, five participants suggest apps which can allow for support among CF patients, similar to social networks; *"Experience/Information sharing between other patients"*.

2.2 Survey discussion

It is noted that slightly more patients own an Android device; however, the number of iPhone owners was still high. The first observation to note from the survey results is the paucity in awareness of CF apps. Only five patients reported being aware of CF mHealth apps, and only two patients have these apps installed. To note one of the apps, "MyFitnessPal", which was regarded as a CF specific mHealth app, is not. This app does not target any specific cohort and includes personalisable goal setting, such as weight gain, weight loss, weight maintenance. When questioned further this seemed to be primarily due to being unaware of such apps; *"I don't think there is any"*. However, despite this lack of awareness, the CF adult participants still demonstrated interest and expectations on what a CF app should focus on. New Research Developments, Medication, and Physiotherapy focused apps were of the most interest to these participants. Additionally, tracking medical data and receiving alerts or reminders were the most popular features.

It is important to note that the participants demonstrated concerns regarding data security and as such any mHealth app created for these patients will need to be fully transparent *i.e* full disclosure on what data is being collected, who is it being used/viewed by, and the security measures in place.

Personalizing educational content in this way is synonymous with patient management mechanisms and interventions, as the multimedia is educating the patient on their medical condition data or personal symptoms. Examples of patient management interventions include: audio tapes, booklets, patient credit card/patient passports, counseling, exercise sessions, individual plan/goal setting, manuals, videos, and lectures/talks [20].

3. App design

3.1 Considerations from similar passports

The issues with patient passports, as listed in the Section 1.3, pertain to diabetes passports only; however, these problems are transferable. As such, they have been considered in the design of the adult cystic fibrosis passport. Firstly, by deploying the CF passport as a mobile app a number of these pitfalls may be resolved. When considering the concerns the patients expressed for security and the possibility of identity theft, an mHealth passport can be secured via a username and password. Furthermore, if the phone was lost or stolen, all passport data will be encrypted and not easily accessible. As the passport will be in a digital form on a smartphone, issues regarding the patient being over encumbered or finding it difficult to carry the passport on their person are removed. Furthermore, as the data entered into the mHealth passport is minimal, there will be no smartphone memory usage issues. Finally, as the passport will be in an mHealth form, it is unlikely that a patient will forget their smartphone and subsequently reduces the risk of forgetting the passport at clinical appointments.

3.2 Considerations from MDT meeting

The remaining issues, as highlighted by members of the diabetes healthcare team, were discussed with cystic fibrosis nurse specialists at the Cork University Hospital. The below discussed solutions were work shopped and agreed upon by consensus before being implemented into the app design. Firstly, identifying the point of care the app should be introduced was considered. In the current healthcare model, the passport shall be introduced to patients who have just transferred from pediatric to the adult orientated facility. However, the app can also be introduced to existing adult patients. During this introduction, a CF nurse specialist will explain the aim of this app and why it will be of use to the patient, the data that can be entered into the passport, and when/how to use this app when meeting members of their healthcare team. The nurse will then assist the patient in entering data that can help set up their profile in the app (e.g. contact information for their healthcare team, genotype). The patient will then be made aware that all data entered into the app is voluntary and cannot be viewed outside the app. The nurse will also explain to the patient that the patient is responsible for entering data into the app.

Finally, concerns surrounding time to enter information into the passport was discussed. In Ireland, An adult CF clinic appointment can last approximately 1 hour and 15 minutes. During this clinic, patients meet each member of the MDT. The first member of this team is a CF nurse specialist who will encourage the patient to enter the data into their passport while the nurse enters the data into their patient file. Between meeting each member of the MDT there is approximately 15 minutes of free time. Therefore, if similar to the diabetic patients, the CF patients feel as though they would prefer to spend the time with the medical team member, they can enter the information during this free time instead.

Considering the benefits of a patient passport and the patient insight provided by the Patient mHealth Survey, it can be stipulated that such a tool would be beneficial to adult CF patients. Hence, this research will develop and evaluate a patient passport targeted at adults with cystic fibrosis. However, unlike the aforementioned passports, the proposed passport will be developed as a mobile application. The agenda for this app is to provide CF adults with their basic medical information and also to allow them to record their medications, along with medical

data from clinical appointments. In doing this, adult CF patients may become more aware of their condition and symptoms. Additionally, three scenarios have been identified in which the proposed app may be of use to a CF adult. Firstly, it can allow a patient to receive immediate care when travelling abroad. Secondly, it will allow patients to receive care if travelling between adult CF centers. Lastly, it can be used to communicate between healthcare team members. These scenarios and the design of the passport app with reference to the General mHealth Design Pipeline will be discussed further in the following section.

