# Face and content validity of a patient questionnaire on self-reported symptoms and practical problems related to medication

A master thesis referred to the faculty of Science of the University of Utrecht in partial fulfilment of the requirements for the degree of Master of Science.

02-11-2021

By Besme Al Gareb, 4256573

Performed at Amsterdam University Medical Centers – location VUmc, Amsterdam, the Netherlands, Department of Clinical Pharmacology and Pharmacy.

Referee: Dr. Jacqueline Hugtenburg
Daily supervisor: Drs. Selma En-nasery – de Heer

Examiner: Prof. Dr. Marcel Bouvy

Utrecht University

Amsterdam UMC
Universitair Medische Centra

Thesis Utrecht University

This thesis was performed at the Department of the Amsterdam University Medical Centers, location VU mc, Amsterdam, the Netherlands.

# Abstract - English

**Background:** ADEs are common after hospital discharge in patients with polypharmacy and currently systematic and feasible approaches to identify are lacking. At present these ADEs can mainly be captured through intensive monitoring after hospital discharge, eg. through a medication review. Performing a medication review is not always feasible in practice due to time constraints. A recently developed digital questionnaire to identify patient-reported ADEs (pADEs) may be a useful tool to identify potential ADEs in polypharmacy patients after hospital discharge. However, the validity of this instrument has not been tested yet.

**Objective:** The objective of the present study was to evaluate the face and content validity of the questionnaire.

**Methods:** The face and content validity of the pADE-questionnaire was assessed using qualitative methods. To investigate the face validity participants were asked to fill out a questionnaire digitally after completing the pADE questionnaire on paper. After 3 to 7 days semi-structured (video-)calls have been performed to obtain their views on the content validity of each item based on the COMSIN methodology. The agreement in answers derived from the questionnaire and interview was used to evaluate the reproducibility.

**Results:** Patients agreed that the questions about the presence of the different medical symptoms were comprehensive, comprehensible, and relevant. Thematic content analysis showed that the pADE-questionnaire lacks background information on hospitalization, and patients find it difficult to indicate whether a symptom is associated with the use of their medication.

**Conclusion:** For patients, the pADE-questionnaire gave a good indication of medical symptoms and practical problems related to medication but is not a good estimate of medication related problems.



**Key words:** Adverse drug event, Hospital discharge, questionnaire, content validity, qualitative study

# Abstract - Dutch

**Achtergrond:** ADEs komen veel voor na ontslag uit het ziekenhuis bij polyfarmaciepatiënten en momenteel ontbreken er systematische en haalbare benaderingen om dit te identificeren. Op dit moment kunnen deze ADEs voornamelijk worden vastgelegd door intensieve monitoring na ontslag uit het ziekenhuis, bijvoorbeeld door middel van een medicatiebeoordeling. Het uitvoeren van een medicatiereview is in de praktijk niet altijd haalbaar vanwege tijdsgebrek. Een recent ontwikkelde digitale vragenlijst om patiënt-gerapporteerde ADEs (pADEs) te identificeren, kan een nuttig hulpmiddel zijn om potentiele ADEs te identificeren bij polyfarmacie patiënten na ziekenhuisontslag. De validiteit van dit instrument is echter nog niet getest.

**Doelstelling:** Het doel van dit onderzoek is om de indruk- en inhoudsvaliditeit van de vragenlijst te evalueren.

**Methode:** De indruk- en inhoudsvaliditeit van de pADE-vragenlijst werd geëvalueerd met behulp van kwalitatieve methoden. Om de indrukvaliditeit te onderzoeken werden de deelnemers gevraagd om een vragenlijst digitaal in te vullen na het afmaken van de pADE-vragenlijst. Na 3 tot 7 dagen zijn semigestructureerd (video-)gesprekken uitgevoerd om de mening van de inhoudsvaliditeit van elke item te achterhalen op basis van de COSMIN-methodologie. De overeenstemming in antwoorden uit de vragenlijst en het interview werden gebruikt om de reproduceerbaarheid te evalueren.

**Resultaten:** Patiënten waren het erover eens dat de vragen over de aanwezigheid van de verschillende lichamelijke klachten duidelijk, begrijpelijk en relevant waren. Thematische inhoudsanalyse liet zien dat de pADE-vragenlijst een gebrek heeft aan de achtergrondinformatie van de ziekenhuisopname en het lastig was voor patiënten om te duiden of een bestaande lichamelijke klacht samenhangt met het gebruik van hun medicatie.

**Conclusie:** Voor patiënten gaf de pADE-vragenlijst een goede indicatie van lichamelijke klachten en praktische problemen, maar geen goede inschatting van medicatie gerelateerde problemen.

**Trefwoorden:** Adverse drug event, Ziekenhuisontslag, vragenlijst, inhoudsvaliditeit, kwalitatieve studie

# List of abbreviations:

ADE - Adverse drug event

pADE – patient reported adverse drug event

MARCH - **M**edications **A**ctions to **R**educe hospital admissions through a collaboration of **C**ommunity and **H**ospital Pharmacists

METC - Medical ethics committee

COSMIN - **CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments

GP – General practitioner

# Table of contents

# 1. Introduction

Adverse drug events (ADEs) commonly occur following hospital discharge.[1] ADEs are injuries caused by drug use due to side effects or medication errors.[2] Medication errors are defined as an error in the process of prescribing, dispensing, or administering the medication. ADEs commonly occur in older people because of their increased prevalence of chronic diseases and drug use.[3] It has been estimated that 11-37% of adults and elderly patients experience ADEs after hospital discharge, of which a large percentage is preventable.[4]

These ADEs may result in hospital re-admissions which is a burden for patients and healthcare providers. The first few weeks following hospital discharge may be a high risk which can be manifested, due to newly prescribed medication errors, dose changes or discontinuities of chronic treatment taken before hospital admission.[1] Once at home, adherence problems may occur due to inadequate communication reflecting changes in the treatment, lack of understanding of their treatment or excessive complexity.[4-6]

Over the years, multiple preventive measures have been developed and implemented such as medication reconciliations and medication reviews.[7] Medication reconciliation is a process of identifying a complete and accurate list of the actual medication use of a patient.[8] A medication review aims to manage the risk of drug related problems and optimize the outcome of medicine therapy.[9,10] These measures aim to reduce the number of ADEs after hospital discharge and could possibly prevent hospital readmission. Despite these strategies ADEs still frequently occur on transition from one health care setting to another.[10-12]

It is difficult to trace ADEs after hospital discharge. At the moment, they can mainly be captured through intensive supervision after hospital discharge or follow-up. This could be done through medication reviews.[10-13] Conducting a medication review is preferred, but is not always feasible in practice due to time restraints.[11]

Recently a self-composed digital questionnaire has been developed to identify patient reported ADEs (pADEs) in polypharmacy patients with at least one change in the chronic medication post-hospital discharge.[14] It is important to know whether this questionnaire is a good instrument for detecting ADEs. Hence, it seems logical and proactive in validating the pADE questionnaire designed to screen for medical symptoms and practical problems.[14] This research therefore focuses on validating a recently developed patient-reported ADE questionnaire using qualitative approaches**.**

# 2. Objectives and research questions

## 2.1 Objective

This research aims to assess the face validity and content validity of a recently developed pADE-questionnaire. The secondary aim of the study is to explore the agreement in information derived from a questionnaire and a personal interview.

## 2.2 Research question

What is the degree of validity of the recently developed pADE-questionnaire?

## 2.3 Overall aim of the questionnaire

To evaluate if this questionnaire correctly detects pADEs.

