MASTER THESIS

SURE

– INCREASING SAFETY IN MEDICATION CARE THROUGH PATIENT EMPOWERMENT

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THANK WORD

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My very last thank you goes out to all the people that showed the courage to open up about their experience and struggles in living with medication. I would like to thank them for sharing their individual stories and making this project come to life because of it.

EXECUTIVE SUMMARY

The design process of the Zeker app is a graduation project of the TU Delft faculty of Industrial Design Engineering in collaboration with Capgemini Invent. Capgemini Invent is evoked by the increased safety measure in the pharmaceutical supply chain. The European legislation: The Falsified Medicine Directive, ensures additional serialisation of medication packaging with QR-codes. This raised the question which stakeholders can be involved in user-centred opportunities these QR-codes have when brought in to the home of patients. With this project, these user-centred opportunities and who and how current and future stakeholders are involved in medication safety and e-Health interventions are explored.

This report describes the user-centred design process that explores opportunities on how patients, taking medication, can be helped in their day to day lives. The research revealed bottlenecks in the medication care process that cause unsafe medication care. Unsafe medication care can cause (preventable) hospitalisation. Research focuses on patients that are most likely to encounter problems due to medication. These are patients with polypharmacy and multi-morbidity, taking medication that influences the cardiovascular system.

PATIENT GROUP

Five in-depth, semi-structured interviews are done with patients to set up a Patient Journey. This journey illustrated pain points in the patient's live to do with their medication and care. These were taken on as a design challenge to resolve, namely:
To empower patients in searching for a regimen in which living with medication is not restrictive and to take away strong negative emotion around adjustments to the medication regimen.

The interviews also showed a gap between norms for safe pharmaceutical care, to relieve bottlenecks, and patient's experience. This project aims to resolve these problems areas from the patient side through patient empowerment. With the four aspects of patient empowerment the following design vision was made: 1) Patients will better understand their responsibilities in keeping and transferring their medication overview. 2) Patients will gain knowledge to engage in a consult conversation about their medication treatment. 3)Patients experience that their home and the consult environment is facilitated for safer medication treatment. 4)Patient experience their healthcare skills regarding their medication treatment are anticipated.

THE ZEKER APP

Trends in the pharmaceutical and healthcare market shows opportunities in using e-Health as a significant part of the solution. The Zeker app embodies e-Health for improved accessibility, effectiveness, efficiency, safety and quality, of medication care for patients. The Zeker app is designed using brainstorming, wireframing and digital user interface mock-ups. For patients with polypharmacy, the Zeker app gives reliable personalised answers in finding a medication regimen. When medication is restrictive it will reduce negative emotion by taking patients seriously and helping in the search as to why and what are alternatives for patients. Knowledge and giving overview empowers patients in increasing

medication safety together with their caregivers:

"Together Sure about your medication."

STAKEHOLDERS

The Zeker app operates in the complex pharmaceutical health care network. For concept validation and further research into the future stakeholders in medication safety and e-Health interventions stakeholder interviews are conducted. Representatives of KNMP, NVZ, VIG, BOGIN and the Patient Federation with expertise in this field, were questioned about their opinion of the mock-ups. As well as their organisation's and other stakeholder's roles in these kinds of developments.

It was made clear collaboration with many different stakeholders required to get this concept of the ground. Both on an organisational level, like involving branch organisations. As well for utilising existing databases and content as building blocks for the app. This project distinguishes three types of data to consider for collaborative development: static data, resilient data and timely data.

The research puts forth the need for nationally arranged (big) data analysis of medication side-effects. This can be used in pharmaceutical development as well as in improvement and personalisation of medication treatment. It is believed the existing side-effect registration centre Lareb can fulfil this role. By digitising Lareb can expand its data collection and increasingly offer analytics as a service.

The government should increase its efforts towards e-Health acceptance and adoption for both patients and caregivers. Current numbers on use of e-Health show patients are still slow to adopt. Besides, patients are unwilling to pay for e-Health. Therefore, it is expected e-Health will increasingly be reimbursed by health insurance companies.

VIABILTY

For the Zeker app, this implies that it should be developed with or by a GP information system provider. Initial data exchange can be set up swiftly. The GP has an overview of all medication which the specialist has not. The GP has the ability to change the prescription, which the pharmacist has not. Reimbursement for e-Health by the GP is already arranged under patient self-monitoring.

With the collaborative development of PGOs and the changes in the financial model towards Value-Based Healthcare it is likely e-Health will soon be reimbursed as a separate type of care transcending individual caregivers.

The last iteration of the Zeker design is based on user-research. Thirteen in scope participants indicated that they understood the app and its four main functions. If it would help or whether they would use it frequently depended on whether they experienced problems with their medication before and if they had not already fixed the problems in another way. These patients also, indicated that they would not pay for such an application unless it needs little effort. When they are clearly shown the benefit as opposed to their current ways of working. The iteration improved the clarity of- and simplified the Zeker app design. Besides this, it was decided to make a clearer distinction between self-measurement and side-effects by adding a menu function.

DEFINITION LIST

PROJECT TERMS

Medication safety:
Aims to ensure that clinicians safely prescribe, dispense and administer appropriate medicines, and monitor medicine use. It also aims to ensure that consumers are informed about medicines, and understand their own medicine needs and risks.

e-Health
e-Health is the cost-effective and secure use of ICT in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research. When applied correctly, e-Health will contribute to more affordable, accessible and higher quality of care.

Patient empowerment
A process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognizes community and cultural differences and encourages patient participation."

PHARMACEUTICAL TERMINOLOGY

Pharmacotherapy: is a treatment therapy using pharmaceutical medication (as opposed to for instance surgery/surgical therapy)

Pharmaceutical care: Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patients' quality of life

Preference policy: (*preferentie beleid*) The Ministry of Health, Welfare and Sport determines the maximum price of medication that suppliers can ask, twice a year. For more medication with the same active substance, the health insurer determines which product or brand is reimbursed.

Specialité: patented medication

Generic: medication of which the patent expired therefore can be made by more companies

Over the counter medication: medication that needs no prescription sold at drugstore or supermarket

Prescription medication: (*medicijn op recep*t) a medication for which you need a prescription by a doctor to obtain it at a pharmacy

Medication leaflet: (*bijsluiter*) the legislative package insert of medication that provides information about the medication.

(Medical) Specialist: someone that completed further education to become a medical specialist. This report might take a broader interpretation of the term and include caregivers that are specialised in a field but not necessarily carry the title.

ABBREVIATIONS

BG-Pharma: Bond van Groothandelaren in het Pharmaceutische bedrijf
Bogin: Biosimilairs en generieke geneesmideelen industrie Nederland
CBG: College ter Beeoordeling van Geneesmiddelen
Cibg: Centraal Informatiepunt Beroepen Gezondheidszorg
EMVS: European medication verification system
EPD: Elektronisch patient dossier
FMD: falsified Medicine directive
GP: General Practitioner (*huisarts*)
HARM: Hospital Admission Related to Medication
IGJ: Inspectie Gezondheidszorg en Jeugd
KNMP: Koninglijke Nederlands Maatschappij te bevordering der Pharmacie
LHV: Landelijke Huisartsenvereniging
LSP: Landelijke Schakelpunt
Ministry VWS: Ministerie van Volksgezondheid, Welzijn en Sport
NMVO: Nederlands Medicatie Verificatie Organisatie
NMVS: National Medications Verification System
NVZ: Nederlandse Vereniging Ziekenhuizen
NVZa: Nederlands Vereniging van Ziekenhuisapotheken
NZa: Nederlandse Zorgautoriteit
NeLL: National e-Health Living lab
PGO: Persoonlijke Gezondheid Omgeving
PSI: Pharmaceutical Security Institute
RIVM: Rijksinstituut voor Volksgezondheid en Milieu
VIG: Vereniging van Innovatieve Geneesmiddelen
VIpp: Versnellingsprogramma Informatie uitwisseling Patient en Professional
VZVZ: Vereniging van Zorgaanbieders Voor Zorgcommunciatie
WHO: World Health Organisation
ZIB: Zorg Informatie Blok

CONTENT

1. INTRODUCTION

This chapter introduces this graduation project, Sure - Increasing safety in medication care through patient empowerment. It explains which steps were undertaken to come to this master thesis document laying in front of you. This includes a description that guides users through this document. It shows the assignment that was set up in collaboration with Capgemini Invent and TU Delft faculty of Industrial Design Engineering that marks the kick-off of this project. Lastly, it introduces the extensive stakeholder network this project operated in.

1.1 DESIGN PROCESS

This thesis describes the result of a design process executed for a graduation project at the Faculty of Industrial Design Engineering. This project was approached from a user-centred design perspective, that closely relates to the more current term "Design Thinking". Design Thinking has not been clearly defined(de Innovator, 2018), but it amounts to a new way of looking at contemporary innovation challenges figure 1.1.1 shows a combination of two Design Thinking process (IDEO, 2018; de Innovator, 2018) to illustrate familiar steps.

THE PROJECT'S DESIGN PROCESS

This design process had three main phases: Exploration, Creation and Validation. These are reflected in the three chapters in this thesis. Exploration can be seen as the steps of understanding, observing and defining in Design Thinking. Creation involves ideation and prototyping and validation corresponds to testing.

Every phase had a starting point, like the assignment or design vision, this is then explored to create content. After which content is structured and lastly reduced to conclude on. This is also known in the process described by Buijs et. Al (2009) as divergence, clustering and convergence.

Designing is an iterative process. That is why the sub-chapters of this thesis do not follow the exact chronological order of steps that were executed. Often sub chapters are developed simultaneously in divergence. Steps of (literature) research, interviews and visualisation are done alongside each other after which they are structured. Structuring can reveal gaps in reasoning that require additional content through exploration.

Figure 1.1.2 shows some of the main steps undertaken in every phase. This chapter further describes the process phases below.

Exploration

For exploration research was done to get familiar with the topics of medication safety. The pharmaceutical market and its stakeholders. This

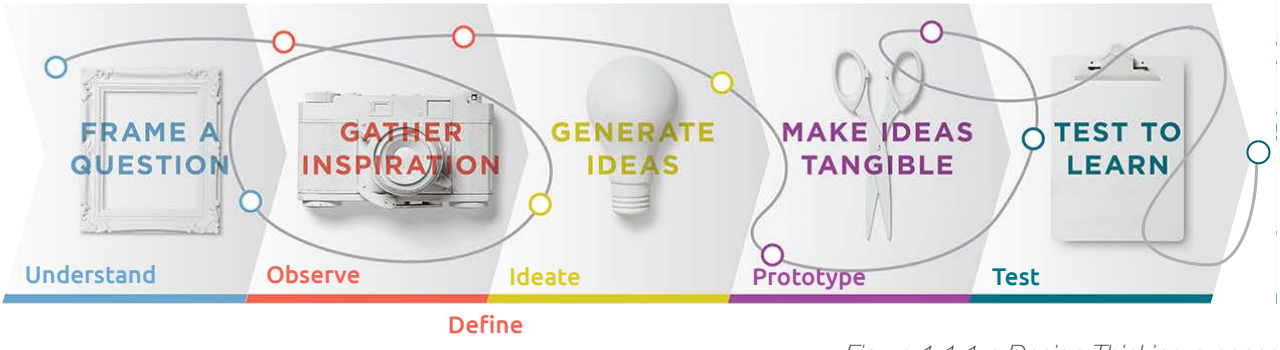


Figure 1.1.1 a Design Thinking process

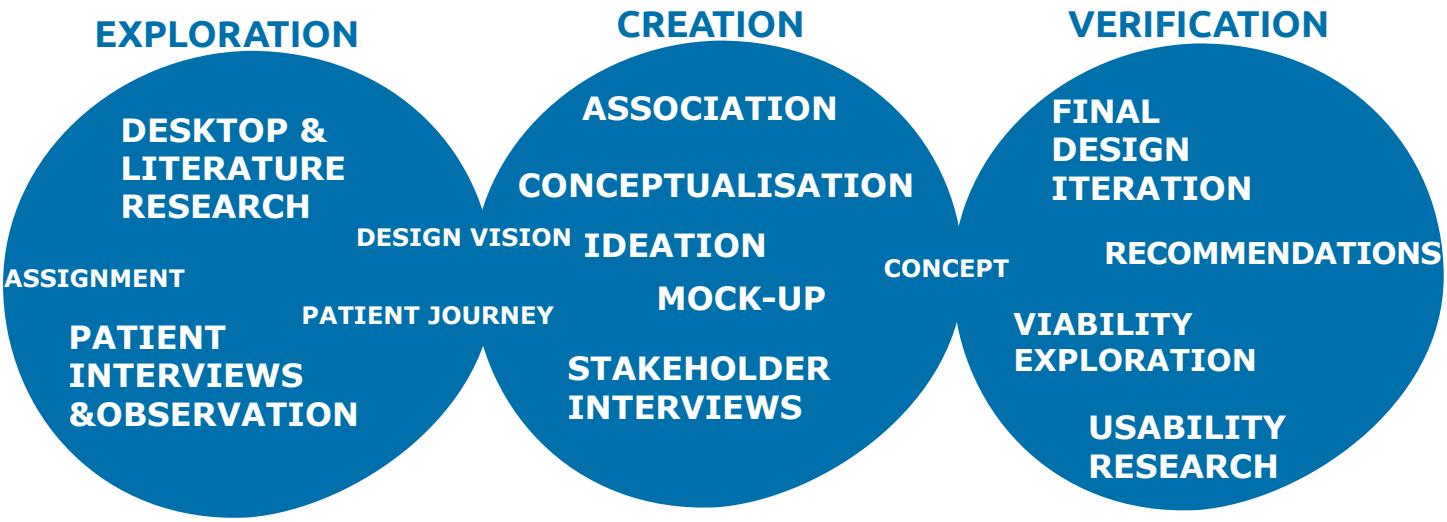


Figure 1.1.2. The project's design process

was mainly retrieved through literature, reports by the Dutch government, trend analyses and stakeholder websites. Next to this desk research, interviews were conducted with patients. This brought about a clear perspective on bottlenecks in medication safety, trends in the pharma and healthcare environment. Also it defined a patient group and journey. Each sub-chapter concludes on implications on the design. These can be found at the end of each chapter, highlighted in the corresponding colour.

The patient journey concluded on pain points from which the design challenge was deduced. During the exploration it was found that it was suitable to construct a design vision to guide the rest of the design process. This vision shows how empowerment can resolve the set design challenge. This follows the Vision in Product design process (VIP) as described by Hekkert et. Al (2009).

Creation

The Exploration was an inspiring journey. The first step in Creation was a quick visual brainstorm that associated on topics touched upon in the research. More ideas were produced in hand-drawn and digital designs for ideation. Standards and benchmarks were explored and constructed to measure the ideas against. This step enabled to go from ideation to conceptualisation. Concepts were digitally created user interface mock-ups. In the course of this phase stakeholder interviews were performed for additional insight. This chapter concludes on the Zeker app concept.

Validation

The design can be reviewed as an intervention in the problem areas found in medication safety. This intervention has been validated through a user test. This chapter further describes how the concept will be viable in the current and future healthcare market and its stakeholders. This is based on what was found throughout the project supported by the stakeholder interviews and literature explorations. The last design iteration is made using a usability research with patients. The entire project and process is concluded upon in recommendations.

1.2 ASSIGNMENT

The project is executed for Capgemini Invent for the Department of Public Insights and Data. In earlier assignments by Capgemini Invent in healthcare, for companies from the pharmaceutical chain, they came across the new European policy against falsified medication. This policy was brought about by the need for better medication verification system through the serialisation of medication. Capgemini Invent's (2017) research turned up user-centred opportunities the implementation of this system brings about. These opportunities are especially interesting for a group of frail elderly for whom the risk of harm in using medication offers room for improvement. This project will further explore the opportunities to align technology and strategy with user needs to cultivate possibilities in patient safety and empowerment.

WHAT EVOKED CAPGEMINI

Capgemini (2018-1) is a global consultancy active in technology services and digital transformation. Capgemini is driven by the conviction that the business value of technology comes from and through people. Their main objective is to help in enhancing the performance of organizations, based on in-depth knowledge of client industries and processes. Capgemini Invent would like to secure a knowledge position in user-centred opportunities changes like medication serialisation can offer for the healthcare market.

In 2016 the European committee established the Falsified Medicines Directive (FMD) that entails all European countries should have a National Medication Verification System (NMVS) (NMVO, 2018-2). This system should avoid falsified medication from entering legal distribution channels. It is assumed that it will increase patient safety by improving the traceability of medication. For the Netherlands, the impact of this system is expected to be minimal (Capgemini Invent, 2017), because of an already effective national legislation that closes off the pharmaceutical chain. Exclusively prescription-only medicines, with many quality requirements, that are supervised by various parties, are reimbursed in the framework of the *Zorgverzekeringenwet*. The expected impact on reducing falsified medication from entering the chain is small. However, a relatively high investment to implement this policy, 0,17€ per package for producers (Capgemini Invent, 2017) and minimally 0,085€ for pharmacists a (KNMP, 2016), is expected. Therefore, Capgemini Invent asked to look deeper into additional user-centred opportunities this policy could bring to the pharmaceutical chain.

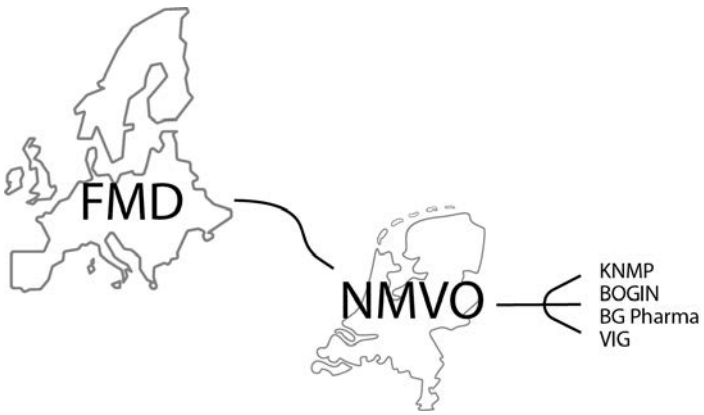


Figure 1.2.1. Set-up anti falsification network

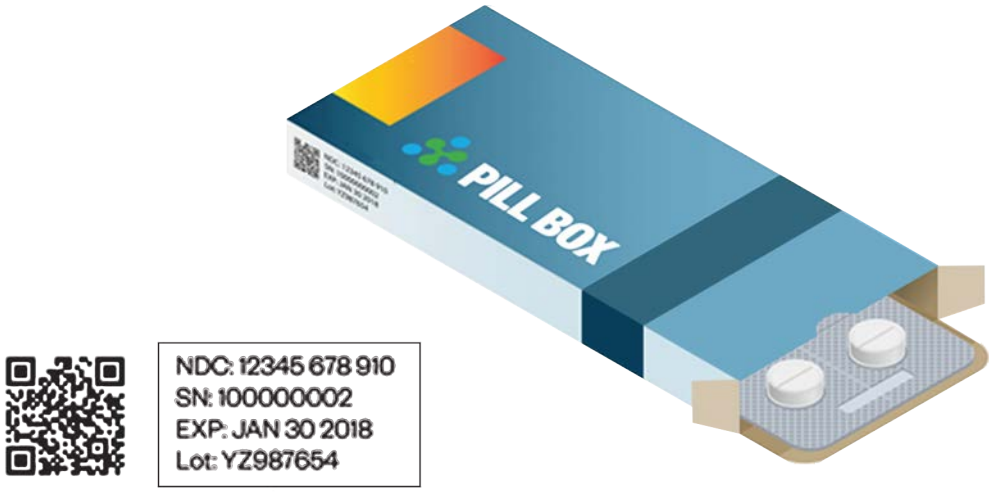


Figure 1.2.2 Anti-tempering seal and QR -code medication package.

MEDICATION SERIALISATION

The *Nederlands Medicijnen Verificatie Organisatie* (NMVO) was established in 2016 to counter drug falsification and enforce this EU regulation in the Netherlands (NMVO, 2018-1). To set up a verification system they closely collaborate with branch organisations of pharmacists and pharmaceutical industry and wholesalers: KNMP, Bogin, BG-Pharma and VIG, as illustrated in figure 1.2.1. Starting in February 2019, these different stakeholders in the pharmaceutical supply chain will contribute to the development and implementation of the NMVS. The NMVS introduces a Unique Identifier (UI) on all the secondary packaging of prescription drugs embedded in a 2D matrix code, better known as QR code, as illustrated in figure 1.2.2 (NMVO-2, 2018).

MEDICATION SAFETY RISKS

Problems related to medication use are a big burden for the current healthcare system (NOS, 2017-1). A quarter of all the reported incidents in medical mistakes are related to medication use, in total over 6.500 cases in 2013. These numbers predominantly relate to patients with polypharmacy: simultaneous use of several medications for in particular chronic diseases (Sinnige, 2016-1). Polypharmacy can lead to side effects or unfavourable interaction between different medicines. Especially, in the group, generally referred to as 'frail elderly', polypharmacy can lead to unnecessary hospital admissions. According to RIVM (2013), the problems, among other things, are the results of inadequate information exchange between different specialist prescribing and/or stopping the medication for one patient. Furthermore, the communication with the patient or informal caregiver can also be improved. Experts (EMGO+ Instituut, 2014) identified increased patient involvement in the medication care as part of resolving the current risk factors of polypharmacy.

Although multiple interventions have been implemented over the years, medication errors are still prevailing in the rate of incidents. Previous studies (Sinnige, 2016-1) indicate that a higher number of chronic conditions is positively associated with polypharmacy. The percentage of patient registered with two or more chronic disorders is expected to increase 5 %, from 25 in 2015 to 30 % in 2040 (VTV, 2018). The focus will be on this patient group with multiple chronic disorders, called multi-morbidity. In addition to the before mentioned parameters, the patient group researched for this project is elderly patients with polypharmacy and multi-morbidity.

PROJECT OBJECTIVE

In the complex healthcare context, the serialisation the NMVS offers and subsequent QR-codes on packages can potentially deliver value to customers. For instance, through, timely access to data that can provide relevant information about medications like signalling about unwanted combinations, timely reorder, access to the leaflet (Capgemini Invent, 2017). This seems indisputable additional value for the patient with the opportunity to decrease the risks of medication use. Therefore, the objective of this project is:

Design a product service system for elderly patients with multi-morbidity and polypharmacy, that increases patient safety and empowers them in their pharmaceutical treatment, using the serialisation of medication.

The project will explore how this patient group can be empowered in their complex medication regimen. It will embody e-Health, technology to support or improve healthcare. The expected outcome is that technology can help increase medication safety. Lastly, it aims to explore the stakeholders in the pharmaceutical chain and beside the Capgemini Invent clients. To assess who could embody a relation of empowerment with the patient in medication safety. That will, in turn, add value for the stakeholder in becoming a more integral part of the healthcare chain with the user at the centre.

1.3 PHARMA MARKET

For this project, the Dutch pharmaceutical market is researched. Care and supply of pharmaceuticals that transcends separate organisations and involves a lot of stakeholders. Figure 1.3.1 below gives an overview of important pharmaceutical stakeholders to be considered for the rest of this project. From left to right it shows stakeholders that have increasingly more interactions with the patient about their medication (care).

GOVERNMENT AND SUPPLY CHAIN

In the Dutch healthcare system, the government plays a big role, policies influence for instance pricing of medication and how (pharmaceutical) care is organised and develops. As shown there are three major parties in the Dutch government that work on medication quality control, policy and research. The *Ministerie van Volksgezondheid, Welzijn en Sport* (VWS) and the *Inspectie Gezondheidszorg en Jeugd* (IGJ) and *Rijksinstituut voor Volksgezondheid en Milieu* (RIVM).

With the implementation of the FMD, a new government organisation was set up, the NMVO. They collaborate with mainly the supply chain of pharmaceuticals: producers, wholesalers and pharmacists (NMVO, 2018-1).

Figure 1.3.1 Pharma market overview

MEDICATION DATABASE SYSTEMS

With the idea to use e-Health as part of the solution comes medical data and data exchange. Interestingly, the serialisation of medication by the NMVO is not designed to collaborate with existing serialisation or care database systems. Like in pharmacies already medication database is used, the Z-index, the CIBG has a database on quality, availability and affordability of medicines called Farmatec. The current national system for medical data exchange between caregivers is the *Landelijk Schakelpunt.*

PHARMACEUTICAL CARE

Pharmaceutical care according to Hepler & Stand (1990) is the provision of a medication therapy (or pharmacotherapy) for the purpose of achieving definite outcomes which improve a patient's Quality of Life. This care provided surpasses individual caregivers or healthcare organisations, already because the doctor prescribes and the pharmacy dispenses. It involves all healthcare professionals that provide 'care', in conversations, physical help or otherwise, in the entire process of prescribing, providing, and using or administering medication to the patient. In the healthcare market, these caregivers are generally considered to be organised in at least two lines. Namely, first line caregivers consisting of but not limited to the GP and Pharmacy and second line caregivers, doctors and specialists from the hospital.

Both supply chain and care chain stakeholders are generally represented by one or more branchorganisations, like KNMP for pharmacists and NHL for hospitals. figure 1.3.1 gives a general overview of these organisations but does not aim to be complete.

2. EXPLORATION

An exploration was done into three topics in pharma healthcare: medication safety, trends and at-risk patients under pharmaceutical care. For this explorations research of literature and desk research was conducted. When some more parameters became clear the patient group was further explored through interviews.

Medication safety was deeper researched to get a sense of what can make medication unsafe. To find out which parties are involved in medication safety, already in making it safe and which (others) could be looked into with regards to adding new patient value. Besides, it had to be reviewed if or which parts of medication safety can be improved upon, from the patient side.

Next, trends in pharmaceutical industry and healthcare were explored for two reasons. To sketch out the market and get a deeper understanding for its current and future state and to be able to talk about it with different stakeholders in future steps. All trends were reviewed from the perspective of different stakeholders. Per trend, the perspective and roles of the biggest stakeholder(s) are discussed. It was attempted to illustrate the perspective or interest of the biggest stakeholders for each trend in a table. With their subsequent behaviour towards it summarised. An evaluation was made on the level of influence each respective stakeholder has on how the trend evolves or who simply has to undergo it. This will give a sense of what is important to which stakeholder, what their role and behaviour is or might become. Therefore, if they see value in fulfilling a new role in patient-centred opportunities.

Capgemini Invent had no prior view of a patient group that user-opportunities could add value for. This is why the choice for a patient group was made for its opportunities in market size and room for improvement. A patient persona was set-up based on patients with a higher risk of problems due to pharmacotherapy. Again, special attention was paid to who is involved with this patient or could possibly become more involved. Patient interviews have been conducted to give a deeper understanding of how these people live with medication on a daily basis and their journey through living with medication. The patient journey was worked out to see where pain points lie and therefore the need for improvement from a patient perspective.

A design challenge was derived from the patient's pain points. This exploration confirmed the trend of patient empowerment was a way to increase patient safety. Therefore, a vision was set up on how to empower patients for increased medication safety. This was done by bringing pharmacotherapy problems in relation to empowerment factors. Further elements of the explorations aided in setting up design implications for the next step of creating designs in order to solve the design challenge.

2.1 MEDICATION SAFETY CONTEXT

This chapter describes what can be unsafe about medication, what is done to make it safer and what are the risks. The assignment was evoked by the implementation of the FMD a new way to protect the pharmaceutical supply chain. Besides this, there was already legislation in place that protects against falsified medication entering the Dutch distribution networks. The second part of this chapter describes the current risks in pharmaceutical care, addressed in norms and guidelines for the healthcare sector.

LEGISLATION PROTECTING THE PHARMACEUTICAL SUPPLY CHAIN

Since early 2000 with the expiration of most patents, a lot of medication production has moved to countries like India and China, Zembla (2018). Besides, before reaching a local pharmacy the medicine has hopped all through Europe passing different parallel importers. Therefore, it is no surprise the medication supply chain is protected on a European and a national level against falsification.

European efforts in medication supply safety

The Falsified Medicine Directive was initiated because worldwide the number of incidents with falsified drugs is rising, 56% between 2012 and 2016 (PSI, 2016), see figure 2.1.1. It is expected by the Pharmaceutical Safety Institute (PSI), that this percentage is even higher since the traceability of the falsification is very difficult because adequate and effective tools are missing. The 2017 yearly international action against illegal trade of medication was unprecedented: over 25 million pieces of medication (NOS, 2017).

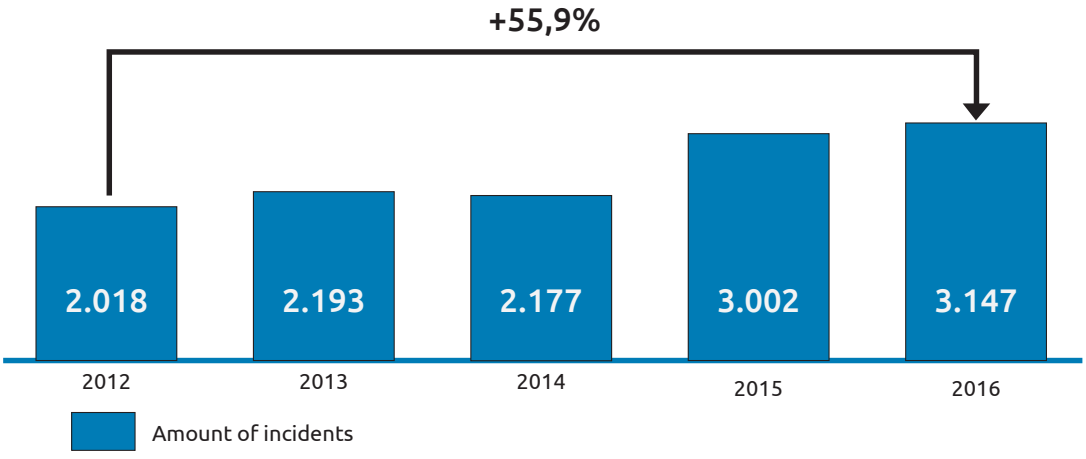


Figure 2.1.1 Rise in the worldwide number of incidents with falsified drugs.

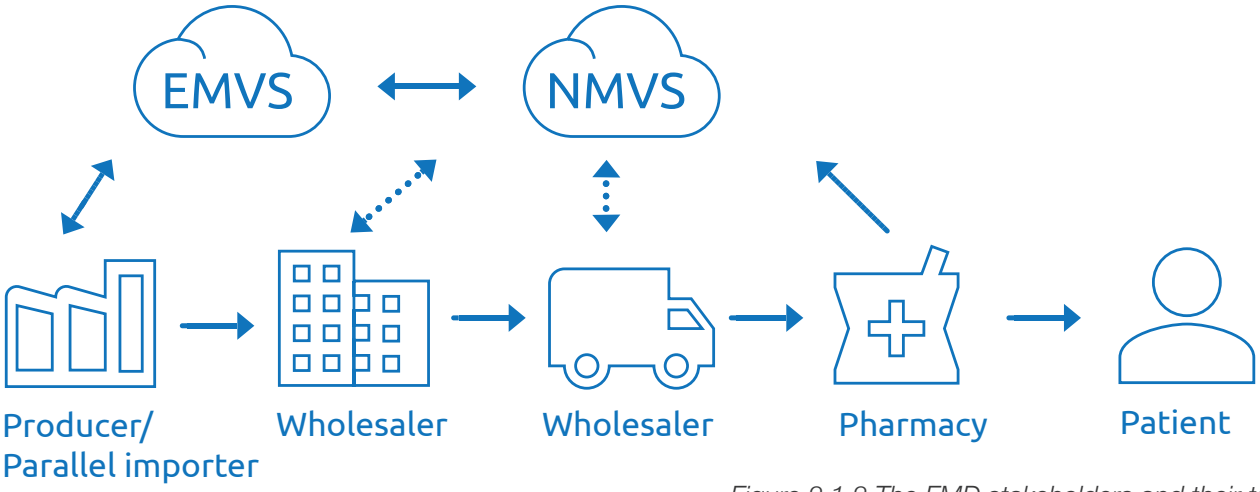


Figure 2.1.2 The FMD stakeholders and their tasks.

"Medication that is deliberately and fraudulently produced and/or mislabelled with respect to identity and/or source to make it appear to be a genuine product. This applies both to branded and generic medication. This entails that medicine can, for instance, have less active pharmaceutical ingredients or none or for instance, a genuine product can have been placed in counterfeit packaging to extend its expiration date." -(WHO, 2016-1)

The FMD helps by sealing of the medication package so it cannot be tampered with. Than producers and parallel importers register the package, to the European Medicine Verification System (EMVS) that sends its information to a national hub where the package is brought to market, the NMVS (NMVO, 2018-2). Wholesalers and parallel distributors will do a standardised risk-based verification. At dispense to the patient at the pharmacy, the medication can be verified, through random checks with NMVS, these steps are shown in figure 2.1.2. Additional information on the FMD can be found in Appendix A1.

Falsified drugs are usually offered on the internet by illegal suppliers and therefore difficult to trace. In an effort to make online trade safer, there is a logo for websites that legally operate online pharmacies that are approved retailers by EU standards. These online pharmacies will provide authentic, authorised medicine. CBS (2017) reports 8,3% of medication, was bought online in 2017, this is not further specified in terms of prescription or over the counter medication or legal or unauthorised websites. A clear increase is visible over the last few years it has grown gradually from 2,6% in 2012. However, the size and growth are incomparable to general online shopping that has grown from 64% to 76,3% over the same 5-year period.

In the Netherlands, everyone has health insurance and exclusively approved prescription-only medicines, are reimbursed in the framework of the Healthcare insurance act (*Zorgverzekeringenwet*). There are a few Dutch online pharmacies of which medication is reimbursed by insurance like normal pharmacies. Buying from unauthorised online suppliers generally has no financial benefit. However, illegal medication seized is usually the so-called "lifestyle" medication, like diet pills, that is generally not available, prescribed or not, because it is dangerous (NOS, 2017-2).

Dutch national legislation

Different organisations work together to improve medication safety and uphold the Geneesmiddelenwet on behalf of the Ministry of Healthcare (VWS), the most important are the IGJ and the RIVM. The *Inspectie Gezondheidszorg en Jeugd* (IGJ), also referred to as the inspection, is responsible for monitoring the safety and quality of medication. They uphold the legal obligation related to the *Geneesmiddelenwet*. According to this act, it is prohibited to produce, prepare, import, deliver or trade medication without a permit and active substances without registration. Besides, it is forbidden to mediate in medication without registration. This licensing system is intended to keep track of import, export, preparation and distribution.

Besides, the Geneesmiddelenwet (2018) also decides who is allowed to sell medications. Medication is fit for sale in only the pharmacy or also at the drugstore or supermarkets. Lastly, there are strict regulations about advertising medication, to avoid unwanted influencing towards patients and prescribers. Advertising prescription medication is altogether prohibited.

In the Netherlands, the pharmaceutical supply chain is already very closed off. Besides registration of (possible), falsified medication is already well recorded. The IGJ (2017-1) reported only sixteen violations of all laws concerning medication in 2016 and the first half of 2017. In combination with each other leading to ten fines for pharmacies, companies or individuals. Four of these incidents concerned medication without trade permits (art.40), and one incident where a wholesaler sold a prescription drug directly without checking it to European safety features (art. 37). The rest mainly concerned advertising medication. This further illustrates the minimal impact the FMD is expected to have on the Dutch pharmaceutical chain.

MEDICATION SAFETY IN PHARMACEUTICAL CARE

Medication safety in pharmaceutical care chain, is a current and significant topic across all involved caregivers, branch organisations and policymakers. Problems and errors in pharmaceutical care can lead to serious problems for patients, at its worst hospitalisation, see figure 2.1.3 (van den Bemt et. Al, 2006). Hospital Admissions Related to Medication (HARM) to illustrate the size of this problem numbers are described in figure 2.1.4. On a weekly basis 1.000 people end up in the hospital due to medication incidents (Nictiz, 2018).

Norms on medication safety

The IGZ established norms about the risks in pharmacotherapeutic care process that bring about problems, see Appendix B2. Van den Bemt et. Al (2006) identified three types of errors typically made in relation to medication: therapeutic mistakes account for 67%, like prescription errors. 22% of mistakes are made in administering medication, including therapy in adherence. Lastly, 11% of admissions are due to mistakes in dosages or any other error in medication.

The biggest risk factor in the pharmacotherapeutic care processes is communication between different caregivers and between the caregiver and the patient (IGJ, 2017-2). This risk splits up into four bottleneck themes: responsibility, medication transfer, electronic prescription systems and medication review, summarised in figure 2.1.5.

These four norms are reoccurring in research (van den Bemt et. Al, 2006; Leendertse et. Al, 2008; Sturkenboom & Dieleman, 2016, Van der Hooft et. Al, 2008), the problems in medicine have been reviewed by both the caregiver side IGJ (2017-2) and the patient side by RIVM (2016). The desired situation in norms set by the IGJ are portrayed against observed situations by researcher ((van den Bemt et. Al, 2006; Leendertse et. Al, 2008; Sturkenboom & Dieleman, 2016, Van der Hooft et. Al, 2008), and at institutions (IGJ, 2017-2) and reviewed by patients and patient organisations (RIVM, 2016).