4. General mHealth design pipeline overview

This section will discuss the design and development of the app under the headings Preparation, Back-End, Front-End, and Deployment, in accordance to the mHealth Design Pipeline described by Vagg et al. [8]. To note, a series of informal scoping meetings was held with the CF nurse specialists from the Cork adult CF unit (>10). Post initial development a further formal meeting with the entire CF multidisciplinary team was held to sign off on the CF passport app.

4.1 Preparation

Before developing or designing the CF Patient Passport, the app's purpose, app type, ethics, and regulations are defined. These considerations are discussed and outlined in the proceeding sub-sections.

4.1.1 Purpose

This section will discuss the components necessary to create a written report before developing the app. Firstly and agenda for the mHealth passport is outlined, so that the app can be implemented into the current health care model and have a positive impact on the patient. Identifying the proposed agenda of the app was discussed with members to serve the patient were identified and are listed below.

Scenario 1 Traveling between CF centers: In Ireland, there are five CF focused centers. Patients can transfer between these centers for varying medical or personal reasons. However, as patient data is stored as a hardcopy, there may be a delay between the patient arriving at the center and the medical professional accessing their clinical data. In this scenario, the mHealth passport can ensure that the patient can provide their basic medical data when arriving to the new unit. Such information can include recent lung function history, medications, allergies, genotypes.

Scenario 2 Travelling abroad: As quality of life and survival rates increase, more and more CF patients are travelling abroad. In this scenario if the patient would require any medical care when travelling abroad, the mHealth passport would ensure that the patient could provide their basic medical data (and contact information for their healthcare team) to the attending medical professional.

Scenario 3 Bridging Gaps between the healthcare team: In Ireland, it can be approximately 3–4 months between clinical appointments in the adult unit. Between appointments, patients may visit a General Practitioner (GP) and begin an antibiotic treatment and this data must be entered into their patient file at their next clinical appointment. The details of the new antibiotics can be either forgotten, or only partially remembered. In this scenario the app can record any interaction with any member of their health care team as well as new prescriptions or changes to care to provide a broader view of their care.

It is anticipated that the app will be first offered to CF adolescents transferring to adult care. However, it can also be suggested to any CF adult. The app will be made available on both iOS app store and Google Play store, in addition to being made available on the Cork Hospital CF Centre web page. Patients will be given time during clinical appointments to enter the data with the CF nurse specialists, or they can enter the data during non-contact time.

All data collected through the app will be stored locally on the device. It shall not be transmitted or viewed by any other personnel. The data recorded will not be analyzed; however, some data shall be visualized in two interactive graphs. The first graph will display Weight over time, and the second will display lung function as FVC% and FEV1%. An example of this graph can be seen in **Figure 1**. The graph is interactive and can allow users to touch different points on the plot to view its corresponding information. The user can also save reminders for clinical appointments or take medications through the app.

4.1.2 Application type

The proposed CF Patient Passport can be considered as both an In Vitro app and a Wellbeing/Lifestyle app. The passport is intended to record a patient's basic medical information and simultaneously plot data on a graph; as such, it is considered an In Vitro app. It is not considered a Medical Device, as this data is not being used to perform a diagnostic or any immediate decision making for the patient.

