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Dynamic ePROM mobile application to improve diabetes consultations

Incorporating patient-gathered data into ePROMs

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To my family, friends and girlfriend.

For being there.

“He knew everything there was to know about literature, except how to enjoy it.”
- Joseph Heller

Preface

People living with diabetes have to constantly be vigilant and manage their illness. Every day they have to consider their blood glucose, insulin, and carbohydrate intake. Being constantly aware of a disease that is potentially fatal is a challenge, both mentally and physically. To have diabetes can be a lonely and isolating experience. This thesis explores the possibility of improving diabetes consultations with a mobile dynamic ePROM application that emphasizes the needs and wishes of the user by incorporating patient-gathered data into the ePROM.

I want to thank Eirik Årsand and Gunnar Hartvigsen for the weekly supervision meetings. From concrete advice to loose discussions of potentially interesting avenues of research, the meetings were always helpful. I have learned a lot from you, and I hope you have learned a little from me as well. I also want to thank Santiago Gil Martinez, Keiichi Sato, Pietro Randine and Juan Carlos Torrado Vidal for being co-supervisiors. The different points-of-views have been valuable and given me several potential solutions to every problem I have faced.

To my girlfriend, Rebekka, thank you for standing by me and supporting me through the thesis even when I have been distracted and absent-minded. I look forward to spending my weekends with you.

I would like to thank my family for their support. Not only during my five years at UiT, but throughout my life. Whether it be big or small, you are always there for me. You are a constant I can rely on, and I appreciate it deeply.

That should be it.
Benjamin Aglen, 2021

Abstract

People with diabetes live a life of constant need to monitor and manage their illness. Unfortunately, a large number of people with diabetes suffer from diabetes-related distress and depression. A better diabetes consultation can directly impact the health of people with diabetes, both mentally and physically.

In this thesis, healthcare practices that previous studies have reported lead to a successful diabetes consultation with an improved health outcome are identified through literature review. The findings are used as the inspiration for designing and implementing a dynamic electronic patient-reported outcome measures (ePROM) mobile application.

The application promotes the identified healthcare practices by using the patient-gathered data of each user and tailoring the contents of their questionnaire to them. The application is usability tested with the System Usability Scale is deemed to have good usability (83.75/100) and be a facilitator for better consultations.

Table of figures

List of tables

Table of contents

1 Introduction

1.1 Background

Diabetes mellitus is a chronic disease, and 463 million people worldwide are living with it[1]. People living with diabetes are at risk for complications such as blindness, kidney failure, heart attacks, stroke, and lower-limb amputations[2-4]. There are two main categories of diabetes, type 1 and type 2. Patients diagnosed with type 1 diabetes have an autoimmune reaction that causes their pancreas to produce little or no insulin. People with type 1 diabetes need daily insulin injections to regulate their blood glucose levels appropriately. In addition, they need a well-structured self-management plan that includes daily insulin injection, exercise, glucose monitoring, and healthy dietary habits to have a healthy life[1].

Type 2 diabetes renders the patients' cells unable to respond correctly to insulin. This is referred to as insulin resistance[1]. To manage type 2 diabetes, patients require a healthy diet, physical activity, and regular consultations with a physician. However, a healthy lifestyle could not be sufficient to control blood glucose levels. If the body still produces some insulin, patients could take oral medicines. Otherwise, patients need to inject insulin via injections.

Both diabetes type 1 and type 2 patients should have at least an annual consultation with their physician. Diabetes patients can suffer complications as a result of living with diabetes over time. These complications can be avoided or delayed through regular visits with health care professionals and a well-structured healthy lifestyle.

In addition to physical illnesses, diabetes patients are prone to psychosocial problems such as depression and diabetes-related distress. Many patients with diabetes have these problems but remain undiagnosed[5]. Through consultations, these illnesses can be discovered and combated, especially if patient-centered care and participatory decision-making are practiced.

1.2 PROMs

Patient reported outcome measures (PROM) is a clinical and research tool used to measure patients' perception of their own health[6]. PROMs can be general or disease-specific. General PROMs can be administered to any patient and can be used to compare the health or quality of life between patients with different conditions. The disease-specific PROMs are used to identify symptoms or complications tied to the specified disease. A study targeted on disease will often utilize PROMs by combining the generic and disease-specific PROMs[6].

1.3 Dynamic ePROM

When a clinic or research lab uses a PROM or ePROM all participants completing identical questionnaires. There are several validated diabetes PROMs with a focus on different problem areas of diabetes such as diabetes-related quality of life, diabetes-related distress, depression, and self-management regimen adherence[7]. This thesis presents a dynamic ePROM. The solution's dynamic part refers to the questions in the ePROM changing depending on the user-gathered data and the user's answers to previous ePROM questions. This dynamic functionality makes the ePROM questions more relevant to the user.

1.4 Scope and research problems

The thesis aims to improve diabetes consultations by designing and creating a dynamic ePROM for people with diabetes by utilizing their sensor data. Diabetes was chosen as a specific target disease because of the amount of health data a diabetes patient collects as part of their self-management regimen and the expertise of the members of the Health informatics and -technology group at the University of Tromsø. The thesis builds on the capstone project written by the author. The idea for the dynamic ePROM comes from the capstone project. More thorough research is done in the thesis with literature reviews, and the system is redesigned and reimplemented. The thesis attempts to solve the following research questions:

Main research question:
How can a mobile dynamic ePROM application be designed to improve consultations for diabetes patients?

The main problem is split into two sub-problems:

Sub-Problem 1:
How can sensors and tech be used to improve ePROMs?

This sub-question is posed to discover the possibilities patient-gathered data offers when used in combination with ePROMs, utilizing the data people with diabetes generate to assist their self-management.

Sub-problem 2:
How can a mobile application be designed to emphasize identified consultation improving healthcare practices?

With this sub-question, the goal is to discover what healthcare practices correlate to improved consultations or health outcomes and how a mobile application can emphasize these practices.

1.5 Assumptions and limitations

The app created in the thesis is designed to be a diabetes consultation tool. This assumes that the ePROM scores are discussed at consultations. Previous studies have revealed low use of paper-based PROMs at consultations[8], despite their beneficial effect. The app does not gather sensor data, and it is designed as a sub-part of a greater system with sensor data gathering capabilities.

Only the client-side of the application is designed and developed. Back-end data storage and data processing are outside the scope of the design. The data handled by the app is sensitive health data, and it is assumed that the data is handled securely. This also includes the secure delivery of the completed ePROM from used to health care professionals.

Due to the one-semester time frame for the thesis, deploying and testing the effect of the dynamic ePROM after designing and implementing it was not feasible. Testing is therefore limited to a usability test.

1.6 Contributions

The thesis describes the first known dynamic ePROM application, a continuation of the author's capstone project. The dynamic nature of the application is designed to promote health care models' previous studies have found to have positive effects on consultations, such as patient-centered care, pre-visit intervention[9], and participatory decision making. The questions used in the ePROMs are from validated PROMs identified through a literature search. Some questions are original, but they are based on the previously validated PROMs.

1.7 Organization

The rest of the thesis is organized as follows:
Chapter 2 Theoretical framework describes the identification of previous research and solutions that guide the design decisions of the thesis.

Chapter 3 Methods describes the research paradigm and research methods used in the design and implementation of the application.

Chapter 4 Requirement Specification describes the requirement specification for the application and how the requirements were identified.

Chapter 5 Design describes the design choices taken and the reasoning behind them.

Chapter 6 Implementation describes the implementation process.

Chapter 7 Test describes the usability testing and the results.

Chapter 8 Discussion reviews the findings and results. Discusses the future work where the application can be used.

Chapter 9 Conclusion review the work completed as a whole.

2 Theoretical framework

This chapter covers the theory behind the design decision made in the thesis. To identify relevant literature, two literature reviews are conducted. The effect on consultations by PROMs and certain healthcare practices discovered in the literature review that defined the design for the ePROM are talked about. Additionally, current ePROM applications are reviewed.

2.1 Diabetes consultations

People with diabetes are advised to have regular consultations with their physicians. The Norwegian Directorate of Health guidelines states that every person with diabetes should have at least two consultations per year. One thorough control consultation is referred to as “yearly control” and one less comprehensive consultation for follow-up [10]. Health care professionals can schedule additional consultations if they deem it necessary. During consultations, digital schemas are used as a checklist. These schemas also serve as a log where the long-term progression of the patient is evaluated. Figure 1 shows the schema used in Norwegian practices is the NOKLUS diabetes schema[11].

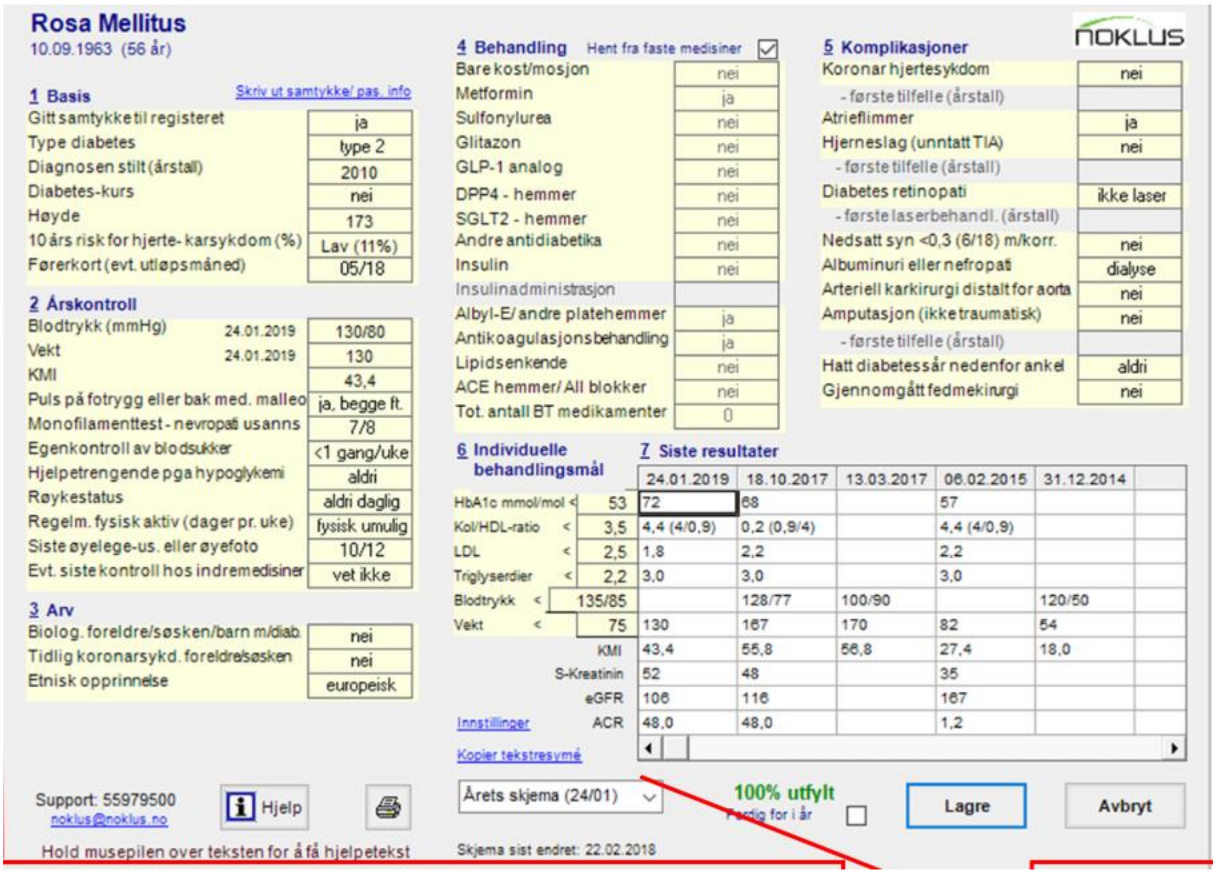

Figure 1: NOKLUS diabetes schema[11].

2.2 Diabetes-related distress

The daily self-management of diabetes and the possibility of complication has a psychological effect on people with diabetes. A study with 2374 individuals found that sixty percent of people with diabetes experience diabetes-related distress[12]. Diabetes-related stress is associated with worse health outcomes, both clinical and psychosocial. People with diabetes experience distress not only from managing their illness but also from a lack of understanding and support from family and healthcare professionals. Among Norwegian people with diabetes, the most distress is physician-related distress[13]. Patients may feel that their concerns are not taken seriously, or they lacka precise health care plan to follow.

2.3 Patient-reported outcome measures

Patient-reported outcome measures (PROMs) is a health care and research tool to measure and report patients perception of their health[14]. The uninterpreted patient report is called patient-reported outcomes (PROs). PROMs are used to measure and report PROs[6]. Patients report in the form of answering one or more questionnaires. PROMs vary based on the metrics measured. There are both general PROMs and disease-specific PROMs. PROMs have been used extensively to improve diabetes care with several validated PROMs utilized in scientific literature, but no standardized PROMs is used consistently in clinical care settings[15]. However, the International Society for Pediatric and Adolescent Diabetes[16], the International Diabetes Federations[17], and the American Diabetes Association[18] recommend continual usage of PROMs in diabetes care.

A previous study[19] has identified patient preference of themes in PROMs:

- Instrument simplicity
- Personalized assessment
- Having measurable aims or objectives
- Distinct items

PROMs are distributed in two ways, a paper-based PROM or a digital ePROM. A previous systematic review regarding the benefits and disadvantages of ePROMs[20] discovered that out of 16 previous studies that measured user (patient) preferences, 13 studies reported a user preference for ePROMs.

The completion time for ePROMs is reported to be lower or equal to paper-based PROMs, except for two papers that were logging in and authenticating users caused the completion time for the paper-based solutions to be lower.

The human resource cost of paper and electronic PROM preparation and distribution was calculated by Engan et al. [21]. They found that the mean human resource time for ePROMs was 9.5 minutes and 24 minutes for paper-based PROMs.

Concerning the missing data reported, in 7 out of 10 papers[21], the data sets from ePROMs were more completed compared to paper-based PROMs, due to pop-up or alert messages when the system detects a missing or incomplete answer. Two papers reported no significant difference between the two solutions, and one paper reported less complete data from ePROMs. Users are more likely to give detailed answers to open-ended questions with text responses when completing an ePROM compared to a paper-based PROM[22]. One previous study[23] found user completion rates to be higher with ePROMs, while another study[24] reported no significant difference in completion rates between the two solutions. Due to inconsistent evidence, it is not yet clear whether ePROMs results in better completion rates.

There are disadvantages to ePROMs as well. Completing an ePROM requires computer and internet knowledge. Completing an ePROM poses a challenge to older patients and patients with little or no computer experience. Such patients may require assistance to complete an ePROM[25]. In addition, the user may experience technical difficulties with ePROMs regardless of their computer literacy with internet connectivity issues or bugs in the ePROM system. A previous study found that users who experienced technical issues were less likely to use the system daily[26].