# Method

Within the present study the face and content validity of the previous developed pADE-questionnaire was evaluated using qualitative approaches. To evaluate the self-reported ADEs (construct of interest) we measured both face and content validity based on the COSMIN methodology.

## 3.1 Study design and recruitment

The present study was a qualitative study conducted from February 2021 to May 2021. Polypharmacy patients aged 18 years or older, discharged from the department cardiology or internal medicine, with at least one change in the chronic medication after hospital discharge were included in this study. Polypharmacy is defined as the use of 5 or more medicines for at least 6 months. Patients were excluded if they were discharged to another residence than their own home, had insufficient knowledge of the Dutch language, had a life expectancy less than 6 months or didn't give the informed consent. Patients were recruited from the Amsterdam UMC, location VU medical center (VUmc) and the Flevoziekenhuis hospital.

At the VUmc patient recruitment was performed by pharmacy technicians from the hospital pharmacy. Pharmacy technicians were informed about the study and received an inclusion protocol. (Appendix A) The inclusion protocol described the patient selection according to eligibility for inclusion with predefined in- and exclusion criteria. Recruitment of patients took place right after the dispensing of medication was done. Patients were asked to fill in an informed consent to be approached for a research study and received a patient information letter. Invitation for participation took place after one day through a phone call by a researcher (BA).

At the Flevoziekenhuis hospital recruitment was performed by a general support staff member. Selection was made through the pharmacy information system based on patients who were discharged from the department internal medicine and cardiology. Eligible patients were approached for participation in the study through a phone call. Patients were included if they are entirely voluntary agreed with participation in the study statement and acknowledged to be clearly informed about the type, method and aim of the study.

All the recruited patients were asked to give a consent statement before the start of the data collection. Due to COVID-19 this consent statement was sent digitally with Castor as opposed to a signed informed consent.

## 3.2 The pADE-questionnaire

The pADE-questionnaire was previously developed with health care professionals, patients, and researchers to obtain information on ADEs one month after hospital discharge. It was developed by two researchers based on existing questionnaires of previous studies.[15-21] It is mainly based on the questionnaire of Sara Daliri *et al.* and Willeboordse *et al.* which also aimed to obtain information on drug related problems.[15,20] Herewith some adjustments were made, such as open ended questions on complaints were altered to answers on a 5-point-likert-scale, questions on actual medication use or what is done about the complaints were removed, because the main focus is to trace drug related problems. Some elements such as questioning using a scale are inspired by other questionnaires about complaints.[17-19, 15] The pADE-questionnaire consisted of two parts. Part A consisted of medication symptoms and part B practical problems of medication use. The questionnaire is presented in Appendix B.

## 3.3 Face validity

The developed questionnaire was subjected to face validity. Face validity is the extent to which your instrument appears to measure what you intend to measure. Only an opinion could be given about whether the instrument looks as though it can measure the construct of interest. To assess the face validity all 15 participants filled in a questionnaire about their opinion on the instructions, comprehensibility, comprehensiveness, clarity, response options and the moment they received the questionnaire. The questions were presented on a 5-point Likert scale ('strongly disagree' to 'strongly agree'). In this way we could determine the extent of face validity. These questions are presented in Appendix E.

## 3.4 Content validity

To evaluate the self-reported ADEs (construct of interest) we measured both face and content validity using qualitative approaches. The face validity is a component of the content validity and is not considered an active measure of validity. The content validation study was performed following the quality criteria for assessing the content validity of patient reported outcomes (PROMs) formulated by the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) methodology.[22] The COSMIN taxonomy defines content validity of measurement instruments as the degree to which the instrument's content adequately reflects the construct to be measured.[22]

To study the content validity in depth, semi-structure (video-)calls were conducted with 15 patients 3 to 7 days after the pADE-questionnaire was filled in. To conduct the personal interviews a topic list was prepared in advance and tested with 3 eligible patients. Through an iterative process adjustments were made in the topic list. The final topic list consisted of: a general impression of the questionnaire, pADE-questionnaire, Set of brief Screening Questions (SBSQ-D) and questions about general participant characteristics. The developed topic list is presented in Appendix C.

In addition, one independent professional (pharmacist) is also interviewed on the same aspects to assess the content validity.

To evaluate the content validity we used the the COnsensus-based Standards for the selection of health Measusrement INstruments (COSMIN) the COSMIN-checklist presented in appendix F.[22] This checklists evaluates the content validity against the 10 criteria for good content validity. It consists of three important aspects: five criteria for the relevance rating, one criterion for the comprehensiveness rating and four criteria for the comprehensibility.

## 3.5 Additive measures

The education level, living situation, native country of the participant and his parents, hospitalization in the past 6 months or medication review in the past 12 were asked of every participant afterwards during the interview. The highest completed education in the Netherlands was divided in three groups: low (no, primary school, or vocational training), middle (secondary or vocational education) or high (professional higher education or university).

The SBSQ- D is used to test the level of Health Literacy. We presented the questions on the PowerPoint to the patients and followed the scoring instructions. This is a self-report instrument used in a clinical practice which measures perceived difficulties with health information. It is based on three 5-point Likert scale statements ranging from 0- 4. An average score of ≤ 2 indicates inadequate health literacy, and a score of>2 adequate health literacy.[23,24]

To assesses the comorbidity level of the participants the CCI is used. It is a measure which takes 19 pre-defined comorbid conditions into account. It provides a weighted score from one to six, with a

weight of six representing the most severe morbidity. To collect the data for the CCI we accessed the medical records on EPIC for each patient.[25] (Appendix D)

## 3.6 Reproducibility

The reproducibility of the pADE-questionnaire was examined with the patients' interviews. The agreement of answers between the questionnaire and the interview were analyzed. The agreement is observed to give an overview of the agreement in physical complaints and the practical problems in the questionnaire, compared with the (video) call interview, which is used as reference standard. The prevalence, frequency and nature of the physical and practical problems were compared. Also, the frequency in which a physical or practical problem is only reported in the interview will be perceived.

This method was based on the study of Willeboordse *et al.*, who checked the reproducibility by looking at the differences in outcome in the questionnaire compared with a personal interview, which is used as reference standard.[15]

## 3.8 Data analysis

### 3.8.1 Descriptive analysis

Descriptive statistics was used to describe patient characteristics. This includes general information about age, number of prescribed drugs and chronic diseases, country of birth, education level, living situation and health literacy, which was analysed with IBM SPSS statistics version 26 for windows (IBM Corp., Aromonk, NY, USA). Descriptive statistics of normal distributed continuous data were presented as means and standard deviation (SD). Descriptive statistics of categorical data were presented as frequencies and percentages.

### 3.8.2 Thematic analysis

For qualitative data all the interviews were recorded by high quality audio and transcribed verbatim. Thematic content analysis based on Braun and Clarck's was performed by an approach of top-down coding driven by the framework of the topic list. Transcripts were thematically coded and analyzed by three independent researchers, which was done separately for the conducted interviews. Differences in coding were discussed until consensus was reached. Subsequently, the coded transcripts were sorted to broader themes. Based on these themes a summary of the transcripts was made. Data were coded by using ATLAS.TI software version 9 (Scientific Software Development GmbH, Berlin, Germany).

After analyzing the data, the COSMIN criteria and rating system for evaluating the content validity of PROMS checklist was used. This checklist should be filled in, rating the relevance, comprehensiveness and comprehensibility using the 10 criteria for good content validity. This was filled in separately by two researchers and differences were resolved through discussion.[22] (Appendix F)

## 3.9 Ethics approval

The study is conducted according to the principles of the Declaration of Helsinki (version 64, October 2013). The study was approved by the accredited Medical research ethics committee (METC) of VUmc.

