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Supporting Improved Adherence In The Treatment of Asthma

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STUDENTERRAPPORT

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Abstract:

Forskning i adherence peger på en mangel på standardiserede mål og definitioner. I dette projekt tages udgangspunkt i behandling med inhalationssteroider hos astmapatienter, kendt for dårlig adherence. God behandling kendetegnes bl.a. ved god lægemiddeldeponering i lungerne, som optimeres ved korrekt inhalationsteknik. Formålet med studiet er at undersøge, om et system kan udvikles til at understøtte patienternes adherence, hvilket derfor også inkluderer informationer om inhalationsteknik. Med udgangspunkt i studier om systemudvikling i sundhedssektoren indsamles domæneviden til brug i udviklingen af et IT-artefakt i form af en testbar prototype. Der tages en objektorienteret tilgang med anvendelse af kendte udviklingsteknikker i form af rich pictures og Unified Modeling Language. I evalueringen af systemet undersøges patientperspektivet af apotekspersonale. Der beregnes en gennemsnitlig System Usability Scale score på 89.58, og 5 ud af 10 mål findes delvist opfyldt ifølge den heuristiske evaluering. Dette indikerer, at apotekspersonalet finder systemet brugbart, hvilket understøttes af kvalitative udtalelser fra deltagerne. En diskussion af resultaternes generaliserbarhed understreger, at afgrænsninger lavet i udvikling og evaluering, nedsætter generaliserbarheden, hvilket antyder behovet for yderligere forskning.

Preface

This project report is a master's thesis in Biomedical Engineering and Informatics at Aalborg University. The report is written in the project period from February 1st to June 1st 2023. The author of the report is group 10408, consisting of one student, who, besides a bachelors degree in Biomedical Engineering and Informatics, has a background as a pharmacy technician (danish: *farmakonom*).

The report aims to present a system, capable of supporting the level of adherence to inhaled corticosteroids for patients with asthma. The system also incorporates an assessment of inhalation technique, as this is essential for the effect of treatment.

Acknowledgements

The community of pharmacy technicians in Denmark provided insights in the domain of adherence assessment in various settings, as they are employed in pharmacies, general practices, and in hospitals. Specifically, the employees of the pharmacy 'Aalborghus Apotek' assisted in the evaluation of the developed system, and for this, the author is grateful.

Also, a special thanks to associate professor Louise Pape-Haugaard, who supervised the project and provided valuable guidance.

Declaration of Interest

Aalborghus Apotek has been an employer of the author in 2012-2015, and again in 2018-2023 in a part time position during the bachelors and masters degree. The evaluation performed by Aalborghus Apotek was however not influenced by this affiliation.

Sofie Bjørn

Aalborg University, June 1st 2023

Reading Guide

The report consists of 9 chapters and is 49 pages long, including the bibliography. It is mostly intended to be read consecutively. The first chapter is a short introduction to the problem domain, which is further elaborated in the following problem analysis. Here, the problems in the field of adherence research are outlined, and the clinical case of adherence in asthma patients using inhaled corticosteroids is presented. This is summarized in a problem statement. A potential solution is presented in a system description, followed by initial requirements. The next chapter describes the methods applied in order to conduct the study. The analysis chapter presents further development of the potential solution, and domain specific requirements. This is presented in a UML domain model. The last part of the analysis consists of the evaluation of the prototypes

Appendix

The appendix consists of six chapters, and a total of 22 pages. Some chapters are divided into sections, as for instance the chapter regarding the evalutation. This contains four different appendices, all related to the evaluation. The last chapter explains the time management during the project period.

Nomenclature

Some of the domain specific terms can not be directly translated from danish to english. This includes e.g. the terms "lægemiddelordination" and "receptordination". The first occurrence where the distinction between these terms is essential for the understanding, the danish terms are written i parenthesis, as e.g. "drug prescription (Danish: *lægemiddelordination*)".
The report also contains abbreviations, which are presented in parentheses at the first appearance of the original term.

Citation Style and Usage

In this report, the Harvard citation method is used. Therefore, references are made using the author's last name followed by the year of publication. In the case of multiple authors, the reference also contains et al., which is placed between the main author's name and the publication year. When a reference is used actively, it is shown as 'Last Name [year]'. When a reference is used passively, it is shown as '[Name, Year]'. If a reference is cited before a period mark, it only covers that exact sentence, as opposed to references placed after a period mark, covering the entire paragraph. All references in the report are made as hyperlinks.

Contents

1 | Introduction

Adherence refers to the extent to which a patient's actual behavior aligns with their prescribed treatment [European Patients' Forum, 2015; Sabaté, 2003]. Non-adherence occurs when there is a lack of alignment between patient behavior and treatment, leading to various consequences such as increased morbidity, mortality, and hospitalization [Williams et al., 2004]. This issue of non-adherence poses a significant healthcare problem worldwide, with up to 50% of all long-term pharmacotherapy patients expected to experience poor adherence at some point. Certain patient groups have a particularly high risk of non-adherence .[Lehane and McCarthy, 2007]

It is worth noting that poor adherence is particularly prevalent in the preventive treatment of asthma, as highlighted by Engelkes et al. [2015]. The assessment of adherence often relies on patient-reported information, which tends to be overreported and may not provide an accurate representation of actual adherence levels. [Dansk Lungemedicinsk Selskab, b]

In the context of asthma treatment, the proper deposition of inhaled medication plays a crucial role in the effectiveness of treatment, which is optimized when patients perform their medication inhalations technically correct. Surprisingly, as noted by Mokoka et al. [2019], only three out of 20 studies have included an assessment of inhalation technique when evaluating adherence in asthma patients [Mokoka et al., 2019].

Numerous studies have emphasized the necessity of standardized definitions and measurements of adherence to address and improve the issue of non-adherence effectively [Clements et al., 2018; Ghimire et al., 2015; Mokoka et al., 2019; Normansell et al., 2017]. By establishing consistent criteria for measuring and defining adherence, healthcare providers and researchers can potentially gain a clearer understanding of the problem and develop targeted interventions to improve adherence rates.

2 | Problem Analysis

2.1 The Definition of Adherence

Adherence and compliance are two closely related concepts, both used to describe the relation between a patient's actual behavior and their prescribed treatment. Compliance is defined as the degree to which the behavior matches the prescriber's recommendations, whereas the concept of adherence requires the treatment to be agreed upon between the patient and the prescriber. Therefore, the patient is involved in treatment decision making, and can thus experience self-motivation towards adhering to the treatment. Due to emphasizing the need of agreement, the adherence concept is often preferred to compliance, but sometimes the two concepts are used interchangeably. [European Patients' Forum, 2015] In 2003, WHO published a report regarding adherence, in which the definition of adherence is: *"the extend to which a person's behavior - taking medication, following a diet, and/or executing lifestyle changes, corresponds with the agreed recommendations from a health care provider"*. This definition encompasses other treatment behavior than pharmaceutical, even though this is the most common focus in the research field of adherence. [Sabaté, 2003]

2.2 Definition and Consequences of Non-adherence

Non-adherence, sometimes referred to as non-compliance, is an expression used when the degree of adherence is low. However, non-adherence is a heterogeneous term, as it can be described by a range of non-adherent behaviors, such as not taking prescribed medications at all, taking different doses, or at different times, taking medications irregularly, or stopping treatment early. [European Patients' Forum, 2015] Additionally, non-adherence is classified as either intentional or unintentional. Regardless of this, medication non-adherence prevents patients from gaining full benefit of their prescribed treatment. [Ghimire et al., 2015]

Non-adherence has been associated with several negative consequences. For instance, treatment efficacy can be reduced, when adherence is poor, and non-adherence has been found to increase morbidity. Additionally, non-adherence can cause the need for additional treatment or even hospitalization, thereby increasing healthcare costs. In Williams et al. [2004], 60% of the hospitalizations in their study population was estimated to be attributed to poor medication adherence. Non-adherence has furthermore been linked to increased mortality. [Ghimire et al., 2015; Williams et al., 2004; Bitton et al., 2013]

When attempting to reduce non-adherent behavior, it is essential to recognize the different reasons for

non-adherence. Therefore, the paper from Lehane and McCarthy [2007] provides an oversight of the literature concerning the classification of non-adherence as intentional or unintentional. This includes key factors related to medication non-adherence. From this, intentional non-adherence is seen as patients ignoring their recommendations by delaying, altering, or missing doses in their prescribed medication regimen on purpose. In the unintentional non-adherence, there is an underlying assumption of some degree of passivity of the patients. This can be expressed by a lack of understanding the importance of their treatment, potentially due to miscommunication between the health care provider and the patient. Additionally, forgetfulness and disruption of daily routines are potential reasons for unintentional non-adherence. [Lehane and McCarthy, 2007] Interventions aimed at improving adherence should be tailored to fit the type of non-adherence for the specific case. For instance, a basic prompt to remember medications would potentially improve the unintentional non-adherent behavior of forgetfulness. However, if the non-adherence is a result of an intentional behavior, a reminder would probably not improve adherence. [Normansell et al., 2017]

The issue of non-adherence is a world wide health care problem, that remains unsolved after decades of research [Lehane and McCarthy, 2007]. It is an issue related to all types of treatment and every type of patient. However, some risk factors for non-adherence have been identified. These include patient groups with complex medication plans, including multiple medications, medications with varying doses, or medications with difficult administrations, e.g. injections or inhalers. Additionally, patients with chronic illness, high age, or challenges such as substance abuse are at high risk of non-adherence. [Forbes et al., 2018; Clements et al., 2018; Lehane and McCarthy, 2007]

2.3 Measurement and Assessment of Medication Adherence

There is no gold standard for how to measure adherence, because all measurements are merely estimates of the actual behaviors of the patients. Therefore, choosing the "best" method rely on the individual case, considering pros and cons of each possible measurement method. [Sabaté, 2003; Clements et al., 2018] In Mokoka et al. [2019], the measures of adherence are categorized as being subjective, semi-objective, or objective. The study by Clements et al. [2018], differ in terminology but use a similar classification, namely patient self-report, indirect non-patient report, and direct non-patient report.

The most common methods of assessing patients' adherence are self-reported by the patients and therefore subjective. They include various validated questionnaires or scales, medication diaries, and patient recall. Several studies have found the level of self-reported adherence to be over-estimated and influenced by patient recall bias. [Ghimire et al., 2015; Forbes et al., 2018] In light of these issues, Gagné et al. [2018]

aimed to investigate several questionnaires, surveys, and scales in terms of their applicability as measures of adherence. The study found that no current patient reported outcome (PRO) could be recommended in routine care or research settings, as there is a lack of investigations into their reliability, validity, and interpretability. Another issue with PROs for measuring adherence, addressed in Gagné et al. [2020], relates to the fact that adherence consists of three elements; initiation, implementation, and persistence. The study found that none of the 87 included studies measured all three elements, and a total of 87% only accounted for one element, predominantly implementation. [Gagné et al., 2018, 2020]

The indirect non-patient reports are classified as being semi-objective measures. They include counting pills, weighing medication containers, or evaluating pharmacy refill records. [Mokoka et al., 2019; Clements et al., 2018] According to Forbes et al. [2018], using pharmacy records has mostly been reported as an accurate, easy, and inexpensive method for assessing medication adherence. However, there are some limitations, as the records do not account for early refills, changes in regimens, or multiple dispensings. The pharmacy records can provide information relevant for calculating adherence by different definitions. Two of these are called the medication possession rate (MPR) and the proportion of days covered (PDC). They are similar because they both describe the ratio between prescription and refill, but they are calculated slightly different from each other. In literature, it can be difficult to identify the difference between the two, because the specific calculations often are omitted. However, adjusting for potentially overlapping refill periods is always recommended. These calculations are useful in retrospective settings, whereas pill counting can be more advantageous in prospective settings. [Forbes et al., 2018]

The direct non-patient reports are classified as being objective measures. This includes directly observed treatments and electronic monitoring, e.g. by use of sensors on an inhaler, or on the cap of a container. Observations are the only method that proves actual medication indigestion. However, the sensors record the date and time of activity, thereby indicating the exact time of medication administration. This method therefore tends to be more accurate, due to it's ability to reveal patterns in medication taking behavior, that the semi-objective methods do not offer. The objective methods are more expensive and often better suited for research compared to clinical practice. [Mokoka et al., 2019; Clements et al., 2018; Forbes et al., 2018]

The lack of a gold standard seems to be persistent due to the heterogeneity in the adherence and non-adherence terms [Lehane and McCarthy, 2007]. However, several studies point to a need for aligning adherence definitions and adherence measures within a patient group, in order to improve interventions for reducing non-adherence. This could potentially also improve the reliability and validity of adherence

measures, and it would allow for meta-analyses to be conducted across disease specific adherence research fields. [Clements et al., 2018; Ghimire et al., 2015; Normansell et al., 2017; Mokoka et al., 2019]

In summary, non-adherence is a major health care problem, that has not yet been solved. It affects patients by an increase in both morbidity and mortality, which is also associated with increased health care costs for society. Some patient groups are at high risk of non-adherence, e.g. patients with chronic illness or complex medication plans. Literature points to a lack of standardized definitions of non-adherence and adherence measures as potential improvements in the research field. If the measures of adherence could be standardized, the validity of measures would potentially increase, making them easier applicable in a clinical health care setting.

2.4 Medication Adherence in the Treatment of Asthma

Non-adherence is significantly present in the treatment of patients having asthma. This is specifically an issue with the preventative treatment using inhaled corticosteroids (ICS), aimed at reducing the need for acute symptom relief using other medications. Low adherence has been associated with higher risk of severe excacerbations. [Dansk Lungemedicinsk Selskab, a,b; Engelkes et al., 2015; Mokoka et al., 2019]

One element often not considered in literature regarding adherence in asthma treatment is inhaler competence. Remarkably few studies include an assessment of inhalation technique, despite it having a major impact on the effect of treatment. When having incorrect inhalation technique, the deposition of medication in the lungs will be poor, even if it is taken daily as prescribed. [Engelkes et al., 2015; Mokoka et al., 2019]

In clinical practice, the goal of asthma treatment is to reduce asthma symptoms to a minimum and keep lung function at it's best. This entails a reduced risk of acute exacerbation and minimal side effects from treatment. [Sundhed.dk] The assessment of adherence to ICS often rely on self-reported information given by the patient during consultation. Due to the risk of recall bias and overestimation of adherence, the Danish Respiratory Society (DLS) recommends that the assessment is supported by an inspection of medical records, such as pharmacy refill records. Additionally, each check-up should include an assessment of inhalation technique. [Dansk Lungemedicinsk Selskab, a,b]

When reporting adherence measures specifically in the field of asthma treatment, the methodologies still differ. Some of the most commonly used measures in the literature are the MPR and various PROs. [Engelkes et al., 2015; Mokoka et al., 2019] Multiple PROs in asthma have been developed and validated in literature [Plaza and TAI study group, 2016; Nassar et al., 2022]. However, incorporating these in

clinical practice has proven to be difficult. The typical challenges include a high amount of questions, making the questoinnaire time consuming. Another challenge relates to the applicability of either too generic or too specific questionnaires. [Plaza and TAI study group, 2016]

An example of a PRO developed specifically for inhaler treatment is "The Adherence to Inhalers" questionnaire (TAI). This questionnaire has been developed with the purpose of supporting health care providers in identifying reasons for non-adherence in patients using inhalers. This should assist them in launching relevant interventions in order to improve adherence, due to an increased understanding of the specific patient. The TAI questionnaire contains 10 questions for the patient, and an additional two questions for the health care provider. These two questions concern inhalation technique and adherence, assessed from medical records, such as pharmacy refill records.[Plaza and TAI study group, 2016]

2.4.1 Medication Adherence in Asthma Treatment in Denmark

In a danish setting, a typical patient with asthma is treated by their general practitioner, which means that the practitioner is in charge of regular check-ups and providing prescriptions. Some patients also receive check-ups at the hospital, but in these cases, the medication is still commonly prescribed by their general practitioner. Every patient, however, has to claim their prescriptions in a pharmacy, which makes pharmacy staff an often utilized resource in improving adherence [Normansell et al., 2017]. This is seen in figure 2.1, where a patient is illustrated having contact with all three types of health care providers.

