Hypercheck

Developing a Reminder and Data Logging System for Hypertension Patients

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Abstract

**Problem:** A Major challenge for healthcare providers is the non-adherence of patients to prescriptions. One important area is hypertension treatment through medication. A treatment often starts with multiple adjustment cycles of medication type or dosage, which are based on regular at-home blood pressure measurements. Patients therefore need to adhere to regular medication intake and blood pressure measurements. **Research Aim:** The project first explored whether or not it is possible to develop a medication reminder system that checks patient adherence based on vital parameters. The project goal was adapted to the design and development of a reminder and data logging system for hypertension patients, based on the following research questions: 1) What are functional and non-functional requirements for the proposed artefact? 2) How can these requirements be implemented? **Method:** The project makes use of Design Science Research to create the system. The problem and requirement explication for the new artefact was achieved by working closely with a general practitioner who deals with hypertension patients. The artefact was evaluated by presenting it ex-post to a focus group of a hypertension patient, developers and founders in digital health. **Results:** The results of expert interviews concluded that the initial project aim is not feasible due to continuous vital monitoring being invasive and intrusive, lack of applicability for health conditions and medications and other potential negative consequences. These insights led to the new research aim. The results address the question: "What are functional and non-functional requirements for the proposed artefact?". The envisioned product is a cross-platform application, illustrating the frequent medication adjustments for hypertension patients. The treating doctor should configure all patient-specific parameters and the app should guide patients through daily tasks like measurements and medication intake. The patient should also be reminded of their tasks. The app should record, display, and export data for the doctor's review, and ensure easy input of measurements. Future remote data exchange capabilities via servers were also considered. To address the research question "How can these requirements be implemented?", the researcher developed a cross-platform mobile application for iOS and Android with .NET Multi-Platform App UI (MAUI) that implements the desired features. A concept for remote data exchange and a system for scanning measured values of blood pressure devices were developed. The evaluation partially validated the problem area and discussed future implementations, such as remote data exchange, usage of patient data for research and adoption to other medication. The perceived high usability of the application was emphasized. **Conclusions:** The researcher concludes that the developed artefact addresses a relevant problem and extends existing solutions in the problem space. It is acknowledged that future research has to be conducted to prove the effectiveness of the tool as well as assess its usability and accuracy. Difficulties for accepting the artefact in real life settings are discussed.

**Keywords:** Hypertension; mHealth; Patient Compliance; Reminder System; Mobile App;
Synopsis

Problem
This study addresses the process of prescribing and adjusting blood pressure medication for new patients. When a medication is prescribed, it gradually modifies the patient’s blood pressure over a span of weeks or months. This necessitates regular monitoring of blood pressure to evaluate the medication’s effectiveness and make necessary adjustments to the treatment plan. Typically, patients are provided with a device to measure their blood pressure at home over the span of a few weeks. The recorded values are later reviewed by a doctor to make adjustment in the medication. New patients may find the task of consistently measuring their blood pressure challenging and overwhelming, potentially affecting their adherence to the process. Moreover, deviations from measurement instructions or errors while recording values from the device can render the collected data unreliable.

Research Question
The study investigated two different goals. The first goal was the development of a software system that uses continuous measurement of vital parameters to assess medication compliance and remind patient’s about forgotten medication. This goal was shifted because of new research insights. The newly defined aim is the development and evaluation of an artefact that helps doctors and patients manage the process of initial hypertension medication adjustment. Based on this aim, the following research questions are formulated:

1. What are functional and non-functional requirements for the proposed artefact?
2. How can these requirements be implemented?

Background
Medication non-compliance is the failure of patients to follow their healthcare provider’s prescriptions due to factors like forgetfulness or intentional non-adherence. It is shown to have enormous financial and societal impacts.

Hypertension, a common health condition, poses a significant risk as it increases the susceptibility to cardiovascular diseases and other health complications. Non-adherence to hypertension medication increases these risks, leading to poor blood pressure control and heightening the possibility of complications. This presents a substantial societal and economic burden, costing the global economy an estimated ten trillion USD annually. The condition is projected to affect over 500 million people by 2025, further underscoring the urgency of addressing this health crisis.

Daily reminders, such as Short Message Service (SMS)-based notifications, have shown promising results in improving patient adherence to hypertension medication and in encouraging at-home blood pressure measurements. Mobile applications serve as useful tools to assist patients in managing their hypertension condition long-term. They offer a wide range of features like recording blood pressure values, providing reminders, supplying educational information, and enabling data visualization.
Therefore, leveraging digital technology is a promising avenue to enhance treatment compliance and manage hypertension more effectively.

Method
The Design Science Research strategy was used to develop the artefact. The selection of this method was due to its problem-oriented approach and its pertinence in computer science. Working closely with a general practitioner in Germany, the researcher was able to understand the problem of hypertension medication adjustment and outline the requirements for the artefact. The model was refined based on the doctor’s feedback and additional requirements from consulting with the company "VitalSigns". The development followed a waterfall-similar approach, with one iteration for refining the application based on feedback. The artefact was evaluated by a focus group of developers, digital health founders, and a hypertension patient, who provided feedback on its usability, effectiveness, and areas for future improvements. A more comprehensive evaluation involving a doctor-patient study in a natural setting was deemed a potential future avenue due to time constraints.

Result
The research addressed the question: "What are functional and non-functional requirements for the proposed artefact?" by discussing with a hypertension-treating doctor. The envisioned product was a universal app, illustrating the frequent medication adjustments for hypertension patients. The treating doctor should configure all patient-specific parameters, and the app should guide patients through daily tasks like measurements and medication intake. The app should record, display, and export data for the doctor's review, and ensure easy input of measurements. Future remote data exchange capabilities via VitalSigns' servers were also considered.

To address the research question "How can these requirements be implemented?", the researcher developed a cross-platform mobile application for iOS and Android with .NET MAUI that implements the desired features. The data structures, data storage and reminder types were described. A concept for remote data exchange via the VitalSigns API and a system for scanning measured values of blood pressure devices were developed. The application has multi-language support, reminds the patient of rest before measurements and gives additional information if the blood pressure of the patient falls too low. Other defined requirements were also implemented and showcased.

Discussion and Conclusion
Existing hypertension apps do not focus on the initial medication adjustment phase; the developed artefact attempts to fill this gap. However, a real-life adoption could face challenges due to resistance in healthcare structures, concerns over data privacy, user’s discomfort with technology, and potential confusion or complications in treatment from inaccurate data input or reminders. Limitations in generalising results due to a limited involvement of stakeholders in requirement definition and evaluation are acknowledged. The artefact fits into existing treatment structures which limits ethical concerns. Reliability of the tool do warrant additional evaluation if the application was to be used in practice. Advanced research would therefore be of relevance. Additional features and implementations, such as remote data exchange, are suggested.

Overall, the application shows promise in improving patient-doctor communication and health monitoring through features like medication reminders, yet its real-world adoption faces several obstacles.
I would like to express my deepest gratitude to my supervisor, Professor Hansson, for his valuable assistance during the course of my Master's thesis. Professor Hansson's experience in guiding research projects and his fast and reliable responses to my questions made it easy for me to understand the research process and the requirements for the thesis.

My heartfelt appreciation also belongs to the general practitioner who generously shared her time, expertise, and insights that directly led to the development of the research topic and final application. Her contributions in the topic of hypertension and patient treatment have been pivotal in shaping the direction and findings of this project.

Lastly, I would like to thank the medical professionals who were available for interviews and could support the thesis with their knowledge about health conditions and their interplay with medications.
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List of Abbreviations

API - Application Programming Interface
AR - Action Research
BP - Blood Pressure
CSV - Comma-Separated Values
DSR - Design Science Research
MAUI - Multi-Platform App UI
mHealth - Mobile Health
mmHg - Millimeters of Mercury
MVVM - Model-View-ViewModel
OCR - Optical Character Recognition
ORM - Object-Relational Mapping
PDF - Portable Document Format
SMS - Short Message Service
UI - User Interface
XAML - Extensible Application Markup Language
Chapter 1
Introduction

Medication non-compliance, also known as medication non-adherence, refers to a situation where patients fail to follow the recommended treatment plan of taking their prescribed medication. It is a widespread problem that can have effects on one's health including worsening symptoms, longer recovery periods or the need for hospitalization. There are different reasons why non-compliance occurs, such as forgetfulness, lack of awareness about the importance of adhering to medication instructions, financial constraints or limited access to medications and concerns about side effects. Healthcare providers face challenges in addressing this issue since it can undermine the effectiveness of treatments and lead to increased healthcare expenses. (Lehane & McCarthy 2007)

The problem of compliance can be extended to hypertension patients, who often need to adhere to regular medication intake or at-home blood pressure (BP) measurements. Several mobile applications address the problem of compliance by implementing reminders and offering logging for blood pressure measurements.

1.1 Problem

The practical problem is the complex process of prescribing and adjusting blood pressure medication for new patients. A prescribed medication gradually alters the patient’s blood pressure over weeks or months, necessitating regular blood pressure measurements to assess its effectiveness and adjust the treatment plan accordingly (Campbell et al. 2022). Blood pressure should be monitored during the first weeks of new medication and then evaluated to determine if changes to the medication type or dosage are necessary. If blood pressure decreases as intended and stabilizes after a few weeks, the treatment is considered successful; otherwise, adjustments might be required. Any changes to medication trigger another period of measurements. Patients are typically given a device to measure their blood pressure at home (Igarashi et al. 2019). They record their measurements either digitally or on paper, and these values are later reviewed by a doctor (Bilo et al. 2010). However, new patients may find the task of consistent self-measurement challenging and overwhelming, which possibly affects their compliance. Additionally, not following certain instructions for measurements or inaccuracies while transcribing the measurement values from a device, can make collected data unreliable.

The need arises for an artefact that reminds patients to regularly take their medication and measurements, guides them through the measurement process, aids in accurately recording the measurements, and stores and processes the data for a doctor’s evaluation. Such an artefact would be useful during the initial phase of medication adjustment. No such existing artefact that focuses on medication adjustment has been identified by the researcher.
1.2 Research Goal

The overall aim of this project is to explore the problem areas of medication compliance and hypertension and find out if and how an artefact can be developed that improves existing processes between doctors and patients.

Initially, the goal of the project was to design and develop a mobile application that connects to body sensors and receives vital parameter data. The application should analyse this vital parameter data to determine if the user is taking their medication on schedule and send reminders to the user to take their medication if necessary. Expert interviews concluded that the proposed project goal would be very hard or even impossible to implement. The detailed reasons are laid out in chapter 4. The thesis focus was subsequently shifted to the following: The development and evaluation of an artefact that helps doctors and patients manage the process of initial hypertension medication adjustment.

Based on this aim, the following research questions are formulated:

1. What are functional and non-functional requirements for the proposed artefact?
2. How can these requirements be implemented?

1.3 Delimitation

The project only focuses on the software portion of the medication reminder system and does not investigate the accurate measurement of blood pressure data. This project also does not measure the actual effectiveness of the artefact in improving adherence to actions and supporting the patient-doctor processes as it would require more time and other resources than are available.

Problem and solution were developed together with a German general practitioner. While parts of the problem have been confirmed by a Swedish hypertension patient in chapter 7 and by additional literature, there could be aspects in the practice of hypertension medication adjustment that differ in other countries and would require adjustment. The findings and results of this study are therefore limited to Germany and partly to Sweden.

1.4 Thesis Structure

Chapter 2 explores the general problems of medication compliance and hypertension. It also explores existing solutions and their shortcomings. Chapter 3 outlines Design Science Research (DSR) as the intended research strategy, introduces used research methods and discusses ethical aspects of the project. Chapter 4 presents the results of the expert interviews regarding the viability of a medication reminder system based on vital parameters and why the project focus was shifted. Chapter 5 exposes the specific problem and practice of hypertension medication adjustment. Based on this problem, functional and non-functional requirements are defined and motivated for developing an artefact that supports patient compliance and information exchange between doctor and patient. The design and development process of the artifact is described in chapter 6 including its features, structure, and justification of design choices. A small-scale evaluation of the artifact was conducted through a focus group consisting of a hypertension patient, software developers and founders in digital health. The resulting feedback is presented in chapter 7. Finally, chapter 8 discusses the scientific contributions and limitations of the project as well as proposes potential avenues for future research.
Chapter 2

Patient Compliance and Hypertension

Background

This section presents the theoretical foundation of the upcoming results. It introduces the problem areas of medication compliance and hypertension and explores existing solutions.

