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D2.4: Second-cycle completion report including video of all scenarios

[Deliverable D2.4, Revision 1.0]

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Lead Editor: Mart Wetzels (TUE) and Peter Peters (TUE)
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This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Executive Summary

This report addresses the work done within Work Package 2 within the DoCHANGE project: User needs and co-design of tools and services. The deliverable consists of the results from the second cycle of the project. Within the total health eco-system multiple stakeholders collaborate to create a service for its users. To substantiate, and guide, the developments of this user-centered service the context, needs, and requirements of all users must be documented. This is achieved within this deliverable by:

- Conducting focusgroups on privacy within healthcare
- Applying methods to visualise patient pathways and discovering opportunities for the DoCHANGE project.
- Performing a co-creation mobile application study to prepare for the second phase clinical trials.

The outcome of this work will feed into other Work Packages as user requirements and enables discussion on the refinement of the use-cases between stakeholders of the ecosystem.

Table of Contents

Index of Figures

List of Tables

List of Abbreviations

SMH
Smart Homes

TUE
Eindhoven University of Technology

ETZ
Elizabeth-TweeSteden Ziekenhuis

ONMI
ONMI

BSA
Badalona Serveis Assistencials

DSD
Do Something Different

DOC
Docobo

EUT
Eurecat

ITRI
Industrial Technology Research Institute of Taiwan

BTCD
Buddhist Tzu Chi General Hospital

METC
Medical Reviews Ethics Committee (Medisch Ethische Toetsings Commissie)

CVD
Cardiovascular disease

HIS Hospital Information System

STEMI
ST Segment Elevation Myocardial Infarction

EDL
Experiential Design Landscapes

1 About this document

This section of the report provides background information on the nature of the document and responsibilities that entail Work Package 2.

1.1 Introduction

The work done from August 2016 until January 2017 reported in this document is:

- Methodology, execution, and analysis of privacy focus groups.
- Methodology, execution, and reporting of mobile application co-creation study.
- Identifying normative patient pathways models and setup for Process Mining application for descriptive pathways.

The following partners have directly contributed to the work presented in this report:

Work	**Partners involved**	**Description**
Privacy Study	TUE ETZ BSA BTCD ITRI	Methodology and protocol setup by TUE and ETZ. METC requests, recruitment of patients, and performing patient interviews done by remaining partners. Full analysis will be performed by TUE and ETZ.
Cardiac DO's	DSD ONMI ETZ TUE	Defining of three cardiac DO programmes and documentation.
Care Pathways	TUE ETZ SMH	SMH provided examples from other work, TUE processed and analysed information obtained from ETZ.
Co-creation / EDL Study	TUE ONMI ETZ DSD SMH	Design, methodology, and execution of study. Other partners contributed by finding participants and evaluation intermediate feedback.

Table 1: Contribution WP2

1.2 Description WP2

In PHC26 (ii) there should be a strong emphasis on co-designing and user needs as a key driver. Therefore, a Cyclic Design or Iterative Design method will be used. This WP2 will therefore continue from the beginning to almost the end of the project (month 33). The objectives are:

- to make sure that the tools + services are refined and developed from concept to practical usage and evaluation.
- the mutual understanding of the partners' values, ways of working and limitations are refined and developed.

This work package will follow an iterative, cyclic process with three cycles of one year each. The process guarantees that not only the tools + services are refined and developed from concept to practical usage and evaluation, but simultaneously the mutual understanding of the partners' values, ways of working and limitations is refined and developed as well. This is essential because the partners have different backgrounds and roles such as user, service-provider, technology developer, and integrator. Each cycle consists of (1) requirements definition (2) co-design and implementation (3) usage (4) cooperative evaluation. The subtask T2.1, T2.2, and T2.3 will be synchronised in the same cycles. Note that it is not just co-design and then testing, the evaluation is a cooperative effort as well since the technology developer's criteria are different from the service developer's criteria, which are not identical to the user's criteria. Each cycle takes one year precisely so a smooth yearly rhythm of meetings and workshops emerges as soon as possible. Lead partner is TUE . The main implementation and testing work takes place in WP3-6 and then the results feed back into WP2.

1.3 Subtasks WP2

Parallel to the iterative, cyclic process three subtasks are defined to include in all iterations. A description of the subtasks are listed below:

- **Task 2.1: Technical and non-technical requirements:** TUE will define the co-design protocols, the observation methods and document the process. SMH will define the facilities and context. EUT and ITRI bring the sensor technology. ONMI will take care of connecting the tools to the services. TUE creates Personas, Scenarios of usage, Patient pathways, and detailed technical specs (for the sensor technology and the software).

- **Task 2.2: Co-design of tools - cyclic:** EUT and ITRI bring the sensor technology. ONMI will take care of connecting the tools to the services. In Year 1, the tools will be designed already as-if functioning, although some of the technology will be not fully embedded. From year 2 onward the tools are functioning (although in year 2 there still may be calibration or initialisation technicalities only to be removed in year 3). The deployment of the tools will occur in the test lab of SMH (year 1) and at the patient's home when the devices are connected at DOC (years 2 and 3). Focus groups, acting out, and speak out loud protocols will be used throughout WP2.

- **Task 2.3: Co-design of services - cyclic:** BSA and DSD will provide the expertise for the services, DSD and DOC contribute to the software technology. DSD and ETZ contribute the psychological and medical perspective, respectively, and organise the co-designed versions of tools and services to be used by citizens and patients. DSD and ETZ will check and if necessary take action towards the local Medical Ethical Committee. The patient's data recorded will be logged on servers of the partner that provides a specific server. The tests themselves are executed in WP6 but the cooperative evaluation belongs to WP2 to involve all the partners in the consortium so that all members are on the same ground in terms of understanding the design requirements for technologies and end users, and the scenarios of using the tools and services.

2 Requirements

This section presents the requirements from work performed in WP2. The requirements are numbered for the purpose of references in other deliverables.

1. Consortium-based

Requirements derived from internal discussion within the consortium; outside the scope of the studies.

- 1.1 Temporary non-adherence, due to personal circumstances or other motivations, to the DoCHANGE-program should be taken into account when determining the overall adherence to, and success of, the provided behaviour change.
- 1.2 The granularity of privacy settings need to restricted, or limited, to a user-friendly level; this needs to be restricted within the privacy study.
- 1.3 The required behaviour change impacts the patient's relatives as well; the inclusion of relatives within the program needs to be considered.