The assessment of a patient's adherence rely mainly on their dialogue with the involved health care providers, resulting in a subjective assessment. In case the provider needs additional information in their assessment, the general practitioner and the pharmacy staff have a tendency to sort through refill data in their respective systems, as opposed to looking in the national Shared Medication Record (FMK)[Informal Interviews, March 2023]. However, no guideline defines how to assess adherence from refill data, making it a subjective assessment as well. This could be an issue for the pharmacy staff assessing adherence, as the patient potentially could claim prescriptions at several pharmacies. This would not be evident in the local pharmacy system, potentially obscuring non-adherence behavior. A similar issue could be present for the general practitioner, as the claim of a prescription made from an on call general practitioner would not appear in the local history in their system. Furthermore, the task of checking the national FMK could potentially be time consuming, depending on the system integrations in the respective local systems.[Informal Interviews, March 2023]

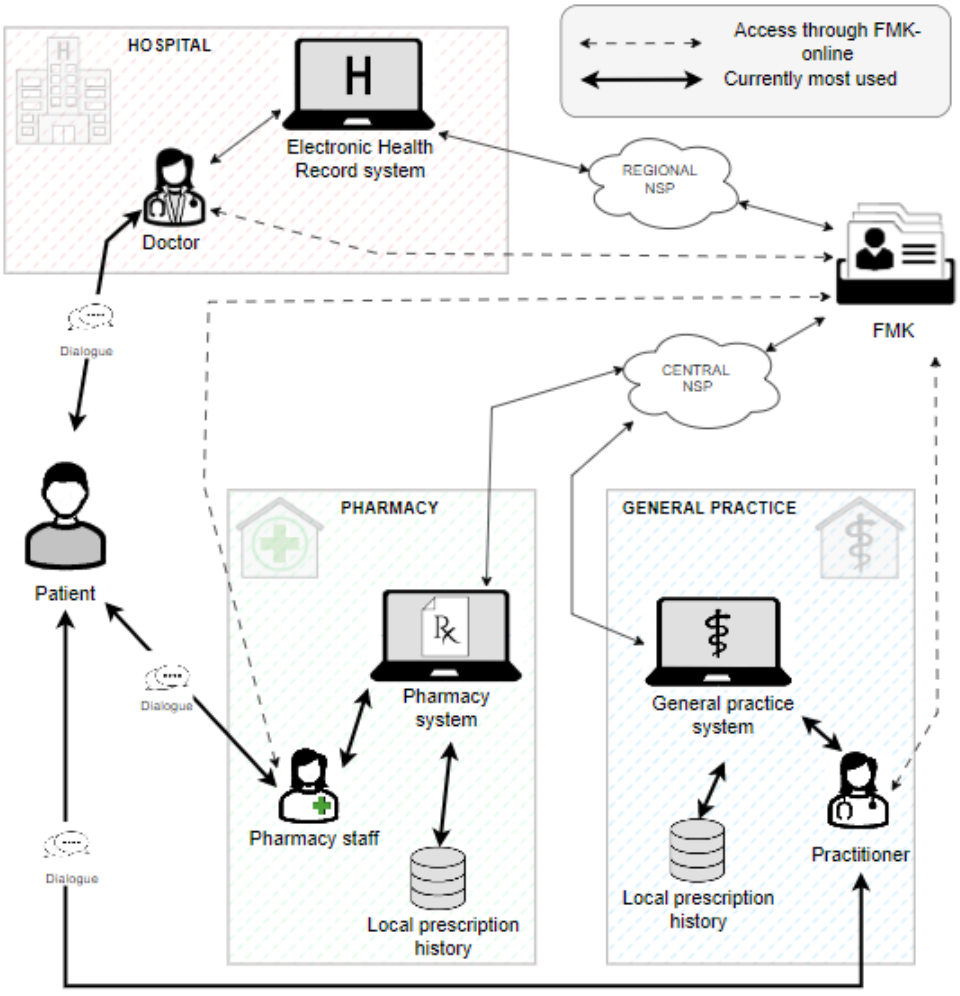


Figure 2.1: Rich picture demonstrating how the assessment of a patient's adherence occurs. The heavy lines show the most predominant information exchanges, and the dotted lines demonstrate data exchanges that are possible, but rarely used.

The hospital doctor uses an electronic health record (EHR) system. However, as this doctor rarely makes prescriptions in ongoing treatments of asthma, the need for checking up on the prescription is scarce and therefore neglected in this project.

The FMK provides a common ground for managing patients medications. However, due to multiple health care professions being involved in asthma treatment, there are different local systems involved in the domain. This means that even if prescription refill data was accessible in every system, the context it is presented in, could vary greatly.

2.5 Problem Statement

In the research field of adherence, one of the major issues identified is the lack of standardized adherence definitions and measures. Since adherence is a heterogeneous term and used differently in various settings, specific measures may not be applicable across the entire problem domain.

In the case of asthma treatment, medication adherence is known to be low, specifically for ICS treatment. Therefore, research has investigated multiple questionnaires in terms of validity and applicability in clinical practice, but none has been successfully implemented. Furthermore, as the goal in asthma treatment is related to the frequency and severity of asthma symptoms, the need for efficient deposition of medication in the lungs is crucial. Therefore, correct inhaler technique is an essential part of supporting adherence in the treatment of asthma.

This has lead to the following problem statement:

Knowing that inhaler technique is an essential part of the treatment of asthma, how can this knowledge be systematically incorporated into a system capable of supporting adherence in asthma patients?

3 | System Description

The system is intended to support the patients in their management of inhaled medications, including supporting their inhalation technique. Currently, the assessment of adherence rely on individual conversations between the patient and the health care provider, and no standardized assessment method has been implemented in clinical practice. An overview of the system is shown in figure 3.1.

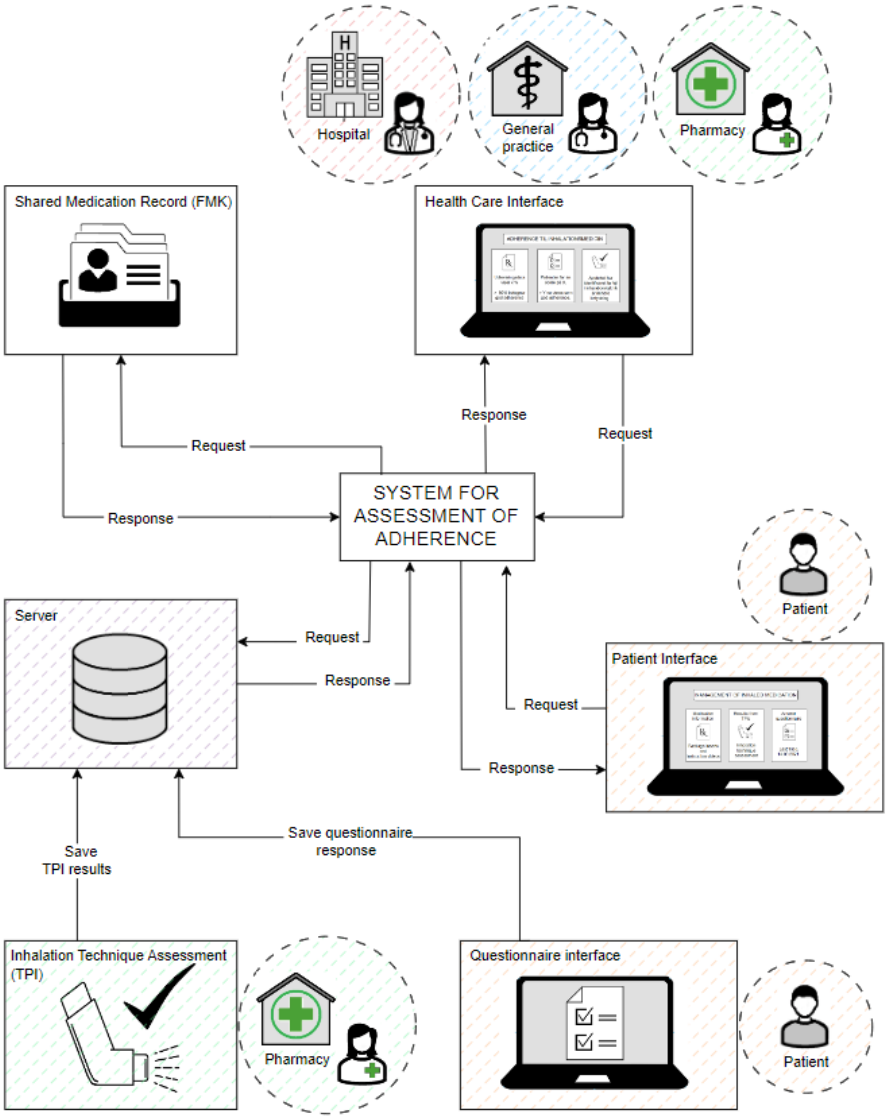


Figure 3.1: The system is shown in a rich pictuce in order to explain it's intended use. There are two general interfaces; one for the patient and one for the health care providers. The data used in the adherence assessment is collected from FMK, the pharmacy and the patient.

In order to systematically assess adherence, the system is developed based on the validated questionnaire from the Plaza and TAI study group [2016]. This questionnaire systematically includes the patients' subjective assessment, but also a health care provider's assessment of medical records and inhalation technique. Therefore, the system consists of an interface for the patient, and an interface for the health care provider.

The patient interface allows the patient to easily find the relevant medication package inserts and inhaler instruction videos in the system, thereby providing support in terms of knowledge regarding treatment. The patient interface also includes an interface for filling out the questionnaire concerning the patients' view on their adherence to inhaled medications.

The interface for the health care providers includes the two elements from the questionnaire; medical records and inhalation technique. The FMK provides prescription data, so this element is developed by defining what specific data is used in the assessment, thus ensuring consistency. In terms of the inhalation technique, the definition of critical mistakes in the Plaza and TAI study group [2016] is mapped according to the pharmacy intervention "Inhalation Technique Assessment" (TPI), currently used to assess the inhalation technique systematically. The form used to document the TPI is seen in appendix B.

4 | Elicitation Requirements

Requirements engineering (RE) is the overall process of developing and documenting requirements in the development of this project. Therefore, requirements are iteratively revisited and adjusted throughout the entire development process. The initial requirements are called elicitation requirements (ER). The ER are derived from the system description, and therefore they concern the aim of the system as well as all five actors of the system; the patient, the hospital, the pharmacy, general practice, and FMK. The ER can be seen in table 4.1.

Table 4.1: Elicitation requirements for the inhaler adherence system, presented in a table.

ID	Requirement
ER_01	The system must support adherence in patients with asthma.
ER_02	The system must support the inhalation technique of the patients.
ER_03	The system must be compatible with multiple pharmacy systems.
ER_04	The system must be compatible with general practice systems.
ER_05	The system must be compatible with multiple hospital EHR systems.
ER_06	The system must be capable of retrieving data from FMK.

5 | Methodologies

In the development of the system, the framework for information system research, presented in Hevner et al. [2004], was used. This framework combines concepts of design science and behavioral science, thereby expressing the need for understanding the domain and business needs, as well as using appropriate methodologies, knowledge, and artifacts to achieve rigor. The development of information systems is therefore influenced by both paradigms, in an iterative process between development and evaluation. [Hevner et al., 2004] This framework is illustrated in appendix C. A similar point is made in Garde and Knaup [2006], where the development of information systems specifically for the health care domain requires comprehensive domain knowledge in addition to the development process itself. [Garde and Knaup, 2006] The author of the current study has a background as a pharmacy technician, and therefore has a significant amount of domain knowledge beforehand.

One of the aims in Garde and Knaup [2006] was to present an approach to requirements engineering that is suited for the high complexity level required in the health care domain. Their initial step was to collect and analyze information from trial protocols. Based on this, an initial domain model was created. From this model, prototypes were created by evolutionary prototyping, with the purpose of testing the prototype in a clinical routine setting. Feedback and experiences with the prototype was collected and applied in the next iteration of the domain model. This process was continued untill no more additional requirements would be identified.[Garde and Knaup, 2006]

In this study, the collection of information was the initial step, aiming at identifying user needs. In order to create a domain model, an analysis was conducted by applying an object oriented approach. Therefore, use case diagrams and activity diagrams were created in order to elaborate the requirements. The requirements were then documented in a domain model, supporting the implementation of a prototype, capable of being evaluated by clinical staff. This evaluation was done by qualitative inquiry. This study therefore used an approach inspired by Garde and Knaup [2006] in one iteration. The methodologies are described in the following sections.

5.1 Prototyping

In Hevner et al. [2004] it is stated that designing information systems is both a process and a product. The process is the sequence of activities that produces an artifact (the product). When the artifact is evaluated, it provides feedback and adds to the understanding of the initial problem. This feedback is therefore used in the next iteration of the design, typically improving it. [Hevner et al., 2004] Prototyping

is a method used in the development of web and software designs, which can incorporate different perspectives, e.g.from the developer's or user's point of view. Specifically, in early development stages, the need for quick modifications and iterations is supported by the use of low-fidelity (LoFi) prototypes, that are low-cost and developed fast. High-fidelity (HiFi) prototypes are more similar to the final product, because their interaction techniques and appearances are similar. These are however more time-consuming and expensive to create. [Walker et al., 2002]
The fidelity of a prototype is not dichotomous, meaning that fidelity is defined on a continuous scale. Therefore, it can be difficult to distinguish between LoFi and HiFi prototypes. It is argued in Virzi et al. [1996] that HiFi prototypes are necessary in usability testing, because of LoFi prototypes potentially being unable to adequately simulate specific aspects of a design. [Virzi et al., 1996]

In this project, the development demonstrated the first iteration of the build-and-evaluate loop, explained by Hevner et al. [2004]. Therefore, graphical user interfaces (GUI) were created, which gave a visual representation of the system in the report. The next step was to implement the GUIs as prototypes, i.e. a testable artifact. These were made in a PowerPoint slideshow with embedded links, in order to mimic the actual behavior of the system. This means that the prototypes were considered to be HiFi prototypes, but in the low end of the scale. This means that they fidelity level was sufficiently low to allow for quick alterations, even though the prototypes were relatively similar to the actual system, and thus considered HiFi.

5.2 Data Material

In order to develop the prototype, there was a need for understanding the problem and the domain thoroughly, in lines with Hevner et al. [2004] and Garde and Knaup [2006]. Therefore, information was collected by two ways; in a structured literature search and through informal interviews with actors in the domain.

5.2.1 Structured Literature Search

In order to obtain knowledge on the research field of adherence, a structured literature search was conducted. The aim of the search was to identify literature explaining how medication adherence is currently measured. The search was structured in a table and performed as a block search, where each column constituted a block.

Identification of search terms

Due to initial searches, patients with asthma was identified as a specifically challenging patient group.

Therefore, the "patient group" column contained a MeSH term for that specific patient group. However, a MeSH term for chronic disease in general was also applied. The purpose was to discover both general adherence measures, and potentially measures specifically aimed for asthma medications.

The focus on adherence measures was managed in the search by including the word "measure" in the search as an independent column. However, no appropriate MeSH terms were identified, so in order to include several versions of the word, i.e. "measure", "measuring", or "measurement", an asterisk was used.

The medication adherence MeSH term only covers the part of adherence related to the pharmacological aspects of treatment, such as timing, dosage and frequency. Therefore this term was chosen over other adherence related MeSH terms. The others either included general treatment adherence (appointments and schedules) or encompass the compliance term more than adherence.
In order to ensure, that the adherence term was related to medication use, the "Drug therapy" MeSH term was used. By adding this column, the amount of results significantly reduced, which was necessary in order to complete the literature search within a limited time frame.

Exclusion phase of the search
For narrowing down the search, multiple filters were applied. Initially, there were 261 results, but by only including literature in Danish or English, and by ensuring full text availability, the number of results was reduced to 250. However, there was a need for further narrowing down the search, and therefore an additional filter was used. This made sure, that all included studies were systematic reviews. These rank high on the level of evidence, and it is presumed that additional relevant studies could be identified from snowballing. The table illustrating the literature search can be seen in table 5.1.

Table 5.1: Structured literature search

Date of search: 10.04.2023	Database: PubMed			
	AND			
	Patient group	**Measure**	**Adherence**	**Medication**
OR	"Chronic disease" [MeSH]	"measur*"	"Medication adherence" [MeSH]	"Drug Therapy" [Mesh]
	"Asthma" [Mesh]			
Results for each column	746,470	4,727,312	25,487	1,500,290
Total results	Filters: english, danish, full text **250** Additional filter: systematic review **15**			

By performing the search, illustrated in table 5.1, 15 studies were identified. One of these, however, was inaccessible. The remaining 14 were evaluated in terms of inclusion and exclusion criteria, initially based on title and abstract.

Exclusion criteria:

- The study does not concern adherence

Inclusion criteria:

- The study mentions specific adherence measures

By applying these criteria to the titles and abstracts, four reviews were excluded. The remaining 10 were included, and 8 was actively used in the problem analysis.

Additional studies

In order to elaborate information from the included systematic reviews, such as specific adherence measures, snowballing was used to identify additional studies. This resulted in an additional four studies to be applied in the problem analysis.

5.2.2 Informal Interviews

Informal interviews can be used to develop an understanding of a specific field of interest, which is e.g not thoroughly explained in literature. The informal interview takes place without the use of a structured interview guide, and the informants often consider it to be a regular conversation. [Cohen and Crabtree, 2006] In this project, the use of informal interviews was chosen to gain insights into the workflows of the three types of health care providers. It was performed in a written format, and the informants were found in a closed group on social media for danish pharmacy technicians. Two informants work in general practice, one works at a hospital, and one had work experience from both general practice and a private pediatric practice. Their responses were used in the description of the domain and thereby influenced the system's development.

5.3 Applied Techniques

In order to process the acquired data, different techniques were utilized. This included rich picture and various diagrams from the Unified Modeling Language (UML).

5.3.1 Rich Pictures

A specific situation or domain can be graphically illustrated using rich pictures [Conte and Davidson, 2020]. In this project, two rich pictures were created. This first was used to describe how adherence is currently assessed in the treatment of asthma in Denmark today. This created an overview of the specific domain. The second rich picture was used to illustrate how the system is intended to fit into the domain, and is therefore presented in the system description.

5.3.2 Unified Modeling Language

UML is a standardized modeling language, used to visualize, specify, or document different systems, e.g. within the object oriented paradigm. It can thus be used to express a system's blueprint, by visualizing structures and relations within the system. [Lucidchart] In this project, UML is applied in three types of diagrams; a use case diagram, multiple activity diagrams, and a domain model.

Use Case Diagram

The use case diagram in this report was created in order to summarize the various interactions a future user could have with the system, and thereby the goals and functionalities of the system.

Activity Diagrams

The activity diagrams in this project were used to elaborate on the system's behavior by describing what happens in the system. This means that the functionalities presented in the use cases were explained in steps, according to different actors, presented in swimlanes.

Domain Model

A UML domain model can be used to describe a specific domain, in a visual representation similar to a UML class diagram. It is therefore based on classes, but the level of detail is lower, because the main objective is to present the domain, as opposed to focusing on the software aspects of the development.[Linnæus University] For this project, the domain model was used to elaborate the specific context of the system, following the analysis. This also included the details regarding how the MPR could be calculated based on the infrastructure of the FMK. Therefore, the domain model is thus a more advanced and detailed representation of the system, compared to the rich picture.

