

Supporting pregnant women in making decisions about the use of medicines during pregnancy

Master Thesis
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In collaboration with the Dutch Medicines
Evaluation Board (MEB) and VU University
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GLOSSARY

Acetylsalicylic acid

Substance name of 'Aspirin', a medicine often used by pregnant women who are at risk of developing pre-eclampsia

CBG-MEB

College ter Beoordeling van Geneesmiddelen, or Medicines Evaluation Board

VUmc

Vanderbilt University Medical Center

Gynaecologist

A doctor specialized in the treatment of women's diseases, especially those of the reproductive organs

HCP

Healthcare professional

Indication

An 'indication' of a medicine refers to the use of that medicine for treating a particular disease or condition

Labetalol

A medicine used to treat high blood pressure

Medication nonadherence

The degree to which patients correctly follow their prescribed treatment

OTC

Over-the-counter drug (or 'zelfzorgmedicijn' in Dutch)

Patient experience

Pregnant women's experiences or feelings towards using medicines during pregnancy and the information provision about medicines

PIL

Patient Information Leaflet

Pre-eclampsia

A pregnancy complication characterized by a combination of high blood pressure and protein loss through the urine.

SmPC

Summary of Product Characteristics

EXECUTIVE SUMMARY

This graduation project is performed for the Dutch Medicines Evaluation Board (MEB) in collaboration with VU University Medical Center (VUmc), Department of Obstetrics and Gynaecology.

For various reasons, pregnant women may need to use a medicine during pregnancy. For instance to treat an underlying chronic disease, pregnancy related complications or conditions (e.g. morning sickness) or incidental illnesses. Especially pregnant women who are treated at VUmc, the target group of this project, often require medicines due to their (history of a) complex pregnancy. When making decisions about medication use, both the maternal and fetal health must be considered. In every situation, the necessity needs to be weighed against the potential risks of the medicine, as well as the risks when not taking the medicine for both mother and child.

Despite the relevance of using a medicine, pregnant women not always take their medicine as prescribed. Literature research has shown that pregnant women's beliefs about the necessity of a medicine and concerns regarding the potential harmful effects on their child are important determinants for women's confidence in and adherence to their medication. Research has also shown that pregnant women often overestimate the risks associated with medicines. Current information sources that women can access, such as patient leaflets and online websites, usually stress the risks and show reluctance towards the use of medicines during pregnancy, while they lack the benefits of medicines. The fact that for most medicines the potential risks are unknown causes anxiety and has contributed to a general view that medicines should be avoided during pregnancy. Additionally, patients have difficulties finding the desired information due to a lack of structure, information overload and difficult language. Information is usually not tailored to pregnant women and therefore contains a lot of irrelevant

information that does not fit their needs. On the other hand, healthcare professionals (HCPs) stress the benefits rather than the risks when prescribing a medicine, to stimulate the patient to use the medicine. This conflict in information from HCPs and other sources further contributes to the issue.

User research was conducted to find out what information pregnant women need. Topics that were addressed are pregnant women's beliefs and attitudes towards medication use during pregnancy, how they experience the communication with HCPs, how they currently seek and experience information sources and what information they need at what moments to make an informed decision about medicines. The research included nine semi-structured interviews with pregnant women who are treated at VUmc.

User research has shown that pregnant women are very afraid of the potential risks of medicines on their child and only want to take a medicine when there is a clear benefit for their child. Usually pregnant women have a lot of trust in their doctor and follow their advice. However, once they start taking a medicine, women easily start to doubt whether their medicine is really safe due to stories from others or in the media, or because they do not clearly remember the benefits of a medicine. Therefore they seek confirmation and reassurance from their doctor or other information sources. Many women simply google for information or consult the patient leaflet before using a medicine, often only to find unnerving information that increases their concerns and uncertainty. Therefore, and since in general information from the HCP is easily forgotten, pregnant women need an information product that they can access at all times and that communicates the benefits of medicines.

Based on the insights from research, the design goal was formulated:

*“Design a product service system, including a **digital application** that informs pregnant women about the use of medicines during pregnancy. The **HCP** should guide pregnant women to use the application, which can be consulted at any time when they are in doubt about the safety of their medicine. The application should communicate **balanced** information about both the **benefits and risks** of a medicine for the mother and unborn child. This allows pregnant women to make an **informed decision** and **feel confident** about using a medicine during pregnancy.”*

Further important requirements were that the information is perceived as trustworthy, is relevant to pregnant women and is written in a user-friendly way. At the start of the design process, several brainstorm sessions were conducted both individually as with members of the MEB and people with a medical, pregnancy or design background. The generated ideas provided input for the design of the application, as well as for the information content and communication and the context of use. The development of the application was iterative in nature and during this process several design decisions were made. Multiple iterations eventually led to the final design: Mijn Medicijn - Zwangerschap.

Mijn Medicijn - Zwangerschap is an application that informs pregnant women about their medicines and supports them in making informed decisions regarding the use of medicines during pregnancy (figure 1). The key aspect is that it provides balanced information about the potential risks and benefits of a medicine for both mother and unborn child. In this way, pregnant women will better understand why a medicine is relevant for their situation, which will make them feel more confident about using a particular medicine during pregnancy. An additional useful function of the app is the possibility to find what medicines can or should not be used during pregnancy for a certain complaint or condition.

The HCP plays an important role in the design as well. When advising the patient to use a certain medicine, the gynaecologist explains the relevance of the medicine by using the same benefit-risk information that is shown on the desktop monitor, in order to ensure consistency in and recall of

information. Furthermore, the gynaecologist will inform the patient about the app by giving her an information flyer. Since pregnant women have a lot of trust in them, this encourages them to use the app rather than other information sources.

An interactive prototype was built to evaluate the app with eight pregnant women. Participants were presented with a few scenarios where they would receive an information flyer from the doctor and search information about the benefits and risks of a medicine in the app. Pregnant women were very positive about the app and valued being able to read benefit-risk information as well as seeing what medicines they can safely use for a certain complaint, without having to call the doctor. They experienced the design as simple in use, easy to understand and trustworthy given the fact that the gynaecologist would advise them to use it. Some points for improvement were identified, for instance to include more detailed information around the potential risks of medicines. Overall it could be concluded that the product service system has a great potential in supporting pregnant women to make informed decisions and feel confident about the use of medicines during pregnancy, leading to increased medication adherence and better use of medicines.



Figure 1. Application Mij Medicijn - Zwangerschap

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INTRODUCTION

This graduation project is performed for the Dutch Medicines Evaluation Board (MEB, or College ter Beoordeling van Geneesmiddelen (CBG)) in collaboration with VU University Medical Center (VUmc), Department of Obstetrics and Gynaecology. The goal of the project was to support pregnant women in making informed decisions about the use of medicines during pregnancy.

Medicines Evaluation Board (MEB)

In the Netherlands, approximately 20.000 medicines are authorised for human use. This number increases with hundreds of new medicines each year, including generic brands of already existing medicines. Before these medicines can be marketed, they need to be approved by the Dutch Medicines Evaluation Board (MEB, or College ter Beoordeling van Geneesmiddelen (CBG)). The MEB is an independent government organisation that regulates the quality, efficacy and safety of all these medicines (CBG-MEB, 2019). This includes all medicines ranging from pain relievers available in drug stores or supermarkets (over-the-counter drugs) to treatments prescribed by medical specialists, and from well-known medicines that have been used for decades, like paracetamol, to completely new medicines.

Part of the approval procedure is the patient information leaflet (PIL). All medicines approved by the MEB are dispensed with a patient information leaflet, which can be found in the medication package. The leaflets inform patients about the use, precautions and potential side effects of their medicine (Herber et al, 2014). It is derived from the Summary of Product Characteristics (SmPC), the more detailed and scientific information about the medicine targeted at healthcare professionals (HCPs). The patient leaflets are drafted by the manufacturer of the medicine but require approval

by the MEB. Besides, the patient leaflet needs to follow a specific requirement and a standard template, established by the European Commission. The MEB manages both the SmPC and patient leaflet and assesses whether the content is correct as well as written according to formal standards. More information about the authorization and monitoring of medicines can be found in appendix A.

Better Use Programme

Research by NIVEL explored the need for information about medicines of patients in the Netherlands. Although it was observed that the patient leaflet was often used as source of information, it became clear that the patient leaflet can also benefit from improvements (Dijk et al, 2016). This is one of the reasons why the MEB launched the 'Better Use' programme ('Programma Goed Gebruik') in 2017, which is in line with MEB's strategic ambition to encourage better use of medicines for the right patient. A central aspect of this programme is the improvement of information about medicines to healthcare providers and patients. More specifically, the goal is to "stimulate good use of medicines by making the information provided by the MEB more accessible and comprehensible for healthcare professionals and patients."

Over the past few years, MEB has been working on improving the information to HCP in a network with other stakeholders. More recently, MEB started with projects to also improve medicine information for patients. The programme consists of two project teams (figure 2). The first one, "Verbeterde ontsluiting van Productinformatie" focuses on improving the access and insight into (changes in) product information for both patients and different parties, like government organizations and professional bodies, who make use of this information. This means for example improving the

usability of the Geneesmiddeleninformatiebank.nl (GIB) and connecting it to different systems. Eventually, the ambition is to offer digital structured medicine information. The second project team, “Verbeterde Informatie aan Patiënten”, focuses on improving the information to patients. This involves improving the usability/comprehensibility of the patient leaflet and exploring new forms of medication information (e.g. a shorter version of the official leaflet). Eventually, the ambition is to have the most important information about a medicine easily and understandable available for the patient.

This graduation project is part of the latter project team. The MEB is interested in the information needs of patients, how these can be translated into a new and improved solution for medication information (as an addition to the patient leaflet) and how this can be implemented in practice and reach the patient. An

important criteria for the MEB is that the information provided in this new product/service should be based on and not be in conflict with the official product information as approved by the MEB.

VUmc & pregnant women

The project will focus on a specific group of patients; pregnant women who are treated at VUmc. At the Department of Obstetrics and Gynaecology at VUmc, women with a complex pregnancy or history of problems during a prior pregnancy are treated. These include women with chronic diseases, such as diabetes, asthma or depression, women who get ill during their pregnancy or are having (a risk of developing) complications, e.g. a premature birth. In many situations, these women need some kind of medicine.

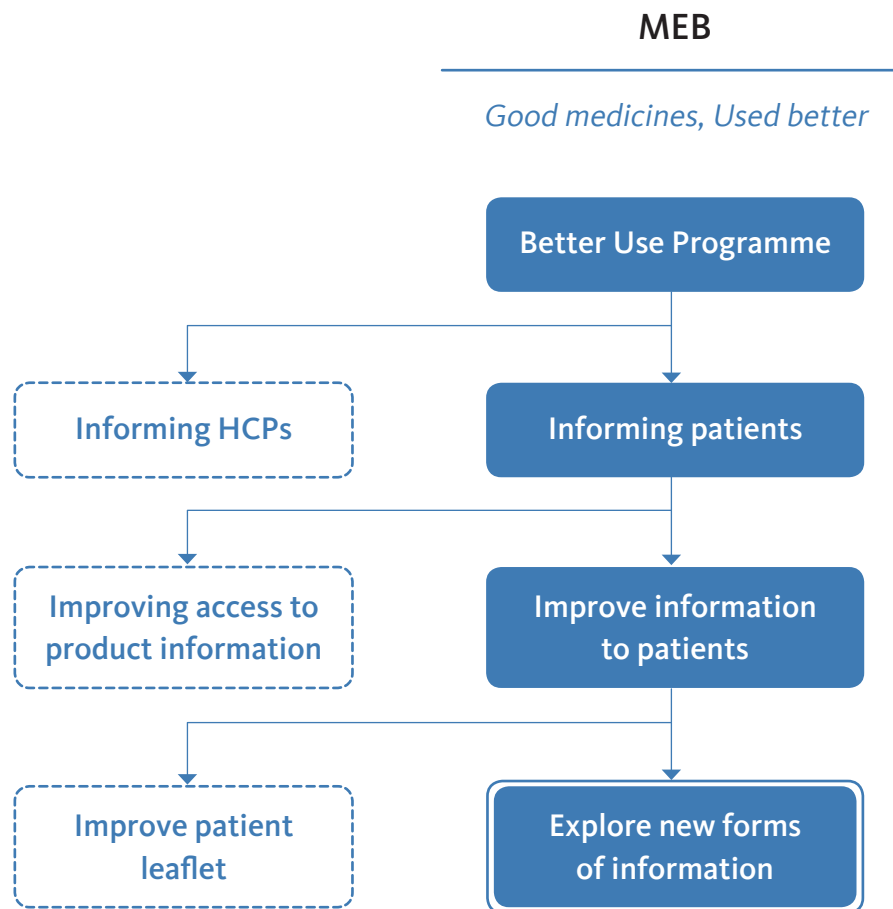


Figure 2. Overview of Better Use Programme

Some medicines are better not used because of the potential risks for the child. While other medicines are known to be safe to use. However, for most medicines the potential risks of adverse effects are not yet (clearly) known. Nonetheless, there are situations where not using a medicine is more detrimental than the possible risks involved. In each case, the necessity for the mother needs to be weighed against the potential risks for the child, taking into account individual factors and the patient's situation.

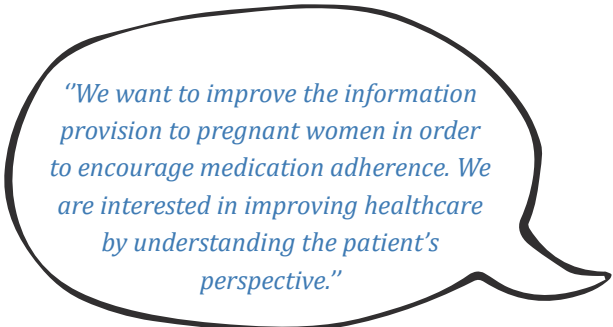
During regular consultations at the outpatient clinic of Obstetrics and Gynaecology at VUmc, gynaecologists discuss the use of medicines with patients and prescribe a medicine that fits the patient and her situation. In order to make a well-considered decision, pregnant women need reliable, understandable and relevant information about the use of medicines.

Pregnant women form an interesting group of patients, considering the fact that both the maternal and fetal health must be taken into account regarding the use of medications. This may affect the mother's decision making process and involves an additional layer of relevant information about the use of medication. This specific group of patients may be different compared to 'normal' pregnant women, since they are under medical supervision by specialists at VUmc, which may affect their medication taking behaviour and information needs. This will be taken into account throughout the project.

The problem

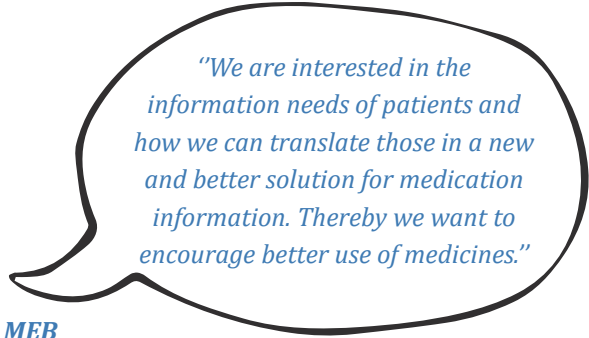
It is in both the patient's and healthcare professional's interest that medicines are taken correctly and that a prescription is completed. However, medication nonadherence forms an issue as pregnant women often do not take their medication as prescribed or do not take them at all. According to gynaecologists at VUmc, this is a common problem encountered in pregnant women. Patient's experience, which is here defined as women's experiences with or feelings towards using medication during pregnancy and the information provision about medication, likely plays an important role here. It is expected that current medication information sources do not sufficiently comply with the needs of patients. This may constrain them from making a well-informed decision about the use of medicines, possibly leading to medication nonadherence.

Currently, an important source of medication information is the patient information leaflet. The patient leaflet is considered as a reliable and trustworthy source of information and many patients use this leaflet to gather information about the medicine. However, research by NIVEL indicated that this product is not user-friendly (Dijk et al, 2016). Users have difficulties finding and understanding the desired information and therefore cannot sufficiently apply it to their situation.



"We want to improve the information provision to pregnant women in order to encourage medication adherence. We are interested in improving healthcare by understanding the patient's perspective."

VUmc



"We are interested in the information needs of patients and how we can translate those in a new and better solution for medication information. Thereby we want to encourage better use of medicines."

MEB

The assignment

This project will focus on the communication of information that supports pregnant women in making a well-considered decision about the use of medication during pregnancy. The initial design goal is:



“Design a medicine information product(-service system) that supports pregnant women in making decisions about the use of medicines during pregnancy, in order to improve patient experience and encourage better use of medicines”.

Methodology and design process

Apart from the problems that were identified by HCPs at VUmc and NIVEL, at the start of the project it was still unclear what exact issues pregnant women experience with the current communication and information about medicines and how those relate to their medication taking behaviour. The Design Thinking methodology focuses on creating design solutions for such unknown problems for a specific group of users (Plattner et al., 2010). This user-centred design method was used to structure the process of this project (figure 3). The project is generally divided into five stages; research (empathize), define, ideate, prototype and evaluate, which is visualized in figure 4 on the next page. Although this seems like a linear process, in reality continuous researching, defining, ideating and evaluating took place.

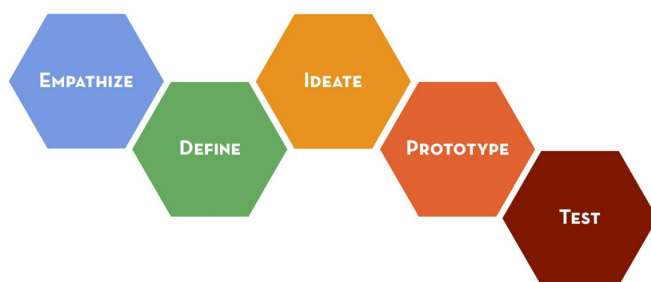


Figure 3. Design Thinking Methodology (Plattner et al., 2010)

Research

The project started by gaining an empathic understanding of the target group, the context and the problem. All aspects that influence the decisions of pregnant women regarding the use of medicines were investigated, as well as the need for information. Literature research (chapter 1) was conducted into medication use during pregnancy, causes on nonadherence, risk perception & communication and current medication sources. Context research (chapter 2) gave insight in HCPs' ideas and perspective on the problem and the communication between HCPs and patients. User research with pregnant women (chapter 3) was conducted to find out pregnant women's experiences and needs regarding the decision making, communication and information about medicines. Insights were visualized in a patient information journey.

Define & ideate

By combining the insights from literature, context and user research, the design brief was formulated (chapter 4). This includes a more specified design goal, interaction vision and a list of requirements and wishes. These form the starting point for the design phase. In the conceptualization phase (chapter 5), ideas were generated during multiple brainstorm sessions which provided input for the design of the information, product and context of use. Multiple iterations across those three elements led to the final design (chapter 6).

Prototype & evaluate

While creating the final design, interactive prototypes were made continuously by using the design and prototyping tool Adobe XD. To evaluate the final design, the final prototype was tested in an evaluation study with pregnant women (chapter 7). Finally, recommendations for future development and for the MEB and HCPs at VUmc were proposed (chapter 8).



Figure 4. Overview of the structure of this thesis

1

Literature research

This chapter starts with background information about medication use during pregnancy, followed by a discussion of factors that may influence medication nonadherence among pregnant women. This will provide insight in how existing information does not suffice. Then pregnant women's perception towards the risks of medicines and the communication of risks in information are discussed. Finally, existing information sources are described and evaluated on positive and negative aspects.

1.1 MEDICATION USE DURING PREGNANCY

Every medicine has its own benefits, risks and side effects and cannot be used by any person. Whether a medicine should be used depends on individual factors and the patient's indication. Some medicines can be bought 'over-the-counter' (OTC) at drugstores, pharmacies or supermarkets, but most medicines require a doctor's prescription.

Most pregnant women use some kind of medicine during pregnancy. Research shows that about 79% of women in the Netherlands received at least one prescription during their pregnancy (Bakker et al, 2006). The study of Mulder et al. (2018) among 136 Dutch pregnant women also shows that 82.2% had used medication during pregnancy. Paracetamol was the most commonly used medicine (42%), followed by acid-suppressive medication (25%), vitamins (21%) and antibiotics (10%).

There are multiple reasons why pregnant women may need a medicine (illustrated in figure 5). First of all, there are women with chronic diseases that require treatment with medicines, which they already have been using for a longer period of time before their pregnancy. Secondly, pregnant women may get sick because pregnancy induces symptoms that can become so bothersome that they need some relief (e.g. morning sickness), or there could be a complication that is dangerous for both mother and

child that treatment is necessary (Dewulf, 2013). Pregnant women can also get complaints or illnesses like any other person (e.g. an infection). Lastly, women may be at risk of developing a complication and need a preventive medicine.

Since women who are treated at VUmc are often dealing with an underlying disease or other complication, they are likely to use more medications compared to women with a 'normal' pregnancy.

Potential risks

For pregnant women, both the maternal and fetal health must be considered regarding the use of medications. Almost all medicines cross the placenta and thus reach the child (TIS, 2019). Some medicines are known to be safe to use, whereas other medicines should not be used during pregnancy because of the teratogenic risks for the child. Teratogens are substances in medicines that may disturb the development of the embryo or fetus and cause birth defects due to the toxic effect on the embryo or fetus (TIS, 2019). Adverse effects comprise for example low birth weight, premature birth, growth retardation or wrong organ development. Whether a medicine could have a harmful effect also depends on the dosage, the duration of use and the stage of pregnancy in which the medicine is used. For instance, in the first



Figure 5. Why pregnant women need medicines

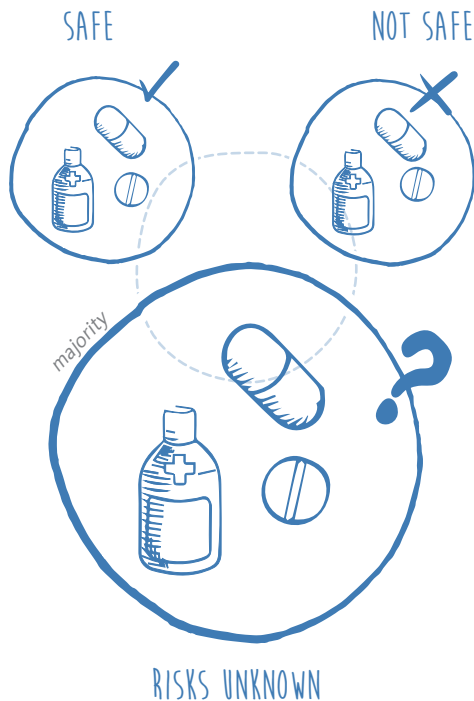


Figure 6. From most medicines, the risks are unknown

trimester there is a higher risk of malformations since the organs of the child are then being formed.

For the vast majority of medicines, however, there is insufficient information about the safety or risks of potential adverse effects (TIS, 2019; Mitchell et al, 2011), as illustrated in figure 6. This holds for both medications by prescription or over-the-counter (OTC) drugs. The reason for this is that research into the potential harmful effects of medicines during pregnancy is complicated, since medicines are generally not tested with pregnant woman because of ethical reasons. Information provided by animal studies can only be partially transferred to humans. Therefore, data about medication use during pregnancy are derived from experience in clinical practice, case reports and observational research (TIS, 2019).

Inevitability or choice

For many pregnant women who are under treatment in a hospital taking a medicine is inevitable due to chronic conditions like asthma, diabetes, epilepsy and Crohn's disease. When such illnesses are not well

controlled during pregnancy, it can affect the health of both mother and child significantly (Lareb, 2017). For example, an uncontrolled asthma involves risks such as inadequate oxygen for the child, preterm birth or a low birth weight (Murphy, 2015). Thus, withholding treatment with medicines would then be more detrimental than the possible teratogenic risks involved when taking the medicine.

In other situations, women do have a choice whether to take a medicine or not. They may decide not to use a medicine even if it would be more beneficial to take it. For some medicines it is well known that they are very beneficial to use during pregnancy, like folic acid. Pregnant women are advised to take 0.4 or 0.5 mg folic acid per day already 4 weeks before they could become pregnant until the 10th week of pregnancy (Thuisarts.nl, 2018). This reduces the chance that the child will have spina bifida (in Dutch: open ruggetje).

In each case, the necessity for the mother and child needs to be weighed against the potential risks for the child, as well as the risks when not taking the medicine, as illustrated in figure 7. This could imply a difficult trade-off for the patient, especially when it is a choice between two wrongs or when there is much uncertainty about risks. What is best may vary per person, situation and possibly even pregnancy.

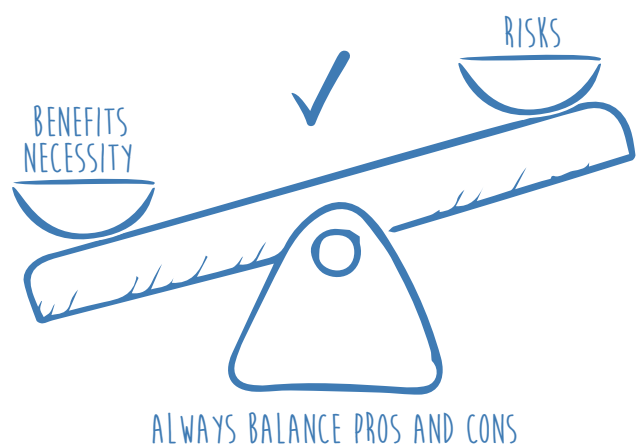


Figure 7. Balancing benefits and risks when making decision

1.2 MEDICATION NONADHERENCE

Despite the necessity or relevance of using a medicine, pregnant women not always take their medicine as prescribed (Matsui, 2012). Medication nonadherence, which is defined as the degree to which patients correctly follow their prescribed regimen, is a complex and multidimensional healthcare problem with serious consequences (Hugtenburg et al, 2013). Desired treatment goals may not be achieved, resulting in increased morbidity and mortality rates as well as increased healthcare costs (Matsui, 2012; Vrijens et al, 2012).

For pregnant women, nonadherence could be detrimental to both mother and fetus (Sawicki, 2011). In the outpatient clinics of an Australian hospital, 59.1% of pregnant women with a chronic health condition did not adhere to their treatment (Sawicki, 2011). According to gynaecologists at VUmc, this is a common problem among pregnant women.

Medication nonadherence can occur during different stages of the patient's treatment. Patients may not pick up their prescription at the pharmacy or decide at home not to start the treatment at all. When using, they could take the wrong dose or use the medicine at the wrong time. Women may also discontinue their treatment before completing it.

Factors influencing (non)adherence

Finding out what may cause pregnant women not to adhere to their treatment may give insight in how current information about medicines does not suffice and what information pregnant women might need. The possible reasons of patients not to adhere to their treatment are diverse. Nonadherence can occur both intentionally or unintentionally. Unintentional nonadherence is unplanned behaviour where patients mean to take their medicine in the right

way but do not, due to a lack of resources or capacity (Hugtenburg et al, 2013; Thomson et al, 2018).

Illiteracy, complex medication regimens and poor memory (resulting in forgetfulness or not knowing how to use the medicine) are related to unintentional nonadherence.

With intentional nonadherence, the patient actively decides not to take the medicine or deviate from the prescribed regimen. Factors associated with this are patient's beliefs about the necessity of taking the medicine, their concerns about taking it, experiences with side effects and the interaction between patient and HCP (Clifford et al, 2008). Next to patients' knowledge, these are essential factors that influence medication adherence, as opposed to individual traits or sociodemographic characteristics, which do not seem to be related to medication adherence (Thomson et al, 2018). Furthermore, in contrast to what one might expect, the type or severity of the underlying condition does not guarantee adherence, as has been found with for example cancer and organ transplant therapy (Matsui, 2012). Nonadherence is likely to be caused by an interplay of factors. For instance, patients who have low perceived necessity of taking the medicine may be more likely to forget to take it.

Pregnancy related factors

In addition to the factors that may affect medication adherence among the nonpregnant population, pregnancy brings unique challenges since both the maternal well-being as the fetal health must be taken into account. Intentional nonadherence is of particular interest here. On the one hand, pregnant women may be motivated to relieve them from complaints or keep their medical condition under control for their own well-being as well as that of their child. On the other hand, the uncertainty about

potential harmful effects of a medicine on the child may cause concern and anxiety among women, which might lead to poor adherence (Matsui, 2012; Mitchel et al., 2015).

The fact that for most medicines the potential teratogenic risks are still unknown may not only make pregnant women to unknowingly take a medicine that poses their child at risk, but also seems to have led to the general view that medicines should be avoided during pregnancy (Mitchel et al., 2015). All medicines involve risks, but women

want to give their child a risk-free, pure and natural development as much possible, so it is not strange women feel like medicines should not be part of this. Pregnant women put the needs of their baby first and therefore often take their illness and discomforts for granted because they do not want to harm their unborn child. However, as a consequence they might unknowingly just put their child at risk. Therefore, it is important to get an understanding of how women perceive and act upon information about risks and how risks can best be communicated.

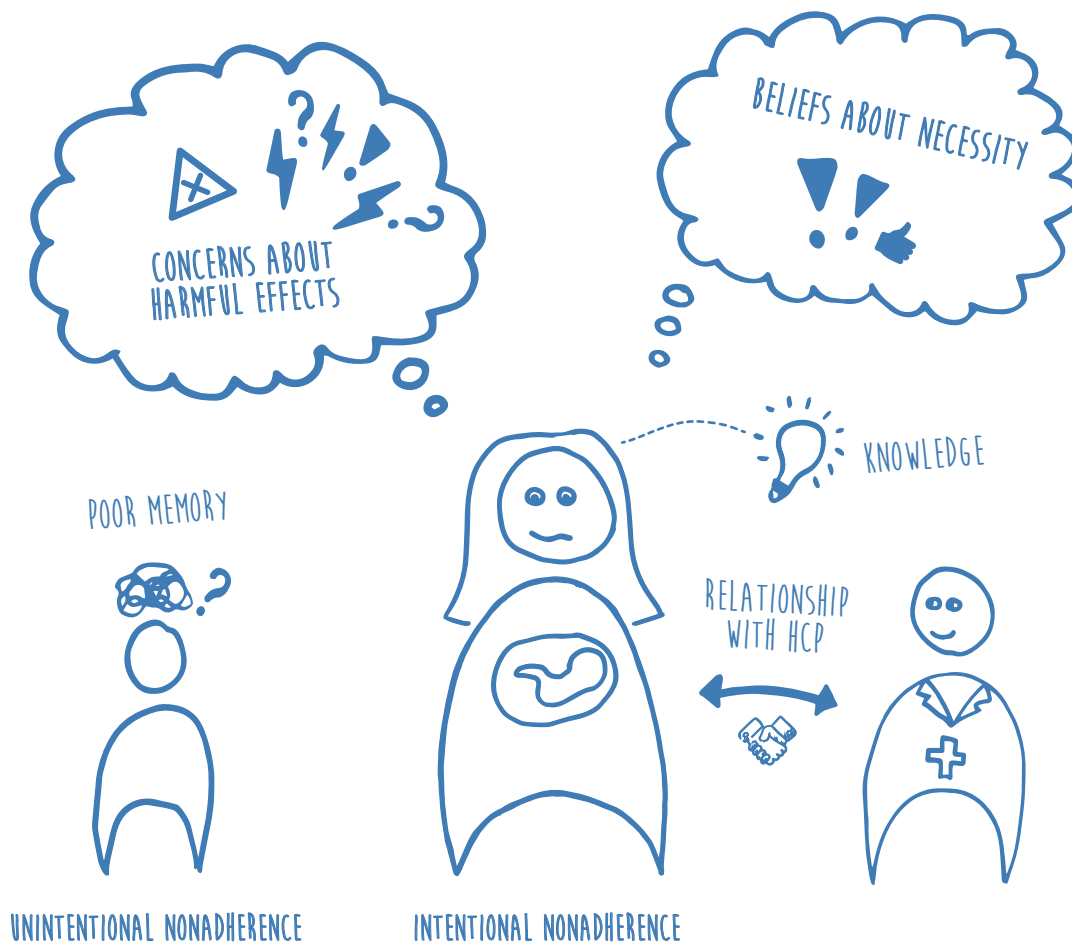


Figure 8. Factors influencing nonadherence among pregnant women

1.3 RISK PERCEPTION & COMMUNICATION

Risk perception

Risk perceptions are important determinants for the confidence of pregnant women in using a medicine and influence their medication taking behaviour. Research has shown that pregnant women tend to overestimate the teratogenic risks associated with medicines (Nordeng et al., 2010; Widnes & Schjøtt, 2017). The media and other sources usually stress the risks related with medicines rather than the benefits or communicate misleading information, thereby provoking fear and anxiety amongst women (Hancock et al., 2007).

Furthermore, people often overstate risks that have a low probability but high impact, such as having a malformed child or being in a plane crash, while underestimating more common risks like hypertension (Widnes & Schjøtt, 2017). This phenomenon could also contribute to the overestimation of teratogenic effects.

Additionally, women's risk perceptions and decisions may be influenced by the experiences, opinions and beliefs of families and friends. If a relative thinks the medicine is not safe and expresses this to a pregnant woman, she might easily decide not to take it.

Women's risk perception may also be affected by what is known about a medicine. In the study by Lynch et al. (2018), women indicated that if the risks of a given medicine are unknown, they would not take that medicine during pregnancy.

Risk communication

The way in which risk information is conveyed, for instance in information leaflets or communicated by HCPs, also affects women's perception of risks (Trevena et al., 2013).

Risk information important to women

In addition to the medication information that is relevant for the health of the mother only (such as side effects, contra-indications and how to use the medicine), information regarding the safety and risks of a medicine for their unborn child is of particular importance for pregnant women. Research has shown that safety issues raises most questions among women (Matsui, 2012). Given that women tend to overestimate these risks, it is important that risk information is conveyed in such a way that realistic risks are perceived (Widnes & Schjøtt, 2017). More awareness and perception of the actual risks will lead patients to make decisions that are better for their well-being (Trevena et al., 2013).

Evidence

If available, information should include evidence-based information on the effects of the medicine during pregnancy, which could avoid misperceptions and reduce anxiety that could lead to nonadherence (Matsui, 2012; Nordeng et al., 2010). However, due the scientific uncertainty regarding teratogenic risks, such concrete information often cannot be provided, which significantly influences the quality of information. Patient leaflets often give restrictive or unclear information regarding medication use during pregnancy, which may lead to feelings of concern and anxiety (Widnes & Schjøtt, 2017). This will be discussed in chapter 1.4 as well.

Lack of benefits

Additionally, when there is a lack of focus on the benefits of treatment with medicines, it may easily result in an unrealistic risk perception. To counterbalance the overestimation of risks, a greater focus on the positive consequences of using a medicine could be beneficial, as well as explaining potential negative consequences when not using a medicine. Belief in the benefits of a medicine will increase patients' empowerment and confidence in the use of a medicine (Dickinson et al., 2016).

Influence of healthcare professionals

The perception and communication of risks by HCP may also have a significant impact on the risk perception of women. Some HCPs may be unaware of potential harmful effects of a medicine and therefore put their patient at risk. However, more commonly, other HCPs overestimate the risks of medicines during pregnancy while evidence suggests that is unnecessary (Widnes & Schjøtt, 2017). It could also be the case that official product information expresses risks or uncertainties with a medicine while HCPs inform patients that the medicine is safe to use, basing their advice on recent studies or experience in clinical practice (which is the case for for example acetylsalicylic acid (Aspirin)). This conflict in information that is provided to patients only further contributes to the issue (Widnes & Schjøtt, 2017).

Written communication

Risk information can be given in verbal chance terms (e.g. "rarely", "usually" or "very small chance that") or numerically ("1-10% chance that..."). Since data on which estimates are based is often not sufficiently precise to be translated into a numerical value, information providers prefer to communicate probabilities verbally because this expresses some

amount of uncertainty (Willems et al., 2019). If a numerical value would then be given, the suggested precision could be misleading.

On the other hand, decision makers (patients) prefer numerical expressions because they are easier to draw conclusions from. To avoid miscommunication, numerical expressions should be preferred since people may have a different understanding of the meaning of verbal descriptions (Widnes & Schjøtt, 2017; Fischhoff, 2012). Communicating risk information numerically rather than in verbal terms ensures a more accurate perception of the probability and likelihood of a side-effect and the risk to health (Raynor et al (2007). Research by Willems et al. (2019) shows that there is a large variability in the interpretation of Dutch verbal probability phrases, especially in less extreme probabilities (e.g. "maybe", "sometimes", "possible") compared to extreme words such as "always", "almost never" and "rarely". They suggest that it is possible to include uncertainty in numerical statements, for example "there is at least 80% chance of..." (Willems et al., 2019).

Other research by Jasper et al. (2001) found out that negatively-framed information (1-3% chance of having a malformed child) results in a significantly higher perception of teratogenic risks compared to positively-framed information (97%-99% chance of having a normal child).

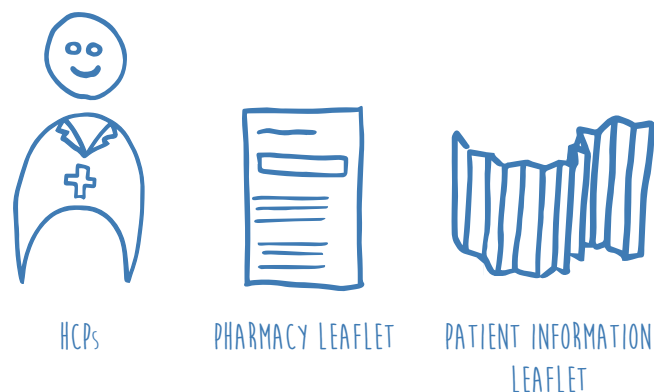
Although numerical expressions may be preferred, in reality the risks of medicines on the unborn child are unknown in most cases or not sufficiently clear that they can be expressed in numerical values. Therefore, information providers often have to make do with verbal descriptions.

1.4 CURRENT MEDICATION INFORMATION

Need for information

In order to make a well-considered decision, women need understandable and reliable information about the use of medicines during pregnancy. Medication information is critical to the safe and effective use of medicines and should encourage patients to adhere to their treatment (Young et al, 2017; Matsui, 2012). Besides, it allows patients to be actively involved in the decision making and be in control of their own medication use (Raynor, 2013; Jose & AlHajri, 2018). Well informed patients are expected to choose a treatment that best fits their needs and preferences.

Research by NIVEL shows that four out of ten people searches information with the aim to decide whether to take a medicine or not (Dijk et al, 2016). This indicates that the start of a therapy is an important moment for providing information to patients. After starting to use a medicine, additional information can be necessary when questions arise about side effects patients experience or whether the prescribed medicine can be used together with an OTC drug (Raynor et al, 2007). For pregnant women, information is not only relevant when starting a new treatment during pregnancy, but also when they (want to) become pregnant and have to decide whether to continue with a prescribed medicine or not, due to the potential teratogenic effects on their child.



Healthcare professionals

For most patients, the primary sources of information are healthcare professionals, such as the gynaecologist, obstetrician or pharmacist (Thürmann, 2006). They have a unique position as they can monitor adherence during consultations and encourage adherence by dispelling misconceptions and providing reliable information about benefits and risks. Besides, HCPs can provide the patient with information that is tailored to their situation.

However, research has shown that 40-80% of medical information provided by HCPs is immediately forgotten by patients and almost half of the recalled information is incorrect (Kessels, 2003). This may be due to difficult medical terminology used by HCP or factors such as low education or poor memory. As a consequence patients may use the medicine in the wrong way or lose confidence in using the medicine at all.

This stresses the importance of additional sources of information that can further support women in their medication taking process. Current sources of information that patients can access independently are the patient information leaflet, the pharmacy leaflet and a plethora of online websites as illustrated in figure 9. A study by Mulder et al. (2018) shows that the patient information leaflet and the Internet were the most used sources of information among pregnant women.

Figure 9. Overview of information sources

Alstablieft Onze informatie speciaal voor u

afdrukdatum: 17-1-2019
VI-2 © SLS/18.10

Bètablokkers

UW MEDICIJN IN HET KORT:

- Helpt bij hoge bloeddruk, hartkrimp en hartfritme stoornissen. Helpt ook bij migraine.
- Meestal voor lange tijd gebruiken, stop nooit zelf!
- Hoe snel de medicijnen helpen is voor elke ziekte anders. Soms meteen, soms na een aantal weken.
- Let op! Kan een ongunstige wisselwerking hebben met pijnstillers die zonder recept te krijgen zijn. Informeer voor gebruik eerst bij uw apotheker.
- Bijwerkingen, zoals vermoeidheid en duizeligheid, gaan meestal na een paar weken over.

Onderstaande informatie is ook beschikbaar in een korte uitlegvideo. Scan de QR code hiernaast met uw smartphone of ga naar www.apotheek.nl en voer de volgende filmcode in: beta1

WERKING

Hoe helpt dit medicijn?
Dit medicijn is een bètablokker en maakt uw hartslag langzamer. Daarom helpt het bij hoge bloeddruk, hartkrimp (angina pectoris) en bepaalde hartstoornissen. U kunt dit medicijn om verschillende redenen krijgen: omdat u al hart- en vaatziekten heeft, of omdat u moet zorgen dat u geen hart- en vaatziekten krijgt. Mensen met migraine gebruiken deze medicijnen omdat ze dan minder vaak migraine hebben.

GEBRUIK

Hoe lang moet u dit medicijn gebruiken?
Meestal moet u dit medicijn heel lang gebruiken, soms wel jaren. Als u wilt stoppen met dit medicijn, moet u dat altijd eerst aan uw dokter vragen. U moet altijd langzaam aan stoppen met deze medicijnen.

Wanneer merkt u dat dit medicijn helpt?
Wat u merkt van dit medicijn is voor elke ziekte anders. Als u een hartfritme stoornis heeft, dan helpen de medicijnen al na een paar uur. Heeft u hoge bloeddruk? Dan kan de dokter na twee tot vier weken meten of het medicijn bij u goed helpt. U kunt zelf niet goed voelen of uw bloeddruk lager is geworden. Ook als u migraine heeft zult u niet direct iets merken van dit medicijn.

Hoe gebruikt u dit medicijn?
Bètablokkers zijn meestal tabletten. Neem ze in met water. Als u één tablet per dag in moet nemen dan kunt u deze tablet het beste 's ochtends innemen. Moet u meerdere tabletten per dag innemen? Doe dit dan niet vlak voordat u gaat slapen omdat u anders misschien minder goed kunt slapen.

Medicijn vergeten?

Pagina 1 van 2

Lees de bijsluiter of kijk op <http://www.apotheek.nl> om te weten wat u moet doen.

Hoe moet u dit medicijn bewaren?
Bewaren op kamertemperatuur in de originele verpakking.

Let op!
Sommige medicijnen kunnen een ongunstige wisselwerking hebben met het medicijn dat u gebruikt tegen hoge bloeddruk of hartfalen. Ook voor medicijnen die u zonder recept kunt kopen (bijv. bij de drogist) kan dit het geval zijn. Informeer daarom eerst bij uw apotheker als u een (ontstekingsremmend) pijnstiller wilt gaan gebruiken. Sommige pijnstillers kunnen er namelijk voor zorgen dat uw middel tegen hoge bloeddruk of hartfalen minder goed gaat werken. Paracetamol mag u wel altijd gebruiken.

BIJWERKINGEN

Wat kunt u nog meer voelen als u dit medicijn gebruikt (bijwerkingen)?
De meeste medicijnen kunnen onbedoelde klachten geven. We noemen dit bijwerkingen. Als u dit medicijn gebruikt dan kunt u in het begin bijvoorbeeld last krijgen van duizeligheid, u kunt een beetje moe worden en slecht slapen. Ook kunt u koude handen en voeten krijgen. Meestal verdwijnen bijwerkingen na een paar weken. Verdwijnen de bijwerkingen niet, of heeft u er veel last van? Overleg dan met uw apotheker of bel uw dokter. Stop nooit zelf met dit medicijn.

EXTRA INFORMATIE

Wat kunt u zelf doen?

- Stop met roken, let op uw gewicht, word niet te zwaar.
- Eet gezond en niet steeds hetzelfde. Gebruik niet veel vet en zout.
- Beweeg minimaal 3 x per week een half uur (bijvoorbeeld fietsen, wandelen of zwemmen).

Lees voor meer informatie ook de bijsluiter.

Pagina 2 van 2

Figure 10. Example of a pharmacy leaflet for the medicine Labetalol

Pharmacy leaflet

The pharmacy is the last and only place where a patient receives written information from a HCP. When a patient uses a medicine for the first time, the pharmacist provides them with an A4 pharmacy leaflet. Contrary to the official patient leaflet, pharmacies are not obliged to give the pharmacy leaflet to patients. The pharmacy leaflet is not always specific for a medicine, nor tailored to an individual situation or pregnancy. Most of the time, it contains general information about what the medicine is for, how to use the medicine and common side effects. For example, the leaflet that is provided with 'Labetalol' (figure 10), a medicine that lowers the blood pressure, is a general leaflet for all beta blockers. It does not contain any pregnancy related information. The information in the leaflet comes from Health Base, a foundation that provides pharmaceutical and medical information to pharmacies and general practitioners. In general, the

pharmacist gives mostly 'technical' information (i.e. how to use it and things patients should be aware of). However, they ask relatively little about patients' thoughts and feelings about using a particular medicine (Koster et al, 2015; Van Dijk et al, 2016).

Official patient information leaflet

The patient information leaflet, which is enclosed in the medication package, is a well-known source of information. The leaflet includes instructions and directions for use, precautions and spells out potential side effects or risks of a medicine. Patient leaflets are written for the general public in a one-size-fits-all format, rather than for the individual patient or group of patients. Each package leaflet is based on the QRD template established by the European Commission. The template regulates the content elements of the leaflets, the order in which these topics should be discussed, headings for (sub)

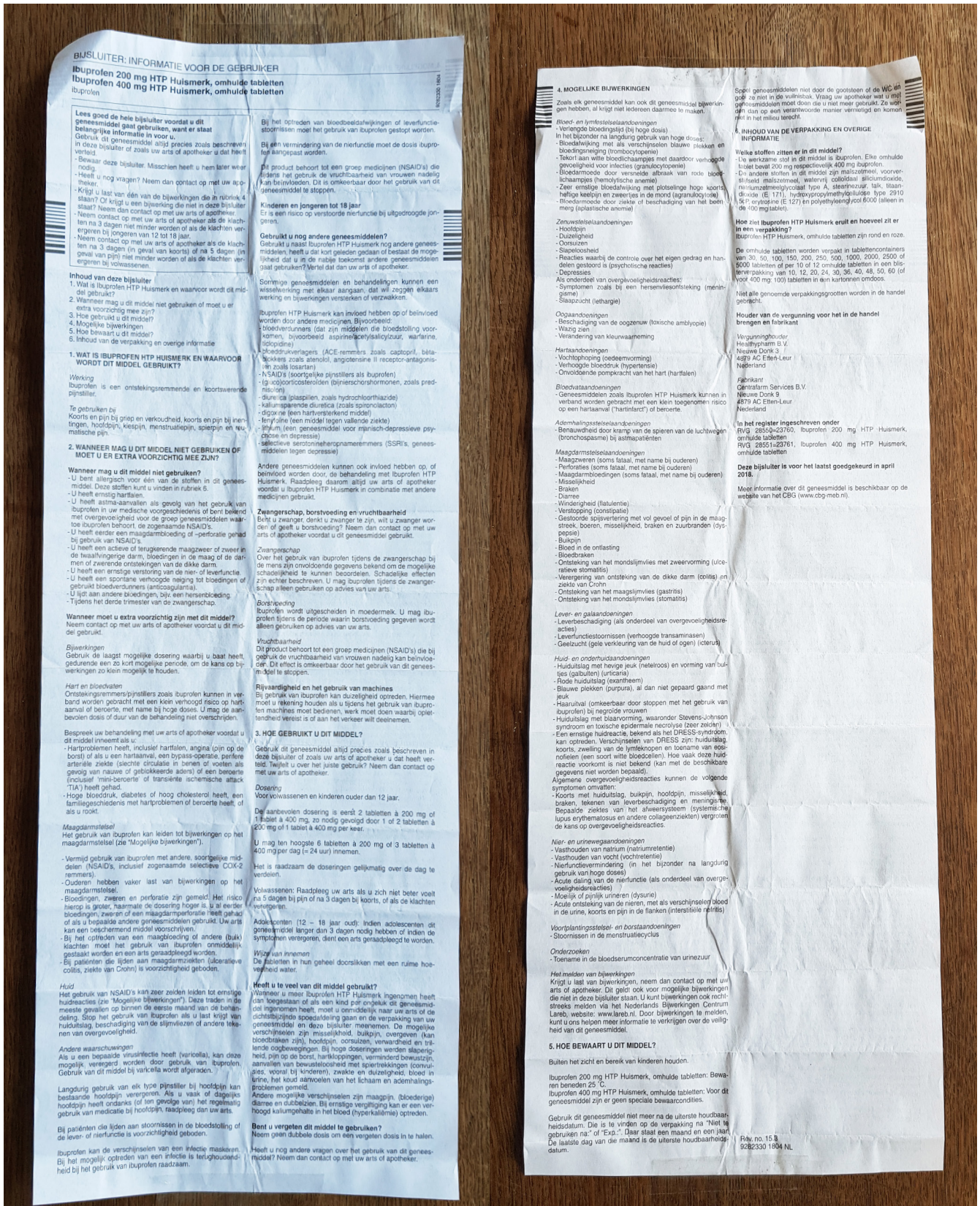


Figure 11. Example of an official patient information leaflet of the medicine Ibuprofen

paragraphs and the wording of specific passages (Maat & Lentz, 2010; EMA, 2016). The template makes sure that all required information is included in the leaflet and should ensure consistency among all leaflets. The patient leaflets contains 6 sections:

1. What X is and what it is used for
2. What you need to know before you <take> <use> X
3. How to <take> <use> X
4. Possible side effects
5. How to store X
6. Contents of the pack and other information

Apart from the medication package, patient leaflets can also be found online on www.geneesmiddeleninformatiebank.nl in PDF. Content wise there are no differences between the package leaflets and online leaflets, but the design differs. The online leaflets are presented on A4, use larger fonts (10.5 points), are in black and white and use 'normal' paper quality when printed, whereas the package leaflets have a two-column layout, use a smaller font,

are in colour and are printed on thinner paper that can be folded (Maat & Lentz, 2010).

Pregnancy and breastfeeding

Pregnancy related information can be found in the second paragraph of the leaflet, under the subheading 'Pregnancy and breastfeeding'. When comparing leaflets from different medicines, there are small differences in the way information is communicated. In general, all leaflets indicate that the patient should contact their doctor before using the medicine in case she is pregnant, thinks she is pregnant, wants to become pregnant or breast-feeds. When a medicine should really not be used, this is clearly communicated. When a medicine may be used, it often states something along the lines of: *"(as far as is known,) the medicine can be used during pregnancy with a prescription from the physician, (only when necessary/only when the possible benefits outweigh the possible risks)"*. This can be seen in the three examples below.

Zwangerschap en borstvoeding
Bent u zwanger, denkt u zwanger te zijn, wilt u zwanger worden of geeft u borstvoeding? Neem dan contact op met uw arts of apotheker voordat u dit geneesmiddel gebruikt.

Hoewel Labetalol HCl ratiopharm in principe geschikt is voor de behandeling van verhoogde bloeddruk tijdens het eerste trimester van de zwangerschap, wordt onnodige toediening afgeraden. Labetalol mag alleen worden gebruikt in het eerste trimester van de zwangerschap wanneer de mogelijke voordelen opwegen tegen de mogelijke risico's.

Labetalol wordt uitgescheiden in de moedermelk. Voorzichtigheid is geboden bij het gebruik van labetalol tijdens het geven van borstvoeding.

Figure 12. Pregnancy related information for Labetalol

Zwangerschap en borstvoeding
Dit geneesmiddel kan voor zover bekend in de aanbevolen doseringen zonder gevaar voor de vrucht worden gebruikt in de zwangerschap.
Uitscheiding in de moedermelk vindt plaats; foliumzuur kan echter in de aanbevolen dosering tijdens de borstvoeding worden gebruikt.

Figure 13. Pregnancy related information for Folic acid (foliumzuur)

Zwangerschap, borstvoeding en vruchtbaarheid
Bent u zwanger, denkt u zwanger te zijn, wilt u zwanger worden, of geeft u borstvoeding? Neem dan contact op met uw arts of apotheker voordat u dit geneesmiddel gebruikt.

Voor zover bekend mag Furadantine MC tijdens de zwangerschap gebruikt worden. Furadantine MC mag niet gebruikt worden vlak voor en tijdens de bevalling omdat de mogelijkheid bestaat dat dit nadelige gevolgen op de baby kan hebben.

Figure 14. Pregnancy related information for Nitrofurantoin

Usability problems

Research by NIVEL into the information needs of patients, commissioned by MEB, shows that patient leaflets are considered as a trustworthy source of information and many patients consult the leaflet to gather information about a medicine (Dijk et al, 2016).

However, prior research shows that users experience many problems with the package leaflets. First of all, users have difficulties finding the desired information (Dijk et al, 2016; Maat & Lentz, 2010). In practice, package leaflets can run to thousands of words, which makes the text very lengthy. Besides, due to the unclear structure users do not have a good overview of where to find the information they need. Also, the leaflets may lack the information users seek or contain information that is irrelevant to them (Young et al, 2017).

Secondly, users find it difficult to read and comprehend the information. Apart from the large amount of information that is presented in a small font size, the leaflets are often written in complicated medical jargon that is difficult to comprehend for laypersons. Also, side effect information often states what happens in the body rather than the actual symptoms patients may experience (e.g. "too much salt in your blood" rather than what the user senses). Furthermore, some text is confusing or unclear about the actions users should take, restraining them from being able to apply the information.

Lastly, users are unnerved by the 'negative' information in the leaflets (Herber et al., 2014). The way risk information is conveyed often provokes negative emotions like fear and anxiety, for example by the vast amount of side effects the leaflet often contains. In order to avoid a legal risk, manufacturers include all adverse effects in the leaflet that are reported in the test phase. If a patient has a headache in the test phase, it will appear on the leaflet, even if it is not caused by the medicine.

As mentioned before, pregnancy related information often contains phrases like "as far as is known, it can be used", "use only when necessary", "unnecessary usage is not recommended", "use only when possible

benefits outweigh the possible risks". This reflects a kind of uncertainty or reticence that could make women feel concerned or anxious. This information seems more relevant for a HCP than for the patient, since the HCP should make the consideration and decide whether a medicine is necessary for the patient.

Note: During a brainstorm session in the conceptualization phase (which will later be discussed in chapter 5.1), the information in the patient leaflet of two medicines 'Labetalol' and 'ferrofumaraat' was presented to the participants. Their reactions, which are discussed in appendix J on p.175 illustrate the above mentioned issue well.

Online information

Although women consider their obstetrician or gynaecologist as their most trusted source of information, research by Lynch et al. (2018) shows that women also turn to online sources to help them make decisions about medication use. There are many online websites that provide information about medication use during pregnancy. These include trustworthy websites like apotheek.nl and thuisarts.nl, but also (less trustworthy) websites like forums or blogs where women share their opinions and experiences. Apart from websites that are targeted at patients, there are also websites with pregnancy information targeted at HCPs, like Lareb TIS (www.lareb.nl/tis-knowledge) and the Farmacotherapeutisch Kompas (www.fk.nl).

Figure 15 shows information of the medicine Labetalol on the website apotheek.nl. The information is written in understandable language and organized in several drop-down menus, such as "Can I use this medicine when I am pregnant, want to become pregnant or breastfeed?" Still, when analyzing the pregnancy related information some issues were identified. This is discussed in appendix B.

The study of NIVEL found out that patients find it difficult to judge the trustworthiness of online information (Dijk et al., 2016). Patients may not know what websites they can consult to find reliable information. Besides, patients sometimes find it difficult to find the desired information due to an overload of information, which is often not clearly organized, as with the patient leaflet.

Apotheek.nl
Alles over medicijnen. Deskundige informatie van de apotheker

Home Medicijnen Klachten & ziektes Zorg & gebruik Vind een apotheker Meer

naar medicijn

labetalol

Trefwoord

Volwassenen Kinderen

Belangrijk om te weten over labetalol

Wat doet labetalol en waarbij gebruik ik het?

Labetalol behoort tot de **bètablokkers**. Het verlaagt de bloeddruk, vertraagt de hartslag en vermindert de zuurstofbehoefte van het hart.

Artsen schrijven het voor bij **hoge bloeddruk**, onder andere bij **zwangerschap**, en bij **angina pectoris (hartkramp)**.

Hoge bloeddruk

Versijnselen

Mensen met een hoge bloeddruk voelen hier in het algemeen niets van. Hoge bloeddruk is ook geen ziekte, maar geeft meer kans op hart- en vaatziekten.

Als de bloeddruk is verhoogd, stroomt het bloed te krachtig door de vaat. Dit is schadelijk voor de bloedvaten. Beschadigde bloedvaten geven kans op een beroerte (herseninfectie of hersenbloeding) en ernstige hartziekten, zoals hartkramp en hartfalen.

Werking

Bètablokkers vertragen de hartslag zodat het hart rustiger pompt. Hierdoor daalt de bloeddruk en is er minder kans op een beroerte.

Bij hoge bloeddruk schrijven artsen bètablokkers meestal voor in combinatie met andere medicijnen, zoals plaastabletten. In eerste instantie schrijft de arts als bètablokker metoprolol voor, omdat dit middel minder bijwerkingen heeft en in onderzoek het effectiever is gebleken. Als metoprolol niet werkt of kan worden gebruikt, kan de arts labetalol voorschrijven.

Effect

Na één tot drie dagen is het volledige effect van dit middel bereikt. Zelf merk u hier niet veel van. U weet pas of het werkt bij een meting van uw bloeddruk. Toch is het belangrijk om labetalol elke dag in te nemen. Alleen dan kan labetalol de hart- en bloedvaten optimaal beschermen.

Hoge bloeddruk tijdens de zwangerschap

Hoge bloeddruk tijdens de zwangerschap vormt een risico voor de zwangere en de baby. Dit komt omdat de bloedvaten door de toename van de bloedstroom al meer te lijden hebben dan anders. Daarom controleert de verloskundige of arts met regelmatige tussenpozen de bloeddruk. Vrouwen kunnen al voor ze zwanger zijn een verhoogde bloeddruk hebben of kunnen tijdens de zwangerschap een verhoogde bloeddruk krijgen.

Als de hoge bloeddruk in de tweede helft van de zwangerschap ontstaat, heet het ook wel **zwangerschapshypertensie** of **zwangerschapvergiftiging**. Deze laatste term is onjuist, omdat er geen sprake van een vergiftiging is. Deze vorm van hoge bloeddruk moet snel behandeld worden. Na de bevalling verdwijnt de hoge bloeddruk meestal weer binnen drie maanden.

Behandeling

Als rust houden of minder zout gebruiken niet helpen om de bloeddruk omlaag te krijgen, zal de arts een medicijn voorschrijven tegen hoge bloeddruk. Dit moet dan een medicijn zijn dat veilig is voor de zwangere en de baby. Labetalol is zo'n medicijn. In het geval van een snel oplopende zwangerschapshypertensie wordt labetalol in injectie toegepast.

Als u al medicijnen gebruikt tegen een hoge bloeddruk en zwanger wilt worden, is het verstandig met uw arts te overleggen. Het is dan mogelijk om op tijd over te schakelen naar veilige medicijnen tijdens de zwangerschap, zoals labetalol.

[Lees meer over hoge bloeddruk](#)

Angina pectoris

Wat zijn mogelijke bijwerkingen?

Hoe gebruik ik dit medicijn?

Wat moet ik doen als ik een dosis ben vergeten?

Kan ik met dit medicijn autorijden, alcohol drinken en alles eten of drinken?

Mag ik labetalol gebruiken met andere medicijnen?

Mag ik dit medicijn gebruiken als ik zwanger ben, wil worden of borstvoeding geef?

Zwangerschap

Meld het aan uw arts en apotheker zodra u zwanger bent, of binnenkort wilt worden. Samen met uw arts kunt u bespreken wat het risico voor de baby is als u doorgaat met het medicijn. Of wat het risico voor u is als u met het medicijn stopt.

Bij gebruik van dit medicijn tijdens de zwangerschap bestaat er namelijk een risico op bijwerkingen bij het kind. Zoals een lage bloedsuikerspiegel, een lage bloeddruk, een lage hartslag, suf worden en moeite met ademen. Mogelijk zal uw arts uw baby extra controleren. Overleg hierover met uw arts. Zo mogelijk kunt u (tijdelijk) overstappen op een ander medicijn.

Borstvoeding

Wilt u borstvoeding geven, overleg dan met uw arts of apotheker. Dit medicijn komt in zeer kleine hoeveelheden in de moedermelk terecht. U kunt, na overleg met uw arts, borstvoeding (blijven) geven. Mogelijk zal uw arts uw baby extra controleren.

Gebruikt u medicijnen op recept of die u zonder recept koopt? Wilt u helpen om de kennis over medicijngebruik tijdens zwangerschap en borstvoeding te vergroten? Meld dan uw ervaring bij [LBEQ.nl](#).

Mag ik zomaar met dit medicijn stoppen?

Onder welke namen is labetalol verkrijgbaar?

Heb ik een recept nodig?

Apotheek.nl
Apotheek.nl is een initiatief van de KNMP, de beroepsvereniging van apothekers in Nederland.

Apotheker in Delft

labetalol is te gebruiken bij:

- Hoge bloeddruk
- Angina pectoris

Beste website

Website van het jaar 2018

Figure 15. Information about the medicine Labetalol on apothek.nl

1.5 DISCUSSION & CONCLUSION

Pregnancy brings unique challenges when it comes to medication use since both maternal and fetal health must be considered. Decisions always involve a **trade-off** between the necessity and risks for both mother and child when taking or not taking a medicine. Pregnant women's **beliefs about the necessity** of a medicine and **concerns regarding the potential harmful effects** on their child are important determinants for women's confidence in and adherence to their medication.

Literature shows that pregnant women tend to **overestimate risks** associated with medicines. This may be influenced by the media and other information sources, such as patient leaflets and online websites, that often **stress the risks and lack the benefits of medicines**. Pregnancy related information in the patient leaflet often communicates uncertainty and shows reluctance towards the use of medication during pregnancy. The overall **lack of knowledge** about teratogenic risks causes fear and anxiety among women and may have contributed to the general view that medicines should be avoided during pregnancy. **Contradictory information** from HCPs and other information sources contributes further to the issue.