2. Patient Interviews

Requirements derived from the patient interviews [23]

- 2.1 The tools to be provided to patients (in the trial and ecosystem) need to be carefully considered, and mutually agreed upon, by patient and clinician to prevent patients from using tools that do not increase the quality of care.
- 2.2 The device COOKiT, as a cooking-utensil, needs to be limited to the kitchen environment; no use-cases outside the home.
- 2.3 The device Horus, as a food scanner, needs to investigate or substantiate the possible stigmatising effects of using the device in a social environment.
- 2.4 The device MySleeve, as a service, needs to allow users to insert liquid intake manually for use-cases where MySleeve is not available or uncomfortable to use.

3. Clinician Interviews

Requirements derived from the clinician interviews [23]

- 3.1 An individual clinician should not be responsible for interpreting data from non-medical devices; too little time is available and there is no qualified expertise in that area.
- 3.2 The ecosystem should position itself as a decision support system on the patient's portal; automated alerts to clinicians needs are to be investigated due to varied opinions on the matter within the study.
- 3.3 Measurements being taken, from devices, that depict the patient's activities of daily living should be used for personalising the cardiac rehabilitation program and therefor presented in a non-technical manner; this will be investigated by user interface development for the clinician portal.

4. App Study

Requirements derived from the experimental app study

- 4.1 Consolidate profile, and its settings, in a separate TabView for the DoCHANGE app.
- 4.2 Within the buddies TabView, the primary interaction should be focussed on linking to existing buddies. Adding new suggested buddies is a secondary feature and should be positioned as such.
- 4.3 The devices should either have a clear icon for the device listing or consolidate the feature in the settings TabView.

5. Privacy Study

Requirements derived from the privacy study Section 5

- To be defined after completion of Privacy Study.

6. Co-creation EDL Study

Preliminary requirements derived from the co-creation EDL study Section 7

- 6.1 Push Notifications should be used to inform patients when receiving a new (responsive) DO.
- 6.2 Data collected through Third Party Interfaces should also be communicated, or visualised, directly. E.g. Moves data is used for the responsive DOs. This relation is not evident for the participants, thus a visualisation in the DoCHANGE app should be included.
- 6.3 A balance should be defined between the data visualised and data available. In the case of Third Party APIs, more parameters are available through the API then presented in the API-specific application. Determining what should be presented should depend on feedback and preference of the participant.
- 6.4 Descriptions of parameters should be available for participants to gain a better understanding of their meaning. E.g. Beddit's 'sleep score' or how Fitbit defines a 'very active minute'.
- 6.5 To limit excludability based on the participant's mobile phone, a wide range of devices, both low- and high-end, should be supported on Android and iOS. This requires a flexible layout system and limitation, or adaption, in the performance resources the DoCHANGE app requires.

3 Clinical pathways

3.1 Introduction

This section is a continuation of the Clinical Pathways Section in D2.2 [23]. As a recapitulation, the application of Process Mining within the DoCHANGE project supports the understanding of the hospital context, patients, clinicians, and processes, and explores the possibility of integrating Process Mining as a service within the DoCHANGE Ecosystem.

To date, two datasets are planned for analysis: STEMI and Cardiac Rehabilitation. The STEMI dataset has been received in February 2016 and is presented in the next subsection. Permission for the Cardiac Rehabilitation set needs to be granted; this is currently in request at ETZ.

3.2 Cases: STEMI and Cardiac Rehabilitation

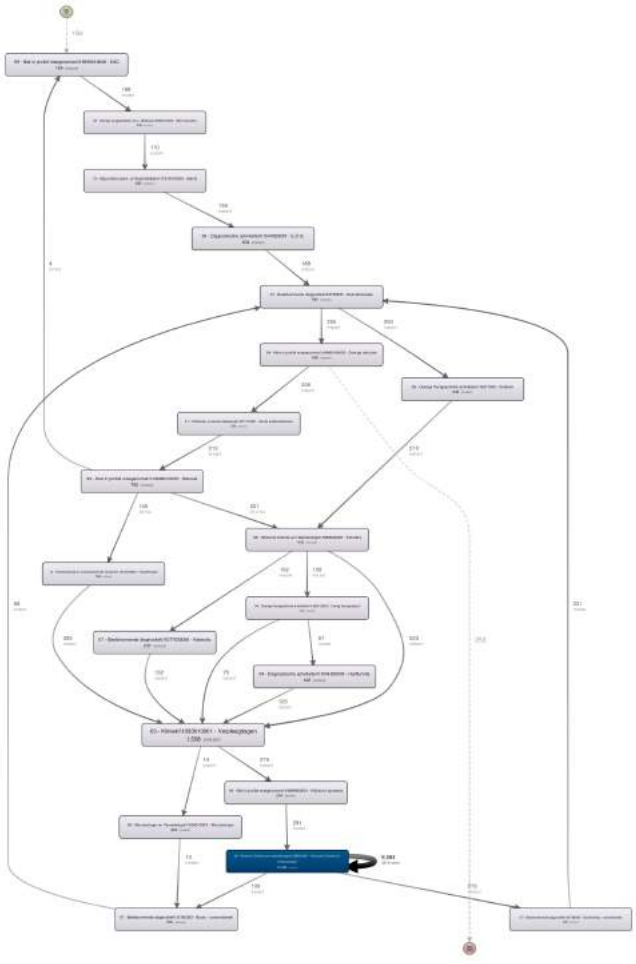


Figure 1: STEMI Model (Activities: 40%, Paths: 0%)

The STEMI-dataset consisted of 292 unique cases (anonymised patients) with 18489 events; every patient has a unique pathway in this dataset. The events range from January 3, 2015 to January 5, 2016. ETZ stores activities (e.g. nursing days) in different degrees (columns in the database) that provide different levels of detail. For simplicity, only one level has been exported for analysis and the risk factors, where available, are included as well.

Figure 1 shows a simplified model of the STEMI-dataset generated by Disco [6]. The top part of the model shows a series of events that include: visit emergency room, stent, ECG, cardiac catheterisation, angioplasty, outpatient appointment. Due to the restricted timestamp, granularity of a day, multiple events on a single day cannot be chronologically ordered. The order of events is determined by the insertion order in the system of ETZ. To provide a general model of the process this granularity is sufficient. However for more detailed insights, a higher granularity is needed to determine, for example, the amount of time a patient spends in the ER or to compare the duration of similar events from different patients.

Risk factor	**Yes**	**No**	**Unknown**
Smoking	107	124	61
Drink alcohol	88	31	173
Family history	91	111	90
Diabetes	32	191	69
Hypercholesterolaemia	76	137	79
Hypertension	91	133	68
Adiposity	69	150	73

Table 2: Risk factors in STEMI-dataset

Table 2 shows a simplification of risk factors within the STEMI-dataset. The *smoking* and *drink alcohol* risk factors are simplified by removing the amount of drinking or smoking to **Yes** or **No**; in both parameters any drinking or smoking is considered as a **Yes** whereas patients that quit smoking are considered as **No**. Remarkable in this table is the amount of unknowns; these values are not present within the dataset and cannot be assumed to be either **Yes** or **No**. An attempt was made to discover clusters with combination of risk factors, to compare the pathways of those patients within either clusters. Unfortunately, no evident cluster definition was defined; probably due to the combination of relatively small number of cases and higher number of parameters.