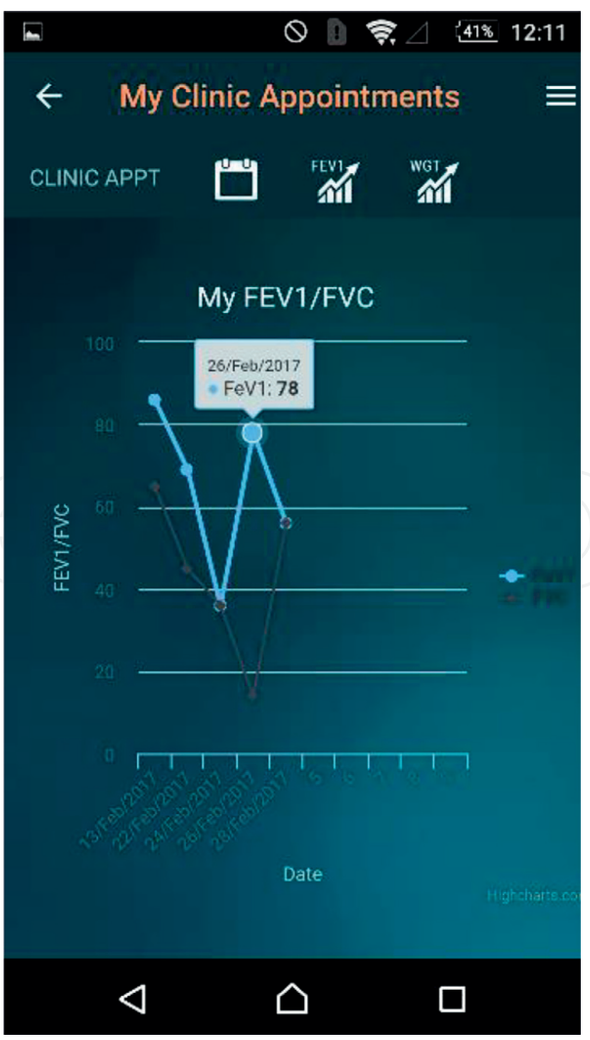


Figure 1.
Lung function (FEV1, FVC) in "My Clinic Appointments".

However, it can also be considered as a Wellbeing/Lifestyle app as it may improve health behaviors among this cohort as they become more aware of their own medical data/symptoms.

4.1.3 Ethics and regulations

All evaluations performed with patients received ethical approval from the Clinical Research Ethics Committee in Cork. The app is currently available on the Google Play store in Ireland and is GDPR compliant.

4.2 Back-end

To ensure that the app can be deployed to both Android and iOS, Cordova PhoneGap [21] was used to develop the mHealth passport. PhoneGap uses web technologies such as HTML, CSS, and JavaScript in addition to Frameworks for navigations and layouts. For this passport, Framework 7 [22] is incorporated into the app to ensure a consistent layout/style across both Android and iOS. The language and dialogue used in the app is simple so that it can be understood by non-medical persons. All graphs are developed using the Highcharts.js framework [23]. This section will discuss the validation of content and dialogue within the application before discussing the data that can be recorded via the passport app.

4.2.1 Content and dialogue validation

As CF is a genetic disease, patients have grown up listening to and using medical terminology to aid in the management of their condition. Therefore, the medical data that can be recorded in the app is familiar to this cohort; however, the manner in which the data is requested may be new to these patients, and subsequently may require validation. A meeting was held with CF nurse specialists to discuss the instructions on how to enter data in the app. The CF Nurse specialists were enlisted for this task due to their extensible knowledge in communicating with this cohort. There is no imagery used within the app, however, there are two proposed graphs. The graphs and app instruction were modified until validation from the nurse specialists was given.

4.2.2 Data information requirements

As the data are not being transferred and viewed by other personnel, an opt-out service and DPA policy was not required in the app. As the CF Patient Passport was developed as part of a pilot study, information pertaining to all intentions of what data was to be collected and how it was then stored was provided to patients in a participant information sheet. It was anticipated that once the app was made available via app stores and over the web, these intentions would also need to be listed.

4.2.3 Data and data analysis

Focusing on the outlined scenarios (travelling between centers, traveling abroad, and bridging the gap between the healthcare team) a meeting was held with the CF MDT to discuss which data should be recorded in the app to fulfill these objectives. From this meeting it was found that the mHealth passport should follow the same architecture as a patient file. In Ireland, a patient file can include information stored once (genotype, date of birth, genotype *etc.*), information that can sometimes be recorded (such as new medical conditions or procedures), and

lastly data that is recorded at every clinical appointment (lung function, weight, height *etc.*). Therefore the mHealth passport is separated into three core sections and described below. To note, all data entered into the passport can be edited or deleted if desired. These sections can be seen in **Figure 2** (right).

Section 1 My CF Information: This section is targeted at the information in the patient file that are only recorded once. This data generally describes a patient profile such as date of diagnosis, genotype, sweat test results, allergies, contact numbers for the healthcare team, and allergies. This can be seen in **Figure 3** (left).