Since patients often **forget information** from their HCP, additional information sources that women can access independently are important as well. However, current information sources like the patient leaflet and online websites are often not user friendly. Apart from providing mostly negative (risk) information, patients have **difficulties finding the desired information** due to **a lack of structure, information overload** and **difficult language**. Additionally, the information is **not tailored to pregnant women** and therefore often includes much irrelevant information

that does not fit their needs. Furthermore, patients have **trouble finding trustworthy information** and/or find it hard to judge the reliability of online information.

To conclude, risk information should be conveyed in such a way that **realistic risks** are perceived, by framing risks positively and **including evidence** from research when available. Additionally, to redress the balance, there should be **more focus on the positive consequences** of medicines (i.e. benefits, relevance). The **information should be easy to find, read and understand**. This means information overload should be avoided, information should be presented in a clear structure and be written in a user friendly way. Furthermore, it would be beneficial to **tailor and prioritize information according to the needs, beliefs and perceptions of pregnant women**.

2

Context research

Since HCPs are an important source of information and literature did not yet provide insight in what information they provide to pregnant women, research is conducted with HCPs. In the first study, HCPs working at the department of Obstetrics and Gynaecology are asked to share their perspective on causes of nonadherence and their ideas about medication information for pregnant women. In the second study, a better understanding is obtained about the interactions between gynaecologists and patients during consultations at VUmc.

2.1 PERSPECTIVE OF HCPs ON MEDICATION NONADHERENCE AND INFORMATION

Research goal

Since gynaecologists at VUmc are interacting with pregnant women every day and consider medication nonadherence a common problem among their patients, they are expected to provide valuable insights on the issue. The goal of this research is to get an understanding of the perspective of healthcare professionals on the causes of nonadherence and what their ideas are for medication information. This could provide guidelines for a new medication information product.

Method

This project, including the user research goal (chapter 3.1), was presented to about 25 HCPs who work at the Department of Obstetrics and Gynaecology at VUmc. At the end of the presentation, they were asked to answer the following questions:



1. *“What are the most important causes of pregnant women not taking their medication (correctly) according to you?”*
2. *“What ideas for a solution (for information provision) do you have?”*

Each person wrote down their answers individually on post-it's that were provided by the researcher. There were no limits to the number of answers and they got enough time to write them down. Afterwards, all answers were digitized. Similar answers were clustered into themes. The results are described below.

Results

Figure 16 gives an impression of the results that were written down on the post-it's. The results can be found in appendix C per theme.

Causes of nonadherence

A variety of answers were given, but overall there was a broad consensus about the most important reasons of patients not adhering to their medicines. The number one reason was that pregnant women are worried or anxious that the medicine may harm their child (23x). Fear of side effects for the patient herself was a less important indicated reason (5x).

Secondly, HCPs think women do not (clearly) understand or are not convinced of the importance or benefit/added value of taking the medicine (20x). They underestimate the relevance of a medicine. This may be related to the view that information about medicines that is currently provided to patients is insufficient (7x). They mentioned for example that information from the HCP or the patient leaflet may be too difficult, unclear or incomplete. Also, patients may forget the spoken information given by HCP or they receive contradictory information from HCP and pharmacist.

A reason related to unintentional behaviour is that women forget to take their medication (11x), possibly because of a change in their daily routine or pregnancy dementia. Other factors mentioned were morning sickness, which makes it difficult to take medication (4x), feeling uncomfortable taking medicines in general (2x), or the medicine does not help well enough (e.g. with a medicine that should prevent morning sickness)(1x). Besides, some patients do not feel ill (2x). For instance, women do not feel a high blood pressure, and consequently may not see the value of the medicine.

Ideas for medication information

Healthcare professionals had many ideas about solutions for the provision of information about medicines. First of all they mentioned that the (oral) information could be improved (10x), for example by explaining the relevance, indication, benefit-risk balance and how it helps the patient more clearly. This should include the risks when the patient would not take a medicine. Three HCPs mentioned that more time for consulting would help. During a consultation, gynaecologists could ask the patient her opinion about medicines (2x). This way, concerns can be addressed and fears can be taken away. A way to let patients remember the relevance of a medicine is to let them repeat the benefits in their own words (1x). To stimulate adherence over time, gynaecologists should check their medication use during next visits, ask their experiences and keep explaining the benefits/relevance of the medicine (3x).

Apart from oral information, HCPs had ideas about additional sources of information that patients can consult independently (self-help). For example, they mentioned that HCPs could provide patients with written information (e.g. a card or a leaflet specifically for pregnant women) or there could be a website or app targeted at pregnant women.

Possibly, such a product could already be used during consultations by HCPs to explain information about the medicine. Afterwards, patients could take it home (in case of a physical product) or HCPs could refer patients where to find (more in depth) information digitally, for instance by giving a card with a link. Another way to let patients remember the information better is to send an email or reminder to the patient with information. One person emphasized that there should be consistency in information provided by gynaecologists, obstetricians, pharmacists and general practitioners.

Overall, HCPs often mentioned that information should be short, to the point, written in understandable language and should include more visual elements like icons (11x). According to HCPs, risks should be explained in numbers and/or by using a clear classification system (5x). Visual elements could make more clear that a medicine is not harmful. Two people suggested to use the information from Lareb, since that is more targeted at medication use during pregnancy.

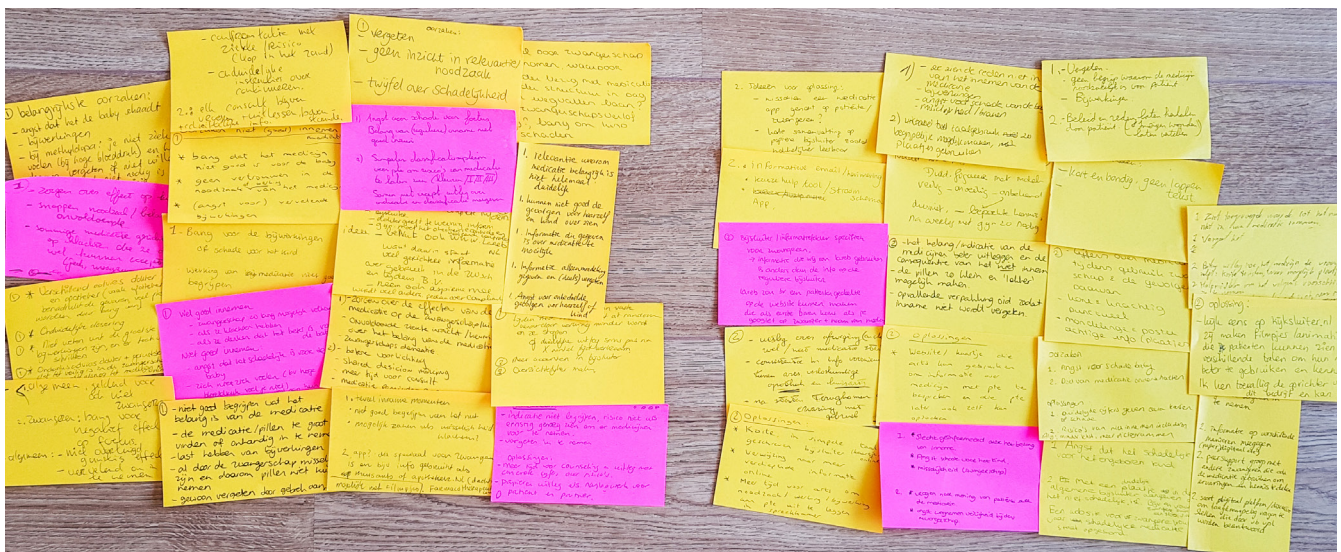


Figure 16. Results on post-its

2.2 INTERACTIONS BETWEEN HCPs AND PATIENTS

Research goal

In order to understand the process a pregnant woman goes through when visiting VUmc for a consultation and to get an impression of the interactions between patients and HCPs, observations were done during consultations at the outpatient clinic.



1. *What is the process like that a pregnant woman goes through at VUmc?*
2. *What matters are discussed during a consultation*
3. *What is the interaction like between patient and HCP?*
4. *What information does a gynaecologist provide to the patient and what questions do patients ask related to medication use?*
5. *What information does a pharmacist give to the patient and what questions do patients have?*

Method

In total 18 consultations were observed on three separate afternoons, with two different gynaecologists. The researcher was sitting next to the gynaecologist in the consulting room and did not intervene the sessions. Notes were written down only in between consultations and at the end of the day rather than during the sessions, to make patients not feel uncomfortable.

In addition to these observations, a short interview was conducted with a pharmacist at the pharmacy of VUmc to answer research question 5.

Results

Visiting the outpatient clinic

Patients regularly visit the outpatient clinic Obstetrics and Gynaecology to discuss the development of the child and condition of the mother with a gynaecologist. How often the patient visits the clinic depends on her situation. When there is more risk involved, the gynaecologist asks the patient to come back more often. Prior to the consultation with the gynaecologist, patients usually have another consultation where an ultrasound is made. This is done separately to focus on the conversation and to guarantee quality.

Discussion topics

Medication use is only one topic of discussion during a consultation of 15 minutes. The gynaecologist starts each consultation by asking the patient how she is doing. The patient's (mental) well-being and complaints or improvements in her condition are discussed. When the patient experiences any discomfort, the gynaecologist will explain potential causes, give advice on how to deal with it and/or prescribe a medicine.

Prescribing a medicine

When a new medicine is prescribed, the gynaecologist usually explains why (s)he prescribes it, what results (s)he hopes to achieve, how long the patient is expected to use the medicine and important side effects. This information is only addressed at that moment, not during later consultations.

Apart from explaining why the patient should use the medicine, there is usually no time to discuss the potential risks involved in a medicine. One of

the gynaecologist mentioned that HCPs will not easily prescribe a medicine without a good reason, especially not for pregnant women. So when they do prescribe one, they find it important the patient uses a medicine. Therefore, they primarily focus on explaining the benefits of the medicine in order to stimulate patients to use the medicine.

She also mentioned that she finds it annoying that patient leaflets say pregnant women should not use a medicine they have advised. Sometimes the gynaecologist would tell the patient that even though the patient leaflet says pregnant women should not use it, research indicates that the medicine is safe. However, this is only addressed when the patients seems very concerned or anxious. In general, this is not explained.

Note: The project was briefly discussed with a general practitioner, who pointed out that he sometimes specifically advises his patients to not look at the patient leaflet, since that will only frighten them.

Checking medication use

In general, gynaecologists always ask the patient about her medication use. This means that she will check what medicines she is using, how often she uses it and on what moment(s) of the day. This is done to check whether the medicines are being used correctly and to see whether the patient information in the system is still up to date. Additionally, the gynaecologist will ask whether the patient still has enough medicines, and prescribes one when necessary.

In case the gynaecologist is unfamiliar with a particular medicine (e.g. when it is prescribed by another doctor), (s)he consults Pharmacovigilance Centre Lareb (www.lareb.nl) or literature to find information about teratogenic effects, when preparing the session.



Figure 17. In the consultation room

Interactions

The gynaecologist always stimulates the patient to share their thoughts by asking “do you have any other questions?” or “do you want to share/say something?” (S)he is very careful and considerate towards the patient and shows empathy in difficult or uncertain situations. Moreover, gynaecologists try to explain everything in clear language so the patient understands the information.

It became clear that pregnant women put everything in their child’s best interest. The gynaecologist mentioned that she notices that in everything. So the questions that pregnant women have are primarily about whether something is harmful for their child. They are looking for certainty and want clear answers. The side effects of medicines for the patient herself is not important to her. The gynaecologist often tries to reassure the patient when there is no reason for concern. Sometimes she advises a patient to write down their questions or concerns at home for the next consultation.

At the pharmacy

Patients can pick up their prescription at the pharmacy of VUmc with the prescription form provided by the gynaecologist. This pharmacy is located in the same building close to the outpatient clinic of Obstetrics and Gynaecology.

The pharmacist usually starts a conversation by asking the patient to summarize what the gynaecologist already told her. Then the pharmacist fills in the gaps by providing additional information. The first time a patient uses a medicine, the pharmacist provides them with an A4 leaflet (discussed in chapter 1.4) and explains the information on it. The pharmacist is obliged by law to explain the risks involved with a medicine, even if the gynaecologist already addressed this. The pharmacist indicated that when patients have questions, it is often about the side effects of a medicine. The pharmacist mentioned that he has the feeling patients do walk around with questions, but do not know what to ask.

More information can be found in appendix D.



Figure 18. The pharmacy at VUmc

2.3 CONCLUSION

In line with literature research, HCPs think that a reason for pregnant women to not adhere to their treatment is that they are afraid of the risks for their child. Furthermore, HCPs believe that pregnant women do not understand the relevance or added value of a medicine. This may be influenced by the fact that other information sources stress the risks and lack the benefits of medicines, but also since information from HCPs may be quickly forgotten, as concluded from literature research.

The ideas for a new information product that were proposed by HCPs were used as inspiration for the design phase.

Since there is only little time for gynaecologists to discuss medication use with patients and because they want to stimulate patients to use a medicine when they prescribe one, gynaecologists focus on explaining the benefits of medicines rather than addressing what is known about potential risks of a medicine. On the one hand this is beneficial since this will motivate them to use the medicine. On the other hand, pregnant women may get confused and concerned when they would read conflicting information online or in the patient leaflet.

In follow-up consultations (i.e. after the medicine has been prescribed) the gynaecologist usually only asks practical questions about the medicine(s) the patient uses. The patient should bring forward their questions and concerns about medicines (e.g. regarding risks, why they need it) themselves, but it is unclear whether all patients would do this. User research should shed more light on the patient's perspective about the communication with HCPs.

3

User research

In order to design a product/service that fits the needs of pregnant women, user research is required. This will help to understand pregnant women's beliefs, concerns and perceptions towards medication use during pregnancy and will provide insight into their information needs. First, the research aim and research questions are described. The next part explains the research method, participants, procedure and analysis. Then the research results are discussed and visualized in a patient information journey. Finally, a conclusion is drawn which will provide important input for the design phase.

3.1 RESEARCH GOAL

In order to get a deep understanding of the experiences and needs of pregnant women related to medication use during pregnancy and the information about medicines, user research will be conducted with pregnant women. In addition to findings from literature and context research, these insights will be used as a basis for creating a design that fits the user's needs.

The main research question and the sub questions of the study are formulated on the right.

For this research, an application is done for the 'Medisch Ethische Toetsingscommissie' from VUmc.

Research questions



“What are the needs of pregnant women with regard to decision making about the use of medicines and the communication and information about these medicines?”

Sub questions

1. *What are the beliefs and attitudes of women towards taking medicines during pregnancy?*
2. *What factors influence pregnant women to take or not take a medicine?*
3. *At what moments do patients receive or seek information?*
4. *How do pregnant women currently seek information about medicines and how do they experience that?*
5. *How do pregnant women experience the current decision making process and communication about medicines with HCPs?*
6. *What information do pregnant women need and seek in order to make a good decision about medicines?*

3.2 METHODS

Contextmapping

The contextmapping method is used to get an understanding of the experiences, needs, emotions and concerns of pregnant women. Contextmapping is a method that uncovers underlying needs and motivations behind people's thoughts, feelings and actions that people may at first not be consciously aware of (Sanders & Stappers, 2012).

To gain insight in the reasons why people do, think, feel or want certain things, participants first need to become aware of those reasons themselves. Therefore, they are asked to fill in a sensitizing booklet before the interview. The booklet was used during the interview as a conversation starter and reference. By filling in this booklet prior to the interview, they could already think about the topic and become aware of their own experiences. Since they were prepared it was less likely that the interview questions would overwhelm them. This also made it possible to build upon their first

thoughts and dive deeper into their minds. By asking 'why?' multiple times, more interesting and valuable insights could be obtained.

Sensitizing booklet

Figures 19 and 20 show an impression of the sensitizing booklet. The complete booklet can be found in appendix G.

The sensitizing booklet includes five parts. First they were asked to introduce themselves by filling in their name, age, living situation, how long she has been pregnant and the reason why they are treated at VUmc (and not a regular obstetrician). This last question also formed the start of the interview in order to understand the patient and her situation.

In the next part of the booklet they are asked to map the persons that play an important role in their live and write down how they help. Then they had to write down what medications they use, what they use it for and how the decision to use it was made, including the considerations and the people who were involved.

In the third part, they filled in their medication taking process on a timeline (e.g. moments when they started, stopped or switched a medicine) and were asked to explain one positive and one negative moment.

In the last section of the booklet participants were asked to write down the questions or concerns they had, what information they received or searched themselves in the past.



Figure 19. Sensitizing booklets

1. Important persons

Step 1. Which persons play an important role for you during your pregnancy? Think about partner, family members, friends, doctors etc. Place the persons that are most important to you close to you on the map on the right, by using the stickers.

Step 2. Write down how every person helps. For example with making choices, mental support or giving information.

2. My medicine(s)

Step 1. Fill in below what medication you are using or used before during/before your pregnancy. These could be medicines prescribed by a doctor or medicines/vitamins you bought at the drugstore, pharmacy or supermarket. Optionally you can also fill in medicines you used during a prior pregnancy (when applicable).

Step 2. Think back to a moment when you (whether or not together with a doctor) decided to start, continue or stop using one of these medicines.

How did you make this decision?

Who were involved?

What were the considerations? (reasons to (not) start, stop or continue)

The medicines I am using/have used: The reason I use this/have used this:

The period I use(d) this: I find taking medicines during pregnancy easy/difficult because--

3. My medication process

Step 1. Fill in the timeline with decision moments that influenced starting or continuing with a medicine or not, or when something changes in your medication. The questions on the right and example on the right page may help you with this.

Step 2. Use the green and red stickers to indicate what moments in the timeline you experienced as positive and negative.

Step 3. Choose one positive and one negative moment and explain why you experienced it like that.

What were different decision moments?
 • What changed when you got pregnant or wanted to become pregnant?
 • Who were involved?
 • When did something change in your medication use and why?

Voorbeeld

What? Because...

What? Because...

before pregnancy pregnancy now

4. Information and communication

Think back to moments you received information, asked information or searched for information about one of your medicines you are using or used before.

What questions or concerns did you have about the medicine?

How did this information help you or not help you (for making a decision)?

What information did you receive from...
 • ...your doctor? • ...the pharmacist?

Did you search for information yourself? If yes, what information and how? For example in the package information leaflet, online etc.

Figure 20. Sensitizing booklet

Participants

Selection of medicines

For this research, a selection of medicines is made that are often used by pregnant women at VUmc. Thereby medicines are chosen whereby the patient has a choice whether or not to use a medicine, which would likely give more interesting insights than with medicines that the patient has to use for a specific medical condition (e.g. epilepsy). Furthermore, a requirement of the MEB was that the medicines that would be focused on in this research should be medicines of which the use during pregnancy is supported by the official product information of

the MEB. Although not officially approved, later it was decided that it is also interesting to include acetylsalicylic acid (Aspirin), since that is an often used by pregnant women at VUmc and a different type of medicine (i.e. a preventive medicine).

The selected medicines are:

- Emesafene
- Labetalol
- Methyldopa
- Nitrofurantoin
- Ferrofumaraat
- Folic acid
- Acetylsalicylic acid (Aspirin)

<i>Nr</i>	<i>Age</i>	<i>Pregnant</i>	<i>Nationality</i>	<i>Medication use</i>
P1	40	16 w	American	Methyldopa Acetylsalicylic acid (Aspirin) Vitamins (including folic acid)
P2	28	16+1 w	Dutch	Folic acid
P3	32	26+1 w	Bulgarian	Methyldopa Nitrofurantoin Acetylsalicylic acid (Aspirin)
P4	40	23+3 w	Dutch	Ferrofumaraat Cabergoline
P5	31	29+1 w	Dutch	Folic acid Propranolol*
P6	36	17+2 w	Dutch	Acetylsalicylic acid (Aspirin) Vitamins
P7	40	19 w	Dutch	Azithromycine Emesafene Sumatriptan*
P8	35	22+2 w	Dutch	Vitamins Ferrofumaraat Acetylsalicylic acid (Aspirin)
P9	35	17+5 w	Turkish	Acetylsalicylic acid (Aspirin) Vitamins Emesafene

Table 1. Participant information

Grey = Stopped using the medicine once pregnant or does not use it anymore
* = Only uses it occasionally

Participants

Nine patients participated in the research. From research it is known that this amount of participants is enough to research a data saturation point. Initially only Dutch patients would be included for convenience of research preparation, but later it was chosen to also include non-Dutch speaking patients in order to get more participants. Eventually six Dutch and three non-Dutch patients participated with varying medication use. Table 1 shows the information about the participants.

Recruitment

Prior to this research, an application was done for the 'Medisch Ethische Toetsingscommissie' of the VUmc. After approval, a list of 35 patients that were eligible for this research (i.e. patients that use one or more of the selected medicines) was made. Those 35 patients received an information letter with consent form at home with information about the research. This information letter and consent form can be found in appendix E and F. After a few days, all patients were called and asked whether they had any questions about the research and wanted to participate or not. When they agreed to participate, a date and time for the interview were set.

Procedure

A week before the interview, patients received the sensitizing booklet at home. An email was sent with additional information about the booklet and to ask whether they received it or not. Two interviews were arranged only a few days before the interview took place, so those patients did not receive and fill in the booklet.

In most cases, the interviews were scheduled after the patient's appointment at VUmc, for convenience of the patient. In one case, the patient preferred to have the interview at her home. One of the consultation rooms at the outpatient clinic was reserved as the place to conduct the interviews.

Interview script

At the start of the interview, the patient was asked to sign the consent form (if not yet sent before). Then the goal of the research was explained and some 'rules' were set (e.g. 'there are no wrong answers'). The interview started by asking how the participant experienced filling in the booklet, followed by discussing why the patient is treated at VUmc. The interview largely consisted of three parts. During the first part, participants were asked about their medication use and how they experience using medication during pregnancy in general (RQ1). In the second part, their experience with the decision making and information provision is discussed (RQ5). This included what information they received (RQ3; RQ4), what questions/concerns they had, what the determining factor was to take a medicine (RQ2; RQ6), what information they have searched themselves and their experience with the patient information leaflet (RQ4). The third part of the interview addressed the ideal information about medicines. For instance, participants were asked what information they find important to receive when making a decision about medicines and how they would want to receive that information. Also an idea about an app was proposed and discussed.

Although the interview protocol was divided in three parts, there was no strict order of the interview questions. New ideas and questions could be brought up during the interview as a result of what the participants said. The key was to keep asking 'why' in order to get to uncover underlying needs and motivations.

The interview script, both in Dutch and English, can be found in appendix H.

Data analysis

For the data analysis, the DIKW (Data-Information-Knowledge-Wisdom) method was used (Sanders & Stappers, 2012).

DATA

1. Transcribing

Each participant was given a code in order of the interviews to ensure anonymity. The interviews were recorded with a voice recorder. After the interview was conducted, a transcript was made of everything the participant and interviewer had said. Making transcriptions is beneficial since you can read much faster than listen to an audio file, which simplifies scanning the data for interesting passages in the next phase. Additionally, this makes it easier to notice trends and recurring themes among the different transcripts.

INFORMATION

2. Statement cards with insights

The next step was to analyse all transcripts. Interesting quotes were selected and put on statement cards. For each statement card, an interpretation of the quotes is made. This gives meaning to the data and turns it into 'useful' information. This resulted in 231 statement cards.

KNOWLEDGE

3. Clustering

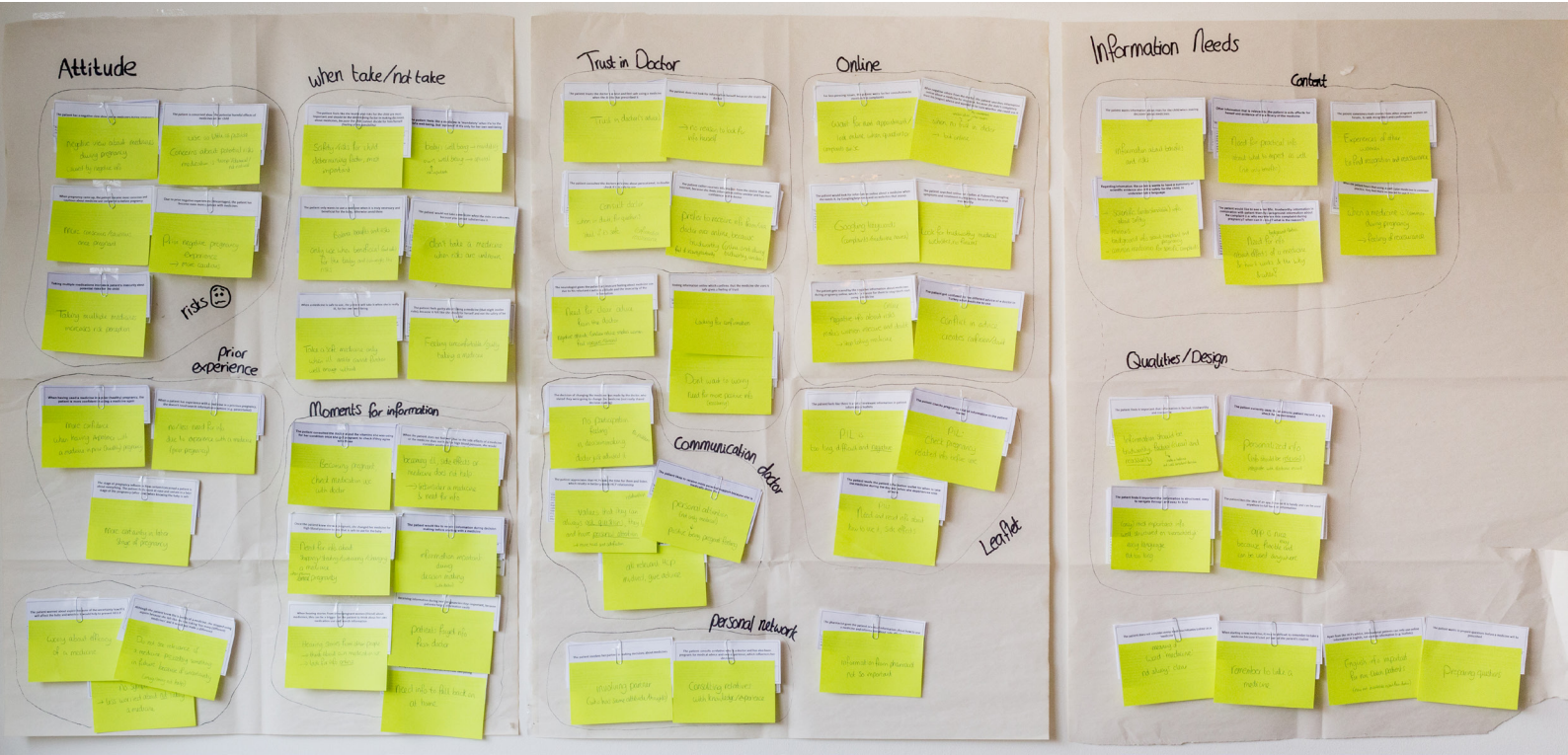
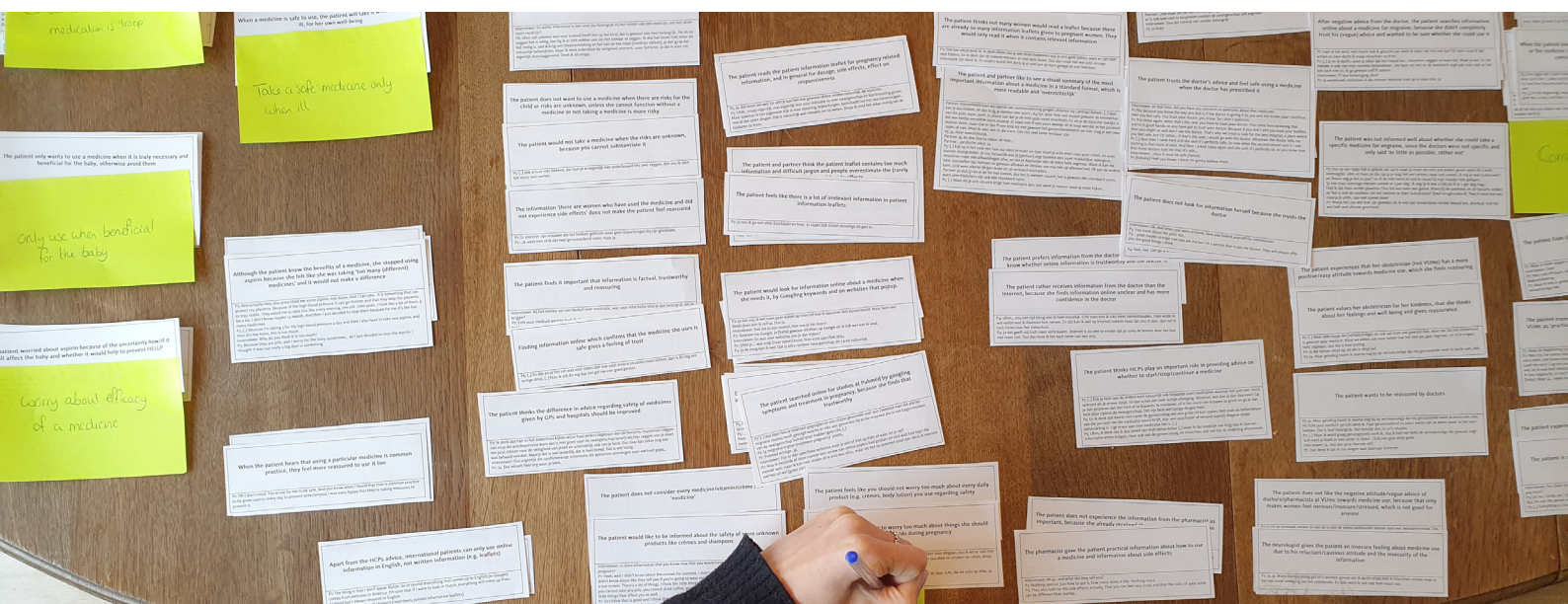
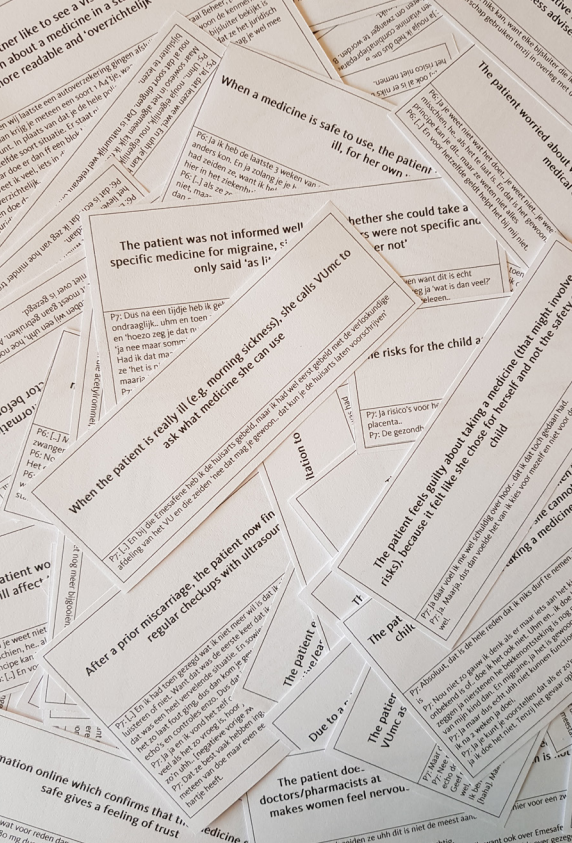
The next step was to structure and organize this vast amount of information. All statement cards were combined and matching insights were clustered. In this way the most important insights and themes could be identified. For instance, when a specific need was expressed by multiple participants, it was considered as an important insight to take into account. For each theme, a short description was written down on a post-it, as can be seen on the right page.

4. Communicating results

The identified themes were divided among the research questions. Each of these insights are discussed in the results on page 46-57, supported by the most interesting quotes that were selected from the statement cards. Next, a patient information journey was made, which is a visual representation of the results.

From the results, a conclusion could be drawn. The knowledge gained from user research was put together with the insights from literature and context research.

Figure 21-24. User research analysis



3.3 RESULTS

In this section, the results of the user research will be discussed. The results are divided per research question, and supported by interesting quotes of the participants. The quotes that were in Dutch are translated to English. The original quotes in Dutch can be found on the bottom of each page. In table 2, an overview of the themes and sub themes can be seen, along with the number of participants that said something about that theme.

Appendix I gives an impression of some interesting results from the sensitizing booklet that contributed to the results that will be discussed in this section.

In addition to a textual description of the results, a visual representation of the results was made. This patient information journey can be found on page 59-61.





<i>Themes and sub themes</i>	<i>Nr of participants</i>
 Attitude towards medicines	
Negative view about medicines	9
Concern about potential risks	9
Cautious attitude	9
Safety and benefits for child are most important	9
Guilt and discomfort	5
More confidence through experience and over time	4
Taking multiple medicines increases risk perception	3
 Moments when information is needed	
When getting pregnant	6
Planning pregnancy	5
When experiencing complaints or side effects	5
Concerns and doubts at home	5
Forgetting information and benefits	5
 Searching for information	
Trust in doctor('s advice)	9
Searching information online	8
Preference for doctor over online	8
Consult doctor for confirmation	4
Reading patient leaflets	3
Negative information online and in leaflets	3
 Communication with doctors	
Value involvement and personal attention of doctors	6
No participation feeling	5
Clear advice needed	1
 Information needs	
Information about risks and benefits	9
(Positive) experiences of other women	6
Background information about complaint and medicine	5
Qualities of design and information	4
App with personalized information	3
Practical information	3

Table 2. Overview of themes and sub themes and nr of participants that gave input for that theme



Attitude towards medicines

RQ1 - What are the beliefs and attitude of women towards taking medicines during pregnancy?

RQ2 - What factors influence pregnant women to take or not take a medicine?

Negative view about medicines

In general, women (and their partner) have a negative view about medicine usage during pregnancy. Medicines are considered as ‘chemicals’, ‘toxins’, ‘troep’ and ‘something unnatural’, which is unhealthy to the baby, while women want their child to get only healthy substances.

“I don’t like the idea of taking medication during pregnancy, because you know you have a baby inside and I don’t want to send the baby toxins and chemicals.” - P9

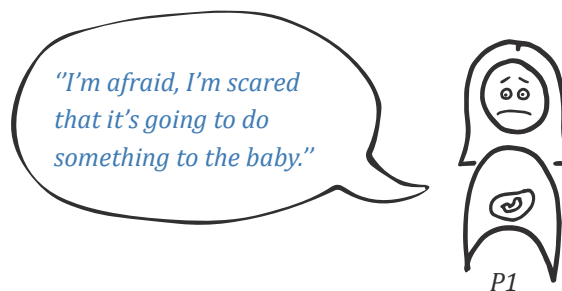
*“I think there is some sort of common view that during pregnancy nothing is possible. And everything seems to be a taboo. I think that is the norm and it is what people expect. And the contrary must be proven.” - P5**

Concern about potential risks

Overall, women are concerned and afraid about the potential risks of medicines on their child. This is mainly because they do not know whether it will affect the child or not, which is consequently caused by the uncertainty and lack of clear knowledge about potential risks of most medicines (since medicines are generally not tested in pregnant women). Women mentioned that they would generally not take a medicine when the risks are unknown. Their concern about the potential harmful effects of a medicine may be a reason for patients to stop with a medicine.

* “Ik denk dat er wel een soort algemeen beeld bestaat dat tijdens de zwangerschap niks kan. En alles eigenlijk taboe is. Dat is wel een beetje de standaard norm waar mensen vanuit gaan. En het tegendeel moet maar bewezen worden.” - P5

** “Ook al is er niks bekend, dan kun je er eigenlijk niet onderbouwd iets over zeggen, dan zou ik toch het risico niet nemen.” - P5



*“Even if there’s no knowledge [about risks], you still won’t be able to say anything substantiated about it, then I still wouldn’t take the risk” - P5***

Cautious attitude

Compared to before their pregnancy, women’s attitude and mindset changes once they become pregnant. They become more conscious and cautious and are extra alert about everything they take, including medicines. When women have had a negative experience with a prior pregnancy (i.e. miscarriage), they are even more cautious with medicines. In that case, they may think the use of medicines could have played a role in causing the miscarriage and they are motivated to avoid any possible risk and repetition thereof in the future.

*“Suddenly, there’s this psychological switch in your mind that makes that you’ll start taking everything into account” - P6****

*“Even with paracetamol I already think... hopefully this will turn out good. And I’ve already lost a baby of course.. back then I also had a lot of migraine and used a lot of medication so then I’m thinking.. what if that’s what caused it?” - P7*****

*** “Ineens komt er een soort psychische omschakeling in je hoofd die maakt dat je met heel veel rekening wilt gaan houden.” - P6

**** “Zelfs met paracetamol denk ik al.. ik hoop maar dat het goed gaat. En ik ben natuurlijk al een kindje verloren, en toen had ik ook heel veel migraines en ook medicijnen genomen dus ik dacht straks kwam het daardoor weet je wel.” - P7

Safety and benefits for the child are most important

Women want to use medicines as little as possible and only when 'necessary'. This means they will only take a medicine when it is beneficial for the child. When there is a clear benefit for the child, women are motivated to use a medicine. The safety and risks for the child are most important to women and are the determining factor in making decisions about medicines. Their own well-being is less important, unless it may affect the child's health as well. Taking a medicine for their own well-being feels 'optional' and something they can avoid, whereas a medicine that is beneficial for the child mostly feels 'mandatory'.

*"Yes, risks for the child, not even myself, but the fetus. The safety of the child is the most important" - P7**

"If I need to avoid any risk for the baby, for the baby's sake, this is mandatory. But the rest, and this one [Emesafene] is optional, it's just to avoid the sickness feeling" - P9

Only when women really do not feel well and/or cannot function well enough in daily life anymore, they would consider to take a medicine for their own well-being. For instance, one patient with severe morning sickness only used the medicine Emesafene when she had to attend to important meetings. Another patient eventually took a medicine for migraine, after laying in bed for multiple days without being able to take care of her other child. Since she was suffering badly she wanted to take a medicine.

*"After a while I called like.. I'm sorry, but you have to give me something because this is unbearable" - P7***

*"If the headache gets really bad then I'd take some paracetamol yes" - P8****

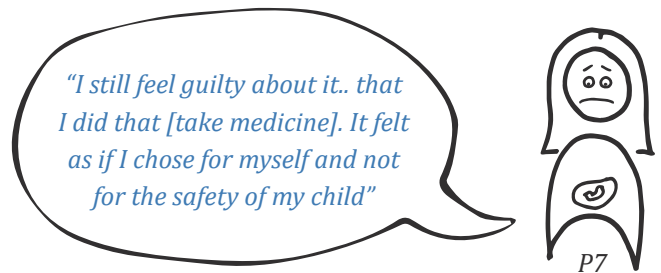
* "Ja risico's voor het kind, niet eens voor mezelf, voor de foetus. De gezondheid van het kind is het belangrijkste" - P

** "Na een tijdje heb ik gebeld van sorry maar je moet me echt iets geven want dit is echt ondraaglijk." - P7

Guilt and discomfort

Even though taking a medicine for women's own well-being could bring relief of symptoms or be more beneficial than risky, women may still feel uncomfortable taking a medicine. They sometimes feel guilty towards the child or find it difficult to accept they need a medicine. On the other hand, not being able to take a medicine for their own well-being because of potential risks for the child may make women feel uncomfortable about their own well-being.

*"At the start I really had some trouble with it, to have some peace of mind that it was really necessary.. That was really a big deal" - P6*****



Taking multiple medicines increases risk perception

When women are taking multiple different medicines, their perception of risks for the child increases, which may even result in patients stopping to take their medicine. When they already take a medicine for a certain condition, they become more reluctant to use a medicine for something else. One patient who was taking Aspirin decided to stop it when she was also taking medicines for high blood pressure and antibiotics at the same time, even though these can be taken all at the same time without further consequences. She did recall what the medicine was for, but still quit the medicine. This indicates that sometimes decisions are driven by emotions rather than a rational assessment of pros and cons.

*** "Als ik echt heel erg hoofdpijn heb dan neem ik wel een paracetamolletje ja." - P8

**** "In het begin heb ik daar wel echt moeite mee gehad, om daar een beetje vrede mee te krijgen dat het noodzakelijk was.. dat vond ik echt wel heel erg" - P6



P3

"Then I just decided to stop them because for me it's like too many medicines."

*"I already took that acetylstuff, so I was like I'm not going to throw in even more." - P6**

More confidence through experience and over time

When having used a medicine during a prior healthy pregnancy, women feel less worried and more confident in using a medicine again. Overall, women feel more certain and at ease about everything (including medicines) in a later stage of their pregnancy when knowing the baby is 'safe', since the first trimester involves more risk.

Influence of partner and other relatives

Patients mentioned that they always discuss their medication usage with their partner, but that they take decisions themselves. The partner usually has the same attitude about medication as the patient. When women have relatives, friends or colleagues with medical knowledge or experience (being in the same situation), they would consult them for additional information or to find confirmation. One participant mentioned she does take the opinion of her friend (who is always worried) with a grain of salt. Yet, the stories of these people can make women think about and reconsider their own medication usage.



Moments and reasons to seek information

RQ3 - At what moments do patients receive or seek information?

Planning pregnancy

When women plan their pregnancy in advance and consult this with their doctor, the doctor will advise on medicine usage for when they become pregnant. This was found to be nice by patients. This could concern women who are using a medicine before they get pregnant or women that should start taking a medicine once they become pregnant. For example, a patient who had a premature birth with a prior pregnancy was strongly advised to start using Aspirin around 8-12 weeks and received information about that beforehand. She found it important to know when she should start with the medicine, so she could anticipate and prepare questions for the doctor once it would be prescribed.

Especially when immediate action is required once a woman gets pregnant, receiving information upfront is essential. One patient was informed that she should quit her medicine directly once she got pregnant because of the risks involved for the child. Since the medicine was essential for her own well-being (avoid a benign tumor to grow) and it was uncertain how long it would take to become pregnant, it was chosen to quit the medicine as soon as she found out she got pregnant.

** "En ik slikte al van die acetylrommel, dus ik had zoiets van ik ga er niet nog meer bij gooien." - P6*

When getting pregnant or a medicine is prescribed

Even though it is beneficial for patients when they are informed upfront about what medication they should use or what changes they should make once getting pregnant, details about the medicine become more important when women become pregnant and a medicine is prescribed/changed. Before a pregnancy, women do not really focus on or think about these things, because getting pregnant first is priority. Receiving information during decision making with the doctor is found to be most important.

*"While you're not yet pregnant, you may think differently than when you are pregnant. You think like oh that will come later, I'd have to get pregnant first." - P6**

*"I think the moment you start to decide whether or not to take a medicine, when you are 1 on 1 with a doctor, as a matter of fact that's the crucial moment when you decide ah yes I'm going home feeling confident to take this medicine, I know exactly what it is for." - P8***

When experiencing complaints or side effects

Other moments when patients need information are when the patient gets ill or experiences new complaints, when her condition deteriorates due to the absence of a medicine or when she experiences side effects of a medicine. These are moments to (re)consider using a medicine and seek information about it. Women then may have questions about their complaint, what possible medicine she could use or what the benefits/risks are.

Concerns and doubts at home

After prescription by the doctor or before/while using a medicine, there may still arise questions or

concerns about the medicine when the patient is at home. For example, when women hear stories from other people about medicines or they read/hear something online or in the media, they may start to doubt their medication and look for information about it. Every piece of information patients receive about potential risks is likely to make women anxious and doubt their medication, which may lead them to stop using it. One patient heard about a new study that questioned the safety of paracetamol use during pregnancy and did not want to take it anymore after reading about it online. On the other hand, finding information online which confirms that a medicine is safe gives a feeling of trust.

"I asked one doctor and she told me it [paracetamol] was ok. Then I read it wasn't, you know they did a new study that the paracetamol is not as safe as they thought.. so I was kind of hmm I'm not going to take it."



Additionally, women may randomly have second thoughts about the safety of a medicine, possibly because they do not clearly remember the relevance of a medicine or were not reassured enough about the potential risks. One woman said that when you are pregnant, you become a little paranoia, which may also play a role in this. Besides, women could doubt or distrust the advice given by the doctor when (s) he did not show involvement in the patient and her complaint or when the advice was vague or unclear. These are all reasons and moments of patients to seek additional information, with the aim to find confirmation and reassurance about the safety of a medicine.

* *"Op het moment dat je nog niet zwanger bent, denk je anders dan dat je zwanger bent. Dan denk je oke dat komt wel, eerst maar zwanger zien te worden." - P6*

** *"Ik denk het moment dat je begint of moet besluiten ga ik dit doen of niet [medicijn nemen], als je 1 op 1 met een arts zit, eigenlijk is dat het cruciale moment waarop je beslist van oja ik ga met vertrouwen naar huis om dit te gaan slikken, ik weet precies waar het voor is." - P8*

Forgetting information and benefits

As was previously discussed on p.30, patients often forget the information they received from the doctor. For example, while planning her pregnancy, one participant received information about a medicine she should take once she got pregnant, but she forgot what was said about it once she needed the medicine. This likely happens on the short term as well. After a medicine is prescribed, patients could forget the relevance of a medicine or the benefits will fade into the background, as mentioned before. Their perception of the risks may easily increase because of external influences (others, media, online info) that only confirm their concerns.

*"I think it's good if there would be link to an explanation or a folder or something along those lines. Also to fall back on when you're thinking "what was it exactly?" Because you don't have 24/7 access to a doctor nor can you remember everything". - P6**



Searching for information

RQ4 - How do pregnant women currently seek information about medicines and how do they experience that?

Reading patient leaflets

Participants mentioned they consulted the patient information leaflet before using a medicine to read whether a medicine is safe to use during pregnancy. This is especially the case for over-the-counter medicines that are not prescribed by their doctor, e.g. cough syrup or paracetamol. Other reasons to read the leaflet is to find out how to use a medicine and about side effects. When it is unclear what medicine women can use during pregnancy from reading the

leaflet (which is often the case, since most leaflets say it should (better) not be used), they will call their doctor.

*"And then you may think "cough syrup" or "strepsils" are quite innocent, but when you look in the patient leaflet it still says you should not take it when you are pregnant, so I won't use it then. In that case I'd go to a HCP to consult which "cough syrup" I can use instead. - P4***

Trust in doctor('s advice)

Overall, women have a lot of trust in their doctor at VUmc and the advice (s)he gives about medicines. After the doctor prescribed a medicine, they usually feel safe to use it. Women often go with the doctor's advice on using a medicine or not. Therefore, women may at first not feel the need to look for additional information about a medicine at home.

"The way you feel is if the doctor is giving it to you and she knows your condition, then you feel safe. You trust your doctor, you know. So I didn't question." - P1

*"To be honest I've never looked into that because.. uhh I just take the doctor's word actually." P4****

Consult doctor for confirmation

Some women will call the doctor about their doubts and questions without looking online, for instance to check whether a medicine is really safe to use, or by asking what medicine she can use for for example morning sickness. Patients value that they can always call VUmc hospital when they have questions or concerns, which gives a feeling of reassurance.

"Of course you can always look online, but I never think about that because I know if I have some question, if something happens with me, I can always call." - P3

* "Ik denk dat het goed is als je een linkje naar uitleg of een foldertje of iets in die richting zou hebben. Ook om op terug te vallen op het moment dat je denkt van hoe zat het ook alweer? Want je hebt niet 24/7 je arts bij de hand en je kan niet alles onthouden." - P6

** "En dan denk je hoestdrank of strepsils is heel onschuldig, maar er staat dan toch op de bijsluiter dat je het niet moet nemen als je zwanger bent, dus dan laat ik dat wel staan. Dan ga ik wel naar een specialist om te vragen van welke hoestdrank je dan wel mag gebruiken." - P4

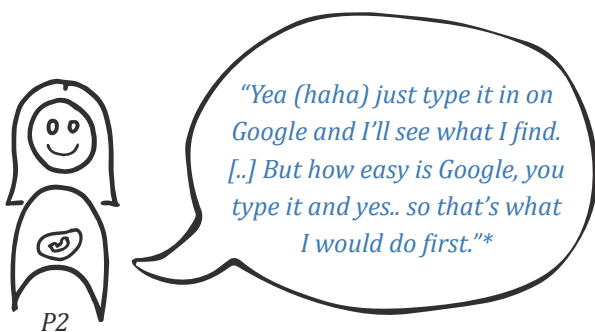
*** "Eerlijk gezegd heb ik me daar ook niet in verdiept want.. uhh ik neem dat gewoon aan van een arts eigenlijk." - P4

Searching information online

Other women will wait for their next appointment to ask their questions or mention their complaints and/or start to look for information online. For example because the doctor is unavailable at the time or the question is not of pressing importance and she does not want to bother the doctor. In some cases the patient may distrust the doctor's advice or question whether the doctor's knowledge is up to date. Pregnant women may also doubt when they have had a prior negative experience with advice from a doctor (who was not right in the end). These are reasons to look for additional information online.

Searching information online is experienced as an easy and accessible way to find information. Therefore patients search a lot online. They usually search with keywords (e.g. complaints or the name of a medicine) on Google. Most of the time, patients click on the website that appears to be most relevant to them rather than using a specific website. If women have experience in the medical field (e.g. due to their profession), they are more likely to search for specific websites such as the "farmacotherapeutisch Kompas". In general, patients do consciously look for reliable information and are aware that not all information online is trustworthy. They try to avoid forums because they know that is not trustworthy.

*"Just via Google. And then I'd type in my complaints or the name of the medication." - P4***



*"Yea (haha) just type it in on Google and I'll see what I find. [...] But how easy is Google, you type it and yes.. so that's what I would do first."**

* "Ja [haha] gewoon intikken op Google en ik kijk wel wat ik vind. [...] Maar hoe makkelijk is Google. Je tikt het in en ja.. dus dat gaat altijd als eerste." - P2

** "Gewoon via Google. En dan typ ik mijn klachten in of de naam van de medicatie." - P4

Preference for doctor over online

To conclude, patients prefer to receive information from/via their doctor rather than online, because they fully trust their doctor and often cannot judge the reliability of online information.

*"On the Internet there is so much to find that you no longer see the wood for the trees. So then I would rather hear it from a doctor. Yes that gives me more confidence." - P4****

*"I try not to search to much [online], because you'll find a lot of nonsense." - P6*****

"You come here believing that you're in good hands, so you have got to trust your doctor. Because if you don't and you trust your leaflets, then you might as well don't see the doctor." - P1

Negative information online and in leaflets

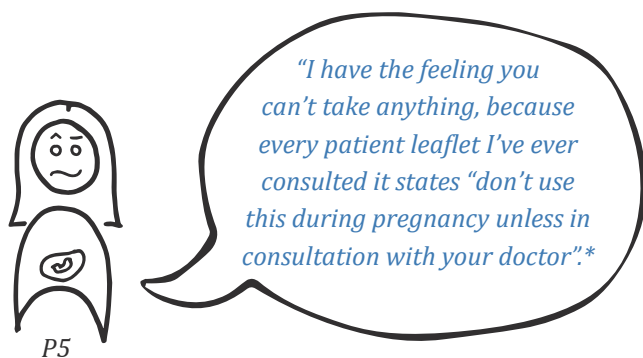
As discussed before in chapter one (literature research, p.30), the Internet usually stresses the risks rather than the benefits of a medicine. So once patients start to look for information online and find the "negative side" of medicines, they feel insecure and start to doubt their medicine. This likely pushes patients to stop using a medicine, as was the case with the patient reading about the new paracetamol study. One patient acknowledged this and mentioned trying to avoid looking for information online at all, because she thinks that doing so will only result in doubt and insecurity about a medicine. Overall, the conflict in information from the doctor versus information in leaflets or online creates confusion and doubt whether a medicine is safe or not.

Regarding the patient information leaflet, patients often felt like the leaflet is too long information, is difficult to read for most people and contains too much negative information or restrictive advice

*** "Internet is zo veel te vinden dat je soms de bomen door het bos niet meer ziet. Dus dan hoor ik het toch liever van een arts. Ja dat geeft mij toch meer vertrouwen." - P4

**** "Ik probeer niet te veel te zoeken [online], omdat je ook een hoop onzin tegenkomt." - P6

about side effects which frightens people. Another patient and her partner have the feeling they cannot use any medicine during pregnancy, because of the negatively framed information in the pregnancy section. One participant mentioned that she did not want to take the medicine Aspirin anymore after reading the patient leaflet. She also pointed out that the patient leaflet contains general information and does not say what it does for pregnant women. Thus, the information in the patient leaflet likely contributes to the cautious attitude of women towards medicines and their concerns about safety.



*"I can imagine that people just drop out [reading the patient leaflet] and think whatever.. Or on the other hand start reading all kinds of things and misjudge them." - P5***

*"I read the patient leaflet and I didn't want it anymore [Aspirin].. The patient leaflet is general, it is not targeted at pregnant women and what it does for them.." - P6****

* "Ik heb dus het idee dat niks kan, want elke bijsluiter die ik wel eens heb geraadpleegd staat er van 'niet tijdens de zwangerschap gebruiken tenzij in overleg met uw arts'" - P5

** "Ik kan me voorstellen dat mensen nu gewoon afhaken [bij de bijsluiter] en denken van nou het zal allemaal wel. Of aan de andere kant juist weer allerlei dingen lezen en ze verkeerd inschatten." - P5

*** "Ik heb de bijsluiter gelezen en ik wilde niet meer [Aspirine].. Die bijsluiter is algemeen, die is helemaal niet gericht op zwangere vrouwen en wat dat dan doet.." - P6



Communication with doctors

RQ5 - How do pregnant women experience the current decision making process and communication about medicines with HCPs?

No participation feeling

Multiple times women mentioned that they did not feel like they had participated in the decision making about the use of a medicine, because 'the doctor just advised it' or decided himself that the patient should change or take a certain medication. However, this did not seem to be a problem to them, because they were generally very positive about the communication with the doctors. Moreover, when a medicine is beneficial for their child, women felt they did not have an 'option' at all whether to take the medicine or not.

*"The moment when you start or have to decide whether or not you are going to do this.. that was not even an option in this case.. It was just like.. well the advice." - P8*****

"I couldn't say they gave me a lot of information. They just told me they were going to change the medication with some good one for the baby. And if I agree with this." - P3

Clear advice needed

One patient specifically mentioned that she wants the doctor to give clear advice about whether to take a medicine or not, rather than giving openly framed advice such as "try to use as little as possible, rather not". This confronts the patient with a difficult decision and would only cause the patient to feel more insecure and stressed.

"Just say if I can use it or not, don't make it such a... "you decide yourself what's best for your fetus". Don't make it

**** "Het moment dat je begint of moet besluiten ga ik dit doen of niet.. dat was nu op zich niet eens een optie. Het was gewoon.. nouja het advies." - P8

***** "Zeg gewoon ja het mag of niet, maar maak het niet zo'n... 'beslis zelf maar wat goed voor je foetus is'. Niet zo laten alsof het nog op voor decision making is voor jezelf. Dat is een rare Hollandse houding over medicijngebruik dus daar moeten die dokters even mee stoppen want het is gewoon of je geeft het of niet, klaar. Dat moet je niet bij de patiënt neerleggen. Want een zwangere vrouw is al zo onzeker." - P7

*seem as if the decision has to be made by yourself. That is a weird Dutch attitude towards medicine use so doctors really need to stop that because you give [advice] it or you don't. You shouldn't put that decision to the patient. A pregnant woman is already very insecure." - P7******

Value involvement and personal attention of doctors

Most patients are very positive about the communication with and attitude of doctors at VUmc. They appreciate that doctors take their time for them, listen to them and that they can always ask questions.

"I appreciate that from coming here to see that the doctors really walk you through the whole process. Whenever I come to an appointment, they take their time. They ask you many times if you have any questions, if everything is clear. That's awesome." - P1

*"Well, we have a very pleasant gynecologist. We really have good contact with him. You feel at ease to say whatever you want to say and ask and you always get good advice in return." - P5**

In contrast, another participant experiences the doctors' attitude and communication at VUmc as 'practical'/'medical' without consideration of the patient's feelings.

*"The doctor who did the ultrasound only said "lie down, watch, hmhm yea I see a kidney" And I was really emotional and she was like "what is it?" "yes what's is it?!, I'm just relieved, this is very exciting moment for me" "Well it doesn't have to be exciting" and I'm like well that's not up to you. But yea.. Veeery medical. Just really mechanically."***

* "Wij hebben een heel erg fijne gynaecoloog. Daar hebben we zo'n goed contact mee. Je voelt je op je gemak om alles te zeggen en te vragen en je krijgt ook goed advies van hem terug." - P5

** "Die dokter die die echo's deed zei echt alleen maar 'liggen, kijken, hmhm, ja ik zie je nier..'. Ik was heel emotioneel dus ik moest toen huilen, zegt ze: 'wat is er nou?' Nou ik ben opgelucht, ik vind het spannend!' 'nou het hoeft niet spannend te zijn' ik zeg nouja dat beslis jij niet. Maar ja... hééél medisch. Gewoon echt machinaal." - P7

One patient mentioned that she appreciates it if the doctor tries to get to know her, which fosters their relationship and builds trust.

"I think if the doctors take their time to know their patient, their relation would be much better. That will make me feel safe and trust my doctor." - P1

Women like to receive personal, and not only medical, attention from doctors at VUmc. This is something two patients valued about their obstetrician outside VUmc, who showed interest in her feelings and well-being.

*"If I compare it to my first pregnancy, then you come at the obstetrics clinic and you'll get a cup of thee and it's like "how are you doing?" [...] It's more personal. You really feel 'pregnant' and oh how nice I am going for my check-up again, and now I'm just thinking ah.. I have to go to the hospital again. A bit as if you are sick." - P8****

Another patient mentioned that because she didn't have a regular/fixed doctor at VUmc, she experiences the communication as less personal. Having the same doctor every time helps to build a good patient-HCP relationship, trust and mutual understanding.

*"You never know who you get. There's not a set point of contact. There are also different doctor assistants who you'll see for the first time. And that's a little.. less personal at times. In the preliminary trajectory I had a regular doctor who guided me and I found that véry nice. Then you really get a connection with the doctor." - P8*****

*** "Als ik het vergelijk met mijn eerste zwangerschap, dan kom je gewoon op de verloskundigepraktijk, dan krijg je een kopje thee en dan goh hoe is het? [...] Wat persoonlijker. Ja dan voel je je echt zo zwanger oh leuk ik ga weer op controle, nu denk ik oja ik moet weer naar het ziekenhuis. Een beetje alsof je ziek bent." - P8

**** "Je weet nooit wie je krijgt. Je hebt geen vast aanspreekpunt. Er zijn ook weer andere arts-assistenten die je dan weer voor het eerst ziet. Dat vind ik ja.. Weleens wat minder persoonlijk. Ik had in het voortraject gewoon een vaste arts die me begeleidde en dat vond ik héél prettig. Daar bouw je dan ook echt wel een band mee op." - P8



Information needs

RQ6: What information do pregnant women need and seek in order to make a good decision about medicines?

Information about risks and benefits

For pregnant women, information that is specifically focused on pregnancy is most important. Receiving information about the risks for their child is most essential. In order to make a balanced decision, patients further want to know whether the medicine is necessary for them, what the benefits are, as well as the consequences for themselves when not taking a medicine. Multiple participants specifically mentioned that they want to be informed about what is known from research about the safety for their child (i.e. scientific evidence) because they want to feel certain about whether it is safe, and scientific evidence is considered as trustworthy.

Next to concerns about potential risks, women sometimes worry about the efficacy of a medicine because of the uncertainty whether it will help or not. For example, two patients who used acetylsalicylic acid (Aspirin) were concerned whether it would be enough to prevent a premature birth or miscarriage. When the benefits for their situation are unclear, women may not see the relevance of such a medicine and therefore not take it.

"To me everything lies in the side effects, if it will affect the baby. To me that's the most important. And are the benefits for the baby?" - P1

*Whether it's possible during pregnancy.. Whether it is really important... like whether it's really necessary. - P2**

*"Then I'd like to know more about what influence it has on my child. When I would take the medicine. And If I would not take it what kind of influence would it have on me? And then I think you have to choose between two evils." - P4***

"I need to see that there is enough scientific evidence, that it's ok to use as a pregnant woman. I like to have a summary of research that anyone can understand, even though they are not people from the health sector." - P9

Background information about complaint and medicine

In addition to scientific information about risks, some patients mentioned wanting to be able to read more information about the complaints they have and the medicine they (will) use. Suggested questions to address are: Why do I experience a specific complaint? When may it occur? What is the reason? And what does a medicine do for pregnant women? Is the efficacy proven? How does it work? When to start and why? These women are specifically interested in the 'why' of things.

*"Really the specific, focused on pregnancy. "What does it do?", "Why do we give it?", "When do I start?" - P6****

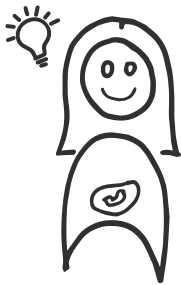
"I want to understand why they are giving it to me. I ask a lot. I interact with the doctor even if they don't want me to [haha]." - P1

* "Of het kan bij de zwangerschap... of het ook echt belangrijk is... of het ook echt nodig is zegmaar." - P2

** "Dan zou ik wel meer willen weten wat voor invloed heeft het op het kind? Als ik het zou slikken. En als ik het niet zou slikken wat voor invloed heeft het dan op mij? En dan moet je kiezen tussen twee kwaden denk ik." - P4

*** "Echt het specifieke, gericht op zwangerschap. 'Wat doet het?', 'Waarom geven we het?', 'Wanneer starten we ermee?'" - P6

*"On the one hand you have this abstract scientific and reliable information, but then a little more patient-friendly thing around it like.. Say you need medication for morning sickness, why am I experiencing this during pregnancy? In which trimester does it occur? What could be the reason? Is it the hormones? Just that sort of stuff which I get from those unreliable apps, "oudersvannu" etc. Well I actually really like those kind of apps."**



P8

to base their decision on, but to find recognition and confirmation ('is it normal/common what I experience?'). When reading positive stories of others who safely used a specific medicine or when hearing that a medicine is 'common' to use during pregnancy, women feel more confident and have more trust in using that medicine. One patient suggested to present the most commonly used medicines for a specific complaint.