2.1 Medication Compliance and Reminder Systems

Different forms of medication non-compliance exist. Generally, a distinction is made between unintentionally and intentionally not taking medicine as prescribed. "Unintentional non-compliance" happens due to patients forgetting to take their medication or being in a situation where it is not possible to take their medication. "Intentional non-compliance" can be caused by patients that do not want to take the medication because of fear of side-effects or not understanding the importance of taking the medication. (Lehane & McCarthy 2007) Further, "primary non-compliance" is the failure of patients filling a medication prescription after receiving it. According to Fischer et al. (2010), 22% of prescriptions are not picked up from the pharmacy after medical staff has initially prescribed them.

Cutler et al. (2018) systematically reviewed 79 studies to determine the economic impact of medication non-compliance across 14 disease groups. It found that lower medication compliance generally leads to greater economic cost which ranged from 949 USD to 44190 USD per person (2015 price level) and included indicators for costs like emergency department visits and hospitalisation. While the study acknowledges that it is impossible to accurately estimate the true magnitude of costs, it concludes that there is a correlation between non-compliance and higher disease rates which is an avoidable burden for the healthcare system.

Gellad et al. (2017) addresses the claim of many publications that non-adherence to medication of chronic diseases is around 50%. It identifies these claims as a myth and places the real value at around 21% based on DiMatteo (2004), a meta-analysis of over 300 medication-related studies. This value can still be seen as significant, given the economic impact of non-compliance. A study from 1999 conducted interviews of elderly heart failure patients with age 70-97 to explore their compliance with given medication and whether they remember their intake instructions. The interviews were conducted 30 days after prescription of the medication. The result was that 27% percent of 22 participants were found non-compliant with their medication. (Cline et al. 1999)

Different approaches try to address the problem of medication non-compliance. Several studies have shown that daily reminders, particularly through Short Message Service (SMS) or mobile phone-based systems, can improve patient adherence to treatment. For example, a study on asthma patients found that a daily SMS reminder increased adherence to treatment (Strandbygaard et al. 2010). Similarly, a study on sunscreen use found that daily text message reminders improved adherence rates (Armstrong et al. 2009). Another study on glaucoma medication dosing found that automated telecommunication-
based reminders improved adherence (Boland et al. 2014). Vervloet et al. (2012) shows short-term effectiveness of electronic reminders in multiple studies. However, not every study has found positive effects of daily reminders on patient compliance. For example, a study on tuberculosis treatment in China found that daily two-way SMS reminders did not improve drug compliance (Mohammed et al. 2016). Additionally, patient-directed reminders in Bennett & Glasziou (2003) have shown mixed results in improving compliance.

Another approach is the use of physical devices such as pill holders or dispensers with integrated, programmable alarms. Some of these systems can send text reminders and track if and when users have taken their medication (Qudah et al. 2010). The effectiveness of such an automatic pill dispenser with daily alarms was measured by Kaminura et al. (2012) with a group of mildly cognitive impaired elderly participants. The result shows an improvement with 72.2% of participants after 3 months. At the same time, it shows an abandonment of the device by 22.2% of participants. In its discussion, it mentions that elderly people might be unwilling to use such new technology. The result therefore indicates that static daily reminders can help with unintentional non-compliance but struggle to solve the problems of intentional non-compliance.

A more novel approach to reminder systems are mobile phone applications that implement static reminders. Santo et al. (2016) identified 272 of such apps in 2016 and classified them according to their features. The effect of such applications is studied in Santo et al. (2019) which shows a measurable, but not significant improvement in medication compliance in coronary heart disease patients.

Overall, available reminder systems operate statically with scheduled reminders that do not take into account whether a medication was taken or not. These solutions can not solve intentional non-compliance because affected patients know that they should take their medication, but do not want to due to different reasons. Static solutions remind the patient of the medication intake even if the reminder was not necessary, which can lead to reduced effectiveness of such systems.

In contrast, Vervloet et al. (2014) shows how dynamic reminders can improve compliance better than static solutions. The study aimed to investigate the effects of real-time medication monitoring and SMS reminders on refill adherence to anti-diabetic medication in patients with Type 2 diabetes. A randomized controlled trial was conducted with 161 participants for a period of 2 years in which the SMS group was given medication reminders only if they missed taking their medication. The SMS group showed significantly higher adherence compared to the control group after 1 year, with a persistent improvement after 2 years. The non-SMS group showed some improvement in adherence but did not differ significantly from the control group. The study suggests that real-time medication monitoring combined with SMS reminders can effectively improve adherence in the long term.

## 2.2 Hypertension

Hypertension, also known as high blood pressure, is a medical condition characterized by elevated blood pressure levels. There are two main types of hypertension: primary hypertension and secondary hypertension. Primary hypertension, also known as essential hypertension, is a common type of high blood pressure caused by a combination of multiple genetic and environmental factors. The development of this multifactorial disease involves complex interactions between various genes and external influences, such as diet and lifestyle. Secondary hypertension is caused by an underlying medical condition such as obstructive sleep apnea, Cushing syndrome or chronic kidney disease. (Warisyu et al. 2023, Büchner et al. 2006, Lin et al. 2016, Pedrosa et al. 2011)

Blood pressure readings involve two numbers, measured in millimeters of mercury (mmHg): the systolic pressure (the first, higher number), representing the force at which the heart pumps blood through the body; and the diastolic pressure (the second, lower number), describing the resistance to blood flow in the vessels between heartbeats. Hypertension is diagnosed if systolic readings are 140 mmHg or higher and/or diastolic readings are 90 mmHg or higher on two separate days. For reference,
ideal blood pressure is typically between 90/60mmHg and 120/80mmHg. (WHO 2023, CDC 2021, NHS 2023a)

Hypertension patients are at risk for a variety of health complications. Hypertension increases the risk for cardiovascular diseases such as stroke, coronary artery disease and heart failure (Leong et al. 2013). Hypertension also causes alterations in organs, such as the heart, kidneys and brain, therefore increasing the risk of other health conditions (Moraes-Silva et al. 2017). Because hypertension is a chronic disease and often shows no apparent symptoms, patients with high blood pressure may fail to take their medication, which can lead to poor blood pressure control and increased risk of hypertension-induced complications (Bramley et al. 2006, Okai et al. 2020). Other risk factors for hypertension include obesity, dyslipidemia, and diabetes mellitus (Barton & Meyer 2009). Because of these immense risks, high blood pressure has a significant impact on society, both in terms of health and economic burden. In the US, hypertension is linked to five of the top nine causes of mortality and accounts for around one in six adult fatalities each year (Fitzgerald & Lepine 2012). Globally, the incidence of hypertension is rising, and by 2025, more than 500 million individuals are expected to be affected (Bommishetty & Kumbhar 2020). The direct and indirect impacts of hypertension are expected to cost the global economy ten trillion dollars annually, which is a huge financial burden (Fitzgerald & Lepine 2012). The healthcare system in the United States alone was under tremendous financial strain in 2009 due to expenses that were estimated to be close to $74 billion (Fitzgerald & Lepine 2012).

A combination of medications and lifestyle modifications is used to control hypertension. Adhering to a healthy, low-salt diet and an active lifestyle, decreasing weight if overweight, and giving up cigarettes and alcohol are just a few examples of lifestyle modifications. When lifestyle adjustments alone are insufficient or when the person’s blood pressure is continuously above a specific level, pharmaceutical therapies are frequently advised. The choice of medication depends on the patient’s blood pressure levels and their risk of related complications. Angiotensin II receptor blockers, calcium channel blockers, diuretics, and Angiotensin-converting enzyme inhibitors are some of the medications used to treat hypertension. These drugs reduce blood pressure via relaxing blood vessels, protecting the kidneys from harm, or getting rid of extra water from the body. Combining these two approaches results in a thorough strategy for controlling hypertension. In some cases, making lifestyle changes early on may reduce or eliminate the need for medication. However, when medication is necessary, it is often used in combination with lifestyle changes to achieve the best outcome. (NHS 2023b, WHO 2023)

Several studies have investigated the effectiveness of daily reminders, including SMS reminders, audio-visual reminders, and electronic monitoring devices, in improving patient adherence to hypertension medication and at-home blood pressure measurements. For example, a study on older hypertensive patients found that daily SMS reminders of antihypertensive medication intake provided by pharmacists increased the proportion of adherent patients (Haramiova et al. 2017). Another study found that patients self-reported that reminders, the daily frequency and time of monitoring, and positive reinforcement were important for maintaining adherence to home blood pressure monitoring (Xiao et al. 2019). Additionally, an interventional study on hypertensive patients found that medication supervision or peer assistance, including daily reminders, improved medication adherence (Pratiwi et al. 2019). Other studies have found that electronic monitoring devices and mobile applications with daily reminders can improve medication adherence and hypertension control (Christensen et al. 2010, Agushyana et al. 2020). Overall, daily reminders can be an effective tool for improving patient adherence to hypertension medication and at-home blood pressure measurements.

The researcher identified many mobile applications that help patients with managing their hypertension condition (klier.net GmbH & Co. KG 2023, UG 2022, evolvemedsys 2023, Klimaszewski 2023, Swiftware 2022, AG 2023). Most of them have very similar features. All of them have a “diary” function that allows users to record their daily systolic, diastolic and pulse values. Some also make it possible to track symptoms that go along with hypertension. All of the applications offer reminders in form of notifications for medication intake and measurements. Some of them show educative blood pressure
information and lifestyle recommendations. All of them can display various plots and diagrams of collected data and export this data to Comma-Separated Values (CSV) or Portable Document Format (PDF) files.

2.3 Summary

The following points summarize the most important aspects of the presented literature. The first part is mainly relevant for the first goal of this study which was only followed initially. The second part is relevant for the developed artefact.

1. General medication non-compliance:

   (a) Medication non-compliance has significant economic costs, is correlated with higher disease rates and is burdening healthcare systems.

   (b) Daily reminders, particularly through SMS or mobile phone-based systems, have shown positive effects on improving patient adherence to treatment in some studies.

   (c) A potential solution that improves upon static reminders could be dynamic reminders that incorporate whether a medication has been taken or not.

2. Hypertension:

   (a) The risk of cardiovascular diseases and other health conditions increases with hypertension; therefore, hypertension medication non-adherence can lead to poor blood pressure control as well as increased risk of complications.

   (b) Hypertension carries a heavy burden on society and economy. It is estimated to cost the global economy ten trillion USD annually and that by 2025 nearly 500 million people will be touched by high blood pressure.

   (c) Daily reminders such as SMS have shown to enhance patient compliance towards hypertension medicine and at-home blood pressure measurements.

   (d) Various mobile applications are available to help patients manage their hypertension condition long-term, offering features such as recording blood pressure values, reminders, educational information, and data visualization.
Chapter 3

Methodology

This chapter presents what research strategy and methods have been chosen, how these have been applied by the researcher and what alternatives were considered. Additionally, research ethics of methods and artefact are discussed.

3.1 DSR Research Strategy

Design Science Research, as described by [Johannesson & Perjons] (2014), was chosen to develop the initial idea of a medication reminder system and was kept as the research strategy after the research goal was adjusted. The DSR methodology focuses on creating and evaluating innovative artefacts to address real-world problems. This methodology is particularly relevant in fields such as information systems, computer science, and engineering. It was chosen because of its problem-oriented approach that focuses on understanding the challenges and identifying relevant needs of patient and doctor. The following are the key steps in DSR, which are typically performed in multiple iterations.

Problem Explication. The first step in DSR is to identify a relevant and significant problem that needs to be addressed. This involves understanding the context of the problem, its importance, and the potential benefits of solving it. Researchers should also consider the existing knowledge base and identify any gaps or limitations in current solutions. This step is crucial in providing a clear motivation for the research and ensuring that the proposed artefact will have a meaningful impact.