2.4 Precision medicine

Precision medicine is a healthcare strategy where patients with the same disease are split into sub-groups where unique issues can be further defined and more effectively treated[27]. Precision medicine is an evolvement of personalized medicine. Personalized medicine is to analyze a patient's genetics and use this information to tailor a treatment and monitoring regimen or prevent the development of diabetes if the patient does not have it yet[28]. Precision medicine creates a treatment plan for sub-groups rather than the individual.

For example, diabetes is a heterogeneous disease despite its type 1 and type 2 classification. Numerous diabetes varieties with different complications and treatments are contained in this classification as shown in Figure 2: Heterogeneity in diabetes. The pie sizes are an approximation of the proportion of the population with this variation of diabetes[27].

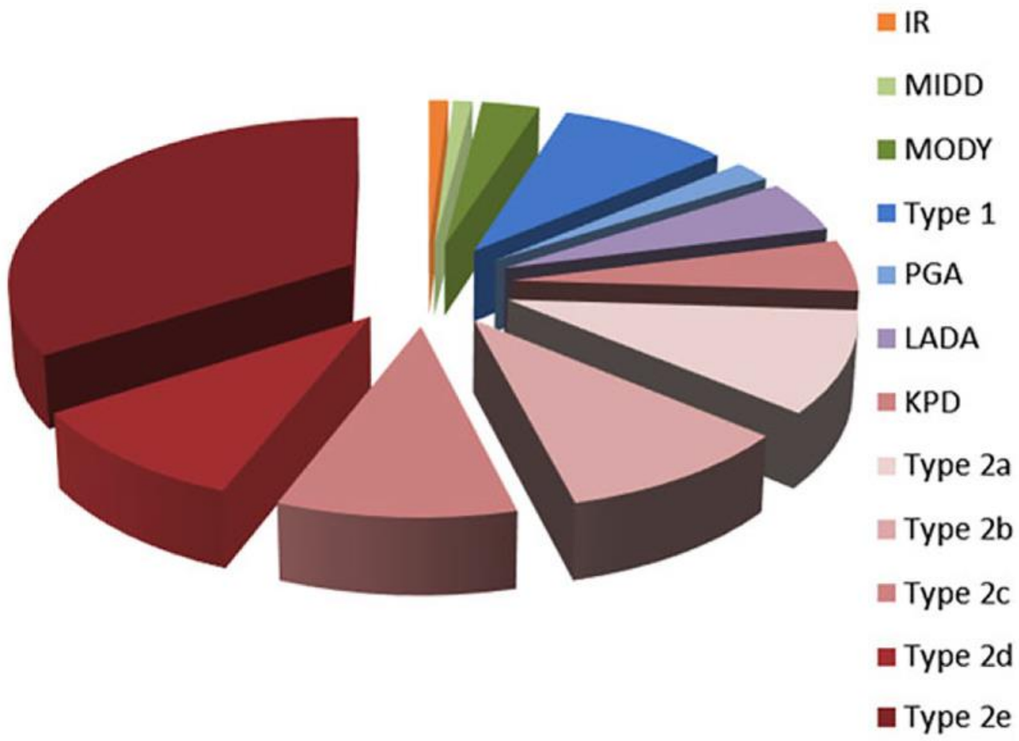

Figure 2: Heterogeneity in diabetes. The pie sizes are an approximation of the proportion of the population with this variation of diabetes[27].

2.5 Health Technologies

People with diabetes rely on sensor data to manage their disease. Technologies such as activity trackers, blood glucose meters, and diabetes health applications are essential for the self-management of diabetes. The regulation of blood glucose is a concern for people with diabetes. Both hypoglycemia and hyperglycemia are potentially life-threatening. To monitor blood glucose levels, people with diabetes use a sample of their blood on a glucose meter or a continuous blood glucose meter. A healthy lifestyle with moderate physical activities and a regulated diet can delay and prevent complications for people with diabetes. Dietary data has to be manually inputted by the user. Physical activity level can be manually inputted or measured automatically via pedometers or accelerometers. These are the most suitable tools due to the large proportion of light-intensity activities compared to high-intensity activities[29].

A study conducted on the use of mobile health applications among people with type 2 diabetes[30] found that 41% of type 2 users with a smartphone use health applications as a tool in their diabetes self-management. Health application features such as activity tracking and carbohydrate intake logging help keep track of dietary and exercise goals.

2.6 State of the art

To design and implement a mobile health application for diabetes consultations it is important to identify existing literature regarding diabetes consultations, mobile health applications, and PROMs. In this section, findings from the literature review and exiting mobile applications are presented.

2.6.1 Literature review

Two literature searches were performed, the selection processes are described in 3.2. The first literature search was conducted to identify consultation-related healthcare practices that positively affect diabetes patients, recording the methods used, the evaluation criteria set, and the results collected. Additionally, the literature search identified previous use of PROMs in studies and in clinical practice. And identifying how people with diabetes use mobile health applications, the degree to which they are used, and user preference. The second literature search was performed to identify valid and relevant questionnaires.

The dynamic nature of the intended application relies on a large set of questions, where the users will fill out a specific sub-set of questions based on their profiling.

The main findings of the literature reviews are the following:

- Patient-centered care and participatory decision-making improves patient health outcomes;
- PROMs facilitate patient-centered care;
- No dynamic ePROMs have been developed previously;
- E-mail-based “light touch” pre-visit intervention improves consultation communication but has no provable effect on glycemic control;
- Using a PROM focusing on diabetes-related distress as a pre-visit intervention tool improves the participants’ diabetes-related distress after 3-6 six months;
- User-centric features in mobile diabetes health applications can improve health outcomes;
- Several validated questionnaires and their target areas were identified.

2.6.2 Existing ePROM applications

All mobile ePROM and ePRO applications available on Apple store and google play are linked to medical clinics or studies and can not be accessed without identification codes. Some screenshots and functionality are available on the application’s pages in the stores, however.

Patient Cloud ePRO

Patient cloud ePRO is a mobile ePRO application made for patient-data collection in research or clinical use.

Pros:

- Intuitive UI
- Offers validated questionnaires.

Cons:

- The provider can not create their own questionnaires.
- Can not collect sensor data.

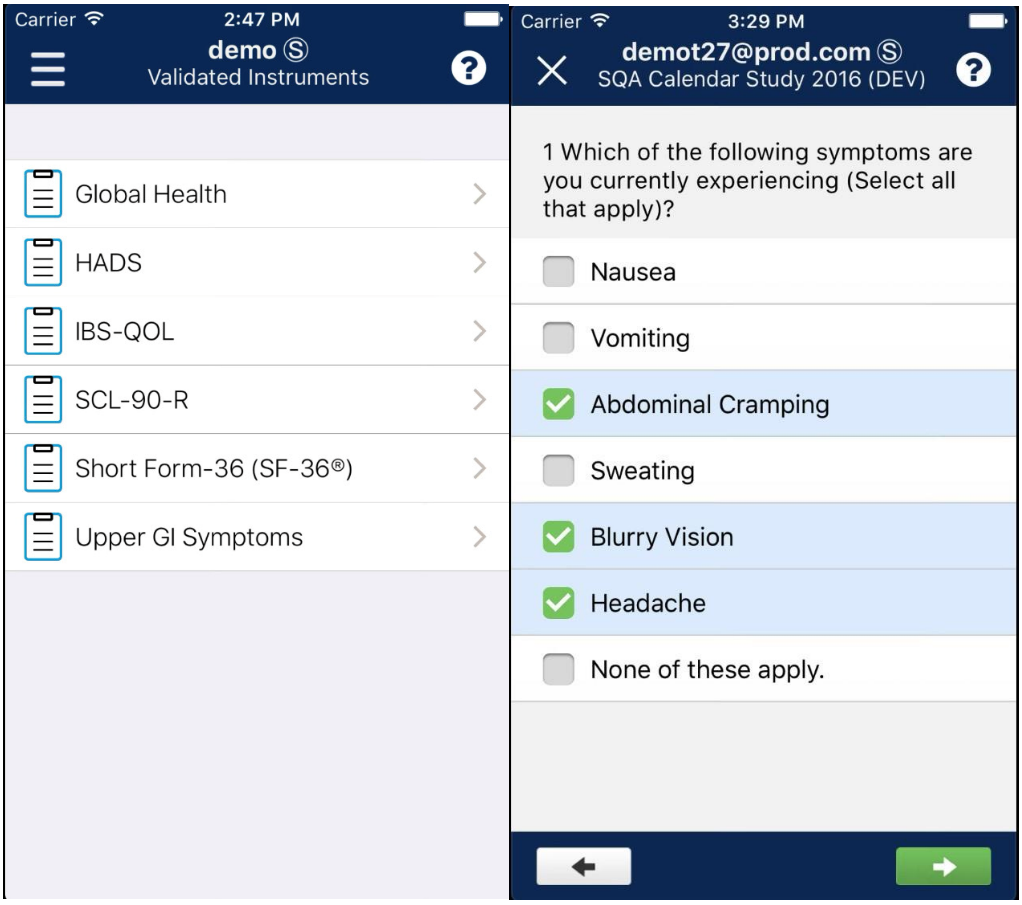

Figure 3, Patient Cloud ePRO[31]

Premier mobile ePRO

This is another mobile application service provided for researchers. The researchers determine the questions that will be answered, and the participants fill out an ePROM. It has the same functionality as the "Outcomes by Nexus" application.

Pros:

- The provider supplies the questionnaire.
- The data is securely returned to the provider after users complete the questionnaire.

Cons:

- The application offers only static questionnaires.
- Can not gather sensor data.

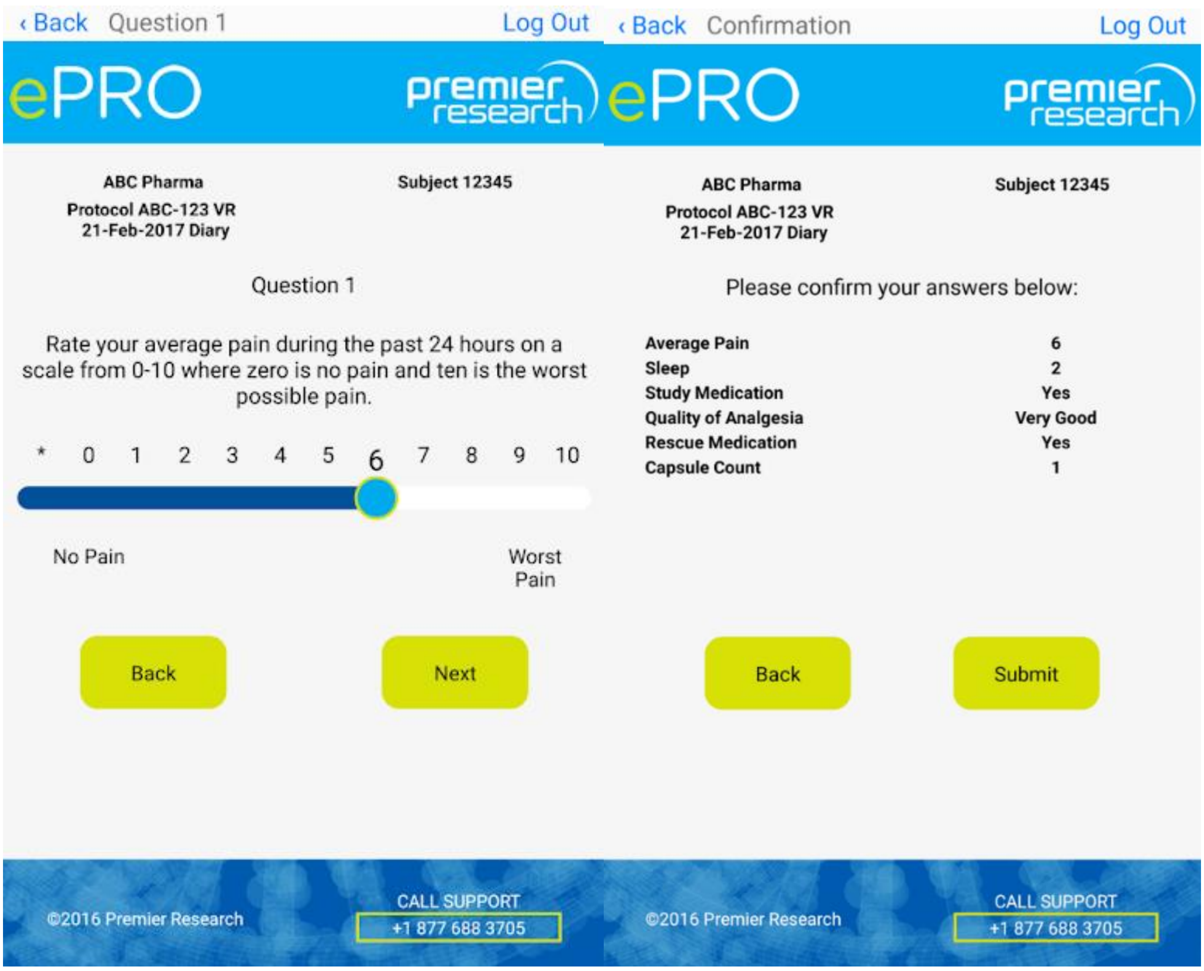

Figure 4: Premier mobile ePRO[32]

Outcomes by Nexus

Outcomes by Nexus is a mobile application for patient-focused studies to collect PRO data from their participants.

Pros:

- The researcher or clinician provides the questionnaire the participants will complete. It can be validated or made by the provider.
- Data securely returned to the provider after users complete the questionnaire.
- Can collect sensor data.

Cons:

- Offers only static questionnaires. The sensor data the application collects is not used in the questionnaires.