5.4 System Evaluation

For evaluating the system's usability, various tests were created and performed. Six staff members from the pharmacy "Aalborghus Apotek" were asked to explore the prototypes. Additionally, a master student in Biomedical Engineering and Informatics at Aalborg University, who is currently writing their masters thesis, was also asked to participate in the evaluation of the system. The master student is referred to as technical peer.

5.4.1 System Usability Score

In order to have a quantitative measure of usability, the System Usability Scale (SUS) was used. It is a low-cost and reliable usability scale, that can be used when assessing a system's usability [Brooke, 1995]. In this project, the SUS was applied by having the six pharmacy staff members use the prototypes and ranking the 10 statements from the SUS on a five step likert scale ranging from "strongly disagree" to "strongly agree". From the rankings, calculations were made in accordance to Brooke [1995], yielding quantitative usability measures between 0 and 100. The final SUS score was calculated as the average score of the six replies. A list of predefined tasks in the system was created, and during the participants' exploration of the system, it was noted if they were able to solve each task. This was to ensure, that the entirety of the system's functionality was explored.

5.4.2 Usability Testing and Heuristic Evaluation

In order to substantiate the findings, statements from the pharmacy participants were noted during their exploration of the prototypes. In usability testing, qualitative testing can help the understanding of behaviors and thoughts of the participants, and provide findings in terms of usability and potential usability problems [NN-group, 2019]. In this project, the statements were paraphrased in writing and ultimately read aloud to the participants for their approval in order to ensure a correct interpretation of their viewpoint. This, however, occurred after the participants had replied to the SUS, thereby complying to the approach from Brooke [1995] by not influencing their replies.

One pharmacy staff member and the technical peer were asked to perform an heuristic evaluation of the system. This is an assessment based on an interface's compliance with 10 known principles, or heuristics, for what makes interfaces easy to use, and it can therefore aid in the identification of usability problems in a design [NN-group, 2020]. Each of the two participants had each heuristic explained, and was afterwards asked to judge the system accordingly. Their statements were noted and paraphrased as short, specific statements, following the principles of meaning condensation by Kvale and Brinkmann [2018].

For each heuristic, a specific goal for the system was created. Whether or not a goal was achieved, depended mostly on the heuristic evaluation, and to some degree the qualitative statements from the remaining pharmacy staff, as these were used to support the findings of the heuristic evaluation. This allowed for combining inductive and deductive reasoning. The heuristic evaluation was considered inductive, and the deductive approach was seen in the remaining statements, that either supported or undermined the evaluation. This meant that if the evaluators considered a heuristic goal to be achieved, the statements from the remaining staff also had to support it, in order to the goal to be fully achieved. Otherwise, it was considered partly achieved, because the qualitative statements in that case would need further exploration. This is illustrated in table 5.2.

Table 5.2: The table illustrates how the results of the evaluation were made.

Heuristic Evaluation	**Qualitative Statements**	**Result**
No usability problems	No usability problems	Achieved ✓
No usability problems	Usability problems	Partly achieved (✓)
Usability problems	No usability problems	Not achieved %
Usability problems	Usability problems	Not achieved %

There were additional cases where the goals were defined as partly achived. This occurred when the evaluators did not find usability problems in the current prototype, but pointed to considerations necessary for future iterations of the prototype. Also, if a goal consisted of multiple "sub-goals", each of these should be achieved in order to be classified as such. Otherwise, the goal was considered partly achieved.

6 | Analysis

6.1 Use Case Diagram

The initial step in the analysis is the creation of the use case diagram. This is used to depict how the different actors interact with the system. In the use case diagram, there are two primary actors of the system; the health care provider and the patient. The secondary actors of the system is a server and the FMK. This is seen in figure 6.1.

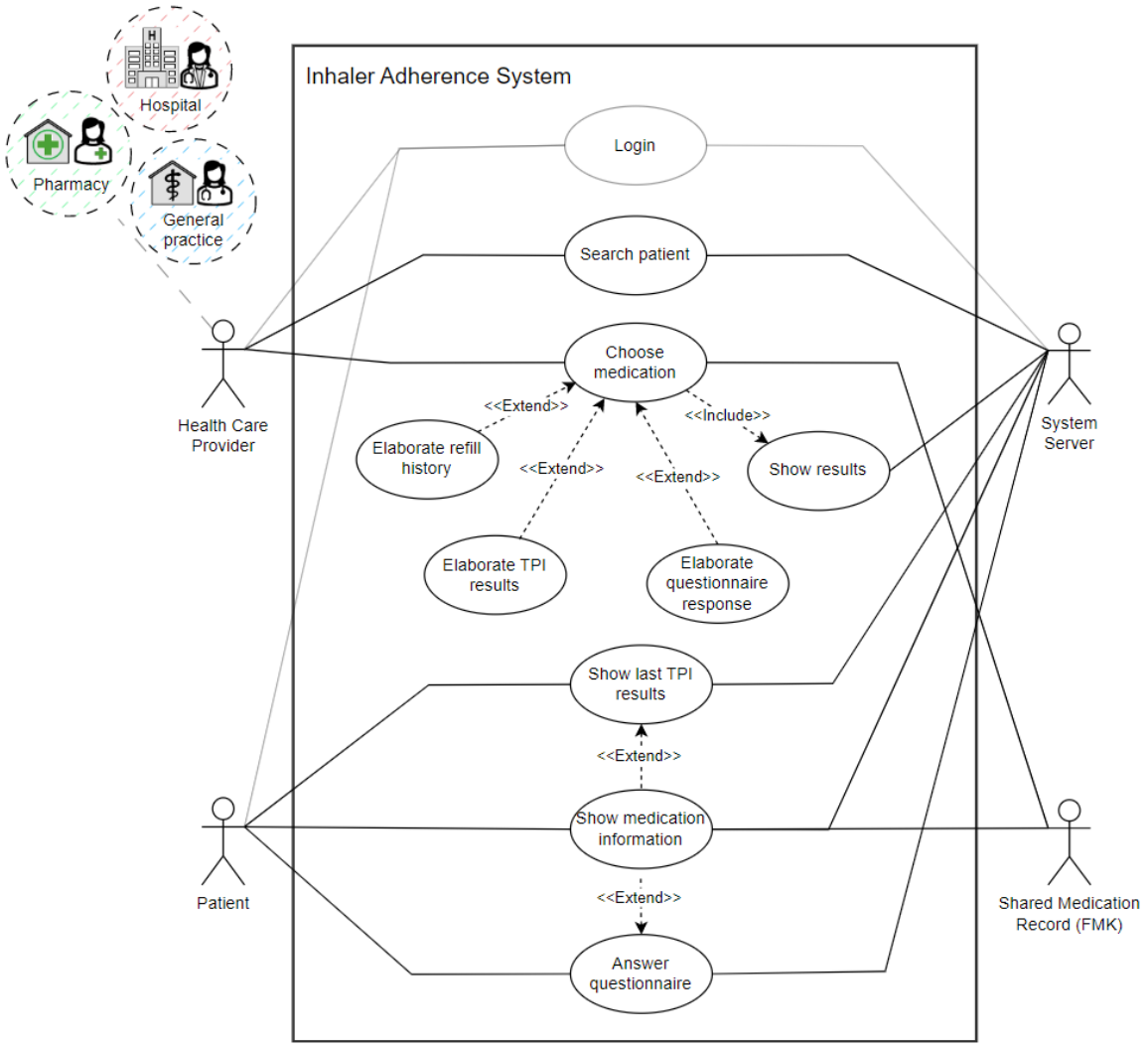


Figure 6.1: Use Case diagram of the Inhaler Adherence System. The primary actors are seen to the left, and the secondary actors are seen to the right.

One of the use cases show a login function, which is included in order to demonstrate the importance of security in a system used in the health care domain. However, further design of this functionality is excluded in this report, because such a function is already used in clinical settings. Therefore this specific use case is shown in a lighter color.

The health care professionals can search for a respective patient in the system by the *Search Patient* use case. This will require the patient information to be collected from the *System Server*. The next use case available for the health care provider is *Choose medication*. This is relevant, if a patient uses multiple preventative inhalers of different types. It requires the system to collect data from *FMK*. When the information is retrieved, and a medication is chosen, the *Show Results* use case is always included. This is where the system displays the adherence results, based on data retrieved from *FMK* and the *System Server*. From the *Choose Medication* use case, three extended use cases are possible, as it is optional to *Elaborate* how the adherence level was calculated. Due to the adherence being explained by three types of data, there are three *Elaborate* use cases.

The patient as a primary actor of the system can, besides login, access three different use cases. These are *Show Medication Information*, *Show Last TPI Results*, and *Answer Questionnaire*. As seen in figure 6.1, the *Show Medication Information* use case also functions as an extended use case to the other two main use cases. This is relevant, for instance, if the patient is looking at the latest results of the TPI and wants easy access to the instruction video, in order to compare the identified errors with the correct inhalation technique. The TPI results and the questionnaires are both retrieved from or saved in the *System Server*, and the *Show Medication Information* connects to both the *System Server* and the *FMK*.

6.2 Activity Diagrams

In order to elaborate on the different functionalities depicted in the use case diagram, multiple activity diagrams are created. The first activity diagram is related to the *Search Patient* use case. This can be seen in figure D.1.1 in appendix D.1. The activity diagram in figure 6.2 shows the interactions in the system related to the use cases *Choose Medication* and *Show Results*. In order to choose the medication, the system must update the possible choices based on information from FMK. When the health care provider then selects a specific medication, the system requests prescription data in order to calculate the level of adherence. Additionally, questionnaire and TPI data from the server is requested, as this is also used in the assessment of adherence in the *Show Results* use case.

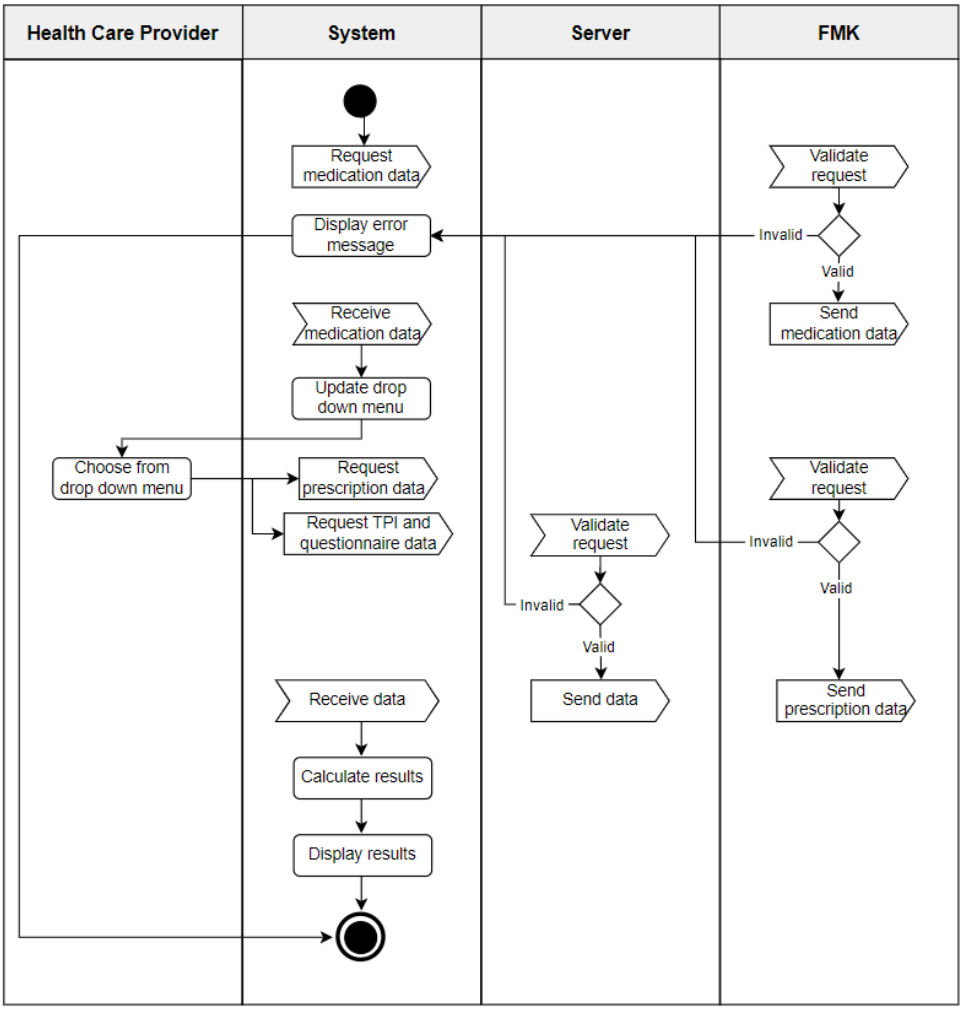


Figure 6.2: The activity diagram illustrates how the use cases *Choose Medication* and *Show Results* are used in the system.

The remaining use cases related to the health care provider are the three *Elaborate* use cases, in which the adherence results are explained. These use cases have similar functionalities, as they all request additional data, in order to present it to the health care provider, when needed. The activity diagrams are therefore combined into one, because the only difference between them is the type of requested data and the name of the third swimlane. This activity diagram is seen in figure D.1.2 in appendix D.1.

The use case diagram presented three main use cases related to the patient, which are elaborated in each their own activity diagram. The *Show Medication Information* use case is explained in the activity diagram in figure 6.3. Initially, the system requests information from FMK in order to update the drop

down menu, from which the health care provider can select a specific medication to assess. When a medication is selected, the system requests data from both the database and FMK, in order to calculate and present the three adherence measures.

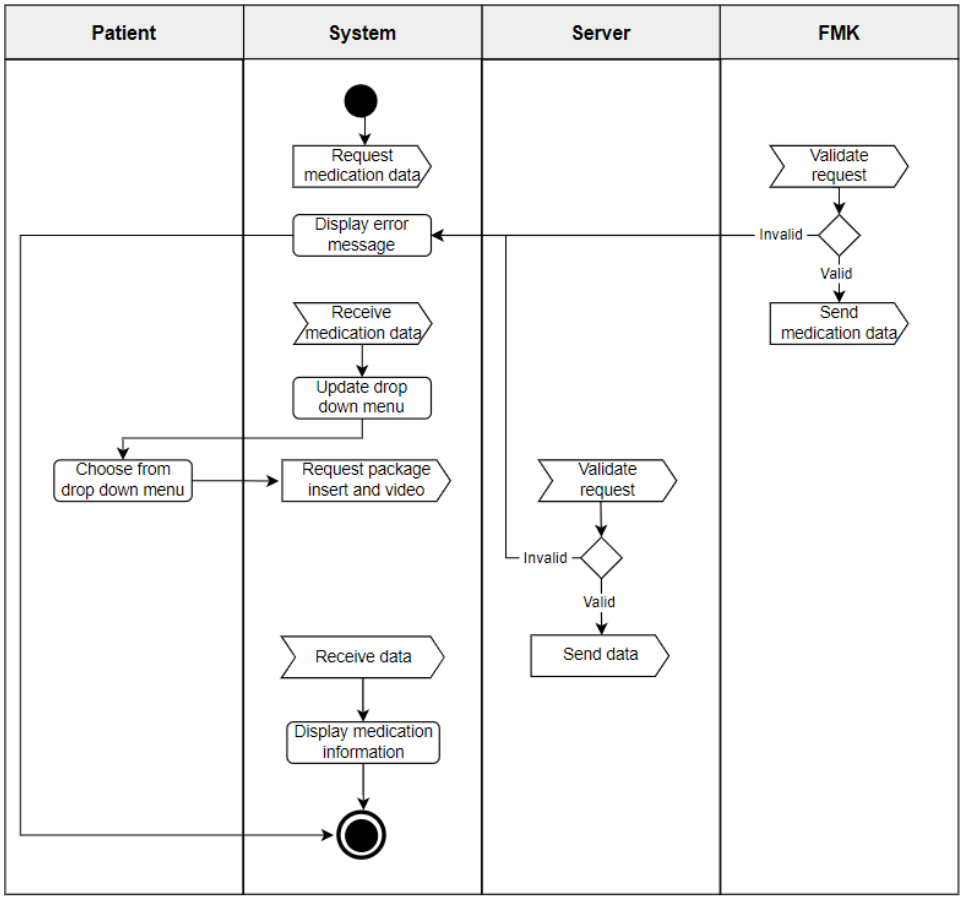


Figure 6.3: The activity diagram related to the *Show Medication Information* use case.

The next activity diagram, seen in figure D.1.3 in appendix D.1, explains how the patient can see their last results from a TPI. This activity diagram is similar to the one in figure D.1.2, where the main objective is to request and retrieve data.

The last activity diagram is related to the *Answer Questionnaire* use case, where the main objective is for the patient to complete the questionnaire, and have the system save these answers. This activity diagram is seen in figure 6.4.

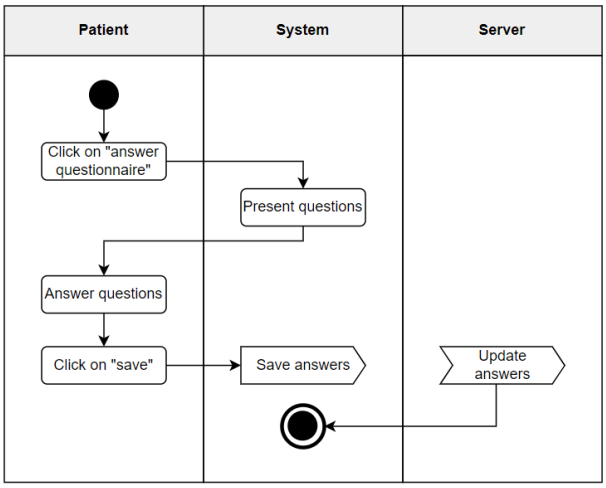


Figure 6.4: The activity diagram related to the use case *Answer Questionnaire.*

6.3 Infrastructure of the Shared Medication Record

As the use cases and activity diagrams demonstrate, there is a need for retrieving data from FMK. Therefore, an analysis of how this can be achieved, and what specific data is necessary is performed.