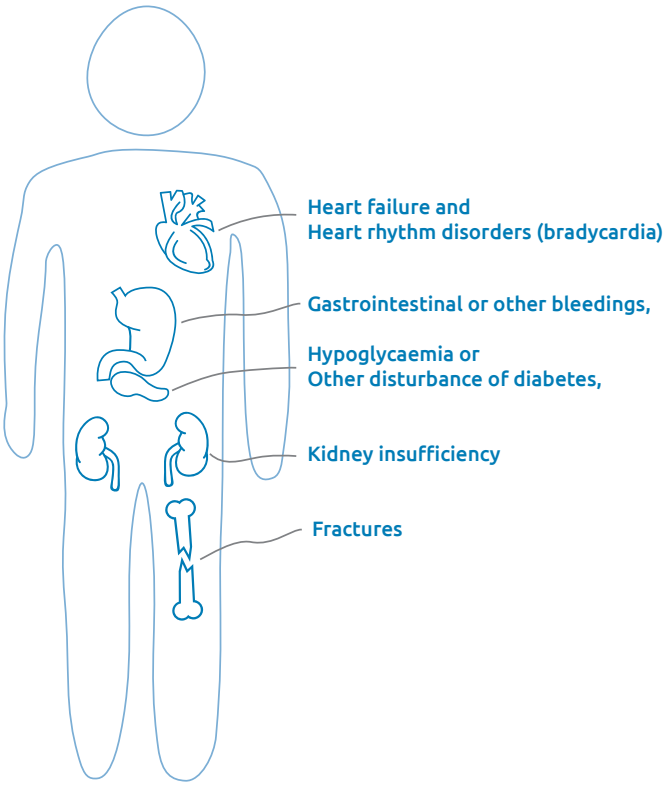


Figure 2.1.3 Reasons for admission for avoidable medication-related hospital admissions.

Responsibility
In more complex care institution better agreements are necessary for coordinating responsibility in the medication care process. Besides IGJ (2017-2) concludes agreements should not just be written down but also be carried out. For patients with multiple prescribers, it should be clear who is the contact person for all things concerning medication. Who is (end) responsible and who is coordinating everything concerning medication. IGZ found that this works relatively well in simple organisations but not yet in more complex institutions.

Patients indicate that for them it is unclear who is end responsible for the total package of prescribed medications (RIVM, 2016). When medication is prescribed by a specialist they do not get told where to go with questions. An additional aim set by IGZ is to put first line caregivers in the position where patients can leave their questions. This is in line with the preference of patients who indicated a preference to ask the GP or Pharmacist.

Medication transfer
The norm is when an institution starts caring for a patient it is imperative to make an overview of all current medication and verify it (RIVM, 2016). So, at the moment of prescribing the prescriber should have an accurate up-to-date medication overview. Within 24h an updated overview should be available for other caregivers. Also, if a prescriber does a kidney function test, they will share this with the pharmacist.

Although medication transfer has improved it is still well below sufficient according to the Inspection (IGJ, 2017-2) and patients still question the completeness and accuracy. Verifying with the patient still needs to improve. Besides, a lot of time is lost because different information systems are not connected to each other. In the patient's opinion adjustments to medications are transferred very slowly to the GP or even within one hospital.

The IGJ appoints the patient as primarily responsible for the safe transfer(RIVM, 2016). It indicates physicians are there to support the patient in transferring their information. Especially since an important part of the information, the actual medication use is only known by the patient. Patients indicated that they don't prefer bringing their own medication overview and transferring information to the GP.

Electronic prescription
With the introduction of *Electronische Patient Dossiers* (EPD) came guidelines also for the medication supply chain. IGZ (2017-2) concludes that generally, most caregivers have a good working EPD system however the risks or limitations of

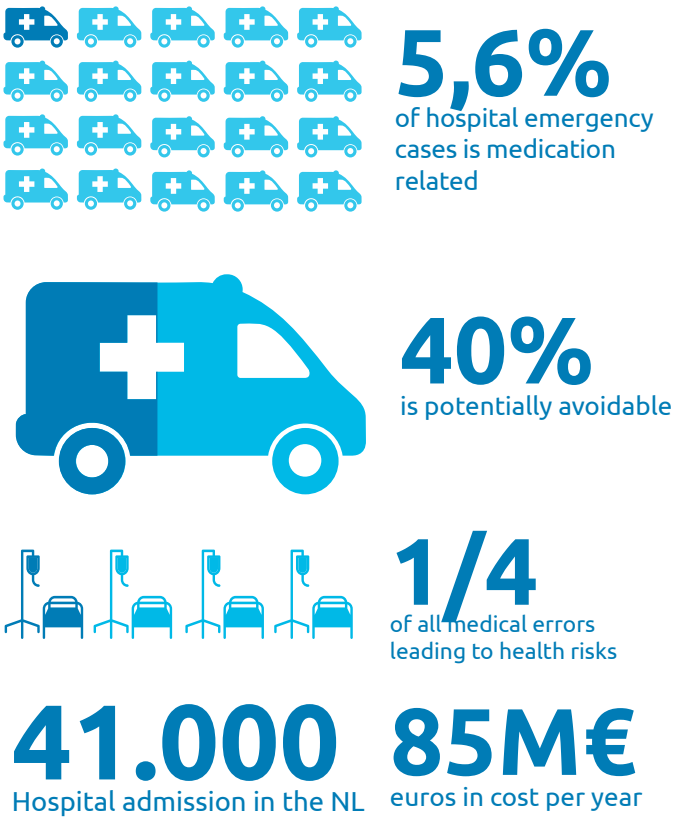


Figure 2.1.4: Hospital adimission related to medication in numbers

these systems are not clear to the users. It is still challenging to get a complete a current medical overview; due to poor logistics of transferring pharmaceutical data between caretakers and care providers.

In the norm about the electronic prescription system, the prescriber carries out a medication check during the consult to ensure an up-to-date overview. However, the IGJ (2017-2) already reviews risks that can occur on the patient side in this type of communication. Because not always: do patients understand questions asked about the medication he/she uses or how to answer them when asked by a doctor, it is not always known if the patient takes medication according to the regulations or if they take them at all, not all traits of a patient's life are known. Their life can affect medication use, for instance, motherhood or their life affected by medication when for instance driving a car. But poor communication goes both ways. In the RIVM (2016) research patient organisations report that there is inadequate information provided by caregivers.

The medical review

Especially elderly that use a lot of medication have a bigger risk of health problems when medication is used in the wrong combination. For these 'frail' elderly the Medication review was set up as a safety net in 2012. IGZ(2017-2) concludes it is currently still in its infancy and not yet a systematic part of the pharmacotherapy of care for fragile elderly. Besides, the Inspection realizes that the group of frail patients should expand. That there are more that can benefit from a medication review, like users of anti-psychotics and cardiologic medication. None of the patients in the study reported on knowing about the possibility of a medication review. The literature (RIVM, 2016) indicated people would like such a medication check.

The current situation and its risks

Figure 2.1.6 illustrates four commonly known problems that occure in medication care process. A risk situation often highlighted in literature (Van der Hooft et. Al, 2008; Van den Bemt et. Al, 2006) is being admitted and discharged from the hospital. Hospitals should provide all the medication the patient is already taking, or the equivalent they have from the hospital pharmacy. This means patients have to know or bring their medication overview on paper.

This transfer on its own is an inconvenience that is prone to human error but hospitalisation brings more risks. Van den Bemt et. Al (2006) reviews several pieces of literature that describe patients being put on the same medication after having

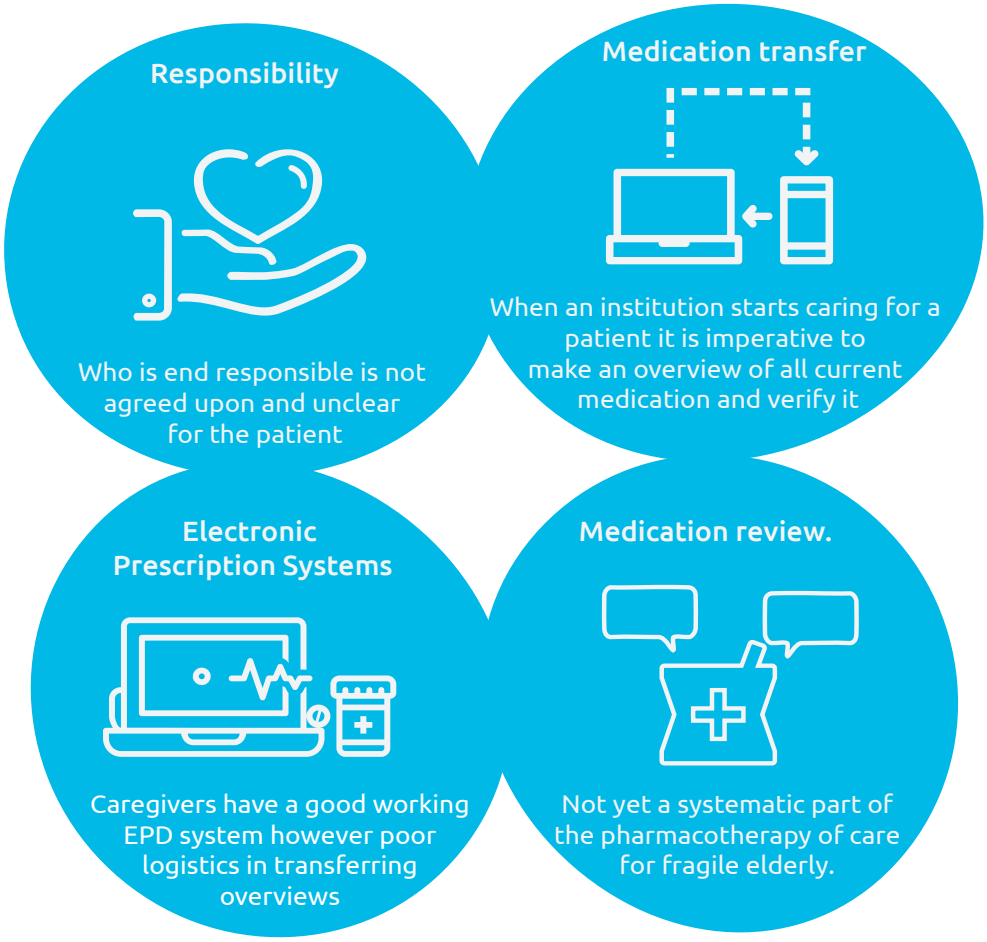


Figure 2.1.5 Overview of identified problems in the current pharmacotherapeutic care.

CONCLUSION MEDICATION SAFETY

Medication safety was reviewed from two sides, that of the supply-chain and the care chain. Both with different stakeholders. The supply chain that has proven to be open to problems with counterfeited or tainted medication that can have no or less active ingredients up to being poisonous. This supply chain consists of producers, wholesalers and the point of dispersion: the pharmacy.

Then there are the risk factors in the pharmaceutical care that lead to decreased medication safety. This causes patients to, for instance, take medications that interact with each other dangerously, to not take medication or too much or take medication the wrong way. The stakeholders involved in providing care to the patient, the pharmaceutical care chain, are all prescribers, like GP's hospital specialists and again the pharmacy.

Both sides showed the great involvement the Dutch government has. Not just on legislating but also researching the problems and setting visions to improve on them. As will also become clear in the next chapter that discusses all trends in the medication and health care.

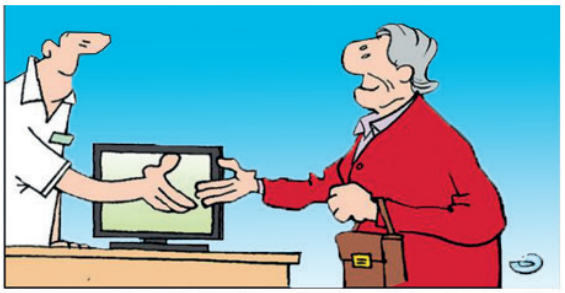
been discharged as before a medication-related admission. Although previous side effects are a clear risk factor indication for the reaction to occur again. Illustrating how important communicating changes to the patient and (digital) transfer of medication information really is. When a medication is stopped or changed, for instance, at the hospital it is important other caregivers (GP, elderly home, doctors and the pharmacy) are informed about this, either by the patient or within the system.

Design to resolve bottlenecks in medication care chain from the patient perspective.

This project aims to relieve risk from medication as much as possible to increase patient safety. Problems in medication safety that can be tackled through patient empowerment are within pharmaceutical care area. The product service system will take the patient as a target group. Leaving communication(problems) between stakeholders without patient involvement, like “Electronic prescribing”, outside of the scope of this project. This chapter described the norms set by the government the chapter “2.3 Patient perspective” will more elaborately describe where gaps lie between these norms and the patient’s experience of medication care.

Not knowing or explaining all medication, prescription and self-care, to the careprovider

The hospital pharmacy changes a medication to the wrong equivalent.



Having an hospitalisation due to medication and being send home with the same medications.

Changes do not reach the GP before the patient’s next visit and are therefore reversed.

Figure 2.1.6. Scenarios of problems that occure. (visuals from Patienten Federatie Nederland, 2017)

2.2 PHARMA TRENDS

Innovation in healthcare is vastly evolving. In a world with a growing and ageing population, health economies are under enormous pressure. The challenge is to transform for improved care results and patient experiences for considerably less cost. Technological innovation drives the change but also aids patients and their network adopt changes. For the pharmacological market and its patients, four big trends were established that are influencing the current environment they are operating in the most, namely: affordability of medication, patient centricity and empowerment, personalising pharmaceutical care and digitalisation of healthcare.
All trends were reviewed from the perspective of different stakeholders. The trends discuss the perspective and roles of the biggest stakeholder(s) in that trend. It was attempted to illustrate the perspective or interest of the biggest stakeholders for each trend in a table. With their subsequent behaviour towards it summarised. Lastly, the tables show an evaluation was made on the level of influence each respective stakeholder has on how the trend evolves or who simply has to undergo it.

AFFORDABILITY OF MEDICATION

Affordability of medication is more important than ever before, caused for instance by the rising of the elderly population. The challenge lies in keeping care affordable for the growing patient demand of today and tomorrow (VWS, 2016)

Increasingly governments and insurance companies are the centre of the healthcare value chain (KPMG, 2017). They have the power to pressure pharmaceutical companies to reduce prices and have them demonstrate greater value from therapies. This has already evoked change and has influenced not only the agenda of the government but also that of the supply chain. Branch organisation like VIG (2018-1), KNMP (2018) all show visions on their websites concerning sustainable affordability and pricing transparency. This sustainable affordability rests mainly on three pillars: collaboration, transparency into pricing and increase competition.

Collaboration

There is increasingly collective procurement of medication, with academic hospitals and hospital pharmacies to achieve price reduction is apparent (VWS, 2016). Overall more cooperative efforts have been achieved toward the same goal. Insurance companies collaborate with doctors, pharmacist and healthcare organisations. The Dutch share of pharmaceutics is too small to exert structural influence on prices or on the behaviour of, internationally operating manufacturers. Therefore, collaboration with other countries in Europe is sought in various ways.

Transparency into pricing

The government (VWS, 2016) aims to make insight into the pharmaceutical market more transparent. More transparency into pricing, can ensure money flows back to the research programme or the taxpayer, instead of profit.

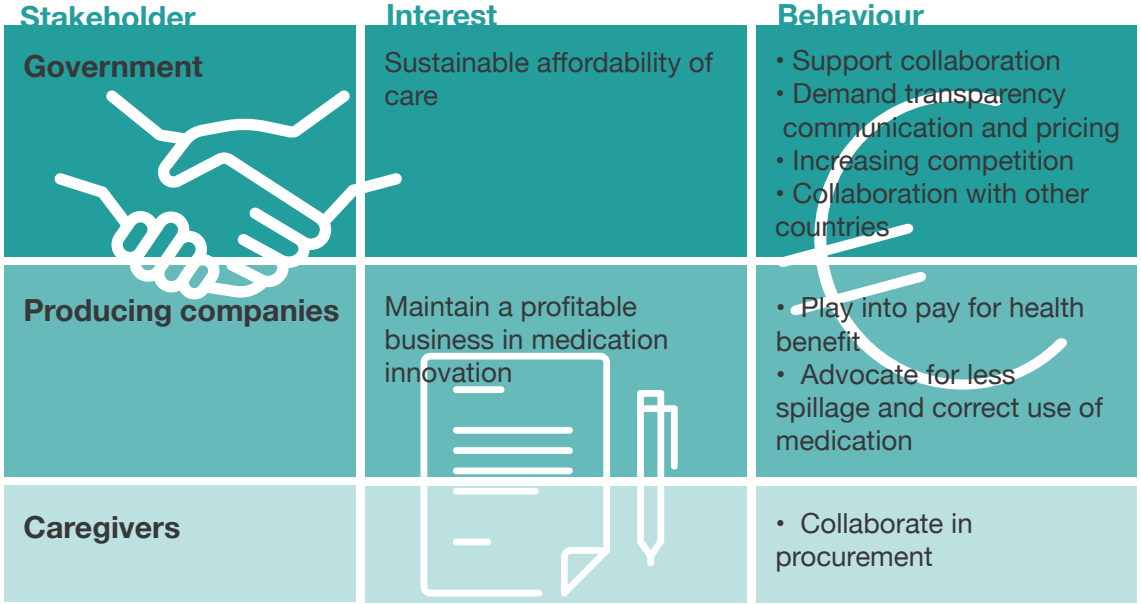


Table 2.2.1 Affordability of medication

A new, more transparent pricing model may emerge in the pay for benefit construction, that bases payment on the value of medicine outcomes. KPMG (2018) illustrates this with examples in the US, where health insurers announced value-based contracts for cholesterol lowering and diabetes drugs. Here the insurer receives discounts, if for instance cholesterol levels are not sufficiently reduced following the therapy. This seems to be a sustainable model for affordable medication however its risks and challenges have yet to be tackled.

Competition

Already there is an increase in competition through among other things the rise of biosimilars, and patents running out, VIG (2018 -1). The Dutch government intends to get more competition to lower prices by adjusting the reimbursement system of determining the levels and approval to the standard insurance package (VWS, 2016). Their effort already brought about het Preferentie beleid. The Ministry of Health (VWS) determines the maximum prices for medicines that suppliers can ask, twice a year. When more medicines have the same active substance, the health insurer determines which product or brand is reimbursed. This has caused a significant decrease in medication prices (Rabobank, 2017). However, for patients, it is mainly incomprehensible and it can elude strong negative emotions towards the executive party, usually the pharmacy (Bogaard et. Al, 2017).

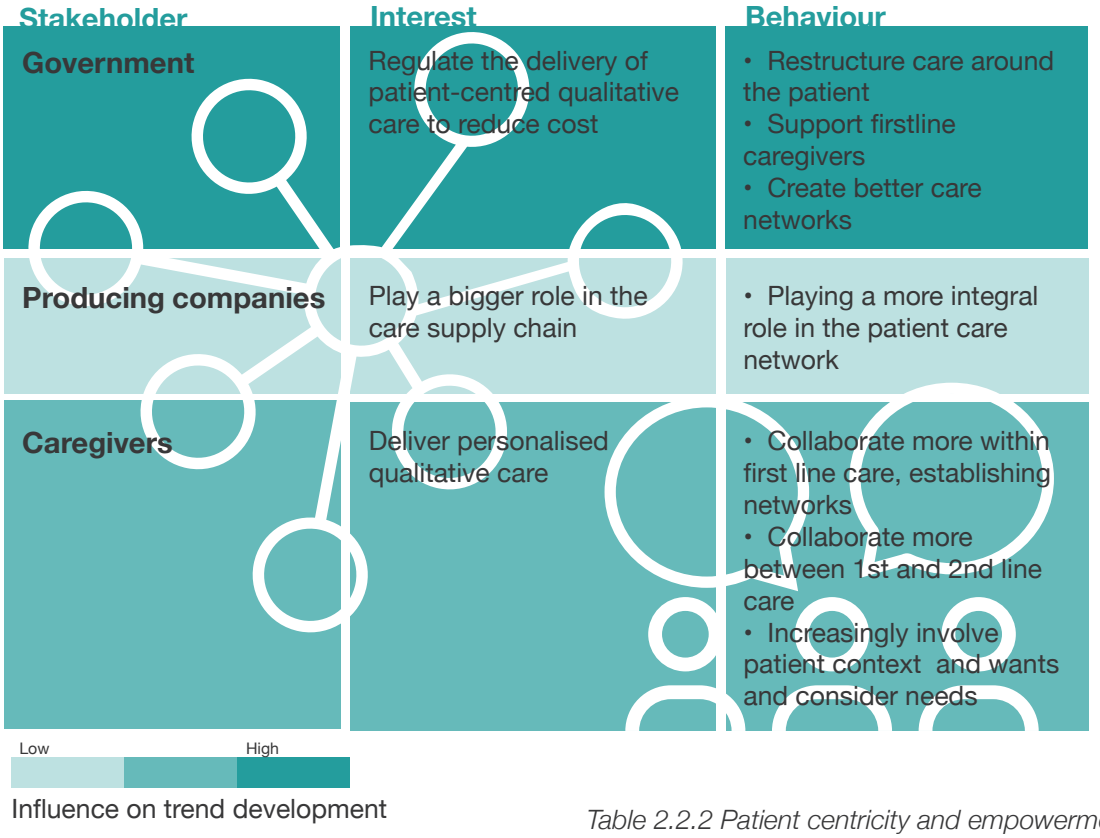


Table 2.2.2 Patient centricity and empowerment

PATIENT CENTRICITY AND EMPOWERMENT

Care is increasingly delivered holistically; the different caregivers are being centred around the patient. This elicited a change in attitude from looking at a product or service into looking at it as value for the patient. It also requires a structural change in the setup of the care provider network. Besides, it assumes a patient that actively participates in its own treatment and is empowered to do so.

Patient empowerment

World Health Organisation (WHO, 2009) defines empowerment as "a process through which people gain greater control over decisions and actions affecting their health and should be seen as both an individual and a community process."
Four components have been reported as being fundamental to the process of patient empowerment, also illustrated in figure 2.2.1. Related to medication they add up to:
1) understanding by the patient of his/her role and responsibilities in medication care;
2) acquisition by patients of sufficient knowledge to be able to engage with their health care providers that prescribe medication;
3) patient skills around medication use; and
4) the presence of a facilitating environment for medication use and care at home and at caregiver consults.

"A process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognizes community and cultural differences and encourages patient participation." **-WHO (2009)**

Figure 2.2.1 Factors of patient empowerment

Re-organising care around the patient

Care is evolving into an integrated care chain towards the patient in which, first-line care becomes most important (VWS, 2014). First-line caregivers are caregivers literally closest to the patient: GP, physiotherapist, pharmacy, home care nurses etc. Better integration and collaboration of first-line care can lead to care that revolves around the needs of the patients and aimed at results. Besides, it will be more proactive in its delivery and therefore decrease the cost.

In delivering care the personal medical history, context and daily life of the patient are considered more. KNMP (2017) gives an example: the pharmacist can advise about the use of medication during Ramadan. This illustrates that besides lab values, shared with the pharmacy, increasingly patient context is considered in prescribing or adjusting medication.

PERSONALISING PHARMACEUTICAL CARE

Healthcare and especially the pharmaceutical industry is working on personalising care which aids the search for more preventive care and better prediction of health conditions. This shift of preventing the illness instead of curing it is driven by underlying developments in technology and data (KNMP, 2017). Disruptive new therapies and advances in pharmaceutical technology make personalising treatment already possible.

Medication delivery technology

In pharmaceutical technology is developing medication for easier, more effective and targeted use (KPMG, 2017). In the form of, for instance, small molecules to medication-implant. Which can secrete medication gradually throughout the day, or based on values measured in the blood. This is also called personalised or individualised medicine. Besides, technology outside of the body, like 3D printing can offer medication to literally be made, printed, on the spot, specifically for one person.

Genetic personalisation

Over 20% of all new medication is precision medication illustrating this is a strongly evolving field, figure 2.2.2 (PMC, 2016). Especially used for oncology treatments. This is driven by technological advances in distinguishing biomarkers, these

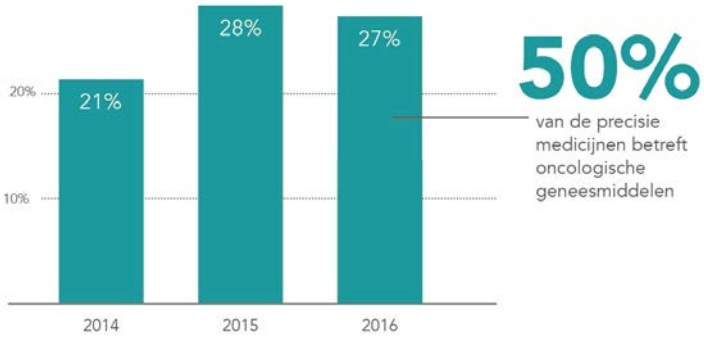


Figure 2.2.2: Over 20% of new medication is precision medication.

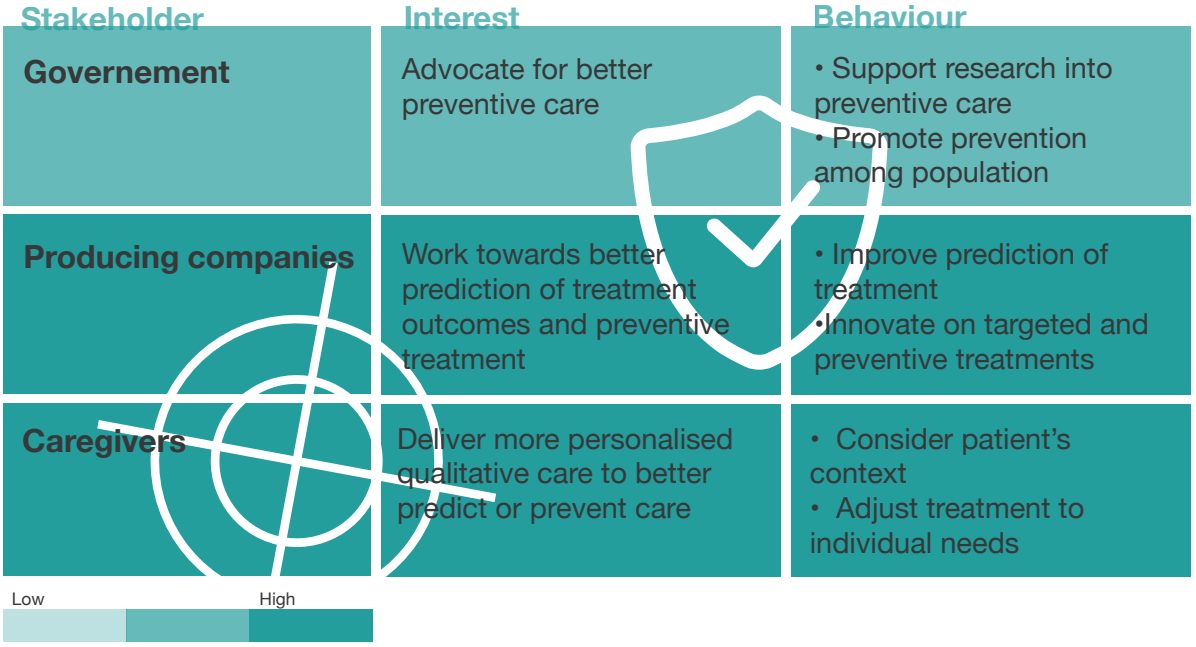


Table 2.2.3 Personalising pharmaceutical care

markers are often genetic. Genes can help diagnose a patient but also give a prognosis of how the disease may develop (VIG, 2018-2). Ultimately, predictive biomarkers can help determine which patients are most likely to benefit from a certain treatment. This study field is called Pharmacogenetics. Pharmacogenetics also tests what medication in what doses will be safest and most effective for patients based on their genetics. Some patients differently process certain medication, like blood thinners, in the body and are at much greater risk of severe side effects.

Big data insights

In combination with genes, (big) data can be used to develop more targeted therapies (KPMG, 2017). It can be used to make a prediction about the effect of the medicine on patient populations and to generate new insights into conditions. An increase in self-reported health data, from for instance wearables, can be used by practitioners to anticipate the likelihood of a patient being diagnosed with a disease (KNMP, 2017). Or be used by producers to review and improve the pharmacotherapy, use and effect of medication on individuals (VIG, 2018-1). This requires new knowledge sharing throughout the supply chain, between the patient, pharmacy and producer, which is still an unmet challenge.

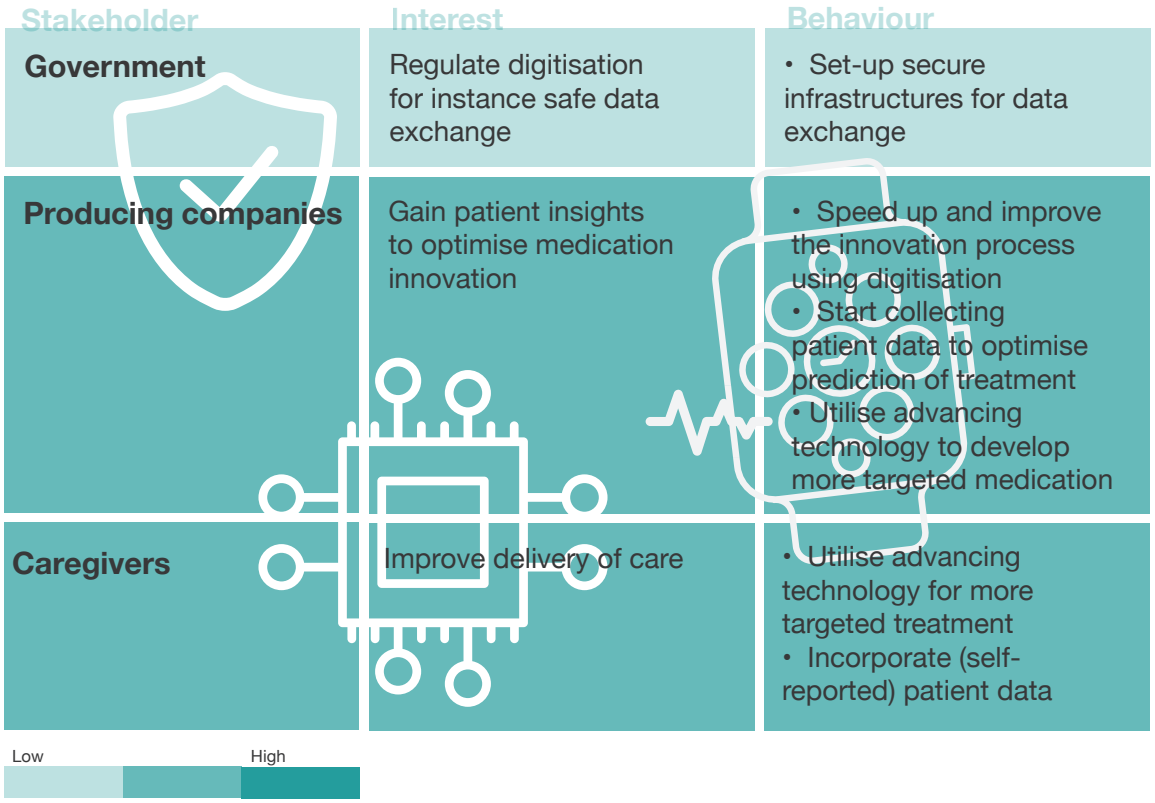


Table 2.2.4 Digitisation of healthcare

DIGITISATION OF HEALTHCARE

Technology plays an important role in the increasing level of accessibility, effectiveness, efficiency, safety, quality and self-management in healthcare for people (VWS, 2014). Not only because the medical possibilities (and therefore the choices) increase, but also because technology makes it possible to organise care, welfare and prevention in a different way. E-Health technologies optimise clinical roles and can be used to deliver more seamless, integrated care, designed around these patient needs. Patient centricity can be enhanced by digitisation of health care.

With the opportunity of doing more themselves with the help of technical gadgets, patients are demanding more control over their healthcare. They increasingly call of personalised health solutions, home-based care and less invasive treatments. Patients are increasingly knowledgeable and empowered about these healthcare options and enabled to receive more and more care at home.

e-Health

All technology in healthcare is defined as electronic health or e-Health. For this report, the definition for e-Health of the WHO (2016-2) is used with the addition of The Covenant Governance e-Health.

e-Health is the cost-effective and secure use of ICT in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge

and research. When applied correctly, e-Health will contribute to more affordable, accessible and higher quality of care. **- WHO (2016-2)**

E-Health includes applications such as mHealth, telehealth, electronic health records systems and eLearning. Other emerging areas discussed earlier like big data for research and social media for healthcare fit within as well. (WHO, 2016-2).

The digitalisation of data and exchange also is expected to benefit producers in, for instance, clinical trials. It could also aid economic drives behind the expected pay for benefit construction and improved R&D spending. Deloitte (2018) discusses four big technologies their advantages for patients and pharmacuetical suppliers that are thought to also be applicable to other (care) stakeholders, see figure 2.2.3.

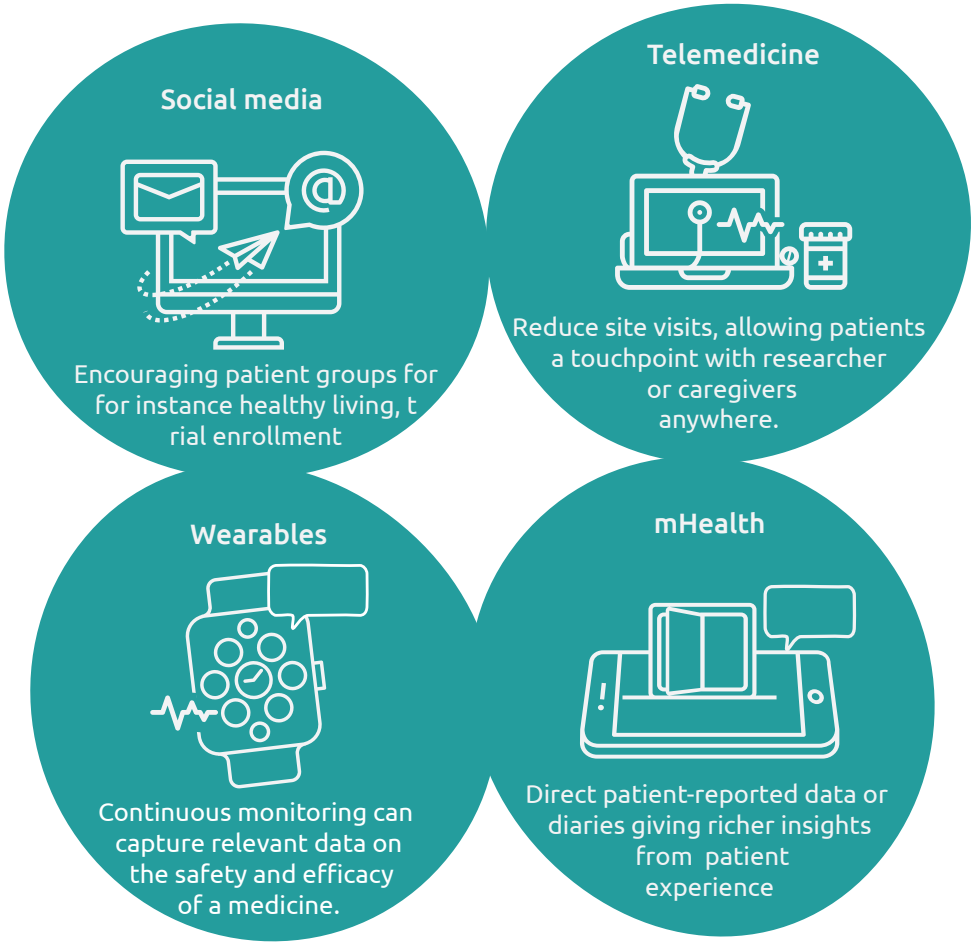


Figure 2.2.3 Opportunities of utilising e-Health technology

Digital patient engagement

Digitisation leaves more time to adjust the care to individual differences. With medication adaptable to the genetic profile, but also more tailored to personal wishes. Because technology takes over tedious tasks from care providers, outside of care, leaving more time for the warm side: conversation and personal contact. Providers have more time to look closely at the person behind the patient and because communication (over a distance) becomes easier, we see that the care is organised around the patient instead of around the care provider (VWS, 2014).

Digital tools make different types of patient engagement possible. Capgemini(2018-2) found four types of existing digital patient engagement initiatives between patients and pharmaceutical companies. However, they are believed to be applicable to more stakeholders in the pharmaceutical care and supply chain.