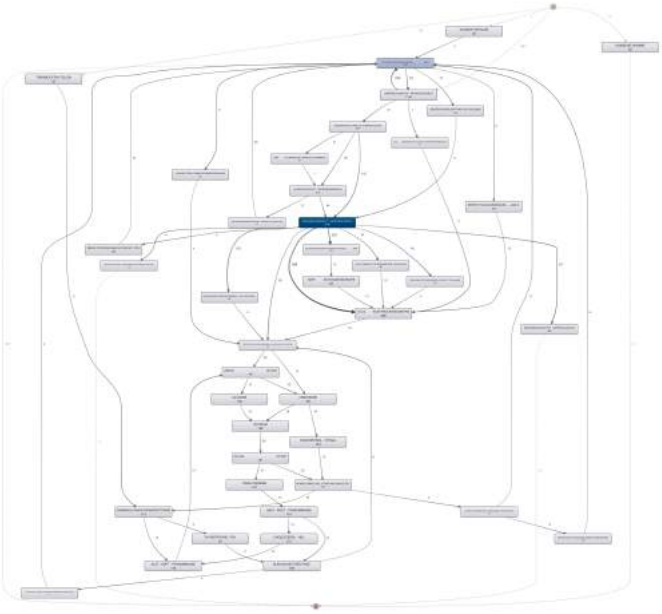


Figure 2: Cardiac Rehabilitation Model (Activities: 36%, Paths: 0%)

The cardiac rehabilitation dataset consisted of 790 unique cases (patients) with 20654 events. The events ranged from January 5, 2015 to December 13th, 2016. The events occurring in 2016 are part of the care pathway of patients starting in 2015, no 2016 patients are included. Similar to the STEMI-dataset, Figure 2 shows a simplified model generated by Disco. Activities such as an ECG, FIT (physiotherapy), contact with cardiologist, and contact with medical psychologist are visible in the model. Table 3 shows the same lifestyle statistics as from the STEMI-dataset.

Risk factor	**Yes**	**No**	**Unknown**
Smoking	112	338	340
Drink alcohol	201	69	520
Family history	215	204	371
Diabetes	92	355	343
Hypercholesterolaemia	202	236	352
Hypertension	197	244	349
Adiposity	149	285	356

Table 3: Risk factors in CR-dataset

3.3 Discussion

The use of the datasets provided the means to (partially) understand how the HIS is structured; what type of data is collected and how this is shaped. The 'cardiac patients', as they are considered within DoCHANGE, will be present in different subsets of the HIS (dots); like the STEMI and Cardiac Rehabilitation. For example, the Simon Schmidt Persona [23] would be part of the STEMI-dataset when arriving at the hospital's emergency room and continue within the Cardiac Rehabilitation-dataset.

The DoCHANGE Ecosystem positions itself following the cardiac rehabilitation track of the hospital, where present, thus modelling how patients proceeded through the care pathway contributes to the overall understanding of the target population.

Considering the services provided by the DoCHANGE Ecosystem, process analysis of care pathways within the hospital can contribute to the Business Intelligence (BI) of the hospital; better insights in how actual events are aligned to the protocol. For example, in the Netherlands, hospitals are rated based on the amount of days a patient is hospitalised after a cardiac event. A clear understanding of what resources (tests, staff, risk factors etc) influence the duration of the nursing days can provide the starting point for further investigation to reduce that amount. In order to investigate the care pathways, data needs to be complete to prevent the amount of 'unknowns' as experienced in both datasets used.

4 Video scenarios

4.1 Introduction

In the DoCHANGE project, a multitude of physical tools is developed to aid patients with rehabilitation. These tools aim at providing the patient information which is not easy to keep track of, or evident to obtain. (E.g. salt concentration of a meal or the amount of fluid taken in throughout the day.)

One of the physical tools is a spatula. The spatula called COOKiT shows the concentration of salt and temperature of the food it is inserted into. This information is visible to the user during cooking and can help decide how much to eat of a particular part/ingredient of a meal. The use of the spatula is monitored by DoCHANGE to create meaningful Responsive DOs surrounding diet and cooking.

Onmi, who develops the COOKiT, also develops MySleeve. MySleeve is a fluid tracker. The shape of MySleeve, as the name suggests, allows the user to slip it around a cup. Once the sleeve is around a cup, it tracks how much is drunk, at what time and how many sips were taken. The user can find the fluid diary in a central place, the DoCHANGE app. Moreover, the tracker information is monitored by DoCHANGE to provide meaningful Responsive DOs surrounding fluid intake.

To show clearly how the tools work, the DoCHANGE team has produced two video scenarios illustrating two real life home settings where the users take advantage of the functionalities of the tools.

4.2 Setup

Figure 3: Photograph of recordings

Our partner, Smart Homes, has the smartest home of The Netherlands. This smart home lends itself perfectly for filming in a homely setting and shooting visually attractive video. Before the actual film day, we visited the location to create a shot-list and see what materials we needed. Our main take-away was the need for light-panels to properly light the scenes.

The actor in the videos is an actual cardiac patient who we met through our partner, Smart Homes.

Our video crew consists of a camera man/video editor and a director. Together they were responsible for the scenarios, shot-lists, production, filming and editing.
The video is shot with Sony a7ii, Zeiss Batis 25mm, Zeiss Loxia 50mm, Beholder DS1 3-axis stabiliser, Rode stereo Videomic pro, Manfrotto tripod, Litepanels 2 Astra 1x1 EP bicolor 1000W,
The videos are edited by Jeroen Cox, with Adobe Premiere Pro and Adobe After Effects. The music is produced by Luke Noothout.

4.3 Scenario 1: MySleeve

Figure 4: Screenshot of Scenario MySleeve

MySleeve's unique selling point is its ability to track the fluid intake of its user. To track all the fluid intake, the user must always put the MySleeve around the cup they're using. In return, the MySleeve app creates an insightful visualisation for easy logging of how much fluid a user has drunk.

The goal of this video scenario is to highlight MySleeve's usefulness throughout the day. We emphasise this by showing moments of a day in the life of cardiac patient Mark. Mark has Heart Failure and must mind his fluid intake. Mark can still drink most of the types of beverages he wants, but is limited to an amount of 1200mLs. Therefore we show that MySleeve can be used to track any drink; in the case of the video, it is orange juice and coffee.