The FMK is a national digital solution aimed at reducing medication errors by providing an updated record of patients' current medications. The systems of various health care professions have local integrations to FMK in order to retrieve and/or update the medication record. Overall, the FMK consists of four parts; the medication record, dose dispensing, registration of patient data, and prescrition requests. [Sundhedsdatastyrelsen, 2023; FMK-Dokumentation, 2022] For the purpose of this project, focus is on the medication record part.

The structure of the medication record itself is based on three different elements; effectuations, prescriptions (Danish: *recepter*), and drug medications (Danish: *ordinationer*). Typically, a practitioner will add a drug medication to the medicine card. This tells the patient and other health care providers, that the patient is currently treated with the specific medication. In order for the patient to pick up their medication at a pharmacy, a prescription is made, usually through FMK and in connection to the drug medication. The act of a patient receiving the medication is called effectuation. This will typically be when the medication is purchased at the pharmacy. However, effectuations can also occur by receiving medication from the practitioner, without a prescription. Additionally, prescriptions can be made without drug medications, or be connected to them later. This is e.g. the case when making physical prescriptions on paper. The structure of the medicine card is seen in figure 6.5, where the solid lines show the typical

case. [FMK-Dokumentation, 2013]

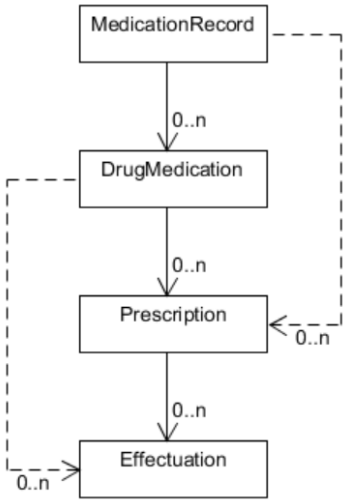


Figure 6.5: The structure of the medication record in terms of drug medications, prescriptions, and effectuations. The solid lines demonstrate the typical case.

6.3.1 Access to the Shared Medication Record

There are more ways of accessing the FMK. The recommended route is through the National Service Platform (NSP), which is a platform providing services and data registries to integrated systems within the health care domain. This allows for local client systems, such as a pharmacy system or a general practitioner system, to access national services, like the FMK, directly from their local systems. [NSP-Dokumentation, 2020b,a] This overall architecture is depicted in figure 6.6, where the providers of data for instance is the Danish Medicines Agency, and the users include e.g. pharmacy systems and FMK [NSP-Dokumentation, 2019].

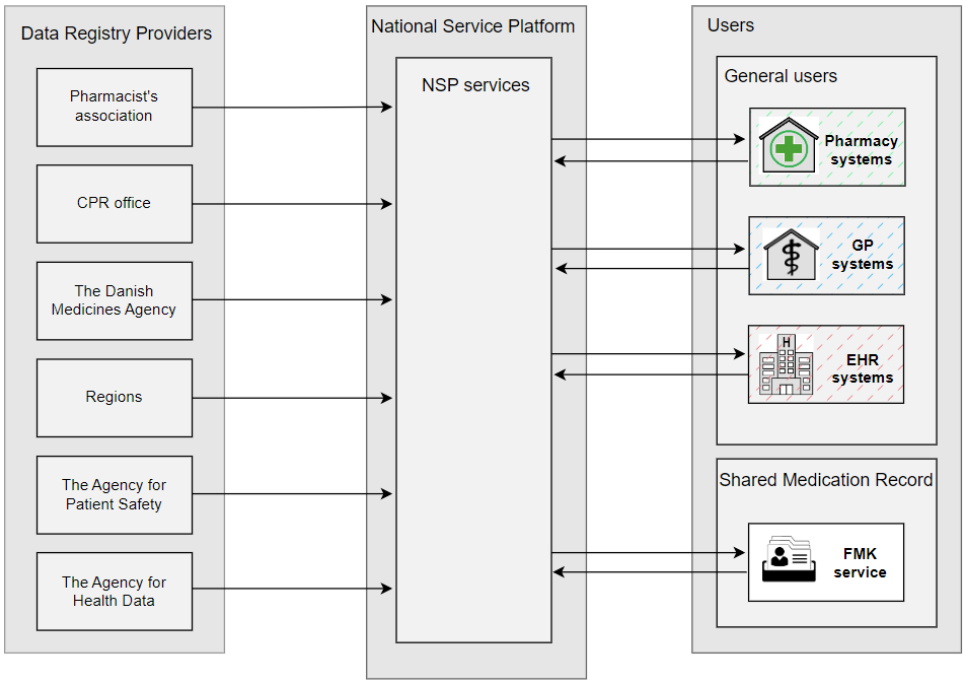


Figure 6.6: NSP architechture. The registries to the right provide data. The users on the right use data in their systems. The communication between providers and users is accomplished through NSP. The figure is modified from NSP-Dokumentation [2019].

In order to use services on NSP, the user system must be capable of gaining access to the National Health Data Network (SDN). This requires the approval of the MedCom organisation and ensures a high level of confidentiality and integrity in the communication. [NSP-Dokumentation, 2020a] SDN is a secure network developed for data communication in the danish health care domain. Connection to SDN can be achieved by different ways, and this infrastructure is used to prevent unauthorized data transmission by either wired connection or encryption. Additionally, data is secured by limiting the access to services based on agreements between users and service providers. This means that service providers can rely on the fact that their data can only be accessed by approved parties. These agreements are managed by the MedCom organisation. [MedCom, 2021]

6.3.2 The Good Web Service by MedCom

MedCom is an organisation that ensures standardized digital communication between actors in the health care domain. One of these standards is called "The good web service" (DGWS), which describes how all systems on SDN can communicate with each other using XML web services. This security model is one of the most essential aspects of the NSP, according to NSP-Dokumentation [2020a]. MedCom [2006]

Web services can be applied in data communication in multiple ways, so in order to ensure interoperability between multiple systems and products in the health care domain, the DGWS provides a definition of how web services in health care should be used. This is called an envelope. The integration between systems using the DGWS is based on the principles of a service oriented architechture (SOA). It is an XML-based SOAP messaging specification protocol, using the internet communication protocol HTTP. This means that communication between client and service provider consists of requests and responses, both consisting of a header and a body. This is illustrated in figures 6.7 and 6.8, respectively.

When communicating on NSP, security is managed by using ID cards embedded in the soap messages. This is handled by use of an identity provider called STS, who issues a signed ID card, which is carried in the header of the soap message. This means that the actual request contains a signed ID card, resulting in the service provider easily verifying the request. [NSP-Dokumentation, 2020a] This is seen in figure 6.7.

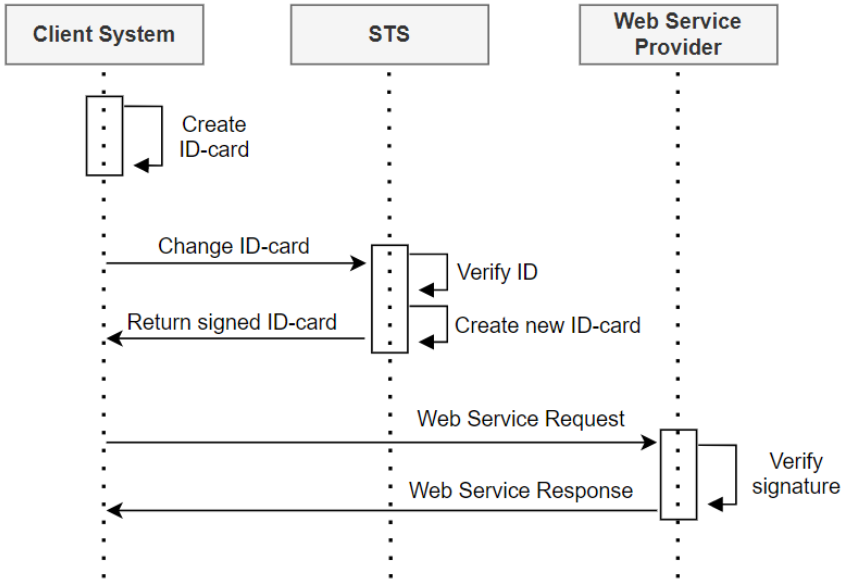
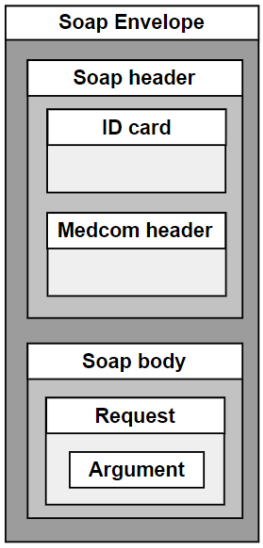


Figure 6.7: The figure illustrates the management of ID cards on NSP. It also shows the request and response nature of the HTTP protocol.

Besides the ID card, the soap header also contains a medcom header, which carries meta data such as the required security level for the specific request. This is seen in figure 6.8, where (a) shows an illustration of a soap message complying with DGWS, and (b) shows the corresponding XML syntax.



(a)

```
<soap:envelope>
    <soap:header>
        <IDcard>
            ...
        <\IDcard>
        <MedCom header>
            ...
        <\MedCom header>
    <\soap:header>
    <soap:body>
        <Request>
            Argument
        <\Request>
    <\soap:body>
<\soap:envelope>
```

(b)

Figure 6.8: The Good Web Service by MedCom defines how SOAP message should be used. This is illustrated in (a). The corresponding XML syntax is seen in (b).

There are a total of five security levels in DGWS, where level 1 requires no user identification. Level 5 on the other hand, signifies the highest level of security by requiring a signature on the entire message, thereby ensuring that no changes were made during transmission. The choice of security level rests on the service provider, and it depends on the type of data in the service, and the level of trust in the identification of the client systems. The most used level is level 2, in which the authentication of the user relies on a username and a password. [NSP-Dokumentation, 2020a; MedCom, 2006]

6.4 Domain Modeling of Inhaler Adherence

In order to model the context in which the inhaler adherence system should be implemented, it is also necessary to define how adherence is calculated.

6.4.1 Medication Possession Rate From Prescription Data

For assessing adherence based on medical records, prescription refill data is chosen in this project. The data is used to calculate the MPR, describing medication adherence based on days' supply. MPR has been found easy to use and calculate, but there is a risk of over-estimating adherence due to early refills [Forbes et al., 2018]. Therefore, a greater period of time is selected for the calculation, as this is assumed to minimize this bias, i.e. if patients always refill prescriptions early, an accumulation of additional

medication doses would probably result in longer intervals between refills in time.

The calculation of MPR is made by identifying the date of every refill made within the last six months. The number of days between first and last refill in this time frame is used as the denominator in the ratio. By identifying the exact item purchased, the number of doses can be calculated, and by dividing this with the patient's individual daily dosage, the number of days' supply is found. This equals the enumerator in the ratio.

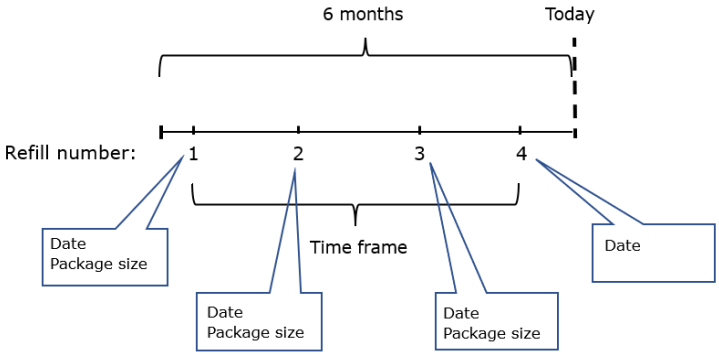


Figure 6.9: Overview of the method for calculating the MPR.

In order to retrieve the required refill data, three potential services are identified. These are: *GetDrugMedication*, *GetMedicineCard*, and *SearchEffectations*. [FMK-Dokumentation, 2022] Requesting the entire medication record from the *GetMedicineCard* service seems excessive, as medication unrelated to asthma treatment will occur using this service. The other two are capable of more specifically returning the required refill data.

The *SearchEffectations* service request uses a patient's CPR-number as an identifier. It has an option to search for a specific date or time frame. Additionally, there are options regarding the type of effectuations to be returned. As explained shown in figure 6.5, effectuations can occur in three ways. The *SearchEffectations* response is therefore capable of containing all three. [FMK-Dokumentation, 2016] The response is illustrated in figure 6.10, where the three types of effectuations are marked as grey. The dotted lines illustrates the two non-typical cases, which in the figure are simplified. The typical case of an effectuation by a medication purchase at a pharmacy is illustrated by the solid lines.

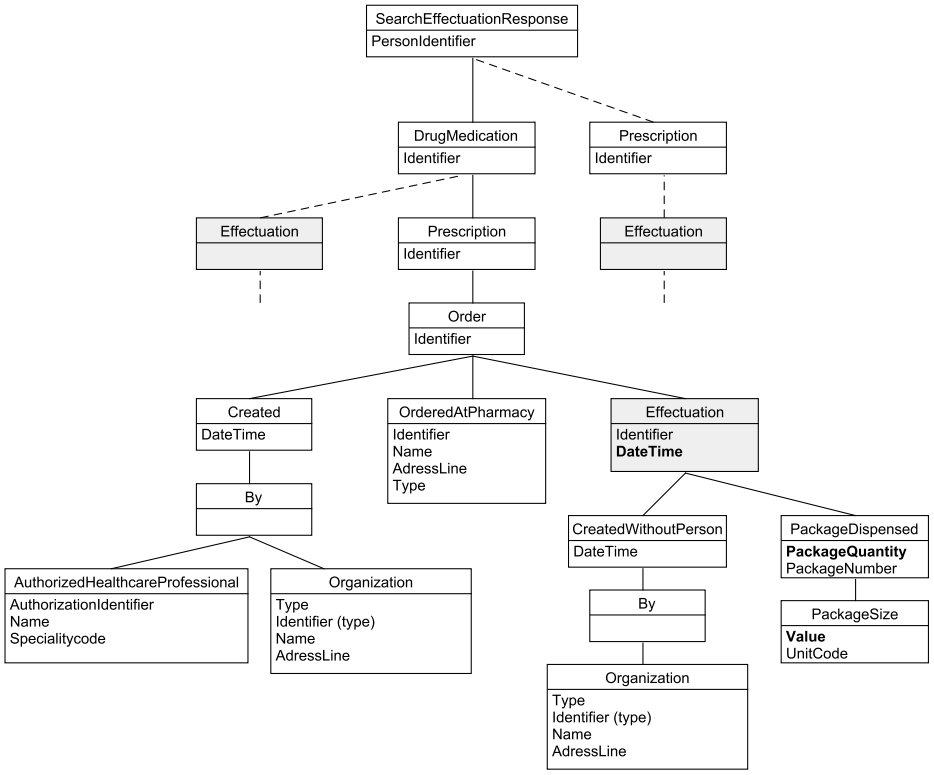


Figure 6.10: Overview of the *SearchEffectuations* response. The three types of effectuations are shown in grey. The illustration is simplified and therefore only explains the typical case of effectuations from presriptions connected to drug medications.

The *SearchEffectations* service can be used to identify dates of effectuations, including specific items' packages numbers and their size, all required for the calculation of MPR. These information are written in bold in figure 6.10 However, the patient's daily dosage is still needed in order to calculate the days' supply for the MPR.

The *GetDrugMedication* service request is capable of retrieving one or more drug medications. The response can contain prescriptions and effectuations as well, depending on parameter settings in the request. In the available XML example found on FMK-Dokumentation [2018], it is not specified what information regarding effectuations can be included in the *GetDrugMedication* response. Therefore, the primary outcome of the service, for the purpose of this project, will be the avarage daily dosage, which is written in bold in figure 6.11, illustrating the *GetDrugMedication* response. Simplifications are shown by a dotted line.

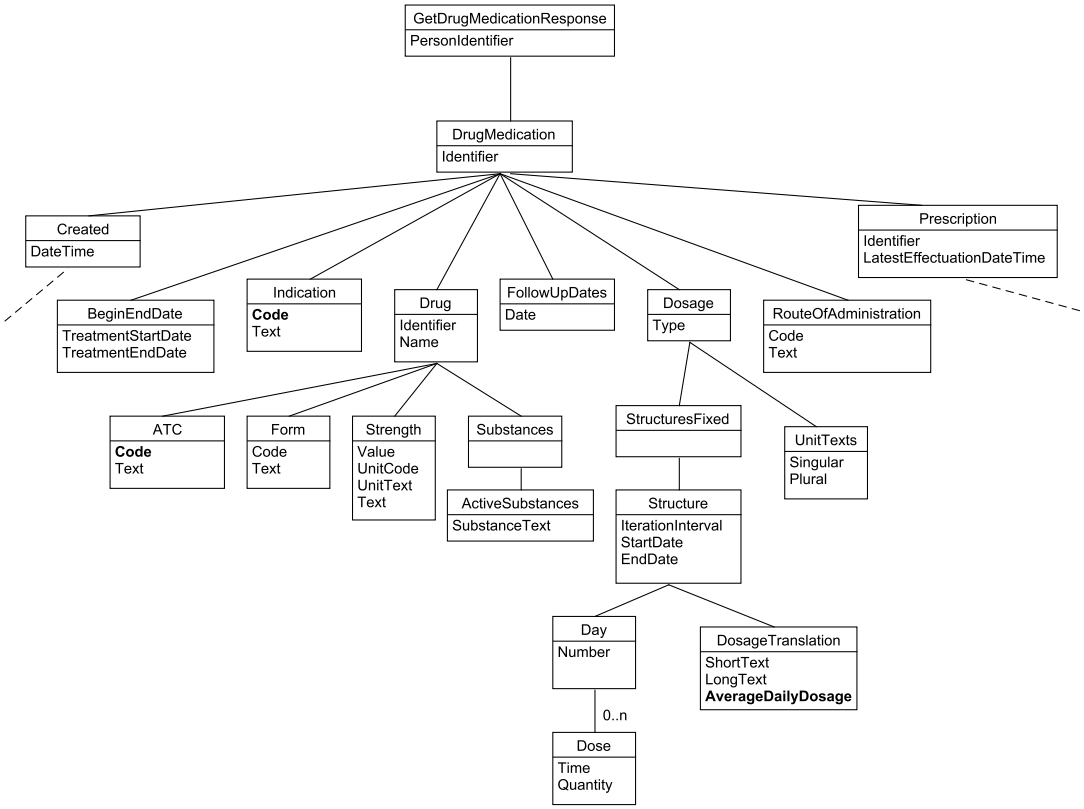


Figure 6.11: Overview of the *GetDrugMedication* response. The dotted lines insinuate simplifications.