*"That's just to find a bit of recognition, like uhhh confirmation of things you already know or something like that" - P4***

*"If the [gynaecologist] says Emesafene is used by thousands of women, never heard anything about it, yes then I say fine I'll take it and then I don't have to sweat about it anymore" -P7****

"When I heard that that is common practice to be given Aspirin every day to prevent preeclampsia, I was even happy that they're taking measures to prevent it." - P1

Practical information

Other, more practical, information that patients want to receive is the side effects for herself, so she knows what she can expect and what she might do about it when it occurs. This could help the patient to feel less worried once she experiences such complaints. Additionally, information about how and when to use a medicine is relevant as well.

(Positive) experiences of other women

Most women mentioned they (want to) read stories from other pregnant women about medicines and/or complaints they have experienced. Often not

Qualities of design and information

Patients want to see that information is presented in a well-structured way and is easy to find and navigate through. One patient and her partner mentioned that they like to see a summary of the most essential information, whereby text is supported with visuals (e.g. icons). Regarding the information itself, important qualities are that it is trustworthy, factual and reassuring, as was concluded from aforementioned results. Additionally, the information should be written in such a way that it is easy to read and understand.

** "Dat je aan de ene kant die droge wetenschappelijke goede betrouwbare informatie hebt, maar een wat patiëntvriendelijker ding eromheen dus als je zegt van nou medicatie voor misselijkheid, hoe kan het dat je tijdens je zwangerschap misselijk bent? In welke periode van je zwangerschap komt het voor? Wat kan de reden zijn? Gewoon dat soort dingen die ik uit die onbetrouwbare appjes haal, oudersvannu enzo, dat vind ik van die heerlijke appjes en daar staan ook dit soort dingen uitgelegd. Zoiets geïntegreerd ofzo." - P8*

*** "Dat is gewoon om een beetje herkenning te vinden, of uhhh bevestiging van dingen die ik al weet ofzo" - P4*

**** "Als ze [gynaecoloog] zegt Emesafene dat gebruiken echt duizenden vrouwen, nog nooit iets over gehoord, ja dan zeg ik prima dan neem ik het en dan hoef ik er niet meer over te zweten." - P7*



"I notice I really like to be reassured.. So preferably the obstetrician just says something along the lines of "ah girl, you don't have to suffer.. relax, this always goes well."

"I would find that [experiences of other woman] pretty nice, but it should not be like a Viva forum. That's important, there has to be some kind of credibility to it."
-P7

App with personalized information

Participants were positive about the proposed idea of an app with personalized information. They liked the idea of an app in general, because you can consult it any time anywhere. Patients find it important that the information they receive is relevant for them.

*"I think an app is most useful. Because then you can just always look it up. I've just now installed a new app from the "voedingscentrum" called "ZwangerHap". That's about what food I should or should not take. I usually know this but it's still useful. Like what if you're in a restaurant and you suddenly start to doubt, then you just type it in and see what they know about it. What they advise."****



*"An app is even better because then you get rid of the paper trash. Almost everyone has a smartphone or a tablet at home, its quick and easy. Paper is also nice but you can't access it everywhere". -P6*****

*"There are already a ton of folders around. I think most people don't even read them. So it has to be very useful information, otherwise it will easily be put aside without being looked at". - P2******

* "Ik word graag gerustgesteld merk ik.. Dus ik heb het liefst de verloskundige die gewoon zegt 'ach meid je hoeft er niet onder te lijden'. Chill.. Het gaat altijd goed." - P7

** "Ik zou dat [ervaringen van andere vrouwen] wel prettig vinden, maar dan zou het niet een Viva forum gehalte moeten zijn. Dat is belangrijk, dus er zou wel enige betrouwbaarheid aan moeten hangen." - P7

*** "Ik denk dat een app nog wel het handigste is. Want dan kan je het gewoon altijd opzoeken. Ik heb net een nieuwe app geïnstalleerd van het voedingscentrum, ZwangerHap. Dat gaat over wat voor voeding ik beter wel of niet kan nemen. En dat weet ik op zich wel maar ik dacht het is altijd handig. Stel je zit opeens in een restaurant en je twijfelt ineens, dan kan je gewoon zo dat intoetsen, en dan krijg je dus wat ze daarover weten. Wat ze adviseren." - P5

**** "Een app is nog mooier want dan heb je geen papieren rotzooi. Bijna iedereen heeft een smartphone of tablet in huis. Snel en makkelijk. Papier is ook prettig maar niet overal raadpleegbaar." - P6

***** "Er zijn al héél veel folders. Ik denk dat de meeste mensen ze niet eens lezen. Dus dan moet het wel echt zinnige informatie zijn, anders wordt het al snel aan de kant gelegd en niet bekeken." - P2

3.4 PATIENT INFORMATION JOURNEY

The previously discussed results of the user research are translated in a patient information journey, which is visualized on the next pages. The information journey describes the use of different information sources on several key moments before and during pregnancy, as well as positive and negative aspects of these sources. Additionally, the thoughts and emotions throughout this journey are illustrated. Finally, opportunities or ideas that could be included in the design are described on the bottom. There are based on the experiences, needs and positive and negative aspects of the information sources described above the opportunity.

Important to note is that this is not necessarily *the* information journey that all pregnant women go through, but rather an overview of all possible key moments where medication information could play an important role. Pregnant women could ‘start’ anywhere in the journey.

Figure 25 shows possible scenarios of medication use among pregnant women with moments when pregnant women (re)consider to start, continue or stop using a medicine.

In the patient information journey, the key moment that will be used as a starting point for the design has been highlighted (main focus). Eventually, the final design also addresses the moment when complaints arise, which is also highlighted in the journey (additional focus). This will be discussed in chapters 5 and 6.

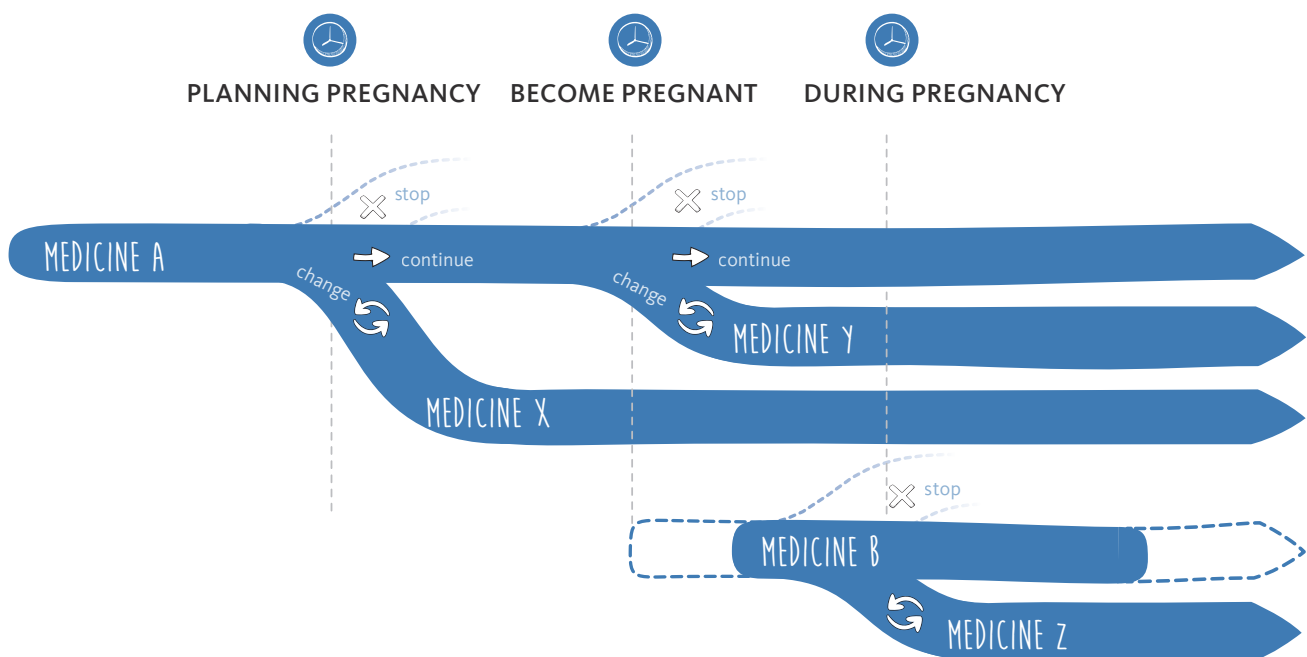


Figure 25. Scenarios of medication use



Moments

At VUmc

CONSULTATION WITH DOCTOR

Discussing medication adjustment

HCP

Doctor gives advice on whether to stop, continue or change a medicine before or once getting pregnant



Trustworthy
Involvement and personal advice
Clear advice



Information feels not yet relevant and is easily forgotten

Doctor gives advice on whether to stop, continue or change a medicine and makes a prescription when necessary

Pharmacist



Sources

Online

Leaflets

Other



Thoughts and Emotions

about medicines

positive



negative



Information will come later. First, I have to get pregnant..



What vitamins should I take?



I need to be more careful with medicines



What should I do with my medication?

What did the doctor explain again..?



Will the medicine be enough to prevent adverse effects? Will it be effective?



Opportunities



- Inform women upfront about safe medicines for their condition
- Give advice on what vitamins to take



- Provide information that pregnant women can read back at home at a later moment
- Explain the effectiveness of a medicine

DURING PREGNANCY

Moments

At home

GETTING COMPLAINTS
OR BECOMING ILL

At VUmc

DURING REGULAR CONSULTATIONS
WITH GYNAECOLOGIST

HCP

Pregnant women call their doctor what medicines they can take because other sources are unclear. The doctor gives advice and sometimes prescribes a medicine

- Trustworthy
- They can call any time
- Involvement and personal advice
- Clear advice
- Higher threshold to contact, questions may not seem important enough to contact doctor

Gives information and advice about complaint and medicine she should take, stressing the benefits

- Trustworthy
- Reassuring
- Involvement and personal, clear advice
- Not always same HCP --> less personal

Pharmacist

Explain side effects, how to use a medicine, risks of medicines during pregnancy

- Sometimes conflicting or double info --> not much value for patient
- Conservative attitude

Sources

Online

Pregnant women search on complaints via Google to see what medicine they can take

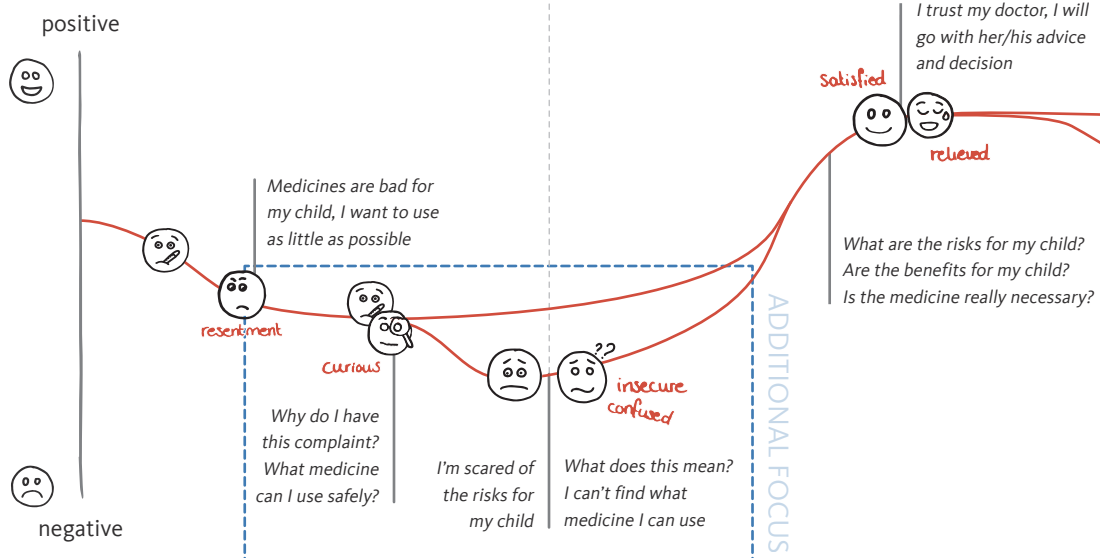
- Very accessible and convenient
- Information overload
- Trustworthiness unknown
- Not tailored to pregnant women --> hard to find desired information

Leaflets

Patients read pregnancy related information about OTC medicines, e.g. cough syrup

- Accessible
- Trustworthy
- Reticent, unclear advice that is difficult to understand
- Information overload
- Not tailored to pregnant women

Thoughts and Emotions about medicines



Opportunities



- Overview of commonly used medicines for specific complaints
- Background information about complaint during pregnancy



- Make sure women know where they can consult trustworthy information
- Allow easy access to information product



- Providing information from/via doctor could give a feeling of trust



- Factual, personal information about benefits and risks for both mother and child
- Ensure realistic risk perception

At home (using a medicine)

START USING THE MEDICINE

EXPERIENCING SIDE EFFECTS

DOUBTS ABOUT SAFETY ARISE

due to stories from others, media, negative information

Patients may call their doctor to ask for an alternative medication when side effects are unbearable

Some patients call their doctor to discuss their concerns

Doctor reassures patient by saying the medicine is safe and common use among pregnant women

👍 Doctor's advice is reassuring
Hearing how common use a medicine gives reassurance

👎 Higher threshold to contact

Googling medicines and risk information

Looking for confirmation and reassurance about safety

👍 Very accessible and convenient
Positive experiences of others gives reassurance

👎 Negative information focused on risks
Conflict with doctor's advice

Check pregnancy related information and how to use the medicine

👍 Accessible
Trustworthy

Read about side effects

👎 Hard to find and read
Negative info focused on risks

Discuss medication use with partner and friends with medical knowledge or experience with pregnancy

How should I use it?
Let me check the leaflet what it says about pregnancy

This medicine is not working for me..

If many others used it, it should be ok

Fjoe, the baby is safe

guilt
uncomfortable
conflicted
I feel guilty towards my child, I don't want to use this medicine but I have to

Is the medicine really safe..?
Was the doctor actually right?

concerned

anxious
confused

I'm not going to take it anymore

reassured

MAIN FOCUS



→ Practical info that is well-structured, understandable, tailored (relevant) to pregnant women and can be consulted at home

→ Information that is easy to find and read



→ Make sure women remember or can read back the benefits/relevance of a medicine at home

→ Give women a feeling of security and reassurance



→ Use experiences of others to give a feeling of reassurance and trust, or how common use a medicine is

3.5 DISCUSSION & CONCLUSION

Similar to the findings from literature research, the user research has clearly shown that pregnant women are afraid of the potential risks of medicines on their unborn child and therefore want to use them as little as possible. Overall, they seem to overestimate the risks involved when taking a medicine compared to their perception of risks when not taking a medicine. Women put the needs of their child first and are only motivated to take a medicine when there is a clear benefit for their child. Therefore, pregnant women find it important to be informed about not only the benefits of a medicine, but also the potential risks for their child. They want to see evidence from research in order to feel certain and have trust in a medicine.

Receiving information is especially important when a medicine is prescribed by the doctor or when complaints arise. Pregnant women generally have a lot of trust in their doctor at VUmc and therefore follow their advice about using a particular medicine. Pregnant women value a doctor who shows personal involvement in their situation, gives clear advice about whether to take a medicine or not and has a more positive attitude towards medicines. These aspects increase their confidence in using a medicine.

However, before/while using a medicine at home, **women easily become concerned and doubtful about whether their medicine is really safe.** This could happen for instance because they do not clearly remember the relevance of the medicine, or they may be influenced by other people's opinion or the media. Consequently, they are **seeking confirmation and reassurance** from their doctor or different sources of information. Many women just 'Google' to search for information because that is convenient, or consult the patient leaflet before using a medicine.

However, as was previously concluded in chapter 1.5, the 'negative' information and reticent attitude in those sources only confirm the doubts women already have and make them even more insecure,

confused and concerned. This is further increased by the conflict with information from the HCP, who stresses the benefits. This is illustrated in figure 26. As a result, they often quit using the medicine or continue using the medicine with an uncomfortable feeling.

On the one hand, it may be beneficial if the doctor informs women not only about the benefits (which is currently the case), but also the known risks and how these are communicated in other sources (e.g. in leaflets). 'Preparing' women in this way may eventually make patients less vulnerable to doubt and concern once they come across such information. On the other hand, considering their anxiety about safety and the likelihood of overestimating risks, **women need to clearly know and remember the benefits of a medicine for their situation and why the doctor advised them to use it,** which is currently missing in leaflets and online websites. This should **give women more trust and confidence in using a medicine.** Therefore, and since in general information from the doctor is easily forgotten, **pregnant women could benefit from an information product that they can access independently at any time which includes such information.** Such a product would also be beneficial when complaints arise and pregnant women want to know what medicine they can use. This information is currently lacking.

Pregnant women were positive about the idea of an application on your phone with information about medicines, since you can access it anywhere at anytime. Apart from being flexible, an application provides more opportunities to communicate information in a structured way and only offer relevant information that is prioritized according to the needs of pregnant women. Information can also be updated easier, for instance when there is new knowledge about potential risks or when there is more experience with a medicine. Therefore it was concluded that the design will be an application.

The application should mainly include information about when and why a medicine is important for pregnant women and their child as well as evidence based information about risks. It should make clear how the benefits outweigh potential risks, or vice versa in case of an unsafe medicine.

Additionally, women could get more confidence when reading positive experiences of other women or how 'common' use a particular medicine is among pregnant women. Since women have a lot of trust in their doctor, involving the doctor in the design would be beneficial. Finally, the information should be consistent with what the doctor tells them to avoid confusion.

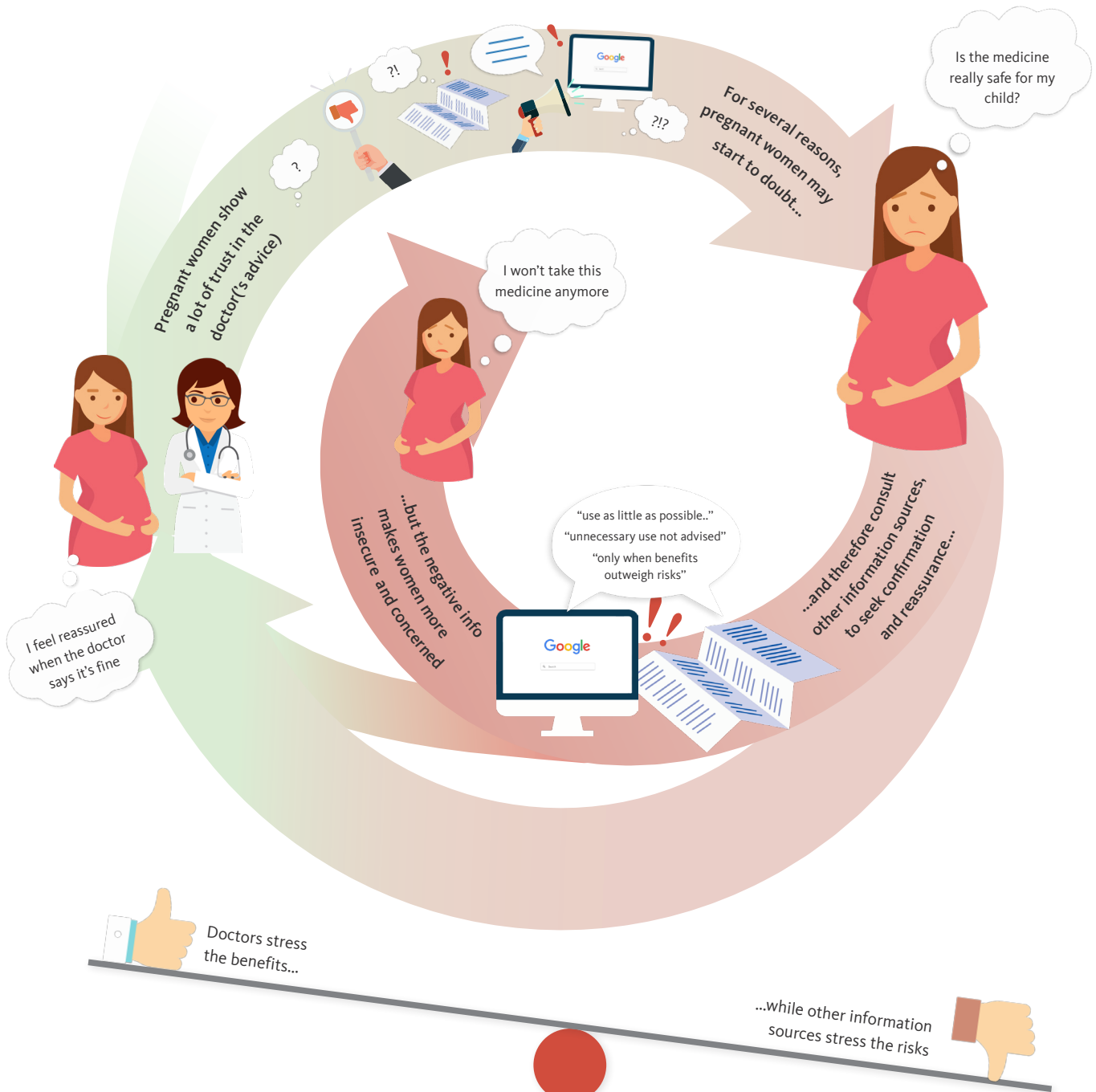


Figure 26. Imbalance between information from HCP and in leaflets & websites, causing doubt and anxiety

3.6 LIMITATIONS OF THE STUDY

Four participants were working in the medical field and therefore had more knowledge about where to find trustworthy information (e.g. *farmacotherapeutischkompas*). The general population likely does not know and consult such sources. This has been taken into account further in the project.

Two participants did not fill in the sensitizing booklet, since they were recruited only a few days before the interview took place. Therefore there was no time to send the booklet. As a result they were less 'sensitized' (prepared) about the topic which might have led to less interesting insights than would have been the case otherwise. However, during the analysis it became clear that this did not have a negative effect since those participants actually gave really interesting insights.

Some parts or questions in the sensitizing booklet were experienced as double by participants. For instance, with the timeline (part 3) it felt like they had to fill in the same information as in the part about their medication use (part 2). As a result, some participants did not fill in the whole sensitizing booklet. In hindsight, in part 1 about their personal network, putting more focus on the role of people on making decisions about medication use rather than on their whole pregnancy might have given more useful insights. Overall, participants noted that filling in the booklet made them more conscious about their medication use and the information they received and sought, which has probably made the interview results more valuable.

For this research, specifically patients who were using a medicine at that moment were selected. Eventually it turned out that some participants were not using a medicine at the moment of the interview. Still, they had been using a medicine before their pregnancy or during an earlier period of their pregnancy, which gave interesting insights as well. So in retrospect, it did not really matter whether the patients were using a medicine or not at the time of the research.

4

Design brief

The literature research, context research and user research provided important guidelines for the design, based on positive and negative aspects of existing information sources, and gave valuable insights into the information needs of pregnant women. The design brief entails a more specific design goal, gives an overview of the current and desired interaction qualities between pregnant women and information sources and states a list of requirements and wishes that help in shaping the design.

4.1 DESIGN BRIEF

Based on the knowledge gained from research, the initial design goal can be more specified to form as a good starting point for the design phase. The original design goal was:

“Design a medicine information product/service that supports pregnant woman in the decision making about the use of medicines during pregnancy, in order to improve patient experience and encourage better use of medicines”.

The new design goal is:



*“Design a product service system, including a **digital application** that informs pregnant women about the use of medicines during pregnancy. The HCP should guide pregnant women to use the application, which can be consulted at **any time** they are in **doubt** about the safety of their medicine. The application should communicate **balanced information about both the benefits and risks** of a medicine for the mother and unborn child. This allows pregnant women to make an **informed decision** and **feel confident** about using a medicine during pregnancy.”*

4.2 INTERACTION VISION

In addition to the design goal, which describes what effect should be achieved through the design, the interaction vision is formulated, which specifies how the interaction between pregnant women and the design should be. This is described in the form of 'interaction qualities', which are words that describe the character of the intended interaction. Based on the research results, the interaction qualities between pregnant women and information sources in the current situation can be described, as well as the desired interaction qualities for the new design. This provides guidance for the design of the application, as well as how it is used in context.

Current interaction qualities

There is a difference in the current interaction between pregnant women and their doctor on the one hand and women and leaflets/online information on the other hand.

The ideal interaction with the doctor (and the information given by the doctor) is **considerate**, **personal**, **involved**, **trustworthy** and **reassuring**, yet sometimes **restrained**.

The interaction with online information (in general) and the patient leaflet is comparable. It could be described as **complicated** (information is hard to find and read), **unnerving** (negative, frightening information), **confusing** (unclear information in conflict with information from doctor) and **impersonal** (not focused on a specific (group of) patients, not always patient friendly). On the positive side, they are easily **accessible** and the patient leaflet is considered as **trustworthy**.

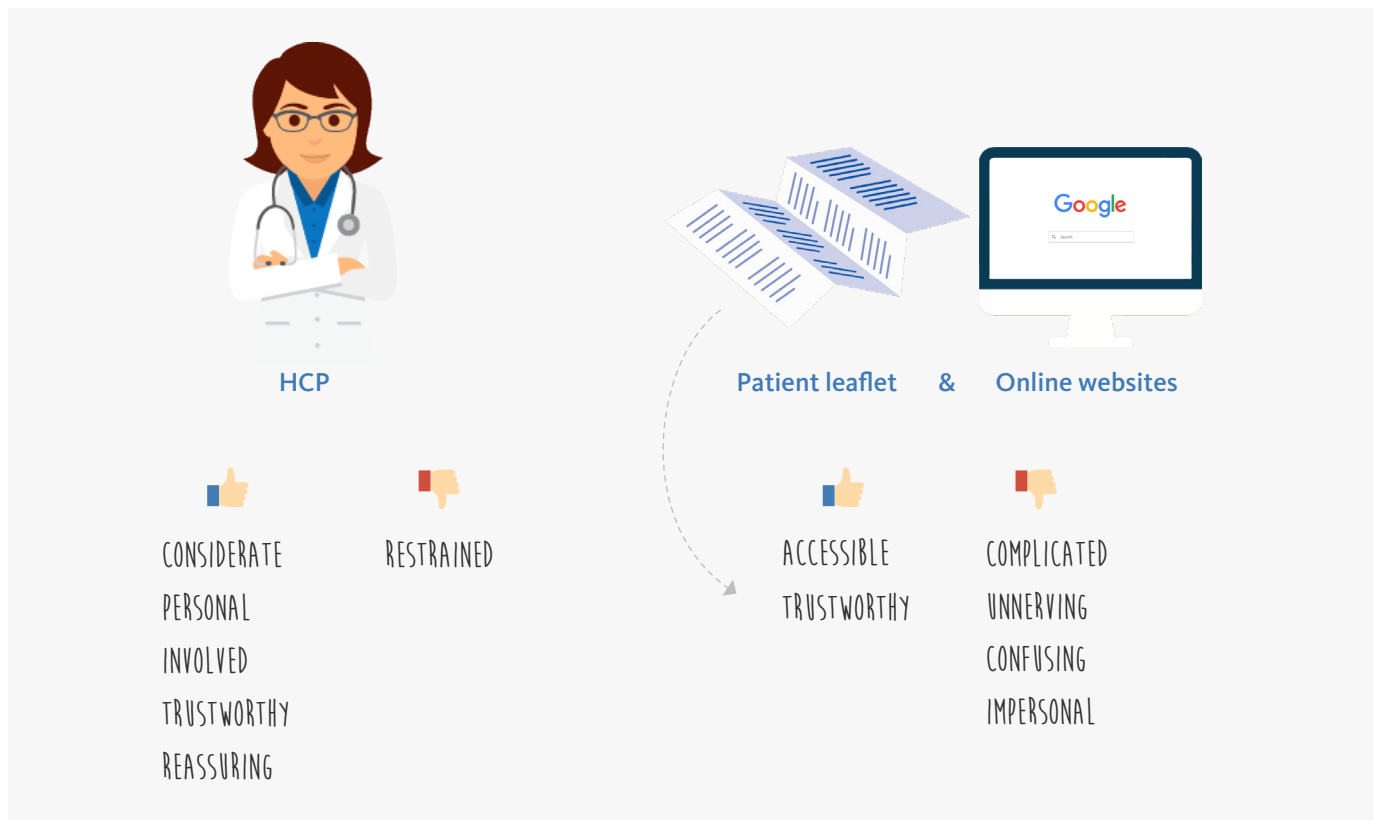


Figure 27. Current interaction qualities

Desired interaction qualities



Transparent

In order to feel confident in using a medicine, pregnant women should understand why a medicine is relevant for them. This does not mean risk information should not be given. The point is that when pregnant women are well-informed about both benefits and risks, they can make a reasoned assessment for themselves of whether the medicine is important for them and whether they want to use it or not (thereby supporting the doctor's decision to use it). Therefore, the product should be transparent about all relevant information.



Balanced

In order to make sure pregnant women have a clear perception of the actual benefits and risks, these should be communicated in a balanced way. It should be clear when and how the benefits outweigh the risks. Therefore should be carefully considered what information precisely should be given and in what way this should be communicated (e.g. in the right tone of voice).



Personal

Pregnant women should get the feeling the information is meant personally for them, which is more likely to result in a feeling of trust and confidence. In order to understand why a medicine is relevant for the patient, the information should be tailored to pregnant women and preferably the patient's individual situation.



Accessible

The new information product should be easily accessible for patients. This is a valued positive aspect about the Internet and the patient leaflet as sources of information. This means that pregnant women should not have to put much effort in finding and accessing the product as well as the specific information they are looking for within the product.

Additionally, every type of user should be able to understand the information. Therefore, it should be written in a user friendly way without complicated medical terms.



Intuitive

The interaction between patient and the product should be intuitive. This means patients should be able to navigate through the product and find, read and understand the desired information in a natural, intuitive (automatic) way, without taking much effort.

4.3 LIST OF REQUIREMENTS

Requirements

Accessibility

- 1.1 The product should be easy to access, anytime at any place

Information content

- 2.1 The product should include information about the risks and benefits when taking and not taking the medicine, for both mother and child
- 2.2 Information should focus on the relevance of a medicine for someone, but without withholding risk information
- 2.3 The product should include available evidence about risks from scientific research or experiences in clinical practice
- 2.4 The product should only include information that is relevant to pregnant women
- 2.5 The product should give patients a feeling of trust and reassurance in their medicine (if the medicine is prescribed by the doctor)
- 2.6 The product includes practical information about how to use the medicine (i.e. dosage, what moment(s) of the day to take it etc.), contraindications, side effects etc.
- 2.7 The information should be consistent with the information provided by the doctor
- 2.8 The information must be complete in the sense that it should not raise further important questions

Communication

- 3.1 The design and communication should make sure pregnant women have a realistic perception of benefits and risks
- 3.2 The product and information should give the user the feeling they can trust the information

- 3.3 Pregnant women should have the feeling the information is directed to them personally
- 3.4 The information must be written in an objective way
- 3.5 The information should be understandable for laypersons without medical knowledge

Design

- 4.1 The information is visually organized using a hierarchy of information, whereby the most important information is most prominent
- 4.2 Information about benefits and risks should have priority and therefore be prominent
- 4.3 The product should not present an overload of information
- 4.4 Information is well-structured and organized
- 4.5 The desired information is easy to find and the product is easy to navigate through

Wishes

1. The information is tailored to the patient's individual situation
2. The product presents as little text as possible at once
3. The product contains or refers to background information about complaints related to pregnancy
4. The product informs about commonly used medicines for specific complaints
5. The user can access the product and find information with a minimum amount of effort
6. The product is applicable for different types of medicines (e.g. prescription drugs and OTC drugs)
7. The product is useful for all pregnant women
8. The product design is applicable for other patient groups

5

Conceptualization

The design goal, interaction vision and requirements form the starting point for the design phase. This chapter discusses the conceptualization of the product service-system. The first section gives an overview of the design process and discusses the ideation phase. Then the process of writing the information is described, followed by the design of the application. Finally, two scenarios are proposed for how pregnant women will be guided to use the application and how the information will be addressed during a consultation.

5.1 IDEATION

Figure 28 gives an overview of the design process.

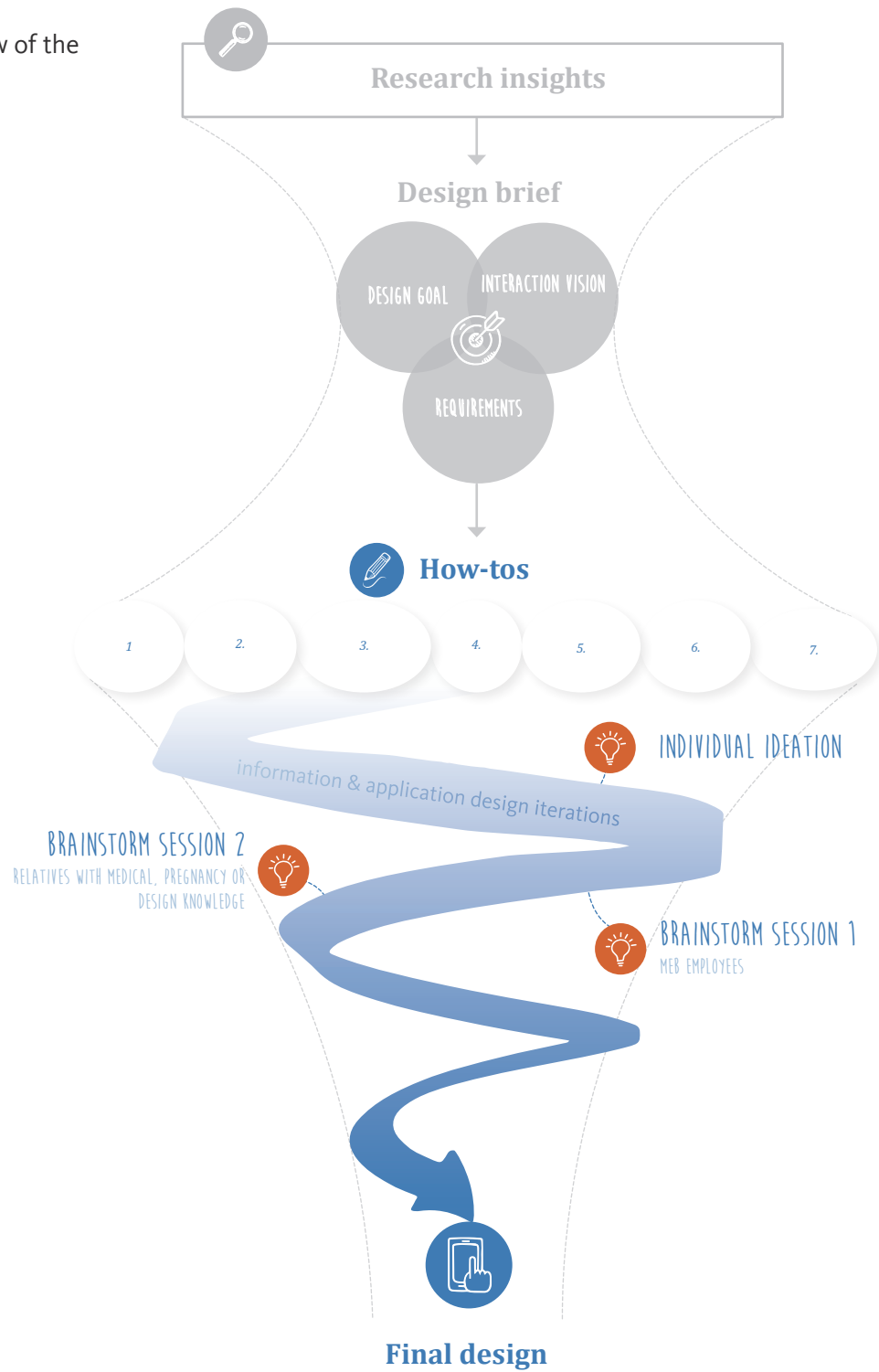


Figure 28. Design process

Design elements

The design and ideation consists of four different components, see figure 29. First of all, the information the product provides has been written, including both the content of information as well as how this information is communicated (i.e. writing style, structure). Secondly, ideas are created for the design of the product, which involves the visualization of the app and the information, in

addition to how the user interacts with the product. The third category is about the context of use, including how the product reaches the patient and possible use scenarios. The last and fourth part involves the product's potential to be applicable for multiple types of medicines and patient groups. This addresses the product's feasibility and viability, including its usefulness for the MEB. Since this is partly out of scope, the primary focus is on the first three components.

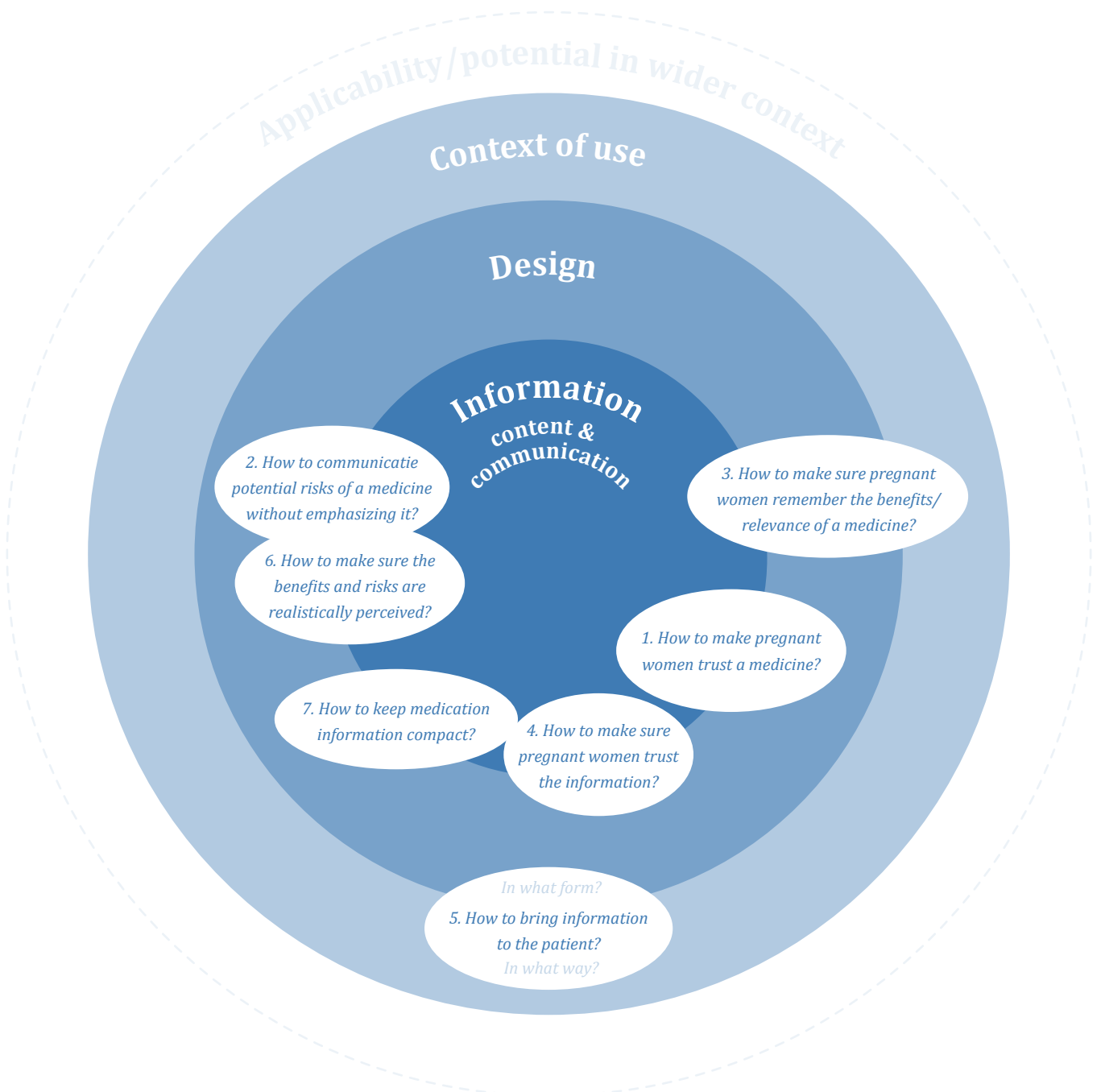


Figure 29. Four design elements

How-Tos

Based on the requirements and wishes stated on p.69, different design challenges are formulated. These are written in the form of problem statements, using a method called 'How-Tos' (Hoe kun je... or HKJ in Dutch). How-Tos are open questions that stimulate to come up with a variety of solutions, thereby forming a good starting point for idea generation (Van Boeijen et al., 2014). The formulated How-Tos are:

1. *How to make sure a patient trusts a medicine?*
2. *How to communicate potential risks of a medicine without emphasizing it?*
3. *How to make sure pregnant women (know and) remember the benefits/relevance of a medicine?*
4. *How to make sure pregnant women trust the information? (i.e. reliability)*
5. *How to bring information to the patient?*
6. *How to make sure the benefits and risks of a medicine are realistically perceived (i.e. not overestimated/underestimated)?*
7. *How to keep medication information compact?*

First, ideas for the first five How-Tos were created individually. Then they were used in two brainstorm sessions. The first session was conducted with four members of the project team 'Improving information to patients' of the MEB (figure 31). The second session was conducted with seven relatives of the graduating student, including participants with either a medical background (3), design background (1) or experience with pregnancy (3) (figure 32). Given their background they could provide extra valuable ideas. The sessions are discussed in appendix J. After the first session at MEB, the second How-To is reformulated into the sixth one. Additionally, a new How-To (7) was added.

Ideas/solutions

The results of the How-Tos can be found in appendix K. An impression can be seen in figure 30. The ideas for each How-To are visually summarized in appendix L per How-To.

The generated ideas provide input for the design across the aforementioned components information content, design and context, as visualized in figure 29. This will be addressed in the next chapters. Additionally, the ideas (or opportunities) that were formulated in the patient information journey are also taken into account.



Figure 30. An impression of the How To results



Figure 31. Brainstorm session 1 with MEB employees



Figure 32. Brainstorm session 2 with experts in the topic, including a GP, nurse, medical student, pregnant woman, partner of pregnant woman, mother and industrial designer

5.2 INFORMATION DESIGN

This chapter discusses the writing process of the information that should be included in the design. Next to the ideas that were generated, additional literature gave input for how the information should be communicated. The information was written in parallel with the design of the product and has been improved in multiple iterations with input from experts.

Chosen medication

Two prescription medicines were chosen to create design concepts for. The first medicine is 'Labetalol', a regularly prescribed medicine for pregnant women to treat high blood pressure. The second medicine is acetylsalicylic acid (for the remainder of this report referred to as Aspirin), which is an often used preventive medicine that lowers the risk of pre-eclampsia in pregnant women who have a high risk of developing it.

Using existing information



1. Gathering existing information about the chosen medicines from the leaflet, apotheek.nl and Lareb.nl

The desired information that should be included in the design does not currently exist yet in one finished form. Therefore, the information is newly created for this design specifically. It is written based on existing information from the MEB in the patient leaflet and SmPC. When reviewing it, it turned out that this information is often incomplete or unclear. For instance, in case of Labetalol it contained ambiguous sentences that could be interpreted in different ways (see p.27, figure 12). Therefore it was decided to complement this with information from Lareb TIS and apotheek.nl. This information can be found in appendix M.

Information content



2. Determine what information elements should be in the product

Based on research it was determined what kind of information the product should generally include, which was formulated in the list of requirements on p.69. It was concluded that the information must address both the risks when taking the medicine and the risks when not taking the medicine (i.e. the risk of not treating the condition), as well as the benefits of the medicine (i.e. why the medicine is relevant or important for the patient) for both mother and child. Regarding the risks of a medicine on the child, available evidence from scientific research should be included. When this is not available, experiences in clinical practice could help give pregnant women more trust in their medicine. By providing this information, patients should be able to make a reasoned assessment for themselves and understand why the doctor advised them to use the medicine. This should give them a feeling of reassurance and trust in the medicine.

The ideas that were generated with the How-Tos provided further input for the information content. To gain trust in a medicine, it was proposed to include either experiences of other women (reviews), mention how many other women have used the medicine or how long the medicine has been used among pregnant women. The idea of including pregnant women's experiences in the product was discussed with the MEB and during the brainstorm sessions, but was discarded since it involves some issues and is not feasible for the MEB. Instead, it was decided to communicate how common the use of a medicine is among pregnant women. This information is often available and may contribute

significantly to make women feel reassured and have trust in their medicine.

Apart from the relevance and risks of a medicine, pregnant women also want information about the side effects, contraindications and other important information about using the medicine. This should be included in the app as well. However, there will be primary focus on the communication of the benefits and risks since that information is most important.



ESSENTIAL INFORMATION CONTENT

- *Why/when to use the medicine (the indication)?*
- *What does the medicine do (the benefits)?*
- *What are the potential risks on the unborn child, including research evidence or experience in clinical practice?*
- *What are the risks when not taking the medicine OR what are the risks of the condition that it treats/prevents?*
- *What is the experience with using the medicine among pregnant women?*

Figure 33. Elements that should be included in the information

Tailoring information



3. Decide to what extent the information will be tailored to pregnant women and their situation

Current information about medicines is written for the general public in a one-size-fits-all format. Consequently, it includes all possible indications, contraindications and instructions which are inevitably not all relevant to pregnant women. In order to meet the information needs of pregnant women, this information should be tailored to this specific group of patients. In this way, important information can become more prominent and irrelevant information can be left out. The benefits of this are illustrated by Bright (2008) who explains

that in general people prefer personalized online experiences due to two factors; the need for control and the information overload problem. Users want to have the feeling that their wishes and needs are taken into account and do not want to dig through and process a ton of information before finding what they need. By only showing relevant information, pregnant women get the feeling more attention is paid to their needs, which is more likely to result in feelings of trust.

Since some medicines can be prescribed for different reasons (i.e. indications) it is a challenge to determine what information should be included and how it should be presented. For instance, the medicine Aspirin can be used for preventing pre-eclampsia but is also used for treating angina pectoris ('hartkramp' in Dutch) or pain and inflammation. For each of these indications, different information may be relevant. Writing information about all the different indication would increase the amount of irrelevant information. This will be further explained in section 5.3.

Communicating benefits and risks

Verbal descriptions

Dickinson et al. (2016) explored how three types of additional benefit information had an impact on patient's attitudes and beliefs towards statins: (1) a textual statement, (2) number needed to treat (NNT) and (3) natural frequency. They found out that patients prefer the textual format compared to numerical statements, since that is more positive, easy to read and helpful as it provides a rationale for taking the medicine. Moreover, it was perceived as reassuring, which is an important requirement for this design. On the other hand, the provision of numerical information could better help to make judgements about their medicine and develop a deeper understanding about the benefits, as has also been found with risks (discussed in chapter 1.3). However, numerical statements could lead to confusion and have the potential to provoke anxiety, disappointment and doubt, which is just what should be prevented. Therefore it was concluded that benefits should be communicated in a textual statement.

Although it is best if risks are communicated numerically (as has been discussed in chapter 1.3), such information is unavailable for most medicines. During this project, the available information was limited to existing information from the MEB, Lareb and apotheek.nl, and therefore is written in verbal descriptions. If possible, probability terms or words that contain uncertainty such as ‘probably’, ‘sometimes’ and ‘so far’ are avoided. Rather, it should be made clear how the benefits and risks when *not* taking the medicine outweigh the potential risks of taking the medicine.

In perspective

In addition to the content of information, the How To ideas (appendix L) provided further ideas about how the information could be communicated together. For instance, in order to make sure patients have a realistic perception of the potential risks and do not overestimate them, the risks should be put in perspective with the benefits of the medicine. Therefore it would be beneficial to communicate risk information together with the benefits (e.g. by visually placing them against each other) or to ‘refute’ the risks by explaining how the benefits for the patient are bigger. This will also help to make pregnant women feel reassured.

Structure and logic

Based on the abovementioned ideas, the information for the two chosen medicines is written on the basis of the information gathered from existing sources. The information was first written in Dutch.



4. Write the text in a structured and logical order

Special attention is paid to the structure and logic of the information and combination of the different information elements. For instance, it makes sense to start with when/why the patient would use a medicine. Additionally, the completeness of the information has been taken into account.

For example, when specifically communicating information about the risks of the medicine in the first trimester of pregnancy, it should also say something about the risks in the second and third trimester. It was considered to divide risk information per trimester, but since the available information was often incomplete it was decided to just write what is known in the best way possible.

Language and writing style

Personalized communication style



5. Optimize the information with the right language and writing style

Research by Berry et al. (2003) found out that using a more personalised style in information about medicines (i.e. addressing the information to the reader by using ‘you’) results in significantly higher ratings of satisfaction and lower perceived risk to health. In their study it also resulted in significantly improved recall for the written information. Since it is important that women do not overestimate the risks and remember the benefits of a medicine, this is a beneficial solution for the design.

A personal, informal way of writing also allows for the display of emotion or empathy, which is a suitable approach for pregnant women considering their feelings of concern. MedlinePlus (2017), who offers guidelines on how to create easy-to-read health materials, also indicates that using a personal voice will help to engage readers. Eventually it was decided to use ‘je’ (informal version of ‘you’) in Dutch instead of ‘u’ (formal version of ‘you’) to address pregnant women. In addition to using a more personalized style of communication, several other guidelines explained by MedlinePlus (2017) have been used for writing user-friendly information, which are shown in figure 34.

Formal and objective vs. personal and subjective

Although using a personalised style of communication is beneficial, it should not be written in a too informal way since that would make the information less credible and trustworthy. Thus, there should be a balance between formal and informal language.

Furthermore, on the one hand you want to stimulate pregnant women to use a medicine when that medicine is relevant for them (so in the case when women have been prescribed the medicine). In that sense emphasizing the benefits in the information and persuading them to use a medicine would be favorable. On the other hand, it is important to remain objective and unbiased, not only because that is important for the MEB, but also because the main point is to inform pregnant women. When they are informed well, pregnant women should be able to make a personal decision that is best for their own health as well as that of their child. As discussed in chapter 4.2 (interaction qualities), this means the information should be transparent and therefore also communicate what is known about potential risks. Furthermore, the information should not 'overstimulate' pregnant women to use a medicine since it remains important to be cautious with taking medicines during pregnancy.

Two versions of information

When writing the information about the indication it was chosen to address the doctor by saying '*your doctor advised you to use this medicine because...*', since this might feel more personal and trustworthy. However, when the patient is not yet using the medicine (i.e. the doctor did not yet prescribe it), this sentence does not apply. Therefore it was chosen to write two versions of the information that slightly differ, one for when the patient is already using the medicine and one general version (e.g. '*this medicine is advised when...*'). This will be further explained in chapter 6.



GUIDELINES FOR USER-FRIENDLY INFORMATION

- *Keep sentences simple*
- *Find alternatives for complex words, medical jargon, abbreviations and acronyms or explain them together with their easier word.*
- *Bulleted lists could make blocks of text more readable, so use them when appropriate*
- *Use an active voice*
- *Avoid abstract/ambiguous language (i.e. be concrete) in giving instructions for actions*
- *Be consistent with terms, for example 'medication' should not be used interchangeably with 'drug'*
- *Frame things positively*

Figure 34. Guidelines for writing user-friendly information (MedlinePlus, 2017)

Understandable information



6. Make sure the information is easy to understand

Apart from the right tone of voice, the information itself should be understandable for laypersons without medical knowledge. Therefore, sentences are kept as simple as possible and difficult medical jargon is avoided or clarified with an easier term between brackets (e.g. placenta (moederkoek), pre-eclampsie (zwangerschapsvergiftiging) in Dutch).



7. Let experts review information and improve accordingly

Eventually, the written information is reviewed by an expert in medicines from the MEB, a gynaecologist from VUmc and a communication expert with experience in writing understandable medication information. The final (two) versions of the information are addressed in chapter 6.

5.3 APPLICATION DESIGN

This section explains the process of designing the application. This was done in parallel with writing the information since they are interdependent.

Interaction vs. visual design

A distinction is made between the interaction design and visual design of the application. The interaction design focuses on designing the content, flow, behaviour, structure and hierarchy of the product, whereas the visual design is about the look and feel of the product, including for example colours, illustrations and font choices. It is important to focus on the interaction design first, because that forces you to think about the usability, functionality and structure (which are foremost important) without being distracted by the look and feel. The interaction design is made in wireframes, which are like skeletons or simple black and white layouts that display the functional elements on a page. These do not have to look 'beautiful' yet. Using wireframes is an efficient way of designing since you can quickly make iterations.

Interaction design of medication page

Each medicine will have their own page. This is where the user can find all information about that specific medicine. This page was designed first, since that contains the benefit-risk information, which is most important to work out. Several iterations were made. After a design was created, it was evaluated on positive and negative aspects, leading to a new iteration. The iterations are shown on the following pages.

Iteration 1

<

Labetalol
Medicijn tegen te hoge bloeddruk

Waarvoor gebruikt u labetalol? ^

U gebruikt labetalol omdat u een hoge bloeddruk heeft en zwanger bent.

Hoge bloeddruk tijdens de zwangerschap
Een hoge bloeddruk tijdens de zwangerschap vormt een **risico** voor u en uw baby. Een hoge bloeddruk kan namelijk zorgen voor een **verminderde doorbloeding** van de placenta. Dit heeft mogelijk een **groeiachterstand** van de baby als gevolg. Daarbij kunnen ook andere organen zoals uw nieren en lever minder goed werken, waardoor u een hogere kans heeft op **pre-eclampsie** (zwangerschapsvergiftiging). Daarom controleert de verloskundige of arts regelmatig uw bloeddruk.

[meer over hoge bloeddruk >](#)

Wat doet labetalol voor u?
Labetalol behoort tot de groep bètablokkers. Het verlaagt uw bloeddruk. Daarbij zorgt het voor een goede doorbloeding van de placenta (moederkoek).

Veiligheid voor uw kind
Onderzoek naar bètablokkers in de zwangerschap laten tot nu toe geen hoger risico op aangeboren afwijkingen zien. U kunt dit medicijn veilig gebruiken tijdens het eerste trimester.

Bij gebruik tijdens het derde trimester is er kans op bijwerkingen bij het kind, zoals een lage bloedsuikerspiegel, lage bloeddruk, lage hartslag, suf worden en moeite met ademen. Deze symptomen kunnen echter ook veroorzaakt worden door pre-eclampsie.

Ervaring
Labetalol behoort tot de voorkeursmedicatie bij hoge bloeddruk tijdens de zwangerschap, omdat daar veel ervaring mee is opgedaan tijdens de zwangerschap. Labetalol is een veelgebruikt medicijn voor hoge bloeddruk bij zwangere vrouwen.

Om ervoor te zorgen dat uw bloeddruk lager wordt en gevolgen van een hoge bloeddruk te voorkomen, heeft de arts u geadviseerd om Labetalol te gebruiken.

Heeft u andere vragen of zorgen over uw medicijn? Neem [contact](#) op met uw arts via deze app.

Hoe gebruikt u labetalol? v

Wat moet u nog meer weten? v

Welke bijwerkingen kunt u krijgen? v



Link to more information about complaint/condition



Presents too much information at once --> lack of overview

Lack of visuals, like icons

Navigation possibilities and flexibility of app not used

Figure 35. Iteration 1

Iteration 2



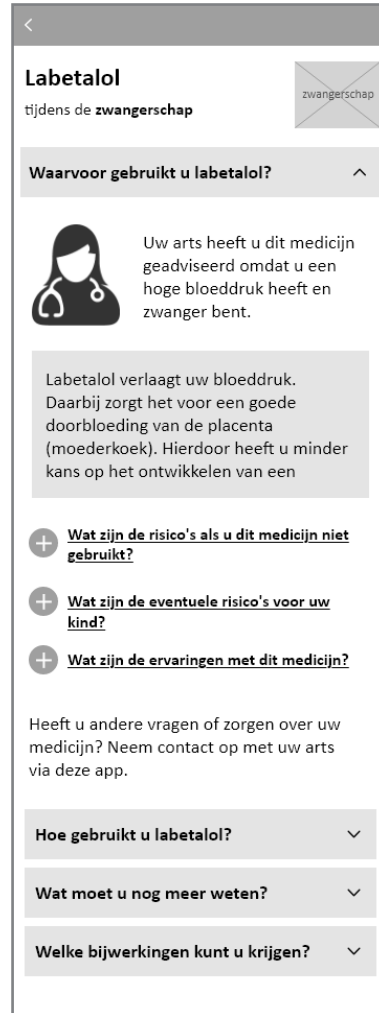
Emphasis on importance

Submenus give better structure and less information overload



Risk information may be hard to find because it is hidden in another menu

Iteration 3



Pregnancy (safe) icon on top could give direct feeling of trust

Visual of doctor could give feeling of trust

Emphasis on benefits, which are more positively framed



Risk information may be hard to find because it is hidden in another menu

Figure 37. Iteration 3

Figure 36. Iteration 2

Iteration 4



Figure 38. Iteration 4



Indication is directly visible when opening the page (no need to open drop-down menu first)

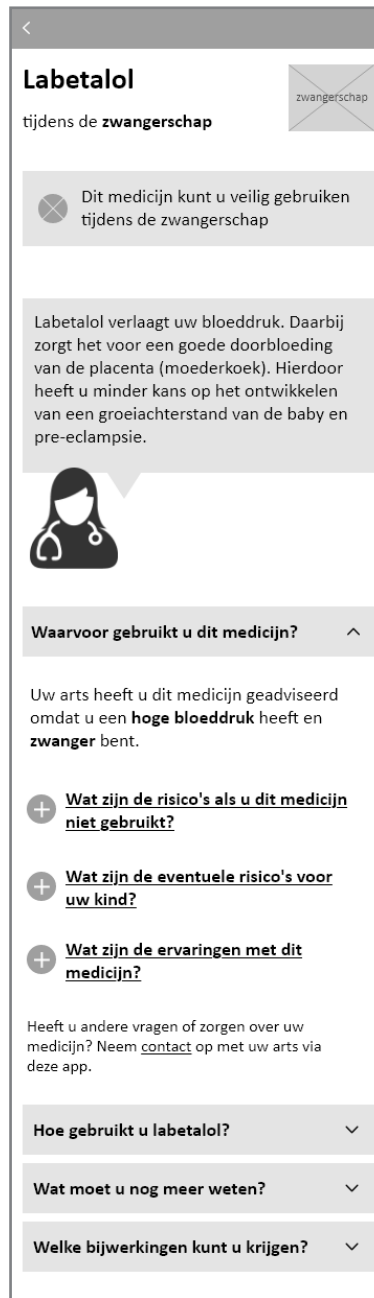
Icons could improve readability and enhance overall appearance



No prioritization of information

Amount of information could be overwhelming

Iteration 5



Directly visible whether medicine is safe

Benefit of medicine is directly made clear

Benefits framed as a quote said by doctor gives personal feeling and trust



Making benefits prominent like this could be overwhelming when it is not the info you are looking for. It actually 'belongs' under the menu 'what do you use it for'

Figure 39. Iteration 5



Figure 40. Iteration 6 - benefits



Figure 41. Iteration 6 - risks



Risks for child in own menu is better which makes it much easier to find

Indication is most logical information to read first, so the reader remembers the reason for taking the medicine

'Read more' = extra way in to benefit info

Dividing risk info per trimester could make it more clear for pregnant women and reassure them that a medicine is safe for a specific trimester

Experiences with the medicine acts as a counterpart for risk info, make women feel reassured



Pregnancy icon on top and sentence are double, one of them is unnecessary

Visual of doctor may not be necessary for the indication because here you don't need to convince women of something

Risk info per trimester is currently not always complete in existing info sources, which makes it hard to make this division. When info for one trimester is missing it would only be confusing

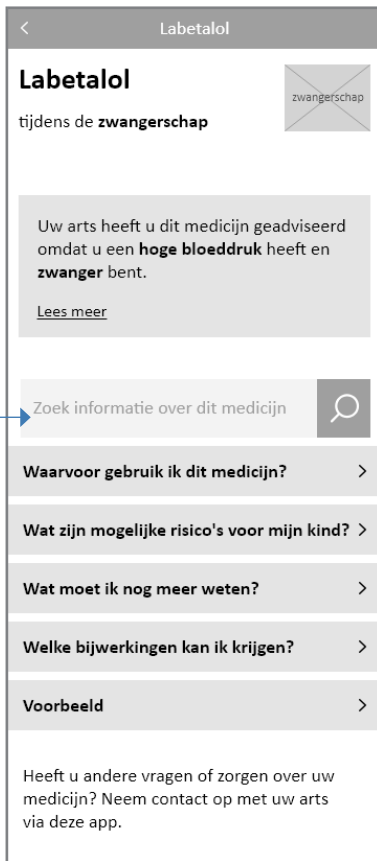


Figure 42. Iteration 7 - medicine page



Figure 43. Iteration 7 - benefits

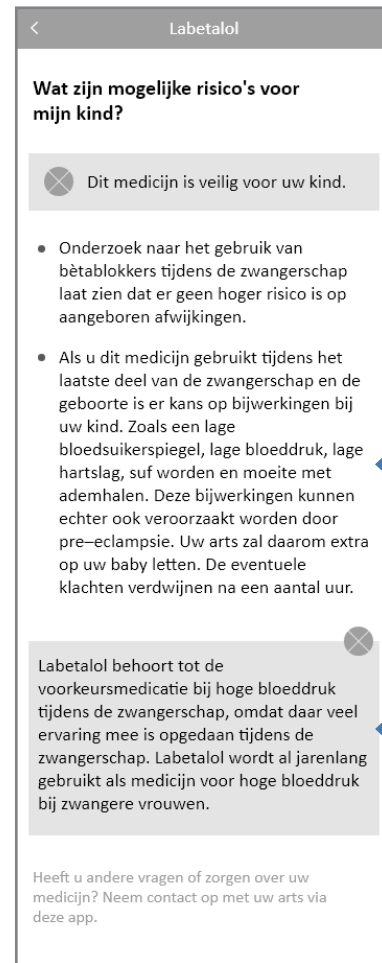


Figure 44. Iteration 7 - risks



Navigating to a new page for each menu makes much more sense for an app instead of everything on one page in dropdown menus

Visualising doctor who 'explains' the benefit information, could have a positive effect on trusting and accepting the information



Searching within the page should not be necessary when it is well designed

Bullet points do not really work for larger paragraphs

It may not be clear what the different parts are about, headings could work here



Figure 45. Iteration 8 - medicine page



It is important to communicate the dosage too, especially when the risks differ significantly per dosage (like with Aspirin)

Menu icons could enhance readability and overall appearance

Framing menu questions with '!' fits more with thoughts of pregnant women

MEB logo gives feeling of trust

Placing risks when not taking the medicine in dropdown menu enhances readability, making the benefits more prominent

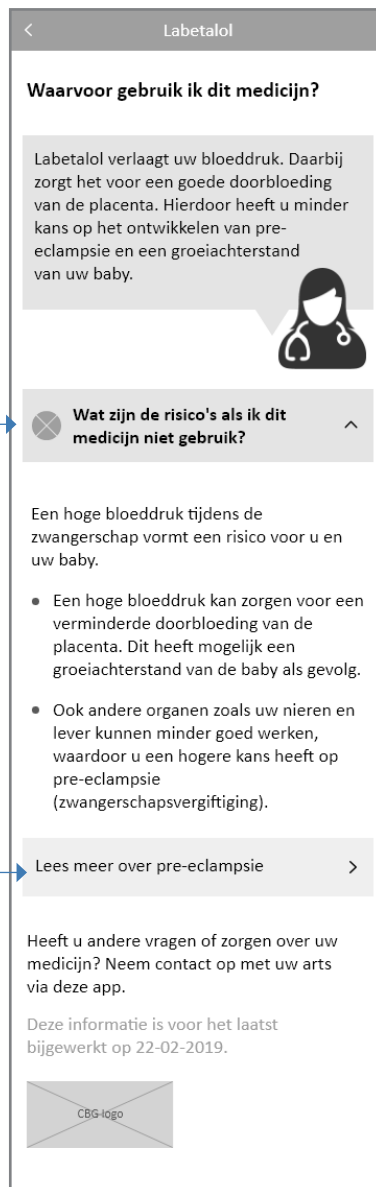


Figure 46. Iteration 8 - benefits

Link to page about preeclampsia

Headings for risk info work well, icons make it more readable and appealing again

Additional piece of information is an important part to put the risks in perspective with the benefits by explaining that the medicine helps to lower the risk of harm on the child



Figure 47. Iteration 8 - risks

Design considerations

In the following part, some important design considerations are discussed.