We have set up the video in such a way that we show a rapid progression of time within a short period of actual video time. To achieve this time lapse effect, we speed up a scene in which Mark drinks orange juice, reads a book, makes coffee in the kitchen, and drinks his coffee on the couch. Later in the video, we show that we use the tracked information to send responsive DOs.

Throughout the scenario, Mark checks the DoCHANGE app. The DoCHANGE app shows how much Mark has drunk and at which point of the day. Moreover, we use the elapsing of time in the video to highlight how the app changes throughout the day.

4.4 Scenario 2: CookiT

Figure 5: Screenshot of Scenario COOKiT

The unique selling point of COOKiT is two fold. The spatula gives direct feedback on salt concentration and temperature of the food it is inserted into. The feedback from COOKiT is visible in the DoCHANGE app. On top of that, the usage of the spatula is tracked and analysed to form an image of the users lifestyle. i.e., the number of times COOKiT is used and the variety in salt concentration in dishes says something about what kind of food the user is or isn't eating.

DoCHANGE uses the lifestyle information to send responsive DOs that match the users condition. Examples of responsive DOs may include messages to increase the amount the number of times the user cooks, increase the variety of dishes or stimulate less sodium usage.

The video scenario shows Mark preparing, cooking and eating a plate of spaghetti bolognese. With this video, we show how COOKiT shows salt levels and temperature, and what differences there are between the foods Mark is preparing. In this case, Mark uses COOKiT for stirring the spaghetti, which has salt in the water, and pre-made pasta sauce, which contains added salt.

Additionally, in the video we highlight an important feature of COOKiT; its ability to be washed. This may seem obvious, but COOKiT is an electronic device, and extra effort was put into making the spatula washable.

The video is ended with the same scene as in the MySleeve video. Mark gets a responsive DO, based on the information that is collected from the COOKiT usage.

4.5 Discussion

The video scenarios for deliverable 2.4 were initially planned as draft videos. Deliverable 2.6 would contain the high-quality video scenarios. However, the tools could already be used as high fidelity prototypes and could - therefore - be used to shoot a high-quality video scenario. We chose to make the high-quality video scenarios for deliverable 2.4 and subsequently alter them for deliverable 2.6, might that need arise.
At the time of production for the videos, the video for Horus had already been made by a professional studio out of Taiwan.

5 Privacy Study

5.1 Introduction

The DoCHANGE ecosystem will aggregate both medical and non-medical data from existing products/services and newly developed products within the DoCHANGE project. The core of the ecosystem is the users ability to determine who can access their data, with certain granularity in defining the access, and providing transparency on the data collected from the user. However, to date, patient perspective on personal data management has not been taken into account. Generally, patients are not involved in discussions addressing their personal (medical) information. While shared decision making and patient empowerment regarding disease management are showing favourable outcomes [21], patient empowerment regarding data management is still understudied. In order to find out what patients preferences are, performing focus groups with the targeted population is of utmost importance.

The purpose of the focus groups is to identify the patients perspective on personal data storage and privacy in a medical context. The discussions within the focus groups will progress from current privacy regulations to future scenarios. The future scenarios will include the implementation of medical and non-medical devices either prescribed by their physician or initiated by the patient. The concept of a Personal Data Store (PDS), a database that holds personal medical and non-medical data, will be introduced to the participants. The observations from the focus groups can lead to design- and user-requirements for the DoCHANGE ecosystem.

Table 4 shows the overview of the privacy study per location. The final results of the study are planned to be presented in D2.5.

Location	Participants (per session)	Date
Netherlands (ETZ)	24 (7/2/2/6/7)	Finalised in August 2016
Taiwan (BTCD)	23 (8/7/8)	Finalised in October 2016
Spain (BSA)	16 (5/6/5)	Finalised in December 2016

Table 4: Privacy Study per country

5.2 Methodology

Focus Groups is a methodology often used to capture the opinions, feelings, and attitudes from a group of similar participants. In the case of this study, the end-user of the ecosystem is invited for this focus group. The setup of the session is as following:

1. Introduction to the focus groups and DoCHANGE project (rules of focus groups).

2. Fill in demographics questionnaire with initial questions on privacy.
3. Introductory round by participants and moderator.
4. Topic 1: sharing of medical data.
5. Topic 2: storage of medical data.
6. Topic 3: transparency and accessibility of medical data.
7. Topic 4: use of medical or life-style devices.

Participants are encouraged to share their own experience with these topics. The order has been defined by initially focusing on current issues -privacy is a hot topic in the last few years - and slowly moving to the future scenarios.

Sessions at ETZ are recorded using a Zoom H6 with multiple Philips LFH 9172 omnidirectional microphones daisy-chained for optimal sound quality. The recordings will be transcribed to the local language and afterwards translated into English for comparison with other countries.

5.3 Participant information

Inclusion criteria: age 18-75 years, newly diagnosed with CAD or HF, having, at least two of the following risk factors: smoking, positive family history, hypertension, increased cholesterol, diabetes, sedentary lifestyle, psychosocial risk factors. Patients should also have access to the Internet (and sufficient knowledge on using a personal computer or smartphone), and have sufficient knowledge of the local language. Additional inclusion criteria for HF patients only is to have a left ejection fraction of 35% and experience HF symptoms (e.g. shortness of breath, chest pain, exhaustion).

Exclusion criteria: significant cognitive impairments (e.g. dementia), patients who are on the waiting list for heart transplantation, life expectancy <1 year, life threatening co-morbidities (e.g. cancers), with a history of psychiatric illness other than anxiety/depression, not having access to internet, and patients with insufficient knowledge of the local language.

5.4 Analysis

The transcripts from ETZ, BSA, and BTCD are being reviewed independently by TUE and ETZ, and afterwards compared to produce a single output document. The review will focus on identifying basic ideas and components, categories, and trying to capture the general thoughts of patients on privacy. To accompany the qualitative analyses, a text analysis will be performed to identify topics and sentiment as has been applied to the patient interviews in D2.2 [23].

5.5 Intermediate results

The analysis of all three locations is currently in progress (qualitative and quantitative) and is expected to be done in March 2017. Intermediate findings from Taiwan are presented below:

Protection of personal data
Most participants of the focus groups are uncertain if personal information is well protected. Younger patients, with a relatively shorting medical history, worry if other (insignificant) people next to their specialist can access their data.

Sharing
Most participants are willing to share their cardiovascular disease history and medical information with friends, family, classmates, neighbours, or wardmates. They want to discuss the content of their health report, remind each other to take care of their health requirements, and support the general understanding of their illness.

Location of information storage
Most participants think that their medical information should be stored at the hospital. The hospital, or clinic, should hold the most complete record. In Taiwan, the National Health Insurance Administration enables patients to view their own health records. The Taiwaneese government has developed an app for patients to check their health records as well.