By using the two FMK services *SearchEffectuations* and *GetDrugMedication* it is possible to retrieve the average daily dosage of a drug medication, as well as the dates and package sizes of purchased medications. From this, it is possible to calculate days' supply and number of days between first and last effectuation, thereby allowing for the calculation of MPR.

6.4.2 Domain Model

In order to successfully develop and implement a system within the health care domain, it is necessary to properly understand the domain. The proposed system is therefore illustrated in a domain model, seen in figure 6.12. In the model, blue represents the main elements of the proposed system, and green show the selected methods of assessment. The purple classes correspond to the infrastructure of the FMK. Red classes represent the actors, and yellow is the information, available for the patient.

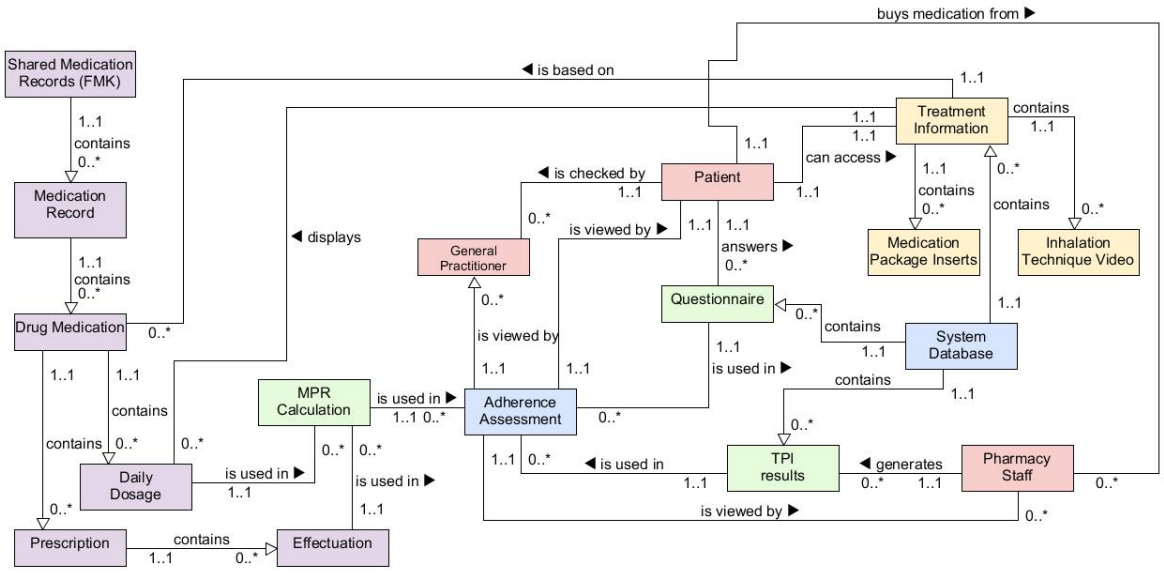


Figure 6.12: Unified Modeling Language Domain Model. The classes are colored in order to group them.

6.5 Prototyping

In order to visualize the functionalities of the system, two prototypes are created. These correspond to the interfaces for the patient and the interfaces for the health care provider, respectively. The prototypes are represented by various graphical interfaces related to use cases identified in figure 6.1. In this section, the interfaces for the two prototypes are presented in subsections, correspondingly.

6.5.1 Health Care Provider Interfaces

The first interface for the health care provider is related to the *Search Patient* use case. This is seen in appendix D.2. When the correct patient is found, the next interface presented in the prototype is the main menu. This is seen in figure 6.13(a). Here, there is a drop down menu in order to select what medication, the adherence assessment should be based on. The menu then presents an overview of the adherence assessment by displaying results of the three methods of assessment. This interface is therefore the main interface of the system. However, if the health care provider wants to examine the results further, each adherence measure can be explained by showing the data used in each measure. This is achieved by clicking the *elaborate* button on the result that needs explaining. If one of the *elaborate* buttons is clicked, the applied data will be presented by displaying either of the interfaces presented in figure 6.13(b), (c), or (d), respectively.

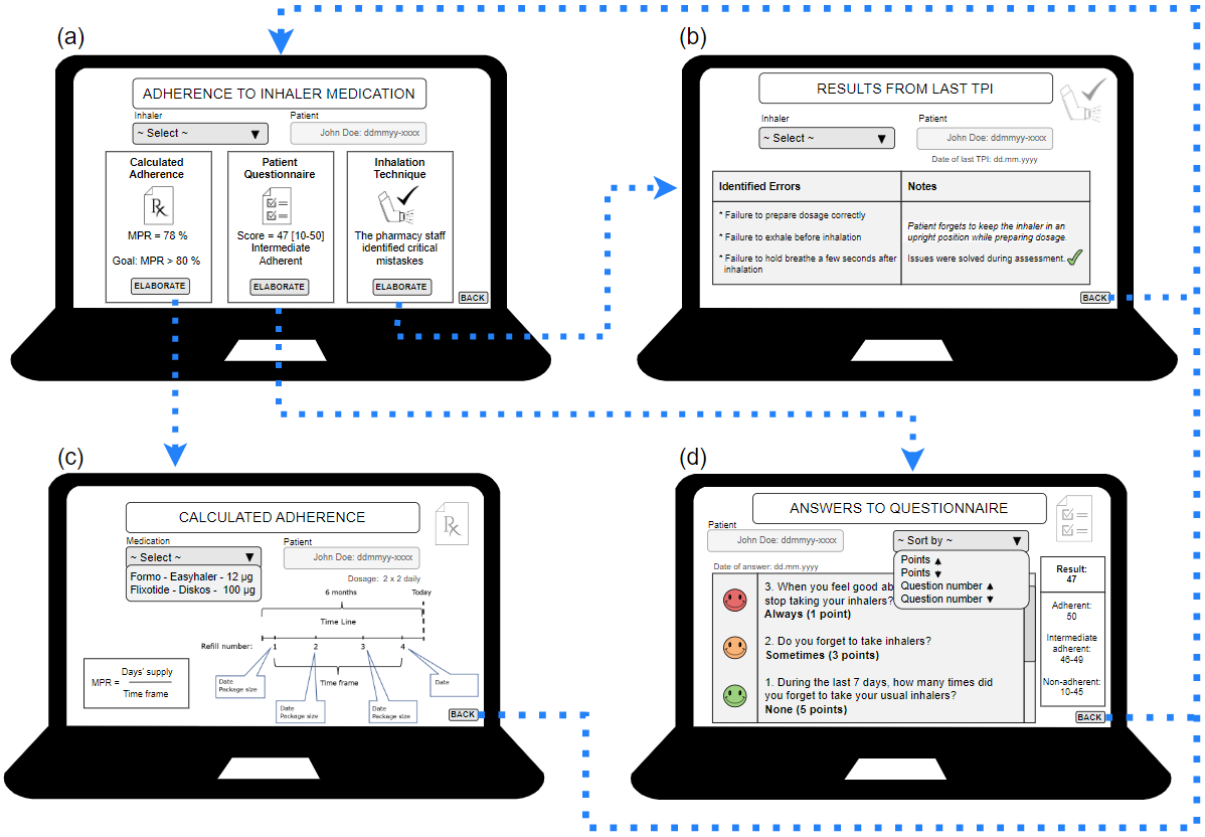


Figure 6.13: The flow between interfaces in the prototype for the system used by the health care providers. The arrows illustrate the flow between the interfaces.

In the three interfaces concerning the *Elaborate* use cases, it is always possible to identify the patient in a light grey bar. The *Calculated Adherence* and the *Results From Last TPI* interfaces furthermore have the same drop down menu as the main interface. This is due to the fact that these adherence measures are calculated using medication specific data. However, the *Answers To Questionnaire* interface does not have this option, because the questionnaire itself is not medication specific.

6.5.2 Patient Interfaces

In the prototype for the patient system, the main menu is presented to the patient, when they have successfully logged in. This is seen in figure 6.14(a). From here, the patient has three options; questionnaire (b), medication information (c), or inhalation technique (d), respectively.

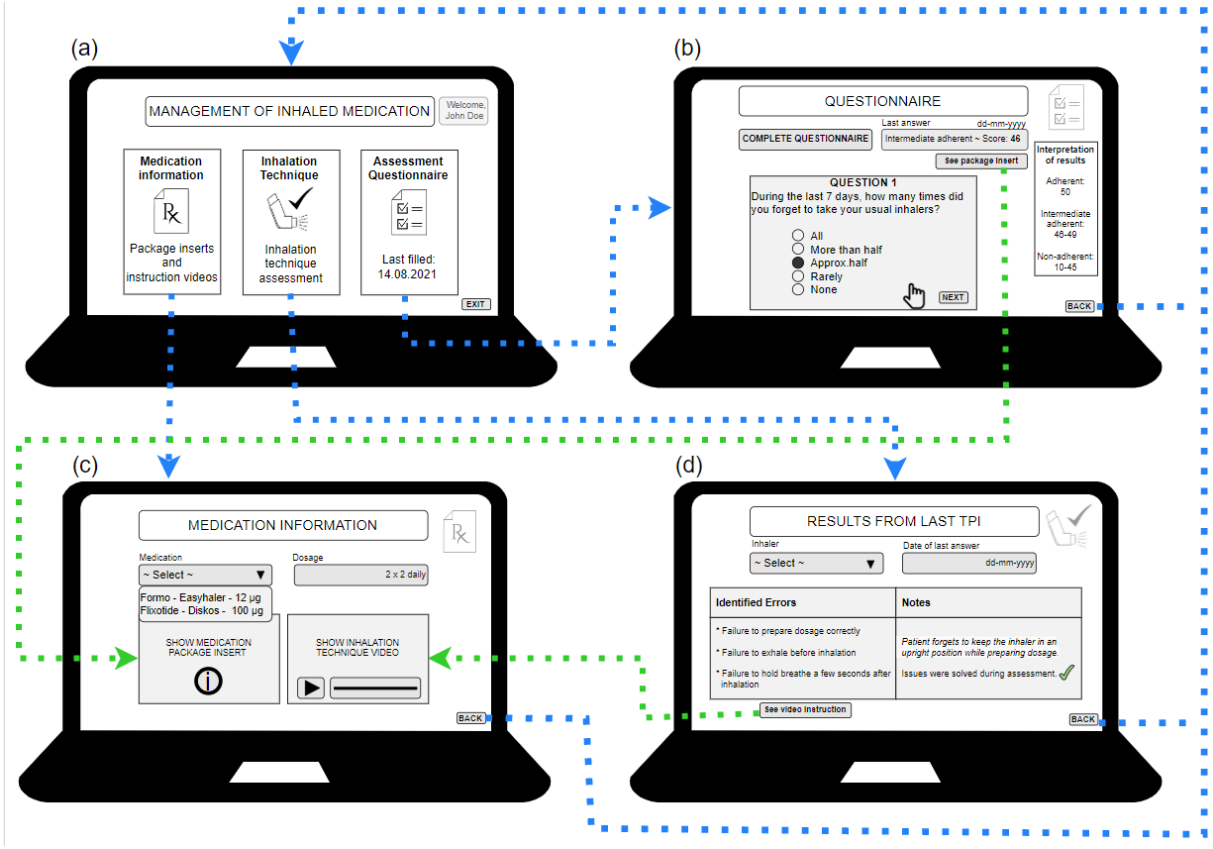


Figure 6.14: The flow between interfaces in the prototype for the system aimed for the patient. The arrows illustrate the flow between interfaces. The green arrows specifically illustrate shortcuts.

In the *Medication Information* interface, figure 6.14(c), the patient must select what medication, they want to see. When a specific medication is selected, the corresponding daily dosage is shown. There are two main options in this interface; showing the medication package insert or showing an instructional video of how to correctly take the medication. These elements should help support the patients adherence by supplying knowledge regarding treatment. The second option from the main menu is to access the *Answer Questionnaire* interface, figure 6.14(c). This interface provides the opportunity for the patient to fill out the questionnaire. Additionally, it shows the date of the last time the questionnaire was answered.

The last interface in the prototype is the *Last Results From TPI* interface, figure 6.14(d). Here the same drop down menu as in the *Medication Information* interface provides the opportunity to view results from multiple inhalers.

A major difference between the flows of the interfaces in the two prototypes is that there are two shortcuts

in the patient system. These are illustrated by the green lines in figure 6.14. They are intended to support the patient, e.g. by allowing quick access to inhalation technique videos when viewing results from the TPI.

In this project, the two prototypes of the system are implemented in a PowerPoint slideshow with embedded links, allowing for conducting usability testing on the prototypes, and thereby assessing the system's potential in clinical practice.

7 | System Evaluation

For the evaluation of the system, pharmacy staff from the pharmacy Aalborghus Apotek is asked to explore and evaluate the prototypes of the system. This consists of using the the System Usability Scale (SUS) and providing qualitative statements during the usability testing. One employee is furthermore used in a heuristic evaluation of the system, alongside a master student from Biomedical Engineering and Informatics at Aalborg University. This student is considered to be a technical peer to the author of this report. Both pharmacy staff and technical peer evaluates the entire system, which means that interfaces for both patients and health care providers are evaluated from a clinical viewpoint from the pharmacy, and a technical viewpoint from the peer. As a side note, the technical peer is also a potential user of the system, due to a diagnosis of asthma and a prescription for ICS.

7.1 Results from the System Usability Scale

The SUS score is based on the assessment of the prototype for the health care providers. Each respondent has used the prototype for up to 5 minutes before ranking the 10 statements on the questionnaire on a five step likert scale ranging from "strongly disagree" to "strongly agree". All participants were able to solve every task from the list seen in appendix E.1, thus ensuring that all functionalities in the system is tried before the evaluation.

By using the replies on the likert scale, which can be seen in appendix E.2, a usability score is calculated for each respondent, in accordance to Brooke [1995], yielding scores in the range of 0 to 100. The results are seen in table 7.1, where they range from 72.5 to 100, with an a average SUS score of 89.58.

Table 7.1: System Usability Scale results presented in a table, demonstrating both the individual scores and the average score.

Respondent	a	b	c	d	e	f	Average
Score	85	72.5	92.5	95	92.5	100	**89.58**

7.2 Results of Usability Test and Heuristic Evaluation

The qualitative usability testing is based on statements made by the participants during their exploration of the system. As the participants are pharmacy staff, their main focus is on the interface for the health care provider. However, they are also exploring the patients' interfaces, in order to understand the entire

system. The statements are paraphrased and analyzed in terms of which of the 10 different heuristics are relevant for the specific statement. This allows for using the statements to support the findings in the heuristic evaluation. The statements and related heuristics are seen in appendix E.3.

The heuristic evaluation is presented in appendix E.4, where each heuristic is listed and presents findings made by the pharmacy staff member and the technical peer. Each heuristic is used to formulate a goal. Based on an analysis of the evaluators findings, supported by the qualitative statements, each goal is assessed. The results of this process is presented in table 7.2.

Table 7.2: Results of the heuristic evaluation supported by statements from the qualitative usability test.

Heuristic	**Goal**	**Result**
#1	There should be feedback from the system, so the user always knows, what is happening.	Partly achieved (✓)
	Explanation: For the current prototypes, there is enough feedback in the form of error messages, but additional feedback from the system should be added, as the development progresses. This could e.g be an indicator of processing time.	
#2	The system should fit into the current workflow and use a language the users can easily understand.	Partly achieved (✓)
	Explanation: The system was primarily tested by pharmacy staff, who seems to agree on the system's applicability in the current workflow. The functionalities of calculated adherence and digitized TPI results would help pharmacy staff in supporting patients improve their adherence. Some language updates could be relevant for both interfaces, or solved by creating help options. This could for the patients include small images or descriptions in the drop down menus, as they might not recognize the names of their inhalers.	
#3	The user should always be able to exit pages in the system in a quick way.	Partly achieved (✓)
	Explanation: Neither evaluators expressed difficulties in identifying or using the exit buttons. The remaining staff members expressed concerns regarding where the back button lead the user, when using the shortcut.	