General or pregnancy medicine app

At first it was considered to design an app that could be used for any type of patient group (i.e. not only pregnant women), in order to make the app relevant for the MEB who is more focused on providing information for the general patient population. When opening the app, the user could personalize the app by indicating that she is pregnant. Then the app would show the information that is relevant for pregnant women. However, to narrow down the scope of the design it was decided to create an app that is specifically for pregnant women. The benefit of this is that it will also make pregnant women feel more like the app is relevant for them specifically which could increase trust. In order to make the design still relevant for the MEB, the app has been designed in such a way that it could be extended to an app for the general patient population or another patient group.

Link to patient record or not

Another consideration that is made is to link the app to the electronic patient record. This would allow the app to import and add the medicines of a patient directly to their personal medication list, increasing the level of personalisation. During the second brainstorm session this was discussed with a doctor who indicated that technically it is very difficult to connect such an app with the electronic patient record. Additionally, users would also have to connect their record and an additional login system would be required. When comparing the effort it would take to implement this with the added benefit, it was decided not to connect the app to the electronic patient record.

Navigation; search on medicine and complaint

It is important to guide the user to the desired information in an intuitive way and to meet their needs and expectations on each point in the app. In case the user wants to know information about a specific medicine, she should be able to search on this medicine directly on the home screen to quickly find the information she needs. Alternatively, users should be able to see a list of all medicines that they can find information about, which is useful when they do not know exactly the name of the medicine.

An app is suitable for incorporating other functions that would be useful for pregnant women as well. So apart from being able to search by medicine, it was decided to also include the option to search on complaints/illnesses. When pregnant women experience a complaint, for instance headache or morning sickness, they often want to know what medicine they can use. In the current situation they would call the doctor for that, since that information is hard to find online, as was shown in the patient information journey. The app could provide an overview of medicines they can use for a specific complaint. This option is also useful when the patient wants to know whether there are any alternative medicines for her complaint than the ones that she is currently using. By incorporating these two functionalities (i.e. the option to search by medicine or by complaint), the application meets the needs that pregnant women have at different key moments.

Figure 48 shows the flow chart of the app.

Make own medication list

To make it possible to quickly find back information in the app about your medicine, it was decided to include the option to make your own medication list.

Structuring information

As explained in the previous section, one medicine may be used for different indications, which influences the information that should be provided.

Therefore it must be determined whether to communicate all information (together), or to make a division in the information and create a different page for each indication. To show pregnant women the most relevant information for their situation, it was decided to divide information per indication on separate pages.

Apart from differences in indication, some medicines also vary in concentration which can strongly influence the safety during pregnancy. For example, Aspirin can safely be used in doses lower than 100mg but is not safe in higher concentrations. However, other medicines such as Labetalol do not have these differences. This increases the complexity of the information and therefore the information structure must be (re)considered for each medicine.

Some wireframes for the home screen, personalization, complaint page and adding a medicine to your personal list are shown in appendix N.

Icons

For the application a set of icons was created. This was done to improve user navigation, quickly indicate important aspects (e.g. that a medicine is safe) and/or increase the overall attractiveness of the app. The icons have been specifically designed for this application over several iterations, which can be found in appendix O. For the design it was important that the icons fitted within the overall theme of the app but also conveyed an unbiased message. For example, the icon for 'potential risks' of the medicine started with a red warning signal (shown on the right) but due to a strong 'this is dangerous' association with such signals, it would be difficult to read the corresponding information unbiased. After experimenting with different designs it was decided to only use icons for the headings of the information rather than for 'explaining' the content, as they would mainly cause concern rather than add value. An additional benefit of this is that the icons would be similar for each medicine since the headings are fixed.

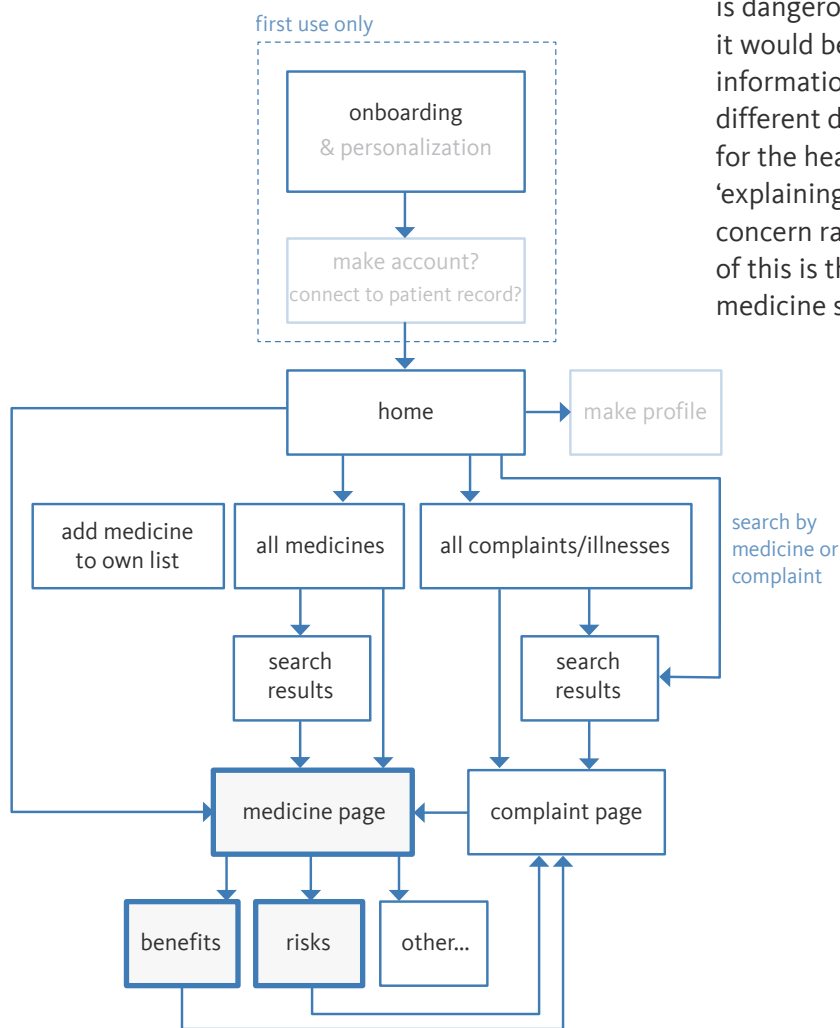


Figure 48. Flowchart of the app

5.4 CONTEXT OF USE

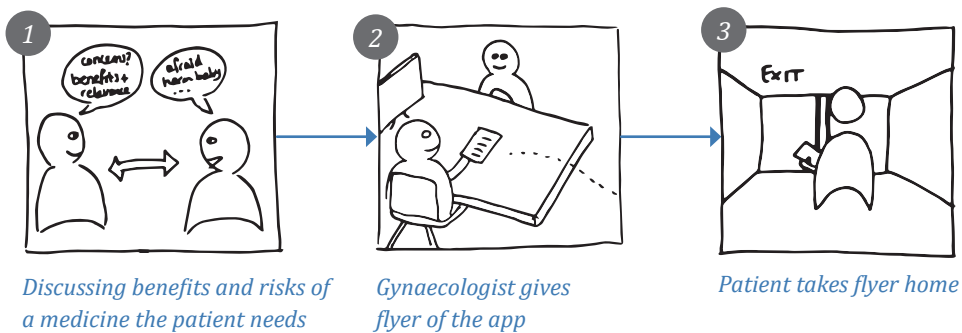
In order to stimulate pregnant women to use the app instead of other sources of information to answer their questions, they must be informed about the app in some way. The reliability of an information source is an important requirement for patients when searching for information. Since HCPs are considered as very trustworthy by pregnant women, it was determined that the gynaecologist should play a role in informing them about the app, as stated in the design goal.

As was concluded from user research, information about the benefits and risks is not only important at

the moment when pregnant women start to doubt whether their medicine is really safe, but also when the medicine is prescribed by their doctor during a consultation. During the brainstorm sessions it was discussed that repetition of information, consistent information across multiple channels and providing information on different moments are beneficial in order to make pregnant women remember the benefits of a medicine. Therefore, it would be good if the gynaecologist would address the same information as in the app when prescribing a medicine.

Scenario 1 - explain benefits-risks verbally and give information flyer

DURING CONSULTATION



AFTER CONSULTATION

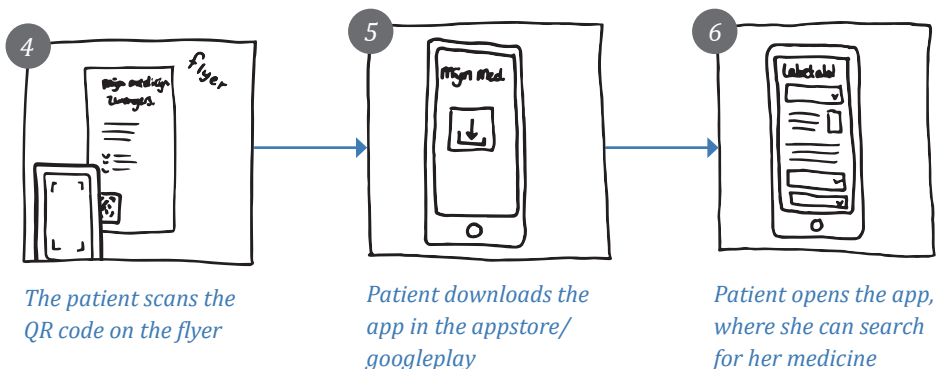


Figure 49. Scenario 1

Different scenarios were created for how pregnant women could be guided to using the application and how the information will be addressed during a consultation, which are shown in figure 49 and 50. Concepts for the information flyer and SMS can be found in appendix N. Furthermore, concepts were created for the visualization of the information on the monitor in the consulting room. This was done in parallel with the creation of the information and application design and therefore includes an interim version of the information.

It was decided to choose a combination of the two scenarios. An information flyer about the app is helpful as a reminder for what the app is about and how it can be accessed after the gynaecologist told them about the app during the consultation.

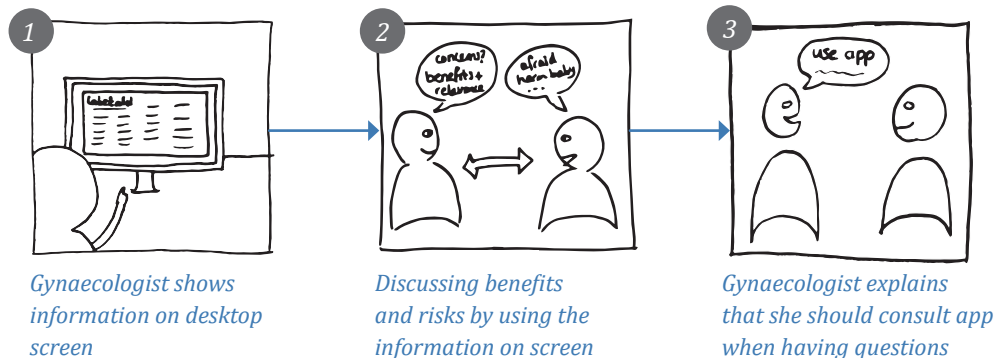
Furthermore, it was decided to let the gynaecologist show the information on her screen to already introduce users to the app.

Therefore it was decided to let the gynaecologist explain the same benefit-risk information as in the app verbally as well as by showing the information on the screen.

It is expected that when pregnant women have heard from the gynaecologist that they can consult this application for trustworthy and pregnancy specific information, that they will remember this when they are looking for information. Therefore also receiving an SMS from the hospital is not considered a necessity.

Scenario 2 - using a desktop version of app information, refer to app verbally and send SMS/Email home

DURING CONSULTATION



AFTER CONSULTATION

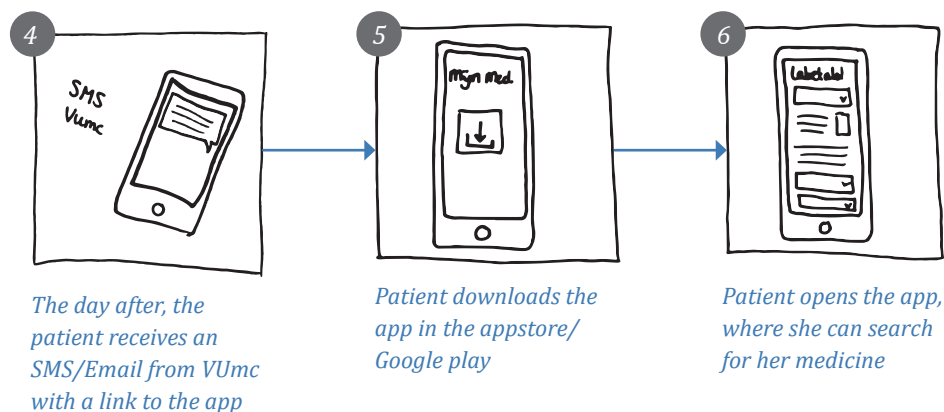


Figure 50. Scenario 2

6

Final design

In this chapter, the final design of 'Mijn Medicijn - Zwangerschap' is presented. First, the design is introduced, followed by an explanation and visualization of the use scenarios, core features and how it is implemented in the care process. Then the design elements are discussed in detail, whereby it is explained how each element contributes to the design goal and interaction vision. Finally, the screen flows and interactions are shown.

6.1 'MIJN MEDICIJN - ZWANGERSCHAP'

'Mijn Medicijn - Zwangerschap' is an application that informs pregnant women about their medicines and supports them in making informed decisions regarding the use of medicines during pregnancy (figure 51). The application responds to pregnant women's doubt and concern regarding the risks of the medicine for their child that arise when they start or are using the medicine. The key aspect of the application is that it informs pregnant women about the potential risks of a medicine on their child as well as the benefits of using a medicine for a particular condition or disease. By presenting this information in a balanced way, pregnant women will have a clear perception of the actual benefits and risks of a medicine for both themselves and their child. Therefore they are better able to understand why a medicine is relevant for them and why the HCP may have advised them to use it. When pregnant women know how the benefits of a medicine outweigh the potential risks, (some) of their concerns can be taken away. This is expected to make them feel more confident in the decision to use a particular medicine during pregnancy.

An additional feature of the application is the option to search on a complaint or illness they experience and find what medicine they can or should not use during pregnancy. This is particularly relevant for OTC medicines that do not require a doctor prescription.

The added value of the final design lies not just in the application, but also in how it will be implemented in the care process (i.e. how it reaches pregnant women). The HCP plays an important role in informing the patient about the app. When prescribing a medicine, the gynaecologist explains the relevance of a medicine for the patient by using the same information as in the app which is shown on the monitor. Additionally, the gynaecologist will distribute an information flyer about the app. Since women showed a lot of trust in their doctor, this is expected to stimulate them to use the app rather than other information sources.

Although the target group of this project was pregnant women that are treated at VUmc, the application can be used by any pregnant woman.

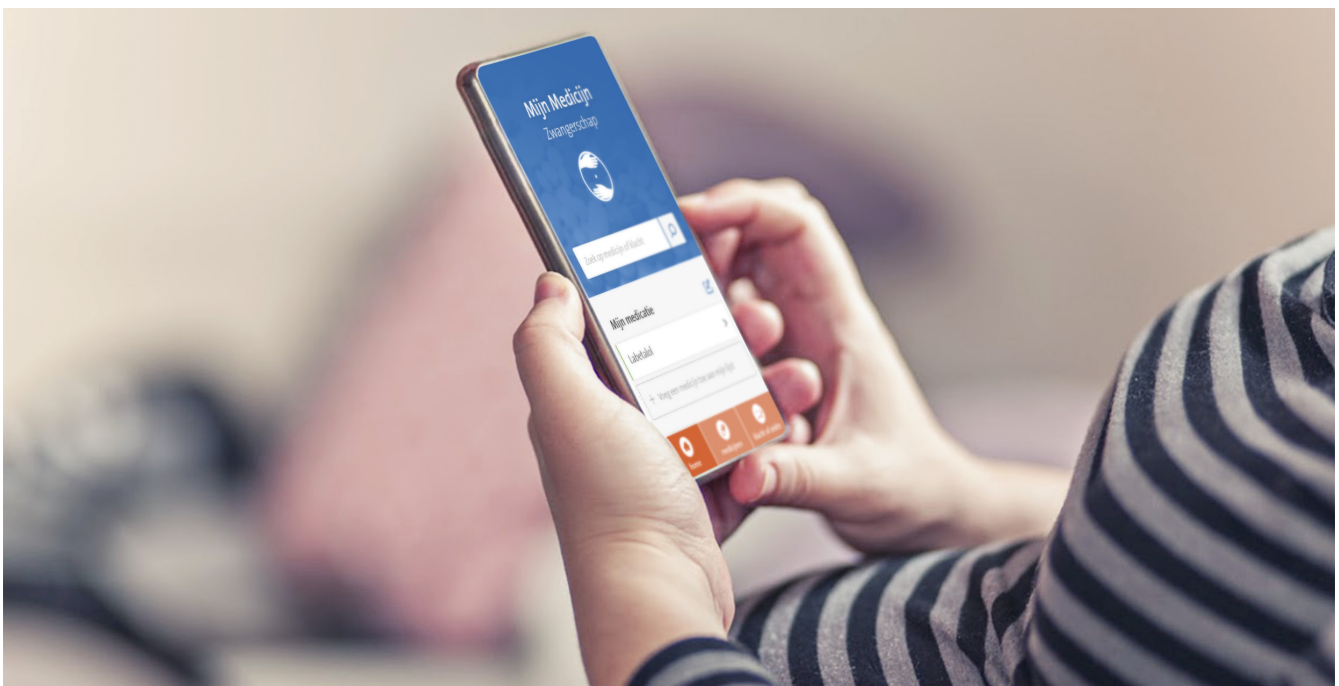


Figure 51. Pregnant women using the app

Mijn Medicijn

Zwangerschap



Zoek op medicijn of klacht



Mijn medicatie



Labetalol



+ Voeg een medicijn toe aan mijn lijst



home



medicijnen



klacht of ziekte

6.2 USE SCENARIOS

Pregnant women can use the application in different situations. The app addresses those situations by providing two different ways in which pregnant women can find information about the medicine they need. The use scenarios of the app as well as the role of the HCP will be discussed below. On the following pages these scenarios are shown in pictures.

Scenario 1 - Seeking confirmation about the safety of her medicine

Role of the HCP

For the target group of this project, most medicines that pregnant women use will be prescribed by the gynaecologist during consultations at VUmc. From user research it became clear that pregnant women consider this an important moment to be informed about why they need a specific medicine and what the potential risks are for their child. Another relevant insight from research was that all information provided to patients should be consistent in order to avoid confusion and concern, but also to enhance recall of the information. Therefore, in addition to the mobile application that pregnant women can consult independently, gynaecologists will address the same benefits-risk information during consultations when advising the patient to use a medicine. At the same time, gynaecologists inform pregnant women about the app by giving them an information flyer about the app.

By using the same information in the app as what is explained during consultation, the following benefits are achieved. First of all, due to the repetition of information, the content and complexity of some situations will be easier to understand for women as they already have heard the key aspects before. Additionally, they can review all the relevant information after the consult at their own pace.

Search information about the medicine when doubt arises

Research showed that pregnant women easily forget information from the HCP. Also, after the doctor prescribed them a new medicine, pregnant women may start to doubt whether the medicine is really safe for their child and therefore seek confirmation. In that situation pregnant women can search on their specific medicine in the app. This will lead them to a page with information about that specific medicine, where they can navigate to information about the benefits and risks of that medicine.

In a follow-up consultation, the gynaecologist should ask back whether they have any concerns or questions about their medicine and reminds her of the application.

Scenario 2 - Experiencing a new complaint or illness

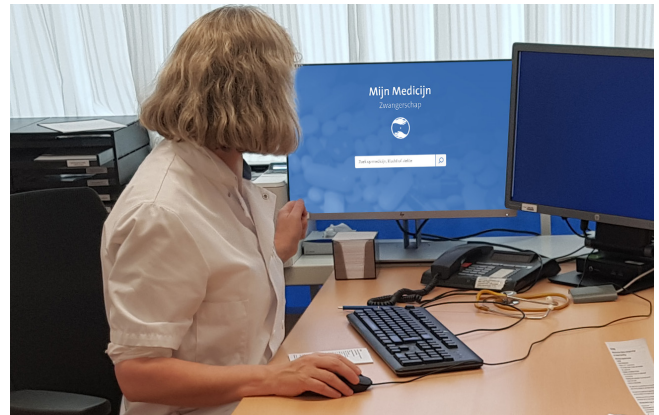
Research has also shown that pregnant women seek information when a new complaint or illness arises. Then they may want to know what medicine they can safely use, for instance for a headache or morning sickness. In that case they can search on a specific complaint or condition in the app and find what medicine they can use during pregnancy. This will eventually lead to a page with pregnancy related information about that complaint or condition and an overview of medicines that can be used or should not be used during pregnancy.

By providing this option, pregnant women do not have to call the doctor anymore to hear what medicines are safe, but can quickly find the information they need at any time. This option is also useful when they want to find an alternative medicine for the medicine that they are using.

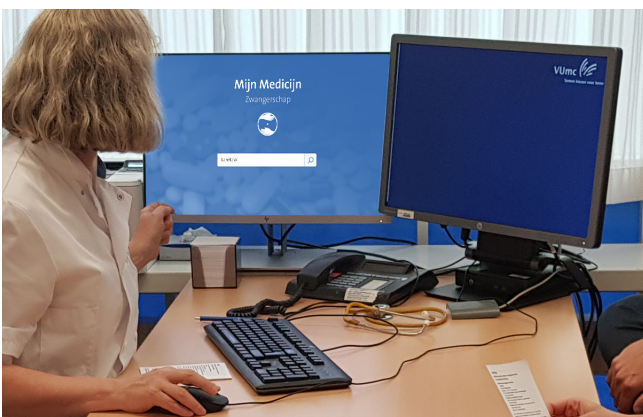
Scenario 1 *Seeking confirmation about the safety of her medicine*



The gynaecologist and patient discuss the patient's complaint or condition and the gynaecologist explains that she advises her to use a particular medicine.



The gynaecologist opens the desktop application (which is open on the background).



The gynaecologist searches for the medicine that she wants to prescribe. The benefit-risk information will directly be shown.



Gynaecologist shortly explains the relevance of using the medicine and addresses what is known about potential risks by referring to the information on the screen.



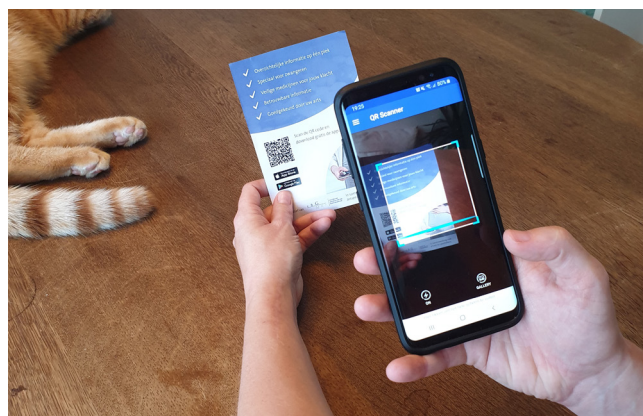
The gynaecologist gives the information flyer to the patient and shortly explains what the patient can do within the app, that it is specifically for pregnant women and that it contains trustworthy information.



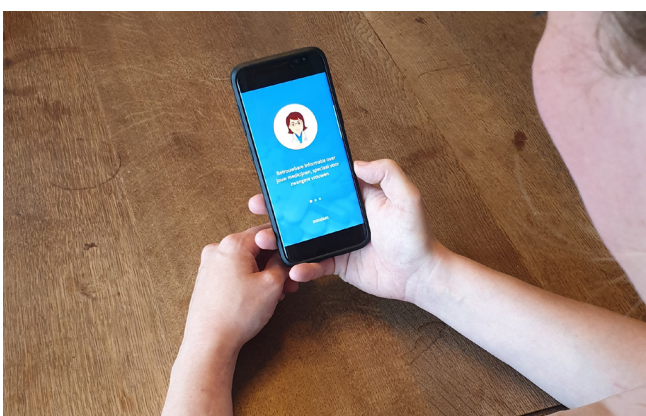
Gynaecologist further explains to the patient that she can consult the app for information when she has any further questions or concerns.



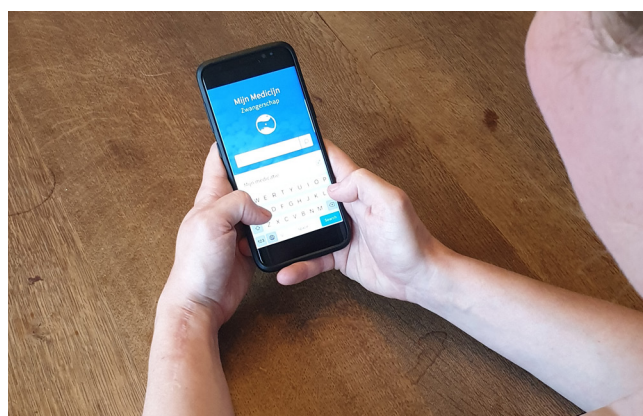
At home, the pregnant woman starts to doubt whether the medicine is really safe due to the negative information in the patient leaflet.



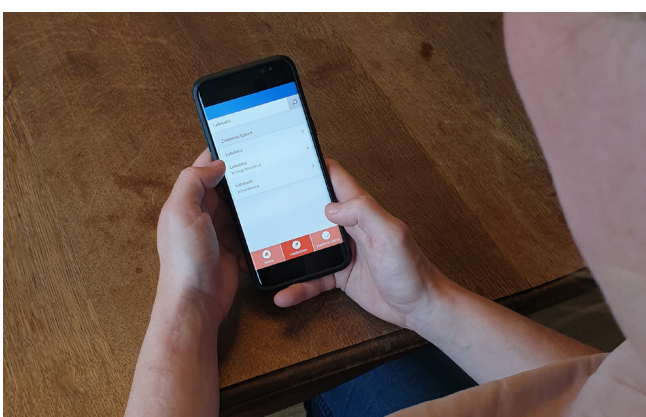
To seek confirmation, she wants to consult the app the doctor advised her to use. She scans the QR code on the information flyer to download the application.



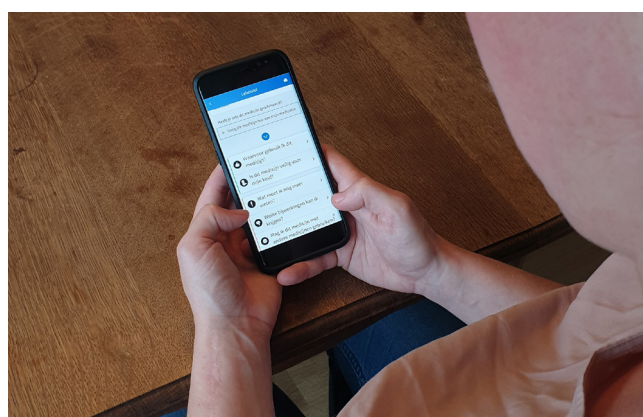
She reads what she can do within the application on the onboarding screens.



She searches on the medicine Labetalol to find information about it.



There are separate pages for each indication of the medicine. From the search results, she chooses to read the information for her indication: high blood pressure.



On the medicine page, she clicks to open the menu 'is this medicine safe for my child?' because that is the question/concern she has.



The pregnant woman feels reassured when reading that the medicine is safe to use and that taking the medicine will help to decrease risk of harm on her child.

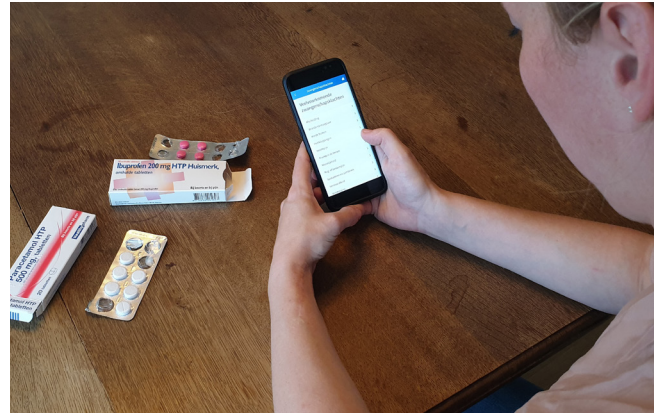


During the next consultation, the gynaecologist asks the patient how she experiences using the medicine and whether she still has any questions. When the patient still has questions or concerns, the gynaecologist answers her question and reassures the patient.

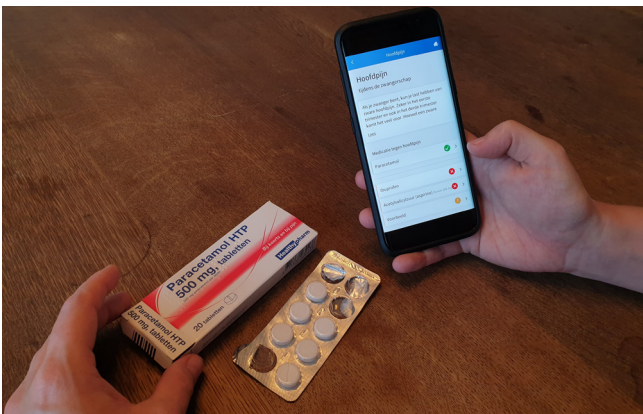
Scenario 2 *Experiencing a new complaint or illness*



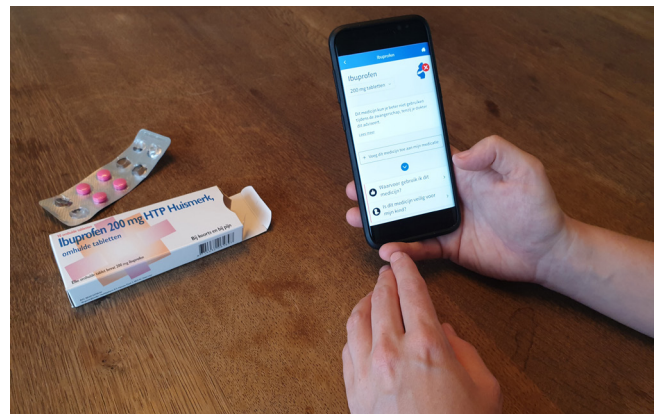
The pregnant woman experiences a severe headache and wants to know whether this is normal during pregnancy and what medicines she can safely use.



Within the 'complaint' tab, she selects headache from the list of most common pregnancy complaints.



On the page about headache, she reads whether experiencing headache during pregnancy is common and sees what medicines she can or cannot use.



Before she was pregnant, she used to take ibuprofen. When seeing the red cross, she wants to know why it is not safe.



After reading that paracetamol is safe to use, she uses the medicine without further concerns.

6.3 INFORMATION AND APPLICATION DESIGN

The current prototype of the app is designed for the two medicines Labetalol and Aspirin, in both Dutch and English. These are medicines that are often used by pregnant women. The design for Labetalol will be shown in the main report in Dutch. The English versions of the information can be found in appendix S. The design for Aspirin (which only differs in the information content) can be found in appendix Q.

Navigation

Search on medicine or complaint/disease

As discussed in the previous section, pregnant women can search both on the name of a medicine or complaint/disease. They can use either the search bar on the home page or navigate to the 'medicine' or 'complaint or illness' tab, where they can scroll through an A-Z list or search via a search bar (see figures 53-55). This will lead them to the medicine detail page, which contains all information about that medicine.

Generic medicine name

In the app, medicines are shown by their generic (chemical) name. Since some medicines are known by their generic name (Labetalol) while other medicines are more known by their brand name (Aspirin), users are able to search on both names to enhance usability. For instance, users can search on the brand name Aspirin to find the information about acetylsalicylic acid, its generic name.

Indication specific information

One medicine may be used for several different indications. Since the risks and benefits and information on how to use the medicine can be different per indication, the information is developed per indication and divided on different pages. As

can be seen in figure 56, the medicine labetalol can be used for either high blood pressure or angina pectoris ('hartkramp' in Dutch). For this project, the information for the more common indication high blood pressure was worked out.

The information and writing style

The information is written specifically for pregnant women. A balance is created between a personal and formal/objective way of informing and communicating. By addressing the information to the user by 'you', pregnant women should feel like the information is personally meant and therefore relevant for them. This will make it more likely that they accept the information and trust their medicine. In Dutch, it is chosen to address the user with 'jij' (more informal way of 'you') instead of 'u' (more formal way of 'you'). On the other hand, the content and tone of voice is not too informal in order to make the information credible and trustworthy. Also, since it was important to stay objective, only factual information is given.

Furthermore, the information is provided in a clear and understandable manner. Complex words and medical jargon are avoided or replaced by an easier explanation (e.g. 'zwangerschapsvergiftiging (pre-eclampsie)'). Sentences are short and simple and overall the information is compact but complete.

A template was created with guidelines for writing the benefit and risk information within the app which can be used when writing the information for other medicines. The template can be found in appendix P, p.202.



Figure 53. Search on medicine or complaint name via the search bar on the home screen

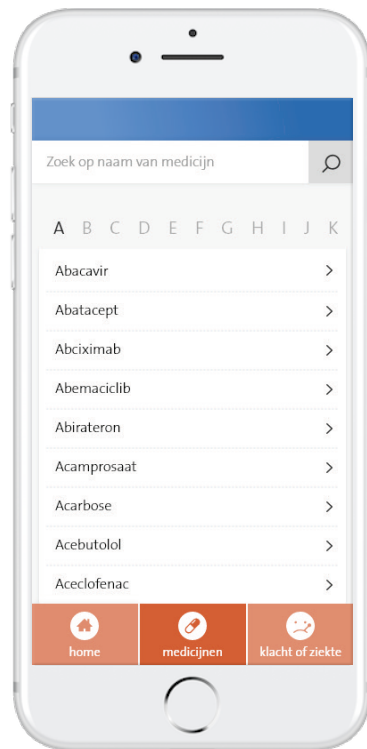


Figure 54. Search on medicine in the medicine tab

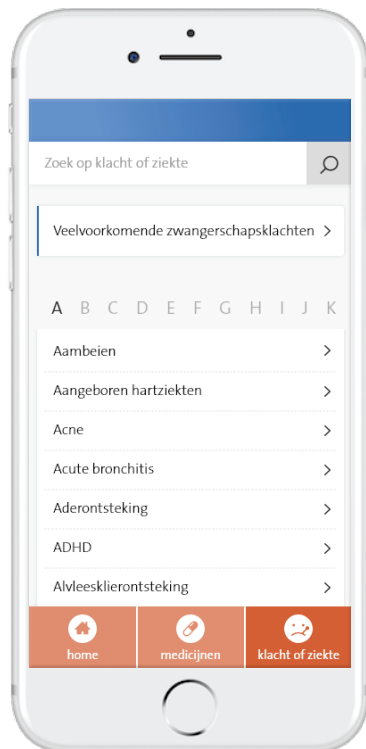


Figure 55. Search on complaint in the complaint tab

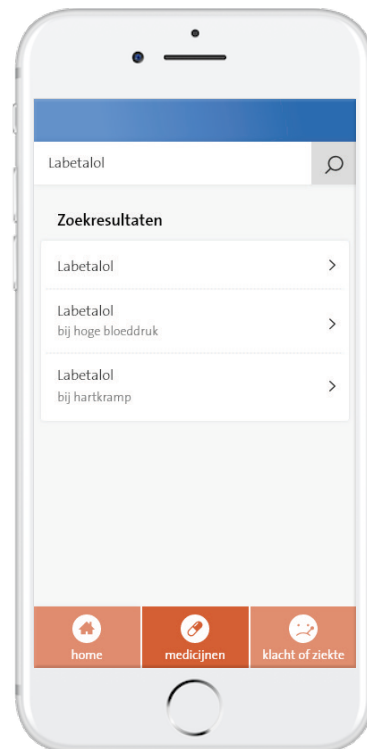


Figure 56. Search results of the medicine Labetalol, divided per indication



Figure 57. Medicine page of Labetalol (top of the page)

Medicine page

The medicine page contains information about a specific medicine, including the benefits and risks for the unborn child, as well as other important information such as possible side effects and how to use the medicine.

The pregnancy icon on top indicates that the information is specifically for pregnant women. The checkmark shows that the medicine is safe to use during pregnancy (in case the medicine is actually safe). By making this directly visible, it could have a positive effect on women's trust in the medicine. When a medicine is not safe, the icon on the right will be visible instead.



The indication describes for what complaint or condition pregnant women would use the medicine, which is considered as the most logical information to communicate first. This gives already a short explanation for why the patient would use the medicine. Since one medicine can be used for multiple indications, the information on this page is specific for one indication. This will be explained later.

To make sure the user is not overwhelmed with a lot of information, all information about the medicine is divided in different menu options. The number of different options are limited, so the user is not overloaded with too many choices, which increases the usability. This will guide the user to the desired information in an easy and intuitive way.

The most important information is placed on top in the first two menu options: The page 'What does this medicine do for me?' describes the benefits or relevance of a medicine, while the second one 'Is this medicine safe for my child?' informs women about the potential risks of the medicine for their child.

The menu options that are related to each other are visually paired together in three groups, each having their own colour on the button's left side. This further enhances the ease with which users can find the information they need. The benefits and risk information are grouped together since they provide the rationale for taking or not taking the medicine. Secondly, other important information to know (such as the effects on driving), potential side effects and contraindications are related to each other (all including an effect and/or warning). The last two options give instructions about how to use and store the medicine.

Each menu option has its own icon. These are not specifically intended to explain what the corresponding menu is about, but rather to support the readability of the menu and to make the design more visually appealing. Appendix O explains the icons.

The menu descriptions are framed in questions that are written in the first person (using 'I'). This resembles the question or concern pregnant women have in their mind (e.g. 'why do I use this medicine?'), which should make it easier for them to find the information they need. The menu descriptions can be used for any type of medicine.

The logo of the MEB, which is shown on every page, should give pregnant women a feeling of trust that the information comes from a reliable source.

The date on the bottom indicates when the information was last updated. Some pregnant women mentioned during the interviews that they sometimes wondered whether the information they received from the doctor was actually up to date. Showing this in the app could make pregnant women feel reassured that the information still applies. A requirement for this is, however, that the information actually should be checked regularly. Otherwise it will have the opposite (undesired) effect.



Figure 58. Medicine page of Labetalol (bottom of the page)

For this project, only the pages for the first two menu options are written and designed, since those include the most essential information for pregnant women. The are visualized and discussed on the next pages.

Communicating the benefits

Clicking the first menu option leads to the page 'What does this medicine do for me?' ('Waarvoor gebruik ik dit medicijn?' in Dutch). The information on this page contains two parts that together explain the relevance of the medicine, or in other words; why the patient should take the medicine.

The first and most prominent part describes the benefits of the medicine. This means what the effect of the medicine is (e.g. it lowers your blood pressure) and what the positive consequences are for both mother and child if the medicine is taken (e.g. it improves the blood flow to the placenta and thereby it lowers the chance of developing preeclampsia and growth retardation).

The illustration of a doctor in combination with the text balloon makes it seem like the doctor explains the information. By framing it in a quote it makes the information more personal and affective. As pregnant women have a lot of confidence in their doctor, this could give an extra feeling of trust and reassurance.

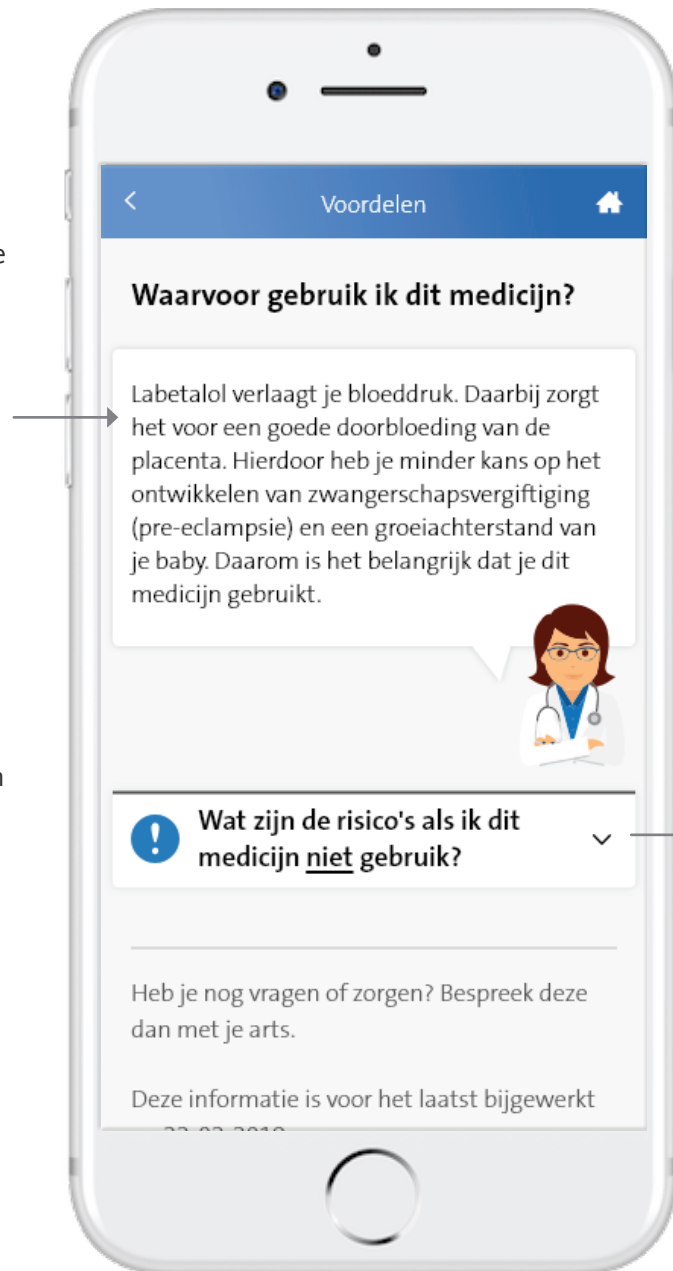


Figure 59. Page with information about the benefits of Labetalol



Figure 60. Page with information about the benefits of Labetalol (drop-down menu opened)

The information under the dropdown menu 'What are the risks when I do not take this medicine?' addresses the relevance of the medicine in a different way, by explaining the risks when the patient would not take the medicine. This involves the risks of the condition/disease that the medicine treats. Instead of making it directly visible the information is hidden in a drop-down menu, because this information generally explains the same information as described above but then from the perspective of the complaint. In this way there is also more focus on the most important benefit information in the text balloon. Furthermore, by presenting less information at once, the user may be more stimulated to read the information. When the patient wants additional information, she can open the dropdown menu.

When reading this information, pregnant women could wonder what high blood pressure or pre-eclampsia actually is and what it entails for pregnant women. Therefore, a link is provided to the page about these conditions. Some participants indicated during the interviews that they would like to have this option.

Communicating risk information

The second menu 'Is this medicine safe for my child?' contains information about the potential risks of medicines for the child. The page is written and designed in such a way that it is transparent about the potential risks, but also gives pregnant women a feeling of reassurance by putting the risks in perspective with the benefits.

On top, it is directly visible whether the medicine is safe or not, which answers pregnant women's most pressing question. Along with the green checkbox icon, this will provide pregnant women a first feeling of reassurance (if the medicine is safe to use).

The next part describes what is known from research about the potential risks, something that pregnant women find important to know. This enhances the credibility of the information and could give women more certainty. Probability terms or words that contain uncertainty such as 'probably', 'sometimes' and 'so far' are avoided.

The information in the text balloon (figure 62) is an important part as it puts the risk information described above in perspective with the positive consequence of the medicine. In case of Labetalol, it clarifies that the medicine actually helps to decrease the risk of harm to the child by reducing the risks of high blood pressure.



Figure 61. Page with information about the risks of Labetalol (top of the page)



Figure 62. Page with information about the risks of Labetalol (bottom of the page)

By visualising this information in the white text balloon together with the doctor's illustration, this information seems more important and draws more attention. Similar to the page about benefits, the illustration of the doctor should help to provide a feeling of reassurance.

The last part explains the experience of using the medicine among pregnant women, which serves as an additional counterpart for the risk information. Reading that many other pregnant women have used a certain medicine without issues will likely give them more confidence to use it as well. This was mentioned repeatedly by pregnant women during the interviews.

It was deliberately chosen to end with this positive information rather than with the risk information. Based on the peak-end rule, a psychological phenomenon "in which people judge an experience largely based on how they felt at its peak (i.e. its most intense point) and at its end, rather than based on the total sum or average of every moment of the experience" (Doll, 2019), it is expected that women will feel more reassured when they last read about the positive experience with the medicine, than when they would read about the potential side effects at the end.

Information about complaint or condition

The page shown in figure 63 informs women about a certain complaint or condition they could experience during pregnancy. This information was not specifically written for this project. For prototyping the information about ‘headache during pregnancy’ was taken from oudersvannu.nl (2019).

The information about a certain complaint will answer questions pregnant women might have. Based on insights from user research, the following questions will be addressed:

- Is it normal that pregnant women experience a certain complaint during pregnancy?
- When does it normally occur (in a certain trimester?)
- How does the complaint relate to being pregnant (e.g. why having more headaches during pregnancy), what are the reasons that she experiences this complaint?
- In what situations may pregnant women best take a medicine for the given complaint?

When there is a trustworthy website for a certain condition, the app could refer to that website, for instance hartvoorhulp.nl for the pregnancy complication HELLP.

Furthermore, an overview is given of the medicines that could be used for that specific complaint. The medicine that is recommended during pregnancy is placed on top. Below that, alternative medicines are shown. The icons indicate whether the medicine is safe to use (green checkmark), should not be used (red cross) or when consultation with the doctor is advised (yellow question mark). Clicking on one of the medicines will open the medicine page as discussed on p100-101.

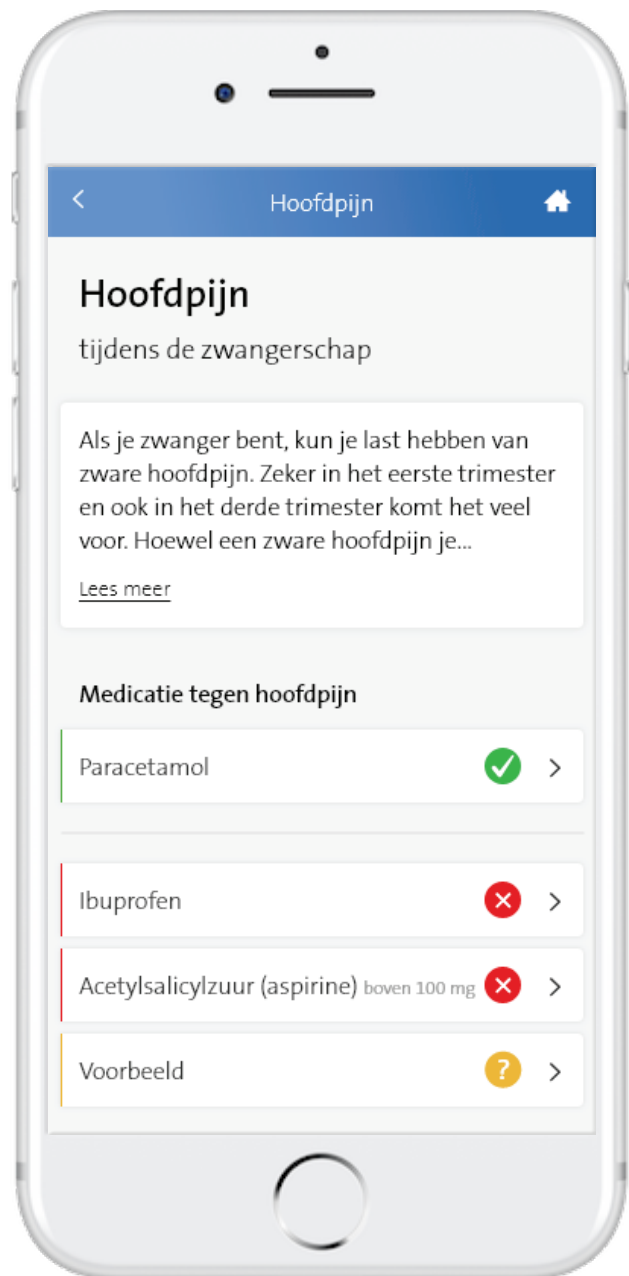


Figure 63. Page with information about a complaint or condition and what medicines can be used



Figure 64. Home screen

Own medication list

An additional feature of the app is the possibility to add medicines to a personal medication list. This allows the user to quickly find information about their medication in the future. The screen flow of this feature is shown in section 6.4. When a medicine is added to the list, the information within the medicine page slightly changes to a more personal version. For instance, instead of *'this medicine is advised when...'*, the indication information changes to *'your doctor advised you to use this medicine because...'*. This is shown in appendix R.

Name and logo

The name 'Mijn Medicijn' ('My Medicine') is chosen for different reasons. First of all it indicates the purpose of the application. Due to its simplicity it can be easily remembered. Additionally, the name includes a personal aspect; "my", which increases the feeling that the application contains information that is personally relevant for pregnant women. Because the name is generalizable, the application could also be used for a broader patient population than just for pregnant women, something that could prove valuable in the future. In this case the 'subtitle' of the application is 'pregnancy' to indicate the use for this specific target group.

The logo symbolizes both a medicine and a pregnant belly. These two meanings highlight the main characteristics of the application. Furthermore, the hands around the belly illustrate pregnant women's protective feelings towards their child and addresses their concern regarding the safety of medicines for their child. In this way, the logo could give pregnant women the feeling that their concerns are being recognized and taken into account, which could make it more likely that pregnant women trust and accept the information in the application.

Visual style

One of the important aspects of the app is that it should be well readable. Therefore, a calm and neutral visual style was created by using tranquil light colours (light grey and white backgrounds), enough white space throughout the whole app, a font type and size that is well readable and enough sentence spacing. This also makes the app look more professional. Blue was chosen as the main colour since it is perceived as trustworthy, responsible and secure. Prescribing a medicine

Desktop app

A desktop version of the application was designed that gynaecologists can use as a reference when advising a medicine and explaining its relevance to the patient. It contains the same information content as in the app and uses the same graphical design elements. The structure is designed slightly differently to optimally supports the HCP and patient while discussing the use of a specific medicine.

During a consultation the desktop app is opened on the background and can be used at any moment. The gynaecologist can type in the name of a medicine they want to advise the patient, leading to a page about that medicine. The benefit-risk information is directly visible after searching the medicine. The fact that both the benefits as the risk information is communicated on one page allows the gynaecologist to explain the information without having to switch between menus. This ensures efficiency, which is important given the short time for a consultation.



Figure 65. Home screen of the desktop version of the app

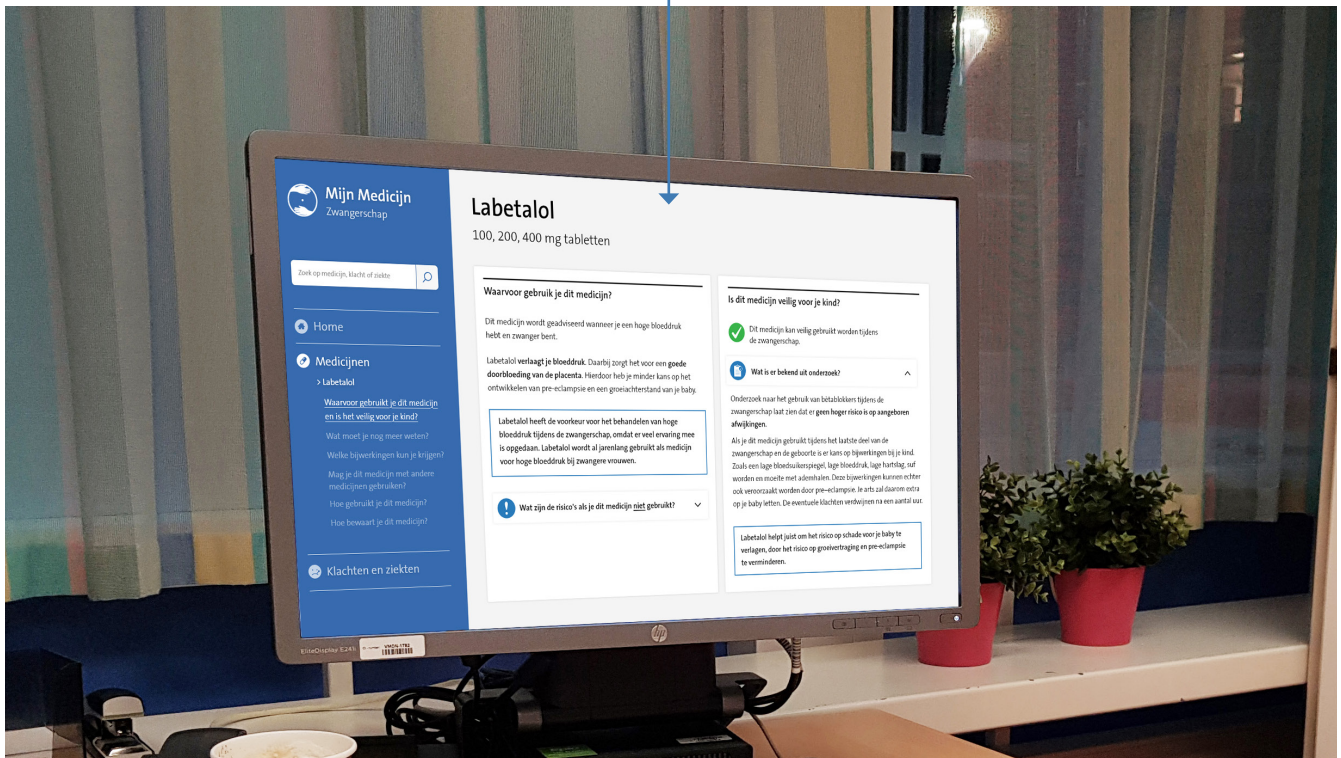


Figure 66. Desktop version of the app showing the benefit-risk information of the medicine Labetalol



Figure 67. Information flyer (front)

Information flyer

An A6 information flyer was designed that informs pregnant women about the app. The front includes a description of what it is about and an image that gives an impression of what the app looks like. On the back, the main features that address the needs of pregnant women are listed. Furthermore, it is shown how and where the app can be downloaded. Finally, the information on the bottom explains that the app is an initiative of the MEB and is made in collaboration with healthcare professionals. This indicates that the information is reliable, which should give pregnant women a feeling of trust. All these aspects should stimulate them to download the app.



Figure 68. Information flyer (back)

This information flyer will be distributed by the gynaecologist during consultations as shown in section 6.2. Furthermore, the information could be promoted in the waiting areas of hospitals. Since the application is useful for any pregnant woman (not only the pregnant women of this target group), the flyer could also be handed out by general practitioners and obstetricians. In addition to the flyer, the app should be promoted online on websites that pregnant women often consult. This makes it more likely that pregnant women know about the app's existence before they visit the gynaecologist or obstetrician the first time during their pregnancy, which is often only after 8-10 weeks.

Script (20-30 minuten)

Introductie (3 min.)

- Het doel van de cursus is om de kennis van de patiëntvriendelijke informatie over medicijngebruik tijdens de zwangerschap te verbeteren.
- De cursus is bedoeld voor verloskundigen, verpleegkundigen en andere medewerkers van de verlosafdeling.
- De cursus bestaat uit drie modules: 1. Het belang van patiëntvriendelijke informatie, 2. Het gebruik van de app 'Mijn Medicijn Zwangerschap', 3. Het gebruik van de app 'Mijn Medicijn Zwangerschap'.

Doel 1 (10 min.)

- De patiëntvriendelijke informatie over medicijngebruik tijdens de zwangerschap is belangrijk voor de veiligheid van de zwangere en het kind.
- De app 'Mijn Medicijn Zwangerschap' is een handige tool om deze informatie te geven en te ontvangen.
- De app is beschikbaar op de website van de verlosafdeling.

Doel 2 (10 min.)

- De app 'Mijn Medicijn Zwangerschap' is een handige tool om de kennis van de patiëntvriendelijke informatie over medicijngebruik tijdens de zwangerschap te verbeteren.
- De app is bedoeld voor verloskundigen, verpleegkundigen en andere medewerkers van de verlosafdeling.
- De app bestaat uit drie modules: 1. Het belang van patiëntvriendelijke informatie, 2. Het gebruik van de app 'Mijn Medicijn Zwangerschap', 3. Het gebruik van de app 'Mijn Medicijn Zwangerschap'.

Mijn Medicijn Zwangerschap



Een handige app met patiëntvriendelijke informatie over medicijngebruik tijdens de zwangerschap

Labetalol

100, 200, 400 mg tabletten

Dit medicijn wordt geadviseerd wanneer je een hoge bloeddruk hebt en zwanger bent of wilt worden.

[Lees meer](#)

Heeft je arts dit medicijn geadviseerd?

+ Voeg dit medicijn toe aan mijn medicatie

✓

👍 Waarvoor gebruik ik dit medicijn?

👤 Is dit medicijn veilig voor mijn kind?

6.4 SCREEN FLOW AND INTERACTIONS

In this section an overview is given of the connection between the different screens as well as the possible functions of each screen. The flows of the screens are divided per functionality of the app. The mobile gestures that are shown in figure 70 are used to explain the intended interaction with the screen elements.