Location of self-recorded data
Opinions of participants are divided on where self-recorded data should be stored. Most participants store self-recorded data on their PC, Smarthphone, or Cloud (Evernote was mentioned) whereas others think it should be stored at the hospital or a combination of both.

Data for research
Most participants are willing to share pseudonminsed data for research. An explicit notion of declining pharmacist is mentioned because they are profit-oriented (*"they just sell drugs"*).

Insurance companies
Most participants do not feel comfortable with insurance companies being able to access their health records. They are afraid it will influence their service (reject case or impair benefits).

5.6 Discussion

The digitalisation of health records, in combination with the sharing of medical data with other care providers, raises the issue of the patient's privacy; where is data stored and who has access? Some hospitals provide patients access to their health records such as the Mayo Clinic [12], and several Dutch hospitals as listed by ZorgvisieICT [27], but do not provide information, or manageability, of access. Unlike other, questionnaire-based studies [19], the method of Focus Groups triggers discussion between participants and enables them to reason

their opinions and perspectives. The outcomes of this study will influence the granularity and default privacy management settings of the ecosystem.
The intermediate results from Taiwan, and initial insights from Spain and The Netherlands, show the patient's concern of their health insurance affecting their coverage or service if the insurance has access to more detailed information about the patient. The Netherlands, Spain, and Taiwan have different health care systems, investigating what information insurances (or governments) have access to might be valuable to include within the concept of DoCHANGE.

6 Pre-EDL Study: Moves

6.1 Introduction

Part of the DoCHANGE ecosystem is the Responsive Do: a personalised behavioural suggestion based on sensor feedback and data analyses. This chapter describes the development of the Responsive DO from a conceptual perspective.

6.2 Response DO Variables

The Responsive Do behavioural intervention measures and acts on peoples habits, rather than their knowledge or health outcomes. It brings about sustainable improvements in everyday behaviour, ultimately resulting in improved health. This section describes the first set of high-level variable habits on which the system intervenes. The variables are established in collaboration between DSD and ONMI. Each sub chapter describes the relevance and importance of the variable in relation to health and habit breaking.

6.2.1 Variable 1: Physical Activity

Sedentary lifestyles increase all causes of mortality, double the risk of cardiovascular diseases, diabetes, and obesity, and increase the risks of colon cancer, high blood pressure, osteoporosis, lipid disorders, depression and anxiety. According to WHO, 60 to 85 percent of people in the world from both developed and developing countries lead sedentary lifestyles, making it one of the more serious yet insufficiently addressed public health problems of our time. WHO[25]

The activity component of Responsive Do represents exercise and generally staying active. The NHS guidelines for physical activity are that adults should get at least 150 minutes per week of moderate exercise, such as walking, swimming, playing tennis, at cycling, or even pushing a lawn mower. Alternatively, one can step up the intensity and go jogging, dancing, or cycling on hilly terrain for at least 75 minutes per week. Research is shows that long periods of inactivity are harmful to both physical and mental health. Some say that sitting is the new smoking, referring to the magnitude of the health risks associated with sitting for too long[20]. A sedentary lifestyle has been linked to an increased risk of stroke, some cancers, depression, heart attack, bone loss, weight gain, and cognitive decline [18]. When considering how much of our current lifestyles are spent sitting (commuting, studying for school, working in an office, sitting at the table to eat, sitting on the sofa watching TV), these consequences are frightening. Some schools and workplaces have replaced sitting desks with standing desks in an attempt to decrease the amount of time spend seated[5]. However, some studies conclude that while sitting isn't great, standing is not much better being sedentary is the problem [17]. Whether sitting or standing, the important point is to keep moving frequently to regularly punctuate an otherwise sedentary day. The NHS recommends taking the stairs instead of the lift, pacing while on the phone, and walking over to colleagues desks rather than calling or emailing them[**?**].

Although any type of exercise is encouraged, there may be specific qualities to the activity of walking that make it a particularly nourishing form of exercise. Biomechanist Kate Bowman

even calls walking the defining movement of a human [10]. There are relatively few barriers to walking (it is free and most people are physically able to do it), it can easily be done outdoors in nature, and it still affords us the opportunity to talk and socialise.

Behavioural science points to a few reasons that our human nature may be working against us by hindering our motivation to get off of our chairs and get active. First, people may live sedentary lives out of habit. Research shows that adults in the workplace may sit for long periods out of habit, expectations and necessity rather than conscious intentions[4]. Not only does being sedentary require much less physical effort than being active (by definition), but also, it requires less cognitive effort. People often have to plan moderate and vigorous activity, for example planning on going to the gym, but do not need to plan sedentary behaviour that is often done without thinking and out of habit. Habitual behaviour feels automatic, even mindless, and can be very efficient (spending mental energy to make each and every decision would be tiring).

6.2.2 Variable 2: Social Opportunity

Social Opportunity describes the opportunity of communicating and connecting with other people. A lack of meaningful connections, sometimes referred to as social isolation, may affect our immune systems [14] and is a risk factor for cardiac arrest and death [11]. Connecting to others is one of five evidence-based approaches to improve wellbeing, and is recommended by the NHS[15]. People should both deepen existing relationships with friends and family and broaden social connections with their community as each type of bond provides benefits[13]. Strong social relationships are supportive, encouraging, and meaningful. Broader, more superficial relationships are important for feelings of connectedness, familiarity and sense of self-worth associated with an individuals position in a community.[2] While current technology and social media apps might help provide breadth of connection, they rarely provide enough depth for our needs as social beings[22].

When it comes to general connections and socialising, some suggest that portable devices lend us the opportunity of bailing out of our lives with each other [4]. Digital communication is not an adequate substitute for face to face interactions: Most of all, we need to remember in between texts and e-mails and Facebook posts to listen to one another, even to the boring bits, because it is often in unedited moments, moments in which we hesitate and stutter and go silent, that we reveal ourselves to one another.[26] Text-based communication is not the same as face-to-face dialogue.

Some research finds that people wrongly believe that they will be happier keeping to themselves, and/or that others wont be interested in connecting with them. Some might not think that they want to speak with others, but studies found that when people speak to their fellow commuters or engage in conversation with their coffee barista, they report higher wellbeing. Research also shows that - in fact - both extroverts and introverts report feeling happier on days with more social interactions, even if the interactions are with weak ties (meaning they were not close connections; rather, they could be someone in the community or the person at the checkout till)[16].

Even in the face of potential behavioural hurdles, people should aim to engage in social opportunities to socialise (off-line) to forge meaningful connections in their lives.