Definition of Requirements. Once the problem has been identified, researchers need to find and specify the necessary features, functionalities, and characteristics that a designed artefact or solution must possess in order to address a particular problem or achieve a specific goal. The requirements serve as the foundation for the subsequent design and development stage of the DSR process.

Design and Development. The next step in DSR is the design and development of the artefact. This involves creating a detailed plan for the artefact, including its features, functionality, and structure. Researchers should consider various design alternatives and select the most appropriate one based on the objectives and research questions.

Demonstration. Once the artefact has been developed, researchers need to demonstrate its functionality and effectiveness in addressing the problem. The demonstration should provide evidence that the artefact is capable of solving the problem and achieving the desired outcomes. This step is crucial in validating the artefact and ensuring its practical applicability.

Evaluation. The evaluation step in DSR involves assessing the artefact’s performance and effectiveness in solving the problem. Researchers should use rigorous evaluation methods, such as controlled experiments, field studies, or expert reviews, to gather data on the artefact’s performance. The evaluation should consider various criteria, such as efficiency, effectiveness, usability, and reliability. This step is essential in determining the artefact’s value and identifying areas for improvement.
3.2 Application of DSR

The problem explication was started for both research goals. The first goal is exploring the possibility of a medication reminder system based on vital parameters. To explore the problem area, three medical professionals were consulted in the form of semi-structured and open-ended interviews. The results are analyzed by theme and presented in chapter 4. The results of the interviews lead to the new thesis goal.

After the shift in project goal, the researcher worked closely with a general practitioner in Germany to explicate the problem of hypertension medication adjustment. Some aspects of the problem were supported by findings in literature. The same medical professional helped to define requirements and workflows of the artefact that describe how an artefact can assist in the practice. The researcher followed an iterative approach in which the problem and a possible solution was described by the doctor first, the researcher then modelled the gathered information graphically and presented this work back to the doctor. The process was repeated once to incorporate the feedback of the general practitioner and refine the model. This approach made sure that the problem and requirements were understood accurately. Some additional requirements were selected by consulting with the company “VitalSigns” in Stockholm and exploring possibilities to connect the artefact to their backend solution for an outlook on telehealth.

The general practitioner brought up the problem and ideas for a solution by their own initiative which is why the researcher was confident about the general interest and relevance of the issue. There could have been more consultation with multiple doctors and medical professionals, but due to the year-long experience of the general practitioner with hypertension patients, the explicated information was deemed enough for the scope of this project. Additional consultations might have also went beyond the available time for the study, especially considering that the research goal was changed once.

The development of the artefact followed a waterfall-similar approach since the scope of the artefact was relatively small. Otherwise or when working in a team, a more iterative approach such as SCRUM would be advisable to make sure that collaboration is organised and functionality can be evaluated and refined. There still was one iteration where the researcher reviewed the first finished version of the application with the general practitioner and made some smaller adjustments in alignment with the feedback. Because the process of requirement explication was done thoroughly enough, no major adjustments were needed. Technology-wise, different cross-platform frameworks were compared and the most suitable was chosen based on the requirements and on recommendation by developers at VitalSigns. For the architecture and incorporated libraries of the artefact, best practices were followed for the selected framework. These best practices are described in the framework’s documentation. The results section includes a concept for connecting the application with remote health services and remote data exchange. Relevant information on this was also gathered together with VitalSigns.

The evaluation of the application was done by presenting the resulting artefact to a focus group of developers, founders in digital health and a hypertension patient, and collecting their feedback regarding perceived usability, effectiveness and missing features/ future improvements. Ideally, the artefact would have been evaluated by a doctor-patient study that puts it in a natural setting and collects qualitative and quantitative feedback about usability and its ability to solve the described problem. This approach was not possible due to time constraints, but could be a future avenue to explore.

It is not uncommon to utilize DSR for developing applications in the mobile health space. Shania et al. (2023) employed interviews in DSR for problem explication and evaluation to design a mobile app which helps with tracking and improving depression in adolescents. While the study works in multiple iterations and has a much more extensive evaluation than the proposed study, it validates the choice of DSR and interviews as acceptable for the context. Similarly, Igarashi et al. (2019) utilizes DSR to develop an Android application that aims at improving at-home health monitoring and treatment.
3.3 Alternative Research Strategy: Action Research

An alternative research strategy for this study could be Action Research (AR). Action research is a research approach that involves collaboration between researchers and practitioners to identify and solve practical problems in a specific context. It is characterized by an iterative process of planning, action, observation, and reflection to improve practice and generate new knowledge. Action Research typically involves collaboration with practitioners and stakeholders in the problem-solving process, which aligns with the involvement of the general practitioner and the focus group in this project. However, AR tends to focus on addressing complex social problems within a specific context, such as education, healthcare, and organizational development and generating knowledge that can lead to broader change. While the development of a mobile hypertension application might be important, it may not necessarily involve a complex social problem that requires the extensive engagement and iterative cycles of AR. Secondly, AR often prioritizes the active involvement of the participants in the research process. While the general practitioner provided insights and requirements for the application, the primary collaboration was only in the initial stages of understanding the problem and gathering requirements. The following design and development was done without any outside collaborators. (Somekh 2005, Cohen et al. 2017)

The subsequent evaluation phase involved presenting the resulting artefact to the focus group for feedback, which aligns more with a design-oriented approach rather than the continuous involvement and collaborative inquiry of AR. Lastly, the emphasis on usability, effectiveness, and missing features/future improvements collected from the focus group aligns more with a design evaluation rather than the reflexive and critical inquiry typically associated with AR.

3.4 Changes in Methodology due to Change of Research Goal

After performing expert interviews, the original topic was shifted to the development of an artefact that can help patients and doctors with hypertension medication adjustment. For the first research goal, the evaluation intended to perform a small study with a group of elderly individuals to learn about their perspective on the application’s usability and what they think about its use case. The study would have collected quantitative data through questionnaires, incorporating the System Usability Scale (Brooke et al. 1996). Due to the change in topic and resulting time reduction, the evaluation of the artefact was changed to the described focus group demonstration.

3.5 Research Ethics

The conduction of interviews for research purposes requires ethical attention. Ethics play a crucial role in conducting qualitative research. Participants must be confident that the researcher will act ethically throughout the process. This involves adhering to various guidelines to address potential ethical concerns. Denscombe (2021, p.25) identifies four primary principles for research practices: protecting participants’ interests, ensuring voluntary participation based on informed consent, avoiding deception while maintaining scientific integrity and complying with applicable laws. These principles were upheld in this study. Prior to conducting interviews, a participant was asked for their consent of recording the audio. The participants were also given an informed consent form containing essential information such as the research objectives, participant anonymity, non-disclosure of sensitive data, and the right to withdraw. The informed consent form can be found in Appendix D. The responses are anonymised in the thesis text and the only personal information, that are exposed, are the participants’ professions. The researcher asked for consent to keep the non-anonymised audio-recordings and transcripts on their personal device.

The development of the mobile application raises several ethical considerations that also must be addressed. In order to ensure the ethical integrity of such a tool, it is essential to prioritize the well-being of the users and incorporate their rights and privacy.
One primary ethical consideration is to ensure that the application does not cause harm or inconvenience to the users. The tool should be designed with care to provide accurate and reliable reminders and blood pressure data collection. Any inaccuracies or technical glitches could potentially result in incorrect medication adjustments or missed reminders, thereby risking the health and well-being of patients. Writing unit tests for code modules can ensure that the application performs as intended without bugs, for example that it is sending reminders only at the correct time and only if certain actions have not been performed yet.

Respecting the privacy of users is another crucial ethical consideration. As the mobile application collects sensitive health data, it is essential to implement robust security measures to protect this information from unauthorized access or breaches. Encryption techniques, secure data storage, and adherence to privacy regulations should be considered in the application’s design.

Any potential future integration of remote data exchange or data analyses would raise many additional privacy concerns. Additionally, it is important to keep in mind the accuracy and reliability of recommendations that descend from data analysis. Wrong analysis could lead to jeopardizing patient health or sub-optimal treatment. In case these aspects would be implemented, it is important to establish clear guidelines and safeguards to ensure that automated analyses do not completely substitute for professional medical judgment and that human oversight remains.
Chapter 4

Feasibility of Using Vital Parameters for Medication Compliance Monitoring

This chapter describes the outcome of the expert interviews that were conducted to realize the initial idea of a medication reminder system that uses vital parameters.

The idea was originally developed based on the findings in chapter 2. Compared to solutions that statically issue medication reminders, the proposed artefact would be able to detect if a medication was taken or not and only issue a reminder notification if it detected medication non-compliance. Such a dynamic approach would issue much less notifications overall and therefore reduce negative effects like intrusiveness. Intentional non-compliance could also be improved because the user might realise that not taking their medication has a measurable effect on their body, which might convince some patients of the importance of taking it as prescribed.

The content of the interviews lead to the conclusion that this way of improving medication compliance is not feasible. Therefore, a decision was made to not continue with the initial goal and no more interviews were conducted. The three interviewed participants were a general practitioner, a medical resident, and a specialist nurse for anaesthesia and intensive care. The interviewees were selected to cover different perspectives on the topic. If the first results had been more promising, a different selection of interviewees might have occurred for extended research.

The interviews were conducted in a loose, open-ended structure to address the following questions:

1. Does the interviewee know of any system that can do or tries to do something similar to the project goal?
2. Does the interviewee think it is possible to develop such a system?
3. If yes, what could be a medical condition/medication where detection of non-compliance via vital parameters is possible?

A full list of potential interview questions are in Appendix C. No extensive data analysis method was applied due to the low number of participants and the broad topic of the interviews. All meaningful statements regarding the above questions were extracted and are presented by theme in the following.

Regarding the first question of existing solutions, all three interviews mentioned diabetes patients:

"My first idea is that with diabetes, you monitor your blood sugar. There are patches with a needle, with which you can then look in an app to see how high your blood sugar is.”

"I was thinking about all of the diabetic patients that we have. You know they have
some kind of automatic [system].”

"There are some things that are already really well algorithmized [...], like diabetics who continuously measure their blood sugar levels through the skin.” "These applications are ideal. These are automated insulin pump deliveries, coupled with blood sugar levels.”

When talking about the feasibility of the project idea, challenges were brought up about different sets of vital parameters. Some arguments were made about blood pressure measurements as vital parameters:

"The thing is if you’re thinking about medication for blood pressure: Normally you see changes in the blood pressure after a few weeks when you start with a medication. It could take a month for stabilised blood pressure. So I wouldn’t say that if you miss two pills, the blood pressure is gonna rise.

When the interviewer asked if any blood pressure medication exists that changes the BP measurably during one day, the answer was:

"None. No medication. So if you don’t take it for one or two days, you might notice it, but your blood pressure won’t necessarily go up on the same day. The changes by the medication are dependant on different factors, like the individual patient or dosage. The blood pressure can also change for other reasons than medication.”

The measurement process itself was also challenged:

"No one tolerates constant blood pressure measurements.”

"High blood pressure is difficult, I think, also because having a device attached to you permanently is extremely uncomfortable for patients.”

"There is no application for continuous blood pressure monitoring - only in intensive care settings.”

Some aspects about other types of measurements and medications were also discussed:

"If you’re an epileptic then it’s not good of course if you don’t take your medication, but you won’t get any physical response if you don’t take it, you just carry a risk of going into seizure.”

"Of course, what is extremely important to take when dealing with atrial fibrillation are blood-thinning medications, so that no blood clots form. However, you cannot determine, based on heart rate, whether they have been taken or not.”

"With COPD, however, one could say that if the oxygen saturation falls below a certain value, it is indicated to perform a more detailed examination. [...] They usually have emergency medications. That is, when they notice in that moment that they are having difficulty breathing or have a coughing fit, they have their emergency medications and then take them. [...] Then, an app is also useless because it already becomes clinically noticeable.”

"[...] you won’t be able to measure other parameters. [For example] Temperature - there is no medication that can be used regularly that is supposed to keep the temperature low.”