# 4 Results

## 4.1 Baseline characteristics

For this study a total of 26 patients met the selection criteria and were asked to participate. Of those eligible 6 patients were excluded, due to refusing to sign informed consent (n=2) or because it was too much of a burden (n=3). The remaining 20 patients took part in the study. 5 of these patients were lost to follow up. In the end a total of 15 patients participated were included in the study. The selection on the patients discharged from the VUmc and Flevoziekenhuis hospital were carried out according to the in- and exclusion criteria. From the 15 patients 9 patients were recruited from the VUmc and 6 from the Flevoziekenhuis hospital. A missing key element was that all the patients recruited from the VUmc were not entirely interviewed adequately according to the research protocol. Not every item of the questionnaire was evaluated separately on relevance, comprehensiveness, and comprehensibility. Only a general impression about the questionnaire is asked during the personal interview. However, all patients of the Flevoziekenhuis hospital did meet the research protocol for evaluating the content validity.

The baseline characteristics of the study population are shown in table 1. The mean age of the patients included in the study was 66.9 years (± 11.3) and most participants were male (73.3%). The majority (93.3%) of patients were discharged from the department of cardiology. All patients had an adequate health literacy and lived together with their partner and/or child(ren). Only 13.3% of the patients used a multi dose drug dispensing system, and 59.9% had an education level categorized as middle. On average patients used 7.7 (± 2.1) medicines per day and an average of 4.67 changes were made in the chronic medication after hospital discharge. Patients were predominantly of Dutch origin (86.7%), 80% of the participants had a mother with a Dutch origin and 73.3% an father with a Dutch origin. 26.7% were hospitalized 6 months before participating for this study and 20% had received a clinical medication review in the past year.

| **Table 1: Baseline characteristics patients (n=15)** | |
|---|---|
| **Age (years)** | |
| Mean (± SD) | 66.87 (11.29) |
| **Gender** | |
| male, n (%) | 11 (73.3) |
| **Department (no. (%))** | |
| Cardiology | 14 (93,3) |
| Internal medicine | 1 (6.7) |
| **Living situation (no. (%))** | |
| Alone | 0 (0%) |
| Together with partner and/or child(ren) | 15 (100) |
| **Multi dose drug dispensing (no. (%))** | |
| Baxter | 2 (13.3) |
| **Education level** | |
| Low | 5 (33.3) |
| Middle | 9 (59.9) |
| High | 1 (6.7) |
| **CCI** | |
| Median (± SD) | 0.93 (1.28) |
| **Health literacy (no. (%))** | |
| Inadequate | 0 (0) |

| | |
|---|---|
| Adequate | 15 (100) |
| **Chronic medication use** | |
| Mean no. (± SD) | 7.7 (2.1) |
| **Change in chronic medication (mean no. (± SD))** | |
| Medication changes | 4.67 (2.3) |
| New | 2.93 (1.6) |
| Stop | 0.87 (1.0) |
| Switch | 0.4 (0.6) |
| Dosage change | 0.8 (0.9) |
| **Native country (no. (%))** | |
| The Netherlands | 13 (86.7) |
| Suriname | 1 (6.7) |
| Other | 1 (6.7) |
| **Native country mother (no. (%))** | |
| The Netherlands | 12 (80) |
| Suriname | 1 (6.7) |
| Other | 2 (13.3) |
| **Native country father (no. (%))** | |
| The Netherlands | 11 (73.3) |
| Suriname | 1 (6.7) |
| Other | 3 (20) |
| **Hospitalization ≤ 6 months before index (no.(%))** | 4 (26.7) |
| **Medication review ≤ 12 months (no.(%))** | 3 (20) |

## 4.3 Face validity questionnaire

Results on the face validity questionnaire are shown in table 2. The participants strongly agreed on the moment receiving the questionnaire (100%), comprehensibility (80%) and response options (80%). They agreed on the instructions given (73.3%) and the clarity of the questions (73.3%). The questions are thought to be less comprehensiveness (46.6%).

**Table 2: Face validity questionnaire. (Scores are given in % that agree with the questions asked)**

| ***Statement*** | ***Scores*** |
|---|---|
| The instructions are clear | 73.3% |
| The questions are comprehensible | 80% |
| The questions are comprehensive | 46.6% |
| The questions are clear | 73.3% |
| The response options are good | 80% |
| The moment of receipt is good | 100% |

## 4.4 Content validity

### 4.4.1 Content validity

Content validity was measured by making a judgment about the relevance, comprehensiveness, and comprehensibility of all the items in the questionnaire. These three aspects of each item were assessed using standardized interviews, where 1 interviewer asked patients a series of open-ended but focused questions. Patients were asked 3 questions:

1. What do you think about the comprehensiveness?

2. What do you think about the comprehensibility?
3. What do you think about the relevance?

Patients agreed that the questions about the presence of the different medical symptoms were comprehensive, comprehensible, and relevant. All questions were understood as we have intended. However, the item asked about the association between a medical symptom and the usage of one of their medication was considered comprehensive, but not relevant and not comprehensible. Most participants indicated it was difficult to tell if the medication was related to any of the medical symptoms. Furthermore, patients believed the questionnaire was missing their medical history, actual medication use and information about their hospital admission.

### 4.4.2 Content validity pharmacist

The pharmacist considered the pADE-questionnaire overall not relevant and not comprehensive. The pharmacist viewed it as a general survey about the physical well-being, which lacked background information about the hospital admission. He stated that the questionnaire has open ends by obtaining information. It is limited to medical symptoms caused by medication usage. Overall, it was comprehensible because all questions asked are clear and could give information needed about the physical well-being.

## 4.5 Reproducibility

The prevalence of the total reported ADEs in the questionnaire are 60/15= 4, and in the interview 70/15=4.7.

### 4.5.1 Accuracy of medical symptoms in questionnaire

The observed overall agreement in medical symptoms is comparable, with a weighted average of 83.1%. (Table 3)

Based on the interview 60% of the patients had balance problems, such as falling, dizziness or a weak feeling. In the questionnaire 33.3% did not fill out the question about balance problems. This is considered as a disagreement.

Table 3: Nature and frequency of medical symptoms reported in questionnaire and interview.

| *Variable* | *Frequency questionnaire* | *Frequency interview* | *Agreement* |
|---|---|---|---|
| Medication symptoms, n | 54 | 65 | 83.1% |
| Pain | 6 | 8 | 75% |
| Eat- and drinking problems | 6 | 7 | 85.8% |
| Stool problems | 3 | 6 | 50% |
| Urination problems | 4 | 6 | 66.7% |
| Balance problems | 4 | 9 | 44.4% |
| Sleeping problems | 7 | 6 | 85.7% |
| Heart- or lung problems | 8 | 7 | 87.5% |
| Skin problems | 5 | 7 | 71.4% |
| Nosebleeds or eye irritation | 5 | 4 | 80% |
| Fever or sweating | 1 | 1 | 100% |
| Any other complaint | 5 | 4 | 80% |

### 4.5.2 Accuracy of practical problems in questionnaire

The observed overall agreement for all practical problems in the questionnaire compared with the interview are not comparable. There is an under- and over reporting for most variables, see table 4.