6.2.3 Variable 3: Variety

There is general agreement that habits are automatic in the sense that they are enacted without purposeful thinking, largely without any sense of awareness, and can be performed quickly in parallel with other activities[7]. Habits form through repeated performance in unvarying settings. The process of forming habits occurs through a gradual shift in cognitive control from intentional to automatic processes [3]. When a behaviour is performed many times, humans begin to use heuristic decision-making strategy, i.e., a cognitive shortcut whereby they do not need to scrutinize all the consequences of enacting a certain behaviour [8].

As behaviour is repeated in the same context, the control of behaviour gradually shifts from being internally guided (e.g., beliefs, attitudes, and intention) to being triggered by situational or contextual cues, such as automatically looking both ways before crossing the street, strapping on the seat belt when entering a car, or saying amen at the end of a public prayer in church.

Empirical findings in various fields suggest that behaviours that are repeated in constant contexts are difficult to change. Therefore, interventions that focus on changing the context that maintains those habits have a greater probability of success. The Variety variable aims to increase the variation in context of behaviour. The context is the environment in which behaviour takes place; the features or cues that trigger action can be anything from physical objects and preceding actions to geographical features or people [1]. Some sort of contextual disturbance provides a window of opportunity in which a behaviour is more likely to be deliberately considered.

To some extent, it is related to Heideggers[9] concept of unreadiness-to-hand, i.e., an unpredicted disturbance that makes someone recognise and see things they do not normally notice or have come to take for granted (presence-at-hand). Because habits are triggered automatically in response to contextual cues, breaking bad habits can be achieved by either removing persons from the environment that cues unwanted habitual responses or by modifying the context, e.g., placing reminders in the environment.

6.3 Methodology

The Pre EDL study is set up in order to obtain data necessary for the generation and validation of algorithms that interpret the behaviour of people in relation to the before mentioned variables: Activity, Social Opportunity and Variety.

For the month September 2015 participants are asked to track their own GPS data with help of the Moves app, and to answer a daily questionnaire about their impressions, experiences and emotions. The contextual information obtained from daily questionnaires can then be

related to measurable habitual behaviour.

Participants: 22 participants are included word-to-mouth, 19 males and 3 females.

During the study 3 participants dropped out, meaning data of 19 participants was collected for the whole month. Over the course of one month 547 questionnaires and a correlating 570 days of Moves data were collected. The analytics performed on this data and the development of the Responsive Do algorithms are reported in *D4.17 Data Analysis and Big Data Analytics Implementation*.

7 Co-creation/EDL Study: Responsive Do's

7.1 Introduction

This section describes the methodology, rationale, object, and study design of the co-creation of the DoCHANGE-app study: Experiential Design Landscapes (EDL) Responsive Dos.

Rationale As preparation for upcoming clinical trials this co-creation study will support several design- and development-decisions. The intent is to provide a small amount of users, 20-25 participants, with tools to be used in the clinical trial and a Minimum Viable Product (MVP) of the DoCHANGE-app called Vire. Using modern technologies and direct digital communications, quick iterations in functionality and design of the application can be produced and evaluated. This helps us, the researchers, to define what functionalities are important for users and how visualisation can support the value perception of the total application. The co-creation approach, in combination with the EDL methodology, is expected to result in desired short feedback loops in iterations and involvement of the users. **Hypothesis: by including end-users in the development and design of the application, the overall experience of using the application will increase.**

Objectives Three main objectives are defined as following: (1) Redefine and finalise the development of the DoCHANGE mobile application, Vire, and the related services by (2) creating an understanding of the end-users requirements and context to redefine the interactions with the mobile application. (3) The development of *Responsive-DOs*, based on data derived from connected devices and services, in addition to the *Core-DOs*.

Study Design The study will use the EDL-methodology, emphasising co-creation. The core of EDL is to respond on feedback by participants and manipulate the user experience to trigger reactions. Due to the ad-hoc responses, the members of the research team have increased responsibility for maintaining professional and ethical conduct, because the specific boundaries are not defined in this protocol. General guidelines are discussed later in this document.

Study Population The study will require 25 healthy volunteers between the ages of 18 and 75. In contrast to the DoCHANGE clinical trial study population, participants with severe cardiac issues are excluded.

Endpoints of Study The intended duration of the study is 3 months. In the situation that saturation occurs before the intended duration, the research team can decide to finish the study earlier. In the situation that saturation has not been achieved, the research team can continue the study if the participant agrees to extend the duration of the study. The study will be limited to a period of 6 months.

Burden and Risks Due to the nature of personal data, the research team has defined the following risks and burden for the participant: (1) The study might be too confrontational due to the obtained insights by the participants concerning their (unhealthy) lifestyles. (2) The

multitude of devices might overwhelm the participants. (3) The burden of the study might be too much for the participants time-wise. In the last case, the involvement of the participant can be limited or the participant can exit the study at any time.

7.2 Participant requirements

The following paragraphs will elaborate the requirements from the participants. Ideally, a participant will meet all requirements but exceptions can be made on an individual basis. Each participant will be given a Fitbit Charge HR and Beddit. They are asked to install the Fitbit, Beddit, and Moves app and are instructed to use the applications as a regular consumer. After a short familiarisation period with the devices and apps, participants will receive an invite from HockeyApp (deployment service) to install the DoCHANGE (Vire) application. Vire will initially include messaging functionality, as a main source of communication between participants and research team, a list of DOs, and dashboard. The primary co-creation elements focus on the development of the dashboard.

Requirement of time We exclude the amount of time the participants voluntary spend using the consumer applications as this is not required by the study. On average, we estimate that the study might occupy $\tilde{1}5$ minutes per day. This estimate takes into account any action required from receiving a DO. The exact duration might increase if the participant is willing to *co-create* for a longer period of time. This also depends on the availability of the primary contact person from the research team.

Requirement of devices In order to run the Vire application, minimum version of the mobile phones OS is determined. For Android we expect an OS higher or equal to 4.1 (API 16) and for iOS (iPhone) a version higher or equal to 8.0. In practise only less than 3% of the Android devices would be excluded due to this restriction and 3.4% for iOS users. Camera requirements are set to a minimum of 3.6MP rear-facing camera for the computer vision (CV) functionality.

Requirement of returning devices Participants are required to return the devices after the study has been concluded or participation is terminated.

7.3 Research guidelines

The research team follows the Dutch Wet Bescherming Persoonsgegevens (WBP). No religious, race, political orientation, or participation in union are discussed or recorded (P.2, Art.16). Health (non-medical) data is recorded with prior consent by the participants (P.2, Art. 23) through the Fitbit, Beddit, and Moves APIs.