Challenges about the general process of triggering medication reminders based on vital parameters were brought up:
"The setting in the wild is difficult, without controlled conditions. And your measurement data, which you collect, are really quite rarely in such a way that one says: reflexively, the value means to take a second tablet or something like that."

"You have to be careful there too: you can also measure blood pressure, for example - it’s too high, they [the patient] forgot the medication, but should that then immediately trigger ‘take it [the medication]’, even though you might be two hours before the next dose? [...] This is also complicated over the time axis. It can be extremely confusing."

"So it’s not as linear as one imagines as a layman, not at all. There are huge fluctuations in it, and it’s incredibly difficult with rhythm."

One interviewee provided a detailed example about difficulties that would arise in cardiac settings.

"A classic cardiac setting is atrial fibrillation. Beta blockers and blood thinners are used, the latter mainly to minimize the risk of stroke. Here there are also catheter based procedures to get the pulse back on track. The Rapid unsteady pulse is also uncomfortable, makes dizziness, some people notice it clearly. Here the beta blocker can lower the heart rate. This is already pleasant. However, the pulse can remain restless. With blood thinning, however, the risk of stroke is reduced. Ideally, the rhythm jumps to a sinus rhythm. This seemingly simple example also shows how complex the subject of arrhythmia alone is. Subjective complaints, asymptomatic patients with risk factors, different drugs with different doses and many other individual factors such as polypharmacy ..... sorry but this cannot be packed into an algorithm."

Some broader thoughts on the project idea were this:

"There is currently no application that really makes sense to me, in the sense of ‘take your medication, you forgot it because a parameter shows a deviation.’"

"The idea is difficult, yes."

In conclusion, based on these interviews, the following challenges make the idea of using vital parameters to determine medication intake and trigger alarms seem not realisable or useful:

- **Invasive and uncomfortable continuous monitoring**: Continuous monitoring of vital parameters can be intrusive and uncomfortable for patients, potentially reducing the feasibility of such a system.

- **Limited applicability**: Medication reminders based on vital parameters might not always be accurate or appropriate, as there can be significant fluctuations and non-linear relationships between vital parameters and medication intake. None of the interviewees could mention a medication, which if forgotten to be taken, would be detectable by vital parameters within a reasonable amount of time.

- **Potential negative consequences**: A reminder system based on vital parameters could inadvertently lead to harmful outcomes, such as patients taking medications at incorrect times or in unsafe situations. The complexity of managing medication dosages and their effects on vital parameters makes it difficult to create a reliable and safe automated reminder system.

Due to these interview outcomes, the project focus was shifted to hypertension medication adjustment as presented in the following chapters 5 to 7.
Chapter 5

Initial Hypertension Medications: Problem and Requirements

The information in this chapter was gathered in direct exchange with a general practitioner in Germany that deals with hypertension patients and regularly prescribes new blood pressure medication. The problem area and resulting requirements were brought to the attention of the researcher by the initiative of the doctor. Relevant aspects were also researched in scientific medical literature, as presented. The problem area as well as the dynamics of some requirements were modelled in figure 5.3, which was created together with the medical professional.

5.1 The Problem of Medication Adjustment

When prescribing blood pressure medication to new patients, it is usually not clear what the right dosage or type of medication is for the individual person. This problem is complicated by the fact that prescribed medication only changes the blood pressure gradually over the span of weeks or months. To assess whether or not the medication is working as intended or if dosage and substance have to be changed, the patient’s blood pressure needs to be measured regularly. Recent guidelines by the World Health Organization for treating hypertension show the process of dealing with first time medications as in figure 5.1 (Campbell et al. 2022).

If blood pressure data of the patient is available to doctors during the first weeks of medication, they can evaluate the data to determine if the medication type and dosage is correct or needs to be changed. If the blood pressure decreases, as expected, and values are stable after four weeks, everything is fine. If the values are not as intended, the doctor might have to change dosage, intake time/ frequency or type of medication all together. If any of these factors are changed, new measurements have to be taken for another four weeks. This usually results in multiple measurement cycles of multiple weeks as seen in figure 5.2.

To gather the data, which is required to make these decisions, patients usually receive a device that they can take home for self-guided measurements. They are instructed to measure during certain times of the day and write down, either digitally or on paper, what their measured values were (Igarashi et al. 2019). The data is then presented to the doctor at the next check-up. Some devices also save the values on an internal storage that the doctor can extract (Bilo et al. 2010). Since new patients are not used to taking medication and performing blood pressure measurements regularly on schedule, the set of instructions for gathering the data correctly over time can be overwhelming and exhausting, which may lead to reduced compliance. Additionally, taking measurements has to follow a certain procedure. During the day, the blood pressure of a person fluctuates between values due to physical activity or factors like stress and anxiety. To have a baseline of measurements and make results comparable, it is standard to have patients rest for a few minutes before measuring blood pressure. A clinical trial...
Figure 5.1: The Cycles of Hypertension Medication (Campbell et al. 2022)

Figure 5.2: The Process of Medication Adjustment
from 2021 sees a mean difference of up to eleven points in systolic and nine points in diastolic values, when comparing resting measurements to a daily average \cite{Hiremath2021}. At the same time, none of the participants in \cite{Boivin2014} were compliant with the resting period. This shows that the correct process of taking measurements is important, but that people struggle to adhere to it. The process of reading the correct values from the measurement device and copying them into a notebook is also a point of failure in the system. Overall, the whole process of medication adjustment and collecting the needed data requires a lot of attention from the patients. Missing measurements or other factors that reduce the quality of data are a common issue. If the data is not reliable, the doctor can not make based decisions, which in return reduces the chance of success for the patient’s treatment.

What is needed is an artefact that can remind people of the regular intake of medication and measurements, that can guide them through the process of measurements, that can assist the user in noting down the correct measurements and can store and process the data to be used by the doctor. Such a system would not be used long-term by a patient. It is only meant to assist the doctor in determining the right medication and its dosage to treat the patients. That process can take only one cycle of a few weeks after receiving the initial medication, or it can require multiple, new cycles after medication has been changed based on the previous cycle’s data.

### 5.2 Artefact Requirements

Based on the described problem, the following requirements of such an artefact have been defined.

1. Functional Requirements:
   
   (a) The treating doctor should be able to configure the artefact to the individual situation of the patient.
   
   Some factors about a measurement cycle are unique to each patient or determined by preferences of the doctor. The following factors should be configured by the doctor for each cycle: The BP goal of systolic/ diastolic values in the current cycle; The time period of the cycle, which is the time until the BP goals should be reached or until the patient checks in with the doctor to analyze the data; At what time(s) of the day the patient should take BP medication; How often and at what times the patient should measure their BP during the day; How long a medication intake or blood pressure measurement can be delayed; What the threshold is for too rapid BP decrease/ too low BP \cite{Boivin2014}. The configuration of this data should happen directly on the patient’s device.

   (b) The artefact should be able to handle multiple cycles of measurements.
   
   One measurement cycle is rarely enough to determine the right medication set for a patient. The artefact should therefore anticipate multiple cycles. The artefact should have data of past cycles archived for later access and exports.

   (c) The artefact should send daily reminders to the patient to take their BP medication.
   
   This is the first requirement that is aimed directly at the user. It is supposed to help the patient remember the intake time and motivate for action. As discussed in chapter \ref{snooze}, daily reminders have the ability to improve compliance.

   (d) It should be possible for the user to delay the intake of a medication for a certain amount of time that can be configured by the doctor. The user should be able to schedule additional reminders at wish.
   
   Sometimes, a patient can not directly take the medication as intended. A ”snooze” function, similar to clock alarms, should be implemented to give the patient the opportunity to be reminded later. At the same time, taking the medication much later than prescribed, can be counter-productive or even dangerous and the artefact should not remind the patient to take the medication later than a configured time. No data regarding the safety of specific delayed intake was found, which is why this behaviour should be configured by the doctor.
(e) The artefact should save whether medication has been taken and at what time.  
The analysis of the data by the doctor has to incorporate how often and at what time the 
medication has been taken/ how compliant the patient was with the instructions.

(f) The artefact should remind the user to take BP measurements at different times during the 
day, depending on the configuration of the doctor.  
The measurements are the most important aspect for the doctor and the correct medical 
outcome for the patient. Similar to the medication reminders, this aims at improving 
patient compliance and making it easier for a patient to remember the measurements. As 
discussed in chapter 2.1, daily reminders have the ability to improve compliance.

(g) It should be possible for the user to delay a BP measurement for a certain amount of 
time that can be configured by the doctor. The user should be able to schedule additional 
reminders at wish.

(h) Before taking a measurement, the patient should be reminded to be at rest for five minutes. 
As described above, rest is important to establish comparable measurement conditions. The 
artefact should remind patients of these details.

(i) The artefact should save the systolic value, diastolic value, pulse rate and time of each 
measurement.

(j) The artefact should check daily if the blood pressure of a patient is too low, based on the 
measurements and configuration of the doctor.  
Low blood pressure, also known as hypotension, can have several risks associated with it. One of the risks is reduced blood flow to vital organs, such as the brain, heart, and 
kidneys, which can lead to organ damage or failure. Taking new medication can cause low blood pressure if the dosage is too high. Additionally, a rapid decrease in blood pressure can cause symptoms for the patient that are very unpleasant and should be avoided, even if blood pressure reduction is the overall goal. If the BP is too low, the artefact should inform the user that a doctor’s appointment needs to be scheduled. If the patient experiences symptoms like lightheadedness or dizziness, the appointment becomes urgent. It can be very individual and dependant on the starting situation of the patient, what changes in blood pressure are too fast or too low. For that reason, the doctor should be able to configure the threshold for this behaviour.

(k) The artefact should display the collected data of the patient.

(l) The artefact should provide outputs of the collected data as CSV and PDF for a doctor to 
evaluate.  
A PDF file can be a report of the data including graphs and tables. CSV is a widespread 
format that can be used to import the collected raw data into programs like Microsoft Excel 
or into another artefact that displays it for the doctor.

(m) The artefact should be cross-platform to make it available for as many users as possible.

(n) The artefact should feature an overview over the instructions of the doctor to the patient, 
so that the patient can make themselves familiar with them.

(o) The user should be able to choose to not get any reminders at all and instead rely on the 
instruction overview to perform required actions. 
Mobile notifications are shown to potentially be disruptive or create stress. Some people might prefer to not get reminders as they can be considered intrusive and annoying. To avoid frustration or negative feelings towards the artefact, which may lead to decreased compliance, the patient should be in total control of the reminders.

(p) All data should be stored locally on the patient’s device and without any exchange over 
the internet.
Privacy is a significant concern for users of mobile Health (mHealth) applications. Several studies have shown that privacy concerns are a major obstacle to the acceptance and use of mHealth apps (Schomakers et al. 2022) (Zhou et al. 2019). A very recent study (von Kalckreuth & Feufel 2023) found that attitude to privacy is one of the three main factors that influence the intention to use mHealth apps in Germany.

(q) The artefact should not make health recommendations.

There was a strong emphasis on patient well-being and safety during discussions with the medical expert, which is also acknowledged in chapter 3.5. Building an application that can issue accurate and reliable medical recommendations to a patient is very hard and requires more medical expertise than is available for this study. Many individual factors and in-depth know-how is required to make wrongful and harmful decisions for the patient impossible. For this reason, the artefact should only assist in existing structures between doctor and patient and all major decisions should still be performed by the doctor.

2. Non-Functional Requirements:

(a) The artefact should be simple to use for all kinds of users. Nabi et al. (2020) shows that usability was a key factor in adoption of a mobile health app for prostate cancer patients. The goal for the artefact is therefore to not overload it with features and keep the user interface (UI) simplistic.

(b) The reminders of the artefact should not be too intrusive while also making sure they are seen. The reasons behind this requirement are the same as for 1o.

(c) The artefact should make it simple and easy for users to enter measurement results. Inputting results is the only time where a user really has to interact with the artefact. This process should be made as simple as possible to avoid inaccurate data input.