Section 2 My Medical History: This section is dedicated to the occasional data and is divided into two sections. "My Medical Procedures" and "My Medical Conditions". The first section is targeted towards procedures a CF patients may have undergone such as the insertion of a gastrostomy tube, or the removal of a portacath. The second section focuses on new conditions or diseases which may have developed, such as diabetes.

Section 3 My Clinic Appointments: The final section records data that are entered into a patient file at each clinical appointment. This data can include Blood Pressure (BP), weight, height, date, lung function (FEV1% and FVC%), bugs in mucus, new treatments. This section can also be used for phone calls with the healthcare team, GP Visits, and annual assessment.

4.2.4 Security operations

As the data is being stored on the smartphone, security precautions are put in place for local storage. First, the mHealth app is password protected (as seen in **Figure 2** left). In the event of a forgotten password, a randomly generated password is created within the app and emailed to the user. All data stored in the CF Patient Passport is optional. Any data that is recorded is encrypted using the Advanced Encryption Standard (AES) algorithm and stored in a local SQLite database. If the app is uninstalled from the device, the databases will also be deleted.

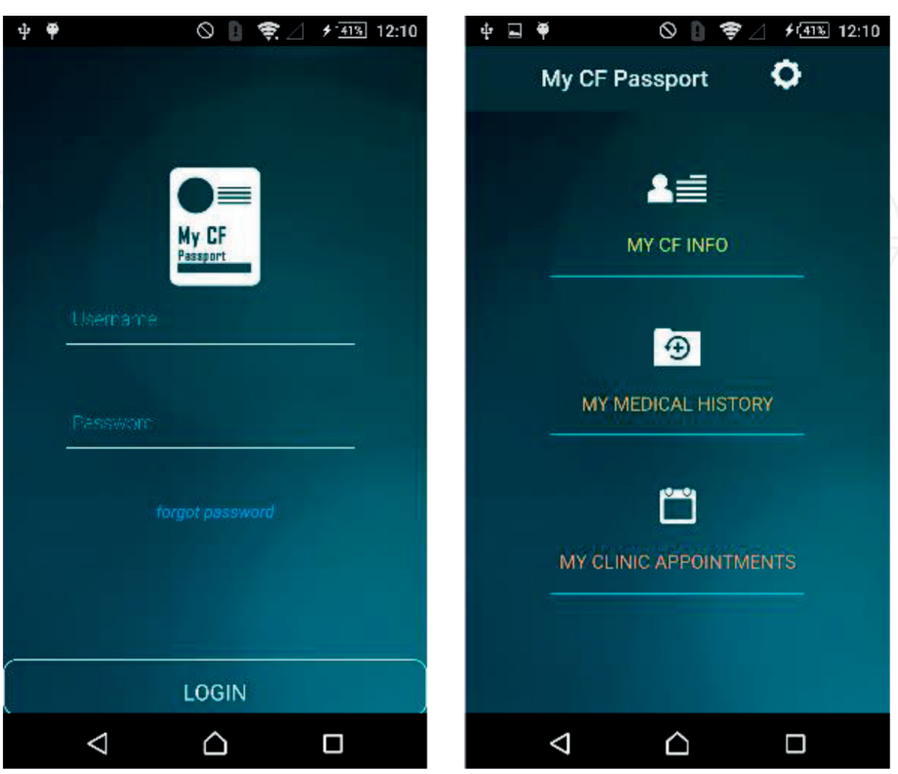


Figure 2.
Login screen (left) and main menu in the passport (right).