- Marketing and communication to raise brand awareness (not applicable to the Netherlands)
- Patient education and training
- Patient treatment adherence and monitoring
- Clinical studies/ real-world evidence

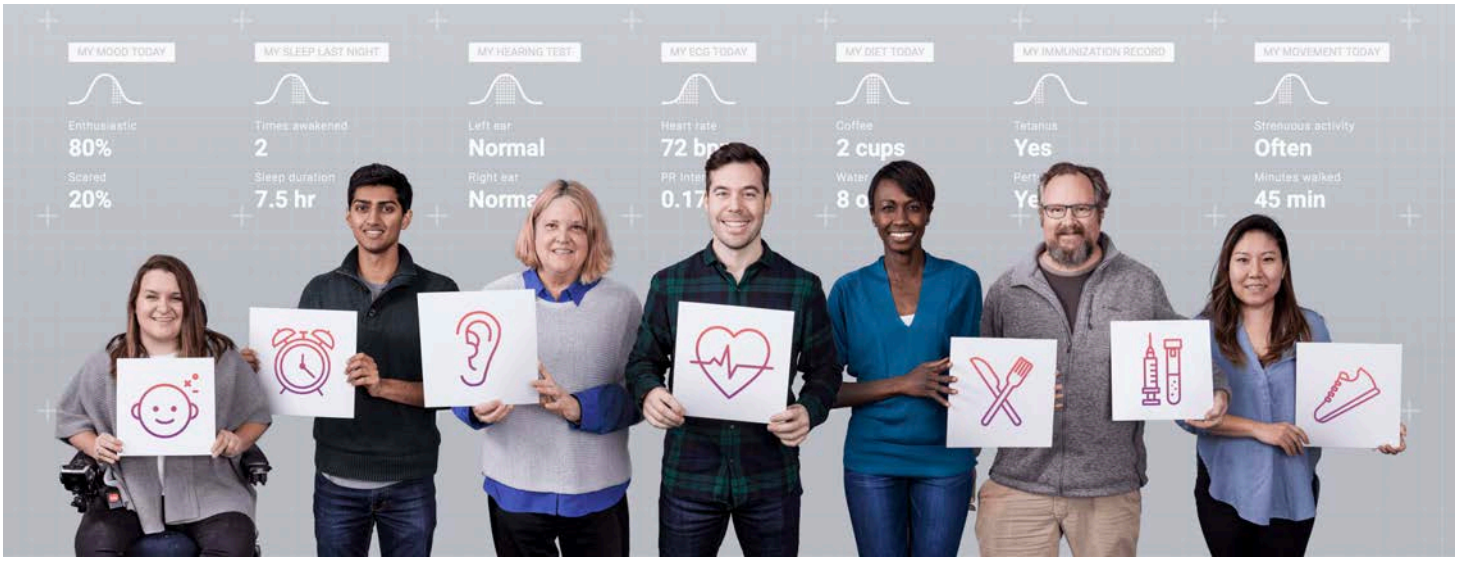


Figure 2.2.4: Project baseline (Project baseline, 2018)

Capgemini (2018-2) found two more digital initiatives that can be an opportunity in adding value, using the full advantages of the capabilities that digital technologies can provide but not yet exist. Better informed decision-making by healthcare ecosystem players and patients and new opportunities in holistic digital. Which means playing fully into the opportunities of patient engagement, personalised & precision medicine and offering pharma as a service.

Digitisation for the supply chain

In medication production, automation technology is already being used in continuous manufacturing technology and robotic process automation to shorten production times an increasing process efficiency, Delloite (2018). Especially, bio-pharmacy companies are increasingly using Artificial Intelligence (AI) to streamline the drug discovery process. Algorithms analyse data sets from clinical trials, health records, genetic profiles and preclinical studies. Patterns and trends within this data can help develop hypotheses much faster than researcher alone, delivering new insights more quickly.

While digital patient engagement is a growing trend within the wider healthcare industry, pharmaceutical companies have been generally slow to adopt (Capgemini, 2018-2). Digital patient engagement is flows of information between a patient and a stakeholder in their pharmaceutical network that is mediated directly or indirectly by digital technologies. Only a few initiatives towards getting closer to patients via digital tools and technologies can be found. In contrast, non-traditional healthcare players like Google, Microsoft and IBM that have established themselves in digital patient engagement. For instance, Google parent Alphabet Inc. launched Project Baseline, see figure 2.2.4 from with their life sciences division. They aim to collect health data from people to study health and disease in more depth.

CONCLUSION PHARMA TRENDS

To conclude trends are reviewed on how they influence the three main stakeholders of the government, producing companies and caregivers. The ageing population brings about a heavy burden on healthcare demand. In solving this we see efforts driven by mainly the government to reorganise care. In ways of procuring medication more financially sustainable and even rethinking reimbursement for medication from a value-based point of view. Organisational set-up of caregivers and reimbursement have been re-organised around the patient to deliver value-based care and decrease costs.

It was found production companies have the intention to comply with this value-based healthcare, but of course have a big influence on pricing. Besides, they are working on new pharma technology for more personalised medication for better outcomes. It is expected the pharma industry will move into three segments of companies. Generic producers, specified providers to one disease, and lastly companies that deliver value through prevention and prediction with the help of big data analysis(KPMG, 2017). For this higher involvement in the patient's care network, through digital engagement, is needed to deliver direct value and not just B2B.

Pharma healthcare providers mainly undergo changes in the field. They practice more personalised care and utilise digital developments to deliver value. They carry out policies and changes made in the organisation of care. For instance, pharmacists are the face of the Preferentie Beleid.

Design for transparent delivery of medication care

Pricing legislation is unclear to patients and currently mainly produces negative emotions towards caregivers and production companies. Transparency and understandable insight into this could help create understanding and acceptance towards the topic. The design will not resolve sustainable affordable care but can advocate for the correct use of medication. Besides, it can support developments in value-based healthcare models as long as value for the patient is clear.

Design for patient empowerment

This implies a medication care process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognises community and cultural differences and encourages patient participation. This is believed to only be achieved if patients are heavily involved in the design and development of an intervention for empowerment.

Design for personalised medication care

This implication is two-fold, the design should aim at personalised delivery of care and adopting technology advances in medication and healthcare. Patient information is and can increasingly be used to deliver better care. This requires collecting personal patient information and utilising opportunities to apply it for preventive or better care. Moreover, participate in knowledge and data sharing to improve delivery of care in the entire supply chain. This requires to also explain to patients what and how their information is used. The other side is that the design should embrace existing and future technological advances like data input from wearables, smart measurement devices etc.. Again with the patient-centred aim to deliver better more personalised care.

Design to optimise medication care utilising the opportunities digitisation offers

Using technology for personalisation is an example of improving quality and possibly effectiveness of care with digitisations. Digitisation can be applied to the design if it achieves one of the aspects of improved: accessibility, effectiveness, efficiency, safety and quality, of medication care for patients. Self-management or affordability is not believed to be a patient-centred goal of digitisations but an expected outcome none the less. Since medication is also taken outside health institutions the use of m-health to have access to medication care any time and any place seems indisputable.

Design for profitable (digital) patient engagement

(Digital) Patient engagement shows how the design would be profitable for pharmaceutical stakeholders. By binding and/or engaging patients to existing or a new stakeholder, profit can be created, in terms of loyalty, financial or otherwise.

2.3 PATIENT RESEARCH

Capgemini Invent had no prior view on a patient group that user-opportunities could give value to. This is why the choice for a patient group is made for its opportunities in market size, see figure 2.3.1 and room for improvement. A patient persona is based on patients with a higher risk of problems due to pharmacotherapy. Again, special attention was paid to who is involved in the patient's network or who could possibly become more involved. Patient interview have been conducted to give a deeper understanding of how these people live with medication on a daily basis. Experiences of these patients complemented the earlier found bottlenecks within medication safety in pharmaceutical care to a list of five problem areas. A patient journey through living with medication was established from the interviews. The journey was worked out to see where painpoints lie and therefore the need for improvement from a patient perspective.

PATIENT PERSONA

This section aims to give a more in-depth persona to what until now was called patients with polypharmacy and multi-morbidity, to be taken into account when designing. There are more indicators as to what patients are at higher risk of problems due to medication. Besides, the same research indicates that heart and vascular medication put patients at higher risk. Therefore, the patient group of this research is into patients taking this medication. Interviews with these patients also turned up a general medication regimen these people follow.

Patients at higher risk

From various research (Van den Bemt et. Al, 2006; Sinnige et. Al, 2016 -1;-2), seven characteristics from patients with higher risk of problems in medication use were retrieved: higher age, polypharmacy, multi-morbidity, lowered cognition, therapy non-adherence, kidney function disorder and/or an assisted living situation. Reading into these different characteristics we find a high causation between all of them.

Ageing

As explained by Zorginstituut Nederland (2018) pharmacotherapy for elderly demands more individualised approach than for younger people. The most important reason for this is that the ageing process differs from individual to individual and

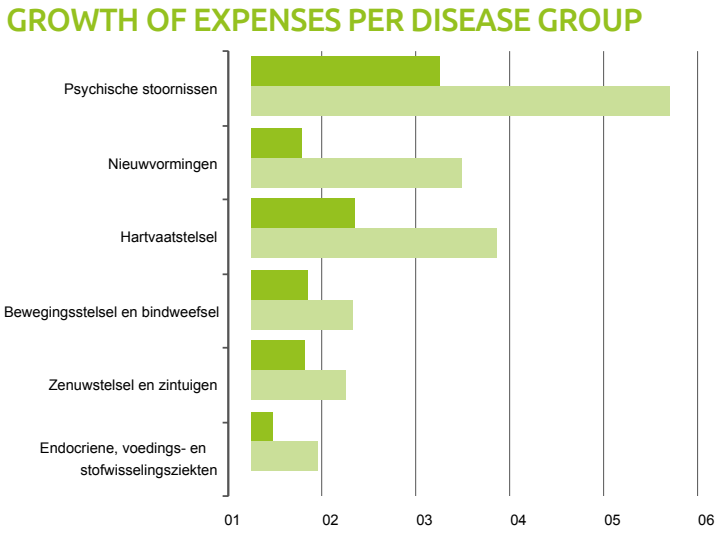


Figure 2.3.1 Expected growth in expenses on cardiovascular disease.

within one person the ageing process of different tissues and organs can already be different. The practical problems elderly experience in following instructions cannot be ignored, like impaired vision or memory, but also impairment in motor skills, to open certain packaging or applying for instance eye drops etc. Van den Bemt et. Al (2006), found that patients over 65 had twice higher chance of medication-related admission. Sturkenboom & Dieleman (2016) even found that in patients over 75 years old, 9,8% of acute admissions were due to medication use.

Polypharmacy

Polypharmacy is defined in many different ways throughout literature. In a literature review Mansoon et. Al (2017) reports the definition: “a daily intake of five or more medications”. Descriptions vary in classifying it as appropriate or inappropriate polypharmacy, generally, it is given a negative annotation. For instance, RIVM (2013) calls problems with medication, problems of polypharmacy. Sinnige et. Al (2016-2), associates polypharmacy with reduced medication adherence, increased risk of potentially inappropriate medication use, adverse drug reactions and unplanned hospitalisations. Higher age, lower socio-economic status (SES) and a number of chronical conditions are highly positively associated with polypharmacy. Of chronical conditions, most strongly positively associated with polypharmacy are cardiac conditions (Sinnige , 2016 -1).

In numbers, polypharmacy affects 30-45% of all 65 years old, in the Netherlands. Among 75-year olds 20% already uses nine or more medications, this is about 200.000 people (RIVM, 2013), and this number is still expected to rise, see figure 2.3.2 (VTV, 2018).

Multi-morbidity

Due to the growing elderly population increasing amount of people have three or more chronic conditions, also known as multi-morbidity. According to VTV(2018), the percentage of people that are registered at the GP with multiple conditions will

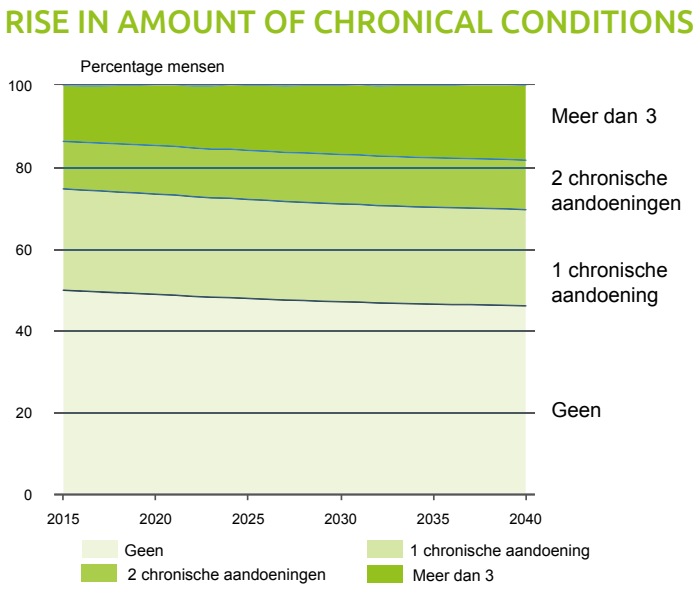


Figure 2.3.2. Excpected rise of polypharmacy population.

rise 25 percent between 2015 and 2040. The biggest increase is in the group of people with multi-morbidity, around 14 percent will grow to 3,3 million people. Interestingly, an increasing number of prevalent chronic conditions is not directly linked to an increase in prescribed medications. In patients with five or more conditions, it seems other factors start acting. For instance, interactions between medications, other treatment options like surgery (Sinnige, 2016-2).

Lowered cognition

Lowered cognition in patients is a big risk factor for medicine-related hospital admissions. De Inspectie (IGJ, 2017-2), lists why prescribing is associated with risks which gives some clear examples of patient cognition. A patient does not always understand the questions the doctor asks about their medications nor knows how to properly answer the question, and they don’t always use medication according to the instructions.

Therapy non-adherence

Also, therapy non-adherence is a complex and multi-dimensional healthcare problem, which has been heavily researched (Hugtenberg, 2013). As a result, patients do not benefit optimally from pharmacotherapy, which causes great risk in older people resulting in poor disease control which in its turn associates to multi-morbidity and polypharmacy. (Older) patients may deliberately choose not to adhere to medication to avoid adverse effects, called intentional non-adherence. However, overall there is little consensus about categorisation and influencing factors. The result, however, is clear: tremendous avoidable healthcare costs.

A range of strategies and interventions have been researched, what is becoming apparent is that the patient role in the decision-making process about medication is critical. This ensures the patients perspective is considered in the communication between the patient and the caregiver. A multifaceted and practical approach, like reducing unnecessary medications and simplifying dosage regimens, so far have also shown to be good solutions.

Kidney function

Kidneys play a crucial role in the natural secretion of medication from your body. Several factors, including certain properties of the drug, influence the ability of the kidneys to secrete drugs. Most drugs are water-soluble and can, therefore, be secreted in the urine. The acidity of the urine affects the speed at which the kidney excrete medicine. The ability of the kidneys to excrete medicine is also dependant on urine flow, the blood flow through the kidneys and condition of the kidneys. All of which can decrease when there is decreased kidney function. Disorders like high blood pressure, diabetes and reoccurring kidney infections can affect kidney function. Besides, renal function decreases with age. Kidneys of an 85-year-old separate drugs only half as efficiently as kidneys of someone aged 35. Two third of elderly experience decreased kidney function (Zorg Instituut Nederland, 2018)

Medication groups most frequently associated with potentially avoidable drug-related hospitalisations according to the international review of (Howard et al. 2007)

Medicationgroup	All potentially avoidable admissions	Admission resulting from therapy non adherence
Trombocytenaggregatieremmers	225 (16%)	2 (2%)
Anticoagulantia	117 (8%)	4 (4%)
Bètablokkers	65 (5%)	4 (4%)
Positief inotrope middelen	45 (3%)	3 (3%)
RAS-remmers	62 (4%)	4 (4%)
Opioïde analgetica	69 (5%)	1 (1%)
Diuretica	223 (16%)	20 (20%)
NSAID's	155 (11%)	4 (4%)
Bloedglucoseverlagende middelen	49 (3%)	9 (9%)
Corticosteroïden	44 (3%)	2 (2%)
Totaal	**1406 (100%)**	**98 (100%)**

Figure 2.3.3. High-risk medication in avoidable admissions and their adherence rate.

Living situation

A counterintuitive find is that, assisted living is positively associated with problems in medication. This is in any form of home care, elderly homes etc. RIVM (2013) found that in elderly homes 40% of the inhabitants are either over- or undertreated. This could be explained by the thought that people most likely get assistance when they have multiple chronical conditions, having to perform multiple acts of care or when their cognition is impaired etc. Interestingly, IGZ (RIVM, 2016) sets up guidelines for who requires frequent medication reviews, they indicate that most 'frail' elderly still live at home.

These parameters that are a brought into relation to higher risk of medicatiion unsafety are summarised in patient persona Miriam, see figure 2.3.4

High-risk medications

There are groups of medication that are most often associated with potentially avoidable HARM. The top ten, see figure 2.3.3, of medications causing most potentially preventable admissions where responsible for over half of all potentially avoidable admissions (van den Bemt et. Al, 2006). The highest potentially preventable admissions were found for cardiovascular remedies (Sturkenboom et. Al ,2006). Out of the top ten, five medications influence mainly the cardiovascular system (VWS, 2008). Second, come medications that influence the central nerves system. Of all admissions due to side effects or overtreatments, 37% relates to these cardiovascular medications. Out of all admissions due to therapy adherence problems 17% relates to these five medications. Interestingly, in comparison diuretics, used to stimulate kidney function, covers 20% of all therapy adherence problem admissions and blood glucose lowering medication 9%. Seemingly, therapy adherence problems are not big for cardiovascular medication.

Patient's medication routine

The patient's routine is reviewed as part of the excisting context the design has to comply with. Of the patients interviewed routines varied between one, two or three take-in moments per day. Taking medication is generally linked to other activities: getting up, lunch, dinner etc. For most interviewees taking medication is simply part of the daily routine and they did not prefer using an alarm to remind them. Most people used a daily, weekly or biweekly pill box as an aid to take the right medication at the right time. This was generally filled once a week or once every two weeks. Four out of six patients had their medication delivered to their homes.

"They once gave me a new kind of medication and I would have to start taking medication twice a day. I wasn't going to do that."

"Alarms, no I rather not use an alarm."

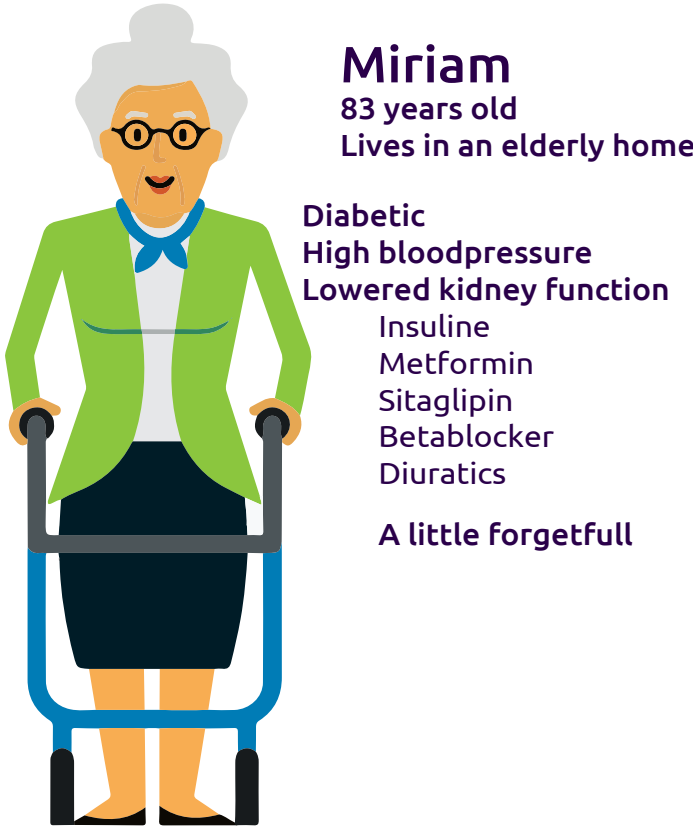


Figure 2.3.4. Patient persona

Negative (side-)effects

Interviewing patients brought forth that high risk in medication safety not only leads to hospital admissions, (HARM) as described before. Minor physiological problems and other impairments of normal living are just as well problems for patients. These will be taken into account as part of problems with medication safety as they can lead to in adherence or inappropriate use just as well.

"When the GP upped the dosage I had a bleeding nose every night, I'm not going to change my sheets every morning"

Figure 2.3.5. General healtcare network for (frail) elderly.

PATIENT NETWORK

General patient healthcare network

Figure 2.3.5 shows the general healthcare network for frail elderly as set up by the IGJ (2018-2). The healthcare network is the personal care network around a client or patient. For example, a caregiver, general practitioner, physiotherapist, district home nurse, help in the household, medical specialist, daytime entertainment and the pharmacist. It is a clear, complete overview of the complex network where patients are placed in. It was chosen to illustrate this general overview to not disregards the extend of the patient's network besides medication caregivers.

Pharmaceutical care chain

Figure 2.3.6 shows the cross-domain chain specific to pharmaceutical care, by RIVM (2016). It shows the patient flow, that start from possible living situations, passing different prescribers and caregiver. Besides it shows the flow of information necessary for a well-integrated care chain, as discussed earlier this information exchange leaves room for improvement.

Set-up patient interviews

In order to retrieve first-hand insights into the care network of patients with polypharmacy using heart and vascular medication, qualitative semi-structured interviews were conducted. The aim was to find out more on patients with complex medication regimens and how they view the role of stakeholders in their medication care network in relation to themselves. The patients were recruited within the researcher's own network. This turned up six people, between the age of 56 and 86, four males and two females. They all still lived mainly independently, or with only the help of a district home nurse. Five had multi-morbidity. The last one was chosen specifically because he recently started medication due to a heart attack. After the first sketch of the patient journey it was found out that at

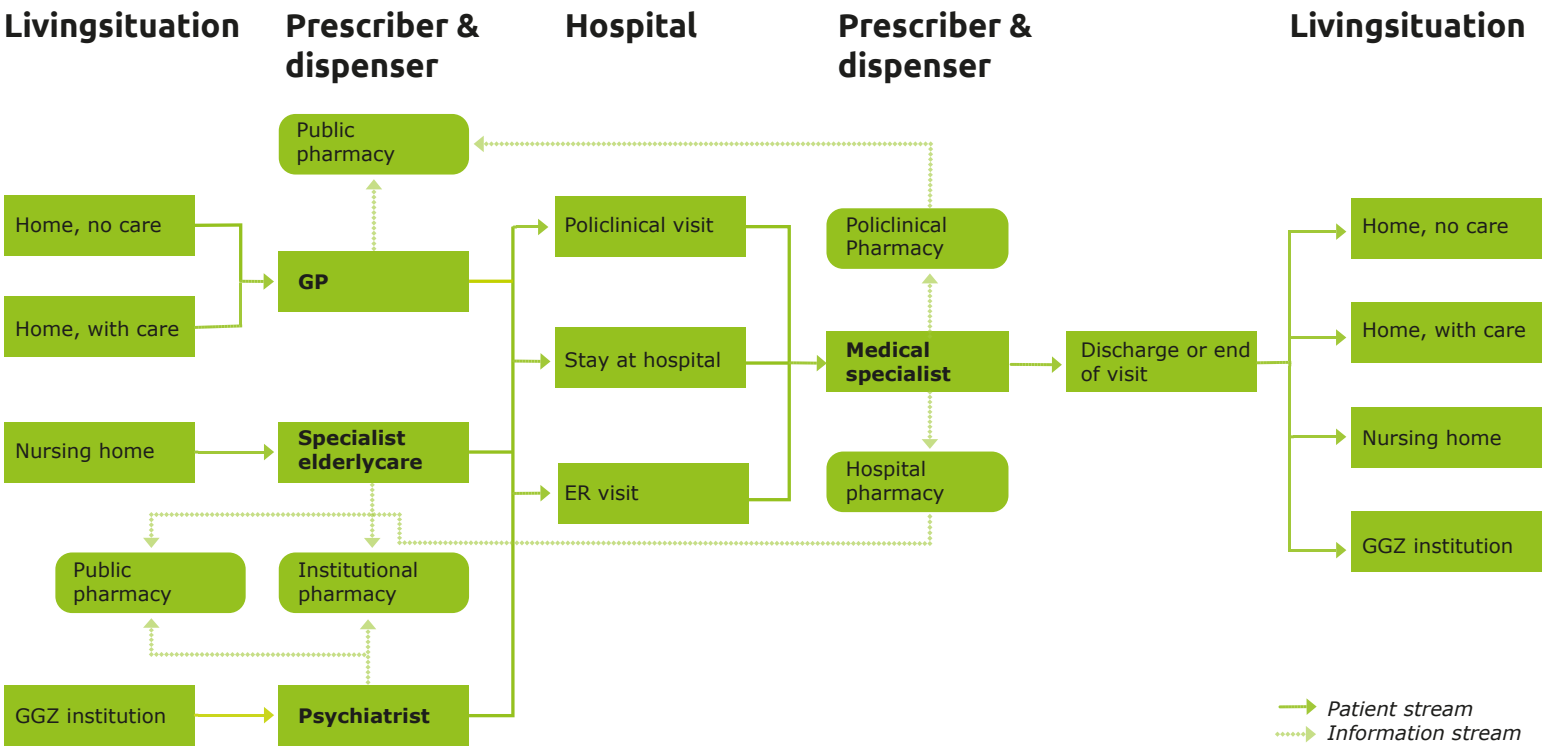


Figure 2.3.6. The patient and information stream in the pharmaceutical chain.

the start of taking a lot of medication, people figure out a lot. However, for all the previous interviewees this was quiet a long time ago. To explore the start in more detail a sixth patient was interviewed that was still making a lot of changes to medication. The interview consisted of a short survey set up in the earlier research by the RIVM (2016), used to gain general insight into the patient. Then moved on to the semi-structured interview, the full list of questions and summarised answers can be found in the Appendix B 1.

Interview network and roles

From this care givers chain a set of cards was made with the caregivers and stakeholders on them. During the interviews, there was always room to add more stakeholders or caregivers. Participants were asked to place each caregiver and stakeholder relative to themselves in terms of importance, see Appendix B1. They were asked to explain more about what role each of these stakeholders played in their life.

At a deeper look into the government and producers of medication, patient indicated them being “unknown stakeholders”. Because previous research indicates empowerment through knowledge and these stakeholders possess just that. Most people by now had enough knowledge and did not feel the need to gain more through these channels. Especially that of the government on pricing and availability was deemed unnecessary. All this information let to a concluding overview with the stakeholders in three two levels of importancy in terms of frequency of visits and feelings of affection, see figure 2.3.7.

Pharmaceutical care network
The literature (RIVM, 2016) indicated that one caregiver in the network should have the main responsibility in, for instance, answering questions about medication. This was the GP for three of the participants and the specialist for two people. All interviewees go to the GP for (minor) ailments, also unrelated to medication.

"Yeah, when she has something like swollen legs I will take her to the GP."

Most patients have regular check-ups with their lead prescriber, these range from every two to three months to once per year. Check-ups are generally performed by nurses or GP-assistant, like drawing blood, and discussing results with the prescriber. Health-related incidents leading to hospital admissions come with a set schedule of check-ups by the specialist.

"After the surgery, I had to come back after one month, then three months thereafter and then six months thereafter. Now I see my cardiologist just once per year."

The pharmacist played an important role in providing medication, in the eyes of the patient. Medication was usually brought by or picked up every week up to every four weeks. However, a bigger role with regards to the information provider was expected to be a result of the re-organisation towards first line care and medication review. An explanation might be that the pharmacy is not visited by the patients since medication was mainly delivered.

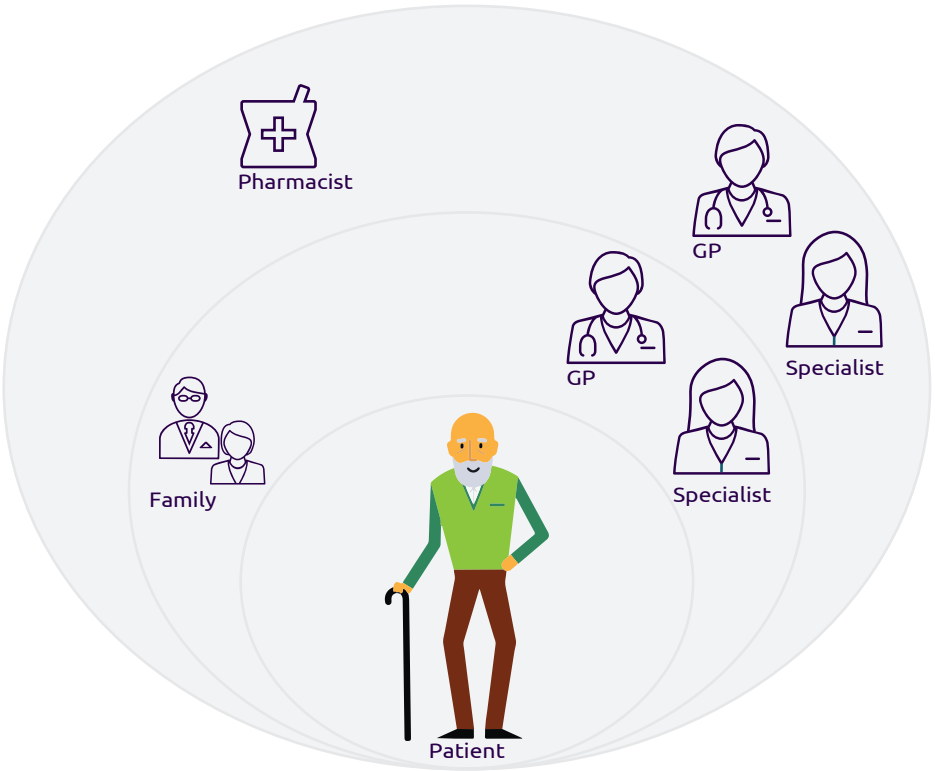


Figure 2.3.7. Pharmaceutical care network importancy indicated by interviewees.

The family was always the partner of the patient, when mentioned they played a rather significant role in the patient's life around medication especially in keeping oversight of all medication.

"She knows my medication overview very well since I was once hospitalised and was given the wrong medication."

Insurance was hardly mentioned when asked interviewees rerferred to it as hardly important. Except if they ever had had any trouble with the preference policy. Than

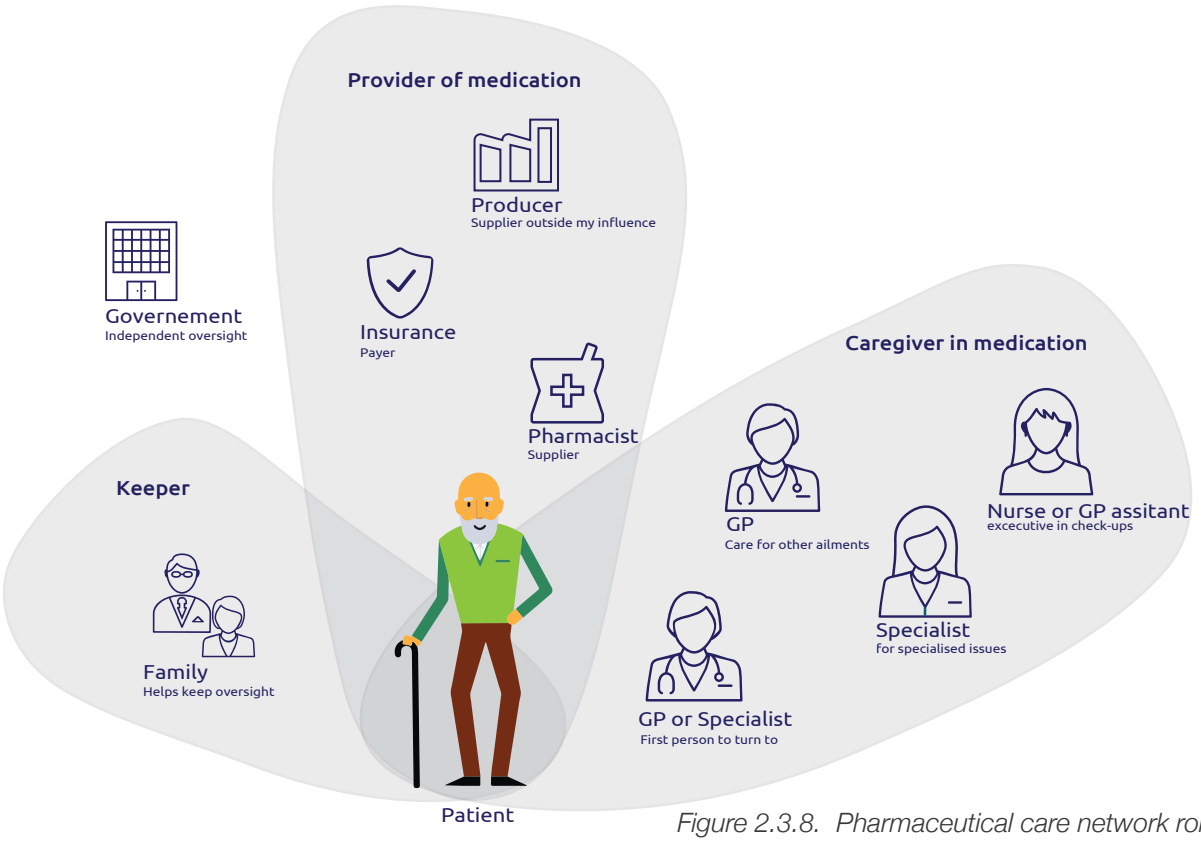


Figure 2.3.8. Pharmaceutical care network roles indicated by interviewees.

insurance was mainly negative factor that slowed down the process of resolving the problem.

Unknown" stakeholders

Three people had strong feelings towards the role that the government currently plays. They especially thought that they did not perform well enough. Others described the government as oversight and independent check.

"The government is there as an independent checkpoint; however, they are not working sufficiently to make it better."

"I feel they are compromising quality for low prices. I rather pay more for better quality"

Most people described the producer as don't know and you don't have an influence on that. One person had very strong negative feelings towards the producers.

"I mean they are way too expensive, and it takes them years to act on the real problems. I feel development should go back to other institutions like hospitals."

All opinions where compared to come to a role devision for the care givers. They were split up in keeper, provider of medication and caregiver in medication, as show in Figure 2.3.8.

PATIENTS EXPERIENCE IN MEDICATION CARE

The earlier mentioned norms by IGJ (2017) on risks or bottlenecks in pharma therapeutic care process also describe the role of the patient in each of them. Within these themes, the patient was reviewed by the RIVM (2016). The full list of norms can be found in Appendix B2 retrieved from the RIVM (2016) research. IGJ norms and further explorations of the patient's role in literature and the interviews bring forth five main problem areas within how patients experience medication care: responsibility in medication transfer, communication and knowledge, shared decision making, the pharmacy and medication review, in the hospital and the preference policy. The desired situation in norms is portrayed against the situation as described by patients for each point. Opportunities for improvement are mentioned.

Responsibility in medication transfer

From the interviews, it became clear that people easily disregard the medication overview and transfer thereof. They have a physical overview from the pharmacist or request one when needed for, for instance, travel. However, they don't take ownership or any responsibility for this overview. Moreover, people do not actively keep track of previously used medication that had negative effects or did not work. The overview and transfer thereof was described by patients as: the doctor knows. Here more understanding by patients of their role in a more proactive capacity could really help.

Communication and knowledge

According to the norm, a prescriber carries out a medication check during the consult to ensure an up-to-date overview. Interviewees mention their medication is hardly discussed by the doctor. Information provision by caregivers was generally referred to as clear and if not I'll ask. One interviewee mentioned that he was not told the risks of a treatment, although he would have liked to have known them. Furthermore, it was reported that care providers do not have enough time during the consultation to talk through the information or issues sufficiently with the patient.

"For the most part I know what is used to treat what issue."

"I think they once explained the difference between how these pills both work to lower my bloodpressure, but I wouldn't remember now."

Knowledge now is especially retrieved from leaflets, however, people generally look for more or accessible information online or in books. When the effects of medication gets too severe people will turn to their prescriber. All six patients have had a conversation about problems with their medication at one point or another. This consult was usually initiated by them because of the discomforts with medication.

"Every leaflet mentions the same there is no way of telling what causes a problem."

Although not reviewed as a problem by the researched patients, the literature (IGJ, 2017) clearly stated that in these types of consults communication is difficult. Patients don't always understand questions or how to answer them. Besides, not everything is known about the patient and whether they take their medication according to the regulations. Good preparation of a consult in terms of knowledge about medication and understanding of what to discuss could really help in making these consults more effective.

The patients interviewed indicated that they had a medium to high level of knowledge of their medication. They mentioned listening very well to what is explained and handle their own daily intake. If the medication causes problems, they are not afraid to take action by contacting a prescriber.