(d) The artefact should be designed to make support for multiple languages easy. Most users prefer if a system is in their native language. To improve user adoption and avoid frustration because of language barriers, the artefact should support multiple languages.

(e) The artefact should not feel like a burden to the user. All the reminders and processes of the artefact should motivate the user to complete, but not make them feel bad if they are missed. Punishing users for not doing everything right can demotivate them for future tasks.

3. VitalSigns Services and Telehealth

As part of the project, there has been some exchange with the company VitalSigns about implementing remote data exchange for the artefact. VitalSigns itself is developing digital health solutions and building a platform for the exchange of health data. In this context, the problem area could be extended with a telehealth perspective. The following functional requirement has been defined together with VitalSigns to make the system compatible with their Application Programming Interface (API) solution:

It should be possible for a user to choose to store their data with VitalSigns. The doctor configurations and patient data are then stored and exchanged on VitalSigns servers.

This provides the advantage that the user’s data is backed up and opens the door for telehealth functionality. More on this is discussed in chapter 8. The option is in direct contrast to the privacy arguments in requirement 1p), which is why the user would have to opt-in to this functionality. This requirement was not implemented in the artefact, but a concept has been created based on the structure of VitalSigns’ backend as shown in section 6.2.3.
Figure 5.3: Visualized Problem and Requirements
Chapter 6

The Artefact

The result of the development phase is a cross-platform application that can be run on iOS and Android and was created on the .NET platform with the Multi-platform App UI (MAUI) framework. The following chapter describes the process of developing the artefact and demonstrates its features and appearance.

6.1 Development Framework

As requirement [1m] states, it is desirable for the app to be accessible for as many devices and users as possible. Mobile devices are an obvious choice for an artefact like this because of their prevalence and because people often have them on their person at all time. Additionally, push notifications are a suitable functionality for implementing reminders.

The researcher decided to develop the application with a cross-platform framework. This decision was made because the artefact does not require much native and platform specific tuning or enhanced optimization and performance, so that the most common features of cross platform frameworks are sufficient. Simultaneously, it saves a lot of time to develop one code base for every platform instead of developing a separate app for multiple operating system. .NET MAUI is a framework that makes it possible to develop native mobile and desktop apps from one code base. It provides native functionality, such as camera access, local storage and native UI elements. Additionally, there are many community plugins that offer extended features, such as local notifications. MAUI apps can be created using either the C# or F# programming language. The researcher chose to use C# because of existing familiarity with the language. ([davidbritch, mhrastegari, jonpryor, Banovvv & jconrey 2023]

A few alternative frameworks, such as Flutter, Ionic and React Native exist. The are advantages that highlight .NET MAUI for the researcher compared to these other options. Firstly, MAUI not only enables mobile development but also desktop applications. Even though the resulting artefact is developed for iOS and Android, the same code base could run as a Windows or MacOS app. The created code, excluding push notifications, already works on both desktop platforms. This not only offers the possibility to publish these apps for desktop in the future, but also enables fast development for future projects, such as a dedicated app for doctors for viewing data/ creating configurations. Secondly, engineers at VitalSigns have used MAUI in the past as well and could therefore assist if any help is needed. Lastly, MAUI apps utilize the .NET Base Class Library, which is an extensive set of classes offering a variety of comprehensive capabilities, such as XML, database, IO, networking support, and more. Current C# code can be compiled for integration into an application, providing access to numerous libraries that enhance functionality.
6.2 Architecture

This section gives a broad overview of the artefact’s structure by providing simplified UML class diagrams of the project’s data types and explanations of important artefact modules.

6.2.1 Data Types

The first data type is the `CycleConfiguration` as seen in figure 6.1. It represents the options that a doctor configures for each cycle of measurements. The properties `ID` and `NotID` are used internally for the database and notification reminders. `StartDate` and `EndDate` set the time frame for each cycle and its daily activities. At any time, there can only be one CycleConfiguration during a time period; Two configurations with overlapping time frames are not allowed. `CurrentAverageSystolic` and `Diastolic` values represent the current BP rates of the patient. These are not actively used by the application, but offer a documentation function and can be displayed in the data report of the app. The same applies to the `GoalAverageSystolic` and `Diastolic` values, which represent the values that the doctor is hoping to achieve during the medication cycle. The `TooLowSystolic` and `Diastolic` properties are used as the threshold at which the app issues a warning to the patient that the BP values might be too low or falling to rapidly and instruct the user to seek medical attention if feeling unwell. The `MeasurementDevice` describes the type of BP device that the patient uses at home to perform measurements. This value is important for the feature that lets patients use the phone’s camera to capture measured values from their BP device. More details regarding this feature are laid out in section 6.3. Finally, `Intakes` and `Measurements` each represent a collection of the daily activities that the patient is supposed to perform. These activities are described by the classes `MeasurementProcess` (meaning a BP measurement) and `IntakeProcess` (meaning a medication intake), which both inherit from the `Process` parent class, as can be seen in figure 6.2.

A process has a distinct `ID` and a reference to its config object. A process’ `ActionTime` is the time of the day when the action should be performed. `MaxDelay` is the amount of minutes that an action can take place after the `ActionTime`. There is also an amount of minutes that an action can be completed before the `ActionTime`. This can not be configured individually, but is set to 15 minutes. For example: If the `ActionTime` for an `IntakeProcess` is 3:00 pm and `MaxDelay` is 30, it means that the medication should be taken between 2:45 pm and 3:30 pm. This time interval is described by `EditTimeStart` and `EditTimeEnd`. Between `EditTimeStart` and `EditTimeEnd`, the user can interact with the action as shown in section 6.3. Finally, a `Process` also includes a textual `Instruction`, which

Figure 6.1: CycleConfiguration Type in UML
can be set by the doctor to display individual details to the patient. To check whether a process has been completed today, MeasurementProcess and IntakeProcess each implement a function `GetStatus` which checks the database for data entries that correspond to the action on the current day and returns a member of the enumeration type `ProcessStatus`. If a data entry is given, the status for today is `Completed`. If no data entry is given, but the current time is still before `EditTimeEnd`, the status is `Not Completed`. If no data entry is given and it is already past the allowed edit time, the user has missed to complete the process and the status is therefore `Skipped`.

Data entries represent the collected data for an Action of each day and are described by the classes `MeasurementDataEntry` and `IntakeDataEntry` (compare figure 6.3). Both entry types contain a reference to their `Process` and its corresponding `CycleConfiguration`. A `MeasurementDataEntry` saves the date and time of measurement as well as the pulse, systolic and diastolic BP values of the patient. A `IntakeDataEntry` saves the date and time of medication intake.

### 6.2.2 Artefact Structure

The artefact source code mostly follows the Model-View-ViewModel (MVVM) pattern, which is the Microsoft-recommended way of structuring MAUI apps. MVVM in MAUI uses Extensible Application Markup Language (XAML) files to define the UI, Models which define the data structure/ business logic (see section 6.2.1) and an intermediate layer ViewModel, which creates data bindings between the View and the Model. Some pages were not defined in a classic XAML view, but instead were built in C# markup to enable more dynamic page rendering. **(davidbritch & adegeo 2023)**
The artefact is designed as a serverless application which means it requires no internet connection and all data is stored on the device itself. This decision has been made in favor of privacy, so that the patient has complete control over their data. Because there is no remote data exchange, the initial configuration by the doctor for each medication cycle is also done directly on the patient’s device. The app generally assumes that the normal processes between doctor and patient are preserved. This means that patients still visit doctors for information exchange or receive diagnoses on the phone. The doctor would configure the patient app during these default processes.

6.2.3 Data Storage and VitalSigns API

SQLite was selected as a database for local data storing on the device. SQLite-Net is an open-source library that implements SQLite3 access for all MAUI supported platforms. The library features an Object-Relational Mapping (ORM) layer that automatically maps C# classes to SQLite tables and makes it very easy to perform CRUD operations. Additionally, the artefact makes use of an open-source library called SQLiteNetExtensions, which extends the ORM-layer of SQLite-net by one-to-one, one-to-many, many-to-one, many-to-many, inverse and text-blobbed relationships, which makes it easy to map Intake- and MeasurementActions to a CycleConfiguration. SQLite was chosen because it is specifically integrated with MAUI apps, recommended by Microsoft, very simple to integrate into a project and provides the possibility to run manual SQL queries instead of the ORM functions if needed. [praclarum 2022] [TwinCoders 2018]

The requirements define a second operation mode of the artefact that enables telehealth functionality by exchanging the health data with VitalSigns servers. VitalSigns exposes an API for their backend service. To create a concept for this requirement, the researcher received access to the API documentation and had multiple exchanges with the backend developer of the company who is responsible for the API. Multiple object types exists that could be used to implement the concept, which is described in the following.

If the user opts-in to this functionality the app configuration no longer takes place on the patient’s device. Instead, the treating doctor would have a separate application (desktop or mobile) that can manage multiple patients, create configurations for these patients and see the collected data in real-time. For a new patient, the doctor creates a new user object in the backend and assigns a configuration to it. The backend will then create a six-digit code that is associated with the user and configuration. The code is shared to the patient who can input it in their app to load the configuration and attach all data uploads to the created user object.

When the patient application is opened for the first time, the user should be asked to choose between only local storage or additional server exchange of data. By choosing the server operation mode, the application of the patient looses its serverless property and internet access is required for effective usage. To still make it possible for a patient to use the app and create data in situations without internet, the local data storage with SQLite is preserved and all data is stored there in the same way. Additionally, each database entry has a field called "synchronizedDate", which is empty by default. When the entry is uploaded to the servers, the date attribute is set. This usually happens immediately when the user inputs the information into the app. If there is no internet connection at input time, the data can not be uploaded and the date is not set in the database. Every time the app starts and has internet connection, it can then query all database entries without an upload date and send these entries to the servers. The doctor can pull the data through their application and follow the patients progress in real-time.

6.2.4 Reminders

Reminders are an integral part of the requirements and aim at improving patient compliance. There are two ways in which reminders could be implemented. The first one is trying to imitate an alarm, similar to alarms that are implemented by the iOS and Android operating systems. Such an alarm
would play a sound at a certain time even if notifications are turned off or "Do-Not-Disturb" mode is activated. During an alarm, the phone would wake-up even if it is locked. On Android this is possible using the AlarmManager class that allows an app to access Android’s system alarms ([amulata2022] [Developer.Android 2023]). On iOS however, no equivalent functionality exists. The closest that is officially allowed by Apple is a normal notification with a custom sound. Apple imposes a constraint on such notifications, that sounds can not be longer than 30 seconds ([Developer.Apple n.d.]). There exist apps on Apple’s App Store that imitate system alarms and are surprisingly good at playing sounds and showing notifications even if the phone is muted, locked or in Do-Not-Disturb mode. Some year-old discussions online try to figure out how these alarm apps operate. The most likely solutions seems to be that an app constantly plays a silent sound, similar as a music player app would, to force the operating system to keep it running in the background. At the alarm time, the silent sound is replaced by the actual alarm sound. Additionally, the app sends a local notification to display for the user. ([Bolero 2017] [hp007 2020] [Canella 2012] [daSn0wie 2011])

There are multiple problems with this approach. First of all, the method could be seen as a workaround that circumvents Apples’ App Store guidelines. So far, Apple seemingly has tolerated this behaviour, but theoretically, the company could change their mind anytime resulting in a ban for these apps. The second problem is that if a user closes the app completely by removing it from the app switcher, the alarm might not fire as intended. A good example of this is the free app "Alarmy" on the App Store. Upon setting an alarm and then closing the app in the app switcher (and therefore completely removing it from memory), when the alarm time comes up, the sound is not played as intended and the app spams local notifications to the user (see figure 6.4). This behaviour is unreliable and confusing. The researcher therefore decided to implement reminders with the second option, which is local notifications. This means that reminders are less intrusive and their behaviour can be set by the user in the device’s system settings, which simultaneously fulfills requirement 10. To implement local notifications a third-party open source library was used ([thudugala 2023]). Local notifications can be scheduled by an app and set to repeat automatically after a certain period of time. This approach differs from so called "push notifications", which require an outside server that decides when a notification is necessary and "pushes" the notification to the device. Because the artefact does not need to react to events or issue dynamic notifications, local notifications are deemed to be sufficient. An Example of the result can be seen in 6.3.