#4	The system should use consistent language and visual design, in an intuitive way.	Partly achieved (✓)
	Explanation: The evaluators found the system design to be consistent. However, the design of the MPR overview is more complex. The two evaluators find it acceptable, but according to the other pharmacy staff members, this page should be simplified. Additional explanations on the MPR page could help the understanding of the term, so these should be integrated in a subtle way to help the users, e.g. as a mouseover.	
#5	The system should prevent errors.	Not achieved %
	Explanation: The technical peer identified potential errors in the patient interface concerning the questionnaire. It is almost too simple to answer it and create multiple answered versions. Maybe some sort of notification system should be present. The pharmacy evaluator did not identify any potential issues not manageable through error messages. Both evaluator agree that the error messages should be updated so they clearly explain how to prevent the error again, potentially with a highlighting function to pinpoint where the error occurred.	
#6	The system should support the user by displaying information rather than relying on the user's memory.	Not achieved %
	Explanation: The shortcuts to medication information in the patient interface is not found to be intuitive enough, even though the functionality is relevant. It could be made shorter by eliminating the drop down menu, as the specific medication is already chosen in the previous menu, from where the shortcut is taken. By minimizing the shortcut, it could reduce the need for relying on the patient's recall. Additionally, previous results should be accessible through a list.	
#7	The system should provide shortcuts and be easy to use.	Partly achieved (✓)
	Explanation: For the current prototype, the evaluators found it easy to use. The technical peer would in future development appreciate key pad shortcuts. Technically challenged users would probably find the system unnecessary, cumbersome, or difficult, and therefore refrain from using the system. This should be accounted for in future design iterations.	

#8	The systems design should not contain irrelevant information.	Not achieved %
	Explanation: Both evaluators think that the system design in general is minimalist, precise, and simple. The pharmacy evaluator found the system to be designed by someone with a profound understanding of the needs and workflow in the every day workflow in a pharmacy.. The technical peer found that the MPR overview should be redesigned to make it more simple, which was supported by remaining staff members. The technical peer did sometimes have difficulties distinguishing between buttons and headlines.	
#9	Error messages should be precise and constructive.	Not achieved %
	Explanation: Both evaluators found room for improvement in the error messages. This could e.g. be from highlighting where on the page, the error occurred. Another example is the wording of the messages; An error message should not start with saying "Error!", as it might be found harsh and thereby discourage technically challenged users from further use.	
#10	The system should provide additional help for the users.	Not achieved %
	Explanation: In general, both evaluators found the system to be simple and intuitive enough to not have a need for additional help options. However, the pharmacy evaluator suspects some of her colleagues to prefer additional help, which is also substantiated by the statements from the other staff members. The pharmacy evaluator also thinks that more help options could be relevant in the patient interface. The current error messages should be updated in a way that is helpful for the users.	

The results in table 7.2 show that in the heuristic evaluation of the system, five goals is partly achieved, and five goals are not achieved.

8 | Discussion

This study aimed to investigate how inhaler technique information could be systematically incorporated into a system, capable of supporting adherence in asthma patients. This was done by developing a prototype of a system with user interfaces for patients and multiple types of health care providers. The prototypes were subjected to various evaluation methods, in order to determine the system's usability in a clinical setting. The evaluation of the system was performed by six pharmacy staff members and a technical peer, and it showed a SUS score of 89.58, and five out of ten heuristic goals to be partly achieved.

In this chapter, the framework from Hevner et al. [2004] and the characteristics of the health care domain from Garde and Knaup [2006] are both used to discuss elements in the current project. Overall, the discussion topics in this chapter revolve around the relevance and limitations of the study's results, system usability, supporting patients' adherence, the complexity of health care information, and the applicability of medication adherence metrics in clinical practice.

Initially, the discussion focuses on the trade-off between relevance and rigor in the current study, based on Hevner et al. [2004]. The variability in the domain substantiates the need for using abstractions in order to simplify the environment, but it is acknowledged, that this limits the generalizability of the results.

The next point of discussion relates to the System Usability Scale (SUS) score obtained from the evaluation by pharmacy staff. The high SUS score indicates that users found the system very usable. However, the interpretation of this numerical score is difficult and therefore considers the results of the heuristic evaluation, which identifies usability problems to be addressed in future development.

The aim of the inhaler adherence system is to support the adherence levels of asthma patients. Therefore, this ability is discussed in accordance to the principles of persuasive technology from Fogg [2009]. The perspectives of pharmacy staff are used to consider the system's potential impact on patients' adherence, but the absence of patient involvement reduces the credibility of the findings.

The discussion furthermore highlights the complexity of retrieving information from the health care domain, specifically in relation to the task of calculating MPR. The multiple types of clinical information and the need for interoperability are addressed, emphasizing the complexity of sharing health information.

The last point of discussion presents the concept of clinical knowledge and its constant evolution and complexity, as presented in Garde and Knaup [2006]. In doing this, the applicability of MPR in clinical

practice is discussed, revealing the need for knowledge in depth to understand it's applicability and limitations, including the impact of false calculations. This underlines the importance of using the MPR as an indicator, instead of an exact measure.

Relevance Versus Rigor

The task of solving the issue of medication adherence in asthma patients, through the development of a system, is great and complex. This is substantiated by both Garde and Knaup [2006] and Hevner et al. [2004] who states that software development in health care is specifically complex and requires significant domain knowledge. In this current study, domain knowledge was collected in order to understand the specific context, in which the inhaler adherence system should be implemented. However, as this included the perspectives of patients and three types of health care providers, the user needs were varying due to different perspectives on patient care. This necessitated the need to use abstraction in order to simplify the environment. This was e.g. done by omitting the hospital perspective early in the development, and by limiting the view points of the general practitioner by focusing on patients and pharmacy staff as actors. This reduced the relevance of the system in terms of applicability in the actual environment. Additionally, this relates to the characteristic from Garde and Knaup [2006] which state that the level of variability in the health care domain is extremely high. Each patient has individual symptoms and severity of their asthma, as well as individual medication regiments and potential barriers reducing their adherence levels. In order to account for all this variability, it is necessary to apply abstractions in the development.

In this current study, it would be desirable to conclude something e.g. regarding the use of MPR in clinical practice or the inhaler adherence system's ability to support the adherence levels of patients. However, the abstractions in terms of relevance limits the generalizability of the results, because only the viewpoints of the pharmacy staff is included in the users' evaluation. The methodology does have some rigor, as the approach was similar to that of Garde and Knaup [2006]. However, the qualitative nature of the evaluation statements points to high requirements for the data analysis, thereby encouraging scrutiny, and potentially reducing the level of rigor. This means that the results in this current study can be used as an indicator for further research, but they are not capable of providing generalizable results.

System Usability Scale Score and Results of Heuristic Evaluation

The SUS score found by the six pharmacy staff members was 89.58 in average. This is rather high on a scale ranging from 0 to 100, and it thus indicates that the users found the system very usable. According to Bangor et al. [2008], the numerical value of a SUS score is very useful in comparisons, e.g. between iterations, but a valid assessment of what an exact numerical score actually means, is difficult. Based on

data from multiple surveys, seven categories have been proposed to explain the SUS scores. Based on the inhaler adherence system's SUS score, it is placed in the high end of the "excellent" category. This does, however, not guarantee acceptability in the environment. [Bangor et al., 2008] This seems to comply with the fact that the heuristic evaluation identified some usability problems to be considered in future development. The results of the heuristic evaluation, showed half of the goals to be partly achieved. These were goals concerning feedback from the system, application of exit-buttons and shortcuts, compatibility with current workflow, and consistency.

An aspect to consider is the stage of the prototypes and it's impact on the results. According to Walker et al. [2002] neither the fidelity level nor the medium of a prototype influences the amount or severity of identified usability problems. The current prototypes used for the evaluation are considered to be low level high fidelity prototypes. This means that the fidelity level is somewhere in between high and low, because the prototypes are developed based on a rather thorough analysis, yet still has plenty of room and potential to improve and change according to the usability testing. However, as this is the first iteration of the prototypes, the results should be considered preliminary. This is also in alignment with Hevner et al. [2004], who states that the feedback from the evaluation provides more insights into the problem and thereby improves the next iteration of the prototype. In this case, it makes sense that the heuristic evaluation uncovered several usability problems and goals that were not achieved, which could aid in future development.

Support of Patients' Adherence Levels

The aim of the inhaler adherence system, developed in this project, is to support the adherence level in patients with asthma, which requires their medication taking behavior to change. This means that the system could be classified as a persuasive technology, aiming to change either thoughts or behaviors of it's users [Fogg, 2009]. In this case, specifically those of the patients. In Fogg [2009] it is found that the most successful persuasive technologies start small and gradually expand over time, when success has been achieved. This means that major behavioral changes are inadvisable in the first iterations of a persuasive system, because the risk of failure would be high. This approach is in alignment with Hevner et al. [2004], who states that the development of information systems in health care is an iterative process between development and evaluation.

Due to the fact that no patients took part in the evaluation, the pharmacy staff was used to determine the systems ability to support patients' adherence. This naturally reduces the credibility, but interesting aspects still emerged. For instance, it was stated that the inhaler adherence system potentially could assist pharmacy staff in identifying patients with low adherence levels, because of the natural fit between

the system and the current workflow. This could benefit the patients, because the increased awareness of potentially low adherence levels could result in increase medical guidance, provided by pharmacy staff, in the attempt to support adherence.
Another topic that several participants presented during usability testing and heuristic evaluation was concerns on behalf of technically challenged users, who might find the system complicated and difficult. This included (typically older) colleagues, but especially patients. It underlines the need for updating the error messages and adding additional help functions in the system.
Since patients were not involved in the evaluation, and pharmacy staff found the system "excellently" usable, it is difficult to determine the usability of the system from the perspectives of these technically challenged users. The system could therefore potentially benefit from applying the steps from Fogg [2009], by focusing on technically challenged users as the receptive audience in a specific increment of the system.

The Complexity of Health Care Information

When comparing the characteristics from Garde and Knaup [2006] with the current study, it explains why it is a complicated task to retrieve information from FMK in order to calculate MPR. Clinical information is a complex term, as it includes various types of information [Garde and Knaup, 2006]. This is evident in the two responses from FMK, presented in figures 6.10 and 6.11. This means that when trying to "simply" identify the dates and package sizes of effectuations related to a specific drug medication, it requires two asynchronous request that are mutually dependent. Additionally, Garde and Knaup [2006] states that health information is more complex to share than information in other domains. This is evident in the current study by the multiple actors involved, requiring compatibility with multiple systems. This concerns both technical and semantic interoperability. The technical interoperability should be achieved by creating the system in accordance to DGWS from MedCom [MedCom, 2006].

Medication Possession Ratio in Clinical Practice

Health knowledge is another term presented in a health care specific characteristic from Garde and Knaup [2006] as constantly changing and requiring great knowledge both in bredth, depth, and complexity. For instance, in clinical practice the MPR term constitutes new knowledge, and therefore could exemplify knowledge in breadth. The fact that MPR is unknown in clinical practice also means, that the health care professionals probably do not have any prior knowledge regarding the term and it's applicability in clinical practice. Therefore, if the term is used without any explanation or caution, the calculated adherence may be used as a goal (or truth), as opposed to an indicator, which is the case.
In the statements from the evaluators, most pharmacy staff members expressed the need for an explanation of the MPR term. This could be seen as a need for knowledge in depth, because the added details

from the explanation could assist the pharmacy staff in using the MPR. For instance, the MPR is known to be sensitive to falsely increased MPR, as a result of early refills [Forbes et al., 2018]. Early refills are regularly occurring in pharmacy practice due to e.g. misplaced medications. In the case of a falsely increased MPR, the pharmacy staff needs to be vigilant in order to identify low adherence levels, because the MPR would not indicate it. On the other hand, falsely low MPR could be caused by a pileup of medications, reducing the frequency of medication purchase by the patient. This could be the case, if misplaced medications were found, or if a dosage was decreased from e.g. twice daily to once. This would falsely insinuate low adherence, and would therefore probably be detected by the pharmacy staff using the system.
Knowledge in complexity is concerned with the relationships between elements in the domain, and this could e.g. be the case, if it was found that functionalities from the inhaler adherence system could be useful in relation to other diseases. This was mentioned by the pharmacy evaluator as a potential for future implementations, because several medications are sensitive to adherence issue.

8.1 Conclusion

In conclusion, this study presented the inhaler adherence system, which incorporates results from the inhalation technique assessment performed at the pharmacy. The aim was to investigate, if this system was capable of supporting adherence in asthma patients. Results showed indications of a high level of usability, due to the match between system and workflow of pharmacy staff. This potentially aids the pharmacy staff in identifying patients with low adherence levels, thereby enabling the possibility of supporting their adherence levels by increased pharmacological guidance.
However, the inhaler adherence system used MPR as an adherence measure, and due to it's limitations, it is important for pharmacy staff to understand the term and be vigilant, keeping in mind that true adherence levels can differ from MPR.

The trade-off between rigor and relevance resulted in the initial prototypes being evaluated by pharmacy staff. The lack of patient perspectives in the evaluation, reduced the generalizability of the results. However, the results of the evaluation provided valuable insights for future iterations of the system, incorporating the patients' perspectives and recognizing that major behavioral changes should be introduced gradually over time to minimize the risk of failure.

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A | Informal Interviews

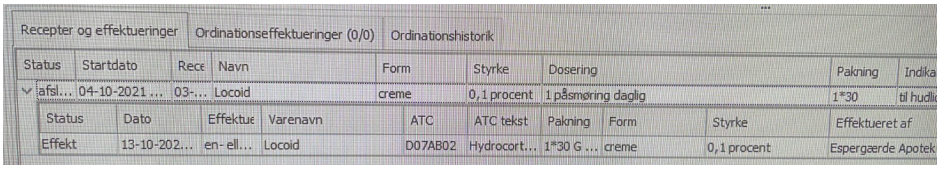
Opsamling på informationerne:

- Lægepraksis
    - Der findes flere forskellige LPS, men specifikt i XMO er det muligt at se de ordinationer, som er lavet i det konkrete lægehus - og herunder de enkelte recepter. Såfremt der er lavet ordinationer fra andre, så fremgår det ikke i det lokale system. Dette skal derfor findes på FMK.
    - Efter hendes eget udsagn er det ikke umiddelbart noget, som de ansatte sygeplejersker bruger - altså tjekker op på effektueringerne.
    - Den anden farmakonom fortæller, at de kigger på tidsintervallet for receptudstedelser (men altså ikke tjekker effektueringerne) i deres lokale system. Derudover fremhæver hun, at der er en løs tilgang til stort lægemiddelforbrug sammenlignet med hendes oplevelser fra privatapotek.
    - En tredje farmakonom fortæller, at i systemerne XMO og Clinea er det ret nemt at se "forventet opbrugt" dato, såfremt en dosering er angivet med fast interval. Derudover kan ordinationer og effektueringer relativt hurtigt findes. Sekretærerne i almen praksis tjekkede altid intervaller inden nye recepter blev lavet.
    - I WinPLC er det svært at følge ordination/effektuering. Systemet kan godt beregne forventet opbrugt dato. Hendes kollega understøtter hendes syn på, at der kun laves tjek af effektueringer el.lign, hvis symptomer ikke hænger sammen med udsagn ift. en behandlingsplan.
- EPJ
    - Umiddelbart er der ingen lokal mulighed for at tjekke op på det, så ved fx indlæggelser tjekker de op på afhentningerne ved at se på FMK, og så laver de medicinanamnese på baggrund af dette og samtale med patienten.

Udgangspunktet for min besked:

Jeg er ved at udvikle en prototype på et system, der skal gøre det lettere for både læger og apotekspersonale at vurdere adherence til inhalationsmedicin. Det betyder, at jeg vil samle data fra TPI'erne fra apo + digitale spørgeskemasvar fra patienter + FMK data der skal vise forholdet imellem afhentning og dosering.. Jeg har i den forbindelse brug for at vide lidt om, hvordan adherence evt kan vurderes i et lokalt EPJ system - eller i et lægepraksissystem (LPS).
På apotekerne kigger vi ofte på udleveringsintervaller eller ser på, hvor ofte der er afhentet medicin. Dette er naturligvis kun en god løsning, hvis der afhentes medicin på samme apotek. Udleveringsintervallet kan give et indtryk af hvor compliente patienterne er, uden at det afhænger af dialogen, fordi et stort interval kan indikere, at der tages mindre medicin end ordineret. Mit spørgsmål er nu: er der en form for pendant til dette i jeres lokale EPJ / LPS? Fx en form for historik over hvor ofte der er udskrevet recept på en given lægemiddelordination?
Jeg ved også, at denne slags data ligger tilgængeligt inde på FMK, men bruges FMK til den slags information i klinisk praksis?

Farmakonom ansat i lægepraksis



- Vi bruger XMO der kan man se det.
  I virkeligheden er det vel integreret FMK.
  Tror ikke mine sygeplejerske kolleger bruger det. Men jeg gør, da det jo ligger i vores opdragelse.

- Ja, det er det nemlig.
  Men jeg vil gerne argumentere for, at man vil bruge data fra sit lokale system fremfor at åbne FMK udenom systemet
  Ved du, om der er en slags pop-up hvis man fx forsøger at bestille noget for tidligt? Altså som en slags indikation på overforbrug?

- Man får ikke pop up.
  Det kunne være smart. Men tror der vil ske for mange fejl alligevel hvis det er lokalt, da vagtlæge mv ikke kan se det.

- Ja, jeg er helt enig 🙂 Men selvom det ligger lokalt, så opdateres det alligevel på FMK. Så det er mest for at understrege, at selvom data ligger der, så vil de fleste nok være tilbøjelige til at tjekke i deres lokale system først, fordi det oftest er hurtigere. Og endnu oftere vil man nok udelukkende vurdere det på baggrund af dialogen med patienten - det er bare meget lidt objektivt. Så derfor tænker jeg, at man kan systematisere det ved at trækkke data fra FMK og vise det samtidig med et standardiseret spørgeskema, som pt selv udfylder - samt data fra den seneste TPI, der er udfyldt på apoteket 🙂 Så er det altid præcis det samme, som man som behandler får præsenteret, når man kigger på adherence for sine inhalations-patienter 🙂

- På billedet er det fra en recept som er oprettet hos jer, ikke? Vil i kunne se recepter lavet fra andre, når nu ordinationer netop håndteres via FMK?