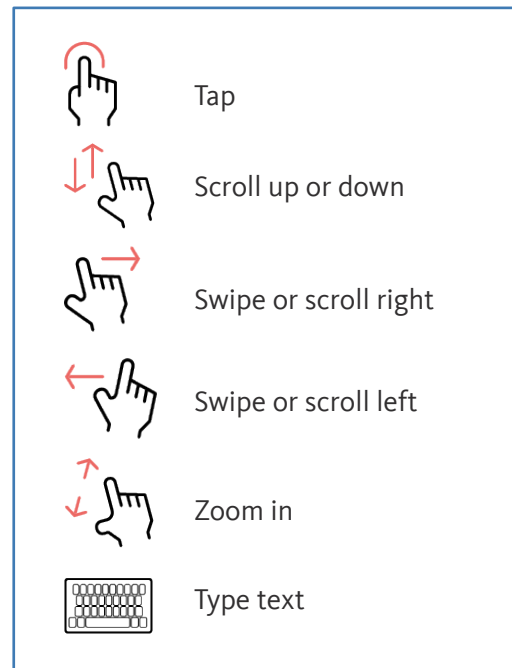
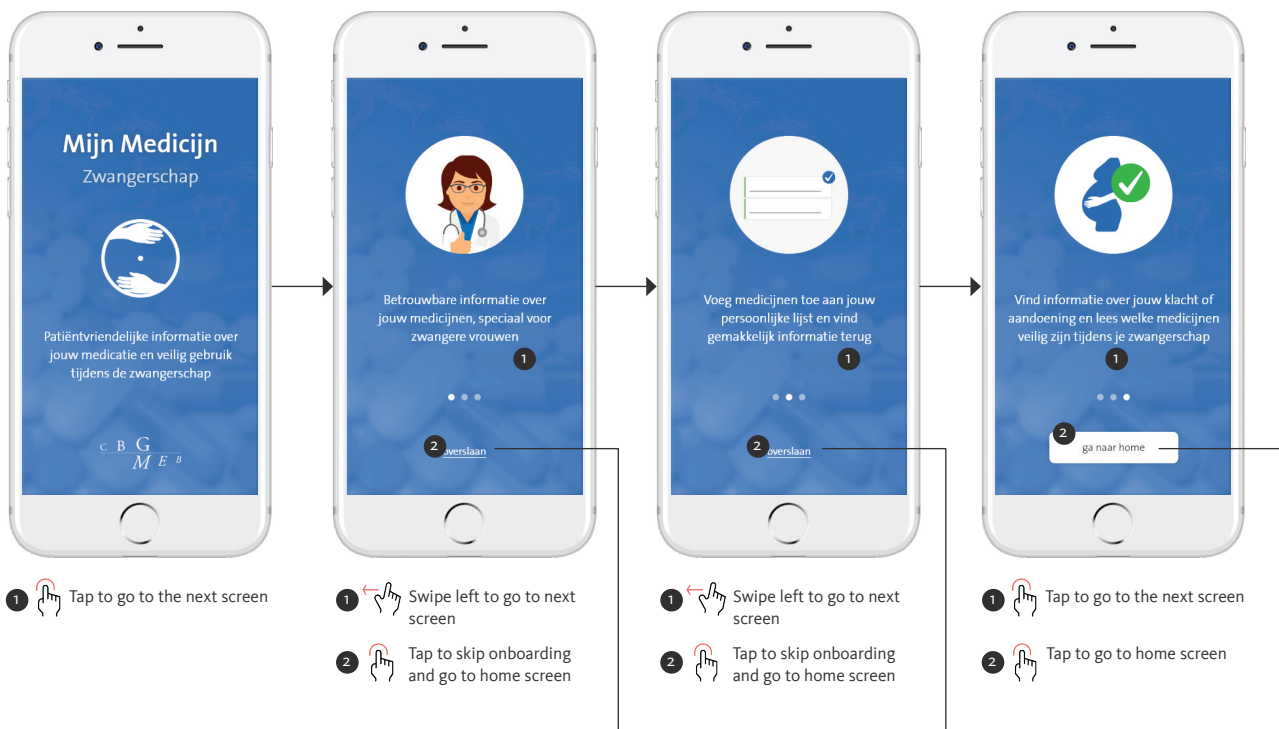


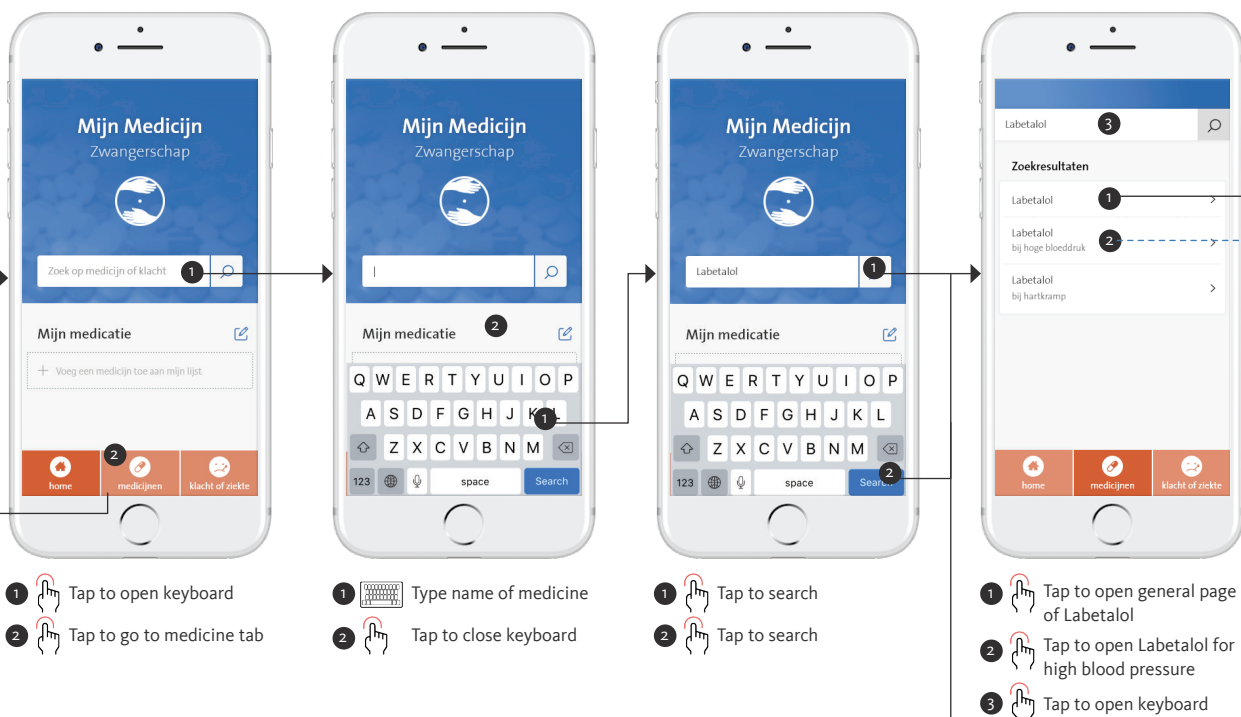
Figure 70. Mobile gestures

1 First use onboarding

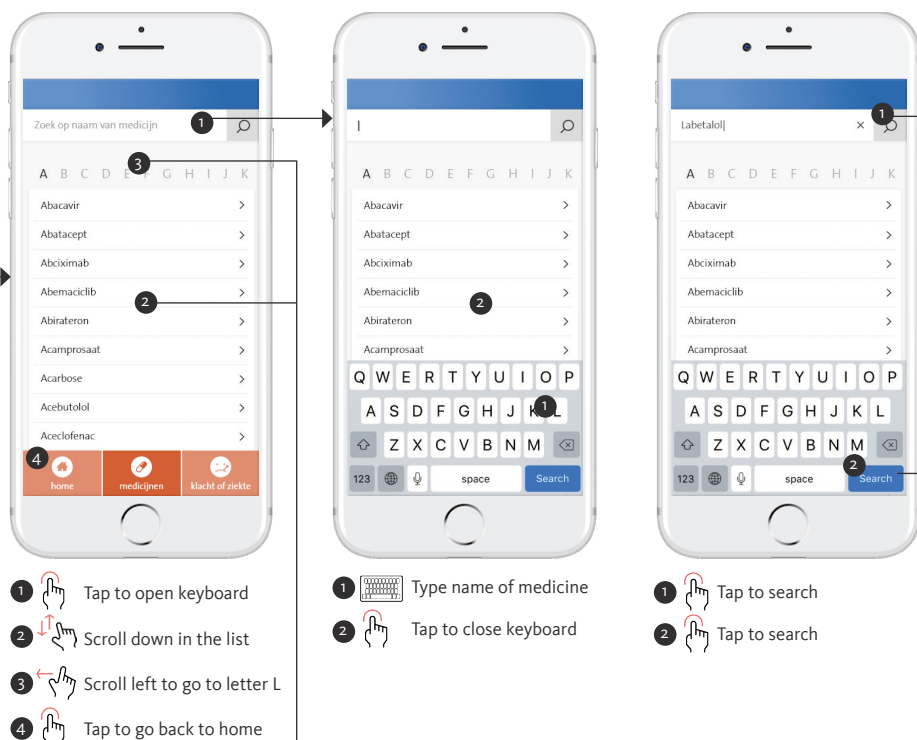


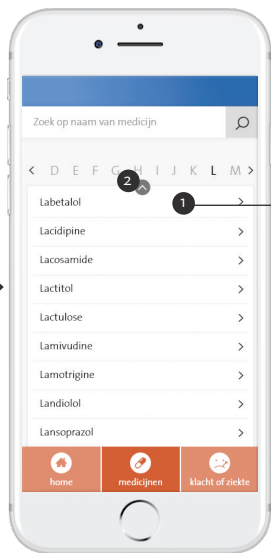
2 Search medicine (Labetalol)

Search medicine from home screen



Search medicine via the medicine tab



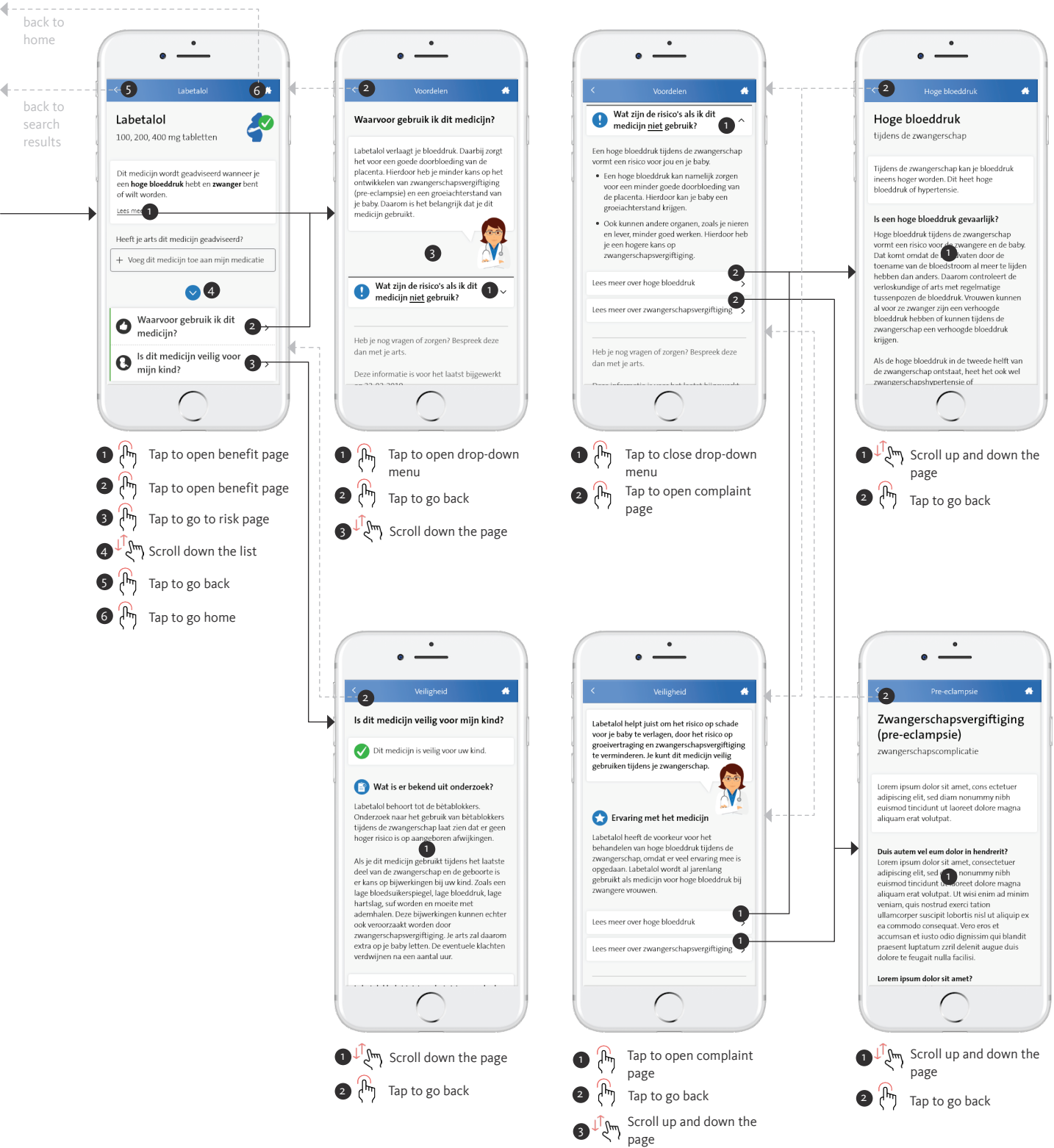


- 1 Tap to open general page of Labetalol
- 2 Tap to go up to A



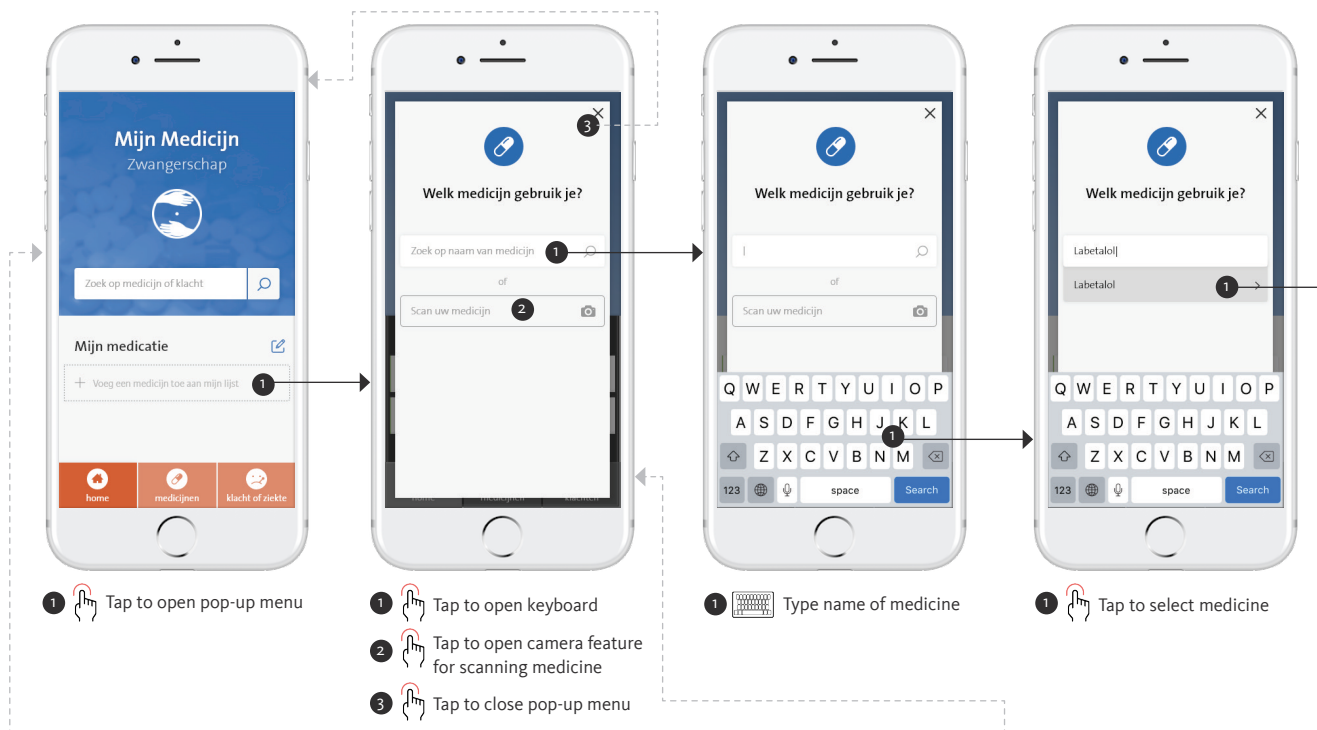
- 1 Tap to open Labetalol for high blood pressure
- 2 Tap to go back
- 3 Tap to go to home

3 Read benefit-risk information about Labetalol

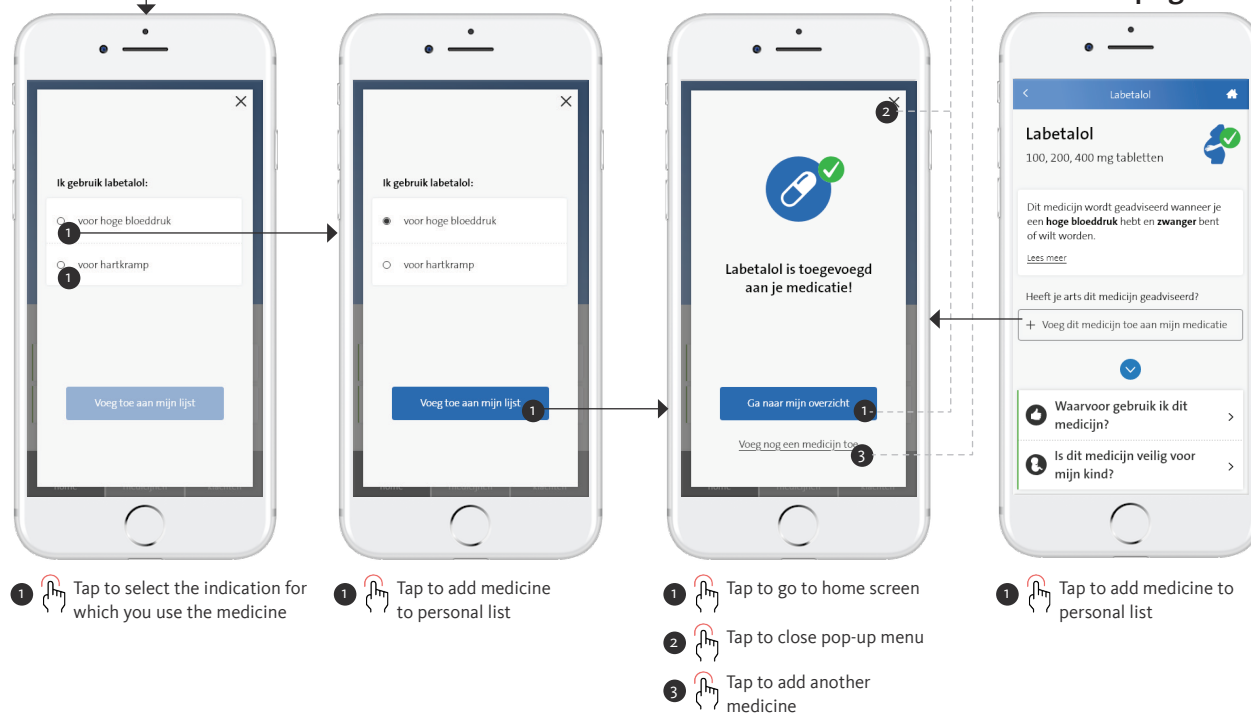


4 Add medicine to personal list

Add medicine via home screen



Add medicine via medicine page



Note: after adding a medicine to your personal list, it will show a more personal version of the information which can be seen in appendix R

5 Search complaint/illness (headache)

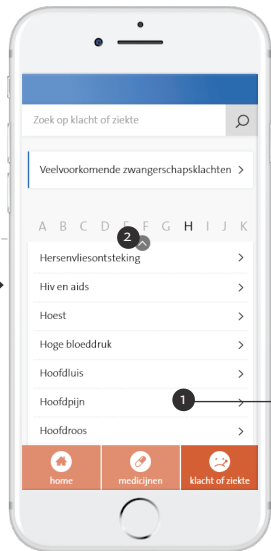
Search complaint from home screen

- 1 Tap to open keyboard
- 2 Tap to go to complaint tab
- 1 Type name of medicine
- 2 Tap to close keyboard
- 1 Tap to search
- 2 Tap to search
- 1 Tap to open general page of Labetalol
- 2 Tap to open Labetalol for high blood pressure
- 3 Tap to open keyboard

Search medicine via the medicine tab

- 1 Tap to open keyboard
- 2 Scroll down in the list
- 3 Tap letter H
- 4 Tap to open common pregnancy complaints
- 5 Tap to go back to home
- 1 Type name of complaint
- 2 Tap to close keyboard
- 1 Tap to search
- 2 Tap to search

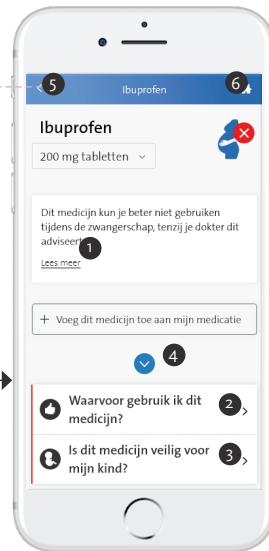
6 Read about complaint (headache) and the medicines that can be used



- 1 Tap to open page about headache
- 2 Tap to go up to A



- 1 Tap to read more information about headache
- 2 Tap to open medicine page
- 3 Tap to go to home
- 4 Tap to go back



- 1 Tap to open benefit page
- 2 Tap to open benefit page
- 3 Tap to go to risk page
- 4 Scroll down the list
- 5 Tap to go back
- 6 Tap to go home

7

Evaluation

In order to assess whether the final design 'Mijn Medicijn - Zwangerschap' has met the design goal and interaction vision and to find out how pregnant women experience the product-service system in general, an evaluation study was carried out. The first section explains the research goal, followed by a description of the participants, prototype and procedure. Then, similar to the user research results, the results are discussed and conclusions are drawn.

7.1 RESEARCH GOAL

This evaluation study is conducted mainly to assess whether the design has met the design goal and interaction vision. Therefore the aim is to evaluate whether the application and information design makes pregnant women feel confident about using a particular medicine during pregnancy. Furthermore, it is tested how pregnant women value the overall product service system as well as whether it evokes the desired interaction qualities as described on p.68. Additionally, the usability of the design is evaluated.

The research questions are described below. Since the reliability of the design was an important requirement, research question 2 was formulated.



1. *How do pregnant women value the product service system in general, including the application, its functionalities, the flyer and the role of the HCP?*
2. *Do pregnant women have trust in the reliability of the design and information?*
3. *Does the information about benefits and risks help pregnant women to make an informed decision and feel confident about using a medicine during pregnancy?*
4. *What important usability issues do pregnant women experience while using the flyer and application and how can they be improved?*
5. *Does the product service system as a whole evoke the desired interaction qualities?*

7.2 METHOD

Participants

Eight pregnant women participated in the research. Four of them had also participated in the user research, where they had indicated to be willing to participate again in the evaluation study. Similar to the previous research, the tests were scheduled after the patient's appointment at VUmc, except for one participant who preferred to do the test at her home.

The other four participants were recruited during consultations at the outpatient clinic at VUmc. At the end of each consultation, the gynaecologist asked the patient if she wanted to give feedback on a design. All of them were willing to participate. Then the researcher walked them to the room that was reserved for the study.

Prototype

In order to be able to test how pregnant women value, interact with and react on the design and information, an interactive prototype of the application 'Mijn Medicijn - Zwangerschap' was created in Adobe Experience Design (Adobe XD). The prototype is made in such a way that users can navigate like they would normally do in an app, but not every element was clickable. The most important functions like searching a medicine, reading the information about benefits and risks, searching a complaint and adding a medicine were operational. In addition to the prototype in Dutch, an English version was made since two participants did not speak Dutch.

Procedure

The script that was made for the evaluation test consists of four parts. Since it was likely that the participants did not use (one of) the two medicines (Labetalol and Aspirin) that the design was created for, some hypothetical scenarios were created. On the basis of these scenarios, participants were asked to perform some tasks in the prototype, after which the researcher asked them questions about their experiences and thoughts about the design.

First, to simulate the real situation, participants were shown the information flyer that the doctor would give them during a consultation. After reading the information flyer, participants explained their first impression of the app, why they would consult it or not and what they thought about the role of the doctor.

In the next part, participants were asked to search and read information about the medicine Labetalol, in order to test their perception of the benefits and risks and whether it would make them feel confident to use the medicine.

In the third part, the usability of the app was tested and overall functionalities and value of the app were discussed. When there was time left, the information of Aspirin was read and evaluated. In the end, half of the participants also evaluated the information of Aspirin.

Finally, participants were asked to choose five words from a list with interaction qualities. Afterwards they explained why they chose those five words. This was done to get more explicit feedback on the quality of interaction, which made it possible to evaluate whether the design evokes the desired interaction qualities that were described in chapter 4.2 on p.68.

For the four tests with the participants that were recruited during consultations, a shorter version of the script (15 minutes instead of 20-30 minutes) was made since the test should not take too much of their time. Therefore part three, where participants would have to search for the medicine Aspirin, was eliminated. When participants had more time, the normal script was followed.

Data analysis

For the analysis, the same procedure as explained on p.43 was used. The sessions were recorded on audio and transcribed afterwards. The transcripts were analyzed using statement cards, which were then clustered in themes per research question. Interesting quotes that illustrate the findings well were collected.

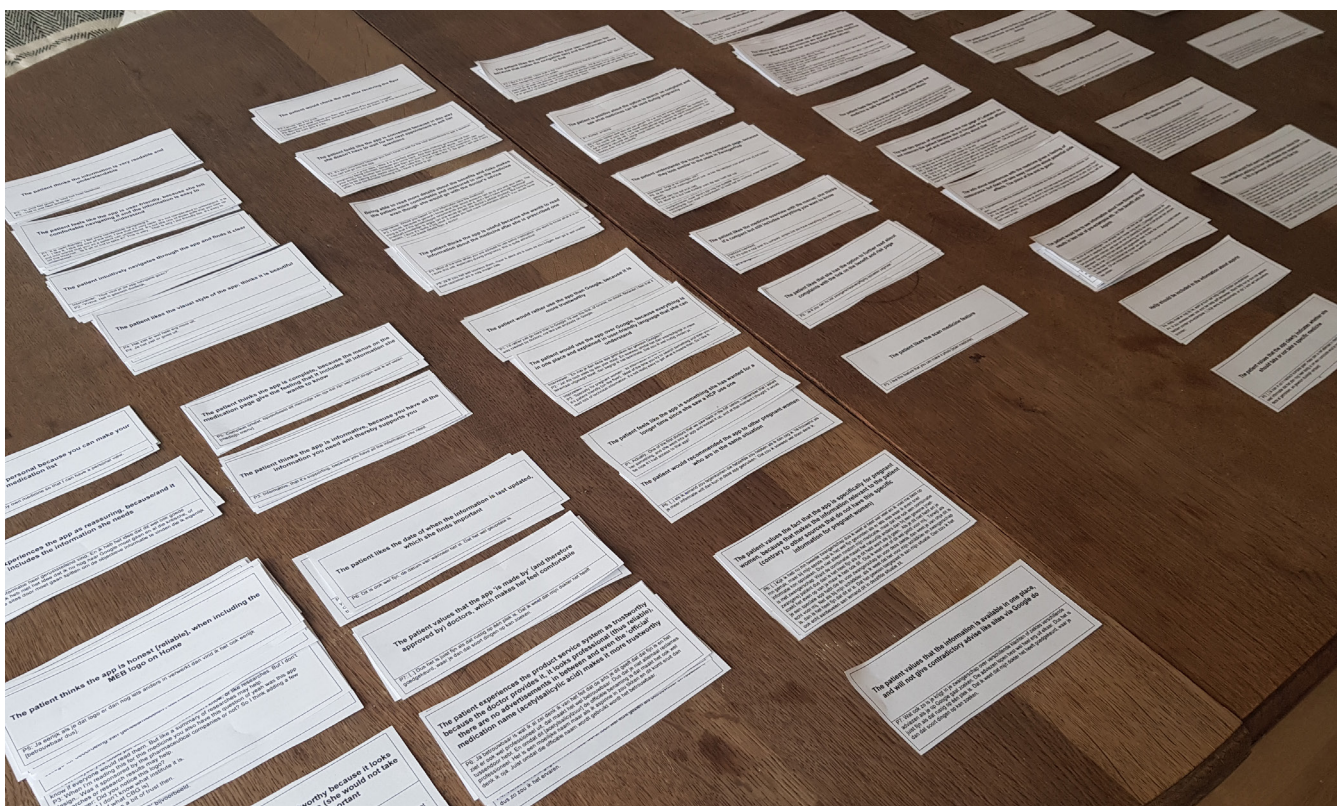


Figure 71. Clustering statement cards per research question

7.3 RESULTS

In this section, the results of the evaluation study will be discussed. Similar to the user research, the results are divided per research question and supported by interesting quotes of the participants.

Apart from the insights for the research questions, some participants had ideas about functions or information that could be added to the application. These are discussed in appendix U.



Overall value of the design

RQ1 - How do pregnant women value the product service system in general, including the application, its functionalities and the role of the HCP?

First impression; useful and convenient

All participants had a positive impression of the application after reading the information flyer. They understood what the application was about and experienced the flyer as clear, well-organized and to the point. The application seemed very useful and convenient to them since you can directly consult the app independently when questions or concerns arise, instead of having to call the doctor or wait until the next appointment. All participants indicated that they would definitely look at the application.

"This is pretty cool. I'll be using it all the time. You have no idea how many times I had to Google.. Things that were ok or not ok, because you don't want to call the doctor every time you think about something saying 'can I take this..?'; 'Can I take that..?'. So I find it super helpful."



P1

Two participants specifically mentioned that they would use the app all the time since they often have questions about medicines. Especially during a first pregnancy and at the start of a pregnancy women have a need for information.

Consult the app for confirmation about safety

All participants mentioned that they would consult the app to get confirmation on whether the medicines that they are using or have been prescribed are actually safe to use during pregnancy. Three of them would do this because they do not completely trust the doctor's advice due to negative experiences in the past when a doctor did not give the right information, or because the doctor seems messy or did not show involvement. This is in line with the findings from previous user research where patients also felt the need to get confirmation about the medicine's safety, although in this study it has become even more apparent. Two participant said that they felt relieved and comfortable knowing that they have a place to go to find information and to be able to read more details about the benefits and risks of a medicine.

*"I would consult the app yes. When I would need a medicine again. Because I still want to check whether the doctor actually paid attention. It happened to me a few times now so now I am more alert." - P2**

"The thing is that if the gynaecologist recommends you to use it, and I don't have enough 'technical' [medical] knowledge to argue.. [therefore go with doctor's advice]. But having more details, I think it's really a big relief, it makes you feel more comfortable using it." - P3

"I feel comfortable knowing that I have a place to go." - P1

Use the app instead of Google

Participants indicated that they would rather use this application than Google. First of all because the information is written in patient-friendly language (as is explained on the information flyer), opposed to online information which is often difficult to understand due to complex medical jargon. Secondly, they value having all information in one place, which makes it easier to find the information compared to Google, in addition to that it will not give contradictory advice, which is often the case when consulting online websites via Google.

More importantly, a reason to consult the app first is that the doctor advises them to use it and has been involved in creating the app, which makes it more trustworthy. One patient said that she would be positively surprised when the doctor would inform her about this app, because she has the feeling that she has a patient usually has to ask for (more) information. When asking how they would feel about receiving an SMS or email about the app from the hospital, participants indicated that they were fine about that and would directly download the app.

"I feel more secure if I know that I'm using an app that was designed by the doctor at the hospital. That makes it more trustworthy." - P1

"I'd rather just go here than to Google. I'll use this first, of course, no doubt. Because I feel that it was created by doctors, not like just anybody on Google." - P3

*"Yes! If everything is in one place anyway. And certainly because it is probably explained in more Layman's terms, then I at least understand it. Yes I would find that useful."***



P2

* "Ik zou de app wel raadplegen ja. Als ik nu weer medicijn nodig zou hebben. Omdat je toch wel wil checken of die dokter wel opgelet heeft. Het is me wel een paar keer overkomen dus nu ben ik wat alerter." - P2

** "Ja! Als toch alles op één plek staat. En sowieso omdat het dan waarschijnlijk in meer leekentaal uitgelegd staat, dan begrijp ik het tenminste. Dat zou ik wel nuttig vinden ja." - P2

*"On Google you often end up with opinions of people and not with the medical information you actually need. Google is not reassuring at all." - P7**

'Specially' for pregnant women

Three participants specifically mentioned that they value that the app is specifically for pregnant women, as opposed to for example the patient leaflet which is not directed to pregnant women. Reading 'specially for pregnant women' on the information flyer makes them feel like the information is relevant and applicable for their situation as a pregnant woman.

*"Specially for pregnant women. Then I directly feel like (oh)! [positively surprised]" - P2***

*"The combination makes it different of course compared to a normal [non-pregnant] patient. If you would not have this app and you search it, then it's like yes but I also have this [pregnant/disease].. So I don't know if this holds for me.. Whereas when you have a special app that is for both pregnancy and the disease, then you know ah yes this is really for me." - P6****

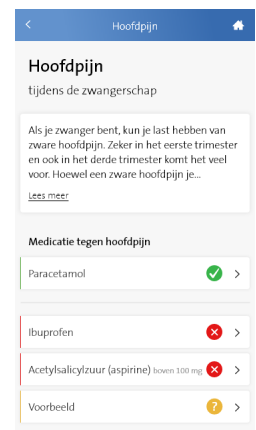
Own medication list

Most participants liked the option to be able to save medicines to your own medication list since that makes it easy to find back information later, which increases the usability of the app. One patient mentioned that this is useful when you want to show to a new doctor what medicines you are using (e.g. when you are on holiday abroad). Some participants also indicated that this makes the app more personal, as will be discussed later.

*"If you have to search every time and you don't know the name exactly.. So when you have a list and then in 3 weeks you want to know what was it again, I read and saw this. Then you can just click on it." - P4*****

Search on complaint

All participants very much appreciated the option to search on a specific complaint and see what medicines can or cannot be used safely during pregnancy. Surprisingly, this seemed to be the most valued function of the app. They found it very useful being able to find this information in the app instead of having to call the doctor for advice. Pregnant women do not want to consult the doctor for every complaint, especially not for something 'simple' such as a headache. Participants understood the green, yellow and red icons well. One participant recognized them from another pregnancy app ZwangerHap from the Dutch 'Voedingscentrum' (nutrition centre) that she often used (even though they were not consciously designed the same).



P4

*"What I especially like is that you get an overview of these medicines you can use for this complaint."*****

* *"Bij Google kom je al heel vaak bij meningen van mensen terecht en helemaal niet bij de medische informatie die je eigenlijk nodig hebt. Google is helemaal niet geruststellend." - P7*

** *"Speciaal voor zwangeren. Dan voel ik me al helemaal (oh)! [positief verrast]" - P2*

*** *"De combinatie maakt het natuurlijk anders dan bij een gewone [niet-zwangere] patiënt. Als je deze app niet hebt en je zoekt het even op dan is het van ja maar ik heb ook dit [zwanger/ziekte].. Dus ik weet niet of dit wel geldt voor mij.. Terwijl als je een speciale app hebt die én voor zwangerschap én voor deze ziekte, dan weet je van oh ja dit is echt voor mij." - P6*

**** *"Als je zelf iedere keer moet gaan zoeken en je weet niet precies de naam.. Dus als je iets kunt toevoegen en je hebt een lijst en over een week of 3 wil je kijken van oh hoe zat het ook alweer, ik heb dit gelezen en gezien. En dan kun je er gewoon op klikken." - P4*

***** *"Wat ik vooral fijn vind is dat je dan zo'n overzichtje krijgt met deze medicijnen kun je gebruiken voor deze klacht." - P4*

"Oh! I also like this one. Because every time I have a complaint, I had it a few times.. I had to call the hospital and ask what I need to do.. I wouldn't complain because they are accessible.. But this is easier, because not for every complaint you want to give a call and ask etc." - P3

*Look! This is clear. With things like headache.. Yes you don't want to call your doctor for that so then it's very nice you can look that up." - P7**

*"Yes this is very nice. It is also very clear, with those icons this you can take, this you cannot take" - P6***

Medicine page

Participants liked the medicine page with all information divided in separate menus with icons. One participant explained that she likes that it's compact, but still includes everything you want to know.

*"[After seeing the menu] Look! this is really an app after my own heart. I cannot click on this yet but you see I will continue reading it right away! I could really enjoy myself with this [haha], looking everything up what I want. And when I have pressing questions." - P7****

Beautiful, calm visual style

Participants were very positive about the visual style of the app. They thought it looked beautiful, calm, clear, well-organized and professional. This has a positive effect on the ease of use and readability of the text. They also liked the logo and menu icons.

"It looks very beautiful." - P4

"Beautiful! Calm and well-organized." - P7

"The logo is nice, I love it." - P1

* *"Kijk! Overzichtelijk. Dit is helder. Met dingen zoals hoofdpijn.. Ja daar ga je je arts niet voor bellen dus dan is het wel heel erg fijn dat je dit kan opzoeken." - P7*

** *"Ja dit is heel fijn. Dit is ook heel duidelijk, van die icoontjes dit wel dit niet." - P6*



Trustworthiness

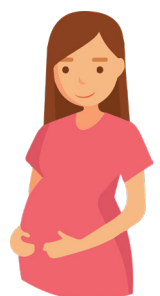
RQ2 - Do pregnant women have trust in the reliability of the design and information?

MEB logo is trustworthy

During the sessions, all participants indicated that they experienced the app as trustworthy. Several reasons were given. Six participants explained that they found it trustworthy because of the MEB logo on the bottom of the pages. The fact that the information is 'government approved' makes them feel secure. Two participants mentioned that they found it reassuring that the app is not made by an organization that wants to earn money. Five participants chose 'trustworthy' on the list that was provided to them, others chose 'reassuring' or 'honest' to describe their feeling of trust.

Some participants did not know what the MEB is. For some of them the logo still gave a feeling of trust. Two others did not perceive it as 'trustworthy' before getting an explanation from the researcher. One participant proposed to make the logo more visible, for example on the home screen, with a short explanation of what the MEB is. She said that she would directly want to see the information source in the app store, which would be a reason for her to download the app.

*"I find the app very reassuring, because when it is approved by the MEB then you know that you can trust on it."*****



P8

*** *"[Na zien van alle menuutjes] Kijkkkk, dit is echt een app naar mijn hart. Ik kan hier nog niet op klikken maar je ziet ik ga gelijk doorlezen! Ik zou me hier prima mee kunnen vermaken [haha], alles opzoeken wat ik wil opzoeken. En als ik dringende vragen heb." - P7*

**** *"Ik vind de app wel heel geruststellend, omdat als dit is goedgekeurd door het CBG dan weet je dat je erop kan vertrouwen." - P8*

*"Because there is a seal of approval on it, by this one, the MEB, then I think this can be trusted." - P2**

*"I think I want to see it [the logo] here [home] already, because when you go to the app store, there are a lot of apps and then I directly want to see like ok that one is reliable. This is a source that I can rely on." - P5***

Trustworthy because the doctor provides it and it looks professional

Six patients mentioned that the fact that the doctor informs them about the app makes it trustworthy, as it indicates that they stand behind the app and approve it. Others trust the app because it looks very professional and calm. Two participants liked the fact that there are no advertisements in between, which again increases the reliability and would make them take the information more seriously. Another participant said that because the (difficult) official medication name is used (acetylsalicylic acid) increases the trustworthiness as well.

*"It looks very professional. It is very 'calm' to see. I think that's important. Then your information is also a bit more serious. Because sometimes medical sites have these advertisements in between and I don't take that seriously." - P7****

*"Information provided by a doctor is really seen as reliable and advisable, that's how I would experience it. I also think that is a signal that they stand behind it and also see it as reliable information. I think that is a very important point in making such an app workable." - P4*****

*"The fact that the doctor gives you this is nice and it also looks professional, which makes it reliable. That you do not have all these advertisements in between. And because this [acetylsalicylic acid] is the official name, it also makes it professional." ******



P5

Last update

Two participants mentioned that they liked to see the date of when the information was last updated on the bottom of the medicine page. This enhances the trustworthiness of the information.

"It's also nice to see the latest update stuff. Because if you put there that it was last updated three years ago, I would have some doubts like is this still the case. Every year there may be some new researches and new findings that changes things so then it's nice to see that the information is up to date." - P3

* "Omdat er inderdaad een seal of approval op staat, door deze, het CBG, dan denk ik dat is te vertrouwen." - P2

** "Ik denk dat ik het hier [op home] al zou willen zien, want als je naar de appstore gaat heb je natuurlijk heel veel apps en dan zou ik wel meteen willen zien van oke die is betrouwbaar. Dit is een bron waar ik op kan varen of niet." - P5

*** "Het komt heel professioneel over. Het is heel rustig om te zien. Dat vind ik wel belangrijk. Dan komt je informatie ook wat serieuzer over. Want soms hebben medische sites van die reclames tussendoor en dat neem ik dan niet serieus." - P7

**** "Vanuit een arts gegeven informatie wordt toch wel echt gezien als betrouwbaar en raadzaam, zo zou ik het ervaren. Ik ook dat dat een signaal is dat zij erachter staan en het ook als betrouwbare informatie zien. Ik denk dat dat een heel belangrijk punt is in het werkbaar maken van zo'n app." - P4

***** "Het feit dat de arts je dit geeft is fijn en het ziet er ook wel professioneel uit, dat maakt het wel betrouwbaar. Dus dat je niet allemaal reclames tussendoor hebt. En omdat dit [acetylsalicylzuur] de officiële benaming is dat maakt het ook wel professioneel." - P5



Benefits vs. Risks

RQ3 - Does the information about benefits and risks help pregnant women to make an informed decision and feel confident about using a medicine during pregnancy?

Value the app's clear advice

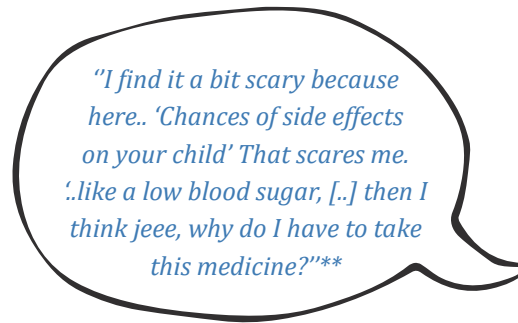
As mentioned earlier, in general participants value that they have a place where they can read about the benefits and risks of a medicine in the app. This makes them feel more reassured. One patient specifically valued the fact that the app indicates whether she should take or not take a specific medicine, rather than having to draw the conclusion herself from a vast amount of (difficult) information.

*"I can go into such a medical website (FK.nl), but then everything is in medical terms and só much information that it is very hard to draw a conclusion from it.. And with this app it is already drawn, and just clearly communicated." - P5**

"It is reassuring, because you want to feel like you're doing the best for your baby. Being able to read this makes you feel better." - P1

Concerns and questions about side effects of Labetalol

The information in the menu 'is this medicine safe for my child?' of the medicine Labetalol caused some problems. Most participants felt anxious after reading about potential side effects of the medicine on their child.



*"I find it a bit scary because here.. 'Chances of side effects on your child' That scares me. ..like a low blood sugar, [...] then I think jeee, why do I have to take this medicine?"***



P6

It raised questions about what the chances of developing those side effects are, what the impact of these side effects are and when the side effects would occur (i.e. when the baby is still unborn or after birth?). Furthermore, women wanted to know whether this medicine is the best option for them when having a high blood pressure and whether there are no alternative medicines that do not involve these risks. One patient mentioned that she would want to know whether and when she should stop with Labetalol to minimize the chance of side effects for her child during birth, and what the effect of that would be on both mother and child. These are questions they would like to get answered in the app. Participants indicated that in this case they would ask their doctor to answer their questions.

Overall, participants seemed to overestimate the actual risks involved with the medicine. It was not clear to them how the benefits of the medicine outweigh these risks. One woman said that when she would know that a medicine is the best option for a given situation, she would feel confident to use the medicine. This suggests that when the information would include the answers on the above mentioned questions, pregnant women would feel confident about using the medicine during pregnancy.

* "Ik kan in zo'n medisch kompas gaan, maar dan is het allemaal in medische termen en zó veel informatie dat het dan nog heel lastig is om een conclusie eruit te trekken soms en dat is bij deze al getrokken, en gewoon duidelijk vertaald." - P5

** "Ik vind het een beetje eng want hier.. 'Kans op bijwerkingen bij uw kind' Dan schrik je. ..zoals een lage bloedsuikerspiegel.. [...] dan denk ik jee.. Waarom moet ik dan deze medicijnen nemen?" - P6

*"I have something with those risks.. If I then read that the child maybe can't breathe anymore then uhh.. I would want to know how big the risk is. When you for example say 'relatively small', and you have a legenda with what that exactly means, then it is also more readable." - P2**

In contrast, one patient found the risk information of Labetalol convincing and understood that it could involve risks, but that not taking the medicine is worse. This could be because she is familiar with the risk of high blood pressure and therefore understands the relevance of such a medicine better.

"It's convincing what it says. There may be a risk, but it would be higher risk if you would get pre-eclampsia." - P3

Experiences with the medicine does not reassure enough

Participants found the information about 'experiences with the medicine' good to see. For some participants, reading this 'kind of' reassured them, but generally it did not take away their concerns about potential side effects. The same counts for the information in the text balloon and the sentences after the side effects. One woman mentioned that she would irrationally focus on those side effects and would want more clarity about them (i.e. her questions should be answered) before she would feel reassured and confident to take the medicine.

"[symptoms disappear after..] Ok, that makes me feel a little better. But you know this does not say that your baby won't have any issue when it's born. It might be the case. You know.. I just want to make sure that if I'm taking it it's because there is no other choice." - P1

*"When you're pregnant you're extra alert.. Here it says everything is ok but what is this [side effects] then.. They don't put this there for nothing. So then I would irrationally really focus on those side effects. [...] If you read this [text balloon] then you think ah yes ok. I get it.. But now I want more clarity about this [side effects]." - P6***



Figure 72. Page with risk information of the medicine Labetalol

* "Als ik dan lees dat het kind misschien niet meer kan ademen dan uhh.. Ik zou wel willen weten hoe groot het risico dan is. Als je bijv. Zegt relatief klein, en je hebt een legenda met wat relatief klein dan precies betekent, dan kan het ook leesbaarder." - P2

** "Als je zwanger bent ben je extra alert.. Hier staat dan dat het allemaal oké is maar wat is dit [bijwerkingen] dan.. Dat zet je er niet zomaar bij. Dus ik zou dan echt irrationeel gefocust zijn op die bijwerkingen. [...] Als je dit leest [in tekstballon] dan denk je van oja oke. Ik snap het.. maar ik wil nu hierover [bijwerkingen] duidelijkheid." - P6

Regarding 'experiences with the medicine', one participant felt like it should be made more clear that it is not about experiences from people but from studies. Another participant agreed with the designer's choice to put the experience with the medicine at the end of the page. Saving the 'bad news' for last would have made her more anxious.

'The medicine is safe' is confusing

One participant said that the app should not say that the Labetalol is safe to use because of the potential side effects on the child. She found that confusing and something the app makers legally cannot say. Instead, she proposed to state that many pregnant women use the medicine (with the green checkmark), which would give her the same positive feeling.

"I would remove this sentence [medicine is safe..] so that you cannot be charged if something goes wrong with Labetalol. You can also say that the medicine is prescribed for many pregnant women with a green check mark. Then it says exactly the same thing, but you say nothing wrong."
- P2*

Anxiety about risks when not taking the medicine

After reading the information on the (benefit) page 'what does this medicine do for me?' of Labetalol, one participant felt anxious about the risks of having a high blood pressure. This is because the information sounded as if it was a fact that a high blood pressure will lead to the negative consequences mentioned in the text. Although this would make sure the patient takes the medicine, this feeling of concern as a 'side-effect' of this information should be avoided.

Indication of Aspirin incomplete

The indication of the medicine Aspirin (i.e. the information about for what reasons the patient would use the medicine on the medicine page)

* "Ik zou deze zijn gewoon weglaten [dit medicijn is veilig..] zodat je niet aangeklaagd kan worden als er iets fout gaat met Labetalol. Wat je ook kunt zeggen is dit medicijn wordt voor veel zwangere vrouwen voorgeschreven met een groen vinkje. Dan staat er precies hetzelfde maar dan zeg je niks verkeers." - P2

was incomplete, since it is not only prescribed for preventing the pregnancy complication preeclampsia but also HELLP. One patient was using Aspirin since she had developed HELLP during her previous pregnancy.

Confident about Aspirin

The participants that read the benefit-risk information about the medicine Aspirin indicated that they would feel confident using the medicine, because the information says the medicine is safe. However, it was unclear to patients that Aspirin is only safe in doses up to 100 mg. After reading the benefit information, one woman wondered whether taking Aspirin would increase the risk of a bleeding since it makes your blood thinner. She expected to find this information in either the menu about side-effects or the menu about important things to know.

*"Yes this [risk info Aspirin] reassures me." - P5***

Link to more detailed information and complaint

One participant wanted to read more detailed information about medicines. For instance how thinner blood results in less risk of developing preeclampsia when taking Aspirin. She mentioned that the app could provide a link to a trustworthy website with more in depth information, for instance hartvoorhelp.nl for the pregnancy complication HELLP. Providing such links would also prevent women from ending up on unreliable websites with contradictory information.

In general participants valued the links to pages about relevant complaints, since the information could raise questions about that as well. These pages could also include in depth information such as mentioned above.

*"Yes now I would also look up pre-eclampsia." - P2****

** "Ja dit stelt me gerust." - P5

*** "Ja ik zou dan nu ook zwangerschapsvergiftiging opzoeken zegmaar." - P2



Usability issues

RQ4 - What important usability issues do pregnant women experience while using the flyer and application and how can they be improved?

Clear information flyer

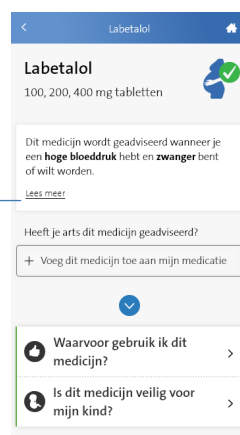
In general, participants found the information flyer clear and they directly understood what the app is about. They liked that the information on the flyer is concise and clear. The bullet points make it well readable. Only one patient did not directly understand that it is an informative app, because in her experience apps are usually not informative but rather expect you to fill in your own information or give medication reminders. After reading the information it became clear. She acknowledged the fact that doctors would be able to explain what the app is about. Another participant expected that not everyone may understand from the flyer that they can download the app in the app or play store, which might require a short description.

*"Yes clear. I understand it directly." - P5**

*"What is nice about the flyer is that it's just very clear, just short and sweet. I find it very 'clean', well-organized." - P4***

Menus were overlooked

In three cases patients clicked 'read more' under the indication information on the medicine page, which opens the (benefit) menu 'what does this medicine do for me?'. After reading the information, they had questions about the risks when taking the medicine, the side effects and



* "Ja overzichtelijk. Ik begrijp het meteen." - P5

** "En wat wel fijn is aan de flyer is dat ie gewoon heel duidelijk is, gewoon kort maar krachtig. Ik vind hem heel netjes, overzichtelijk. En uhh puntsgewijs zeg maar, niet te veel informatie." - P4

contraindications. Without their knowing the app did provide answers to these questions within other menus. Since they started reading the medicine page on top and directly clicked on 'read more', they did not notice the menu below. They were unaware that they had opened the benefit page and did not directly know where to find the other information. Other participants did not have difficulties with this and intuitively clicked on back < and found the menus on their own.

*"[When reading the risks involved for the child] Yes what I would like to know is the contraindications or when you experience some side effects.." - P5****

Purpose of own list unclear

For one participant it was unclear what the purpose was of adding medicines to your own list. She expected that this would require her to fill in personal information. Therefore she would first want to search for the medicine in the search bar, looking for general information first before giving personal information.

*"This [own medication list] gives me the feeling that I have to inform something about myself, but why? Why do I have to do that? That is not clear to me. So then this feels safer [using search bar]." - P6*****

Intuitive and simple to use

Apart from the above mentioned issue, participants experienced little to no usability issues when using the app. Overall, participants intuitively knew how to navigate through the app and found it easy to find and understand the information. This is further explained in the next part.

*"I also find it, and that is what an app is supposed to be, that it is very simple. Not too complicated, not too uhh.. Just you can click on this and you can click on that." - P8******

*** "Ja wat ik nog zou willen weten is de contra-indicaties of als je last krijgt van bepaalde symptomen.." - P5

**** "Dit [eigen lijst] geeft mij het gevoel dat ik iets van mezelf moet informeren, maar waarom? Waarom moet ik dat doen? Dat is mij niet duidelijk. Dus dan voelt dit veiliger [gewoon zoeken]." - P6

***** "Ja ik vind het ook wel, en zo hoort een app ook te zijn, dat het heel simpel is. Niet te ingewikkeld, niet te veel uhh.. gewoon je kan daarop klikken en je kan daarop klikken." - P8



Interaction qualities

RQ5 - Does the product service system as a whole evoke the desired interaction qualities?

The words that participants chose on the list that was presented to them (see appendix T, p.212, 215) and the discussion about it afterwards provided insight for this research question. See the overview in figure 73 on p.133. Other questions asked throughout the test provided additional insight. Some of the words on the list did not specifically say something about one of the interaction qualities, but were still important aspects of the design that were described in the list of requirements on p.69 (e.g. trustworthy and complete).

Information is very readable and understandable

When asking participants what they thought about the information, all of them said that they found the information very readable, clear and easy to understand. They liked the fact that is not written in complex language with difficult medical terms. Two participants mentioned that the size of the text is even big enough for people with vision issues. This makes the product and information **accessible**, which was one of the desired interaction qualities.

"I like it, I like the size of the text, I like that it's very clear. It's not complicated to understand. It is put into words that you as a patient can understand. It's not like one of those pdfs that you look up on the Internet.. 'Is it ok or not to take it?' That is why I put friendly too." - P1

*"Yes understandable. It is not uhh unnecessarily medical. It's not 'Jip en Janneke' language, not too simple, but also not unnecessarily complicated what some doctors are very good at [haha]." - P7**

*"Clear, even without my glasses I can read it." - P8***

* "Ja begrijpelijk. Het is niet uhh onnodig medisch. Het is niet Jip en Janneke taal, het is niet te eenvoudig, maar het is ook niet onnodig ingewikkeld wat sommige artsen heel goed kunnen [haha]." - P7

** "Duidelijk, zelfs zonder bril kan ik het lezen." - P8

The app is user-friendly, convenient and intuitive

From the list of interaction qualities that was presented to participants, all participants chose 'user-friendly' as one of the five words that they most associate with the product service system as a whole. Next to that, five participants indicated that they experienced it as 'convenient', three participants chose 'friendly' and two participants chose 'intuitive', which are all related to user-friendliness.

As reasons, women stated that the app was simple and comfortable to navigate through, the information was easy to find and understand (as explained above), and they liked that the information is concise (i.e. not too much text). When the participants were using the prototype, it was also observed that they all intuitively knew how to use the app and quickly found the information they needed.

One woman came up with the word 'overzichtelijk' (which means something like 'clear' or 'well-structured' in English). Although it was not on the list, this word was repeatedly mentioned during the interview by four of the six Dutch participants to describe their thoughts about the app. These are aspects that pregnant women apparently value a lot, probably even more because existing information sources lack this quality. Overall, these qualities make the app very accessible.

"It's user-friendly! I like it, it's simple, I think that is the most important thing, that it's easy to navigate, easy to find. Also navigating between the pages." - P3

*"Yes user-friendly speaks for itself, I don't have to think like 'oh, what do they mean here?' Until now the information that I see is relevant and easy to understand." - P5****

*** "Ja gebruiksvriendelijk het spreekt vrij voor zich, ik hoef niet te denken van oh wat bedoelen ze hier mee of wat bedoelen ze daarmee. Tot nu toe de informatie die ik zie is wel relevant en makkelijk te begrijpen." - P5

*"And this [intuitive] because I just knew what I had to do and it all worked like that." - P6**

Informative and complete

Five participants chose the word 'informative' to describe their associations with the design. This is an obvious choice since the app gives information. Participants mentioned that they thought it was informative because it includes information they need and expect, but also because it was clear and relevant information. Additionally, two participants chose 'complete', because they found that the menu on the medicine page includes all the information they want to know.

"Informative, that it's supporting, because you have all the information you need." - P3

*"Complete because, for example this menu, those are really things I would like to know." - P5**

Transparent

The desired interaction quality 'transparent' was already accomplished by providing risk information in the app. It also became clear that pregnant women value being able to read about potential risks for their child, so this indicates this interaction quality is achieved. From the list, only one participant chose the word 'transparent' and another participant chose 'honest'. For this survey 'transparency' may have been a poor word choice as the word is commonly used in different settings and users may have associated another meaning with the word.

'Balanced' should be improved

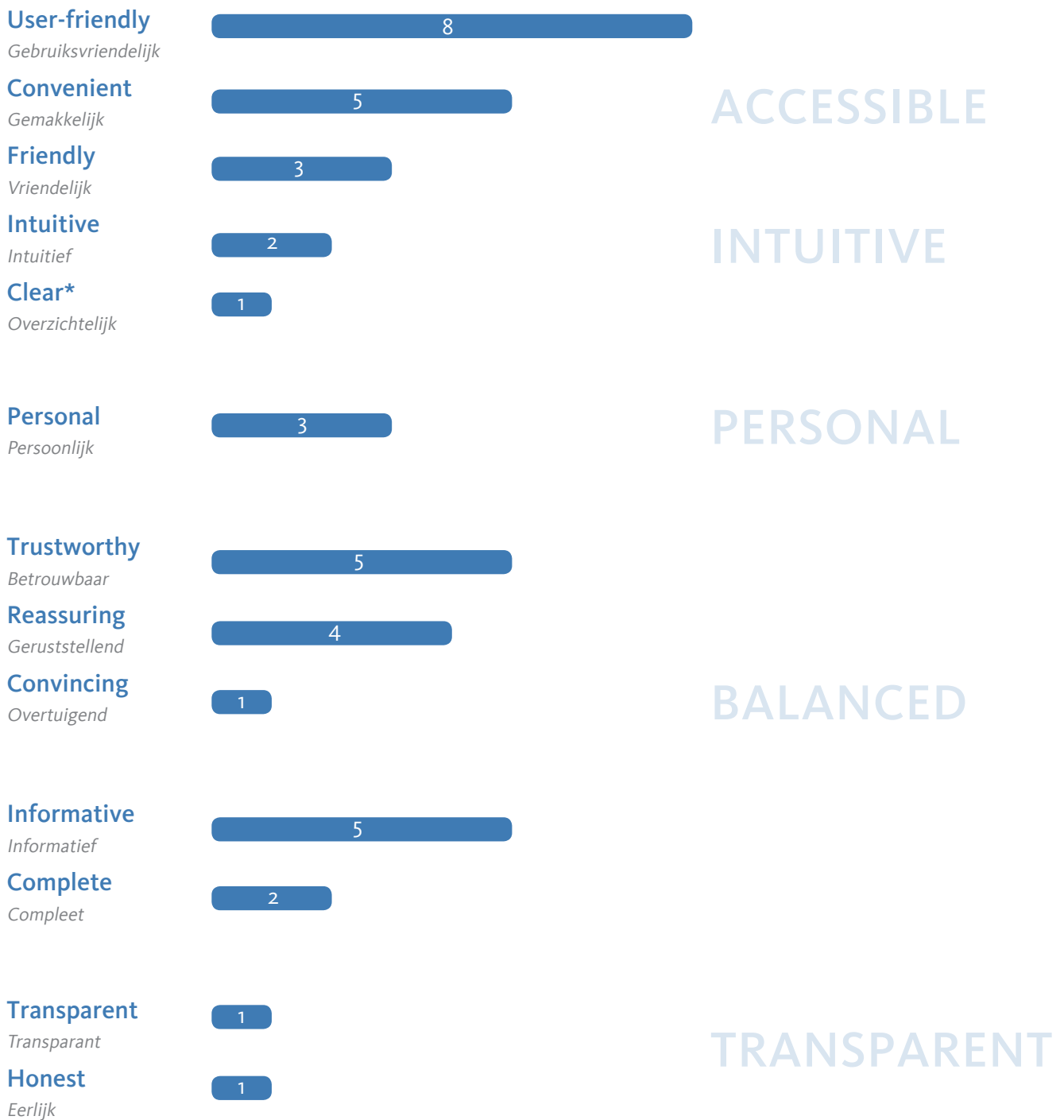
As was explained earlier, most participants did not clearly understand how the benefits of the medicine Labetalol outweigh the potential risks, since the potential side effects on the child still raised questions and resulted in an overestimation of the risks. Thus, there is some room for improvement here.

Personal

Three participants indicated that they found the app personal, one of the desired interaction qualities. Two of them explained that they experienced it as personal because they can make their own medication list. Apart from that, participants indicated that they liked the fact that the information is written for pregnant women specifically, which makes it personally relevant for their situation.

* *"En dit [intuïtief] want ik wist gewoon wat ik moest doen en het werkt allemaal zo." - P6*

** *"Compleet omdat, bijvoorbeeld dit menuutje van oja dat zijn wel echt dingen wat ik wil weten." - P5*



* One participant came up with this word herself

Figure 73. Overview of how many times a quality of interaction was chosen from the list that was presented during the evaluation study.

7.4 DISCUSSION & CONCLUSION

The evaluation study showed that pregnant women see great value in the application, its functionalities and the role of the HCP. They find it very useful and convenient to be able to consult this app when having questions instead of having to call the doctor for advice, which is something they rather not do for every single question and complaint. Especially the option to see what medicines they can use or cannot use for a specific complaint is seen as very helpful, since pregnant women are often in such a situation that they need this information. Moreover, pregnant women value being able to read about the benefits and risks because they often seek confirmation about whether a medicine is really safe and whether taking the medicine is the best decision, which has also been found in the previous user research.

The fact that the doctor would provide the information flyer and advise them to use the app is a sign that the app is reliable, which is an important reason to consult this app instead of using Google. The MEB logo within the app and on the flyer also gives a feeling of trust that the information is reliable. However, the logo should be made more prominent and include a short explanation so every user notices it and understands its meaning. Furthermore, participants value that the information is specifically for pregnant women, that it is written in patient-friendly language and that they can find all information in one place. These are additional reasons to consult the app rather than Google or the patient leaflet. The visual style is experienced as calm and professional, which further increases the trustworthiness as well as the usability and readability.

The information in the menu 'is this medicine safe for my child?' of the medicine Labetalol could benefit from improvements, since it still raises concerns and questions around the potential side effects

on the child and therefore does not make women feel confident to use that medicine. This means the design goal and desired interaction quality 'balanced' are not yet fully achieved. However, the benefit-risk information about Aspirin does not raise further pressing questions. Based on that information, women would feel confident to use this medicine when they would be in such a situation. One point of improvement is that it should be made more clear that Aspirin is only safe in doses up to 100 mg per day and involves risks in higher doses. In general, the links to information about the complaint/condition on the benefit and risk menu are valuable.

During this study it became even more clear that it is very important that the information is complete and answers all questions pregnant women might have, since they will not rest before they know everything and are certain that taking the medicine is the best decision. The question is, however, whether this information is available. Although the risk information about Labetalol lacks some content, the overall structure and content elements of the benefit-risk information are good. When the information would be more complete (i.e. answer the questions pregnant women might have), it is expected that pregnant women will better understand how the benefits outweigh the risks and feel confident about the decision to use the medicine. This would also prevent them from consulting their doctor again, or consult other information sources that will probably only make them more concerned (as discussed before).

Regarding usability, pregnant women experience the app as very user friendly and intuitively know how to navigate it and find the desired information. Moreover, the information is clear, readable and easy to understand. This means the desired interaction qualities 'accessible' and 'intuitive' are definitely

achieved. A small point of improvement is that the link 'read more' on the medicine page should be left out or link to the menu below since users overlooked the menu in the current design.

It could be concluded that the interaction quality 'transparent' is achieved since it provides pregnant women with information about the potential risks involved for the child in addition to the benefits. Furthermore, the interaction is experienced as 'personal' since pregnant women feel like the app contains relevant information for them and because they are able to create their own medication list.