**Table 4: frequency and nature of practical problem only reported in questionnaire and interview**

| ***Variabele*** | ***Frequency questionnaire*** | ***Frequency interview*** | ***Agreement*** |
|---|---|---|---|
| Practical problems, n | 6 | 5 | 83.3% |
| Yes because it's a lot of drugs (at once) | 2 | 0 | 0% |
| Yes, because I forget to take the drugs | 1 | 0 | 0% |
| Yes, because I have problems with the times of the day. | 1 | 1 | 100% |
| Yes, because the drug strip or packaging is difficult to open. | 1 | 0 | 0% |
| Yes, for other reasons, namely… | 1 | 0 | 0% |
| Yes, because I cannot keep apart the drugs | 0 | 1 | 0% |
| Yes, because I have a hard time swallowing the pill/capsule | 0 | 1 | 0% |
| Yes, because I find it difficult to administer the drug. | 0 | 2 | 0% |

# 5.Discussion

## 5.1 Interpretation of findings

The validation of the pADE-questionnaire is reported in this study. This potentially useful instrument, designed to identify potential drug related problems 4 weeks after hospital discharge in patients using five or more long-term medicines for the MARCH-trial, is filled in 1 to 3 weeks after hospital discharge. This instrument is purporting to report patient experience of medication symptoms and practical problems.

Furthermore, the COSMIN methodology was used to assess content validity of this instrument. The COSMIN criteria and rating system for evaluating the content validity only met two criteria for content validity. Patients agreed that questions about the presence of the different medical symptoms were comprehensive, comprehensible, and relevant. The pADE-questionnaire could therefore be a very useful tool to detect medical symptoms and practical problems with medication. However, it is estimated to give only a small indication of medical or practical symptom causes. The questions asked about the association between their medical symptoms and medication use were considered not relevant, nor comprehensive. Determining a causal relationship between drug exposure and an ADE is challenging. Diagnostic tests that show an association are not readily available. To assess if a drug could result in an ADE causality assessment tools could be used.[26,27] Unfortunately, the results of such tools are highly variable.[28,29]

In this study, we found that patients found it difficult and confusing to link their complaints to their medication. One reason could be that the questionnaire didn't contain any background information about the hospital admission. Some complaints could be explained by the hospitalization, since this information was missing some people seemed very confused. For example, one patient assumed that all his problems were linked to his medication even though that may not have been the cause. Another patient formulated links during the survey, which later turned out to be incorrect. The professional we interviewed mentioned that the questionnaire was not related to hospital admission, but a general survey to track down medical and practical symptoms. Furthermore, patients don't have the knowledge to make an association between a complaint and the drug. It is therefore difficult to conclude if this tool will be used for medication related symptoms instead of for a medication review. A medication review is still important, however people who normally wouldn't qualify for a medication review would be included in this study.

Overall, good agreement has been shown in the comparison of the medical symptoms reported in the questionnaire and interview. The medical symptom with the most disagreement is balance problems. It is not known why balance problems are underreported in the questionnaire compared to the interview. One reason may be, during the interview different balance problems are depicted on the screen and patients could recognize them earlier as a medical problem. This difference is an important finding, because balance problems may lead to falling and thus serious consequences.

In contrast to the medical problems, the practical problems were not comparable between the questionnaire and interview. There were under- and over reported variables. There was a lack in questioning the named practical problems during the interview. Therefore, more participants are needed. So, this is a recommendation for future research.

## 5.2 Strengths and limitations

A strength of this research is the well-designed qualitative approach to assess the content validity of the questionnaire. First the participants filled in a questionnaire and later a structured personal

interview was conducted, recorded and transcribed to fully capture the context and content. By entailing direct communication with patients, the perspective on issues and the importance of each item asked could be adequately captured. Also, the personal interviews were based on an appropriate interview guide. Patients are explicitly asked for each item whether they thought it was comprehensive, comprehensible, and relevant. In this way an appropriate method is used to assess these concepts. In addition, a widely recognized method was used to analyze the data. A thematic content analysis was performed by coding the verbatim transcripts and then grouping the codes into thematic categories.

While group discussion may have further enriched gathering information, we chose to conduct personal interviews.[30-32] Interviews are suitable for more intimate issues. Besides we expected questionnaires may take longer to fill in, which may discourage patients. To our surprise, patients liked answering questionnaires and being able to explain how they feel. Feedback on questions was recommended to deal with recall bias.

Another important strength is that it was tested in an appropriate number of patients. For qualitative studies at least 7 patients are needed, so data saturation is reached.[22] However not enough professionals were asked about the relevance of each item of the questionnaire. We only asked one community pharmacist about the relevance and comprehensiveness. For this reason, we are limited to one professional from one discipline. It is doubtful if this one person could give an appropriate reflection of the content validity.

In addition, next to the well-being questions, we added a question in the interview about the emotional state of the patients. As pharmacists we often forget to take this aspect into consideration, which can provide important information.[33]

As stated, patients who aren't qualified for a medication review could be included. A strength of this study is that it could also be recommended to recognize patients suitable for a medication review in practice. Young people who normally wouldn't get a medication review, could also be included.[9]

This study is limited to patients with adequate health literacy. Since we can conclude that all the respondents are able to read and write it is unknown how people with inadequate health literacy will answer the questionnaire. Estimated 21,1% of the Dutch community has a limited health literacy, so it is hard to generalize this information for the Dutch population.[34]

Another limitation of this study is the lack of practical problem questions during the interview. Therefore, this would be a recommendation for future studies.

## 5.3 Future prospects

First, it is important to discuss the future feasibility of implementing the pADE-questionnaire. For practice, this can be an asset to select patients after discharge for a medication review in primary care. It could provide general information about the physical well-being of a patient. However, in daily practice it would be time consuming and feasible for a pharmacist to investigate all the medical and practical problems. It could become a routine action carried out by a pharmacy technician or a practical supporter, with some extra education. When any medical or practical problem are found, a pharmacist or a general practitioner-based nurse specialist could be asked. Altogether more research should be done.

For future research, research should be done for relevance and completeness for finding ADEs. There are still no other appropriate instruments to detect potential ADEs.

# 6 Conclusion

Patient interviews highlight the strengths and shortcomings in the content validity of the pADE-questionnaire. For patients, the pADE-questionnaire gives a good indication for medical and practical complaints, but less capable of estimating medication related problems. Patients find it difficult to connect practical problem to their medication.

# 7 References


[1] Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. *Adverse drug events occurring following hospital discharge*. Journal of general internal medicine. 2005 Apr 1;20(4):317-23. L

[2] Division of Pharmacoepidemiology & Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences. *Eindrapport HARM-onderzoek*. [Intenet]. Available from: Microsoft Word - Eindrapport_HARM_definitief_200611.doc (knmp.nl) [accessed 3rd March 2021]

[3] Garcia-Caballos M, Ramos-Diaz F, Jimenez-Moleon JJ, Bueno-Cavanillas A. *Drug-related problems in older people after hospital discharge and interventions to reduce them. Age and ageing*. 2010 Jul 1;39(4):430-8.

[4] Alqenae FA, Steinke D, Keers RN. *Prevalence and nature of medication errors and medication-related harm following discharge from hospital to community settings: A systematic review. Drug safety*. 2020 Jun;43(6):517-37.

[5] Maher RL, Hanlon J, Hajjar ER. *Clinical consequences of polypharmacy in elderly. Expert opinion on drug safety.* 2014 Jan 1;13(1):57-65.

[6] Leendertse AJ, Egberts AC, Stoker LJ, van den Bemt PM. *Frequency of and risk factors for preventable medication-related hospital admissions in the Netherlands. Archives of internal medicine.* 2008 Sep 22;168(17):1890-6.

[7] Geurts MM, Talsma J, Brouwers JR, de Gier JJ. *Medication review and reconciliation with cooperation between pharmacist and general practitioner and the benefit for the patient: a systematic review.* Br J Clin Pharmacol. 2012;74(1):16–33.