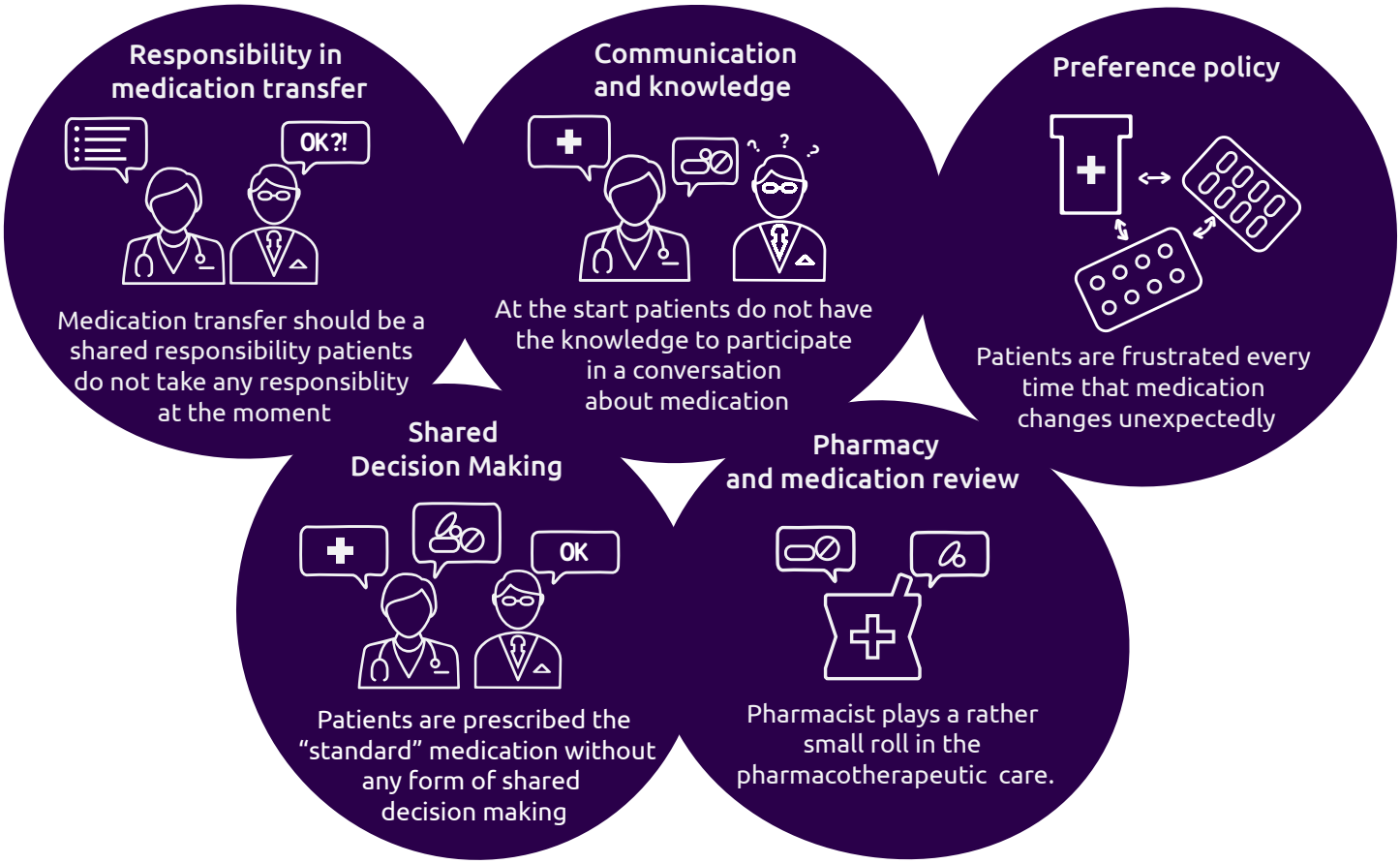


Figure 2.3.9. Problem areas in pharmaceutical care for patients.

However, one interviewee illustrated how this level of participation can change over time.
"I used to do it myself. But now they prepare it for me at the pharmacy. I'm getting older and keeping the overview became to much of a hassle. You get more forgetfull you know."

It is important to note that the patient sample may not entirely be in line with the general population. Pharos (2016) indicates 28,7% of the Dutch population has (extremely) limited healthcare skills. This is in terms of functional skills like reading or calculating but also skills in interaction or communication and critical thinking. In terms of these skills, it is good to take into account the biggest part of the population. For inclusive design starting from the assumption of low skill level will ensure all levels above will most likely also understand.

Shared decision making

Patients see it as their role to be alert and critical when their medication is adjusted. No one reported on ever being given the opportunity to choose between two treatment options. Only reactively when negative effects occurred a conversation about alternatives was held. Prescribers then helped to look for alternatives, patients mentioned feeling involved in these changes. Most interviewees expected the

doctor would tell them if better alternatives were/ became available.
"I'm really on top of it"

Patients clearly indicated that being critical requires the knowledge they have gained over time and vice-versa that they have/had to trust the doctor's knowledge when something new is prescribed. RIVM (2016) concludes that for each situation, the prescriber will have to provide the patient with sufficient information about the medication and must check to what extent the patient wants to and can decide. Again, increasing the knowledge of the patient is a great opportunity to come to more shared decisions.

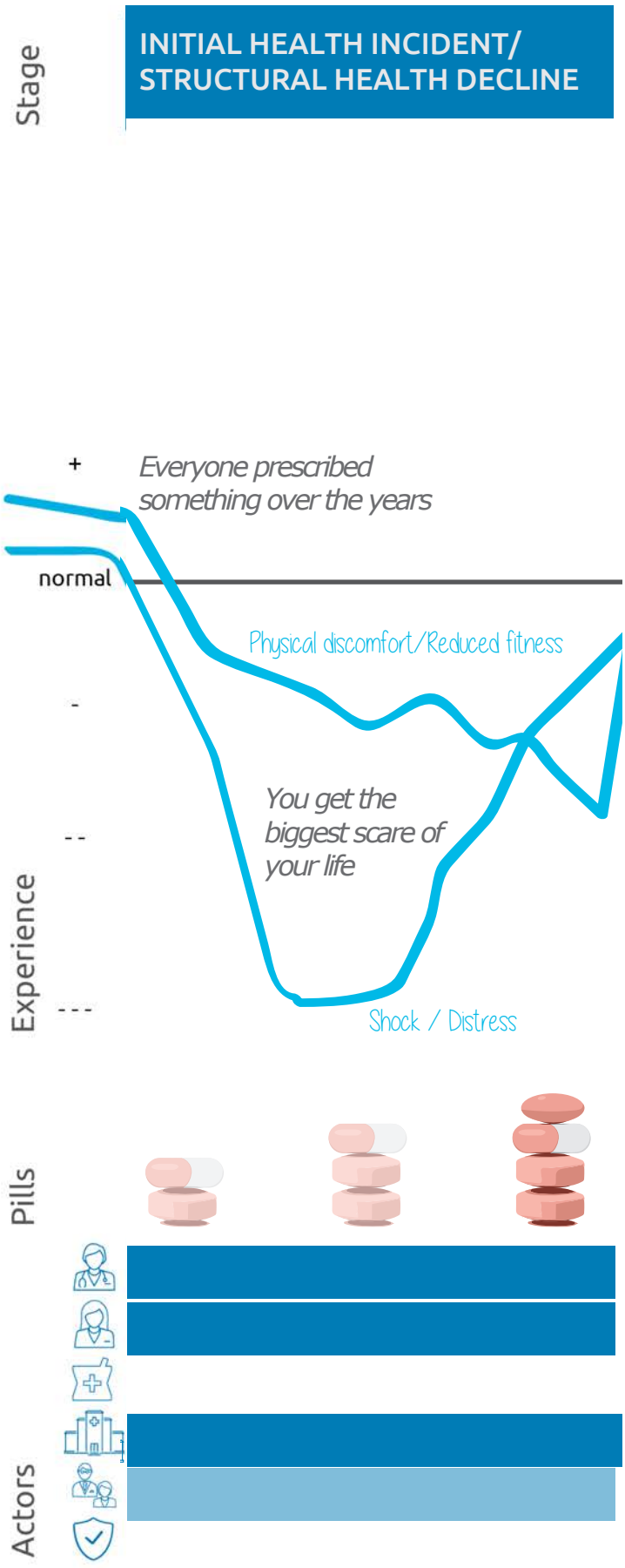
"Now a days when I don't like the result I will call them up and say I'm quitting these pills."

Pharmacy and medication review
The preference of patients is in line with the literature, there is a general preference to ask first line care providers, mainly the GP, about medication. Interestingly patients had very little contact with the pharmacist, most interviewees did not even frequent the pharmacy but got medication delivered. However, they do offer great knowledge of medication. Where doctors prescribe the active ingredient in medication pharmacist know why and how it works much better. Pharmacists are already working towards fulfilling a more consulting role for patients (KNMP, 2017). None of the patients in the study reported on knowing about the possibility of a medical review let alone having had one. The pharmacy overall plays a relatively small role in providing knowledge currently. Knowing a medication review or just information exists is a real opportunity to ensure more safety around medication. Understanding this role of the pharmacist can be interesting for the patient in finding solutions for the unwanted effect of medication faster.

Preference policy
From the patient perspective, it is also good to address the preference policy the Dutch medication chain utilizes. Patients have difficulty keeping up and they lose oversight of their medication because packaging constantly changes (RIVM, 2016). Besides, patients can suffer from side effects due to other additives in the medication. Patients in the research of RIVM indicated they would like to see this policy adapted for people with polypharmacy. Patients from the interview mentioned negative side effects as a consequence of this policy. Having to contact the doctor, but also the insurance company to get back to former medication. However, minor changes, like in colour or shape of the medication, already cause difficulty in distinguishing between pills. Or the amount of take-in moments of the medication changes with the change of supplier. Although it is policy, knowing what causes a sudden change in physical (dis)comfort is valuable for these people. Opportunities lie in keeping them up-to-date about changes or providing knowledge on effects when something has changed.

In the hospital
The patients did discuss medication, but especially the quality of care, at the hospital. They mentioned being disappointed in the level of knowledge on their medical history. Changing to hospital pharmacy-provided medication is the policy, and the quality of care at the hospital relates to more than just medication, therefore, hospitalisation is reviewed as outside the scope of this project. One interviewee mentioned they gave the wrong medication once at the hospital when it was changed to hospital pharmacy-provided medication. This made him very proactive in watching over that the right medication is given. This mainly relates back to problems in medication transfer already addressed.

The five problem areas that bring opportunities within the scope of this project will be addressed in the vision statements on how to increase medication safety, see figure 2.3.9.



PATIENT JOURNEY

From the interviews, a patient journey was derived through several iterations, these can be found in Appendix B3. It illustrates experiences with patient quotes from the interviews and some main events or activities are plotted. Since the patient group will be taking medications for the rest of their lives a timeframe of several years, was chosen. The top axis describes the stages patients go through over the years. The order of activities is random. In reality, activities could occur more than once for some people or not at all for others. The second axis plots an emotion line and describes what patients collectively experienced during every stage, based on the emotion toolkit of (Desmet, 2015). This line represents the combination of experiences that several people talked about. Positive emotions were not described as much by patients because the medication is part of life it is just 'normal' without any (strong) positive emotion to describe it. The journey shows the stakeholders involved in every step, as shown in the blue bars. Observations made during the interview are shown at the bottom.

Health incidents

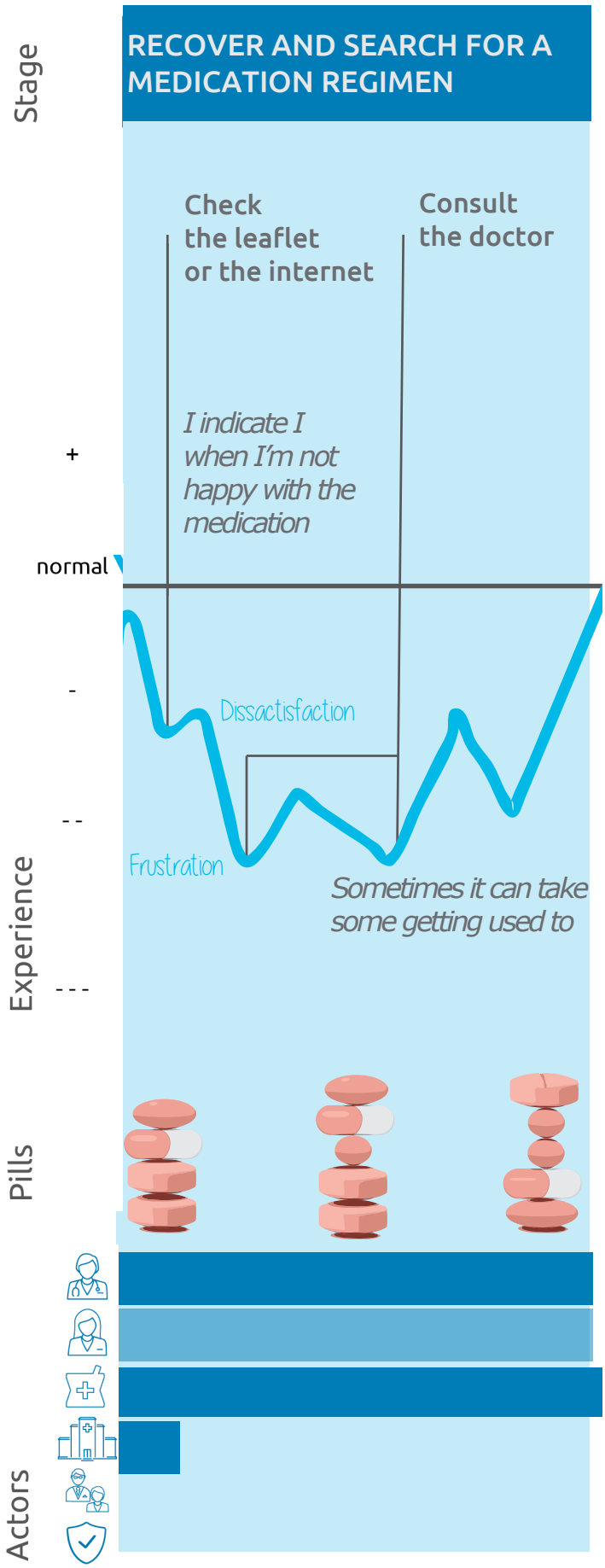
The first stage is an initial health incident, where someone has a serious health incident like, heart attack or brain bleed that causes them to have to start taking (more) medication to avoid another event or treat the underlying cause. It can also be that someone is in structural health decline, it can take several years until they get to 5 or more medication. Conditions like, high blood pressure, diabetes, chronical kidney decline, slowly build up in number or severity. Becoming more severe because of old age or an additional diagnosis that requires a lot more medication. Medication can over time be described by several specialists and/or the GP, in case of a health incident when people generally end up in the hospital family was included in the care process.

A later stage can be a first or secondary (and so on) health incident. An incident can be a serious

illness as before or be caused by medication. During hospitalisation, medication is changed to the medication by the hospital pharmacy per protocol. Hospitalisation involves (several) specialists from the hospital. People reported they were disappointed by the little knowledge these specialists have on their patient history. The next step of discharge and/or recovery also took too long according to patients. A hospital visit like this will generally have a couple of scheduled follow-ups at the hospital. It can include finding a whole new regimen with emotions, which is described next.

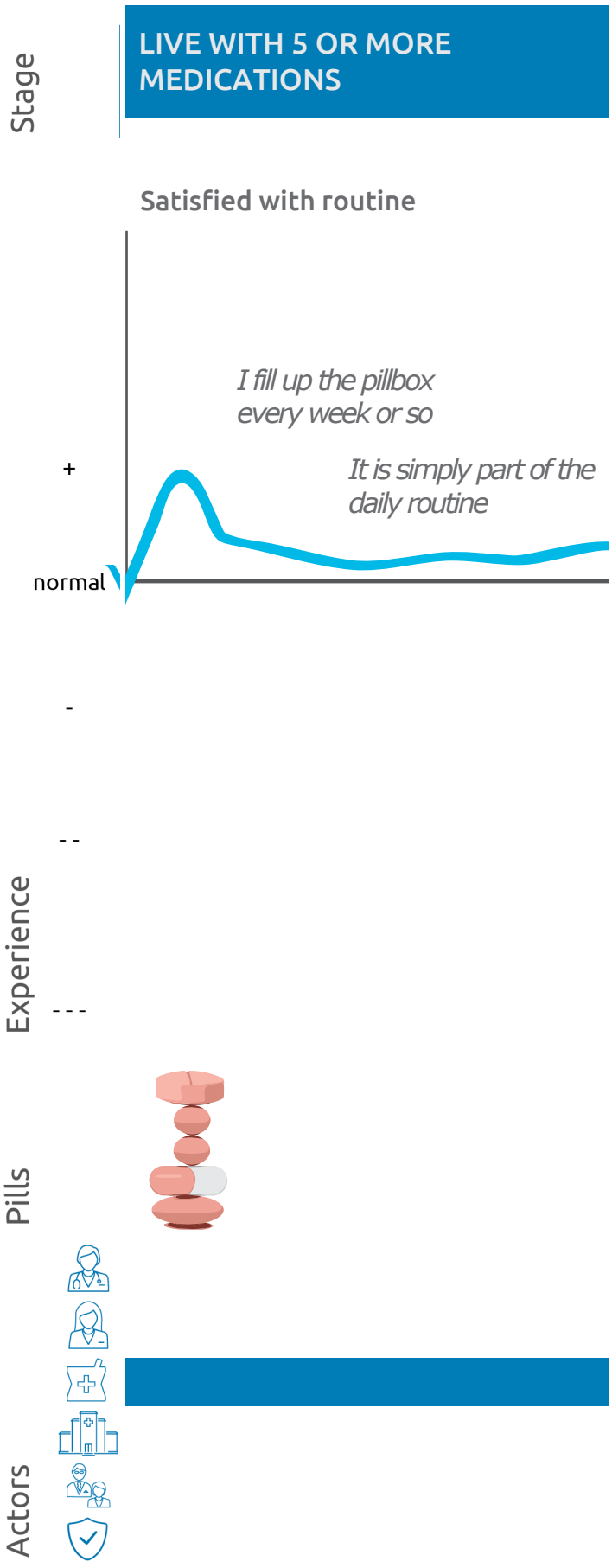
Search for medication regimen

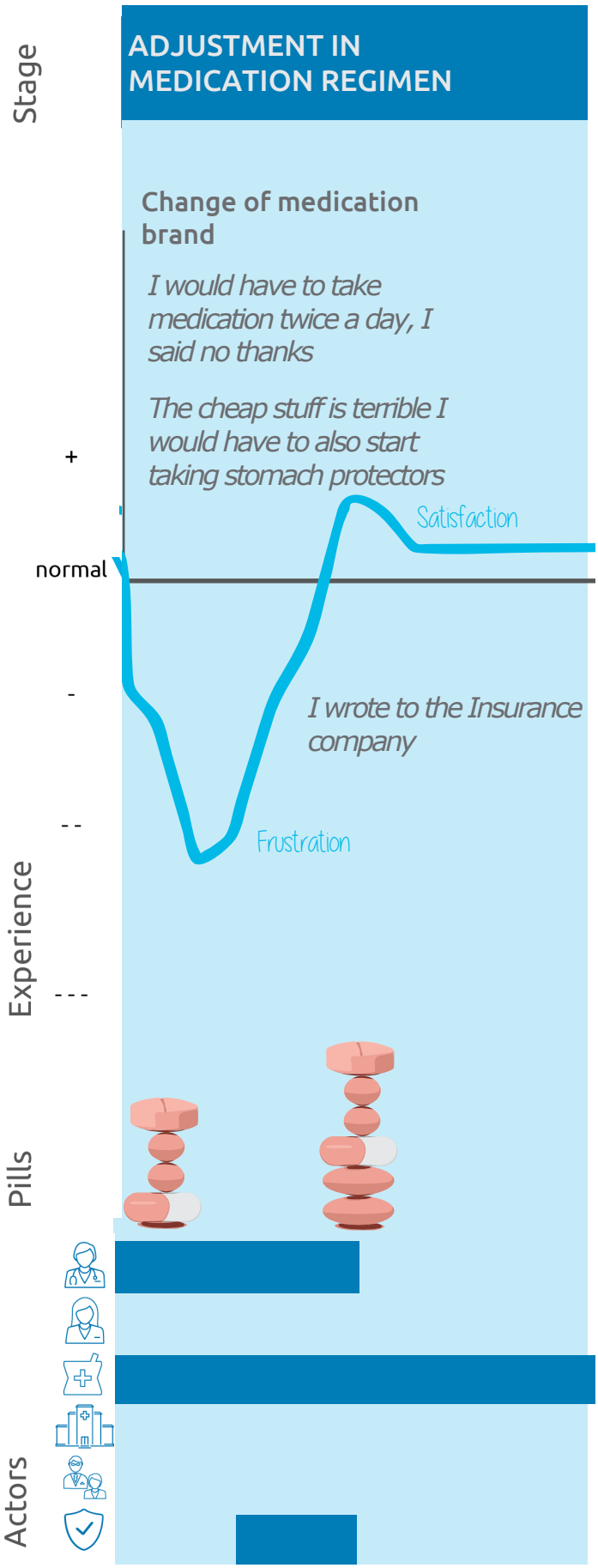
After a health incident, the process is recovery and with the increasing amounts of medication, finding a medication regimen that works. This search can occur after every new pill prescribed at every stage and can take several forms. It can last long or short and it can elude very strong emotions or more moderate. Searching for a regimen will take place when the 'normal' protocol does not suffice. Meaning a patient experiences (side-)effects of medication that inhibit them from living their life as they want to. The side-effects can be for instance, nosebleeds nausea and vomiting. When medication does not reach expectations, people become disappointed. They start looking for solutions in the medication leaflet or online. When effects are minor or can be solved people will move on and start living with the medication regimen. If effects are more severe or lasting, people can get frustrated with their medication. At this point most people will have contacted a doctor, generally the GP, depending on who is the lead prescriber. They find their road to normal living blocked but nevertheless will keep trying to take their medication, maybe at different intervals or dosages in consult with a doctor. If side-effects occur the GP can also choose to refer the patient to a specialist, who might have more in-depth knowledge of what is causing the side-effects or knowledge about more alternatives. It can be an iterative process of finding a regimen.



Live with five or more medications
When a regimen is satisfactory people simply live with five or more medication. It becomes part of their day-to-day routine. With these amounts of medication, people are bound to have regular check-ups ranging from every 2 months to once per year. Results,
can lead to an adjustment in medication; a change in dosage, a new medication.

Besides scheduled consults, patients can also experience decreased fitness, physical discomfort or pain and decide to visit the GP. Depending on the diagnosis the GP will act accordingly.





Adjustments in medication regimen

An event that can also happen is the change of medication brand, generally due to the preference policy or changes in colour and format by the production company. If a patient experiences negative effects due to the changes they become frustrated. They will generally contact the pharmacy or GP about their problems. Usually it can be turned back, however, it has consequences for reimbursement policies set by insurance when the preference policy is not followed. People indicated having to have contacted the insurance company to get treatment without effects reimbursed.

Patients with years of experience in the use of certain medications would like to make changes in consultation with the doctor or without. This concerns for example, the dosage or the moment of intake. Over time patients indicate to have gained a lot of knowledge and self-efficacy to form stronger opinions about the decision made being made about (new) medications. Some people feel so strongly about the negative effects they experience, they get annoyed. Meaning that to stop what was happening they (threaten to) stop taking a medicine

Design for patients in the high-risk group

To scope the rest of the project the high-risk patient will be described as polypharmic. This means they chronically take five or more medication a day. This generally means they suffer from multiple chronic illnesses. It was chosen to design for people of 50 years and older because then people are engaged and empowered from the beginning. Additionally, it was chosen that this research will revolve around patient taking medication that influences the heart and vascular system. As indicated this is risky medication, in terms of serious and life-threatening side-effects. Designing for this patient group entails and a big and diverse group that has to be accommodated for. This implies a certain level of personalisation is possible in the design so patients relate to more.

Design to lower risk factors of problems due to medication (care)

The design should accommodate for patients that have lowered cognition. Patients with conditions like dementia have been placed outside of the scope because they require a more specialised approach that can not be achieved in this project. Lastly, any technique to improve therapy adherence should be welcomed. The importance of kidney function in medication treatment should be represented in the design.

Design for the existing and near-future context of patients

This implies the design accommodates for the existing medication routine of patients, like their pillboxes and the home environment. Besides, it takes into account the complex healthcare network that patients encounter. It can help in keeping an overview of caregivers and transferring knowledge between the different caregivers.

Design to relieve problem areas in pharmaceutical care

This exploration showed gaps between patients experience in medication care and set norms in healthcare. The design will challenge these gaps with a patient centred approach. Different opportunities are mentioned in this chapter.

Design to relieve two pain points in the patient journey

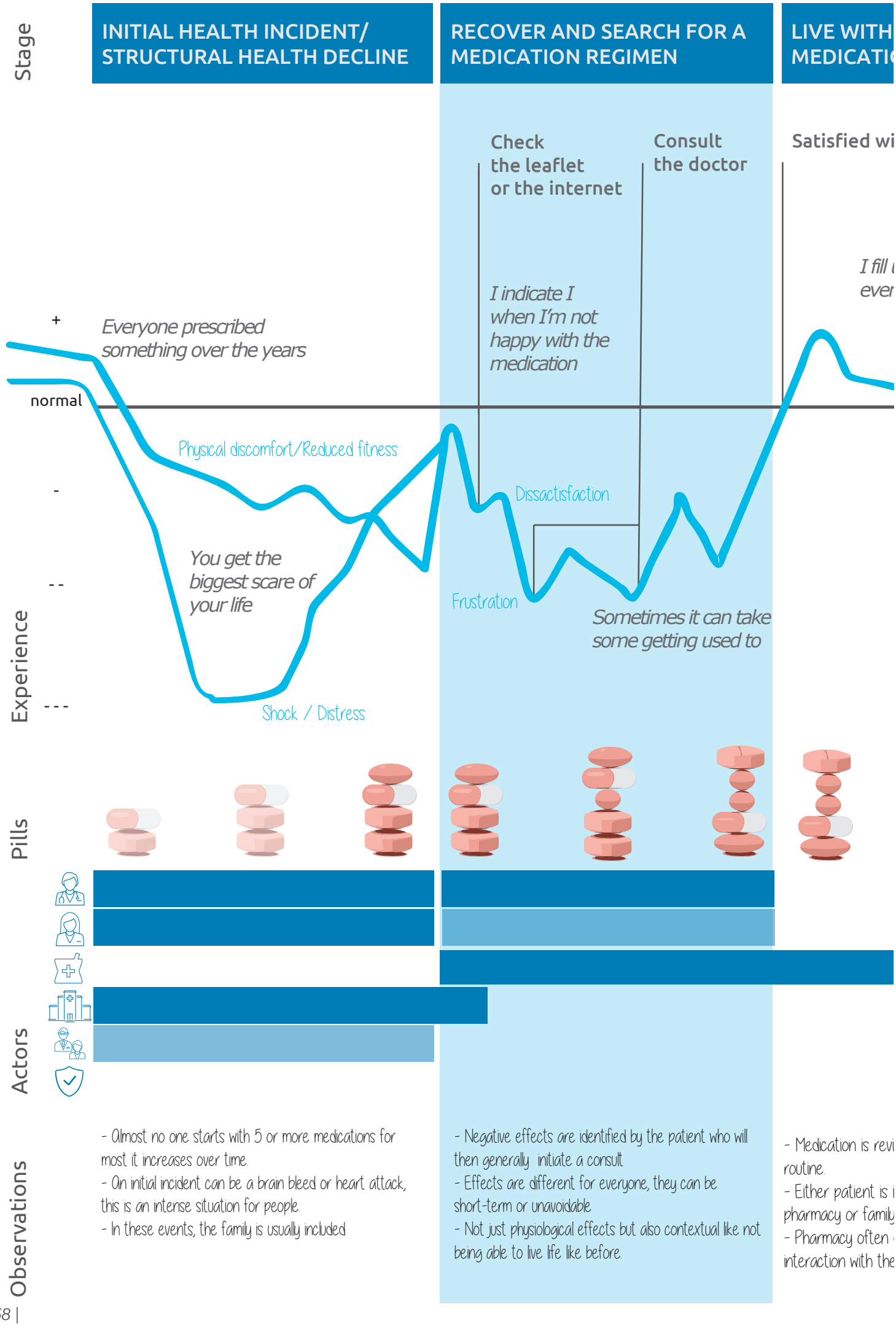
From the patient journey four ultimate low points in emotional experience of stages were derived. From these four, two are chosen within the scope of this project: dissatisfaction and frustrations about searching a medication regimen and frustration and annoyance about adjustments to the medication regimen. The product serve system will aim at decreasing the negative emotions or shorten the experience of them through user-centred design with e-Health as part of the solution.

shock and distress at a health incident
Health incidents like a heart attack or stroke are not avoidable by medication safety through patient empowerment. Hospitalisations due to medication however are, these can be avoided or less severe through better medication safety.

dissatisfaction about hospital care and recovery processes
Hospitalised care has been placed outside the scope of this assignment. Medication is provided by the hospital pharmacy in accordance with policy, little room for improvement on the patient side of medication safety seems apparent.

Design to relieve dissatisfaction and frustrations about searching a medication regimen
Negative effects inhibiting people from living their life, causes immense dissatisfaction and frustration in patients. Finding a liveable regimen can be a long and iterative process that requires a lot of communication between the patient and caregivers. Patients closely track results and (negative) effects from (small) adjustments in dosage, time of intake or type of medication.

Design to relieve frustration and annoyance about adjustments to the medication regimen
Adjustments in the medication regimen can lead to negative emotions when negative effects occur or are expected by the patient. Changes can result from a caregiver consult, or a change of medication due to the preference policy, or changes in packaging or format by the producer. In the first case, it is very clear people become more knowledgeable over time and are therefore more critical towards changes in their regimen. In the latter case, people notice the change in appearance or unwanted effects of the product and they will then request a consult with the prescriber or pharmacist.


Stage
INITIAL HEALTH INCIDENT/ STRUCTURAL HEALTH DECLINE
RECOVER AND SEARCH FOR A MEDICATION REGIMEN
LIVE WITH MEDICATI
Check the leaflet or the internet
Consult the doctor
Satisfied wi
I fill
ever
I indicate I when I'm not happy with the medication
+
Everyone prescribed something over the years
normal
Physical discomfort/Reduced fitness
-
Dissactisfaction
You get the biggest scare of your life
--
Frustration
Sometimes it can take some getting used to
Experience

Shock / Distress
Pills
Actors
Observations
- Almost no one starts with 5 or more medications for most it increases over time.
- An initial incident can be a brain bleed or heart attack, this is an intense situation for people.
- In these events, the family is usually included
- Negative effects are identified by the patient who will then generally initiate a consult
- Effects are different for everyone, they can be short-term or unavoidable
- Not just physiological effects but also contextual like not being able to live life like before.
- Medication is revi routine.
- Either patient is i pharmacy or family
- Pharmacy often interaction with the

TH 5 OR MORE TIONS

ADJUSTMENT IN MEDICATION REGIMEN

LIVE WITH 5 OR MORE MEDICATIONS

l with routine

fill up the pillbox very week or so

It is simply part of the daily routine

Change of medication brand

I would have to take medication twice a day, I said no thanks

The cheap stuff is terrible I would have to also start taking stomach protectors

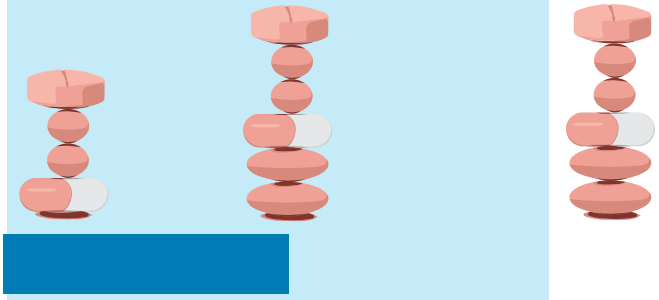
Satisfaction

I wrote to the Insurance company

Frustration

The pharmacy delivers it here nicely at my home

Physical disc



: reviewed as simply part of the daily

t is in charge or aided in routine by the amily.
ten delivers medication which reduces n the pharmacist

- Changes in medications are due to the preference policy or just change in colour/ packaging.
- To solve it can involve speaking to the doctor, pharmacist or insurance.

- The lead prescriber can be GP or specialist(s).
- Part of living with medications are regular check-ups
- Check-ups are generally executed by nurses.
- Intervals range from every 2 months to once per year.

HEALTH INCIDENT

RECOVER AND SEA
MEDICATION REGI

Visit the GP for ailment

If I think it is better to skip one I will or take extra for the pain

I was admitted twice because of medication toxicity

She joins to keep extrer good oversight of what medication they'll give n

We'll visit for other things like swollen legs

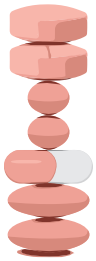
They said I might loose my leg.

It takes too long back out of the h

scomfort/Reduced fitness

Shock / Distress

Dissactisfaction



- Different people have a different relation to their GP, from very close to non-existent.
- However for minor ailments, like pain or swollen legs, everyone goes to the GP

- Some people get a (new) health incident when already on medication.
- This can be because of the medication or existing condition or because of something.
- The hospital will change medication to the medication from the hospital pharmacy

- Dissatisfaction is caused by: li professionals on medical history and mistakes that are/were m
-Similar searching can take pla regimen.

EARCH FOR A
GIMEN

LIVE WITH 5 OR MORE MEDICATIONS

ADJUSTMENT IN MEDICATION REGIMEN

Satisfied with routine

Check-up with adjustment of medication

emely
t
me

Satisfaction

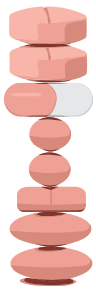
Almost every time they'll adjust something

g before I'm
hospital

It's been practically the same for 20 years now

I'll call the GP and say I'm quiting those things

Annoyance



little knowledge by
ory, time processes take
made.
place as at the first

- As people grow more knowledgeable over the years they feel they can be more critical when adjustments are made

2.4 DESIGN VISION

The Exploration brought about a review of three big stakeholder groups in Dutch pharma healthcare: the government, supply chain and care chain. These were reviewed on their current involvement in medication safety, their role and influence on trends and their relation to the patient. These conclusions will be used in further steps of establishing who can embody a relation of empowerment with the patient in medication safety. Or play a part in a design that does that: empower the patient in medication safety. This chapter will further conclude on the design challenge derived from patient needs and the vision on how to empower patients in medication safety. Lastly, it illustrates the design implications derived from the exploration of medication safety, trends and the patient research. This aims to formulate a set-up for the next step of creating ideas and a design.

DESIGN CHALLENGE

The aim of this project was sharpened with this exploration. It now states: to design a product service system for elderly patients with poly-pharmacy and compounded multi-morbidity, that increases medication safety through patient empowerment in medication treatment. As shown in the research, medication safety is a complex and multi-faceted challenge. The aim is to design to relieve problem areas in pharmaceutical care, depicted in figure 2.3.9. For this project, it was chosen to look at how to increase safety specifically from the patient side. Part of safer medication treatment is higher involvement of the patient in the process through patient empowerment.

The patient journey brought forth two pain points that will be tackled in this project, searching for a medication regimen and dealing with adjustments in medication. They amount to the following challenge:

"The design challenge is to empower patients in searching for a regimen in which living with medication is not restrictive and to take away strong negative emotion around adjustments to the medication regimen."

The project will focus on patients that have three or more chronic conditions and take five or more medications for among others, heart and vascular symptoms. At these two pain points, patients are especially in contact with first-line caregivers, the GP and the pharmacy. In exploring the patient's experience in medication use and care it became clear problems around medication from the patient's perspective are not necessarily hospitalisations or extreme physiological symptoms. But smaller physiological or other consequences of medication can cause impediments in 'normal' living, described before as negative effects of medication. After every change in medication, but especially at the start of the journey with multiple medications, these effects can occur. A patient will (try to) find a medication regimen that does fit their lifestyle together with prescribers. With better information provision, it is expected that this now lengthy process could be shortened and that negative emotions can be reduced.

A special adjustment to medication happens as a result of changes within the same medication, for instance, because of the preference policy. Changes

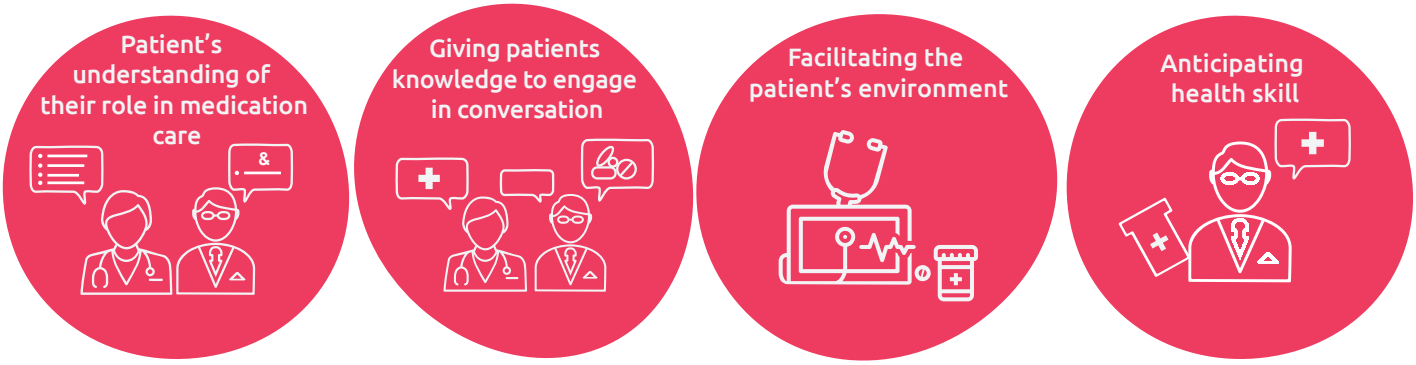


Figure 2.4.1. Vision on patient empwoerment elements

can have a great impact on the regimen that a patient has in place, ranging from physiological symptoms to changes in intake moments per day or distinguishing between pill packages or pills themselves. This causes a great burden on the patient's lives that solicits the need to improve the process. The challenge offers room for improvement on how long searching for a regimen currently takes and/or decreasing the negative emotions surrounding it. The next part describes how empowerment is thought to help in these processes.