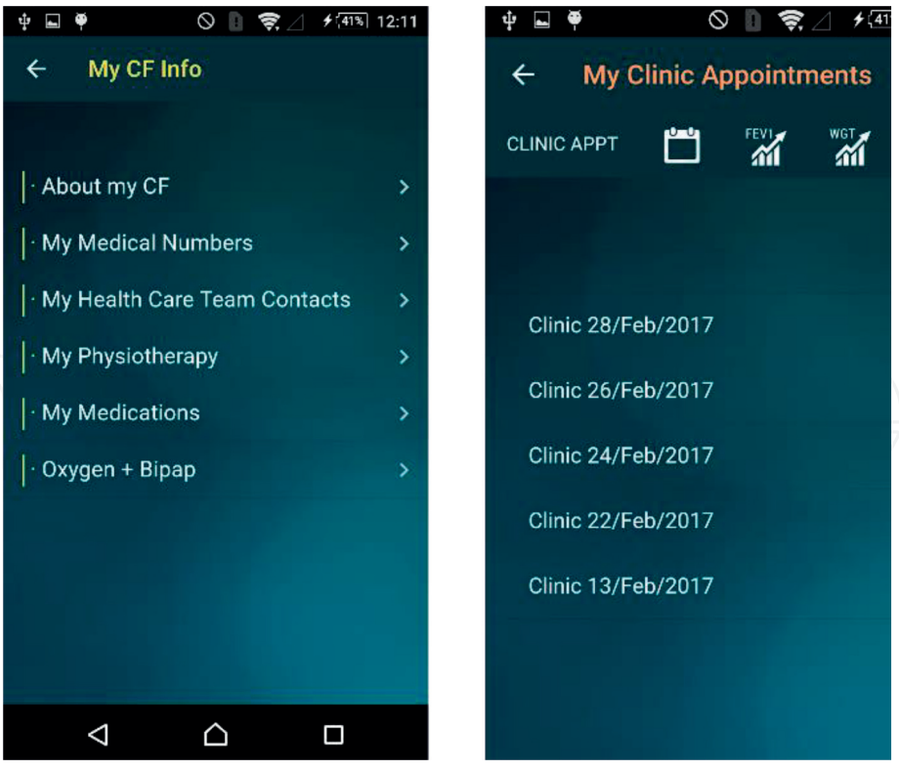


Figure 3.
Menu from the "My CF Info" section (left) and list of saved clinical appointments in "My Clinic Appointments" (right).

4.3 Front-end

In keeping with the mHealth pipeline discussed previously, the User Interface (UI) and User Experience (UX) of the app are discussed.

4.3.1 User interface (UI)

A meeting was held with CF nurse specialists and physiotherapists to discuss the plausibility of an Adaptive UI. From this meeting it was determined that a UI model was not required. It was considered that perhaps an Adaptive Navigation model may be beneficial for the use cases as described in 6.5.1 under Preparation; however, this was later dismissed as data recorded and shown in the app is at the patient's discretion.

Informal discussions between the CF nurse specialists and the CF adults attending clinic found that this cohort would prefer the UI to be designed so that it does not appear to be a mHealth app. As such, the icon that was to appear on the main screen of the user's smartphone does not contain any indications that the app is for CF; hence this icon is named "My Passport". Furthermore, the style and UI elements in the app were designed so that they do not appear to be "medical" or "clinical". Similarly, all menus and buttons were created to reflect the data collected.

4.3.2 User experience (UX)

On reviewing diabetic patient passports, a number of issues which could prevent the use of such of an intervention was found. Of interest to the UX aspects of this mHealth app is outlining how the app should be implemented into the current care system. A solution for this is discussed in Section 3.2. It is agreed by CF nurse

specialists that the app will be offered to CF adolescents transferring to CF adult care and CF adults already registered in the hospital. If the patients are interested in using the app a workshop will be given by nurses on how to use the app and the data that can be recorded. The nurses will then assist the patient in entering any historical and profile data. Time is then allocated during clinical visits for patients to enter this data with a CF nurse or during non-contact time.

4.4 Deployment

In this section, further testing and reviews conducted on the app are discussed. Following on from the results of the reviews and testing, future plans for the deployment of this mHealth app are outlined.

4.4.1 Stress test

The purpose of this test was to evaluate the performance of this app and its design. Seven participants without CF were enlisted who all owned Android devices. The decision to recruit non-CF participants was intended to identify performance and design issues and to remedy them. For the stress test, participants from a similar age range to the target CF adult cohort were chosen. Five participants (three females and two males) between 19 and 51 were recruited. The technical capability of this participants varied, some participants were novices at using technology, while others were ICT professionals.

The participants were asked to download the mHealth passport onto their smartphones and test for 3 months. During this time participants were required to enter, edit, and delete data to "My CF Information" and "My Medical History" a minimum of once a month. However, they were requested perform the same tasks in the "My Clinic Appointments" more frequently (once a week). Each month the participants sent a report of any issues they encountered using the app (such as performance, usability, or general feedback) via email.

At the end of this stress test it was found that there were no major performance issues and the users did not find the mHealth passport difficult to use. The primary issue reported on was a style issue that occurred on different phone screen resolutions whereby the submit button to enter data would remain behind the keyboard (users must close the keyboard before being able to submit). Another issue reported was the lack of clarity or structure when entering dates into the mHealth app. The final issue reported on was that the default "Go" button on the smartphone keyboard did not move to the next text field as expected. Following this feedback, the styling was adjusted and retested on different devices to ensure the submit button was no longer hidden, a calendar was implemented to enter in the date, and finally functionality was created and bound to the "Go" button to ensure users could navigate through the form items. The above solutions were implemented in preparation for pilot testing with CF adult patients.