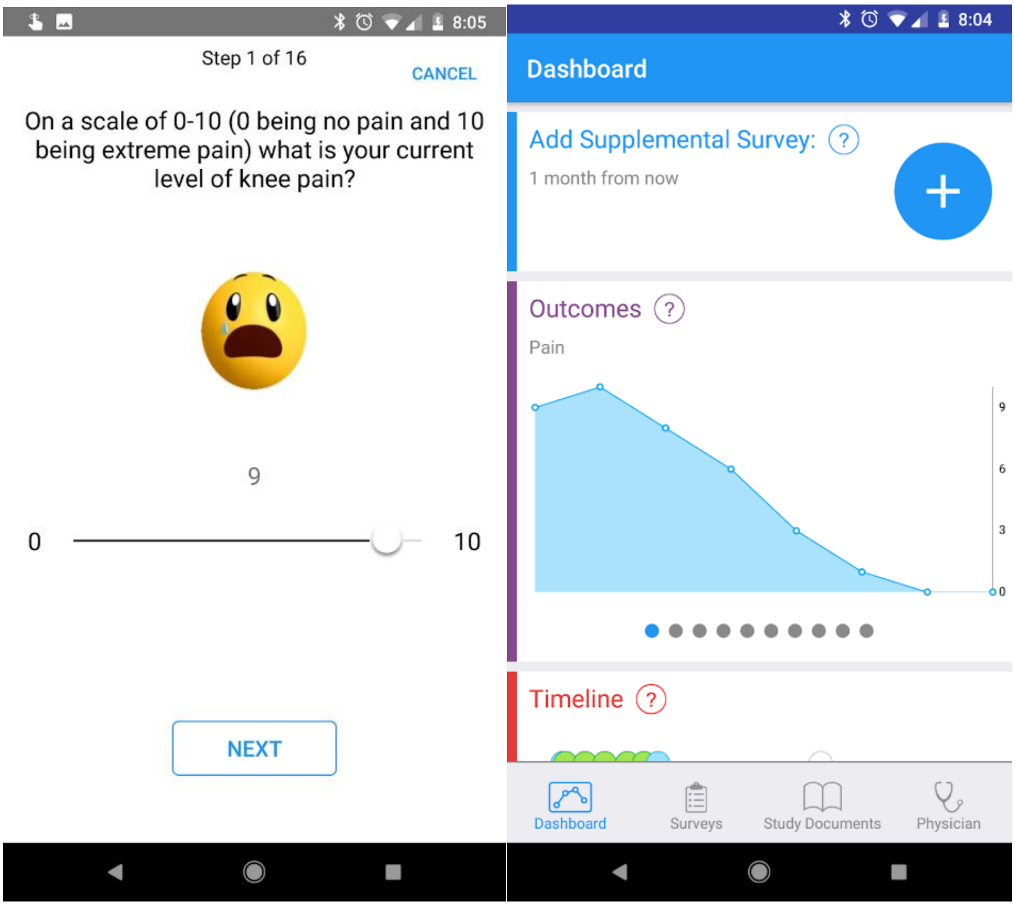

Figure 5: The "Outcomes by Nexus" app[33]

None of the reviewed applications have dynamic questionnaire solutions. Outcomes by Nexus is the only application that can capture sensor data from the user but does not use sensor data in the questionnaire. All applications serve the same purpose of patient data collection.

2.7 Patient-centered care and participatory decision-making

Patient-centered care is a health care practice where the individual patient's needs, wishes and mental and emotional state have priority over the illness itself[34]. The end goal of patient-centered care is to have individualized care where patients are actively involved.

Participatory decision-making is an essential aspect of patient-centered care[35]. The core of participatory decision-making is to value and incorporate the patients' input into clinical care decisions[36]. Additionally, a study[37] found that Hemoglobin A1c, LDL cholesterol, patient satisfaction, and adherence improve when participatory decision-making is practiced during diabetes consultations.

Practicing patient-centered care increases patient-satisfaction[38], lowers depression symptoms and improves patient physical function[39]. In addition, increasing the patient's knowledge through basic education or via innovative methods such as mobile health applications[30] could improve self-management and patients' health outcomes.

2.8 Pre-visit intervention

In 2010 J.S Wald et al.[40] had patients complete an eJournal before the scheduled consultations. The participants were split into two groups and completed different eJournals. The eJournals contained patients' medical history or their family and personal history and health maintenance. Participants from both groups reported that they felt more prepared for their consultation than earlier experiences. Meanwhile, the health care professionals presented more accurate patients information during the consultation. A second study[41] sent the participants an e-mail as pre-visit preparation and found that this improved the consultation communication. Using a PROM as a pre-visit intervention resulted in focused and direct consultations with more emphasis on the patients' needs and wishes [42]. Both approaches improved the consultation communication, neither could prove increased patient health outcomes.

Another study[13] administered the Problem Areas in Diabetes (PAID) questionnaire to patients before consultations. They found an increased discussion about diabetes-related distress during the consultation, and after 3-6 six months, a decrease of distress in the patients. This indicates that identifying and discussing specific diabetes-related concerns can improve patients' health outcomes.

3 Methods

This chapter describes the methods, tools, research paradigm, and testing methodology utilized in the project.

3.1 Research paradigm

The Task Force on the core of Computer Science describes in their final report Computing as a discipline[43] three major paradigms for computing discipline: theory, abstraction and design.

Theory rooted in mathematics and consists of four steps followed in the development of a coherent, valid theory[43]:

1. Characterize objects of study (definition)
2. Hypothesize possible relations among them (theorem)
3. Determine whether relationships are true (proof)
4. Interpret results

Abstraction rooted in the experimental scientific method and consists of four stages that are followed in the investigation of a phenomenon[43]:

1. Form a hypothesis
2. Construct a model and make a prediction
3. Design and experiment and collect data
4. Analyze results

Design rooted in engineering and consists of four steps followed in the construction of a system to solve a given problem[43]:

1. State requirements
2. State specifications
3. Design and implement the system

4. Test the system

The work this report describes is within the design paradigm. Requirement and specifications are specified. A prototype is then designed, implemented, and tested, and the steps are reiterated until the system is satisfactory.

3.2 Literature reviews

This section describes the method used in the two literature reviews. Figure 6 summarizes the process for the first literature review and Figure 7 for the second one.

3.2.1 Literature review #1

The first literature review aimed to document previous studies evaluating PROMs or ePROMs used in clinical settings for diabetes or other chronic illnesses. And to determine if a dynamic PROM had been developed previously. There were not discovered publications describing a dynamic PROM. Secondly, the literature review was used to discover publications on diabetes consultations in order to identify practice factors that can improve the consultations and, in turn, treatment outcomes. Lastly, the review was performed to unveil diabetes patients' usage of health-related mobile applications in their day-to-day self-management, how many patients use mobile applications, how much do they depend on these applications in their self-management, and which factors influence their user experience. Table 1 presents the findings from the first literature review.

The databases queried in the literature review were:

- PubMed
- Web of Science
- IEEE Explore
- ACM Digital Library

The exact queries used in the different databases are documented in Appendix A.

Publication inclusion criteria:

- Usage or studies of PROMs or ePROMs in clinical settings
- The goal of the study was to improve diabetes consultations
- The goal of the study was to identify diabetes patients use of health applications in their self-management

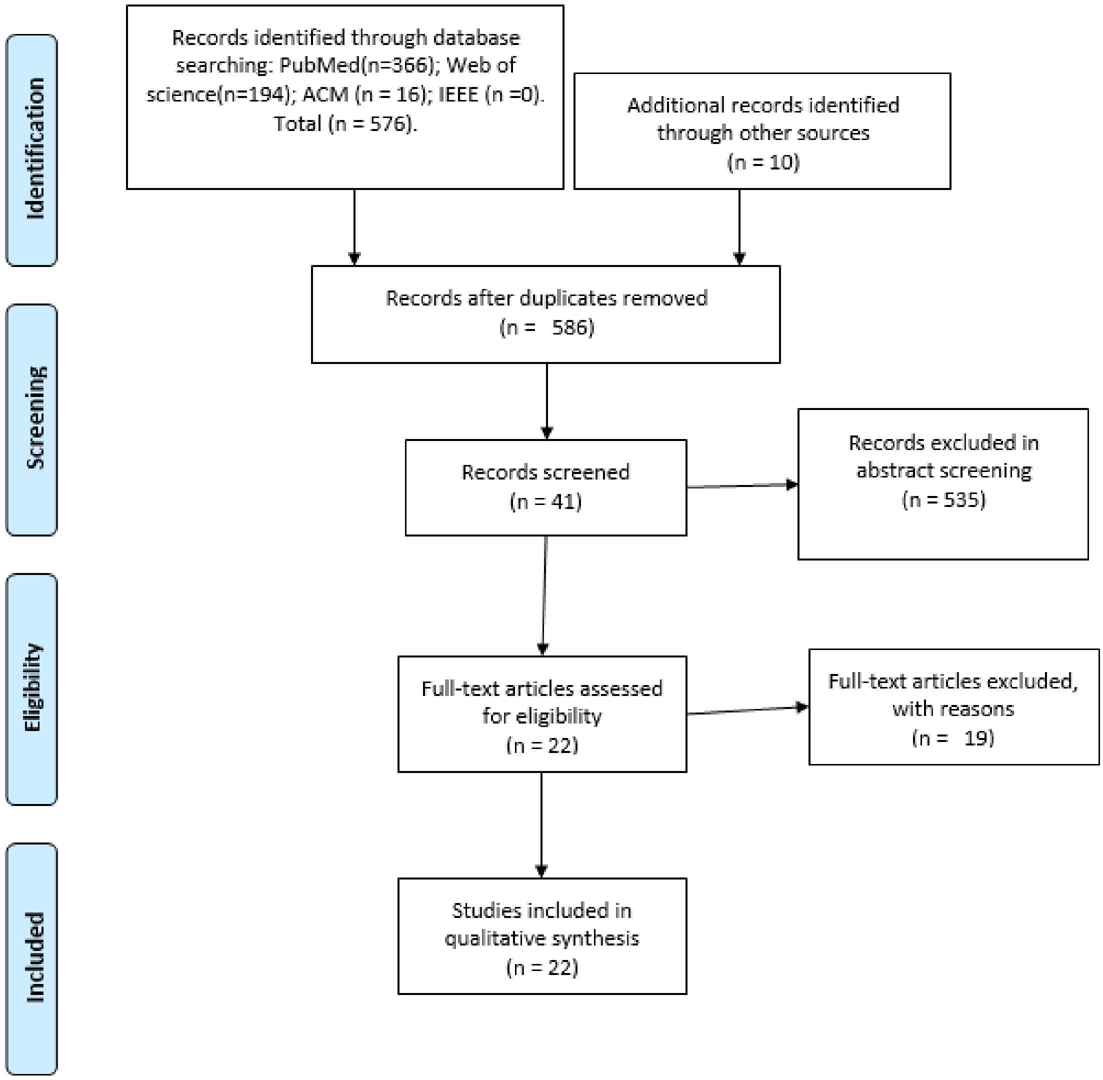

Figure 6: PRISMA flow chart of the selection process for literature review 1

Table 1: Findings from the first literature review

Paper	Goals	Target group	Evaluation criteria	Result
[39]	Examine the relationship between selected practice characteristics, patient engagement, and patient-reported outcomes of care.	Diabetes or cardiovascular disease patients.	Depression, physical functioning, social functioning, patient assessment of chronic care, and patient activation	Patients who received care from practices with more patient-centered care cultures reported lower depression symptoms and better physical functioning.
[44]	Test the feasibility of all components of an empowerment-based intervention using PROMs as dialogue support in clinical diabetes consultations.	Diabetes patients who have had type 1 for at least a year and aged >= 18 to <40.	Diabetes-related distress	Preparation for qualitative study.
[42]	Exploring young adults experience of outpatient follow-up appointments and completing ePROMs.	Diabetes patients who have had type 1 for more than a year aged 22-39 who participated in pilot trial.	Diabetes-related distress	Findings suggest that by utilizing diabetes distress data alongside health and biomedical outcomes, consultations became more attuned to the young adults’ wishes and needs.

[40]	Documenting the effect of having patients complete pre-visit eJournals containing medication, allergies and diabetes(study arm 1) or health maintenance, personal history and family history (study arm 2)	Diabetes patients with scheduled visits to their physician.	Patient and physician perception of completing two different pre-visit eJournals	Study arm 1 respondents reported great satisfaction with the pre-visit preparation as they felt more prepared for their consultations. Arm 2 respondents also reported satisfaction, but to a far lesser degree (78% - 22%).
[45]	Evaluate experiences, barriers and facilitators for app usage among patients with type 2 diabetes and secondly to determine recommendations to improve the usage of diabetes apps.	Diabetes type 2 patients aged >=18 years.	Diabetic users perception of health facilitation apps	User-centered features engaging the user in self-management tasks can improve health outcomes.
[41]	To test the pre-visit prioritization hypothesis that a secure e-mail message can improve visit communication and glycemic control among type 2 diabetes patients	Diabetes type 2 patients with a HbA1c level >= 8.0%	Glycemic control, patient-provider communication and patient care experiences.	E-mail based pre-visit intervention resulted in improved visit interaction, but did not improve the glycemic control. Paper concludes that more intensive approaches to pre-visit preparation is needed to improve clinical outcomes.

[37]	Examine a casual model linking participatory decision making (PDM) to improved clinical outcomes.	Diabetes type 2 patients.	Glycated hemoglobin, systolic blood pressure and low-density lipoprotein.	Participatory decision making during consultations by diabetes type 2 patients improved hemoglobin A10 levels, LDL cholesterol, patient activation and in turn patient adherence.
[46]	Explore how health consumers use apps for health monitoring, their perceived benefits of health apps and suggestions for improving health apps.	Mobile app consumers aged >= 18.	Users perceived benefit from usage of health apps	User experience is most influenced by: Engagement, functionality, information management and ease of use.
[19]	Use PROMs to evaluate patient preference of PROMS, measurements of patient goals and patient responsiveness to treatment.	Patients 18 years or older with scheduled elective hand surgery.	Responsiveness after treatment, preference of PROMs and measures of patient goals.	Patients preferred four themes in PROMs: Instrument simplicity, personalized assessment (individualization and relevance), having measurable aims or objectives, distinct items (concrete or specific instrument items or functions). Concludes that employing PROMs that address patient-specific goals may better assess aspects of care most important to patients.
[38]	Examine the impact of patient-centered care for patient satisfaction and treatment outcome.	Patients in rehabilitation centers.	Treatment outcomes and patient satisfaction.	Patient-centered care improves patient satisfaction and treatment outcome.

[47]	Take stock of evidence previously found to understand by what means and in what circumstances the feedback of PROMs leads to the intended service improvements.	PROM providers	PROM feedback	The most relevant conclusion the paper draws is that clinicians and patients perceived that individualized PROMs supported relationship-building when used in first assessments. However individualized PROMs were less useful as an outcome measure to judge change over time.
[48]	Integrate PROMs into the care of chronically ill patients.	PROM providers	PROM integration	A description of the framework developed.
[49]	Expressing the usefulness of PROMs in Routine practice.	PROM providers	The impact of PROM in clinical practice	A summary of principles and lessons learned in the use cases covered in the paper.