6.2.5 Globalization and Localization

Another defined requirement is the support for multiple languages. The .NET platform offers a variety of tools that allow apps to easily implement localization. Additionally, not only switching language but also globalized formats such as date and time strings are simple to include. To achieve these features, the .NET Globalization and Localization package is used ([IEvangelist & gewarren 2023]). The app so far only supports English and German, but adding another language is as simple as duplicating a particular .resx file and replacing all English text entries with translations. The language that is selected in the operating system of the device is automatically detected and the corresponding translations are shown. English is the backup language if the user’s preferred language is not supported.

6.2.6 Data Visualization

For graphically displaying data in the app, the open-source library "LiveCharts2" is used ([beto rodriguez 2023]). It offers a wide variety of features and plot types and is the only free and open-source library compatible with MAUI that could be found by the researcher.
6.2.7 Automatic Measurement Input

Requirement 2c aims at making the process of inputting measurement results into the app as easy as possible. Besides manual value input, the first method that comes to mind for this is using a measurement device that supports a Bluetooth connection and sends the measurements to the phone. This approach would limit the number of compatible BP devices to those with Bluetooth capability. Furthermore, many BP Bluetooth devices only support their own application or health apps of the operating system, such as Apple Health. Implementing a proprietary Bluetooth standard for different devices inside the app would take a lot of work. Additionally, a Bluetooth connection can be flawed and frustrating if there are connection issues or user errors, such as Bluetooth being turned off on the phone. Especially elderly patients could experience problems with this approach.

The method that is being used in the artefact to improve usability, is the option to capture the measured values from a BP device’s screen automatically using the phone’s camera. Implementing this feature proved to be much more difficult than anticipated. The initial idea was to utilize Optical Character Recognition (OCR) to detect all the text in a picture from the camera and then filter for the necessary values. OCR is the process of recognizing text in images. It is often used for digitizing scanned documents and enabling them to be searched and making the text copy & paste-able by overlaying a so called ”OCR Layer” on top of it. There are many OCR libraries in existence, one of the most popular open-source libraries is Tesseract (tesseract ocr 2023). After some experimenting with OCR libraries, it became clear that simply running OCR over a picture of a BP device screen is not working very well. The approaches, problems and solutions are going to be demonstrated on the example of figure 6.5a.
Problem: Scattered Values

The first problem is that OCR libraries are aimed at detecting fluent text that is written in a block of text. BP devices, such as our example, have scattered, unrelated values in an arbitrary layout.

Problem: Skew

The second problem is that OCR libraries like Tesseract expect an input image that is a flat-top view on the text. If the image is rotated or skewed in any way, detection will be much less reliable. It is likely, that an app user will not always point the camera exactly straight at the BP device display. The researcher found projects that do the kind of pre-processing that is necessary to straighten and deskew images of displays and read their contents (Rosebrock 2017, upupnaway 2016, ashuta03 2019). These approaches rely on computer vision libraries, mainly "OpenCV", to perform edge detection and find the four corners of the display to be scanned. After the corners of the display have been located, a deskewing algorithm is applied. There are two factors that must be given for the corner detection to succeed: 1) The display that needs to be detected has to have sharp corners and 2) the algorithm needs to know the size of the display compared to other rectangle-shaped objects in the image. These requisites are necessary because after finding all the corners in the picture, the algorithm filters only these that span four vertices and then takes the nth-smallest rectangle. The number n is the input that describes the display size. For example, the algorithm has to know that the display in the picture will be the fifth largest rectangle. Figure 6.6 shows an example for how an image of a thermostat will look, before the algorithm tries to detect the display by its corners. In this picture, the display is the smallest (n = 1) and only rectangle in the picture.

The two conditions are not guaranteed to be fulfilled in the scenario of the artefact. First of all, as our example device shows, the display of the BP device does not necessarily represent a rectangle with sharp corners. The example in figure 6.5a has rounded corner, which are much harder to detect. Secondly, it is not possible to know the number of detected rectangles in any picture. A user can have all kinds of objects in the background of the picture, which would confuse the algorithm. The researcher tried to modify and apply the above algorithms, but ultimately confirmed that they do not work for the example image.
Problem: Seven-Segment-Display

The last problem that came up is that, unlike printed text, BP devices often make use of so-called seven-segment-displays. This means that numbers do not consist of a continuous line, but of 1-7 lines with small spaces in between. By default, OCR libraries are not able to detect these numbers.

Solutions

The seven-segment-display problem can be solved relatively easy. Some projects have trained the Tesseract algorithm with custom images to support seven-segment-displays (ameera3 2019, arturaugust 2021, shreeshri 2019). These models can be used to perform detection. Alternatively, the c-library “SSOCR” is an OCR library, developed specifically for seven-segment-displays (auerswal 2023). The library would have to be compiled for iOS and Android to be used. Some of the projects discussed in the skew section also implement their own OCR detection that could be imitated.

The problem with scattered values can be solved by separating the image of the display into smaller segments. One advantage that the the blood pressure use-case has, is that the layout of the scanned device will always be the same for one patient. If the skew problem can be solved and the algorithm knows where the display is placed in the image, it can easily know where the numbers for the systolic, diastolic and pulse rate are. For example, figure 6.5b shows the regions for the example device. The systolic numbers are located between 1/5 and 2.5/5 of the device height. Once the pixel areas for each value are located, the image can be cut into three different parts and each segment be fed into the OCR algorithm separately. Of course, the separation into segments for each device model has to be known to the algorithm. This is something that needs to be mapped by the developer for each device that the application supports. The device is then selected for each patient by the doctor. This value is saved in the MeasurementDevice property of the CycleConfiguration class (see section 6.2.1). For each scan process, the algorithm will load the relevant mapping using the MeasurementDevice attribute.

The researcher did not come up with a solution that can deskew device pictures reliably. Instead, the approached solution is to make it easy for the user to take a picture that does not need to be deskewed. This can be done by overlaying the grid, that was mapped above, over the camera view of the user when they scan the device. The overlay shown in figure 6.5c would help the user place...
the device correctly in the camera view so that OCR detection can be performed. It would be very tiresome to let the user take single pictures and have the algorithm check individually if the view was placed correctly. This could lead to many trials and errors. Instead, to make this process as seamless as possible, the app constantly takes single frames of the camera view (while the camera is opened) and tries to process them in the background. As soon as believable systolic, diastolic and pulse rate values are detected, the camera view closes and the values are saved.

The discussed solutions have been implemented with a mapping for a test blood pressure device. Even though MAUI includes a module for accessing device cameras, the researcher decided to program this feature in JavaScript. The included camera module does not allow to display any overlay on top of the camera, which is required for the mapping solution. MAUI does allow to run local JavaScript and html files, by opening an in-app WebView of the corresponding operating system (davidbritch, adegeo, gewarren & alexbuckgit 2023). This made it possible to code the camera scanning feature with web technology and therefore make it cross-platform compatible.

6.3 Finished Artefact

This section showcases the UI and workflows of the artefact by using screenshots of the iOS app as an example. The Android application looks identical in most aspects excluding native system UI elements. Screenshots that show the differences in Android can be found in Appendix A.

The app has two main pages that can be chosen from the tab bar at the bottom: The status page, which shows the activities for the day including their status, and the data page, which shows plots or raw data of current and past cycles as well as options and settings. Figure 6.7 shows how the pages look if the app is opened for the first time. The status page shows a greeting and offers the user (or their doctor) to create a new cycle configuration. The data page shows no active, past or future cycles and offers some user options.

Figure 6.8 shows the pages for configuring a new cycle, which is done by a doctor directly on a patient’s device. All information that are discussed in section 6.2 can be input and changed here using the platforms native input methods. After clicking “save” the configuration is stored in the database and notifications for each process time are scheduled for every day between the start and end date.

Figure 6.9a shows how the status page lists processes of a future cycle. The processes are sorted by time and shown with their type, their action time and their instruction. Figure 6.9b shows the status page during the day of a running cycle. Now processes are sorted by status and then by time. This means that completed or skipped processes are grayed out at the bottom of the list. Upcoming processes or such that can be interacted with right now, are shown at the top. If a process is currently enabled for interaction, it shows three buttons. The "Finish" button opens the dialog window for inputting the process data (see next paragraph). The buttons on the bottom control notifications for the process. The first button lets the user turn notifications for this action on and off for today. More on this is explained later. The second button gives the user the option to schedule a reminder for this process in 15 minutes. When pressed, the button shows the time of this upcoming extra reminder. When a process is completed, it is grayed out and put to the bottom. Figure 6.10c shows the previously active intake process at the bottom with status "Finished" and one last upcoming measurement process at the top.

Figures 6.10c and 6.10b show the windows for inputting data for each process type. Before the page for measurement input is opened, the user receives an instruction that they should be at rest for 5 minutes before performing the measurement (compare figure 6.10a). This message can either be only confirmed or chosen to not be shown again next time. When the input page for measurements is open, the user can choose to get measurement data by scanning the measurement device with the phone’s camera by clicking the "Use Camera" button. After clicking, a camera view opens and if the user correctly aims the camera at the measurement device with the help of the red frame (as shown in figure 6.11b), the camera closes and the captured values are put into the corresponding text fields.
Figure 6.7: Unconfigured Application
Figure 6.8: Configuring a Cycle
Figure 6.9: Processes on Status Page
Figure 6.10: Data Input

(a) Rest Reminder

(b) Measurement Process Input

(c) Intake Process Input
Figure 6.11: Low BP, Camera Scanning and Notifications
The user can then quickly check the values before saving. If the user has put in a value for diastolic or systolic that is lower than the threshold that the doctor set in the configuration, the warning in figure 6.11a shows up in an orange color and lets the user know that they should meet and discuss with their doctor before taking any more medication. The warning shows up when a low value was input once and goes away if a measurement shows that blood pressure has gone back to normal. The code was implemented in such a way that makes it easy to require two or more low measurements until the warning appears. The warning does not prevent the user from completing medication intake actions because the user’s behaviour should still be guided by the doctor and not by the app.

Reminders are scheduled twice per process and day. The first notification is 15 minutes before the action time (EditTimeStart) and the second one is 15 minutes before EditTimeEnd. If a data entry has been saved for a process or if the user has selected to turn notifications off, no more reminders for this process are issued on the current day. An example of a reminder notification can be seen in figure 6.11c. It shows the first daily reminder of a measurement process. Other notifications have slightly different titles and texts.

The data page shows information and options of the selected cycle at the top, followed by plots of all available data for a cycle. When “Raw Data” is selected, the page in figure 6.12c is opened. It shows all available cycle data, grouped by creation date. When “Export” is selected, a bottom sheet opens and gives the user the choice between a CSV and a PDF export (figure 6.13a). After choosing either option, the app generates the requested file and opens it with the default system sharing menu of the platform (figure 6.13b). This sharing menu typically contains messenger apps, such as Whatsapp and Signal or other useful options like e-mail and saving to system files. Examples of the export files can be seen in Appendix B.
By default, the data page shows data for the current cycle. This includes the medication intake times (x-axis: time of day, y-axis: date), pulse values and BP values. The plots can be zoomed and scrolled to see data more precisely. Systolic and diastolic measurement data is displayed in a combined plot (see figure 6.12). At the bottom of the data page are past and future cycles (figure 6.13c). When clicking on a past cycle, all plots and options (including data export) are shown in the same way as for the current cycle. When clicking on a future cycle, the configuration page for the cycle is opened and its parameters can be modified as in figure 6.8.
Chapter 7

Evaluation

The evaluation was performed after the finalisation of the artefact. A presentation was held in front of a focus group of experts from VitalSigns, both developers and founders in digital health, and a patient recently diagnosed with hypertension. The presentation included a description of the specific problem that the artefact wants to solve, a demonstration of the finished artefact on an iOS simulator and an open discussion, guided by the following questions:

1. Does the concept seem relevant to the participants? Specifically:
   (a) Is the problem relevant from the participants’ perspective?
   (b) Can the application solve the presented problem?