[8] Karapinar-Carkit F, Borgsteede SD, Zoer J, Smit HJ, Egberts AC, Bemt PM. *Medication safety: effect of medication reconciliation with and without patient counseling on the number of pharmaceutical interventions among patients discharged from the hospital.* Annals of Pharmacotherapy. 2009 Jun;43(6):1001-10.

[9] Nederlands Huisartsen Genootschap. *Module Medicatiebeoordeling Onderdeel van de multidisciplinaire richtlijn Polyfarmacie bij ouderen.* [Internet]. Available from: https://www.nhg.org/sites/default/files/content/nhg_org/uploads/final_module_medicatiebeoordeling_2019.pdf. [Accessed 3rd March 2021]

[10] GEURTS, Marlies ME, et al. *Medication review and reconciliation with cooperation between pharmacist and general practitioner and the benefit for the patient: a systematic review*. British journal of clinical pharmacology, 2012, 74.1: 16-33.

[11] Ensing HT, Stuijt CCM, Van Den Bemt BJF, et al. Identifying the optimal role for pharmacists in care transitions: a systematic review. J Manag Care Spec Pharm. 2015;21(8):614-638. *https://doi.org/10.18553/jmcp.2015.21.8.614. PubMed Web of Science®Google Scholar*

[12] Wheeler AJ, Scahill S, Hopcroft D, Stapleton H. Reducing medication errors at transitions of care is everyone's business. Aust Prescr. 2018;41(3):73-77. *https://doi.org/10.18773/austprescr.2018.021.* https://agsjournals.onlinelibrary.wiley.com/doi/full/10.1111/jgs.17041

[13] Drenth-van Maanen AC, Spee J, van Hensbergen L, Jansen PA, Egberts TC, van Marum RJ. *Structured history taking of medi- cation use reveals iatrogenic harm due to discrepancies in med-ication histories in hospital and pharmacy records*. J Am Geriatr Soc. 2011;59(10):1976–7.

*[14]* En-Nassery, S. (2021) *The effect of a transitional pharmaceutical care program on the occurrence of ADEs after discharge from hospital in patients with polypharmacy [Ongepubliceerd manuscript].* Department of Clinical Pharmacology and Pharmacy, Amsterdam University Medical Centers VUmc

[15] Willeboordse F, Grundeken LH, van den Eijkel LP, Schellevis FG, Elders PJ, Hugtenburg JG. *Information on actual medication use and drug-related problems in older patients: questionnaire or interview?.* International journal of clinical pharmacy. 2016 Apr 1;38(2):380-7.

[16] Schoenmakers TW, Teichert M, Wensing M, de Smet PA. *Evaluation of potentially drug-related patient-reported common symptoms assessed during clinical medication reviews: a cross-sectional observational study.* Drug safety. 2017 May;40(5):419-30.

[17] Verdoorn S, Kwint HF, Blom J, Gussekloo J, Bouvy ML. *DREAMeR: Drug use Reconsidered in the Elderly using goal Attainment scales during Medication Review; study protocol of a randomised controlled trial.* BMC geriatrics. 2018 Dec 1;18(1):190.

[19] Ponjee GH, van de Meerendonk HW, Janssen MJ, Karapinar-Çarkit F. *The effect of an inpatient geriatric stewardship on drug-related problems reported by patients after discharge.* International Journal of Clinical Pharmacy. 2020 Sep 10:1-2.

[20] SARA DALIRI. *Vragenlijst medicijngebruik.* [Internet]Available from: https://www.knmp.nl/downloads/promise-vragenlijst-medicijngebruik.pdf [Accessed at 3rd March 2021]

[21] Hodgson K, Uher R, Crawford AA, Lewis G, O'Donovan MC, Keers R, Dernovšek MZ, Mors O, Hauser J, Souery D, Maier W. *Genetic predictors of antidepressant side effects: a grouped candidate gene approach in the Genome-Based Therapeutic Drugs for Depression (GENDEP) study*. Journal of psychopharmacology. 2014 Feb;28(2):142-50.

[22] COSMIN. *COSMIN methodology for assessing thecontent validity of PROMs.* [Internet]. Available from: https://cosmin.nl/wp-content/uploads/COSMIN-methodology-for-content-validity-user-manual-v1.pdf. [Accessed 31 august 2021]

[23] Nivel. *Health literacy: an asset for public health.* [Internet]. Available from: https://www.nivel.nl/sites/default/files/bestanden/Proefschrift_vd_Heide.pdf? [Accessed 31 august2021]

[24] Fransen MP, Van Schaik TM, Twickler TB, Essink-Bot ML. Applicability of internationally available health literacy measures in the Netherlands. Journal of health communication. 2011 Sep 30;16(sup3):134-49.

[25] Austin SR, Wong Y. N, Uzzo RG, Beck JR, Egleston BL. *Why summary comorbidity measures such as the Charlson comorbidity index and Elixhauser score work.* Med Care. 2015;53:e65.

[26] Arimone Y, Bégaud B, Miremont-Salamé G, Fourrier-Réglat A, Moore N, Molimard M, Haramburu F. *Agreement of expert judgment in causality assessment of adverse drug reactions.* European journal of clinical pharmacology. 2005 May;61(3):169-73.

[27] Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, Janecek E, Domecq C, Greenblatt DJ. *A method for estimating the probability of adverse drug reactions. Clinical Pharmacology & Therapeutics.* 1981 Aug;30(2):239-45.

[28] Théophile H, Arimone Y, Miremont-Salamé G, Moore N, Fourrier-Réglat A, Haramburu F, Bégaud B. *Comparison of three methods (consensual expert judgement),(algorithmic and probabilistic approaches) of causality assessment of adverse drug reactions*. Drug safety. 2010 Nov;33(11):1045-54.

[29] Varallo FR, Planeta CS, Herdeiro MT, Mastroianni PD. *Imputation of adverse drug reactions: Causality assessment in hospitals*. PloS one. 2017 Feb 6;12(2):e0171470.

[30] Sim J. *Collecting and analysing qualitative data: issues raised by the focus group. Journal of advanced nursing.* 1998 Aug;28(2):345-52.

[31] Kitzinger J. *Qualitative research: introducing focus groups.* Bmj. 1995 Jul 29;311(7000):299-302.

[32] Coenen M, Stamm TA, Stucki G, Cieza A. *Individual interviews and focus groups in patients with rheumatoid arthritis: A comparison of two qualitative methods.* Quality of life research. 2012 Mar;21(2):359-70.

[33] van Eikenhorst L, van Dijk L, Cords J, Vervloet M, de Gier H, Taxis K. *Pharmacists' responses to cues and concerns of polypharmacy patients during clinical medication reviews—A video observation study.* Patient education and counseling. 2020 May 1;103(5):930-6.