[50]	Describing how to deploy PROs effectively.	PROM providers	PRO deployment	A set of methodical and practical decisions that need to be assessed before implementing routine PROs.
[51]	Review evidence and highlight opportunities and challenges related to active clinical use of PROMs to support person-centered diabetes care.	PROM providers	PROM evaluation in person-centered care	Significant trend towards participatory development of multi-dimensional PROMs with the aim of IT-enabled integration into routine diabetes care to facilitate person-centered diabetes care and quality of life.
[7]	Review the PROMs used in registrar based studies of patients with type 2 diabetes and describe the association between these PROMs and type 2 diabetes.	PROM providers	Validation rate for PROMs used on type 2 diabetes patients	PROMs among registries of patients with type 2 is uncommon, non-routine and few PROMs are validated before use.
[20]	Provide an objective and comprehensive overview of benefits, barriers and disadvantages of ePROMs.	PROM providers	PROM and ePROM comparison	ePROMs are preferred over paper-based methods, improve data quality, result in similar or faster completion time, decrease costs, and facilitate clinical decision making and symptom management

3.2.2 Literature review #2

The second literature review was conducted to find scientifically validated questionnaires, target groups, and questionnaire measurement targets of the different questionnaires. The results are presented in Table 2. The identified questions in the questionnaires are used as inspiration for the complete set of questions in the application. Meanwhile, the dynamic ePROM will determine a tailored sub-set of these questions for each user.

The databases queried in the second literature review were:

- PubMed
- Web of Science
- IEEE Explore
- ACM Digital Library

The exact queries used in the different databases are documented in Appendix B.

Publication inclusion criteria:

- The study considered diabetes-related questionnaire
- The questionnaire used in the study is validated

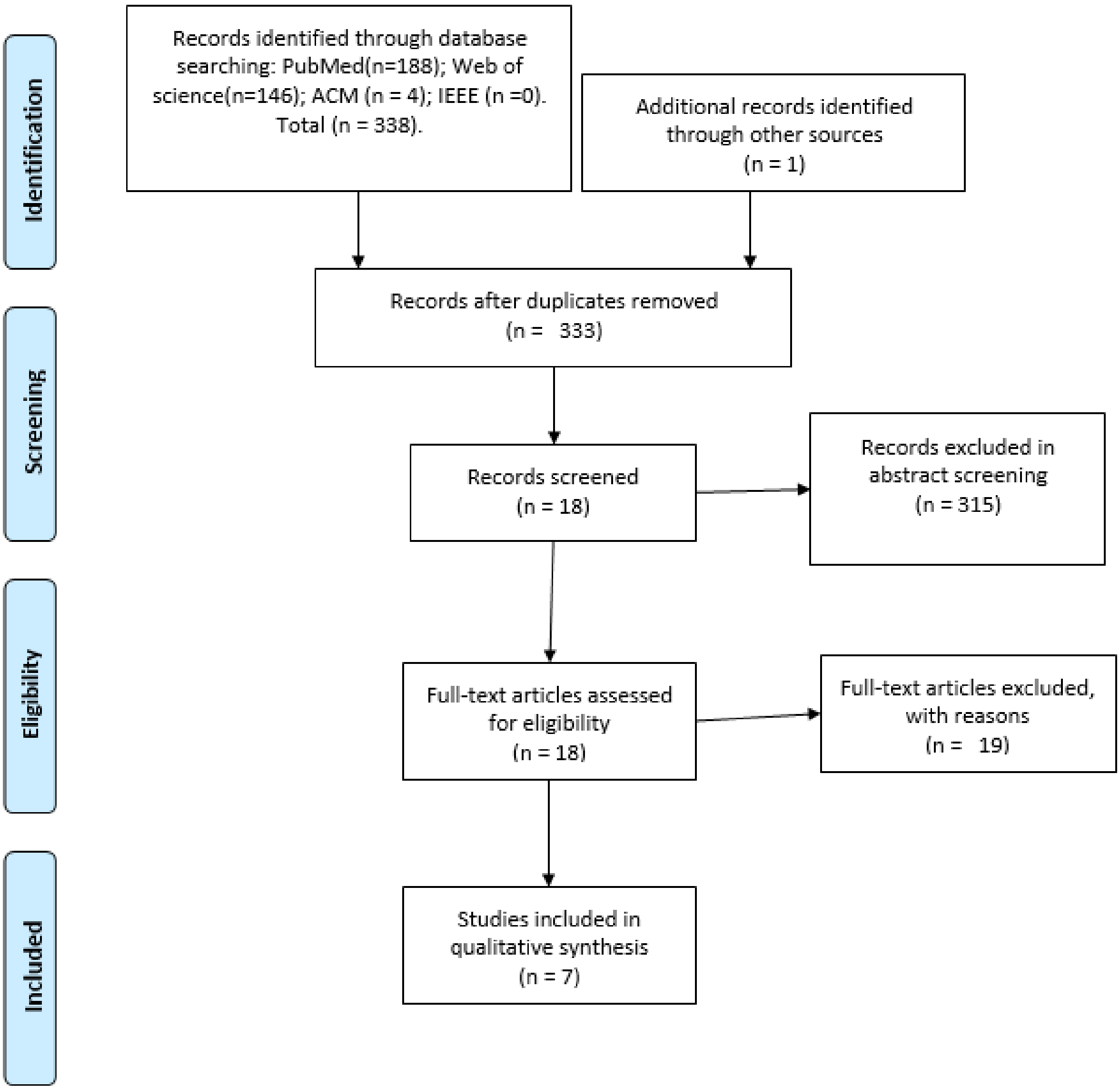

Figure 7: PRISMA flow diagram of the selection procedure for literature review 2

Table 2: Findings from the second literature review.

Paper	Goal	Target group	Result	Questionnaire target area
[52]	Validating the World Health Organization's Well-being index, the WHO-5 questionnaire	Patients with type 2 diabetes	WHO-5 is reliable and has valid outcomes	Screening for depression in diabetes patients
[53]	Develop and validate a new questionnaire	Patients with type 1 diabetes	Developed and validated a new questionnaire, the ViDa1	Health-related quality of life
[13]	Investigate the correlation between diabetes-related distress and glycemic control and evaluate the Problem Areas in Diabetes (PAID) questionnaire as a screening tool.	Patients with type 1 and type 2 diabetes	PAID is discussed as a valid screening tool and a correlation between diabetes-related distress and glycemic control is found.	Diabetes-related distress
[54]	Validating the EuroQol 5D (EQ-5D) questionnaire on Korean patients	Patients with type 2 diabetes	The EuroQol is concluded as a valid tool for Korean patients	Health-related quality of life
[55]	Assessing the validity and reliability of the brief Diabetes Quality of Life questionnaire (DQoL) on Chinese patients	Patients with type 2 diabetes	DQoL questionnaire is reliable and valid as an evaluation tool for quality of life.	Health-related quality of life
[56]	Comparing the acceptability, reliability and validity of five Diabetes quality of life questionnaires. The questionnaires tested were: ADDQoL-19, DCP, DIDP, DSQOLS and DQoL-Q	Patients with type 1 diabetes	Evaluation of acceptability and psychometric value showed DIDP, ADDQoL-19 and DQoL-Q as the best. All questionnaires were however acceptable.	Health-related quality of life

3.3 Discussion with experts

The thesis is written under the Health informatics and -technology group at the University of Tromsø. Weekly supervision meetings were held for the duration of the thesis. The group contains a diabetes type 1 expert, a diabetes type 2 expert, and e-health and telemedicine experts. The supervision meetings initially provided guidance in the research phase when the literature review was conducted and provided feedback in the later stages to the application's requirement, design, and implementation stages.

3.4 Technologies used

The programming language Dart with the Flutter SDK version 1.20.3 and Android studio were used to develop the application. Flutter operates with all objects as widgets. Widgets are immutable blocks and form the app's UI interface. One page can display several widgets and nested widgets with little delay because there is no recursive call when processing the display. A hierarchy of the widgets is determined before redering, and it is presented in **Error! Reference source not found.**[57].

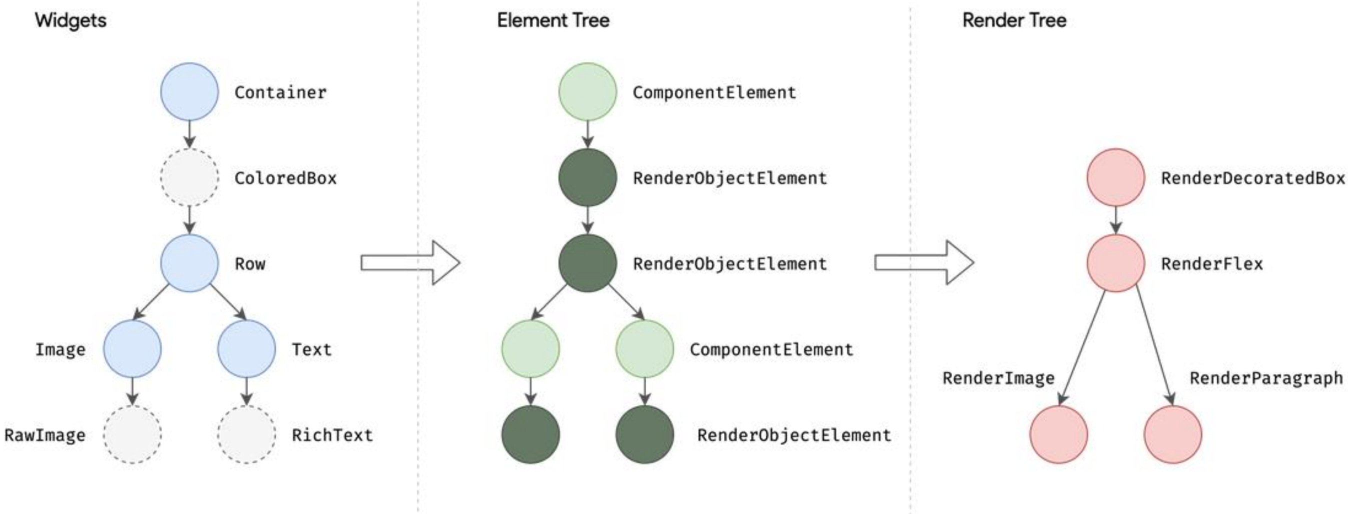

Figure 8: Rendering widgets[54]

Widget layout is performed by traversing down the render tree with the size constraints of the parent nodes. The size of the child nodes must be within the restrictions of the parents. Child nodes then pass their size up the tree. Widget layout is performed at O(n) time[57]. Testing new features during development is fast in flutter due to the hot reload functionality. Flutter runs the source code in a Dart virtual machine (DVM). Updated source code is sent to the DVM, and widget trees are rebuilt. This allows for adding and tweaking features without restarting either the application or emulator.

Android studio was used to test the application on an emulator. The emulator was a Google Pixel 3a with an x86 CPU running Android 10.0. The emulator was spun through Android studios' Android Virtual Device Manager.

3.5 Evaluation method

The evaluation of the application is a usability test followed by a semi-structured interview and two users tested the application. Due to the COVID-19 pandemic, the testing was planned remotely with the application running on a screen shared emulator and participants verbally choosing their answers to the different questions. One of the participants explicitly wished to perform the test in person, so this was done in accordance with the current COVID-19 regulations. The usability of the application was tested with a System Usability Scale (SUS). In this procedure, the users test the application and complete a ten-question Likert scale[58]. The questionnaire results can be quantified and indicate the system usability. In addition to the SUS, a semi-structured interview was conducted with the test users for additional feedback. The questions used in the semi-structured interview are listed in Appendix C.

4 Requirements specification

In this chapter, the application requirements are listed and the methods used to identify the requirements are explained.

4.1 Source of requirements

The requirements for the application were identified through discussion with experts (3.3) combined with literature identified with literature review (**Error! Reference source not found.**) and the previous software experience of the author.

4.2 Use case

Scenarios are used to showcase the functionality of a product. A scenario can be used as the foundation for the requirement specification[59].

Use case 1 :
Bob is a 41-year-old man with type 2 diabetes. He has lived with diabetes for 15 years and is used to it. To assist him with his daily diabetes self-management, he uses a mobile diabetes health application that records his blood glucose, how many steps he takes per day, and he manually enters his meals and insulin dosages into the application. A week before his next diabetes consultation, he is prompted to complete a dynamic ePROM. He sits down in this living room in the afternoon to complete the dynamic ePROM. The self-gathered data from his diabetes app is incorporated into the dynamic ePROM, and Bob starts completing the ePROM. Some questions are easy; he does not have any pain, he has no problem walking. Other questions are more problematic. Does he feel alone with his diabetes? His wife knows and supports him, but she does not entirely understand what it is like living with diabetes. Why is he not active enough? He does not have pain, and he knows he should be exercising more. Bob completes the questionnaire, and a report is sent to his physician. At the consultation the following week, they discuss the report. They sent a concrete goal for Bob to increase his activity levels. The physician also talks about Bob’s mental health, for he displays signs of distress and depression. An extra consultation is scheduled for Bob because of this.

Use case 2:

Alice is a 14-year old girl and got her diabetes type 1 diagnosis five months ago. Together with her parents, she is starting to get used to the daily management of her diabetes. She has a continuous glucose meter connected to a mobile health app on her phone, which also measures her activity levels through a step counter.

In a week, she has her first annual diabetes consultation, and she is prompted to complete the dynamic ePROM. Her diet and activity levels are good. The only thing she worries about is her glucose management. The fact that mismanagement of her diabetes can be fatal scares her. The completed ePROM reflects her fears but also shows that she and her parents have done everything right. Her glucose management is good, but she is still scared. At the consultation, her physician sees this, and the consultation revolves around reassuring her about the disease and how well she is doing with her self-management.

4.3 Functional requirements

Functional requirements describe what the application must do or what actions it must take[60]. Components from the Volere requirement specification template[60] are used to display the requirements for the project. The components described in Table 3 used are to:

- **Requirement number:** The unique number of the requirement.
- **Description:** The intention of the requirement.
- **Rationale:** Justification of the requirement.
- **Originator:** Who introduced the requirement.
- **Fit criteria:** A measurement of the requirement that the solution has to meet in order to fulfill the requirement.

Table 3: Volere requirement specification

Req. number	Description	Rationale	Originator	Fit Criteria
1	The application must be able to start an ePROM.	If the user can not initiate the ePROM the application is useless	Author	The application can display the first question in the ePROM.
2	When a question is answered, the next question is displayed.	The questionnaire must progress for the user to complete the ePROM.	Author	When a question is answered, the next question is displayed.
3	When the last question is answered, the ePROM should be concluded.	The ePROM should have a defined ending and allow the user to return to the home page.	Author	When the last question is answered, an ending page is displayed with a button allowing the user to return to the home page.

4	The application must read the user’s sensor data.	The ePROM can not be dynamically tailored to the user if their data is not read.	Author, supervisors	The application can read and store the user’s sensor data.
5	The application should record the age and gender of the user if the user consents to this.	The ePROM will be more accurately tailored to the user if age and gender are known.	Supervisors	The user can enter their age and gender before starting the ePROM.
6	The sensor data should be parsed based on metrics.	The application must be able to distinguish the different sensor metrics to have aggregate data on individual metrics.	Author	The application can access each sensor metric.
7	The application should be able to apply aggregate functions to the sensor data.	If the application is to tailor the ePROM to the user’s sensor data, it has to be able to apply aggregate functions to the data.	Author	The application gets correct results from the aggregate functions for each metric.
8	The ePROM should be changed in accordance with the user’s sensor data.	For the ePROM to be tailored to the user, it has to change based on the user’s sensor data.	Author, experts	The ePROM changes appropriately when the sensor data input changes.
9	The user answers should be stored.	If the answers given during the ePROM are not stored, they can not be used in consultations and they can not be used to dynamically improve the ePROM.	Author	The user’s answers are stored as they complete the ePROM.
10	The ePROM should be changed based on the user’s previous answers.	If the ePROM reacts to the user’s previous answers, more complete data will be gathered.	Author, experts	The ePROM can change based on the user’s previous answers.