4.4.2 Peer review

The CF Patient Passport was then presented to CF nurse specialists, CF physiotherapists and respiratory consultants for review. During this review, the app purpose, aesthetics, dialogue, content, and functionality was reviewed. Slight modifications are recommended by the reviewers to improve the quality of data entered and prevent errors. Examples of this feedback included the incorporation of a drop-down menu which contains all possible bugs that can be growing in mucus as opposed to the patient manually entering this data. Similarly, in places where

patients must enter a date range (*e.g.* start date and end date) it should be possible for the user to enter just a month and year as opposed to date, month, and year. Overall it is agreed that the CF patient passport can be of benefit to CF adult patients as it will allow for this cohort to always have access to their basic medical data and become more aware of their own condition and symptoms.

4.4.3 Patient review

Following on from the stress test and peer review, ethical approval was granted by the Clinical Research Ethics Committee in the University College Cork for pilot testing with CF adults from the Cork University Hospital. The inclusion criteria for this study was that patients must be 18 years old or older and own an Android smartphone. Participation in this study was voluntary and was offered to patients during clinical appointments over two consecutive days. Five eligible patients were identified and recruited by the CF nurse specialists. All five patients agreed to partake in the study; one participant was female and the remaining four were male. Each participant was provided with an information sheet outlining the purpose of the app, the data collected, intentions for the data, and security measures. After the app was installed on their devices, the participants partook in a short workshop with the CF nurse specialists, who demonstrated how to use the app. The CF nurse specialists also assisted the participants in entering any of their historical or patient file data into the passport app. The patients were then asked to test the app over 3 months before completing a feedback questionnaire, which was provided to them at their next closest clinical appointment.

5. Results

During the three-month study period, one male participant lost his smartphone and as such was unable to complete the feedback questionnaire. Of the remaining four participants, three reported their smartphone models: a Oneplus 5, Sony Xperia M5, and Samsung Galaxy. All four participants agreed that they were provided with sufficient information to use the app. The participants were then asked to rate the appearance of the app from 1 to 5 (1 being Do not Like It, 3 being Neutral, and 5 being Like It), with two participants rating the app a 3 and the remaining participants rating the appearance a 4.

During the study period all participants reported inserting data into the app. Two participants confirmed they used the app to share their medical information. When asked to explain this further, one participant reported using the app in a clinical appointment. When asked to rate the difficulty of the app from 1 to 5 (1 being Difficult, 3 being Moderate, and 5 being Easy), one participant rated the app a 5, two participants rated the app a 4, and the remaining participant rated the app a 3. When asked which parts of the app was difficult, the participant who rated the app a 3 reported difficulty in inputting "some information". One other participant also advised that the built-in back button on their device caused the app to close instead of returning to the previous page and was therefore reliant on the built-in navigation bar. When asked which features the participant would like to remove from the app, three participants reported none. When asked what features the participant would like to add to the app, one participant advised they would like for their doctor to be able to access the data or input new data remotely.

The participants were next asked to rate the helpfulness of the app from 1 to 5 (1 being Not Helpful, 3 Indifferent, and 5 being Helpful). One participant reported a 5 for this question, two reported a 4, and one participant reported a 3. When

asked to explain their answer, the participant who reported a 3 did not elaborate further. However, two other participants remarked that the app is helpful as it allows them access to their medical information:

"It's useful to have this information in an easily accessible place"
"It's handy for me to have my information so readily accessible"

This is further enforced in Question 10, where all participants agreed that it was beneficial to have access to their basic medical information through the app. When asked who the participants believe is responsible for inputting data into the app, three participants reported that the responsibility is theirs, while one participant believed it was the shared responsibility of the participant and their CF treatment team. The users were then asked to explain their answer. It was found from these answers that users believe it is their responsibility as entering data should be at their discretion. However, one participant welcomes guidance from their healthcare team.