[34] Nivel. *Drie op de tien Nederlanders heeft lage gezondheidsvaardigheden.* [Internet]. Available form: https://www.nivel.nl/nl/nieuws/drie-op-de-tien-nederlanders-heeft-lage-gezondheidsvaardigheden [Accessed 31 august 2021]

# 8. Appendix

## 8.1 Appendix A: Inclusion protocol

### Inclusieprotocol

1) Screen of de patiënt voldoet aan de eisen van inclusie of exclusie (bijlage I)

2) Indien geschikt voor inclusie:

a) Nodig patiënt uit voor deelname m.b.v. de patiënteninformatie (bijlage II):

**Informeer de patiënt na het ontslaggesprek over de studie m.b.v. de patiënteninformatie (PIF), benoem in ieder geval:**

- **Het doel van de studie:** *Om mensen die worden ontslagen uit het ziekenhuis beter te kunnen begeleiden na het ziekenhuisontslag, voeren wij een onderzoek uit waarbij er vanuit het ziekenhuis samen met de apotheker en huisarts wordt gekeken of er zaken verbeterd kunnen worden aan de medicatie.*
- **Wat meedoen inhoudt:**
  *"Meedoen houdt in dat u direct na ontslag en 4 weken na uw ontslag zal worden gebeld om een vragenlijst over uw geneesmiddelen af te nemen. Indien gewenst, kan de vragenlijst ook elektronisch (online) worden verstuurd en ingevuld."*
- **Dat deelname vrijwillig is:**
  *"Deelname is vrijwillig. Indien u wilt meedoen aan het onderzoek, dan kunt zich altijd bedenken. U hoeft niet te zeggen waarom u stopt. Wel moet u dit direct melden aan de onderzoeker (zie contactgegevens op PIF). De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek."*
- **Dat gegevens worden gecodeerd:**
  *"Alle medische- en persoonsgegevens die worden verzameld en gebruikt zullen worden gecodeerd en blijven vertrouwelijk. Alleen de onderzoeker en uw eigen zorgverleners weten welke code u heeft."*

***Vraag of de patiënt aan dit onderzoek mee zou willen doen***

b) Indien patiënt mee wil doen:

- Laat de patiënt **2x een informed consent formulier** (zie bijlage PIF) ondertekenen **en teken zelf namens de onderzoeker**.
- **Geef 1 formulier mee aan de patiënt** en geef ook de **patiënteninformatie** mee aan de patiënt. Het andere informed consent formulier houdt je zelf.

c) Vul de gegevens in op het Inclusieformulier (bijlage III)

d) Leg het ingevulde IC formulier + inclusieformulier in het bakje van de MARCH studie in het M-team kantoor

### Indien de patiënt ongeschikt is voor inclusie:

Noteer de patiëntgegevens en waarom de patiënt geëxcludeerd is (reden van exclusie).

- Volg hierbij de stappen in bijlage I: voldoet stap 1 niet, dan hoef je niet meer naar de overige criteria te kijken en noteer je alleen stap 1. Voldoet stap 1 en 2 wel, maar stap 3 niet, dan hoef je niet meer naar de overige criteria te kijken en noteer je alleen stap 3.etc

## Appendix B: pADE-questionnaire

*A)Lichamlijke klachten*

*De eerste vragen gaan over klachten die kunnen optreden bij het gebruik van medicatie. Niet iedereen heeft hier last van, wij zijn benieuwd of u last heeft van genoemde klachten. Met behulp van uw antwoorden kunnen wij onderzoeken hoe we de zorg nog verder kunnen verbeteren.*

| | | Geen | Mild | Matig | Ernstig | **Indien score ≥ 1: Denkt u dat dit door een medicijn komt?** | **Zo ja, welk medicijn?** | **Sinds wanneer heeft u hier last van? (enkele dagen, weken, maanden of jaren)** |
|---|---|---|---|---|---|---|---|---|
| | **<u>Had u de afgelopen week last van pijn *(zoals hoofdpijn, keelpijn, buikpijn, rugpijn, spierpijn)*?</u>** | | | | | | | |
| 1 | Hoofdpijn | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 2 | Keelpijn | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 3 | Buikpijn | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 4 | Rugpijn | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 5 | Pijn aan handen/voeten | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 6 | Spierpijn/gewrichtspijn | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 7 | Andere pijn, namelijk: …….. | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Had u de afgelopen week problemen met eten/drinken, droge mond, maagzuur of bent u misselijk?** | | | | | | | |
| 8 | Niet meer kunnen eten | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 9 | Verminderde eetlust | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 10 | Misselijkheid en braken | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 11 | Maagzuur | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 12 | Droge mond/vaak dorst | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week problemen met uw ontlasting (zoals diarree, verstopping, zwarte ontlasting, opgeblazen buik)?** | | | | | | | |
| 13 | Diarree | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 14 | Verstopping | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 15 | Zwarte ontlasting | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 16 | Opgeblazen gevoel in de buik | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week problemen met plassen of het niet op kunnen houden van uw urine?** | | | | | | | |
| 17 | Minder plassen | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 18 | Vaker plassen | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 19 | Urine niet goed kunnen ophouden (incontinentie) | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week problemen met uw evenwicht (bijv.vallen, duizeligheid of een zwak gevoel)?** | | | | | | | |
| 20 | Vallen zonder duidelijke oorzaak | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 21 | Duizeligheid/draaierigheid | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 22 | Vermoeidheid/zwak gevoel | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week problemen met in slaap komen of last van slaperigheid?** | | | | | | | |
| 23 | Slaperigheid/sufheid | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 24 | Slapeloosheid | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week last van hart of longen? (bijv. hoesten, benauwdheid, pijn op de borst, hartkloppingen of dikke benen/enkels)?** | | | | | | | |
| 25 | Hoesten | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 26 | Benauwdheid | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 27 | Pijn/Druk op de borst | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 28 | Hartkloppingen | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 29 | Dikke enkels/benen | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week last van jeuk, huiduitslag of blauwe plekken?** | | | | | | | |
| 30 | Huidreactie (jeuk/uitslag) | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 31 | Blauwe plekken | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week last van bloedneuzen of oogirritatie/slecht zien?** | | | | | | | |
| 32 | Bloedneuzen | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 33 | Oogirritatie/slecht zien (wazig of dubbel) | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week last van koorts of zweten?** | | | | | | | |
| 33 | Koorts | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| 34 | Zweten | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |
| | Geen klachten | | | | | | | |
| | **Had u de afgelopen week verder nog overige klachten die niet in deze vragenlijst aanbod zijn gekomen?** | | | | | | | |

| | **Anders:** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 36 | **……..** | 0 | 1 | 2 | 3 | Ja / Nee | Zo ja: | Sinds: |

B)Praktische problemen

***Sommige mensen kunnen moeite hebben om medicijnen te gebruiken zoals de arts ze heeft voorgeschreven.***

| **Heeft u moeite om uw medicijnen te gebruiken zoals de arts ze heeft voorgeschreven?**<br>**U kunt meerdere redenen noemen:** | | |
|---|---|---|
| Ja, omdat het veel medicijnen (tegelijk) zijn | eens | oneens |
| Ja, omdat een of meer middelen niet werken | eens | oneens |
| Ja, omdat ik niet weet waarvoor ik het neem | eens | oneens |
| Ja, omdat er bijwerkingen zijn | eens | oneens |
| Ja, omdat ik bang ben voor bijwerkingen | eens | oneens |
| Ja, omdat ik er geen zin in heb | eens | oneens |
| Ja, omdat ik de medicijnen vergeet in te nemen | eens | oneens |
| Ja, omdat ik de medicijnen niet goed uit elkaar kan houden | eens | oneens |
| Ja, om andere redenen<br>Namelijk:<br>……..……..<br>…….. | | |

| **Heeft u praktische problemen om uw medicijnen te gebruiken?**<br>**U kunt meerdere redenen noemen:** | | |
|---|---|---|
| Ja, omdat ik problemen heb met de tijdstippen van de dag | eens | oneens |
| Ja, omdat ik de pil/capsule moeilijk krijg doorgeslikt | eens | oneens |
| Ja, omdat de medicijnstrip of verpakking moeilijk is open te maken | eens | oneens |
| Ja, omdat ik het etiket op de verpakking niet kan lezen en/of niet begrijp | eens | oneens |
| Ja, omdat het medicijn vies smaakt | eens | oneens |
| Ja, omdat ik het moeilijk vind het medicijn toe te dienen (bv. inhalatie, oogdruppels) | eens | oneens |
| Ja, om andere redenen<br>Namelijk:<br>……..……..<br>…….. | | |

## 8.2 Appendix C: Topic list for interview with patients

# Topic lijst – persoonlijk interview

**Introductie**

| |
|---|
| Social talk<br>• Een praatje maken<br>Voorstellen<br>• Naam<br>• Studie |
| Bedanken voor deelname |
| Korte samenvatting<br>• Waarom we deze interviews houden |
| Duur van het interview<br>• Ongeveer 30 minuten |
| Informed consent vragen<br>• Doel: terugluisteren, transcriberen, analyse<br>• Wordt uitsluitend gebruikt voor dit onderzoek en informatie is niet herleidbaar<br>Q: Mag dit gesprek worden opgenomen?<br><br>Recorder aanzetten<br>Wilt u hierbij op recorder bevestigen, dat u mr/mvr. [ACHTERNAAM], zojuist door mij Besme Al Gareb bent geïnformeerd over het interview van het MARCH-onderzoek, en u hierbij toestemming geeft om dit interview op te nemen op recorder? |

**Intake - Algemeen**

| |
|---|
| Q: Hoe gaat het op dit moment met u? |
| Q: Hoe ging het gebruik van uw medicijnen in de weken nadat u was ontslagen uit het ziekenhuis?<br>• Was alles duidelijk?<br>• Kon uw de medicijnen goed gebruiken?<br>• Waren er moeilijkheden bij het gebruik van uw medicijnen?<br>• Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van de vragenlijst?<br>Q: Hoe gaat het nu met het gebruik van uw medicijnen? |
| Q: Heeft u op dit moment vragen? |
| • Samenvatten belangrijke punten en bruggetje maken naar de anamnese. |

**Anamnese - lichamelijke klachten**

| |
|---|
| Q: Heeft u in de periode na ontslag last gehad van pijn? (Denk aan hoofdpijn, keelpijn, rugpijn, handpijn, voetpijn, gewrichtspijn)<br>• Wat voor pijn ervaart uw?<br>• Hoe hevig ervaart u deze pijn op een schaal van 1 tot 10?<br>• Sinds wanneer heeft u hier last van?<br>• Heeft u enig idee waar deze klachten vandaan komen?<br>• Zou deze klacht denkt u kunnen komen door u medicijnen? Zo ja; door welke medicijnen komt deze pijn? En waarom denkt u dat het door dit middel komt? |

- Heeft u nog last gehad van andere pijnklachten die we nog niet hebben besproken?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de perioden na ontslag moeite gehad met eten en drinken? (Denk aan niet meer kunnen eten, toegenomen eetlust, misselijkheid, braken, maagzuur, droge mond of vaak dorst)

- Zo ja; waar heeft u precies last van gehad?
- Sinds wanneer heeft u hier last van gehad?
- Weet u ook waar dit aan zou kunnen liggen?
- Kan het komen door u medicijnen? Zo ja; door welke medicijnen? En waarom denkt u dat het door dit middel komt?
- Heeft u nog van andere klachten last gehad m.b.t. het eten en drinken?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de periode na ontslag last gehad van een verandering in uw ontlasting? (Denk aan diarree, verstopping, zwarte ontlasting of opgeblazen gevoel in de buik)

- Welke klachten ervaart u precies?
- Sinds wanneer heeft u hier last van?
- Heeft u enig idee hoe dit komt?
- Zou het kunnen komen door u medicijnen? Zo ja; door welke medicijnen? En waarom denkt u dat het door dit middel komt?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de periode na ontslag problemen gehad met plassen? (Denk aan minder plassen, vaker plassen of incontinentie van de urine)

- Welke klachten ervaart u precies?
- Sinds wanneer heeft u hier al last van?
- Heeft u enig idee hoe dit komt?
- Zou het kunnen komen door u medicijnen? Zo ja; door welke medicijnen? En waarom denkt u dat het door dit middel komt?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de periode na ontslag last gehad van evenwichts- of bewegingsproblemen?(vallen zonder duidelijke oorzaak, duizeligheid/draaierigheid, vermoeidheid/zwak gevoel)

- Wat voor problemen heeft u precies ervaren?
- Sinds wanneer heeft u hier al last van?
- Heeft u enig idee hoe dit komt?
- Zou het kunnen komen door u medicijnen? Zo ja; door welke medicijnen?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de periode na ontslag last gehad van slaapproblemen? (Slaperigheid, sufheid)

- Wat voor slaapproblemen ervaart u?
- Sinds wanneer heeft u hier last van?
- Heeft u enig idee hoe dit komt?
- Zou het kunnen komen door u medicijnen? Zo ja; door welke medicijnen? En waarom denkt u dat het door dit middel komt?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de periode na ontslag last gehad van u hart en/of longen? (Denk aan hoesten, benauwdheid, pijn of druk op de borst, hartkloppingen en dikke enkels of benen)

- Wat voor hart- of longklachten ervaart u?
- Sinds wanneer heeft u hier last van?

- Heeft u enig idee hoe dit komt?
- Zou het kunnen komen door u medicijnen? Zo ja; door welke medicijnen? En waarom denkt u dat het door dit middel komt?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de periode na ontslag last gehad van uw huid? (Denk aan een huidreactie met jeuk of uitslag en blauwe plekken)

- Wat voor huidproblemen ervaart u?
- Sinds wanneer heeft u hier last van?
- Heeft u enig idee hoe dit komt?
- Zou het kunnen komen door u medicijnen? Zo ja; door welke medicijnen? En waarom denkt u dat het door dit middel komt?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u in de periode na ontslag last gehad van overige klachten? (Denk aan bloedneuzen, koorts, zweten, oogirritatie, slecht zien, wazig of dubbel zien)

- Wat voor klachten ervaart u?
- Sinds wanneer heeft u hier last van?
- Heeft u enig idee hoe dit komt?
- Zou het kunnen komen door u medicijnen? Zo ja; door welke medicijnen? En waarom denkt u dat het door dit middel komt?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

➔ Samenvatten alle lichamelijke klachten en overgaan op de praktische problemen.
➔ Vragen welke klachten voor patiënten het belangrijkste zijn/het meest hinderen?

**Anamnese – praktische problemen**

Q: Hoe ziet u dagschema eruit? Lukt het u om u aan dit schema te houden?

- Vindt u dat u teveel medicijnen moet gebruiken? → Zo ja, hoe zou de patiënt het in dat geval het liefste zien?
- Lukt het u om de medicijnen uit elkaar te houden?
- Heeft u problemen met het innemen van medicijnen op bepaalde tijdstippen op een dag?
- Wat doet u als u medicijnen vergeet in te nemen?
    - Hoe komt het dat het niet lukt?
- Zijn er momenten waarbij u geen zin heeft in het slikken van de medicijnen? (+ wat doen ze dan?)

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Tegen welke problemen loopt u aan bij het gebruik van uw medicijnen?

- Heeft u moeite met slikken van de tabletten of capsules?
- Heeft u moeite met het toedienen? (inhalatiemedicijn, oogdruppels)
- Hoe vindt u de smaak van de geneesmiddelen? Indien vies, is dit een belemmering voor het innemen?
- Heeft u moeite met het openen van de verpakkingen? Zo, ja, hoe doet u dit dan?
- Vindt u het lastig om het etiket te lezen op de verpakking?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Heeft u bepaalde zorgen over het gebruik van medicijnen?

- Heeft u zorgen over de hoeveelheid medicijnen?

- Heeft u zorgen over bijwerkingen?
- Heeft u zorgen over de werking?
- Waarvoor de medicijnen zouden zijn?

Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

Q: Ervaart u lichamelijke of mentale klachten?
Q: Wat vond u van de relevantie, duidelijkheid en begrijpelijkheid van deze vraag?

→Samenvatten alle praktische problemen en overgaan op het aantal chronische aandoeningen

**Gezondheidsvaardighedentest - SBSQ**

Q: Hoevaak helpt iemand u thuis bij het lezen van brieven of folders van uw huisarts, het ziekenhuis of andere zorginstellingen?

- Nooit
- Af en toe
- Soms
- Vaak
- Altijd

Q: Hoe zeker bent u ervan dat u medische formulieren zelf goed invult?

- Heel erg
- Nogal
- Een beetje
- Een klein beetje
- Helemaal niet

Q: Vind u het moeilijk om meer te weten te komen over uw gezondheid, omdat uw geschreven informatie niet begrijpt?

- Nooit
- Af en toe
- Soms
- Vaak
- Altijd

4. Is er iemand die u thuis helpt bij het gebruiken van uw medicijnen (zoals thuiszorg, familieleden)

- Nee
- Ja, toelichting…….

**Vragen algemene patiënt karakteristieken**

Q: Wat is uw hoogst voltooide opleiding?

- Geen opleiding afgerond
- Lagere school/basisonderwijs
- Lager beroepsonderwijs (zoals huishuidsschool, LTS, LEAO)
- Middelbaar algemeen voortgezet onderwijs (zoals MAVO, (M)ULO)
- Middelbaar beroepsonderwijs (zoals MBO, MTS, MEAO, MHNO, INAS)
- Hoger algemeen voortgezet onderwijs (zoals HAVO, VWO, HBS, MMS)
- Hoger beroepsonderwijs (zoals HBO, HTS, HEAO, PABO)
- Wetenschappelijk onderwijs (universiteit)
- Anders

| |
|---|
| Q: Wat is uw woonsituatie op dit moment?<br>• Ik woon alleen<br>• Ik woon samen met mijn partner of kinderen<br>Q: In welk land bent u geboren?<br>Q: In welk land is u moeder geboren?<br>Q: In welk land is u vader geboren?<br>Q: Bent u de afgelopen 6 maanden eerder opgenomen geweest in het ziekenhuis?<br>Q: Heeft u de afgelopen 12 maanden eerder een medicatiegesprek met de apotheker gehad?<br>Q: Is er iemand die u helpt bij het gebruik van uw geneesmiddelen? |

**Afronding**

| Samenvatting geïnventariseerde kwesties |
|---|
| Vervolgafspraken, indien van toepassing.<br>• Bij klachten/problemen vragen of de patiënt wilt dat dit doorgegeven wordt aan de thuisapotheker. Zo ja; verifiëren welke thuisapotheker dit is. |
| Afsluiting:<br>• Goed dat we dit zo door hebben genomen. Fijn dat u wilde delen hoe het voor u is.<br>• Afscheid |

## 8.3 Appendix D: CCI

**CCI score:**

| | |
|---|---|
| CLZ= Chronische longziekte (= gebruik inhalatie medicatie) | 1 |
| DMC= Diabetes Mellitus chronische complicatie | 1 |
| NZ= Nierziekte (=egfr <50) | 1 |
| RZ= Reumatische ziekte | 1 |
| CHF= Congestief hartfalen (= gebruik lisdiuretica/digoxine) | 2 |
| LZL= leverziekte in lichte vorm | 2 |
| DEM= Dementie | 2 |
| HP= Hemiplegie of paraplegie | 2 |
| MN= Maligne neoplasma | 2 |
| LZM= leverziekte in matige/ernstig | 4 |
| AID= aids/HIV | 4 |
| STM= Solide tumor metastase | 6 |

## 8.5 Appendix E: Face validity

**Wat vond u van de instructie van de vragenlijst?**

- Zeer onduidelijk, omdat ……
- Onduidelijk, omdat ……..
- Neutraal, omdat ……
- Duidelijk, omdat ……
- Zeer duidelijk

**Hoe begrijpelijk vond u de vragen?**

- Zeer onduidelijk, omdat……..
- Onduidelijk, omdat ……
- Neutraal, omdat ……..
- Duidelijk, omdat……..
- Zeer duidelijk

**Wat vond u van de volledigheid van de vragenlijst?**

- Zeer onvolledig, ik miste veel vragen, omdat……
- Onvolledig, ik miste een aantal vragen, omdat……
- Neutraal, omdat……
- Volledig, ik miste bepaalde vragen, omdat……
- Zeer volledig, ik miste geen vragen

**Wat vond u van de antwoordopties van de vragen?**

- Zeer slecht, ik miste heel veel opties, omdat……
- Slecht, omdat……
- Neutraal, omdat……
- Goed, omdat……
- Zeer goed, ik miste geen opties

**Wat vond u van het moment waarop u de vragenlijst ontving?**

- Zeer slecht
- Slecht
- Neutraal
- Goed
- Zeer goed

**In hoeverre denkt u dat deze vragenlijst kan bijdragen in het opsporen van lichamelijke klachten en/of andere problemen bij medicatiegebruik na ziekenhuisontslag?**

……

**Wat zou u nog aan de vragenlijst willen verbeteren?**

……

**Table 1. COSMIN criteria and rating system for evaluating the content validity of PROMs**

| Name of the PROM or subscale: …… | PROM development study | Content validity study 1 | Content validity study 2[2] | Rating of reviewers | OVERALL RATINGS PER PROM[3] (see step 3b) | QUALITY OF EVIDENCE (see step 3c) |
|---|---|---|---|---|---|---|
| **Criteria (see Table 2)** | **+ / - / ± /?[1]** | **+ / - /± / ?** | **+ / - / ± /?** | **+ / - / ± /?** | **+ / - / ±** | **High, moderate, low, very low** |
| **Relevance** | | | | | | |
| 1 Are the included items relevant for the construct of interest?[4] | | - | | | | |
| 2 Are the included items relevant for the target population of interest?[4] | | - | | | | |
| 3 Are the included items relevant for the context of use of interest?[4] | | - | | | | |
| 4 Are the response options appropriate? | | - | | | | |
| 5 Is the recall period appropriate? | | - | | | | |
| **RELEVANCE RATING (see Table 3)** | | | | | | |
| **Comprehensiveness** | | | | | | |
| 6 Are all key concepts included? | | - | | | | |
| **COMPREHENSIVENESS RATING (see Table 3)** | | | | | | |
| **Comprehensibility** | | | | | | |
| 7 Are the PROM instructions understood by the population of interest as intended? | | + | | | | |
| 8 Are the PROM items and response options understood by the population of interest as intended? | | + | | | | |
| 9 Are the PROM items appropriately worded? | . | | | | | |
| 10 Do the response options match the question? | | | | | | |
| **COMPREHENSIBILITY RATING (see Table 3)** | | | | | | |
| **CONTENT VALIDITY RATING (see Table 4)** | | | | | | |

[1] Ratings for the 10 criteria can only be + / - /?. The RELEVANCE, COMPREHENSIVENESS, COMPREHESIBILITY, AND CONTENT VALIDITY ratings can be + / - / ± /?

[2] Add more columns if more content validity studies are available

[3] If ratings are inconsistent between studies, consider using separate tables for subgroups of studies with consistent results.

[4] These criteria refer to the construct, population, and context of use of interest in the systematic review.