8

Conclusion

This final chapter describes a general conclusion about the project. Based on insights from the evaluation study recommendations for the future development of 'Mijn Medicijn - Zwangerschap' are discussed. Furthermore, additional advice for the MEB and HCPs of VUmc Department of Obstetrics and Gynaecology is provided.

GENERAL CONCLUSION

Pregnancy brings unique challenges when it comes to medication use, since both the health of the mother as well as that of the unborn child must be considered. In every decision about medication use, the necessity of taking the medicine (and risks when not treating the condition) for both mother and unborn child must be weighed against the potential risks of a medicine to the unborn child. Despite the fact that many pregnant women need a medicine during pregnancy, literature and user research have shown that pregnant women often overstate the risks associated with medicines and are very afraid that they will harm their child. Although pregnant women showed to have a lot of trust in their doctor('s advice), they easily start to doubt whether the medicine that they have been prescribed is really safe and therefore often seek confirmation in information sources like the patient leaflet and online websites. The problem that was found with those sources, however, is that they usually emphasize the risks of medicines, communicate uncertainties and show reluctance towards the use of medicines while information about the benefits is missing. This makes pregnant women feel more concerned and insecure, which may lead them to stop using the medicine. Therefore it was concluded that pregnant women are in need of more balanced information about both the risks and benefits that they can access independently, which should allow them to make informed decisions and feel more confident about using medicines during pregnancy.

During this project a product-service system was designed around the digital application 'Mijn Medicijn - Zwangerschap', which informs pregnant women about medication use during pregnancy. By providing transparent and balanced information about both the benefits and risks and putting the risks in perspective with the benefits, pregnant women will better understand why a medicine may be important for their situation and subsequently feel more confident to use it. Apart from the option

to search information about a specific medicine, the application allows pregnant women to find what medicines they can or should not use during pregnancy for a particular complaint or illness, which is especially relevant for OTC medicines. The HCP stimulates pregnant women to use the application by providing an information flyer. Additionally, to ensure consistency and enhance recall of the information, the HCP addresses the same benefit-risk information when prescribing a medicine by using a desktop version of the application.

The product-service system was positively experienced by pregnant women in the evaluation study. Based on the information flyer and the fact that the HCP would advise them to use the app, pregnant women considered the app as a trustworthy source of information and therefore would definitely consult it. Being able to find what medicines they can use for a specific complaint without having to call the doctor was highly valued, as well as the fact that the information is written in patient-friendly language, that the app is simple in use and is specifically made for pregnant women. Furthermore, they valued being able to read more about the benefits and risks of a medicine whenever they seek confirmation about its safety. It also became clear that regarding the content, pregnant women need more detailed information about the potential risks/side effects and seek certainty about whether taking that specific medicine is the best option. When this information would be communicated in the app, they can make an informed decision for themselves and feel more confident about taking the medicine. Despite room for improvement regarding the content, it can be concluded that the design goal has been met. Overall, the product service system shows great potential to support pregnant women in making decisions about medicines during pregnancy, is expected to increase medication adherence and result in better use of medicines which is in line with MEB's and VUmc's ambitions and interests.

8.2 RECOMMENDATIONS

In this project a design was proposed for an application that informs pregnant women about medicines. However, there are still steps that need to be taken before this final design would be ready for implementation and use. Further development of 'Mijn Medicijn - Zwangerschap' and additional research are needed for a successful implementation. The evaluation study provided insights for how the design could be improved, which are described in recommendations for future development. Furthermore, additional recommendations for the MEB as well as for HCPs from the Department of Obstetrics and Gynaecology are given.

Future development of 'Mijn Medicijn - Zwangerschap'

Design and test information for other medicines

In this project, the design was created for only two medicines. Every medicine is unique and involves a different benefit-risk balance with different information aspects to address, which may influence the design. For example, very harmful medicines that should not be used during pregnancy may require a different design (e.g. a big red cross saying 'do not take this during pregnancy (!)'). Furthermore, it should be investigated how to communicate information for medicines that involve more uncertainty about potential risks. Also, for a medicine that does not so much involve risks when it is not taken (e.g. morning sickness), the heading 'what are the risks when I do not take this medicine' may not be that relevant. In that case it could be considered to remove this information.

Thus, when the application will be developed, the information and design should be created and tested for other (types of) medicines too. Attention must also be given to whether and how the information

will be divided on separate pages to make the information relevant for the patient's situation. In case of Labetalol, the information was divided per indication of the medicine (i.e. one page for high blood pressure and one page for angina pectoris). This division must be considered for every medicine.

Test medication taking behaviour in future research

The evaluation study did not yet provide insight in how the app would affect pregnant women's medication taking behaviour. Future research could investigate whether pregnant women would adhere more to their medication after having read the information in the app.

Consider what medicines to include in the app

In general it must be considered whether all medicines should be included in the app, or for instance only the ones that are often considered by pregnant women. In the latter case; what medicines should then be included and which ones should be left out? On the one hand it is beneficial to be as complete as possible in order to support the use of uncommon medicines as well, but to make the development of the app feasible it may be necessary to only include the medicines that are most important.

Write and design information about complaints and conditions

This project did not focus on writing the information for the complaint/condition pages that pregnant women may experience and will be included in the app. As it turned out pregnant women value reading about this, it is recommended to work out this information too.

First of all, it should be considered what complaints and conditions will be included in the app. Secondly, it should be investigated what medicines the app would recommend to use or not use for each complaint. Moreover, similar to the information about benefits and risks, the information about complaints should aim to answer all questions pregnant women might have, because pregnant women often do have many (detailed) questions. The aspects to address were explained on p.106. A suggestion is to explore whether the information on Thuisarts.nl from the NHG could be used for this. Furthermore, another look should be given to the design of this information on the complaint page (p.106). A suggestion is to structure different topics on different pages, similar to the medicine page.

Design information for other pages of the menu

The other pages about potential side effects, contraindications and how to use a medicine etc. should be designed as well. First of all, attention must be given to how much information the app will communicate and how this can best be structured and communicated. For instance, it should be considered whether the app must communicate all potential side effects that are included in the patient leaflet, or whether it would contain a shorter list with the most important side effects with a reference to the patient leaflet. It is expected that it is better to include all the information in the app. In that case the information should be layered/structured to prevent information overload.

In the proposed design, the information is shown by the medicine's generic name. This means for instance that there is one page for paracetamol. However, there are multiple brand names for the same medicine, whereby the medicine could differ in the way it looks, must be stored and how it should be used. So when designing these pages, it should be explored how to deal with this. A suggestion is to add a pop-up screen when opening this page where the user would choose her specific brand name and receive the right information upon that.

Include information about breastfeeding

It could also be relevant to include information about breastfeeding, which was not yet covered in the proposed design. This information could be included on the page 'is this medicine safe for my child?'

Make sure risk information is complete and balanced with benefits

It must be ensured that the information about benefits and potential risks is always as complete as possible, which means that it should answer the questions pregnant women might have as best as possible. It turned out that this is important for pregnant women to be able to make an informed decision and feel confident about using a medicine. So when there may be risks involved in a medicine, the information should not only state that there may be a risk, but also the size of the risk is, when it would occur (i.e. what stage of pregnancy, during or after pregnancy) and what the impact is when it would occur. Additionally, it should be clear whether that specific medicine is the best option for a given indication compared to alternative options.

However, the question remains whether this detailed information that pregnant women seek is available. As was explained in chapter 1.1, for most medicines the potential risks are unknown and therefore contain much uncertainty. In that case, the design should still make clear how this uncertainty relates to the risks when not taking the medicine as best as possible. In general it is not that easy to be transparent about potential risks/uncertainties while at the same time making sure pregnant women do not overestimate them. To support pregnant women as best as possible in making a decision (and having a realistic benefit-risk perception), the risk information should always be put in perspective with (or in other words; be in balance with) potential benefits, regardless of whether the benefits outweigh the risks or vice versa. Future research and development must point out how to provide the most complete information possible from the available knowledge.

For some medicines there may not be much experience with the use of it among pregnant women, while it may still be beneficial to use. In that case it must be considered whether the part 'experience with the medicine' on the page 'is this medicine safe for my child?' (see p.104) should be left out to avoid it from having the adverse effect of increasing women's anxiety, or whether it is important to keep it in order to be consistent and transparent.

Use information template

When writing the information, it is advised to make use of the information template that was created (appendix P, p.202). This will ensure consistently among the different medicines and will help to communicate the necessary information in the right way. While writing and testing the information and design for other medicines, this template should be constantly updated.

Work together with HCPs and patients when writing risk information

When writing the information for other medicines, it should be assessed whether pregnant women may have additional questions than the ones explained above. Since pregnant women often consult HCPs, they know what questions pregnant women have about a particular medicine. Therefore it is recommended to work together with HCPs and discuss what pregnant women would want to know, so this could be addressed in the app. Furthermore, it is advised to continuously test the information with patients themselves. In this way it can be ensured that the design will fit the needs of pregnant women as best as possible.

Test the effect of communicating risks in numbers

In case of Labetalol and Aspirin, the risks were communicated verbally rather than numerically due to lack of knowledge in numbers. For other medicines it may be known how large the risks are numerically. Since literature has shown that communicating risks

in numbers results in a more accurate perception of the risks, it is recommended to test this with patients too to see whether this has a desired effect. However, in order to see the risks in perspective with the benefits, the risks when not taking the medicine should then be communicated in the same way. This may prove difficult.

Investigate the safety label

A complex aspect of creating the design is what safety label (e.g. the green checkmark icon) you could give a certain medicine, since it is not always legally possible to state that a medicine is safe when it might involve risks or side effects for the child. This should be further explored. It must be investigated in what cases a medicine can be given a certain label, potentially by using a classification system. Furthermore, in the app it should be clearly explained to the user what each label means.

Another possibility is to give a different meaning to the green checkmark. For instance, it could mean that many other pregnant have used the medicine without negative consequences, as one participant in the evaluation study suggested. This could then be communicated on top of the page 'is this medicine safe for my child?'. This may have the same positive effect compared to saying that a medicine is safe.

Make source of information more visible with an explanation

The MEB logo that communicates the source of the information should be made more prominent. It is recommended to make it already visible on the Home screen, so users directly know that the information is reliable and objective. Additionally, an explanation of what the MEB is must be included. A suggestion is to add an information icon that opens a pop-up menu with background information about the app, including who made it and the source of information.

Add general information about medication use during pregnancy

A good addition would be to add general information about medicine usage during pregnancy, including for instance an explanation about the fact that medicines are generally not tested in pregnant women. This might help pregnant women to better understand why there is often little knowledge about potential risks and that this does not necessarily mean the medicine will harm their child. To prevent information overload, it might be good to add a menu on the home screen where this information can be found, together with background information about the app.

Improve desktop design and test with HCPs

The desktop version of the application that HCPs would use during consultations requires more attention, since in this project the emphasis was more on the mobile application. A suggestion would be to explore how the information about benefits and risks could be explained more gradually instead of showing all information at once. Apart from the design, it should be tested how using this desktop application fits within a consultation and more research is required with HCPs to find out how they would experience using it. Eventually, HCPs should be trained how to use it.

Put together a team of professionals for development

In order for the application to be implemented into the market, a team of UX designer(s), visual designer(s), software developers, healthcare professionals, medicine experts and writing experts should be put together for successful implementation.

Appendix V describes some additional recommendations for the design.

Additional recommendations for MEB

Include benefits in medication information

This project clearly showed the importance of communicating the benefits of medicines to patients, which is currently lacking in the patient leaflet. Information about the benefits would help patients to understand their medicine better and feel more confident in taking it, leading to better use and adherence to their medicines. This fits with MEB's strategic ambition. Therefore a recommendation for the MEB is to (continue) focusing on including the positive effects of medicines in information for patients.

Make sure that (pregnancy) information is complete and clear

Information about the effects of the medicine when used before or during pregnancy, as well as advices in the patient leaflet and SmPC are often unclear, incomplete and restrained. Some sentences are ambiguous and therefore difficult to interpret. Therefore, in addition to the information from the patient leaflet and SmPC, additional information from Lareb TIS and apotheek.nl was required for this project to write information that meets the needs of pregnant women. It is recommended to collaborate with other stakeholders (KNMP, NHG) to provide the most optimal information to patients.

Design information from the perspective of the user and do qualitative research into the information needs of other patient groups

This project can be used as inspiration for how to approach the design of an information product, e.g. doing qualitative user research, designing a product based on a formulated design goal and requirements and evaluating your design with users.

When writing information and designing an information product, always try to keep the user in mind. Who are the patients that would use the medicine in question? What are their information needs? And in what context would they use the information product? What you as experts in

medicines may think is important to communicate may not always be in line with what the patient needs.

In order to design information that fits the needs of the users, it is important to get an understanding of the patient and what he or she needs by doing research. Pregnant women only cover a small part of the patient groups that use the information that you as MEB provide. Therefore it is recommended to do qualitative in-depth research into the information needs of other patient groups as well. Stay connected with patients on a continuous basis in order to enhance the quality of the information that you provide in line with the needs of patients.

In general it is advised to keep in mind what goal you want to achieve with the information that you provide and whether the information and design contributes to that goal.

Use this design as a basis for an app for the general patient population

From this project, it can be learned that an application can be a useful product for providing information about medicines. Patients can access it anywhere at anytime, the information can be presented in a well-structured way that gradually guides users to the desired information. Furthermore, it is possible to offer relevant information that is prioritized according to the needs of the patient (group). The app for pregnant women was designed in such a way that it can be converted to the design of an app for the general patient population. The current design of the A4 compact medication information can be used as a guideline for what content to include. It should be investigated whether an application fits with all other patient groups, like older patients or low literate patients.

Structure information according to the needs of patients

In order to make the desired information easy to find and to make sure patients can easily read and understand it, information should be structured well.

The most important information should be most apparent and users should be guided intuitively to the information they need.

Explore how to tailor information to specific patients and their situation

In case a medicine can be used for several indications (e.g. acetylsalicylic acid), it is recommended to develop information per indication as the risks and benefits and information on how to use the medicine can be different per indication. In this way patients get to read only relevant information. Furthermore, when designing for multiple groups of patients, it is recommended to explore how the information can be further tailored to the individual patient, for example by taking into account gender, age, medical history or other relevant background information.

Use icons only when they add something

In general, icons can be used for different purposes. They are useful for enhancing readability, attracting attention to certain information, explaining information or for making the information more visually appealing. In case icons are intended to explain something, research should be done into the comprehensibility of icons. Overall, icons should only be used when they add value and are sufficiently tested.

Additional recommendations for HCPs at VUmc

Explain to the patient how the benefits weigh up to the risks of the medicine

Considering the concerns of pregnant women about potential risks of a medicine, it is recommended to HCPs to not only stress the benefits of the medicine when prescribing a medicine, but also address what is known about risks. In this way (s) he could make clear how the benefits weigh up to the risks of the medicine. This will make it less likely that pregnant women will be influenced by other negative information and become concerned after the consultation.

Ask how the patient feels about taking a medicine

It is expected that not every patient brings forward their concerns about taking a medicine to the gynaecologist during a consultation. Therefore it might be good if the gynaecologist asks the patient how she feels about taking the medicine, for instance when prescribing a new medicine or during a follow-up consultation when asking about the medicines she is using. In this way the gynaecologist can take away their concerns by explaining the positive consequences of the medicine.

Guide pregnant women in their search for information

In order to make sure pregnant women will not end up on unreliable websites when they have questions or concerns, it would be good if HCPs tell the patient where she should look for information in case she wants to search online (when the app would not be there). It is advised to warn the patient for negative information she could encounter in current information sources that may tell the patient the medicine may not be safe. This may prevent them from getting doubtful and concerned.

PERSONAL REFLECTION

Overall I am looking back at this graduation project very positively. I got to work on an interesting topic that suits my interests well, I learned to work together with multiple stakeholders and I was able to refine my research and design skills.

When searching for a graduation project I was looking for a topic in the healthcare sector since I consider this a context where I can make a difference as a designer. Besides, over the past years I have developed an increasing interest for designing digital products in which the communication of information plays an important role. I am happy that I got the opportunity to work on a project with a combination of these two elements.

Working in a large company where I was the only designer while at the same time managing other stakeholders involved and doing research in a hospital environment was a valuable learning experience. Sometimes I found it difficult to explain my design approach and what I was working on to colleagues that are unfamiliar with 'design', because over the past few years I mostly worked together with other designers that understood my work and process. However, it was a valuable experience having to step outside my own (design) bubble and interact more with people from other backgrounds. The fact that I was working at the MEB and not at VUmc may have restrained me from diving fully into the healthcare context and interact more with healthcare professionals. Though I believe I still did good research and this did not influence my final result much, I think the final design could have been even better if I had also involved HCPs more during the design process.

From other design students I have heard that doing research in the healthcare context is often challenging, but luckily I did not experience it that

way. Apart from the hassle of writing an METc application, everything went quite smoothly, partly due to the great help I got from Christianne and other employees at VUmc in selecting participants and speeding up the approval of the METc application. I enjoyed doing the interviews with pregnant women a lot. It was interesting to hear their stories and ideas and to learn about their values and needs, which gave me a lot of energy in working on the project. Now I have finished the design, I like seeing that some of the ideas that participants shared with me are implemented in the design, as well as ideas proposed by HCPs. In general, I gained more experience in conducting interviews, asking the right questions and doing an evaluation study with a prototype.

I particularly enjoyed the conceptualisation phase of the application. I learned a new design and prototyping tool (Adobe Experience Design) which allowed me to refine my design skills, quickly iterate on my design and share it with stakeholders. Apart from gaining more experience with the design of an application, I also liked to apply my user-centred design skills to writing the information within the app, which was something new to me.

As a perfectionist I have always had difficulties with accepting anything less than perfect in my work. During this project I again experienced that I sometimes spend (too) much time focusing on details and therefore lose sight of the bigger picture. However, during this project I have also really learned to set boundaries and stop myself from doing too much. I would have loved to work out other parts of the design as well and develop the designs for other medicines. As there was a limited amount of time I had to set priorities in order to hold on to my planning and I am happy to say that I succeeded in that. Although being a perfectionist is sometimes

difficult, I also see it as a strength that brings my work to a higher level.

Overall I think I can manage working independently quite well, although at certain moments I would have liked to discuss the project with a fellow designer and get inspired by their ideas. In the future I hope to be working in a (design) team because I believe the best results are achieved when working together.

My biggest goal for this project was to create a design that would be meaningful and useful for all stakeholders involved. At certain points I found it challenging to make my product as useful as possible for the MEB, who is more focused on providing information for the general patient population, while at the same time create a design that fits the needs of this specific target group. In the end I think the insights I gained from research and the design I made will be inspiring for the MEB and can be used as a starting point to improve their information to patients. Based on the feedback I received during the evaluation test I believe the app would really support pregnant women in their lives. Eventually I think this will lead to better use of medicines, which fits with the goals and interests of both the MEB and VUmc.

In the future I hope to bring my experiences from this project into practise and add to society in a meaningful way.

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I want to thank all my colleagues of the 'Better Use' team at the MEB. It was interesting to hear your ideas and perspective on the subject, and it is great to see your motivation for improving information to patients. Thank you for giving me the opportunity to show you my ideas and designs and for your feedback!

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A. ABOUT CBG-MEB

Authorization

The MEB works together with the European Medicines Agency (EMA) as part of a wide European network. Hence, MEB is responsible for the authorization and monitoring of medicines on the Dutch market as well as co-responsible for the authorization of medicines throughout the European Union.

Before a medicine can be authorised and enter the market, the manufacturer of the medicine must provide MEB with scientific data about its quality, efficacy and safety. After thorough assessment of all these data, the MEB decides whether the medicine sufficiently works as intended and if the side effects are within acceptable levels. Only if there is a positive balance between the benefits and risks, the medicine will be authorised and can become available on the market and used by the patient.

Once a medicine is approved, the efficacy and safety of the medicine when used in clinical practice will be monitored on a continuous basis. If needed, the patient leaflet can be updated based on new information that has been collected and assessed by MEB. For example, based on reports of adverse drug reactions which in the Netherlands can be reported at The Netherlands Pharmacovigilance Centre Lareb. When there are reports providing sufficient evidence for a new side effect with a specific medicine, Lareb will inform MEB about it and MEB will further assess the need to update the patient leaflet. Sometimes this requires discussion with the EMA and other European countries.

Network of reliable information

One of MEB's initiatives for improving medicine information for patients is the Network Patient Information (Netwerk Patiënteninformatie), a

collaboration between seven organisations. Their goal is to facilitate the digital search for reliable and understandable information about medicines for patients in the Netherlands. A first step is to connect/link four websites together: The MEB (GIB), The Netherlands Pharmacovigilance Centre Lareb, NHG (thuisarts.nl) and KNMP (apothek.nl). Research institute NIVEL, Dutch Centre of Expertise on Health Disparities Pharos and Patients Federation Netherlands advise all parties within the network about patient' needs and wishes.

Kijksluiter

In december 2018, the MEB started a collaboration with Stichting Kijksluiter. Stichting Kijksluiter offers animated videos that explain important information from the patient information leaflet in understandable spoken language. This is especially valuable for low literate people who have difficulties with reading and writing and understanding information. In the Netherlands there are 2,5 million low literate people, so these form a large group of patients. This initiative illustrates the need for more user friendly and understandable medication information.

B. ANALYSIS OF INFO ON APOTHEEK.NL

The pregnancy related information about the medicine ‘Labetalol’ on apothek.nl was analyzed.

Even though this is one of the more user friendly websites, some issues were identified with the information for pregnant women. In the first drop down menu “What does Labetalol and what do I use it for?” it says that Labetalol is a safe medicine (see the parts in bold). However, in the menu “Can I use this medicine when I am pregnant, want to become pregnant or breastfeed?” it explains that there is a risk of side effects on the child which could be a reason to switch to another medicine. At first sight this information sounds contradictory. In fact, the information is actually correct, but how it is communicated causes confusion. In the design of the product this is improved.

verhoogde bloeddruk krijgen.

Als de hoge bloeddruk in de tweede helft van de zwangerschap ontstaat, heet het ook wel **zwangerschapshypertensie** of **zwangerschapshypertensie**. Deze laatste term is onjuist, omdat er geen sprake van een vergiftiging is. Deze vorm van hoge bloeddruk moet snel behandeld worden, na de bevalling verlaagt de hoge bloeddruk meestal weer binnen drie maanden.

Behandeling

Als rust houden of minder zout gebruiken niet helpen om de bloeddruk omlaag te krijgen, zal de arts een medicijn voorschrijven tegen hoge bloeddruk. Dit moet dan een medicijn zijn dat veilig is voor de zwangere en de baby. Labetalol is zo'n medicijn. In het geval van een snel oplopende zwangerschapshypertensie wordt Labetalol in injectie toegepast.

Als u al medicijnen gebruikt tegen een hoge bloeddruk en zwanger wilt worden, is het verstandig met uw arts te overleggen. Het is dan mogelijk om op tijd over te schakelen naar veilige medicijnen tijdens de zwangerschap, zoals Labetalol.

[Lees meer over hoge bloeddruk](#)

- Angina pectoris
- Wat zijn mogelijke bijwerkingen?
- Hoe gebruik ik dit medicijn?
- Wat moet ik doen als ik een dosis ben vergeten?
- Kan ik met dit medicijn autorijden, alcohol drinken en alles eten of drinken?
- Mag ik Labetalol gebruiken met andere medicijnen?
- Mag ik dit medicijn gebruiken als ik zwanger ben, wil worden of borstvoeding geef?

Zwangerschap

Meld het aan uw arts en apotheker zodra u zwanger bent, of binnenkort wilt worden. Samen met uw arts kunt u bespreken wat het risico voor de baby is als u doorgaat met het medicijn. Of wat het risico voor u is als u met het medicijn stopt.

Bij gebruik van dit medicijn tijdens de zwangerschap bestaat er namelijk een risico op bijwerkingen bij het kind. Zoals een lage bloedsuikerspiegel, een lage bloeddruk, een lage hartslag, suf worden en moeite met ademen. Mogelijk zal uw arts uw baby extra controleren. Overleg hierover met uw arts. Zo mogelijk kunt u (tijdelijk) overstappen op een ander medicijn.

Borstvoeding

Wilt u borstvoeding geven, overleg dan met uw arts of apotheker. Dit medicijn komt in zeer kleine hoeveelheden in de moedermelk terecht. U kunt, na overleg met uw arts, borstvoeding blijven geven. Hetzelfde geldt voor uw baby na de geboorte.

Figure A1. Labetalol information on apothek.nl

Wat doet Labetalol en waarbij gebruik ik het?

[..]

Behandeling

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Source: apothek.nl/medicijnen/Labetalol

C. INPUT FROM HCPS

Below the answers given by HCP on the post-it's are described per theme (exactly how they were written down).

Vraag 1. Wat zijn volgens jou de belangrijkste oorzaken dat zwangere vrouwen hun medicatie niet (goed) innemen?

Angst voor schade voor het kind (23x)

- Twijfel over schadelijkheid
- Eng? Bang om kind te schaden
- Angst voor onbedoelde gevolgen voor haarzelf of kind
- Angst dat het schadelijk is voor de baby
- Bang voor negatief effect op foetus
- Angst voor schade voor foetus
- Bang dat het medicijn niet goed is voor de baby
- Zorgen over effect op kind
- Angst dat het de baby schaadt
- Zorgen over de effecten van de medicatie op de zwangerschap/kind
- Bang voor nadelen voor baby
- Angst voor schade van de baby
- Ondanks advies dokter + geruststelling dat het veilig is in de zwangerschap uit angst alsnog het medicijn niet innemen
- Bang voor de bijwerkingen of schade voor het kind
- Angst dat het schadelijk is voor het ongeboren kind
- Angst voor schade baby
- Angst schade voor het kind
- (Angst voor) vervelende bijwerkingen
- Bijwerkingen
- Bijwerkingen
- Bijwerkingen

- Bijwerkingen (misselijk, diarree)
- Last hebben van bijwerkingen

Belang van relevantie/noodzaak niet begrijpen (20x)

- Geen inzicht in relevantie/noodzaak
- Relevantie waarom medicatie belangrijk is niet helemaal duidelijk
- Kunnen niet goed de gevolgen voor haarzelf en het kind overzien
- Niet overtuigd van gunstig effect (ook in het algemeen)
- Indicatie niet begrijpen, risico niet als ernstig genoeg zien om er medicijnen voor te nemen
- Belang van (reguliere) inname niet goed inzien
- Niet goed begrijpen van het nut
- Niet goed begrijpen wat het belang is van de medicatie
- Geen vertrouwen in de noodzaak (of werking) van het medicijn
- Snappen noodzaak/belang onvoldoende
- Werking van medicatie niet goed begrijpen
- Niet weten wat de grootste bijwerkingen zijn, en er toch van schrikken
- Belang van medicijn wellicht niet beseffen
- Onvoldoende ziekte inzicht/kennis over het belang van de medicatie
- Geen begrip waarom het medicijn noodzakelijk is voor patiënt
- Ziet toegevoegde waarde of het nut niet in van medicatie innemen
- Doel van medicatie onderschatten
- Ze zien de reden niet in van het innemen van de medicatie
- Slecht geïnformeerd over het belang van inname
- Sommige medicatie gericht op klachten die ze ook wel kunnen accepteren (jeuk, maagzuur etc.)

Vergeten in te nemen (11)

- Vergeten
- Minder structuur in dag door wegvallen baan? Bij zwangerschapsverlof
- 'Gewoon' vergeten in te nemen
- Vergeten (ze hebben veel aan hun hoofd)
- Vergeten in te nemen
- Gewoon vergeten door gebrek aan routine
- Zwangerschapsdementie
- Vergeten
- Vergeet het
- Te veel inname momenten
- Te veel door zwangerschap ingenomen, waardoor minder bezig met medicatie

Vervelend om in te nemen

- Vervelend om in te nemen (ook in het algemeen)
- De medicatie/pillen te groot vinden of onhandig in te nemen

Voelen zich niet ziek

- Zich niet ziek voelen (bv. Hoge bloeddruk voel je niet)
- Bij methyldopa: je niet ziek voelen (bij hoge bloeddruk) en het daarom vergeten of niet willen, denken dat het niet nodig is

Helpt te weinig

- Emesafene: helpt te weinig

Misselijkheid

- Mogelijk zaken als misselijkheid? Klachten?
- Misselijkheid/braken
- Al door de zwangerschap misselijk zijn en daarom pillen niet kunnen nemen
- Misselijkheid (zwangerschap)

Informatie is onvoldoende

- Informatie die gegeven is over medicatie te moeilijk
- Informatie alleen mondeling gegeven en (deels) vergeten
- Onduidelijke instructies over continueren
- Onduidelijke dosering
- Onvoldoende en incomplete informatie in bijsluiter
- Dokter geeft te weinig informatie

Tegenstrijdige informatie

- Verschillend advies dokter en apotheker (vaak apotheker benadrukt de gevaren, veel pte worden daar bang van)

Willen niet geconfronteerd worden met ziekte

Confrontatie met ziekte/risico (kop in het zand)

Redenen wel innemen

- Wel goed innemen: Zwangerschap zo lang mogelijk volhouden, als ze klachten hebben, als ze denken dat het beter is voor de baby

Leefstijl

- Vanuit voorkeur voor 'natuurlijke' leefstijl liever geen medicatie innemen

Continues on next page

Vraag 2. Wat voor ideeën voor een oplossing (informatievoorziening) heb je?

medicatie

Betere (mondelijke) informatie

- Betere voorlichting
- Samen met recept uitleg over indicatie en classificatie meegeven
- Uitleg over afweging (en doel) wel/niet medicatie kansen
- Betere uitleg hoe het medicijn de vrouw helpt
- Angst wegnemen veiligheid tijdens zwangerschap
- Het belang/indicatie van de medicijnen beter uitleggen
- Beter uitleggen van de consequentie van het niet innemen
- Risico's van niet innemen includeren
- Duidelijke uitleg soms pas na X aantal tijd werkzaam
- Belang benadrukken van vaste tijden medicatie innemen, niet at random waardoor werking minder wordt en ze stoppen

Meer tijd voor consult en uitleg

- Meer tijd voor counseling
- Meer tijd voor arts om noodzaak/werking/bijwerking aan de pte uit te leggen in spreekkamer
- Meer tijd voor consult

Checken tijdens consult

- Elk consult blijven vragen en uitleggen + schriftelijke info
- Gynaecoloog moet het checken, controle en volgende controles
- Na starten terugkomen op ervaringen met gebruik

(Mening) patient meer betrekken

- Beleid en reden laten herhalen door patiënt (in eigen woorden laten vertellen)
- Shared decision making
- Vragen naar mening van patiënt over de

Zelfhulp/extra info

- Keuzehulp tool/stroomschema

Papier

- Samen met recept uitleg over indicatie en classificatie meegeven
- Bijsluiter/informatiefolder specifiek voor zwangeren. Informatie die wij van Lareb gebruiken is anders dan de info op de reguliere bijsluiter
- Papieren uitleg als naslagwerk voor patiënt en partner
- Schriftelijke info
- Kaartje die arts kan gebruiken om informatie over medicijn met pte te bespreken en die pte later ook zelf kan opzoeken
- Hulpmiddelen om het volgens voorschrift in te nemen
- Informatie op verschillende manieren meegeven (papier, digitaal etc.)
- Informatieve email/herinnering

Digitaal

- Informatie op verschillende manieren meegeven (papier, digitaal etc.)
- Verwijzing naar meer verdiepende informatie online
- Bij ieder recept briefje met link naar info site geven
- Soort digitaal platform/discussie om laagdrempelig vragen te stellen die door bijv. Vpl worden beantwoord
- Website die arts kan gebruiken om informatie over medicijn met pte te bespreken en die pte later ook zelf kan opzoeken
- App? Die speciaal voor zwangeren is en bijv. Info gebruikt als thuisarts of apotheek.nl of FK (dacht ik). Mogelijk met filmpjes
- App
- Informatieve email/herinnering
- Misschien een medicatie app gericht op patiënten/zwangeren
- Een website voor zwangere vrouwen waar een schadelijke medicatie staat opgesomd.

Informatie Lareb erbij betrekken

- Lareb zou bijv. Een patiëntengedeelte op de website kunnen maken die als eerste boven komt als je Googlet op zwanger + naam van medicijn
- Benut ook www.lareb.nl want daarin staat veel gerichtere informatie over gebruik in de zwangerschap en tijdens b.v. (borstvoeding?)

Consistente informatie

- Consistentie in info voorziening tussen arts, verloskundige, apotheek en huisarts

Duidelijke cijfers over risico's

- Uitleg met concrete cijfers over risico's
- Simpler classificatiesysteem voor pte om risico's voor medicatie te laten zien (kleuren / I/II/III)
- Cijfers over medicament tijdens gebruik zwangerschap en de gevolgen daarvan
- Duidelijke cijfers geven over kansen op schade

Weinig tekst, meer visuele elementen

- Korte teksten, waar mogelijk plaatjes
- Kort en bondig, geen lappen tekst
- Kort & krachtig, punctueel
- Korte, in simpele taal geschreven bijsluiter (kaartje/online)
- Korte samenvatting op papieren bijsluiter zodat makkelijker leesbaar
- Mondelinge & poster-achtige info (plaatjes)
- Algemeen: minder tekst, meer pictogrammen
- Taalgebruik zo begrijpelijk mogelijk maken
- Plaatjes gebruiken
- Met een duidelijk plaatje in de algemene bijsluiter aangeven dat het niet schadelijk is. Bijv. een vrouw met zwangere buik met een groen vinkje ernaast.
- Meer accenten in bijsluiter en overzichtelijker maken

Make more clear a medicine is safe

- Naast schriftelijke tekst ook duidelijk figuur met model(?) veilig-onveilig-onbekend dus niet-beperkte kennis, na overleg met gynaecoloog zo nodig
- Met een duidelijk plaatje in de algemene bijsluiter aangeven dat het niet schadelijk is. Bijv. een vrouw met zwangere buik met een groen vinkje ernaast.

Peer support

- Peer support groep met andere zwangeren die ook de medicatie gebruiken om ervaringen en kennis te delen

(Herinneren) inname makkelijker maken

- De pillen zo klein en 'lekker' mogelijk maken
- Opvallende verpakking oid zodat inname niet wordt vergeten
- Informatieve email/herinnering
- Medicatie reminder app

D. VISITING THE OUTPATIENT CLINIC

Gynaecologist prepares consultations

One day before the consultation, a note with the most important information about each patient is made in the patient's medical file. Shortly before the consultation, the gynaecologist looks into this file so (s)he knows the patient's situation and what needs to be discussed during the consultation. Sometimes the gynaecologist looks up information online. For instance, when the prognosis of a patient is unclear, the gynaecologist looks into literature (e.g. to find evidence for chances of survival for an unborn child when the mother's water has broken at 20 weeks). Another case could be that the gynaecologist does not know the teratogenic risks of a medicine the patient uses, which could happen when a medicine is prescribed by another doctor. Then, (s)he consults Pharmacovigilance Centre Lareb to look into side effects of a medicine in pregnancy and results of studies.

Arriving at VUmc

Pregnant women almost always arrive in time for their appointment. Sometimes they come alone, but often the partner is there as well, especially when the patient's situation is somewhat critical. For the gynaecologist it is very inconvenient if a patient shows up late or not at all, not only because it delays their schedule and that of their patients, but it also signals a worrisome situation as most pregnant women are punctual and act responsible when it comes to their child. In some cases, when it is not very necessary that the patient comes to VUmc, they will have a phone call appointment.

When the patient arrives, she has to sign in at the front desk, so the gynaecologist can see in the system that she has arrived. Then the patient waits in the waiting area until the gynaecologist picks her up and walks her to the consulting room.

During consultation

The gynaecologist usually starts each consultation by asking the patient how she is doing, how she feels. When the partner is present, the gynaecologist still focuses solely on the patient. Sometimes this involves asking about her daily life (e.g. her daily activities, their job) depending on the situation.

After discussing the complaints, progress and medication use, the gynaecologist checks the blood pressure of the patient and the position and heartbeat of the baby in the adjacent treatment room. When everything is well, they agree upon when the next appointment should take place. The gynaecologist also always asks the patient if she has the card with contact information of VUmc and says she can always call.

At the pharmacy

When a woman that visits the pharmacy is pregnant, the pharmacist records this in their system by adding 'pregnancy' as a contraindication. The system will give a notification of contraindication when the medicine in question should not be used during pregnancy. When this is the case, they will search for an alternative in consultation with the gynaecologist.

The information in the Pharmacy Information System originates from the The Royal Dutch Pharmacists Association (KNMP), which is a knowledge base that contains information about all registered medicines. Regarding side effects or risks during pregnancy, the pharmacist uses the information that is known by Lareb. So when the system gives a notification for a contraindication (pregnancy related), the pharmacist consults The Netherlands Pharmacovigilance Centre Lareb to find out what is known about that particular medicine during pregnancy.



Figure A2. Waiting area of the outpatient clinic

E. INFORMATION LETTER FOR PARTICIPANTS

Proefpersoneninformatie voor deelname aan onderzoek

Uw ervaringen en behoeften als zwangere vrouw met betrekking tot informatievoorziening bij besluitvorming over medicijngebruik

Inleiding

Geachte heer/mevrouw,

Ik vraag u vriendelijk om mee te doen aan een wetenschappelijk onderzoek. Meedoen is vrijwillig. Om mee te doen is wel uw schriftelijke toestemming nodig.

Dit onderzoek wordt uitgevoerd onder toezicht van VUmc afdeling Verloskunde & Gynaecologie, door Noëlle Lugtenburg, masterstudente aan de TU Delft, faculteit Industrieel Ontwerpen. Het project is een samenwerking tussen het VUmc, het College ter Beoordeling van Geneesmiddelen (CBG) en de TU Delft. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt.

Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

In sommige situaties is het voor zwangere vrouwen noodzakelijk of beter om bepaalde medicijnen te (blijven) gebruiken tijdens de zwangerschap. Voor de besluitvorming over het gebruik van deze medicijnen is het belangrijk dat vrouwen goed geïnformeerd worden, zodat medicijnen goed gebruikt worden. Daarvoor is het doel van dit onderzoek:

1. Het in kaart brengen van uw ervaringen en knelpunten in de communicatie en informatie over medicijnen
2. Het bedenken van oplossingen om de huidige communicatie en informatievoorziening te verbeteren

2. Wat meedoen inhoudt

Meedoen betekent dat u deelneemt aan twee onderdelen:

- Een eenmalig interview van ca. 30 minuten. Het interview zal plaatsvinden aansluitend op uw afspraak bij de polikliniek of, wanneer door u gewenst, op een ander tijdstip.
- Het invullen van 5 voorbereidende vragen. Elke vraag duurt ongeveer 10 à 15 minuten. Deze dienen als voorbereiding voor het interview en worden besproken tijdens het interview.

Een week voor aanvang van het interview ontvangt u thuis de voorbereidende vragen. Deze vragen gaan over uw ervaringen met medicijnen, beslissingen over het gebruik van deze medicijnen en informatie over medicijnen. Vervolgens zal het interview plaatsvinden met de onderzoeker. Tijdens het interview zullen de vooraf beantwoorde vragen besproken worden. Verder zal er worden gevraagd naar

uw positieve en negatieve ervaringen als zwangere vrouw in de communicatie en informatie over medicijngebruik tijdens de zwangerschap, en uw behoeften hierin.

3. Mogelijke voor- en nadelen

U heeft zelf mogelijk voordeel van meedoen aan dit onderzoek:

- Delen van uw ervaringen, frustraties en behoeften
- Bijdrage leveren aan vernieuwende informatiemogelijkheden door uw ervaringen te delen

Nadelen kunnen zijn:

- Extra tijd die het u kost

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig.

Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het onderzoek stoppen.

U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek met uw toestemming.

5. Gebruik en bewaren van uw gegevens

Voor dit onderzoek is het nodig dat uw persoonsgegevens, zoals leeftijd, beroep, geslacht en woonplaats worden verzameld en gebruikt. We gebruiken en bewaren de gegevens uit het interview en de vooraf ingevulde vragen. Elke proefpersoon krijgt een code die op de gegevens komt te staan. Dit heet gecodeerd. Uw naam wordt dan niet meer gebruikt.

Daarnaast vindt er tijdens het interview een audio opname plaats die alleen wordt gebruikt voor onderzoeksdoeleinden, zoals het uittypen en analyseren van uw ervaringen naar ontwerpthema's. Het audio materiaal wordt uiteraard niet commercieel gebruikt en zal na uittypen direct verwijderd worden.

Uw gegevens

Al uw gegevens blijven vertrouwelijk en worden niet herleidbaar tot de persoon opgeslagen. Alleen de onderzoeker weet welke code u heeft. Voor het onderzoek worden uw onderzoeksgegevens gecodeerd gedeeld met de samenwerkende organisatie CBG (College ter Beoordeling van Geneesmiddelen). De resultaten van het onderzoek kunnen worden gepubliceerd, bijvoorbeeld in wetenschappelijke tijdschriften. Uw persoonlijke gegevens zijn in publicaties niet terug te vinden. Als u graag op de hoogte wilt worden gesteld van de uitkomsten van het onderzoek, dan kunt u dit aangeven aan de onderzoeker.

Als u de toestemmingsverklaring ondertekent, geeft u toestemming voor het verzamelen, bewaren en inzien van uw persoonsgegevens. De onderzoeker bewaart uw gegevens 5 jaar. Daarna worden de persoonsgegevens vernietigd.

Voor meer informatie over uw rechten bij de verwerking van uw persoonsgegevens kunt u contact opnemen met Noëlle Lugtenburg. Zij is verantwoordelijk voor het volgen van de regels voor de verwerking van uw persoonsgegevens. Indien u ontevreden bent over hoe wordt omgegaan met uw

privacy dan kunt u een klacht indienen bij de Functionaris Gegevensbescherming via privacy@vumc.nl. Ook kunt u zelf terecht bij de Autoriteit Persoonsgegevens via <https://autoriteitpersoonsgegevens.nl/>.

6. Geen vergoeding voor meedoen

Voor het meedoen aan dit onderzoek krijgt u geen onkostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met Noëlle Lugtenburg.

Contactgegevens

Noëlle Lugtenburg (masterstudente Industrieel Ontwerpen aan de TU Delft)

Email: n.lugtenburg@vumc.nl

Telefoon: +31 6 44 111 054

Dank voor uw aandacht.

F. CONSENT FORM PARTICIPANTS

Toestemmingsformulier proefpersoon

Uw ervaringen en behoeften als zwangere vrouw met betrekking tot informatievoorziening bij besluitvorming over medicijngebruik

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens op de manier en voor de doelen die in de informatiebrief staan. Ik geef toestemming om mijn gegevens nog 5 jaar na dit onderzoek te bewaren.
- Ik geef toestemming voor het verzamelen en gebruiken van geluidsopnames. Deze opnames zullen na transcriptie vernietigd worden.
- Ik wil meedoen aan dit onderzoek.

Ik geef toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek

Naam deelnemer:

Handtekening:

Datum : __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

De proefpersoon krijgt een volledige informatiebrief mee, samen met een kopie van het getekende toestemmingsformulier.

Naam onderzoeker:

Handtekening:

Datum: __ / __ / __

G. SENSITIZING BOOKLET

Beste deelnemer,

Fijn dat u wilt meedoen aan mijn onderzoek!

Ik ben een master student Industrieel Ontwerpen aan de TU Delft. Voor dit onderzoek wil ik graag meer weten over uw ervaringen en behoeften binnen de communicatie en informatie over medicijnen tijdens de zwangerschap. Uiteindelijk is het doel om een nieuwe oplossing te bedenken om de informatievoorziening over medicijnen voor zwangere vrouwen te verbeteren.

Dit boekje is bedoeld om u alvast voor te bereiden voor het interview. Het bevat 4 delen met vragen die ieder ongeveer 10-15 minuten duren.

Er zijn geen foute antwoorden. Uw ervaringen geven ons een waardevol inzicht in hoe de informatie verbeterd kan worden. U mag het invullen naar eigen inzicht. Als u iets niet begrijpt, kunt u de vraag leeg laten, of als u nog iets anders wilt delen, kunt u dit erbij schrijven. Alles wat u opschrijft is waardevol voor het onderzoek.

Tijdens het interview zullen we uw ervaringen aan de hand van dit boekje bespreken. Daarom wil ik u vragen om dit boekje ingevuld mee te nemen naar het interview. Uw input tijdens het interview en het boekje zullen alleen voor dit onderzoek en anoniem gebruikt worden.

Als u vragen of opmerkingen heeft kunt u altijd contact met mij opnemen, of ze achterin het boekje opschrijven.

Alvast bedankt!

Noëlle Lugtenburg



Interview op...

om...

op locatie...



Noëlle

+31 6 44 111 054
n.lugtenburg@vumc.nl

Mijn gegevens

Voornaam:

Leeftijd:

Nationaliteit:

In het dagelijks leven houd ik mij bezig met:

Ik woon samen met:

Ik ben nu weken zwanger

Ik ben bij VUMc terecht gekomen via

Ik word bij VUMc behandeld omdat

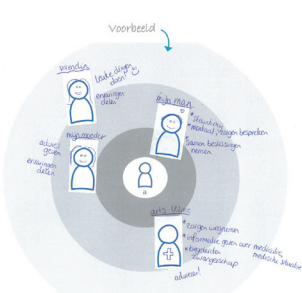
Figure A3. First spread of sensitizing booklet; introduction and general information

1. Belangrijke personen

Stap 1. Welke personen spelen voor u een belangrijke rol tijdens uw zwangerschap? Denk aan familieleden, vrienden, artsen etc. Plaats de personen die het belangrijkste voor u zijn het dichtst bij u op de kaart, met behulp van de stickers.

Stap 2. Geef aan hoe iedere persoon u helpt of ondersteunt. Bijvoorbeeld bij het maken van keuzes, mentale steun of het geven van informatie.

Voorbeeld



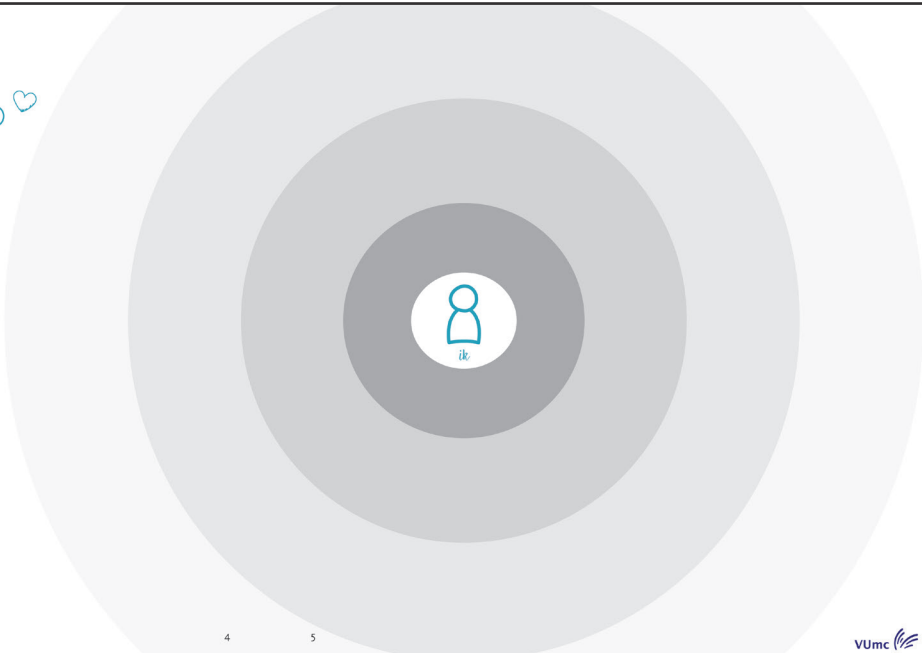


Figure A4. Second spread of sensitizing booklet; important persons

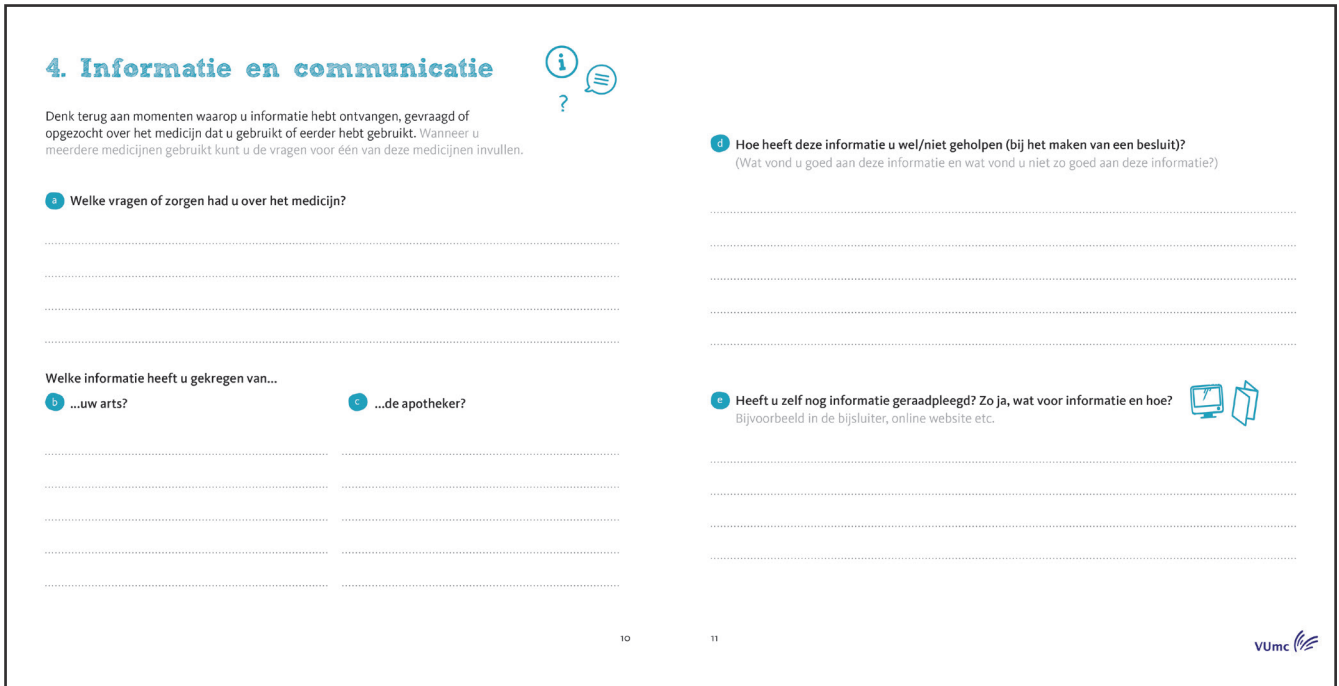


Figure A7. Sixth spread of the sensitizing booklet; information and communication



Figure A8. Front of sensitizing booklet

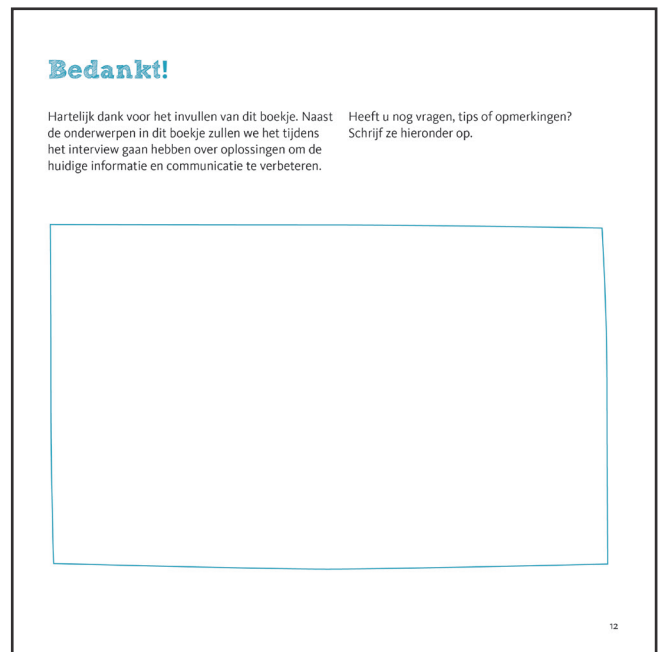


Figure A9. Last page of sensitizing booklet

H. INTERVIEW SCRIPT

Dutch

Interview

Introductie (± 5 min.)

- Bedankt voor deelname
- Uitleg onderzoek
 - Voorstellen
 - Doel onderzoek
- Interview
 - Duurt ong. 30 minuten
 - Boekje bespreken en nog wat extra vragen
- Opname
 - Uitleg audio opnemen
 - Alleen voor onderzoek, vertrouwelijk en anoniem
 - Eventueel tekenen formulier en kopie overhandigen
- 'Regels'
 - Er zijn geen foute antwoorden
 - Vraag liever niet beantwoorden? Dat is prima
 - Tussendoor vragen stellen
- Nog vragen?
- Ervaring boekje invullen
 - Is het gelukt met het invullen van het boekje?

Deel 1. Medicijngebruik (± 5 min.)

- Zou je iets kunnen vertellen over hoe je bij VUmc terecht bent gekomen? (wanneer, via wie en waarom?)
- Welke medicijnen/vitaminen gebruik je of heb je gebruikt?
 - Wanneer ben je begonnen met dit medicijn? (*begonnen voor of tijdens zwangerschap?*)
- Wat vind je van het gebruiken van dit/deze medicijn(en) tijdens je zwangerschap?
 - Vind je het moeilijk om het (consequent) in te nemen? *Waarom?*
 - Wat voor verwachtingen had je over medicijngebruik tijdens zwangerschap voordat je zwanger was? *Waarom?*
 - *Wanneer gestart voor zwangerschap:*
 - Ben je op een andere manier naar je medicatie gaan kijken toen je zwanger werd?
 - Wat veranderde er toen je zwanger werd?

Deel 2. Ervaringen besluitvorming & informatievoorziening (± 10 min.)

- *Voorgescreven door arts?* Hoe is dat [de besluitvorming] gegaan?
 - Welke informatie heeft de arts gegeven? Wat vond je daarvan? *(Was dit verschillend per medicijn?)*
 - Welke vragen of zorgen had je? Waarom/hoe zijn die ontstaan? *(Was dit verschillend per medicijn?)*
 - Hoe heeft de informatie die je hebt gekregen je wel/niet geholpen? *(wat vond je van die informatie?)*
 - Welke informatie gaf de doorslaggevende factor? Waarom juist die informatie?
- *Medicijn opgehaald bij apotheek in VUmc?* Wat voor informatie kreeg je bij de apotheek?
 - Was die informatie anders?
 - Wat vond je van de informatie die je daar hebt gekregen?
 - Had je toen nog vragen of zorgen? *[die niet waren beantwoord door arts]*
- Heb je thuis zelf nog informatie opgezocht of gelezen over het medicijn?
 - Op welk moment? *(Voor consult, na voorschrijven thuis, later?)*
 - Waarom? *(Welke vragen/zorgen waren nog onopgelost?)*
 - Waar? *(Welke bron?)*
 - Wat vond je van die informatie?
- Lees je wel eens de bijsluiter? Wat vind je daarvan?
- Zocht je voor je zwangerschap wel eens informatie op over medicijnen? (los van zwangerschap)

Deel 3. Ideale informatie over medicijnen (± 10 min.)

- Stel, er zou een nieuwe informatievoorziening gemaakt worden, hoe zou dat er dan voor jou uit moeten zien?
 - Wat staat er in die informatie?
 - Welke informatie had je nu niet gekregen die je wel had willen hebben?
- Welke informatie is voor jou belangrijk bij het nemen van een goed besluit (over medicatie)?
Waarom?
 - Wat zou voor jou de doorslag geven dat een medicijn goed/niet goed is in jouw situatie?
- Hoe zou je die informatie willen ontvangen? *Stel niet bij arts, hoe dan..?*
 - Op welk moment zou je die informatie dan willen ontvangen of kunnen raadplegen (al voor zwangerschap, tijdens consult, thuis)

Afsluiting

- Bedankt voor deelname
- Jouw input is heel waardevol
- Zou ik je mogen benaderen voor een vervolg interview? *(Gaat om het evalueren van een ontwerp dat ik ga maken op basis van de inzichten uit dit onderzoek)*

English

Interview

Introduction (± 5 min.)

- Thank you for participating
- Explanation research
 - Introduce myself
 - Goal research
- Interview
 - Around 30 minutes
 - Discuss the booklet
- Recording
 - Audio
 - Only used for this research, confidentially and anonymously
 - Consent form, give copy
- 'Rules'
 - No wrong answers
 - You can decide not to answer a question
 - You can ask me questions
- Any questions?
- Experience booklet
 - How did it go filling in the booklet?

Part 1. Medicine use (± 5 min.)

- Would you mind explaining why you are treated here at VUmc hospital? (*when, who referred you, why treated here?*)
- What medicines are you using or did you use before during/before pregnancy?
 - When did you start taking the medicine? (*before or during pregnancy?*)
- How do you feel about taking these medications during your pregnancy?
 - Do you find it difficult to take your medicine consistently?
 - What were your expectations for using medicines during pregnancy before you got pregnant?
 - Do you look differently at taking medicines now than you would have before your pregnancy?
 - *When started before pregnancy:*
 - Did you look at your medication in a different way when you became pregnant?
 - What changed when you became pregnant?
- Did you use other medications before your pregnancy?
 - Also not for a headache or when you have a cold?

Part 2. Experiences decision making & information provision (± 10 min.)

- *Prescribed by doctor?* How did you decide to take the medicine?
 - What were reasons to start/continue or not start/continue taking the medicine?
 - What questions or concerns did you have about the medicine? Why/how did they arise? (*was it different for different medicines?*)
- What information did the doctor gave you? How did you experience that? (*was it different for different medicines?*)

- How did the information you got help you or not help you (in making a decision)?
How did you feel about that information?
- What did you think was good about the information? Why?
- What could be better? Why?
- What was the key information that made for this decision? **Why** this information?
- Did you feel like you had taken part in the decision-making?
 - Do you want to see that differently?
- *You picked up the medicine at the pharmacy here at VUmc?* What information did you receive at the pharmacy?
 - What did you think about this information?
 - At that point did you still have questions or concerns that were not yet taken away by the doctor?
 - How did you feel about the medicine after leaving the hospital?
- Did you search for or read information yourself at home about the medicine? *(for example in the patient leaflet or online)*
 - Are there good information sources in English that you can consult?
 - When did you do this *(before consultation, after prescription, later?)*
 - Why did you do that? (what was the goal, what questions/concerns were unsolved?)
 - Where? *(what source?)*
 - How did you experience this information?
 - How did it help/not help you?
- Do you sometimes read the information leaflet that is included in the package of medicines? What do you think about that?
 - Often in the leaflet it says for example “as far as is known, there are no harmful effects for the child” or “only in case it is necessary it can be used on prescription by the doctor”. How do you feel about such information?
- Before your pregnancy, did you then sometimes search for information about medicines? (apart from pregnancy)

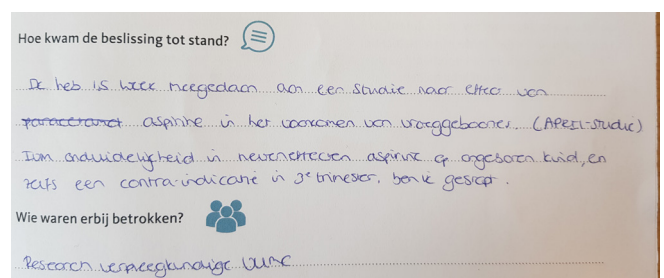
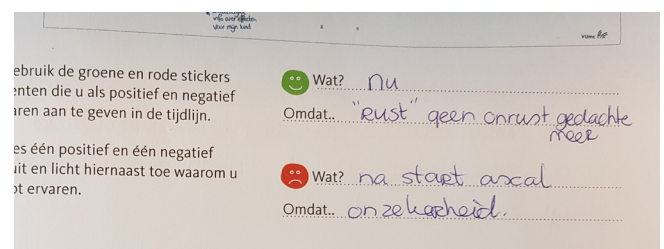
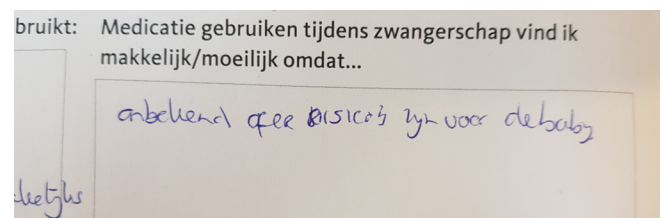
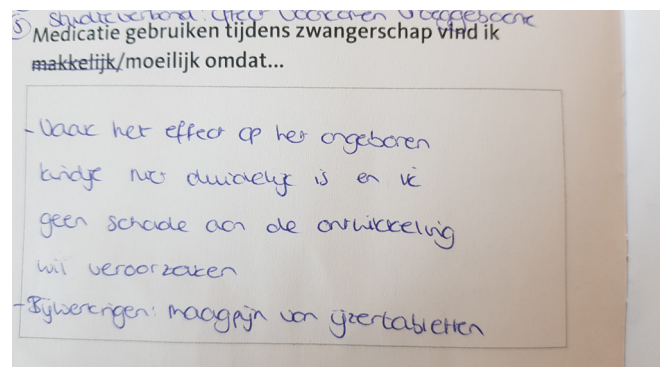
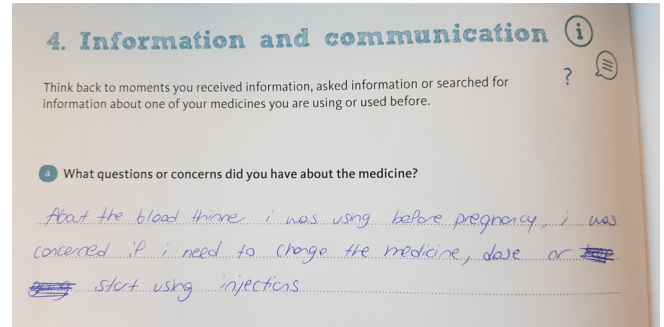
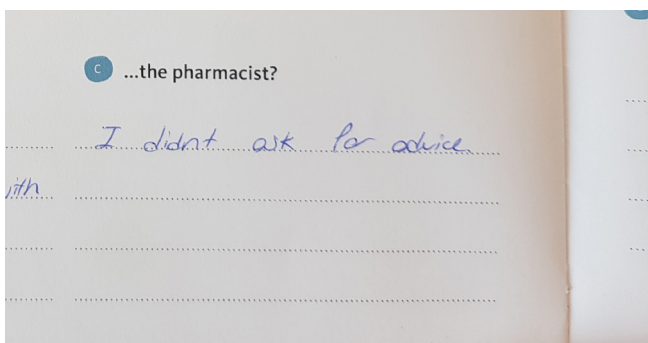
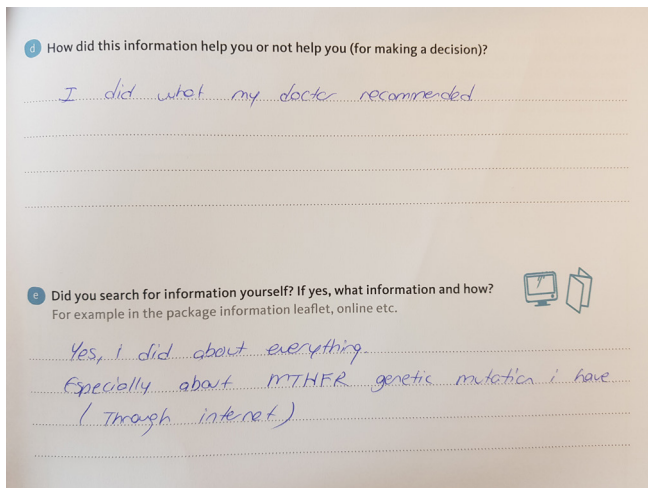
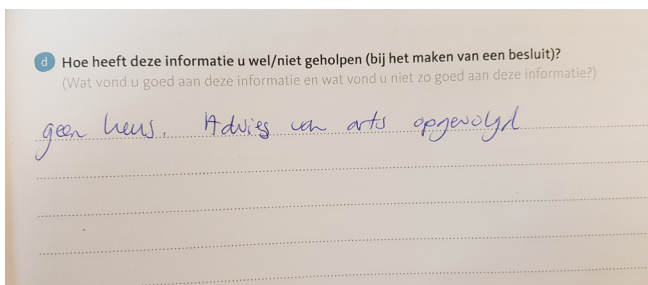
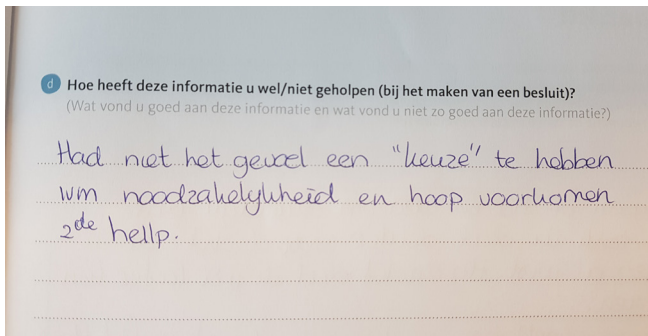
Deel 3. Ideale informatie over medicijnen (± 10 min.)