Communication with participants The Vire app provides a communication channel through a messenger for the participant and research team. Participants cannot exchange messages with other participants. The research team will only ask question related to the study or respond to questions or remarks stated by the participant. The participant can, at

any time, refuse to answer a question and is not obligated to discuss the reason for doing so. The messaging is intended as informal communication to provide an open settings to facilitate a comfortable dialogue to gain understanding on the participants ideas, opinion, and experiences.

Communication in research team The research team can discuss their communications and experiences with participants if it is beneficial for the study. In case of disagreement between researchers in how to proceed with the study, the principal investigator is responsible for the final decision.

Data storage Data resulting from the study will be stored at servers positioned at the Eindhoven University of Technology and at ONMI. Data will be archived for 15 years at Eindhoven University of Technology.

7.4 Environments

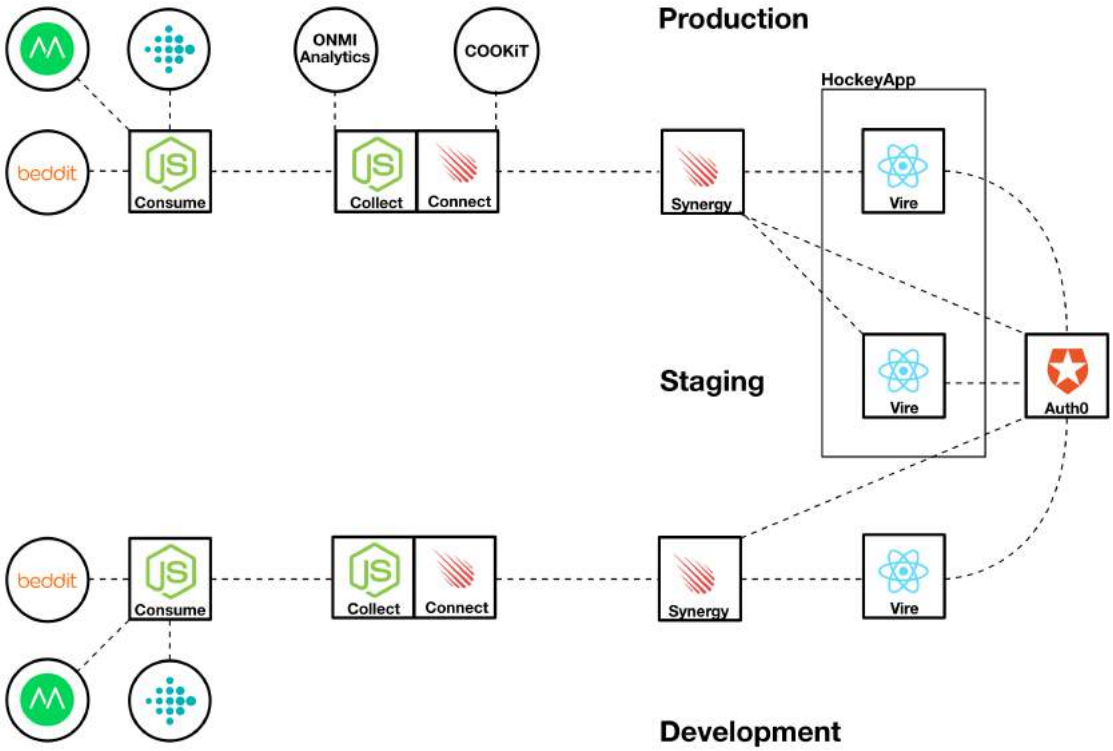


Figure 6: High-level system architecture for study

Figure 6 illustrates the different environments used for the study; production, staging, and development. All environments use the same identify provider domain at Auth0. The production and staging Vire application are hosted at HockeyApp. Both environments contain

an iOS and Android version. Windows Phone 8.1+ support is investigated but due to the low percentage of mobile phones running this OS (<1.8%) it was decided to locate those efforts in the development of iOS and Android.

As reported in D2.3 [24], the initial start of the study was planned for October 2016. In preparation for the second phase clinical trials it was decided that the study should also test, and developed further, the version of the ecosystem that will be used for the trial. Besides the development and co-creation of the DoCHANGE-app, the study is also functioning as a test-bed for the other services in the ecosystem.