- Ja det er vores ordination. Nej vi kan ikke se hvad andre har lavet.
  Tak 🙂

Fra farmakonom ansat i privat praksis

- I vores praksis går patienter til kontrol enten hvert halve eller hele år.
  Vi kigger primært på interval for udskrivelse af medicinen, svarende til antal udleveringer på apoteket.

- Er det noget i kigger på i jeres eget system? Eller går i på FMK og ser det?

- Ikke som sådan i forhold til medicinefterlevelsen. Faktisk…

- Okay.. Men når i så udskriver lægemidler, tjekker i så hvornår i sidst har lavet en recept på det?

- Ja det gør vi 🙂 men på apoteket oplevede jeg fokus på højt forbrug af anfald. Hvor jeg i praksis oplever at man er ret large med stort forbrug

- Det er en spændende pointe 😀 Tusind tak for hjælpen og input

Fra farmakonom ansat på sygehus

- Altså helt overordnet så bruges EPJ Syd til at håndtere patienternes medicin under indlæggelse. Er det under indlæggelsen du tænker på, om patienterne er compliente?
  Vi tjekker op patienternes afhentninger i FMK ved indlæggelse, samt oftes har vi en samtale med patienten. Altså laver vi en medicinanamnese.

- Nej, jeg tænkte mere på situationer, hvor sygehuset står for ordination af lægemidler til ikke-indlagte patienter. Det var tænkt som en pendant til at apoteket får en fornemmelse af compliance baseret på udleveringsintervaller.

- Jeg vender det lige med vores EPJ ansvarlige her i løbet af ugen, så får du et helt rigtigt svar
  Hej Sofie, vi har lige snakket om det her på arbejdet. Vi har ikke noget smart i vores EPJ til det, vi bruger FMK og kigger efter udleveringsintervallerne som i primærsektoren.

- Super 😀 Tusind tak for hjælpen

Fra farmakonom der har været i privat almen praksis og hos privat børnelæge

- Hej Sofie og beklager mit sene svar. Har kendskab til lægesystemerne XMO, Clinea og arbejder i øjeblikket i en klinik der bruger WinPLC.
  Det var i almen lægepraksis, at vi brugte XMO og Clinea og i begge systemer var det meget nemt at se i lægeprogrammet, hvornår en recept forventes at være opbrugt (hvis den altså var udfyldt korrekt med en dosering der gjorde at systemet selv kunne regne forventet slutdato ud) og også hvornår de havde afhentet medicinen på apoteket og hvor mange pakninger de havde afhentet.
  Når patienterne bestilte medicin hos os sekretærer, så fulgte vi altid op på om udleveringsintervallerne blev overholdt og ellers tog vi en snak med patienterne om det.
- Jeg ved, at der var fokus på at lægerne og sygeplejerske gjorde det samme, når patienterne var til kontrol ved dem og der blev altid tilstræbt, at de som udgangspunkt skulle sørge for, at der var gyldige recepter der dækkede perioden indtil patientens næste kontroltid.
- Nu er jeg ved en privatpraktiserende børnelæge og der bruger vi WinPLC og i dette system er det desværre slet ikke lige så nemt at følge ordinationer/udleveringerne. Systemet kan godt også selv regne en forventet "opbrugtsdato" ud, men da mange af vores patienter får medicin til brug efter behov eller med svingende dosering (Movicol, astmamedicin, allergimedicin i form af øjendråber, næsespray og tabletter, steroidcremer til eksem, modermælkserstatninger, ernæringsdrikke m.v), så kan systemet ofte ikke automatisk regne ud hvornår en recept forventes opbrugt. Og i disse tilfælde, så er det faktisk det bøvlet at gå ind og se, hvornår der er afhentet medicin og om der bliver brugt/hentet for meget eller for lidt medicin.
- Har lige talt med en af sygeplejerskerne og hun bekræfter, at det især kun er hvis patienternes symptomer/historie ikke passer sammen med den behandlingsplan der er lagt, at hun så begynder at prøve at finde ud af hvordan medicinen reelt er blevet bestilt/hentet. Jeg ved, at børnelægen følger mere op på det og det er jo også hende der i sidste ende skal godkende de recepter vi andre laver. Men personligt så ville jeg ønske en bedre oversigt i WinPLC.
- Som du skriver, så kan vi også altid gå på FMK-online og denne mulighed benyttes også nogle gange.
- Ved ikke om disse svar kan bruges, men ellers så er du meget velkommen til at skrive for en uddybning😊

- Det er en helt perfekt svar! Tusind tusind tak for så grundig en forklaring af det. Det er virkelig dejligt! 😃 😃

- Det var så lidt og kommer du i tanke om mere, så skriver du bare👍😊

- Tusind tak 🙂

B | Inhalation Technique Assessment

Formular: Tjek på inhalation

Dato: _____ Initialer: _____

Inhalator: _____ Spacer: _____

Ydelsen er gennemført for:

☐ Ny bruger ☐ Erfaren bruger med nyt device ☐Flergangsbruger

Inhalationsprocessen	**JA**	**NEJ**
Klargøring		
Åbner inhalatoren korrekt		
Klargør dosis korrekt (fx indsætter kapsel, fremfører dosis, omryster)		
Hvis spacer: - Samler spaceren korrekt, evt. med maske - Tager beskyttelseshætten af sprayen og sætter sprayen på spaceren		
Inhalation		
Ånder ud inden inhalationen		
Placerer mundstykket mellem tænderne (bider let i mundstykket), og lader læberne slutte tæt om det		
Korrekt hovedstilling - holder luftvejene åbne og frie		
Inhalerer dosis korrekt		
Tager inhalatoren ud af munden (før der pustes ud)		
Holder vejret nogle sekunder efter inhalation		
Hvis spacer: - Placerer mundstykket mellem tænderne/masken over mund og næse - Trækker vejret som angivet for den pågældende spacer		
Afslutning		
Lukker inhalatoren korrekt		

Kommentarer:

_____

☐ Problemer med inhalationsteknik blev løst

Der er rådgivet om:

☐ Inhalationsteknik ☐ Lægemidlet ☐ Inhalatoren (rengøring, opbevaring m.m.)

☐ Anbefaling af kontakt til læge

Figure B.0.1: The form used to document the results of the inhalation technique assessment.

C | Hevner's Design Science Framework

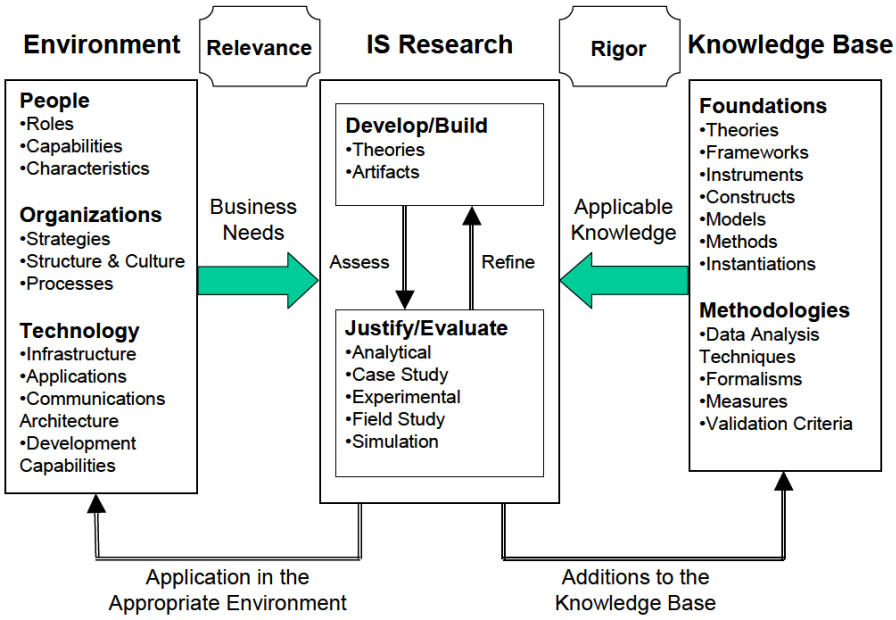


Figure C.0.1: Design Science Framework as presented in Hevner et al. [2004].

D | Additional Diagrams and Interfaces

D.1 Activity Diagrams

Search Patient

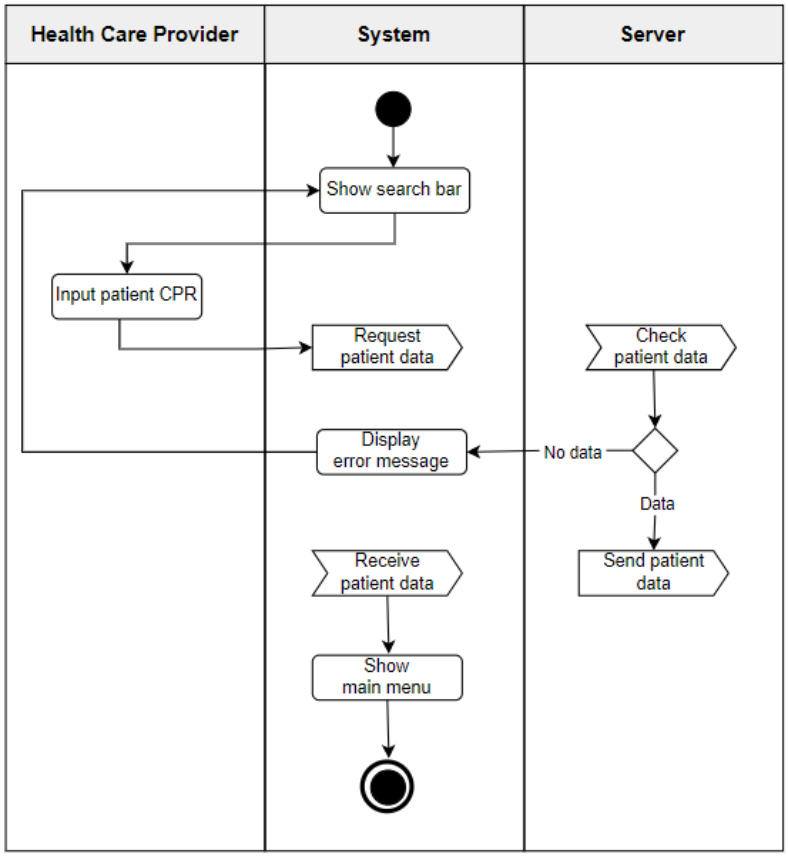


Figure D.1.1: The activity diagram elaborating the "search patient" use case.

Elaborate

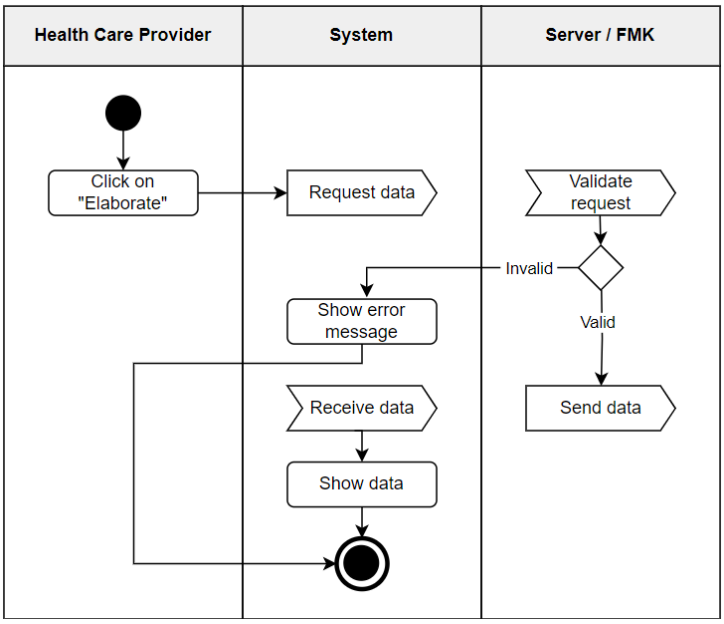


Figure D.1.2: The activity diagram used to describe the "Elaborate" use cases.

Last TPI Results

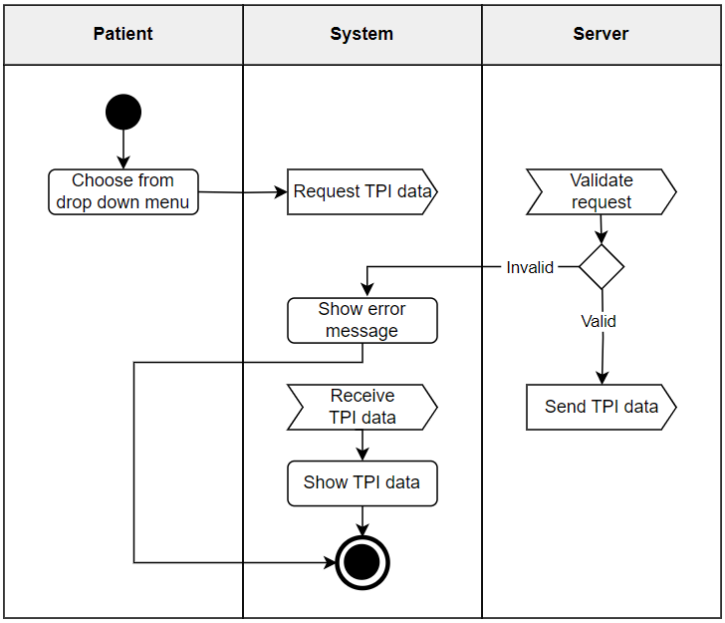


Figure D.1.3: The activity diagram presenting how the "Show last TPI results" use case is handled.

D.2 Graphical User Interface

Search Patient Interface

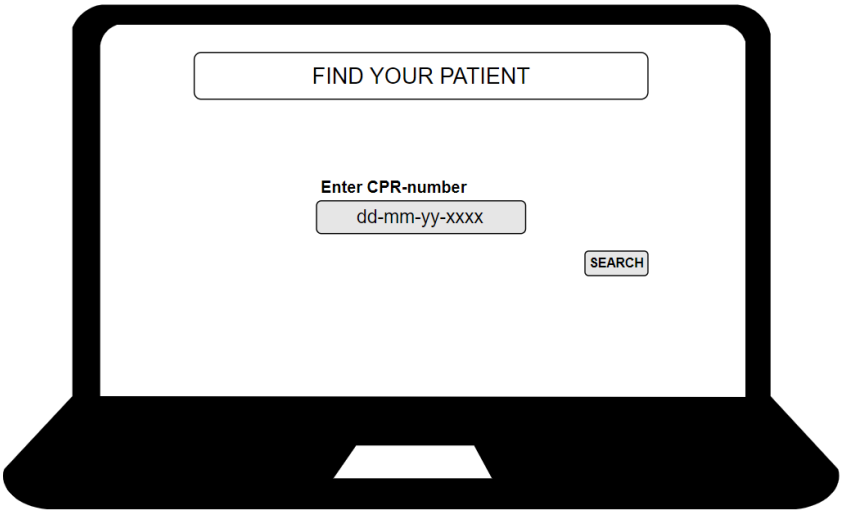


Figure D.2.1: The figure shows the graphical user interface used by the health care provider to search for a specific patient.

E | Evaluation

E.1 Performed Tasks Before Evaluation

Interfaces for the healthcare provider

1. Find ud af, hvor god adherence patienten har	
Forventet fremgangsmåde: - Søger på pt - Vælger flixotide - Ser resultaterne og forholder sig til mål	Faktisk fremgangsmåde: - Søger på pt - Vælger flixotide - Ser resultaterne ✔
2. Find datoer og pakningsstørrelser for de sidste købte pakker flixotide, som ligger til grund for MPR beregningen	
Forventet fremgangsmåde: - Søger på pt - Vælger flixotide - Vælger uddyb ved MPR	Faktisk fremgangsmåde: - Søger på pt - Vælger flixotide - Vælger uddyb ved MPR ✔
3. Find de fejl, der er fundet i den sidste TPI	
Forventet fremgangsmåde: - Søger på pt - Vælger flixotide - Vælger uddyb ved TPI	Faktisk fremgangsmåde: - Søger på pt - Vælger flixotide - Vælger uddyb ved TPI ✔
4. Find ud af hvilket svar der har givet færrest point i spørgeskemasvar	
Forventet fremgangsmåde: - Søger på pt - Vælger flixotide - Vælger uddyb ved spørgeskema	Faktisk fremgangsmåde: - Søger på pt - Vælger flixotide - Vælger uddyb ved spørgeskema ✔

Figure E.1.1: The tasks to be completed for the health care provider interfaces, before the evaluation can begin.

Interfaces for the patient

5. Find resultatet fra sidste spørgeskema og lav ny besvarelse.	
Forventet fremgangsmåde: - Vælg spørgeskema - Notér resultat - Vælg “besvar” - Vælg “næste” - Vælg “Gem”	Faktisk fremgangsmåde: - Vælg spørgeskema - Vælg “besvar” - Vælg “Næste” - Vælg Gem ✔
6. Find ud af hvilke fejl i inhalationsteknik der er fundet. Hvordan kan pt. få hjælp til at afhjælpe disse?	
Forventet fremgangsmåde: - Vælg TPI - Vælg flixotide - Se resultaterne - Vælg lægemiddelinformation - Se video - (Vælg “tilbage” for at se fejlene igen)	Faktisk fremgangsmåde: - Vælg TPI - Vælg flixotide - Se resultaterne - Vælg genvej til “lægemiddelinformation” - Se video ✔
7. Hvor kan pt. finde sin aktuelle dosering?	
Forventet fremgangsmåde: - Vælg information - Vælg præparat Alternativt: - Vælg TPI eller spørgeskema - Vælg information - Vælg præparat	Faktisk fremgangsmåde: - Vælg lægemiddelinformation - Vælg flixotide ✔

Figure E.1.2: The tasks to be completed for the patient interfaces, before the evaluation can begin.