- Suppose there would be a new information product for pregnant women, how should that then look like according to you?
 - What is in that information?
 - What information did you now not get, what you actually would have wanted to have? Why?
- What information is important to you for making a good decision about taking a medicine?
 - What would be the deciding factor for you that a medicine is good / not good in your situation? *(for example, do you want research evidence that it is safe, or would you say if the doctor says it's safe then it's okay?)*
- How would you want to receive that information? *In case you're not at the doctor, how then?*
 - At what moment would you like to receive that information (before pregnancy, during prescription, at home)

End

- Thank you for participating
- Your input is very valuable
- May I contact you for another interview later in my project? *(about evaluating a product I will design based on the insights of this research)*

I. IMPRESSION OF RESULTS SENSITIZING BOOKLET



Figures A10-A18 (from top left to bottom left, top right to bottom right).
Interesting answers in sensitizing booklets

J. BRAINSTORM SESSIONS

Brainstorm session 1

The first of the two brainstorm sessions was conducted with members of the project team 'Improving information to patients' of the MEB.

Goal

The goal was to come up with a variety of solutions for the different problem statements (How-Tos) mentioned on p.74. Additionally, the session was intended to introduce them to the designer's approach of problem solving and designing.

Method

All nine members of the team were invited. Eventually, four of them participated in the session. The brainstorm, brainwriting/brain drawing and

How-Tos method were used for the session, which stimulate to create a wide variety of ideas for parts of the design challenge (Van Boeijen et al., 2014).

Materials for the session included:

- A3 sheets of paper with How-Tos
- Markers
- Stickers
- Tape
- Camera
- Large paper sheet for the group How-To
- Cookies

Procedure

Prior to the session, the How-Tos explained on p.74 were created based on requirements for the design. At the start of the session, the conclusion from research was explained to the participants, followed



Figure A19. Brainstorm session 1 at MEB

by the design goal and goal of the session. Then the brainstorm rules as described by Van Boeijen et al. (2014) were spelled out. It was stressed that they should not think about the utility or feasibility of ideas, which should lead to more (unexpected) ideas.

After the introduction, we started by creating ideas for 'How to bring information to the patient' together, so everyone could get used to the methodology. Everyone wrote down ideas on post-it's and handed them over to the facilitator (graduating student), who stuck them on a large poster on the wall. Different ideas were directly clustered.

Subsequently, ideas were created for the four remaining How-Tos. These were written down on A3 sheets of paper. Each participant wrote down or drew ideas and after three minutes, the papers were passed to the next participant.

Once everyone created ideas for each How-To, the group selected the most interesting ideas by adding green stickers on the papers. Afterwards, everyone explained why they found these ideas to be most promising. Eventually, this resulted in a plenary discussion of how the designer could use these ideas in the product.

Brainstorm session 2

Goal

As with the first brainstorm session, the aim of the second session was to generate a variety of ideas for the design problems. Additionally, the goal was to come up with ideas for how to write risk information in a more positive way and to translate all the ideas in product concepts.

Method

The session was conducted with family and friends of the facilitator (graduating student). Among the

seven participants there was a general practitioner, a medical student, a nurse, an industrial designer, pregnant woman, partner of the pregnant woman and mother. Given their medical, design or 'pregnancy' background, they could provide extra valuable ideas.

Like with the first session, the brainstorm, brainwriting/brain drawing and How-Tos method were used (Van Boeijen et al., 2014).

Materials for the session included:

- A3 sheets of paper with How-Tos
- Markers
- Stickers
- Tape
- Sheet with brainstorm rules
- Sheet with the design goal
- A4 sheets with MEB's official medication information of Labetalol and ferrofumaraat
- Template for creating concepts
- Snacks and drinks

Procedure

At the start of the session, the conclusion from research was explained to the participants, followed by the design goal and goal of the session. Then the brainstorm rules as described by Van Boeijen et al. (2014) were spelled out. It was stressed that they should not think about the utility or feasibility of ideas, which should lead to more (unexpected) ideas.

After the introduction, the creative session started by creating ideas for six How-Tos. Each participant wrote down or drew ideas. After three minutes, the papers were passed to the next participant. Some participants chose to elaborate on the ideas written down by others. Other participants chose not to read their ideas since they wanted to focus on their own ideas and not be influenced too much.

Once everyone created ideas for each How-To, the facilitator asked their experience with the activity. Everyone selected the most interesting/promising ideas by adding green stickers on the papers.

Meanwhile, participants explained to each other which ideas they found interesting and promising and why, which resulted in a plenary discussion where everyone reacted and elaborated on each other's ideas.

During the second part of the session, each participant was given an A4 with the information that is included in the patient leaflet's pregnancy section of the medicine Labetalol (1) and ferrofumaraat (2). Each participant reacted on what they thought after reading the information. Then they discussed how this information could be written in such a way that it would not frighten pregnant women and give them more confidence (thus more positively). The first concept for the medication information was shown to the participants, whereby the general practitioner gave tips on how it could be improved.

In the third part, the group was split into two. Each group was asked to come up with a product concept by keeping the design goal in mind. After 20 minutes, the groups explained their ideas to each other and discussed their potential.

Results brainstorm session 2

- Manier van opschrijven is belangrijk, volgens arts NNT
- Nadelen weegschaal gebruiken; als je het niet gebruikt gebeurt er dit, als je het wel gebruikt krijg je deze bijwerkingen. Dan kun je het beter afwegen. De nadelen wegstrepen tegen de voordelen. Als symbool een soort weegschaal. "Het is nu een beetje krom, omdat je alleen ziet wat er met je gebeurt als je het wel inneemt. Maar er staat niet wat er mogelijk met je gebeurt als je het niet inneemt. Terwijl eigenlijk zou je dat gewoon naast elkaar moeten hebben."
- Je kan ook doen voor medicijnen die in zwangerschap gebruikt worden dat je los voor moeder en los voor kind de risico's en voordelen opschrijft. Want dat zijn ook nog verschillende grootheden. "Oja dat wil je eigenlijk ook wel weten."
- Het zou goed zijn als de verloskundige, waarbij je ook al je ziektes en aandoeningen moet noemen, dat zij ook die papiertjes hebben, en dan speciaal voor zwangerschap en borstvoeding. Dat is ook waar veel mensen mee zitten (borstvoeding). Dat de verloskundige dat bij de intake ook doornemen. Dus op het moment wanneer er iets verandert, als je dus zwanger wordt, dat je dan die informatie krijgt.
- Breed platform waar je je informatie vandaan kan halen, bijv. Via zorgverzekeraar. Arts moet verwijzen naar veilige (betrouwbare) websites.

See next page.

Zwangerschap en borstvoeding

Bent u zwanger, denkt u zwanger te zijn, wilt u zwanger worden of geeft u borstvoeding? Neem dan contact op met uw arts of apotheker voordat u dit geneesmiddel gebruikt.

Hoewel Labetalol HCl ratiopharm in principe geschikt is voor de behandeling van verhoogde bloeddruk tijdens het eerste trimester van de zwangerschap, wordt onnodige toediening afgeraden. Labetalol mag alleen worden gebruikt in het eerste trimester van de zwangerschap wanneer de mogelijke voordelen opwegen tegen de mogelijke risico's.

Labetalol wordt uitgescheiden in de moedermelk. Voorzichtigheid is geboden bij het gebruik van labetalol tijdens het geven van borstvoeding.

Figure A20. Pregnancy related information in the patient leaflet of the medicine Labetalol

Zwangerschap en borstvoeding

Bent u zwanger, denkt u zwanger te zijn, wilt u zwanger worden of geeft u borstvoeding? Neem dan contact op met uw arts of apotheker voordat u dit geneesmiddel gebruikt.

Zwangerschap

Hoewel er weinig gepubliceerde gegevens zijn over het gebruik van ferrofumaraat in de zwangerschap bij de mens, wijst uitgebreide ervaring met ijzersupplementen tijdens de zwangerschap tot nu toe niet op schadelijke effecten voor het ongeboren kind (teratogene of foetotoxische effecten). Beperkte gegevens uit dierstudies wijzen niet op nadelige effecten op de zwangerschap of de ongeboren vrucht. Dit middel kan tijdens de zwangerschap op doktersvoorschrift worden gebruikt.

Borstvoeding

Na gebruik van orale ijzersupplementen komt ijzer in zeer kleine hoeveelheden in de moedermelk. Nadelige effecten op zuigelingen na gebruik van orale ijzersupplementen door de moeder zijn tot nu toe niet gemeld. Tijdens behandeling met dit middel kunt u borstvoeding blijven geven.

Figure A21. Pregnancy related information in the patient leaflet of the medicine Ferrofumaraat

Responses to information about the medicine Labetalol from the patient leaflet

- Moeder: "Oh dit is inderdaad dat je denkt pfff"
- Zwangere vrouw: **"Oh dit is echt.. Staat dit er zo? Mijn hemel. Ik word er helemaal tureluurs van en ik zou het meteen niet meer nemen."**
- Arts in opleiding: Het is heel erg indekken van de farmacie. "Ze dekken zichzelf in ieder geval in."
- Moeder: **"Het is ook zo vaag. Wanneer de mogelijke voordelen opwegen tegen de mogelijke risico's. Dan kun je totaal niet inschatten wat.."**
- Nu moet je er zelf invulling aan gaan geven, de informatie is vaag en onduidelijk.
- Zwangere: **"Er mist zoveel informatie in dit stukje" "De mogelijke risico's.. Ja welke mogelijke risico's? En wanneer is toediening onnodig?"**
- Verpleegster: "In principe" is ook zo vaag
- Moeder: "Je kan hier toch totaal niet iets op baseren als je een leek bent. Of je dit nou wel of niet moet nemen." **Arts: "Sterker nog, als je dit leest ga je het niet nemen"**
- Suggestie arts: "Hoge bloeddruk in de

zwangerschap kan uw placenta versneld doen verouderen. Hierdoor krijgt u een vroeggeboorte. Als we uw hoge bloeddruk behandelen, voorkomen we dit risico. Het risico van slikken is op grond van jarenlange ervaring nihil." "Alle zwangeren met hoge bloeddruk gebruiken tijdens de zwangerschap Labetalol / Als voor de behandeling van hoge bloeddruk in de zwangerschap gekozen wordt voor een medicijn, wordt altijd gekozen voor Labetalol." Moeder: "Dat vind ik ook heel betrouwbaar."- "De risico's van het niet behandelen van een hoge bloeddruk zijn veel hoger dan de risico's van het gebruik van het medicijn." Dat moet er eigenlijk in. Dat wil je weten, dan ga je het slikken.
- Hoe minder tekst, hoe beter

Responses to information about the medicine Ferrofumaraat from the patient leaflet

- Verpleegster: Sowieso iets leesbaarder maken voor zwangere vrouwen, zonder termen als teratogeen etc.
- Moeder: "Als die dierstudies naar voren komen met beperkte gegevens, dan denk ik wat doet dat

in dit stukje.”

- Arts: “6 op de 10 zwangere vrouwen slikt ferrofumaraat. Al deze kinderen worden gezond geboren. Slikt u het gerust.”
- **Arts: “Tot nu toe’... het wordt al 100.000 jaar gebruikt. Er is gewoon geen risico.”**
- Het communiceren van de ervaringen zal echt helpen. Arts denkt dat oprecht 6/10 vrouwen dit slikken. Want bloedarmoede krijg je heel makkelijk tijdens de zwangerschap.
- “Je gaat hierdoor wel een beetje twijfelen..”
- **Vrouwen moeten van tevoren worden verteld waar ze terecht kunnen met hun vragen of zorgen, en er moet van tevoren verteld worden dat ze bijv. Niet in de bijsluiter moeten kijken.** Daar is iedereen het mee eens
- **Voor andere zwangeren is de verloskundige een belangrijk aanspreekpunt, degene die naar informatie moet verwijzen**

Creating concepts

- Heel snel overzichtelijk vinden welke middelen je kan gebruiken per klacht. Zoeken op klacht
- Als je een app maakt is het belangrijk dat de bron betrouwbaar is
- Duidelijke categorieën van veiligheid als je een medicijn opzoekt
- Als je al drie dagen niet hebt gebruikt (tracken) dat je dan weer een bericht krijgt van de voordelen
- Overall moet je consistente informatie krijgen, dus daarom is zowel papier als app belangrijk. Iedereen kan terugverwijzen daarnaar

Concept 1

- App die je krijgt als je zwanger bent, via je verloskundige of arts
- Je hebt zwangerschaps portaal online waar je in kan. Als het goed is kunnen daar ook alle zorgverleners in. Daar kan het ook aan gekoppeld worden
- Gekoppeld aan patiënt dossier
- Inloggen via flyer, lijst met jouw medicijnen, voor-

en nadelen weegschaal. Hoe je dat het meest overtuigend kan brengen moet nog uitgezocht worden.

- Ook algemeen veelgebruikte medicijnen OTC drugs, checkboxjes. Dus eigenlijk zoeken op klacht & welk medicijn kun je gebruiken en welke niet?
- Icoontje met ooievaar
- Ook reviews van anderen, alleen als je het voorgeschreven hebt gekregen, waardoor het betrouwbaar is.
- Eigenlijk moet je geen reviews gebruiken want vrouwen hebben er geen verstand van en schrijven vaak alleen een review als ze een slechte ervaring hebben gehad
- Misschien als alternatief dat je ziet hoeveel andere zwangere vrouwen dit medicijn ook voorgeschreven hebben gekregen
- **Arts: Een veelgebruikte strategie is zeggen van oh we doen dit heel vaak bij patiënten, we geven dit heel vaak, het is heel normaal**

Naam concept: _____

Bedacht door: *Anne, Thomas, Maartje*

Teken of beschrijf hieronder het concept.

Wat is er goed aan dit concept? _____

Wat kan er beter? / Wat ontbreekt er nog? _____

Figure A22. Concept 1 created during brainstorm session 2

Concept 2

- Er zijn 2 verschillende groepen; vrouwen die al een medicijn gebruiken voor ze zwanger worden (die moeten dus op voorhand geïnformeerd worden over het product) en vrouwen die tijdens de zwangerschap met een medicijn starten (die geïnformeerd kunnen worden tijdens een consult. Eigenlijk 3 groepen want je hebt ook OTC medicijnen
- Voor de 1e groep vul je medicijn in en krijg je gelijk categorie van stop, overleg met uw arts (hangt er vanaf waarvoor je het gebruikt) en veilig (hoe dan ook veilig, ga er vooral mee door) Snel en overzichtelijk zien wat er bij jouw medicijn aan de hand is. Als er staat STOP, dan alternatieve medicijnen laten zien.
- Bij de andere groep een soort app die hen stimuleert om het medicijn te blijven gebruiken
- Ook achteraf terug kunnen zien of een medicijn gevaarlijk is geweest in de weken dat je nog niet wist dat je zwanger was. Wat dan de eventuele schade daarvan is. Dat er dan staat van "ik heb dit medicijn ingenomen, wat nu?" Neem contact op met je arts.
- Website maken; medicatie tijdens zwangerschap (zwangerschapmedicatie.baby) waarnaar dus door iedereen wordt verwezen, en die je ook kan gebruiken voordat je bij een verloskundige/arts komt.
- Hoe kom je dan over die website te weten? Je kan het op alle betrouwbare websites plaatsen, op meerdere websites om awareness te creëren, of in elke bijsluiter zetten
- Artsen zouden jouw medicatie moeten kunnen koppelen aan het portaal
- Linkje waarop je kan doorklikken op het portaal

Naam concept: *Vul HA specialit Apo*

Bedacht door:

Teken of beschrijf hieronder het concept. *een concept*

Website / app / papier

Veel gebruikte medicatie tijdens de zwangerschap.

Pariteters: *STOP* *OVERLEG + hulpje.* *VEILIG: kan je zo gebruiken.*

Middelen bij bloedsuiker

Middelen bij depressie: *die je al gebruikt voor je zwangerschap.*

Anti-allergie:

Astma medicijnen:

Die je kunnen worden voorgeschreven tijdens de zwangerschap

- Ascal

- Ferro

- labetalol

- Anti-uricolyse

Wat is er goed aan dit concept?

Wat kan er beter? / Wat ontbreekt er nog?

Figure A23. Concept 2 created during brainstorm session 2

K. 'HOW TO' IDEATION

'How to...' results of individual ideation



Figure A24. How to... make sure a patient trusts a medicine?

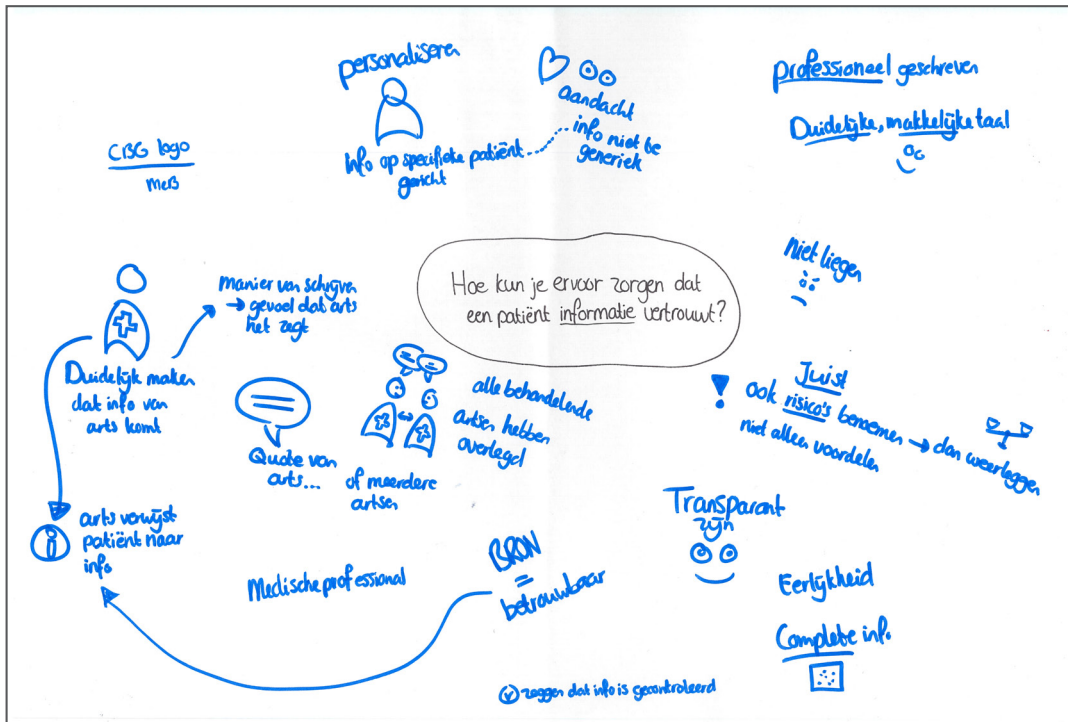


Figure A25. How to... make sure a patient trusts information?

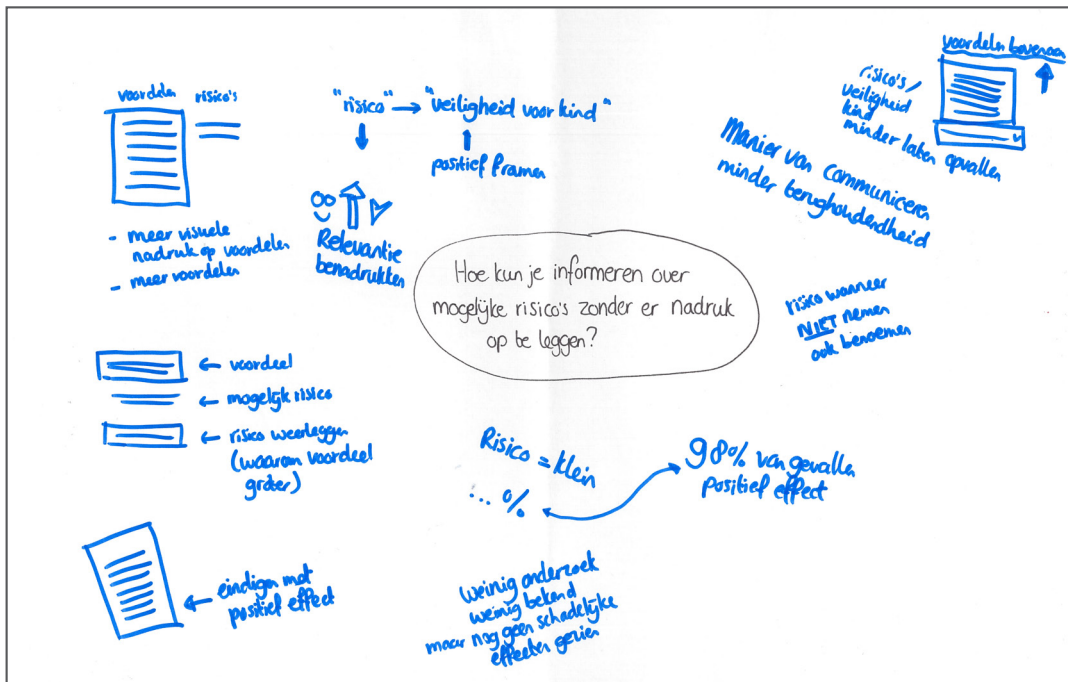


Figure A26. How to... communicate potential risks of a medicine without emphasizing them?

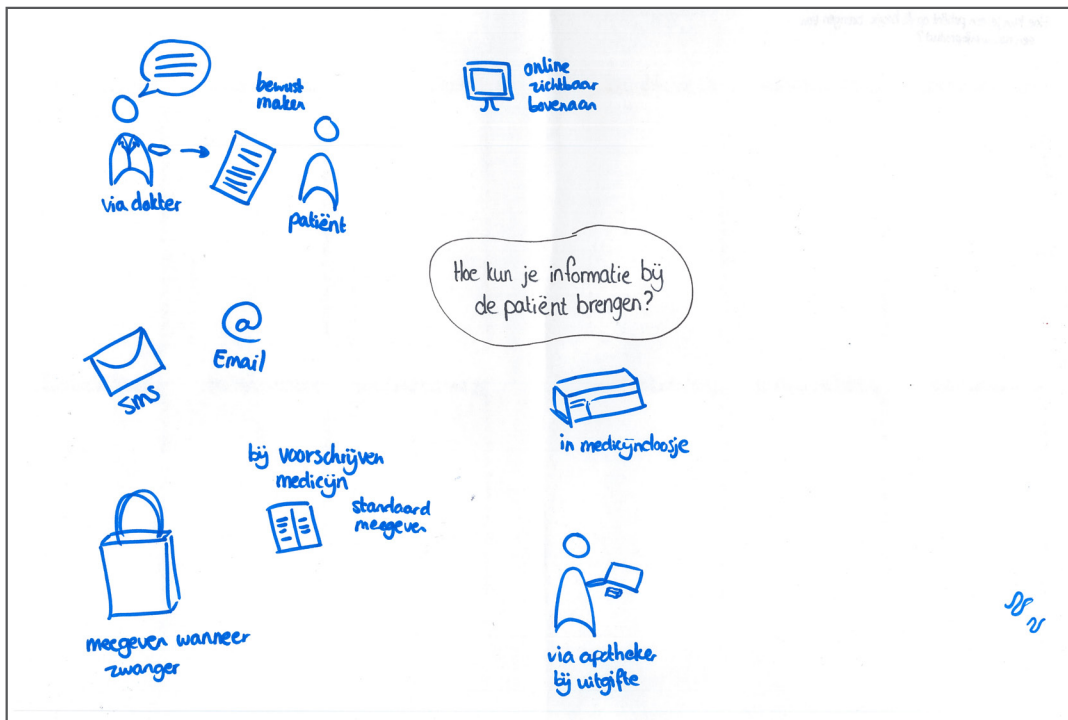


Figure A27. How to... bring information to the patient?

'How to...' results of creative session with MEB employees

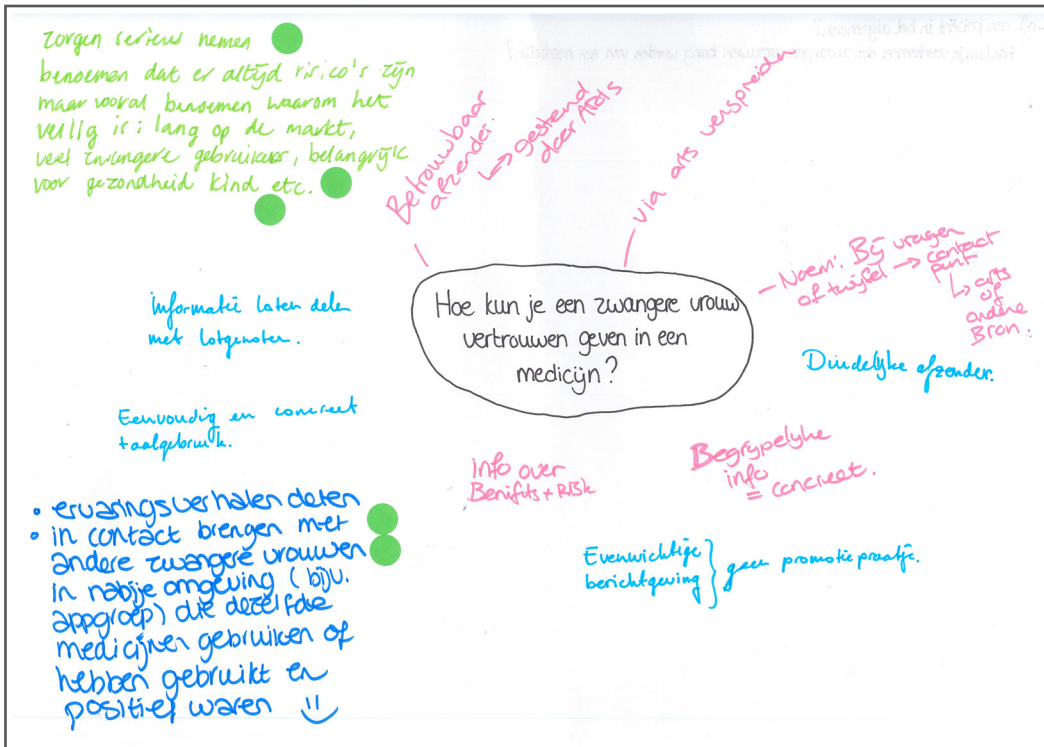


Figure A28. How to... make sure a patient trusts a medicine?

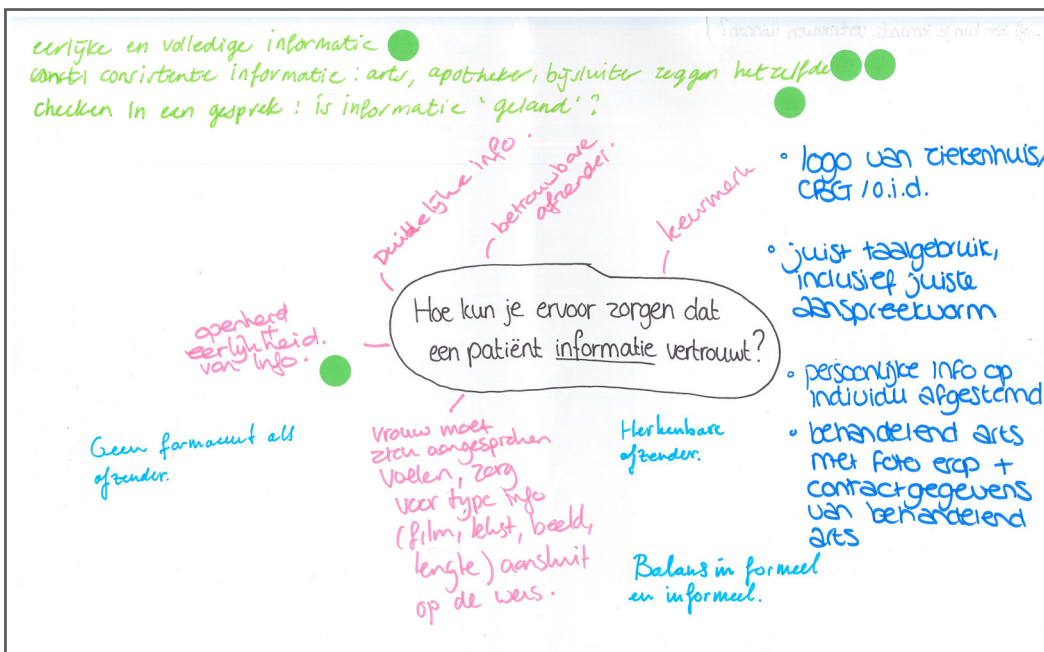


Figure A29. How to... make sure a patient trusts information?

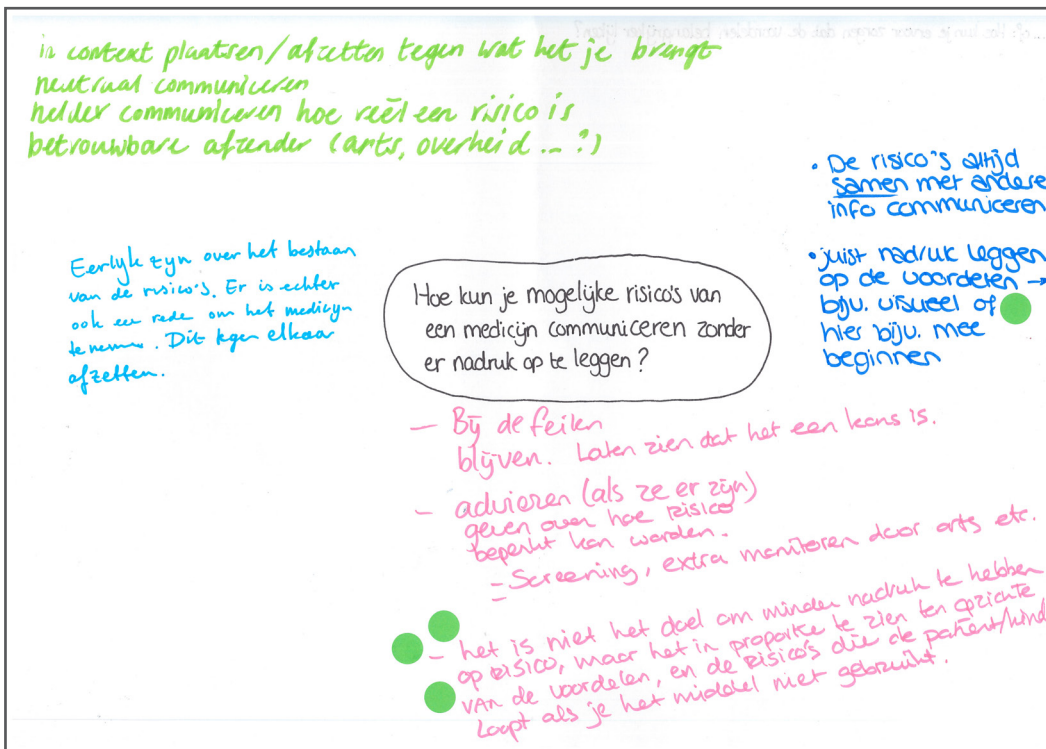


Figure A30. How to... communicate potential risks of a medicine without emphasizing them?

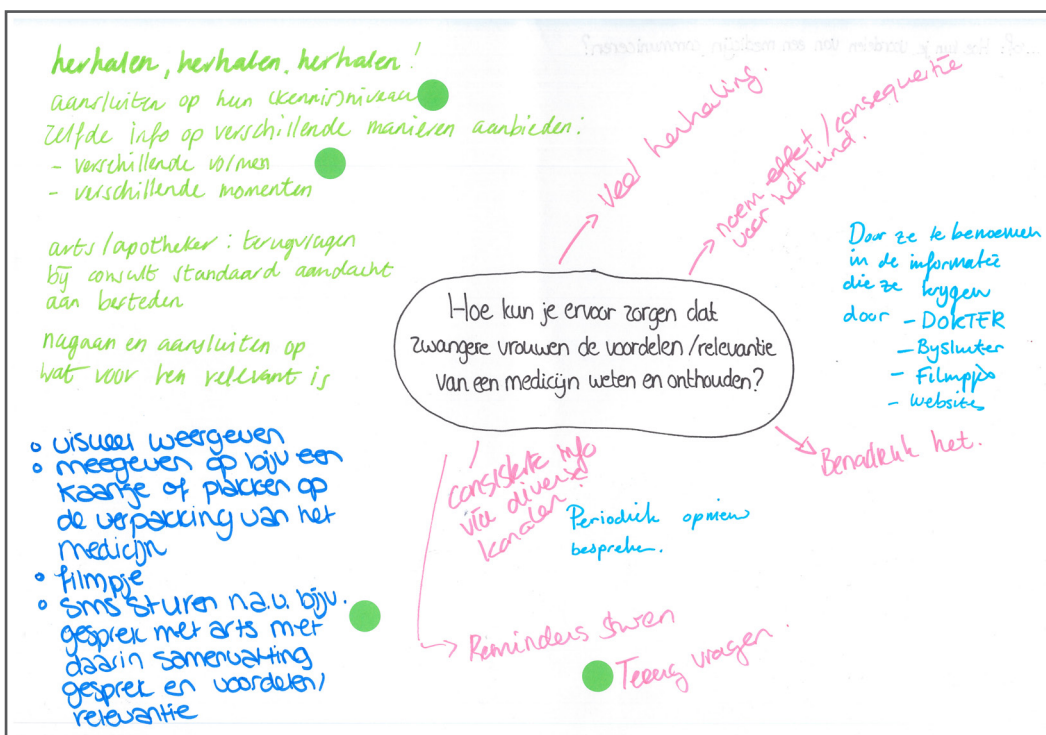


Figure A31. How to... make sure pregnant women know and remember the benefits/relevance of a medicine

'How to...' results of creative session with MEB employees

Noem voordelen voor 't kind.
 Noem lotgenoten

Vergelijk met andere risico's (die, groter maar 'normaler' zijn) - Duidelijk consequenties voor het kind uitleggen bij staken

Zeg hoe lang 't middel al gebruikt wordt, wat is de ervaring.

Noem de nadelen + risico's van niet gebruiken.

Wys op de 'indianen verhalen en ontkracht deze b' voorbaat'.

↳ Wilkes over de werking
 ↳ beden wel van niet
 ↳ handout

Hoe kun je een zwangere vrouw vertrouwen geven in een medicijn?

↳ Verhalen van andere
 ↳ "Bevrijzen" dat de voordelen op wegen tegen de nadelen.
 ↳ wetenschappelijk?
 ↳ onzekerheden wegnemen

↳ Verhalen v. anderen waarbij het goed is aangelegem heten
 ↳ outmosthipplek online voor vrouwen die in het ziekenhuis zitten.

* Gebruikerservaringen van andere vrouwen.
 * Het belang goed duidelijk maken (voornamelijk voor het kind).

↳ Ervaringen van peers
 ↳ Invloeden van positieve effecten
 ↳ Levenswijze bevoegen
 ↳ Invloeden in contact kunnen patiënt en zorgverleners

Figure A32. How to... make sure a patient trusts a medicine?

* Fabels noemen in de voorlichting (ontkrachten dus!)

* Verwijzen naar één plek voor info.

↳ Duidelijke huisstijl
 ↳ Eén voorbeeld
 ↳ Informatie centrum (beard met ze het zelf kunnen checken) controleren
 ↳ Jip & Janneke

- eventueel hulplijn voor vragen (apothek?)

Hoe kun je ervoor zorgen dat een patiënt informatie vertrouwt?

- Het laten meegem door de arts die ze vertrouwen
 - Keurmerke van ten dat betrouwbaar is.

keurmerk **CBG**

informatie van betrouwbaar persoon
 ↳ familie, vrienden
 ↳ dokter
 ↳ apothek
 ↳ kan ook verlost uitpakken

wetenschappelijk onderbouwd.
 logisch & leerbaar

* Fake news ook noemen, want dat komen ze later tegen.

* Eerlijk over risico's maar wel in proportie, ie moet visico kunnen stoppen.

* Web site waar je betrouwbare info kunt vinden, NIET vd fabrikant

↳ Kennis over (lij) werking
 ↳ Kennis over het open middel systeem in Nederland.
 ↳ Zwangerschapsvormen
 ↳ Medicatie
 ↳ Levenswijze
 ↳ Farmacie

Figure A33. How to... make sure a patient trusts information?

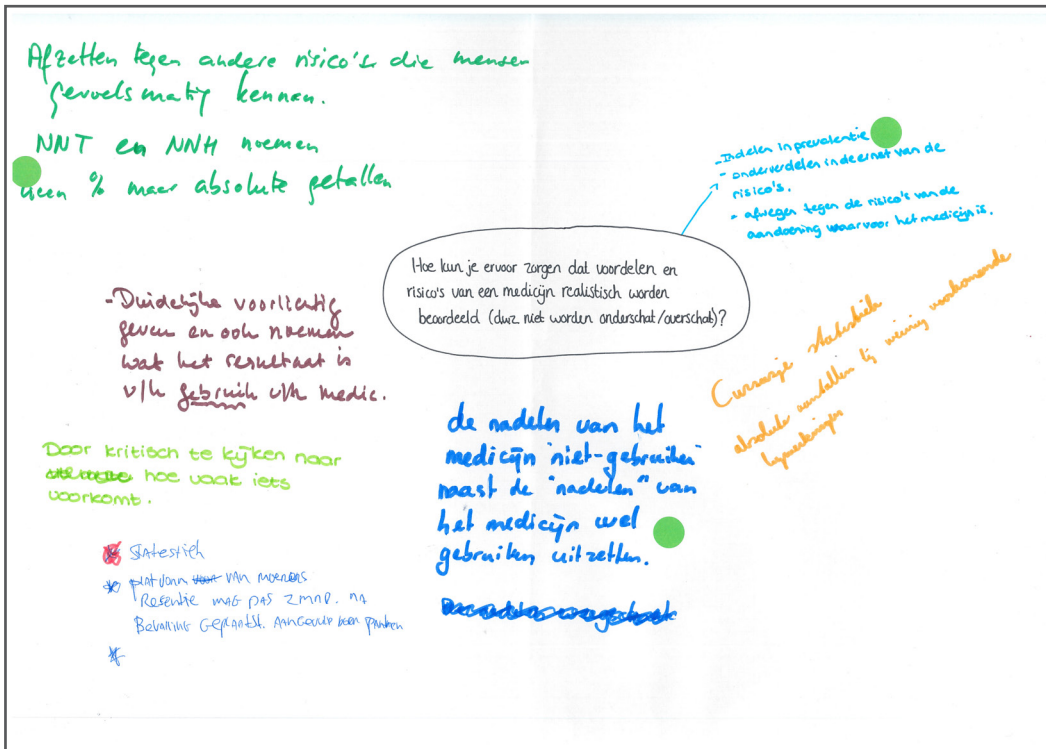


Figure A34. How to... make sure the benefits and risks of a medicine are realistically perceived (i.e. not overestimated/underestimated)?

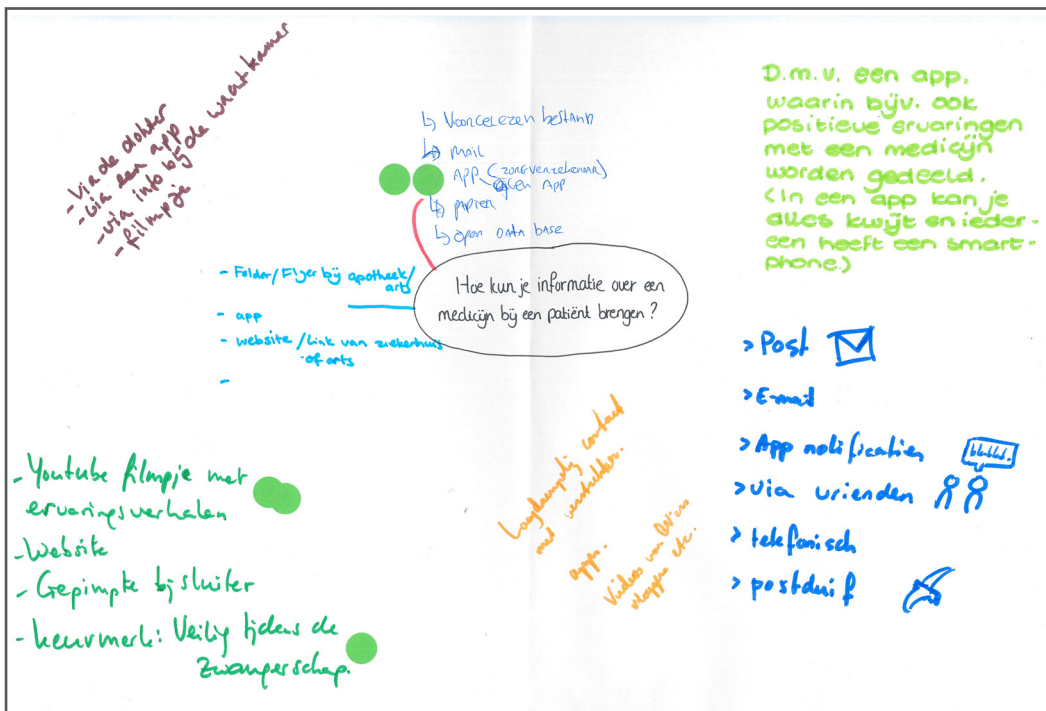


Figure A35. How to... bring information to the patient?

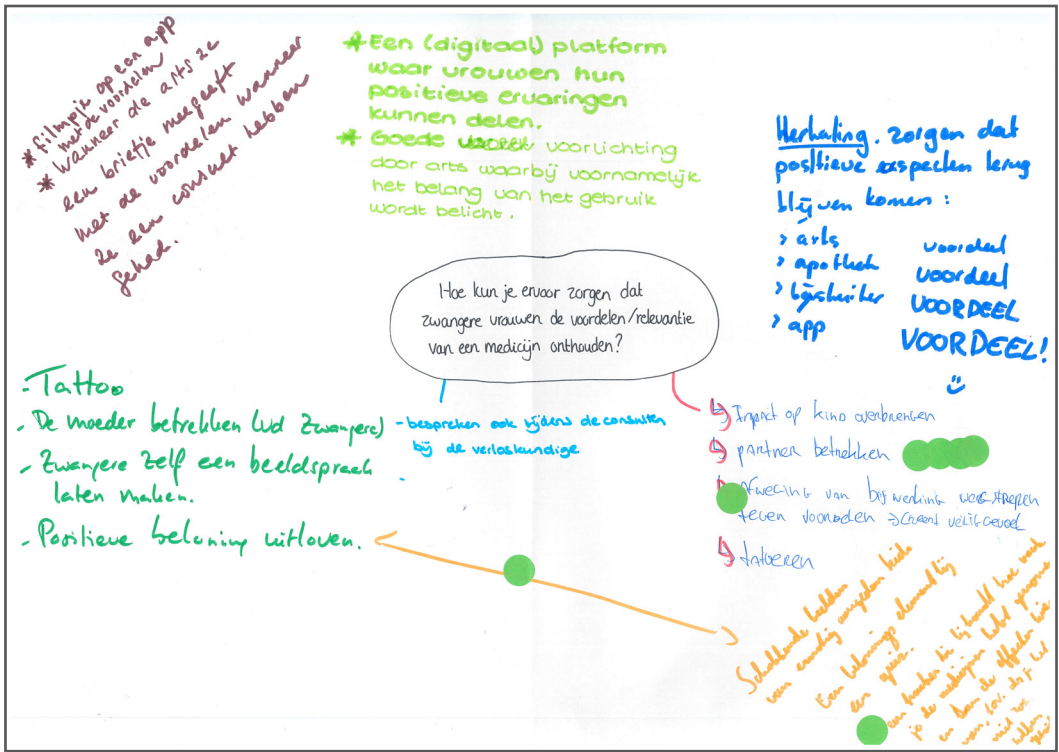


Figure A36. How to... make sure pregnant women (know and) remember the benefits/relevance of a medicine?



Figure A37. How to... keep medication information compact?

L. SUMMARY OF HOW TO IDEAS

1. How to make sure a patient trusts a medicine?



Figure A38. Summary of ideas for the 'How to make sure a patient trusts a medicine?'

2. How to communicate potential risks of a medicine without emphasizing it?

6. How to make sure the benefits and risks of a medicine are realistically perceived (i.e. not overestimated/underestimated)?

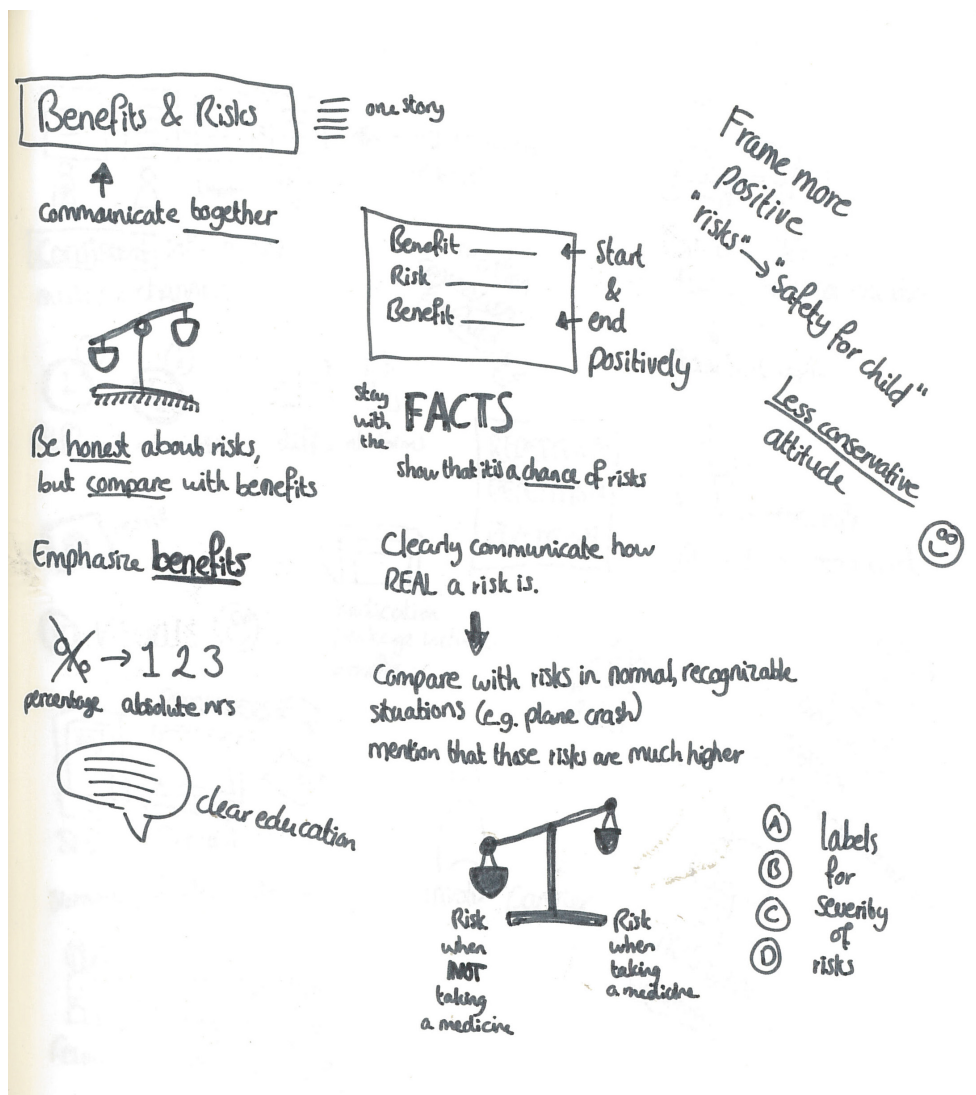


Figure A39. Summary of ideas for 'How to communicate potential risks of a medicine without emphasizing it?' & 'How to make sure the benefits and risks of a medicine are realistically perceived (i.e. not overestimated/underestimated)?'

3. How to make sure pregnant women (know and) remember the benefits/relevance of a medicine?

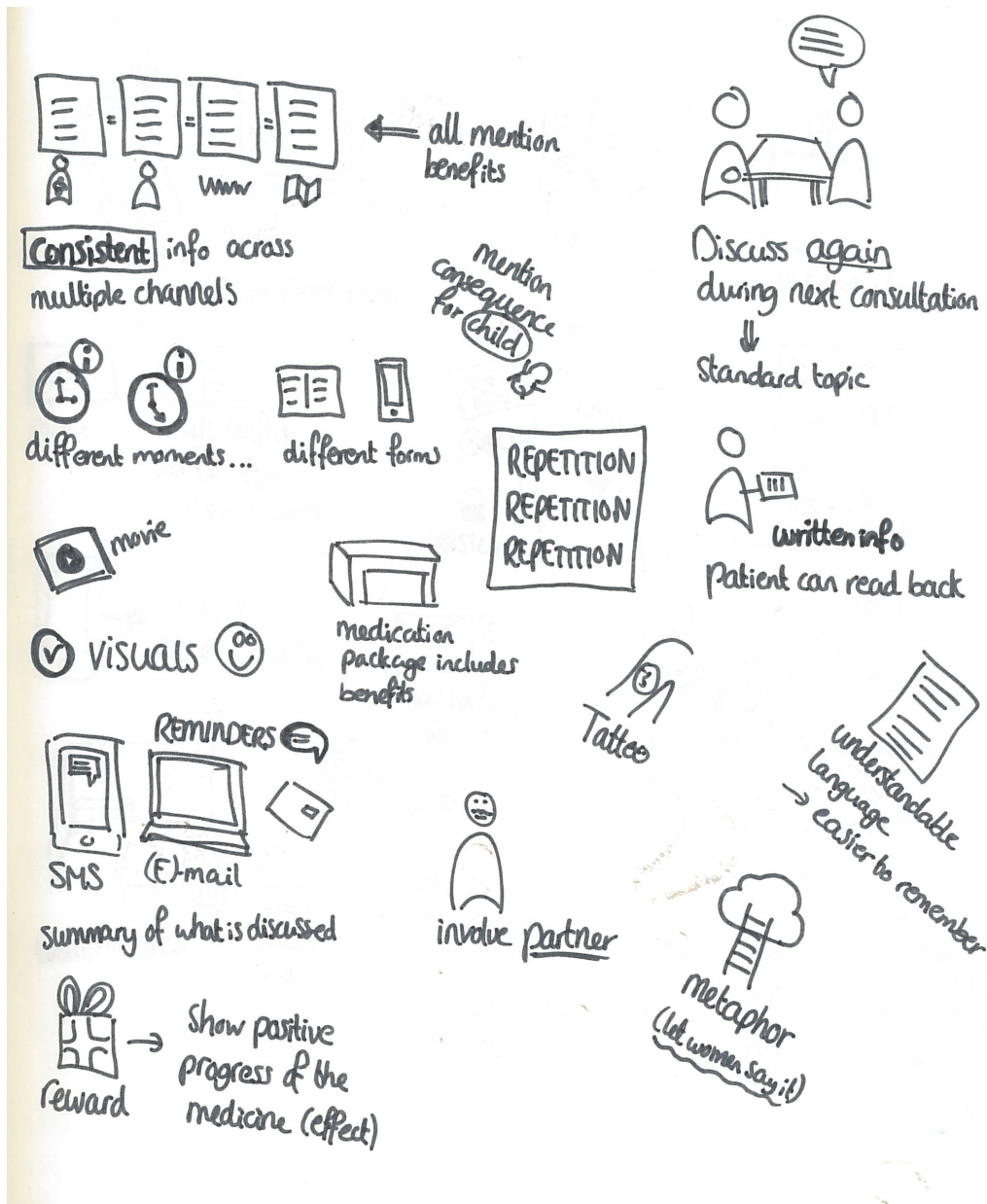


Figure A40. Summary of ideas for 'How to make sure pregnant women (know and) remember the benefits/relevance of a medicine?'

4. How to make sure pregnant women trust the information?

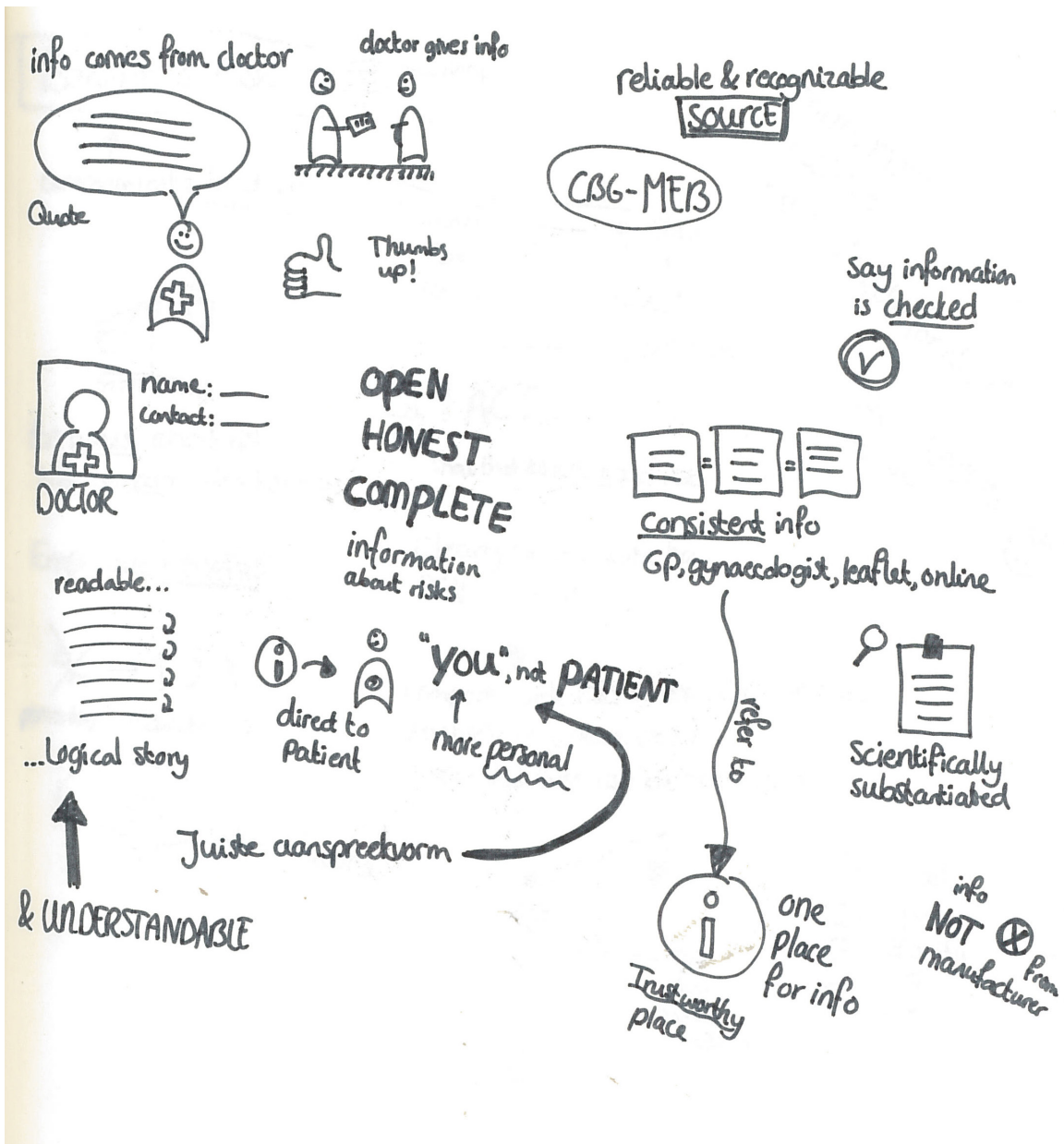


Figure A41. Summary of ideas for 'How to make sure pregnant women trust the information?'

5. How to bring information to the patient?



Figure A42. Summary of ideas for 'How to bring information to the patient?'

Note: The last How To (keep information compact) did not provide interesting insights and were therefore dismissed

M. EXISTING INFO LABETALOL AND ASPIRIN

Labetalol

Informatie van apotheek.nl

<https://www.apotheek.nl/medicijnen/Labetalol#!>

Wat doet Labetalol en waarbij gebruik ik het?

Labetalol behoort tot de bètablokkers. Het verlaagt de bloeddruk, vertraagt de hartslag en vermindert de zuurstofbehoefte van het hart.

Artsen schrijven het voor bij hoge bloeddruk, onder andere bij zwangerschap, en bij angina pectoris (hartkramp).

Effect

Na één tot drie dagen is het volledige effect van dit middel bereikt. Zelf merkt u hier niet veel van. U weet pas of het werkt bij een meting van uw bloeddruk. Toch is het belangrijk om Labetalol elke dag in te nemen. Alleen dan kan Labetalol de hart- en bloedvaten optimaal beschermen.

Hoge bloeddruk tijdens de zwangerschap

Hoge bloeddruk tijdens de zwangerschap vormt een risico voor de zwangere en de baby. Dat komt omdat de bloedvaten door de toename van de bloedstroom al meer te lijden hebben dan anders. Daarom controleert de verloskundige of arts met regelmatige tussenpozen de bloeddruk. Vrouwen kunnen al voor ze zwanger zijn een verhoogde bloeddruk hebben of kunnen tijdens de zwangerschap een verhoogde bloeddruk krijgen.

Als de hoge bloeddruk in de tweede helft van de zwangerschap ontstaat, heet het ook wel zwangerschapshypertensie of zwangerschapsvergiftiging. Deze laatste term is onjuist, omdat er geen sprake van een vergiftiging is. Deze vorm van hoge bloeddruk moet snel behandeld worden. Na de bevalling verdwijnt de hoge bloeddruk meestal weer binnen drie maanden.

Behandeling

Als rust houden of minder zout gebruiken niet helpen om de bloeddruk omlaag te krijgen, zal de arts een medicijn voorschrijven tegen hoge bloeddruk. Dit moet dan een medicijn zijn dat veilig is voor de zwangere en de baby. Labetalol is zo'n medicijn. In het geval van een snel oplopende zwangerschapshypertensie wordt Labetalol in injectie toegepast.

Als u al medicijnen gebruikt tegen een hoge bloeddruk en zwanger wilt worden, is het verstandig met uw arts te overleggen. Het is dan mogelijk om op tijd over te schakelen naar veilige medicijnen tijdens de zwangerschap, zoals Labetalol.

Mag ik dit medicijn gebruiken als ik zwanger ben, wil worden of borstvoeding geef?

Zwangerschap

Meld het aan uw arts en apotheker zodra u zwanger bent, of binnenkort wilt worden. Samen met uw arts kunt u bespreken wat het risico voor de baby is als u doorgaat met het medicijn. Of wat het risico voor u is als u met het medicijn stopt.

Bij gebruik van dit medicijn tijdens de zwangerschap bestaat er namelijk een risico op bijwerkingen bij het kind. Zoals een lage bloedsuikerspiegel, een lage bloeddruk, een lage hartslag, suf worden en moeite met ademen. Mogelijk zal uw arts uw baby extra controleren. Overleg hierover met uw arts. Zo mogelijk kunt u (tijdelijk) overstappen op een ander medicijn.

Informatie van Lareb

<https://www.lareb.nl/tis-knowledge-screen?id=233&page=1&searchArray=Labetalol&pregnancy=true&brea stfeeding=true>

Bètablokkers tijdens de zwangerschap

Overzicht

Er zijn geen aanwijzingen voor een hoger risico op aangeboren afwijkingen met bètablokkers. Ze kunnen mogelijk de groei van het ongeboren kind remmen. Labetalol en metoprolol hebben de voorkeur in de zwangerschap.