4.4 Non-functional requirements

Data security

The General Data Protection Regulation dictates the use of personal data for applications[61]. The user data handled by the application is sensitive and cannot be used without the user’s explicit consent. The data must also be deleted if the user withdraws their consent, and the data can not be shared unless the user explicitly agrees to it.

Questions are readable

The question-and-answer texts must be clear and readable for the user. The users of a diabetes app can be elderly, and having small text can cause issues for such users. In addition, the phrasing of the questions must be easy to understand to get accurate answers from the users.

Questions must be valid

The questions in the dynamic ePROM must be validated or closely resemble validated questions. Validating a questionnaire and proving its effectiveness at clinical and research settings for the desired problem area is established work with specific methods to follow[62]. To use validated questions and base all self-made questions on validated questions gives more weight to the dynamic ePROM.

Ease of use

The application must be intuitive to use and easy to navigate. People who are not technologically inclined, often older users, must be able to use the application.

5 Design

This chapter describes the design choices made for the application. When designing a mobile application, some considerations have to be made. The size of the screen is limited. The placement of display objects must be decided with the size constrictions in mind. The user must be able to press buttons and enter text without problems. When users interact with the application, buttons should be large enough to press with ease but be small and distanced enough from each other not to click the wrong buttons.

5.1 User introduction to the application

The home screen, shown in Figure 9, prompts the user to fill in their gender and age(R #5). This is not mandatory, and the dynamic functions of the application work without knowing the user's age and gender. However, age and gender can be combined with sensor data and used to detect if the user belongs to a high-risk group for certain complications. After this is done, the user can import their sensor data and start the ePROM(R#4). The application is not designed to read sensor data from the user's sensors, so the user will have to press a button to import their sensor data from an external source. There are also icons explanations on the home page. These icons represent the different types of questions in the ePROM and clarify the questions types.

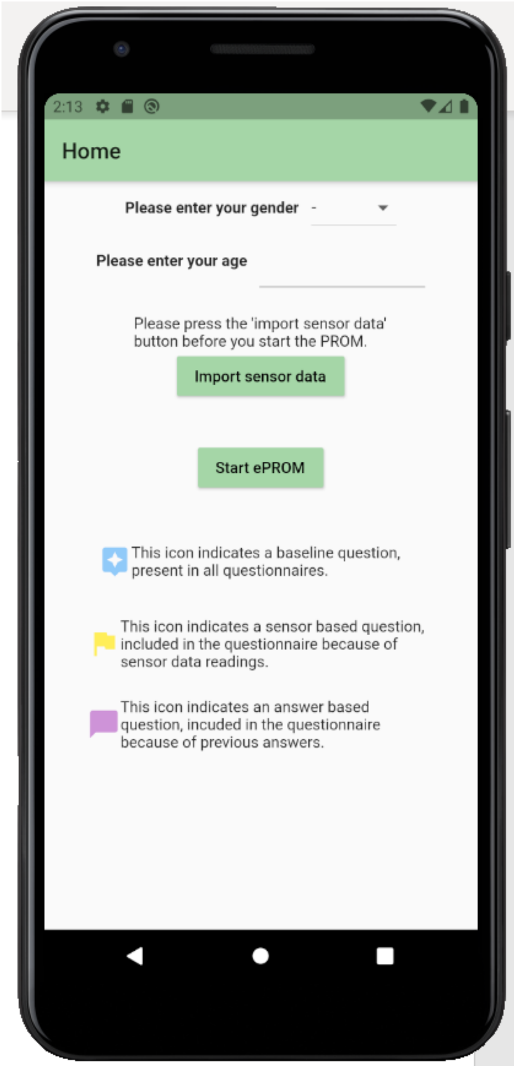

Figure 9, Home screen

5.2 Dynamic question selection

The application has a set of questions divided into three categories: baseline, sensor-based, and answer-dependent. Each answer the user gives is stored (R#9). Since the questionnaire is different for each user, both questions and answers are stored. The baseline questions are present in the questionnaire for all users. This category is designed for questions that have no connection to the sensor- or patient data, such as the emotional well-being of the user. Figure 10 shows an example of a baseline question.

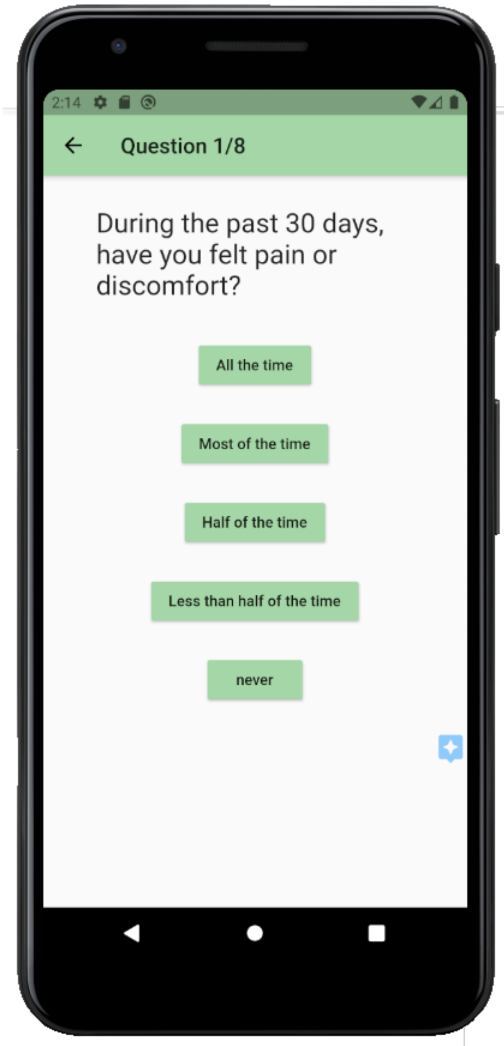

Figure 10, Baseline question example

The sensor-based questions are all dependent on the user data. They are only included if the data displays specific pre-determined criteria, such as dangerous blood glucose levels or less than recommended activity levels (R#7 & R#8). In order to access a single metric at the time the sensor data input is parsed, and the metrics are stored separately (R#6). Combining multiple user data metrics is also a valuable tool, especially for older users. A previous study [63] found more complications among older people with diabetes, despite reasonable glycemic control. Therefore, it can be valuable to adjust the sensor data criteria for questions based on the user's age, lowering the threshold for including sensor-based questions for older users. The answer-dependent questions are included in the ePROM if the user answers something pre-determined to require a follow-up question or a text explanation (R#10).

Each question has a category, answering format, and dependency tag. The question category indicates what category the question belongs to (i.e., baseline, sensor-based, answer dependent). The answering format tag indicates what answering options the user will receive to the question. The different validated PROMs identified during the literature review had several different answering options, and the ePROM should imitate these PROMs. This functionality also allows the application to let the user answer with a textbox (Figure 12) or slider(Figure 11).

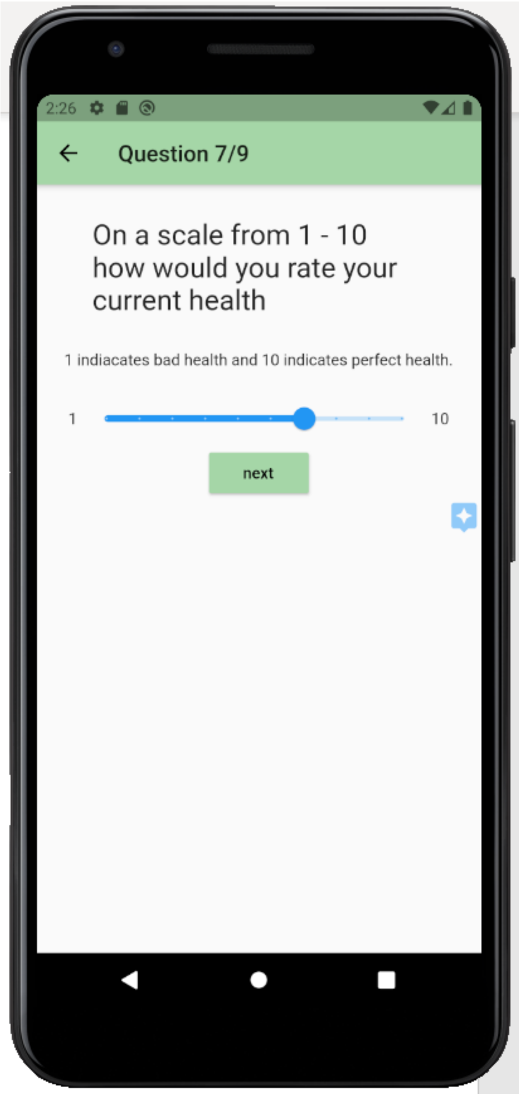

Figure 11, a question with a slider as the answering option

The dependency tag can be active or inactive. An active dependency tag indicates that the outcome of the question may result in an answer-dependent question being added to the questionnaire. If the application displays a question with the dependency tag, it will check the outcome and add the corresponding answer dependent question if the outcome dictates it.

5.3 ePROM Display

The ePROM is designed to be easy to complete. The application is designed to be used on mobile devices, and the mobile screen size is taken into account in the design. Only one question is displayed at the time. When a question is answered, the next question is displayed (R#2). This prevents the screen from being cluttered.

Additionally, not allowing the user to see the questions all at once will prevent the user from being overwhelmed and increase the chance that they will complete the entire questionnaire. The answering formats that require the user to push a button, such as a baseline question in Figure 10, have the buttons spaced out, so the user does not accidentally click the wrong option. The questions with a text box have a ‘next’ button, so the user can evaluate and alter their answer before they proceed. When the users have finished the ePROM, they are directed to an ending screen that allows them to return to the home page (R#3).

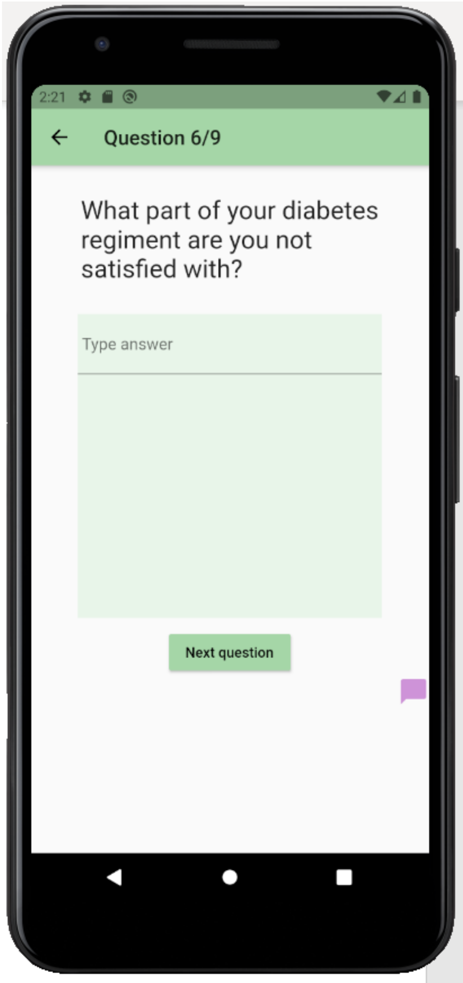

Figure 12, Question with a text answer

5.4 Completed ePROM

When the user completes the ePROM, a report of the user's answers should be generated. The report can be used in consultations to promote and emphasize the patient's preferences concerning their diabetes management. Since diabetes management is primarily self-management, it is essential that the individual patient is content with their regimen and understand its reasoning. An example of a completed ePROM report is illustrated in Figure 13.The report is designed to be simple and only contain the questions the user's dynamic ePROM posed the user and the user's answers. The answer-dependent questions do not have a separate category in the report, but they are appended to questions that they depend upon in quotation marks.

Dynamic ePROM results

Age: 35
Gender: Male

Baseline questions:	**Answers**
During the past 30 days, have to felt pain or discomfort?	Less than half the time
During the past 30 days, have you had trouble walking around?	Never
During the past 30 days, have to felt anxiety or depressed?	Half of the time
How often do you measure your blood sugar levels?	Once per day
Are you unsatisfied with your current diabetes regimen?	Yes, "I don't have enough concrete direction, i feel my diabetes management is just trial and error."
Rating of own health from 1-10.	7
Sensor based questions:	**Answers**
You walk less than the recommended 10,000 daily steps, is you diabetes limiting your daily activity?	No
Your blood glucose levels have dropped below 2.5 mmol/L, do you think your glucose management is good?	"It is good, except when i am travelling."

Figure 13, completed ePROM example

6 Implementation

In this chapter, the implementation of the dynamic ePROM application is explained.

6.1 Handling sensor data

Since the application has no data capturing capabilities, it relies on the user exporting their sensor data from another source. The data used to develop the applications is 94599 genuine sensor data entries gathered over eight years by the data provider. The sensor data is imported from a CSV file, and flutter's CSV library is used to convert the raw readings from the file to a list. Each data line parsed, and the metrics are stored separately. The values stored for each data entry line are the metric type, date, time, and value. The data handled is generated through the diabetes self-management of the user. Because of this, there is no guarantee of consistency in the entries. The metrics have to be stored separately to combat the inconsistency because some users may neglect one or more metrics utilized by the application. Additionally, the user can have added descriptions to some entries, such as meal descriptions for carb entries and work out descriptions for activity entries. Since the application only stores dateTime and value for each metric RegExp is used to parse the entries. For each metric, there is an aggregate function to find the average value. Since the user can add several entries per day, the function must count the number of unique days in the data set for the entry and the total value of the entries.

6.2 ePROM generation

Each question is a list, and the set of ePROM questions is a list of lists. A question list contains four items. The question text that will be displayed to the user, the question type, the answering format the question requires, and the flag to indicate if another question depends on the answer to this question. Figure 14 shows a flow chart of the processes in the system.