2. Are there any additional features that could be beneficial for the application?

3. How do participants rate the usability of the app?

In that sense, the evaluation is summative and ex post. This form was chosen to get an opinion about the artefact from people in the industry and affected patient. It was a good fit for the limited available time during the thesis project. The discussion was recorded with the participant’s consent and can be organized according to the categories established in the initial presentation, namely: Relevance of concept, additional features, and usability. Each of these themes include responses from the participants that give insights on the project and its potential for real-world application.

Relevance of Concept  These aspects assess the applicability and necessity of the application in the current healthcare context, especially in relation to hypertension treatment. It also evaluates whether the application can adequately address the defined problem.

"I can guess, it will solve the problem because you’re gonna have a much more efficient way to fine-tune the medication."

"...It’s not a good thing having bad blood pressure. And I think the solution with medication, isn’t complex in the sense that, [even though] it’s not a one-size-fits-all solution, but it’s quite easy because it’s basically trial and error. And then if you’re adding the complexity that I need to go see the doctor to kind of evaluate the trial and error then you’re adding complexity. If you’re taking away one of the problem hassles, to actually running to the doctor to get the measurements, I think that’s a perfect digital solution."

"And also the feedback [...] , instead of having a meeting with a doctor you could just adjust the medication [...] or exchange the medication and maybe it’s shortening the time to get this medication"
The attending hypertension patient confirmed the problem that the artefact is trying to solve:

"I had to measure myself for a couple of weeks to see the effect of it [the medication]."

"I had a device at home for checking my pressure so I have it at home and I did some [measurements]. I should have done it several times and I did it just a couple, maybe 3-4 times and I should’ve done it more, so actually he [the doctor] is still waiting for my response. I actually haven’t reported any results yet and so I should call him soon maybe to tell him what it is like right now."

The patient was also asked how they shared the data with their doctor and what the benefit for the doctor could be from the artefact:

"Probably he gets the data, maybe more continuous data, from my blood pressure. Maybe even every day data or whatever you decide [if the artefact was used]. But for today, for me, I call him and I give him just some data for three or four times that I actually remembered and I wrote it down on paper. So maybe the data he gets from me is not really continuous data."

**Additional Features** This part presents suggestions for potential improvements or extensions of the application’s features, including its adaptability to other health conditions and the opportunity for data sharing for research purposes.

"Here you get data from each patient saved and then I guess that would be really valuable for medical companies as well."

"Given that on how information is being stored today... we’re not using them. I guess it’s at least hard to use them in a research and a medical [context]. If you can say ‘ok my name is Karl, I would like to anonymously share my background information and my progress for research’ and then I guess a company would probably want to sell that information... but then it’s my information... so maybe I get a discount or whatever. I think that would make sense in a way."

"This sort of application could be used on other medications as well. The first thing I think of is diabetes and insulin or epilepsy [...] also Parkinson’s maybe and then it would not be with measurements [...] but maybe the app could ask ‘how do you feel?’ and ‘what symptoms do you have?’.”

**Usability** This category assesses the ease of use of the application from the perspective of both the patients and the medical professionals. It gauges how user-friendly and functional the app is, as well as its potential to streamline communication between patients and doctors.

"My feeling is that usability is very good"

"It’s great and I think usability is great, a lot of potential"

"You have a direct connection with your doctor, you can also change medications, get prescriptions maybe... it seems like there’s a lot of possibilities”

The patient was asked specifically if they would be annoyed by reminders and about the usability of medication and measurement reminders:

"I think it would be helpful and I might need it I think because as I told you I will forget. [...] So yeah I think it would be very useful."

The following points summarize the feedback of the focus group.
1. The application received positive feedback regarding its potential for improving patient-doctor communication, reducing the need for physical meetings and providing more continuous data for monitoring patient’s health, improving upon current methods where patients manually note down measurements and communicate them intermittently.

2. Participants suggested additional features for the application, such as the potential to adapt it for other health conditions like diabetes or Parkinson’s, and the option to share health data for research purposes.

3. The usability of the application was highly rated by the participants. It was considered user-friendly, functional, and a potential tool to streamline communication between patients and doctors.

4. The feature of medication and measurement reminders was perceived positively by the patient, who expressed that such reminders would be helpful due to their tendency to forget scheduled tasks.
Chapter 8

Discussion

This chapter discusses the artefact’s features and how it contributes to the problem area. Current limitations are identified, discussed how they could be overcome in future work and how this changes social and ethical aspects. Some future possibilities for research are presented and the artefact is compared to existing solutions.

8.1 Artefact Significance

The artefact addresses a relevant, real-life problem of hypertension medication adjustment in form of a mobile application. The application can help with patient compliance by sending reminders for medication intake and blood pressure measurements and giving the user an overview over all their daily tasks. The user can save their intake times and measurements inside the application and create reports from that data that can easily be send to the doctor. If blood pressure values fall too much, the user is reminded to talk to their doctor immediately. The application can be individualised by a doctor at the beginning of a treatment to reflect each patient’s needs.

In chapter 2 the possibility of dynamic reminders for improving medication compliance was discussed. It could have been a great contribution to build upon Vervloet et al. (2014) and explore flexible medication reminders based on vital parameters. Even though this approach was dismissed, the newly developed artefact also exists in the realm of medication compliance. It falls back to static reminders which have extensively been studied and evaluated as being able to improve medication compliance. Increased adherence to medication can increase the success rate of treatment, as many other applications try to improve with reminders already. Before medication can be taken regularly though, the correct dosage and medication type is crucial for achieving the best possible treatment. The developed artefact helps by specifically guiding the user through daily activities during initial medication cycles and therefore improving the data that the doctor receives and bases decisions on.

Existing hypertension applications, as shown in chapter 2, do not capture the same focus as the developed artefact. These solutions lack in the practical problem area in the sense that they are not developed for the initial phase of hypertension medication adjustment. They do not have a central and individual configuration by the doctor. Instead, they are intended to be configured by the patient to their perceived needs during ever-day life with hypertension. Similarly, these solutions do not place an emphasis on an overview of daily activities or completing them in time. While most solutions also feature reminders, their implementation is not specifically coupled with the actions that a patient should complete. Because these apps do not incorporate initial medication adjustment, blood pressure measurements that are too low do not play an important role. The risk for low blood pressure is higher if the right medication has not been found yet, which is why the developed application gives an explicit warning to the user if it occurs. The separation of data into medication adjustment cycles is also unique to the developed application. On the other hand, existing applications often have much more detailed
data reports, feature detailed lifestyle recommendations or other educational content and are able to track patient symptoms. These aspects could be part of the artefact’s future work.

These differences show that existing solutions are made for people who live with high blood pressure and want to constantly control their values and health. The developed artefact instead is intended to be used temporarily during medication adjustment.

An adoption of the artefact in existing health care structures faces challenges. Resistance to change is particularly prevalent in the sensitive and conservative structures of health care. The features of the application and how it is structured effect how much resistance it faces. Since the application changes as little as possible of current practices, there is a higher chance of adoption by patient or doctor. On the other hand, the small changes that it does promote can hinder its usage. Some patients might not be comfortable with relying on technology to remind them of important tasks. Data privacy, even though considered in the tool, can be perceived worse than it is. Users normally can not actually check if the app treats their data in the way it claims. The application could still send data to remote servers in the background without the user knowing. For many people this can be a valid reason not to trust and use a tool.

Doctors might consider the tool unnecessary or worry about how it might complicate treatment. Reminders can confuse patients if they do not mark their processes as complete or be annoying to patients and therefore lead to less compliance. Inaccurate data input could lead to worse decision making by the doctor. The artefact tries to incorporate these aspects, but the small scale of the study means that many aspects could be improved. Requirements and their detailed implementation were considered by only one doctor and the reasoning of the developer, but it is hard to actually verify them without extensive evaluation.

All of these aspects would hinder the adoption of the tool in real-life settings.

8.2 Reflections on the Methodological Approach

DSR as a strategy for a Master’s thesis is only partially reasonable. Extensive evaluations, both ex-ante and ex-post, and multiple iterations of the different research phases are usually part of a complete DSR study. This study attempts to fit the concept of DSR into the limited time and resource frame of a Master’s thesis. Difficulties with this approach arose while trying to decide which part of DSR should be laid an emphasis on. In the end, the problem and requirement explication together with the design and development of the artefact took the most time, while only limited time was available for an in-depth evaluation. Additionally, the chosen evaluation form yielded less results than was hoped for, but more evaluation was not possible. Overall, it is very hard to fit a complete DSR research contribution into the time frame of a Master’s thesis. Future attempts at similar projects should be aware of these limitations or can consider other forms of research.

In terms of development, the researcher experienced that implementing features usually takes longer than planned. Some components need more detail and design than initially thought and bug fixes can consume a large amount of time. It also occurred multiple time that too much time was spent on rather insignificant features or UI improvements. For a finished commercial product, all aspects should be as perfect as possible, but for a prototype that has to be finished in a certain time, a developer should remember to focus on the big picture and not get lost in too much detail.

8.3 Conclusions

This study first explored if it would be possible to develop a medication reminder system that can detect a patient’s non-compliance by monitoring vital parameters and only issue medication reminders if necessary. Three expert interviews concluded that it would not be practical to explore this idea further due to limited applicability and potential negative consequences. The focus of the project then
shifted to the development and evaluation of an artefact that helps doctors and patients manage the process of initial hypertension medication adjustment.

The study answered the research question "What are functional and non-functional requirements for the proposed artefact?" by consulting with a general practitioner who treats hypertension patients. The aspirations for the artefact were a cross-platform application that can depict the multiple adjustment cycles that are usually necessary for hypertension medication. All parameters for the individual patient should be set by the doctor. The patient should then be reminded of and guided through their daily tasks of measurement and medication intake. It should further record and display relevant data and be able to export data so it can be sent to the doctor. The artefact should consider usability and make it easy for the user to input measurements. Additionally, the artefact should consider future options of remote data exchange over VitalSigns servers.

To address the research question "How can these requirements be implemented?", the researcher developed a cross-platform mobile application for iOS and Android with .NET MAUI that implements the desired features. The data structures, data storage and reminder types were described. A concept for remote data exchange via the VitalSigns API and a system for scanning measured values of blood pressure devices were developed. The application has multi-language support, reminds the patient of rest before measurements and gives additional information if the blood pressure of the patient falls too low. Other defined requirements were also implemented and showcased.

The evaluation results suggest that the application has the potential to enhance patient-doctor communication and provide consistent health data. Its usability and helpful features like medication and measurement reminders were acknowledged. Additionally, suggestions were made to extend the application’s use to other health conditions and to allow health data sharing for research. The application offers improvements over current, more manual methods of health monitoring and communication.

While the artefact shows potential in delivering improvement in the problem area, actual adoption in real-life scenarios is still hindered by a multitude of factors.

8.4 Limitations

The study can partially validate the explicated problem in Germany and Sweden. The consulted general practitioner is based in Germany. The interviewed hypertension patient in the evaluation is Swedish and confirmed the problem. While similar conditions could be assumed for other countries, it is not evident that processes are the same or that cultural differences do not change treatment adherence significantly.

Additionally, the evaluation only shows selected opinions of a small sample size of individuals and the problem and requirements were explicated with the help of only one doctor. Other patients could have different experiences and other doctors could handle hypertension medication adjustment in advanced ways that do not create the same problems.

Limitations also exist for the accuracy of the application, for the scanning of blood pressure measurement devices and reminders, as discussed in section 8.5.

8.5 Ethical and Societal Consequences

As mentioned by participants of the evaluation, the artefact was developed in a way to fit current doctor-patient processes. A user of the application still needs to visit the doctor or otherwise talk to the doctor directly. The patient data is only stored on the user’s device and must be sent to the doctor over an external channel that is chosen by the patient. The application makes no recommendations for treatment or medication and all individual parameters are set by the doctor. From a doctor
perspective, not much changes in existing processes. The received data might be digital and of better quality, but has to be analysed as usual and any resulting feedback is also given as usual. This approach has the advantage that there can be no false recommendations by the application which protects user well-being and safety. The doctor is still responsible for changing the medication type and dosage. It is also the best possible solution for user privacy. No data leaves the patient’s device and the patient decides themselves, when, how or if their data is sent to the doctor. Printing out the data reports on paper and physically exchanging it, would also be possible. Ethical consequences are therefore limited.

Ethical implications do exist for the accuracy of the tool. Reminders as well as data input have to be precise and error-free to not risk patients’ health. A reminder at the wrong time or one that appears even though the user has already taken their medication, could lead to incorrect intakes and possible health risks. The scanning of a measurement device display to read blood pressure values can similarly lead to wrongful medication adjustment if values are read inaccurately. Before the application can be used in real doctor-patient relationships, these aspects have to be tested and validated.

Hypertension, even if not immediately affecting patient’s well-being, has been shown to majorly increase risk for various illnesses and to be responsible for many adult deaths. The global economic burden of these effects are expected to grow further. Scientific research and contributions in this area are therefore needed to improve quality of life for patients and global economic factors. The developed artefact has the potential to help manage hypertension and increase the success rate of medication treatment. Reminders can help improve the compliance of patients in taking their medication and performing their blood pressure measurements, as shown in chapter 2. This in turn increases treatment success by assisting the doctor in making correct medication decisions. As the evaluation anecdotally has shown, the problem of incomplete data and forgetting to take medication does exist and the artefact could potentially improve it.

8.6 Future Research and Development

There is more scientific work that could be done. Existing limitations of countries and generalisation of results can be overcome by performing a similar DSR study that incorporates multiple field experts and affected patients to iteratively develop a similar application or improve the existing solution. There are many aspects and requirements of the artefact that can be added, expanded or changed. The delicate nature of the problem would probably cause different opinions on how much the tool should guide the patient or how it should communicate from a doctor and patient perspective. To really find the best possible solution, more than one expert voice should be incorporated.

The current form of evaluation is short and features opinions that are hard to generalise. With more time and resources, the artefact could be evaluated in a naturalistic setting between patient and doctor when prescribing and adjusting initial hypertension medication. Such a study could feature qualitative data in form of interviews as well as quantitative data in form of questionnaires to assess the perceived usability and effectiveness of the application. Usability would mainly fall on the patient side, while doctors can evaluate if or how compliance and data quality improved when using the artefact compared to default processes. Such studies can be performed with an emphasis on different kinds of user groups. Elderly patients might have different views and needs than young or tech-savvy individuals.

As discussed in section 8.5, the reliability of the device display scanning and reminder functions should be tested precisely to make sure that the application does not worsen data quality with falsely read values.

Apart from future research, functionalities of the artefact can also be extended. The effectiveness of the artefact is somewhat limited by its adherence to existing healthcare processes. In its current form, doctor and patient still have to meet up in person or exchange information in existing ways. For configuring the adjustment cycles, the doctor needs to have physical access to
the patient’s device and a patient has to choose an external channel for sharing their collected data with their doctor. While the application still has the potential to make data collection more reliable and data exchange more efficient, the concept could be expanded to feature real-time data exchange over servers. A concept for implementing this into the artefact has been presented in chapter 5.2.3. Data exchange over servers would have the advantage of doctors having direct access to the patient’s blood pressure values, receiving alarms if values go out of range and configuring medication cycles for the patient’s application remotely. This would also increase productivity for the doctor-side of the problem by offering a central application for different patients and managing their conditions with interactive data visualisation. The drawback would be that this heavily affects the data privacy of the patient. A remote data exchange, contrary to the current local storage solution, would require informed user consent, adherence to applicable data privacy laws and encrypted data exchange and data storage.

Beyond real-time data exchange, a server infrastructure holds additional advantages. It would be possible to implement direct communication paths between patient and doctor. Doctors could send updated instructions or adjusted medication plans directly inside the application. Patients could have the ability to confirm their understanding of treatment plans and provide consent for any adjustments. Feedback mechanisms can be implemented to allow patients to comment on their experiences, report side effects, or ask questions. The application could support a structured communication flow, starting with data collection, followed by comments, approvals, advice from the doctor, and patient compliance. All these functionalities would extend existing healthcare structures further, which has the potential to increase treatment efficiency. It does, however, yield the danger of alienating patients that prefer a more traditional, personal contact with their doctor or might increase the risk of misunderstanding details of treatment measures.

Remote data storage would make it easier to use patient data for research or commercial purposes. The data could be used on a large scale to train machine learning algorithms, benefitting both doctors and patients. For doctors, machine learning models can assist in identifying trends and anomalies in patient data, providing valuable insights for treatment decisions. It could automatically flag instances where medication adherence is a concern or when blood pressure readings fall outside the target range, prompting doctors to intervene. Additionally, machine learning could help in predicting a patient’s response to different medications, aiding in personalized treatment plans. For patients, it could provide educational aspects, explaining the significance of their data and suggesting lifestyle changes or interventions. It could offer personalized health recommendations based on the patient’s data, such as dietary adjustments, exercise routines, or stress management techniques. However, it is essential to strike a balance between providing useful information and overwhelming the patient with data or recommendations. Furthermore, it is important to keep the safety and well-being of patients in mind. Automated recommendations or treatment plans could be inaccurate and potentially dangerous. For this reason, it would take extensive training of models and evaluation of accuracy before recommendations about medication adjustment itself could be made reliably. The sharing of patient data for enabling the training of models would also yield the same privacy issues as mentioned before that would have to be addressed.

In its current form, doctors need to configure adjustment cycles on a patient’s device. This means that patients have the same access to raw configuration data and settings as the doctors. For non-tech-savvy users, this access can be confusing or lead to unintentional altering of configurations. To address this problem, doctors could have a separate application for configuring cycle data, which is then transferred to a patient device by scanning a QR code. This would offer an in-between step before actual server exchange. The doctor would not have to interact with the patient’s phone directly and could also configure a new cycle remotely by sending the QR code to the patient. This method would work without servers and therefore not impact data privacy.

The application could implement direct Bluetooth connections and data exchange between phone and blood pressure measurement devices. A specific form of device is specialized smartwatches or other wearables. Since the measuring of BP requires air compression, the amount of smartwatches...
capable of measuring BP is slim. It can be assumed that these devices are not very common amongst patients or doctor’s offices. Further, a constant or frequent measuring of BP is not necessary to achieve the application’s goals. Nevertheless, the integration of direct Bluetooth connections might increase the reliability of the received data, even if only available on certain devices. On the other hand, the pitfalls of maintaining a Bluetooth connection could lead to user error and user frustration.

To cater to a broad user base, the application could adapt its UI based on age groups. For older users, a simplified UI with larger icons and straightforward navigation can enhance usability. In contrast, for younger users, gamification elements can be incorporated to encourage usage of the application. Customisable UI themes could allow users to choose the interface style that suits their preferences and needs. The goal would be to ensure that the application remains accessible and appealing to users of all age groups.
Bibliography


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Appendix A

Android App Screenshots

This appendix only features a selection of Android screenshots that show differences to the iOS application.

Figure A.1: Rest Reminder and Notification
Figure A.2: Android Exports
Appendix B

Data Export Examples

CSV File

The CSV file export technically consists of three parts, each with its own csv header. The first are the configured values of the corresponding CycleConfiguration of the data. The second are the Intake and Measurement processes of this config, distinguishable by the type field (0 for a MeasurementProcess and 1 for an IntakeProcess). The last part is the actual raw data, distinguishable by the type field (0 for a MeasurementDataEntry and 1 for an IntakeDataEntry). Intake data shows only the date and time, while measurement data also includes pulse, systolic and diastolic values.

Config

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<th>endDate</th>
<th>currentAvgSys</th>
<th>currentAvgDia</th>
<th>goalAvgSys</th>
<th>goalAvgDia</th>
<th>lowSys</th>
<th>lowDia</th>
<th>measurementDevice</th>
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<td>100</td>
<td>120</td>
<td>80</td>
<td>100</td>
<td>80</td>
<td>0</td>
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Processes

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<th>maxDelay</th>
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<tbody>
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<td>Take measurement</td>
<td>60</td>
</tr>
<tr>
<td>0</td>
<td>18:00:00</td>
<td>Take measurement</td>
<td>60</td>
</tr>
<tr>
<td>1</td>
<td>08:00:00</td>
<td>Take medication as discussed</td>
<td>60</td>
</tr>
</tbody>
</table>

Data

<table>
<thead>
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<th>diastolic</th>
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</thead>
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<td>100</td>
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<td>99</td>
</tr>
<tr>
<td>0</td>
<td>07/06/2023 10:02:00</td>
<td>70</td>
<td>146</td>
<td>98</td>
</tr>
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</table>

PDF File

The PDF file export shows the used configuration of the cycle at the top. Next it shows the graphs which are also available in the user application. In the future, the report can include much more information, such as tables of mean values for measurements of each day or week and the average deviation of the patient from original intake and measurement times.
Hypertension Report [Patient Name]
11/05/2023 - 04/06/2023

Current Avg Systolic 150
Current Avg Diastolic 100
Goal Avg Systolic 120
Goal Avg Diastolic 80
Low Systolic 100
Low Diastolic 80
Measurement Device 0

Daily Activities

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<tr>
<th>Type</th>
<th>Time</th>
<th>Instructions</th>
<th>Maximum Delay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement</td>
<td>10:00</td>
<td>Take measurement</td>
<td>60</td>
</tr>
<tr>
<td>Measurement</td>
<td>18:00</td>
<td>Take measurement</td>
<td>60</td>
</tr>
<tr>
<td>Intake</td>
<td>08:00</td>
<td>Take medication as discussed</td>
<td>60</td>
</tr>
</tbody>
</table>

BP Values

![BP Values Chart]
Appendix C

Interview Protocol

Interviews were conducted in the following fashion:

"Thank you very much for your participation. Is it ok if I make an audio recording of this conversa-
tion?"

[When confirmed, the recording is started.]

Can I ask what your profession is?"

[Interviewer gives an introduction to the thesis topic]

The following is a collection of possible questions to be asked, depending on the progression of the interview. Some of the questions were not asked due to responses to previous questions or because the topics of the questions came up by themselves.

- Do you know of any systems that try to do achieve this or something similar?
- Do you have any thoughts on whether it would be possible to develop an artefact like this?
- Do you know of any health conditions/ medications where it would be possible to detect non-compliance in the described way?
- Do you have any thoughts on how effective such a system could be/ whether people would use it/ whether it would be better than static reminder systems?
Appendix D

Informed Consent Form

Researcher: Ferdinand Martini
Institution: Stockholm University, Department of Computer and Systems Sciences (DSV)
Course: Master’s Thesis, VT2023

Purpose of the Study
This study is conducted as part of a Master’s thesis in the Master’s program of Computer and Systems Sciences. The goal is to find out whether it is possible to develop an IT system that continuously measures specific vital parameters of patients to detect if a prescribed medication has been taken or not. The system would be helpful in assessing medication compliance and reminding patients of forgotten medication intake. The interview is semi-structured and aims at learning about the feasibility of such a system, which illnesses or medications it could be developed for, what a solution could look like and what other aspects should be considered.

Participant’s Agreements

1. I confirm that I voluntarily participate in this research study.

2. I agree to participate in this Master’s thesis, which will be submitted to Stockholm University as part of the degree in Computer and Systems Sciences.

3. I understand that all collected data will only be used in the described context or other forms of research as authorised by Stockholm University.

4. I understand that I will not be named in the final result.

5. I understand that my profession will be named as the only personal information in the final result.

6. I understand that my answers to research questions might be cited word-by-word in the final thesis.

7. I agree to an audio recording of the interview.

8. I agree that all recordings will be kept not anonymised, but secure and confidential in the possession of the researcher.

9. I understand that I will not receive any benefits by participating in this study.

10. I understand that I can refuse to answer any questions or withdraw from the study entirely at any time and without consequences.
11. I understand that I have four weeks after the interview to prohibit usage of my interview data, which will lead to the deletion of my recordings and other data. The final work will not include any of my contributions in this case.

Date

Participant’s Full Name

Participant’s Signature