E.2 System Usability Scale Responses

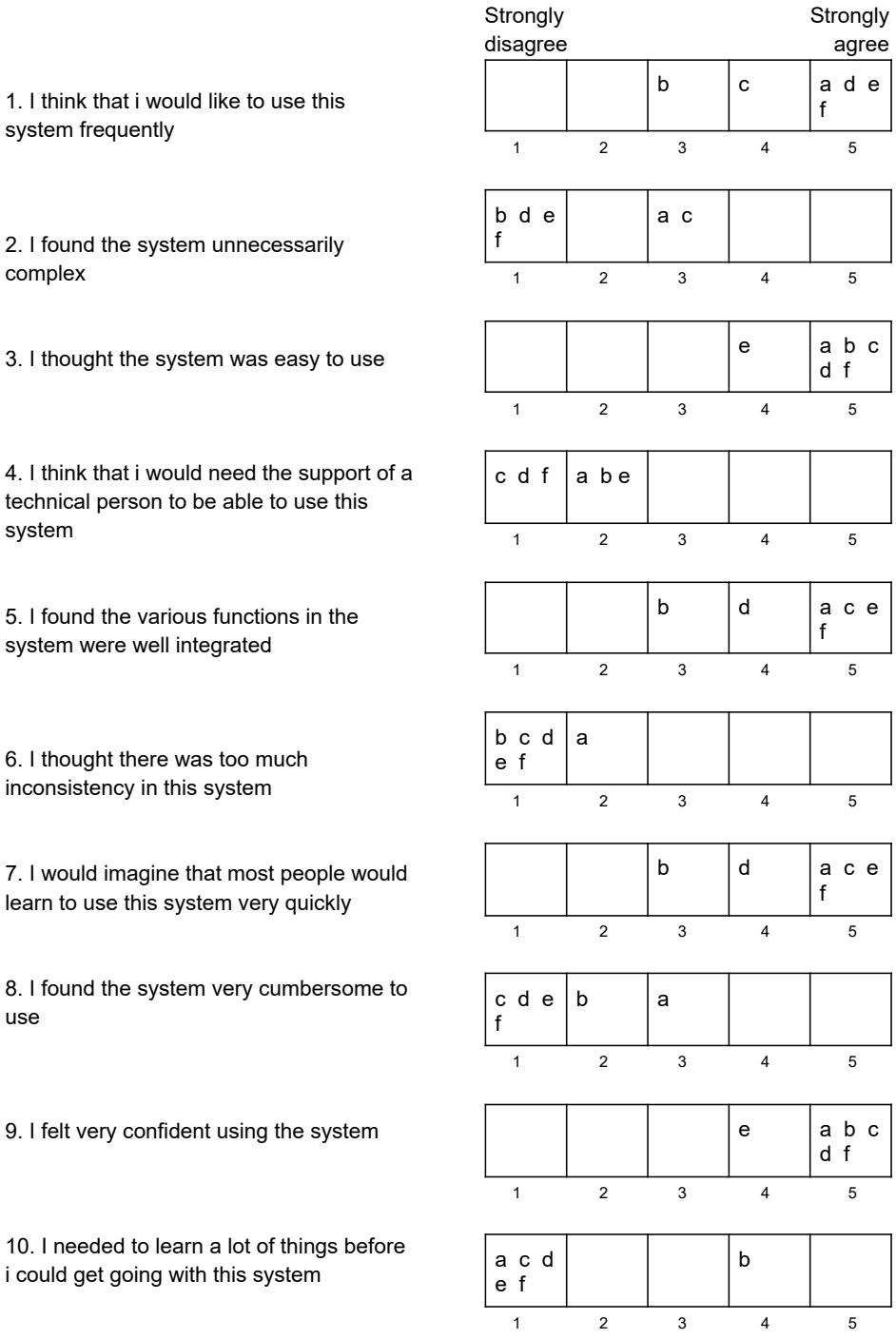


Figure E.2.1: Combined results of the system usability scale. Each letter constitutes a respondent.

E.3 Qualitative Usability Test

Table E.1: Paraphrased statements by five pharmacy staff members and the heuristics related to each statement.

Paraphrased statement	Related heuristic
"I would use the adherence calculation to refer relevant patients to an in depth compliance conversation with the pharmacist."	#2 - Match between system and the real world
"I think I would use it unless the pharmacy was very busy, in which case I probably wouldn't use it."	#2 - Match between system and the real world
"The placement of the Exit/Back-buttons was intuitive, but sometimes I would have preferred it to take be to the initial overview-page instead of just a single page back"	#3 - User control and freedom #7 - Flexibility and efficiency of use
"The MPR menu was a bit confusing, and more complicated than the other two."	#4 - Consistency and standards #8 - Aesthetic and minimalist design
" I would like to have some more explanation of the MPR term in the system. Maybe a mouse-over option to provide a definition of the term."	#4 - Consistency and standards #8 - Aesthetic and minimalist design #10 - Help and documentation
"I liked that the date of the last TPI was shown, when I looked at the TPI results. That is a feature I sometimes miss, when I recommend having a TPI."	#2 - Match between system and the real world #3 - User control and freedom #10 - Help and documentation
"It is easy to imagine the system being used by users with a high degree of self confidence in using technology. Others might struggle or not use it at all."	#3 - User control and freedom #5 - Error prevention #7 - Flexibility and efficiency of use #9 - Help users recognize, diagnose, and recover from errors #10 - Help and documentation
"I enjoyed the little icons for the three menus. They were cute, simple, and self-explanatory."	#6 - Recognition rather than recall #8 - Aesthetic and minimalist design
"I just got the same error message twice. It made me realize that I apparently don't read error messages that thoroughly."	#1 - Visibility of system status #5 - Error prevention #9 - Help users recognize, diagnose, and recover from errors
"I would like it, if the TPI could be digitized, because it would make the cooperation between pharmacy and general practitioner better."	#2 - Match between system and the real world

"I was a little confused about the shortcut from the TPI results to the page with medical information. But now that I think about it, it could make sense for the patient at home, if they have a hard time figuring out their inhaler."	#2 - Match between system and the real world #6 - Recognition rather than recall #7 - Flexibility and efficiency of use #9 - Help users recognize, diagnose, and recover from errors #10 - Help and documentation
"I really think that the patient could benefit from having such easy access to both their package insert and the inhalation technique video. I think they forget a lot of the information they get at the pharmacy once they are home."	#2 - Match between system and the real world #7 - Flexibility and efficiency of use
"I think that maybe half of the patients would use the system - mostly young people or parents of small children. I think they would find it helpful."	#2 - Match between system and the real world #7 - Flexibility and efficiency of use
"Even if the patients do not use the system, I think they would benefit from it, because the pharmacy and GP could work coherently in finding patients with low adherence that needs assistance."	#2 - Match between system and the real world

E.4 Heuristic Evaluation

Table E.2: Paraphrased statements by the two evaluators in the heuristic evaluation.

Heuristic #1 Visibility of system status	
Pharmacy staff member: "In case the calculations takes a little time in an actual system, it would be nice to know that it is in fact processing, and not just frozen."	**Technical peer:** "There are some error messages, but maybe there should be more, when additional functionality is implemented."
Heuristic #2 Match between system and the real world	
Pharmacy staff member: "We often consider refill data vs. amount in order to assess a patient's adherence. This seems similar to what MPR expresses, and therefore fits very nicely into our current workflow." "Using MPR would be more precise, if it uses data from FMK - multiple prescriptions and pharmacies makes the current manual assessment more difficult." "I see potential for using the system for other medications, because of the MPR calculation. Currently the system warns in cases of early prescription refill indicating overuse, but this could also help identify cases of underuse." "The clinical language is at an acceptable level. Some pharmacy staff members might have difficulties remembering the term adherence, because compliance is more commonly used. The GP might find the language too simple."	**Technical peer:** "There is a clear distinction between terminology between the two interfaces. Potentially, the patients could be confused about what is covered in the term "medical information." "The patients might not remember the names of their inhalers, so the drop down menu could benefit from images or color-coded descriptions as the actual physical inhalers."
Heuristic #3 User control and freedom	
Pharmacy staff member: "I had no issues with understanding how to use the exit buttons in the system, or where they led me."	**Technical peer:** "I thinkt the placement of the exit button is quite intuitive, and it is placed identically on all pages."

Heuristic #4 Consistency and standards	
Pharmacy staff member: "I think the design is pretty consistent throughout the system. The MPR view might be a little more busy and confusing, but if the system was implemented, the term would be easily incorporated into the workflow, and the design would be simple enough."	**Technical peer:** "I find that the items on the pages are generally placed where they should be." "I think the layout is in line with the layout of sundhed.dk. Potentially, a layout suited for phones (long, instead of wide) could be designed with inspiration from the app "minsundhed"."
Heuristic #5 Error prevention	
Pharmacy staff member: "I can't currently see, what errors could be made, that is not accounted for by e.g. error messages."	**Technical peer:** "It is surprisingly easy to save a new questionnaire. Maybe it is too easy?" "I would suggest that the patient is informed, when their new questionnaire is being saved and send to the health care provider". "With one of the error messages, i noticed that the item related to the error was highlighted. That was a nice feature. This should be implemented throughout the system."
Heuristic #6 Recognition rather than recall	
Pharmacy staff member: "I think the shortcuts from results to medical information are relevant for the patient, and can benefit them. However, this benefit could potentially be communicated more precisely."	**Technical peer:** "I don't think there are issues with recall. I did, however, have some difficulties in remembering what was part of the medication information page in the patient interface. That made the shortcuts from the results less clear to me." "I think previously filled questionnaires should be visible through a list."

Heuristic #7 Flexibility and efficiency of use	
Pharmacy staff member: "I clearly feel that younger pharmacy staff would find the system usable and beneficial. I think that some of the more technically challenged staff members or patients would find it difficult, cumbersome, or maybe even unnecessary."	**Technical peer:** "At the current stage of the prototype, I would not expect there to be shortcuts. However, it would be useful to add key pad shortcuts in a future version, in order to reduce the need for a mouse or mousepad."
Heuristic #8 Aesthetic and minimalist design	
Pharmacy staff member: "I prefer designs that are "back to basics", meaning that no unnecessary or fancy design choices confuses me or distracts me from the actual purpose. This design is in my opinion precise and to the point." "The system is clearly designed by someone with insights into the needs and workflow of the pharmacy staff."	**Technical peer:** "The design i minimalistic and uses simple icons to explain the pages." "I likes the fact that the packages inserts was shown as fold-out menus." "The visual design of the calculation of MPR was a bit chaotic. Maybe a horizontal slide bar could be used for the figure, making the uppermost parenthesis unnecessary." "Sometimes, I had some difficulties distinguishing between buttons and headlines. "
Heuristic #9 Help users recognize, diagnose, and recover from errors	
Pharmacy staff member: "Maybe the error message should be rephrased, in order to ensure that the technically challenged users do not increase their reluctance towards the system." "I think there should be a kind of warning, if the user is trying to do something that is inappropriate in regards to data, e.g exiting the system while answering the questionnaire, without saving it. "	**Technical peer:** "The error massages were ok. Potentially they could be improved by highlighting, where e.g. missing input was needed"

Heuristic #10 Help and documentation	
Pharmacy staff member: "I suspect that some of my colleagues would prefer more clear definitions of terms such as MPR. I don't think it is necessary, because there is a clear goal stated on the overview page. I can therefore quickly see, if the calculated adherence is acceptable." "Maybe there should be a little more help or information available for the patient interface."	**Technical peer:** "I find the choice of wording on the interfaces to be good, and i don't think that any further explanation is necessary. " "I think the buttons make the system rather intuitive to use."

F | Time Management

Time Schedule for Providing Overview

At the beginning of the semester, a time schedule was created as part of the masters thesis approval document. This initial time schedule is seen in the GANTT chart in figure F.0.1.

	Februar				Marts				April				Maj				Juni
	Uge 6	Uge 7	Uge 8	Uge 9	Uge 10	Uge 11	Uge 12	Uge 13	Uge 14*	Uge 15	Uge 16	Uge 17	Uge 18	Uge 19	Uge 20	Uge 21	Uge 22**
Problem domain/ Requirements																	
Indledende søgning og problembeskrivels	x	x															
Struktureret litteratursøgning		x	x	x	x												
Workflowanalyse			x	x													
Use case				x	x												
LoFi prototype					x	x											
Aktivitetsdiagrammer						x	x										
Kravspecifikation						x	x	x	x								
Test case planlægning						x	x	x	x								
Systemdesign																	
Designklassediagram							x	x	x								
Systemimplementering																	
Kodning										x	x	x	x				
Test																	
Verifikation												x	x				
Validering													x	x	x		
Formidling																	
Rapportskrivning																x	x
* Statusseminar d. 4/4																	
** Aflevering d. 1/6																	

Figure F.0.1: The initial time schedule created at the beginning of the semester.

The GANTT chart was used to ensure progress throughout the semester, by creating deadlines for specific tasks and phases of the project. For instance, initially there was a deadline set for the "Statusseminar", approximately halfway through the semester, to be done with collecting domain knowledge, specifying requirements and documenting the developed system. This is seen in figure F.0.1, where these phases, marked as green and pink, end by week 14. However, due to the evolvement of the project, and some unforeseen complications, the time schedule needed to be updated, and the deadlines were revisited accordingly. This was done following the "statusseminar" by updating the processes, seen to the left, as the progression of the project did not completely cohere with the initial schedule. In figure F.0.2, the two versions of the time schedule processes can be seen.

Problem domain/ Requirements
Indledende søgning og problembeskrivelse
Struktureret litteratursøgning
Workflowanalyse
Use case
LoFi prototype
Aktivitetsdiagrammer
Kravspecifikation
Test case planlægning
Systemdesign
Designklassediagram
Systemimplementering
Kodning
Test
Verifikation
Validering
Formidling
Rapportskrivning

(a)

Problem Domain and Analysis
Indledende søgning
Struktureret litteratursøgning
Problembeskrivelse
Systembeskrivelse
Initielle krav
Use Case diagrammer
Aktivitetsdiagrammer
Dokumentation
Domæne modellering
Graphical User Interfaces
Implementering
Prototyper
Evaluering
Planlægning og udførelse
Dataanalyse
Formidling
Rapportskrivning

(b)

Figure F.0.2: The progression of the time schedule. The initial version is seen on (a), and the updated version is seen on (b).

As seen in figure F.0.2, the overall phases of the projects, shown in color, remained almost the same. The major reason for the differences is the fact that initially, the idea was to conduct the development according to the V-model. However, during the initial weeks, the process model from requirements engineering was chosen instead, influencing the phases slightly. Also, as knowledge was collected and processed in the initial weeks, it became clear that some of the original tasks were no longer needed. This was e.g. the work flow analysis, which was supposed to outline the management of TPI in pharmacy. Initially, this was planned due to emphasizing the digitization of the TPI. However, as the problem analysis took form, the TPI was included as a smaller part of the system, thereby reducing the need for a substantial workflow analysis. The updated time schedule thus stretched from week 14 to week 22, where the project was due. This is seen in figure F.0.3.

The GANTT chart was based on weeks as opposed to days, because the purpose of the schedule was to provide an overview of the project period. This meant that the chart was used to further specify actual activities included for each task.

	April				Maj				Juni
	Uge 14*	Uge 15	Uge 16	Uge 17	Uge 18	Uge 19	Uge 20	Uge 21	Uge 22**
Problem Domain and Analysis									
Indledende søgning									
Struktureret litteratursøgning									
Problembeskrivelse	x								
Systembeskrivelse	x								
Identifikation af initielle krav	x	x							
Use Case diagrammer	x	x	x						
Aktivitetsdiagrammer	x	x	x						
Dokumentation									
Domæne modellering			x	x	x				
Graphical User Interfaces			x	x	x	x			
Implementering									
Prototyper					x	x	x		
Evaluering									
Planlægning og udførelse					x	x	x		
Dataanalyse							x		
Formidling									
Rapportskrivning	x						x	x	x
* Statusseminar d. 4/4									
** Aflevering d. 1/6									

Figure F.0.3: The figure shows the updated time schedule in a GANTT chart, created after the "Statusseminar".

Specifying Activities from the Time Schedule

In order to apply the GANTT chart in practice, it was assessed each week, in order to align the overview with the actual activities, and potentially adjust the time consumption. This was done in relation to the weekly meetings with the supervisor. Before the meetings, it was used to align the agenda. After the meetings, it helped setting specific goals to be achieved before the next meeting. These goals were then used to identify specific activities to be performed during that week, in a week plan. An example of a week plan is seen in F.0.4.

Mål inden næste møde:

- Gennemføre evalueringen med apoteket
- Analysere evalueringen
- Gennemføre evalueringen med peer
- Analysere evalueringen
- Skrive afsnittet i rapporten
- Have outline til diskussionen klar til vejledermøde

Onsdag	Klargøre materiale til evaluering ✓ Opdatering af metode-afsnit ✓ - Se kommentarer fra vejledermøde 12
Torsdag **(Kristi Himmelfartsdag)**	Klargøre materiale til evaluering ✓
Fredag	Udføre evaluering med apoteket ✓ Evt. analyse af evalueringen (✓ påbegyndt)
Weekend	Evaluering med peer ✓ Analyse af evalueringen ✓ Formidling til resultatafsnit (✓ påbegyndt) Formidling af metode ✓
Mandag	Formidling af resultatafsnit ✓ Outline til diskussion (✓ Påbegyndt)
Tirsdag	Outline til diskussion ✓ Forberede vejledermøde ✓ - Husk at sætte PBL læringsmål på dagsorden **Deadline:** Materiale sendes senest kl 8.30 onsdag morgen

Figure F.0.4: An example of a week plan containing goals based on the time schedule, and specific activities in order to achieve the goals.