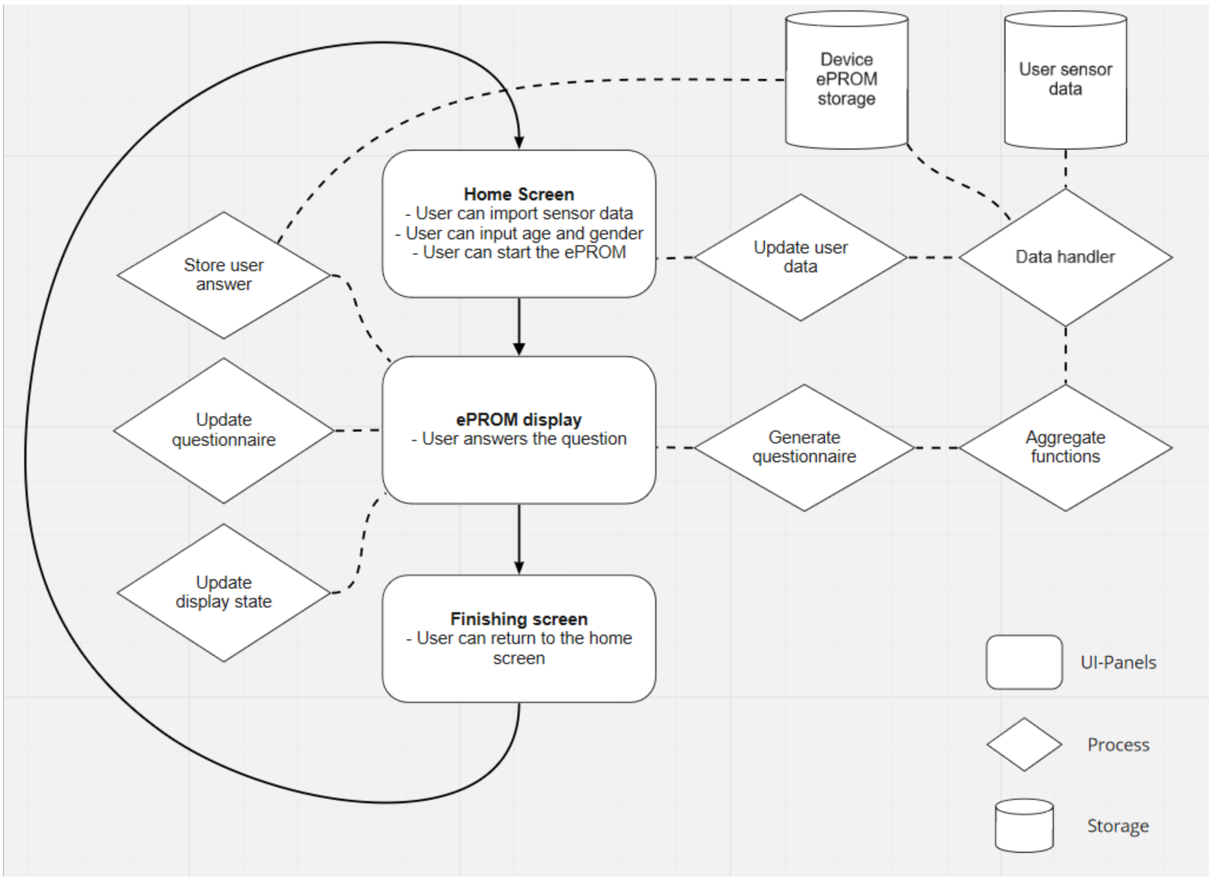

Figure 14, process chart

When the initial ePROM is generated, all baseline questions are added. The sensor-based questions are individually evaluated. Each sensor-based question has a correlating sensor metric and aggregate function. The system reads what aggregate function to use from the 'question type' part of a sensor-based questions list. The sensor-based questions have several sub-types that allow the system to determine what aggregate function the question is linked to. A sensor-question type can, for instance, be of the 'average blood glucose' type. This question type uses the result from average blood glucose to determine if the question is added to the questionnaire or not. The result from the aggregate function is evaluated against a threshold for questionnaire inclusion. This inclusion threshold is based on diabetes health recommendations and the user's gender and age. When the users start completing their ePROM only the baseline and sensor data questions are included in the ePROM. Figure 15 shows a flow chart of the dynamic ePROM generation.

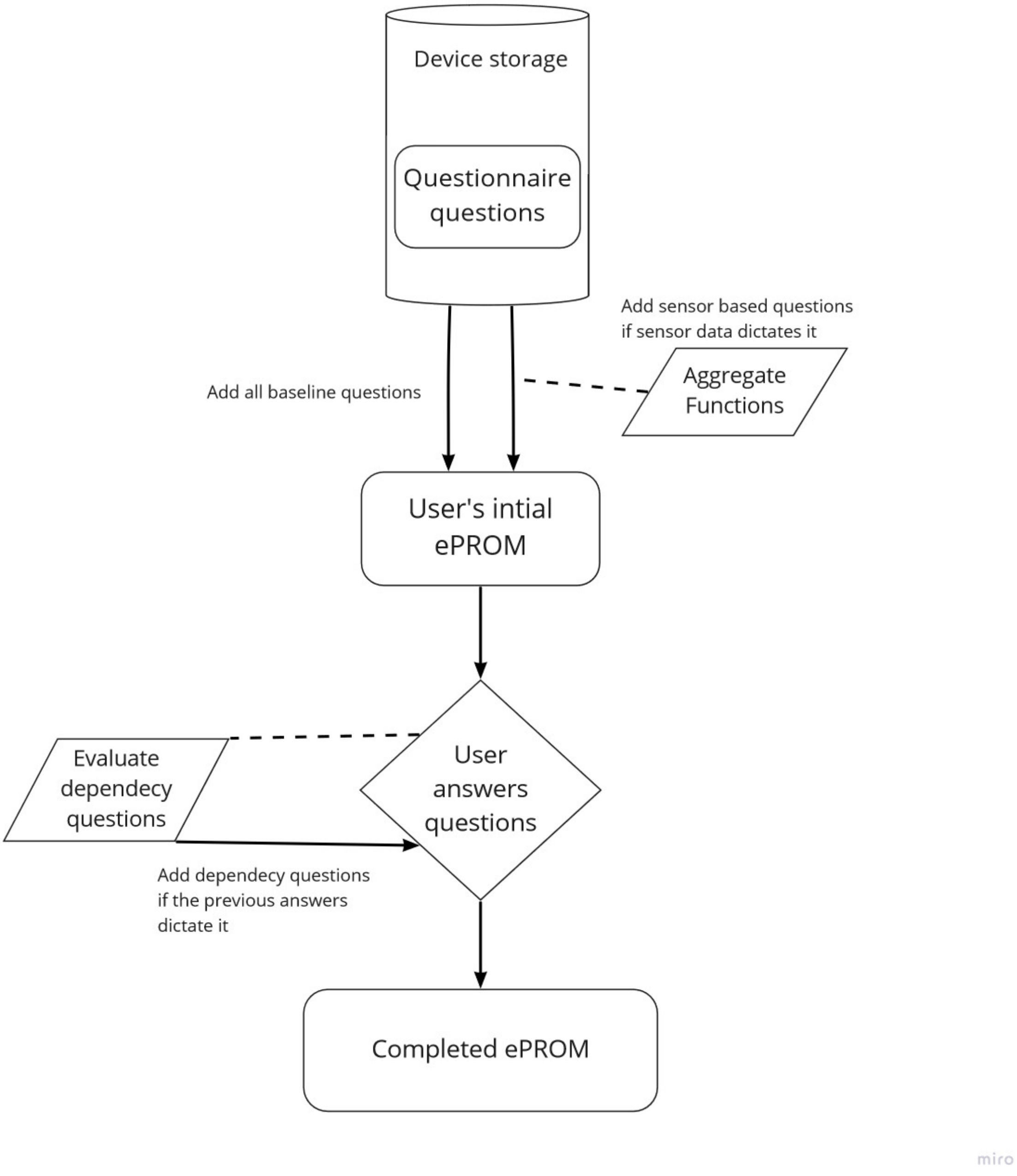

Figure 15, building the ePROM

The answer dependant questions are added while the user completes the ePROM. If a question has the dependency flag, the system will check if an answer-dependant question should be inserted into the questionnaire before displaying the next question. The answer-dependant questions are ordered after the questions they depend upon. This way, the system keeps track of what answer-dependent question to add after an answer that requires it.

6.3 Question display

Each question list contains the information that the system needs to display the question. The question body is always displayed at the top of the screen. The answering options are then displayed under the question text. The answering formats implemented are multiple-choice, text-based, and a slider. The multiple-choice answers can come with two or five alternatives. The alternatives are represented with labeled buttons. When the user selects a button, this alternative is registered as the user's answer. The multiple-choice with two alternatives will always have the labels 'yes' and 'no.' The format with five alternatives can have different labels, two different labels are shown in Figure 10 and Figure 16. If the answering format is a text box or a slider, then a 'next' button is inserted at the bottom of the screen. The user's answer is recorded, and the display update function is called. The update function checks for answer dependency and adds the answer dependent questions. After this is checked, the next question is displayed. If the questionnaire is completed, a finishing screen is displayed instead.

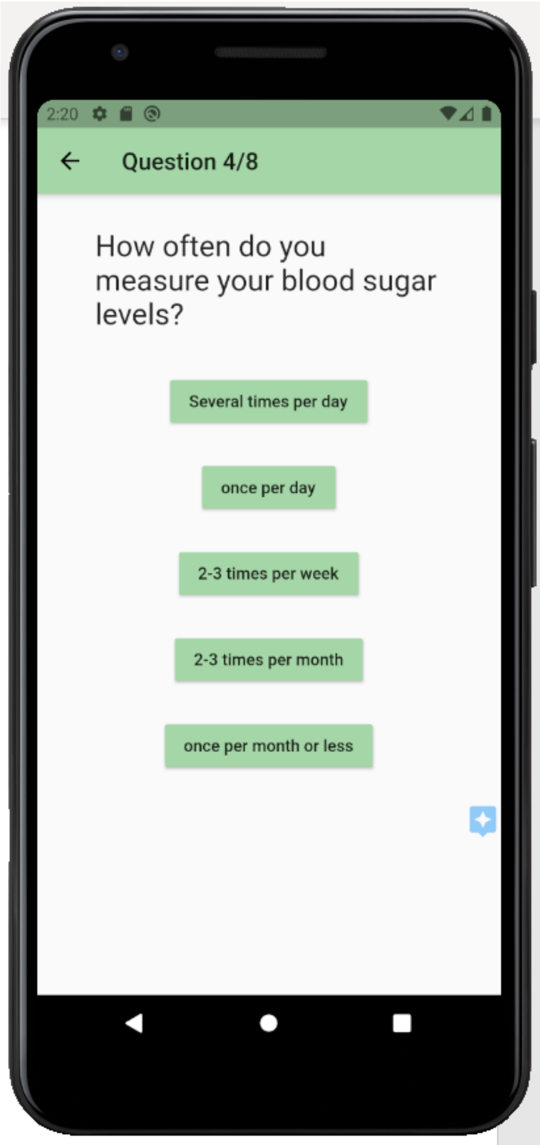

Figure 16, Baseline question

7 Testing and results

During early supervision meetings, it was decided that after designing and implementing the application, the most reasonable testing given the time constraints of the thesis was to conduct a usability test. The System Usability Scale(SUS)[64] was chosen as a testing scale. The SUS test is reliable and valid. The test measures usability with users responding consistently and works on small sample sizes[65]. Two people with diabetes participated as test users.

7.1 Testing

The test consisted of two steps. First, the testers completed the ePROM. The sensor data used for the ePROM they complete was not the tester's own data, but they completed a dynamic ePROM with artificial sensor data. They were informed about the dynamic functionality of the ePROM and the artificial underlying sensor data. The second step was a semi-structured interview (Appendix C)The testers completed the ten-questions SUS questionnaire and were then asked follow-up questions where they supplied additional information to shape the future work of the application.

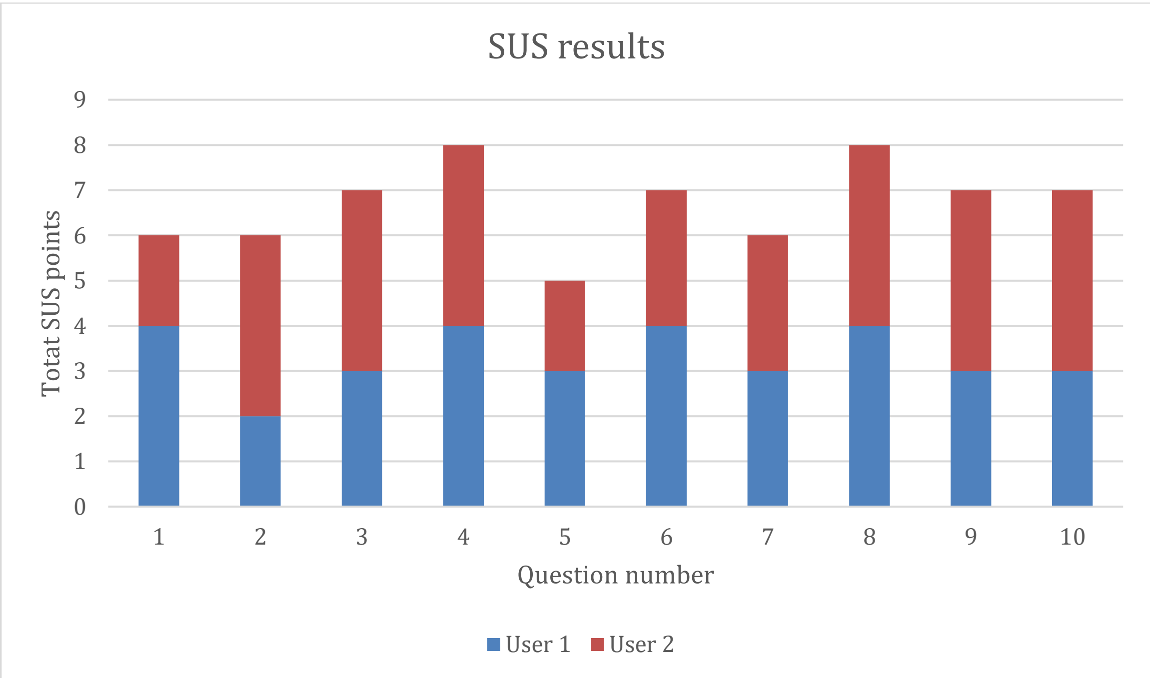

Figure 17, Accumulated SUS score for each question

7.2 Usablity results

The SUS results represent the overall usability of the system. Figure 17 shows the accumulated SUS scores from the two test users. The SUS questionnaire contains five positive and five negative questions. The SUS question score for the positive questions is calculated by taking the raw score minus 1, and for the negative questions, the scores are calculated by subtracting the raw score from 5. When this is done for all ten questions, the scores are summed and multiplied by 2.5. This result is the SUS scale score. The SUS scale ranges from 0-100, with 0 being unusable and 100 being perfect usability. Figure 17 shows the scores given by the test users.