VISION ON PATIENT EMPOWERMENT

A vision on patient empowerment in medication treatment was made to tackle the before mentioned challenge. Patient empowerment in the WHO definition has four elements namely: understanding responsibility, knowledge, a facilitating environment and skill. The current experience of patients with their medication treatment and the patient journey pain points show an inadequate level of patient empowerment on these four topics. A vision statement was made for every element of empowerment, that utilise the opportunities digitisation offers. The vision on all four empowerment aspects is explained here.

Patient's understanding of their role in medication care

With the design, patients will better understand their responsibilities in keeping and transferring their medication overview. Patients that are most likely to have problems with medication generally cope with multi-morbidity, this involves a network of several caregivers, GP, specialists etc. that care for one patient. It was shown that the patient is insufficiently aware of his/her role in the medication overview transfer between caregivers. A patient-centred approach excluded medication transfer between caregivers and organisation EPD systems involved.

Having patients gain knowledge to engage in conversation

The design will have patients gain the knowledge to engage in a consult conversation about their medication treatment. Besides, the project focusses on the day-to-day living with a complex medication regimen, which excluded hospitalisations. It includes the “at home” day-to-day living of the patient, which involves the home but also work and holidays. Living with medication introduces communication with caregivers during regular check-ups into the lives of people. The research found that communication causes a bottleneck in the medication care process. Communication on the patient side is expected to improve when they are well informed about the medications and the conversation to come.

Next, it is believed that medication processes can be made safer through medication reviews and shared decision making with the patient. However, patients are unaware of the medication review and, especially at the beginning of their medication journey, lack the knowledge to participate in or initiate shared decision making.

Facilitating the patient’s environment

Patients experience that their home and consult environment are facilitated for safer medication treatment with the design. Patient empowerment requires the presence of a facilitating environment. The product service system design will aim to enable a facilitating environment at the home of the patient. It is expected this will be made possible using E-Health technology. m-Health can make understandable medication knowledge more accessible to patients. Besides, overall shortening the lengthy process, improving communication can lead to higher quality of care and reduced healthcare costs. The design will not be a permanent change of the environment in the consultation room of caregivers but will, where possible, be mobile to bring to the caregiver and also facilitate the consult for the patient.

Anticipating health skill

Patients experience that the design anticipates their healthcare skills regarding their medication treatment. For people interviewed, their medication routine was running smoothly and they had the skill and tools to execute it. When talking about lack of skills in medication use, two things come to mind. First is physical skill, the ability to open packages; reduced strength in the hands is a big problem in elderly when for instance opening pill bottles that twist. Changing the packaging of medication is placed outside the scope of this project.

The second point in skill is before mentioned healthcare skills. This can lead to forgetting medication up to not understanding what to take when which can lead to (in adherence) problems. These skills in terms of cognitive understanding, communicating and interacting and critical thinking can be aided by the design. Cognitions in terms of understanding will be tackled in the knowledge explained earlier. Special attention will be paid to how knowledge can be provided in a comprehensive way for different levels of healthcare skills. Problems beyond these solutions regard people most likely with a condition in impaired cognition, like dementia. These people require a very specific approach and are regarded as outside of the scope of this project.

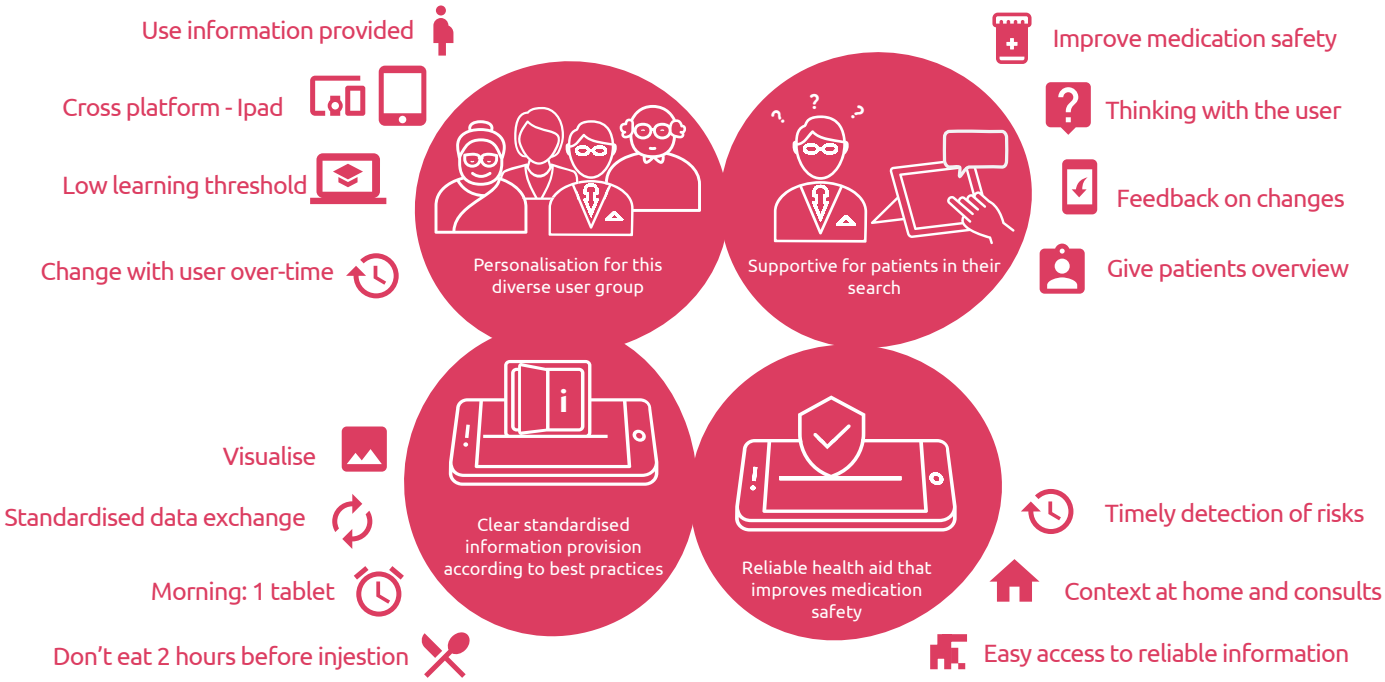


Figure 2.4.2. Design implications

DESIGN IMPLICATIONS

Throughout the exploration research was converted into implications it would have for the design, a full list can be found in Appendix B4. These can be used for further assessment of the design. It was chosen not to make the more usual list of wishes and requirements because the design has no owner that can verify them. In comparison to a usual list, the design implications touch mainly upon the following subjects in the Roozenburg & Eekels (2003) list of wishes and requirements: ergonomics, performance, product facilities, standards rules and regulations, safety, reliability, context. Design implications are more wishes than requirements but some additional information was found to make them more quantifiable. They are split up around four themes below and summarised in figure 2.4.2.

Design to personalise for this diverse user group

The user group of this app are patients with multi-morbidity, polypharmacy and heart and vascular medication. This encompasses a great variety of people, empowerment will have to deal with especially the different levels of healthcare skill. The design will attempt to personalise information provision as much as possible. For instance, by using information provided by the user: e.g. an 86-year-old man does not need information on risks of medication during pregnancy. The design takes into account the elaborate patient care network and focusses on the medication caregivers in the journey.

It was chosen that the design is for the age of 50 years and older. Although ageing increases the risk of mistakes in medication care it is believed involving patients more from the beginning will benefit also later stages. It will attempt to take into account the changing needs of patients over time like shown in

the research knowledge increases over time while at some point the involvement of the patient and cognition might decrease.
The design should be taken into account that these people might have limited digital skills. Therefore, the design should be intuitive, for instance, by using existing interaction patterns to ensure a low learning threshold for use. Keeping in mind e-Health applications the standard is that services are delivered on different devices, but especially Ipads are used by the elderly.

Design to support patients especially in their search

In terms of its function, the design should improve medication safety. For instance, by making people more aware of their role in keeping and transferring a medication overview. It can aid in keeping this overview and for instance distinguishing a medication or pill. Nictiz (2015) also found when patients make changes to their medication overview, feedback should be provided that “something” is being done with that information. Besides, this research found that patients should be able to note all experiences.

Moreover, it should resolve the challenge and therefore ensure a regimen is found faster. This can be done among other things by better detection and registration of negative effects or symptoms and to find the right person to talk to. This should help in reducing (extreme) emotion about the negative effects and lower abundant visits. It should support the patient in its search for answers: thinking with the user instead of pushing large amounts of information.

Design for clarity in information provision using standardised information provision according to best practices

To improve clarity information provision should be personalised as much as possible to individual patients. This requires collecting personal patient information and utilising opportunities to apply it for preventive or better care.

Besides, the pharmaceutical market is working towards digital systems that are better at the exchange of information (Nictiz, 2018). For this information, standards are being set-up. These should be used to ensure information can be exchanged also from the patients to other healthcare systems in the future.

As mentioned healthcare skill is an important point to take into account for the design. Different research (HealthBase, 2018; Pharos, 2018), can be found on best practices for the provision of medication information. These should be used in the design and will among other things simplify jargon to normal talk and simplify and clarify instructions. Furthermore, it is believed information should be visualised where possible.

Design to improve medication safety through a reliable health aide

The design will be a health aid for the at home context and (partially) mobile to bring to consults. This context brings that the design should accommodate current medication products and tools. Like existing packages and pillboxes or Baxter roll.

It improves medication safety by timely detection of risks. Besides, lowering patient risk factors like lowered cognition. Being a health aid it should provide and rely on reliable information and safely and securely store. In line with the digital trend possibly exchange and analyse information.

3. CREATION

Chapter 3 describes the Creation phase in the overall design process. This marks the step from research and observations to creating ideas for solutions. The Design Vision chapter defined a challenge, a design vision and design implication derived from the exploration.

This chapter commences with a brief brainstorm done on topics that were touched upon in the research. Associations were made to How Could You (HCY) questions in terms of how it is now and what are possible improvements. Here the choice was made to design an app. The next step was a function analysis to define what functions the app should have. This led to a first set-up of the user flow, that depicts the relations and steps the user has to undertake to switch between different functions. Ideation was finalised wit wireframe sketches of some of the functions after a visual exploration of existing apps.

To make the step from ideation, free and ample visualising of ideas to conceptualisation health data exchange standards and benchmarks were explored. Conceptualisation is the step towards clustering ideas and normally having ideas adhere to the requirements and wishes set. Since these were not explicitly appointed in this project it was chosen to quantify the design implications. An exploration of the standardisation in healthcare data exchange establishes the current and future state to design for in terms of information that will be or is standardised. This is used to make solutions valid in the current and future market.

The benchmarks found in e-Health medications solutions touch upon several design implications. The solutions show well-regarded examples of personalisation, how to support patients, clarity in information provision, best practices in information provision, how to improve medication safety. Benchmarks illustrate what is possible and how to compare to that examples or transcend them.

The next visualisation of ideas was made in digital mock-up concepts of the main functions of the app. The idea of the app and mock-ups were evaluated by representatives of stakeholder organisations in the pharmaceutical field. The interviews also

This brought about to the Zeker app concept. The last sub-chapter describes how the different functions fulfil the design vision and solve the design challenge. Besides is explains how the app works and is used by patients.

3.1 IDEATION

The Exploration concluded with a challenge and a design vision. To generate ideas a first exploration was done on the topics brought forth by the product service system's function and context as described in the Design Implications. This led to the decision to design an app. The next step was doing a functional analysis of the app. After mapping all functions, a first set up was made of a function flow. Furthermore, the functions were ideated on and for visual inspiration other apps where sought that fulfilled similar functions.

FIRST ASSOCIATIVE EXPLORATION

The Design Implication based the exploration and best practices gives direction to the creation phase. It gives guidelines to the function the design should fulfil and in which context. To get ideation going some of these guidelines were explored in questioning how they could be fulfilled, in a “How could you (HCY)” brainstorm session, see figure 3.1.1 below.

Direction were explored in the field of a facilitating home & consult environment, scanning a medication barcode, understanding by the patient of their role in medication care and how to obtain knowledge as a patient. Although not unexpected from digitisation developments and trends in healthcare and outside. It was chosen to design an app based on the extensive knowledge database needed to facilitate and empower the patient, that needs to be up-to-date and accurate. Beside, the context requires a certain level off mobility of the product service system. A separate device for information provision and scanning would ensure yet another ‘smart device’ in the household of the user to learn and understand. Besides bringing added unnecessary costs in the development of functions a smartphone already possesses.

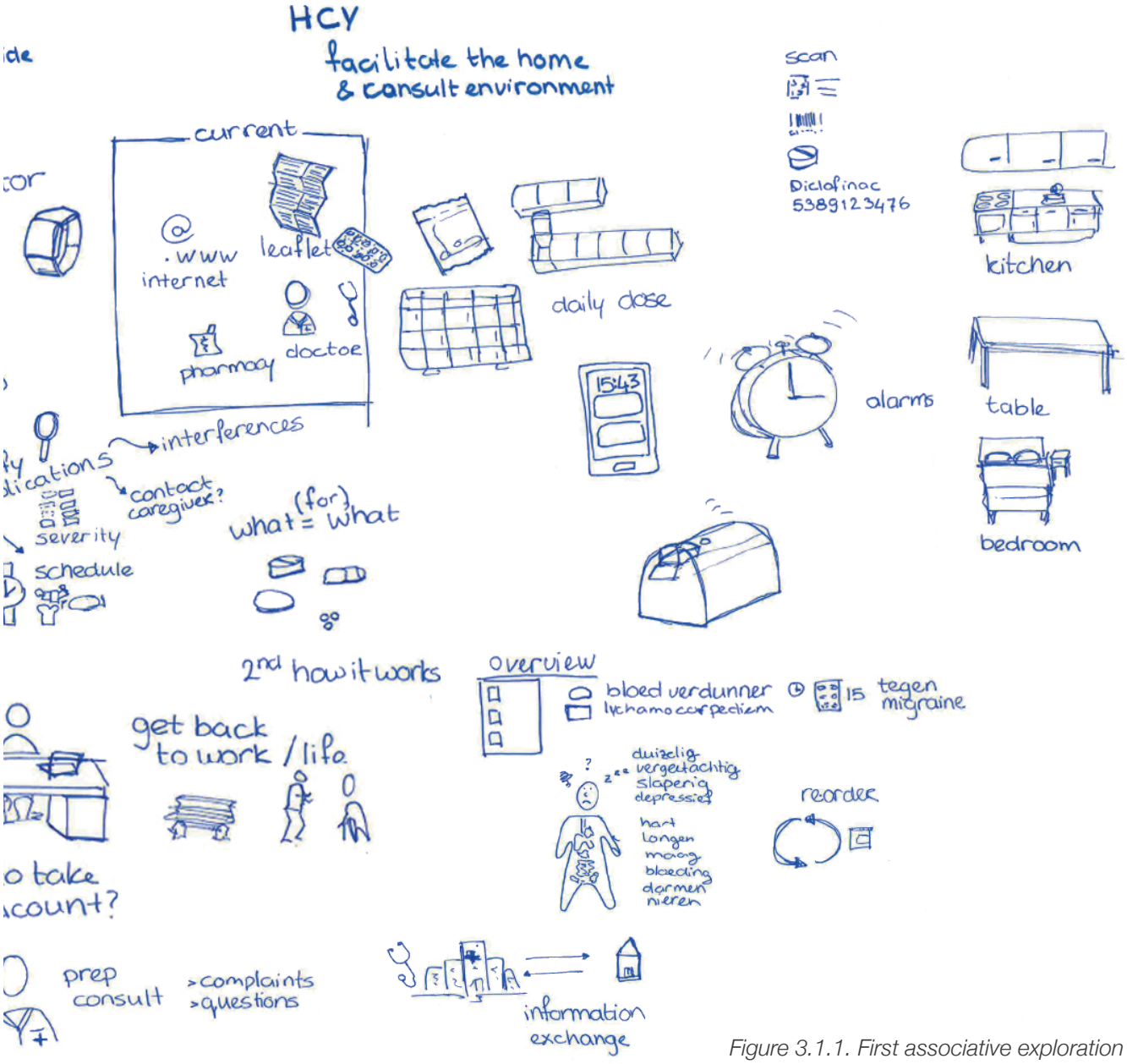


Figure 3.1.1. First associative exploration

FUNCTION ANALYSIS

A function analysis was executed to define the functions the app should have. The main functions of the design is to create a medication overview and help the patient in search of their medication regiment without negative effects. The list of function underwent several iterations after reviewing previous research and discussing the functions with project supervisors, these can be found in Appendix C1.

Medication overview

The vision describes the need to make patients understand their role in the medication overview. This is not an easy thing to do with the app because when people are unaware of their role there is no motivation to download an app that aids them in this role. An option is to make patients more aware of their role through caregivers or in a promotional campaign. It helps that the app also fulfils identified user problems, that might convey them to use it. However, since there is currently no intrinsic need by the patient for a medication overview this should be made as easy as possible.

This overview can further increase medication safety by applying medication monitoring policy for early detection of for instance unwanted interactions or unsafe dosages. If the medication information from the prescriber can be retrieved, it can be compared to the actual medication the patient has at home as an additional check. Although Nictiz (2016) warns that if a patient comment on such a difference they want feedback 'something' is done with this information.

The patient interviews also showed the need to keep track of medication that was stopped due to negative side-effects. Although there should be a log by prescribers, an additional archive of medication can be valuable.

Finding a regimen

To find a regimen the system first needs to know what effects the patient is experiencing that they would like to see changed. These effects should be compared to when medication is taken. Hence patients need to track the effects and the medication they are taking.

Upon exploring the function of effect tracking it was identified that an effect has an intensity (amount of pain) and frequency (for how long at which times of the day). Lastly, since the effects are restrictive to living a 'normal' life to what extent it prohibited the patient from living life.

An additional safety factor is tracking dangerous negative (side-) effects of medication. If for instance, someone is experiencing a dangerous symptom like extreme pain or in a dangerous frequency, like bleedings.

Consult preparation

If both effects and medication have been tracked for a while they can be compared for advice. The aim of the app is not to advise on stopping or changing medication. It will indicate correlations between factors and advice which care provider to talk to for advice. A change in medication or take-in schedule can then be set-up by the care provider. By tracking and the consequential report, the patient will be helped in talking about what is the problem, how and when it occurs etc. By tracking different schedules or effects after a medication change improve or stagnation in the negative effects can be identified.

Patient Context

In order to convey knowledge in a more advanced personalised matter some personal information is needed. Therefore, the basic context of the patient needs to be filled out. Demographics like age, gender, marital status and diagnoses, doctors etc. Personalised information can shorten the amount of information given and make it easy to understand. Giving people more understanding of how or what applies to them.

SET-UP FUNCTION USE FLOW

After creating a deeper understanding of the main functions discussed a first set-up was made at a use flow of the app shown in Figure 3.1.2. From left to right the 'layers' of the app deepen. By clicking/tapping a function it enters the next page of information and/ or function, shown as the collumns in the flowchart.

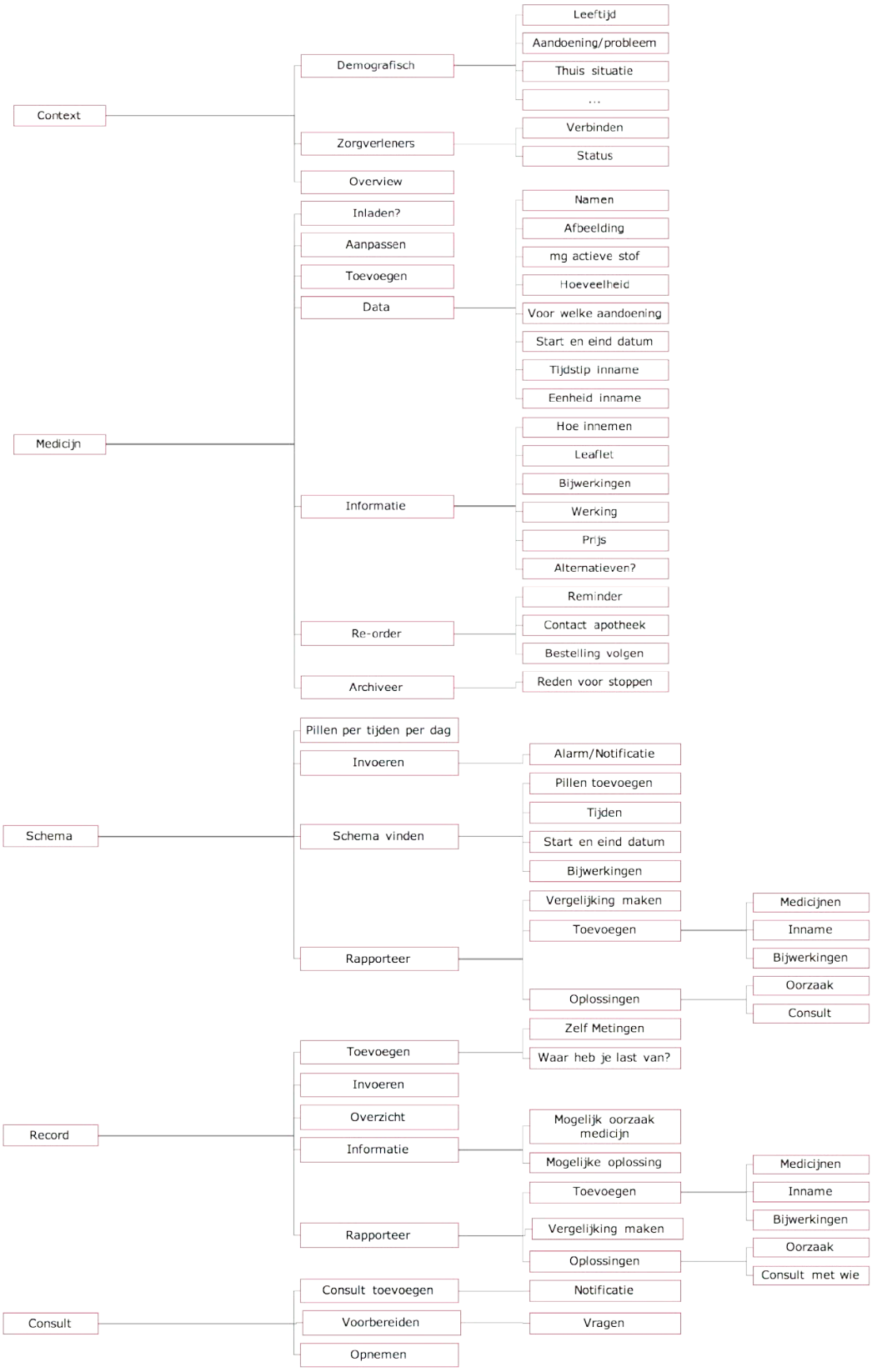


Figure 3.1.2 Use flowchart

APP IDEAS

The functions where ideated on in sketching wireframes of different options on to visualise them in an app. For inspiration, existing apps that fulfil similar functions have been explored, see Appendix C2. Only a few ideas where sketched by hand. After the ideas were visualised in digital mock-ups. Digitally is more effective to visualise dimensions and proportions of text and image.

The ideas in figure 3.1.3 show different thoughts on the different functions discussed before. It was attempted to visualise them in different ways. It was quickly decided that the medication overview had to have a visual of the medication. Most patients' medicines are no longer in the original packaging so this offers a visual check whether you are taking the right medication. There could be a database of visuals for it, but of course, users can also take a picture.

Different levels of health skill were kept in mind for further simplification of keeping an overview. It was chosen to put the "usual" name first, like a bèta-blocker and then the scientific name and brand as probably displayed on the box. The rest of the medication information uses earlier discussed

developments in how to relay information. For instance, Morning: 1 tablet, oral use, 2 hours before or after eating,

For symptom tracking, it soon became clear you need to clearly convey a timespan over which you (have) tracked data. There were different examples found on this in tables, horizontally or vertically, circles etc. Entering in information on symptoms can be graded with a number but other more visual options were also explored, with sliders, emoticons or size.

What became clear from a good example in symptom tracking was that side-effects are twofold. On the one hand, you would like to track how often and/or how intense these symptoms are. However, how the patient experiences the limitations these symptoms bring is just as important. As also found in the patient interviews side-effects cause patients to not be able to live life as normal. For instance, being able to go to work as normal again, which is now limited by intense tiredness around the end of the day. This has the added benefit that it sets a goal for what patients would like to achieve by making changes to their medication.

Figure 3.1.3. Ideation

3.2 SETTING STANDARDS AND BENCHMARKS FOR CONCEPTUALISATION

For the conceptualisation of ideas, the step is made from free thinking about ideas to ensuring concepts are in line with the design implication set in the exploration and evaluated by stakeholders. In order to do so, a deeper look was taken into the current state and future of standardisation and exchange of healthcare data. To position, the app with its unique functions, existing medication e-Health solutions that set a benchmark for the market were established and explored, more on this exploration can be found in Appendix C3. Benchmarks were set to compare solutions and show what parties are involved in existing e-Health for medication. The total of this research ensures concepts can be designed future proof. In terms, of using standardisation that is out there and involving the right stakeholders for data exchange between patients and caregivers.

Conceptualisation was done with the help of interviews with healthcare branch organisations, VIG, Bogin, NVZ, KNMP and Patienten Federatie Nederland, for summaries of the full set-up and interviews see Appendix C4. The people interviewed had different backgrounds in the field of healthcare with compounded experience in the field. Usually related to their organisation, the representative for KNMP was a pharmacist. Representatives of the organisations generally fulfilled a role for their relative organisation in patient contact, medication (safety) and/or e-Health. They were asked to comment on their (organisation's) view on bottlenecks in medication safety, (the future of) e-Health especially caregiver-patient data exchange and their organisation's role and that of others in these developments. The next visual step was set in creating digital mock-up concepts, these were also evaluated in the interview.

STANDARDISATION AND EXCHANGE OF HEALTHCARE DATA

Data volumes continuously grow, with products being increasingly connected to internet, also in healthcare. The physical and digital world are collecting massive amounts of data, that can be continuously accessed in real-time. Patient engagement, prediction, production automation and medication discovery were applications of how data can improve efficiency, quality and safety of healthcare. This chapter will focus on improved communication between healthcare professionals and between professionals and the patient

Exchange of digital patient record can aid in the medication safety of the patient. When care professionals have access to up-to-date information it can prevent unwanted combinations of medication, harmful and unnecessary use. When used correctly, caregivers can ensure more personalised care, considering patient trades, lab results and other relevant information of the medical patient record. However, the medication safety exploration already found this is currently not the case. Therefore, a deeper look was taken at the current status and developments of healthcare data exchange and subsequent standardisation of data. Literature study is supported by the interviews done with different branch organisations in the healthcare field. They were questioned about e-Health and medication safety. Answers used are on what according to them were the biggest bottlenecks in medication safety and especially on how to solve it.

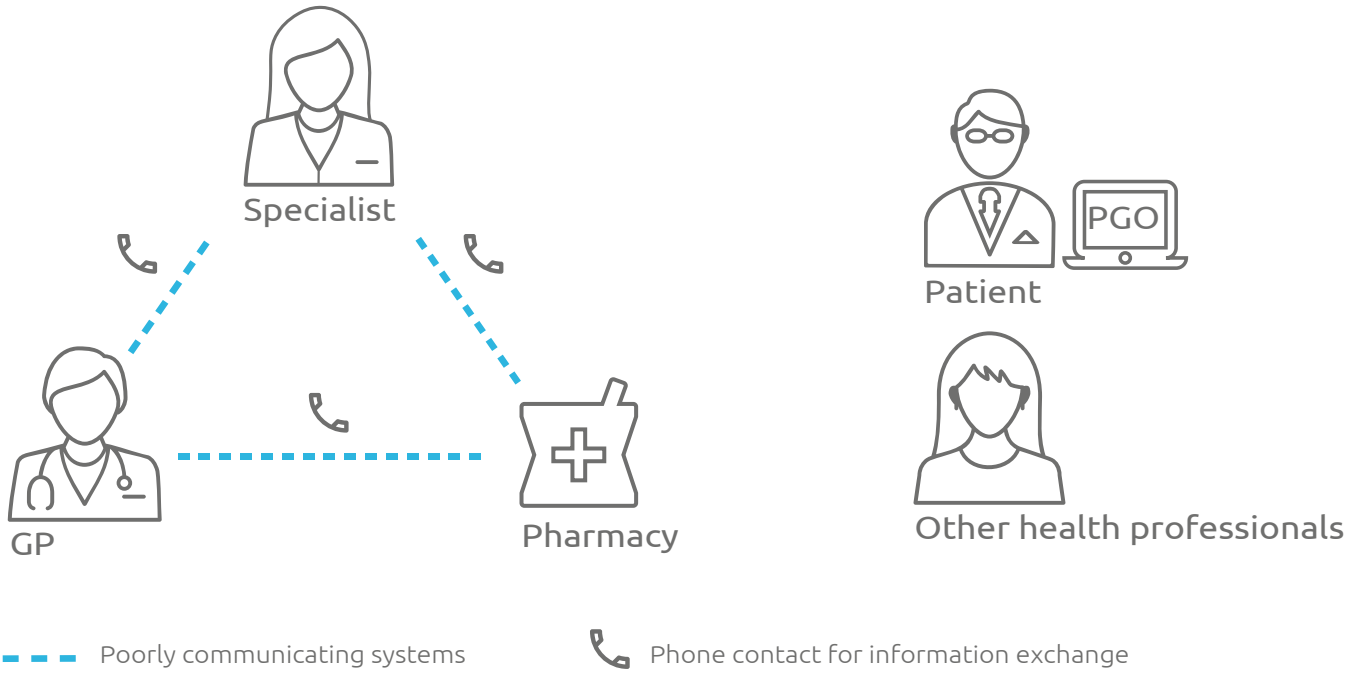


Figure 3.2.1. Data exchange current level.

Government encourages e-Health

In light of the considerable advantages of e-Health in terms of efficiency, quality and reduced costs the national government stimulates the healthcare sector to offer more digital healthcare. Especially, to bring the possibilities to the attention of their patients. The national government has set the following four goals for 2019 (VWS, 2018):

- Access to medical data, at least 80% of the chronically ill have direct access to their own medical data. Besides at least 40% of the other Dutch people have too.
- Do independent measurements, 75% Of the chronically ill and frail elderly can take measurements themselves and share them with their care provider. Think of measurements of blood pressure or cholesterol levels.
- Online contact with a healthcare provider. People who receive care and support at home can - if they wish - contact a care provider 24 hours a day.

Since e-Health is on the agenda of the government developments have accelerated. One of the biggest hurdles also identified by the government is the digital exchange and safe collecting and exchange of medical data. They set up het Informatieberaad to make agreements, standards and provide service for a sustainable information systems network in health care. Who in their turn have medication safety as one of their four prime outcome goals. They discuss standards with suppliers of ICT systems. Beside they work together with other healthcare parties on the MedMij initiative. To offer a safe way for people to get more insight into their own health, through existing websites and apps. This will be discussed in more detail later. First, a deeper look will be taken at initiatives already implemented.

Existing inter-organisation exchange

Increasingly practitioners catalogue data about treatments, like test results, X-rays or (referral) letter to a specialist in an electronic patient dossier (EPD). An ‘electronic patient dossier’ (EPD) is a software application that digitally stores and offers medical

Figure 3.2.2. Data exchange initiatives.

patient records, (Patienten Federatie, 2018-1). Sometimes, this is also referred to as an electronic health dossier to indicate it also covers healthy data. An EPD system is generally restricted to one organisation, hospital or GP practice, or even part of an organisation. Inhibited by privacy concerns, developments slowly work towards a central system that exchanges between organisations. The current 'national' system is one where caregivers keep using their own information systems and exchange medical information over the Landelijk Schakelpunt (LSP), managed by de Vereniging van Zorgaanbieders voor Zorgcommunicatie (VZVZ). It splits up the Netherlands in 44 regions between which only hospitals can access data (VZVZ, 2018).

"Concerns for security scrutinised the quality."

This ensures access to medical data cross caregivers is still not optimised. In this project, it was found this set-up surprises a lot of people that gladly sign all documents that allow data exchange.

Figure 3.2.1 aims to illustrate the current level of data exchange. Practically all interviewed organisations commented on the incredibly low-level digitisation in medication exchange.

"If a pharmacist needs to ask a question they will call the doctor, in case of a GP this is usually possible within in a day, with specialists it might take up to 5 days before there is contact."

"It is ridiculous that so much is still done on paper."

In first-line care within a geographical region exchange of medical information is most often good and mainly digitised. Especially between first and second line care like from the hospital to the pharmacy a lot of information is still printed, then faxed over and then typed into the computer again. Most organisations saw standardisation and connecting all systems as the solution to medication exchange problems.

"A universal system"

"It is important that everyone that does things with medication has an up-to-date digital overview"

Quality control

The Consumentenbond (2018) pleas for a comparative analysis of the different EPD systems to find the best examples. Quality control is not just an issue in EPD systems but also in applications and other e-Health solutions offered to patients.

"We don't call it quality assessment but quality registration of systems."

Besides healthcare organisation record systems, there are also patient owned systems. These are all apps and websites utilised by patient and (care)

consumers to collect, manage and share health data. Branch organisations expressed concern for quality of these systems as well.

"It (e-Health) is so dispersed how can you distinguish if an app is good or not?"

Several parties are working towards better quality oversight on patient health apps. The Patienten Federatie has the Digitale zorggids, the GGD has their own "app store", both offering 'checked' apps only. The LUMC has started a research lab at the National e-Health Living Lab (NeLL, 2018). Where studies are being conducted into the efficiency, safety and reliability of e-Health applications and, together with patients, consumers and healthcare professionals, they also test, user-friendliness, effectiveness, added value. None of them shows clear standards to adhere to for qualitative e-Health systems yet. It is, however, interesting to keep up-to-date with them for future reference.

"Problems that initiatives like NeLL run into are that by the time they finish their research the app has had about eight updates."

Patient data exchange with caregivers

Digital health records exchange with the patient is becoming offered increasingly as well. However, it is definitely not the standard yet. From the organisations interviewed most also see creating patient engagement through patients having access to certain information as part of the solution.

"Developments in data exchange also between caregivers will speed up if we start involving the patient"

Already, more and more hospitals have so-called patient portals. With functions like accessing lab results and other data, to messaging functionalities or tele-consult options. Pharmacies have online facilities for ordering (repeat prescription) medication. Other first-line care providers like the physiotherapist also offer apps with appointment reminders. Although, development is slow the organisations interviewed and a lot more work together on different initiatives to speed up safer medication transfer through, creating standards and developing better exchanging systems and patient exchange. A few are discussed next.

"We need more initiatives from the field, like MedMij"

"MedMij might be the way to better data exchange with patients."

Developments in data exchange

The Nictiz (2017) is the centre of expertise in e-Health, mainly financed by the VWS. They do a lot of research and are a partner in most big e-Health initiatives in the Netherlands. Moreover, they advise most national organisations like het Informatieberaad. Furthermore, they provide information standards and medical terminology for the development and implementation of e-Health applications. These standards are developed in national programs such as MedMij, VIPP and Registratie aan de bron, in which Nictiz is a partner (VWS, 2018). These three initiatives are explained here and shown in connection to each other in figure 3.2.2.

Registratie aan de bron focuses on the unambiguous recording of care information during the care process, for multiple uses. This recording is done on the basis of care information building blocks, "zorg informatie blokken" (ZIB). The basic data set care is the minimum transfer information and consists of 26 ZIBs.