Let op

Bij gebruik van betablokkers in het laatste deel van de zwangerschap of tijdens de bevalling kunnen bij het ongeboren kind of de pasgeborene verschijnselen optreden van lage bloedsuiker, lage hartslag, lage bloeddruk, sufheid en ademhalingsproblemen.

Gebruik eerste trimester

Labetalol behoort tot de voorkeursmedicatie bij hypertensie in de zwangerschap. Onderzoek naar bètablokkers in de zwangerschap laten tot nu toe geen hoger risico op aangeboren afwijkingen zien. De meeste ervaring tijdens de zwangerschap is opgedaan met Labetalol, gevolgd door atenolol, metoprolol en propranolol. Met de overige bètablokkers is weinig tot geen ervaring in de zwangerschap.

Gebruik derde trimester

Na toepassing in het laatste deel van de zwangerschap en tijdens de bevalling kunnen bètablokkers wel farmacologische effecten hebben bij de foetus of de pasgeborene. De farmacologische effecten bestaan onder andere uit hypoglykemie, hypotensie, bradycardie, sedatie en ademhalingsproblemen.

Risico groeivertraging

Langdurig gebruik van atenolol leidt mogelijk tot groeivertraging. Wees terughoudend met het gebruik van deze bèta-blokker. Ook Labetalol, metoprolol en propranolol zijn in verband gebracht met groeivertraging. Bij deze bètablokkers is het verband minder duidelijk. Met de andere bètablokkers is nauwelijks ervaring opgedaan tijdens de zwangerschap. Het is niet bekend of deze middelen een nadelig effect op de foetale groei hebben.

Labetalol

Bij Labetalol gebruik tijdens de zwangerschap zijn verschijnselen van het fenomeen van Raynaud in de tepel beschreven. Een case-report beschrijft persistente ernstige hypoglykemie, hyperbilirubinemie en polycythemie bij de neonaat nadat de moeder de laatste vier maanden van de zwangerschap nebivolol gebruikt had.

Informatie in de bijsluiter

Gebruiken bij:

Labetalol HCl ratiopharm is bestemd voor de behandeling van verhoogde bloeddruk (ook b.v. tijdens de zwangerschap). Labetalol HCl ratiopharm kan ook worden gebruikt voor de behandeling van patiënten met angina pectoris (hartkramp), die tevens een verhoogde bloeddruk hebben.

Zwangerschap en borstvoeding

Bent u zwanger, denkt u zwanger te zijn, wilt u zwanger worden of geeft u borstvoeding? Neem dan contact op met uw arts of apotheker voordat u dit geneesmiddel gebruikt.

Hoewel Labetalol HCl ratiopharm in principe geschikt is voor de behandeling van verhoogde bloeddruk tijdens het eerste trimester van de zwangerschap, wordt onnodige toediening afgeraden. Labetalol mag alleen worden gebruikt in het eerste trimester van de zwangerschap wanneer de mogelijke voordelen opwegen tegen de mogelijke risico's. Labetalol wordt uitgescheiden in de moedermelk. Voorzichtigheid is geboden bij het gebruik van Labetalol tijdens het geven van borstvoeding.

Informatie in de SmPC

4.6 Vruchtbaarheid, zwangerschap en borstvoeding

Zwangerschap

Hoewel er geen teratogene effecten zijn aangetoond bij dieren, dient Labetalol alleen tijdens het eerste trimester te worden gebruikt wanneer het mogelijke

voordeel opweegt tegen de mogelijke risico's. Daar Labetalol de placenta passeert, dient echter met de mogelijke gevolgen van een α - en β -receptorblokkade in de foetus en de neonat – zoals bradycardie, hypotensie, hypothermie, ademhalingsdepressie en hypoglycaemie – rekening te worden gehouden.

Borstvoeding

Labetalol wordt in kleine hoeveelheden uitgescheiden in de moedermelk (ongeveer 0,004% van de maternale dosis). Schadelijke gevolgen voor kinderen die borstvoeding ontvangen met onbekende oorzaak (plotseling doodsyndroom, diarree, hypoglycaemie) zijn zelden gemeld. Voorzichtigheid is aan te raden wanneer Labetalol wordt toegediend bij vrouwen die borstvoeding geven.

Acetylsalicylic acid (Aspirin)

Informatie van Apotheek.nl

Belangrijk om te weten over acetylsalicylzuur als antistollingsmiddel

Acetylsalicylzuur (Aspirine) zorgt ervoor dat bloed minder makkelijk samenklontert (antistollingsmedicijn). Hierdoor heeft u minder kans op trombose.

Mag ik dit medicijn gebruiken als ik zwanger ben, wil worden of borstvoeding geef?

Dosering tot 100 mg

Overleg eerst met uw arts of u dit medicijn moet blijven gebruiken. Doseringen tot 100 mg kunt u veilig gebruiken als u zwanger bent of binnenkort wilt worden. Het wordt al jarenlang gebruikt door zwangere vrouwen zonder nadelige gevolgen voor het kind.

Doseringen hoger dan 100 mg

Gebruik dit medicijn NIET tijdens de tweede helft van de zwangerschap. Dit medicijn is dan schadelijk voor de baby. Het risico op aangeboren afwijkingen bij de

baby is verhoogd. Ook kan het problemen geven bij de bevalling. Gebruikt u dit medicijn al? Overleg dan met uw arts. Misschien kunt u overstappen op een ander medicijn. Een medicijn dat wel veilig is tijdens de zwangerschap.

Overleg met uw arts als u dit medicijn wilt gebruiken tijdens de eerste helft van de zwangerschap of als u zwanger wilt worden. Ook dan kunt u dit medicijn beter NIET gebruiken. Bij pijnklachten tijdens de zwangerschap kunt u beter paracetamol gebruiken als dit mogelijk is. Met paracetamol is meer ervaring bij gebruik tijdens de zwangerschap.

Informatie van Lareb

Bloedplaatjesremmers tijdens de zwangerschap

Overzicht

Acetylsalicylzuur of carbasalaatcalcium kan in lage doseringen tijdens de zwangerschap worden gebruikt.

De beperkte gegevens over het gebruik van dipyridamol tijdens de zwangerschap wijzen niet op nadelige effecten bij het ongeboren kind.

Over de overige middelen zijn onvoldoende gegevens bekend om een goede inschatting van de risico's te maken.

Risico indeling

Meest veilig

- acetylsalicylzuur (maximaal 80 mg per dag)
- carbasalaatcalcium (maximaal 100 mg per dag)

Risico onbekend

- abciximab
- cangrelor
- clopidogrel
- dipyridamol
- eptifibatide
- prasugrel
- ticagrelor
- tirofiban

Bij het gebruik van acetylsalicylzuur of carbasalaatcalcium als trombocytenuitstroomremmer tijdens de zwangerschap zijn geen nadelige effecten gezien bij de moeder, het ongeboren kind of de neonat. Door het gebruik van salicylaten kunnen zowel bij de moeder als bij de pasgeborene bloedingen optreden, maar dit geldt niet voor de lage doseringen. Acetylsalicylzuur en carbasalaatcalcium worden tijdens de zwangerschap profylactisch toegepast bij vrouwen met een hoog risico op pre-eclampsie of bij intra-uteriene groeivertraging. Het gaat om vrouwen die tijdens een eerdere zwangerschap pre-eclampsie ontwikkelden en vrouwen met ernstige hypertensie of een nierziekte. Ook voor de secundaire preventie van arteriële trombose worden lage doseringen acetylsalicylzuur en carbasalaatcalcium tijdens de zwangerschap toegepast.

De beschikbare gegevens over dipyridamol betreffen zowel gebruik tijdens de gehele zwangerschap, vaak in combinatie met acetylsalicylzuur, als gebruik dat in het tweede of derde trimester is gestart. Tot nu toe zijn bij de foetus of neonat geen nadelige effecten gezien. Eén case-report beschrijft maternale hematomen en een verlengde stollingstijd postpartum na gebruik van dipyridamol en een lage dosis acetylsalicylzuur. Gegevens uit meerdere onderzoeken met enkele honderden zwangerschappen laten echter geen verhoogd risico op bloedingen of andere nadelige effecten zien. Over de gevolgen van het gebruik rondom de partus is geen duidelijkheid.

Informatie in de bijsluiter

Zwangerschap en borstvoeding

Bent u zwanger, denkt u zwanger te zijn, wilt u zwanger worden of geeft u borstvoeding? Neem dan contact op met uw arts of apotheker voordat u dit geneesmiddel gebruikt.

Zwangerschap

Dit middel mag alleen op advies van uw arts gebruikt worden tijdens de zwangerschap.

Borstvoeding

Bij gebruik volgens de doseringsaanwijzingen hoeft de borstvoeding niet te worden gestopt.

Informatie in de SmPC

4.6 Vruchtbaarheid, zwangerschap en borstvoeding

Zwangerschap

Lage doseringen (tot 100 mg/dag):

Klinische studies hebben uitgewezen dat doseringen tot 100 mg/dag voor verloskundige toepassing onder specialistische controle veilig blijken.

Doseringen van 100-500 mg/dag:

Er is onvoldoende klinische ervaring betreffende het gebruik van doseringen boven 100 mg/dag tot 500 mg/dag. Daarom zijn de aanbevelingen hieronder voor doseringen van 500 mg/dag en hoger ook van toepassing voor dit doseringsbereik.

Doseringen van 500 mg/dag en hoger:

Remming van de prostaglandine synthese kan de zwangerschap en/of de embryo/foetus ontwikkeling nadelig beïnvloeden. Gegevens uit epidemiologisch onderzoek suggereren een verhoogd risico op miskraam en op cardiale malformaties en gastroschisis na gebruik van een prostaglandine syntheseremmer in het begin van de zwangerschap. Het absolute risico op cardiovasculaire malformatie werd verhoogd van minder dan 1%, tot ongeveer 1,5 %. Er wordt aangenomen dat het risico toeneemt met de dosering en de duur van de behandeling. Bij dieren resulteerde de toediening van een prostaglandine syntheseremmer in een verhoogde pre- en post-implantatie verlies en embryo/foetus letaliteit. Bovendien werden verhoogde gevallen van verscheidene malformaties, inclusief cardiovasculaire, gemeld bij dieren die een prostaglandine syntheseremmer ontvingen gedurende de periode van organogenese. Tijdens het eerste en tweede trimester van de zwangerschap, mag acetylsalicylzuur niet gegeven worden tenzij dit duidelijk noodzakelijk is. Als acetylsalicylzuur

gebruikt wordt bij een vrouw die probeert zwanger te worden, of tijdens het eerste en tweede trimester van de zwangerschap, moet de dosis zo laag mogelijk en de duur van de behandeling zo kort mogelijk gehouden worden. Tijdens het derde trimester van de zwangerschap, kunnen alle prostaglandine syntheseremmers de foetus blootstellen aan:

- cardiopulmonaire toxiciteit (met vroegtijdige sluiting van de ductus arteriosus en pulmonaire hypertensie);
- nierstoornis, wat zich kan ontwikkelen tot nierfalen met oligo-hydroamniosis;

De moeder en de pasgeborene, aan het einde van de zwangerschap, aan:

- mogelijke verlenging van de bloedingstijd, een anti-aggregatie effect dat zelfs bij zeer lage dosis kan voorkomen;
- remming van baarmoedercontracties resulterend in vertraagde of verlengde bevalling.

Als gevolg hiervan is acetylsalicylzuur in doseringen van 100 mg/dag en hoger gecontra-indiceerd tijdens het derde trimester van de zwangerschap.

Borstvoeding

Salicylaten en de metaboliëten worden afgescheiden in kleine hoeveelheden in de moedermelk. Omdat tot op heden geen schadelijke effecten op de pasgeborene zijn aangetoond na incidenteel gebruik, is het niet nodig borstvoeding te onderbreken na een eenmalig gebruik. Bij regelmatig gebruik of inname van hoge doseringen moet borstvoeding stopgezet worden.

Vruchtbaarheid

In dierstudies is gevonden dat acetylsalicylzuur een nadelige invloed kan hebben op de vrouwelijke vruchtbaarheid. Klinisch is er enige aanwijzing dat geneesmiddelen die de cyclooxygenase/prostaglandine synthese hinderen, verlaging van de vrouwelijke vruchtbaarheid kunnen veroorzaken. Dit is omkeerbaar na staken van de behandeling.

N. CONCEPTS

App screen explorations

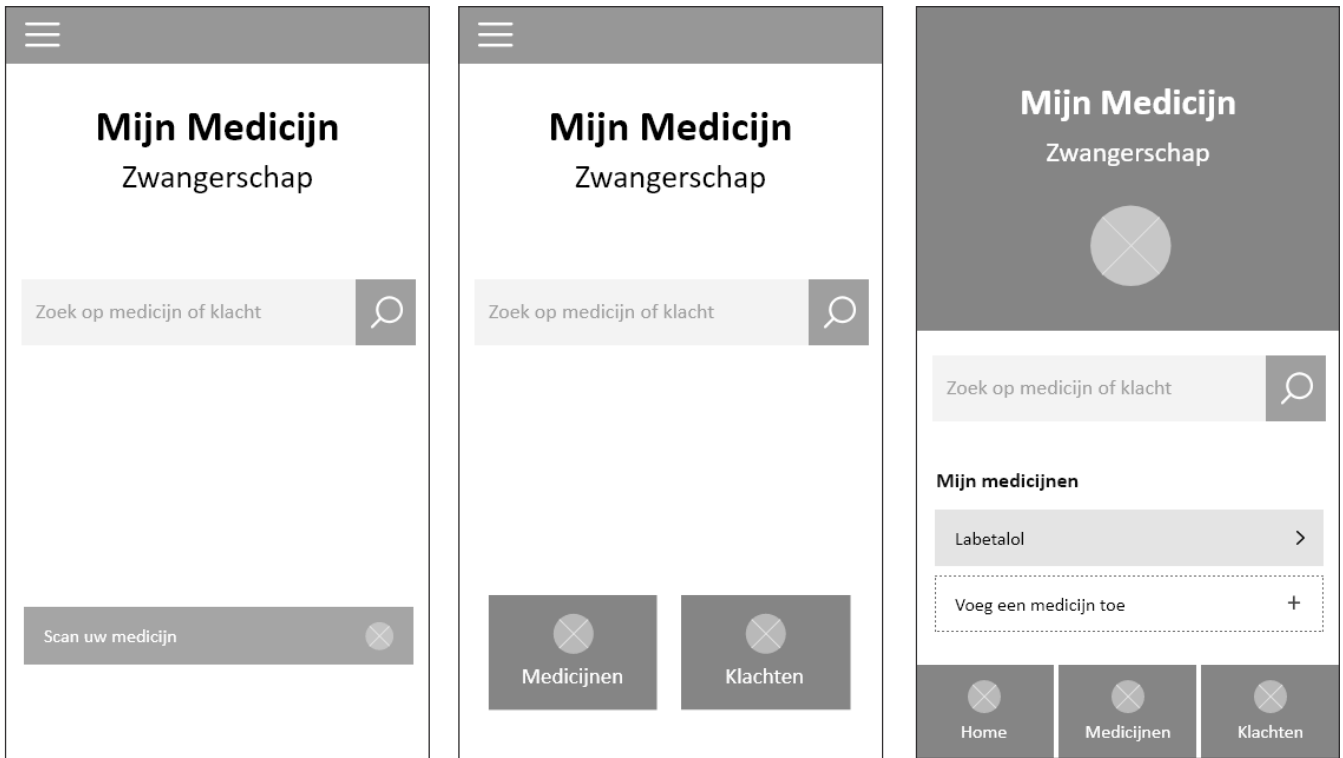


Figure A43-45. Home screen wireframes

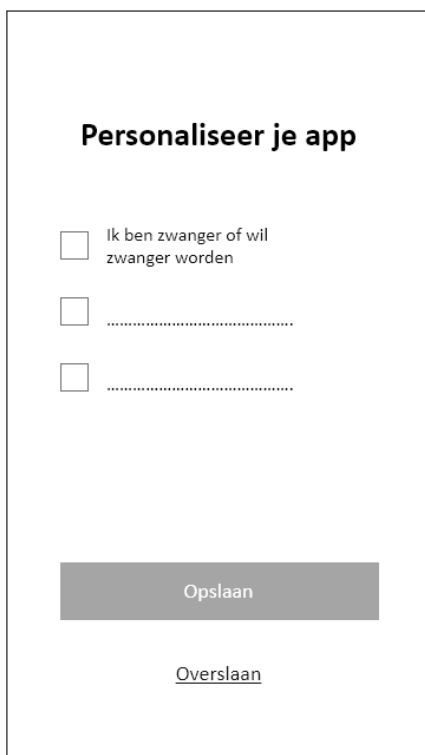


Figure A46. Personalization screen

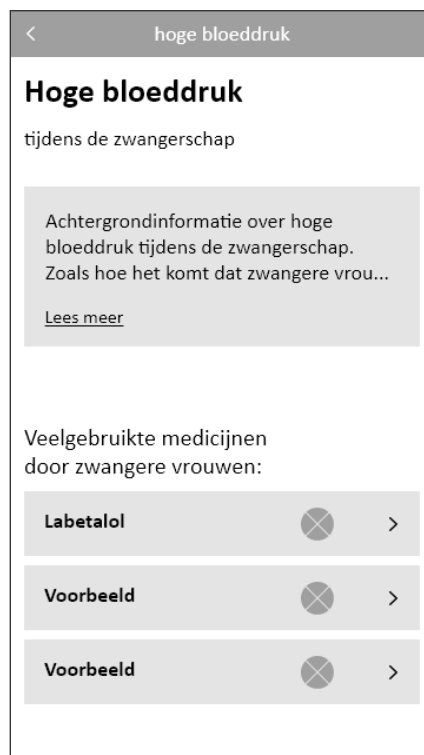


Figure A47. Complaint page wireframe

add a medicine

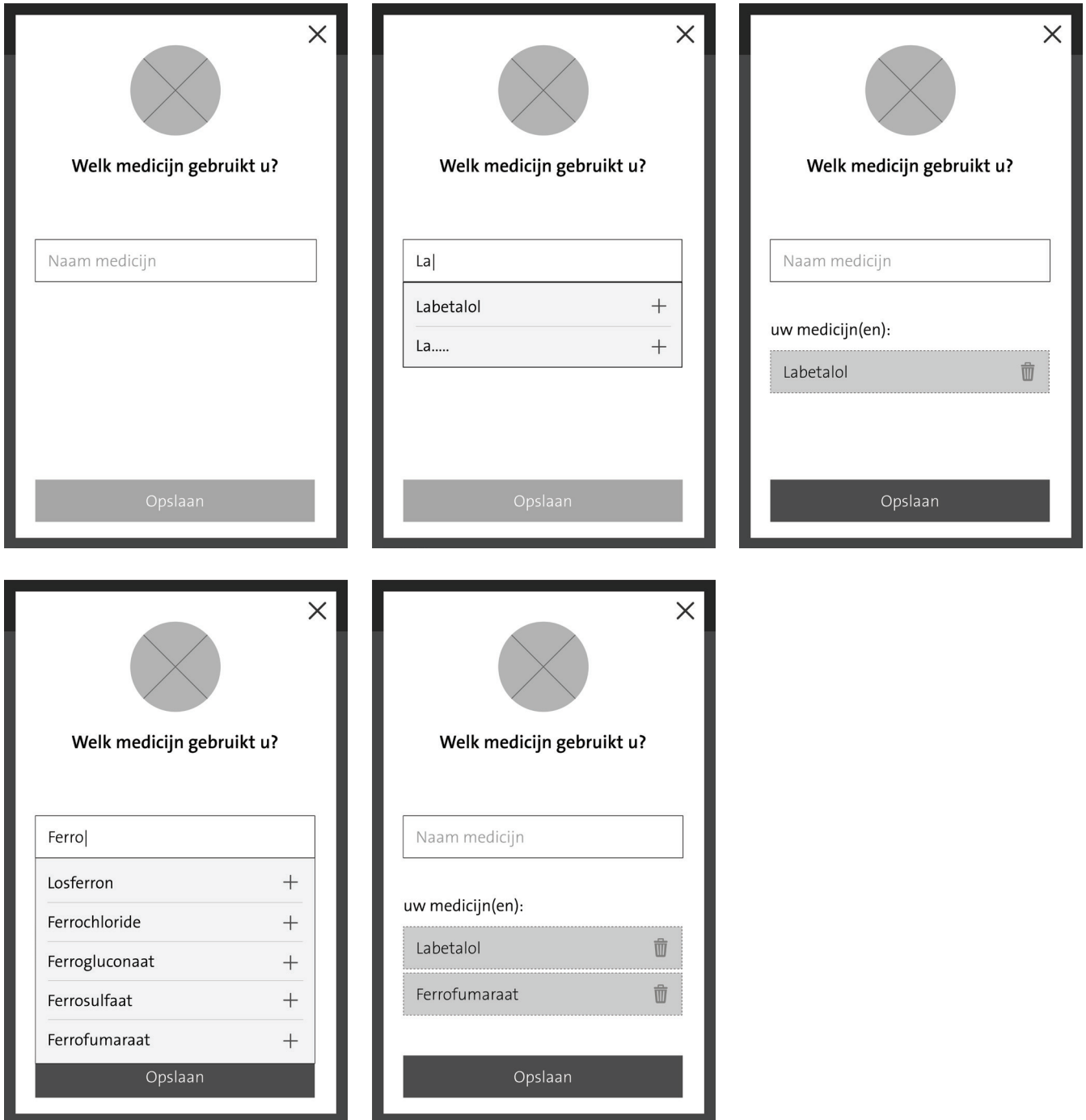


Figure A48-52. Screens for the flow adding a medicine to your personal list

Information flyer

Mijn Medicijn 

Zwangerschap

Een handige app met informatie over uw medicatie en veilig gebruik tijdens de zwangerschap

- ✓ Een overzicht van uw medicatie
- ✓ Digitale bijsluiter
- ✓ Veilige medicijnen tijdens de zwangerschap
- ✓ Advies van uw dokter
- ✓ Betrouwbare informatie

 Scan de QR code en download gratis de app.
Of download de app via de AppStore of GooglePlay.



Figure A53. First version of information flyer

SMS

Vodafone 4G 10:40 AM 82% 

< Messages VUmc Contact

Thu, Sep 19, 1:26 PM

Uw arts heeft u gisteren een nieuw medicijn voorgeschreven. Wilt u meer weten over dit medicijn? Raadpleeg dan de app 'Mijn Medicijn' voor informatie over uw medicatie en veilig gebruik tijdens de zwangerschap.

 Text Message Send

Figure A54. Proposal for SMS that VUmc could send to patients

Two versions of information on A4

Version A: Portrait, icons supporting text, doctor thumbs up

Uw medicijn **Labetalol**

Medicijn tegen te hoge bloeddruk

Vragen of zorgen? Neem contact op met uw arts.



Waarvoor gebruikt u dit medicijn?

Uw arts heeft u dit medicijn voorgeschreven omdat u een **te hoge bloeddruk** heeft en **zwanger** bent.



Labetalol behoort tot de bètablokkers. Het verlaagt uw bloeddruk. Daarbij zorgt het voor een goede doorbloeding van de placenta.

Hoge bloeddruk tijdens de zwangerschap

Een hoge bloeddruk tijdens de zwangerschap vormt een risico voor u en uw baby.

- Het zorgt voor een verminderde doorbloeding van de placenta, met als mogelijk gevolg een groeiachterstand van de baby.
- Uw nieren en lever kunnen minder goed werken, waardoor u een hogere kans heeft op pre-eclampsie (zwangerschapsvergiftiging). Het risico op pre-eclampsie is groter dan het risico van het medicijn.

Daarom is het belangrijk dat u dit medicijn gebruikt.

Veiligheid voor uw kind

- Onderzoek naar bètablokkers in de zwangerschap laten tot nu toe geen hoger risico op aangeboren afwijkingen zien.
- Bij gebruik tijdens de geboorte is er kans op bijwerkingen bij uw baby, zoals een lage bloedsuikerspiegel, lage bloeddruk, lage hartslag, suf worden en moeite met ademen. Daarom zal er extra op uw baby gelet worden. De eventuele klachten verdwijnen na een aantal uur.



U kunt dit medicijn veilig gebruiken tijdens de zwangerschap.

Ervaring met dit medicijn

Labetalol behoort tot de voorkeursmedicatie bij hoge bloeddruk tijdens de zwangerschap, omdat daar de meeste ervaring tijdens de zwangerschap mee is opgedaan. Labetalol wordt al jarenlang gebruikt als medicijn voor hoge bloeddruk bij zwangere vrouwen.

Hoe gebruikt u dit medicijn?



Neem **2** tabletten per dag, één **'s ochtends** en één **'s avonds**.

Neem de tabletten geheel in tijdens of direct na de maaltijd.

Neem de tabletten in met een vol glas water.



Scan de QR-code voor digitale informatie in de app 'Mijn Medicijn' en voor meer informatie over gebruik van dit medicijn.


C B G
M E B

COLLEGE TER
BEOORDELING VAN
GENEESMIDDELEN

Figure A55. Version A of information on A4 that could be shown during consultations

Uw medicijn Labetalol

Medicijn tegen te hoge bloeddruk



Veilig tijdens zwangerschap

Waarvoor gebruikt u dit medicijn?

Uw arts heeft u dit medicijn voorgeschreven omdat u een **te hoge bloeddruk** heeft en **zwanger** bent.

Labetalol behoort tot de bètablokkers. Het verlaagt uw bloeddruk. Daarbij zorgt het voor een goede doorbloeding van de placenta.

Hoge bloeddruk tijdens de zwangerschap

Een hoge bloeddruk tijdens de zwangerschap vormt een risico voor u en uw baby. Een hoge bloeddruk zorgt voor een verminderde doorbloeding van de placenta. Dit heeft mogelijk een groeiachterstand van de baby als gevolg. Bij een hoge bloeddruk kunnen uw nieren en lever minder goed werken. Als de nieren niet goed werken is er een hogere kans op pre-eclampsie (zwangerschapsvergiftiging).


Het risico van een hoge bloeddruk is groter dan het risico van het medicijn. Daarom is het voor de gezondheid van u en uw kind belangrijk dat u dit medicijn gebruikt.

Veiligheid voor uw kind

Onderzoek naar bètablokkers in de zwangerschap laten tot nu toe geen hoger risico op aangeboren afwijkingen zien, dus u kunt dit medicijn veilig gebruiken. Bij gebruik tijdens de geboorte is er kans op bijwerkingen bij het kind, zoals een lage bloedsuikerspiegel, lage bloeddruk, lage hartslag, suf worden en moeite met ademen. Daarom zal er extra op uw baby gelet worden. De eventuele klachten verdwijnen na een aantal uur.





Ervaring

Labetalol behoort tot de voorkeursmedicatie bij hoge bloeddruk tijdens de zwangerschap, omdat daar de meeste ervaring tijdens de zwangerschap mee is opgedaan. Labetalol wordt al jarenlang gebruikt als medicijn voor hoge bloeddruk bij zwangere vrouwen.



Heeft u nog vragen of zorgen?
Neem dan contact op met uw arts.

Hoe gebruikt u dit medicijn?







Neem **2** tabletten per dag, één 's ochtends en één 's avonds.


Neem de tabletten geheel in tijdens of direct na de maaltijd.

Neem de tabletten in met een vol glas water.

Mogelijke bijwerkingen



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GENEESMIDDELEN

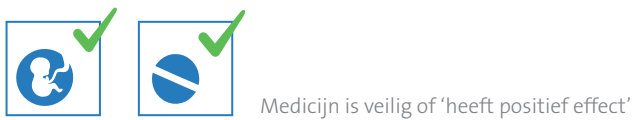
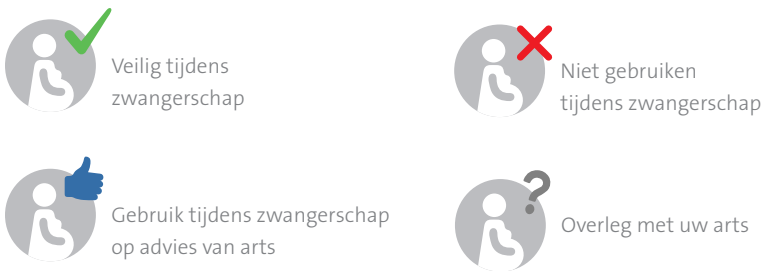


Scan de QR-code voor digitale informatie in de app 'Mijn Medicijn' en voor meer informatie over gebruik van dit medicijn.

Figure A56. Version B of information on A4 that could be shown during consultations

O. ICONS

Icons that indicate whether the medicine is safe or not



Icons that communicate risks for taking and not taking medicine



At first, the icon above was created that would explain that not taking the medicine involves risk. The second icon would then be used to explain that the medicine labetalol could have potential side effects on the child. However, in both cases it was expected that this would only scare pregnant women before they would have even read the information. Eventually it was decided to create icons for the headings rather than to explain something about risks.

Final design

Heading 'risks when not taking medicine'

Heading knowledge about risks from scientific research

Heading 'experience with the medicine'

Icons for the menu



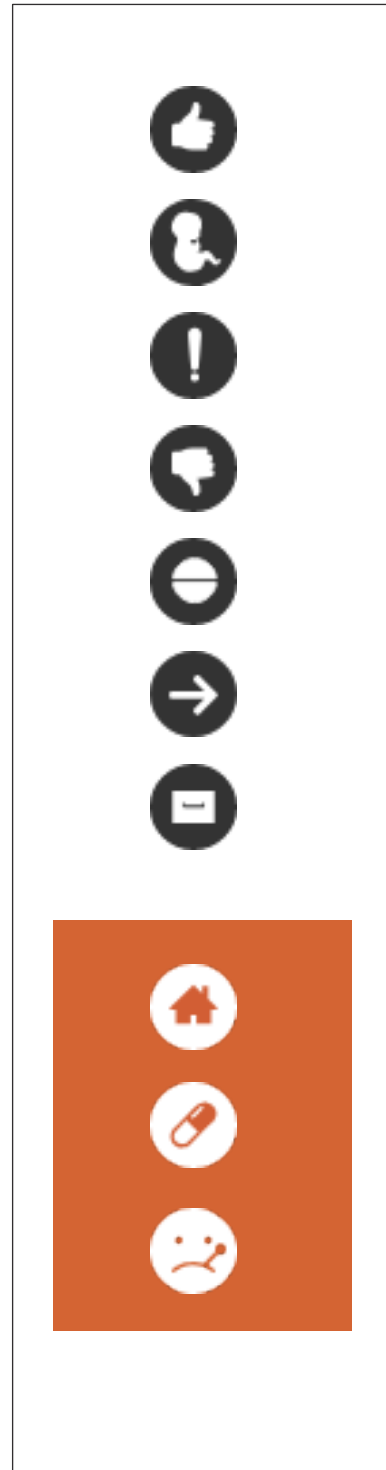
'is this medicine safe for my child?'

For the menu icons on the medicine page, it was tried to keep them as simple as possible, visualize the meaning of the menu and create a unity in visual style. The icon with the medicine for the page explaining contraindications was designed differently compared to the medicine icon on the tab 'medicines' (see below), since this one looks kind of like a stop sign which represents the meaning contraindications well (i.e. you should not take the medicine for those contraindications)

Icons for the tabs

For the tabs on the home page, icons were chosen that are recognizable for many people. Especially the first two are recognizable since they are often used in other apps/websites/media. To explain the meaning complaint/illnesses/conditions, a sad looking smiley with a thermometer was chosen since it is expected to explain the meaning the best in an understandable way.

Final design



P. INFORMATION TEMPLATE

The information for Labetalol and Aspirin was written in a similar communication style by using the same sentences where possible. A template was created with example sentences and guidelines for writing the different parts for the two pages ‘what does this medicine do for me?’ and ‘is this medicine safe for my child?’ in the app. This can be found on the right page. This template could be used when writing information for other medicines. It is likely that the information content will change once the design has been written and tested for other medicines too, the template could be updated throughout the process.

Figure A57 (right page). Information template

Template informatie voor zwangere vrouwen

Indicatie

Leg uit voor welke reden de zwangere vrouw dit medicijn gebruikt.

“Dit medicijn wordt geadviseerd wanneer je [klacht/aandoening/ziekte] hebt/bent en zwanger bent of wilt worden.”

Waarvoor gebruik ik dit medicijn?

Leg uit wat het medicijn doet en wat de voordelen daarvan zijn voor de zwangere vrouw en het kind.

“[Naam medicijn] [wat het medicijn doet (in het lichaam)] [wat is daar het voordeel van, bijv. Minder kans op...]”

Voorbeeld

“Labetalol verlaagt uw bloeddruk. Daarbij zorgt het voor een goede doorbloeding van de placenta. Hierdoor heeft u minder kans op het ontwikkelen van pre-eclampsie en een groeiachterstand van uw baby.”

Wat zijn de risico's als ik dit medicijn niet neem? [optioneel]

Leg uit wat het risico is als de zwangere vrouw het medicijn niet neemt, door uit te leggen wat het risico is van de klacht/aandoening/ziekte voor zowel moeder als kind.

Deze informatie kan worden weggelaten wanneer er niet zozeer sprake is van een risico als de zwangere vrouw het medicijn niet neemt en wanneer het nemen van het medicijn minder belangrijk is.

“Als je dit medicijn niet gebruikt, [wat is het risico van de klacht/aandoening/ziekte voor de moeder en voor het kind]”, bijv: ‘heb je meer kans op het ontwikkelen van...’]

OF

“[klacht/aandoening/ziekte] kan een risico vormen voor jou en de baby. [wat is het risico van de klacht/aandoening/ziekte voor de moeder en voor het kind]”

Voorbeeld

“Een hoge bloeddruk tijdens de zwangerschap vormt een risico voor jou en je baby. Een hoge bloeddruk kan namelijk zorgen voor een minder goede doorbloeding van de placenta. Hierdoor kan je baby een groeiachterstand krijgen. Ook kunnen andere organen, zoals je nieren en lever, minder goed werken. Hierdoor heb je een hogere kans op zwangerschapsvergiftiging.”

Is dit medicijn veilig voor mijn kind?

Wat is er bekend uit onderzoek?

Leg op een transparante en objectieve manier uit wat er bekend is over mogelijke risico's voor het ongeboren kind, hoe groot het risico is (wanneer bekend) en wanneer het risico optreedt (bijv. Welk trimester). Geef advies of het medicijn veilig gebruikt kan worden en zet altijd de risico's in perspectief met de voordelen. Wees concreet, duidelijk en vermijd woorden die onzekerheid bevatten zoals 'mogelijk', 'tot nu toe', 'soms'.

“Wetenschappelijk onderzoek laat zien dat [naam medicijn, eventueel dosering] veilig gebruikt kan worden tijdens [bepaald trimester] de zwangerschap.”

OF

“Wetenschappelijk onderzoek laat zien dat [naam medicijn, eventueel dosering] geen hoger risico geeft op aangeboren afwijkingen.”

Voorbeeld

“Labetalol behoort tot de bètablokkers. Onderzoek naar het gebruik van bètablokkers tijdens de zwangerschap laat zien dat er geen hoger risico is op aangeboren afwijkingen.”

Er is verder onderzoek nodig naar communicatie bij medicijnen die wel risico of meer onzekerheid bevatten.

Ervaring met het medicijn

Leg uit hoe gebruikelijk het gebruik van het medicijn is onder zwangere vrouwen en in hoeverre dit medicijn de voorkeur heeft voor het behandelen van die klacht/aandoening/ziekte in kwestie.

Q. FINAL DESIGN FOR THE MEDICINE ASPIRIN

Below, the design of the medicine Aspirin is shown, including the information that was specifically written for this project.

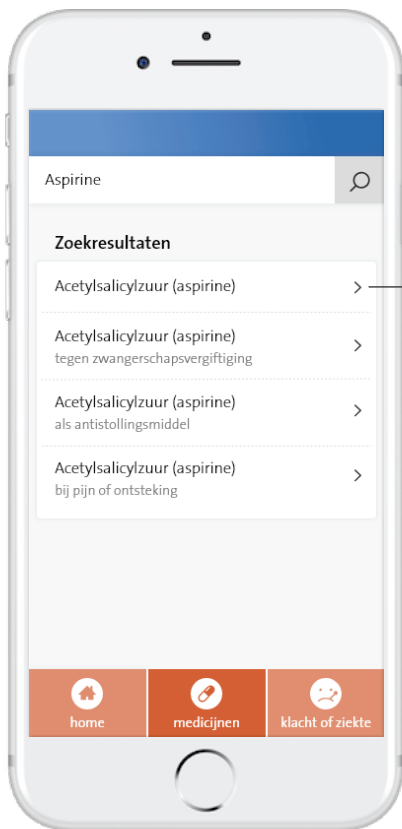


Figure A58. Search results of Aspirin

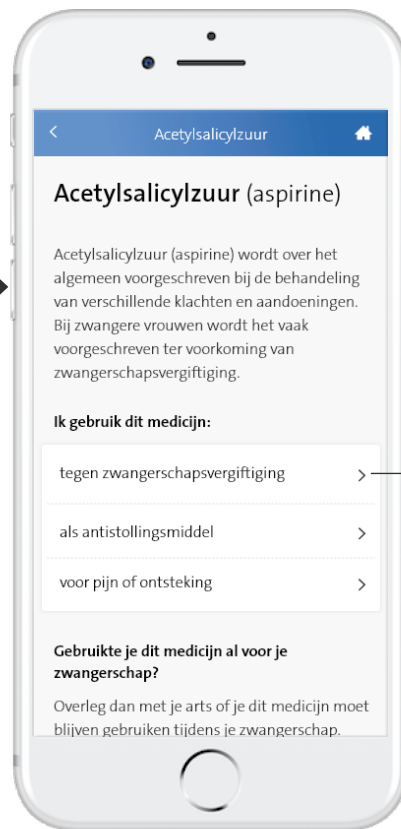


Figure A59. General page about Aspirin



Figure A60. Medicine page of Aspirin against preeclampsia



Figure A61. Benefits of Aspirin (top of the page)



Figure A62. Benefits of Aspirin (middle of the page)

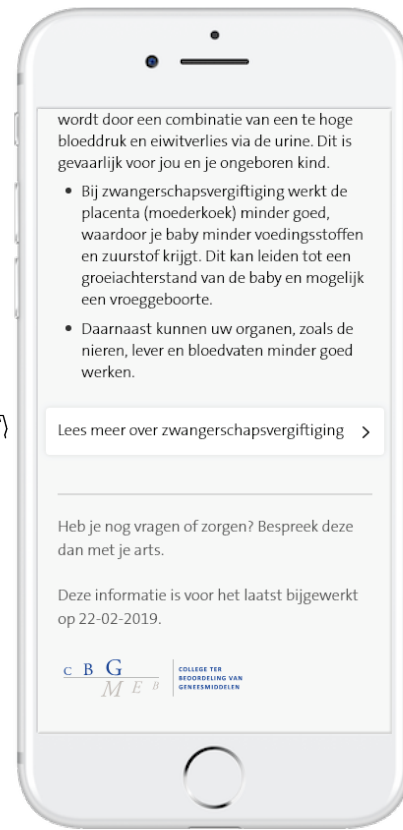


Figure A63. Benefits of Aspirin (bottom of the page)



Figure A64. Risks of Aspirin (top of the page)

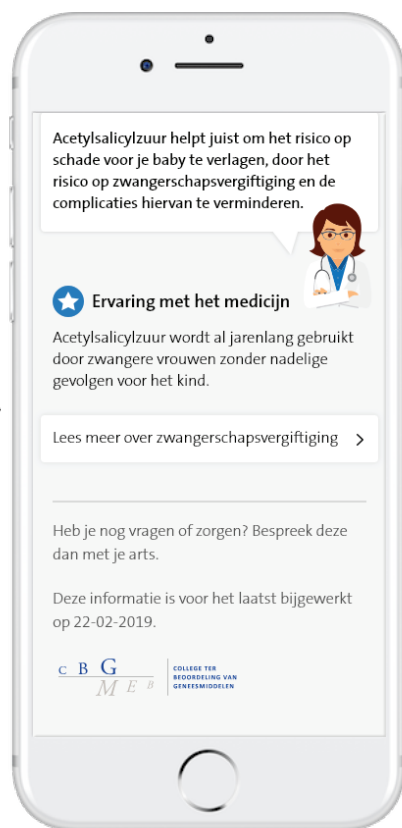


Figure A65. Risks of Aspirin (bottom of the page)

R. TWO VERSIONS OF INFORMATION

There are two slightly different 'versions' of the information of a medicine. When a medicine is added to the list, which means that the user uses the medicine, the information within the medicine page changes from a general to a more personal version. In this way, the information seems more personal and applicable for the personal situation of the user. The differences are highlighted in blue.

Labetalol (general)

Dit medicijn wordt geadviseerd wanneer je een hoge bloeddruk hebt en zwanger bent.

Waarvoor gebruik ik dit medicijn?

Labetalol verlaagt je bloeddruk. Daarbij zorgt het voor een goede doorbloeding van de placenta. Hierdoor heb je minder kans op het ontwikkelen van pre-eclampsie en een groeiachterstand van je baby.

(no further differences)

Labetalol (personal)

Je arts heeft je dit medicijn geadviseerd omdat je een hoge bloeddruk hebt en zwanger bent.

Waarvoor gebruik ik dit medicijn?

Labetalol verlaagt je bloeddruk. Daarbij zorgt het voor een goede doorbloeding van de placenta. Hierdoor heb je minder kans op het ontwikkelen van pre-eclampsie en een groeiachterstand van je baby. Daarom is het belangrijk dat je dit medicijn gebruikt.

Acetylsalicylic acid 80mg (general)

Dit medicijn wordt geadviseerd wanneer je een verhoogd risico hebt op problemen bij de ontwikkeling van de placenta (moederkoek). Hierdoor kun je pre-eclampsie (zwangerschapsvergiftiging) krijgen en/of groeit je kind minder goed.

Waarvoor gebruik ik dit medicijn?

Wat zijn de risico's als ik dit medicijn niet neem?

Als je dit medicijn niet gebruikt, heb je meer kans op het ontwikkelen van zwangerschapsvergiftiging (pre-eclampsie) en/of een groeivertraging bij je kind **wanneer** je een verhoogd risico hebt.

Wanneer heb ik een verhoogd risico?

Je hebt een verhoogd risico **wanneer** je tijdens een eerdere zwangerschap pre-eclampsie hebt ontwikkeld of een ernstig verhoogde bloeddruk hebt gehad. Het kan ook zijn dat je andere risicofactoren hebt op een van deze aandoeningen zoals suikerziekten, hoge bloeddruk, gevorderde leeftijd etc.

Acetylsalicylic acid 80mg (personal)

Je arts heeft je dit medicijn geadviseerd omdat je een verhoogd risico hebt op problemen bij de ontwikkeling van de placenta (moederkoek). Hierdoor kun je pre-eclampsie (zwangerschapsvergiftiging) krijgen en/of groeit je kind minder goed.

Waarvoor gebruik ik dit medicijn?

Wat zijn de risico's als ik dit medicijn niet neem?

Als je dit medicijn niet gebruikt, heb je meer kans op het ontwikkelen van zwangerschapsvergiftiging (pre-eclampsie) en/of een groeivertraging bij je kind **omdat** je een verhoogd risico hebt.

Waarom heb ik een verhoogd risico?

Je hebt een verhoogd risico **omdat** je tijdens een eerdere zwangerschap pre-eclampsie hebt ontwikkeld of een ernstig verhoogde bloeddruk hebt gehad. Het kan ook zijn dat je andere risicofactoren hebt op een van deze aandoeningen zoals suikerziekten, hoge bloeddruk, gevorderde leeftijd etc.

S. ENGLISH VERSIONS OF THE INFORMATION

Labetalol

This medicine is advised when you have a high blood pressure and when you are pregnant or want to become pregnant.

Read more

What does this medicine do for me?

Labetalol lowers your blood pressure. Thereby it improves the blood flow to the placenta. This means you have less chance of developing pre-eclampsia and growth retardation of your child. Therefore it is important that you use this medicine.

What are the risks when I do not take this medicine?

A high blood pressure during pregnancy forms a risk for you and your child. A high blood pressure can cause a poorer blood flow to the placenta. As a result, your child may not grow as well as it should. Other organs, such as your kidneys and liver, may also not function properly. As a consequence, you have a higher chance of developing pre-eclampsia.

Is this medicine safe for my child?

This medicine is safe for your child.

What is known from research?

Research into the use of beta-blockers during pregnancy shows that there is no higher risk of birth defects.

If you use this medicine during the last part of your pregnancy and birth, there is a risk of side effects on your child. Such as low blood sugar, low blood pressure, low heart rate, drowsiness and difficulty in breathing. However, these side effects can also be

caused by pre-eclampsia. Your doctor will therefore pay extra attention to your baby. Any symptoms disappear after a few hours.

Labetalol helps to reduce the risk of harm to your child by reducing the risk of growth retardation and pre-eclampsia. You can safely use this medication during your pregnancy.

Experience with the medicine

Labetalol is one of the preferred medications for treating high blood pressure during pregnancy, because there is a lot of experience with this medicine. Labetalol has been used for years as a medicine for high blood pressure in pregnant women.

Acetylsalicylic acid (80mg)

This medicine is advised when you have an increased risk of problems with the development of your placenta. In that case you may develop pre-eclampsia and/or your child will grow less well.

Read more

What does this medicine do for me?

Acetylsalicylic acid (Aspirin) makes your blood platelets clump less, resulting in thinner blood. This reduces the risk of developing pre-eclampsia and/or a growth retardation of the child when you have an increased risk of these conditions.

Acetylsalicylic acid only prevents pre-eclampsia and/or growth retardation. It is not used to treat these conditions when they have already occurred.

What are the risks when I do not take this medicine?

If you do not use this medicine, you are more likely to develop pre-eclampsia and/or a growth retardation in your child when you have an increased risk.

When do I have an increased risk?

You have an increased risk when you have developed pre-eclampsia during a previous pregnancy or have had a very high blood pressure. You may also have other risk factors for one of these conditions such as diabetes, high blood pressure, higher age, etc.

What is pre-eclampsia?

Pre-eclampsia is a pregnancy complication characterized by a combination of high blood pressure and protein loss through the urine. This is dangerous for you and your child.

With pre-eclampsia the placenta functions less well. As a result, your child receives less nutrients and

oxygen. This can lead to a growth retardation of your child and possibly a premature birth. In addition, your organs, such as the kidneys, liver and blood vessels, may not function well.

Read more about pre-eclampsia.

Is this medicine safe for my child?

What is known from research?

Scientific research shows that acetylsalicylic acid (in doses of maximum 100 mg per day) can be used safely during pregnancy. There is no evidence that this medication leads to birth defects in your child.

Acetylsalicylic acid actually helps to reduce possible harm to your baby by reducing the risk of pre-eclampsia and its complications.

Experience with the medicine

Acetylsalicylic acid has been used for years by pregnant women without harming the child.

T. SCRIPTS EVALUATION TEST

Dutch

Script (20-30 minuten)

Introductie (3 min.)

- Fijn dat u feedback wilt geven
- Voordat we beginnen, even het consent formulier tekenen. Daarmee geeft u net als vorige keer toestemming dat ik de audio data mag gebruiken voor mijn onderzoek.
- Op basis van de resultaten van de interviews heb ik een app ontworpen met informatie over medicijnen voor zwangere vrouwen
- Het doel is nu dat we gaan kijken of deze app past bij waar je als zwangere vrouw behoefte aan hebt wat betreft informatie over medicijnen, wat er goed aan is en wat nog verbeterd zou kunnen worden
- Ik heb een prototype gemaakt van de app. Het ziet er allemaal echt uit, maar niet alles werkt perfect. Je kunt door de schermen heen klikken zoals je normaal zou doen maar niet alle knoppen zijn actief
- Dus wat we gaan doen is ik leg een aantal situaties of scenario's uit waarbij ik u wil vragen om u in te leven in die scenario's en vervolgens vraag ik u om een aantal 'taken' uit te voeren met het prototype
- Probeer hardop na te denken en geef vooral uw mening, ik ben zowel geïnteresseerd in wat er goed is als waar er verbeteringen liggen
- Heeft u nog vragen?

Deel 1. Flyer (3 min.)

[Evaluate how women would react on receiving the information flyer and whether they would use the app or not based on information from their doctor and the flyer]

Stel, u bent zwanger en komt bij de arts in het ziekenhuis voor een consult. Daar wordt uw bloeddruk gemeten en die blijkt te hoog te zijn. Uw arts adviseert u daarom om het medicijn 'labetalol' te gebruiken. Aan het eind van het consult krijgt u deze flyer mee over een app met medicijninformatie. Hierbij vertelt uw arts u dat u deze app kunt raadplegen wanneer u vragen of zorgen heeft over het medicijn. Je kunt nu de flyer even bekijken. [Laat participant flyer doorlezen]

- Wat denkt u na het zien/lezen van deze flyer?
- Zou u de app downloaden/raadplegen? Waarom wel/niet? (wanneer? In welke gevallen?)
 - Denkt u dat u de app het eerst zou raadplegen (vóór bellen, of bijv. Googlen?)
Waarom?
- Wat vindt u van de rol van de arts hierin, dat hij of zij je informeert over de app en je deze flyer geeft? Waarom?
- Stel dat u een email of SMS zou ontvangen van het VUmc over de app, wat zou je daarvan vinden? Waarom?

Deel 2. Voordeel-risico informatie (7 min.)

[Evaluate women's perception of the benefits and risks after reading the information in the app, and check whether it would make them feel confident/have trust in using the medicine]

Stel, uw arts heeft u dus het medicijn 'labetalol' voorgeschreven. Wanneer u thuis bent weet u niet meer precies waarom de arts u het medicijn heeft voorgeschreven en u maakt zich zorgen of het medicijn wel veilig is voor uw kind. Op advies van de arts besluit u de app 'Mijn Medicijn' te downloaden en deze informatie op te zoeken. Zou u kunnen voordoen hoe u dat zou doen?

[Voor nu is de app al gedownload]

- Hoe ging dat? Waarom?
- Wat denkt u na het lezen van deze informatie [over voordelen]? Waarom?
[Check of ze de relevantie snappen en of de informatie duidelijk en compleet is]
- Wat denkt u na het lezen van deze informatie [over risico's kind]? Waarom?
[Check wat hun perceptie van de risico's zijn en of de informatie duidelijk en compleet is]
- Als u dit leest, roept het dan nog andere vragen op? Waarom?
[Check wat er eventueel nog mist of wat anders moet qua informatie]
- Zou u op basis van deze informatie het medicijn slikken?
- In hoeverre zou u deze informatie vertrouwen? Wat maakt dat u de informatie vertrouwt?
 - Stel, u hoort van iemand uit uw omgeving dat het medicijn toch niet veilig is, hoe zou u dan reageren?

Deel 3. Usability (5 min.)

[Evaluate whether users understand how to search information about a medicine in the app and whether they can easily (intuitively) navigate through the app. Evaluate overall experience and how women value the app. Additionally, when there is time left, evaluate the information about aspirin]

Stel, uw arts heeft u vóór uw zwangerschap verteld dat u bij een nieuwe zwangerschap een verhoogd risico heeft op het krijgen van een vroeggeboorte. Daarom heeft de arts u geadviseerd om acetylsalicylzuur (aspirine) te gebruiken wanneer u zwanger bent, om de kans op een vroeggeboorte te verkleinen. Thuis besluit u dat u nog eens informatie over dit medicijn wilt opzoeken. Hoe zou u dat doen?

[Start op home screen]

- Hoe vindt u dat gaan? Waarom?
- Hoe vindt u het gebruik van de app gaan?
 - Wat vindt u moeilijk/makkelijk en waarom?
- Wat vindt u van de mogelijkheden van de app?
- Wat vindt u van de app in het algemeen? Waarom?
 - Wat zijn positieve aspecten?
 - Wat kan er nog verbeterd worden?
- Zou u de app gebruiken als de arts dit u heeft geadviseerd, in plaats van andere informatiebronnen?
- Wat vindt u ervan dat u met u wordt aangesproken? Liever jij?

Deel 4. Evaluatieformulier (3 min.)

[Evaluate desired interaction qualities]

Op basis van wat u heeft gezien van de app en heeft gelezen in de app, zou u vijf woorden kunnen aankruisen op deze lijst die u het meest associeert met deze app.

- Waarom heeft u deze woorden gekozen?

Afsluiting

- Bedankt voor uw deelname
- Uw input is heel waardevol

- Persoonlijk
- Betrouwbaar
- Geruststellend
- Compleet
- Moeilijk
- Informatief
- Transparant
- Verontrustend
- Intuitief
- Overtuigend
- Gebruiksvriendelijk
- Omslachtig
- Gemakkelijk
- Betrokken
- Eerlijk
- Vriendelijk
- Onduidelijk
- Objectief
- Anders,

English

Script (20-30 minuten)

Introduction (3 min.)

- First of all, thank you for participating again
- Before starting, let's first sign the form. Like last time, hereby you give permission that I can use your input for this project
- Based on all the information I have received from the interviews last time, I designed an app that includes information about medicines specifically for pregnant women
- The goal of this research is to evaluate whether this app fits with your information needs as a pregnant woman, what are good things about the design and what things could be improved
- I have made a prototype of the app which I will show you. It looks real but not everything works perfectly, but you can click through the screens like you would normally do in an app
- So what we will do is I will explain some hypothetical situations or scenarios and then I will ask you to perform some 'tasks' in the prototype
- Try to think out loud and give your opinion about the design, I'm interested in both the positive things and how I can further improve it

Part 1. Flyer (3 min.)

[Evaluate how women would react on receiving the information flyer and whether they would use the app or not based on information from their doctor and the flyer]

Before going into the app, imagine that you are pregnant and you come here to the hospital for a consultation. The doctor measures your blood pressure, which turns out to be too high. Therefore, the doctor advises you to use the medicine 'labetalol' and makes a prescription. At the end of the consultation the doctor gives you this flyer about an app. The doctor tells you that you should consult this app when you have any questions or concerns about your medication at home. You can now look at the information flyer.

[Let participant read flyer].

- What do you think after seeing/reading this flyer?
- Would you download and consult the app? Why yes/no? When would you do that?
 - Do you think you would first consult the app before for example calling the doctor or search on Google?
- What do you think about the role of the doctor in this, that he or she notifies you about the app with a flyer during consultations? How would you feel about that?
- Suppose you would receive an email or a text message on your phone from the hospital about the app, what would you think about that?

Part 2. Benefit-risk information (7 min.)

[Evaluate women's perception of the benefits and risks after reading the information in the app, and check whether it would make them feel confident/have trust in using the medicine]

Let's go to the next part. So continuing on the previous scenario, imagine your doctor has prescribed you this medicine 'labetalol'. When you are at home you do not know exactly anymore what the medicine is for and you are concerned about whether it is really safe for your child. On the advice from the doctor you decide to download this app and search this information. Could you show me how you would do that?

[For now the app is already downloaded]

- How did that go?
- What do you think after reading this information [about benefits]? Why?
[Check of ze de relevantie snappen en of de informatie duidelijk en compleet is]
- What do you think after reading this information [about risks for your child]? Why?
[Check wat hun perceptie van de risico's zijn en of de informatie duidelijk en compleet is]
- When you read this, would this raise any further questions? What and why?
[Check wat er eventueel nog mist of wat anders moet qua informatie]
- To what extent would you trust this information? What makes you trust or not it and why?
- How would you feel about taking the medicine after reading this information?

Part 3. Usability (5 min.)

[Evaluate whether users understand how to search information about a medicine in the app and whether they can easily (intuitively) navigate through the app. Evaluate overall experience and how women value the app. Additionally, when there is time left, evaluate the information about aspirin]

Now we have a new scenario.

Imagine, your doctor told you before your pregnancy that you have a high risk of developing pre-eclampsia in a new pregnancy. Therefore, the doctor advises you to use the medicine 'aspirin' once you get pregnant, to decrease the risk of developing pre-eclampsia. So at one point you decide to search information about this medicine in the app. Could you show me how you would do that?

[Start on home screen]

- How did that go?
- How do you experience using the app?
 - Did you experience any issues?
- What do you think about the possibilities the app offers?
- What do you think about the app in general?
 - What are positive aspects?
 - What could be improved?
- What do you think about the writing style?
- Would you use the app when the doctor advised you to, instead of other sources?

Part 4. Evaluatieformulier (3 min.)

[Evaluate desired interaction qualities]

Based on what you have seen from the app and the flyer, I would like you to choose five words on this list that you associate most with this whole design, so the app, the information in it, the flyer etc., so the words that fit best with it (see next page). Take your time.

- What words did you choose?
- Why did you choose those words / Why did you choose [word]?

(cumbersome = inefficient in use, badly organized)

End

- Thank you very much for participating
- This is very valuable for me!

- Personal
- Trustworthy
- Complete
- Difficult
- Informative
- Transparent
- Worrying
- Reassuring
- Intuitive
- Convincing
- Friendly
- Cumbersome
- Convenient
- Involved
- Honest
- Unclear
- Objective
- Other,

U. FURTHER INSIGHTS EVALUATION STUDY

Other menu pages

One patient mentioned that on top of the medicine page, she would like to see how many medicines she may use per day, e.g. with paracetamol. For her it was not completely clear that she would be able to find that on the page “How do I use this medicine?”

In the menu “What side effects may I experience?”, one participant expected to read about side effects for her child there as well, not only for herself. This would mean the information would overlap with the information on the page “Is this medicine safe for my child?”. This could be something to discover later.

Additions

One participant mentioned that an addition to the app could be the option to ask for a refill of her medicine and the possibility of taking notes (e.g. questions the patient may want to ask her doctor during a next consultation).

Another participant said that she very much would like to get information about supplements as well in addition to medicines, since she feels uncertain about whether she is taking every vitamin she should.

P8: “Would you not do this for supplements too? I miss this very much.. Now during pregnancy yo have to.. Well everyone takes this mama vitamins you know. And coincidentally I know due to my condition that I cannot take vitamin A and E so I don’t take that. But I’m a vegan and I got calcium now but I had to ask for that myself, search that myself. But then I often thin do I still miss anything? Do I miss vitamin B or uhh? I don’t know, am I doing it right?”

One participant and her partner were so enthusiastic about the app that they suggested to make a similar app voor child vaccination as well, since that is also a difficult and touchy subject.

P1: “You should do this for vaccines. Because that’s a touchy subject. We are discussing it almost every day, what do we do, what are the side effects, why are people so afraid of it. Because you hear stuff from France, from people, from the Internet, whatever, especially now. This is one of those things that is so polarized. You are either in favour, or you are against. There is no gray area. So if you could have a tool like this that is backed by a professional organization, it would put many people at ease. Especially for pregnancy.”

Another participant proposed to add an explanation about the fact that medicines cannot be tested with pregnant women, which is a reason why there is little knowledge about the safety during pregnancy. This may help pregnant women to understand it better and maybe feel more reassured. She would add this on the Home page, in a menu ‘General information about medicine usage during pregnancy’, in addition to an explanation about what the app does and who made it. This would be a good addition anyway.

One participant explained that she would like to be able to make something like a ‘pregnancy passport’ in the app, an overview of what medicine she has used during each of her pregnancies and how often she has used it. This could be visualized on a timeline. She mentioned that this would be useful since you often forget what medicines you have taken and how often, mostly with medicines that are not used on a daily basis (for instance paracetamol for a headache). Being able to read back what medicines she used during a prior pregnancy could give a feeling of reassurance when using it did not lead to any problems with her child. This would give her

more confidence to use the medicine again. Such an overview could also be shared with the doctor, who could then give further advice about her medication use.

Interviewer: "Why do you think having such a list is valuable?"

P2: "Because you become a little paranoia when you are pregnant, you want to control/confirm everything, and then you want to see what you have actually done [medicines you have taken]."

P2: "I would find it nice if I had recorded that during my first pregnancy, that I could look back how often I actually used Sumatriptan during my first pregnancy, because I had many doubts about that the second pregnancy. So then I could go back in my prior pregnancies and then it would really reassure me like oh yeah then I also used Emesafene and then it was fine you know."

V. FURTHER RECOMMENDATIONS

Put less focus on risks when not taking medicine

Although including the risks when not taking a medicine in the information is good, it would be better to put less visual focus on this information compared to the benefits on top of the page ‘what does this medicine do for me?’, since the current design sometimes has a frightening effect rather than that it contributes to feeling more confident. For instance by removing the icon with an exclamation mark. The information itself should not make it sound as if not taking a medicine will always have bad consequences (e.g. high blood pressure resulting in pre-eclampsia), because that is not true.

Make the difference in safety per dose clear

For some medicines a low dose is safe, whereas a higher dose may involve risks for the unborn child, which is the case for Aspirin. This should be made clear in the information, especially when the information for different doses are divided on separate pages. Currently this was lacking in the design of Aspirin.

Guide users to the desired information

On the medicine page, it is advised to either remove the ‘read more’ link or make it an anchor link that scrolls down to the menu when clicking it, instead of opening the benefit page. In this way users will not overlook the menu and get lost.

Take another look at all icons

There is room for improvement in creating more unity between the logo and icons in the app (i.e. icons on the home page buttons and menu icons). When developing the app this should be explored.

Explore the option to personalize the app

Whether a medicine involves risks often depends on the trimester in which it is used. Therefore it could be beneficial if pregnant women could personalize the app by adding their due date, so the app knows what trimester they are in and could adjust the information accordingly.

Explore additional features

Some participants gave suggestions for additional features that could be added in the design, for instance the option to save how many medicines you have used throughout your pregnancy, which could be shown on a timeline as discussed in appendix U on p.216. It should be explored whether more pregnant women would value such an option.

Some people may prefer to have a printed version of the information. Therefore it could be explored to include the option to print the information. This may especially be a valuable option for a similar app for other patient groups that include elderly.

Other design elements

On the medicine page, it would be good to make a distinction between an OTC drug and prescription drug, so the user knows whether she can buy a certain medicine ‘over the counter’ or whether she needs a doctor’s prescription.

Furthermore, on the medicine page it should be visible when a certain medicine is added to your personal list.

Additionally, it should also be communicated when the patient could notice any effect of the medicine, which makes sense to include on the page ‘what does this medicine do for me?’