"I put what I think is necessary"
"Personal info on a personal device should only be entered by the owner unless explicit permission is given. I think I am ultimately responsible for knowing about my condition and recording the information but I might not always know the most important information to be recorded which is why my nurses and doctors should also have input."
"It's my app and on my phone, so it's my own responsibility to keep it updated"

One participant reported a barrier which prevented the editing of data. This participant found that some saved data in the My CF Info section of the app could not be edited, and instead needed to be deleted and inputted again, which they regarded as frustrating. The participants were then asked to rate the regularity of using the app from 1 to 5 (1 being Not Regularly, 3 being Sometimes, and 5 being Regularly). Two participants rated this question a 1, one participant reported a 3, and the remaining participant reported a 4. When asked to list scenarios in which they felt the app maybe useful, the participants reported the following scenarios:

"If I got sick on holidays could show what I'm on"
"Listing medication/medical details at clinics etc"
"Sharing information with my GP or if I'm traveling and need to share information with a doctor. Going abroad or another hospital/GP"

It can be seen from the above scenarios that participants felt that the app maybe of most benefit when travelling abroad or sharing information with medical and healthcare professionals. Lastly, the participants were asked to rate how adequate the security precautions within the app are from 1 to 5 (1 being not adequate and 5 being adequate), to which two participants rated a 5, and the remaining two rated a 4.

5.1 Initial observations

It is acknowledged that some limitations of this study are the small number of participants and the disproportionate ratio of male to female participants, which could present a potential gender bias. There was a notable difference in the participants reported regularity of the apps use. Patients were asked about how often they

would use the app. At face value, not regularly could be perceived as concerning; however, CF patients attend CF clinic appointments quarterly, and entering data is at the patient's discretion. In addition to this, minor issues in device functionality were reported by this cohort, which have since been addressed and resolved.

Interestingly, unlike the findings of the paper-based patient passport, participants of this study identified themselves as the sole or major inputter of data. This is perhaps a clear advantage to paper-based passports, which reported uncertainties in this responsibility, as discussed previously. This may be attributed to the passport being based on a patient's personal device, as opposed being provided to them in a hospital branded booklet.

Moreover, the app in its current form was received positively by the participants of this study. All participants agreed that having access to their basic medical information is of benefit to them. Furthermore, these patients envision practical scenarios in which this app may be of benefit to them in the future.

6. Conclusion and future works

The app is currently available for free on the Google Play Irish store. Future works would include deploying the app to iOS app store and being linked to the Cork CF Centre website. Information pertaining to data usage intentions and storage will is made available on the app store description page. The results of the patient survey conducted found that this cohort showed interest in the recording and viewing of their medical data in a convenient and manageable way. To this end, it was found that the concept of a patient passport could prove to be a suitable solution. Patient passports have been proven to help patients with self-management as it facilitates the ability to closely monitor their own condition. Hence a passport application was developed so that CF adults could record their medications and basic CF information. It is also anticipated that this will allow these patients to receive care when travelling between centers and abroad. A pilot study with four participants demonstrates that CF adults perceive this passport app to be beneficial as it allows them access to their basic medical information. It was also found through the pilot study that participants would not use this mHealth app frequently. This is a similar finding to paper-based passports, as patients only enter the data into the app during clinical appointments (quarterly) and share data in specific scenarios such as with a GP, or when travelling abroad. As the app is password protected, the user must be able to enter in their correct credentials and navigate through the app to share data. However, in situations such as needing to attend the accident and emergency room, this may cause further frustration to the patient, whereas a paper-based passport can be handed to medical professional who can locate all data needed in order to provide care. This is perhaps one advantage of the paper-based system over the digital mHealth app. To contend with this, future iterations of the app may include a Generate PDF button on the main menu which will compile all the most pertinent medical data into an A4 PDF which can be shown to medical professionals via the device or emailed to them directly. This suggestion can also be applied to mHealth patient passports for other conditions. It is also noted that the data from the app is stored locally only. For this reason if the phone became lost or stolen, it would not be possible to restore a profile onto a new phone, in this case the user would have to re-input all their data. This design choice was made based on the feedback from the mHealth survey regarding security and the app connecting to other online sources. However, future iterations of this app will implement the ability to migrate data from one smartphone to another in the event the user purchases a new phone. Once the data has been migrated, data stored

on the old smartphone device will be deleted. In conclusion, an mHealth patient passport is desirable among the adult CF cohort and we believe it can have significant impact on how patients can manage their condition and have access to their data.

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Conflict of interest

There is no conflicts of interest.

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