MedMij (2018) develops a compliance system and standards to enable exchange with personal health environments (PGO). Its standards are for data registration are according to the Information standard medication process. This program facilitates the better recording and therefore exchange of medication data between healthcare providers and care providers and patients. This is done by the development of the information standard in the medication process. with the aim of clear and up-to-date insight into the actual medication use of the

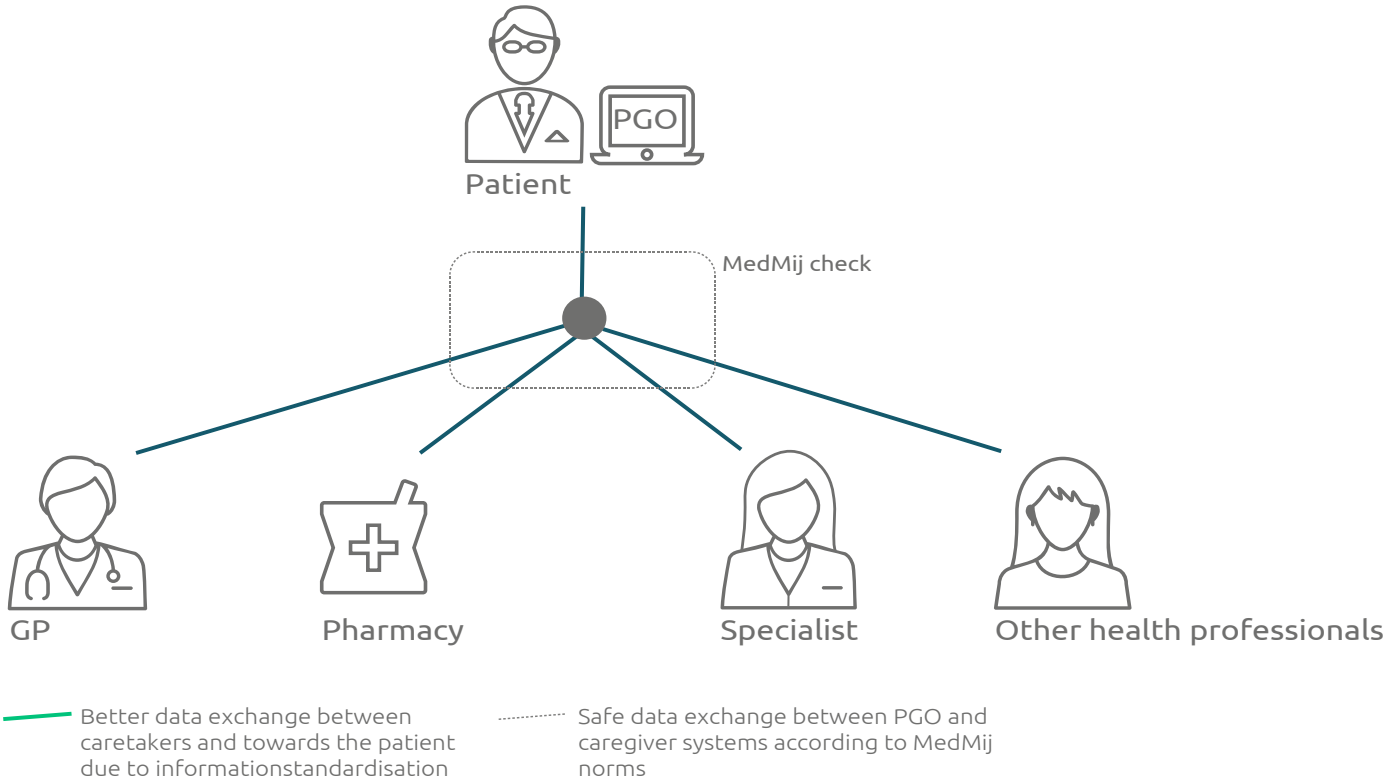


Figure 3.2.3.Data exchange future scenarion

patient.

Besides data registration standards it is working on creating standards for so-called Patient Gezondheids Omgevingen (PGO). These PGOs are patient owned systems that can record and exchange health data. MedMij provides a sort of certificate for 'safely' operating PGOs. In the sense that this data storage and transfer is secure for exchange between the caregiver and patient.

Different caregiver groups, GPs or pharmacist, have a program to improve data exchange with the patient. Usually driven by the different caregiver group branch organisations. The acceleration program patient and professional, "Versnellingsprogramma Informatie Patient en Professional" (Vipp), is an example of such an implementation program for hospitals. It is aimed at making personal medical data accessible for patients and the standardised exchange of medication data with the public pharmacy and the patient. It shows the clear need for better integration of first and second line caregivers set up by the Nederlandse Vereniging Ziekenhuizen (Vipp, 2018). It has a separate step by step module implementation plan with a program specifically for patients and medication:

- Each institution can offer an up-to-date overview of medication as part of the medication process in clinical and outpatient settings by 1 July 2018;
- Every healthcare institution can offer medication prescriptions digitally as a pre-announcement and/or prescription on 31 December 2019;
- Every healthcare institution can digitally provide a

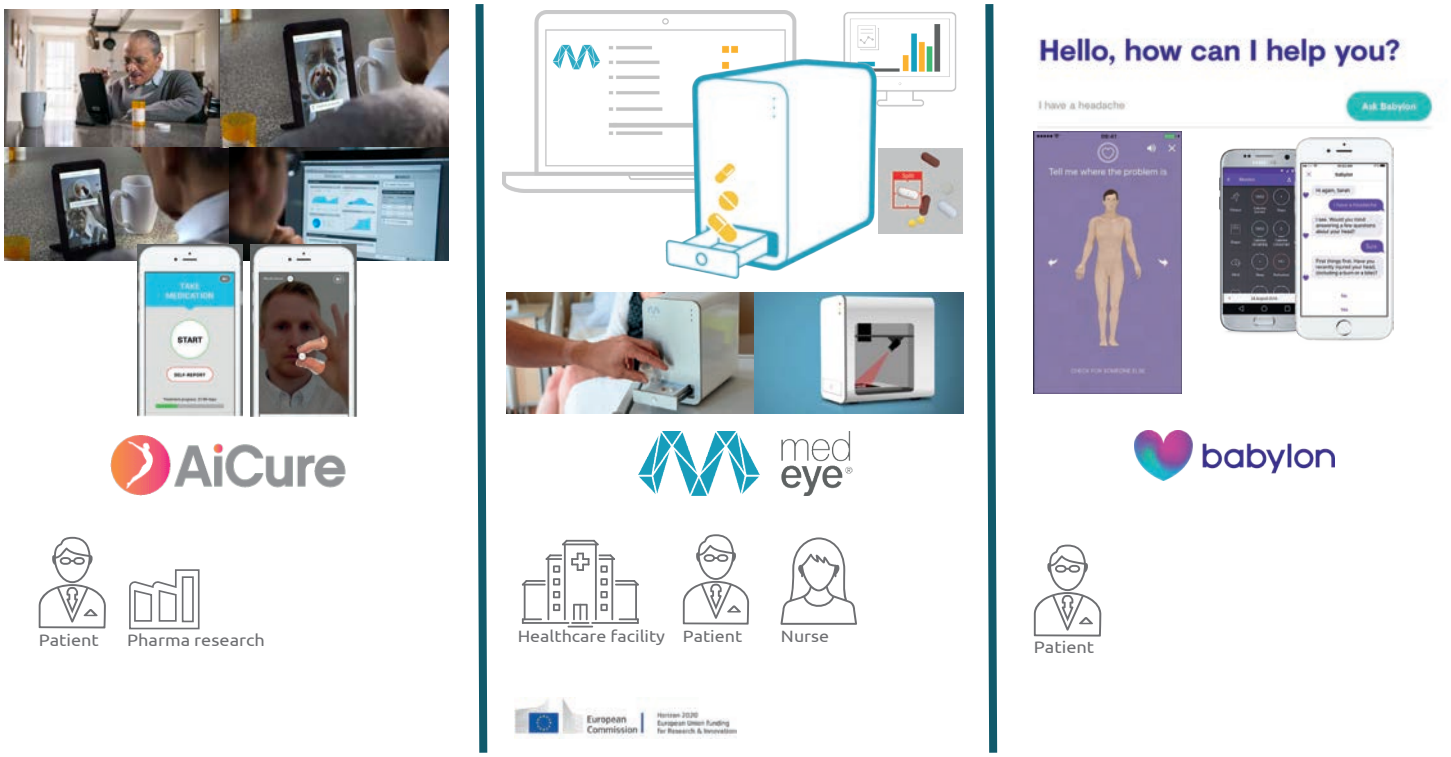


Figure 3.2.4a Excisting e-Health solutions reviewed.

standardized up-to-date medication overview (including medication agreements) to the patient on 31 December 2019 upon discharge in accordance with the current medication guideline.

These developments in the field of patient data caregiver health data exchange and standardisation will lead to an optimised system as shown in figure 3.2.3. As information exchange is one of the bottlenecks in medication care safety any and all improvements are welcome. Systems cannot communicate if, for instance, one works with a brand name of a medication and the other with its chemical composition name. That is why standardisation is necessary. Therefore, the design will aim to adhere to standardisation from the beginning. Instead of being subjected later to valuable alteration to fit in a bigger network. Like existing systems are in these types of programs.

It is important however to stay user-centred. It is desired to simplify information for patients, like, from a Latin diagnosis, Cystic Fibrosis, to for instance common Dutch words for a disease, Taaislijmziekte. In order to do this the app might need to 'translate' standards and databases to 'patient' language and back to optimise exchange.

BENCHMARK MEDICATION E-HEALTH SOLUTIONS

To get a broader sense of medication e-Health solutions in the market an internet research was done. Besides interviewed branch organisations were asked what developments inspired them the most in medication safety. Solutions were selected on their (unique) function and evaluation thereof by the general public on the internet, use of advanced technologies and/or involvement or collaborations of healthcare parties. Branch organisations evaluation t brought three additions to the list: Kijksluiter, Babylon and mijngezondheid.net. These were added based on the high regards of several organisations but also how inspiring they were in terms of setting the benchmark in this field.

Benchmark technologies

In terms of the use of advanced technology AICure MedEye and Babylon stand out. They all make use of different applications of Artificial Intelligence. AICure uses AI to check footage of intake of pills for 'proof' that the pill was taken correctly. MedEye aims to avoid medication mistakes inside the hospital at a critical point of dispense. With its user filled database of medication images, it can verify medication placed in a small drawer on correctness. Even split pills are recognised by the system on their dosage. Babylon is a chat-bot application that combines big

Figure 3.2.4b Excisting e-Health solutions reviewed.

data on medical expertise to provide a personalised, comprehensive health service for humans. The use of a bot is the perfect example of fulfilling the need of patients over pushing tons of information.

Benchmark the new pharmacy service

Several apps aim at improving the pharmacy service to a service centred around user wants an needs. The most advanced in this is the American PillPack. It offers a delivery service at the patient door of all prescribed and over the counter medications. It takes away the burden for the patient of having to juggle administrative responsibilities between prescribers the pharmacy and insurance companies. That is more significant in the US. Echo offers a similar service of bringing all healthcare providers together, in the UK. It is set up by the National Health Service, it gives the patient timely reminders on when and how to use medication and reordering it. Insurance 'pays' for the medication as patient keep their exemption up-to-date.

These developments are recognised by VIG as the thread public pharmacies are under. They even foresee that the pharmacy might move into the supermarket that is more convenience driven for customers. Which seems to be in line with developments like Amazon purchasing PillPack.

The Dutch healthcare system does not seem accessible enough to set up such a system yet, with the *Zorgverzekeringenwet* and *Geneesmiddelenwet* in place. The most advanced, well-known and regarded pill re-order and alarm app seem to be MedApp. Besides, it offers (additional) information about the medication leaflet and price. This information is retrieved from CBG and the Zorginstituut.

Benchmark patient data exchange

Data exchange, especially towards the patient, is not where it should be yet. However, as mentioned there is some care organisation owned systems that do offer insight into health data. Two examples are shown here, Zorgdoc and mijngezondheid.net

Mijngezondheid.net gives patients insight into their medication overview. It offers patients the opportunity to make and check an overview off all medication they are taking. Also, if their health care provider is not connected to the system. Unlike mijngezondheid.net that requires a first-line care provider to give you access with your DigiD. Pharmasystems developed this patient portal that gives patients insight into among other things their medication overview but without the opportunity to adjust it. In its additional functions, it is, however, more complete. It offers access to lab results and the

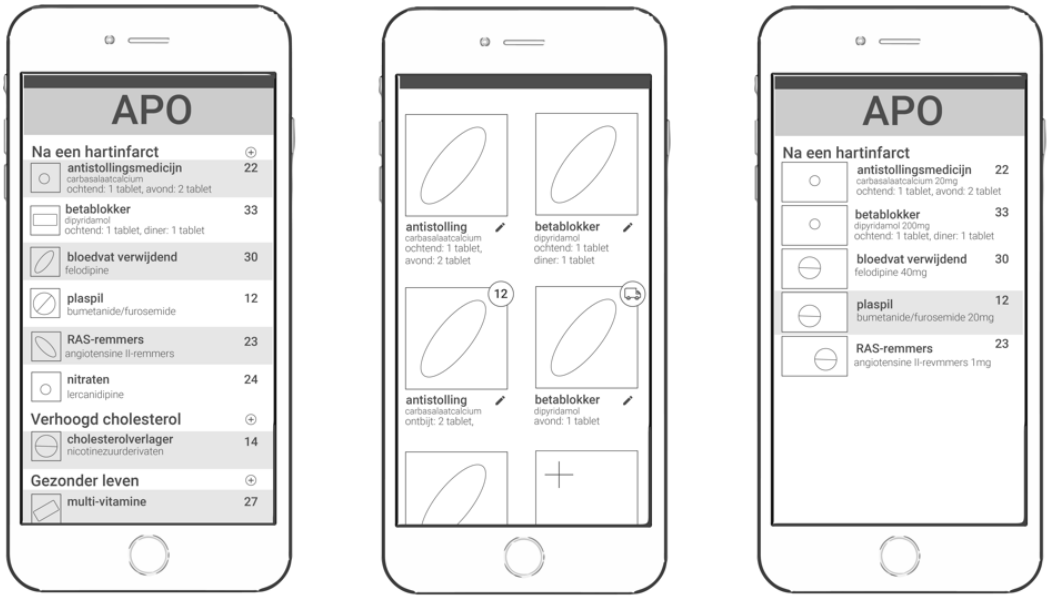
Figure 3.2.4c Excisting e-Health solutions reviewed.

general patient dossier. Besides, it has the function to send messages from care providers and remind the patient of appointments.

An interesting and well-regarded app is Consult+. It aims to avoid the massive loss of information between the caregiver and the patient. By recording the doctor's consult and store it locally and safely. It asks the physician for consent to record and can guide a patient through a conversation in three main questions. It was developed by a former nurse and funded by Menzis, the website states Menzis did not infringe on the content or functionality of the app. It was put on the shelve until the ministry of healthcare put e-Health as a high priority. Interesting here is that the patient from the beginning is given information and then really "owns" it.

3.4 MOCK-UPS

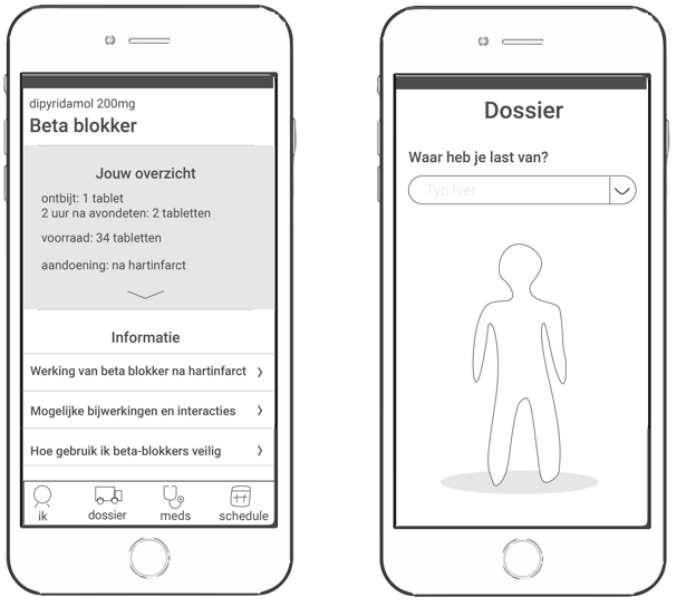
The next visual step was made from ideation to conceptualisation in creating digital mock-up concepts of the three-main function in the app: general personalised overview, medication overview and finding a schedule. These were reviewed in the interviews with branch organisation representatives to see if they are in line with how they think medication care safety can be improved. The respective visuals of functions and evaluation are described in this chapter.



MEDICATION OVERVIEW

Firstly, naming, the medication by their more 'casual' names like Beta-blockers are used. In addition, it is clearly indicated what condition medication is described to.

It was attempted to create a visual part of the medication overview. Patients very often don't have their medication in the original packaging. Visually an additional check of the right medication is easily made. Which also play into this existing context of pillboxes and Baxter rolls.



MEDICATION INFORMATION

By clicking on a medicine more explanation should appear. The aim is to offer an additional valid source of information besides the leaflet.
To avoid an extensive list of information instead it should be personalised and faceted.
People take the time to input information like I'm a 86 year old man, then information about pregnancy does not have to be displayed here. Not all information should be shown at once, maybe even asking what would you like to know over putting everything on the screen. Frequently asked questions on existing sites or from the app itself can be put forward. When possible like in the case of how to properly take medication, information can be visualised.

People take the time to input information like I'm a 86 year old man, then information about pregnancy does not have to be displayed here. Not all information should be shown at once, maybe even asking what would you like to know over putting everything on the screen. Frequently asked questions on existing sites or from the app itself can be put forward. When possible like in the case of how to properly take medication, information can be visualised.

Ideally, the app requires little effort especially on the overview which people now do not consider to be part of their responsibility. For instance, the MedMij system can allow to 'download' the medication overview from the different caregivers. The QR-code that comes with the implementation of the FMD can be used to check the overviews against what a patient has at home. Another good quick source of information is the label the pharmacy places on the packaging. This contains a short summary of the medication for the specific patient like which condition it is prescribed for or how many tablets to take-in. There are existing apps for making a medication overview, however, these aim at adherence through alarm clocks or notifications as their main function. In patient interviews conducted it became clear that for especially people that have been taking the same medication for over 20 years alarms are unnecessary. Alarms can be part when a new medication is added or for individual medication with odd intake moments. However, the main functions remain to create an overview and to find a regimen.

HELP FIND REGIMEN

For finding a regimen again the aim is to think with the user. Make it easy to track side effects. The idea is that the app puts side-effect next to you daily intake of medication. It will not draw a conclusion in line with: have this medication changed out for this one by your doctor. However, it should help patients prepare for a consult to talk about their medication. At a consult, people are often put on the spot to explain their problems in 2 minutes. Their story is then defined by the narrative of the doctor that has to ask when do you experience these problems and for how long, it is hard to come up with for some patients. By having tracked use and symptoms patients can enter such a conversation with a better preparation of what's to come and knowledge.

HOMEPAGE OVERVIEW

The last piece of the app is a homepage or an overview of the apps different functions. This page's content is filled according to the use of the patient. It takes into account the changes in the needs of the patient over time. In the beginning side, effects and medication tracking might be really important. But later it might only relevant whether you have to order something new or when you have an appointment with the doctor. If you want to discuss something about the medication that can be prepared for a while, then also that the main page will adapt to what people use.

HEALTHCARE ORGANISATIONS EVALUATION

Organisation representatives where asked what according to them are the biggest bottlenecks in medication safety and how they think they should be solved. The transfer of the medication overview was mentioned most often. The former chapter explains how developments in digital data exchange and standardisation are part of the solution. Organisations, however, also saw involving the patient more in the pharmaceutical care process as a solution for increasing medication safety. This section will talk about what organisations think about engaging the patient. The organisations were shown mock-ups of the app design, their evaluation is discussed next.

"The patient should have more of a directive role."

"An up-to-date medication basic set is simply a very critical point where a lot of room for improvement is still apparent."

Almost all organisation saw involving the patient more, as a solution to current problems in medication overview transfer. Some also see it as a solution for more:

"Therapy adherence is shared responsibility"

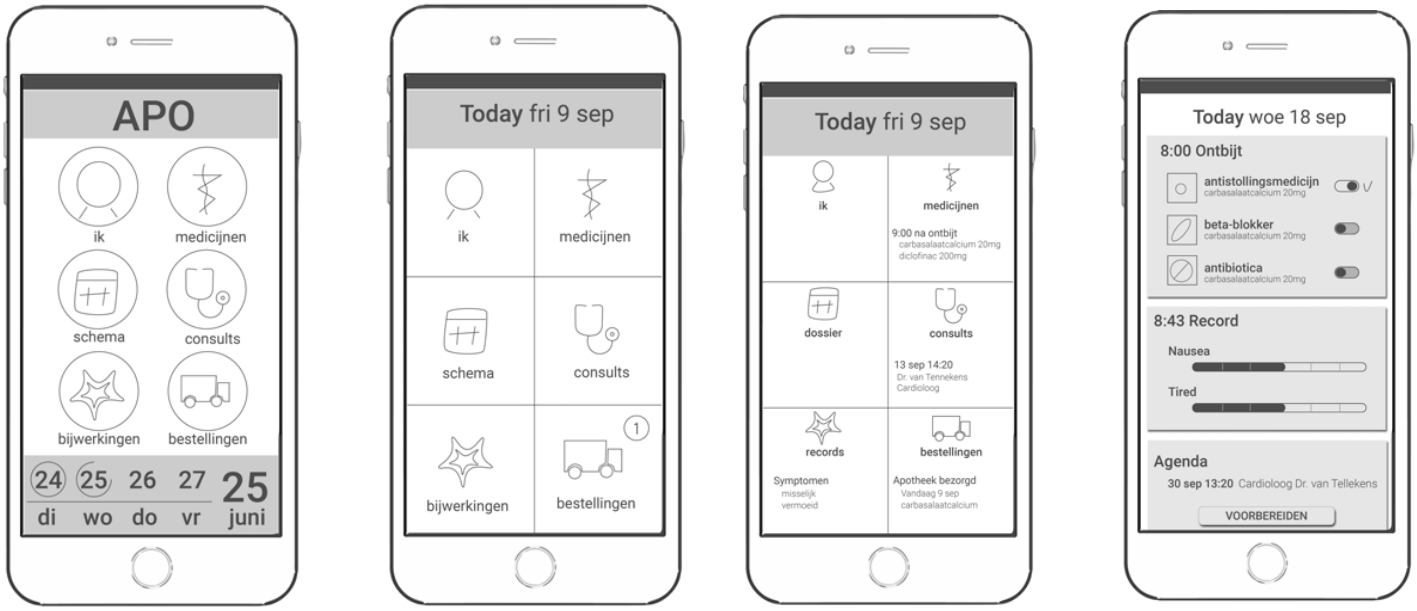
They also saw that this is not yet the case:

"We need to make patients more aware, the patient should be given more overview"

"Clear agreements should be made about the patient."

With this, it becomes apparent that there is a need for a patient-side interventions among branch organisations. as well

The choice for the patient group and journey pain points was also briefly discussed. The journey was recognisable by most organisations, especially the increasing amount of knowledge people gain over time. KNMP representative pointed out that the term



'complex' medication regimen is still twofold in their framework. There is such a thing as actual complex medication, for instance, prepared to be delivered through IVs. Then there are, what was meant in this project, taking a lot of medication especially brought in connection with frail elderly, that are a little more forgetful, more prone to in adherence etc.

One of the representatives of the Patient Federatie also pointed out in their framework what was called a 'health incident' in this patient journey they named 'life event'. It is interesting to take these notions into account for urther reference with organisations.

The idea of an app

For the interview patient empowerment was brought in relation to understanding the role in medication transfer and giving the knowledge to participate in a conversation. With the subsequent functions of the app of respectively, medication overview and finding a schedule. Overall the app was reviewed as a good solution for the problem:

"I think it should be part of the starting fase of a treatment.That's when you really need it"

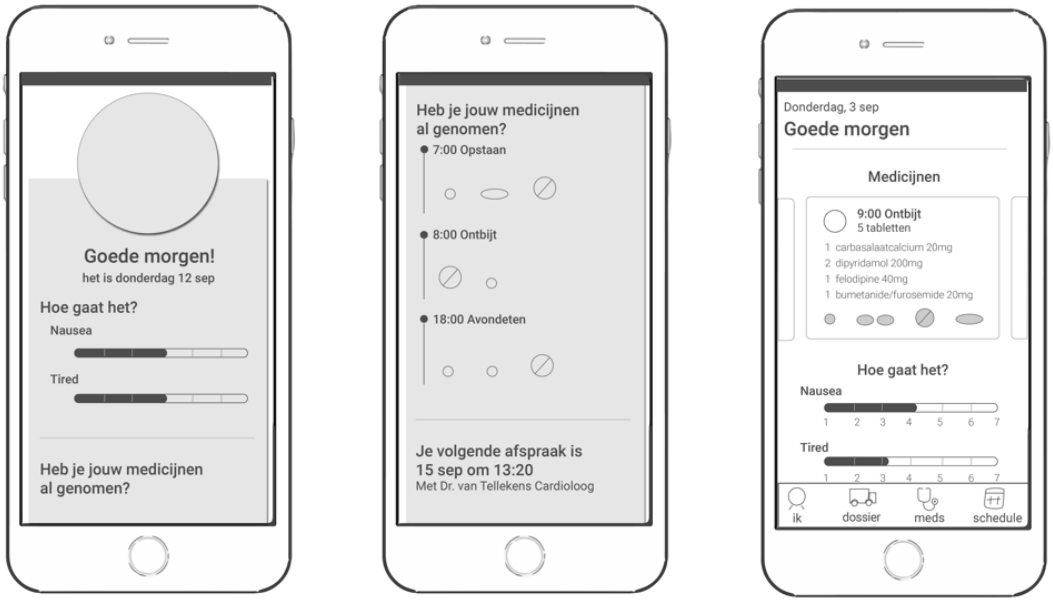
"Logically sound and well-organized"

"Gives patients a directive role and makes them work on it themselves"

Medication overview

"It is really good you are looking into this, when you would change everyone's bank balance with one euro everyone would notice. Change people's medication overview and no one bats an eye."

Already stressed in the project and mentioned again was that patient's need for feedback that if they change something, 'something' is done with that information. It was mentioned to strengthen this feedback loop even more by having life feedback with the doctor when really bad side-effect occur. Although interesting to further explore one should be critical that it needs to deliver value for both the patient and the doctor.



Besides, interviewees either mentioned by themselves or applauded the idea of an archive function. It starts with adding an end date to non-permanent medication, like an antibiotics course. Besides old medication especially when stopped because of side-effects, should be stored and the reason why it was stopped. In line with this, it was also mentioned to not forget to add self-care medication which can also have interactions with medication.

"Stopping medication is also really important but often still goes wrong."

Patient understanding of their role in medication
A strong comment, already identified earlier in the process, is that to make people more aware of their role they need to download the app. But if they are unaware they will not download it. This crux was also identified by the Patienten Federation, they specified this to fragile patients that are already less active in their care.

"They really need to be made aware. On their own, they will never come up with the need of using an app."

They thought this could be solved by the prescriber advocating and introducing the app. By introducing the app at the in the first consults people are made aware from the start.

"A lot of people don't even pick up the medication or pick it up without any intention of ever using it."

Information provision
Important to the representatives was the validity of the information. The app holds a lot of information about medication about which they justly commented that information fed into the app should be from a valid source. Official websites like the apotheker.nl, from the KNMP, were mentioned as an example. The Bogin representative thought the medication leaflet should also be visible in one tab. In the MedApp we already saw the use of 'valid' information provided by the CBG and Zorginstituut.

Interviewees also thought the personalised and step-by-step way of giving information was interesting. It was easily related to or explained with the Kijkwijzer. Someone mentioned using the data collected by the app itself for analysis and input.

"Use data to discover trends"

A good illustrative example also given by the VIG representative was shopping websites these days give probes of products 'other shopper' also looked at. Another mentioned something similar in terms of 'sharing information with fellow patients'.

The next thing mentioned about information was to make it low threshold. It was really stressed by most organisations how important earlier mentioned health skill is these days and to adjust to all levels.

"Easy language, you'll be surprised how many people don't understand the information given to them."

Finding a comfortable medication schedule

People were impressed by the idea to solve regimen finding in this way. It is really the newest feature the app brings in comparison to apps already out there.

"It is interesting especially for a few most important side effects"

Preparing a consult was seen as the definite advantage. It was even mentioned that it can assist in being taking seriously. The advantage was also seen in the fact that big groups of people stop taking medication because of side effects. Recognising this and helping to solve issues might reduce in adherence.

"People get confused when doctors start talking about when and which part of the day these side effects took place."

Additional functionality

Lastly, an interesting new problem was arrived at after critically reviewing the designs. Representatives mentioned it should start with why you are taking these medications more clearly. They promote being more active in the consultations also in ensuring that you do not get too much medication prescribed.

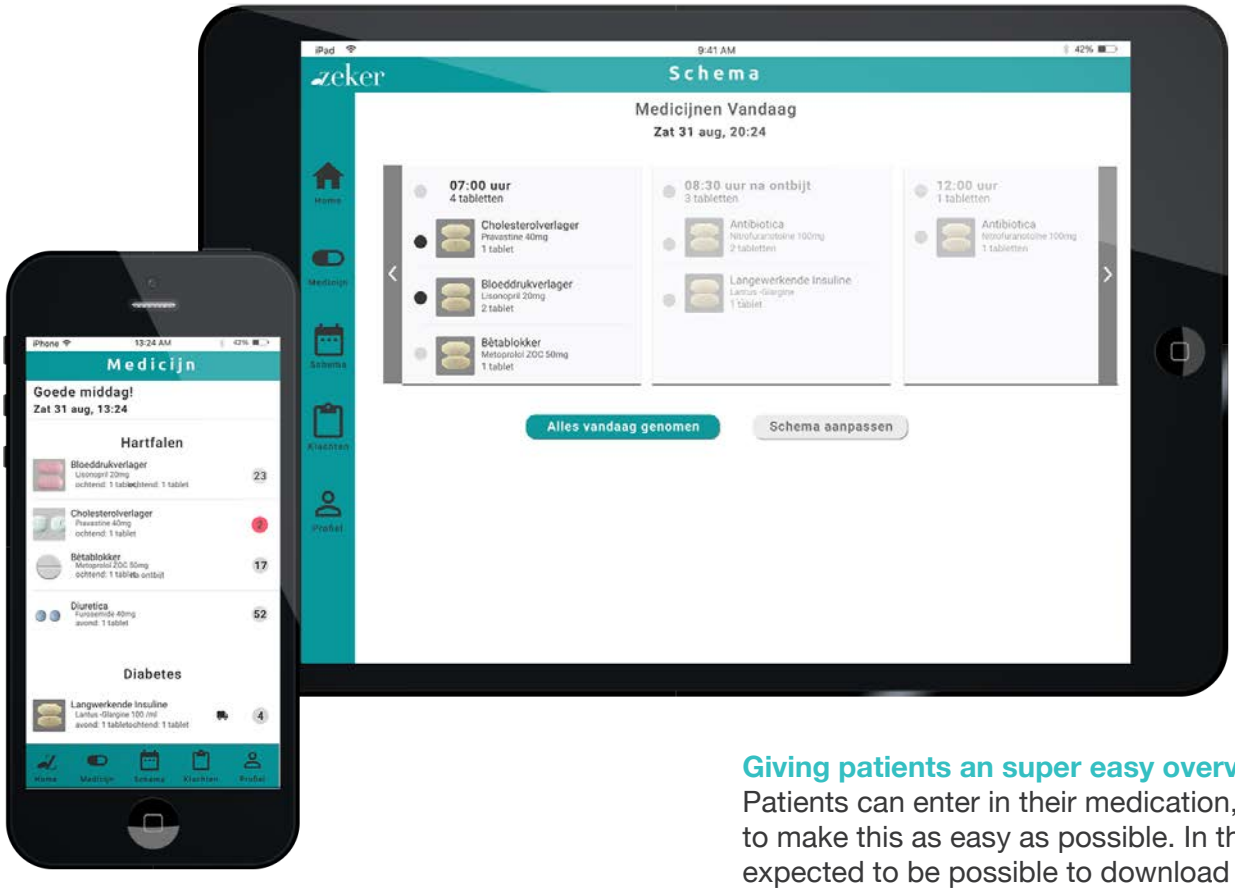
"Maybe I'm asking for too much but I would have hoped that it would be even smarter. Care professional prescribe according to guidelines entered into a system that spits out the prefered treatment. However, for some patients, it could be incredibly helpful if they did not have to take their medication three times per day."

"Especially among elderly people if the doctor prescribes it they will take it regardless. For example, a certain type of medication causes dizzy spells which can increase the chances of falling. Since you are this and this old the chances of the symptom this medication is treating occur is much smaller and falling is a way greater risk."

3.5 THE ZEKER CONCEPT

To describe the final concept, it is explained how the vision on patient empowerment for medication safety was embodied to tackle the design challenge that was formulated: ***"To empower patients in searching for a regimen in which living with medication is not restrictive and take away strong negative emotion around adjustments to the medication regimen."*** *For patients with polypharmacy, the Zeker app gives reliable personalised answers in finding a medication regimen. When medication is restrictive it will reduce negative emotion by taking patients seriously and helping in the search as to why and what are alternatives for patients. Knowledge and giving overview empowers patients in increasing medication safety together with their caregivers.*

Zeker (sure) aims to underline that medication safety is shared responsibility in which a patient, the user of the app, plays a role. The name purposefully does not highlight health, med(ication) or anything related. However, it was based on a word play between assure, safe, secure, self-assured. Its slogan states: Together Sure about your medication. The design underwent several iteration that can be found in Appendix C5.



With the design, patients will better understand their responsibilities in keeping and transferring their medication overview.

The app endeavours to give patients a clear overview of their medications. They are ordered per symptom to help make them understand why they are taking medication. The idea is that the pills are shown in pictures retrieved from the database or taken by the patients themselves. Most patients don't have the medication in the original packaging so as an extra check to in identifying what to take when. By making the app about more than just a medication overview the app nudges users to look more often and be more aware of their overview or when something changes.

Giving patients an super easy overview

Patients can enter in their medication, the aim is to make this as easy as possible. In the future, it is expected to be possible to download medication overviews from different caregivers through the advances in data exchange like MedMij. Patients can then check what they have at home against what is in the system. They will be made aware of adding self-care medication. Medication monitoring (*Medicatie bewaking*) standards, now used by the pharmacy, can be added as an additional safety check for dangerous combinations or dosages. If the patient enters in how much medication they got and how many they take per day. The app can track how much medication is left and when to order new medication. It makes it easy for patients to check their medication overview with a caregiver when asked. Besides, it has the opportunity to 'archive' medication if reasons for stopping medication were allergies or bad reactions it can help doctors avoid prescribing them again.

The design has patients gain the knowledge to engage in a consult conversation about their medication treatment.

The concept aims to ensure patients have access to valid information about their medication at any time. The idea is that this information is made relevant instead of overflowing people with generalised information. People input information about themselves like their disease, age, gender, other medications etc. this can be used to make information personalised to a user. Besides, information will be linked to setting up a consult with the right caregiver. The aim of the app is not to take over the role of current caregivers by telling the patients the alternatives to medication. But to inform them there are other options available or to aid them in talking about side-effects or other experiences.

Help patients define what to talk about

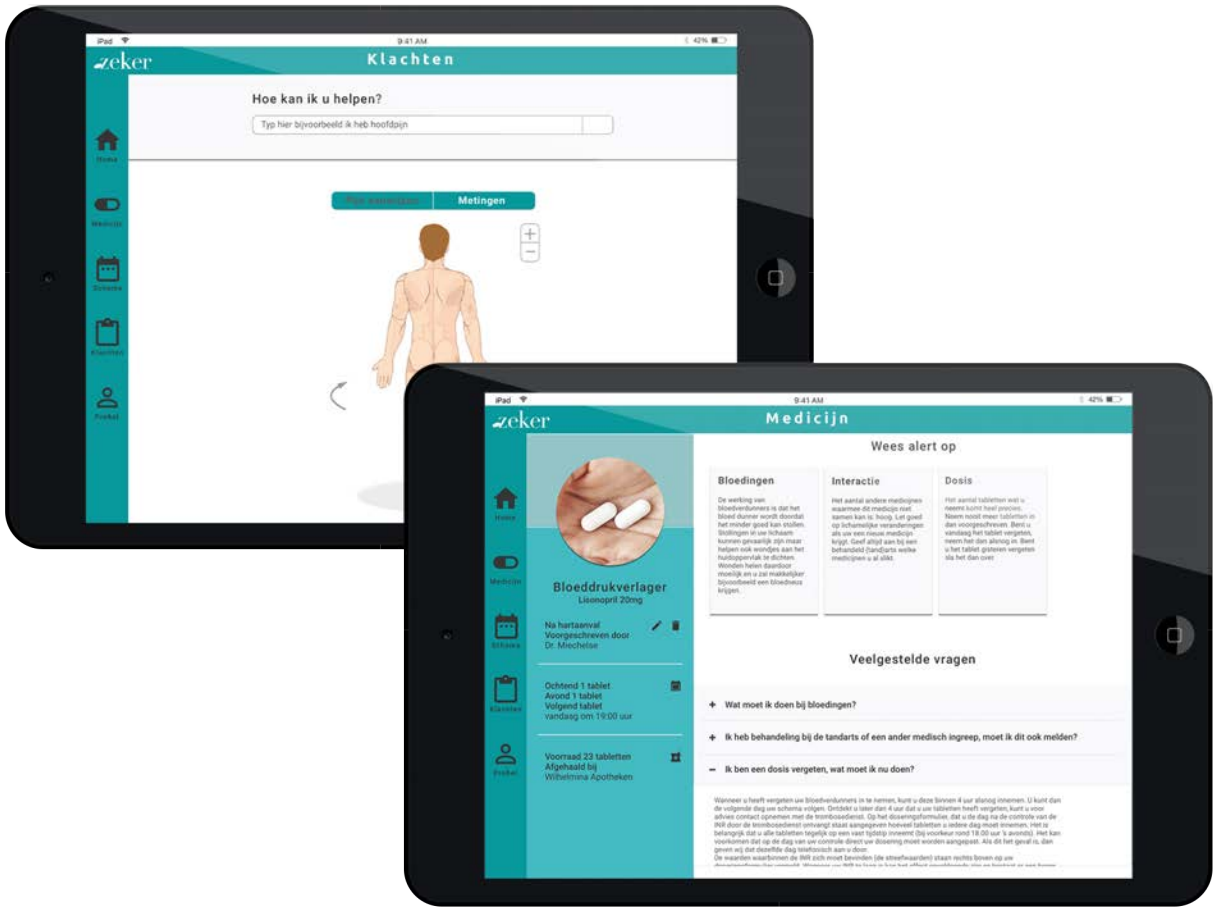
This is done by giving the patient an easy way to track their side-effect. The app helps patients first in defining and describing what the problem really is and how it is constricting their life. Then by tracking it they can get an overview of how often it occurs and when it occurs. In the beginning, it might be necessary to also track medication intake. To see if there are specific connections between medication intake and complaints. In a later stadium of someone's journey sudden changes in physique can probably more easily be traced back to changes, for instance, due to the preference policy. The aim is that the app makes and explains connections between complaints and medication that might be hard to convey in a short consult both for the patient and caregivers. It offers the additional opportunity to detect immediate high-risk situations and alarm a doctor or recommend a patient to contact a doctor.

Patients experience that the design facilitates their home and consult environment for safer medication treatment.

The app attempts to make an easy transition from at home use to using the information in the consultation room. By linking the patient to the caregiver, they need for that moment. It is a none invasive aid in the existing environment of the patient. It aims to comply with different existing medication tools like pillboxes, Baxter rolls etc.

Support at home and in the consultation room

Patients are facilitated in their medication care by having an overview, being reminded of medication, orders and appointments. Besides being able to structurally report problems and search for answers. The aim is that the app makes a clear and fluent step from the home environment to that in the consult. Caregivers are inputted into the app and connected to for data exchange. With patient caregiver exchange, information can be shown in each user's respective interface that they are used to. Patients can input and prepare if medication needs to be discussed in the consult and bring their device to back them up. By preparing patients for what information is needed they can think about it, before they are put on the spot in a consultation office.



Patients experience that the design anticipates their level of healthcare skills regarding their medication treatment.

From an inclusive design perspective, it was chosen to ensure the design adopts healthcare skills of many levels. It uses easy language and gives information step-by-step. Besides patients are not overloaded with information, information is personalised to them and ordered in importance. Preferably, based on a self-learning algorithm and data trends that adjusts the information to the patient's needs for that time.

Provide clear infromation in facets

Patients experience that the design is on their level of healthcare skills regarding their medication treatment. Information is personalised where possible and increasingly so if the app is self-learning in identifying patient populations or trends. Information provision is faceted, first, the patient sees a short-summarised overview then with every click more information can be given. Deeper layers go into more detail and explain how the app arrived at certain conclusions. For people that would also like to know more about what data it is based on, why it is as it is etc. Important information like notification about recalls of medication etc. will be displayed on the main overview.

4. VERIFICATION

In this Verification chapter the Zeker app is verified. The assignment of this project set out to explore how the patient group with polypharmacy can be empowered in their complex medication regimen. This has been explored and the Zeker app was created. To aim at concrete optimisation aspects of validity and viability are analysed. The assignment additionally aimed to explore the stakeholders in the pharmaceutical value chain. To assess who could embody a relation of empowerment with the patient in medication safety. That will, in turn, add value for the stakeholder in becoming a more integral part of the healthcare chain with the user at its centre.

This chapter reviews the changing roles and possible relations of empowerment for patients for five stakeholders: the pharmaceutical industry, the pharmacy, caregivers and the government. To this end, healthcare stakeholders from the interviews were questioned about who they see as part of developments in medication safety and e-Health. Also, which role they expect to fulfil. E-Health also puts forth a new role: (big) data analyst, for which this reasearch appoints a stakeholder.

Next, the stakeholder interests are reviewed in terms of value added by the app. Besides two financial models were drafted for the app. In terms of possibilities for financial reimbursement through the current and future Dutch healthcare system. For this additional research of among other things a quick-scan of PGOs and the current financial models for e-Health was done. The project provided the information to set up which existing sources of information and data can be used for the app.

Lastly, the Zeker concept and its functionalities were reviewed by patients. This user-research was aimed at whether the four main functions are understood, if patients think it could help them in using medication and if they would then also use the app. This resulted in a last iteration of the design. The last chapter of this project describes the recommendations for the future of this app, its stakeholders and further research.

4.1 VIABILITY

The future roles of stakeholders in medication safety in relation to e-Health interventions were explored in the interviews and complementary research. This chapter describes the role of the stakeholders: pharmaceutical industry, pharmacies, caregivers and the government. Which are concluded upon with the stakeholders (future) relation in patient empowerment. Besides, this research appoints the new role of (big) data analyst to an existing party: the Lareb. The Zeker app needs to balance, as was well stated in one of the interviews: "what does it add for the caregiver the insurance company and the patient". This stakeholder value in the Zeker app was explored. Lastly, two reimbursement models were drafted, one similar to existing and current practices and one is a more futuristic outlook.

PHARMACEUTICAL INDUSTRY

Since this project was initiated with the implementation of the FMD which was a supply chain safety intervention, the pharmaceutical producers will be explained first. The pharmaceutical industry has a great influence on the pricing of medication now and in the future. With patents running out competition is rising high and old revenue models do not suffice any more. Branch organisations like VIG show interest in participating in value-based health care (VIG, 2018-1). Besides, they do not view medication safety in the care chain as safety but call it the proper use of medication (ZonMW, 2018). Their view is that the best intervention is, for all medication to be used correctly which will lead to a sustainably affordable model.

"We advocate for the right use of the right medication."

KPMG (2016) reviewed the role of the pharmaceutical industry and came to three roles in the future. That according to KPMG, will make pharmaceutical producers ready for the trends of value-based healthcare and the changes towards prevention over treatment. These three 'archetypes" are: active pharmaceutical portfolio company, virtual value chain orchestrator and pharmaceutical niche specialist.

An ***active portfolio company*** is typically active in several therapeutic areas within its portfolio. For example, those operating in pharma tech, genetics and immunotherapy are constantly looking for new forms of therapy, while simultaneously reappraising their product mix to match unmet needs. This type of development where technology and pharmaceutical development come closer together was also recognised by the VIG representatives.

"Our members are looking intensively at what's happening in the consumer technology product market"

As shown before these advances in technology offer more personalised treatment with added possibilities to treat patients at home. A patient-centric view is important for these companies. However, with the current set up of the supply chain of medication in

the Netherlands based on the Geneesmidddelenwet true interaction digital or otherwise still seems unlikely.

Although it is a great disadvantage for producing companies with the increase in falsified medication it is more valuable than ever that the Dutch supply chain network is well protected. Therefore, it is unlikely legislation will ease.

Niche specialists will be focussing on a single disease or clinical diagnose, like diabetes or arthritis. For this specific group of patients, they develop a treatment instead of a single treatment. For instance, in arthritis, they would treat symptoms but also create a better lifestyle by extending their business to include comfortable shoes for painful joints.

Interesting for this project in terms of the unmet challenge of health data exchange and bringing it a step further with big (health) data analysis. The ***virtual value chain orchestrators*** are companies offering 'virtual value". They do not own anything tangible they own data much like a company like Google. The (large) amounts of data on therapies, patients and research can be used to drive major change and development in the sector. Although trends earlier showed that especially in biomedicine big data analysis is very valuable for discovery, we have not seen other evidence of producers moving in this value chain direction. As Capgemini has pointed out especially tech companies are moving into this direction. Again, in the current legislative systems production companies probably have to completely let go of their current portfolio before being able to have this much (digital) patient engagement.

These archetypes will not offer a new relation that empowers the patient. However, will deliver more holistic pharmaceutical services to the patient.

PHARMACY

It is believed by some that the current public pharmacy as it's known now will soon disappear. As pointed out by one of the representatives the 9-17 opening hours do not offer customers service for people that work during those hours. From the patient interviews, it was also derived that the pharmacist does not play a big role in the current patient network in terms of the physical store and people. They are seen as a supplier of the medication.

Besides, medication e-Health benchmarks have shown companies mainly outside of the Netherlands have started to explore new pharmacy as a service offering. In a future scenario, this is what the public pharmacy might move into, a convenience service offered by a consumer goods provider.

"I see Ahold and bol.com moving into this field as Amazon did."

KNMP (2017) sketches a different scenario. They show great volition in becoming a stronger player in consulting on medication. Offering the service of medication control and consultation for especially at-risk patients. Guidelines include multi-morbidity, elderly, polypharmacy and some other factors to be eligible for a medication check, the safety net of medication safety according to VWS (2016).

Another strategic placement came to light by talking to KNMP representative the General pharmacist (*Huisapotheker*) a combination of the words GP and pharmacist. KNMP further explains this pharmacist will take on the responsibility of keeping oversight of all medication of at-risk patients.

Problems that arise in this consulting role of the pharmacist is that the current infrastructure at pharmacies does not allow for this type of contact. The high counter barrier and such do not invite patients to have a conversation, Erkelens (2017). Patient interviews show that patients hardly even visit the physical store. The type of overview and consultation that is described is perfect for digitisation into tele-consult. Besides, that physical dispense will be taken over by convenience and customer service-driven selling companies like supermarkets or online shops. This is already possible for most medication within existing legislation, for instance at medicijnen.nl. There are some Dutch online pharmacies that offer medication like this further adoption will be an incredible change in culture.

Hospital pharmacies will remain in their position and expand when public pharmacies would disappear. One representative mentioned the move for reimbursement of medication is also increasingly moving towards hospital pharmacies. It could happen that hospital pharmacies become a division in a hospital as big as others like oncology or gynaecology. Here patient's medication checks can still take place also physically since patients go to the hospital for check-ups already for other specialisms too. This also underlines the valuable role pharmacist can have for especially complex patients. Pharmaceutics is a completely separate specialism that intentionally has a completely different education than doctors do. This also enables the forecasted opportunity, KNMP (2017), for pharmacies(pharmacists) to also specialise in certain diseases, since hospitals or separate doctors do that too.

Overall pharmacies will move into more service driven delivery of medication care. There are (digital) opportunities for pharmacies to become a more integral part of patient's networks. In which they can embody a relation of empowerment with the patient.

CAREGIVERS

The role in the bigger network is not likely to change as such for caregivers, specifically doctors like the specialist or the GP. The organisational set-up though of their delivery of care will change even further. Care is increasingly being set up around first-line care this trend will persevere until the entire chain for all patients is set-up in this way. As also seen in the patient interviews some patients still prefer to contact their specialist first, the aim is that everyone contacts the GP first who will then forward them to a specialist if necessary. This ensures cheaper, more proactive delivery of care.

Secondly, digitisation in healthcare can still drastically improve. As one of the representatives said:

"Healthcare has been automated but not digitised. Meaning what was on paper is now on the computer but to optimisation of using technology has not been achieved. Using for instance analytics to help in consults. As simple as this diagnose offers more fear and distress about losing abilities, in women over 70."

Visiting a conference, "Van Hippocrates tot data-driven Dokter" (2018), on IT in healthcare has shown that a promising select few were interested in driving technology to a higher level in their relative hospitals. As one of the representatives said during the interviews:

"IT is now something a doctor does additionally to their work. IT employers are looked down upon by most doctors."

However, at the state it is at now, it can be derived healthcare is still far behind as opposed to other markets. At the conference, it was mentioned this is because healthcare organisations are (one of) the most complex organisations in existence.

However already shown by the speakers at the conference that they heavily invest in change management. Meaning it is not just about the complexity of the system, but more so about the willingness to change. In the reflection of this project and the conference it is felt doctors/healthcare IT providers forget they do not have to reinvent the wheel because they are in healthcare. A lot can be learned about different aspects from different organisations. Like: high-end security and banks, optimising EPD flows and CRM systems used by service operators, (international) complex system integration by logistics companies or tele providers.

There is something to be said for the fact that these type of companies have more investment capital for digital transformation. However, a lot of these companies are aware healthcare is a large and growing industry with therefore a growing demand for affordability. More companies are willing to share these days than before.

It is believed sustainable affordability of medication, and in general, can be achieved by digitising healthcare (processes) which means roles don not necessarily change but the content of the work by doctors will.

Digitisations and proper implementation of e-Health leaves more time for doctors to incorporate patient empowerment.

GOVERNMENT

Throughout this project, it has been illustrated that the role and influence of the government on the Dutch healthcare and medication market and delivery of care is important. This is not expected to change. The government documents used as references clearly showed how the government sets the agenda for healthcare. In this research, it was found the government should focus on two main outcomes namely, setting standards and guidlines for e-Health (development) and promote adoption of e-Health in the entire society.

In digitising healthcare it has been shown that the government has made only a little progress. The completely stripped version of the national health registration that is now in place does not suffice. This project has at least shown it is insufficient for safe medication care. Several of the representatives applaud the recent efforts of MedMij

"The government parties must create frameworks and requirements that everyone must meet, and you have to implement that would always be much more customized work."

"The government should not make the IT they should set up the blueprints and let the market deliver."

Although MedMij has received some negative feedback over the last few months (Trouw, 2018). It did set an interesting example in extensive collaboration in the healthcare market between commercial parties, (patient) organisations and government representatives like Nictiz. The government should keep focussing on setting standards and guidelines for digitisation of healthcare. By looking at best practices on the market in

terms of security, accessibility and usability.

"The government must keep oversight, you do not want this kind of extreme privacy sensitive information in the hands of a commercial or non-European party."

Secondly, the government should focus on increasing the adoption of e-Health. For the Zeker app, it became apparent in talking to the representatives that adoption is (only) possible when it is pointed out by the doctor to start using it. Organisations interviewed with care providers as members, KNMP and NVZ mentioned this as their role in an app like Zeker.

"Doctors can stimulate distribute and share these types of initiatives. "

"We can make patients aware that empowerment is important in medication within and outside of the pharmacy."

This is not just for the Zeker app. General adoption by patients of e-Health applications has been slow. 55% Of mHealth apps has been downloaded less than 5000 times (Research2guidance, 2017). As a comparison, Dutch national banking apps like Rabobank or ING that have been downloaded over 1 million times in the GooglePlay store (2018). Countries that have implemented a national system to exchange health data between patient and caregiver have user rates of less than 3% of patients that log on to these systems. It is, however, a two-sided story because most of the dossiers were also not filled by doctors, because they did not see the point. Besides, recent efforts like the "National E-Health Week" the government should invest in the promotion of e-Health use towards professionals and the (patient) society.

The governement wil not get a direct care relation with the patient. However, promotion of e-Health and further adoption is believed to boost patient empowerment.

(BIG) DATA ANALYST

The next big challenge this app and also other e-Health initiatives bring about is the collection of health data. In the chapter Trends, it was shown that in medication big data analytics is expected to improve medication development tremendously. Currently, healthcare data is very dispersed and when used it is mainly used regionally within one hospital for scientific research.

Two big examples were identified by organisation representatives as good national collection and application of data: DICA and IKNL. Respectively for data on surgical interventions and cancer treatments. One of the important demands of several representatives for data collection and analysis is that it is stored locally and not with a big third-party corporation like Google or Facebook.

There is already a national centre for registration of side effects; Lareb. Also they have to digitise. The Bogin app collaborated with Lareb to have a plugin to Lareb-website for patients to easily register side effects. This plug-in is still very minimalistic implementation. Lareb side-effect registration should take part in setting standards for registration in MedMij, so every PGO can collect data.

For PGO or app development it should still be taking into account patient value. If registration is a long complicated process it can be made optional. The additional steps can be clearly indicated as minimal effort to improve on medication and treatments. Or as said by one of the representatives:

"Donate your data for science."

This will be a new stakeholder in the patients network. Similar to the role of the pharmaceutical industry now, they do not have to be known by name. However, with an data insight flow back into medication care and development they defenitely ensure improved medication safety and personalised care.

STAKEHOLDER VALUE

Almost all representatives expressed the need to collaborate and involve different stakeholders. Both on an organisational level, like involving branche organisations, where everyone can have a say. Besides, as shown will be shown in the next data chapter, to utilise existing content.

"You will have to try to organise it more on an overarching level instead of with one hospital or one production company."

"To make it airtight you need to involve a lot of parties."

"It will only work if you don't have to develop all data and databases."

However, it remains a challenge to manage in the extensive and complex healthcare stakeholder network.

"Sometimes I see great solutions but they disappear into thin air. I think it also has to do with how we organise care and especially finance it. All the different interests can ensure a remarkable clear problem and solution remain out of the picture."

Added value for the patient side is very clear for the Zeker app. The aim is also to utilise opportunities data exchange from the patient towards the caregiver. First and foremost, in making medication care safer is high-risk detection. If unsafe combinations of medications that can cause interactions or intense side-effects are monitored and high risk is imminent the app can give caregivers a warning. Besides, the app offers the opportunity for patients to come better prepared for to consults and check-ups. Different caregivers have different benefits: at the emergency care at the hospital quick access to a complete medication overview is readily available, the GP can prepare for and/ or better understand questions by the patients that

come prepared and with data to back up their story, the pharmacy can be put forward more in their consulting role. Besides, stock information from patients on particular medications can be interesting also for pharmacies to keep their stock more up to date.

"I see a great advantage of patients coming better prepared to a consult."

Better use and use of medication are in the interest of stakeholders, the patient, the care provider, the government and commercial parties, such as the pharmaceutical industry and health insurers (ZonMW, 2018). For insurance companies, it is especially about the cost that is avoided when medication is used effective, safe and efficient. It is seemingly a more preventive measure as opposed to the current situation. Numbers on hospital admission related to medication (HARM) have shown the need and also the cost reduction improvement can offer.

After extensive deliberation and taking stakeholder comments into account, research reviewed the future of the Zeker app has two financial reimbursement scenarios. Both are under the assumption that the financing of care will remain through health insurance that reimburses costs. One is the more traditional way to set up a healthcare app. The other follows more the developments of PGOs and value-based patient-centric healthcare. Most representatives mentioned reimbursement or financing the concept as an important aspect.

"Financing this is really important."

REIMBURSEMENT THROUGH FIRST-LINE CAREGIVERS

Currently if e-Health, like tele-consults, is reimbursed, this falls under care by an individual caregiver (Nederlandse Zorgautoriteit (NZa), 2017). The most interesting caregivers to approach are in first-line care, seemingly the GP and possibly also the pharmacy. Specialists are only involved in their specific part of the medication treatment and have little time to offer help outside set check-ups. The GP has the opportunity to actually change something in the medication whereas the pharmacy can only dispense medication and provide information.

To connect an app to GPs is not easy. Firstly, they are small (ZZP) businesses with little capital to invest unlike (big) hospitals were a lot of e-Health systems start. Therefore, it is interesting to look at system providers for GPs for further product development. These Huisartsinformatiesystemen (HIS) have the added advantage that they already work with patient health data. Needed for the data exchange of this app to work. Coincidently most of the bigger GP health system providers also provide a system for pharmacists which integrates nicely with functions like the reordering of medication.

REIMBURSEMENT OF PGOS

The second option for the future of Zeker is a new reimbursement that is likely to follow from the developments around PGOs. A quick scan of the most advanced in terms of development PGOs showed that they more often have multiple contributors. Like patient organisation, health insurance companies, healthcare institutions. An overview of which PGOs were considered can be found in Appendix D1. As shown the Zeker app would benefit from (data) contributions from many different sources. Additionally, this quick-scan turned up PGOs are trying out different financial models. Some are still only accessible when given access to by a healthcare organisation, that is then paid for by that organisation. The patient federation mentioned that soon they will not grant these closed apps the name PGO anymore.
Next, there are PGOs that ask the patient to pay a subscription fee, for use or for premium functionalities. It is unlikely that this will be a common form of reimbursement in the future. NYU Langone Medical Centre concludes 41% of adult smartphone users don't want to pay anything for a health app. Moreover, 20% would pay up to 1,99$ and 23% are willing to pay anything between 2-5$. Interviewed organisations conclude the same.

"Some party will have to pay for this. The patient is definitely not the person to do that right now."

"E-Health can be a true aid in their health but not everyone views it like that currently."

A last interesting development is the SelfCare website that also targets employers to pay for the PGO for their staff.

Most likely an (even better) system will be set-up from health insurance companies to pay for e-Health including PGOs.
To deliver patient centred value-based healthcare through PGOs they will be developed transcending individual caregivers. Especially, for patients with multimorbidity and polypharmacy reviewed in this project. For instance, in patient interviews, it became apparent that some patients need multiple pharmacies to supply in their medication. While the GP is increasingly the first person to go to, some very specific problems really can only be solved by the specialist. An application can offer just that, care as a service that transcends (reimbursement through) a single caregiver. It is not unimaginable that this type of care as a service will, especially for this patient group, be reimbursed as a new form of care by health insurance. This is not yet the case. NZa states reimbursement of e-Health is possible in the following form: care that was not insured in the original form will also not be insured if it is offered in the form of e-Health. However, in their reimbursement overview NZa (2017) also states the possibility to apply for an innovation budget. The innovation must focus on one of the following improvements:

- New or renewed care delivery with a better price to quality ratio.
- A more efficient healthcare organisation.
- Better quality of care.

Which is in line with what Zeker is trying to achieve and can be interpreted as what the NZa views as the future of e-Health and reimbursement thereof.

4.2 NECESSARY DATA AND EXISTING DATABASES

This part describes different parties that are of interest to Zeker to collaborate with for different types of data. The apps databases/ information provision has been split up into three categories for this project:
Static data: information that does not change very often and cannot be adjusted by the user.
Resilient data: information that is prone to change per user and up to several times per year
Timely data: information that is patient specific and can be entered into the system real-time. Multiple stakeholders showed interest in participating in the app initiative by supplying "building blocks" to a system.

"Anyone who wants to use our app is welcome to do so. We will keep maintaining the Biosimilar medication database."

STATIC DATA

The biggest part of static data is the information about medication, see figure 4.2.1. The MedApp, explored earlier in the chapter "Benchmarks", already utilises the databases from the CIBG and Zorginstituut Nederland, these parties provide all medication accepted into the Dutch healthcare supply chain, their prices and leaflets. Digitising leaflets is promoted all together by the pharmaceutical industry.

"The advantages of a digital leaflet are huge. Now all packages have to contain the leaflet of a specific country's language and if anything changes it is a massive operation to change them all out."

Additionally, to the leaflets that are not regarded as a nice form of information provision by patients KNMP offers more accessible information on their website and app. In the interviews, it became clear they are willing to share this information. They are willing to collaborate if the app clearly shows benefit for the patient and when it is in line with their agenda points.

"Prevention is on the agenda and also eHealth, it's like when everything is "green". It looks very much whether it contributes to the main pillars, looking at the year plan."

Moreover, they stress the importance of validated information provision in these types of initiatives. As mentioned in the introduction Bogin is willing to share their database set up of Biosmiliar medication which offers additional information on batchnumbers, which are really important in biobased medication.

Other interesting parties to involve, to improve data provision about medication that this research came across are MedEye and Kijksluiter. MedEye has an up-to-date and user filled visual database of all medication as part of their service. Which can be used to visualise the medication overview as it is now also in the designs. Kijksluiter is regarded by a lot of the representative as a good example on medication and e-Health. It is interesting to utilise their short movies to help explain medications and their use to patients.

Figure 4.2.1. Static data of the app and interesting parties

RESILIENT DATA

Resilient data is for instance patient demographic and contextual information. Their age, diagnoses, living situations but also their doctor and appointments. This data can be retrieved and exchanged with the MedMij implementation (Informatiestandaarden Nictiz, 2018). To optimise the use of the Zeker app it is assumed that information from different caregivers can be retrieved into one application, for instance to compile a complete medication overview. Research by the Patiënten Federatie (2018) has found that a medication overview is one of the most desired functions of MedMij. MedMij has adopted this research it is therefore likely this will become possible. Other functionalities that came up in the research and that are also part of the Zeker app are:

- Create, change and view online appointments
- Request repeat recipes online

As stated before in the software development of the Zeker app standardisation by MedMij and others like Nictiz should be followed to allow for data exchange between patient and caregivers. Not just one data field but also in terms of privacy and security of the data.

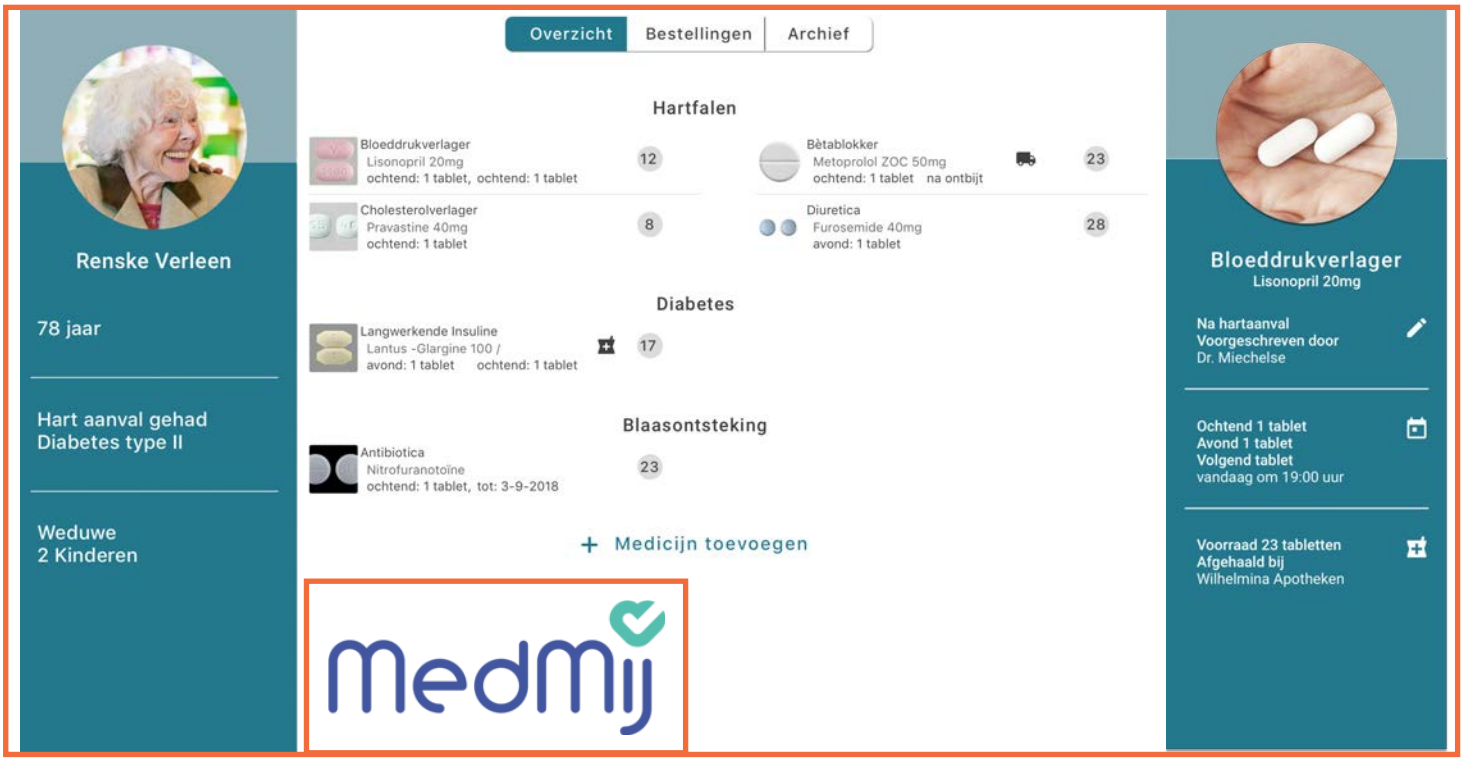


Figure 4.2.2.Resilient data of the app and interesting parties

TIMELY DATA

This real-time data is mainly symptom and medication tracking done by the patient. This information includes self-measurements, like bloodsugar levels or bloodpressure and side-effects. Preferably also patient goals or impact on the day in order to quantify the improvements in symptoms to something the patient would like to achieve as 'normal' living. An interesting party to get in contact with is the British National Health Service that set up the Babylon app. They might be able to supply the database for translation to Dutch or at least to get a better sense of their set-up and architecture.

Self-measurements and exchange thereof are already part of MedMij directory (Informatiestandaarden Nictiz, 2018). Because it is an important tool for caregivers to monitor patient's conditions. Symptoms, unless high risk, are not necessarily meant for direct digital exchange from the patient to the caregiver. However, they need to be stored and data points need to be analysed to comprise a summary of data for patients to use in consults.

Tracking of self-measurements can increasingly be done with smart devices. Like the smart scale, thermometer and blood pressure devices from Withings or smart devices like watches and phones that track vital functions like sleep and heartrate. The Drimpy (2018) PGO has for instance a connection with the Mysgar app for diabetes and SelfCare(2018) with among others Withings, Fitbit, Runkeeper and Apple Health or Google Fit.

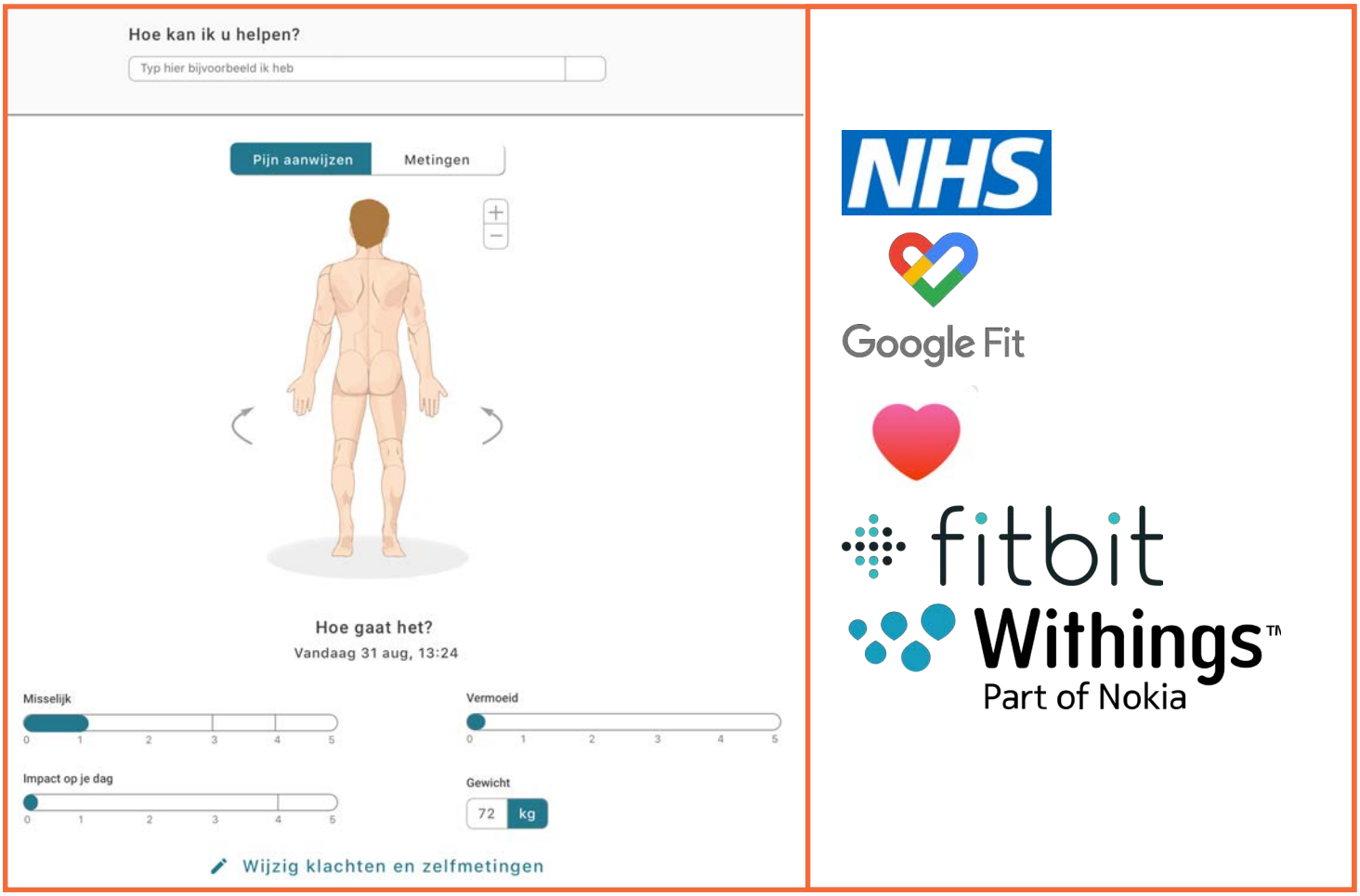


Figure 4.2.1.Timely data of the app and interesting parties

4.3 USER RESEARCH

The user research was set up to get a qualitative review of the Zeker app. Patients were asked to review four functions: the medication overview, finding a regimen, tracking symptoms to prepare a consult and the home page overview. At last, participants were asked to review the app as a whole. Each function was explained based on an user scenario, patients were however invited to take their own experience into consideration when answering the questions.

RESEARCH SET-UP

The participants were asked to rate to what level (on a scale from 1-7) they understood the function shown, to what extend it would help them in their medication use and to would extend they would use it. The functions under review are: the medication overview, regimen finding, preparing a doctors consult and the hompage overview. Figures 4.3.3-7 show the results per function. For the full results of the user test see Appendix D2.

The next sections describe the feedback in more detail and conclude on the results. First, the peoples understanding of the app is discussed. Next per function feedback of respondents on whether it would help them and whether they would use it is discussed. The aim of the app was never for all patients to use all functionalities. Therefore, in concluding on the results for instance patients that report having side effects that review the regimen finding and preparing for consult are used to verify functionalities. Suppose someone mentions having side effects but feels this is not a solution to their problems the function does not resolve its designed

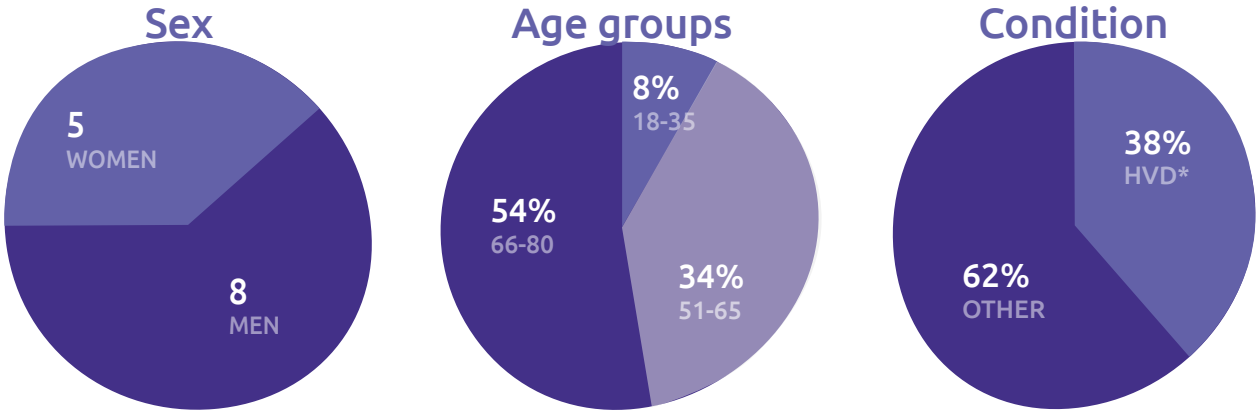


Figure 4.3.1. In scope demographics
**HVD: heart and vascualar disease.*

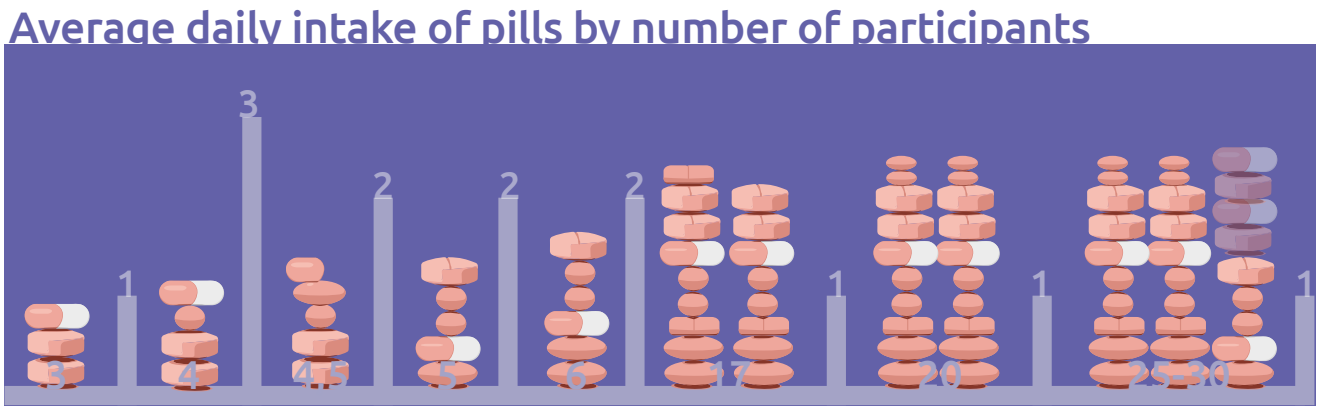


Figure 4.3.2. In scope demographics

goal. Besides verifying functionalities participant's recommendation for improvement or additional functions are discussed.

A consideration was made between having more qualitative answers or more respondents. To widen the net of respondents the survey was conducted online. All scale questions had a why/how followup question for patients to leave qualitative insights into their answers. Also, taking into consideration, not all intended users might be tech savvy enough to fill out the survey it was opted to conduct physical interviews as well. For four respondents, the survey was set up as an interview with the researcher. This aided in getting more elaborate qualitative answers with the opportunity to get more depth with multiple follow-up questions.

In total 18 respondents filled out the survey. One respondent was taken out because they reported to not be taking any medication at the moment. Furthermore, results were split up for the review into in scope and out of scope respondents. In scope are either patients with polypharmacy, so 5 medications or more, or respondents over 50 years old that take medication for heart and vascular symptoms. People with less than 5 medications and/or under 50 were reviewed as additional feedback but their results are not used in the average grading of the functions. The inquiry that was forwarded included these people to again widen the net but with the additional wish that these patients had either just started their medication or had or were having 'trouble' with medication.
In total 13 respondents were considered in scope and 4 outside the scope. Figures 4.3.1&2 show the demographics of in scope patients in short.

A lot of feedback that came in on understanding could have been answered in a physical interview since they are already resolved in the concept. As mentioned the choice for conducting the survey online had its advantages and disadvantages.

"How does it track what you have used, do you have to do it yourself?"

"You always have to consider the other side. The medical side of things does it also support the doctor."

"Our pharmacist sometimes has long order time, how do you resolve that?"

In several ways, the medication in its accuracy in quantity or individual use was questioned. Also for instance
This is solved in the concept by allowing for exchange with caregivers.
For the understanding of the functions, others

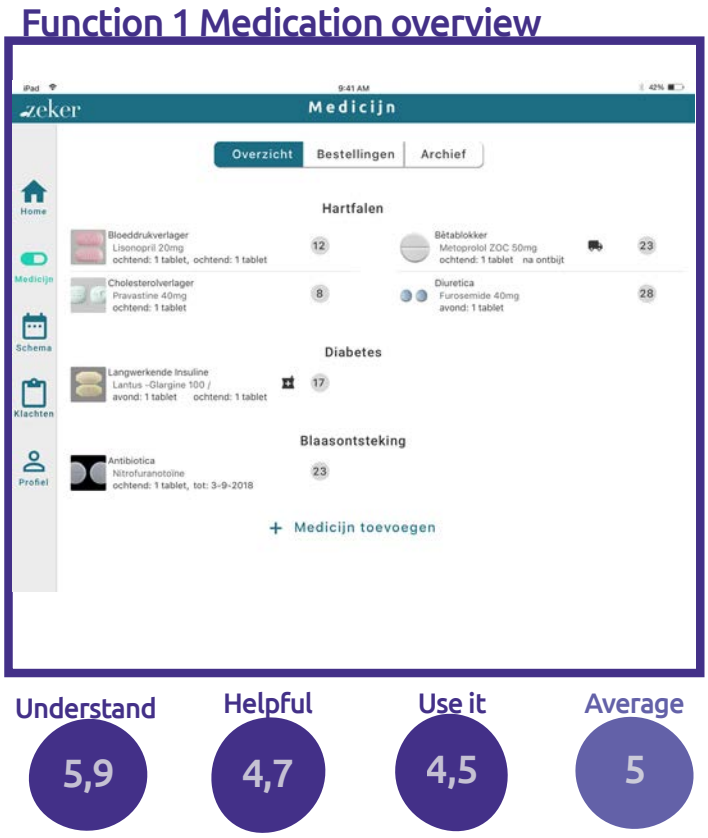


Figure 4.3.3. Medication overview scores and feedback

call for improvement on the visual design or more explanation thereof.

On function 1: What are the numbers and icons?
On function 2: What colour indicates what?

Lastly on different functions people indicated it was still too complex and extensive. The designs should be simplified

"Too unclear and too much effort."

"Too much information it's like opening up a newspaper I don't know where to look"

"What are those figures behind the medicine?"

"Especially keeping track of how much you still have is useful if it goes automatically."

"It is useful to have an overview of your medication history because I can not always remember those names properly. This is especially useful so that you know which medicines you did (not) respond to properly."

"In addition, a "help" function. How much I have to have at any time of the day, if it is more complicated so it can help you."

"It must be very up-to-date to add value. How is that done"

"Good: Interactions and package leaflet"

MEDICATION OVERVIEW

A medication overview is not reviewed helpful by everyone. In the in-depth, interviews people mentioned already having an overview on paper or knowing it by heart. Indicating that for especially people with a lot of medication an overview is handy. The overview in itself was not regarded as high but aspects like the archive, the leaflet, interactions and visuals of medication were reviewed well by respondents.

"It hardly supports me. However, pictures of medication are helpful."

One out scope respondent gives an example of exactly the type of problems the overview tries to avoid. One patient makes the connection to the

Function 2 Regimen finding

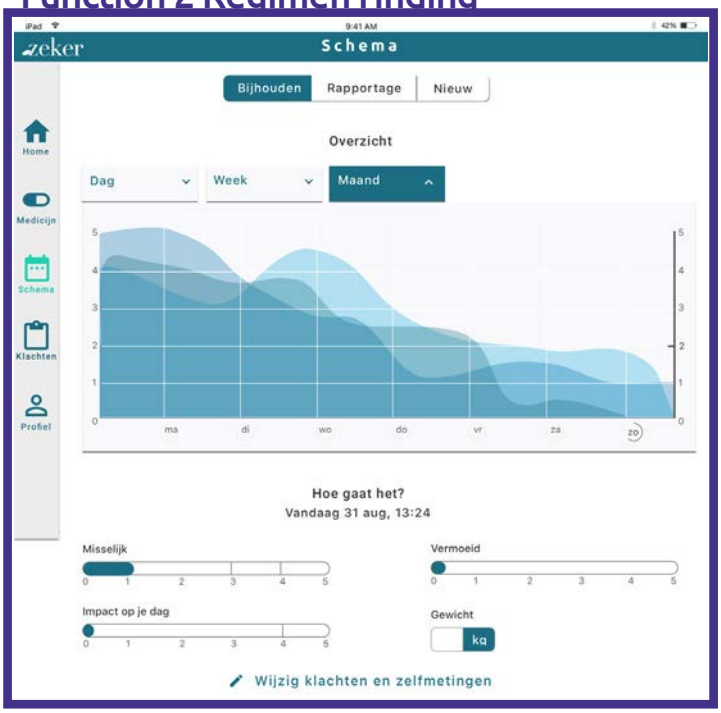


Figure 4.3.4. Regimen finding scores and feedback

supply or rather belated delivery of medication by pharmacies. As stated in the previous chapter it is interesting to explore how patients personal stock can be related back to the backorder of pharmacies. The average score on whether people would use it is clearly lower than their understanding and its usefulness. The feedback indicates that the ease of use of entering the medication into the system should be really easy and is mainly interesting when people take a lot of medication. For others with less medication simply looking up a medication in a database with similar information provision is enough.

"Which color is what? Can every patient read statistics?"

"It is very subjective what you feel you can also just be tired. But I can imagine that you try it."

"I have never received help from a pharmacy or doctor for complaints. Always had to figure it out by myself or learn to live with it."

"I do not have that much trouble with medication right now. Maybe later ...?"

"I do not use medication that depends on time. I just have to take them during the meal."

"I find it unclear whether my medicines help my well or not. I have had many problems with medication and have also stopped taking it completely."

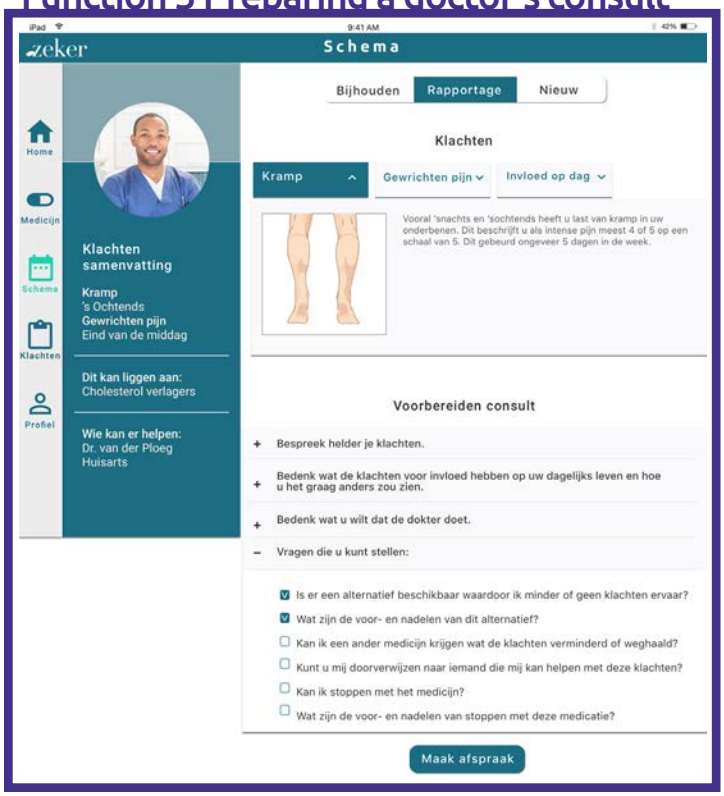
REGIMEN FINDING

Five people did not review this function as useful because they had never experienced side-effects. Although some indicate they would use it when they did experience complaints. Others were sceptical because they previously did not receive help from doctors or a pharmacy. Two participants indicated they had or are struggling with side-effects and review the app as helpful.

"Now I try to keep up with photos, the app would help!"

Three other important aspects were highlighted in the feedback. Mentioned in two interviews is that the app should support the tracking of self-measurement. It became clear that especially in heart

Function 3 Preparing a doctor's consult



Understand	Helpful	Use it	Average
5,7	4,5	4,2	4,8

and vascular treatment a lot of people track their heart rate and blood pressure at the request of their doctors and to adjust medication. It is interesting to explore if this relation between measurements and medication can be explained better. Secondly, it again became clear that a lot of people have a handle on the timing of their medication. It would be interesting to explore timing notification using for instance location tracking. Because a lot of people take their medication with their food or when they get out of bed. These moments are more related to activities, and possibly location, than exact times. Lastly, an interesting addition to tracking symptoms is tracking through taking pictures of for instance side effects that show on the skin.

"Why doesn't Wim go directly to his specialist?"

"Not quite. I prefer piece by piece information not too much in the screen"

"Logical, I always do that otherwise why do you go."

"It can indeed help to keep up with complaints to prepare the conversation with the doctor."

"If I have complaints, I contact my specialist."

"Essential that you can also fill the values sugar or blood pressure."

"I keep track of everything on paper what happened during the year then you can always tell everything."

"Only if I were to get complaints."

Preparing according to complaints is a very good initiative. Saves time at the GP. Concretely sketches your own case. How do you feel, when and when not"

Figure 4.3.5. Prepearing a doctor's consult scores and feedback

PREPARING A DOCTOR'S CONSULT

Some people indicated that for them it would not be useful because they already prepare their consults

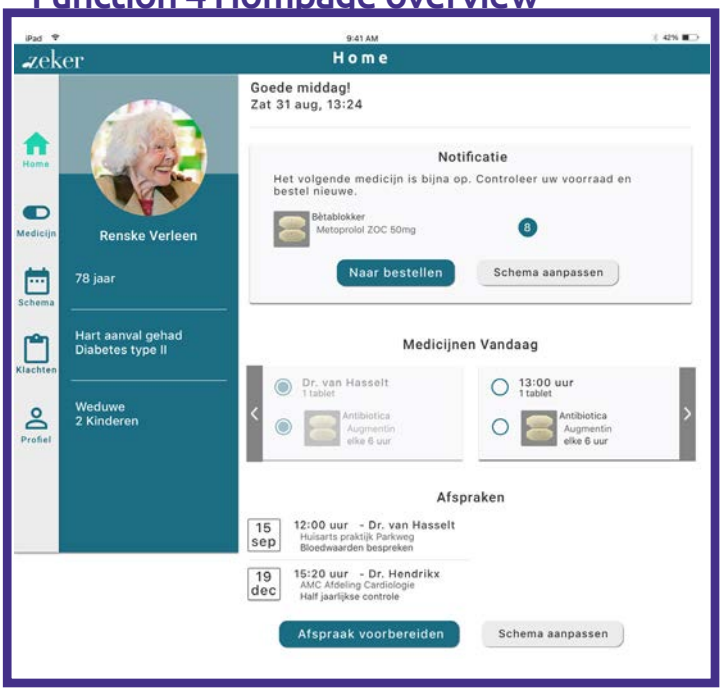
"For me, this is a normal interaction with my doctor."

Respondents that indicated having had problems in medication seem really interested in this function.

"For me, it was very difficult to clearly state my complaint. Usually, they gave me the run-around. This offers overview and clarity."

Some others would use it in case they had complaints or try it out.

Function 4 Hompage overview



Understand	Helpful	Use it	Average
6,5	4,4	4,3	5

"Two radio button for 1 action? Notification daily under order notification?

"Antibiotics are always super difficult with 2 hours before or after eating between 10/11."

"If you often take medication at fixed times, this can certainly help. I remember it myself:

"Too cumbersome."

"Use my medication every morning I have a good overview myself."

"Pharmacy supplies automatically. Appointments are already in the normal agenda"

I do not have medication that depends on a moment of time. I take it in during the meal.

Figure 4.3.6. Homepage overview scores and feedback

"I would try it out for about a month put it on the side and use it again every now and then so I can exactly know what's going on."

In one of the interviews, the interviewee explained they prepared their conversation already however on paper. They did not see a point in digitising this but what was interesting to learn was that the overview contained all healthcare related events. The patient explained only visiting a specialist once a year so they would bring an overview of symptoms, diagnoses, ailments etc. that had happened that year. It is interesting to explore an option to make a summary like that. Maybe make it part of the resilient data that can be shared with the caregiver.

HOMEPAGE OVERVIEW

The feedback on the overview verifies that different people see different things as useful.

"Reminders would work"

"It would help because now I have to count every time."

However, people are fairly critical because they had resolved a lot of the underlying issues.

"I have a perfectly fine overview myself."

"I now use the alarm on my iPhone"

"I always have additional medication in storage at home"

"In the beginning it will take some time to figure it out, but I think that I would understand it on my own."

"Maybe combine with data on food intake"

"Maybe also a bit of mental side effects. For people who take their pills for an improved state of mind"

"I would like to try it out completely. Especially the memories and measuring moments of discomfort. It creates clarity and that helps"

"Too much trouble for too little result."

"I would hardly use it, It does not help me, I think that for lots of people it will help."

"I usually have sound off so that alerts do not (immediately) come through."

Figure 4.3.7. The zeker app overall scores, feedback and inspiration.

Improvements on the appointment aid came from an interview and respondent feedback.

"Arranging transport the day before?"

"Sometimes I forget to ask something, if it is important I will use the telephone consultation hour, that is available every day."

It would be interesting to explore additional functions besides preparation of the consult in terms of information provision. Besides, consultation 'aftercare', like, did all your questions get answered, did it cause additional questions, might also come in handy for some people.

THE ZEKER APP OVERALL

The biggest new concern raised when questioned about the app as a whole are costs. Costs need to way up to the effort necessary and what it adds in comparison to how people run their medication regiment now.

"Depends on what it costs, the use is also displayed on the box, my wife keeps track of when to order and doctors' appointments."

"The things that make sense for me, I can also find in free apps. (when obtaining I assume that I have to pay for it, if it is free I would buy it anyway)"

Using it a big leap?

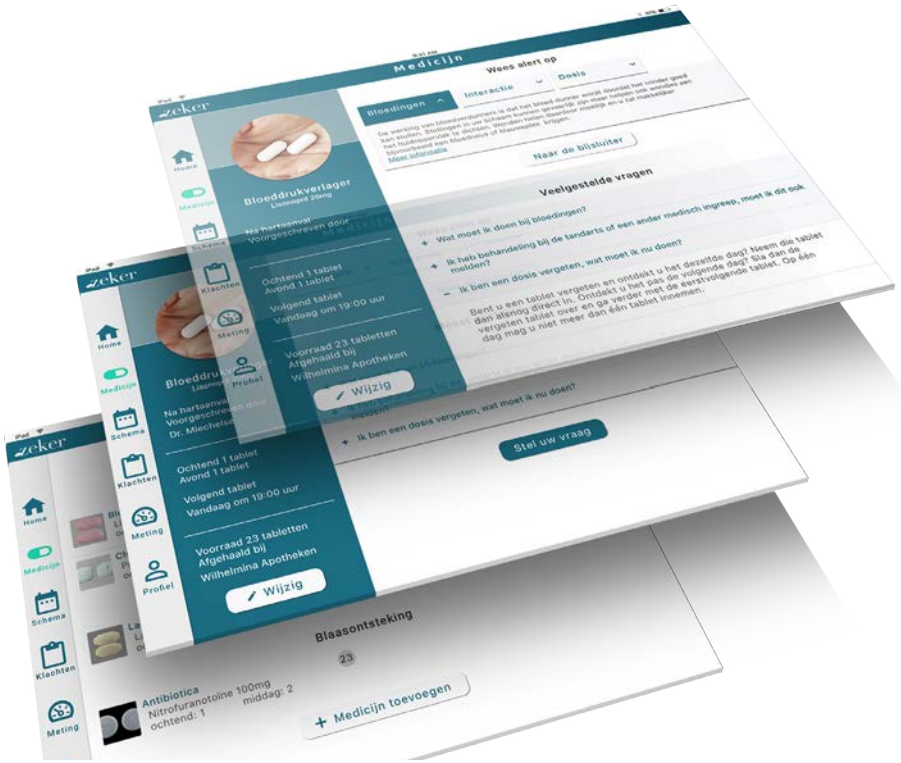
As mentioned previously e-Health is not adopted by patients as much yet. This seems to reflect especially in these overall scores. Patients indicate high scores of understanding the app and its functions, they score a little lower on whether it would help them. Next, the lowest scores are on making the step to actually use the app. Although the sample was too small to make significant comparisons, looking at the numbers it seems this way for every function.

4.4 THE ZEKER APP FINAL DESIGN

This chapter explains the last iteration done inspired on the results and feedback of the user research. The Zeker app final design is illustrated in a scenario. This scenario was set up using a case study, set up by Informatiestaandaarden Nictiz (2018), for PGOs in the MedMij framework.

DESIGN IMPROVEMENTS

This new design improved clarity and simplicity mainly with typography, moved self-measurement to the main menu, added the legend to the graph and a screen for a yearly consult was set up.



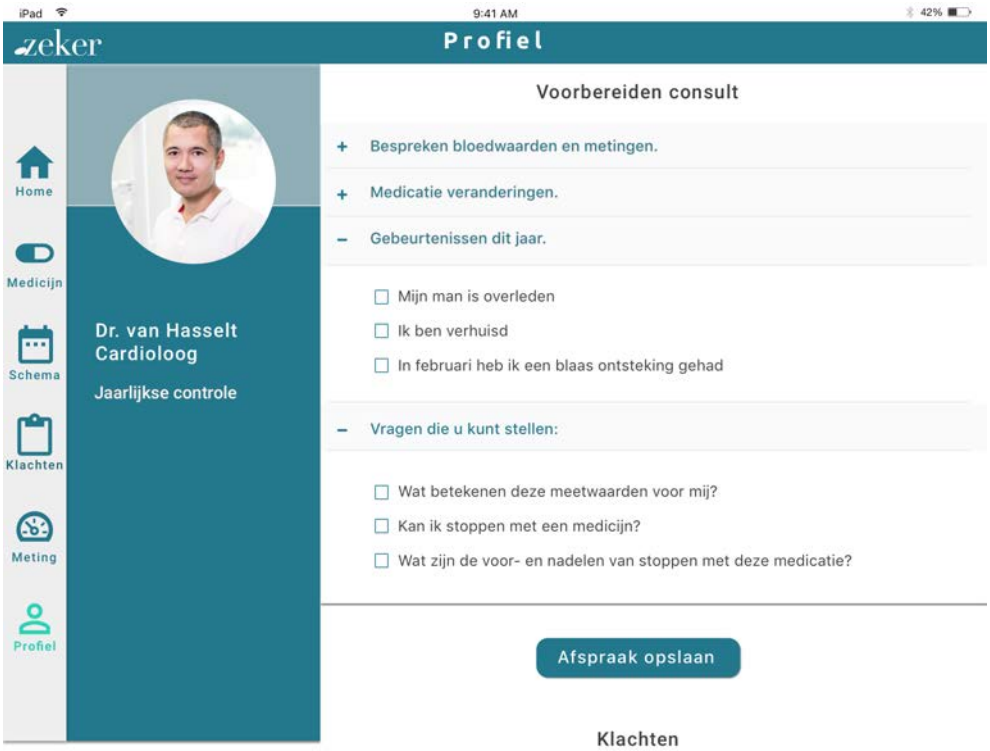
Simplicity and clarity

Anything that is clickable and leads to a next page is now the same colour blue. The typography was further adjusted to make a clear differentiation between (function) titles and text. To simplify pages, fewer functions are shown per page. For instance, on the medication overview page, the option to ask questions was taken away. Clarity of the app can be continuously monitored during development with usability tests: do user use the app as intended when asked to execute set tasks.

Self-measurement
Patients indicated self-measurement is already an important part of their routine. This is more clearly supported by taking it separate from the complaint section. (changes in) Self-measurement can be related back to medication use. However, they are not always a complaint, they can also be a necessary part of patient care. The app set-up can be user tested through card sorting.

Legend

The legend was added to the graph in the regimen finding function. This is shown in the coloured bar for rating complaints only when the overview is shown. This keeps the page less crowded but makes the legend pop when the overview is opened.
It was attempted to stick with known interactions, or instance, the menu on the side, clear call-to-action buttons and familiar icons. However, some interaction and visuals might still need additional explanation. This can be provided in an app on-boarding that takes a user through the app's main functions or when changes are made.

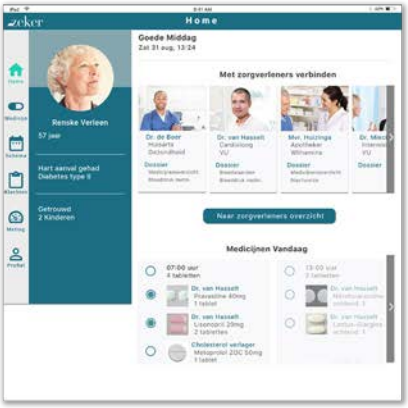


Consults

It became clear in the user test that preparing a consult is very useful for people. However, it can be more elaborate, aspects mentioned were to prepare a phone consult, yearly overview of events and arranging transport. Also, reviewing with the patient after a consult can be interesting. Did the patient get all their questions answered, did they or their informal caregivers get any additional questions they can maybe send to the caregiver? The final design includes a screen that aims to help prepare a yearly check-up. For further realisation, it is interesting to do more observations on people that already prepare a consult and during consults. To make preparations effective it is valuable to include caregivers in the further development of this function.

SCENARIO

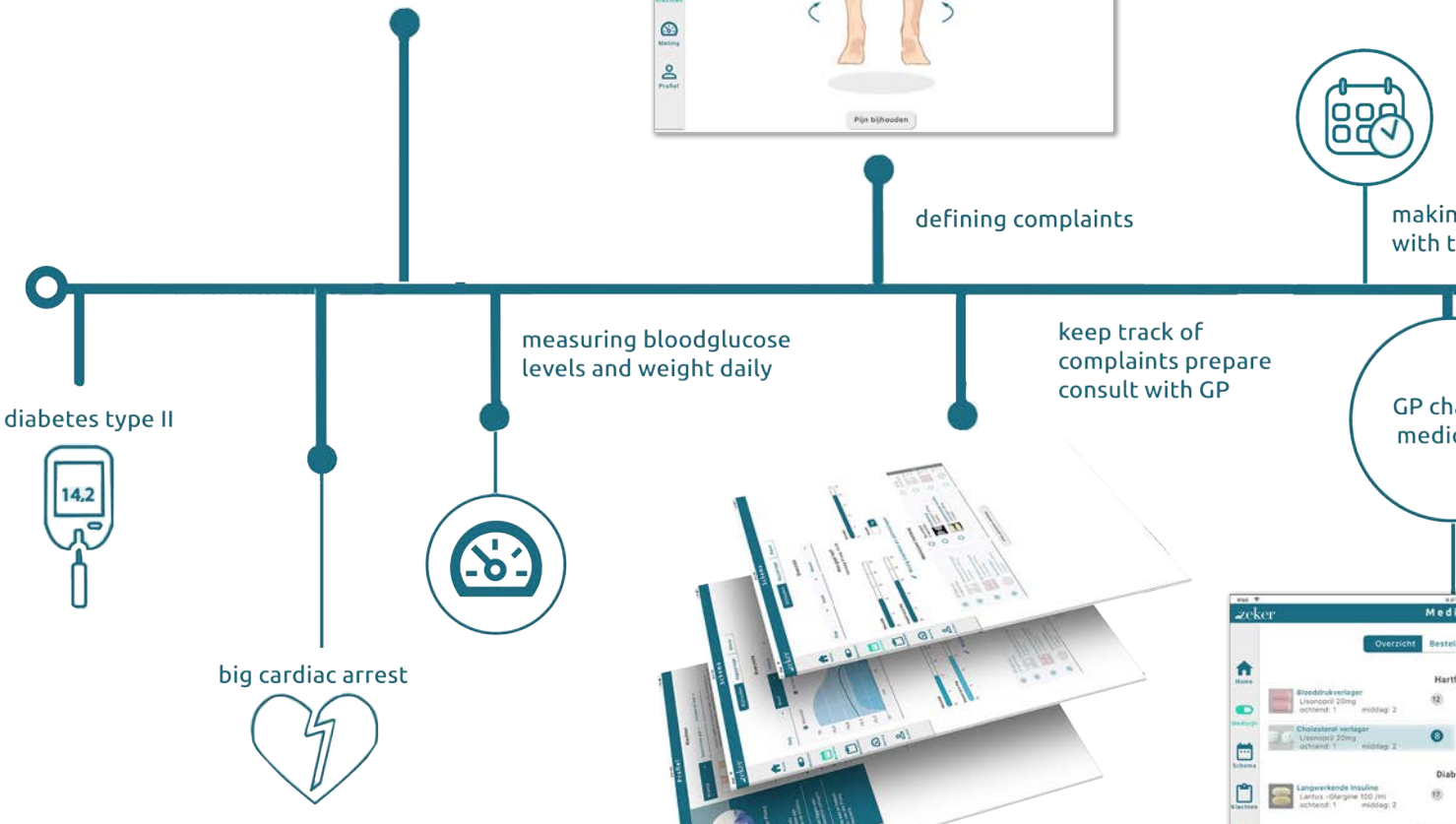
Renske was diagnosed with type II Diabetes at 51. For which she receives medication and has to inject insulin four times a day. She has a good handle on her blood sugar levels got used to living with it without major problems. At 62 she has a major heart attack. In the aftermath she now also suffers from chronic heart failure; her heart no longer functions properly and Renske swallows a lot of medication every day to keep her heart working as well as possible.



Because of the incredible increase in medications and the fluctuating blood sugar levels she has the feeling that she has lost control of her health. Therefore, she decides to start using the Zeker app.

Renske keeps track of her blood glucose values. In addition, she now has to weigh herself daily in connection with her heart failure. In heart failure, the pump output of the heart is reduced. The heart does not pump enough blood around, this allows you to retain fluid. To monitor this, Roos weighs herself daily and keeps track of it in the app.

Renske has not been feeling very well but it's hard to put a finger on what is bothering her. The app helps her specify her complaints better. For a while, she tracks here complaints and decides to make an appointment with the GP.



After examining her and reviewing the complaints he changes her medication that improves secretion of fluid. Besides, he gives her a new schedule that states how much insulin she needs to inject extra if the blood glucose values exceed a certain value.

These medication changes are also clearly visible in the medication overview of her Zeker app. It slowly gets a little better but to make sure Renske checks if the new medication does not cause any side-effects.

Renske visits her family after two days she starts not feeling very well. She also measures she has a temperature. After examination, the local GP at her daughters concludes that she has a bladder infection. The GP sees in the medication overview of the Zeker app that Roos is allergic to the antibiotics that are most often used in bladder infections. After which he prescribes another drug.

It is time for Renske's yearly check-up with her cardiologist. The app helps her create an overview of things that happened over the last year. The medication changes can also easily be retrieved in the Zeker app. She can also show the cardiologist the app of her weight and blood pressure over the past period.

When entering the antibiotic in the app she gets a notification to talk to her internist because an infection can influence her blood sugar levels. In a short phone consult the internist adjust the amount of diabetes medication accordingly, for the period of the antibiotics course.

4.5 RECOMMENDATIONS

Recommendations were set up to conclude the Verification chapter. First, the stakeholders are described of whom the role changes with the introduction of e-Health. Secondly, e-Health roles that are foreseen but do not have a stakeholder in the current pharmaceutical care market and supply chain are described. Besides this, further development of these roles and research are suggested. Lastly, this chapter describes steps for future development of the Zeker app. Important stakeholders to ensure the Zeker app will become a success are highlighted in their respective roles within the app.

STAKEHOLDERS AND FUTURE IN E-HEALTH

Strategies throughout the pharmaceutical value chain need to conform with the developing roles of stakeholders developments. Organisations need to be supported in completing their respective roles in the network. Figure 4.4.1 shows an overview of the prospective patient network, roles are described here in more detail.

The pharmaceutical industry

It is expected that the pharmaceutical industry will move into two archetypes: active portfolio company and niche specialist. The active portfolio company is expected to increase their use of big data analysis for medication discovery and development. Whilst the niche specialist has great advantages in using other e-Health technology developments to contribute to preventive and personalised health care. As a whole the industry is believed to be taking a more patient-centred approach therfore delivering more holistic medication servies

Pharmacies

It is expected that the public pharmacy will move more into customer service driven companies. However, Dutch regulation and cultural customs have to change a lot before supermarkets can dispense medication. Tele- and mobile health can and already currently contribute in increased pharmacy service by delivering better access to care.

Caregivers

Digital development is moving fast at the moment. Urban (2015) illustrated how hard it is to grasp the speed of current developments. It has been shown the health care sector is currently running behind in digitisation. For caregivers to start accepting these changes they need to be eased into them. First by using the existing education framework for caregivers to adopt digitisation through teaching, examples and training. As well as continuous involvement of caregivers in future digital development.

Government

The government can create frameworks for the adoption of e-Health. Providing a platform for a collaboration and innovation, but especially branch organizations and health insurers should take steps towards caregivers and patients. It is important to note that the government imposing e-Health does not aid, as shown in countries like France (Trouw, 2018). That is why the development of MedMij which is driven from the market is so interesting. After standardisation steps by branch organisations and the government should include an assessment framework for both healthcare institutions as individual caregivers.

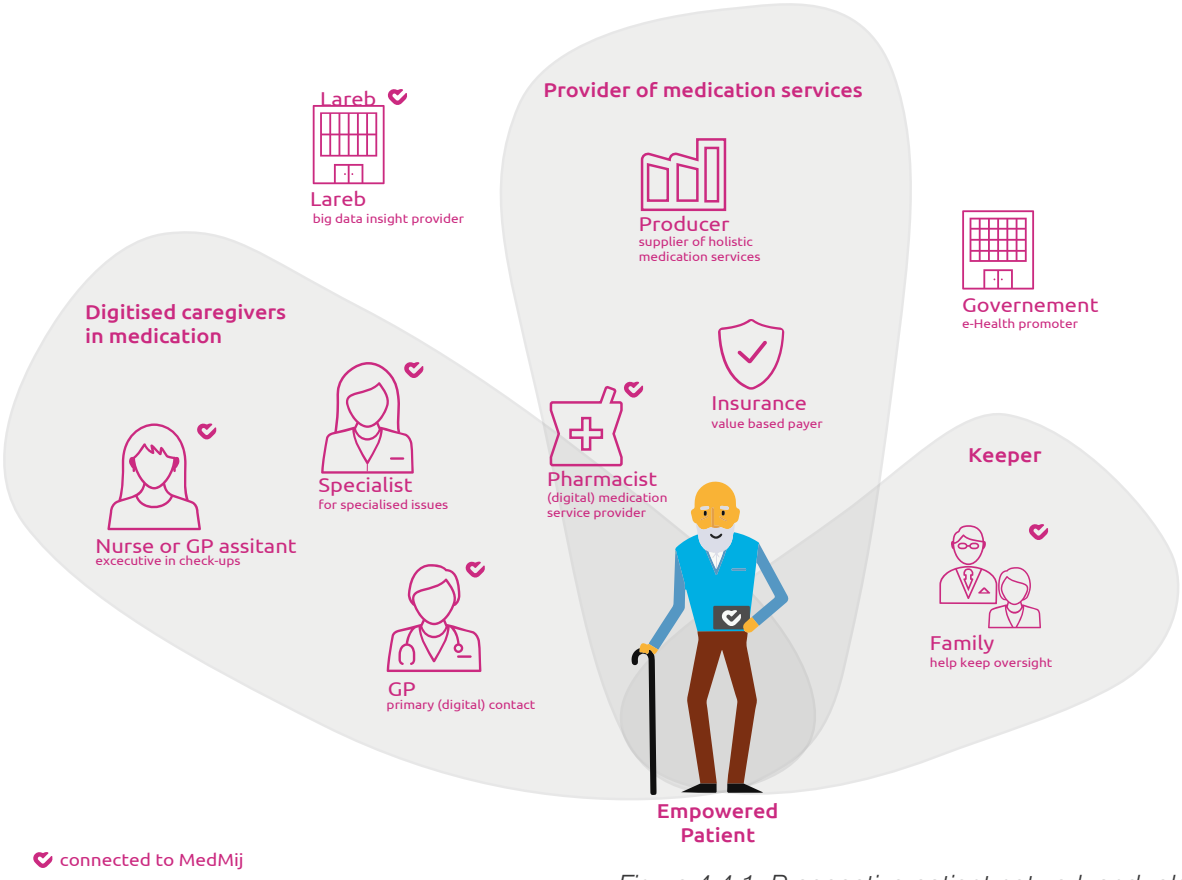


Figure 4.4.1. Prospective patient network and roles

FUTURE ROLES AND RESEARCH

This project appointed the Lareb institute for side-effect registration as the data-analyst for increased medication safety and overall improved proper use of medication and pharmaceutical development. To fulfil this role, a good starting point would be to make their side-effect registration standards part of the MedMij directory.

The role of quality control has not yet been fulfilled. An organisation has to judge which e-Health becomes part of the Dutch healthcare system.

Ensuring e-Health can be brought to patients through a validated recommendation. Sectors to consider are research institutes, like NeLL, or health insurance companies that are expected to reimburse e-Health. The Patient Federation also continues their efforts towards setting up a platform with “accepted” PGOs. E-Health quality measurement is also an interesting topic for further research.

Other research topics that remain unexplored in this project are the informal caregivers and their possible participation in the MedMij framework. In the MedMij network, they can have their own app that exchanges data between them and the one they are caring for. Or when functions of a patient are significantly impaired directly with caregivers. Secondly, how to improve on medication safety within hospitals has largely been left unexplored.

THE ZEKER APP

For further development of the app a GP information system developer has to get involved. An interesting one could be Pharma Partners because they already have a patient portal and provide systems for both GPs and pharmacies. Besides, their overall score is highest (8,9/10) in the HIS-research by the LHV (2016).

Since the app is now moving into the GP market it is important to involve the GP branch organisation for collaboration, these are the LHV and NHG. They can also provide contact to GPs to involve in the further development of the Zeker app. A GP-focus group can provide insight into if and how they would like to receive the different datatypes the app can exchange. This also requires the involvement of MedMij. Medmij offers a set up for patient self-measurements exchange, however, for instance, the notification when faulty medication combinations are made or severe side-effects reported is not described yet.

MedMij currently focusses on the development of the PGOs, the patient side, in their public information. In looking how to best report data back to doctors HIS developers but also that of other EPDs have to get involved in MedMij. Hospitals and other healthcare organisations have started their own programs towards patient data exchange, like ViPP. The latest report (Smarthealth, 2017) was pessimistic on the implementation of MedMij in hospitals. It reported that to include connecting to patient owned apps was still a bridge too far for most hospitals. For vast implementation of MedMij the caregiver side has to develop too.

When the Zeker app developer is established further conversations can also be held on information building block collaborations with different parties. MedEye and Kijksluiter are currently the most interesting commercial parties to consider for static data content. KNMP showed interest in participating.

To use the KNMP knowledge base the proposal for collaboration needs to clearly reflect the advantage for their members.

As stated in the design implications the patients need to be continuously involved in the design process. The next step after the app is further developed, is research with patients into the usability and user experience of the app.

The last important stakeholder to involve are the health insurance companies. Involving them throughout the process can ensure the app can be reimbursed at launch and no arrangements have to be made afterwards.

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