7.5 Minimal Viable Product: Vire and Synergy BackOffice

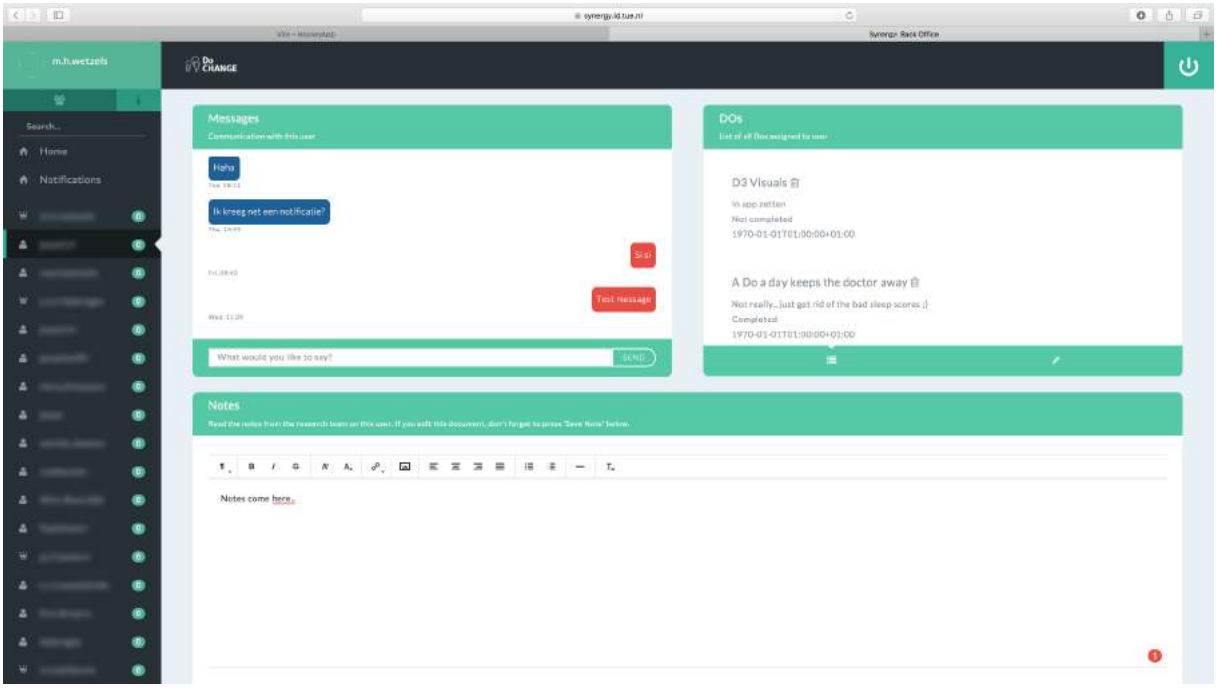
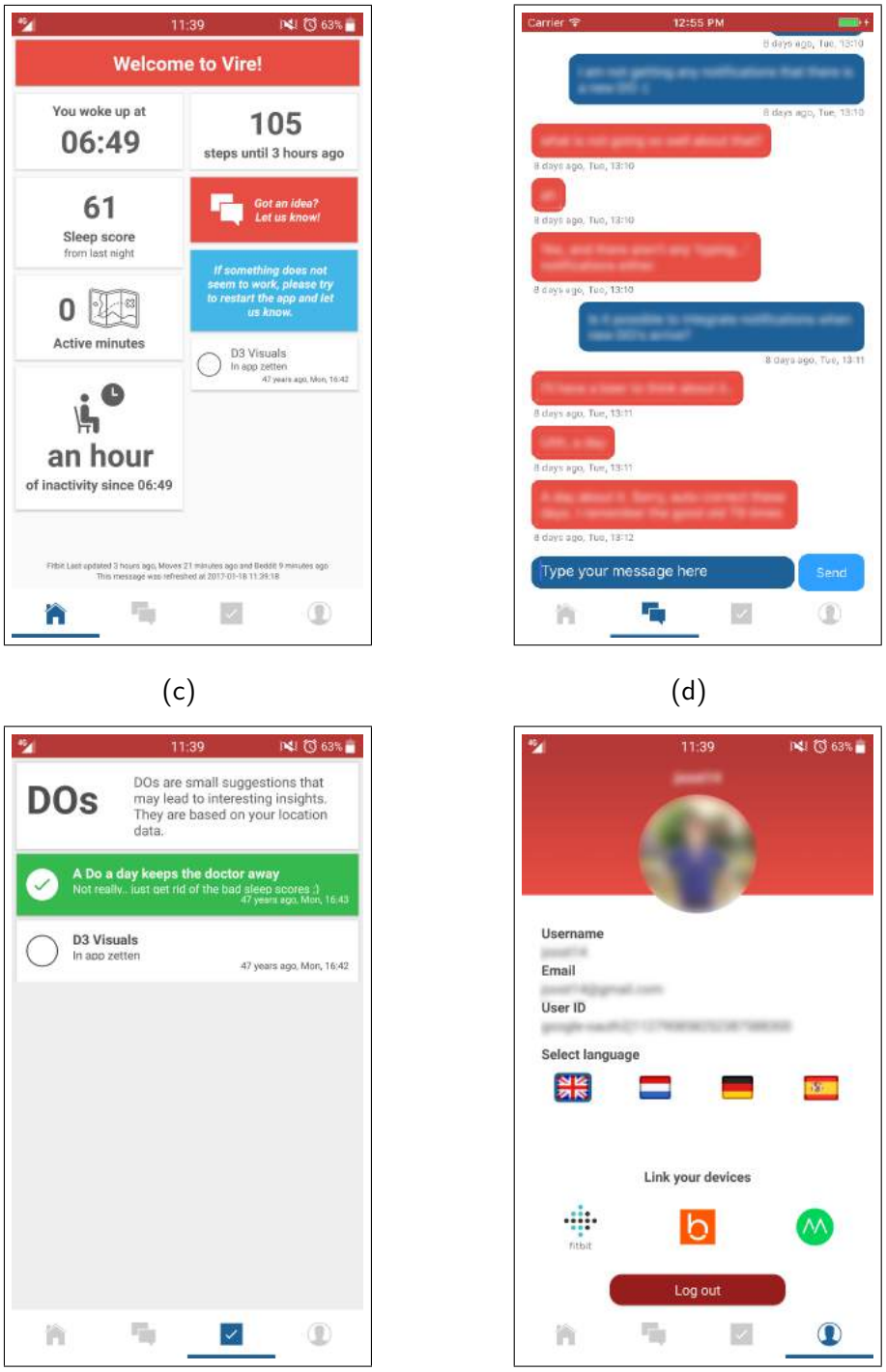


Figure 7: Screenshot of BackOffice participant view

Figure 7 shows the participants view of the Synergy Back Office for the study. On the left pane is a lift of all users with a notification label that shows a counter of unread messages through the chat. In the centre pane, top-left, is the chat module to communicate with the participant. Participants do not know with which of the researchers he or she is talking to. On the top-right, a list of current DOs for the participants, and the completion state, is listed. New DOs can be added there as well. On the bottom pane, there is room for notes from the researcher about the participants.

Researchers share notes on the Home page and have a single-page for Notifications. Future efforts include push notification for the Back Office, so the website does not need to stay open for updates.

(a) (b)



(c) (d)

Figure 8: (a) Vire Daily (b) Chat with BackOffice (c) List of DOs (d) Profile information and settings

Figure 8 shows four screenshots containing the homepage, where the visualisation work will be done, the messenger, where participants can communicate with the research team, the list of dos, where participants can see and mark their dos complete, and the profile page

where participants can link their devices and change language. The primary focus is on the homepage, now called Vire Daily.

7.6 Discussion

The continuous developments, through small iterations, generate many user needs and requirements. Some requirements take minor effort to tackle whilst others need to be investigated if the nature of the 'requirement' is a necessity or feature request. In addition, the scope of the DoCHANGE-app needs to be continuously refined to determine what information is needed and what should be left out. Current developments, based on feedback from participants, involve integrating push notifications in both the mobile application and Back Office; we expect this to increase engagement. Deliverable 2.5 will present the final outcome of the study.

8 Discussion

The results from the first cycle of Work Package 2 provided the foundation for understanding the end-users; interviews, personas, and use-cases. The second cycle was focussed on investigating the integration of DoCHANGE in the cardiac population; privacy study, app study, pre-EDL, and EDL: responsive Do's etc.. The third cycle, mainly through integration efforts, will flow from WP2 to WP3, WP4, WP5, and later be evaluate from WP6 to WP2.

Evident from the patient interviews, different views on the topic of privacy within the health context are expected. This raises the challenge of flexibility within the design of a health ecosystem; it should be adoptable for different contexts or cultures or provide different implementations. In addition, preliminary insights show that, the information that a health insurance (or government) holds about a patient is not clear. Investigating this topic might provide an interesting discussion as a 'counter-argument' to the patient perspective.

The Co-creation EDL: Responsive DOs study has started later than scheduled, but substantiations are valid for long-term progress; with the prior planning there was little time allocated to test the stability of the ecosystem for 3rd-party integrations. Current experiences, related to WP3, WP4, and WP5, have proven the need for this testing environment to prepare both usability (through the DoCHANGE-app) and technical maturity (services presented in the chapter and other deliverables).

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