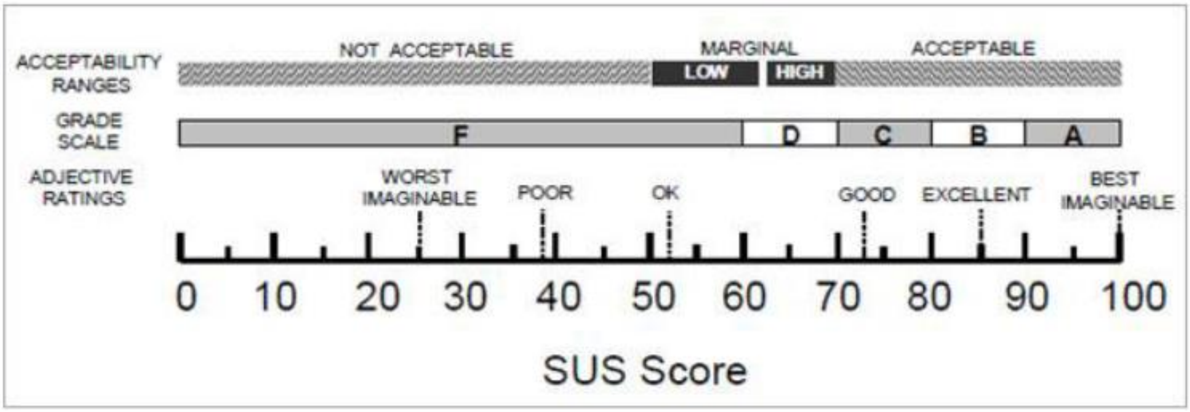

Figure 18, SUS grade scale[66]

The users' results are shown in Figure 17, and the average SUS score is (33+34) * 2.5 / 2 = 83.75. Following the SUS grade scale (Figure 18), the result is graded as:

- “GOOD” on the adjective rating scale.
- In the acceptable range.
- “B” on the grade scale.

The SUS test performed in this thesis is limited to two participants due to the pandemic, limiting their significance compared to extensive testing.

7.3 Semi-structured interview results

Both test users have previous experience with mobile health applications and utilize such applications in their diabetes self-management.

Missing from application question; more questions regarding the day-to-day diabetes management and more follow-up questions.

Do the test subjects think the application will improve diabetes consultation?

Both users answered that they thought using the application would result in a better communication structure during the consultation. One user has experienced that their desired talking points are not discussed during consultations and thinks using the application will help to avoid this. The ePROM results would be used as a checklist. Additionally, one of the users thinks the application will have more impact on recently diagnosed patients. The reasoning is that they have little experience living with diabetes, and a questionnaire tailored to them will help them be prepared for consultation and help them formulate questions or concerns to their physician.

When should the ePROM be completed?
The users both thought the ePROM should be used before consultations and that a scheduled consultation should prompt them to complete the ePROM, with a push notification or similar methods.

Additional data metrics?
One user suggested adding the user's potential diabetes-related complications to the ePROM and using it as another metric for improving the tailoring accuracy of the ePROM generation.

General feedback.
One tester wanted more questions regarding the day-to-day stress of diabetes self-management and the mental toll this stress makes on people with diabetes. One tester wanted the user to be able to customize the background and color theme of the application.

8 Discussion

In this chapter, the semi-structured interview, future work, and the research questions of the thesis are discussed.

8.1 Dynamic ePROM promoting healthcare practices

The dynamic ePROM is designed to improve diabetes consultations. Three diabetes consultation-improving healthcare practices were identified through the literature review3.2.1: patient-centered care, participatory decision-making, and pre-visit intervention. Patient-centered care improves patient outcomes by incorporating preferences, needs, and values into clinical decisions. The patient has to be educated about the aspects of diabetes management they do not understand. Pre-visit interventions prepare the patients for the consultation and improve communication during the consultation[40, 41]. Using PROMs as the pre-visit intervention emphasizes the needs and wishes of the patients and thus facilitates patient-centered care. However, the participants in the study found the PROM to be insufficient and uncomfortable to complete[42]. Participatory decision-making(PDM) includes the patient in the clinical decisions regarding their diabetes self-management regimen. PDM causes patient activation[37], meaning the patient has a more active role in their care, resulting in improved health outcomes, patient adherence, and patient satisfaction[38].

8.2 Standardized ePROM

As previously noted, there is not standardized PROM or ePROM for diabetes patients. There are several different validated diabetes-specific PROMs focusing on different aspects of the health of a diabetes patient. Diabetes is a heterogeneous disease, and people with diabetes have different problems with their diabetes or diabetes self-management. Since each individual patient handles their diabetes in their own way, it is difficult to construct a PROM that will cover all potential problem areas of diabetes. The Vida1 questionnaire[53] is a quality of life questionnaire with questions regarding four dimensions of diabetes. The dimensions are interference with everyday life, self-care, well-being, and worrying about diabetes. The problem areas in diabetes scale(PAID)[67] is, on the other hand, is a single dimension questionnaire solely devoted to diabetes-related distress. If a patient is suffering from diabetes-related distress, they should complete the PAID questionnaire, but if they are not, the Vida1 questionnaire will yield more valuable information. A dynamic ePROM, as presented in this thesis, can work as a bridge between the quality-of-life oriented questionnaires and the single dimension questionnaire. By registering the answers of the user and changing the questionnaire in real-time, the questionnaire can pose follow-up questions regarding a specific dimension. A dynamic ePROM can be used as a standardized diabetes ePROM and receive accurate information about the individual patients it is administered to.

8.3 Limitations

Due to the time frame and focus of the thesis measuring the effect of the dynamic ePROMs on diabetes consultations was infeasible. Such a test requires access to the user's personal data and would need to be approved by the Regional Committees for Medical and Health Research. The limited number of consultations a person with diabetes attends in the five-month time frame allotted to this thesis made testing the application after design and implementation not feasible.

The effect of the dynamic ePROM requires the completed ePROM to be discussed at the consultations. This is not a given, as physicians have hesitated to incorporate PROMs into consultations [8].

8.4 Research question

In section 1.41.4, the research questions were stated. In this section, the solutions to the problems are presented and discussed.

Sub-Problem 1:
How can sensors and tech be used to improve ePROMs?

With the sensor data diabetes patients gather through their self-management, several assumptions can be made. If the user has volatile blood glucose readings, their self-management regimen should be questioned. If their activity levels or diets are not satisfactory, this should be questioned. Since there is not one standardized diabetes-specific PROM used for clinical consultations and diabetes being a heterogeneous disease having the dynamic ePROM tailor itself to the user can more accurately assess the individual patient's needs and problem areas.

Sub-problem 2:
How can a mobile application be designed to emphasize identified consultation improving healthcare practices?

The application is designed to produce a unique report for each user that completes the dynamic ePROM. This design uses the user's data and answers to tailor the questionnaire to the user. The user's needs and wishes will be reflected in the completed ePROM, and it will then be easier to focus on them during the consultation and thus promoting patient-centered care. The design of the dynamic also allows the user to propose alterations to their diabetes regimen through text answers. The final decisions regarding the user's diabetes management are determined at the consultation, and the dynamic ePROM functions as an avenue to start the communication from the patient.

It is established that pre-visit intervention increases the consultation communication quality. Using PROMs as the pre-visitation tool can improve patient health outcomes on the focus area of the PROM used. The dynamic ePROM attempts to fill the role as an intensive pre-visit intervention tool and, through the dynamic functionality of the ePROM, to help identify the diabetes-related areas of the patient's health, be it physical or psychological, that need to be addressed in the consultation.

Main research question:
How can a dynamic ePROM be designed to improve consultations for diabetes patients?

By designing a mobile application that promotes patient-centered care, participatory decision-making and can be used as a pre-visitation tool, the dynamic ePROM can improve the consultations for the users. By answering questions that reflect the diabetes management areas they are struggling with, the completed ePROM can result in consultations more focused on the needs of the patient.

8.5 Future work

In this section, theoretical improvements to the application are discussed.

8.5.1 Expanding the ePROM

The intention behind the design of the dynamic ePROM is to improve diabetes consultations. In order to accomplish this, the dynamic ePROM must be a more helpful tool compared to the ePROMs available today. One of the feedback points from the semi-structured interview was the lack of questions regarding the user's mental state. This is valid feedback, and studies with PROMs such as the problem areas in diabetes scale and diabetes distress scale[68] have shown that many people with diabetes have diabetes-related stress and a greater percentage of undiagnosed depression compared to the general public. Questions regarding the mental state of the user would in the dynamic ePROM be classified as baseline questions. The current questions set for the application only contain six baseline questions. This is because baseline questions are a constant, and the dynamic nature of the application does not impact their inclusion. The ePROM can easily be expanded to include more baseline questions, and a final version of the application would consist of more baseline questions from validated PROMs. Thus the dynamic ePROM with only baseline questions would be equal to a conventional ePROM, and the dynamically added questions are an improvement upon them. The current dynamic ePROM implementation has a limited question set and is made to showcase the design idea and for testing purposes.

8.5.2 Additional user data

The dynamic ePROM uses blood sugar levels, carbohydrate intake, insulin intake, activity levels, user age, and user gender when tailoring the ePROM to the user. The decision to use these metrics was made through conversations with the experts in the supervision group and the evaluation criteria of previous studies. The selection of metrics can be changed or expanded. Metrics such as sleep, user weight, and Hemoglobin A1c were considered but are not currently added in the dynamic ePROM. One feedback point received from the semi-structured interview was to add the user's illnesses or complications aside from diabetes as a metric in the ePROM.

8.5.3 Storing previous ePROMs

A functionality that was considered, but in the end, not included in the design and implementation of the dynamic ePROM was the feature to look back at a user's previous ePROMs and the sensor data readings to create questions based on the progression of the user. User profiles must be in place for this, and this was deprioritized since it is a known concept included in most mobile applications.

8.5.4 Electronic health records

The current iteration of the system is not connected to electronic health records(EHR) and does not have the capability to communicate the completed ePROM to a potential clinician. Electronic health records are a stored log of a patient's medical history and can also contain administrative data[69]. The NOKLUS diabetes schema shown in Figure 1 is linked to the EHR of patients. A diabetes patient's lab results are logged in the EHR and are used to measure the patient's progress since the last consultation. The design of the dynamic ePROM presented in this thesis produces a report of the completed ePROM (Figure 13). Future iterations of the dynamic ePROM can be linked to the patient's EHR, and the report can be stored in the EHR. By doing this, the changes in the patient's perception of their own health over time can also be examined and discussed. Additionally, linking the system to a user's EHR will increase the amount of data the system has access to, allowing greater accuracy in the tailoring of the ePROM to the user.

9 Conclusion

In this thesis, a way to improve diabetes consultations has been investigated by designing and implementing a dynamic ePROM mobile application. The application is designed to promote beneficial diabetes consultation healthcare practices.

There is not yet a standardized diabetes-specific PROM used in clinical practice. Using PROMs as a pre-visitation intervention tool on diabetes patients has shown to have positive effects on the focus area of the PROM used. The dynamic ePROM presented in this thesis attempts to change the focus of the ePROM to the individual user and thus cause positive health outcomes in the areas the user wishes and needs.

A usability test was conducted, and the application was considered usable. The test subjects believed the dynamic design has the potential to improve communication at diabetes consultations. The long-term effect of the system is, however, unproven.

During 2020 and the COVID-19 pandemic, the importance of e-health solutions became apparent. The number of Norwegian health services available digitally increased from 29% to 44% from 2019 to 2020[70]. This increase is even bigger in e-consultations, with only 3% of consultations being performed digitally in 2019 to 23.7% in 2020[70]. Therefore, digital solutions such as the dynamic ePROM could be a permanent component for healthcare in the future.

Diabetes patients have to manage their illness every single day. The constant monitoring of health data can cause distress and depression. There is more undiagnosed depression among people with diabetes compared to the general population. To combat diabetes-related problems focus on the individual patient is paramount, and the dynamic ePROM attempts to do just this.

10 Bibliography

1. Federation, I.D., *IDF Diabetes Atlas.* 2019. **9th edition**: p. 176.
2. Sarwar, N., et al., *Diabetes mellitus, fasting blood glucose concentration, and risk of vascular disease: a collaborative meta-analysis of 102 prospective studies.* Lancet, 2010. **375**(9733): p. 2215-22.
3. Saran, R., et al., *US Renal Data System 2014 Annual Data Report: Epidemiology of Kidney Disease in the United States.* Am J Kidney Dis, 2015. **66**(1 Suppl 1): p. Svii, S1-305.
4. Bourne, R.R., et al., *Causes of vision loss worldwide, 1990-2010: a systematic analysis.* Lancet Glob Health, 2013. **1**(6): p. e339-49.
5. Snoek, F.J., et al., *Monitoring of Individual Needs in Diabetes (MIND): baseline data from the Cross-National Diabetes Attitudes, Wishes, and Needs (DAWN) MIND study.* Diabetes Care, 2011. **34**(3): p. 601-3.
6. Weldring, T. and S.M. Smith, *Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs).* Health Serv Insights, 2013. **6**: p. 61-8.
7. Chen, Y.T., et al., *Patient-Reported Outcome Measures in Registry-Based Studies of Type 2 Diabetes Mellitus: a Systematic Review.* Current Diabetes Reports, 2019. **19**(11): p. 135.
8. Barr, P.J., et al., *No date for the PROM: the association between patient-reported health events and clinical coding in primary care.* Journal of Patient-Reported Outcomes, 2020. **4**(1): p. 17.
9. Vo, M.T., et al., *Prompting Patients with Poorly Controlled Diabetes to Identify Visit Priorities Before Primary Care Visits: a Pragmatic Cluster Randomized Trial.* J Gen Intern Med, 2019. **34**(6): p. 831-838.
10. Helsedirektoratet. *Rettningslinjer for diabetes*. 2021 [cited 2021 5/4]; Available from: https://www.helsedirektoratet.no/retningslinjer/diabetes.
11. Noklus. *Noklus diabetesskjema*. 2006 [cited 2021; Available from: https://www.noklus.no/norsk-diabetesregister-for-voksne/noklus-diabetesskjema-allmennpraksis/.
12. Pintaudi, B., et al., *Correlates of diabetes-related distress in type 2 diabetes: Findings from the benchmarking network for clinical and humanistic outcomes in diabetes (BENCH-D) study.* Journal of Psychosomatic Research, 2015. **79**(5): p. 348-354.
13. Reddy, J., K. Wilhelm, and L. Campbell, *Putting PAID to diabetes-related distress: the potential utility of the problem areas in diabetes (PAID) scale in patients with diabetes.* Psychosomatics, 2013. **54**(1): p. 44-51.
14. Guyatt, G.H., et al., *Measuring quality of life in clinical trials: a taxonomy and review.* Cmaj, 1989. **140**(12): p. 1441-8.

15. Marrero, D.G., et al., *Using patient reported outcomes in diabetes research and practice: Recommendations from a national workshop.* Diabetes Res Clin Pract, 2019. **153**: p. 23-29.
16. Delamater, A.M., et al., *ISPAD Clinical Practice Consensus Guidelines 2018: Psychological care of children and adolescents with type 1 diabetes.* Pediatr Diabetes, 2018. **19 Suppl 27**: p. 237-249.
17. Federation, I.D., *Global Guidelines for Type 2 Diabetes.* 2017.
18. Young-Hyman, D., et al., *Psychosocial Care for People With Diabetes: A Position Statement of the American Diabetes Association.* Diabetes Care, 2016. **39**(12): p. 2126.
19. Shapiro, L.M., et al., *The Patient Perspective on Patient-Reported Outcome Measures Following Elective Hand Surgery: A Convergent Mixed-Methods Analysis.* J Hand Surg Am, 2021. **46**(2): p. 153.e1-153.e11.
20. Meirte, J., et al., *Benefits and Disadvantages of Electronic Patient-reported Outcome Measures: Systematic Review.* JMIR Perioper Med, 2020. **3**(1): p. e15588.
21. Engan, H.K., et al., *Are web-based questionnaires accepted in patients attending rehabilitation?* Disability and Rehabilitation, 2016. **38**(24): p. 2406-2412.
22. Rada, V.D.d. and J.A. Domínguez-Álvarez, *Response Quality of Self-Administered Questionnaires:A Comparison Between Paper and Web Questionnaires.* Social Science Computer Review, 2014. **32**(2): p. 256-269.
23. Gamper, E.M., et al., *Evaluation of Noncompletion Bias and Long-Term Adherence in a 10-Year Patient-Reported Outcome Monitoring Program in Clinical Routine.* Value in Health, 2017. **20**(4): p. 610-617.
24. Shah, K.N., et al., *Patient-Reported Outcome Measures: How Do Digital Tablets Stack Up to Paper Forms? A Randomized, Controlled Study.* Am J Orthop (Belle Mead NJ), 2016. **45**(7): p. E451-e457.
25. McCleary, N.J., et al., *Feasibility of Computer-Based Self-Administered Cancer-Specific Geriatric Assessment in Older Patients With Gastrointestinal Malignancy.* The Oncologist, 2013. **18**(1): p. 64-72.
26. Jonassaint, C.R., et al., *Usability and Feasibility of an mHealth Intervention for Monitoring and Managing Pain Symptoms in Sickle Cell Disease: The Sickle Cell Disease Mobile Application to Record Symptoms via Technology (SMART).* Hemoglobin, 2015. **39**(3): p. 162-168.
27. Merino, J. and J.C. Florez, *Precision medicine in diabetes: an opportunity for clinical translation.* Annals of the New York Academy of Sciences, 2018. **1411**(1): p. 140-152.
28. Klonoff, D.C., *Personalized medicine for diabetes.* Journal of diabetes science and technology, 2008. **2**(3): p. 335-341.
29. Rockette-Wagner, B., et al., *Measuring Physical Activity and Sedentary Behavior in Youth with Type 2 Diabetes.* Child Obes, 2017. **13**(1): p. 72-77.

30. Stühmann, L.M., et al., *Health App Use and Its Correlates Among Individuals With and Without Type 2 Diabetes: Nationwide Population-Based Survey*. JMIR Diabetes, 2020. **5**(2): p. e14396.
31. Solutions, M., *Patient cloud ePRO.* 2017.
32. Research, P., *Premier mobile ePRO.* 2019.
33. Nexus, *Outcomes by Nexus.* 2018.
34. Keirns, C.C. and S.D. Goold, *Patient-Centered Care and Preference-Sensitive Decision Making.* JAMA, 2009. **302**(16): p. 1805-1806.
35. REYNOLDS, A., *Patient-centered Care.* Radiologic Technology, 2009. **81**(2): p. 133-147.
36. Smith, M.A., *The Role of Shared Decision Making in Patient-Centered Care and Orthopaedics.* Orthop Nurs, 2016. **35**(3): p. 144-9.
37. Parchman, M.L., J.E. Zeber, and R.F. Palmer, *Participatory decision making, patient activation, medication adherence, and intermediate clinical outcomes in type 2 diabetes: a STARNet study.* Ann Fam Med, 2010. **8**(5): p. 410-7.
38. Plewnia, A., J. Bengel, and M. Körner, *Patient-centeredness and its impact on patient satisfaction and treatment outcomes in medical rehabilitation.* Patient Educ Couns, 2016. **99**(12): p. 2063-2070.
39. Shortell, S.M., et al., *A Multilevel Analysis of Patient Engagement and Patient-Reported Outcomes in Primary Care Practices of Accountable Care Organizations.* Journal of General Internal Medicine, 2017. **32**(6): p. 640-647.
40. Wald, J.S., et al., *Implementing practice-linked pre-visit electronic journals in primary care: patient and physician use and satisfaction.* J Am Med Inform Assoc, 2010. **17**(5): p. 502-6.
41. Vo, M.T., et al., *Prompting Patients with Poorly Controlled Diabetes to Identify Visit Priorities Before Primary Care Visits: a Pragmatic Cluster Randomized Trial.* Journal of General Internal Medicine, 2019. **34**(6): p. 831-838.
42. Hernar, I., et al., *Young adults with type 1 diabetes and their experiences with diabetes follow-up and participation in the DiaPROM pilot trial: A qualitative study.* Diabet Med, 2021: p. e14535.
43. Comer, D.E., et al., *Computing as a discipline.* Commun. ACM, 1989. **32**(1): p. 9–23.
44. Haugstvedt, A., et al., *Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomised controlled trial pilot study*. BMJ Open, 2019. **9**(1): p. e024008.
45. Jeffrey, B., et al., *Mobile phone applications and their use in the self-management of Type 2 Diabetes Mellitus: a qualitative study among app users and non-app users.* Diabetology & Metabolic Syndrome, 2019. **11**(1): p. 84.
46. Anderson, K., O. Burford, and L. Emmerton, *Mobile Health Apps to Facilitate Self-Care: A Qualitative Study of User Experiences.* PLoS One, 2016. **11**(5): p. e0156164.
47. Greenhalgh, J., et al., *Health Services and Delivery Research*, in *Functionality and feedback: a realist synthesis of the collation, interpretation and utilisation of patient-reported outcome measures data to improve patient care*. 2017: Southampton (UK).

48. Santana, M.J. and D. Feeny, *Framework to assess the effects of using patient-reported outcome measures in chronic care management.* Qual Life Res, 2014. **23**(5): p. 1505-13.
49. Forsberg, H.H., et al., *Using patient-reported outcomes in routine practice: three novel use cases and implications.* J Ambul Care Manage, 2015. **38**(2): p. 188-95.
50. Snyder, C.F., et al., *Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations.* Qual Life Res, 2012. **21**(8): p. 1305-14.
51. Skovlund, S.E., et al., *Can the Routine Use of Patient-Reported Outcome Measures Improve the Delivery of Person-Centered Diabetes Care? A Review of Recent Developments and a Case Study.* Current Diabetes Reports, 2019. **19**(9): p. 84.
52. Cichoń, E., et al., *Validation of the Polish version of WHO-5 as a screening instrument for depression in adults with diabetes.* Diabetes Res Clin Pract, 2020. **159**: p. 107970.
53. Alvarado-Martel, D., et al., *ViDa1: The Development and Validation of a New Questionnaire for Measuring Health-Related Quality of Life in Patients with Type 1 Diabetes.* Front Psychol, 2017. **8**: p. 904.
54. Lee, W.J., et al., *Health-related quality of life using the EuroQol 5D questionnaire in Korean patients with type 2 diabetes.* J Korean Med Sci, 2012. **27**(3): p. 255-60.
55. Tang, Z., et al., *Validation of the Simplified Chinese Version of the Brief Diabetes Quality of Life (DQoL) Questionnaire Based on a Cross-Sectional Study.* Int J Environ Res Public Health, 2020. **17**(23).
56. Holmes-Truscott, E., et al., *A comparison of the acceptability and psychometric properties of scales assessing the impact of type 1 diabetes on quality of life—Results of 'YourSAY: Quality of Life'.* Diabetic Medicine, 2021. **38**(6): p. e14524.
57. Google, *Flutter architectural overview.* 2021.
58. Joshi, A., et al., *Likert scale: Explored and explained.* Current Journal of Applied Science and Technology, 2015: p. 396-403.
59. S. Robertson, J.R., *Mastering the requirements process: Getting the requirements right.* 2013. **3**.
60. J. Robertson, S.R., *Volere Requirement Specification.* 2012.
61. Parliament, E., *General Data and Protection Regulation*, E.U. Law, Editor. 2016.
62. Tsang, S., C.F. Royse, and A.S. Terkawi, *Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine.* Saudi J Anaesth, 2017. **11**(Suppl 1): p. S80-s89.
63. Ki, M., et al., *Age-related differences in diabetes care outcomes in Korea: a retrospective cohort study.* BMC Geriatr, 2014. **14**: p. 111.
64. Brooke, J., *SUS: a "quick and dirty'usability.* Usability evaluation in industry, 1996: p. 189.
65. Brooke, J., *SUS: a retrospective.* Journal of usability studies, 2013. **8**(2): p. 29-40.
66. Bangor. A, K.P., Miller. J, *Determining What Individual SUS Scores Mean: Adding an Adjective Rating Scale.* Journal of usability studies, 2009. **4**: p. 114-123.

67. Polonsky, W.H., et al., *Assessment of diabetes-related distress.* Diabetes Care, 1995. **18**(6): p. 754-60.
68. Graue, M., et al., *Diabetes-related emotional distress in adults: reliability and validity of the Norwegian versions of the Problem Areas in Diabetes Scale (PAID) and the Diabetes Distress Scale (DDS).* Int J Nurs Stud, 2012. **49**(2): p. 174-82.
69. Ambinder, E.P., *Electronic health records.* J Oncol Pract, 2005. **1**(2): p. 57-63.
70. e-Helse, D.f., *Utviklingstrekk 2021*. 2021.

Appendix A

Numbers are from 28/02/21

Literature review #1 Queries:

Pubmed:

((patient reported outcome measures[Title/Abstract] OR patient-reported outcome measures[Title/Abstract]) AND (diabetes[Title/Abstract] OR eprom[Title/Abstract] OR pre-visit preparation[Title/Abstract] OR pre-visit intervention[Title/Abstract] OR patient centered [Title/Abstract] OR patient-centered [Title/Abstract])) OR ((diabetes[Title/Abstract]) AND (mobile phone usage[Title/Abstract] OR pre-visit preparation[Title/Abstract] OR pre-visit intervention[Title/Abstract])) -> 366 results

ACM:

(("patient reported outcome measures" OR "patient-reported outcome measures" OR "patient reported outcome measurement" OR "patient-reported outcome measurement") AND ("diabetes" OR "eprom" OR "pre-visit preparation" OR "pre-visit intervention" OR "patient centered" OR "patient-centered") OR (("diabetes") AND ("mobile phone usage" OR "pre-visit preparation" OR "pre-visit intervention"))) -> 16 results

Web of science:

AB = ((("patient reported outcome measures" OR "patient-reported outcome measures" OR "patient reported outcome measurements" OR "patient-reported outcome measurements") AND ("diabetes" OR "eprom" OR "pre-visit preparation" OR "pre-visit intervention" OR "patient centered" OR "patient-centered")) OR (("diabetes") AND ("mobile phone usage" OR " pre-visit preparation" OR "pre-visit intervention"))) -> 341 results

IEEE:

("Abstract": "patient reported outcome measures" OR "Abstract": “patient-reported outcome measures) AND ("Abstract": "diabetes" OR "Abstract": "eprom" OR "Abstract": "pre-visit preparation" OR "Abstract": “pre-visit intervention” OR "Abstract": "patient centered" OR "Abstract": “patient-centered”) OR (("Abstract": "diabetes") AND ("Abstract": "mobile phone usage" OR "Abstract": "pre-visit preparation" OR "Abstract": “pre-visit intervention)) -> no results

("patient reported outcome measures") AND (“diabetes" OR "eprom" OR "pre-visit preparation" OR "patient centered care") OR ("diabetes") AND ("mobile phone usage" OR "pre-visit preparation" OR “pre-visit intervention”) -> no result

Appendix B

Literature review 2 query:

PubMed:

((questionnaire[Title/Abstract] OR questionnaires[Title/Abstract]) AND ((diabetes[Title/Abstract] OR diabetes-related distress[Title/Abstract]) AND (quality of life[Title/Abstract]) AND (validation[Title/Abstract] OR validity[Title/Abstract]))) -> 188 results

ACM:

(Title:("questionnaire" OR "questionnaires") AND ("diabetes" OR "diabetes-related distress") AND("quality of life") AND("validation" OR "validity")) -> 4 results

Web of science:

AB = ((("questionnaire" OR "questionnaires") AND ("diabetes" OR "diabetes-related distress") AND ("quality of life") AND ("validation" OR "validity"))) -> 146 results

IEEE:

("questionnaire" OR “questionnaires) AND ("diabetes" OR "diabetes-related distress") AND ("quality of life") AND ("Validation" OR "validity") -> no results

Appendix C

Disse spørsmålene er laget for å høre hvordan du tror denne mobil appen er å bruke for personer med mild/moderat grad av psykisk utviklingshemming.

Veldig uenig — Veldig enig

	1	2	3	4	5
1. Jeg tror appen kan bli brukt jevnlig.					
2. Jeg tror appen er for komplisert.					
3. Jeg tror appen er lett å bruke.					
4. Jeg tror jeg må ha hjelp fra noen med teknisk kyndighet for å bruke appen.					
5. Jeg synes de forskjellige delene av appen henger godt sammen.					
6. Jeg synes det er for mye inkonsistens i appen. (Det virker ulogisk)					
7. Jeg tror det er lett å lære seg å bruke denne appen.					
8. Jeg synes appen er for vanskelig å bruke.					
9. Jeg er komfortabel med å bruke denne appen alene.					
10. Jeg tror det vil kreve omfattende opplæring før appen kan brukes.					

Spørsmål om test av diabetes app(semi-structured intervju):

Var det noe du savnet i appen?

Var det mange problemer underveis?

Tror du appen kan bidra til en bedre diabeteskonsultasjon?

Hva synes du burde utløse (trigge) utfyllingen av PROMen?

Er du komfortable med å dele din sensordata?

Hvilke hjelpemiddler/apper bruker du for å monitorere din diabetes?

Appen bruker blodsukker, aktivitestsnivå, karbohydrater, Insulininntak, alder og kjønn for å skreddersy PROMen til brukeren, er det noen andre verdier du trur kunne brukes for å skreddersy PROMen bedre?

Når du har samtaler med din lege, er det noe informasjon du har som du skulle ønske legen din hadde tilgang til?

Generelle tilbakemeldinger: