



Medication self-management during hospitalisation in patients with polypharmacy

Identifying medication self-management challenges, developing supportive strategies and preparing for effectiveness evaluation



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Medicatie zelfmanagement tijdens ziekenhuisopname bij patiënten met polyfarmacie

Identificeren van medicatie zelfmanagement problemen, ontwikkelen van
ondersteunende strategieën en voorbereiding op de evaluatie van
effectiviteit

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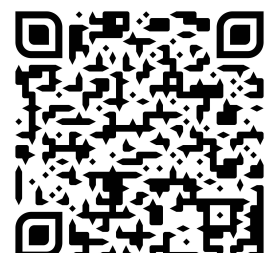
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Table of contents

List of abbreviations		7
Chapter 1	General introduction	11
PART I	Problems and perceptions regarding medication post-discharge	
Chapter 2	What happens after hospital discharge? Deficiencies in medication management encountered by geriatric patients with polypharmacy	51
Chapter 3	Beliefs about medication after hospital discharge in geriatric patients with polypharmacy	81
PART II	Refinement and extension of the SelfMED intervention	
Chapter 4	Medication literacy and medication self-management: a cross-sectional study in hospitalised patients (65+) with polypharmacy	109
Chapter 5	The development of recommendations for healthcare providers to support patients experiencing medication self-management problems	139
Chapter 6	Nurses' responses to patients' medication self-management problems in hospital and the use of recommendations	167
Chapter 7	Shared decision making on medication use between nurses and patients in an oncology setting: A qualitative descriptive study	185
Chapter 8	The development and evaluation of a medication diary to report problems with medication use	215
PART III	Preparatory studies for evaluating SelfMED's effectiveness - medication adherence measurement and intervention protocol	
Chapter 9	Evaluation of methods measuring medication adherence in patients with polypharmacy: a longitudinal and patient perspective	243

Chapter 10	The effect of an in-hospital medication self-management intervention (SelfMED) on medication adherence in polypharmacy patients post-discharge: protocol of a pre-post intervention study	267

Chapter 11	General discussion	295
	Summary / Samenvatting	337
	Appendices	347
	List of tables and figures	379
	Acknowledgements / Dankwoord	385
	Curriculum Vitae	393

List of abbreviations

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BMQ	Beliefs about Medication Questionnaire
CF	Cystic Fibrosis
CI	Confidence Interval
CPG	Clinical Practice Guidelines
DRP	Drug Related Problems
EHR	Electronic Health Record
EQF	European Qualification Framework
GIN	Guideline International Network
GRADE	Grading of Recommendations, Assessment, Development, and Evaluations
GRP	Geriatric Risk Profile
HCP	Healthcare professional
ICMJE	International Committee of Medical Journal Editors
IQR	Interquartile Range
MCAR	Missing Completely At Random
MED-fLAG	MEDication Literacy Assessment of Geriatric patients and informal caregivers
MedMaIDE	Medication Management Instrument for Deficiencies in the Elderly
MEMS	Medication Event Monitoring System
MeSH	Medical Subject Headings
MMC	Medication Management Capacity
MPC	Medical Pharmaceutical Consultations
MSM	Medication self-management
NHG	Nederlands Huisartsen Genootschap (Dutch College of General Practitioners)
NICE	National Institute for Health and Care Excellence
NUPHAC-EU	NURse and PHARmaceutical Care Europe
OECD	Organisation for Economic Co-operation and Development
OPTION	Observing Patient Involvement
OR	Odds Ratio
PAPA	Perceptions and Practicalities Approach

PC	Pharmaceutical Care
PCC	Person Centred Care
POM	Patients Own Medication
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
ProMAS	Probabilistic Medication Adherence Scale
RCT	Randomized Controlled Trial
SD	Standard Deviation
SDM	Shared Decision Making
SIGN	Scottish Intercollegiate Guidelines Network
SMM	Self-Management of Medication
SPSS	Statistical Package for the Social Sciences
WHO	World Health Organization

Chapter 1

General introduction

1. The rising number of people affected by multimorbidity and polypharmacy

Ageing of the global population is a phenomenon that has been apparent for several decades. In 2023, more than one-fifth (21.3%) of the European population was aged ≥ 65 years¹, a number expected to rise to 30% by 2050². Additionally, life expectancy at birth has steadily increased over the years, rising from an average of 74.3 years for men and 80.9 years for woman in 2002 to 77.9 years for men and 83.3 years for woman in 2022^{2, 3}.

Both population ageing and longevity led to a growing number of people affected by chronic diseases. Multimorbidity - the co-occurrence of two or more chronic diseases in one person^{4, 5} - affects 30% of individuals aged 45-64 years, escalates to 65% among those aged 65-84 years, and peaks at 82% in individuals aged ≥ 85 years⁶. While the increase in the prevalence of multimorbidity is often attributed to extended life expectancy, multimorbidity is also rising at a fast pace among younger patients. Between 2000 and 2015, the standardised prevalence rate of multimorbidity in Belgium doubled for individuals under the age of 50 years⁷.

Multimorbidity is often characterized by the occurrence of polypharmacy, defined as the concomitant intake of five or more medicines daily⁸. Globally, the prevalence of polypharmacy is observed in about 37% of the general population and found to even increase to 45% among older adults (≥ 65 years)⁹. In Belgium, the prevalence of polypharmacy was 29.5% in 2015, with approximately 40% of those affected being aged ≥ 65 years¹⁰. Due to the multitude of medicines and more complex medication regimens, patients with polypharmacy are at increased risk of facing difficulties with self-management, suboptimal medication adherence and unsafe medication use¹¹⁻¹⁴, often resulting in increased healthcare service utilization¹⁵⁻¹⁸.

Due to chronic shortages of healthcare professionals, healthcare staffing is insufficient to meet current and future healthcare demands of multimorbid and ageing populations^{19, 20}. To alleviate the burden on healthcare systems, there is a growing need to empower patients to become co-managers of their care process and to self-manage their chronic condition(s) in all aspects^{21, 22}.

Reflecting the growing number of individuals with multimorbidity who are deemed to self-manage their medication regimen, oftentimes characterized by polypharmacy, this thesis aimed to focus particularly on empowering patients with polypharmacy to achieve effective medication self-management.

2. Patients as active partners in healthcare: core concepts

Traditionally, healthcare has been dominated by a paternalistic approach, where patients are considered as rather passive recipients of care^{23, 24}. This approach, however, does not reflect reality, as only a small portion of healthcare is provided by professionals^{25, 26}. Nowadays, patients with chronic conditions are required to attain a more active approach in self-managing their care, with the possibility to receive support, guidance and counselling from informal caregivers but without direct, continuous supervision from healthcare professionals^{25, 27}. Therefore, over recent years, a clear shift towards a more person-centred approach in healthcare management has emerged, where patients are supposed to take a more active role and become co-managers in their care management²⁸⁻³¹.

Person-centred care (PCC) has been considered as an essential factor in improving quality of care^{32, 33}. PCC has been defined as *“an approach where individuals’ values and preferences are elicited and, once expressed, guide all aspects of their health care, supporting their realistic health and life goals. PCC is achieved through a dynamic relationship among individuals, others who are important to them, and all relevant providers. This collaboration informs decision-making to the extent that the individual desires.”*³⁴ PCC can result in patient empowerment, described as *“a process that enables patients to exert more influence over their individual health by increasing their capacities to gain more control over issues they themselves define as important”*³⁵. Consequences linked to patient empowerment include the achievement of patient participation and self-management³⁵⁻³⁷. However, in reverse, patient participation and self-management are considered as strategies to make healthcare more person-centred and to make patients feel more empowered^{35, 38}. Patient participation has been described as *“a patient’s rights and opportunities to influence and engage in the decision making about his/her care through a dialogue attuned to his/her preferences, potential and a combination of his/her*

experiential and the professional's expert knowledge³⁵. Self-management refers to *“an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition”³¹*. As pharmacotherapy plays a crucial role for many patients afflicted by chronic disease to achieve optimal clinical outcomes³⁹, medication self-management is considered to be a key aspect of self-management.

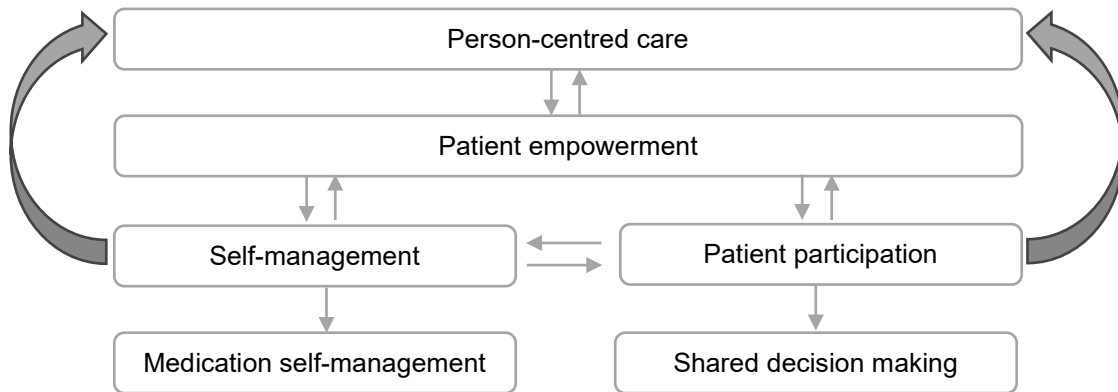


Figure 1.1: Relationship between concepts focusing on patients as active partners in healthcare, a concept map adapted from Hickmann et al. (2022) ³⁰

3. Medication self-management

Medication self-management (MSM) encompasses a range of tasks that individuals must successfully perform to self-manage their medication regimen as prescribed by healthcare professionals. It entails several aspects including patient knowledge, skills, motivation and behaviours necessary to take medicines as prescribed and sustain treatment adherence over time. As illustrated in Figure 1.2, the process of medication self-management has been unravelled into a six-phase model by Bailey et al. (2013). The MSM process is initiated by a medication prescription that must be filled and picked up by the patient. Subsequently, the patient needs to learn and understand how to use the prescribed medicines safely and correctly, which requires sufficient levels of knowledge about the respective medication(s). The practical organisation and planning of medicines intake are depicted in the third step of this model. The fourth step involves the actual administration of the prescribed medicines, while the fifth step emphasizes the importance of patients monitoring their medicine intake, evaluating any side effects, symptoms or usage problems related to their medicines, and taking action if necessary. The sixth and final step

involves maintaining a proper medication intake routine in a safe and effective manner for as long as indicated.⁴⁰

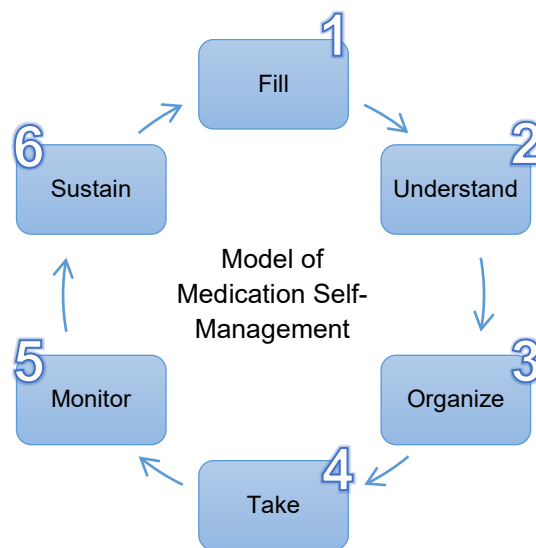


Figure 1.2: Model of medication self-management as developed by Bailey et al. (2013)⁴⁰

3.1 Determinants of medication self-management

Several factors can influence the process of medication self-management. First, medication literacy, as derived from health literacy, appears to be an important prerequisite for effective medication self-management⁴⁰. Medication literacy is defined as *“the degree to which individuals can obtain, comprehend, communicate, calculate and process patient-specific information about their medications to make informed decisions to safely and effectively use their medication”*⁴¹. Other patient-related factors, such as cognitive functioning, motivation for self-care and the patient’s perception of the prescribed therapy, can either support or hinder effective medication self-management⁴².

Second, medication-related factors that affect a person’s ability to properly manage and organize medication intake include the occurrence of polypharmacy, the use of complex medication regimens with multiple daily dosing schedules and the duration of treatment^{11, 12, 42, 43}. Additionally, condition-related factors such as the level of disease severity, the presence of symptom(s), and whether the disease is acute or chronic, can affect medication self-management^{42, 44}. Furthermore, receiving medication-related information from multiple healthcare providers, the quality of

patient-provider communication and relationships, and medication shortages are examples of healthcare system- or provider-related factors^{42, 44}. Lastly, socioeconomic factors, including the cost of the prescribed pharmacotherapy, poor financial or socioeconomic status may hinder a person's ability to purchase medicines^{42, 44}, thereby undermining the entire medication self-management process.

3.2 Medication self-management problems

Problems with medication self-management have been extensively reported in literature⁴⁵⁻⁶⁹. These problems include, but are not limited to, failing to fill prescriptions⁴⁵⁻⁴⁸, difficulties in understanding medication-related instructions and information⁴⁹⁻⁵² and insufficient medication knowledge, such as not being able to recall the name of medications, prescribed dosages or indications⁵³⁻⁵⁶. Additionally, difficulties in organising correct and timely medication intake have been reported⁵⁷. Integrating medication intake into daily routines often remains a challenge, with patients forgetting to take their medicines at the prescribed time points⁵⁷. Problems with packaging, such as child-resistant packaging and blister packs that are difficult to open, have also been documented⁵⁸⁻⁶¹, along with cases of patients taking expired or improperly stored medicines^{57, 62, 63}.

Medication administration itself can be problematic with common errors including incorrect dosing, taking the wrong medicine or missing a dose^{46, 64, 65}. The occurrence of medication administration errors at home has been estimated between 19% and 59%, increasing to 75% among older adults afflicted by polypharmacy⁶⁴. Monitoring therapeutic and adverse effects requires patients to be aware of possible side effects, risks and warnings, but knowledge of common side effects, precautions and interactions has been reported to be insufficient^{54, 66, 67}. Additionally, patients do not always report or communicate medication-related problems to healthcare providers⁶⁸. Furthermore, patients sometimes reduce the use of their medicines over time or stop taking them prematurely when they start to feel better^{57, 69}.

Failure in the process of medication self-management is directly related to patients' medication adherence. For instance, forgetting to take medicines, being unable to

follow medication-related instructions or being unable to open medication packages may result in diminished adherence rates.

3.3 Medication adherence

Medication adherence can be defined as *“the process by which patients take their medicines as prescribed”*⁷⁰, and can be divided into three phases, more specifically the initiation, implementation and discontinuation of pharmacotherapy (See Table 1.1).

Table 1.1: Definitions related to medication adherence

Initiation	When the patient takes the first dose of a prescribed medication ⁷⁰ .
Implementation	The extent to which a patient’s actual dosing corresponds to the prescribed dosing regimen, from initiation until the last dose is taken ⁷⁰ .
Discontinuation	When the patient stops taking the prescribed medication (when the next dose to be taken is omitted and no more doses are taken thereafter), for whatever reason ⁷⁰ .
Persistence	The length of time between initiation and the last dose ⁷⁰ .

The World Health Organization stated that 50% of patients afflicted by chronic conditions do not adhere to prescribed medication regimens⁴². More recent estimates of non-adherence among people with multimorbidity ranged from 7% to 83.5%⁷¹. This broad range indicates that non-adherence rates can vary significantly depending on the condition, treatment, measurement method and the definition or phase of non-adherence^{39, 71}. Nevertheless, polypharmacy is associated with poorer medication adherence due to the multitude of medicines and the often more complex medication regimen^{12, 13, 44}.

Although various intrinsic and extrinsic factors influence medication adherence, the Perceptions and Practicalities Approach (PAPA) provides a framework for understanding the fundamentals of medication adherence. The PAPA posits that (non-)adherence results from the interaction of individual motivation (i.e., perceptions) and ability (i.e., practicalities) (Figure 1.2). A lack of motivation often

leads to intentional non-adherence, where an individual decides not to follow the treatment recommendations (e.g., due to concerns about the value or effectiveness of medicines, their side effects, or the inconvenience of taking the medicines at the prescribed times and frequency). In contrast, a lack of ability results in non-intentional non-adherence, where the individual wants to follow the treatment recommendations but is hindered by practical barriers (e.g., cognitive deficiencies, lack of organisational skills, problems obtaining medicines).⁷²

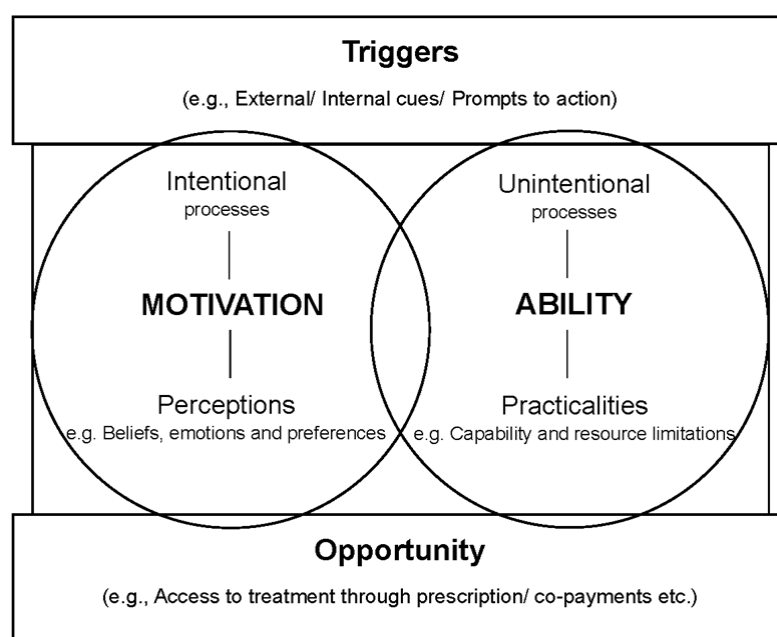


Figure 1.3¹: Perceptions and Practicalities Approach (PAPA): motivation and ability as core intrinsic attributes for adherence⁷².

Whether it is intentional or not, non-adherence among patients with chronic conditions represents a public health concern impacting health and economic outcomes for both individuals and society^{39, 73}. Non-adherence can result in suboptimal response to treatment, poor health outcomes (e.g., recurrence of illness, increased morbidity and mortality, reduced quality of life), adverse drug events, increased healthcare service utilization (e.g., unplanned hospitalisation, emergency department visits) and increased healthcare expenditures⁷⁴⁻⁷⁹. Medication non-adherence is responsible for nearly 200 000 deaths per year, and the associated costs are estimated between 80 to 125 billion euros in the European Union⁸⁰.

¹ Used with permission from *European Psychologist* (2019), 24(1), 82–96 © 2019 Hogrefe Publishing www.hogrefe.com <https://doi.org/10.1027/1016-9040/a000353>

4. Interplay between medication-related problems and hospitalisation

A lack of self-management competencies is associated with medication-related problems, also called drug-related problems (DRP's), such as low adherence levels and medication errors, which can harm patients' health. These DRPs may lead to hospitalisation^{15, 81, 82}. A systematic review found that, on average, 15% of hospital admissions are linked to DRPs, with one-third of them being preventable⁸³. While DRPs at home can result in hospitalisation, hospital stays in itself can increase the risk of DRPs after discharge⁸⁴⁻⁸⁶. The prevalence of post-discharge DRPs has been reported to range from 14% to 49%⁸⁷.

Although medication adherence is already poor in daily life, it is expected to decline further after hospitalisation due to inadequate knowledge, lack of understanding or excessive regimen complexity⁸⁷. Research showed that 24% to 70% of patients appeared to be non-adherent to medication post-discharge⁸⁸⁻⁹⁰. Furthermore, approximately 50% of patients experienced a medication error or unintentional medication discrepancy following discharge⁹¹. A systematic review found that one fifth of all hospital readmissions within 30 days after discharge were medication-related with a preventability rate of 69%⁹². A more recent study showed similar results, indicating that 16% of readmissions were medication-related, of which 40% were potentially preventable. About 35% of these preventable readmissions were due to non-adherence and 30% due to transition errors (e.g., failure to communicate medication changes to the patient and/or healthcare providers).⁹³ A few key problems contribute to DRPs post-discharge.

4.1 Problem 1: Medication substitution

In Belgium, in line with many European countries, it is common practice to provide all inpatient medication according to the hospital's formulary to patients being hospitalized. Non-formulary medication is often substituted to a different brand and/or a different pharmacotherapeutic class, depending on the hospitals pharmaceutical policy. Also, in case of medication shortages emerging in the hospital's pharmacy, alternative products are sought on the Belgian or international market^{94, 95}. Medication dispensed by the hospital pharmacy consists of unit doses

which are individually identifiable and scannable. Consequently, the medication may look different from the medication used at home, making it less recognizable for patients^{96, 97}. If medication is not switched back to the home medication upon hospital discharge, there is an increased risk of medication errors post-discharge as patients may use both the initial medication and the substitute.

4.2 Problem 2: Lack of patient involvement

At this moment, medication management in Belgian hospitals is still driven by a paternalistic approach, rather than by patient empowerment and stimulation of self-management. Since healthcare professionals are responsible for the storage, preparation and administration of patients' medicines during their hospital stay, patients do not have the opportunity to practice their medication management, nor to continue their medication intake routines from home. However, patients are expected to self-manage their medication regimen after hospital discharge, often with limited guidance⁹⁸. The lack of patient involvement in medication management during hospital stays may result in discontinuity of care and cause patients to lose control over their medication management.

4.3 Problem 3: Lack of shared decision making (SDM)

Although evidence demonstrates the benefits of SDM – such as increasing patient satisfaction by aligning care with patients' values and preferences, improving communication, and ensuring that patients feel well-informed^{99, 100}; as well as promoting patient autonomy^{101, 102} and improving adherence to treatment^{101, 103, 104} – SDM is still rarely adopted in practice^{99, 105-107}. Decisions about (pharmaceutical) care and treatment during hospitalisation are often made by healthcare providers', without encouraging patients to be involved in the decision making process^{108, 109}. There appears to be limited dialogue between patients and healthcare providers about patients' expectations and preferred ways of participating during their hospital stay^{110, 111}, including medication management. Nevertheless, most patients want to be involved in decision making^{112, 113}.

4.4 Problem 4: Inadequate communication and information transfer

Hospitalisation may introduce several changes to the medication regimen^{85, 114, 115}. Instructions describing these changes are not always explicitly nor adequately communicated to patients^{97, 98, 116}. If instructions on medication changes are provided, this usually takes place at the time of discharge. However, at discharge, patients are often distracted, overwhelmed with information and eager to leave for home, therefore paying less attention to medication instructions⁹⁸. It has been shown that after discharge, 51% to 82% of patients cannot name which medication precisely was changed during hospitalisation, and 55% do not use medication at home as initially intended at discharge^{86, 90, 117, 118}. This is also due to a lack of patient involvement in medication management during hospitalisation.

4.5 Problem 5: Lack of assessment of patients' medication self-management competences

During hospitalisation, healthcare providers do not systematically assess patients' ability of using and managing medication independently post-discharge. Vulnerable patients, such as those prescribed polypharmacy, are at increased risk of incorrect medication use after discharge, especially if they do not receive guidance on medication use during hospitalisation^{97, 98}.

5. In-hospital medication self-management: a promising strategy

Given that a significant proportion of patients experience problems with medication management after discharge⁸⁷⁻⁹⁰, there is a need for a person-centred approach enabling patients to practice medication self-management during hospitalisation and strengthen their medication self-management competencies.

In this regard, in-hospital medication self-management can be a promising strategy allowing patients to self-store, -prepare and -administer their medication during their hospital stay, on the condition that patients are deemed capable of self-managing medication and are supervised and guided by the healthcare team¹¹⁹. Healthcare providers can monitor and support patients, offering education and counselling on medication management during patients' hospital stay. If problems arise, healthcare providers can detect and address these issues in consultation with the patient during

hospitalisation, thereby reducing DRPs after hospital discharge and promoting effective and safe medicine use at home¹¹⁹⁻¹²².

Furthermore, through the provision of in-hospital medication self-management, patients will have the opportunity to become acquainted with medication that are newly prescribed or altered, supervised by healthcare providers. This strategy will stimulate patient participation, autonomy and independence regarding medication self-management, making the healthcare process of patients more person-centred¹²³⁻¹²⁵. Moreover, making optimal use of the knowledge and skills of patients whom are capable to self-manage medicines can contribute to more effective deployment of healthcare professionals^{121, 126-128}. This is essential for addressing chronic nursing shortages and reducing high workloads, thereby making healthcare more sustainable.

5.1 Evidence on in-hospital medication self-management

The concept of in-hospital medication self-management is not new. It was first introduced in literature in 1959¹²⁹ and has been studied internationally over the past decades^{121, 122, 130-134}. In-hospital medication self-management interventions have shown considerable diversity in their structure and content. Two systematic literature reviews found that these interventions often include multiple stages for a patient to complete, ranging from patient medication requests to supervised self-administration by nurses, followed by unsupervised self-management^{130, 131}. Programs in rehabilitation settings often required patients to progress through multiple levels over extended periods, whereas acute settings tended to follow a single-stage approach¹³⁰. In most studies, nurses monitored the self-administered medication intake; however, this monitoring was conducted to measure outcomes rather than to observe and assess medication self-management^{130, 131}. The vast majority included an educational element, informing patients about self-managed medicines¹³¹, but education was provided in an unstructured manner or lacked a clear description of its content or frequency^{128, 130, 131, 135, 136}. Additionally, no explicit support is described in case of problems. Despite this diversity, in-hospital medication self-management interventions have already demonstrated benefits for both patients and healthcare providers.

Medication errors and hospital readmissions

In hospital settings, medication administration errors by nurses, including harmful ones, are common with prevalence rates ranging from 8 to 14% of administrations, excluding wrong-time errors¹³⁷⁻¹³⁹. Two randomized controlled trials (RCT) showed that the implementation of medication self-management during hospitalisation improved medication safety, as it resulted in significantly less medication errors^{121, 132}. Furthermore, one RCT investigated hospital readmissions 60 days post-discharge and reported significantly lower readmission rates in the intervention group (11.4% versus 31.4%). Patients who did not self-manage their medicines whilst in hospital were readmitted earlier.¹²¹

Medication adherence

Two systematic reviews on in-hospital medication self-management showed inconclusive results regarding its effect on medication adherence, as multiple studies showed an increase in medication adherence rates due to medication self-management, while others found no significant differences^{130, 131}. A possible explanation for this inconclusiveness is that the measurement methods for medication adherence varied between studies. However, two more recent RCTs reported significantly higher adherence rates two weeks post-discharge in patients who self-managed their medicines during hospitalisation compared to those who received nurse-led medication management^{121, 122}.

Patients' medication knowledge

Multiple studies showed a significant increase in medication knowledge at hospital discharge in patients who self-managed their medicines during hospitalisation compared to those who did not^{121, 140-142}. Furthermore, an RCT showed that medication knowledge remained significantly higher two weeks and 60 days post-discharge¹²¹.

Patients' and healthcare providers' satisfaction

An increase in patient satisfaction has been reported when patients self-manage their medication during their hospital stay^{132, 134, 143-145}. Qualitative research with patients has highlighted potential benefits of medication self-management, including an increased sense of autonomy and a feeling of independence, which enhances

their satisfaction with the hospital stay¹²³⁻¹²⁵. Only a few studies have investigated healthcare providers' satisfaction, but findings indicate that the majority of nurses (between 60% and 91%) were satisfied with patients self-managing medication during hospitalisation^{122, 127, 128}.

Nurses' workload

Medication administration is a time-consuming process, estimated to account for 68 to 72 minutes of nursing time^{146, 147}. A few studies found that implementation of in-hospital medication self-management by patients reduced nurses' time spent on medication administration^{121, 127, 128}. Another study indicated that starting medication self-management was time-consuming, however, time savings resulted from dispensing, administration and discharge preparation as medication counselling was already performed during hospitalisation¹⁴⁵. Although the results seem inconclusive, it is hypothesized that nurses will be able to spend their time more efficiently.

5.2 Prevalence of in-hospital medication self-management in Belgium

Despite the possible benefits, medication self-management during hospitalisation is still not a standard practice in Belgium, as evidenced by a cross-sectional study performed in 12 Flemish hospitals¹⁴⁸. Out of 1,269 patients, 22% did self-manage at least one medication during their hospitalisation, with up to 16 different self-managed medicines and an average of four. Most self-managed medications were oral medicines (83.5%), followed by inhalation therapies (7.7%). According to the judgement of head nurses, up to 41% of patients would be able to fully self-manage their medicines.¹⁴⁸

When in-hospital medication self-management is allowed, it rarely is provided using a structured, evidence-based format. Out of 56 hospital wards, less than one-fifth was found to have a procedure for medication self-management and less than 10% had a screening tool assessing patients' eligibility to self-manage medication.¹⁴⁸ These findings highlighted the need to develop a structured, evidence-based approach to facilitate medication self-management in Belgian hospitals, which complies with current regulations.

5.3 Legal context of in-hospital medication self-management in Belgium

The Royal Decree of March 4th 1991, stipulates that all medicines for hospitalised patients should be delivered by the hospital pharmacy¹⁴⁹. Apart from this, there is no legislation outlining the prerequisites for medication self-management. However, the Care Inspection of the Flemish division of Wellbeing, Public Health and Family cited several aspects that must be adhered to. In-hospital medication self-management is allowed if the self-managed medication is duly documented in the patient's personal medical file. Throughout this process, healthcare providers have a duty of care and surveillance which implies the following: (1) the nurse will assess whether a patient is able to manage his/her medication independently during their hospital stay; (2) the treating physician bears the responsibility of authorizing and evaluating medication self-management; (3) the nurse will supervise medication management during hospitalisation, asking the patient at each medication round if the medication has been taken as required, and will record this in the patient's file; (4) the nurse will evaluate the current situation at each medication round. If the patient's condition changes during the hospital stay, a reassessment may be necessary to determine whether the conditions for medication self-management are still being met (Care Inspection of the Flemish Division of Wellbeing, Public Health and Family; personal communication, October 2015; personal communication, May 2024).

5.4 Healthcare providers and patients' perspectives and prerequisites concerning medication self-management in Belgium

Implementing in-hospital medication self-management is not possible without the support of healthcare providers. Therefore, as part of the SelfMED project, several studies were performed to gain insight into healthcare providers' and patients perspectives^{96, 123, 150}. The majority of patients (n= 112, 84%) had a positive attitude towards in-hospital medication self-management¹²³ and about 89% of nurses (n= 159), 75% of physicians (n= 76) and all of the hospital pharmacists (n= 36) expressed their willingness to allow this¹⁵⁰. Important prerequisites mentioned by patients included the following: motivation of patients to self-manage medication during hospitalisation, medication self-management at home before hospitalisation, regular assessment of the patients' ability to self-manage, and prospect of returning

home¹²³. Healthcare providers additionally mentioned the following conditions: patients' mental and physical capability for medication self-management, medication reconciliation, medication delivery by the hospital pharmacy, and safe storage of medication^{96, 150}.

5.5 The SelfMED intervention

Informed by previous literature review^{130, 131}, the findings on the prevalence and current practices of MSM in Flemish hospitals¹⁴⁸, the legal context, the willingness and attitudes of healthcare providers and patients^{96, 123}, and the prerequisites for in-hospital MSM⁹⁶, the SelfMED intervention has been developed in 2017 as part of the SelfMED project^{151, 152}. The SelfMED intervention is a complex intervention that aims to facilitate in-hospital MSM and consists of multiple components¹⁵¹ (See Figure 1.4).

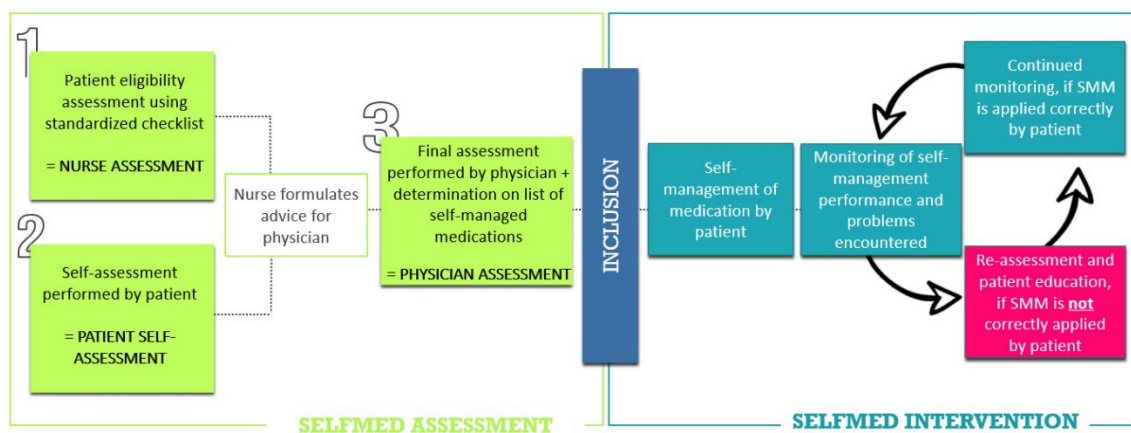


Figure 1.4: Overview of subsequent interventional SelfMED components.

(1) The **SelfMED-assessment** is a validated step-wise assessment evaluating the eligibility of patients for MSM during hospitalisation, performed by a nurse (1), the patient (2) and a treating physician (3). On admission, a 10-statement assessment allows a nurse to evaluate patients' eligibility for MSM. Elements addressed include, for example, the patients' mental and physical ability, MSM at home before hospitalisation and the prospect of returning home. Subsequently, a self-assessment is completed by the patient, which inquires the patient's medication self-management at home, the willingness to self-manage medication in hospital and any potential need for assistance. A nurse formulates an advice to the treating physician regarding whether to allow or decline MSM, taking into account the

patients' abilities and preferences. Based on the nurse's advice, as well as the information from both the nurse's assessment and patient's self-assessment, the treating physician must take the final decision on allowing or declining the patient to self-manage medication, as the physician bears legal responsibility during hospitalisation.

(2) Starting MSM: If a patient is eligible of MSM, several practical arrangements have to be made including the documentation of the self-managed medication in the patient's medical file, providing the patient with a personalized medication list, providing correct medication to the patient room and counselling on self-managed medication and the use of a monitoring system.

(3) The SelfMED-monitor involves a monitoring system allowing healthcare providers to follow-up intake of self-managed medicines and detect possible medication errors or other medication-related problems. As healthcare providers need to monitor medication safety, patients have to register their medication intake during hospitalisation on a daily base. For registration, a medication list is used, similar to the one received by the patient at discharge. Aids used at home can be used during hospitalisation. During medication administration tours, nurses need to check the registrations on the medication list to identify any discrepancies with the prescribed medication regimen. If problems occur, or there is doubt about medication intake, a pill count must be performed to detect medication errors. Discrepancies and problems experienced by the patient, while self-managing their medicines, are discussed with the patient.

(4) SelfMED-support: Literature review showed that most in-hospital medication self-management interventions include an educational component, informing patients about self-managed medicines^{130, 131}, but they lack explicit support tools for addressing problems. Therefore, it was hypothesized that SelfMED should include supportive measures for healthcare providers to support MSM for patients, especially in case of medication-related problems. However, supportive measures were not yet developed as part of the SelfMED project.

Patient participation is considered to be a common thread throughout the intervention. First, the decision to initiate medication self-management during hospitalisation is a shared endeavour, made in consultation between the physician, nurse and patient, taking into account the patients' abilities and preferences. If patients do not wish or do not feel capable to self-manage medication, this should be respected. Additionally, during monitoring rounds, healthcare providers inquire about problems with medication use, giving patients explicit opportunities to communicate their experiences, problems and needs regarding medication. When problems are detected, patients and healthcare providers should engage in a dialogue and collaborate to find an approach that addresses the problems and is supported by the patient.

A paper-and-pencil version of the SelfMED-intervention (including components 1 to 3) has been pilot tested at one cardiology unit of a general hospital. A total of 159 patients were screened using the SelfMED assessment, resulting in 38% of patients self-managing their medicines during hospitalisation. A total of 367 medicines were self-managed. Pill counts showed 0.8% administration errors and in 1.7% the registration of medication intake was incorrect. In summary, pilot-based results indicated the SelfMED-intervention facilitates medication self-management and was found to be safe.¹⁵³

5.6 Current knowledge gaps

Although initial steps towards developing a structured approach for in-hospital MSM were taken during the SelfMED project, significant gaps in our current knowledge base remain unaddressed. First, it is unclear whether the SelfMED assessment sufficiently accounts for medication literacy as an important prerequisite for medication self-management.

Second, supportive measures for medication-related problems have not yet been included in the SelfMED-intervention. Before developing such measures, it is necessary to gain insight into the specific problems patients experience with medication management post-discharge, their perceptions of medication use and potentially influencing factors.

Furthermore, patient participation through shared decision-making is a central aspect of the SelfMED-intervention. However, nurses' and patients' current experiences with medication-related shared decision-making during hospital stay, as well as their role perceptions, remain unclear.

Although the SelfMED-intervention aims to detect and address as many medication-related problems as possible during hospitalisation to prevent issues after discharge, complete avoidance of problems post-discharge may not be feasible. Therefore, measures are needed to support patients in reporting and communicating post-discharge problems with healthcare providers in a structured manner.

Even though the SelfMED-intervention has been pilot tested, evidence regarding its effectiveness on various outcomes after discharge is currently lacking. Since medication self-management problems are directly related to medication adherence, medication adherence is considered as a key primary outcome.

6. Aims of this doctoral study

This PhD dissertation aimed to address three main objectives (See Figure 1.5).

- Aim 1:** To identify medication management problems encountered by patients with polypharmacy post-discharge, along with their perceptions regarding medication use and influencing factors.
- Aim 2:** To refine and expand the SelfMED-intervention by developing and/ or evaluating strategies and tools to support patients with polypharmacy in medication self-management.
- Aim 3:** To prepare for the evaluation of SelfMED's effectiveness in patients with polypharmacy by assessing adherence outcome measurement methods and outlining the study protocol.

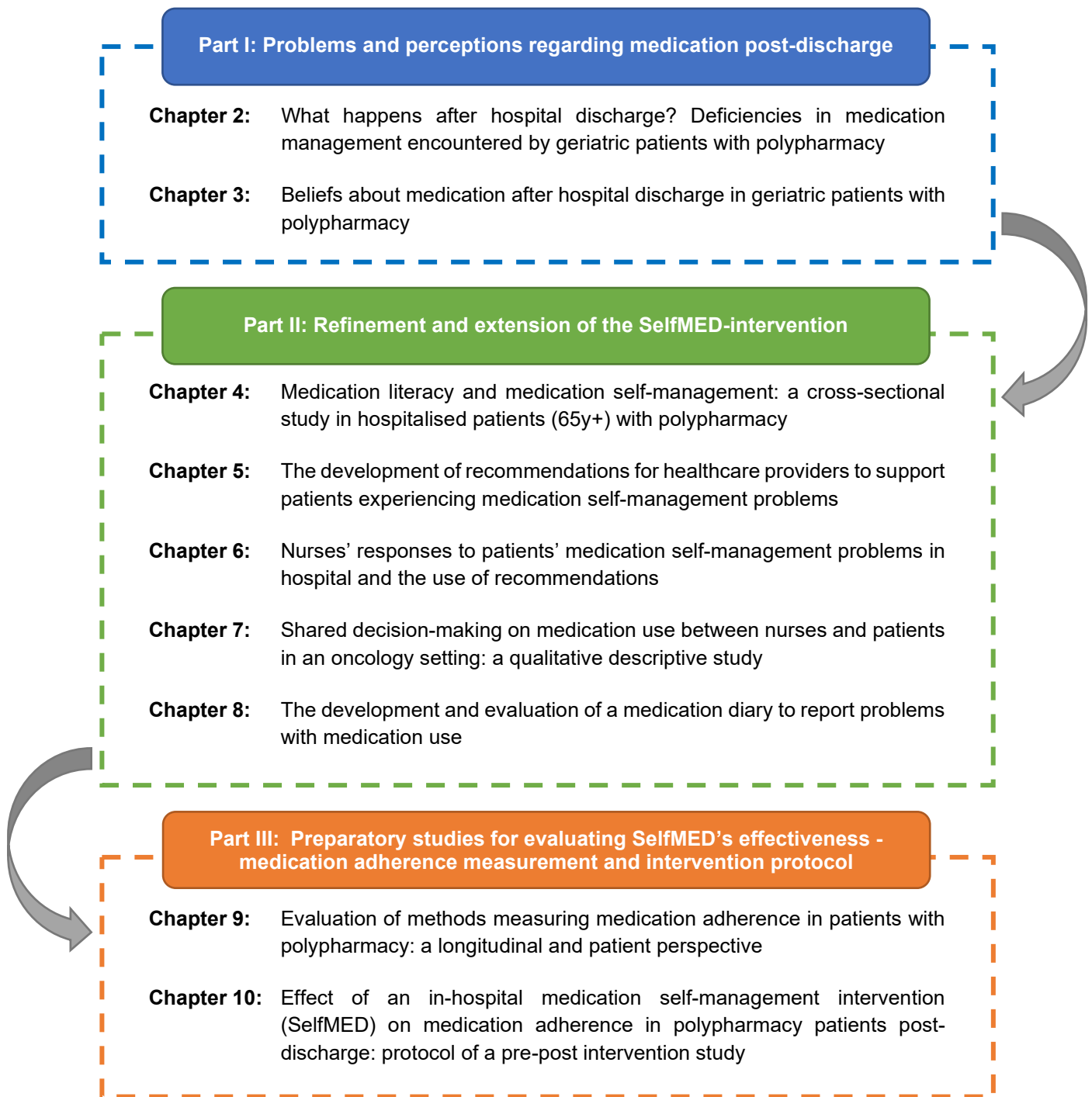


Figure 1.5: Overview of research objectives addressed in this PhD dissertation

7. Outline of this doctoral thesis

As derived from the three main objectives, this thesis consists of three parts. The chapters (2-10) within these three parts are based on articles published in international peer reviewed journals.

Part I focuses on medication management problems and perceptions regarding medication use after hospital discharge in patients with polypharmacy. **Chapter 2** explores problems experienced by patients with medication management after hospital discharge and the influencing factors. **Chapter 3** describes patients' beliefs about medication post-discharge and evaluates the impact of discharge management on these beliefs. The findings from this first part provided a basis for the second part of this thesis, in particular for chapters 5 and 8.

Part II focusses on the refinement and extension of the SelfMED-intervention. **Chapter 4** evaluates whether assessing medication literacy would add value to the SelfMED-assessment in determining a patient's capability for in-hospital medication self-management. **Chapter 5** describes the development of recommendations for healthcare providers to support patients in case of medication self-management problems. **Chapter 6** describes the use, feasibility and user-friendliness of the recommendations as a guide for healthcare providers in clinical practice. **Chapter 7** explores patients' and nurses' experiences with medication-related shared decision making during hospitalisation. In **Chapter 8**, the development and evaluation of a medication diary to report problems with medication use is described.

Part III prepares for the evaluation of the in-hospital medication self-management intervention (SelfMED) on medication adherence post-discharge. In **Chapter 9**, a combination of methods measuring medication adherence in patients with polypharmacy is evaluated. **Chapter 10** provides the protocol of a pre-post intervention study to assess the effect of in-hospital medication self-management (SelfMED) on medication adherence two-months post-discharge.

A general discussion and future perspectives on research and practice are provided in **Chapter 11**.

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Part I

Problems and perceptions regarding
medication post-discharge

Chapter 2

What happens after hospital discharge?

Deficiencies in medication management
encountered by geriatric patients with
polypharmacy

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Abstract

This study aimed to describe post-discharge medication self-management by geriatric patients with polypharmacy, to describe the problems encountered and to determine the related factors. In a multicenter study from November 2019 to March 2020, data were collected at hospital discharge and two to five days post-discharge. Geriatric patients with polypharmacy were questioned about medication management using a combination of validated (MedMalDE) and self-developed questionnaires. Of 400 participants, 70% did self-manage medication post-discharge. Patients had a mean of four different deficiencies in post-discharge medication management (SD 2.17, range 0–10). Knowledge-related deficiencies were most common. The number of medicines and the in-hospital provision of medication management by nurses were significant predictors of post-discharge medication management deficiencies. In addition to deficiencies in knowledge, medication-taking ability and obtaining medication, non-adherence and disrupted continuity of medication self-management were common in geriatric patients with polypharmacy post-discharge. Improvements in in-hospital preparation could avoid medication self-management problems at home.

1. Introduction

Medication management capacity (MMC) can be defined as *“the cognitive and functional ability to self-administer a medication regimen as it has been prescribed”*¹.

Medication self-management requires patients to know their medication, to understand their medication schedule, to be able to purchase medication and to have the functional skills such as correctly identifying medications, opening containers, and selecting the proper dose and time of administration².

The term medication self-management refers to the patient's need to fulfill a set of actions in order to manage medicines³. The process starts with fulfilling a prescription. During the second step, patients should learn how to use medicines in a safe and correct manner which requires medication knowledge. Organizing medication intake and planning daily medication schedules is the third step. The fourth step comprises of actually taking the prescribed medication. Monitoring medication intake and evaluating possible effects or symptoms related to medicines in order to undertake any action if needed is described as the fifth step. The last step concerns the act of sustaining a correct medication intake routine in a safe and appropriate way^{3, 4}. However, the literature suggests individuals struggle in various ways during the completion of this set of actions influencing medication adherence⁵⁻¹⁰. Adherence can be defined as *“the process by which patients take their medications as prescribed”*¹¹.

During hospitalization, medication management is usually performed by healthcare professionals, although after discharge, patients have to manage their medicines themselves, often with limited guidance from healthcare professionals¹². If support is lacking, shortcomings in medication self-management can lead to non-intentional therapy nonadherence. About 24% to 40% of patients are found to be non-adherent to their medication regimen after hospital discharge^{5, 13}. It is crucial to detect and address self-management problems prior to hospital discharge in order to promote adherence and safe medication use at home, especially in the elderly¹⁴.

Geriatric patients are at risk of medication self-management problems because of functional and cognitive decline and geriatric syndromes that accompany aging¹⁵. In addition, aging increases the risk of polypharmacy. Polypharmacy is commonly

defined as *“the minimum concomitant intake of at least five medicines”*^{16, 17}. Prevalence rates of polypharmacy in Flanders, Belgium for patients aged 75 years and older increased significantly by 1.3% per year between 2011 and 2015¹⁸. Furthermore, polypharmacy is associated with drug-related problems such as side effects, interactions and medication errors¹⁹. Moreover, pharmacokinetic and pharmacodynamic changes make the elderly more vulnerable to adverse events from aberrant medication intake²⁰. Unfortunately, previous studies on medication self-management are scarce and have not focused on geriatric patients after hospital discharge²¹⁻²³. Therefore, the results of these studies are not transferable to this subpopulation.

This study aimed (1) to evaluate post-discharge medication self-management and the problems encountered by geriatric patients with polypharmacy and (2) to identify the factors associated with post-discharge medication management deficiencies.

2. Materials and methods

2.1 Design

A multicentre, quantitative cross-sectional observational design was used to investigate medication management in geriatric patients with polypharmacy. A two-part survey was administered between November 2019 and March 2020. The first part of the questionnaire was administered at the day of hospital discharge. Two to five days after discharge, a home visit was scheduled for the completion of the second part of the questionnaire that focused on medication management.

2.2 Participants and setting

Twelve general hospitals in Flanders, Belgium participated. At each hospital, patient selection was initiated from a convenience sample of wards, based on the availability of eligible patients. Hospitalized patients were eligible if they were at least 75 years old, used five or more prescribed medicines at the time of hospital discharge (i.e., polypharmacy) and spoke Dutch. Patients receiving palliative care (i.e., palliative status, palliative file, palliative care pathway), having a neuropsychiatric diagnosis of dementia, being legally incapable and patients who did not return home after discharge were excluded. Patients' eligibility, based on the aforementioned criteria, was evaluated by the (head)nurse of the ward. All eligible

patients from the selected wards who were willing to participate were included during the data collection period until the desired sample size was reached (consecutive sampling).

The sample size was calculated prior to the study, using the Sampsize calculator for prevalence studies²⁴. Precision (%), prevalence (%), target population size and confidence level were entered. To reach the highest estimated sample size, an infinite population size (defined by the number 0) and an estimated prevalence of 50% (default value) was used. To ensure the validity of the data with a precision of 5%, an estimated prevalence of self-management problems of 50%, an unknown population size and a 95% confidence interval, the desired sample size was 385. Due to the maxim of $n = 40 \times \text{number of predictors}$, stepwise multiple logistic regression was allowed with this sample size to determine the factors related to post-discharge medication management deficiencies²⁵.

2.3 Data collection

Data collection proceeded in several steps. Firstly, eligible patients were invited to participate in the study during hospitalization. If patients refused to participate, the reasons for a non-response were surveyed. Secondly, patients willing to participate were visited in hospital at the day of discharge. A questionnaire on socio-demographic data was administered, a geriatric risk profile was calculated, the patients' medication schedule was copied to collect data about patients' medication use and a home visit was scheduled two to five days after discharge. Thirdly, during this home visit, a questionnaire about medication self-management and medication management deficiencies was administered. Trained research assistants, who were all nurses with a Bachelor's degree, collected data between November 2019 and March 2020. Through an information session, the research assistants were informed about the administration of the questionnaire upon discharge and during the home visit.

At the day of discharge, patients were informed about the fact that the study was focusing on discharge management in the broad sense in order to avoid research bias. During the home visit, the fact that the study focused on medication management in the context of discharge management was clarified.

Measurements

To describe the population, the following data were collected: age, gender, educational level, type of hospitalization, reason for hospitalization, length of hospital stay, chronic diseases and support to reside at home. Patients were screened for geriatric care problems through a calculation of a geriatric risk profile, based on the Triage Risk Screening Tool²⁶. The latter was scored as follows: cognitive impairment present (2 points), living alone or no help by partner/family possible (1 point), difficulties with transfers in the past six months (1 point), hospitalized within the past three months (1 point) and taking five or more medicines (1 point). A score equal to or higher than 2/6 meant that the patient had a positive geriatric risk profile. The lowest possible score was 1 as each participant received 1 point for polypharmacy.

The data on medication management capacity were collected using the Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE)²⁷. This validated instrument consists of three areas important for proper medication management: (1) medication knowledge (8 questions), (2) functional ability to take medication (5 questions) and (3) obtaining medication (6 questions). MedMaIDE items were dichotomous responses that could be scored Yes (0) and No (1), respectively. Although the MedMaIDE is comprised of 19 items, only 13 items were used to calculate the deficiency sub scores (per area) and the overall deficiency score. These 13 items are considered critical by Orwig et al., as they are crucial for the self-management of medication. These consisted of five medication knowledge-related items, five items related to medication-taking ability and three items related to obtaining medication. Therefore, sub scores related to medication knowledge and medication-taking ability ranged between 0 and 5 points while the deficiency sub score related to obtaining medication varied between 0 and 3. The total medication management deficiency score had a maximum of 13. The MedMaIDE uses dichotomous variables to collect data on medication knowledge, which only provides information on whether or not knowledge is present. To gather information on the extent to which a patient has knowledge of his medication, the number of medicines for which the patient knew the name, indication, dose, route of administration and time of intake were noted. Medication knowledge was objectively assessed by research assistants for all the patients' medicines based on the medication

schedule. Patients were not allowed to use their own medication schedule or notes to answer questions related to medication knowledge.

In-hospital medication management (i.e., storing/ preparing/administering medication), discharge policy (i.e., in-hospital preparation for medication self-management and medication-related information at discharge), post-discharge management of side effects by patients, medication changes after discharge and correct medication intake after discharge were surveyed using four- and five-point Likert scales, 10-point rating scales and self-developed multiple-choice questions.

2.4 Data analysis

Data were analysed using SPSS 27.0. Categorical variables were described using frequency distributions while mean and standard deviations were used for continuous variables. The normality of the data was tested using absolute skewness and kurtosis²⁸. The Little's MCAR test was used to assess missing values which were found to be missing completely at random (MCAR)²⁹. Listwise deletion was used to treat missing cases in each sub analysis. Paired analyses were performed to determine the differences in medication management before and after hospitalization using McNemar statistics. The differences between patients who did fully self-manage (preparing and administering medicines independently) and those who did not fully self-manage their medication after discharge, were calculated using parametric statistics (chi-squared tests for nominal and independent t-tests for continuous variables).

To determine which factors influenced medication management deficiencies after hospital discharge, a stepwise logistic regression analysis was conducted. Four binary outcome variables were created: (1) medication management deficiencies in general, (2) medication-related knowledge deficiencies, (3) deficiencies related to medication-taking ability and (4) deficiencies related to obtaining medication. Based on the total deficiency score and sub scores of the MedMaIDE, patients were subdivided into patients with (deficiency score of at least 1) and without deficiencies (deficiency score of 0). First, a univariate analysis was performed to determine which factors were significant predictors of medication management deficiencies. Subsequently, only significant variables from the univariate analysis were included

in the multiple logistic regression. Multicollinearity was assessed using correlation matrices. A p-value < 0.05 was considered statistically significant.

3. Results

3.1 The research population

A total of 469 patients were invited to participate in the survey of which 69 refused (14.7%). Reasons for non-participation were not willing to spend time on research (n = 17), did not want to share personal data (n = 7), did not want a home visit (n = 25), felt too weak/too sick (n = 8), and other reason(s) (n = 7). Ten patients did not want to provide an explanation for non-response.

Four hundred participants completed the survey (85.3%). The characteristics of the research population are shown in Table 2.1. The mean age of the participants was 82 years [SD 5.0] and 53% were women. Only 25% had an educational level higher than level four of the European Qualification Framework³⁰. About half of the sample (49%) spent more than seven days in hospital. Approximately 8% were admitted for medication review. Most of the participants (91%) had a positive geriatric risk profile. The participants had a mean of two chronic diseases and took a mean of nine different prescribed medications at discharge. Moreover, 62% needed support to reside in their own home.

About 81% of patients reported at least one medication change during the six months prior to their last hospital admission. Furthermore, medication changes after hospital discharge were frequent: new medication was started in 58%, medication was stopped in 18%, dose changes occurred in 13% and changes in time of intake occurred in 5% of patients. According to the participants, the main causes for these medication changes included altered health status (74%) and different prescribers (6%).

Table 2.1: Sample characteristics (n = 400).

Patient Characteristics	%	Mean [SD]
Age (years)		81.7 [4.97]
Gender		
Women	52.5	
Men	47.5	
Level of education (EQF ^a) (n = 399) ^b		
None	4.3	
Level 1	21.3	
Level 2/3/4	49.4	
Level 5	11.5	
Level 6	8.0	
Level 7	5.5	
Length of hospital stay		
1 to 3 days	24.5	
4 to 7 days	26.5	
8 to 11 days	21.3	
12 to 15 days	11.5	
≥16 days	16.2	
Reason for hospitalization (multiple answers possible) ^c		
Treatment	63.9	
Examination	26.7	
Observation	13.5	
Medication review	8.4	
Geriatric risk profile (score 0–6) (n = 389) ^b		2.7 [0.95]
Positive geriatric risk profile (≥2/6)	90.7	
Number of chronic diseases		2.1 [1.61]
Number of prescribed medicines at discharge		9.3 [3.38]
Help needed to reside in their own home (n = 396) ^b	62.4	

^a European Qualifications Framework³⁰. ^b Deviating sample size due to missing data (missing completely at random)²⁹. ^c Multiple answers were possible which resulted in a total of more than 100%.

3.2 Medication management before, during and after hospitalisation

About 78% of the patients did fully self-manage their medicines before hospital admission. In hospital, this was only 13%. In 74% of the patients, nursing staff managed all medicines during hospitalization. The remaining 13% received help in preparing their medication but administered them independently. After discharge, 70% did fully self-manage their medication, 27% received help with preparing their medication but self-administered their medicines and 3% received help with preparing and administering medicines at home (See Figure 2.1).

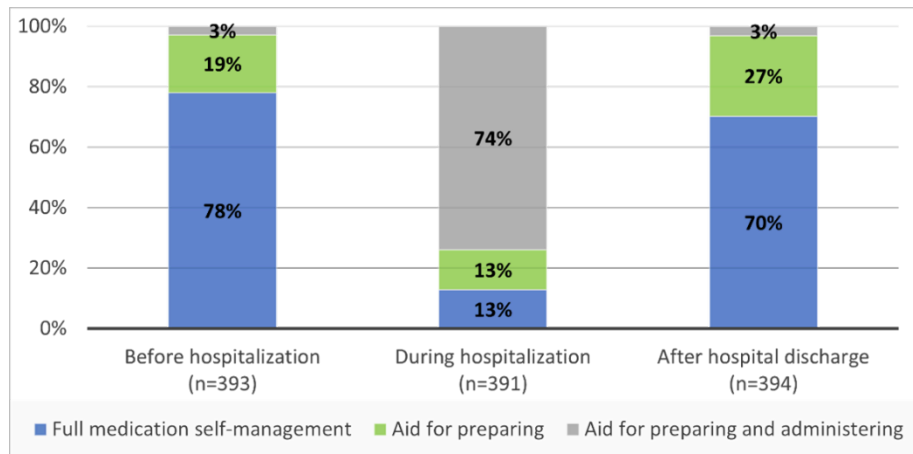


Figure 2.1. Prevalence of medication self-management before, during and after hospitalization.

Comparing medication self-management before and after hospitalization, some patients lost their ability to prepare their medication ($p < 0.001$). Taking medication independently remained unchanged (both 97%). Significantly more participants used aids such as a calendar or a pillbox after hospital discharge (58% vs. 63%, $p < 0.001$).

About 54% of patients indicated they were not prepared or insufficiently prepared during their hospital stay to self-manage their medication at home. Patients who did fully self-manage their medication after discharge were more likely to indicate they were adequately prepared during hospitalization in contrast to those who did not (52.6% vs. 31.0%; $\chi^2 = 4.091$; $p < 0.001$). About 74% had no conversation about how to manage their medication at home. Furthermore, only 26% indicated that they received enough information about medication at time of discharge. Patients were most frequently informed about time of intake (78%) and dose (70%), while only 10% were informed about potential side effects. About 15% received no schedule at all for medication intake after discharge. When a schedule was given to the patient, in addition to the name of the drug, dose and time were indicated in 94% and 98% of patients, respectively. Medication-related information was mostly provided by nursing staff (70%). The participants who did fully self-manage after discharge received information more often from the nursing staff at discharge as compared to those who did not (74% vs. 58%; $\chi^2 = 6.467$; $p = 0.011$) (See Table 2.2).

On average, participants rated their satisfaction with the help received during hospitalization to take their medication correctly after discharge 7.3/10 [SD 2.3]. Nevertheless, 62% had to ask for additional help regarding medication after discharge. Furthermore, 13% indicated it was difficult to take back responsibility for their medication management after discharge. Significantly more patients who found it difficult to take back responsibility did not fully self-manage ($\chi^2 = 42.321$; $p < 0.001$). Medication management assistance should be extended according to 8% of self-managing patients and according to 26% who did not fully self-manage their medicines at home ($\chi^2 = 24.530$; $p < 0.001$). Patients who did fully self-manage their medicines post-discharge were significantly more satisfied with their own medication management after discharge ($t = -7.413$; $p < 0.001$) (See Table 2.2).

Table 2.2. Differences between patients who did fully self-manage medication after discharge and patients receiving help with medication management after discharge.

	Total n = 393	SMM ^a n = 276	No SMM ^b n = 117	p [*]
In-hospital medication management, %				
I did fully self-manage my medicines during hospitalization.	12.8	14.9	7.8	0.053
I am ... in hospital to self-manage my medicines at home.				<0.001
Not prepared	43.6	41.2	49.2	
Insufficiently prepared	10.3	6.2	19.8	
Sufficiently prepared	46.1	52.6	31.0	
I stored my medication in my room during hospitalization. ^c	n = 322 19.6	n = 227 22.9	n = 95 11.6	0.019
I made my own decisions about medication intake during hospitalization. ^c	n = 329 53.8	n = 231 57.6	n = 98 44.9	0.035
Medication-related information at discharge, %				
I had a conversation on how to manage medicines at home.				0.051
Yes	18.7	18.6	18.8	
No	74.2	76.3	69.2	
I don't know	7.1	5.1	12.0	
I received ... information about medication at discharge.				0.006
No	5.6	5.9	5.1	
Too little	31.6	26.5	43.6	
Enough	26.3	26.9	24.8	
Too much	36.5	40.7	26.5	
I received information about ... at discharge. ^{c,d}	n = 267	n = 193	n = 74	
Working area	33.2	34.0	31.0	0.642
Indication	54.0	55.0	51.4	0.603
Dose	69.3	74.1	56.8	0.006
Time	77.9	81.9	67.6	0.012
Side effects	9.6	10.5	7.1	0.412

Table 2.2 (continued). Differences between patients who did fully self-manage medication after discharge and patients receiving help with medication management after discharge.

	Total n = 393	SMM ^a n = 276	No SMM ^b n = 117	p [*]
Information about medication was provided ... ^{c,d}	n = 267	n = 193	n = 74	
Oral	85.8	87.6	81.3	0.189
On paper	55.8	60.1	44.6	0.022
The ... gave me information about my medicines at discharge ^{c,d}	n = 267	n = 193	n = 74	
Physician	40.7	40.8	40.3	0.934
Physician assistant	9.2	8.5	11.3	0.487
Nurse	69.7	74.1	58.1	0.011
Other	2.3	2.7	1.4	0.553
Medication schedule, %				
I received a medication schedule at discharge.				<0.001
No	14.5	15.9	11.2	
Yes and I understand	69.4	78.6	47.4	
Yes and I don't understand	16.1	5.5	41.4	
The ... was mentioned on the medication schedule. ^{c,d}	n = 331	n = 232	n = 99	
Medication name	97.9	97.8	98.0	0.938
Working area	8.3	7.5	10.2	0.422
Indication	20.4	19.8	21.9	0.676
Dose	93.7	96.6	86.9	0.001
Time	97.9	98.7	95.9	0.108
Side effects	0.6	0.0	2.1	0.030
Medication management after discharge, %				
Taking responsibility for my medication management after discharge was.....				<0.001
Difficult	13.0	5.8	29.9	
Easy	87.0	94.2	70.1	
Medication management assistance ...				<0.001
Should be extended	13.0	7.6	25.9	
Should remain the same	83.6	88.4	72.4	
Should be restricted	3.4	4.0	1.7	
I stopped the prescribed therapy earlier than agreed with the physician.	22.7	21.1	26.5	0.242
I changed the way medicines should be taken based on own knowledge/experience (without consultation).	25.4	24.3	28.2	0.413
Patient satisfaction (mean [SD])				
Satisfaction with help during hospitalization to self-manage medication after discharge. (scale 0–10)	7.3 [2.32]	7.4 [2.36]	7.1 [2.23]	0.211
Satisfaction with own medication management after discharge. (scale 0–10)	8.2 [1.88]	8.7 [1.16]	6.9 [2.55]	<0.001

^a SMM: Full self-management of medication after discharge (preparation and administration). ^b No SMM: Help with medication management (preparation and/or administration) after discharge. ^c This question could only be completed under certain conditions which resulted in a smaller sample size. Some patients had to skip this question based on their answer to a previous closed-ended question. ^d Multiple answers were possible which resulted in a total of more than 100%. * p-values were calculated using chi-squared tests for nominal and independent t-tests for continuous variables, p-values in bold: it indicates the significant values.

3.2.1 Correct medication intake after discharge

Two to five days after discharge, almost 23% indicated that they had stopped their prescribed medication therapy earlier than agreed with the physician and 25% changed the way medicines should be taken based on their own knowledge and experience (See Table 2.2). Furthermore, approximately 20% of patients indicated that they sometimes took their medication incorrectly: 9% of them took an incorrect dose and 63% took their medication at the wrong time. The reasons given for not correctly taking medication were forgetfulness (64%), adjusting the medication regimen seems better to the patient (19%), not knowing how to do so (6%), not being able to do so (6%) and not willing to do so (3%).

3.2.2 Management of side effects

Approximately 17% of patients reported that they experienced side effects of their medication after discharge. The most common side effects were nausea/vomiting (28%), followed by dizziness (15%), drowsiness/sedation (14%), constipation (12%) and skin rash/itching (12%). Of the participants who experienced side effects, 23% did nothing while 8% (temporarily) stopped taking their medication. Furthermore, 14% reported side effects to the home care nurse and 55% reported these to the general practitioner.

3.2.3 Medication management deficiencies after discharge

Approximately 90% of patients experienced at least one medication management deficiency after discharge. The deficiency scores are shown in Figure 2.2. Patients had a mean of four different deficiencies in medication management (range 0–10). Most deficiencies were related to medication knowledge (mean 3.1 [SD 1.8]). About 86% experienced at least one knowledge-related deficiency. On average, patients knew the name of the medication for 55% of their prescribed medicines. Furthermore, they could correctly identify the time of intake for an average of 70% of their medicines, the route of administration for 84%, the indication for 62% and the dose for 44% of their medicines. Only 26% of patients knew the name of all the medicines they had to take. Furthermore, 57% of patients could not correctly identify the time of intake for all medicines and 40% could not correctly indicate the route of administration for all medicines. In addition, 66% did not know the indication and 77% did not know the correct dose of all prescribed medicines.

Deficiencies related to the functional ability required to take medication (mean 0.2 [SD 0.6]), as well as deficiencies in obtaining medication (mean 0.4 [SD 0.6]) were less common. However, 2% of patients reported to be unable to fill a glass of water to take their medicines, 11% were unable to open the medication container (e.g., vial, pill box), 4% were unable to bring their medication up to their mouth, 3% were unable to count the number of pills needed and 3% were unable to swallow medication.

In terms of obtaining medication, almost half of patients (48%) did not have all the required medicines available at home after discharge. Furthermore, 31% indicated that they had not required prescriptions and 3% did not know who to contact for a new prescription. In addition, 3% indicated they did not have the resources to obtain medication (e.g., cannot arrange transportation to pharmacy, pharmacy does not deliver medication at home, no help from others to pick up medication).

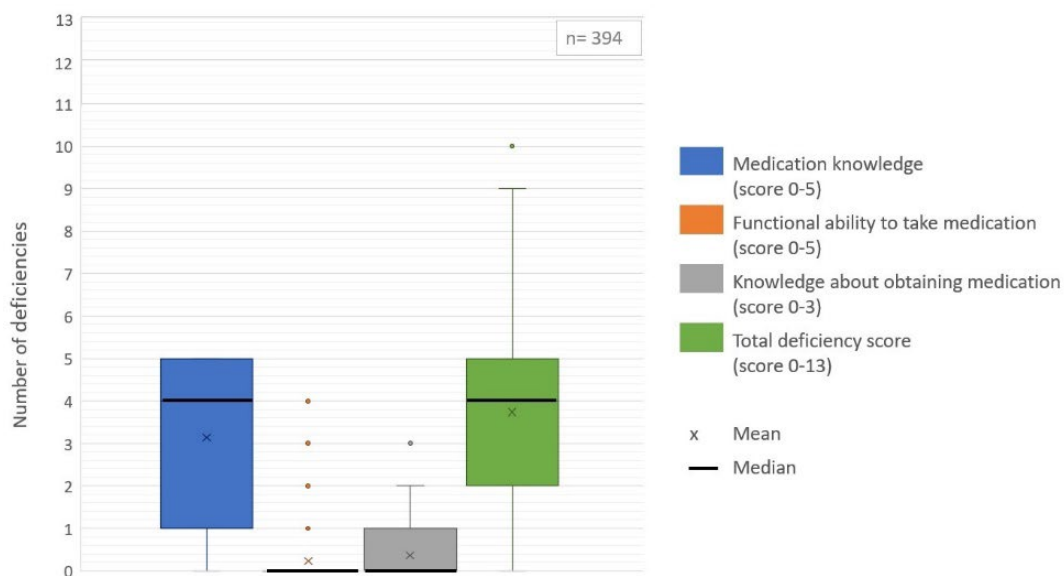


Figure 2.2. Boxplots of medication management deficiency scores

Patients who fully self-managed their medicines after discharge experienced less knowledge-related deficiencies (mean 2.8 [SD 1.9] vs. mean 3.9 [SD 1.5]; $t = 5.924$; $p < 0.001$), less medication-taking ability deficiencies (mean 0.1 [SD 0.3] vs. mean 0.6 [SD 0.9], $t = 6.003$; $p < 0.001$) and, therefore, less medication management deficiencies in general (mean 3.2 [SD 2.1] vs. mean 4.9 [SD 1.9]; $t = 7.642$; $p < 0.001$) compared to those who received help with their medication management after discharge. No differences were found in deficiencies related to obtaining medication ($t = 1.027$; $p = 0.306$).

3.3 Factors influencing medication management deficiencies after discharge

Using a stepwise logistic regression analysis, the factors associated with medication management deficiencies after discharge were studied. Patient and medication management related factors were considered. As shown in Table 2.3, patients experiencing medication management deficiencies took a larger number of medicines at discharge (mean 9.4 [SD 3.4] vs. mean 7.7 [SD 2.5]; $W = 9.212$; $p = 0.002$). Patients with in-hospital medication management performed by nurses experienced post-discharge deficiencies more often in medication management as compared to patients who fully/partially self-managed medication during hospitalization (76.1% vs. 23.9%; $W = 8.518$; $p = 0.004$). Furthermore, patients who were not prepared or insufficiently prepared in hospital to manage medication at home were more likely to have post-discharge medication management deficiencies (OR = 2.00; 95% CI [1.02, 3.94]). In the multiple logistic regression, the number of prescribed medicines at discharge (OR = 1.19; 95% CI [1.05, 1.35]) and in-hospital provision of medication management by a nurse (OR = 2.42; 95% CI [1.21, 4.82]) were found to significantly predict the occurrence of post-discharge medication management deficiencies. This model explained 9% of the variance of the respective outcome ($p < 0.001$).

Furthermore, the factors associated with the different types of deficiencies were studied. No patient or medication management characteristics were found to be significant predictors of deficiencies in obtaining medication. Compared to the multiple logistic regression analysis of medication management deficiencies in general, in-hospital medication management by nurses was no significant predictor of medication knowledge deficiencies. However, patients who were not prepared or insufficiently prepared in hospital had a greater chance of experiencing knowledge-related deficiencies (OR = 2.02; 95% CI [1.12, 3.64]) (See Table 2.4)

Table 2.3. Logistic regression of predictors of medication management deficiencies (general).

	Univariate Analysis ^{a,b}				Multiple Logistic Regression ^e (n = 391)
	Yes ^c	No ^d	p	OR [95% CI]	OR [95% CI]
Number of prescribed medicines at discharge (mean [SD])	n = 354 9.4 [3.42]	n = 40 7.7 [2.52]	0.002	1.22 [1.07–1.38]	1.19 [1.05–1.35]
In-hospital medication management	n = 352	n = 39			
By nurses (%)	76.1	53.8	0.004	2.74 [1.39–5.37]	2.42 [1.21–4.82]
By patients (full/partial) (%)	23.9	46.2		Ref.	
Patient was ... in hospital to manage medication at home	n = 351	n = 39			
Not/insufficiently prepared (%)	55.6	38.6	0.045	2.00 [1.02–3.94]	
Sufficiently prepared (%)	44.4	61.5		Ref.	/

Note: CI = confidence interval; ref = reference, OR = odds ratio; / = these variables were not included in the model. ^a All patient and medication management characteristics were studied in univariate analysis. Only significant variables were presented in this table. ^b Deviating sample size due to missing data (missing completely at random) [29]. ^c Patients with medication management deficiencies after discharge. ^d Patients without medication management deficiencies after discharge. ^e Multiple logistic regression analysis: Nagelkerke R² : 0.086, p < 0.001. Colored background: This ensures uniformity as deviating n-values have a colored background.

Table 2.4. Logistic regression of predictors of medication knowledge deficiencies.

	Univariate Analysis ^{a,b}				Multiple Logistic Regression ^e (n = 390)
	Yes ^c	No ^d	p	OR [95% CI]	OR [95% CI]
Number of prescribed medicines at discharge (mean [SD])	n = 337 9.5 [3.45]	n = 57 7.9 [2.58]	0.001	1.18 [1.07–1.31]	1.17 [1.05–1.30]
Geriatric risk profile (score 0–6) (mean [SD])	n = 330 2.7 [0.96]	n = 53 2.4 [0.87]	0.039	1.41 [1.02–1.95]	/
In-hospital medication management	n = 335	n = 56			
By nurses (%)	76.4	58.9	0.007	2.26 [1.25–4.07]	/
By patients (full/partial) (%)	23.6	41.1		Ref.	
Patient was ... in hospital to manage medication at home	n = 334	n = 56			
Not/insufficiently prepared (%)	56.6	37.5	0.009	2.17 [1.21–3.89]	2.02 [1.12–3.64]
Sufficiently prepared (%)	43.4	62.5		Ref.	

Note: CI = confidence interval; ref = reference, OR = odds ratio; / = these variables were not included in the model. ^a All patient and medication management characteristics were studied in univariate analysis. Only significant variables were presented in this table. ^b Deviating sample size due to missing data (missing completely at random) [29]. ^c Patients with medication knowledge deficiencies after discharge. ^d Patients without medication knowledge deficiencies after discharge. ^e Multiple logistic regression analysis: Nagelkerke R² : 0.076, p < 0.001. Colored background: This ensures uniformity as deviating n-values have a colored background.

As shown in Table 2.5, a multiple logistic regression analysis resulted in a model explaining 18.7% of the variance in deficiencies in medication-taking ability after discharge. Four predictors were found to be significant: increasing age (OR = 1.08; 95% CI [1.02,1.15]), increasing number of chronic diseases (OR = 1.28; 95% CI [1.07,1.54]), the need for help to reside in their own home (OR = 3.83; 95% CI [1.54,9.52]) and making their own decisions about medication intake in hospital (OR = 0.38; 95% CI [0.19,0.75]).

Table 2.5. Logistic regression of predictors of deficiencies in medication-taking ability.

	Univariate Analysis ^{a,b}			Multiple Logistic Regression ^e (n = 310)	
	Yes ^c	No ^d	p	OR [95% CI]	OR [95% CI]
Age (mean [SD])	n = 58 83.2 [5.22]	n = 336 81.5 [4.91]	0.019	1.07 [1.01–1.13]	1.08 [1.02–1.15]
Number of chronic diseases (mean [SD])	n = 57 2.7 [1.78]	n = 315 1.9 [1.55]	0.002	1.30 [1.10–1.53]	1.28 [1.07–1.54]
Number of prescribed medicines at discharge (mean [SD])	n = 58 10.5 [3.93]	n = 336 9.1 [3.24]	0.004	1.12 [1.04–1.21]	/
Gender	n = 58	n = 336			
Men (%)	34.5	48.4	0.045	0.55 [0.31–0.99]	/
Women (%)	65.5	51.2		Ref.	
Help needed to reside in own home (%)	n = 58 82.8	n = 332 58.7	0.001	3.37 [1.65–6.89]	3.83 [1.54–9.52]
Type of hospitalization	n = 58	n = 336			
Unexpected hospitalization (%)	74.1	59.2	0.033	1.97 [1.06–3.69]	/
Planned hospitalization (%)	25.9	40.8		Ref.	
During hospitalization, patient made own decisions about taking medicines, (%)	n = 49 32.7	n = 280 57.5	0.002	0.36 [0.19–0.68]	0.38 [0.19–0.75]
Patient was in hospital to manage medication at home	n = 57	n = 333			
Not/insufficiently prepared (%)	70.2	51.1	0.009	2.26 [1.23–4.14]	/
Sufficiently prepared (%)	29.8	48.9		Ref.	

Note: CI = confidence interval; ref = reference, OR = odds ratio; / = these variables were not included in the model. ^a All patient and medication management characteristics were studied in univariate analysis. Only significant variables were presented in this table. ^b Deviating sample size due to missing data (missing completely at random) [29]. ^c Patients with deficiencies in medication-taking ability after discharge. ^d Patients without deficiencies in medication-taking ability after discharge. ^e Multiple logistic regression analysis: Nagelkerke R² : 0.187, p < 0.001. colored background: This ensures uniformity as deviating n-values have a colored background.

4. Discussion

Medication self-management comprises a wide range of tasks that individuals must successfully perform to correctly follow a prescribed medication regimen. Knowledge, functional skills and behaviors are, therefore, indispensable³. This study demonstrated that geriatric patients with polypharmacy experience various struggles during the process of medication self-management as they were found to have on average four different deficiencies in post-discharge medication management.

The medication self-management process starts with a prescription which has to be filled and picked up³. This study showed a considerable proportion of patients already experience problems at this stage as they do not possess the required prescriptions, do not know who to contact for a prescription or do not have the resources to obtain medication. A study by Marques et al. confirmed that accessing the medication prescribed upon discharge is a hurdle frequently encountered by patients³¹. Being unable to obtain medication jeopardizes the entire medication self-management process. Therefore, prior to hospital discharge, healthcare providers should assess if patients are able to obtain their medicines and if they can rely on (in)formal caregivers to purchase medication^{31, 32}.

In addition to being able to obtain medication, patients should have knowledge and understanding of their medicines that are mandatory to ensure safe and effective use. Yet, this appears to be problematic for geriatric patients with polypharmacy as 86% experienced at least one knowledge-related deficiency. Approximately three-quarters of patients did not know the name or correct dose of their entire set of prescribed medicines and two-thirds did not know the indication of all medicines after discharge. Furthermore, 40% could not correctly identify the administration route of all medicines. This is a high percentage and a somewhat odd result, as most medicines had to be administered orally. Perhaps the phrasing of the question was too complex and patients did not understand what was meant by the administration route. However, inadequate medication knowledge was also addressed in previous research by Romero-Sanchez et al. where only 28% of patients showed adequate knowledge⁷. In our sample, in-hospital preparation was unsatisfactory, which seems to be an important predictor of post-discharge

knowledge deficiencies. Although a medication schedule can be helpful in organizing how and when to take medicines within daily routines, approximately one-third did not understand the medication schedule or did not receive one at all at discharge. Furthermore, more than half of the sample needed to ask for additional help after discharge to take medicines correctly. These results emphasize the need to properly educate patients about medication names, purpose, dose, time of intake, administration route and important side effects prior to discharge³³. Prior to discharge, medication-related information should be given both verbally and in written form³⁴. Nursing staff have a pivotal role in providing such information as they are in contact with patients on a regular basis³⁵.

However, pharmacists can provide discharge counselling and education as well³⁶.³⁷. Since 2007, pilot projects funded by the government have been launched in more than half of the acute Belgian hospitals to implement clinical pharmacy activities, such as medication counselling at discharge³⁷. Furthermore, since 2017, patients with polypharmacy can choose a home pharmacist, i.e., a community pharmacist as a reference pharmacy. The added value of a home pharmacist consists of the individualized support of these patients and the provision of an up-to-date medication schedule^{38, 39}. In their systematic review, Ensing et al. corroborated the important role of pharmacists to secure continuity of care in multifaceted programs across healthcare settings. Still, they also emphasized that close collaboration with physicians and nurses is essential during and after hospitalization⁴⁰. To stimulate collaboration between the general practitioner and the pharmacist to improve the safe and rational use of medication, Medical Pharmaceutical Consultations (MPC) can be organized in Belgium. Hospital physicians and hospital pharmacists can also be involved. The main aim of the MPC is to discuss problems in practice and to provide possible solutions to improve pharmaceutical care provided to patients⁴¹.

Although lacking medication knowledge was the most common deficiency, not being able to take medication might have a larger impact on the medication self-management process as this hinders the act of administering. A small percentage of patients experienced problems such as opening medication packages or swallowing medication. Previous research among older patients showed similar problems^{8, 42}. Healthcare providers should assess patients' competencies to self-

manage medication at home, taking into account not only physical but also mental conditions^{43, 44}. If patients are unable to self-manage their medicines at home, assistance from (in)formal healthcare providers appears to be indispensable.

Considering post-discharge medication management deficiencies in general, in-hospital medication management by nursing staff was a significant predictor. During hospitalization, nurses took over patient's medication management in 74% of cases, resulting in a disruption of the continuity of medication self-management. In daily practice, allowing more patients to self-manage medication during their hospital stay might be beneficial. Preliminary research showed an improvement in self-care competences, medication knowledge, adherence rates, patient satisfaction and patient safety as a result of in-hospital medication self-management^{43, 45, 46}.

According to Bailey et al., problems with medication management may affect medication adherence³. In this study, a significant proportion of patients forgot to take their medicines, took medicines at the wrong time, administered an incorrect dose or were not physically able to take medication (i.e., non-intentional non-adherence). Furthermore, 23% of patients stopped their medication therapy earlier than allowed by their prescription, for example because of side effects (i.e., intentional non-adherence). An interpretation of this high intentional non-adherence rate, two to five days after discharge, should, however, be performed with caution. Participants may have reported medication non-adherence over a longer period rather than only medication non-adherence after hospital discharge. Nevertheless, the study by Mulhem et al. indicated a higher non-adherence rate (43%) 24 to 48 h after hospital discharge⁴⁷. Non-adherence can result in poor health outcomes (e.g., increased mortality, decreased quality of life, loss of productivity), increasing healthcare service utilization and healthcare expenditures⁴⁸⁻⁵². To address medication non-adherence at home, interventions should focus on identifying and addressing the abovementioned deficiencies prior to discharge. Healthcare professionals should improve patients' self-management capacity (i.e., physical and cognitive ability) and should involve the support of (in)formal caregivers if necessary⁶.

4.1 Implications for practice

Healthcare providers should identify and address medication management deficiencies prior to hospital discharge as a strategy to avoid the development of problems at home. Therefore, patients' individual ability to self-manage a medication regimen after hospital discharge should be assessed, taking into account physical and mental conditions. Various tools are available to assess medication management capacity in older adults such as the Drug Unassisted Grading Scale, the MedTake Test or the MedMaIDE⁵³.

If patients appear to be unable to obtain their medicines themselves, several possibilities should be considered in consultation with the patient such as delivery of medicines by a pharmacy, an informal carer or home care nurse who picks up prescriptions/medicines or a regular home visit by the general practitioner to provide the patient with the necessary prescriptions. Prior to discharge, opportunities to address medication-taking ability deficiencies should be explored as well, such as supplying tools designed to help open specific packaging forms⁵⁴.

To address medication knowledge-related deficiencies, healthcare professionals should pay attention to whether geriatric patients understand their medication and intake instructions. Medication self-management support by healthcare providers should be improved. Interventions, such as providing medication related education prior to discharge, should be clearly described in terms of content and frequency as such information is currently lacking ^{45, 46, 55-57}.

Furthermore, allowing more patients to self-manage medicines during a hospital stay would provide an opportunity to sustain continuity in patients' medication self-management process, detect problems related to medication self-management and increase patients' self-management capacity. Healthcare providers (i.e., nurses, pharmacists and physicians) can support patients during this process, providing education and counselling. In-hospital medication self-management, under supervision of healthcare providers, will make patients feel more empowered to self-manage medicines after discharge.

4.2 Strengths and limitations

This is the first study examining home medication experience issues and factors related to medication management deficiencies after hospital discharge in a geriatric population with polypharmacy. This study had a high participation rate as 85% of all eligible patients completed the survey. The impact of the non-response bias is, therefore, rather small. To detect deficiencies in medication management, a validated instrument suited for the elderly was used²⁷.

However, this study had some limitations. Firstly, the use of self-reported data may be subjective to desirability and recall bias. Secondly, although there was an almost equal proportion of male and female participants (47% vs. 53%) which positively affects generalizability of the study results, other demographical variables (e.g., country) and the use of convenience sampling will limit generalizability. Thirdly, the survey was administered by different research assistants. Despite the fact that training was provided on the methodology used to collect data, the uniformity of the data collection may be disputable. Fourthly, patients were questioned about medication changes after discharge. Based on the high prevalence of medication changes two to five days post-discharge, we suspect participants could have misinterpreted this question. It is likely that patients compared medication before and after hospitalization and indicated, based on this comparison, whether there were any medication changes two to five days after discharge. Therefore, we should be cautious about these results. Fifthly, some questions allowed patients to fill in multiple answers, which resulted in multiple dichotomous variables. Instead of defining multiple response sets, each possible answer was treated as a separate dichotomous variable in the analysis and chi-squared tests were used. However, since the answers of the row variables were not completely independent of each other, the chi-square statistic might have inflated. Lastly, we focused on medication management in patients with polypharmacy (i.e., complex pharmacotherapy) without considering the differences in medication management between different medication(classes). This can be seen as a limitation of the study as some medications (classes) are more difficult to manage than others with a possible impact on experiencing medication management deficiencies. Therefore, we recommend that this aspect is included in subsequent research.

5. Conclusions

This study identified problems related to post-discharge medication self-management in geriatric patients with polypharmacy including deficiencies in obtaining medication and medication-taking ability, lack of medication knowledge, non-adherence and disrupted continuity of patients' medication self-management. During hospitalization, healthcare providers should identify and address medication self-management issues. To prevent problems after hospital discharge, in-hospital preparation should be improved to support medication self-management at home.

Author Contributions

Conceptualization, L.M., E.D.B., E.G. and T.D.; Methodology, L.M., E.D.B., E.G. and T.D.; Formal analysis; L.M., Writing—Original Draft, L.M., Writing—Review and Editing, L.M., E.D.B., E.G. and T.D. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of each participating hospital. The Ethics Committee of the Antwerp University Hospital acted as the central Ethics Committee (reference 19/39/431, approved on 28/10/2019).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

Data are available from the corresponding author upon reasonable request.

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Conflicts of Interest

The authors declare no conflict of interest.

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Chapter 3

Beliefs about medication after hospital discharge in geriatric patients with polypharmacy

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Abstract

Objectives

To describe beliefs about medication in geriatric patients with polypharmacy post-discharge and to evaluate the impact of discharge management on patients' medication beliefs.

Methods

A cross-sectional study was conducted between November 2019 and March 2020 in twelve general hospitals in Belgium. Four hundred geriatric patients with polypharmacy were surveyed at hospital discharge and two to five days post-discharge using the Beliefs about Medicines Questionnaire and self-developed questionnaires.

Results

According to participants, the benefits of medication outweighed the disadvantages as the mean necessity score (19.4/25) outweighed the mean concern score (11.9/25). Patients receiving help with medication management post-discharge had stronger necessity-, concern- and overuse-related beliefs. No patient- or discharge management-related factors were significant predictors of medication beliefs.

Conclusions

Assessing patients' medication beliefs and identifying and addressing patients' concerns, can be an opportunity to improve medication use, to prevent non-adherence and to enhance safe medication practices at home.

1. Introduction

Non-adherence is a major health concern, especially in older patients as prevalence rates range between 6% and 55%.¹ Older patients are at higher risk for medication non-adherence due to functional and cognitive decline accompanying aging,² the larger number of prescribed medicines and the complexity of the medication regimen because of multimorbidity and polypharmacy.^{3, 4}

Patients' beliefs about medication are an important determining factor of medication adherence.⁵ Research in patients with chronic conditions showed that negative beliefs about medication are associated with lower medication adherence⁶⁻⁸ and explained 20% of variance of non-adherence in this population.^{9, 10} More concerns about medication use, greater beliefs about overuse of medication by physicians and greater harm-related beliefs (e.g., adverse effects of medicines) are linked to non-adherence, while greater beliefs about the need for medication are related to adherence.^{6, 8-10}

Hospital discharge may lead to changed medication beliefs and may increase the risk of non-adherence, mainly because several changes to the patient's medication regimen may have been introduced during hospitalization but also due to inadequate transfer of information at discharge.^{11, 12} Although after hospital discharge, a subgroup of older patients will receive support from (in)formal caregivers to manage their medication regimen, others will be fully responsible for their medication management.¹³ Since social support seems to be an important determinant of medication adherence,⁵ patients are more vulnerable to improper medication use after hospital discharge if such support is lacking.¹¹

Assessing medication adherence and its hindering factors (e.g., medication beliefs), supporting patient self-management and transition of care coordination have been described as part of nurses' role in pharmaceutical care.¹⁴ The healthcare team, including nurses, is responsible for providing patients with the necessary medication-related information to ensure continuity of pharmaceutical care. Nurses should assess patients' needs, educate patients (e.g., counselling, coaching, patient training), support and empower them before discharge towards home.¹⁴⁻¹⁶ However,

discharge preparation is not always conducted effectively.¹⁷ Hence, we hypothesize that discharge management affects patients' beliefs about medicines.

Several studies investigated the relationship between adherence and respective beliefs about medication expressed by patients.⁶⁻¹⁰ Unfortunately, current studies did not describe beliefs about medication in a geriatric population with polypharmacy recently discharged from hospital. Furthermore, little is known about the impact of discharge management on beliefs about medication post-discharge.

The aims of this study were twofold: (1) to describe beliefs about medication in geriatric patients with polypharmacy after hospital discharge and (2) to evaluate the impact of discharge management on patients' beliefs about medication.

2. Materials and methods

2.1 Design

Between November 2019 and March 2020, a cross-sectional survey study was conducted in geriatric patients with polypharmacy after hospital discharge.

2.2 Setting and participants

A convenience sample of 12 Flemish general hospitals (Belgium) was obtained. Considering the availability of eligible patients, wards within each participating hospital were selected through convenience sampling. A hospital ward nurse evaluated patients' eligibility to participate in the study and served as a liaison between the researchers and the patients. A researcher contacted the hospital wards on a weekly basis to check for eligible patients. Patients had to meet the following criteria: (1) aged ≥ 75 years, (2) polypharmacy at moment of hospital discharge (i.e., ≥ 5 prescribed medicines), (3) being discharged towards home and (4) Dutch-speaking. Exclusion criteria consisted of: (1) patients with a neuropsychiatric diagnosis of dementia, (2) patients with a palliative status, palliative care pathway or palliative file and (3) patients who are incapable of giving consent to participate in a study. During the data collection period, all patients who met the inclusion criteria and consented to participate were included (i.e., consecutive sampling) until the desired sample size was reached. The required sample size consisted of 400 participants due to the maxim $n = 4 \times$ number of

predictors in order to perform a multivariable logistic regression which includes 10 predictors.¹⁸

2.3 Data collection

Between November 2019 and March 2020, patients who met the inclusion criteria were invited to participate in the study. If patients declined study participation, reasons for non-participation were collected. Participants were visited in hospital on the day of discharge and asked to complete a questionnaire on socio-demographic data. Furthermore, the patient's geriatric risk profile was determined, patient's medication schedule was copied, and a home visit was scheduled two to five days after discharge. Data on medication management and beliefs about medication were collected during this respective home visit.

Measurements

The following socio-demographic data were collected describing sample characteristics: gender, age, highest educational level, reason for hospital admission, length of hospital stay and number of chronic conditions. Patients' level of education was classified according to the European Qualifications Framework (EQF).¹⁹ An explanation of the different EQF levels can be found in Appendix 3.1. To collect data about medication use, medication schedules of participants were copied. Furthermore, the Triage Risk Screening Tool was used to calculate patients' geriatric risk profile enabling the detection of geriatric care problems. Therefore, the following elements were scored: polypharmacy (i.e., taking ≥ 5 medications) (1 point), no help by partner or family possible or living alone (1 point), hospital admission in the last three months (1 point), difficulties with transfers in the last six months (1 point) and cognitive impairment (2 points).²⁰ A patient was considered to have a positive geriatric profile if a score of at least 2 out of 6 was observed. Since polypharmacy was an inclusion criterion, all participants already got one point.

Post-discharge beliefs about medications were evaluated using the 'Beliefs about Medicines Questionnaire' (BMQ) which consisted of two parts.²¹ Firstly, the BMQ-Specific scale assesses patients' ideas about their prescribed medication and comprises 10 questions: 5 about the need for prescribed medication (Specific-Necessity) and 5 about the potential negative effects of prescribed medication

(Specific-Concerns). Statements are scored on a 5-point Likert scale from completely disagree (score 1) to completely agree (score 5) with subscale-scores ranging from 5 to 25. Higher scores indicate stronger beliefs. The difference between necessity and concern varies from -20 to +20. An overall positive score means that the benefits (necessity beliefs) of medication outweigh the disadvantages (concerns). Secondly, the BMQ-General scale assesses general ideas about medication and comprises of 8 questions: 4 about the harmful effects of medication in general (General-Harm) and 4 about the excessive use of medication by doctors (General-Overuse). Statements are scored on a 5-point Likert scale. Subscale scores vary between 4 and 20 with higher scores indicating stronger beliefs representing an overall negative perception of medication.

Elements of discharge management (i.e., in-hospital preparation for medication self-management and medication-related information prior to or at discharge) were surveyed using multiple choice questions. To gain insight in post-discharge medication self-management, the following data were collected using multiple choice questions: independently preparing and administering medication, use of aids to take medicines, and whether patients asked for additional help from (in)formal caregivers regarding medication after discharge. In a previous article, a detailed analysis of post-discharge medication self-management in geriatric patients with polypharmacy, problems encountered and related factors was performed.¹³

2.4 Ethical considerations

The research was conducted in accordance with the Declaration of Helsinki. On October 28, 2019, the (central) ethics committee of the Antwerp University Hospital approved the study protocol (Registration number B300201941829). In addition, local ethics approval of each participating hospital was obtained. All participants received study information and gave written informed consent prior to participation.

2.5 Statistical analysis

All analyses were performed using IBM SPSS Statistics V.27.0. Depending on the normality of the data, continuous variables were described using mean (M) and standard deviations (SD) or median and range, while frequency distributions were used for categorical variables. Absolute skewness and kurtosis were used to test

normality of data.²² Pearson correlation was used to determine the relationship between the respective BMQ-subscales. Chi-squared tests and independent T-tests were used to determine differences in beliefs about medication between patients who fully self-managed their medicines after hospital discharge and patients who received help regarding their medication management. Patients were considered as 'self-managing patients' if they prepared and administered their medicines independently. A univariate and multivariable logistic regression analyses were conducted to evaluate whether patient-related factors and factors regarding discharge management were associated with beliefs about medication. Therefore, a dichotomous outcome variable was created based on the BMQ-Specific necessity-concern differential. Patients were categorized as either having positive beliefs (i.e., a positive differential (score 1)) or having negative beliefs (i.e., a negative differential (score 0)) about their medication. Patients with a necessity-concern differential equal to zero were excluded from the analysis given the observation that the number of positive beliefs equalled the number of negative beliefs representing a neutral position towards medication. A two-sided significance level of 0.05 was used.

3. Results

3.1 Sample characteristics

About 14.7% of eligible patients (69/469) were not willing to participate in the study. Several reasons for non-participation were mentioned: 8 patients felt too ill or too frail to participate; 7 patients were not willing to share personal data; 17 patients did not want to spend time on research; 25 patients refused to have a home visit; 2 patients did not want to participate because they did not consider any personal benefit and 15 patients did not explain non-participation.

Four hundred questionnaires were completed (response rate: 84.3%). Participants' characteristics are shown in Table 3.1. Participants were on average 82 years [SD 5.0 year] old and 48% were men. Approximately 75% had an educational level lower than EQF level 5.¹⁹ The length of stay of the current hospitalization was one week or less in 51% of patients. About 8% of patients were hospitalized because of medication review. Patients had a median geriatric risk profile score of 3 out of 6

(range 1 – 6), had a median of two chronic conditions (range 0 – 9) and took on average nine different prescribed medicines at hospital discharge [SD 3.38].

Table 3.1: Participant characteristics (n = 400)

Characteristics		
Age in years	mean [SD]	81.7 [4.97]
Gender (men)	n (%)	190 (47.5)
Highest educational level (n= 399)*	n (%)	
No education		17 (4.3)
EQF level 1		85 (21.3)
EQF level 2 or 3 or 4		197 (49.4)
EQF level 5		46 (11.5)
EQF level 6		32 (8.0)
EQF level 7		22 (5.5)
Geriatric risk profile (GRP) (n= 389)		
Score 0 – 6	median (range)	3 (1 – 6)
Positive GRP ($\geq 2/6$)	n (%)	353 (90.7)
Number of chronic conditions	median (range)	2 (0 – 9)
Number of prescribed drugs at hospital discharge	mean [SD]	9.3 [3.38]
Length of stay in hospital (days)	n (%)	
1 - 3		98 (24.5)
4 - 7		106 (26.5)
8 - 11		85 (21.3)
12 - 15		46 (11.5)
≥ 16		65 (16.2)
Reason for hospital admission (multiple answers possible)	n (%)	
Medication review (n= 394)		33 (8.4)
Observation (n= 394)		53 (13.5)
Examination (n= 393)		105 (26.7)
Treatment (n= 399)		255 (63.9)

* An explanation of the different EQF levels can be found in Appendix 3.1.

3.2 Post-discharge medication self-management

Most patients (70%) managed their medication regimen autonomously after discharge, comprising both the preparation and administration of medication. Furthermore, 27% of patients received assistance with medication preparation only. In 3% of patients, medication preparation and administration was provided entirely by an (in)formal caregiver after hospital discharge.

3.3 Beliefs about medication after hospital discharge

Most geriatric patients with polypharmacy believed that their health, at present and in the future, depends on their medicines (81% and 79%), as well as medicines protecting their health from declining (78%). However, one in four patients was concerned about the danger of dependence, 28% had concerns about long-term effects and 11% about the disruptive effects of medication. One in three patients reported their medicines are a mystery to them and one in five patients found it worrisome they needed to take medication. About 30% of patients believed that doctors rely too much on medicines and 28% indicated that doctors prescribe too many medications. Furthermore, some patients agreed with the statements indicating medicines are harmful (9%), addictive (21%) or poisonous (18%) and should not be taken continuously (14%) (Table 3.2).

3.4 BMQ-subscale scores

The mean necessity score of 19.4 [SD 3.98] reflected an overall strong belief of the need for prescribed medication and outweighs the mean Specific-Concerns score (11.9 [SD 3.78]). The positive necessity-concern differential (M 7.5 [SD 5.09]) implies the benefits of medications outweigh the disadvantages according to participants. About 91.4% had a positive necessity-concern differential, 4.6% of participants had a negative differential and 4% had a differential equal to zero. Furthermore, participants scored on average 9.2 [SD 2.78] on the General-Harm subscale and 11.0 [SD 3.14] on the General-Overuse subscale (Figure 3.1).

3.5 Relationship between BMQ subscales

The more patients were convinced of the need for prescribed medication, the less they believed in medication-related harm ($r = -0.229$, $p < 0.001$) and overuse of medication by physicians ($r = -0.137$, $p = 0.007$). There was a weak correlation between beliefs regarding necessity and concerns ($r = 0.141$, $p = 0.005$). Furthermore, the more concerns patients had about the possible negative effects of prescribed medicines, the more they believed in the harmful effects of medication use ($r = 0.327$, $p < 0.001$) and the more they believed in excessive medication use by physicians ($r = 0.317$, $p < 0.001$). Moreover, a higher score on the beliefs about

harm subscale was associated with a higher score on the beliefs about overuse subscale ($r = 0.568$, $p < 0.001$) (Table 3.3).

Table 3.2: Percentage of Participants Agreeing With ‘Beliefs about Medicines Questionnaire’ Statements

	Total n = 394	SMM ^a n = 277	No-SMM ^b n = 117	Test statistic	p- value
Necessity subscale, n (%)					
My health, at present, depends on my medicines.	320 (81.2)	219 (79.1)	101 (86.3)	$X^2 = 2.845$	0.092
My health, in the future, will depend on my medicines.	313 (79.4)	210 (75.8)	103 (88.0)	$X^2 = 7.523$	0.006
My medicines protect me from becoming worse.	306 (77.7)	215 (77.6)	91 (77.8)	$X^2 = 0.001$	0.972
My life would be impossible without my medicines.	287 (72.8)	196 (70.8)	91 (77.8)	$X^2 = 2.049$	0.152
Without my medicines I would become very ill.	258 (65.5)	173 (62.5)	85 (72.6)	$X^2 = 3.782$	0.052
Concerns subscale, n (%)					
Having to take medicines worries me.	85 (21.6)	57 (20.6)	28 (23.9)	$X^2 = 0.547$	0.460
I sometimes worry about the long-term effects of my medicines.	112 (28.4)	69 (24.9)	43 (36.8)	$X^2 = 5.670$	0.017
My medicines are a mystery to me.	127 (32.2)	67 (24.2)	60 (51.3)	$X^2 = 27.644$	< 0.001
I sometimes worry about becoming too dependent on my medicines.	99 (25.1)	63 (22.7)	36 (30.8)	$X^2 = 2.816$	0.093
My medicines disrupt my life.	45 (11.4)	22 (7.9)	23 (19.7)	$X^2 = 11.160$	0.001
Harm subscale, n (%)					
Most medicines are addictive.	84 (21.4)	60 (21.7)	24 (20.5)	$X^2 = 0.074$	0.786
People who take medicines should stop their treatment for a while every now and again.	54 (13.7)	38 (13.8)	16 (13.7)	$X^2 = 0.001$	0.980
All medicines are poisons.	69 (17.6)	46 (16.7)	23 (19.7)	$X^2 = 0.486$	0.486
Medicines do more harm than good.	34 (8.7)	19 (6.9)	15 (12.8)	$X^2 = 3.664$	0.056
Overuse subscale, n (%)					
If doctors had more time, they would prescribe fewer medicines.	124 (31.6)	78 (28.3)	46 (39.3)	$X^2 = 4.650$	0.031
Doctors place too much trust in medicines.	119 (30.3)	77 (27.9)	42 (35.9)	$X^2 = 2.490$	0.115
Natural remedies are safer than medicines.	89 (22.7)	58 (21.1)	31 (26.5)	$X^2 = 1.366$	0.242
Doctors use too many medicines.	112 (28.4)	77 (27.8)	35 (29.9)	$X^2 = 0.181$	0.670

^a Patients who fully self-manage their medicines after discharge (i.e., preparing and administering medication)

^b Patients receiving full/partial assistance with medication management after hospital discharge.

Beliefs about medication after hospital discharge in geriatric patients with polypharmacy

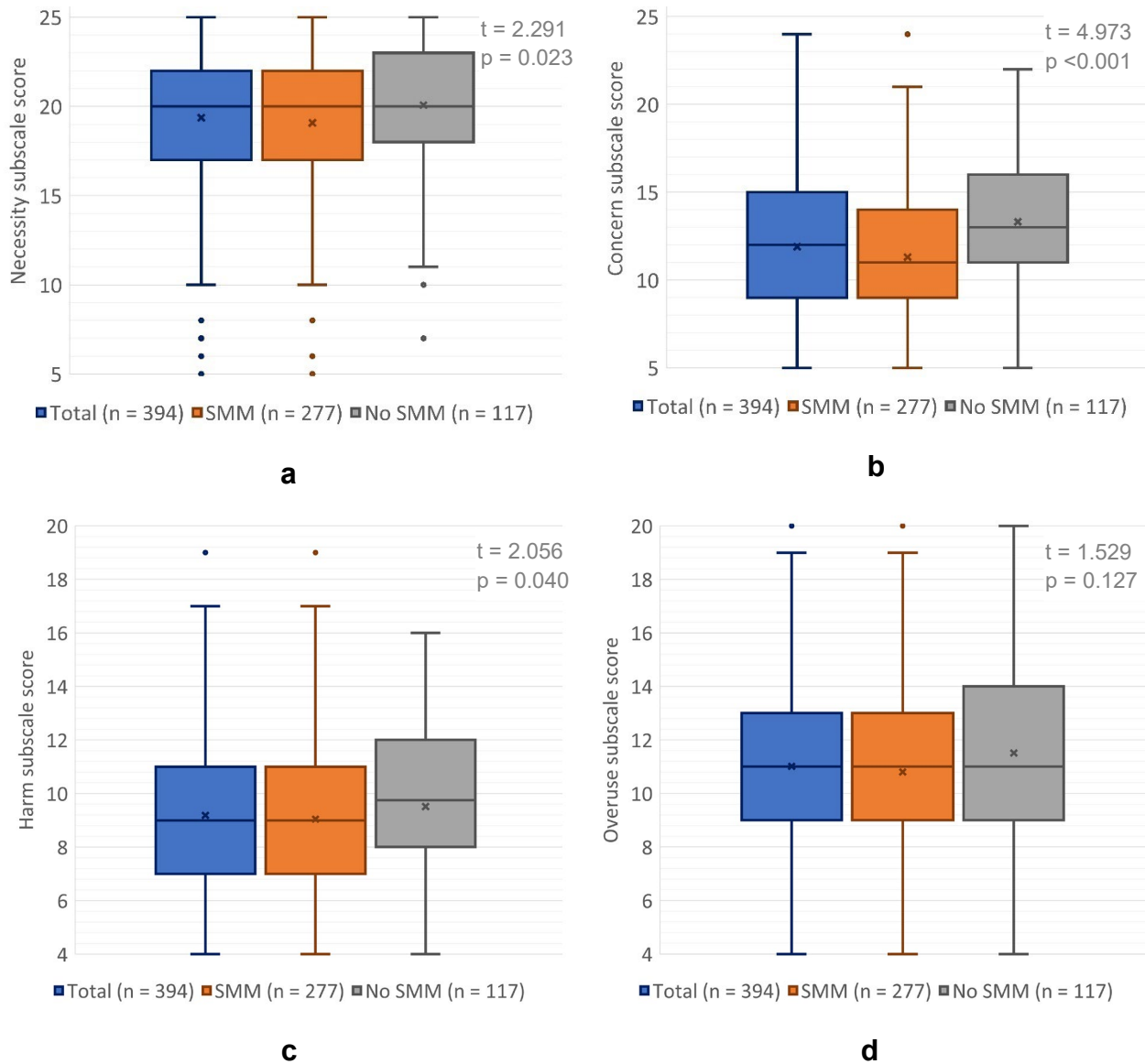


Figure 3.1. Boxplots representing the BMQ-Subscales Scores.

Table 3.3: Correlations between Subscale Scores of the Beliefs about Medicines Questionnaire

	BMQ Necessity	BMQ Concern	BMQ Harm	BMQ Overuse
BMQ Necessity	1			
BMQ Concern	0.141*	1		
BMQ Harm	-0.229**	0.327**	1	
BMQ Overuse	-0.137***	0.317**	0.568**	1

* p = 0.005; **p < 0.001, *** p = 0.007; Pearson Correlation

3.6 Differences in post-discharge beliefs about medication in patients who did and did not self-manage medication

Significantly more patients who received help with their medication management believed that their future health depends on their medication (88% vs. 76%; $X^2 = 7.523$, $p = 0.006$). This group was significantly more concerned about the long-term (37% vs. 25%; $X^2 = 5.670$, $p = 0.017$) and the disruptive effects of medication (20% vs. 8%; $X^2 = 11.160$, $p = 0.001$). About 52% of patients receiving help agreed with the statement about medicines being a mystery, as compared to 24% of patients who fully self-managed their medicines ($X^2 = 27.644$, $p < 0.001$). Significantly less self-managing patients believed that doctors would prescribe fewer drugs if they had more time (29% vs. 39%, $X^2 = 4.650$, $p = 0.031$) (Table 3.2).

Comparison of the subscale scores between the two groups showed that patients who received help with their medication management scored significantly higher on the necessity- (M 20.1, SD 3.66 vs. M 19.1, SD 4.08; $t = 2.291$, $p = 0.023$), concerns- (M 13.3, SD 3.79 vs. M 11.3, SD 3.63; $t = 4.973$, $p < 0.001$) and overuse-subscale (M 11.5, SD 3.02 vs. M 10.8, SD 3.17; $t = 2.056$, $p = 0.040$). This implies stronger post-discharge beliefs about the need for medication, the possible adverse effects and the excessive use of medication, respectively (Figure 3.1).

3.7 Impact of discharge management on beliefs about medication

Data on discharge management are presented in Table 3.4. Only one in four patients indicated they received enough medication-related information at discharge. Patients received the least information on side effects, followed by information on working area and indication. Approximately one third of patients did not discuss the medication schedule with someone and 15% did not receive such a schedule at all. Only 19% of patients had a conversation during their hospitalization on their medication management at home. Less than half of the sample (46%) felt adequately prepared to manage medicines after hospital discharge.

Using a univariate logistic regression analysis, factors associated with positive beliefs about medication after discharge were studied. All patient (See Table 3.1) and discharge management related factors (See Table 3.4) were considered. However, no significant predictors of positive beliefs about medication were found

in this univariate analysis. Consequently, no multivariable logistic regression analysis was conducted.

Table 3.4. Medication-related discharge management.

	n (%)
The patient received information about medication at discharge. (n= 392)	
No	22 (5.6)
Too little	124 (31.6)
Enough	103 (26.3)
Too much	143 (36.5)
The patient received information about ... at discharge. ^{a,b}	
Working area (n= 262)	87 (33.2)
Indication (n= 263)	142 (54.0)
Dose (n= 267)	185 (69.3)
Time (n= 267)	208 (77.9)
Side effects (n= 260)	25 (9.6)
The manner in which the patient received medication-related information. ^{a,b} (n= 267)	
Oral	230 (85.8)
On paper	149 (55.8)
The person who provided the patient with medication-related information at discharge. ^{a,b}	
Physician (n= 263)	107 (40.7)
Physician assistant (n= 260)	24 (9.2)
Nurse (n= 267)	189 (70.8)
The patient had a conversation on how to manage medication at home. (n= 391)	
Yes	73 (18.7)
No	290 (74.2)
I don't know	28 (7.1)
The patient was in hospital to self-manage medication at home. (n= 390)	
Not prepared	170 (43.6)
Insufficiently prepared	40 (10.3)
Sufficiently prepared	180 (46.1)
The patient received a medication schedule at discharge. (n= 392)	
No	57 (14.5)
Yes and I understand	272 (69.4)
Yes and I don't understand	63 (16.1)
The ... was mentioned on the medication schedule. ^{a,b}	
Medication name (n= 331)	324 (97.9)
Working area (n= 324)	27 (8.3)
Indication (n= 323)	66 (20.4)
Dose (n= 331)	310 (93.7)
Time (n= 330)	323 (97.9)
Side effects (n= 318)	2 (0.6)
The patient discussed the medication schedule with someone (yes) ^a (n= 330)	221 (67.0)
The patient received the necessary medication at discharge (yes) (n= 385)	252 (65.5)

^a Some patients had to skip this question based on their answer to a previous close-ended question which resulted in a smaller sample size.

^b Multiple answers were possible which can result in a total of more than 100%.

4. Discussion

We explored medication-related beliefs in a geriatric population with polypharmacy after hospital discharge since beliefs about medicines are linked to patients' motivation to correctly take medicines and sustained use over time. The Necessity-Concern Framework postulates that adherence is, in particular, influenced by perceived personal need for prescribed medications and concerns about the potential adverse effects of taking them.²³

This study showed that most geriatric patients with polypharmacy held strong beliefs about the necessity of medication for maintaining their health now as well as in the future. However, a significant proportion of patients was concerned about the possible negative effects of medication such as long-term effects and the development of medication dependence. Previous studies among patients with multiple chronic diseases showed comparable results.^{9, 24-26} About 5% of patients held mainly negative beliefs and indicated that the concerns outweighed the perceived needs. Elevated levels of concern can pose a threat to treatment adherence, which in turn can jeopardize drug effectiveness and beneficial health outcomes.^{7, 9} In this study, more concerns were associated with greater beliefs about harmful effects and overuse of medication. Therefore, specific attention should be given to addressing patients' concerns.^{6, 24} Although this study could not demonstrate an impact of discharge management on beliefs about medication, previous studies showed that communication with healthcare providers does influence beliefs about medication.^{27, 28} Discussing beliefs about medication and medication adherence with patients should be part of standard clinical care especially in patients taking chronic medicines since improving medication-taking behavior may have a larger impact on clinical outcomes than improvement in treatment.⁷

Taking medicines as prescribed (i.e., being adherent) is a cornerstone of successful treatment. However, nearly 14% of geriatric patients reported to believe that individuals should stop their treatment from time to time. Yet, this refers to adherence beliefs and not to actual behavior. Nevertheless, our previous study in this respective sample showed that almost one in four patients actually stopped their

prescribed therapy earlier than agreed with the physician shortly after hospital discharge.¹³ Other studies showed that about 40% of older patients are found to be non-adherent 48 hours to 1 month after hospital discharge.^{29, 30} To understand and address non-adherence, healthcare providers should consider both patients' perceptual factors (i.e., preferences and beliefs) affecting patients' motivation to start and continue with treatment, as well as practicalities linked to patients' ability to adhere to the prescribed medication regimen.²⁷ Assessing medication adherence and its hindering factors was previously described as part of the nurses' role.¹⁵

Beliefs about the excessive use of medication by physicians were common in geriatric patients with polypharmacy. A few studies reported that individuals with higher trust in their physician were less likely to believe in overuse of medicines.^{28, 31} Although this study did not show any impact of discharge management on medication beliefs, a study by Horne et al. indicated that environmental factors, such as the availability of social support and quality of communication with healthcare providers do influence perceptual factors (i.e., beliefs).²⁷ Therefore, good patient-healthcare professional communication will help patients to form positive beliefs about medicines. Encouraging an open discussion about medicines with patients will ensure that pharmaceutical care is better aligned with patients' values, needs and preferences in turn increasing their trust in the prescriber and his/her prescribing behavior.⁸ To actively involve patients and thus to provide more person-centered care, nurses can rely on existing guidelines on shared decision making about medicines.³²⁻³⁴

4.1 Differences between patients who fully self-managed medicines and those who did not

Patients who received help with their medication management after discharge scored significantly higher on the necessity-, concerns- and overuse-subscale as compared to those who fully self-managed their medicines. Loss of independence and need for assistance after discharge may be associated with functional decline and an impaired health status.³⁵ which may explain the higher perceived need for medication. The higher concern- and overuse-related scores are possibly linked to a lack of being well informed about medicines and their possible effects. A previous

study, performed within the same sample, showed that about half of the patients, who were not fully self-managing their medication, received little to no medication-related information upon discharge, whereas 70% of patients with full self-management received enough or even too much information.¹³ Moreover, the fact that patients receiving help with medication management rely on other caregivers and lose some control can result in more concerns. Care dependent patients may also experience more difficulties understanding information. Although patients are not fully self-managing their medication, they should be involved and appropriately informed about their pharmacological treatment.

It is remarkable that a quarter of those who managed their medicines autonomously reported that their medicines are a mystery to them. We must wonder whether these patients have sufficient knowledge and understanding of their medicines to effectively self-manage their medication regimen. Patients must be properly educated about their medication regimen to be able to take it in a safe and correct manner³⁶ which belongs to the nurses' responsibility.¹⁴ However, medication-related information at discharge seems to be unsatisfactory since not every patient received information, had a conversation about their medicines or received a medication schedule. Discharge counselling and education by nurses should be improved.³⁷⁻³⁹

4.2 Factors associated with beliefs about medication

In our sample, neither patient-related factors nor discharge management factors affected positive beliefs about medication after hospital discharge. However, the group of patients with overall positive beliefs and the group with overall negative beliefs were very unequal in size (360 vs. 18 participants). Almost all participants had predominantly positive beliefs about medication according to the necessity-concern differential. This disparity in group size may have had an impact on the significance of the results since previous studies did show an association between medication beliefs and socio-demographic characteristics (i.e., age, gender, income, level of education and cultural background) as well as clinical factors (i.e., medication use, self-rated health status, chronic diseases).⁴⁰⁻⁴⁴ According to previous research, discharge management-related factors, such as communication about medicines between healthcare provider and patient seemed to have an impact on medication beliefs as well.^{27, 28}

4.3 Implications for practice

Nurses have responsibilities regarding supporting medication management and medication adherence as well as providing medication-related education/information.¹⁴⁻¹⁶ This includes discussing any concerns patients may have related to their medication use. Nurses have the obligation to help patients make informed decisions about medicines and appropriately use prescribed medicines to derive the best effect. Nurses should be aware that patients' concerns about medicines and their perceived need, could affect treatment adherence. Assessing patients' beliefs about medication, as well as identifying and addressing patients' concerns, should serve as an opportunity to improve medication use, to prevent medication non-adherence and to enhance safe medication practices at home.²⁴ Valid and reliable tools are available for nurses to assess patients' medication beliefs, for example by means of the Beliefs about Medicines Questionnaire.²¹

Since the healthcare professional-patient communication appears to be important to form positive beliefs about medicines, an open and honest discussion about the medication regimen with the patient prior to discharge should be encouraged.³² Actively involving the patient in (decisions about) medication enables patients to express doubts and concerns about their medicines and ensures that pharmacotherapeutic care is more attuned to the patients' values, preferences and needs.⁸ However, nurses should provide patients with sufficient and correct information to avoid misconceptions and misplaced concerns and to allow patients to make an accurate assessment of the pros and cons of medicines.⁴⁵ Existing guidelines can be used by nurses to guide this discussion with the patient and to provide patients with the mandatory medication-related information.³²⁻³⁴ Furthermore, techniques such as the use of motivational interviewing and cognitive behavioural therapy have proven to be effective in modifying beliefs about medicines.^{46, 47} These techniques can be used, for example by home care nurses, nurse practitioners or clinical nurse specialists, in situations where the patient is seen on a regular basis and where a more long-term therapeutic nurse-patient relationship exists.^{48, 49} However, as beliefs can change over time, they should be assessed on a regular basis, particularly when changes in a patient's medication regimen occurred.

4.4 Strengths and limitations

To our knowledge, this is the first study examining beliefs about medication after hospital discharge in a geriatric population with polypharmacy, considering differences in patients managing medication independently as compared to patients receiving help with medication management. The chance of participation bias will be rather small as this study had a high response rate of 85%. The instrument used to capture patients' beliefs about medication has been validated and used internationally in a diversity of study populations, including patients afflicted by chronic illnesses. Limitations of this study were the use of a non-probability sampling strategy, which may affect the generalizability of the results, and the use of self-reported questionnaires given the risk of recall and desirability bias. Another potential limitation of the study is the fact that we did not have data on beliefs about medication prior to hospital admission. Therefore, we could not determine whether beliefs had changed because of hospitalization.

5. Conclusions

Geriatric patients with polypharmacy hold some negative beliefs about the responsible use of medication by physicians and the possible harmful effects of medication. However, the majority of polymedicated patients had overall positive beliefs about medication after hospital discharge as they believed that the benefits of medication (necessity) outweighed the disadvantages (concerns). However, patients receiving help with medication management at home reported stronger beliefs about the need for medication, the possible adverse effects and the excessive use of medication as compared to patients who fully self-managed their medication regimen after discharge. No patient- or discharge management-related factors were identified as significant predictors of post-discharge positive beliefs about medication in this sample. Discussing and addressing beliefs and concerns about medication can, however, provide an opportunity for healthcare providers to improve medication use at home and should, therefore, be part of standard clinical care of patients taking polypharmacy.

Availability of data and material

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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Declaration of Competing Interest

None.

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Part II

Refinement and extension of the SelfMED intervention

Chapter 4

Medication literacy and medication self-management: a cross-sectional study in hospitalised patients (65+) with polypharmacy

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Abstract

This study aimed to examine the relationship between medication literacy and the degree to which patients are considered capable of medication self-management, the factors influencing the strength of this relationship and the factors influencing a patient's capability for medication self-management. Between January and April 2022, a cross-sectional survey was conducted on hospitalised patients (65+) with polypharmacy. Medication literacy was evaluated using the MEDication Literacy Assessment of Geriatric patients and informal caregivers (MED-fLAG). The SelfMED assessment determined a patient's capability for medication self-management. The relationship between MED-fLAG and SelfMED was explored with Pearson's *r*. Moderation analysis was used to explore the factors influencing the strength of the relationship between both. Linear regression explored the factors influencing SelfMED scores. In total, 169 patients participated in the study. Patients considered themselves more capable of in-hospital medication self-management (8/10 rating) compared to nurses' and physicians' opinions (6/10 rating). Interactive medication literacy scored higher (mean = 3.0) than functional (mean = 2.9) and critical medication literacy (mean = 2.8). The more medication literacy skills, the more patients were considered able for medication self-management by healthcare providers ($r = 0.630$, $p < 0.001$). Moderation analysis could not reveal any factors that significantly affected the strength of the relationship between both. Age, managing medication independently at home, the number of chronic conditions and medication literacy were significant predictors of a patient's capability for in-hospital medication self-management. This study demonstrated a rather strong correlation between the results of the MED-fLAG and the SelfMED assessment. Hence, SelfMED can be used as a stand-alone first screening instrument to determine a patient's capability for in-hospital medication self-management, without first assessing medication literacy. MED-fLAG can provide valuable insights into the medication literacy of patients considered less capable of managing their medication, allowing medication information and interventions to be tailored to the patient.

1. Introduction

In 2022, more than one fifth (21.1 %) of the population in Europe was aged 65 and over ¹. Global population aging leads to a growing number of people affected by chronic diseases, which represents a major challenge to healthcare systems to meet the healthcare needs of these patients ². To relieve pressure on healthcare systems, patient empowerment and self-management, as part of self-care, are increasingly encouraged ^{3, 4}.

Self-management of medication is a complex self-care activity requiring patients to have knowledge, skills and behaviours to manage a medication regimen as prescribed ⁵. However, research showed that older patients often experience their medication self-management as difficult ⁶⁻⁸. Elderly, in particular, are more likely to experience problems with medication self-management due to functional and cognitive decline ⁹ as well as pharmacokinetic and pharmacodynamic changes making them vulnerable to adverse events ¹⁰. In addition, aging increases the risk of polypharmacy (i.e., concurrent use of five medications or more) ¹¹ which is associated with a higher number of medicines, a more complex medication regimen and drug-related problems such as side effects, interactions and medication errors¹². Furthermore, older adults living with chronic conditions are more frequently hospitalised and exposed to medication changes during their hospital stay: rather than being simplified, medication regimens are often made more complex, dosages are changed and new medicines are initiated which in turn complicate medication self-management post-discharge ^{13, 14}.

Research showed that medication self-management is worse in patients with low health literacy skills ¹⁵⁻¹⁹. Medication literacy, as derived from health literacy, is indispensable for proper medication self-management. Medication literacy was recently defined as ‘the degree to which older adults can develop and maintain functional, interactive and critical skills’ ^{20, 21}. These skills include, for example, the capacity to comprehend, prepare and self-administer medicines (functional skills), the capacity to actively engage with healthcare professionals, communicate concerns and participate in decision-making (interactive skills), as well as the capacity to seek reliable medication-related information, gain control over

medication management and address problems appropriately (critical domain) ²⁰. To gain insight in medication literacy of older adults, the MEDication Literacy Assessment of Geriatric patients and informal caregivers (the MED-fLAG) was recently developed, and its first measurement properties have been tested ²⁰.

Literature already highlighted the importance of assessing an individual's capacity to manage medication ^{22, 23}, but formal assessment of medication self-management is not routinely performed in clinical practice ²³. Insight into a patient's ability to manage medications whilst in hospital can, however, be used as a resource to tailor interventions to the patient's needs (e.g., arranging help with medication use at home) to enhance the safe and correct use of medication post-discharge. The SelfMED assessment, a stepped assessment performed by a nurse, the patient and the treating physician, has been used to determine the extent to which patients are considered capable for medication self-management, whilst in hospital ²⁴. The SelfMED assessment is a very short and easy scale based on the perception of the patient, nurse, and physician while MED-fLAG is a more comprehensive scale, developed to get in-depth understanding of medication literacy and all its domains.

It remains uncertain whether evaluating medication literacy would contribute to the evaluation of older hospitalised patients' eligibility for self-managing their medication. Nevertheless, our working hypothesis posits a potential relationship between the level of medication literacy, measured by the MED-fLAG and the extent to which a patient can be considered competent in managing their medication independently based on the SelfMED assessment.

The primary objective was to examine the relationship between the medication literacy and the extent to which older patients with polypharmacy (65+) are considered capable for medication self-management during hospital stay. The secondary objectives were as follows:

- (1) to examine the influence of sociodemographic and clinical factors on the relationship between medication literacy and medication self-management.
- (2) to examine the influence of sociodemographic and clinical factors on the extent to which patients are considered capable for medication self-management.

2. Methods

2.1 Design

A multicentre quantitative, cross-sectional survey study was conducted in hospitalised patients (65+) with polypharmacy.

2.2 Setting, participants and sample size

Patients were recruited from an internal medicine ward, a cardiology ward, two oncological wards, a geriatric ward and a surgical ward at two hospitals in the Netherlands. All eligible patients admitted to the participating wards between January and April 2022 and willing to participate were included (i.e., consecutive sampling). Eligibility was considered by the (head)nurse based on the following criteria: being at least 65 years old, polypharmacy at hospital admission (i.e., daily intake of at least 5 chronic medicines) and speaking Dutch. Patients with a neuropsychiatric diagnosis of dementia and patients incapable of providing consent to participate in the study were excluded.

Power calculation showed that, to detect a significant Pearson correlation of at least $r = 0.3$ between the level of medication literacy and the patients' capacity to self-manage medication, with a power of 0.80, and a type I error rate of 0.05, a minimum sample of 84 patients would be needed. However, multiple regression requires higher sample sizes. According to the guideline by Tabachnick and Fidell, the sample size should be greater than 50, plus 8 times the number of predictors²⁵. Considering 11 predictors (i.e., 11 socio-demographic factors), a sample size of at least 138 patients is needed.

2.3 Data collection

After obtaining signed consent from the participants, they were included in the study. Patients refusing to participate were asked to fill out a nonresponse form. Patients were asked to complete a paper-based survey consisting of three parts: (1) self-developed questions on sociodemographic characteristics, (2) the MEDication Literacy Assessment of Geriatric patients and informal caregivers (MED-fLAG) to measure medication literacy and (3) the patients' self-assessment (SelfMED) to assess the own capacity to self-manage medication during hospitalisation. The

nurse and the attending physician were asked to carry out an assessment of the patients' ability to manage their in-hospital medication, using the SelfMED instrument.

Measurements

The following sociodemographic characteristics were collected to describe the research population: age, gender, highest level of education, living situation, help from others, type and reason for hospitalisation, length of hospital stay, number of chronic conditions and number of medicines per day. The European Qualifications Framework (EQF) was used to classify patient's level of education ²⁶.

The MED-fLAG was used to evaluate the patient's medication literacy skills ²⁰. The MED-fLAG is a patient-reported outcome measure with evaluative application for prescribed and nonprescribed medicines, irrespective of the galenic form. The MED-fLAG consists of 56 items in three domains: (1) functional medication literacy (22 items), (2) interactive medication literacy (13 items), and (3) critical medication literacy (21 items) ²⁰. The scoring options are graded as follows: a) level of difficulty (Likert scale from 4 = not difficult at all to 1 = very difficult/impossible) and b) frequency of actions (Likert scale from 4 = always to 1 = never) ²⁰. Higher MED-fLAG scores indicate higher medication literacy skills.

The 56-item MED-fLAG was originally developed in the French language and tested for its content validity ²⁰. A proficient bilingual speaker translated from French to Dutch. The Dutch version was then back-translated by a native French speaker from the University of Antwerp's language institute, which led to minor wording adjustments. Subsequently, the Dutch translation of the MED-fLAG was used to collect data.

The SelfMED assessment is an assessment tool evaluating patients' eligibility for in-hospital medication self-management, originally developed in Dutch language ²⁴. The assessment has been validated by healthcare providers and through a multidisciplinary expert meeting. The questions of the nurse assessment were tested for interrater reliability ²⁴. Subsequently, the assessment was pilot tested in a hospitalised patient population taking chronic medicines ²⁷. In the current study, the SelfMED assessment was used as originally developed and consists of three parts:

- (1) A nurse assessment: It is a ten-statement assessment based on the information obtained during the intake or information available in the patient's file. Nurses had to indicate whether they agreed or disagreed with the statements from the assessment and whether there was a contraindication for medication self-management. At the end of the assessment, the nurse formulated an advice for the treating physician about the patients' capability to self-manage medication (capable or not). Furthermore, the nurse indicated on a ten-point scale the extent to which the patient is capable.
- (2) A patient self-assessment: The questions in the assessment comprised current medication management at home (1 item), the patient's willingness to self-manage medication in hospital (1 item) and the patient's medication adherence at home (7 items). On a ten-point scale, participants had to indicate the extent to which they believe they are capable to self-manage their medicines during hospitalisation (1 = absolutely not capable, 10 = fully capable).
- (3) A physician assessment: The treating physician indicated if the patient was capable to self-manage medication during hospitalisation (yes/no) and the extent to which the patient was capable (ten-point scale). Both the nurse's assessment and the patient's assessment were available to make an informed decision.

Normally, the stepped SelfMED assessment is used to decide whether in-hospital medication self-management is allowed or not. However, this study was limited to performing the assessment and did not involve actual in-hospital medication self-management by the patient.

2.4 Data analysis

The data collected were entered into Excel. Subsequently, data were analysed using IBM SPSS Statistics Version 28.0. For descriptive statistics, continuous variables (MED-fLAG scores, SelfMED scores, age, length of hospital stay, number of chronic conditions and number of medicines per day) were expressed as mean and standard deviation (SD) or median and range, depending on the distribution. The categorical variables (i.e., gender, level of education, living situation, help from others, type and reason for hospitalisation, assessment of medication self-management by patients and nurses using statements) were expressed in relative

and absolute frequencies. Normality of the distribution was assessed using Z-scores²⁸.

Utilising the Pearson r test, inferential statistics were applied to explore the relationship between medication literacy scores and the extent to which patients were considered capable of medication self-management during hospital stay. Using moderator analysis, the factors influencing the strength of the relationship between MED-fLAG and SelfMED were explored. Sociodemographic characteristics were considered as potential moderator variables. Standardised values were created. Subsequently, interaction terms were calculated by computing the product between the independent (MED-fLAG) and the moderator variable. Lastly, a linear regression analysis was conducted to test the interaction effect.

Using linear regression analysis, the factors associated with the extent to which patients are considered capable of medication self-management (dependent variable) were studied. Patients' medication self-management capacity here refers to the mean score of the physician's and nurse's rating, considering this score is likely to be more objective than the patient's score. Sociodemographic characteristics of the respondent and medication management-related factors (i.e., number of medicines, medication management at home) were considered. In preparation of the regression analysis, the relationship between these factors and the dependent variable was described using independent t-test and Spearman's rho correlations. Afterwards, a univariate analysis was performed to determine which factors were significant predictors of the extent to which patients are considered capable of in-hospital medication self-management. Subsequently, only significant variables from the univariate analysis were included in the multiple linear regression using enter-method. A two-sided p value < 0.05 was considered significant.

2.5 Ethics

This study was conducted in accordance with the Declaration of Helsinki²⁹. All individuals signed an informed consent form. The research protocol was approved by the ethics committee of both participating hospitals (ID 2021.075 and ID 2021-3023).

3. Results

3.1 Characteristics of the research population

Of the 193 patients invited to participate in the study, 169 completed the survey (response rate 87.6%). Reasons for nonparticipation were as follows: too sick/too tired ($n = 6$; 25%), not willing to share personal data ($n = 4$; 16.7%), not willing to spend time on research ($n = 3$; 12.5%), research is too difficult ($n = 3$; 12.5%), not interested in participating in research ($n = 2$; 8.3%), participating is too much of an effort ($n = 1$; 4.2%) and not willing to sign informed consent ($n = 1$; 4.2%). Three patients did not want to provide a reason for nonresponse.

Participants' mean age was 76 years, with 57% being male and 49% having attained an EQF educational level of 5 or 6. Most of the participants (69%) were admitted to the hospital without prior planning, and roughly half had hospital stays lasting 2 to 3 days. The main reason for hospitalisation was treatment (50%) followed by observation (17%). Only 6% were admitted due to medication review. Most participants (76%) indicated that they take 5 to 10 medicines each day. Participants' characteristics are shown in Table 4.1.

3.2 Medication literacy scores

Patients scored on average 2.9 (SD = 0.69) out of a four-point Likert scale on the MED-fLAG. The interactive domain scored highest ($M = 3.0$, SD = 0.79), followed by the functional ($M = 2.9$, SD = 0.76) and critical domains of medication literacy ($M = 2.8$, SD = 0.68). Analysis of the individual items included within the MED-fLAG instrument can be found in Appendix 4.1.

Table 4.1: Sample characteristics (n = 169)

Characteristics		n (%)
Gender	Male	97 (57.4)
	Female	72 (42.6)
Highest education level (EQF*)	EQF level 1	21 (12.4)
	EQF level 2/3/4	65 (38.5)
	EQF level 5/6	82 (48.5)
	EQF level 7	1 (0.6)
Living alone	Yes	57 (33.7)
Help needed to reside at home	Yes	107 (63.3)
Type of hospitalisation	Planned	52 (30.8)
	Unplanned	117 (69.2)
Reason for hospitalisation	Treatment	83 (49.1)
	Observation	28 (16.6)
	Surgery	24 (14.2)
	Examination	24 (14.2)
	Medication review	10 (5.9)
Type of hospital ward	Oncology	59 (35.0)
	Cardiology	39 (23.1)
	Geriatrics	31 (18.3)
	Surgical ward	25 (14.8)
	Internal medicine	14 (8.3)
Length of hospital stay	2 – 3 days	85 (50.3)
	4 – 7 days	54 (32.0)
	> 7 days	30 (17.8)
Number of medicines per day	< 5 medicines	2 (1.2)
	5 – 10 medicines	129 (76.3)
	> 10 medicines	36 (21.3)
	Don't know	2 (1.2)
		Median (min-max; IQR)
Age		76 (65 – 101; 9)
Number of chronic conditions		2 (0 – 5; 1)

* European Qualifications Framework²⁶; level 1: primary education, level 2: lower secondary education, level 3: upper secondary vocational education, level 4: upper secondary education, level 5: associate's degree, level 6: bachelor's degree, level 7: master's degree

3.3 Patients' capacity to self-manage medication

The results of the patients' self-assessment are shown in Table 4.2. The majority of participants (67%) self-managed their medication completely independently at home. About 58% indicated their willingness to self-manage medication during hospitalisation. Patients rated their ability to self-manage medication in-hospital on average 8/10.

Table 4.2: Patient self-assessment (N = 169)

		%		
Medication management at home	Completely independent	66.9		
	Help with organization and preparation, independent administration	30.1		
	Help with organization, preparation and administration	3.0		
Willingness to self-manage medication in hospital (n = 167)	Willing	58.1		
	Not willing	41.9		
		Mean $\pm$ SD [range]		
Self-rated ability to self-manage medication in hospital (n= 128)		8.1 $\pm$ 1.57 [1 – 10]		
		%		
Statements regarding medication adherence (n= 128)	Never	Sometimes	Often	Always
Forgot to take medicines	76.6	23.4	0.0	0.0
Not taking medicines for other reasons than forgetting	82.0	18.0	0.0	0.0
Stopped taking medicines without reporting to a physician	89.8	9.4	0.8	0.0
Not taking medicines on vacation	92.2	7.0	0.8	0.0
Stopped medicines use when feeling better	86.7	11.7	1.6	0.0
Difficulties to stick to the treatment schedule	90.6	9.4	0.0	0.0
Difficulties to remember medication taken	89.1	10.9	0.0	0.0

Results of the nurse assessment are shown in Figure 4.1. Most patients were considered physically and mentally capable by nurses for in-hospital medication self-management, respectively, 75% and 78%. The statements that nurses most often disagreed with were related to the patient's capability to administer and prepare medication at home after discharge and the ability of patients to manage treatment, respectively, in 28% and 26% of the cases.



Figure 4.1: Nurse assessment regarding medication self-management by patients during hospitalisation

The patients' self-rated ability to self-manage medication in hospital was on average higher (mean score 8/10 [SD 1.57]) compared to the nurses' rating (mean score 6.3/10 [SD 2.71]) and physicians' rating (mean score 6/10 [SD 2.93]) (Figure 4.2).

However, the patients' self-rated ability to self-manage medication during hospitalisation correlated significantly with the nurses' rating (Spearman's $r = 0.425$, $p < 0.001$) and with the physicians' rating (Spearman's $r = 0.383$, $p < 0.001$). Furthermore, there was a strong relationship between the rating of the nurse and physician regarding the patient's ability to self-manage (Pearson's $r = 0.821$, $p < 0.001$).

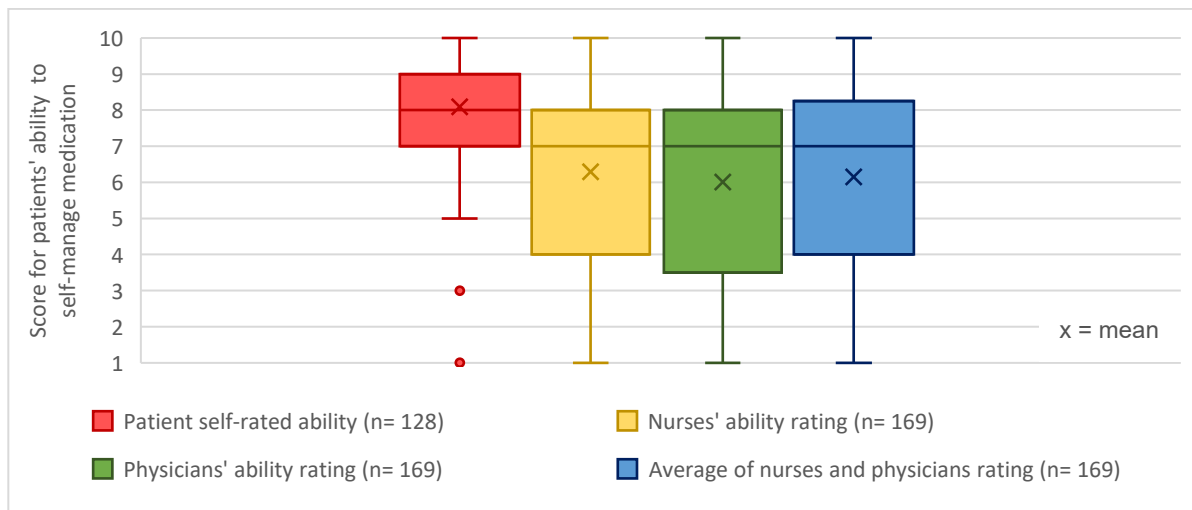


Figure 4.2: The extent to which a patient is considered capable for medication self-management during hospitalisation

3.4 Relationship between medication literacy and medication self-management

There was a strong positive correlation between patients' medication literacy skills and the extent to which patients are considered capable to self-manage their medication during hospitalisation according to nurses and physicians (Pearson's $r = 0.639$, $p < 0.001$) (Figure 4.3). Patients' ability for medication self-management most strongly correlated with the functional medication literacy domain (Pearson's $r = 0.630$, $p < 0.001$), followed by correlation with the interactive domain (Pearson's $r = 0.590$, $p < 0.001$) and the critical domain (Pearson's $r = 0.582$, $r < 0.001$). The more medication literacy skills showed by patients completing the MED-fLAG, the

more patients were considered capable of self-management of medication as estimated by healthcare providers using SelfMED.

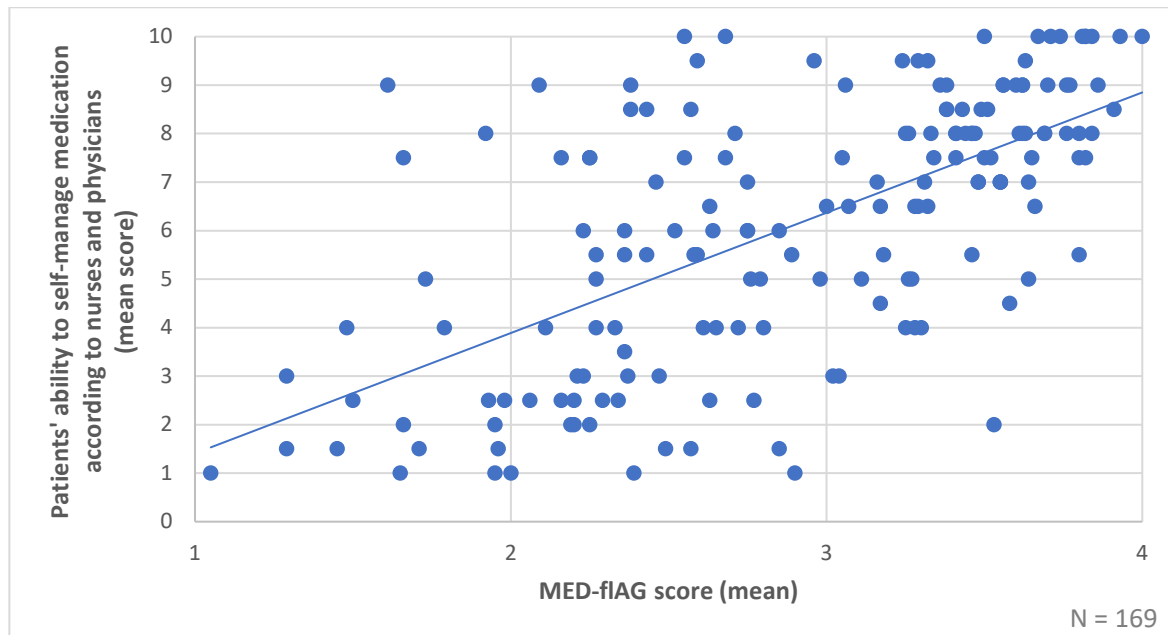


Figure 4.3: Scatterplot of the relationship between medication literacy skills (MED-fLAG) and patients' medication self-management capacity

3.5 Factors influencing the strength of the relationship between MED-fLAG and SelfMED

Table 4.3 shows that 48.2% of participants fell in the same quartile for both SelfMED and MED-fLAG. For 39.6% of participants, SelfMED results are located one quartile higher or lower than MED-fLAG results. Moderation analysis could not identify any factors that significantly influenced the strength of the relationship between MED-fLAG and SelfMED. Age, education, gender, living situation, type of hospitalisation, the number of medications and the number of chronic conditions did not appear to be moderator variables.

Table 4.3: Percentage of patients classified by MED-fLAG and SelfMED quartiles (N = 169)

	MED-fLAG < 25%	MED-fLAG 25% - 49%	MED-fLAG 50% - 75%	MED-fLAG > 75%	Total
SelfMED < 25%	14.5%	6.6%	0.0%	0.6%	21.7%
SelfMED 25% - 49%	5.4%	10.8%	8.4%	2.4%	27.1%
SelfMED 50%-75%	3.0%	3.0%	10.2%	9.6%	25.9%
SelfMED > 75%	1.2%	4.0%	6.6%	12.7%	25.3%
Total	24.1%	25.3%	25.3%	25.3%	100%
	Results fall within the same quartile.				
	Results differ by one quartile.				
	Results differ by more than one quartile.				

3.6 Factors influencing the extent to which patients are considered capable of medication self-management

Detailed results are shown in Table 4.4. Significant differences in the extent to which patients were considered capable of medication self-management were observed. Higher scores were observed in patients who worked in healthcare (7.8/10 vs. 5.9/10, $p = 0.003$), in patients who took 10 chronic medicines or less (6.4/10 vs. 5.2/10, $p = 0.013$) and in participants who self-managed medication completely independent at home (7.3/10 vs. 3.8/10, $p < 0.001$). Furthermore, higher scores regarding medication self-management capacity were associated with lower age ($r = -0.335$, $p < 0.001$), less chronic medicines ($r = -0.254$, $p < 0.001$) and higher medication literacy skills ($r = 0.639$, $p < 0.001$). The multiple linear regression model explained 57.1% of the variance in the patients' medication self-management capacity score with medication self-management at home, age, number of chronic conditions and MED-fLAG scores as significant predictors.

Table 4.4: Influencing factors of the extent to which patients are considered capable of medication self-management (N = 169)

Variables	Descriptive analysis		Univariate linear regression		Multiple linear regression (n= 169, Adjusted R ² = 0.571, p < 0.001)			
	Mean score medication self-management capacity (.../10) *	Independent t test p-value	B	Beta	p-value	B	Beta	CI 95% B (lower) CI 95% B (upper) p-value
Gender								
Male (n = 97)	6.2	0.425	-0.052	-0.010	0.901			
Female (n = 72) - ref.	6.1							
Education								
≥ than EQF level 5 (n = 83)	6.0	0.541	-0.255	-0.048	0.539			
< than EQF level 5 (n = 86) – ref.	6.3							
Worked in health care								
Yes (n = 19)	7.8	0.003	1.909	0.225	0.003			
No (n = 150) – ref.	5.9							
Living situation								
Cohabitation (n = 112)	6.1	0.877	-0.068	-0.012	0.877			
Alone (n = 57) – ref.	6.2							
Help needed to reside at home								
Yes (n = 107)	5.5	<0.001	-1.690	-0.304	< 0.001			
No (n = 62) – ref.	7.2							
Type of hospitalisation								
Unplanned (n = 117)	6.2	0.820	0.103	0.018	0.820			
Planned (n = 52) – ref.	6.1							
Reason for hospitalisation								
Medication review (n = 10)	6.9	0.364	0.799	0.070	0.364			
Other reason (n= 159) – ref.	6.1							

*Mean score of the physician' s and nurse' s ratings of a patient' s medication self-management capacity.

Table 4.4 (continued): Influencing factors of the extent to which patients are considered capable of medication self-management (N = 169)

Variables	Descriptive analysis		Univariate linear regression		Multiple linear regression (n= 169, Adjusted R ² = 0.571, p < 0.001)			
	Mean score medication self-management capacity (.../10) *	Independent t test p-value	B	Bèta	p-value	B	Bèta	CI 95% B (lower) CI 95% B (upper)
Number of chronic medicines								
≤ 10 medicines (n = 131)	6.4	0.013	-1.241	-0.191	0.013			
> 10 medicines (n = 36)	5.2							
Medication self-management at home								
Completely independent (n = 113)	7.3	< 0.001	3.466	0.608	< 0.001	1.667	0.293	0.965 2.369
Help with preparing and/or administering (n = 56) – ref.	3.8							< 0.001
	Spearman correlation	Rho						
Age (n = 169)	-0.335	< 0.001	-0.134	-0.366	< 0.001	-0.075	-0.205	-0.114 -0.036
Number of chronic conditions (n = 169)	-0.254	< 0.001	-0.683	-0.278	< 0.001	-0.532	-0.217	-0.794 -0.270
	Pearson correlation	P-value						
Mean medication literacy score [1 - 4] (n= 169)	0.639	< 0.001	2.479	0.639	< 0.001	1.626	0.419	1.155 2.097
								< 0.001

*Mean score of the physician' s and nurse' s ratings of a patient' s medication self-management capacity.

4. Discussion

The first step to guide and support patients towards appropriate medication self-management is to assess the extent to which a patient is capable to self-manage medication ^{22, 23}. Medication literacy is, thereby, considered an important aspect for the performance of proper medication self-management. The main goal of this study was to explore the relationship between medication literacy and medication self-management. Findings suggest higher scores in interactive medication literacy, than in the functional and critical domains. For medication self-management, patients considered themselves more capable of in-hospital medication self-management than what perceived nurses and physicians. Finally, a strong positive association between medication literacy and medication self-management was found; the more medication literacy skills, the more patients were considered capable of medication self-management by healthcare providers. Age, managing medication independently at home, the number of chronic conditions and medication literacy were significant predictors of a patient's capability for in-hospital medication self-management.

Medication literacy was explored using the recently developed MED-fLAG ²⁰. Since no previous studies published assessment of medication literacy with this scale, it is therefore difficult to compare our findings with other study populations. Nevertheless, the functional domain of MED-fLAG covers the basic knowledge about medication allowing patients to prepare, self-administer and monitor the effects of their therapy ²⁰. In this regard, difficulties reported by the study participants are comparable to previous findings, showing substantial knowledge deficits in older patients concerning their medication. Congruent with our study, these include failing to recall the medication names, the reasons, the dosages, the times of administration, the treatment durations, the side effects and the precautions ³⁰⁻³⁸.

Interactive medication literacy had the highest score. In contrast to several other studies ^{39, 40}, participants in the current study reported low difficulties to actively interact with healthcare providers and providing medication-related information (i.e., problems, preferences).

The critical domain of medication literacy, which refers to the strategies initiated to keep control over the medication management and the actualisation of medication-related knowledge from reliable sources of information, had the lowest score. The critical domain of medication literacy encompasses the degree to which patients can update medication-related knowledge from reliable sources²⁰. In this regard, the package insert is the officially approved document to provide relevant and reliable information about the medication. However, participants in the current study indicate to not read the package insert often, which is congruent with previous research⁴¹. In today's digital era, people are using internet to access health-related information and make decisions⁴²⁻⁴⁴. With the perspective to support patients in using online medication-related information, healthcare professionals should consider supporting the patients to find quality and reliable online information, particularly among patients who show low digital health literacy^{43, 45}.

The extent to which patients were considered capable of in-hospital medication self-management was explored using SelfMED. In the SelfMED self-assessment, a patients' motivation is one of the elements taken into account when considering the ability to self-manage medication⁴⁶. About 60% of patients would be willing to self-manage medication whilst in hospital. However, a previous study in hospitalised patients showed a higher willingness rate of 84%⁴⁶. This may be due to a different study population: the current study focussed specifically on the hospitalised elderly with polypharmacy and not on the hospitalised general population.

It is noteworthy that patients considered themselves more capable of medication self-management compared to healthcare providers' assessment. We have to wonder whether patients overestimate their own ability to self-manage medication as several studies already showed that patients often encounter problems with medication management^{5-8, 47, 48}. This emphasizes that medication self-management assessment tools should not rely solely on patient self-assessments and highlights the added value of a stepped assessment that includes healthcare providers' perspectives (i.e., SelfMED).

The current study showed that the more medication literacy skills patients have according to the MED-fLAG, the more patients are considered able to self-manage

medication, assessed by SelfMED, or vice versa. Thus, this study confirmed our hypothesis that there is a relation between both scores. Given the rather strong relationship between the two scores, it seems that SelfMED can be used as the first screening instrument to determine a patient's eligibility for in-hospital medication self-management, without first assessing medication literacy. However, if patients are considered less capable of medication self-management, the MED-fLAG can be of added value to provide more insight into medication literacy skills. Insight into these skills can help healthcare providers better tailor medication-related information and interventions to each patient's level.

SelfMED has the advantage of being a brief instrument, whereby the administrative burden for patients and nurses remains limited (i.e., filling out only 10 statements). Using only one instrument to determine patient's eligibility for medication self-management, rather than two, is more feasible in clinical practice and research, considering the current workload, staff shortages and time constraints. Our study demonstrated that the strength of the relationship between MED-fLAG and SelfMED is not affected by sociodemographic factors such as age, gender, education, etc. Therefore, it is not possible to tailor the additional administration of MED-fLAG to specific target groups based on these results.

This study showed that patients with excessive polypharmacy (taking > 10 medicines) are considered less able to self-manage medication, compared to those who are taking less than 10 medicines. The complexity of the medication regimen associated with excessive polypharmacy probably contributes to this ⁴⁹. Assessing, monitoring and supporting medication management in this group of patients should be, therefore, considered as a priority.

Age seems to be an influencing factor of the extent to which patients are considered able to self-manage medication. Previous research already showed that higher age is associated with lower self-management capacity and lower health literacy ^{8, 50}. Furthermore, independent medication self-management at home appears to significantly predict being considered capable of in-hospital medication self-management. This result seems logic since patients who manage their medicines themselves are assumed to have better skills compared to patients who already

receive support and guidance at home. In addition, as medication literacy is a predictor of the extent to which patients are considered capable for medication self-management, the study proves that medication literacy is an important element of medication self-management.

4.1 Strengths and limitations

A first strength of the study was the high participation rate of 88%. The impact of participation bias is, therefore, rather small. Second, a heterogeneous sample of patients with different profiles was obtained due to the inclusion of patients on five different types of hospital wards, which benefits the generalisability of the results. Thirdly, the SelfMED assessment incorporates not only the patient's perspective to evaluate the extent to which a patient is capable to self-manage medication but also the perspective of the nurse and treating physician, which is likely to be more objective.

Nevertheless, there are some limitations. MED-fLAG is a patient-reported outcome measure which may be subject to desirability bias. However, further psychometric studies are needed to evaluate the measurement properties of MED-fLAG and to reduce the number of items before considering its clinical application. The SelfMED assessment aims to assess the extent to which patients are considered capable of self-management of medication whilst in hospital but does not include a formal assessment of medication management skills as such.

4.2 Implications for Nursing Management

The results in the current study may provide information for planning interventions, offering nurse managers (i.e., head nurses) an opportunity to improve the nursing discharge process, previously described as inconsistent^{51, 52}. Congruent with previous research, our findings suggest that integration of medication intake into the daily routine could be challenging⁶, including maintaining correct medication intake after prescription changes⁵³⁻⁵⁵.

Nurse managers could improve the nursing discharge process by integrating systematic assessment of the difficulties encountered with medication management at home^{7, 56}, and providing individualized interventions (i.e., educational strategies,

simplification of medication prescribing, medication aids) ^{57, 58}. In this regard, nurse managers should consider implementing in-hospital medication self-management , as it can be a promising strategy for patients to become acquainted with medication that is newly prescribed or altered, which probably will benefit medication knowledge ⁵⁹. The SelfMED assessment and the MED-fLAG are valuable tools to support these interventions.

5. Conclusion

This study showed a significant positive relationship between medication literacy, measured by the MED-fLAG, and the extent to which patients are considered capable to self-manage medication in hospital, measured by the SelfMED assessment. This correlation implies that the SelfMED assessment is appropriate for assessing patients' eligibility for medication self-management during hospitalisation, without first explicitly assessing medication literacy skills as an important aspect of medication self-management. MED-fLAG is very valuable to provide additional insight in order to tailor medication-related information and interventions to the patients' medication literacy level.

Data Availability

Data are available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare no conflict of interest.

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Author contributions

Conceptualization, L.M., J.G., T.D.; Methodology, L.M., J.G., T.D.; Formal analysis; L.M., Writing—Original Draft, L.M., Writing—Review and Editing, L.M., J.G., and T.D. All authors have read and agreed to the published version of the manuscript.

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Chapter 5

The development of recommendations for healthcare providers to support patients experiencing medication self-management problems

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Abstract

Medication self-management problems such as the inability to correctly obtain, understand, organize, administer or monitor medication can result in negative patient outcomes. However, supportive tools for healthcare providers to assist patients with medication self-management problems are lacking. This study aimed to develop recommendations for healthcare providers to support patients with polypharmacy who experience medication self-management problems.

A three-phase study was conducted starting with (1) the mapping of medication self-management problems, followed by (2) a scoping review providing a list of relevant interventions and actions for each respective problem and (3) a three-round modified e-Delphi study with experts to reach consensus on the relevance and clarity of the recommended interventions and actions. The cut-off for consensus on the relevance and clarity of the recommendations was set at 80% expert agreement. Experts could propose additional recommendations based on their professional experience and expertise. The experts ($n = 23$) involved were healthcare professionals (i.e., nurses, pharmacists, and physicians) with specific expertise in medication management of patients with polypharmacy. Simultaneous with the second e-Delphi round, a panel of patients with polypharmacy ($n = 8$) evaluated the usefulness of recommendations. Results obtained from the patient panel were fed back to the panel of healthcare providers in the third e-Delphi round. Descriptive statistics were used for data analysis.

Twenty medication self-management problems were identified. Based on the scoping review, a list of 66 recommendations for healthcare providers to support patients with the identified medication self-management problems was composed. At the end of the three-round e-Delphi study, the expert panel reached consensus on the relevance and clarity of 67 recommendations, clustered according to the six phases of the medication self-management model by Bailey et al.

In conclusion, this study resulted in a guidance document including recommendations that can serve as a resource for healthcare providers to support patients with polypharmacy in case of medication self-management problems. Future research should focus on the evaluation of the feasibility and user-friendliness of the guide with recommendations in clinical practice.

1. Introduction

Patient-centered care, empowerment and self-management are increasingly encouraged in current healthcare systems^{1,2}. Self-management, as part of self-care, is gaining importance, especially given the growing number of people with multiple chronic conditions^{2,3}.

Self-management of medication involves patients performing a range of actions, requiring knowledge, skills and behaviors, to manage their medication regimen as prescribed⁴. According to the medication self-management model of Bailey et al. (2013), this process starts with picking up prescribed medication at the pharmacy and filling prescriptions. Furthermore, medication self-management requires patients to have knowledge of their medication and to be able to understand the medication schedule, organize and plan daily medication intake, take the prescribed medicines, monitor their medication intake, and evaluate possible side effects or problems regarding their medication. The final step consists of maintaining a safe and effective daily medication intake routine as long as indicated.⁴

Patients often experience problems regarding medication self-management, which affects medication adherence and safe medication use. A systematic review showed that 17% of patients with chronic diseases did not pick up their medicines from the pharmacy⁵. Furthermore, a study on patients with polypharmacy showed that 48% did not have the required medicines available, 31% did not have the necessary prescriptions and about 3% did not have the resources available to fill their prescriptions (e.g., no help from others, no transport)⁶. Patients experience deficiencies in understanding medication-related instructions or information⁷⁻⁹ and in medication knowledge including not knowing the medication name, dosing or indication^{6,10-13}. In addition, problems have been reported in organizing correct and timely intake of medication¹⁴, opening medication packages¹⁵⁻²⁰ or storage of medicines^{14,21,22}. The medication intake itself also proves problematic: taking an incorrect dose, taking the wrong medicine, forgetfulness or deliberately not taking medicines are common problems reported^{6,23}. Patients' knowledge of side effects and interactions seems insufficient^{8,12}. If patients experience adverse effects, they do not always take appropriate actions, but rather abruptly stop their medication

intake or self-adjust their medication regimen⁶. Moreover, patients sometimes reduce the use of their medicines over time or discontinue them prematurely^{14, 24, 25}.

Identifying and addressing problems in medication self-management during hospitalization is an opportunity to prevent medication-related problems after discharge and promote medication adherence and safe medication use at home²⁶. Healthcare providers and patients have highlighted the importance of measures to support patients in medication self-management²⁷. Training and supporting patients in the performance of medication self-management, as a partner in care, is recommended so patients feel ready to be responsible for the management of their medication after discharge, thereby maximizing therapeutic effects and minimizing side effects. Patients with polypharmacy may particularly benefit from medication self-management support, given the larger number of medicines and the more complex medication regimen²⁸.

However, in-hospital preparation and support for medication self-management proved to be inadequate⁶. Supportive tools for healthcare providers guiding patients through problems with medication self-management are lacking. Therefore, this study aimed to develop recommendations for healthcare providers to support patients with polypharmacy who experience medication self-management problems.

2. Materials and methods

2.1 Study design

A three-phase study was performed to develop recommendations for healthcare providers supporting polypharmacy patients with problems in medication self-management. Several components were performed, including (1) mapping of medication self-management problems, (2) a scoping review providing an overview of relevant interventions and actions for each respective problem and (3) a three-round e-Delphi study with experts to reach consensus on the relevance and clarity of the recommended interventions and actions. The steps are illustrated in Figure 5.1 and are explained below.

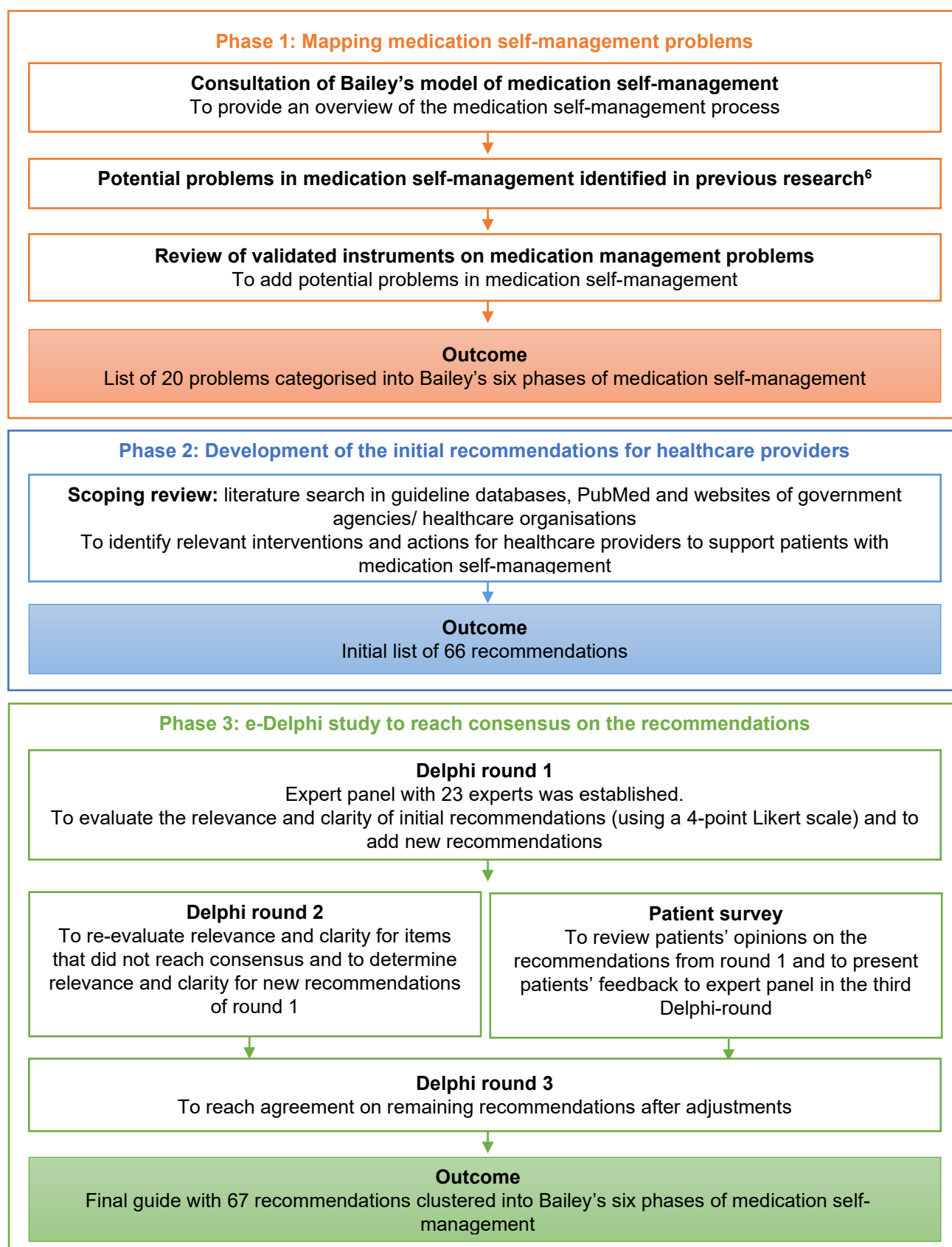


Figure 5.1. Study design of the development of recommendations for healthcare providers supporting patients with medication self-management problems.

2.2 Phase one: mapping of medication self-management problems

In the first phase, a list of frequently encountered medication self-management problems was compiled. The medication self-management model developed by Bailey et al. (2013) served as a framework, dividing the medication self-management process and related problems into six phases⁴. A recently conducted cross-sectional study investigating medication self-management deficiencies after hospital discharge was used to identify common problems encountered by patients with polypharmacy⁶. Furthermore, to complete the mapping of medication self-management problems, validated tools for assessing medication management problems were consulted²⁹⁻³².

2.3 Phase two: scoping review

A scoping review was performed to provide an overview of interventions and actions to support patients with medication self-management problems. The selection process and results are reported in a flow diagram according to the PRISMA reporting guidelines (Figure 5.2)³³.

First, the National Institute for Health and Care Excellence (NICE), Guideline International Network (GIN), Scottish Intercollegiate Guidelines Network (SIGN), guidelines of the Dutch College of General Practitioners (NHG), the Dutch Guideline Database, Clinical Practice Guidelines (CPG), EBPracticeNet and the Belgian Health Care Knowledge Centre were manually reviewed for recommendations to support medication management.

Consequently, PubMed was searched through combinations of Medical Subject Headings (MeSH terms) and free text terms related to the different phases of the medication self-management process and the self-management problems listed in the first phase (Appendix 5.1). Guidelines and systematic reviews published between 2012 and 2022 in English, French or Dutch were eligible. The final search results were exported to Endnote X9, and duplicates were removed. The search results were screened by title and abstract for relevance. To be included, the abstract had to clearly report on interventions or actions intended to improve (elements of) medication management of adult patients. Subsequently, the full text

of articles was reviewed, and successful interventions or actions described were extracted.

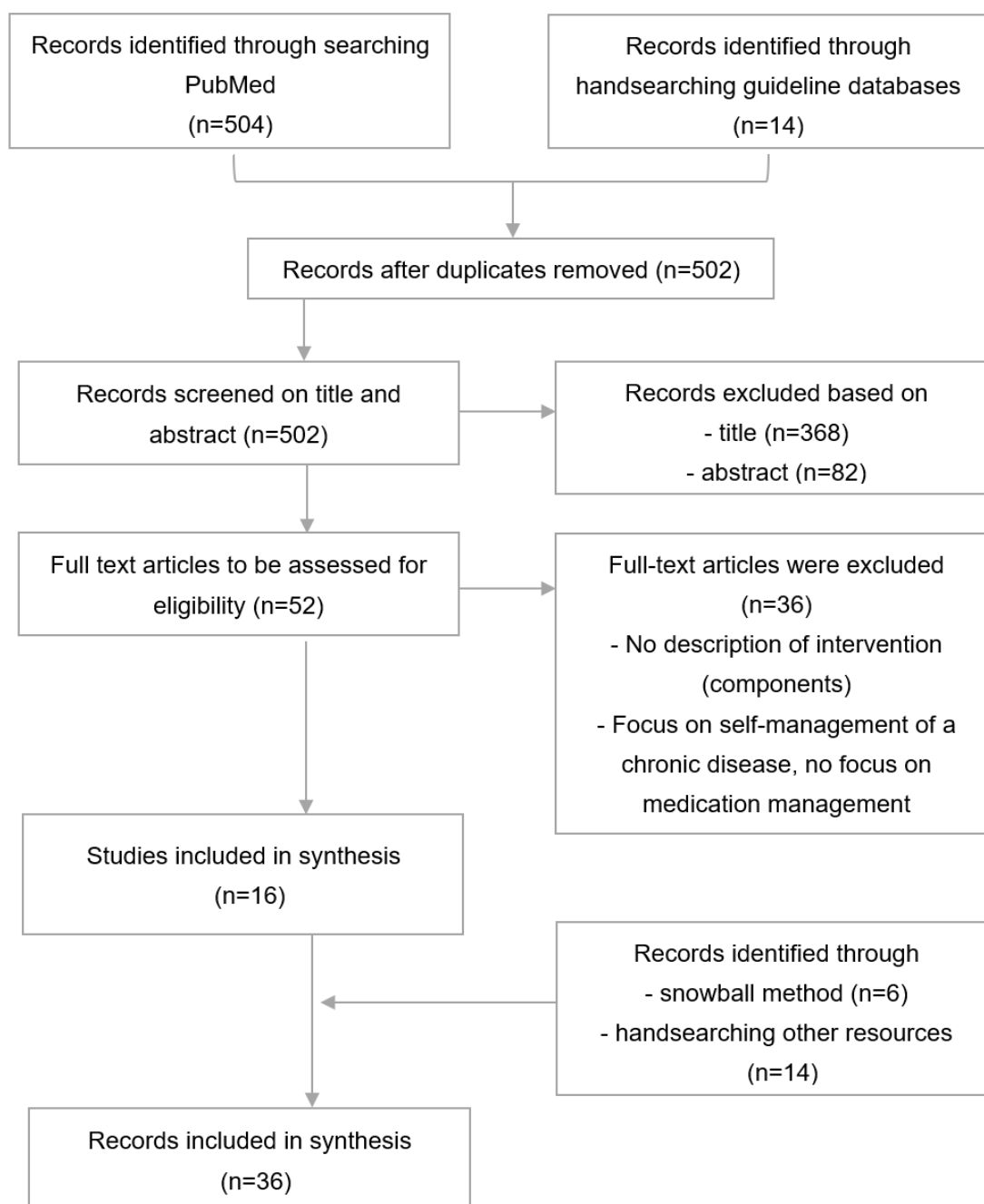


Figure 5.2. Selection of sources of evidence.

Finally, records from guideline databases and PubMed were supplemented with other resources. For this purpose, websites of government agencies and healthcare organizations were manually reviewed (e.g., Federal Agency for Medicines and Health Products, National Institute for Health and Disability Insurance, the Dutch Institute for Rational Use of Medicine).

Based on the interventions and actions found in the literature, a list of recommendations was composed. The recommendations were categorized according to the six phases of Bailey's medication self-management model⁴. The list of recommendations was supplemented with background information on the medication self-management model and problems with medication self-management encountered by patients, the purpose of the guide, end users, target patient population and methodology. To validate this guide with recommendations, a modified e-Delphi study was conducted.

2.4 Phase three: a modified e-Delphi study

A Delphi study is a structured consensus method that uses a group facilitation technique, consisting of multiple survey rounds. This technique is used when the aim is to transform individual experts' opinions into a single group consensus³⁴⁻³⁷. Instead of a classical Delphi method, characterized by a first round of open-ended questions, a modified Delphi was used. Panelists were provided with a set of pre-selected items, drawn from the scoping review, and were asked to quantitatively assess the relevance and clarity of these predefined items^{38, 39}. Since the administration of surveys was performed by email, the study is called an e-Delphi³⁹.

2.4.1 *Sample*

Experts were selected through purposive sampling. Eligibility criteria were as follows: (1) being a nurse, physician or pharmacist; (2) being employed in Belgium or The Netherlands; (3) having an established (inter)national profile in the field of medication management/patients with polypharmacy, recognized by scientific publications, policy reports and/or extensive participation in specialized thematic conferences, meetings or interest groups, or being involved in medication management of patients with polypharmacy in daily practice, as potential users of the guide; (4) having good Dutch language skills to complete the survey rounds.

Experts were recruited at university/general hospitals, community healthcare, university colleges and faculties of medicine and health sciences or pharmaceutical sciences of universities. A balanced representation of all professional groups and settings (academic versus clinical practice) was pursued during the selection process. The number of experts needed to participate in the e-Delphi study did not

depend on statistical power, as representativeness in such studies is assessed according to the quality of the sample rather than its size⁴⁰.

2.4.2 e-Delphi procedure

Experts received an email explaining the objectives of the study and were asked for consent to participate prior to the first e-Delphi round. Non-responders received up to two reminders. After expert consent was obtained, the distribution of Excel surveys and collection of data were performed by email. Written instructions for filling out the Excel file were provided. Participants were given four weeks to complete each survey form. Two reminder emails were sent to non-responders during each round. Each round was followed by a three- to four-week period for analyzing responses and integrating results into the next e-Delphi round. After each round, experts were provided with a synthesis document indicating the median score; agreement percentage; and decision on acceptance, removal or modification of an item. An instructional video clarified the content and interpretation of this document. The e-Delphi study was conducted between June and November 2022.

Round 1

During the first e-Delphi-round (1 June–6 July 2022), experts were asked to perform the following actions (Appendix 5.2):

1. Provide information on their demographics, professional background and specific area(s) of expertise for descriptive purposes and to confirm their eligibility in the first survey round.
2. Rate the level of relevance and clarity of each recommendation, using a 4-point Likert scale (1 = not relevant/not clear at all; 4 = very relevant/very clear). For each statement, participants were given the option to select 'is not within my area of expertise' as an alternative response. Free text space was provided, giving participants the opportunity to propose changes to the original recommendations, propose new recommendations based on their professional experience and expertise or emphasize their rating.
3. Rate the relevance of including the background information within the guide as well as the clarity of this information.

4. Assess different formats of the guide with recommendations (e.g., digital or paper version, use of index cards, tabular form) for usability and feasibility in clinical practice, using a 4-point Likert scale. This was intended to identify the most appropriate format of the guidance document to implement the recommendations in practice.

Descriptive statistics were used to describe participants' characteristics and group responses to each statement using Microsoft Excel. Consensus for both relevance and clarity was defined as $\geq 80\%$ of the experts assigned a score of 3 or 4 to a recommendation, which led to item retainment. If $\geq 80\%$ of respondents assigned a score of ≤ 2 , the recommendation was removed from the item list. For each item not reaching consensus, experts' comments were used to revise the respective recommendations. Reformulated or modified recommendations were presented to the experts in the next survey round.

Round 2

The second survey round (10 August–16 September 2022) consisted of a modified item list, including the initial recommendations for which no consensus was reached and new recommendations from the first round. Experts were invited to (1) re-evaluate relevance and clarity and add comments for items that did not reach consensus on relevance in the first round and (2) assign a score for the relevance and clarity of each new item.

Simultaneously with the second e-Delphi round, recommendations were presented to a panel of patients with polypharmacy. Patients were purposefully recruited from a cardiology ward, the Multidisciplinary Oncological Centre, and the cystic fibrosis (CF) center of a Belgian University hospital. Patients admitted to these wards often take multiple chronic medicines for their condition. Patients with CF were specifically chosen given the higher likelihood of inclusion of young adults. Eligibility criteria were as follows: (1) being ≥ 18 years, (2) polypharmacy (i.e., taking ≥ 5 chronic medicines daily), (3) self-managing medication at home and (4) being Dutch-speaking. The eligibility of patients was assessed in consultation with the nurse pathway supervisors of the respective departments. In selecting participants, the

aim was to have a heterogeneous panel in terms of age, gender, education and type of chronic conditions.

Socio-demographic data were surveyed to describe sample characteristics and confirm the eligibility of patients to participate in this study. Patients' overall impression of recommendations was surveyed using statements. Patients were asked to mark each recommendation as useful or not useful, using green and red markers, respectively. If patients had no opinion on a particular recommendation, they had to leave the recommendation blank. Open-ended questions were used to identify which recommendations patients might not have considered useful, along with their reasoning. Subsequently, patients had the opportunity to suggest new recommendations. Space was provided for additional comments on the guidance document. As patients need to comprehend the content of the recommendations to ensure a proper evaluation, the extent to which patients found it difficult to understand the recommendations was probed (Appendix 5.3). Surveys were administered face-to-face, so that, if necessary, additional information could be gathered. The duration of the face-to-face surveys ranged from 45 min to 1h30. Patients' feedback and suggestions were summarized in a narrative report and fed back to the expert panel of healthcare providers during the third e-Delphi round.

Round 3

In the third round (11 October–7 November 2022), consolidated feedback was presented for all items on which consensus on relevance or clarity was not reached in previous rounds. Furthermore, items that reached consensus on relevance among experts but were considered not meaningful by $\geq 80\%$ of patients in the second round (or vice versa) were re-presented to the expert panel of healthcare providers during the third round. Experts had the opportunity to re-evaluate the items accordingly with (1) new relevance and clarity scores and (2) the formulation of comments (optional).

The number of survey rounds was set at three to prevent research fatigue. Three survey rounds also allowed free-text responses from Round 1 to be incorporated as new statements in Round 2 and re-evaluated based on the group consensus in Round 3. Recommendations with a lack of consensus after three rounds were removed.

2.5 Translation

For publication purposes, the Dutch version of the guide with recommendations was translated into English by a native English speaker of the University of Antwerp's language institute (Linguapolis). The translator was not involved in this study.

3. Results

3.1 Phase one: mapping of medication self-management problems

Twenty potential medication self-management problems were identified and categorized into Bailey's six phases of medication self-management (Table 5.1).

Table 5.1. List of medication self-management problems.

Phase of Medication Self-Management Process (Bailey)	Potential Problems Based on Literature
Picking up the medicines at the pharmacy	1. The patient cannot afford the medicines. 2. The patient cannot independently pick up medicines at the pharmacy (e.g., due to lack of transport, poor state of health). 3. The patient has no prescription (or repeat prescription) available/does not know <u>when</u> to obtain a new prescription. 4. The patient does not know <u>how</u> to obtain new or repeat prescriptions/medicines (e.g., patient does not know whom to contact).
Knowledge and understanding of medicines	5. The patient has no knowledge concerning some or all of the patient's medicines (i.e., knowledge of name, dosage, timing, administration route and/or indication). 6. The patient is having trouble understanding information and/or instructions concerning the medicines.
Practical organization and scheduling of medication intake	7. The patient is having trouble organizing/filling a medication box. 8. The patient is having trouble opening packaging (e.g., removing tablets/capsules from blister packaging). 9. The patient is having trouble splitting medicines. 10. The patient is having trouble reading labels/stickers/information/instructions (e.g., on drug packaging, package leaflet, medication schedule). 11. The patient is having trouble establishing a daily routine. 12. The patient is having trouble storing medication properly.
Medication intake	13. The patient has swallowing problems. 14. The patient does not want to take the medication (deliberately) 15. The patient is taking incorrect doses of medicines (under-dosing, over-dosing, extra doses, forgotten doses). 16. The patient is not administering the medicines properly. 17. The patient is taking the medicines at the wrong time of day.
Monitoring therapeutic and adverse effects of medicines	18. The patient lacks knowledge of side effects, contraindications, interactions and/or precautions 19. The patient lacks knowledge of measures to be taken/does not take appropriate measures in case of side effects or after missing a dose.
Sustaining safe and appropriate medication use	20. The patient has discontinued taking the medication prematurely.

3.2. Phase two: scoping review

After removing duplicates, 502 articles were identified from guideline databases and PubMed. Based on the title and abstract, 450 articles were excluded. A total of 52 articles were included for full-text review. Sixteen articles were considered eligible. These were supplemented by 21 records identified through handsearching other resources, resulting in 36 records being included in the synthesis (Figure 5.2). A summary of the included records can be found in Appendix 5.4. Based on the interventions and actions found literature, a list of 66 recommendations was composed.

3.3 Phase three: e-Delphi study

Of 41 experts invited to participate in the e-Delphi study, a total of 23 experts confirmed participation and completed the first round (56.1% response rate). In the second round, 21 of the 23 experts who participated in the first round completed the survey (91.3% response rate), and 20 experts completed the third round (86.9% response rate). Participants' characteristics are presented in Table 5.2.

Table 5.2. General characteristics of panelists of the e-Delphi study (n = 23).

Variables	n (%)
Gender (female)	14 (60.9)
Age in years (median, range)	40 (28–64)
Country of employment	
Belgium	13 (56.5)
the Netherlands	10 (43.5)
Professional status *	
Physician	9 (39.1)
Pharmacist	8 (34.8)
Nurse	6 (26.1)
Work setting *	
Clinical practice	19 (82.6)
Hospital care	18 (78.3)
Primary care	2 (8.7)
Residential care	1 (4.3)
Education	11 (47.8)
Policy	2 (8.7)
Research**	7 (30.4)

* Participants could indicate more than one professional status/work setting.

** Three participants had expertise in primary care.

3.3.1 Round 1

Consensus on both relevance and clarity was achieved for 44% (29) of 66 statements. In this first round, consensus was reached for more than 50% of recommendations in the domains of problems with organizing and planning medication use; medication intake; and monitoring side effects, risks and warnings (Appendix 5.5). A total of 14 new recommendations were added, and 26 recommendations were rephrased based on experts' feedback. Furthermore, 13 recommendations were combined, and 2 recommendations were removed due to overlap (Appendix 5.6).

Consensus was reached on the relevance of all aspects of the background information presented alongside the recommendations (i.e., the medication self-management model and problems with medication self-management encountered by patients, the purpose of the guide, end users, target patient population and methodology). All aspects were, therefore, retained. In terms of clarity, the objective of the guidance document and intended patient population failed to reach consensus (79%) and were reformulated based on experts' comments. The initial focus on patient support was extended to patient and (informal) caregiver support. After evaluating various guide formats and recommendations, a consensus was reached that an online/electronic tool would be the most user-friendly and feasible option for practical use.

3.3.2 Round 2

Consensus was achieved for 79% (56) of 71 recommendations. In Round 2, 100% consensus was reached for recommendations in the domain of sustaining safe and appropriate medication use through the duration of the prescription (Appendix 5.5). Fourteen recommendations were rephrased, two were differentiated between Belgian and Dutch context, three recommendations were split into more than one recommendation, and one was removed due to consensus on irrelevance (Appendix 5.6).

Simultaneously with the second e-Delphi round among experts, eight patients provided feedback on the guide with recommendations. Patients' characteristics are presented in Table 3. Seven patients indicated that recommendations were (very)

easy to understand, while one patient rated the difficulty in understanding the recommendations as neutral. All patients found the guide useful. All participants agreed with the statement that the recommendations are meaningful to healthcare providers helping patients who experience problems with their medicines. Moreover, patients felt that healthcare providers can help with advice from the guide if they experience problems with their medicines. Patients indicated that the guide is important for healthcare providers to properly support patients in their medication self-management problems. Only 5 of 71 recommendations were marked as not helpful by one person each time.

Table 5.3. General characteristics of patients (n = 8).

Variables	n (%)
Gender (female)	4 (50)
Age in years (median, range)	53.5 (23–77)
Caregiver *	2 (25)
Education	
Primary education	1 (12.5)
Secondary education	5 (62.5)
Higher education (bachelor)	2 (25)
Number of chronic medicines (median, range)	11.5 (5–24)
Type of chronic condition	
Cardiac condition	4 (50)
Cystic fibrosis	2 (25)
Malignancy	2 (25)

* Two participants were not only a patient themselves, but they were also an informal carer for a family member and prepared medication for him or her.

3.3.3 Round 3

In the third e-Delphi round, consensus on 92% (68) of 74 recommendations was reached (Appendix 5.5): sixty-seven recommendations on both relevance and clarity to be retained, one on irrelevancy to be removed from the list. The remaining six recommendations were removed due to a lack of consensus (Appendix 5.6). The final guide consists of 67 recommendations categorized according to the six phases of Bailey's medication self-management model (Appendix 5.7).

4. Discussion

Supporting patients during the process of medication self-management—as a partner in care—is necessary to address challenges in medication management and to empower patients in self-care activities. Hence, in this study, we developed a guide with recommendations for healthcare providers supporting polymedicated patients with medication self-management problems. The recommendations were derived from scientific evidence and existing literature combined with practical experience, knowledge and expertise of experts in the field of medication management of patients with polypharmacy.

In the first phase of this study, we composed a list of twenty medication self-management problems. Previous research has shown that problems with medication self-management are various and not solely limited to medication intake 6, 7, 9, 10, 12-15, 17-23, 25, 41. Therefore, within the project group, we made a conscious decision not to prioritize just a few problems, but to focus as broadly as possible on the entire process of medication self-management. Bailey's model of medication self-management provided us with a structure when mapping problems, but also when searching for interventions and actions⁴.

We created an overview of interventions or actions that healthcare providers can perform in supporting patients for each medication management problem a patient may experience. For this purpose, a scoping review of systematic reviews, guidelines and grey literature seemed most appropriate⁴². Conducting a systematic review was not convenient, given the multitude of problems does not allow a single systematic search for interventions. Furthermore, only a limited number of interventions have been evaluated in a rigorous clinical trial.

The scoping review resulted in a list of 66 potential actions or interventions, which were formulated as recommendations. However, since multiple medication self-management problems mapped are rather practical in nature (e.g., opening packages, maintaining a daily intake routine), multiple recommendations were not evidence-based but rather experience-based. Therefore, professional experience and expertise were necessary to validate the list of predefined recommendations. Hence, an e-Delphi study was set up for this purpose. The consensus rules along

with the rating scales (score 1–4) for this e-Delphi study were inspired by the content validity index, as this simplifies the decision-making process⁴³. Furthermore, four-point Likert scales have been shown to produce stable findings in Delphi studies⁴⁴. The guidance document was developed with a focus on hospitalized adults with polypharmacy for various reasons. The prevalence of polypharmacy is high and rising^{45–47}. Furthermore, polypharmacy patients have an increased risk of medication self-management problems as a result of the larger number of medicines prescribed and the increased complexity of the medication regimen²⁸. The focus on the hospitalized patient lies in the fact that hospitalization poses risks to patient safety after discharge from the hospital^{48, 49}. For instance, various changes may have been introduced into the patient's medication regimen during hospitalization^{50, 51}. It has been shown that after discharge, 54 to 82% of patients cannot name which medication precisely was changed during hospitalization, and 55% do not use medication at home as initially intended at discharge^{52–54}. The HARM study showed that 5.6% of all unplanned hospital admissions are medication-related and almost half (46.5%) of these admissions are potentially preventable⁵⁵. Polypharmacy was identified as the most important medication-related potential risk factor for unplanned medication-related hospital admissions⁵⁵. Because of the reasons above, hospitalized patients with polypharmacy are a priority group. Nevertheless, the recommendations may also provide guidance for other patient groups (e.g., non-hospitalized adults or patients taking fewer than five medicines).

4.1 Strengths

Supporting and guiding patients in medication self-management requires an interdisciplinary approach. A strength of the study, therefore, is the involvement of individuals from different professional groups (physicians, nurses and pharmacists) with relevant experience in clinical practice and/or research regarding medication management. The selection of a heterogeneous expert panel in terms of professional status and work setting might ensure the integration of diverse expertise and experiences which might enhance the relevance of the recommendations for a broader population of patients in different healthcare settings. Not only healthcare providers but also patients were involved during the validation of the recommendations. The panel of patients was rather small, but

diverse in terms of socio-demographic characteristics. However, patients' opinions on the recommendations were consistent, suggesting that the recommendations are meaningful and useful for a variety of patients regardless of their age, level of education or chronic condition. Patients' opinions were explored simultaneously with the second e-Delphi round. This timing seemed ideal, given that important ambiguities in the recommendations had already been adjusted based on feedback from healthcare providers from the first e-Delphi round. Moreover, during the third round, experts could take patients' feedback into account. Another strength of the study is the high participation level of experts over the three e-Delphi-rounds. Panelists actively used the free text fields and provided valuable suggestions for the next rounds.

4.2 Limitations

When interpreting the results of this study, there are some limitations to bear in mind. First, given the extensive list of medication self-management problems and the choice to formulate recommendations for each of these problems, only secondary sources (i.e., systematic reviews and guidelines) were included in the scoping review. A search of primary sources (e.g., randomized controlled trials) might have yielded different results. Second, the studies included within the systematic reviews used in the scoping review are usually not rigorous clinical trials. Therefore, the effectiveness of the interventions to support medication self-management (problems) has seldomly been evaluated. Hence, the guide does not include an assessment of the effectiveness or reliability of the recommendations using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE). The guide provides an overview of the interventions/actions described in the literature, which were in addition assessed as relevant and clear by the expert panel. Third, there is no clear guidance for the level of consensus to be employed in a Delphi study^{37, 56, 57}. Percentage agreement varies widely from 50% to 97%⁵⁷, but 75% has been considered to be the minimal level of agreement³⁷. We chose to set the cut-off for consensus on relevance and clarity at 80% of expert agreement.

4.3 Implications for practice and future research

The current study resulted in a guidance document with recommendations considered relevant and clear for healthcare providers to support polypharmacy patients with problems in medication management. However, when using the guide in clinical practice, the following aspects should be considered:

1. Supporting patients regarding medication self-management requires an interdisciplinary approach, in which individual healthcare providers can contribute to improving patient medication self-management based on their own competences. In other words, the recommendations can be applied by a variety of healthcare providers (e.g., pharmacists, physicians, nurses) within their areas of expertise, preferably after coordinating with the members of their team.
2. Supporting patients in medication self-management requires the involvement of the patient (and/or informal carer) in the care process. The patient should be explicitly provided with the opportunity to inform the healthcare provider of any problems with self-management, as well as any personal experiences and preferences that might affect medicine use. To arrive at shared decision-making (i.e., decisions that the patient will support), the patient needs to have sufficient information about the problems at hand, the decisions to be made and the options available.
3. Providing advice to patients regarding their medication (and/or its management) should not be limited exclusively to the time of hospital discharge. Patients should receive as much support as necessary in self-management during hospitalization, as well as after discharge.
4. It is not the intention to go through all the recommendations in the guidance document systematically for every patient. The guidance document is intended as a resource for helping healthcare providers intervene when there is evidence of problems in medication self-management. Patients admitted due to drug-related problems (e.g., medication errors, therapy non-adherence) should be regarded as having the highest priority.

This study does not demonstrate whether the developed tool is actually feasible and user-friendly in clinical practice. Therefore, a pilot study is recommended in which the guide would be evaluated at a few hospital wards, starting with an evaluation of the medication self-management problems encountered by patients, followed by healthcare providers supporting these patients during hospitalization with the reported problems based on the guidance document.

We have to acknowledge that the recommendations stated in the guidance document can become outdated as new evidence is published. Therefore, a periodic reassessment of the guidance document is needed for it to remain valid. According to various authors, an update of recommendations is generally required after three to five years⁵⁸⁻⁶¹.

5. Conclusions

Based on a scoping review and e-Delphi study, a guide with recommendations for healthcare providers to support polypharmacy patients with medication self-management problems has been developed. Twenty-three experts reached consensus on the relevance and clarity of 67 recommendations categorized according to the six phases of medication self-management. The guidance document is intended for use by different healthcare providers in an interdisciplinary context to enhance patients' competences in medication self-management. Future research should focus on the evaluation of the feasibility and user-friendliness of the guide by healthcare providers in clinical practice.

Author contributions

Conceptualization, L.M., E.G. and T.D.; Methodology, L.M., E.G., A.-M.D.C., M.P., P.v.d.B. and T.D.; Formal analysis, L.M.; Writing—Original Draft, L.M.; Writing—Review and Editing, L.M., E.G., A.-M.D.C., M.P., P.v.d.B. and T.D. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Antwerp University Hospital, Belgium (reference B3002022000061, approved on 23 May 2022).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

Data are available from the corresponding author upon reasonable request.

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Conflicts of Interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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Chapter 6

Nurses' responses to patients' medication self-management problems in hospital and the use of recommendations

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Abstract

This study aimed to describe the use of recommendations as a guide for healthcare providers to support patients experiencing medication self-management problems and to evaluate their feasibility, user-friendliness and usefulness. Between March and August 2023, 58 hospitalized patients completed a self-assessment on medication self-management problems. The problems addressed in this self-assessment were based on a list of frequently encountered medication self-management problems from previous research. Consequently, 18 nurses responded to the reported problems using the recommendations. Nurses evaluated the feasibility, user-friendliness and usefulness of these recommendations through a survey. A total of 217 medication self-management problems were reported by 58 patients. Nurses intervened in 52% of the problems using the recommendations. According to nurses, the recommendations were user-friendly and feasible but required a substantial time investment. Considering these pilot-based results, the recommendations have the potential to be a valuable resource for nurses in practice, though this potential requires further exploration.

1. Introduction

Patients face numerous challenges in self-managing their medication. These challenges include, for example, not being able to fill prescriptions at the pharmacy^{1, 2}, a lack of knowledge and understanding of medication²⁻⁴, poor organizational skills⁵, incorrect intake of medication⁶ and an inability to recognize side effects or other medication-related problems⁴. Problems in medication self-management can significantly affect medication adherence (i.e., the process by which patients take their medication as prescribed⁷) and the safe use of medication at home. Hospitalized patients are particularly vulnerable to medication self-management problems post-discharge, as several changes in the medication regimen may have been introduced during hospitalization^{8, 9}. Therefore, training and supporting patients in medication self-management during hospitalization is indispensable to empower patients in self-care activities at home¹⁰. However, in-hospital preparation and support for medication self-management have been found to be insufficient². Both healthcare providers and patients have emphasized the need for measures to assist patients in self-managing their medications, as such measures are currently lacking¹¹.

In a previous study, recommendations for healthcare providers to support patients who experience problems in medication self-management were developed¹². The recommendations were developed with a focus on hospitalized patients but may also provide guidance for other patient groups. These recommendations were established based on scientific evidence and grey literature combined with clinical experience and knowledge of experts in the field of medication management¹². The recommendations have not yet been evaluated in clinical practice. Hence, this study aimed to implement the recommendations in clinical practice, to describe its use and to evaluate the feasibility, user-friendliness and usefulness of the recommendations for nurses in daily practice.

Box 1: Definitions

Feasibility refers to the extent to which the recommendations can be successfully carried out within a given setting.

User-friendliness refers to the extent to which the recommendations are easy to use or understand.

Usefulness refers to the degree to which a nurse believes that using the recommendations can achieve the goal of supporting patients with medication self-management problems.

2. Methods

2.1 Design

Between March and August 2023, a quantitative descriptive pilot study was conducted. The recommendations for healthcare providers were implemented in clinical practice, and its use was evaluated. First, patients completed a self-assessment of medication self-management problems they encountered, followed by nurses supporting patients during hospitalization using the recommendations. Subsequently, nurses completed a cross-sectional survey evaluating the feasibility, user-friendliness and usefulness of the recommendations in daily practice.

2.2 Setting and participants

In two hospitals, one in Belgium and one in the Netherlands, three geriatric and one pulmonary ward were included. Hospitalized patients were eligible if they were at least 18 years old, took at least five chronic medicines on a daily basis (i.e., polypharmacy¹³), were responsible for their medication management at home (preparation and/or administration), returned home after hospital discharge and were Dutch speaking. Patients with a Mini-Mental State Examination score of <24/30, patients with delirium and those unable to provide consent were excluded. Nurses were asked to include all eligible patients based on the aforementioned criteria. All nurses of the participating wards were invited to use the recommendations and to complete the survey.

2.3 Implementation of the recommendations

The recommendations were previously developed through a three phase study¹². First, a mapping of medication self-management problems was conducted. Subsequently, a scoping review provided an overview of relevant interventions (i.e., recommendations) for each problem identified in the first phase. Finally, a modified Delphi study with 23 experts (i.e., healthcare professionals with expertise in medication management) was performed to reach consensus on the relevance and clarity of the recommendations.

This three-phase study resulted in a guide consisting of a list of possible problems concerning medication self-management, along with specific recommendations to address each problem¹². The problems and associated recommendations were structured according to the six phases of Bailey's medication self-management model¹⁴. A total of 67 recommendations were included. The recommendations were made accessible to nurses in both paper and digital formats.

Upon admission, patients had to fill out a self-assessment on medication self-management problems at home (see Section 2.4). Nurses could identify the problems experienced by a patient, based on the answers given in this patient-reported self-assessment (see Section 2.4). Subsequently, nurses had to select and apply the respective recommendations to support patients experiencing the identified problems.

2.4 Data collection

After obtaining informed consent, patients were asked to complete a paper questionnaire on socio-demographic data (i.e., age, gender, educational level classified according to the European Qualification Framework [EQF]¹⁵, type of hospitalization and reason for hospitalization) and data on medication management (i.e., number of medicines, preparation and administration of medicines at home and assistance with medication management).

A patient self-assessment was employed to gather data on medication self-management problems encountered at home. The self-assessment comprised 27 statements to be rated on a 5-point Likert scale (1 = always and 5 = never) (see

Appendix 6.1). The problems (i.e., statements) in the patient self-assessment were based on a mapping of frequently encountered medication self-management problems¹². This mapping was performed in preparation of the development of recommendations and was based on previous literature¹². Specifically, a cross-sectional study on medication self-management deficiencies encountered by patients post-discharge was used to identify common problems². Additionally, validated assessment tools for evaluating medication management problems were consulted to finalize the mapping of medication self-management problems¹⁶⁻¹⁹. The list of medication self-management problems and consequently the problems in the patient self-assessment were categorized according to the six phases of Bailey's medication self-management model¹⁴. A nurse researcher in Belgium (L.M.) and a pharmaceutical consultant in the Netherlands (J.V.) were available to assist patients in completing the assessment.

In addition, data were collected on nurses' responses to patients' medication self-management problems. For this purpose, the patient self-assessment included a section for nurses. In the nurse section, for each medication self-management problem, the number of the corresponding recommendation(s) was listed. Nurses could tick off which of the corresponding recommendations were implemented to address the patient's problems (see Appendix 6.1).

At the end of the study, nurses were asked to rate the feasibility, user-friendliness and usefulness of the recommendations using a 10-point scale (1 = totally disagree and 10 = totally agree). Free-text comments could be provided at the end of the questionnaire (see Appendix 6.2).

2.5 Study outcomes

The main outcome measures of this study were the use of the recommendations by nurses, the feasibility, user-friendliness and usefulness of the recommendations in clinical practice.

2.6 Data analysis

IBM SPSS Statistics® version 29 (IBM Corp; Armonk, New York, USA) was used to analyse the data. Descriptive statistics were used to describe socio-demographic characteristics, patient-reported medication self-management problems, the application of recommendations by nurses, user-friendliness and perceived time investment. Discontinuous data were described using frequency distributions. Continuous data were described using mean and standard deviation if normally distributed or using median and range (minimum-maximum) if not normally distributed. The normality of the distribution was determined using Z-scores. Microsoft Excel® for Microsoft 365 (Microsoft Corporation; Redmond, Washington, USA) was used to store free-text comments, add labels and cluster the data. Afterwards, relevant data were described in a narrative way. No formal power analysis was conducted due to the descriptive nature of this study. However, we aimed to include 50 patients per country.

2.7 Ethics approval

The study was conducted in accordance with the Declaration of Helsinki²⁰ and approved by the Ethics Committee of the Antwerp Hospital Network, Belgium (reference B0092023000083, approved on 11 January 2023) and the Medical Ethics Review Committee of the University Medical Center Groningen, the Netherlands (reference 11450, approved 09 March 2023). Before participation, patients were verbally informed about the purpose, design and execution of the study by the nurse researcher in Belgium (L.M.) or the pharmaceutical consultant in the Netherlands (J.V.). Subsequently, written informed consent was obtained from all subjects involved in the study. Data were pseudonymized before analysis.

3. Results

3.1 Socio-demographic characteristics

A total of 58 patients and 18 nurses participated in the study. Patients were on average 76 years, and 50% were female. The majority (67%) had been acutely hospitalized. Patients took a median of eight chronic medications. Nurses had on average 7 years of work experience, and about 50% had a bachelor's degree (level 6). General participant characteristics are presented in Table 6.1.

Table 6.1: Participant characteristics.

	Patients (n= 58)	Nurses (n= 18)
Gender (female), n (%)	29 (50)	15 (83.3)
Age in years (mean [range])	75.7 [46 - 95]	33.1 [22 – 59]
Country, n (%)		
Belgium	34 (59.6)	5 (27.8)
the Netherlands	24 (41.4)	13 (72.2)
Education, n (%)		
EQF level 1	21 (36.8)	-
EQF level 2 or 3	22 (38.6)	-
EQF level 4	8 (14)	4 (22.2)
EQF level 5	0 (0)	5 (27.8)
EQF level 6	3 (5.3)	9 (50.0)
EQF level 7 or 8	3 (5.3)	0 (0)
Number of chronic medications (median [range])	8 [5 – 19]	-
Help needed to reside at home (yes), n (%)	35 (39.7)	-
Geriatric ward (yes), n (%)	34 (59.6)	5 (26.3)
Acute hospitalisation, n (%)	39 (67.2)	-
Length of hospitalisation, n (%)		-
1 to 3 days	9 (16.4)	
4 to 7 days	28 (50.9)	
More than 7 days	18 (32.7)	
Reason for hospitalisation ^a , n (%)		-
Observation	3 (5.2)	
Surgery	3 (5.2)	
Examination	22 (37.9)	
Accident	10 (17.2)	
Treatment	26 (44.8)	
Work experience in years (median [range])	-	7.0 [2 – 37]

3.2 Use of the recommendations in clinical practice

A total of 217 problems were reported by 58 patients. The majority of problems were related to medication knowledge, followed by the practical organization of medication intake and monitoring of effects. In 52% of the problems, action was taken by nurses (i.e., report of the use of the recommendations). Nurses most frequently took action in addressing problems with medication knowledge and least frequently in case of problems with maintaining appropriate medication use on the longer term (Table 6.2).

Table 6.2: The extent to which recommendations were applied by nurses

Problems in medication self-management (identified through the patient self-assessment)		Number of problems experienced (%)	Number of cases where action was taken ^a (%)	Total percentage of cases where action was taken ^{a,b} (%)
Picking up medication at the pharmacy	Financial constraints	1 (1.7)	1 (100)	37.5
	Medication not in stock	2 (3.4)	2 (100)	
	Medication prescriptions not available	1 (1.7)	0 (0.0)	
	Not able to pick up medicines in the pharmacy	4 (6.9)	0 (0.0)	
Knowledge and understanding of medication	Not knowing the name	37 (64.9)	29 (78.3)	80.3
	Not knowing the dosage	2 (3.4)	2 (50.0)	
	Not knowing the administration route	0 (0.0)	-	
	Not knowing the indication	19 (32.8)	17 (89.4)	
	Not knowing time of administration	0 (0.0)	-	
	Not knowing instructions for medication intake (intake on empty stomach, with food,...)	8 (13.8)	6 (75.0)	
	Difficulties in understanding explanations about medicines	3 (5.2)	2 (66.7)	
	Difficulties in understanding information on packaging, leaflets and labels	2 (3.4)	1 (50.0)	
Practical organization and scheduling of medication intake	Difficulties with opening medication packaging	8 (13.8)	6 (75.0)	39.7
	Difficulties splitting medicines	4 (6.9)	0 (0.0)	
	Difficulties reading labels, information or instructions	5 (8.6)	0 (0.0)	
	Taking medicines at wrong time/ forgetting to take medicines	28 (48.3)	18 (64.2)	
	Difficulties with storage of medicines (not knowing the storage instructions, e.g. in refrigerator or at room temperature, or not checking expiration date)	23 (39.6)	3 (13.0)	
Medication intake	Swallowing problems	5 (8.6)	2 (40.0)	30.0
	Taking incorrect doses of medicines	2 (3.4)	0 (0.0)	
	Not administering medicines properly	1 (1.7)	1 (100)	
	Not taking medicines	2 (3.4)	0 (0.0)	
Monitoring therapeutic and adverse effects of medicines	Not knowing the benefits of medication	13 (22.4)	1 (7.7)	40.7
	Not knowing the side effects of medication	35 (60.3)	20 (57.1)	
	Not knowing what to do in case of side effects	6 (10.3)	1 (16.7)	
Sustaining safe and appropriate medication use	Stop taking medicines earlier than prescribed	3 (5.2)	0 (0.0)	16.7
	Not knowing who to contact in case of any problems	3 (5.2)	1 (33.3)	
Total		217	113	52.1

Note: Total number of patients = 58;

^a Action reported by nurses, action based on the recommendations, ^b the number of problems for which action was taken divided by the number of problems reported and multiplied by 100.

3.3 Evaluation of recommendations by nurses

A total of 18 nurses completed the survey. Overall, the recommendations were evaluated as being feasible and user-friendly (7/10 rating). Nurses felt that the recommendations were useful to support patients experiencing problems with their medication and that application of the recommendations could contribute to better medication self-management of patients post-discharge (7.5/10 rating). Applying the recommendations in clinical practice was time-consuming (8/10 rating) (see Table 6.3).

Several barriers in applying the recommendations in practice were mentioned in the free text comments. The high nursing workload, the administrative burden and care intensity hindered nurses from offering patients the necessary information and support. Additionally, applying the recommendations within a geriatric population was often not possible due to cognitive deficits. The comprehensive nature of the recommendations emerged as a barrier. Nurses suggested that condensing the recommendations, for instance by using bullet points, could enhance their usability.

Table 6.3: Feasibility, user-friendliness and usefulness of the recommendations as reported by nurses (n=18)

Statements ^a	Median [range]
Implementing the recommendations in practice was <u>feasible</u> .	7 [3 – 8]
The recommendations are <u>user-friendly</u> .	7 [3 – 8]
Implementing the recommendations in practice is <u>time-consuming</u> .	8 [4 – 10]
The recommendations are <u>useful</u> in supporting patients who experience problems with their medications.	8 [5 – 10]
The recommendations <u>can help</u> me as a healthcare provider <u>to support and advise patients</u> if they experience problems with their medications.	7 [5 – 9]
Using the recommendations can <u>improve communication</u> about medication therapy with the patient.	7 [6 – 9]
<u>Supporting and counselling</u> the patient with medication self-management problems based on the recommendations <u>contributes to better medication self-management</u> of the patient <u>after discharge</u> .	7.5 [6 – 9]
In the <u>future</u> , I would like to <u>use</u> the recommendations as a tool for supporting patients.	7 [4 – 9]

^a Ten-point scale: 1 = strongly disagree and 10 = strongly agree

4. Discussion

Supporting patients in medication self-management, as part of self-care, is gaining importance. This study evaluated the use, feasibility and user-friendliness of recommendations for nurses to support patients in their medication self-management.

Although the recommendations were considered feasible, user-friendly and useful by nurses, their actual application in clinical practice was rather limited. Only half of the patient-reported problems were addressed using a recommendation. On the one hand, high workload and care burden were mentioned as potential barriers to application. On the other hand, it is possible that nurses supported patients, based on their own expertise and experience, without using the recommendations. The latter was not registered. The recommendations should, however, be considered as a resource in case nurses or other healthcare providers do not know how to address a specific medication self-management problem. In other words, the recommendations can be consulted as-needed in daily clinical practice, rather than intended for systematic use.

It is noteworthy that nurses mainly focussed on addressing deficiencies in patient's medication knowledge, while supporting patients in other aspects of the medication self-management process (e.g., correct medicine intake and monitoring side effects) is just as important. However, knowledge deficiencies were the most commonly reported medication self-management problem in this study. This aligns with previous research involving patients with polypharmacy after hospital discharge². Providing education or counselling, as an intervention to improve medication knowledge, can be more easily combined with other nursing tasks, such as administering medication to the patient, which possibly can explain the high action rate in this problem category.

Nurses indicated that condensing the recommendations could increase their usability. However, prior to this study, the recommendations were validated through a Delphi study, in which experts, who were also healthcare providers, assessed the relevance and clarity of each individual recommendation¹². These experts recommended keeping the recommendations as comprehensive as possible. This

is to avoid losing valuable background information needed to understand or apply the recommendations in clinical practice. However, the Delphi study included a more diverse and balanced sample of healthcare professionals encompassing physicians, pharmacists and nurses. The different samples might explain the difference in opinions. Highlights or bold text can, however, be used to emphasize the action to be taken. Another possible solution is to provide the nurses with a short summary only detailing the recommendations potentially useful within hospital.

The recommendations were available in both paper and digital format, but for unknown reasons, only the paper version was used by nurses in this study. Hence, conclusions can only be drawn regarding the paper version. Yet, the digital format may offer advantages over its paper counterpart, enabling navigation through the incorporation of crosslinks.

The study was performed in a population of patients with polypharmacy, as this patient group has a more complex medication regimen and is therefore more likely to experience problems with medication management²¹. However, the recommendations can also be used as a resource when dealing with other patient populations.

We acknowledge several limitations of the study. First, self-reported data may be subject to desirability and recall bias. Possible under- or over-reporting of problems experienced by patients and use of the recommendations by nurses in clinical practice should be considered. Second, the sample size of patients was limited despite the rather long recruitment period and the use of consecutive sampling. Nurses indicated that, due to time pressure and workload, other priorities hampered including patients for research purposes. Furthermore, geriatric patients were often ineligible for participation due to cognitive deficits or not being responsible for their own medicines at home. On the pulmonary ward, patient turnover was low and few patients with polypharmacy were admitted.

Third, we solely assessed the feasibility and user-friendliness of the recommendations, not the actual effect of supporting patients during hospitalization, using the recommendations, on medication self-management post-discharge. However, the recommendations will be used as a supportive tool within the

SelfMED-intervention, an intervention where patients are allowed to store, prepare and administer their medicines themselves during hospitalization, with monitoring and support provided by nurses, physicians and pharmacists^{22, 23}. In a future pre-post study, the effect of the SelfMED intervention will be evaluated on various outcomes post-discharge, thereby also assessing the value of the recommendations²².

Fourth, our study primarily focussed on the evaluation of the recommendations by nurses, as they are key persons in detecting and addressing problems. However, medication self-management also involves other healthcare professionals, such as physicians and pharmacists. Fifth, the recommendations have been evaluated in specific patient populations by a limited number of nurses from one hospital in Belgium and one in the Netherlands, which limits the generalizability of the results. Finally, the recommendations were exclusively available for healthcare providers. In future research, the recommendations should also be made directly accessible to patients.

5. Conclusion

This study provides initial insight into the feasibility, user-friendliness and usefulness of the recommendations and has the potential to be a valuable resource for nurses in clinical practice. However, the actual effect of using the recommendations on medication self-management problems needs to be examined. Additionally, the added value of the recommendations for other healthcare providers and settings (e.g., primary care) requires further exploration.

Author contributions

Conceptualization: Laura Mortelmans, Eva Goossens and Tinne Dilles; Methodology: Laura Mortelmans, Eva Goossens, Anne-Marie De Cock, Patricia van den Bemt and Tinne Dilles; Formal analysis: Laura Mortelmans; Writing–Original Draft: Laura Mortelmans; Writing– Review and Editing: Laura Mortelmans, Eva Goossens, Anne-Marie De Cock, Patricia van den Bemt and Tinne Dilles. All authors have read and agreed to the published version of the manuscript.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

Data availability statement

Data are available from the corresponding author upon reasonable request.

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Chapter 7

Shared decision making on medication use between nurses and patients in an oncology setting: a qualitative descriptive study

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Abstract

Purpose

(i) To explore patients' and nurses' experiences with medication-related shared decision making (SDM) (i.e., familiarity with the concept, application of medication-related SDM, barriers and facilitators towards its application) and (ii) to explore their role perceptions, respectively.

Methods

A qualitative study was conducted in which seven interviews with oncological patients and a focus group interview with six nurses were performed. Prior to the interviews, observations of the application of shared decision making were conducted using the OPTION-12 scale. The observations were used exclusively to trigger the group discussion. Data were collected from November 2020 until March 2021.

Results

According to participants, the application of SDM regarding medication by nurses in oncology is limited. Barriers mentioned were health status, medication-related knowledge, the therapeutic nurse-patient relationship, time pressures and workload. Patients valued nurses' contribution to SDM regarding medication and perceived them as key persons because of their advocating, informative, facilitating and supportive role. Individual and contextual factors determined patients' desire for involvement in medication-related decisions.

Discussion

Participants solely concentrated on SDM concerning drug choice and management of therapeutic and adverse effects. The patients' and nurses' experiences and perceptions towards SDM in other domains of pharmaceutical care need further investigation.

1. Introduction

Although medical decision making remains characterised by a paternalistic paradigm, with healthcare providers making decisions for patients, there is a clear shift towards greater patient involvement and Shared Decision Making (SDM)¹. SDM is defined as *“an approach where healthcare professionals and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences”*². The patient, family members and healthcare providers are ought to collaborate in making decisions about treatment and care to obtain the best quality of care and patient outcomes^{3, 4}. Several benefits of SDM are described, such as increased medication knowledge, increased patient satisfaction with treatment, less anxiety regarding the care process, and greater alignment of care with patients' values and preferences⁵⁻⁷.

Decision-making is an important task of the healthcare team, including nurses, to fulfil responsibilities in several domains of pharmaceutical care: management of therapeutic and adverse effects of medication, management of medication adherence, management of patient medication self-management, management of patient education and information about medication, prescription management, medication safety management and care coordination^{8, 9}. SDM is, for example, relevant in oncological pathologies where one drug treatment does not provide better outcomes as opposed to another and where the choice mainly depends on potentially uncomfortable side effects^{10, 11}. Furthermore, involving patients in clinical decisions should be obvious in the transition from an adjuvant to a palliative setting. This transition requires sensitive decisions, such as continuing a physically demanding therapy or cessation of the therapy to preserve quality of life. Although patients would like to be more involved in decision making¹², healthcare providers find it difficult to include patients and their families^{13, 14}.

Previous studies mainly focussed on investigating SDM between patients and physicians^{5, 6, 15-19}. Nevertheless, nurses have a pivotal role within the SDM process as they have contact that is more frequent with the patient as compared to other healthcare providers. Nurses can act as a reliable source of information²⁰, can

represent patients' interests, assess patients' willingness to participate in decision making, and guide and support them throughout the SDM process²¹.

Currently, it is not clear whether oncology nurses in Belgium do apply SDM principles in their care provision. There is a lack of information on the experiences of patients and nurses with SDM regarding medication use in clinical oncology practice in Belgium. Furthermore, patients' and nurses' role perceptions regarding SDM about medication management are unclear at this moment.

The aim of this study was twofold: (1) to explore patients' and nurses' experiences with medication-related shared decision making in clinical practice (i.e., familiarity with the concept, application of medication-related SDM, barriers and facilitators towards its application), and (2) to explore patients' and nurses' role perceptions in shared decision making about medication.

2. Methods

2.1 Study design

A qualitative study was conducted comprising individual interviews with both patients in an adjuvant and palliative setting and a focus group interview with nurses. Prior to the interviews, a few observations were performed to gain insight into the application of shared decision making in practice. The results of the observations were solely used to initiate discussion among nurses during the focus group.

2.2 Participants and setting

The study was performed at an oncology ward of a general hospital in Belgium. All nurses of the oncology department (n = 14) were invited to participate in the study. They were informed about the study during an information session and through the provision of an information leaflet. Both patients in an adjuvant or palliative treatment stage, hospitalized at the oncology ward, were included if they were at least 18 years old, were physically and mentally able to participate and were willing to participate in the study.

We tried to maximise variation in the study sample by selecting patients of different ages and educational levels as this was found to affect the desire for involvement

in decisions²². Furthermore, we deliberately ensured a balance between patients in the adjuvant and palliative setting. This way, we tried to achieve the broadest possible scope of views on patients' experiences and perceptions on SDM regarding medication use. Patients were recruited through purposive sampling until data sufficiency was achieved.

2.3 Data collection

Each participant had to complete a short questionnaire containing socio-demographic characteristics. In addition to age, gender and highest educational level, patients were surveyed about the number of prescribed medicines, oncological diagnosis and number of years of diagnosis; while nurses were questioned about their overall work experience and their work experience in oncology.

2.3.1 Observations of the application of medication-related shared decision making

Every nurse who agreed to observation was followed during one shift. Half of the nursing sample was observed during the morning shift, the other half during the evening shift. Prior to observation, nurses were informed about the study focus on communication between nurses and patients in a broad sense to limit research bias. In this stage, the researcher did not inform the participants that the study emphasized SDM on medication use.

SDM between nurses and patients was observed using the Observing Patient Involvement Scale (OPTION-12)²³. With the OPTION-12 scale, it is possible to determine the extent to which the caregiver applies SDM-principles from the perspective of an independent observer^{24, 25}. This scale consists of 12 items to be scored on a five-point Likert scale (0 = the behaviour is not observed and 4 = the behaviour is exhibited to a very high standard). A user manual and training pack was available which provided the raters with detailed information on how to interpret and score each individual OPTION item²⁶. The scores can be summed to a number ranging between 0 and 48. This raw score can be transformed to a score ranging from 0 to 100²⁶. The results of the observations were used during the focus group

interview to initiate discussion among nurses about the application of SDM on medication as well as their experiences and role perceptions within this topic.

2.3.2 Focus group interview

Each observed nurse was invited to participate in the focus group. A focus group interview was chosen to encourage discussion and the expression of equal and contrasting opinions on SDM about medicines²⁷⁻³⁰. First, nurses' familiarity with the concept of SDM was explored. Subsequently, nurses' experiences regarding the application of medication-related SDM were explored (e.g., Which steps are applied? How is SDM applied?), including the facilitators and barriers encountered in practice. For this purpose, the results of the observations were used to trigger the group discussion. Each item of the OPTION-12 scale was discussed and the nurses' experiences and role perceptions in relation to each item were explored. The focus group interview lasted 1 h and 50 min.

2.3.3 Semi-structured interviews

The nine essential steps of the integrative model of shared decision making were used to guide the interviews (Figure 7.1)³. Patients' familiarity with the concept of SDM, their experiences with the application of the respective steps in practice, patients' perceptions on their role and the nurses' role at each step was explored during the interview. Hindering or facilitating factors regarding medication-related SDM were explored as well. Moreover, patients in a palliative phase were interviewed about changing role perceptions and differences in the application of SDM compared to an adjuvant setting. The interviews took place in the patient's room or in a separate meeting room. Interviews with patients receiving adjuvant therapy lasted on average 1 h and 47 min (SD 0:36:48, range 1:22:51–2:29:34), whereas interviews with patients in a palliative setting lasted on average 55 min (SD 0:21:32, range 0:31:33–1:21:43).

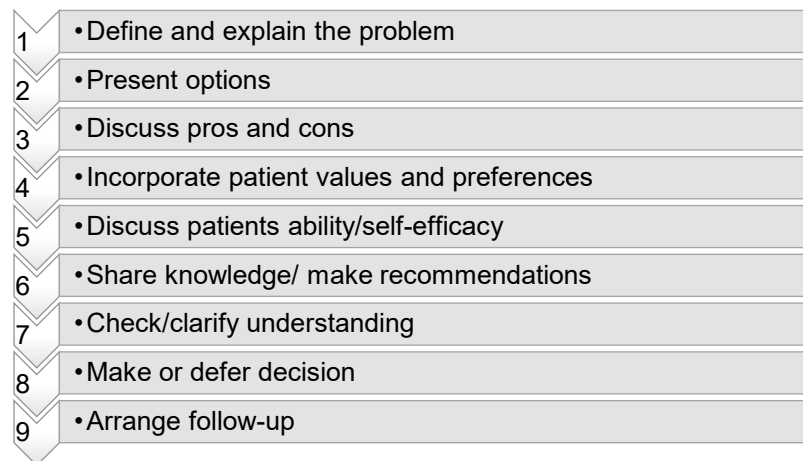


Figure 7.1. Integrative model of SDM according to Makoul and Clayman³.

Both the individual and focus group interviews were audio recorded and field notes were taken. Data were collected between November 2020 and March 2021.

2.4 Data analysis

The individual and focus group interviews were transcribed verbatim. Subsequently, the analysis was performed according to the six phases of thematic analysis offered by Braun and Clarke³¹. Transcripts were read and re-read to become familiar with the data. Initial notes were made and subsequently the analysis was broadened, moving from a descriptive to an interpretative level. Related codes were grouped into potential themes and subthemes, with the relevant participant quotations filed under each theme or sub-theme heading. This helped to adjust theme titles, boundaries and position and to check whether themes were faithful to the data at a glance. The themes were refined by re-evaluating the entire data analysis process and relationship between themes. The final codebook consisted of six themes. The analysis was carried out inductively, developing a codebook in an iterative way starting from the first interview. The first and second author analysed the richest interview and the focus group independently. One author analysed all other transcripts, but a fellow author verified the accuracy and completeness of the coding. Disagreements about the accuracy, completeness or clarity of the coding were discussed until consensus was reached. Microsoft Excel® was used to store quotations, add labels and arrange the data.

Credibility was achieved as verbatim quotations were used to support the researchers' data interpretations. The researchers carried out self-reflection meaning that thoughts, insights and ideas were put on paper prior to the interviews and the analysis. This reflexivity of the researcher created a constant awareness of the own background and perspective and was intended to mitigate the potentially deleterious effects of preconceptions that may taint the research process.

2.5 Ethical considerations

The Medical Ethics Committee of the participating hospital (reference 201156) approved the study. All ethical principles of the Declaration of Helsinki were followed while performing the study³². All participants received information on the purpose, design and execution of the study. Written informed consent was given prior to participation. Data were pseudo-anonymized.

3. Results

Nine of the fourteen nurses were willing to participate in the study. Reasons for non-participation consisted of maternity leave (1), not comfortable with observations (3) and solely having night shifts (1). The nine observed nurses were invited to the focus group, in which only six nurses participated. A total of nine patients were interviewed but only seven interviews were analysed. One interview was lost due to malfunctioning of the audio recorder and one patient did not answer the questions, so the interview was not considered relevant. Demographic characteristics of the interviewees can be found in Table 7.1.

Table 7.1. Sample characteristics.

	Nurses (n = 9)	Patients (n = 7)
Age in years		
Median (range)	38 (22 – 59)	66 (25 – 86)
Women (n)	8	4
Marital status (n)	/	
Married		5
Single/widow(er)		2
Highest education (n)		
Level 2 (Lower secondary education)	0	1
Level 3 (Upper secondary vocational education)	0	0
Level 4 (Upper secondary education)	0	1
Level 5 (Higher vocational education)	2	2
Level 6 (Bachelor/postgraduate degree)	7	2
Level 7 (Master's degree)	0	1
Work experience in oncology (years)		
Median (range)	14 (0.5 – 27)	/
Overall work experience (years)		
Median (range)	14 (0.5 – 31)	/
Number of years since diagnosis		
Median (range)	/	1 (0 – 16)
Diagnosis (n)	/	
Acute Myeloid Leukemia		1
Metastatic thyroid cancer		1
Multiple myeloma		1
Non-Hodgkin lymphoma		2
Ovarian cancer		1
Testicular cancer		1
Number of prescribed medicines		
Median (range)	/	7 (1 – 12)
Palliative status (n)	/	4

3.1 Results of the observations

A total of nine nurses were observed. Opportunities for SDM regarding medication were mainly observed and evaluated in the field of choice of medication therapy, management of therapeutic and adverse effects. For three nurses, there were multiple situations during their shift where SDM on medication could be applied. Each of these situations was registered as a separate observation moment, making a total of 12 observations. See Table 7.2 for an overview of the extent to which items of SDM were observed according to the OPTION-12 scale. Four of the twelve behaviours required for SDM were observed in (more than) half of the observations: stating that there are multiple ways to deal with the identified problem (50%); assessing the patient's preferred approach to receiving information to assist decision making (50%); listing options which can include the choice of no action (75%); and checking if the patient understands the information (50%). None of the SDM-behaviours were exhibited to a very high standard. Exploring the patient's concerns about how to manage a problem was not observed at all. Total scores on the OPTION-12 observation scale ranged between 0 and 40 points out of 100.

Table 7.2. Shared decision making on medication use between nurses and patients in an oncology setting: a qualitative descriptive study^a

OPTION-12 items	The behaviour is not observed	A minimal attempt is made to exhibit the behaviour.	The behaviour is observed and a minimum skill level achieved.	The behaviour is exhibited to a good standard .	The behaviour is exhibited to a very high standard .
The nurse draws attention to an identified medication-related problem as one that requires a decision-making process.	75%	0%	8.3%	16.7%	0%
The nurse states that there is more than one way to deal with the identified medication-related problem ('equipoise').	50%	8.3%	0%	41.7%	0%
The nurse assesses the patient's preferred approach to receiving information to assist decision making (e.g., discussion, reading printed material, assessing graphical data, using videotapes or other media).	50%	33.3%	16.7%	0%	0%
The nurse lists 'options', which can include the choice of 'no action'.	25%	25%	0%	50%	0%
The nurse explains the pros and cons of options to the patient (taking 'no action' is an option).	58.3%	16.7%	16.7%	8.3%	0%
The nurse explores the patient's expectations (or ideas) about how the medication-related problem(s) are to be managed.	58.3%	8.3%	33.3%	0%	0%
The nurse explores the patient's concerns (fears) about how medication-related problem(s) are to be managed.	100%	0%	0%	0%	0%
The nurse checks that the patient has understood the information.	50%	41.7%	0%	8.3%	0%
The nurse offers the patient explicit opportunities to ask questions during the decision-making process.	91.7%	8.3%	0%	0%	0%
The nurse elicits the patient's preferred level of involvement in decision-making.	91.7%	8.3%	0%	0%	0%
The nurse indicates the need for a decision making (or deferring) stage.	58.3%	8.3%	33.3%	0%	0%
The nurse indicates the need to review the decision (or deferment).	75%	0%	16.7%	8.3%	0%

^a Twelve observations

3.2 Results of the interviews and focus groups

Six themes were identified based on thematic analysis: (1) knowledge of SDM, (2) patient involvement, (3) medication-related information, (4) patients' role in medication-related SDM, (5) nurses' role in medication-related SDM, and (6) perceived barriers and facilitators towards the application of medication-related SDM.

3.2.1 Knowledge of SDM

Both nurses and patients were not familiar with the term 'Shared Decision Making'. However, some participants were able to derive its meaning from the Dutch term. Patients and nurses indicated that SDM comprised of the following components: (1) the need to make a choice, (2) being informed, (3) collaboration, communication and/or consultation between the healthcare providers and the patient, (4) patient involvement and (5) giving attention to the patients' preferences and needs. Nurses stated that SDM means that patients make decisions based on information they have received while some patients indicated that SDM means that a decision will be made in consultation. However, a few patients indicated that healthcare providers make decisions for patients and patients themselves have no voice.

"This reminds me of consultation between the nurse and the patient. Nurses make a suggestion and the patient can choose whether to agree or not, but also that the patient might suggest what he/she needs." ~ Patient 1

"Shared decision making ... Yes, normally you don't have much to say in that, I guess." ~ Patient 6

"That through collaboration, there is more attention for the preferences of the patient. That there is more consultation between the patient and the nurse instead of nurses making decisions for patients." ~ Patient 7

"Involving the patient" ~ Nurse 5

"I would think that you discuss with the patient what is going to happen, that he is informed. Yes, decision making, yes, that you explain, that he knows exactly what's going to happen so he can make a choice. Is he going to do it or not, is he going to take it or not, I would think." ~ Nurse 6

3.2.2. Patient involvement

The extent to which patients want to be involved in medication-related decisions depends on the individual and the context. A few patients did not wish to be involved in medication-related decisions due to a lack of knowledge or because they fully trust the physician's decision. Others indicated that they wanted to be involved in as many medication-related decisions as possible. Some patients only wanted to be involved in specific situations, such as in case of adjustments to their medication regimen or familiar medicines. One palliative patient indicated that she would like to be more involved in decisions regarding medication in the palliative phase given that these decisions have a greater impact on (quality of) life. Others indicated that they want to be equally involved in decisions in an adjuvant or palliative situation. Being involved in medication-related decisions gave patients a sense of reassurance, was considered beneficial for treatment adherence and patient satisfaction, and reduced feelings of regret.

Some nurses stated they made decisions for patients without consultation, for example decisions about dosage form or the administration of 'if needed' medication. Others considered the patients' wishes and preferences and gave patients' the chance to indicate whether they want medication. Furthermore, they indicated that in the palliative phase, more attention is given to patient involvement and preferences. However, nurses indicated that they should check to what extent patients want to be involved in medication-related decisions.

"I experience that as very pleasant, reassuring too, that I indeed know that I can partly decide. I can also say stop. I even think that it can positively influence the healing, if you sometimes have to make a certain choice of medication yourself, that you believe more that it will work." ~ Patient 1

"No, actually I don't, because I don't know what medication I should get. I am not trained for that." ~ Patient 6

"You don't discuss it and the patient doesn't decide. We decide for him, but we do it to do good, it's for his advantage that we decide." ~ Nurse 4

3.2.3 Medication-related information

Most patients would like to be informed about different medication options while others would prefer to be presented with only one option. A few patients preferred not to be informed about side effects of medication fearing that these would manifest more easily or because they would be too focused on them. Some patients were eager to know the side effects since they would be better prepared when they occur; while others indicated that too much information could have a negative effect on actually experiencing side effects. They only wanted to be informed about common or serious side effects. They indicated that information should, therefore, be tailored to the patient and to the patients' preferences. However, most patients recognised the need for information to enable them to decide if needed, especially in case of life-determining decisions (i.e., discontinuation of treatment in a palliative phase).

Nurses indicated that disadvantages of medication are rarely discussed with patients. They do not actively list side effects of medication fearing patients will not take the necessary medication as a result. Patients rarely ask about side effects and therefore, nurses manage side effects from a more reactive approach. They only inform patients when side effects occur.

"If they can play an important role. You know, every medication has a number of side effects, but if they occur often enough, then yes, some information should be shared about them. But not the whole package leaflet, because that makes no sense." ~ Patient 1

We often say it afterwards, when they are sweating: Ah yes, it's because you had that pill. We don't always say it immediately. ~ Nurse 4

3.2.4 Patients' role in medication related SDM

SDM is only possible if patients actively cooperate, for example by means of expression of their wishes, values and preferences. Both nurses and patients indicated that patients should draw the nurse's attention to problems (e.g., side effects), indicate if information was not understood and ask questions if additional information is needed. Patients should share their views on medication and indicate when they do not agree with a drug treatment. Furthermore, some patients felt that they should discuss their self-reliance so healthcare providers can take this into

account when making decisions. According to nurses, patients should also indicate to what extent they want to be involved in decision making

"But then it is also up to me to describe as clearly as possible, what is right, what I think is not right or what I would prefer to be different" ~ Patient 7

"I do observe, but I leave it up to the patient to ask questions or indicate problems."
~ Nurse 2

3.2.5. Nurses' role in medication related to SDM

Patients stated that nurses are their first point of contact to report problems, whether or not medication-related, and to ask questions. According to patients, nurses can have a facilitating role in expressing problems through several provoking questions. Furthermore, nurses must be able to quickly detect problems themselves. Patients perceived nurses as representatives or intermediaries between themselves and the physician. Most patients did not consider the nurse as the person who makes decisions but expects their problems, questions, expectations and preferences to be discussed by the nurses with the physician first. Afterwards, the physician makes decisions about medication or treatment, whether or not in consultation with the patient. Providing medication-related information (e.g., benefits, side effects, instructions on medicine intake) and to inform patients about the physician's decisions are roles that patients did see for nurses.

In terms of medication, nurses experienced that they are usually not the ones who are allowed to make decisions. They discuss their own observations or problems indicated by patients with the physician. Nurses defined other important roles within SDM such as determining the patient's needs and drawing the physician's attention to them, providing medication-related information, creating realistic expectations of medication, ensuring that the patient has everything to decide and guiding or supporting the shared decision making process.

"The nurse is also always the first to get the information on what it does to the patient and then that can be passed on if necessary." ~ Patient 1

"Then nurses say the physician has prescribed this medication and it's used for that" ~ Patient 4

"I think that we, as observers, are already very important. We are the ones who see the patients the most and I think that we are also the ones that the patient dares to ask the most questions to." ~ Nurse 2

"It often happens that we feel that a patient would be comfortable with certain medicines and when we propose this to our physicians, they say: oh yes, that is true. We need their approval to do it. Yes, you know, oh, he would be fine with that now, but yes, you always have to ..., you can't just give it on your own initiative" ~ Nurse 5

3.2.6. Perceived barriers and facilitators towards the application of medication-related SDM

Health status

Both nurses and patients indicated that the patient's health status plays a major role in the application of SDM. Experiencing symptoms such as pain, nausea, fatigue, feeling mentally unwell and/or experiencing strong emotions are examples cited by patients. In such situations, patients would show less initiative and would be less willing or less able to participate in decisions. Nurses stated that their own state of mind, such as fatigue or a difficult day, could be a barrier to applying SDM.

"That could also possibly be a factor from the patient's point of view. That at a certain point they are not bright at all and are not able to make a decision themselves." ~ patient 7

Medication-related knowledge

Both nurses and patients indicated a lack of medication-related knowledge as a barrier to the application of SDM. On the one hand, some patients did not want to be involved in the decision making process because of a lack of knowledge and they preferred to leave the decision to healthcare professionals. On the other hand, patients wanted to be more involved in decisions about medicines with which they had a great deal of experience or knowledge. Some patients stated that nurses know less about medication as compared to the physician and therefore have a more limited role in the medication-related SDM process. Nurses felt that they had too limited medication-related knowledge and had to rely on the package leaflet or literature. Therefore, they gave less information to patients and did involve patients to a lesser extent. Nurses attributed this knowledge-related deficiency to nursing

education, where medication is only discussed to a limited extent, which they noticed with recently graduated nurses and internship students as well.

"I do that less, I can't really explain why, but I notice that I don't do that very much. I won't go on about those pros and cons. I think because sometimes I'm too insecure about the knowledge I have about it. If I want to propose those alternatives, I should actually see for myself beforehand what the advantages and disadvantages are." ~ Nurse 2

Therapeutic relationship

According to nurses and patients, the interpersonal relationship is an important facilitator or barrier to the application of SDM regarding medication use. One patient preferred to discuss medication with the general practitioner given the existing bond of trust, while nurses were no benefit for her. Other patients were convinced that a good relationship between nurses and patients could facilitate medication-related decisions. Nurses who succeed in building a long-term and sustainable therapeutic relationship with the patient could go through the different steps of the SDM process more easily. Patients indicated that in case of a sustainable relationship with nurses, both parties know each other better, feel each other and can therefore collaborate in decision making. Patients felt that they, therefore, would be treated more as a person and less as a patient.

"The more you feel comfortable with someone, the more information you'll give them at your own initiative. If you don't have that connection, you will tell less and be more closed." ~ Patient 7

Time pressure and workload

Some patients experienced that nurses were busy and therefore sometimes could not pay enough attention to them. Nurses stated that the workload is high, they need to work very hard to complete their tasks, meaning that they did not have the time to consider what the patient was thinking or wishing for. They also indicated that they did not have the time to wait for a decision for every patient. One nurse acknowledged that she would have to look up a lot of information to discuss the pros and cons of medication, for example, and there would not be enough time for this either.

"I think when it's busy you don't always ask patients how they feel about something – When you have time, you ask those questions, but when it's busy, you don't really go into it." ~ Nurse 1

4. Discussion

Shared decision making can be considered as one of the key features of patient-centred healthcare provision³³. Nurses, as part of the interprofessional team, should collaborate and communicate with the patient and/or family to obtain the best quality of care. According to the NUPHAC-EU framework, nurses have responsibilities in seven domains of pharmaceutical care (PC): management of therapeutic and adverse effects of medication, medication adherence, patient medication self-management, patient education and information about medication, prescription management, medication safety management and care coordination⁹. SDM can be performed within all these domains. However, it is noteworthy that nurses and patients had a very one-sided mindset towards SDM concerning medication. Participants solely envision SDM in the context of prescription management (i.e., drug choice) and management of therapeutic and adverse effects. This focus should be kept in mind when interpreting the results of this study. For example, it is not surprising that nurses feel they are not the ones who should make drug choices in consultation with patients, since there is currently no legal framework allowing nurse prescribing in Belgium. Participants did not discuss SDM in other PC-domains during the interviews, which leaves it unclear whether SDM is applied or considered relevant by participants within these domains.

Previous research showed the acceptance and implementation of SDM by healthcare providers has lagged despite its benefits and the support from healthcare organizations and policy makers³⁴. Actively involving patients in decisions and placing patient perspectives and choices at the centre of patient-caregiver interactions can be challenging in the nursing profession, because of a dominating paternalistic approach³⁵⁻³⁷. This paternalistic approach was also noticeable among participants given nurses were not familiar with the term SDM, did not know the model of SDM and the different steps to be followed, which may lead to suboptimal performance on crucial parts of it³⁸. It is recommended to include SDM-competencies and SDM-models into academic curricula and training programs for healthcare providers³³.

Although most patients and nurses acknowledged the benefit of medication-related SDM, several barriers were mentioned that might explain its limited use. Firstly, the patient's health status determines whether the patient is able or willing to participate in the decision making process. This is in line with previous research showing that (older) patients participate to a lesser extent in SDM due to poor health, cognitive and/or physical impairment³⁹. Secondly, a long-term and sustainable nurse-patient relationship was mentioned to be an important facilitator for medication-related decisions. A good relationship and personal connection with the patient will enable open and valuable conversations about treatment and patients are more at ease to ask questions⁴⁰. Patients confirmed the latter during the interviews. Furthermore, a study by Keij et al. (2021) showed that a poor clinician-patient relationship results in patients not absorbing information properly, not expressing themselves properly, and asking fewer questions which complicates the SDM process²². Thirdly, a lack of medication-related knowledge resulted in nurses informing and involving patients in decisions regarding medication to a lesser extent. A study by Tariman et al. (2016) showed that the degree of participation in SDM is influenced by nurses' level of knowledge⁴¹. However, this perceived barrier should be interpreted with caution given the narrow focus on prescribing and monitoring effects. Nurses' medication-related knowledge is potentially not considered to be a barrier when it comes to other PC domains. Lastly, time pressure and workload were mentioned during the interviews. These barriers were also reported by previous studies^{22, 40, 42, 43}.

Even though SDM about medication seems to be no integral part of nursing care yet, both nurses and patients described the importance of nurses' contribution in this process. Firstly, the nurse can act as a representative of the patient or a liaison between the patient and other healthcare providers. Patient advocacy can be accomplished by discussing patients' preferences, problems and questions with physicians. Secondly, nurses can inform patients about medication (e.g., benefits, side effects, and adherence). Thirdly, nurses can guide and facilitate the SDM process. Previous research showed that nursing tasks within SDM are focusing on patient education and providing evidence-based information, advocacy, detecting patient needs for knowledge and support and evaluating patients' opportunities and desire for involvement in decisions^{21, 41, 44, 45}.

The desire to be involved in decisions about medication depends on the individual and the situation. The patient's wish to be involved may be different within various domains of pharmaceutical care. It is likely that patients want to be more involved in decisions regarding medication adherence or medication self-management, but rather rely on the healthcare provider for decisions regarding drug choice. Therefore, the extent to which patients want to be involved in decisions should be regularly assessed given the personal and contextual differences^{13, 19}. Healthcare providers have a main responsibility in enabling patient participation in SDM concerning medication⁴⁶. Patients often place caregivers on a pedestal, are reluctant to disagree with them for fear of being offended or underestimate the value of their knowledge. Encouragement and guidance by the healthcare team, including nurses, is required to truly engage patients within SDM⁴⁷. Various benefits of patient involvement in medication-related decisions were mentioned by patients during the interviews such as improved treatment adherence, increased patient satisfaction and reduced feelings of regret, which is fully in line with previous research performed in other settings^{48, 49}. This strengthens the benefit of SDM regarding medication treatments.

4.1 Implications for clinical practice

SDM is an essential element in the provision of high-quality, person-centred care^{50, 51}. Patients appreciated nurses' contribution and want them to be involved in shared decision making^{52, 53}. Nurses are key players within the interprofessional team as they have closer contact with patients and can, therefore, more easily assist patients in decision making in different domains of pharmaceutical care⁵⁴. However, nurses should be more aware of the benefit of applying SDM in all domains of pharmaceutical care, given their current restricted vision regarding the use of SDM in domains of prescribing and monitoring effects. Future research should focus on nurses' and patients' experiences and (role) perceptions towards SDM in other domains of pharmaceutical care such as medication adherence or medication self-management.

However, to facilitate implementation and to ensure that nurses can apply SDM-principles in different domains of pharmaceutical care, it is important to create an enabling environment. A positive and supporting hospital culture regarding nurses

as partner in SDM is needed^{33, 40}. Nurses should be trained in coaching patients in decision-making^{55, 56}. A nurse practitioner or clinical nurse specialist is ideally placed to guide the implementation of SDM as well as coach patients and healthcare providers in its application^{57, 58}. Existing guidelines about SDM can be used as a supportive measure to actively involve patients in several domains of PC and to provide person-centred care⁵⁹. Tools such as health information technology also offer opportunities to support SDM through interactive decision aids and electronic health records (EHR)^{60, 61}. For example, the EHR may contain prompts to nurses to initiate SDM in certain clinical situations⁶⁰.

Nevertheless, it is vital to bear in mind that not all patients want to or are able to participate in SDM about medication. Therefore, it is necessary to assess patients' desire and/or ability to become involved at crucial time points such as moments when changes are made to the medication schedule, starting or stopping medication or medication self-management, et cetera^{13, 19}.

4.2 Strengths and limitations

To the best of our knowledge, this is the first study to describe SDM in relation to medication use between nurses and patients in a Belgian oncology setting. The study is relevant to nursing practice as it provides insight into patients' expectations of the nurses' contribution to the medication-related SDM process. The interviews were conducted by the second author who worked as a nurse in the oncology department and hence the existing therapeutic relationship may have created a more confidential and open atmosphere.

However, we need to acknowledge certain limitations of the study. Firstly, the OPTION-12 scale has been validated for use during consultations, not for use during hospitalization^{24, 25}. Secondly, the OPTION-12 scale was developed to observe SDM but is not specific for SDM regarding medication. Therefore, the interpretation of the observations should be performed with caution. Thirdly, although every nurse at the participating ward was observed during at least one shift, there was only a limited number of observations being performed. However, since the observations were only intended to trigger group discussion, large numbers of observations were not necessary. Fourthly, although the interviews were conducted in civilian clothes,

social desirability bias should be considered given the existing nurse-patient relationship between interviewer and interviewee⁶². Fifthly, the transferability of the data is limited. Despite our efforts to provide maximum variation in the study sample, only female palliative patients could be included. Sixthly, only one focus group was conducted which consisted of nurses who had all been recruited from the same hospital ward. Lastly, our study focused exclusively on the oncology department since this setting requires sensitive decision-making. Normally, recruitment would gradually be broadened to other settings. However, due to COVID, hospitals went into lockdown, and including patients and nurses for further interviews was neither feasible nor considered a priority at that time. However, any patient using chronic medication can benefit from SDM in relation to medication use, particularly patients who are prescribed numerous medicines. Therefore, it might be interesting to conduct future research focusing on the experiences regarding SDM on medication use and perceptions of patients with polypharmacy and nurses working in other healthcare settings such as geriatrics or cardiology.

5. Conclusion

According to participants, the application of SDM concerning medication by nurses is limited in clinical oncology practice. Health status, medication-related knowledge, the therapeutic nurse-patient relationship, as well as time pressure and workload were perceived as facilitators or barriers to its application by nurses. Nurses' contribution to SDM regarding medication is appreciated by patients. From a patient and nursing perspective, nurses can act as a patient's advocate and can fulfil an informative, facilitating and supportive role within the SDM process. The desire for patient involvement in decision making regarding medication depends on characteristics of the person and context. Therefore, the patients' ability and desire for SDM in several domains of pharmaceutical care should be assessed on a regular basis. Given the current focus of participants on SDM in domains of drug choice and management of therapeutic and adverse effects, there is a need for further research into SDM between nurses and patients in other domains of pharmaceutical care, such as medication adherence and medication self-management.

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CRediT authorship contribution statement

Laura Mortelmans: Conceptualization, Methodology, Funding acquisition, Formal analysis, Writing – original draft, Writing – review & editing. Sarah Bosselaers: Conceptualization, Methodology, Formal analysis, Writing – review & editing. Eva Goossens: Conceptualization, Methodology, Writing – review & editing. Helen Schultz: Conceptualization, Methodology, Writing – review & editing. Tinne Dilles: Conceptualization, Methodology, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Laura Mortelmans reports financial support was provided by Research Foundation Flanders. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Chapter 8

The development and evaluation of a medication diary to report problems with medication use

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Abstract

Purpose

The study aimed to develop and evaluate a medication diary for patients to report problems with medication use to enable shared decision making and improve medication adherence.

Methods

Based on a search for existing diaries, a review of the content, and a list of medication self-management problems compiled from previous research, a paper and pencil version of a medication diary was developed. The diary was reviewed for clarity and overall presentation by five healthcare providers and nine patients. Afterwards, user-friendliness was evaluated by 69 patients with polypharmacy discharged from hospital during a quantitative prospective study.

Results

The medication diary consists of several parts: (1) a medication schedule allowing patients to list their medicines, (2) information sheets allowing patients to write down specific medication-related information, (3) a monthly overview to indicate daily whether medication-related problems were experienced, (4) problem sheets elaborating on the problems encountered, (5) space for specific medication-related questions for healthcare providers to facilitate shared decision making. The review phase resulted in minor textual adjustments and one extra problem in the problem sheet. Most participants, who tested the medication diary for two months, found the diary user-friendly (80%) and easy to fill in (89%). About 40% of participants reported problems with medication use. Half of the patients indicated that the diary can facilitate discussing problems with healthcare providers.

Conclusion

The medication diary offers patients the opportunity to report problems regarding their medication use in a proven user-friendly manner and to discuss these problems with healthcare providers. Reporting and discussing problems with medication use can serve as a first step towards making shared decisions on how to address the problems encountered.

1. Introduction

Medication self-management capacity can be defined as *“the cognitive and functional ability to self-administer a medication regimen as it has been prescribed”*¹. Self-management of medication entails a diverse set of actions that individuals need to execute effectively to manage their medicines. Knowledge, skills and behaviours are mandatory to correctly take medication and sustain adequate use over time²: patients have to be able to obtain medication or fill their prescriptions, know their medicines and comprehend their medication schedule, and should possess functional skills (e.g., recognizing medicines, opening medication packages and choosing the appropriate dose and time of administration)^{2, 3}. Furthermore, proper self-management of medication requires medication literacy, defined as *“the degree to which individuals can obtain, comprehend, communicate, calculate and process patient-specific information about their medications to make informed decisions to safely and effectively use their medications”*⁴.

Literature highlights that patients commonly face difficulties in self-managing their medicines, impacting both medication adherence and the safe use of medicines^{2, 5-11}. Medication non-adherence can result, for example, from forgetting to take medicines, being unable to open medication packages or not being able to follow instructions for medication intake¹². Non-adherence refers to not taking medicines as prescribed¹³ which is reported to be the case for about 50% of patients with chronic conditions^{14, 15}. After hospital discharge, non-adherence to medication is observed in 24% to 40% of patients^{16, 17}. The prevalence of medication errors by community-dwelling patients is estimated between 19 and 59% which is a threat to safe medication use¹⁸. For older people with complex therapeutic regimens, this prevalence increases to 75%¹⁸.

Patients with polypharmacy are at increased risk of experiencing problems with medication self-management, adherence and safe medication use due to the multitude of medications administered and the higher complexity of their medication schedule^{19, 20}. Furthermore, patients recently discharged from hospital are more vulnerable to medication-related problems as hospitalisation is often accompanied by several changes in the medication regimen^{21, 22}. Research showed that 54–82%

of patients were unable to name changes in their medication regimen and 55% did not utilize medicines at home as recommended at discharge²³⁻²⁵. A systematic review showed that drug-related hospital readmission rates varied from 3% to 64%²⁶. Ensuring medication safety in polypharmacy and during transitions of care are priority areas according to the World Health Organisation²⁷.

To enhance adherence and safe medication use at home, it is important to identify and address difficulties in self-management of medication²⁸. To achieve this, healthcare providers need to understand how patients' medication use and self-management proceed at home. Patient involvement, as a cornerstone of patient-centered care and quality of care, is, therefore indispensable²⁹⁻³¹. Patients, as respected partners in care, should be given the chance to communicate their experiences, problems and needs regarding medication to healthcare providers. In response, healthcare providers can inform patients about different options to deal with the medication-related problems encountered, taking into account patients' preferences and values. This way, patients and healthcare providers can work together to find the best solution or approach to deal with problems. The process of sharing information and supporting patients to consider options to achieve informed decisions is called shared decision-making^{32, 33}.

A medication diary allowing patients to register problems with medication use in a structured way can help them to discuss these problems with healthcare providers, in order to intervene if necessary and to tailor the pharmacotherapeutic care to the patient's needs. Medication diaries, used in previous research, mainly focus on reporting the extent to which medicines were taken (adherence)³⁴⁻³⁷, but do not focus on reporting problems leading to not taking medicines as prescribed. Furthermore, medication diaries are often not evidence-based. Therefore, the main aim of the study was to develop and evaluate a structured medication diary for patients to report problems with medication use to enable shared decision making and to improve medication adherence.

2. Materials and Methods

2.1 Stage 1: Development of the medication diary

As shown in Figure 8.1, several actions were undertaken during the first stage of developing the medication diary. First, a PubMed search was conducted to identify research articles on the development, evaluation or utilization of medication diaries. The following search strategy was used: (((("medication diar*") OR ("medicine diar*")) OR (("patient diary") AND ("medication")))). Articles published until November 1, 2021 in English, French or Dutch were eligible. To assess the relevance of the search results, the title and abstract were screened. Articles were included if the abstract reported on the development, evaluation or use of a medication diary in adult patients. Afterwards, the full text was reviewed to assess the content of the medication diary used and the extent to which diaries offer patients an evidence-based structure for reporting medication-related problems. Appendix 8.1 presents the selection process and results. Additionally, websites of bookshops and websites of healthcare organisations (i.e., hospitals) were hand-searched. Digital medication diaries were searched via Google Play, using the Dutch and English terms for medication diary. Diaries were mainly intended for the registration of medicines and medicine intake. None of the diaries provided a list of medication self-management problems to be reported.

Hence, a list of problems in medication self-management was derived from previous research as a basis for developing the diary. In this context, a cross-sectional study on the prevalence of medication self-management problems post-discharge was employed to pinpoint the difficulties faced by polypharmacy patients³⁸. The study results indicated that patients face many problems in managing their medications, averaging four problems after hospital discharge. These problems included difficulties to obtain medication, a lack of medication-taking abilities and a lack of medication knowledge³⁸. Subsequently, to finalise the list of problems, PubMed was searched for literature reviews that evaluated instruments for assessing medication management problems. For this purpose, the following search strategy was used: (("medication management") AND ("assessment") AND ("instrument") AND (("review") OR ("Review" [Publication Type]))). The search yielded 10 records, but only four of them consisted of reviews on instruments assessing medication

management problems³⁹⁻⁴². The content of the different instruments included in the reviews was examined, and the medication management problems assessed in the instruments were listed.

Based on reviewing existing diaries and the list of potential problems with medication, a draft version of the diary was developed by the authors. Afterwards, a graphic designer from the University of Antwerp was consulted to determine the diary's design. The format, colour, font and text size were discussed considering readability and user-friendliness.

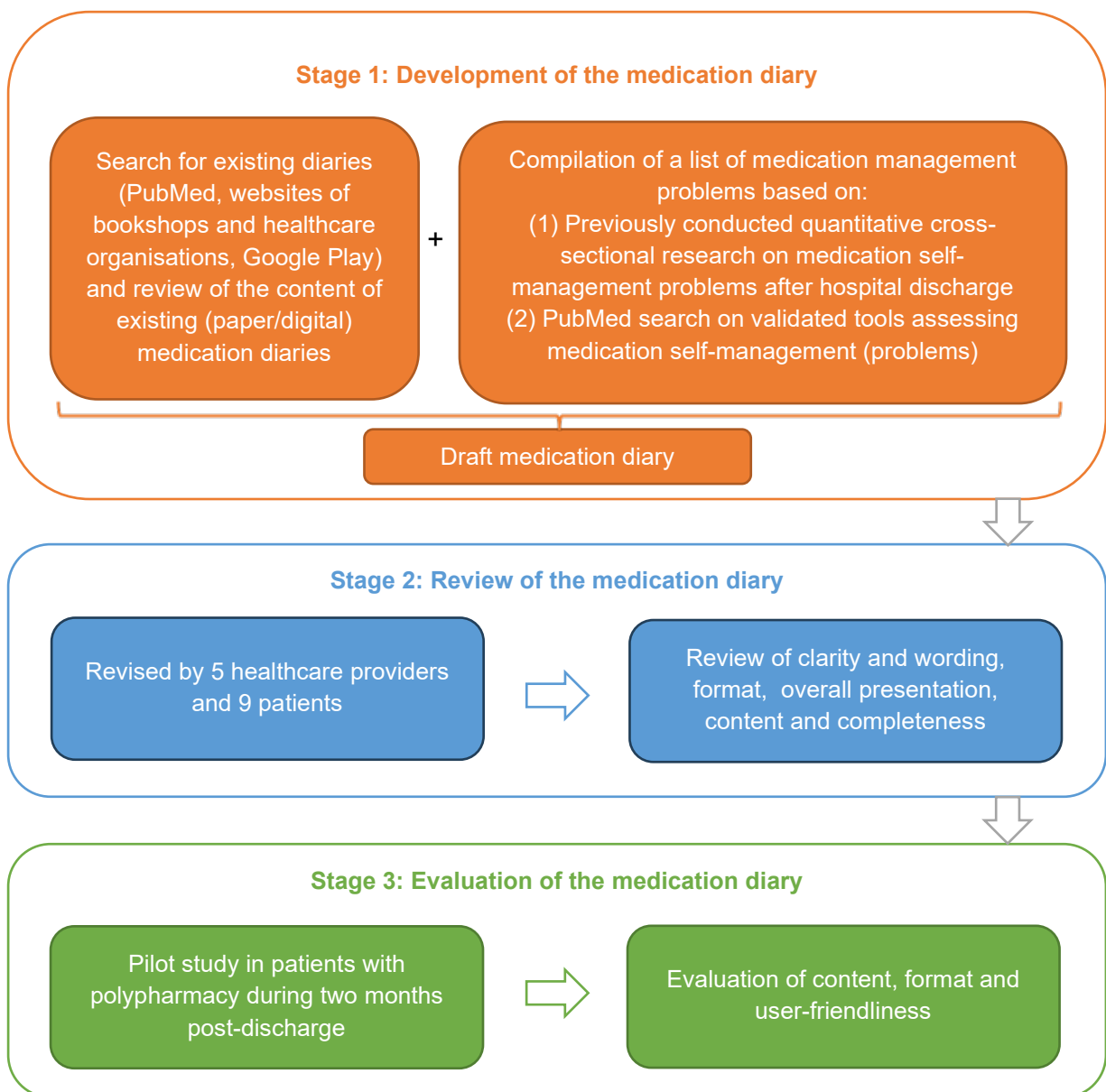


Figure 8.1: Flowchart of the methodology

2.2 Stage 2: Review of the medication diary

The draft of the medication diary was reviewed for clarity and wording, format, overall presentation, content and completeness. Two hospital pharmacists, a physician and two nurses, employed in both university and regional hospitals, as well as nine patients with polypharmacy (i.e., taking five or more chronic medicines daily), reviewed the medication diary. Healthcare providers were selected based on their knowledge of hospital medication management and their role in direct patient care. Feedback was provided verbally.

2.3 Stage 3: Evaluation of the medication diary

As part of a larger prospective descriptive study on the feasibility and validity of different methods measuring medication adherence, the medication diary was pilot tested by patients. This article will not report a detailed analysis of the feasibility and validity of the different measurement methods. This report focuses on evaluating the content, format and user-friendliness of the medication diary.

2.3.1 *Participants*

Using consecutive sampling, patients were recruited out of two Belgian hospitals at two geriatric, four internal and five surgical wards between January and March 2022. During this period, all eligible patients who were willing to participate in the study were included. Patients' eligibility was evaluated by a hospital ward nurse who served as a liaison between the researchers and the patients. Hospitalised patients had to meet the following criteria: (1) aged ≥ 18 years, (2) taking five or more chronic medicines at discharge (i.e., polypharmacy), (3) being discharged towards home and (4) being Dutch-speaking. Exclusion criteria consisted of: (1) being not responsible for own medication administration at home, (2) incapable of giving consent to participate in the study, (3) having a neuropsychiatric diagnosis of dementia.

As the evaluation of the content, format and user-friendliness of the medication diary is descriptive in nature, no power analysis was conducted. However, as part of the larger prospective descriptive study, the sample size was determined, based on the expected correlation between the different methods measuring medication

adherence ($r = 0.3$), a power of 0.80 and a type I error rate of 0.05. The sample size determined was 84 patients

2.3.2 Data collection

Between January and June 2022, data were collected on the day of hospital discharge (i.e., the moment of inclusion) and two months post-discharge. Patients willing to participate in the study were administered a questionnaire on socio-demographic data (e.g., age, gender, educational level,...) and medication management (e.g., number of medicines, use of medication aids, ...) for descriptive purposes. At the time of discharge, patients received instructions on using the medication diary for two months (± 60 days). Teaching patients how to use the diary was performed by two nurse researchers, one in each participating hospital. For this purpose, the written instructions presented in the diary itself (see appendix 8.2) were discussed with the patient, and additional explanations were given if necessary. Patients received a printout of their medication scheme which was pasted or transcribed into the diary by the nurse.

During two months post-discharge, patients were asked to record (changes in) their medication scheme and to indicate whether they experienced any problems concerning their medication use. If so, patients were asked to fill in a structured problem sheet indicating the medication-related problems encountered. To determine whether the completion of the diary went well (i.e., whether patients experienced any difficulties in completing the diary or had any questions about the diary) and to gather information on dropouts (i.e., patients not completing/using the diary), patients were contacted by telephone at weeks 1, 3 and 5 after hospital discharge.

Two months post-discharge, a home visit was conducted where a self-developed questionnaire was administered. Statements and multiple-choice questions were used to assess the user-friendliness of the medication diary. Statements could be answered using a 4-point Likert scale (1 = strongly disagree to 4 = strongly agree). In an open-ended question, patients were asked whether items should be added or removed (see Appendix 8.3).

Telephone calls and home visits were performed by three nurse researchers. To ensure uniformity among data collectors, the content of the telephone calls and the administration of the survey during the home visit was discussed in a meeting before the start of the study. Regular online and live meetings throughout the process of data-collection were performed.

2.3.3 Data analysis

The data analysis was conducted using the Statistical Package for the Social Sciences (SPSS) version 28. Frequency distributions were used to describe discontinuous data. The mean value and standard deviation were used for the description of continuous data with a normal distribution, whereas for non-normally distributed data, the range and median were used. The normality of the distribution was tested using Z-scores. Descriptive statistics were used to describe changes needed to make the medication diary more user-friendly. Drop-out rates and reasons were described. Drop-outs were excluded for analysis.

2.4 Translation of the diary

To facilitate publication, a native English speaker from the University of Antwerp's language institute (Linguapolis) translated the Dutch version of the medication diary into English. The translator was not engaged in this study or any prior research on this topic.

3. Results

3.1 Stage 1: Development

The paper and pencil version of the medication diary consists of several parts.

- 1) The medication schedule allows patients to list their (non-)prescribed medicines. Patients can indicate the name, indication, dosing frequency, quantity, time of administration and administration route for each medicine. Changes in the medication schedule, such as stopping or starting medication therapy, can be indicated.
- 2) The information sheets allow patients to write down specific information, such as common side effects or precautions for each medicine.

- 3) In the monthly overview, patients can indicate daily whether they experienced problems taking medicines. To reduce the burden of completing the diary, a deliberate choice was made to focus solely on reporting problems with medication use, and not to indicate every medication intake.
- 4) In case of problems, patients can fill in a structured problem sheet indicating the problems they were experiencing. Problems in the problem sheet are divided into categories: (1) problems with obtaining medicines (i.e., medicines out of stock, forgot to collect medicines from the pharmacy, cannot afford medicines, no refill prescription available), (2) side-effects, (3) problems with medication use (wrong dose, wrong time, wrong administration route, forgot to take medicines, administration problems), (4) problems with medication packages (problems with opening or storage), (5) other problems. Patients can indicate with which medicine they experienced problems (all or specific ones) and whether they took any action to address the problem (e.g., contact with the general practitioner, pharmacist, ...).
- 5) Shared decision making: Patients can write down specific questions for their general practitioner or another care provider, new medication instructions, appointments with healthcare providers concerning their medicines, ...

In collaboration with the graphic designer of Antwerp University, an A5-sized medication diary was chosen so it can be easily carried by a patient in a handbag or backpack. The Calibri Font was used since a sans-serif font is more readable. To make the medication diary visually appealing and enhance clarity, tabs were used in different colours for each part of the medication diary. The complete medication diary, both in Dutch and English, is available online (see Appendix 8.2).

3.2 Stage 2: Review

After a review of the clarity and wording of the medication diary by healthcare providers and patients, some minor textual adjustments were made based on their feedback. Only one extra problem category was suggested which was added to the structured problem sheet: 'I cannot read or understand all the information about my medication.'. The other problems were considered appropriate for inclusion in the diary by healthcare providers and patients and were, therefore, retained. The format

and overall presentation required no changes according to the evaluators (i.e., healthcare providers and patients).

3.3 Stage 3: Evaluation

3.3.1 *Research population*

Of the 85 patients willing to fill in the diary during two months post-discharge, 69 patients completed the study (18.8% dropout). Reasons for dropout are shown in appendix 8.4. The mean age of the participants was 68.9 years [SD 8.8] and 73% (n = 50) were men. The majority (69%, n = 43) had at least a higher secondary education level. Participants took on average seven different medicines at discharge [SD 2.5]. Participants' characteristics are shown in Table 8.1.

Table 8.1: Sample characteristics

Characteristics (n = 69)	
Age in years, mean [SD, min – max]	68.9 [8.8, 43 - 86]
Gender (male), % (n)	72.5 (50)
Highest level of education, % (n)	
No education	5.8 (4)
Primary education	4.3 (3)
Lower secondary education	20.3 (14)
Higher secondary education	31.8 (22)
Higher vocational education	18.8 (13)
Bachelor's degree	14.5 (10)
University (master's degree/PhD)	4.3 (3)
Number of chronic medicines at discharge, mean [SD, min – max]	7.2 [2.5, 5 - 15]
Number of medication changes during two months post-discharge ^a , mean [SD, min – max]	1 [0 – 12]
Use of medication aids (yes), % (n)	61.8 (42)

^a Patient-reported, SD = standard deviation, min = minimum, max = maximum, PhD = Doctor of Philosophy

3.3.2 *Use of the medication diary*

About 85.5% of participants (n = 59) wrote their medicines in the diary's medication schedule, while 11.6% (n = 8) stuck a copy of their medication schedule in the diary. Only 2.9% (n = 2) did not fill in the medication schedule. Medication-related information was added to the information sheets by 28% of participants (n = 19). All

patients, except one, indicated in the monthly overview whether they were experiencing problems with medication. Approximately 40% of the participants ($n = 28$) reported problems with their medication intake in the problem sheets over two months. Forgetting to take medicines was reported by most patients, followed by experiencing side effects and not having medicines in stock at home (Figure 8.2). Nineteen percent ($n = 13$) wrote down questions for healthcare providers, appointments with healthcare providers or new medication instructions.

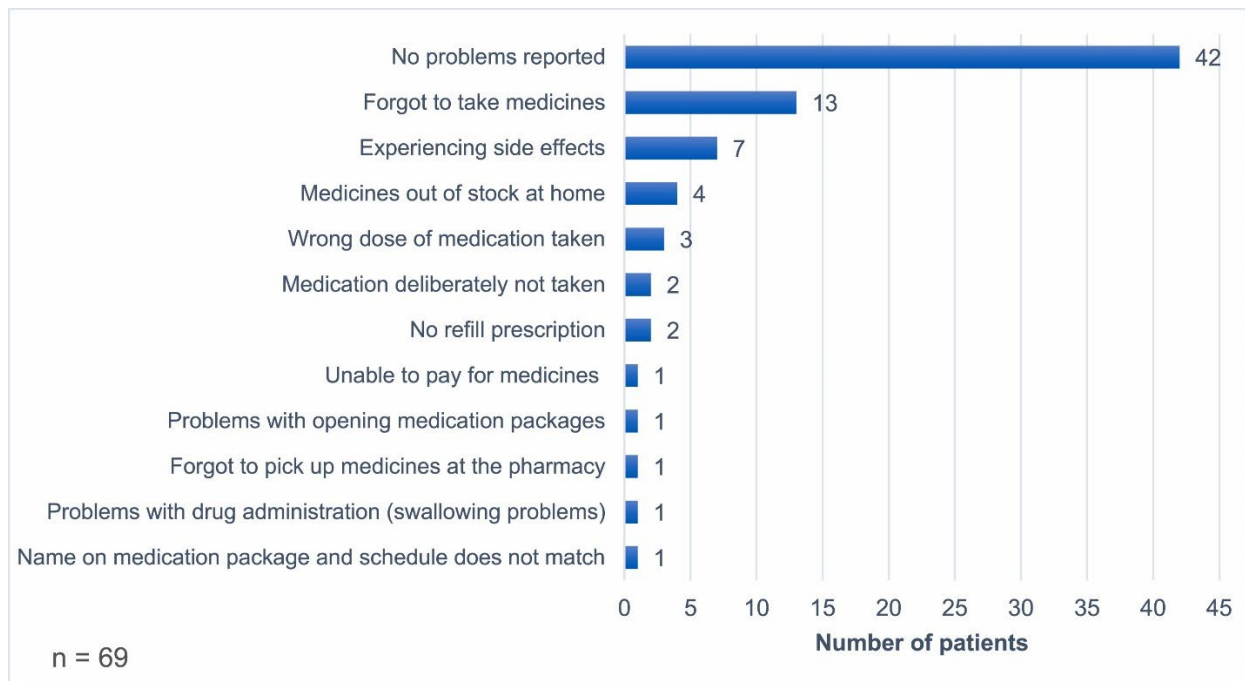


Figure 8.2: Problems reported in the medication diary

3.3.3 Evaluation of the content, format and user-friendliness of the medication diary

Most participants (89%, $n = 61$) indicated that filling in the diary over two months was easy. Half of the participants (49%, $n = 34$) reported that the medication diary could help them discuss problems regarding medication use with healthcare providers such as the general practitioner, pharmacist, home nurse, ... Only 16% ($n = 11$) of the participants would prefer to keep a digital diary (Figure 8.3).

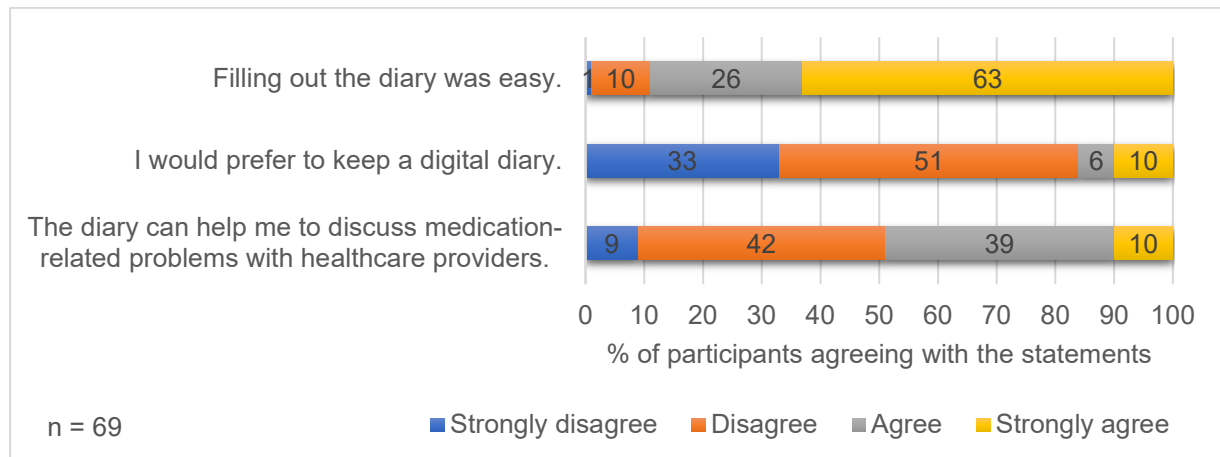


Figure 8.3: Overall evaluation of the medication diary

After filling in the medication diary for two months, 80% of participants ($n = 55$) indicated that no changes were needed to make the diary more user-friendly. The remaining participants indicated that user-friendliness could be increased and provided the following suggestions: smaller size ($n = 4$), more structure ($n = 3$), less structure ($n = 3$), more space for free text notes ($n = 3$), less extensive problem sheets ($n = 2$), larger font size ($n = 1$), more space for comments in the monthly overview for example to report parameters such as blood pressure ($n = 1$), provide columns in the medication schedule (morning, afternoon, evening) to indicate the time of intake ($n = 1$), smaller columns in the monthly overview ($n = 1$), fewer problem sheets ($n = 1$). Only 9% ($n = 6$) indicated that items should be added and/or removed from the diary. Two participants suggested adding a page for parameters such as blood pressure measurements, one suggested adding space for contact details of important persons (e.g., general practitioner) and another suggested adding examples of how to fill in the diary. The information sheets could be removed according to three participants. Furthermore, two participants indicated that a monthly overview covering one year is sufficient, and therefore, the dual monthly overview could be removed. One participant suggested deleting the problem sheets because s/he did not experience any problems.

4. Discussion

To our knowledge, this is the first study developing a paper and pencil version of a medication diary that can serve as a resource for reporting problems concerning medication self-management and medication use. A search in PubMed did not yield any research papers focusing on the development or evaluation of a medication diary at all. The research articles found used the medication diaries as a method for data collection and were mostly intended for monitoring medication intake. Our diary is unique because it focuses on problems in various stages of the medication self-management process (i.e., obtaining medication, understanding medication related-information, medication administration, monitoring side effects, ...) and not solely on medication intake. The diary guides patients by offering an evidence-based structure since scientific research into medication self-management problems experienced by patients was used in the development. Furthermore, the diary offers the possibility to record actions taken by the patient in case of problems. This can give healthcare professionals insight into how patients deal with problems and determine whether additional support is needed.

During the development, the opinion of, not only healthcare providers but also patients as potential users of the medication diary was considered. A minority of patients (20%) did suggestions to make the diary more user-friendly. However, those suggestions were very diverse and dependent on the individual. For example, one participant wanted more structure in the diary while another wanted less structure. It is difficult to tailor the medication diary to each individual need or preference. No fundamental changes were made to the diary at the end of the pilot test, as the majority found the diary user-friendly and did not consider any changes necessary. We should acknowledge that there is an overrepresentation of male respondents in our sample, who may have a different opinions about the medication diary than women.

The researchers chose to develop a medication diary on paper instead of a digital version since paper is more accessible to an older population. In Belgium, only half of the people aged 65 or over have a smartphone and only 42% have a tablet⁴³. We certainly want to reach the older population, given their heightened vulnerability to

difficulties in managing their medicines as a result of the cognitive and physical decline that is part of the aging process⁴⁴. Furthermore, aging raises the likelihood of polypharmacy, which, in turn is related to medication-related problems⁴⁵. The results of our study showed that the paper and pencil version was a good choice, since only 16% would prefer to keep a digital diary. However, making the diary available both digitally (via an application) and on paper could be of added value. It will allow patients to make a choice that suits their preferences.

The diary is mainly intended for those who experience problems with their medication. However, in this study, a large proportion of patients (60%) reported no problems during two months. These results are inconsistent with previous research. A study on medication self-management problems after hospital discharge in geriatric patients showed that about 90% encountered at least one problem in medication management³⁸. Another study in community-dwelling adults (65+) showed that 70% of patients experienced one or more medication management problems⁴⁶. However, these results relate only to older patients (≥ 65 years), who are more vulnerable to problems in medication management because of physical and cognitive decline⁴⁴. In the present study, the diary was evaluated in a population of adult patients (18+) with an age varying between 43 and 86 years which may explain the lower percentage of problems encountered. Nevertheless, we should wonder whether they did not experience any problems or did not want to report problems. We must be aware that registering, reporting or discussing problems regarding medication use always requires a certain level of willingness and effort from the patient. Not experiencing problems or not wanting to communicate problems could explain why only half of the participants indicated that the diary has the potential to help them discuss problems with caregivers.

Furthermore, we should be aware that self-reported data in the medication diary may be subject to errors and social desirability bias. Errors in the medication scheme, for example, were minimised, since the nurse involved in the study, wrote or stuck an up-to-date scheme in the diary at discharge. However, we cannot guarantee the correctness of the schedule two months post-discharge as we did not have access to the medication list after a patient's discharge. This should be considered a limitation of the study. To minimise the risk of incorrect data, patients

were advised to have any changes in their medication noted by the general practitioner or to request a new printout if changes occurred.

Most patients found the diary user-friendly and easy to fill in. However, only a limited proportion of patients actively used all elements of the medication diary. For example, only 19 patients filled out the information sheets. Furthermore, more than half of the participants have not completed the problem sheets as they did not experience medication-related problems. Consequently, we have to be cautious about conclusions regarding the user-friendliness of the diary. It is desirable to have the diary used by a larger sample of patients experiencing problems. In this regard, it would be recommended to assess whether patients experience medication self-management problems using validated tools^{39, 40, 46}.

4.1 Study limitations

First of all, only one database was searched for existing medication diaries. Therefore it is possible that not all existing diaries were identified. Secondly, the questionnaire evaluating user-friendliness and the medication diary itself relies on self-reported data, which may be subjective to social desirability bias. Thirdly, the medication diary was pilot tested by a small sample of patients, and only a limited number of participants utilized all components of the diary. Lastly, there was an overrepresentation of male respondents in our study. Both the small sample size and the lack of gender equality may limit the generalisability of the results.

4.2 Clinical relevance

Good communication between patients and healthcare providers is crucial for optimal drug treatment⁴⁷⁻⁴⁹. On the one hand, it is important that medication therapy can be aligned with the patient's needs, experiences and goals. On the other hand, healthcare providers need to know how the patient's use of medicines proceeds.

This medication diary offers the possibility of registering problems with medicines, making it easier to discuss problems with general practitioners, pharmacists, nurses or other healthcare providers. This enables healthcare providers to intervene if necessary and to tailor the pharmacotherapeutic care to the patient's needs.

5. Conclusions

The developed medication diary can potentially serve as a supportive tool for patients to report their problems regarding medication management. The user-friendliness of the diary was demonstrated. The medication diary has the potential to help discuss problems regarding medication management with healthcare providers. However, self-reporting problems related to medication requires a certain willingness from the patient.

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Ethical approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval for part 3 of the study (i.e., the evaluation of the medication diary in patients with polypharmacy) was granted by the Ethics Committee of The Antwerp University Hospital (registration number B3002021000224). All participants received information on the purpose, design and execution of the study. Written informed consent was given by all study participants.

Availability of data and material

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

CRedit authorship contribution statement

Laura Mortelmans: Writing – original draft, Visualization, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Tinne Dilles:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Laura Mortelmans reports financial support was provided by Research Foundation Flanders. Tinne Dilles reports a relationship with Arega that includes: funding grants. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Part III

Preparatory studies for evaluating
SelfMED's effectiveness:
medication adherence measurement
and intervention protocol

Chapter 9

Evaluation of methods measuring medication adherence in patients with polypharmacy: a longitudinal and patient perspective

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Abstract

Purpose

To explore patients' willingness to have medication adherence measured using different methods and evaluate the feasibility and validity of their combination (i.e., pill counts, a medication diary and a questionnaire assessing adherence two months post-discharge).

Methods

(1) A cross-sectional evaluation of the willingness of patients with polypharmacy to have their medication adherence measured post-discharge. (2) Medication adherence was monitored during two months using pill counts based on preserved medication packages and a diary in which patients registered their adherence-related problems. During a home visit, the Probabilistic Medication Adherence Scale (ProMAS) and a questionnaire on feasibility were administered.

Results

A total of 144 participants completed the questionnaire at discharge. The majority was willing to communicate truthfully about their adherence (97%) and to share adherence-related information with healthcare providers (99%). More participants were willing to preserve medication packages (76%) than to complete a medication diary (67%) during two months. Most participants reported that preserving medication packages (91%), completing the diary (99%) and the ProMAS (99%) were no effort to them. According to the majority of participants (60%), pill counts most accurately reflected medication adherence, followed by the diary (39%) and ProMAS (1%). Medication adherence measured by pill counts correlated significantly with ProMAS scores, but not with the number of diary-reported problems. However, adherence measured by the medication diary and ProMAS correlated significantly.

Conclusion

Combining tools for measuring adherence seems feasible and can provide insight into the accordance of patients' actual medication use with their prescribed regimen, but also into problems contributing to non-adherence.

1. Introduction

Medication adherence defined as *"the process by which patients take their medications as prescribed"*¹, is indispensable to maximise therapeutic effectiveness and disease management. Optimization of adherence is needed, however, as approximately 50% of patients with chronic conditions do not adhere to prescribed medication regimens². Moreover, polypharmacy, usually defined as the concomitant intake of at least five medicines³, is found to be associated with poorer medication adherence because of the larger number of medicines and the complexity of the medication regimen⁴⁻⁶. Non-adherence rates between 6% and 55% were reported in older patients with polypharmacy⁷, contributing to poorer health outcomes, increased healthcare service utilization and higher healthcare expenditures⁸⁻¹².

To improve medication adherence, a multitude of interventions have been developed in recent years¹³⁻¹⁶. An accurate measurement of medication adherence is crucial to correctly assess the effectiveness of such interventions, but remains a major challenge in research and clinical practice, despite the different methods being available. To date, there is no 'gold standard' for the evaluation of adherence in patients with polypharmacy. The best strategy seems to be a combined use of at least two methods^{2, 17-19}.

A systematic review concluded that a simultaneous use of multiple instruments validating adherence to polypharmacy from various perspectives would be beneficial for future researchers²⁰. However, the patient's perspective is hardly taken into account when measuring adherence to medication. Currently, there is a lack of information on the willingness of patients with polypharmacy to have their medication adherence measured by healthcare providers. Moreover, it is unclear whether a combination of subjective and objective methods measuring adherence is considered feasible by patients with polypharmacy in practice.

The combination of subjective (e.g., self-report scales) and objective measures (e.g., measurements of clinical outcomes, pill counts, pharmacy records, electronic monitoring of medication administration) is considered as the current state of the art^{17, 18}. Previous research compared medication adherence measured by pill count with adherence measured by several self-report scales²¹⁻²³, pharmacy data²¹ and

electronic monitoring^{24, 25}. Furthermore, the Medication Adherence Report Scale²⁶ and Electronic Monitoring data²⁷ were used to validate the Probabilistic Medication Adherence Scale (ProMAS). To our knowledge, the ProMAS has so far not been validated using pill counts. A medication diary, used to report problems related to medication adherence, has been developed in previous research, but was not validated yet²⁸. Therefore, in this study, the combination of pill counts, a patient diary and a self-report questionnaire for assessment of medication adherence has been evaluated during two months post-discharge.

The aims of the study were to explore the willingness of patients with polypharmacy to have medication adherence measured using different methods after hospital discharge; to evaluate the feasibility and validity of a combination of pill count, a medication diary and a questionnaire for assessment of medication adherence in patients with polypharmacy two months post-discharge.

2. Methods

2.1 Design

A quantitative prospective descriptive study was conducted. The first part of the study consisted of a survey assessing the willingness of patients with polypharmacy to have their medication adherence measured after hospital discharge. For this purpose, patients completed a questionnaire at the day of hospital discharge. At the end of this survey, patients could indicate whether they were willing to participate in the second part of the study. In part two, medication adherence was evaluated based on empty medication packages kept by patients for two months and a diary in which patients reported their adherence-related problems. During a home visit two months post-discharge, the Probabilistic Medication Adherence Scale (ProMAS) and a survey on the feasibility of the different methods were administered.

2.2 Setting and participants

Participants were recruited from internal medicine (n=4), surgical (n=5) and geriatric wards (n=2) of two hospitals in Belgium. Hospitalised patients were eligible for inclusion if they were at least 18 years old, took at least five chronic medicines daily (i.e., polypharmacy), returned home after discharge and could understand and speak Dutch. Patients not responsible for their own medication administration at

home, those incapable of providing consent to participate in the study or having a diagnosis of dementia were excluded. Between January and March 2022, all patients who met the inclusion criteria and were willing to participate were included (i.e., consecutive sampling).

2.3 Data collection

In this study, data were collected at the day of hospital discharge (i.e., moment of inclusion) and during two months post-discharge.

2.3.1 *Study part 1: at hospital discharge*

Patients who consented to participate in the study were asked to complete a self-developed questionnaire at the day of hospital discharge. Socio-demographic characteristics (age, sex, education level, living situation, type and reason for hospitalisation) and data on medication management at home (number of medicines, preparation and administration of medication, medication aids) were collected. Additionally, statements regarding truthfulness of communicating adherence-related information to healthcare providers, the willingness of patients to have their adherence measured by various methods after discharge, and the expected feasibility of these methods were surveyed using 4-point Likert scales. Finally, factors that may influence truthful communication about medication adherence, taking prescribed medication and the feasibility of the methods according to the patient were questioned. At the end of this questionnaire, patients could indicate whether they were willing to participate in the second part of the study, in which medication adherence was measured using different methods over a course of two months post-discharge. If patients refused to participate in the second part, the reasons for non-participation were surveyed.

At discharge, the medication schedule of patients, who consented to participate in part two, was copied to collect data about medication use. At this time, patients received instructions on the use of the medication diary and the preservation of their medication packages for a period of two months (± 60 days).

2.3.2 Study part 2: two months post-discharge

Within the two-month period, participants had to fill out a self-developed medication diary²⁸. Participants were asked to record (changes in) their medication schedule and to indicate on a daily basis whether they experienced any problems related to their medication use. In case of problems, participants had to fill out a structured problem sheet indicating the problems they were experiencing (e.g., no medication left in stock, forgot to take, took an incorrect dose, ...), which medication the problems relate to (all or specific ones) and whether they took any action to address the problem. Participants were not supposed to record every medication intake. Participants were contacted three times (i.e., 1 day, 3 weeks and 5 weeks post-discharge) to find out if completing the diary and preserving medication packages went well and to collect information on drop-outs.

Approximately 60 days after hospital discharge, a home visit was conducted by one of the researchers (LM, MDG, JVD). At this moment, the Probabilistic Medication Adherence Scale (ProMAS) was administered²⁶. The instrument was developed in Dutch and consisted of 18 questions assessing a wide range of medication adherence behaviours (i.e., taking less or more medicines than prescribed, forgetting to take medicines, adapting the medication regimen, fulfilling the prescription too late and stopping or not starting prescribed medication). All questions could be answered with yes or no. Based on the sum score of the ProMAS, a distinction between four categories of medication adherence can be made: low (0-4), medium-low (5-9), medium-high (10-14) and high (15-18)²⁶.

Furthermore, a self-developed questionnaire with statements regarding the feasibility of preserving medication packages, filling out the medication diary and the ProMAS was administered. Statements could be answered using 4-point Likert scales (1= strongly disagree to 4= strongly agree). Patients were asked to rank the different methods (i.e., pill count, diary and ProMAS) from the one that most accurately reflected their medication adherence over a course of two months to the one that least accurately reflected this. Finally, the preserved medication packages were collected to perform a pill count and the medication diary was collected for analysis. During the home visit, the diary was already reviewed by the researcher. Additional questions could be posed, if clarification was needed.

2.4 Study outcomes

The main outcomes of this study were: willingness to have medication adherence monitored by healthcare providers including willingness to communicate about medication adherence, feasibility and validity of methods measuring medication adherence.

2.5 Sample size calculation

No power analysis was conducted for the outcomes 'willingness' and 'feasibility' given their descriptive nature. However, an a priori power analysis was performed using G-power version 3.1 to explore the correlation between the degree of medication adherence measured by pill counts, the number of problems reported in the medication diary and the ProMAS score. A sample size of 84 participants would be required considering a power of 80%, an alpha of 5% and an expected correlation of 0.3²⁹.

2.6 Data analysis

Data were analysed using IBM SPSS version 28. A significance level of 0.05 was used. Discontinuous data were described using absolute numbers and percentages, continuous data were described using mean and standard deviations or median and range. Normality of the distribution was tested using Z-scores. Differences in patient characteristics and willingness between the group of patients who participated and the group who did not participate in study part 2 were tested using Chi-square test (categorical variables) and independent-T test (continuous variables).

Medication adherence measured by pill counts was calculated using the following formula: $\frac{\text{the number of pills taken based on the preserved medication packages}}{\text{the number of pills to be taken}} \times 100$. Both the average overall adherence rate and the adherence rate per medicine were calculated. Patients were considered adherent to their medication if their medication adherence percentage was between 90% and 110%. To obtain an adherence score of the ProMAS, items marked with (R) in the original questionnaire were first reverse coded. Afterwards, the items were summed whereby higher scores represent a higher degree of medication adherence. In terms of adherence measured by the diary, the number of problems reported in the diary as well as the percentage of days with problems leading to non-adherence were considered.

Correlation between adherence rates measured by pill counts, the medication diary and the ProMAS was assessed using Pearson R in case of normal distribution of the data or using Spearman's Rho if non-normally distributed. Cases with missing data (e.g., drop-outs) were excluded for analysis.

2.7 Ethics

The Ethics Committee of the Antwerp University Hospital (Belgian registration number B3002021000224) provided ethical approval. This study was conducted in accordance with the Declaration of Helsinki. All participants received written information on the purpose, design and execution of the study. All respondents gave written informed consent before participating in the study. Data were registered and analysed after pseudonymisation to ensure privacy.

3. Results

3.1 The research population

In the first part of the study, 144 patients consented to participate and completed the survey at discharge. The characteristics of the research population are shown in Table 8.1. The mean age of the participants was 70 years [SD 9.96] and 58% were men. The majority of participants (63%) had at least a higher secondary education degree. Almost one-third (27%) lived alone and 44% needed help to reside in their own home. Most hospital admissions were planned (56%). Surgery was the main reason for hospitalisation (46%), followed by treatment (22%) and examination (19%). Participants took on average seven chronic medicines at discharge [SD 2.32, range 5 – 15] and 67% used medication aids.

Of the 144 participants, 85 consented to participate in the second part of the study (59%). Participants were significantly more often male (68% vs. 42%, $p = 0.002$), needed significantly less help to reside at home (37% vs. 54%, $p = 0.035$), were less often unexpectedly hospitalised (35% vs. 58%, $p = 0.008$) and used fewer medication aids (61% vs. 77%, $p = 0.041$) compared to those who did not participate in part 2. Reasons for non-participation are shown in Appendix 9.1.

Table 9.1: Sample characteristics

	Total population (n= 144)	Respondents unwilling to participate in part 2 ^a (n= 59)	Respondents willing to participate in part 2 ^b (n= 85)	P ^c
Age in years – mean [SD, min - max]	69.5 [9.96, 37-88]	70.6 [10.88, 37-88]	68.7 [9.25, 43-86]	0.242 ^d
Sex (male) (%)	57.6	42.4	68.2	0.002^e
Highest educational level (%)				0.236 ^e
No education	4.9	3.4	5.9	
Primary education	4.2	3.4	4.7	
Lower secondary education	27.8	37.3	21.2	
Higher secondary education	31.3	32.2	30.6	
Higher vocational education	16.0	8.5	21.2	
Bachelor's degree	10.4	8.5	11.8	
University (master's degree/ PhD)	5.6	6.8	4.7	
Living alone (%)	27.1	30.5	24.7	0.441 ^e
Help needed to reside in own home (%)	43.8	54.2	36.5	0.035^e
Unexpected hospitalisation (%)	44.4	57.6	35.3	0.008^e
Reason for hospitalisation (%)				0.015^e
Surgery	45.8	33.9	54.1	
Treatment	22.2	22.0	22.4	
Examination	18.8	23.7	15.3	
Medication review	5.6	5.1	5.9	
Accident	4.2	10.2	0.0	
Observation	2.8	5.1	1.2	
Other	0.7	0.0	1.2	
Length of hospital stay (%)				0.500 ^e
1 to 3 days	27.1	22.0	30.6	
4 to 7 days	36.1	37.3	35.3	
8 days or more	36.8	40.7	34.1	
Number of chronic medicines at discharge ^f – mean [SD, min - max]	7.1 [2.32, 5-15]	7.2 [2.31, 5-15]	7.0 [2.34, 5 -15]	0.316 ^d
Number of medication changes during two months post-discharge ^f – median [min - max]	/	/	1 [0 – 12]	/
Use of medication aids (yes) (%)	67.4	77.2	60.7	0.041^e

^a This group of participants completed the questionnaire on willingness to measure adherence using different methods, but was not willing to participate in the second part of the study where adherence was monitored using different methods two months post-discharge. ^b This group of participants completed the questionnaire and consented to participated in the second part of the study. ^c Significant p-values (p < 0.05) are marked in bold. ^d Independent T test. ^e Pearson Chi-Square test. ^f Reported by participants.

Of the 85 participants enrolled in the second part of the study, 16 dropped out (18.8%) leaving a population for analysis of 69 participants. Reasons for drop-out were: (deteriorating) health status (n=7), personal reasons (n=4), diary or medication packages not kept consistently (n=3), getting nervous of participating in the study (n=2), not wanting a home visit once returned to home (n=1), participating is too much of an effort (n=1), not returned home (n=1), not wanting to participate once returned home (n=1), no medication self-management anymore applicable

(n=1). No differences in population characteristics were found between the group of dropouts and non-dropouts (See Appendix 9.2).

3.2 Willingness to communicate about medication adherence

Most participants with polypharmacy were willing to communicate truthfully about their medication adherence (97%), to share this kind of information with healthcare providers (99%) and to ask healthcare providers for help if problems with medication intake arise (94%). Participants who were willing to have their medication adherence monitored post-discharge were more likely to indicate that they actually communicate honestly about medication use (92% vs. 75%, $p = 0.005$), considered it more important for healthcare providers to be aware of their medication adherence (99% vs. 86%, $p = 0.003$), were more likely to report problems concerning medication intake (95% vs. 85%, $p = 0.030$), to tell healthcare providers if medicines are not being taken as prescribed (95% vs. 83%, $p = 0.015$) and found it easier to admit incorrect medication intake (95% vs. 83%, $p = 0.015$) compared to those who were unwilling to have their medication adherence monitored (Table 9.2). According to participants, some factors may influence truthful communication: fear of reaction from healthcare providers (57%), not wanting to disappoint healthcare providers (43%) and not having a good relationship with healthcare providers (14%).

3.3 Willingness to have medication adherence measured after discharge and the expected feasibility of different measurement methods

At the time of hospital discharge, more participants with polypharmacy indicated they were (rather) willing to preserve medication packages (76%) than to complete a medication diary (67%) over a course of two months. The majority of participants (65%) considered the combination of both measurement methods feasible in practice (Figure 9.1). However, participants indicated several factors that may influence the feasibility of keeping a medication diary: duration (44%) and frequency of diary completion (45%), the busyness of daily life (39%), forgetfulness (34%) and deteriorating health status (32%). The same factors were mentioned considering the feasibility of preserving medication packages: duration (47%), the busyness of everyday life (35%), forgetfulness (35%) and deteriorating health status (31%).

Table 9.2: Willingness to communicate medication adherence-related information

Statements concerning medication adherence-related information	Agree (%)			P*
	Total population (n = 144)	Non-participants part 2 (n= 59)	Participants part 2 (n= 85)	
I am <u>willing to communicate</u> honestly about my medication adherence.	98.6	96.6	100	0.087
I always <u>communicate</u> honestly with healthcare professionals about my medication use.	84.7	74.6	91.8	0.005
I am willing to share information about my medication adherence a healthcare provider.	99.3	98.3	100	0.228
I consider it important that my healthcare provider is aware of my medication adherence.	93.8	86.4	98.8	0.003
If I experience any problems with my medication adherence, I immediately report it to my healthcare provider.	91	84.7	95.3	0.030
I find it difficult to admit when I am not taking my medicines correctly.	9.7	16.9	4.7	0.015
I report problems concerning correct medication intake to my partner, children or friends rather than to my healthcare provider.	46.5	45.8	47.1	0.878
If I experience problems concerning correct medication intake, I ask a healthcare provider for help.	94.4	91.5	96.5	0.203
If I take medicines in a different way than prescribed, I <u>dare to tell</u> this to my healthcare providers.	95.8	96.6	95.3	0.698
If I take medicines in a different way than prescribed, I <u>tell</u> this to my healthcare providers.	90.3	83.1	95.3	0.015

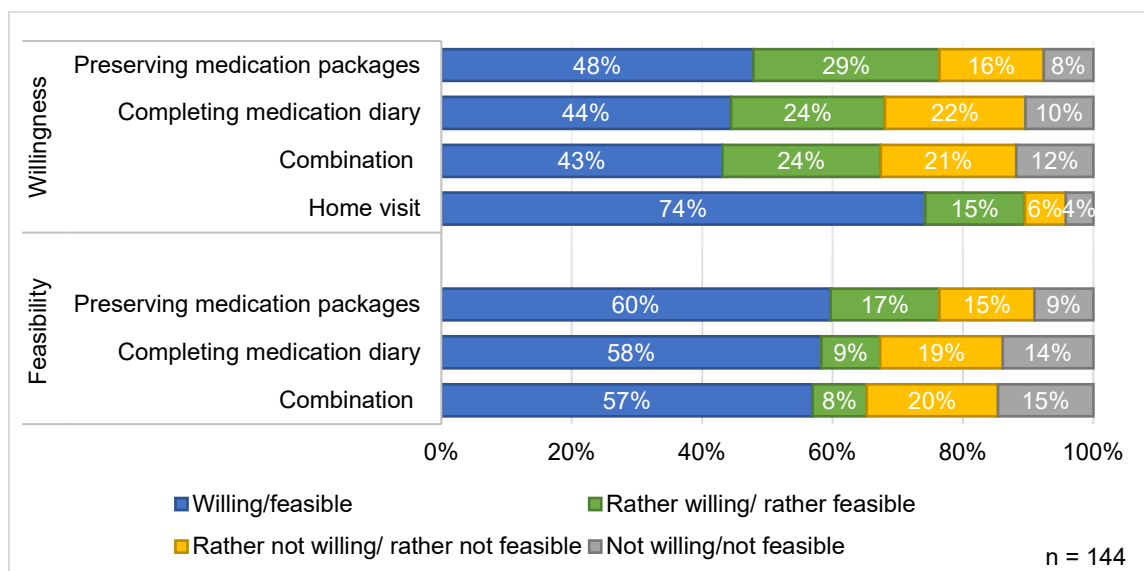


Figure 9.1: Willingness of patients with polypharmacy to apply different methods measuring adherence after discharge and the expected feasibility of the methods.

3.4 Medication adherence measured using different methods during two months post-discharge

3.4.1 Pill count

The mean medication adherence rate, measured by pill counts based on empty medication packages, was 96% [minimum 69%, maximum 124%]. Applying a cut-off of 90% to 110% of medicines taken, 78% of the participants was found to be adherent according to the average overall adherence rate, while only 32% of the participants appear to be adherent taking into account the adherence rate per medicine.

3.4.2 Medication diary

About 60% of the participants reported no problems with medication intake over a two-month period. Of those who experienced problems, forgetting to take medicines was most commonly reported in the medication diary (Table 9.3).

Table 9.3: Reported medication adherence-related problems

	Number of participants experiencing problems (n= 27)	Frequency of problems
Forgot to take medicines	13	37
Experiencing side effects	7	32
Medicines out of stock at home	4	23
Took medication at the wrong time	3	8
Wrong dose of medication taken	3	3
Medication deliberately not taken	2	4
No refill prescription	2	2
Problems with drug administration (swallowing problems)	1	62
Problems with opening medication packages	1	62
Unable to pay for medicines	1	20
Forgot to pick up medicines at the pharmacy	1	1
Name on medication packaging does not match name on medication schedule	1	1

3.4.3 Probabilistic Medication Adherence Scale

Participants had a mean score of 13 out of 18 on ProMAS ([SD 2.7], minimum 6/18, maximum 17/18). Based on the ProMAS scores, 10% of the participants were categorized as being medium-low adherent, 49% were medium-high adherent and 41% were high adherent to their medication. Analysis of the individual questions included in the ProMAS can be found in Appendix 9.3.

3.4.4 Correspondence between measurement results and actual medication adherence according to participants

Respectively 90%, 91% and 97% of the participants indicated that the medication diary, the pill count based on empty medication packs and the self-report questionnaire (ProMAS) correctly reflected how well the participant had taken his/her medication during a two-month period. According to the majority of participants (60%), pill counts most accurately reflected medication adherence, followed by the medication diary (39%) and the ProMAS (1%).

3.5 Feasibility of methods measuring medication adherence in practice

Most participants reported that preserving medication packages (91%), completing the medication diary (99%) and the ProMAS (99%) were no effort to them. Furthermore, filling out the medication diary and the ProMAS was found to be easy for most participants, respectively 88% and 99%. All participants reported that they completed the ProMAS and the diary truthfully. However, one participant indicated he did not preserve all medication packages honestly. Approximately 87% of participants indicated that they would be willing to preserve medication packages once again. Only 19% would like to continue using the medication diary in the future.

3.6 Validity of methods measuring medication adherence

The higher the medication adherence according to ProMAS, the higher the mean percentage of medication adherence according to pill counts ($r = 0.333$, $p = 0.005$) and the higher the percentage of medicines with which participants are adherent to (threshold of $\geq 90\%$ - $\leq 110\%$) ($r = 0.251$, $p = 0.037$).

Furthermore, medication adherence measured by the ProMAS correlated negatively with the total number of problems participants reported in the medication diary ($r = -$

0.492, $p < 0.001$) and with the percentage of days participants experienced problems ($r = -0.516$, $p < 0.001$). Thus, the more problems participants experienced according to the diary, the less adherent they were according to the self-report questionnaire.

A weak negative correlation was found between mean percentage of adherence based on pill count and total number of problems reported in the diary ($r = -0.168$). The correlation was not significant ($p = 0.181$). The same applies to the correlation between the average adherence rate and the percentage of days with problems experienced ($r = -0.182$, $p = 0.147$). Additionally, no correlation was found between the percentage of medicines to which participants were adherent and problems reported in the diary.

4. Discussion

Identifying and monitoring medication adherence in patients with polypharmacy remains a challenge despite several measurement methods being currently available^{17, 18, 20}. This study evaluated a combination of pill counts and self-reported measures assessing medication adherence (i.e., medication diary and ProMAS). Using self-reports, truthful communication about medication adherence by patients is indispensable requiring a certain level of willingness and cooperation from the patient. To the best of our knowledge, this is the first study exploring patients' willingness to communicate about medication intake and willingness to have medication adherence monitored.

The results of this study showed an overall high willingness of participants with polypharmacy to communicate truthfully about medication use and to share medication adherence-related information with healthcare providers. However, despite this high willingness, only 59% of patients participated in the second part of the study. There seems to be a discrepancy between this willingness and the actual act of having medication adherence monitored. It is noteworthy that patients who were not willing to communicate problems concerning medication intake, including not taking medication correctly, were also not willing to have their adherence monitored after discharge and did not participate in part two of the study. These patients are likely to be less adherent. Furthermore, some subgroups were less

willing to participate in the second part of the study and, as a result, were less well presented. These subgroups included women, patients using medication aids and those needing help to reside at home. Research showed that women are less likely to be adherent to medications as compared to men³⁰⁻³⁴. Patients using medication aids or requiring assistance from others may already face challenges with medication intake, affecting medication adherence as well. The fact that these subgroups are not duly represented and that only 'willing' or 'dedicated' patients participated in this study may lead to a potential misinterpretation of the results, could limit generalisability and should, therefore, be considered as a limitation. Overestimation of medication adherence should be considered, given that the second part of the study consisted of a self-selecting sample of dedicated patients.

This may also explain the overall high adherence rates in the study sample. Based on pill counts, patients had taken 96% of their medicines on average. We would have used the conventional threshold of $\geq 80\%$ to differentiate between adherent and non-adherent patients³⁵⁻³⁸. However, analysis showed only four patients in our sample would be classified as non-adherent. Given this result and given the historical cut-off of 80% can be questioned as 'standard'³⁸, it was chosen to use a stricter threshold of $\geq 90\%$ in this sample.

Two methods were applied to differentiate between adherent and non-adherent patients, based on pill counts. The first method consisted of calculating the average overall adherence rate and resulted in 78% adherent patients. However, this method potentially overestimates multiple medication adherence when a patient is more adherent to one treatment over another and hence averaging introduces an estimation bias where the observed value appears higher than the true value³⁹. Therefore, the adherence rate for each medicine was calculated as well, resulting in only 32% adherent patients. This proves that even different approaches to one measurement method produce different results. The high variation in adherence rates between medicines taken by a patient underscores the importance of measuring adherence for individual medications.

Researchers and healthcare providers often have to balance reliability and practicability when choosing appropriate measurement tools¹⁸. The pill count was

chosen since it is a low cost method, which can be used for different types of formulations (e.g., tablets, capsules and inhalers). However, it offers no insight into behaviours predicting non-adherence and problems causing non-adherence. Patient self-reports can be complementary in this regard: the medication diary can provide on a daily basis information on problems leading to not taking medicines as prescribed while a self-report questionnaire can provide additional information on adherence-related behaviours and attitudes^{17, 18}. Furthermore, patient self-reports are inexpensive, well-validated and straightforward and are, therefore, often used in research and clinical practice^{17, 18}.

Practicability of the combination of these three methods was demonstrated as the combination was feasible and easy to use in practice according to patients. Nevertheless, our results imply that preserving medication packages for two months was highly acceptable to patients, more so than completing a medication diary. This is evident, as the majority of patients expressed a willingness to preserve medication packages once again, while less than a fifth would like to continue using the diary. When interpreting the feasibility of the methods, it is important to consider that among those who declined adherence monitoring, almost half did so due to the need of completing a diary, and a third refused because of the need to preserve medication packages. This suggests that these methods were perceived as too demanding for them.

Combining the different methods in practice also revealed some difficulties. First, a few patients already had a filled pill box at home at time of hospital discharge. The packages of these medicines were no longer available for pill count. Although this unavailability was recorded and taken into account in the actual pill count two months post-discharge, this may lead to a less accurate measurement of adherence. Second, some patients indicated that they did not experience any problems with their medication and therefore did not report any problems in the diary while the ProMAS questionnaire showed that they, for example, sometimes forgot to take a medicine. In the medication diary, problems with medication were possibly underreported because there may be a difference in what the patient himself perceives as a problem and the actual presence of a problem. Last, self-reported adherence may be subject to recall bias and social desirability bias^{18, 19, 40, 41}. Efforts

were made to minimise the risk of recall bias by asking patients to report problems in the medication diary on a daily basis. However, some patients indicated that they did not complete the medication diary daily, but weekly or monthly. Daily completion of the diary is probably too burdensome for these patients.

Not only the feasibility of a combination of pill counts, the medication diary and the ProMAS but also their respective validity was tested. Regrettably, a perfect reference standard for the validation of adherence measures does not exist at this moment^{42, 43}. Previous studies have already contrasted different methods of measuring adherence²¹⁻²⁷. To the best of our knowledge, this was the first study validating the ProMAS using pill counts. Our study showed a significant positive correlation between adherence measured by both methods: the less medication adherence according to the pill count, the less medication adherence according to the ProMAS. The ProMAS can provide insight into the behaviour underlying the failure to take medicines as prescribed. Considering the patients' perspective on validity, only 1% of the participants deemed ProMAS as the most accurate reflection of their medication adherence. ProMAS provides a snapshot of medication adherence and is more susceptible to recall bias, while the diary and pill count enable the daily and longitudinal measurement of medication adherence. The latter potentially instils greater confidence in patients regarding the accuracy of the measured adherence.

The medication diary was recently developed and, therefore, not previously validated. The self-reported adherence measurement tools, i.e., the medication diary and the ProMAS, correlated significantly. This result indicates that the medication diary can be used as a complementary measurement in order to gain insight into problems leading to non-adherence behaviours. In contrast, no significant relationship could be demonstrated between pill count and problems (leading to non-adherence) reported in the medication diary. The a priori calculated sample size of 84 participants was not achieved, due to dropouts which possibly explains the non-significant result. Our study showed a dropout rate of 19% over two months. Researchers should take attrition into account when calculating the sample size needed, considering that the longer the follow-up period, the higher the dropout rate will be.

5. Conclusion

Despite the high willingness to communicate truthfully about medication adherence and to share adherence-related information with healthcare providers, only 59% of patients had their adherence effectively monitored during two months. The combination of pill counts, a medication diary and the ProMAS assessing medication adherence two months post-discharge seems feasible in practice. The different methods are complementary to each other. While a pill count can assess the extent to which a patient's actual medication use corresponds to the prescribed medication regimen, self-reports can give additional information about adherence-related behaviours. Moreover, the medication diary has the potential to provide insight into daily problems and patterns contributing to non-adherence

Author contributions

Conceptualization, L.M., E.G., M.D.G., J.V.D., AM.D.C. , M.P., P.v.d.B and T.D.; Methodology, L.M., E.G., M.D.G., J.V.D., AM.D.C. ,M.P., P.v.d.B and T.D.; Funding acquisition: L.M.; Formal analysis; L.M., Writing—Original Draft, L.M., Writing—Review and Editing, L.M., E.G., M.D.G., J.V.D., AM.D.C. , M.P., P.v.d.B and T.D. All authors have read and agreed to the published version of the manuscript.

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Data availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare no competing interests.

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Chapter 10

Effect of an in-hospital medication self-management intervention (SelfMED) on medication adherence in polypharmacy patients postdischarge: protocol of a pre-post intervention study

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Abstract

Introduction

Healthcare providers usually manage medication for patients during hospitalisation, although patients are expected to self-manage their medication after discharge. A lack of self-management competencies is found to be associated with low adherence levels and medication errors harming patients' health. Currently, patients seldom receive support or education in medication self-management. When self-management is allowed during hospitalisation, it is rarely provided using a structured, evidence-based format. Therefore, an in-hospital medication self-management intervention (ie, SelfMED) was developed based on current evidence. To date, empirical data demonstrating the effect of SelfMED on medication adherence are lacking. This study primarily aims to evaluate the effect of the SelfMED intervention on medication adherence 2 months postdischarge in polypharmacy patients, as compared with usual care.

Methods and analysis

A multicentre pre–post intervention study will be conducted. The study will start with a control phase investigating usual care (ie, medication management entirely provided by healthcare providers), followed by an intervention period, investigating the effects of the SelfMED intervention. SelfMED consists of multiple components: (1) a stepped assessment evaluating patients' eligibility for in-hospital medication self-management, (2) a monitoring system allowing healthcare providers to follow up medication management and detect problems and (3) a supportive tool providing healthcare providers with a resource to act on observed problems with medication self-management. Polymedicated patients recruited during the control and intervention periods will be monitored for 2 months postdischarge. A total of 225 participants with polypharmacy should be included in each group. Medication adherence 2 months postdischarge, measured by pill counts, will be the primary outcome. Secondary outcomes include self-management, medication knowledge, patient and staff satisfaction, perceived workload and healthcare service utilisation.

Ethics and dissemination

The ethics committee of the Antwerp University Hospital approved the study (reference no: B3002023000176). Study findings will be disseminated through peer-reviewed publications, conference presentations and summaries in layman's terms.

Trial registration number

ISRCTN15132085

Strengths and limitations of this study

- The medication self-management intervention offers the opportunity to enhance patients' medication self-management competencies during hospitalisation, under supervision and with support from healthcare providers to promote safe medication use at home.
- The study targets a high-risk population of hospitalised patients with polypharmacy.
- The study's pragmatic nature will help healthcare organisations and providers to make informed decisions about implementing medication self-management programmes in clinical practice.
- Due to the possible risk of contamination and safety issues, patients will not be individually randomised into intervention or control groups.

1. Introduction

The WHO states that 50% of patients afflicted by chronic conditions do not adhere to prescribed medication regimens¹. After hospital discharge, 24%–70% of patients are found to be non-adherent to their medication^{2–5}. Furthermore, polypharmacy is found to be associated with poorer medication adherence due to the larger number of medicines and the complexity of the medication regimen^{5–8}. Such medication non-adherence can result in poor health outcomes (e.g., increased mortality, decreased quality of life and loss of productivity), increasing healthcare service utilisation and healthcare expenditures^{9–15}.

Self-management of medication (SMM) is one of the promising strategies to improve patients' medication adherence and self-care competencies, as well as a method to increase patient satisfaction and patient safety^{16, 17}. SMM comprises a range of tasks that individuals must successfully perform to self-manage their prescribed medication regimen and entails knowledge, skills and behaviours mandatory to correctly take medication and sustain use over time¹⁸. According to Bailey's model, the medication self-management process consists of six steps: (1) filling prescriptions and picking up medicines at the pharmacy; (2) knowledge and understanding of medicines; (3) practical organisation and scheduling of medicine intake; (4) medication intake; (5) monitoring therapeutic and adverse effects and (6) sustaining safe and appropriate medication use over time¹⁹. Failing the process of medication self-management can affect medication adherence. For instance, forgetting to take medicines, being unable to follow medication-related instructions or being unable to open medication packages may result in non-adherence²⁰. Therefore, interventions tailored to increase medication self-management are expected to improve medication adherence²¹.

The idea of in-hospital SMM consists of patients who store, prepare and administer their medication themselves. During the process of in-hospital SMM, nurses, physicians and hospital pharmacists monitor and support patients, provide education and counsel on supportive measurements. If problems arise, the multidisciplinary team can identify and address issues and prevent medication-

related problems after discharge. SMM during hospitalisation may provide patients an opportunity to continue medication management routines from home.

However, the number of patients allowed to self-manage their medication during hospitalisation is currently limited as hospital procedures are designed for medication management by healthcare providers. A multicentre study performed in Belgium demonstrated that although up to 41% of patients would be able to self-manage their medication during hospitalisation, only 22% did self-manage one or more medication(s)²². This prior study demonstrated only 10 out of 57 wards had a procedure for SMM and 4 out of 57 wards had a screening tool to assess the competences of patients to self-administer their medicines. When SMM was allowed and supported during hospitalisation, it seldom occurred in a structured, evidence-based way²².

Hence, an evidence-based intervention (i.e., medication self-management intervention, SelfMED) supporting in-hospital SMM was developed and tested²³. The SelfMED intervention consists of four components: (1) a procedure clarifying the SMM process and affiliated responsibilities (i.e., SelfMED procedure); (2) an assessment evaluating patients' eligibility for SMM during hospitalisation (i.e., SelfMED assessment); (3) a monitoring system allowing healthcare providers to follow adherence and detect errors in patients' SMM (i.e., SelfMED monitor) and (4) measures for healthcare providers to support SMM in patients (i.e., SelfMED support). A paper-and-pencil version of the SelfMED intervention has been pilot tested at one cardiology unit of a general hospital. Pilot-based results indicated the intervention facilitates in-hospital SMM and was found to be safe. However, an important knowledge gap exists on the effectiveness of the SelfMED intervention on patients' outcomes after discharge.

Literature on the effects of in-hospital SMM suggests an increase in patient adherence, medication knowledge and patient satisfaction^{16, 17, 24-26}. These findings are, however, based on a limited number of studies and the overall quality of studies was rather low making it hard to draw any firm conclusions. In addition, these studies focused solely on the short-term effects of SMM (e.g., during hospitalisation, at hospital discharge, 2 weeks postdischarge). To date, no study has been conducted

investigating the effects of SMM on various outcomes 2 months postdischarge in patients with polypharmacy.

The primary objective of this study is to evaluate the effect of in-hospital medication self-management (i.e., SelfMED intervention) on medication adherence in patients with polypharmacy 2 months postdischarge, as compared with usual care (i.e., medication management by healthcare providers). Secondary objectives are to evaluate the effect of in-hospital medication self-management on outcomes at the patient level (i.e., self-management, knowledge, satisfaction), at the healthcare provider level (i.e., staff satisfaction, workload) and at healthcare system level (i.e., healthcare services utilisation).

The primary hypothesis is that, compared with usual care, the SelfMED intervention improves medication adherence at 2 months postdischarge. The secondary hypotheses are that patients' medication self-management, medication knowledge and patient and staff satisfaction improve while workload and healthcare service utilisation will decrease.

2. Methods

2.1 Study design

A multicentre prospective pre–post intervention study will be conducted from February 2024 to February 2025. The study will start with a 4-month control phase investigating usual care. Medication management of patients included during this phase will be entirely provided by healthcare providers. The control phase is followed by a 4-week period to train and prepare healthcare providers on the SelfMED intervention. Subsequently, the study will proceed with a 4-month intervention period investigating the effects of the SelfMED intervention with rigorous monitoring and support of medication-taking behaviour during hospitalisation. Patients recruited in both the control and intervention periods will be monitored over a course of 2 months postdischarge. Figure 10.1 presents a schematic illustration of the study design.

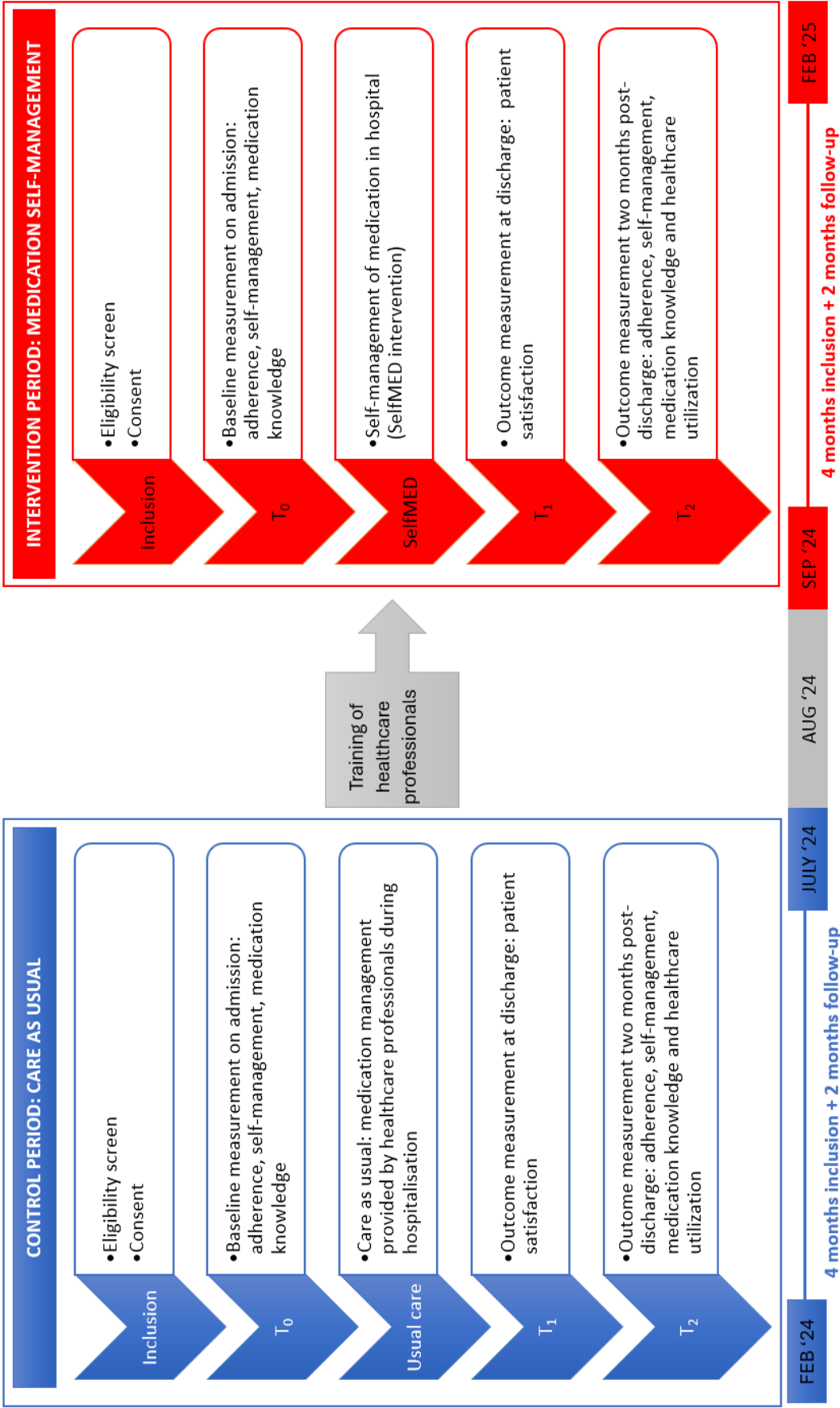


Figure 10.1: Schematic illustration of study design.

A pre–post design was selected as random allocation of patients to the study groups at one ward is associated with a high risk of contamination bias (i.e., anticipated effect of the intervention on usual care provided to the control group). Furthermore, this design reduced the risk of safety issues as healthcare providers would have to follow different procedures for different patients. Moreover, a stratification in intervention and control wards has also been rejected due to potential ward-related bias.

2.2 Study setting

Patients will be recruited in two Belgian hospitals (i.e., Antwerp University Hospital and Jessa Hospital). Hospital wards will be chosen based on the presence of patients with chronic conditions and associated polypharmacy (e.g., oncology, cardiology and diabetology).

2.3 Study population

Dutch-speaking patients (≥ 18 years), taking ≥ 5 chronic medications at the time of hospital admission (i.e., polypharmacy) of which at least three are administered orally, expected to be hospitalised for at least 3 days and a planned discharge towards home, will be eligible. A medication is classified as chronic when it is intended to be taken consistently for a minimum of 3 months (minimum expected treatment period). Nursing home residents, patients with a neuropsychiatric diagnosis of dementia or Mini Mental State Examination $< 24/30$, patients with a terminal illness (i.e., life expectancy less than 3 months), and those unable to provide consent, will be excluded. An additional criterion for patients being recruited consists of being eligible for medication self-management according to the SelfMED-assessment tool (see further)²³. All patients meeting the inclusion criteria and willing to participate will be included (consecutive sampling).

2.4 Sample size

Sample size estimation is based on the primary outcome, more specifically medication adherence at 2 months postdischarge measured using pill counts. The intervention is deemed successful if the medication adherence rate is significantly higher in the intervention group than in the control group. A systematic review and meta-analysis on medication adherence outcomes of 771 intervention trials showed

a standardised mean difference of 0.290 comparing treatment and control groups²⁷ and is, therefore, considered as effect size for power calculation in this study. This rather small effect size was used, so that even small differences in adherence can be detected, although a larger effect of the intervention is expected.

Power calculation using G-power showed that, to detect an effect size of at least 0.29, with an alpha of 0.05 and a power of 0.80, a minimum sample of 374 participants would be needed (n=188 per group). Previous research on the evaluation of measurement methods for medication adherence in patients with polypharmacy for 2 months showed a drop-out rate of 19%²⁸. Hence, to provide a sufficient margin, we assume 20% attrition. In summary, the recruitment of 225 patients in each group will be needed to achieve the desired sample size.

2.5 Control period (preintervention)

During the control period, care as usual will be provided comprising medication management (i.e., storage, preparation and administration) entirely provided by healthcare providers during hospitalisation. Patients are not actively involved in the medication process and do not administer their medication themselves during hospitalisation.

On admission, a medication anamnesis is conducted to complete and verify the patient's medication list (home medication). During hospitalisation, physicians electronically prescribe medication, considering the medication list and the hospital's formulary. All medications for in-hospital are dispensed by the hospital pharmacy. Most hospitals use a mixed drug distribution system, with ward stocks for common medications and patient-level dispensing from the central pharmacy. Nurses are responsible for medication administration and documentation of the administration in the electronic medical record. On discharge, patients are provided with an updated medication list along with information about any newly initiated or modified pharmacotherapy. If necessary, patients receive prescriptions for newly initiated or modified pharmacotherapy, which should be filled by the outpatient pharmacy.

2.6 Healthcare providers' training

Healthcare providers involved in the study will receive a 1.5-hour training session from the first author (LM). During this session, healthcare providers will be informed of the study objectives and detailed intervention protocol. Healthcare providers will learn how to complete the SelfMED assessment to ensure uniformity. They will gain insight into the prerequisites and practical organisation of medication self-management by patients during hospitalisation. Furthermore, it will be explained how to use the SelfMED monitoring system and SelfMED support tool (supportive measures).

To give everyone the opportunity to attend a training session, considering work schedules, holidays etc, multiple training sessions will be organised over a 4-week period. Healthcare providers can attend sessions multiple times if needed. At least all full-time working nurses should attend the training to ensure the correct implementation of the intervention. Healthcare providers will also receive a written standardised operation procedure. The PhD researcher (LM) or a trained research assistant will visit the hospital ward(s) daily to support healthcare providers in implementing the intervention components, including performing the SelfMED assessment, monitoring SMM and supporting SMM.

2.7 Intervention

During the intervention period, SMM during hospitalisation (ie, SelfMED) will be provided with rigorous control of medication-taking behaviour, including education and support from healthcare providers to improve pharmaceutical self-care. SelfMED is an evidence-based intervention consisting of multiple components²³ (see Figure 10.2).

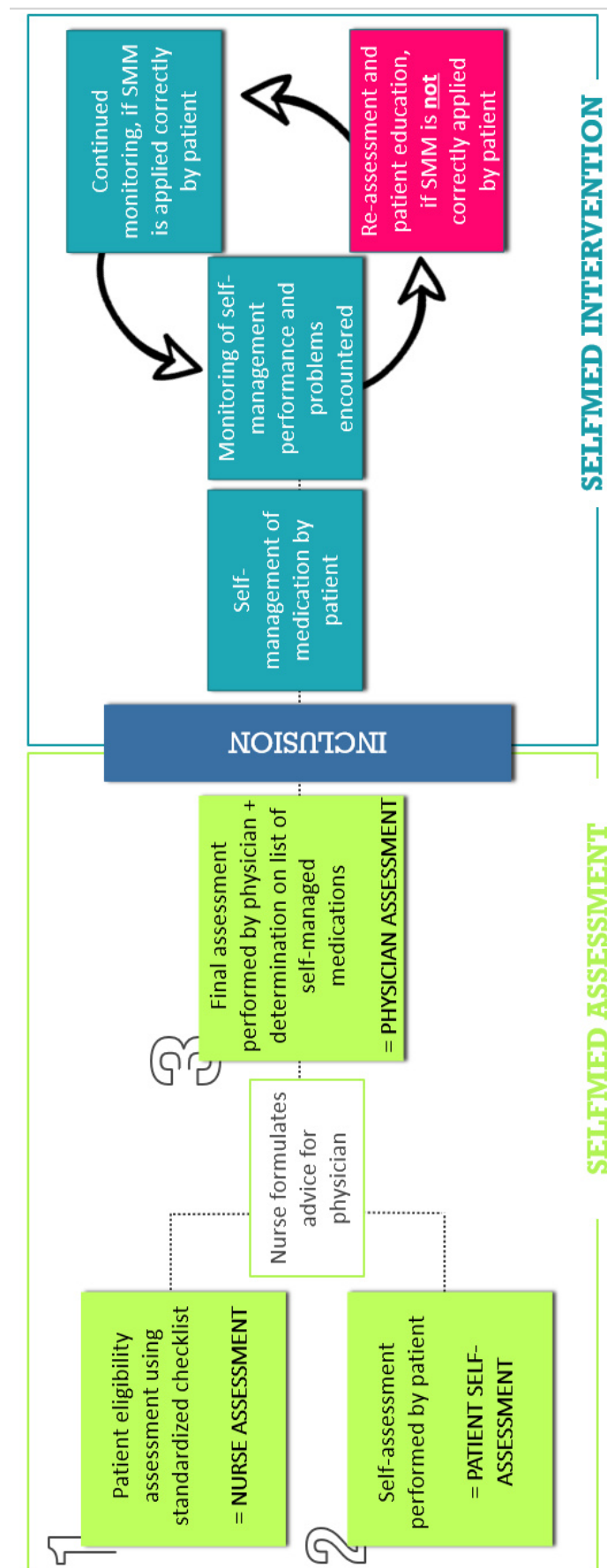


Figure 10.2: Overview of subsequent interventional SelfMED components.

(1) SelfMED assessment: A validated stepped assessment tool evaluating patients' eligibility for SMM during hospitalisation²³.

- Nurse assessment: A 10-statement assessment allows the nurse to assess patients' eligibility for SMM on admission. Completing this assessment is performed based on information gathered during the intake process and data accessible in the patient's electronic medical records. Nurses can indicate their response to the statement in the first column (ie, agree/not agree/not known) and evaluate whether the statements pose a barrier to self-management in the second column (ie, barrier/possible barrier/no barrier to self-management). At the end of the assessment, the nurse indicates if the patient is eligible for self-management and subsequently invites the patient to complete the patient self-assessment.
- Patient self-assessment: If the nurse deems the patient capable of self-managing medicines, the next phase of the procedure consists of a patient questionnaire. The questions in the assessment consist of the current medication management at home (one item), the patient's willingness to self-manage medication in hospital (one item), a possible need for aide while self-managing in hospital (one item) and the patient's therapy adherence out of hospital (seven items). If patients indicate they are not self-managing medication at home or are not willing to self-manage medication, they do not have to complete the questionnaire.
- Nurses' advice: The information from both the nurse's assessment and the self-assessment enables nurses to advise the treating physician to allow or decline medication self-management. If the nurse does not recommend SMM, there is a possibility to advise a reassessment at another moment in time since improvement in health status can result in improvements in self-management capability.
- Physician assessment: In the next phase, the patient's physician has to make the final decision on allowing the patient to self-manage medication. The advice formulated by the nurse, the nurse's assessment and the patient's self-assessment are available to make an informed decision. If the treating physician decides to not allow medication self-management, there is a possibility to reassess the patient at another time point. If a patient is deemed

eligible and self-management is allowed, the actual self-managed medicines need to be specified by the treating physician and registered in the patient's electronic medical file. The physician can, for example, decide not to allow SMM for specific acute or high-risk medications. Intravenous medication or medication that patients typically do not administer themselves in the outpatient setting will be excluded from SMM and administered by nurses during the standard medication rounds.

(2) Starting SMM: If a patient is deemed eligible for SMM, several practical arrangements must be made to enable the execution of SMM:

- The self-managed medication needs to be documented in the patient's electronic medical file.
- The patient should be provided with an up-to-date personalised medication list.
- The hospital will provide all inpatient medication according to the hospital's formulary. The medication should be delivered by the hospital pharmacy to the patient's room. Therefore, X number of medicines should be ordered from the hospital pharmacy, so that the patient has a possible supply of medication, simulating the home situation. The practical organisation of medication delivery to the patients' room will be determined and aligned with common procedures in each hospital in consultation with the hospital pharmacist(s) prior to the start of the study (e.g., for how many days medication will be delivered as well as the mode of delivery).
- The patient needs to be educated on the self-managed medication and the use of the medication list. Since the hospital will provide all inpatient medication according to the hospital's formulary, medication will be substituted to a different brand or pharmacotherapeutic class (if a home medication is not on the hospital's formulary). Therefore, extra attention should be paid to educating patients about switching medication.
- The patient needs to be educated on the use of the SelfMED-monitoring system (see further).
- Medication should be safely stored in the patient room (preferably in a lockable locker, personal closet or bedside table). Possibilities of medication

storage will be discussed in advance with the patient care department of each hospital.

(3) SelfMED monitor: A monitoring system allowing healthcare providers to follow up adherence and detect errors in patients' SMM. As healthcare providers monitor patient adherence and safety, patients have to register per medicine the dose and timing of the medication intake on a daily base. For medication registration, a paper-based medication list is used similar to the one provided to the patient at discharge. It allowed the patient to use additional aids such as a clock or an alarm to remind him of the medication intake. Nurses are required to check the registration form twice a day, that is, during both the early and late shifts, to identify any discrepancies with the prescribed regimen. If problems concerning medication self-management occur or there is doubt about medication intake during these two control moments, a pill count can be performed optionally to detect medication errors. Discrepancies and self-management problems experienced will be discussed with the patient.

Since medication management should be monitored twice a day, the monitoring file should also be completed twice. The monitoring tool consists of a first column to define the date and initials of the monitoring nurses that day. The second and third column questions whether the patient is still capable to self-manage medication. If not the reason should be formulated (eg, sudden illness and mental decline). If the status of the patient has not changed and he/she was self-managing medication, the medication list is then evaluated, and a pill count is optionally performed. The results should be noted in the monitoring file in the patient's room. If the patient succeeds in every aspect of self-management, self-management can be continued. If patients fail to self-managing their medication, the nurse can intervene by providing patient education to prevent this error from occurring again. The intensity and duration of the action will depend on the specific problem encountered. If the errors in the self-management are found to be problematic, it is possible to stop self-management. In case a patient is not capable of self-managing medication anymore, self-management stops. A possibility to reassess over a period of time is then provided.

(4) SelfMED support: A guidance document for healthcare providers to support patients with SMM was developed based on scientific evidence and expert consensus. The guidance document consists of a list of possible problems concerning medication self-management and specific recommendations to address these problems. The guide can be used as a resource for healthcare providers to take action in consultation with the patient²⁹. To fully support patients in medication self-management, the advice from the guide will also be made directly available to patients through an information leaflet.

2.8 Randomisation and blinding

Given the nature of the intervention, blinding is not possible. Since usual care comprises medication management provided by healthcare providers, patients in the intervention group will notice a change in the method of medication administration. Therefore, it is not possible to blind participants or healthcare providers. There will be no random allocation of patients to an intervention or control group (cfr. study design).

2.9 Outcome measures

Figure 10. 3 provides an overview of the outcome measures and measurement time points. All outcomes will be evaluated in participants of both the control and intervention groups, except for healthcare providers' satisfaction and workload.

2.9.1 *Primary outcome*

The primary outcome consists of 'medication adherence' measured by pill counts, based on preserved medication packages, and determined at 2 months postdischarge. A threshold of 80% of medications taken will be used to differentiate between adherent and non-adherent patients³⁰.

2.9.2 *Secondary outcomes*

Patient-reported medication adherence will be measured in addition to pill counts, as the best strategy for measuring adherence appears to be the combined use of at least two methods^{30, 31}. A self-report questionnaire (ie, Probabilistic Medication Adherence Scale—ProMAS) will be completed by patients on admission and 2 months postdischarge³². During 2 months, patients are requested to keep a

structured medication diary in which medication-related problems are registered (on paper)³³. Problems could be, for example, forgetting to take medication or not taking medication because of side effects. The feasibility and validity of the combination of pill counts, a medication diary and a self-report questionnaire have been pilot-tested²⁸.

SMM will be defined as 'the patients' ability to manage their medication regimen'¹⁸. On admission and 2 months postdischarge, problems with medication self-management experienced by patients will be evaluated through a self-report survey (see Appendix 10.1). Problems with medication self-management will be surveyed using statements to be answered on a 5-point Likert scale (1=always, 5=never). The medication self-management problems in the self-developed survey are divided according to the six phases of Bailey's medication self-management model¹⁹ and are based on a list of medication self-management problems compiled in previous research²⁹.

Medication knowledge: On admission and 2 months postdischarge, four types of medication will be randomly selected from the patient's medication list. Regarding these medications, knowledge will be assessed including medication name, indication, dose, administration route and administration time (correct yes/no). The sum scores (=sum of all correct answers) of total knowledge of chronic medication will be calculated.

Patient satisfaction with pharmaceutical care: At discharge, patients will be surveyed about their satisfaction with the received pharmaceutical care during hospitalisation through a Visual Analogue Scale³⁴.

Healthcare provider's satisfaction with pharmaceutical care: At the end of the study, nurses, physicians and pharmacists will be surveyed about their satisfaction with pharmaceutical care provided through a visual analogue scale, as well as the advantages and disadvantages of usual care and medication self-management using open-ended questions. Free-text comments will allow healthcare providers to list the (dis)advantages of both working methods.

Healthcare providers' workload: At the end of the study, nurses, physicians and hospital pharmacists indicate the impact of pharmaceutical care on their workload using a 10-point rating scale.

Healthcare service utilisation: Two months postdischarge, patients will be questioned about medication-related advice-seeking behaviour and health services utilisation through a self-reported questionnaire including number of hospital readmissions, nurse visits and consultations with general practitioners.

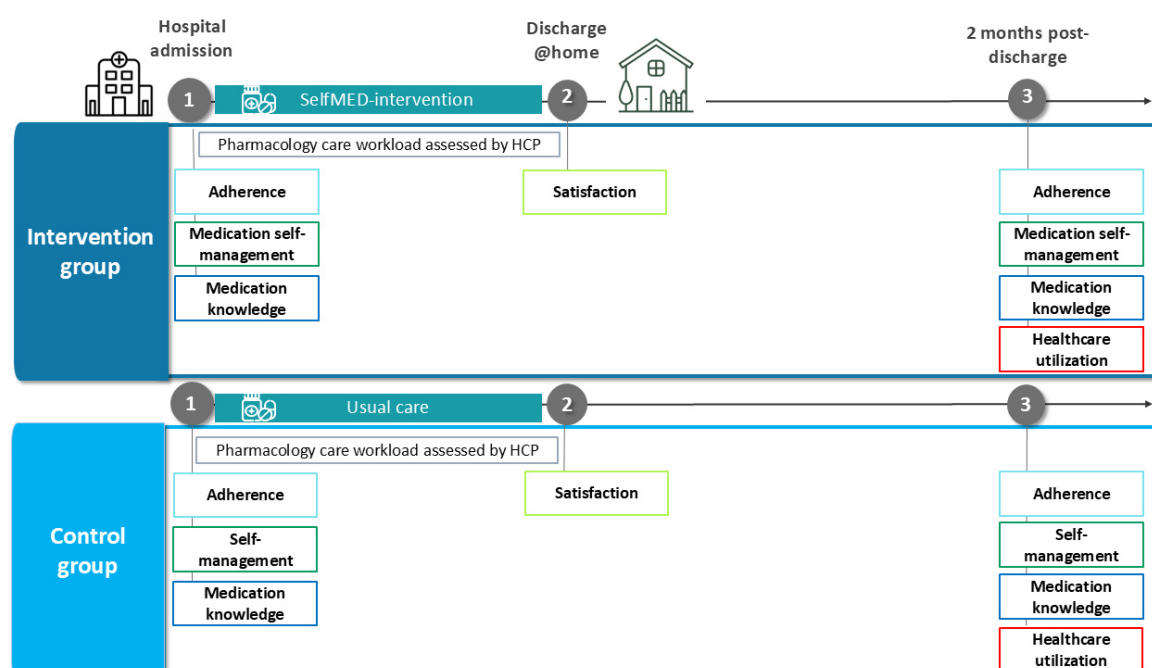


Figure 10.3: Overview of data collection and outcomes.

HCP, healthcare professional; SelfMED, medication self-management intervention.

2.10 Potential covariates

At baseline, participants' sociodemographic characteristics will be collected. Information about age, gender, highest educational level, type of hospitalisation (acute/planned), reason for hospitalisation and the number and type of prescribed medications will be collected. To gather information on medication, we will copy the medication list on admission and at discharge.

Compliance with the different interventional components will be evaluated per participant at the end of the study based on available data from the documents

completed by healthcare providers. This includes determining whether the SelfMED assessment was completed by the nurse, patient and physician; checking if daily monitoring was performed according to the SelfMED monitor/follow-up form, and verifying whether action was taken if problems with medication self-management were identified according to the follow-up form.

2.11 Data collection

Data collection will proceed in several steps. First, patients' eligibility will be evaluated by the (head)nurse of the participating wards based on the inclusion and exclusion criteria. If patients are eligible, the nurse assessment will be performed. If nurses deem the patient eligible for medication self-management, patients will be invited to participate in the study. If patients refuse to participate, reasons for non-response will be surveyed. Patients willing to participate will be asked to sign informed consent, and subsequently to complete the patients' SelfMED self-assessment. This assessment will be extended with a questionnaire on demographics (i.e., age, gender, educational level, type and reason for hospitalisation) and medication intake at home. Afterwards, the treating physician will complete the physician assessment. Further participation in the study is only possible if the physician decides that the patient is eligible for in-hospital medication self-management. The SelfMED assessment will be performed in both the intervention and control groups.

On admission (after inclusion), a baseline measurement will be performed in which data on medication adherence, medication self-management and medication knowledge will be collected in both the intervention and control groups (see the 'Outcome measures' section). During hospitalisation, in the intervention group, the SelfMED monitoring tool will collect data from the patients' log of the medication scheme and the nurse's pill count. At discharge, the medication schedule of patients from both groups will be copied to collect data about medication use. Furthermore, data on patient satisfaction with pharmaceutical care will be collected in both groups (see the 'Outcome measures' section). At discharge, patients from both the intervention and control groups receive oral and written instructions on the use of the medication diary and the preservation of their medication packages for a 2-month period (± 60 days). Two months postdischarge, a home visit will be conducted

in both the intervention and control groups by the first author or a trained research assistant. During this home visit, several questionnaires will be administered to collect data on medication adherence, medication self-management, medication knowledge and healthcare service utilisation (see the 'Outcome measures' section); the preserved medication packages will be collected to perform a pill count and the medication diary will be collected for analysis. Approximately 2 weeks before the home visit, participants will be contacted by phone to remind them of the upcoming appointment. At the end of the study, healthcare providers will be questioned about their pharmacology care workload and their satisfaction with pharmaceutical care (both usual care and medication self-management).

To ensure uniformity of data collection, the administration of questionnaires will be conducted by the first author or trained research assistants. Through an information session, research assistants will be informed about the instructions (medication diary and medication packages) to be given to patients and the administration of questionnaires on admission, at discharge and 2 months postdischarge. Data will be collected by means of paper questionnaires.

2.12 Statistical analysis

Data will be analysed by using IBM SPSS Statistics V.29. Descriptive analysis of the study population will be performed with a comparison of the characteristics of the preintervention and postintervention sample. Discontinuous data will be described using frequency distributions. Continuous data will be described using a mean value and SD if normally distributed or using a median and range if non-normally distributed. Z-scores and Shapiro-Wilk test will be used for testing the normality of the data. χ^2 test, Fisher's exact test, independent t-test or Mann-Whitney U tests will be used to measure differences. A $p \leq 0.05$ will be considered as statistical significance, all tests will be performed two-sided.

Medication adherence measured by pill counts, the main outcome, will be measured using the following formula:

$$\frac{\text{the assumed number of pills taken based on the preserved medication packages}}{\text{the number of pills supposed to take based on the prescription}} \times 100. \text{ Both the}$$

average overall adherence rate and the adherence rate per medicine will be

calculated. A threshold of 80% of medications taken will be used to differentiate between adherent and non-adherent patients. Differences in medication adherence between the preintervention and postintervention group will be tested using independent t-tests or Mann-Whitney U tests (in case of adherence rates as dependent variable) or using Fisher's exact test (in case of the categorical variable adherent/non-adherent as the dependent variable).

To adjust for the possible imbalance between the preintervention and postintervention sample, a multivariable linear regression analysis will be performed, with medication adherence 2 months postdischarge as dependent variable and the group allocation and potential confounders as independent variables. Possible confounders based on differences in baseline characteristics between patients included in the preintervention and postintervention periods will be entered consecutively into the model. 95% CIs will be displayed when reporting the linear regression results.

Secondary outcomes (ie, patient-reported medication adherence, medication knowledge, self-management, nurses' and patients' satisfaction, perceived workload, health service utilisation) will be continuous outcomes (ie, the number of problems reported in the medication diary; the sum score on the ProMAS questionnaire, the sum score of total medication knowledge; the number of medication self-management problems; satisfaction and workload ratings on a 10-point scale, the number of readmissions/ consultations/nurse visits). Differences in secondary outcomes between the preintervention and postintervention group will be tested using Independent t-tests or Mann-Whitney U tests.

2.13 Patient and public involvement

In preparation for the development of the SelfMED intervention, patients were surveyed about their willingness towards in-hospital medication self-management and its prerequisites^{35, 36}. During the development of the SelfMED support tool (i.e., guidance with recommendations for healthcare providers), a panel of patients was involved and asked to assess the usefulness of the recommendations²⁹. The feasibility of measurement methods for measuring the primary outcome (i.e.,

medication adherence) was explored in a sample of 69 patients, which informed our choice of measurement method²⁸.

2.14 Ethics and dissemination

This study will be conducted in accordance with the Declaration of Helsinki³⁷. All participants will sign written informed consent prior to participation, obtained by the PhD researcher (LM) or a trained research assistant. Data will be pseudonymised and the keys to coding will be stored separately in an encrypted file. The research protocol was approved by the ethics committee of the Antwerp University Hospital (reference no: B3002023000176). Any modifications to the protocol, which may impact the conduct of the study, may affect patient safety, including changes in study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be approved by the Ethics Committee of Antwerp University Hospital prior to implementation.

Scientific valorisation will be achieved through peer-reviewed publications and conference presentations. Authorship will be based on the criteria of the International Committee of Medical Journal Editors (ICMJE). Summaries or reports in layman's terms will be disseminated to healthcare professionals through their professional organisations. Deidentified datasets will be available from the authors on request.

Contributors

Conceptualisation: LM, EG and TD; Methodology: LM, EG and TD; Writing—original draft: LM; Writing—review and editing: LM, EG and TD. All authors have read and agreed to the published version of the manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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Chapter 11

General discussion and conclusion

Discussion

Medication self-management during hospitalisation is a promising strategy for improving the safe and effective use of medication at home¹⁻⁵. Enabling patients to practice medication self-management during their hospital stay, with guidance and support from the healthcare team, not only ensures continuity of care but also provides an opportunity to detect and address potential medication-related problems in collaboration with the patient prior to hospital discharge.

Additionally, this approach enables patients to become familiar with newly prescribed or modified medications. By promoting patient participation, autonomy and independence, in-hospital medication self-management contributes to a more person-centred approach to healthcare, and results in increased patient satisfaction⁶⁻⁸. Moreover, evidence suggests that in-hospital medication self-management programmes hold promise for reducing medication errors^{3, 5}, lowering hospital readmissions³, improving medication adherence^{3, 4} and increasing medication knowledge^{3, 9}.

Due to the potential of in-hospital medication self-management, the SelfMED intervention was previously developed to facilitate and implement this approach within the Belgian context. The SelfMED intervention includes a procedure outlining the medication self-management process and affiliated responsibilities, as well as tools for assessment and monitoring¹⁰. This thesis aimed to strengthen the SelfMED intervention by developing and/or evaluating supportive tools and strategies, as well as preparing for the evaluation of the intervention's effectiveness by assessing adherence outcome measurement methods and outlining the study protocol.

The following sections reflect on the main findings, methodological considerations and implications for clinical practice, policy-making, education and future research. The discussion of the main findings is structured around the three aims (three parts) of the thesis.

1. Part I: Problems and perceptions on medication use of patients post-discharge

The first aim of this thesis was to identify medication management problems encountered by patients with polypharmacy post-discharge, along with their perceptions regarding medication use and influencing factors (Chapters 2 – 3). Gaining insights into patients' practical problems and perceptions is necessary for developing tailored tools and strategies to support them in their medication management.

1.1 Post-discharge medication management deficiencies and influencing factors

In Chapter 2, it became clear that 90% of the patient population characterized by polypharmacy encountered at least one medication self-management issue post-discharge. The post-discharge problems encountered included non-adherence, knowledge deficits, difficulties with medication-taking and challenges obtaining medications. Half of the patients felt inadequately prepared during their hospital stay for medication self-management at home. Approximately 13% of patients were allowed to self-manage their medicines in hospital, while 70% had to do so after discharge. Patients who received nurse-led in-hospital medication management experienced post-discharge issues more frequently than those allowed to fully or partially self-manage their medication in the hospital. Hence, our findings underscore the need to improve in-hospital preparation for medication self-management.

First, to ensure patients are adequately equipped to manage their medications at home, it is critical to provide thorough information and education about their medication regimens, including any changes made during hospitalisation. However, our research identified significant gaps in current counselling practices, with knowledge-deficiencies post-discharge being among the most prevalent issues. To address this, standardized medication counselling conversations could be recommended. Such counselling sessions should follow established guidelines to ensure consistency and quality in the information provided¹¹, equipping patients with a clear and comprehensive understanding of their medication regimen. These

should occur at least 24 hours prior to hospital discharge, providing patients time to ask questions and voice concerns^{11, 12}. Moreover, counselling should not be limited to discharge but should be integrated throughout the hospital stay, particularly during medication rounds and at times of medication changes.

Furthermore, nurses taking responsibility for managing patients' medications during hospitalisation disrupts the continuity of medication self-management by patients^{13, 14} and contributes to a higher incidence of medication-related problems after discharge¹⁵⁻¹⁸. Therefore, to ensure continuity of care, patients should be given opportunities to practice self-managing their medications during hospitalization, preparing them for the responsibilities they will assume post-discharge.

A hospital stay presents a window of opportunity to improve medication self-management skills, as it provides a controlled environment with direct access to multidisciplinary healthcare teams, including physicians, nurses, and pharmacists. Unlike in primary care settings, where patient interactions are typically limited to brief 15-minute encounters^{19, 20}, hospitalization offers a longer timeframe (i.e., a few days) and resources for comprehensive education, observation, and hands-on practice with medication management. This structured environment allows for personalized interventions in medication management, such as identifying potential barriers to medication self-management, and providing patient-tailored counselling and support. Interventions like SelfMED provide a structured approach combining skill practice, problem detection and personalised counselling and support while in hospital.

However, the hospital context may also pose certain limitations to promoting medication self-management, as patients are often at their most vulnerable during hospitalisation. Physical illness or cognitive impairment can make it challenging for patients to take up medication self-management responsibilities, necessitating nurse-led medication management. A comprehensive assessment of a patient's medication self-management ability is therefore needed (see paragraph 2.1).

Hence, it is unrealistic to expect that all patients will be able to self-manage their medicines, nor that all medication-related problems can be identified and resolved during hospitalisation. The transition from hospital to home is complex, and

challenges can emerge after discharge. Therefore, interventions aimed at enhancing self-management should not only be initiated in the hospital but also reinforced through continued support and follow-up in primary and community care settings. The efforts of primary healthcare professionals are crucial for preventing medication-related problems, reinforcing education provided during hospitalisation, and addressing new challenges that patients may encounter at home.

General practitioners (GPs) and primary care nurses, as the first and central points of contact in primary healthcare, are well-positioned to guide patients in developing self-management skills and improving their capacity to manage their health and medication regimens^{21, 22}. GPs can also consider delegating advanced tasks to practice nurses to alleviate GPs' workload, improve satisfaction for both patient and healthcare provider and enhance both the efficiency and quality of care delivery²³⁻²⁶. Examples of such more advanced tasks include identifying patients' self-management needs and challenges, offering targeted medication self-management education and ensuring effective care coordination. Additionally, patients with polypharmacy have the opportunity to choose a "home pharmacist", i.e., a community pharmacist as a reference pharmacy. The home pharmacist can perform medication reviews, provide personalised support in the proper use of their medicines and maintain an up-to-date medication schedule.²⁷⁻²⁹ Raising awareness about the availability and benefits of the home pharmacist is essential for maximizing the impact of this initiative.

1.2 Patients' beliefs about medication and influencing factors

Besides practical barriers, patients' beliefs about medicines are associated with non-adherence, leading to suboptimal medication use and reduced treatment effectiveness³⁰⁻³³. Therefore, in chapter 3, patients' medication beliefs after discharge and the impact of medication-related discharge management (i.e., in-hospital preparation for medication self-management and medication-related information prior to or at discharge) was explored. Although concerns about the potential adverse effects existed, patients generally held a strong belief in the necessity of their prescribed medications. For over 90% of patients, the perceived benefits of prescribed medication(s) outweighed the possible disadvantages.

Previous research conducted among patients with multiple chronic conditions have reported similar findings^{31, 34, 35}.

Neither patient-related factors, nor factors related to the discharge management appeared to significantly influence patients' beliefs about medication post-discharge. This outcome was expected, given that the vast majority had a positive necessity-concern differential. However, existing evidence suggests that medicines beliefs can be influenced by patient-related factors such as cultural background³⁶ and past negative experiences with medicines, including side effects and medication-related burden³⁷⁻³⁹. Furthermore, the trust established between patients and their healthcare providers, alongside quality of communication about medicines, are key factors known to shape medication beliefs⁴⁰⁻⁴³.

This highlights the importance of shared decision making (SDM) between patients and healthcare providers whenever medicines are prescribed, discontinued, or altered. SDM ensures that patients' values, preferences, needs and prior experiences with medications are expressed and incorporated into care, thereby tailoring pharmacotherapeutic treatment to the individual³³. Additionally, SDM has been shown to enhance trust between patient and healthcare providers as well^{44, 45}. As stated earlier, to improve the quality of communication about medicines during hospitalisation, more standardized medication counselling can also be considered, given the considerable variation in counselling practices (Chapter 2).

2. Part II: Refinement and extension of the SelfMED intervention

The second aim of our research was to strengthen the SelfMED-intervention by reviewing its assessment component and developing and/ or evaluating strategies and tools to support patients with polypharmacy in medication self-management (Chapters 4 – 8).

2.1 Refinement of the SelfMED assessment tool

Enabling patients to self-manage their medications during hospitalization requires an evaluation of their ability to do so. The SelfMED assessment was developed for this purpose and considers factors such as physical and mental abilities and prior medication self-management at home. However, it remained uncertain whether the

assessment sufficiently accounted for medication literacy, prompting an investigation into the added value of incorporating a new medication literacy scale (MED-fLAG).

Findings from Chapter 4 demonstrated a strong relationship between MED-fLAG and SelfMED, indicating that higher medication literacy skills were associated with a higher degree of patients' perceived capacities for in-hospital medication self-management. The strong relationship suggests that the SelfMED assessment serves as a suitable screening tool for evaluating patients' eligibility to perform in-hospital medication self-management, even without a standard evaluation of medication literacy levels.

However, for patients who are deemed less capable of medication self-management, tools like MED-fLAG can offer valuable insights into medication literacy skills. This enables healthcare providers to tailor medication information and interventions to patients' specific needs. In this context, the guide with recommendations outlined in Chapter 5 can serve as a resource for healthcare providers when selecting interventions. Several strategies included in the guide have been proven particularly effective in supporting patients with limited health literacy, including the teach-back method⁴⁶⁻⁴⁸, the use of visual aids such as pictograms, icons or animations^{47, 49, 50}, and plain language communication^{47, 51}.

2.2 Tools for healthcare professionals to support medication self-management

Once patients are deemed eligible for medication self-management, the SelfMED intervention aims to support them throughout the process of medication self-management while they are still hospitalized, identifying and addressing any problems that arise. By resolving potential challenges, the intervention aims to enhance patients' self-management capacity, empowering them to take an active role as co-managers of their care trajectory and plan after discharge. Providing healthcare providers with actionable recommendations to assist patients facing medication self-management difficulties helps maximize the impact of the SelfMED intervention. In this context, chapter 5 was dedicated to developing such recommendations.

First, a mapping of medication self-management problems identified 20 distinct problems, including difficulties with obtaining medicines, knowledge, organisation and administering medications, monitoring effects and ensuring sustained use. Subsequently, a scoping review generated a list of potential actions or interventions for each respective problem, which were then transformed into recommendations. Finally, a Delphi-study involving 23 experts resulted in 67 recommendations deemed relevant and clear for supporting medication self-management in clinical practice. Since the recommendations were designed to address issues throughout the entire medication self-management process rather than focusing on a single issue, they have a broad scope, making them applicable to a wider range of patients. Although the recommendations were initially developed as part of the SelfMED intervention for hospitalised patients with polypharmacy, most offer valuable guidance beyond the hospital setting and can benefit other patient populations experiencing similar problems.

In Chapter 6, the recommendations were evaluated as being feasible, user-friendly and useful in supporting patients experiencing medication-related problems, though their application proved time-consuming. Nurses reported intervening in 52% of the medication self-management problems encountered in patients using the set of recommendations. It remains unclear whether the remaining 48% of problems were addressed based on the healthcare provider's expertise or left unresolved. The guide is intended primarily as a resource for healthcare providers, rather than as a systematic tool for addressing every identified problem. Furthermore, due to high workloads, medication self-management support is not always a priority for nurses.

Making the recommendations directly available to patients could add value by enabling them to take action themselves when issues arise. For instance, if patients feel they lack knowledge about their medications, the recommendations can guide them to trustworthy information sources. Similarly, a patient experiencing difficulty opening medication packages could benefit from practical tips, such as using a pill pen or pill pusher. Therefore, as part of the SelfMED intervention, patients will receive an informational brochure containing these recommendations (Chapter 10).

2.3 Shared decision making in pharmaceutical care as a strategy for medication self-management support

Ensuring that medication self-management support aligns with patients' needs and preferences requires adopting a SDM approach. SDM enhances self-management by helping patients define medication management priorities and building confidence in their ability to manage care independently⁵². However, implementing SDM remains challenging in both medical and nursing professions, which have traditionally operated under a rather paternalistic model⁵³⁻⁵⁵. This traditional approach continues to influence healthcare providers' behaviour, often preventing SDM from being integrated into patient-healthcare provider interactions⁵⁵⁻⁵⁸.

Chapter 7 explored nurses' and patients' experiences and role perceptions regarding medication-related SDM and revealed its limited application during hospitalisation. Several barriers were identified, such as patients' health status, medication-related knowledge, the therapeutic nurse-patient relationship, time constraints, and workload. Notably, when SDM was discussed, participants primarily envisioned SDM in the context of prescribing medications and managing side effects. Since nurses are not currently trained to prescribe medicines, it is unsurprising that medication-related knowledge emerged as a barrier. Nurses should be made aware that they can support patients and participate in collaborative decision-making in other domains of pharmaceutical care. This is particularly important, as patients valued nurses' contributions to SDM, viewing them as key persons thanks to their informational, facilitative and supportive roles. For example, if patients frequently forget to take their medicines, nurses can work with them to evaluate available options to address this issue, such as reminders apps, pill timers, pill boxes, or associating medication with routine daily activities, while considering patients' preferences.

Our research aims to create several opportunities for SDM within medication management support. The SelfMED intervention incorporates SDM by involving patients in decision-making about initiating medication self-management during hospitalisation, encouraging participation in monitoring rounds to discuss problems, concerns, experiences and needs, and engaging patients in collaborative decisions

on how to address identified problems. Furthermore, the diary developed in chapter 8 promotes patient involvement and SDM, and empowers patients to take the lead in managing their medication data, by providing a structured way to report medication-related problems in a user-friendly manner. This enables discussions and collaborative decisions with healthcare providers on how to address the problems encountered. However, our research also highlighted the importance of assessing the extent to which a patient wants and is able to participate in decision-making, as patients' desire for involvement in medication-related decisions can be influenced by both individual and contextual factors (Chapter 7).

Healthcare providers should cultivate a mindset focused on the provision of person-centred care, strengthening patient empowerment and fostering patient participation. This requires a significant role for patients in the education of healthcare professionals⁵⁹. Actively engaging patients in educational processes helps students develop the knowledge, skills and attitudes essential for establishing person-centredness in health and care processes⁶⁰⁻⁶². Moreover, patient involvement ensures that educational programmes remain responsive to the patients' needs. Hence, integrating partnerships with patients must become a foundational element of educational curricula for healthcare professionals in medicine, nursing, pharmaceutical sciences and other disciplines⁶⁰.

Additionally, these curricula should embed competencies in self-management support⁶³. These competencies should include assessing individuals' needs and preferences, collaborative goal setting, establishing partnerships and patient-centredness, employing clear and effective communication techniques and using approaches like motivational interviewing and SDM⁶³⁻⁶⁸. SDM training, in particular, plays a critical role in increasing students' awareness of their responsibility in collaborative decision-making, while providing practical experience before healthcare provider-patient interaction patterns are established⁶⁹.

2.4 Strategies to support communication regarding medication self-management

Collaboration and communication between healthcare providers across healthcare lines is deemed essential to create a seamless continuum of integrated care that prioritizes patient safety and empowers individuals in managing their medications effectively^{70, 71}. Healthcare providers must be able to access and rely on structured, up-to-date patient information, such as medication schedules, through user-friendly and integrated interfaces⁷². However, transmural exchange of information through the use of digital platforms remains problematic^{73, 74}. In Belgium, such systems are not sufficiently developed nor integrated, with technical incompatibilities between different healthcare providers' software packages, or incomplete functionality of sharing medication schedules⁷⁵. Improving the integration of the digital eHealth platform into all software packages, including the hospital's electronic health record system, is crucial for achieving better and more effective digital information flow between all healthcare providers.

Due to a lack of seamless data sharing, initiatives like the “green envelope” have been introduced as a practical communication tool to convey discharge medication schedules to community pharmacists⁷⁶. Upon discharge, patients receive their medication schedule in a green envelope, which they hand over to their community pharmacy to facilitate information transfer. Additionally, carrying paper or electronic patient-held medication lists has been found to be helpful for sharing information with healthcare providers across settings and can also serve as an aid in conversations about medicines⁷⁷⁻⁷⁹. In this context, the concept of a structured medication diary was developed (Chapter 8). The diary not only includes a patient-held medication list, but also helps patients document medication management-related problems through structured ‘problem sheets’. The latter seemed particularly important, as Chapters 2 and 3 highlighted several practical problems and concerns related to medication. Reporting such issues is crucial for improving medication management⁸⁰, tailoring the pharmacotherapeutic care to individual needs and achieving optimal outcomes^{1, 81, 82}.

When evaluating the medication diary, 40% of participants reported medication-related problems within two months after discharge. Most patients found the diary user-friendly and easy to complete, and half of the sample indicated that the diary could facilitate discussions with healthcare providers about medication-related issues. The diary offers a practical means for patients to communicate medication-related issues across healthcare settings and to different healthcare providers. In primary care, it can assist general practitioners, primary care nurses and home pharmacists in identifying medication self-management challenges, thereby informing prescribing practices, optimizing medication schedules, and providing tailored patient education. Additionally, when patients are admitted to the hospital, the patient-held medication list in the diary can enhance medication reconciliation practices. Patients could also document medication changes or problems encountered during hospitalisation (e.g., side effects) for communication after discharge.

The diary was initially developed in a paper-and-pencil format, as this format is more convenient for the older population, who are particularly vulnerable to medication-related problems due to the higher likelihood of polypharmacy and increased cognitive and functional decline. When evaluating the diary, we inquired about patients' preferred format, and approximately 4 out of 5 participants favoured a paper diary. Considering person-centred care, the digitalisation of the diary could be explored in the future, allowing patients to choose the format that best suits their preferences. A digital diary would offer opportunities to enhance the transferability of patient-reported medication management issues with healthcare providers, especially if the information can be linked to the digital eHealth platform. When digitalizing the diary, patient involvement will be necessary to ensure the format remains accessible and user-friendly.

2.5 Future research on supportive tools and strategies

The developed tools and strategies, including the medication diary and the recommendations for healthcare providers, underwent an initial evaluation in clinical practice, focusing on feasibility and user-friendliness for potential users. The actual effect of using these recommendations to support patients during hospitalisation in terms of medication self-management outcomes has not been assessed yet.

Additionally, it has not been evaluated whether the diary actually improves the identification of, and communication about, medication management problems encountered by patients. Future research can address these aspects.

The SelfMED-intervention and the supportive tools primarily aim to support healthcare providers and patients who have to manage their medication independently at home after discharge. If patients manage their medication together with family members or other caregivers, these caregivers should also be empowered to provide high quality (pharmaceutical) care and to act as advocates for the persons they care for⁸³. It may be beneficial in the future to integrate informal caregivers into the SelfMED intervention. They can also benefit from adequate training in order to be able to perform medication self-management activities and support patients effectively. Additionally, caregivers require informational, practical and emotional support to sustain their caregiver role⁸³. As informal caregivers can serve as valuable sources of information about potential medication-related issues, they should be actively involved in medication management along the patients' entire care journey. For example, caregivers should participate in medication intake interviews upon admission, be involved in medication counselling during hospitalisation, and engage in follow-up encounters with primary healthcare providers. Future research on their roles, responsibilities, perspectives, and needs in medication management support is recommended to integrate them into the SelfMED intervention

3. Part III: Preparatory studies for evaluating SelfMED's effectiveness – medication adherence measurement an intervention protocol

After reviewing the SelfMED assessment and developing and evaluating supportive measures, it was time to prepare for the evaluation of the overall effectiveness of the intervention. Therefore, the third and final aim of this thesis was to prepare for the evaluation of SelfMED's effectiveness in patients with polypharmacy by evaluating adherence outcome measurement methods and outlining the intervention study protocol (Chapters 9 – 10). Medication adherence is considered

as the key primary outcome, since medication self-management problems are directly related to medication adherence⁸⁴.

3.1 Measurement(s) of medication adherence

Accurately assessing medication adherence in patients with polypharmacy remains a clinical and research challenge, even with the availability of various measurement methods⁸⁵⁻⁸⁷. Generally, measurement methods are divided into two groups: (1) direct measures (i.e., the observation of medication intake and measurement of drug levels or drug metabolites in the blood or urine) and (2) indirect measures (i.e., self-reports, prescription refill rates, pill counts, and electronic monitoring systems). As there is no standardized method in clinical practice nor in research, combining multiple methods simultaneously seems to be indispensable to improve the accuracy of adherence measurement and to validate medication adherence from various perspectives⁸⁵⁻⁸⁸. When selecting methods, it is crucial to consider the patient population and setting (e.g., inpatient vs. outpatient or research vs. clinical setting), the availability of data and resources (e.g., funding, personnel), reliability and practicality for researchers or healthcare providers, as well as the feasibility for patients.

Although each method has its advantages and drawbacks, some appear to be particularly impractical or infeasible for multidrug regimens. For instance, in cases of polypharmacy, drug-drug interactions can affect the accuracy of drug level measurements⁸⁶. Due to the multiple medicines, each often with different timing schedules, direct observation would require continuous supervision, which is not feasible, especially when assessing adherence in a home setting. Medication Event Monitoring Systems (MEMS) have been proposed as the gold standard for adherence measurements, as they provide detailed data on dose timings, intervals, and frequency. However, they can be very costly for polypharmacy, requiring substantial funds to implement.⁸⁹

After weighing the trade-offs between reliability, practicality and available resources, we decided to evaluate patients' perspectives on the feasibility and validity of combining pill counts, a medication diary and a self-report questionnaire over a two-month period. Chapter 9 revealed that this multi-method approach provided

complementary insights into medication adherence. From the patient's perspective, this approach was feasible for assessing adherence two months after discharge. However, patients considered pill counts as the most accurate reflection of their medication adherence.

Pill counts in our research revealed high adherence rates, with an overall average of 96% pills taken. In clinical research and practice, a threshold of 80% pills taken is often considered as a standard cut-off to differentiate between adherent and non-adherent patients⁹⁰⁻⁹³. However, this threshold should not be regarded as a universal standard, as its applicability varies across different types and classes of medications, as well as health conditions^{90, 94}. Higher and lower thresholds have been identified to best define optimal adherence for specific populations, diseases, and medications⁹⁵⁻⁹⁸. For example, medications like vitamin K-antagonists and immunosuppressants, require near perfect adherence, with thresholds exceeding 80% to achieve favourable clinical outcomes⁹⁹⁻¹⁰¹. In contrast, evidence suggest that for certain statins, such as atorvastatin, adherence rates between 40% and 60% are sufficient to maintain the serum low-density lipoprotein cholesterol levels within the target range⁹⁴.

Therefore, future research and clinical practice should adopt evidence-based thresholds for each individual medication (class), informed by studies evaluating the relationships between outcomes and varying adherence levels, rather than relying on arbitrary cut-offs¹⁰². In contrast to the standardized cut-off proposed in the protocol paper (chapter 10), the adherence rates from this study should be interpreted in line with the thresholds for the respective medication, if available. Moreover, although dichotomizing against a fixed threshold is common, it is essential to interpret '*the extent to which actual medication intake corresponds to the prescribed regimen*' not merely as a binary outcome but as a dynamic process that considers individual patient circumstances and the complexities of medication-taking. The developed medication diary may help account for patient circumstances and medication-taking complexities by providing valuable insights into the patients' unique experiences and challenges with medication management.

3.2 Patients' willingness regarding adherence measurement

Furthermore, our results revealed that while patients expressed a high willingness to share information about their medication adherence, only 59% had their adherence monitored over a two-month period. Patients unwilling to communicate problems concerning medication intake were also reluctant to have their adherence being monitored and therefore did not participate in the follow-up study. These individuals are likely to be less adherent and are the ones who could benefit the most from adherence support. Similarly, in clinical practice, non-adherence is often undisclosed¹⁰³.

Therefore, it is important to develop methods that encourage honest disclosure and foster non-judgemental discussions about medication-taking behaviours during consultations^{89, 104}. Furthermore, explicitly questioning patient goals, their experiences, concerns, preferences and values when prescribing or reviewing medicines is needed for promoting adherence. The most commonly used definition of adherence - *'the extent to which the patient's behaviour corresponds with the agreed recommendations of a healthcare provider'*^{105, 106} - emphasizes the importance of a collaborative partnership between the patient and the healthcare provider(s)¹⁰⁷. Actively involving patients in decisions about their medications fosters a sense of ownership and responsibility, increasing the likelihood that patients will adhere to their prescribed regimens¹⁰⁸. Research, including findings from chapter 7, demonstrates that patients perceive SDM as beneficial for medication adherence¹⁰⁷⁻¹⁰⁹.

3.3. Pre-post intervention study evaluating SelfMED's effectiveness

Once the feasibility and practicality of a combination of medication adherence measurement methods has been determined, evaluation of the interventions' effectiveness can take place. Chapter 10 outlines the protocol of a pre-post intervention study primarily aimed at evaluating the effectiveness of the SelfMED intervention in terms of medication adherence two months post-discharge. Patient recruitment is progressing slower than expected and is, therefore, currently still ongoing (i.e., Feb 2025). Although results cannot be presented yet, we can reflect on the barriers encountered thus far in setting up and conducting the pre-post study.

Despite investing in research on stakeholders' opinions and the context, the implementation of this complex intervention proved to be very challenging.

First, at present, no legislation in Belgium describes the act of in-hospital medication self-management by patients, but inquiries with the Flemish Care Inspection identified prerequisites for in-hospital medication self-management (see Chapter 1 – §5.1 legal context). Although we have taken these prerequisites into account while developing SelfMED, these preconditions are not explicitly described in official reports (e.g., a policy document or national guideline), leaving healthcare organizations uncertain about the rules to follow when evaluating and thereafter possibly implementing medication self-management.

Hence, a detailed and clear description on the legal conditions required to allow the establishment of medication self-management and the responsibilities of both patients and healthcare providers should be developed. Such a description should be approved and subscribed by the legal advisory boards of the professional organizations, healthcare inspection and accreditation organisations. Only in case such descriptions are available, we can guarantee the hospital boards that the evaluation and implementation of medication self-management can be established in a legal and safe way.

Second, during the preparatory meetings, stakeholders expressed concerns that medication substitution during in-hospital medication self-management may cause confusion among patients, resulting in improper use of medicines and medication errors. A potential solution to overcome this issue comprises allowing patients to bring their own medication, supplied by the community pharmacy, into the hospital upon admission. With patients' own medication use (POM), medication substitution is no longer necessary, and medicines remain recognizable to patients, thereby preventing medication errors and improving the quality of medicines used¹¹⁰⁻¹¹². POM may also enhance opportunities for problem detection and patient counselling related to home medication. Additionally, it can ensure the continuation of medication therapy during hospital stays and can enhance continuity of care across healthcare settings^{110, 113}. According to a Dutch study, POM can reduce medication

waste costs and can decrease the time spent by hospital staff on the medication process¹¹⁴.

Despite the benefits, POM is not permitted under current Belgian regulations, as inpatient medication must be supplied by the hospital pharmacy¹¹⁵. A recent press report attributes this restriction to the need for drug traceability¹¹⁶. Additionally, the distinct financial structures for medication reimbursement in the inpatient and outpatient settings hinder the use of POM. This imposes significant limitations to the potential 'solutions' we can offer in practice. As a result, POM was not adopted in the SelfMED procedure.

Due to concerns about medication substitution during hospitalisation, it is important to investigate the impact of using a hospital formulary on the frequency of medication switches and its effect on patient safety. We explored options to investigate this, but had insufficient access to reliable data from hospitals. Furthermore, it would be of interest to investigate the reasons for adhering to the hospital's formulary and the attitude and willingness of stakeholders to allow POM use in Belgian hospitals.

Third, nurse managers and head nurses have expressed concerns about the potential impact of introducing this complex, multicomponent SelfMED-intervention on nursing wards, as they already face high workload and care burden. The intervention will require nurses to shift from current fixed medication management routines – such as storing, preparing and administering medicines for patients – to assessing patients' medication self-management competencies, monitoring medication self-management and providing support and counselling to patients. This shift is expected to increase the workload for nurses, and physicians are also concerned about additional tasks, such as completing the physician assessment and specifying self-managed medications.

While the introduction of this new approach may be time-consuming, once properly established, SelfMED is expected to increase the value and effectivity of nurses' actions. Preparing and administering medication by patients themselves can result in time savings for nurses^{3, 117, 118}. Part of these time savings can be reallocated to

coaching patients in medication management, interprofessional communication concerning medication changes and collaboration between team and patient.

The current SelfMED intervention targets patients with complex medication regimes who are hospitalised for longer periods. However, to improve the sustainability of healthcare, it may be beneficial to expand the scope of SelfMED to include patients with shorter hospital stays and less complex medication regimens. For these patients, the primary focus of in-hospital medication self-management would shift towards generating time savings for nurses, rather than on improving medication adherence and self-management.

Fourth, SelfMED's components (i.e., assessment, monitoring system and the supportive measures) are currently paper-based, which increases administrative burden and limits feasibility. Digitalizing these components and integrating them into the hospitals' electronic health record (EHR) streamlines workflows. It facilitates not only data sharing among various healthcare providers involved, but also data exchange between the patients' medical file and the SelfMED tools, thereby reducing the administrative burden, saving time and increasing the feasibility of the intervention for healthcare professionals.

If the SelfMED assessment can be completed using an electronic device linked to the EHR, results can be instantly accessed by nurses and physicians. Additionally, the EHR could include a feature that marks which medications a patient is allowed to self-manage and which should be nurse-administered, making the information immediately visible to all involved parties (i.e., physician, nurses, patient, hospital pharmacy). Patients would always have access to an up-to-date medication list, ensuring automatic and timely updates in case of medication changes. Additionally, patients could digitally register their medication intake, providing healthcare providers with a continuous overview that can be checked in the patients' medical file, saving nurses time by eliminating manual sign-offs. A digital system also enables the provision of a wider range of educational or supportive measures, such as videos or digital information leaflets for patients. However, evidence on the interventions' effectiveness is needed to justify the financial resources required for digitalization of the interventional components.

Supporting patients in medication self-management will be only successful if all healthcare providers across healthcare lines communicate and collaborate. Hence, transmural exchange of medication-related information should be facilitated. If SelfMED proves to be effective and could be digitalized in the future, the possibilities of integration of the intervention and tools into the Belgian eHealth platform should be explored immediately.

Furthermore, future research on SelfMED should take the following methodological considerations into account. Although follow-up and self-management support after discharge are important, SelfMED focuses solely on the period during hospitalization to support and better prepare patients for medication self-management at home. Interventions that include transmural components rather than focusing exclusively on either the hospital admission or post-discharge periods, have shown to be more successful¹¹⁹. Given that SelfMED is already a complex multi-component intervention, it was deliberately decided to first evaluate the effects of the current components. Ultimately, it is desirable to add transmural care components to the SelfMED intervention, such as post-discharge follow-up consultations by community or clinical pharmacists, or advanced practice nurses working in close collaboration with general practitioners.

As implementation science typically applies interventions that have already been proven safe and effective in a research setting, the study protocol (Chapter 10) primarily focuses on evaluating SelfMED's effectiveness rather than assessing implementation outcomes, as evidence on the effectiveness of SelfMED is not yet available. However, prior to and during the development of SelfMED, principles of implementation science were considered. Contextual factors were explored, including the prevalence and current practices of MSM in Flemish hospitals¹²⁸, and the legal context. Furthermore, key stakeholders (i.e., nurses, physicians, pharmacists, patients) were engaged to investigate their willingness and attitudes towards in-hospital MSM along with the prerequisites for implementing this new approach^{6,118}. Based on this contextual analysis, stakeholders' opinions' and literature review of existing MSM interventions, SelfMED was developed¹⁰. Stakeholders were involved during the development or evaluation of the SelfMED components (i.e., assessment, monitoring, supportive measures). All intervention

components were evaluated for feasibility in practice before moving to the effectiveness evaluation. Nevertheless, future research should address implementation outcomes such as acceptability, appropriateness, and fidelity as well as the implementation pathway as perceived by healthcare providers.

4. Methodological considerations

4.1 Strengths

A considerable strength of this PhD study is its focus on a vulnerable population of hospitalised patients with polypharmacy, who are particularly prone to medication self-management issues^{120, 121}, non-adherence and medication errors^{122, 123}. Additionally, a significant proportion of patients characterized by polypharmacy are elderly, whose age-related pharmacokinetic and pharmacodynamic changes increase their vulnerability to adverse events caused by improper medication use^{124, 125}. Furthermore, more than one in ten hospitalisations is likely caused by medication-related events¹²⁶ and the prevalence of drug-related problems post-discharge remains high¹⁸. Given these factors, hospitalised patients taking multiple medications represent a high priority group for fostering and improving medication self-management.

The conceptual model of medication self-management by Bailey (2013)¹²⁷ was used as a common thread across the different studies of this PhD to define and organise the concept into manageable components, promoting consistency across studies. The model provided a roadmap for the mapping of medication self-management issues (Chapter 2), guided the development (Chapter 5) and evaluation of recommendations, targeting healthcare providers, to support medication self-management (Chapter 6) and was used in developing the medication diary as a tool to foster medication adherence and medication self-management (Chapter 8).

Another strength of this PhD is the interdisciplinary approach and patient involvement which was employed in the development of strategies and tools to support patients in establishing medication self-management. Various stakeholder groups, including physicians, nurses and pharmacists, participated in the validation phase of the recommendations for healthcare providers (Chapter 5) and the review phase of the medication diary (Chapter 8). In addition, patient involvement ensured

the integration of patient perspectives in the development of these respective recommendations and the medication diary (chapter 5 and 8), as well as informing the choice of measurement tools used to assess medication adherence in patients with polypharmacy (chapter 9).

4.2 Limitations

Although the sample sizes, as determined a priori using power analyses, were achieved in the cross-sectional studies (chapter 2 – 4), the pilot studies evaluating the recommendations (Chapter 6), the medication diary (Chapter 8) and the feasibility of a combination of adherence measurement methods (Chapter 9) had rather small sample sizes (range 58 – 69 participants). These pilot studies required a more active and long-term involvement of participants. For example, in chapter 9 a high non-response rate of 41% for the longitudinal part was observed, along with a drop-out rate of 19%, which may explain the smaller sample size. Furthermore, a significant challenge in recruiting this vulnerable group of hospitalized patients was their willingness to engage. Common reasons for non-participation included feeling too sick or unwillingness to allocate time to research activities. Patients' primary focus was on their immediate medical needs and quality of life rather than participation in research studies. Moreover, nurses were often involved in selecting patients (i.e., checking eligibility against inclusion and exclusion criteria), but high workloads sometimes hampered the inclusion of patients for research purposes.

Throughout the studies, outcomes related to medication self-management (e.g., self-management problems, beliefs about medication, medication literacy and medication adherence) were measured using self-reported questionnaires. As a result, the risk of social desirability bias should be acknowledged. However, this bias was minimized by ensuring participants' privacy through pseudonymisation of personal data. Nevertheless, self-reports provide valuable insights into patients' opinions and experiences, supporting the development or evaluation of strategies and interventions from a patient-centred perspective. Moreover, beliefs about medication, for example, may not be observable through clinical assessments or objective measures. In the case of medication adherence, subjective and objective measurement methods were combined to address the limitations of relying solely on self-reports.

5. Summary of implications and recommendations

Action points for clinical practice, policy-making, education and research are integrated throughout the discussion. In conclusion, the most important implications and recommendations are summarized below.

5.1 For clinical practice

At present, medication self-management is not facilitated within Belgian hospitals. Patients are rarely supported during hospitalisation to take up responsibilities in medication management post-discharge. Medication self-management support is often not considered a priority by healthcare providers, primarily due to time constraints, heavy workloads and staff shortages. The failure to support medication self-management and ensure continuity of medication self-management is contributing to drug-related problems post-discharge, avoidable patient harm and unnecessary healthcare service utilization and costs. If hospitals are truly committed to improving patient outcomes and reducing healthcare costs, they must take full accountability now. This requires deploying healthcare professionals more effectively and integrating medication self-management support as a mandatory component of patient care.

- Comprehensive assessments of patients' medication management abilities and potential challenges should be implemented for high priority groups, such as patients with polypharmacy, before hospital discharge. To facilitate this, healthcare providers can implement the SelfMED protocol. Crucial to this process is the support that healthcare providers receive from management. Hence, hospitals should integrate SelfMED tools into their electronic patient record to streamline workflows and reduce administrative workload for healthcare providers.
- Medication counselling during hospitalisation should be provided in a standardized manner. Quality coordinators and nurse managers should implement established guidelines for healthcare providers to ensure consistency and quality of the information provided to patients. Our recommendations for medication self-management support can serve as a valuable resource.

- Hospitals should prioritise sustaining continuity of medication management during hospitalisation. They must adopt a more flexible approach, allowing patients to use their own medication when appropriate rather than being forced onto hospital formulary alternatives.
- SDM-principles should be adopted throughout (pharmaceutical) care provision, prioritizing patients' preferences, values and needs. Healthcare organisations should provide training for healthcare providers on SDM-techniques and person-centred communication.
- If patients manage their medication with family members or other caregivers, these significant others should be involved throughout the care journey. Hospital protocols should require that, with the patient's permission, informal caregivers are contacted during the medication intake interview upon admission and invited to participate in medication counselling sessions before hospital discharge.
- Healthcare organisations should establish clear recommendations for selecting adherence measurement methods by healthcare providers, based on patient population, available resources, reliability, practicality and feasibility for patients. Pill counts based on preserved medication packages, a medication diary and validated adherence questionnaires can be considered as low cost, practical and feasible approaches, providing complementary insights into medication adherence on short term.
- Foster non-judgemental conversations about medication-taking behaviours to encourage open communication about medication non-adherence. Healthcare organisations should ensure that all healthcare providers are trained in empathic communication, active listening, and non-judgemental interviewing techniques.

5.2 For policy-making

- A clear description of the legal conditions for establishing medication self-management, outlining the responsibilities of patients and healthcare providers, should be developed and approved by legal advisory boards, professional organizations, and accreditation bodies.

- Legislation on the use of a hospital formulary and financial structures for medication reimbursement should be reviewed to facilitate patient's own medication use during hospitalisation.
- We urge the government to invest in the seamless integration of the digital eHealth platform into all software packages, including hospital electronic health record systems, to enhance the efficiency and effectiveness of digital information exchange among healthcare providers. If SelfMED proves to be effective, digitalisation and integration of the intervention and tools into the Belgian eHealth platform should be explored

5.3 For education

- To develop a mindset on person-centred care, patient empowerment and patient participation, partnerships with patients in educational curricula for healthcare providers should be established.
- Curricula for healthcare professionals should include competencies in self-management support, such as assessing individuals needs and preferences, collaborative goal setting, establishing partnerships and patient-centredness, clear and effective communication techniques. SDM training should be an integral part of healthcare professionals training.

5.4 For research

- The actual effect of using the recommendations to support patients with medication self-management problems during hospitalisation on medication self-management outcomes should be assessed.
- Further research is needed to evaluate whether the medication diary effectively enhances the identification of, and communication about, medication management problems encountered by patients with healthcare providers in clinical practice.
- The impact of using a hospital formulary on the frequency of medication changes and its effect on patient safety should be investigated, as well as the reasons for adhering to the hospital's formulary and the attitude and willingness of stakeholders to allow patients' own medication use in Belgian hospitals.

- To enhance the sustainability of healthcare, the scope of the SelfMED intervention should be expanded to include patients with shorter hospital stays and less complex medication regimens.
- The incorporation of transmural intervention components into SelfMED should be explored.
- The roles, responsibilities, perspectives, and needs of informal caregivers in supporting medication management should be investigated.

What this dissertation adds

This research uncovers several new findings in the field of medication self-management support of patients with polypharmacy.

- Nurse-led medication management during hospitalisation disrupts continuity of care, contributing to medication-related problems post-discharge.
- A strong belief in the necessity of prescribed medicines was demonstrated in patients with polypharmacy after hospital discharge.
- The SelfMED assessment can be used as a first screening tool to determine a patient's eligibility for in-hospital medication management, without the need for prior assessment of medication literacy.
- Practical recommendations for healthcare providers were developed which allow them to provide support to patients facing medication self-management problems, encompassing the entire process of medication self-management. A first evaluation of their usefulness, user-friendliness and feasibility in practice was confirmed by nurses.
- A medication diary was designed to help patients report medication-related problems, with a focus extending beyond medication intake alone. An initial evaluation demonstrated its user-friendliness for patients and its potential to facilitate discussions on medication-related problems with healthcare providers.
- A narrow focus has been identified among patients and nurses, where shared decision making is primarily linked to prescribing medications and monitoring effects, explaining the rather limited application of SDM between nurses and patients during hospitalisation.
- Our research showed that a combination of pill counts, a medication diary and a self-report questionnaire provided complementary insights into medication adherence, while being a feasible method for patients in short term.
- A discrepancy exists between patients' stated willingness to communicate adherence-related information and having adherence actually monitored.
- This thesis described barriers for implementation of SelfMED in clinical practice, including the lack of a legal framework, the lack of the possibility for patient's own medication use and the lack of a digitalised intervention.

Conclusion

This PhD study aimed to strengthen the SelfMED intervention by reviewing its assessment component, developing and/or evaluating supportive tools and strategies for both patients and healthcare providers, and preparing the evaluation of its overall effectiveness. Key insights were gained into the medication beliefs and practical challenges faced by patients with polypharmacy in managing their medications shortly after hospital discharge, along with their influencing factors. The findings confirmed the need for improved preparation and support during hospital stays to ensure continuity of care and facilitate medication self-management at home.

The study explored the added value of a medication literacy scale within the SelfMED assessment for determining a patient's eligibility for in-hospital medication self-management. However, our research confirmed the appropriateness of the SelfMED assessment as an initial assessment tool. The results also highlighted the limited application of shared decision making during hospitalisation, emphasizing the need for creating explicit opportunities for patient participation in pharmaceutical care decisions, which SelfMED aims to address in multiple ways. Practical tools, including a set of recommendations for healthcare providers and a medication diary for patients to report medication-related problems, were introduced. Preliminary evaluations of feasibility and user-friendliness indicated their potential utility in clinical practice, though further assessment is required to determine their effectiveness within the broader SelfMED intervention.

In preparation of the evaluation of the impact of SelfMED on medication adherence post-discharge, a combination of measurement methods was assessed. The multi-method approach of pill counts, a medication diary and a self-report questionnaire was deemed feasible by patients and found to provide complementary information on patient's adherence. Subsequently, an intervention study was initiated, revealing several challenges. The intervention could benefit from clearer regulations, the use of patient's own medication, an expanded scope beyond patients with polypharmacy and the digitalisation of intervention components. Addressing these aspects will be essential to fully support the potential of in-hospital medication self-management and to evaluate its effectiveness on a larger scale.

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Summary/ samenvatting

Summary

During hospitalisation, healthcare providers typically manage medication for patients, while patients are often expected to self-manage their medicines after discharge. Hospitalisation disrupts continuity of care and puts patients at risk of compromised medication safety, often resulting in medication-related problems at home. To address this issue, a patient-centred approach that enables patients to practice medication self-management during their hospital stay is needed. In-hospital medication self-management programmes have shown promise in enhancing safe and effective medication use by reducing medication errors, improving medication knowledge and increasing adherence.

To facilitate in-hospital medication self-management in Belgium, the SelfMED intervention was developed. This intervention includes a procedure outlining the medication self-management process and affiliated responsibilities, as well as tools for assessment and monitoring. However, this thesis aimed to further strengthen SelfMED by developing and evaluating supportive tools and strategies for both healthcare providers and patients, as well as preparing for the evaluation of the intervention's effectiveness by assessing adherence outcome measurement methods and outlining the study protocol.

The first part of this thesis aimed to identify medication management challenges faced by patients with polypharmacy post-discharge, along with their perceptions of medication use and the influencing factors, as a foundation for developing tailored tools and strategies to support patients in managing their medications. The findings revealed that half of the patient population characterized by polypharmacy felt inadequately prepared during their hospital stay for medication self-management at home, with 90% encountering at least one issue post-discharge. These issues included non-adherence, knowledge deficits, difficulties with medication-taking ability and challenges obtaining medications. Patients receiving full medication management by nurses during hospitalization, as well as those on a higher number of medications, were at greater risk of experiencing post-discharge problems.

Exploration of patients' medication beliefs post-discharge showed that while some concerns about adverse effects existed, patients generally had a strong belief in the necessity of their prescribed medicines. For over 90% of patients, the perceived benefits of prescribed medications outweighed the possible disadvantages. Neither patient characteristics nor factors related to discharge management appeared to significantly influence patients' medication beliefs after discharge.

The second part of this thesis focused on refining the SelfMED intervention by reviewing its assessment component and introducing supportive tools and strategies for both healthcare providers and patients. The relationship between medication literacy (MED-fLAG) and the degree to which patients are considered capable for medication self-management (SelfMED assessment), the factors influencing the strength of this relationship and the factors influencing a patient's capability for medication self-management were investigated. Findings revealed a strong positive relationship indicating that the more medication literacy skills, the higher the perceived medication self-management capability. Our study could not reveal any factors that significantly affected the strength of the relationship between both. Age, managing medication independently at home, the number of chronic conditions and medication literacy were significant predictors of a patient's capability for in-hospital medication self-management. The study confirmed that SelfMED is a suitable screening tool for assessing patients' eligibility to perform in-hospital medication self-management, without requiring a separate medication literacy assessment.

To support healthcare providers, a comprehensive set of recommendations was developed to assist patients with medication self-management problems. First, a mapping of medication self-management problems identified 20 distinct problems. Next, a scoping review generated a list of potential actions or interventions, which were then transformed into recommendations. Finally, a three-round Delphi study involving 23 experts established consensus on the relevance and clarity of 67 recommendations. A pilot study demonstrated that the recommendations were feasible, user-friendly and useful in supporting patients experiencing medication-related problems, although their application proved time-consuming. Nurses reported intervening in 52% of the medication self-management problems

encountered in patients with the use of the set of recommendations, most frequently addressing knowledge deficits in patients.

Additionally, interviews were conducted to explore nurses' and patients' experiences and role perceptions regarding medication-related shared decision making (SDM) during hospitalisation. Results revealed limited application of SDM in clinical practice, with barriers such as patients' health status, medication-related knowledge, the therapeutic nurse-patient relationship, time constraints, and workload. Nevertheless, patients valued nurses' contributions to SDM, viewing them as key persons thanks to their advocacy, informational, facilitative, and supportive roles. Patients' desire for involvement in medication-related decisions was influenced by both individual and contextual factors. SDM was mainly associated with prescribing medications and managing side effects.

To help patients report and communicate medication-related problems with healthcare professionals after discharge, a medication diary was developed and evaluated. The diary consisted of five key components: (1) a medication schedule allowing patients to list their medicines, (2) information sheets for recording important medication-related information, (3) a monthly overview to indicate whether medication-related problems were experienced, (4) problem sheets to elaborate on specific issues and (5) a section for specific medication related questions to healthcare providers. A pilot test revealed that about 40% of patients reported medication-related problems within two months after discharge. Most found the diary user-friendly and easy to complete, and half of the sample believed that the diary could help facilitate discussions with healthcare providers about medication-related issues.

The final part of this thesis focused on preparatory studies for evaluating the effectiveness of the SelfMED-intervention on medication adherence post-discharge. Medication adherence is considered the primary outcome as medication self-management problems are closely linked to adherence. First patients' willingness to have medication adherence monitored using a multi-method approach was explored, followed by an evaluation of its feasibility and validity from a patient perspective. Results showed that while patients were highly willing to share

information about their medication adherence, only 59% had their adherence monitored during two months. A combination of pill counts, a medication diary and the ProMAS questionnaire provided complementary insights into medication adherence. From a patient perspective, this multi-method approach was feasible for a two-month period post-discharge. However, patients considered pill counts to be the most accurate measure of their medication adherence.

Finally, a pre-post intervention study was prepared to evaluate the effectiveness of SelfMED in improving medication adherence two months post-discharge. Several challenges already emerged during the setup, including the absence of a clear legal framework for in-hospital medication self-management, restrictions on the use of patients' own medication during hospitalisation, and the lack of digitalised intervention components. Addressing these issues will be crucial to fully support the potential of in-hospital medication self-management and to enable large-scale evaluation of its impact.

Samenvatting

Tijdens een ziekenhuisopname beheren zorgverleners doorgaans de medicatie voor patiënten. Nochtans worden patiënten vaak verwacht de medicatie zelf te beheren na ontslag. Een ziekenhuisopname verstoort de continuïteit van medicatie management en verhoogt het risico op medicatie-gerelateerde problemen thuis, wat de medicatieveiligheid in gevaar brengt. Om dit probleem aan te pakken, is een patiëntgerichte benadering nodig die patiënten in staat stelt om medicatie zelfmanagement te oefenen tijdens hun ziekenhuisverblijf. Programma's voor medicatie zelfmanagement in het ziekenhuis tonen veelbelovende resultaten bij het verbeteren van veilig en effectief medicatiegebruik door het verminderen van medicatiefouten, het vergroten van medicatiekennis en het verhogen van therapietrouw.

Om medicatie zelfmanagement door patiënten tijdens ziekenhuisopname in België te faciliteren, werd de SelfMED-interventie ontwikkeld. Deze interventie omvat een procedure die het proces van medicatie zelfmanagement en de bijbehorende verantwoordelijkheden beschrijft, evenals tools voor assessment en monitoring omvat. Dit proefschrift had echter tot doel de SelfMED-interventie te versterken door ondersteunende tools en strategieën voor zowel zorgverleners als patiënten te ontwikkelen en evalueren, evenals de evaluatie van de effectiviteit van de interventie voor te bereiden door het beoordelen van meetmethoden voor therapietrouw en het opstellen van een interventie protocol.

Het eerste deel van dit proefschrift had tot doel om de uitdagingen te identificeren die patiënten met polyfarmacie ervaren bij het beheer van hun medicatie na ontslag uit het ziekenhuis, samen met hun percepties over medicatiegebruik en de beïnvloedende factoren. Dit diende als basis voor het ontwikkelen van op maat gemaakte tools en strategieën ter ondersteuning van patiënten bij hun medicatiebeheer. De bevindingen toonden aan dat de helft van de patiënten met polyfarmacie zich tijdens hun ziekenhuisverblijf onvoldoende voorbereid voelde op medicatie zelfmanagement thuis, waarbij 90% minstens één probleem ondervond na ontslag. Deze problemen omvatten therapietrouw, kennis-gerelateerde tekortkomingen, moeilijkheden bij het innemen van medicatie en uitdagingen bij het

verkrijgen van medicatie. Patiënten waarbij het medicatiebeheer tijdens ziekenhuisopname volledig door verpleegkundigen werd overgenomen en patiënten die een groter aantal geneesmiddelen gebruikten, liepen een groter risico op het ervaren van problemen met medicatiebeheer na ontslag.

Het verkennen van de overtuigingen over medicatiegebruik bij patiënten na ontslag toonde aan dat, hoewel er zorgen bestonden over nadelige effecten, patiënten over het algemeen een sterk geloof hadden in de noodzaak van hun voorgeschreven medicatie. Voor meer dan 90% van de patiënten woog het waargenomen voordeel van voorgeschreven medicatie zwaarder dan de mogelijke nadelen. Noch patiëntkenmerken, noch factoren met betrekking tot het ontslagbeheer leken de overtuigingen over medicatie na ontslag significant te beïnvloeden.

Het tweede deel van dit proefschrift richtte zich op het verfijnen van SelfMED door de assessment component te herzien en ondersteunende hulpmiddelen en strategieën voor zorgverleners en patiënten te ontwikkelen. De relatie tussen medicatiegeletterdheid (MED-fLAG) en de mate waarin patiënten in staat werden geacht voor medicatie zelfmanagement (SelfMED-beoordeling), de factoren die de sterkte van deze relatie beïnvloeden en de factoren die de mate waarin patiënten in staat worden geacht voor medicatie zelfmanagement beïnvloeden, werden onderzocht. De bevindingen lieten een sterke positieve relatie zien, wat aangeeft dat hoe meer medicatiegeletterdheidvaardigheden een patiënt heeft, hoe hoger de waargenomen capaciteiten voor medicatie zelfmanagement. Onze studie kon geen factoren onthullen die de sterkte van de relatie significant beïnvloedden. Leeftijd, het zelfstandig beheren van medicatie thuis, het aantal chronische aandoeningen en medicatiegeletterdheid waren significante voorspellers van de mate waarin een patiënt in staat werd geacht voor medicatie zelfmanagement tijdens ziekenhuisopname. De studie bevestigde dat SelfMED een geschikt screeningsinstrument is voor het beoordelen van de geschiktheid van patiënten om medicatie zelfmanagement in het ziekenhuis uit te voeren, zonder dat een aparte beoordeling van medicatiegeletterdheid nodig is.

Om zorgverleners te ondersteunen, werd een uitgebreide set aanbevelingen ontwikkeld om patiënten met medicatie zelfmanagementproblemen te begeleiden.

Op basis van mapping werden 20 verschillende medicatie zelfmanagement problemen geïdentificeerd. Vervolgens werd op basis van een scoping review (een literatuuronderzoek) een lijst van mogelijke acties en interventies gegenereerd, die werden omgezet in aanbevelingen. Ten slotte werd via een Delphi-studie met 23 experts consensus bereikt over de relevantie en duidelijkheid van 67 aanbevelingen ter ondersteuning van medicatie zelfmanagement. Een pilootstudie toonde aan dat de aanbevelingen haalbaar, gebruiksvriendelijk en nuttig waren bij het ondersteunen van patiënten met medicatie-gerelateerde problemen, hoewel hun toepassing tijdrovend bleek. Verpleegkundigen gaven aan in 52% van de medicatie zelfmanagementproblemen ondersteuning te hebben geboden met behulp van de set aanbevelingen, waarbij kennis-gerelateerde problemen het vaakst werden aangepakt.

Daarnaast werden interviews uitgevoerd om de ervaringen en rolpercepties van verpleegkundigen en patiënten met betrekking tot medicatie-gerelateerde gedeelde besluitvorming (GBV) tijdens de ziekenhuisopname te verkennen. De resultaten toonden een beperkte toepassing van GBV in de klinische praktijk, met barrières zoals de gezondheidstoestand van patiënten, medicatie-gerelateerde kennis, de therapeutische relatie tussen verpleegkundige en patiënt, tijdsdruk en werkbelasting. Desondanks waardeerden patiënten de bijdragen van verpleegkundigen aan GBV, aangezien zij hen beschouwden als sleutelfiguren dankzij hun belangenbehartiging, informerende, faciliterende en ondersteunende rollen. De wens van patiënten om betrokken te zijn bij medicatie-gerelateerde beslissingen bleek afhankelijk van zowel individuele als contextuele factoren. GBV werd echter voornamelijk gezien in de context van het voorschrijven van geneesmiddelen en het omgaan met bijwerkingen.

Om patiënten te ondersteunen bij het rapporteren en communiceren van medicatie-gerelateerde problemen met zorgverleners na ontslag, werd een medicatiedagboek ontwikkeld en geëvalueerd. Het dagboek bestond uit vijf onderdelen: (1) een medicatieschema waarin patiënten hun geneesmiddelen kunnen noteren, (2) informatiefiches voor het registreren van belangrijke medicatie-gerelateerde informatie, (3) een maandoverzicht om aan te geven of medicatie-gerelateerde

problemen werden ervaren, (4) probleemfiches om problemen verder te specificeren en (5) ruimte voor het noteren van vragen over medicatie aan zorgverleners. Een piloottest liet zien dat 40% van de patiënten binnen twee maanden na ontslag medicatie-gerelateerde problemen rapporteerde. De meeste patiënten vonden het dagboek gebruiksvriendelijk en eenvoudig in te vullen, en de helft gaf aan dat het dagboek kan helpen bij het faciliteren van gesprekken met zorgverleners over medicatie-gerelateerde problemen.

Het laatste deel van dit proefschrift richtte zich op het voorbereiden van de evaluatie van de effectiviteit van de SelfMED-interventie op therapietrouw na ontslag. Therapietrouw wordt beschouwd als de primaire uitkomst omdat problemen met medicatie zelfmanagement nauw verband houden met therapietrouw. Eerst werd de bereidheid van patiënten om hun therapietrouw te laten monitoren met behulp van een multi-methode benadering onderzocht, gevolgd door een evaluatie van de haalbaarheid en validiteit vanuit het perspectief van de patiënt. De resultaten toonden aan dat hoewel patiënten bereid waren om informatie over hun therapietrouw te delen, slechts 59% hun therapietrouw gedurende twee maanden actief liet monitoren. Een combinatie van pillentellingen, een medicatiedagboek en de ProMAS-vragenlijst bood complementaire inzichten in de therapietrouw van de patiënt. Vanuit het perspectief van de patiënt was deze multi-methode benadering haalbaar voor een periode van twee maanden na ontslag. Patiënten beschouwden echter pillentellingen als de meest accurate maat voor hun therapietrouw.

Tot slot werd een pre-post interventiestudie voorbereid om de effectiviteit van SelfMED bij het verbeteren van therapietrouw twee maanden na ontslag te evalueren. Tijdens het opzetten van deze studie kwamen echter verschillende uitdagingen naar voren, waaronder het ontbreken van een duidelijk wettelijk kader voor medicatie zelfmanagement in het ziekenhuis, beperkingen op het doorgebruik van eigen medicatie door patiënten tijdens opname, en het ontbreken van digitale interventiecomponenten. Het aanpakken van deze knelpunten zal cruciaal zijn om het volledige potentieel van SelfMED te ondersteunen en een grootschalige evaluatie van de impact mogelijk te maken.

Appendices

Appendix 3.1

Table: EQF levels.

European Qualification Framework (EQF)	
EQF level 1	Elementary or primary education
EQF level 2	Lower secondary education (i.e., junior high school)
EQF level 3	Upper secondary vocational education (i.e., senior high school)
EQF level 4	Upper secondary education (i.e., senior high school)
EQF level 5	Associate's degree
EQF level 6	Bachelor's degree
EQF level 7	Master's degree
EQF level 8	Doctorate

Appendix 4.1

Table: Mean item scores categorised by medication literacy domain.

	Description of each item	Mean [SD]*
Interactive medication literacy (IML)	Providing information about known allergies or poorly tolerated drugs (IML 30)	3.3 [0.99]
	Asking health professionals for additional information about your medicines (IML 23)	3.3 [0.86]
	Discussing any difficulties in following the medication plan or following instructions (IML 31)	3.2 [0.90]
	Reporting about mistakes, omissions or other problems with medication (IML 32)	3.2 [0.93]
	Telling a health professional if you have stopped or changes the dosage of a medicine (IML 33)	3.2 [0.95]
	Expressing your expectations; giving you opinion about medicines (IML 27)	3.1 [0.97]
	Asking health professionals for advice about natural remedies (IML 24)	3.1 [1.00]
	Understanding information about medicines given by health professionals (IML 25)	3.0 [1.05]
	Seeking professional advice about information about medicines obtained from the media, social networks, ... (IML 35)	3.0 [1.08]
	Talking about conflicting information you have received about your medicines (IML 34)	2.9 [1.09]
	Describing the latest changes that have been made in the list of medicines (IML 26)	2.8 [1.15]
	Providing information about the effects observed or experienced (IML 29)	2.6 [0.99]
	Expressing your interest in natural remedies (IML 28)	2.6 [1.09]
	Across all items of the functional domain	3.0 [0.79]
Functional medication literacy (FML)	Telling how/where to store medicines (FML 5)	3.3 [0.99]
	Telling which medicine should be taken before, during or after a meal (FML 11)	3.2 [0.98]
	Telling the schedule (hours) for taking each medicine (FML 12)	3.2 [0.98]
	Telling whether any of your medicines require special precautions (FML 22)	3.2 [1.09]
	Telling which medicines are pills, drops, inhalations,... (FML 4)	3.1 [1.00]
	Saying how long each medicine should be taken (FML 14)	3.1 [1.06]
	Telling whether certain foods or drinks should be avoided (FML 21)	3.1 [1.06]
	Saying whether the list of current medicines included PRN medicines (FML 10)	3.1 [1.09]
	Saying how many times a day each medicine should be taken (FML 13)	3.1 [1.08]
	Counting how many medicines need to be prepared to cover several days of treatment (FML 17)	3.1 [1.06]
	Preparing the correct dosage of medicines (FML 16)	3.1 [1.03]
	Describing medicines by their appearance (colour and shape) (FML 3)	3.1 [1.01]
	Telling whether any of the medicines may have effects that require monitoring (FML 19)	3.0 [1.08]
	Explaining what effect each medicines is expected to have (FML 8)	3.0 [1.04]
	Explaining why medicines has been prescribed (FML 7)	3.0 [1.07]
	Describing the problems that might occur if the medicines are not taken/taken differently than instructed (FML 9)	2.8 [0.98]
	Giving the names of the various prescribers of the medicines you manage (FML 6)	2.6 [1.08]
	Listing the names of natural remedies you manage (FML 2)	2.6 [1.01]
	Listing the names of medicines you manage (FML 1)	2.5 [1.04]
	Telling whether certain medicines are incompatible with the medicine you are managing (FML 20)	2.3 [1.09]
	Telling the dosage of each medicine by heart (FML 15)	2.2 [1.15]
	Listing the main side effects of medicines (FML 18)	2.2 [1.05]
	Across all items of the functional domain	2.9 [0.76]

Critical medication literacy (CML)	Setting up daily routines to avoid forgetting to take medicines (CML 49)	3.3 [0.93]
	Going to the same pharmacy to get medicines (CML 48)	3.3 [0.99]
	Organising stock of medicines and knowing when to go to the pharmacy to get a refill or to get new medicines (CML 51)	3.3 [0.87]
	Adapting daily routines after the list of medicines has changed (CML 52)	3.2 [0.92]
	Knowing which healthcare professional to contact in case of problems with medicines (CML 56)	3.2 [0.95]
	Getting answers to questions about medicines, obtaining advice (CML 53)	3.2 [0.96]
	Knowing when to schedule a prescription renewal (CML 50)	3.2 [1.03]
	Getting help from health professionals in case of problems with medicines (CML 55)	3.1 [0.92]
	Getting help from you family in case of difficulties with medicines (CML 54)	3.1 [1.03]
	Writing down questions about medicines for health professionals (CML 46)	2.8 [1.08]
	Carrying a list of the medicines you manage (CML 41)	2.8 [1.20]
	Reading patient leaflets about medicines (CML 37)	2.8 [1.04]
	Using a routine, some tricks that allow to check that the medicines have not been forgotten (CML 43)	2.7 [1.18]
	Reading the package leaflet (CML 36)	2.6 [1.09]
	Questioning the reliability of information about medicines obtained from the media, social networks,... (CML 40)	2.6 [0.98]
	Taking some medicines with you when you leave home (CML 45)	2.6 [1.15]
	Using a treatment plan that describes the medicines that need to be taken (CML 42)	2.6 [1.17]
	Keeping a record of the decisions that have been made about medicines (CML 47)	2.5 [1.17]
	Seeking advice from a health professional before taking any over-the-counter medicines (CML 38)	2.4 [1.01]
	Using a pillbox (CML 44)	2.3 [1.23]
	Seeking information when a new medicines has been prescribed (CML 39)	2.2 [1.18]
	Across all items of the critical domain	2.8 [0.68]
* Mean score of each item on a four-point Likert scale (1= very difficult/never; 4 = not difficult at all/always). The higher the score, the more medication literacy skills.		

Appendix 5.1

Table: Search terms.

Concept	Search Term
Polypharmacy/ medication	'polypharmacy (MeSH)', 'polypharmacy', 'polymedication', 'multiple drug therapy', 'multidrug therapy', 'multidrug regimen', 'multiple medication', 'multiple drug*', 'medication', 'medicine*', 'drug'
Self-management	'self manag*', 'self-management', 'self-management (MeSH)', 'self-management support'
Filling a prescription	'obtain', 'purchase', 'access*', 'prescription'
Knowledge and understanding of medication	'medication knowledge', 'drug knowledge', Patient Medication Knowledge (MeSH), 'Patient drug knowledge', 'knowledge', 'comprehension', comprehension (MeSH), 'dosage', 'dose', 'administration route', 'indication', 'readability', 'comprehension', 'labels', 'information', 'instruction',
Medication intake	'dysphagia', 'presbyphagia', 'swallowing problems', 'swallowing difficulties', 'swallowing disorder', deglutition disorders (MeSH)
Monitoring therapeutic and adverse effects	'adverse effect*', Drug-related side effects and adverse effects (MeSH), 'therapeutic effect', 'precaution', 'side effect', 'contraindication*', 'contra-indication*', contraindications (MeSH), 'interaction', Drug Interactions (MeSH), 'warning*', 'monitoring'
Sustaining appropriate medication use	'persistence', 'medication persistence', 'medication adherence (MeSH)', 'medication adherence', 'drug adherence', 'medication compliance', 'Medication Nonadherence', 'Medication Non-Adherence', 'Medication Non Adherence', 'Medication Noncompliance', 'Medication Non-Compliance', 'Medication Non Compliance'
Population	'patient*', 'client*', 'consumer*', 'adult', adult (MeSH)

Appendix 5.2

Scan the QR code below to access the Excel file with the content of the first e-Delphi round, as was presented to the experts (English translation).

Appendix 5.3

Scan the QR code below to access the survey used in patient panel (English translation).

Appendix 5.4

Scan the QR code below to access the summary of the included records in the scoping review.



Appendix 5.5

Table. Summary of grouped recommendations by phase of medication self-management.

Phase of Medication Self-Management	Number of Recommendations in Each Phase			Percentage of Statements Where Consensus Was Achieved for Both Relevance and Clarity (n) *		
	Round 1	Round 2	Round 3	Round 1	Round 2	Round 3
Picking up the medicines at the pharmacy	7	8	10	0% (0)	25% (2)	80% (8)
Knowledge and understanding of medication	13	12	13	23% (3)	75% (9)	92% (12)
Organizing and planning medication use	13	18	18	54% (7)	94% (17)	100% (18)
Medication intake	22	20	20	55% (12)	90% (18)	95% (19)
Monitoring therapeutic and adverse effects	9	11	11	78% (7)	73% (8)	82% (9)
Sustaining safe and appropriate medication use through the duration of the prescription	2	2	2	0% (0)	100% (2)	100% (2)
Total (across all phases)	66	71	74	44% (29)	79% (56)	92% (68)

* Consensus on relevance and clarity was achieved when ≥80% of the experts assigned a score of 3 (relevant/clear) or 4 (very relevant/very clear) to an item **OR** when ≥80% of the experts assigned a score of 1 (very irrelevant/very unclear) or 2 (irrelevant/unclear) to an item.

Appendix 5.6

Table. Number of changes to recommendations in each round according to type.

	Number of Changes after Round 1					Number of Changes after Round 2					Number of Changes after Round 3							
	Rephrased	Adapted to Context	Combination of Recommendations	Splitting up Recommendations	New Recommendation Added	Removed Due to Overlap	Rephrased	Adapted to Context	Combination of Recommendations	Splitting up Recommendations	New Recommendation Added	Removed Due to Consensus on Irrelevance	Rephrased	Adapted to Context	Combination of Recommendations	Splitting up Recommendations	New Recommendation Added	Removed *
Phase of Medication Self-Management																		
Picking up the medicines at the pharmacy	5	2	4	-	3	-	3	1	-	2	-	-	1	-	-	-	-	2
Knowledge and understanding of medication	6	1	6	-	3	-	4	1	-	1	-	-	-	-	-	-	-	1
Organizing and planning medication use	6	-	-	-	4	-	3	-	-	-	-	-	-	-	-	-	-	1
Medication intake	6	-	1	-	1	2	1	-	-	-	-	1	-	-	-	-	-	1
Monitoring therapeutic and adverse effects	2	-	-	-	2	-	3	-	-	-	-	-	-	-	-	-	-	2
Sustaining safe and appropriate medication use through the duration of the prescription	1	-	2	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Total (across all phases)	26	3	13	-	14	2	14	2	-	3	-	1	1	-	-	-	-	7

* In the phase of medication intake, one recommendation was removed since there was consensus on irrelevancy. The recommendations in the other domains were removed due to a lack of consensus after the third e-Delphi round.

Appendix 5.7

Scan the QR code to access the full guidance document with recommendations and references (English translation).

The 67 recommendations included are listed below.

Recommendations based on practical clinical experience are indicated with the letters ExpB (experience-based).



1. Picking up the prescribed medication at the pharmacy

1.1. The patient might be experiencing financial problems

- 1.1.1. If there is a suspicion or indication of financial problems, or if there are opportunities to reduce the cost of drugs, ask about the extent to which patients are interested in recommendations on the financial aspect of their drugs and how to address any financial difficulties in purchasing drugs (**ExpB**).
 - If the patient is not interested in recommendations on the financial aspect of medication, no further action should be taken.
 - If the patient is interested, see the following recommendations.

- 1.1.2. **Belgium:** Inform the patient that prescription drugs are subject to co-payment (i.e. a patient pays a personal share). Refer the patient to the hospital's social services department, family pharmacist or mutual insurance company for guidance and advice on reimbursement schemes, increased allowances or supplementary insurance options under which the co-payments required of the patient are reduced (**ExpB**). Information on the reimbursement of drugs is available on the website of the National Institute for Health and Disability Insurance (RIZIV) (in Dutch or French only), or on the website of the Belgian Centre for Pharmacotherapeutic Information (BCFI) (in Dutch or French only).

Netherlands: Inform the patient that the vast majority of prescription drugs are reimbursed under the basic health insurance. The preference policy of health insurers means that, in general, no additional payment is required of patients. In this preference policy, a health insurer designates a preferred drug within a group of similar drugs (i.e. drugs with the same active ingredient) to be reimbursed. In the Netherlands, the patient is subject to a required deductible. More specifically, patients are required to pay at least the first €385 (2022) of drug and/or hospital costs themselves. Only after this deductible has been paid are the costs covered by the basic health insurance. If necessary, refer the patient to the health insurer for counselling and advice on reimbursement schemes, increased allowances or supplementary insurance options (**ExpB**). Information on drug reimbursements is available at:

- The website of the national government
- The website 'medicijnkosten.nl' (in Dutch only). On this website, one can check whether a drug is included in the basic health insurance package; which costs count towards the patient's deductible; what the patient's co-

payment will be (if any); and whether there is a less expensive medicine for which the patient will be reimbursed in full.

- 1.1.3. **Belgium:** Determine whether the patient is taking the least expensive variant of drugs from the point of view of the patient's personal contribution.⁷⁴
- The RIZIV's online search engine 'Least expensive drugs' (in Dutch or French only) can be used to identify the specialities belonging to the group of 'least expensive' drugs for each substance name.^{75,76}
 - In the application or on the website of the Belgian Centre for Pharmacotherapeutic Information (BCFI; in Dutch or French only), the 'least expensive drugs' in the directory are indicated by the symbol .⁷⁶

1.2. The patient has an excessive, insufficient or no supply of medication

Patients may not have the required medication at home due to lack of repeat prescriptions, or they may be having trouble in picking up drugs from the pharmacy.⁵ It is also possible for patients to have double medication at home after hospitalisation (i.e. they have medication from before hospitalisation and medication given by the hospital). Patients unnecessarily use both drugs at the same time, as they do not know they are equivalent drugs, due to differences in the name or appearance of the drugs.

- 1.2.1. **Belgium:** Upon discharge, provide a supply of medication for up to three days to bridge the period between hospital discharge and a visit to the community pharmacy.^{78,79}
- Inform the patient about the number of days for which the medication was supplied.^{78,79}
 - Advise the patient not to take medication left at home during this period to avoid double intake (**ExpB**).
 - In some cases, a different brand of medicine is used in hospital than at home. If applicable, indicate the home medication to which the hospital's formulary product corresponds.⁷⁸
 - Inform the patient about which drugs were already administered on the day of discharge to avoid double intake.⁷⁸
 - Ensure that necessary prescriptions were sent electronically upon discharge, especially in the case of newly started drugs (**ExpB**).

Note:

- *If an outpatient pharmacy is present in the hospital, patients can immediately pick up their discharge medication there and, in principle, no medication supply needs to be given.*
- *This recommendation does not apply in case of continued use of home medication during hospitalisation or in case of delivery of home medication during admission at the start of new medicines.*

Netherlands: Advise the patient to pick up discharge medication at the hospital's outpatient pharmacy or their own community pharmacy.

- Inform the patient about which drugs were already administered on the day of discharge to avoid double intake.
- Ensure that necessary prescriptions were sent electronically upon discharge, especially in the case of newly started drugs (**ExpB**).

Note: This recommendation does not apply in case of continued use of home medication during hospitalisation and in case of delivery of home medication during admission at the start of new medicines.

- 1.2.2. Advise patients to keep track of when repeat medication or repeat prescriptions are needed by using a calendar, a diary or an app with reminders.⁸⁰ Advise the patient to contact the physician by telephone or schedule a consultation in a timely manner in the absence of the necessary prescriptions. The physician can then send an electronic prescription in the patient's name that the patient can pick up at the pharmacy (**ExpB**).

Community pharmacies in the Netherlands provide an automatic repeat service, whereby the pharmacy periodically dispenses repeat medication in case of chronic drugs. Upon discharge, the hospital should inform the community pharmacy about medication so that repeat service can be coordinated accordingly (**ExpB**).

- 1.2.3. Estimate the patient's ability to obtain drugs by asking how and where the patient obtains new prescriptions and/or drugs.⁸¹ If the patient is having trouble in obtaining or picking up drugs, options such as arranging home delivery of drugs by the pharmacy or organising assistance in picking up drugs by an informal carer or family help should be considered in consultation with the patient and arranged, if desired.⁸¹

2. Knowledge and understanding of medication

2.1. The patient lacks knowledge of the medicines: name, indication, dosage, time of administration, method of administration

- 2.1.1. During hospitalisation, evaluate what patients already know regarding their medication.^{74,78}
- Ask the patient to name the following elements for each medicine: name of the medicine, why the medicine should be taken (indication), method of administration, quantity, dosage and dosing interval.
 - Most importantly, the patient should know the drug's indication. The other elements should be stated on the medication schedule (see Section 2.1.2), which the patient should understand.
 - If a patient does not have sufficient knowledge about a particular drug, specific information about that drug can be provided. For elderly people with cognitive problems, it is advisable to involve an informal carer in providing drug-related information.
- 2.1.2. Provide the patient with an up-to-date medication schedule upon discharge, and include the following information for all current medicines.^{78,79,82,83}
- Name, including dosage, dosage unit and formulation
 - Indication
 - Dosage frequency (per day, per week, per month)
 - Time of administration (+ state whether it should be taken with food or on an empty stomach)
 - Amount + unit per administration
 - Route of administration

- State the ending date for medicines with a fixed duration (e.g. pain medication)

Use the medication schedule as a guide when informing patients about their drugs. This schedule should be clear and include only terms that the patient understands. Explain to the patient how to apply the schedule.^{78,83}

Explain all medication changes that occurred during the hospital stay (what was stopped, started or changed) and the underlying reasoning.^{78,79,82}

- In consultation with the physician, draft a pharmaceutical discharge letter and/or, if possible, use colours to provide a visual indication of what is new and what has changed on the medication schedule.⁷⁸ A 'new' drug is hereby defined as any drug that the patient was not using at the time of admission or any drug that the patient was using at the time of admission but whose formulation, dosage, frequency or route of administration has changed.⁷⁹
- Note all discontinued drugs:^{78,79,82} do not summarise them in the actual medication schedule, but separately in order to avoid confusion.

Discuss the items below for all newly started drugs and for all drugs for which additional information is indicated (e.g. high-risk medication, drugs that were involved in the reason for admission):⁷⁸

- Provide information on the indication (why a drug should be taken).⁷⁸
- Provide information on dosage and dosing interval (per day, per week), along with quantity and unit per administration, time of administration, and route of administration.⁷⁸

Note: The guideline entitled Overdracht van medicatiegegevens in de keten [Transfer of medication data in the chain; in Dutch] define the medication data that must be included in the schedule, including medication that has been changed or discontinued.

- 2.1.3. Verify whether the patient has understood the medication schedule and/or drug-related information, and whether the patient considers them clear and complete.^{86,90}
- Use the 'teach-back' method:^{74,78,85-87} ask patients to repeat in their own words what has been explained to them about their medication (and medication schedule).
 - If necessary, ask the patient to answer a specific question using the medication schedule (e.g. 'When should you take Drug X?'). This will make it possible to detect any problems related to reading and interpreting the schedule.
 - Determine whether any information is missing according to the patient.
 - Determine whether the patient has additional questions and/or whether there is anything that needs to be repeated or explained again.
- 2.1.4. Efforts should be made to implement an operational electronic health platform on which at least an up-to-date medication schedule can be accessed by all healthcare providers, both inside and outside the hospital. In the meantime, it is advised to send a medication schedule home with the patient/informal carer upon discharge. Explain that this medication schedule should be shown to all healthcare providers

who need to be informed about it (e.g. GP, family pharmacist, home nurse), and encourage the patient/informal carer to have an up-to-date medication schedule with them whenever contacting a healthcare provider. If a healthcare provider makes any changes to the medication schedule, the healthcare provider should provide the patient with an adjusted, updated schedule (**ExpB**).

- 2.1.5. Inform the patient of the right to select a 'family pharmacist'. This means that the patient can designate a community pharmacist as a reference pharmacy. The main task of a family pharmacist is to guide and continuously monitor the patient's medicinal treatment. Other tasks of the family pharmacist can include keeping the medication schedule up to date and making it accessible to other healthcare providers with whom the patient has a therapeutic relationship. Advise the patient to discuss this with the community pharmacist.⁸⁸

2.2. The patient is having trouble understanding information and/or instructions concerning the medication

- 2.2.1. Determine the most effective way to communicate with each patient and, if necessary, consider ways to make information more accessible and understandable.^{74,85}
- Adapt the mode of communication to the needs of the patient: ask what the patient needs.
 - Determine whether the patient can read before providing drug instructions in writing.
 - If possible, combine written and oral drug instructions with visual elements (e.g. pictograms or images,⁸⁹⁻⁹² or audio or video materials.^{74,85,92} Pictograms can be printed from 'bijsluiterinbeeld.nl'. The KIJKsluiter Foundation provides information through animated videos and icons (<https://www.kijksluiter.nl/>).
 - If possible, provide instructions or instructional videos in the patient's native language, and use an interpreter if possible.^{74,85} Apotheek.nl provides instructional videos on the proper use of drugs in Dutch, English, Turkish, and Arabic (<https://www.apotheek.nl/videos>).
 - For elderly people with cognitive problems, an informal carer should be involved in providing drug-related information.
- 2.2.2. Drug instructions should be brief, clear and specific. Avoid medical jargon (e.g. 'subcutaneous', 'inhalation') and complex words (e.g. 'prolonged exposure to the sun', 'tablets'), replacing them instead with simpler words (e.g. 'under the skin', 'inhalation', 'short time in the sun', 'pills').^{93,94}
- 2.2.3. For written drug instructions, use large print, bullet points or a list format.⁸¹
- 2.2.4. Link medication use to specific time periods during the day to clarify the dosing interval.^{89,91,93,94} The indication of time periods (morning, afternoon, evening, bedtime) is usually contained in the medication schedule. If necessary, the time periods can be specified in greater detail for the patient (e.g. on waking, before breakfast, before lunch, with lunch, before dinner, before bed).

- 2.2.5. Do not make any assumptions about a patient's ability to understand the information provided, but ask for feedback. Verify whether the patient has understood the drug-related information and instructions, and whether the patient considers them clear and complete.^{86,90}
- Use the 'teach-back' method.^{74,78,85-87}
 - Ask patients to repeat in their own words what has been explained to them about their drugs.
 - Ask patients to demonstrate any new self-care tasks that they will have to perform at home (e.g. using an inhaler, administering a subcutaneous injection, preparing medicines according to the medicine schedule).
 - Determine whether any information is missing according to the patient.
 - Determine whether the patient has additional questions and/or whether there is anything that needs to be repeated or explained again.
 - Encourage patients to ask questions by asking: 'What questions do you have?'
 - Ask whether the patient would like to receive additional written information (e.g. brochures, if available).
- 2.2.6. Indicate where patients can find reliable information and support after hospitalisation. For example, send written information home with them or refer them to other sources of information (e.g. GP, pharmacist, drug package leaflets, websites such as apotheek.nl).^{74,78}

3. Practical organisation and scheduling of medication intake

3.1. The patient is having trouble preparing the medication (or drug intake)

Preparation includes such tasks as opening drug containers, breaking or splitting drugs in half, filling a medication box and using tools to administer eye drops.

- 3.1.1. In consultation with the patient, discuss whether assistance from an informal carer or home-care nurse is needed to prepare and set out drugs for a certain period of time. Arrange such help for the patient, if necessary (**ExpB**).

Recommendations 3.1.2 to 3.1.6 are applicable only if the preparation, setting out and taking of drugs are performed by the patient.

- 3.1.2. Ask patients whether they are having trouble opening drug packaging. In case of problems with opening the packaging, ask the pharmacist whether the medication is also available in another form of packaging that is easier to open.⁸⁰
- 3.1.3. Advise the patient to use tools to open various types of containers (e.g. pill pusher, ampoule opener, pill pen). These tools are usually available from the pharmacist (including the family pharmacist).^{80,95,96}

Note: Pill pushers should not be used for all medication. The pharmacist (or family pharmacist) can provide additional information about the application of such tools.

- 3.1.4. Consult with the pharmacist about tablets that are easier to break (if breaking tablets is allowed) or tablets with the correct dosage so that breaking is not necessary.⁸¹

- 3.1.5. Advise the patient to use a tablet or pill splitter to halve or further divide the drugs into the appropriate and measured size (only if drug division is allowed). This tool is usually available from the pharmacist.^{80,95,96}
- 3.1.6. Advise the patient to use eye-drop tools if the patient has trouble:
- Aiming/positioning the vial;
 - Grasping the vial (not enough grip);
 - Holding the hand with the drops still;
 - Squeezing the vial (not enough strength);
 - Keeping the eye open and not blinking;
 - Pressing the tear duct shut after administering the eye drops.
- Tools are usually available from the pharmacist.⁸⁰

3.2. The patient is having trouble reading labels, package leaflets, information, instructions

- 3.2.1. Determine whether the patient uses/needs glasses (**ExpB**).
- 3.2.2. Refer the patient to instructional videos on drugs if reading drug-related information is difficult. Apotheek.nl provides short videos (in Dutch) with explanations by pharmacists for many drugs (<https://www.apotheek.nl/videos/medicijnen?>). KIJKsluiter provides animated videos in which the most important information from the package leaflet is explained in comprehensible language (<https://www.kijksluiter.nl>). (**ExpB**)
- 3.2.3. For documents to be drafted or document types that may be changed, the following principles can be used to improve legibility:
- Use sans serif fonts (e.g. Century Schoolbook or Helvetica).⁹¹
 - Use a minimum font size of 12.^{91,92,97}
 - Structure instructions or information.^{91,92,98}
 - Use boldface to emphasise important information.
 - Use summary lists instead of full paragraphs of text.
 - Use headings.
 - Provide adequate white space.
 - Use visual elements (e.g. pictograms and symbols). A package leaflet containing pictograms for each drug can be created through bijsluiterinbeeld.nl.
- 3.2.4. In case of illegible information on packaging: if possible, affix a sticker to each drug package stating the most important usage information (name, dosage, instructions for use) in a more readable font and size (**ExpB**).

3.3. The patient is having trouble establishing a daily routine

- 3.3.1. Discuss with the prescriber(s)/pharmacist whether the medication regimen can be simplified,^{86,99} while trying to limit the number of intake times per day.⁸⁶
- 3.3.2. Advise the patient to link taking medication, if possible, to fixed, recurring times in the day (e.g. before a meal, before brushing teeth or at bedtime).¹⁰⁰

- 3.3.3. Inform patients about the possibility of setting medication out in places that remind them of intake, thereby linking intake to a habit or fixed routine of the patient. For example, medication on the bedside table is medication at bedtime; medication on the breakfast table is medication to be taken in the morning, and so forth. (**ExpB**)
- 3.3.4. In consultation with the patient, review the use of tools that can help with taking drugs in a timely manner/establishing a daily routine. However, evaluate the suitability of the tools for each patient individually.
- Pill box for setting drugs out by day and by time of intake (morning, afternoon, evening): various shapes and formats are possible, with and without an alarm function.^{95,96}
 - Pill timers, watches or alarms: a signal reminds the patient that it is time to take the medicines.^{95,96}
 - Digital applications for medicine usage: patients can maintain an overview of when which drugs should be taken. Most applications give a reminder at the time when the drugs should be taken.⁹⁶
 - Medication role: for ‘drugs on a roll’, tablets are packed in transparent pouches for each client by administration time. Each pouch includes a description of which medication it contains. The pouches are delivered sealed together in the form of a medication roll for each client.⁸⁰

3.4. The patient is having trouble storing the medicines properly

- 3.4.1. Inform the patient about the *conditions* under which the drugs should be stored to maintain their effectiveness (e.g. storage in the refrigerator, in a dark environment, a moisture-free environment). Storage instructions are stated on the packaging and/or package leaflet for each drug. In addition, inform the patient that the drugs should be kept in the original packaging (the packaging supplied by the pharmacy) and with the package leaflet attached.¹⁰¹

Note:

- *When using a medication box in which medicines are set out for one week, the medicines for that week can be removed from the original packaging and stored in the medication box. The remaining medicines should be kept in the original packaging until the medication box is refilled.*
- *For ‘drugs on a roll’, the drugs should be stored in the sachets supplied by the pharmacy.*

- 3.4.2. Inform the patient about drugs with limited shelf life (e.g. eye drops or magistral preparations).¹⁰¹ Advise patient to write the expiry date on the packaging upon opening it.⁸⁰
- 3.4.3. Advise patients to check at regular intervals the expiry dates of the drugs they have at home (or have them checked) and to return expired drugs or unused drugs without the packaging and leaflet to the pharmacist.¹⁰¹

4. Medication intake

4.1. The patient has swallowing problems

- 4.1.1. Advise the patient to swallow with the chin on the chest (chin-tuck technique).^{80,102-104} An instructional video is available at:
<https://www.apotheek.nl/instructies/slikken-van-medicijnen/alternatieve-methode>.
- 4.1.2. Determine whether more suitable oral administration forms are available (e.g. liquid form, effervescent tablets, powder).^{105,106} Consult the pharmacist, Oralia VTGM of KNMP (NL) or the medication-crushing sheets (BE).¹⁰⁶
- 4.1.3. If necessary, adjust the medication administration route in consultation with the prescriber, pharmacist and patient.¹⁰⁵
- 4.1.4. Dividing, pulverising or dissolving drugs in water can be useful for facilitating intake. However, always check carefully whether the medicine is suitable for being divided, pulverised or dissolved in water.¹⁰⁶ Consult the pharmacist, Oralia VTGM of KNMP (NL) or the medication-crushing sheets (BE) before issuing this recommendation to the patient.
- 4.1.5. If swallowing medicines using water is unsuccessful, the use of a swallowing solution (e.g. MediSpend) may be considered or, in consultation with the pharmacist, determine whether the medicine can be taken with food (e.g. yoghurt or apple sauce).¹⁰⁴
- 4.1.6. If necessary, refer patients to a speech therapist with known experience in treating swallowing disorders.¹⁰⁵

4.2. The patient is not using the medicines properly

The patient is taking the medicines at the wrong times

See Section 3.3: The patient is having trouble establishing a daily routine.

The patient is taking incorrect doses (under-dosing or over-dosing, extra doses, forgotten doses)

- 4.2.1. Advise the patient to consult the drug package leaflet and/or a physician or pharmacist if a dose has been forgotten (**ExpB**).
- 4.2.2. Advise the patient never to take a double dose of the medicine to make up for a forgotten dose, unless specifically stated otherwise in the package leaflet or if otherwise advised by the physician/pharmacist (**ExpB**).
- 4.2.3. Advise patients to try to contact the prescriber of the drug in the first instance if they exhibit a reaction to drugs or if too much of a drug has been taken. Patients can also contact the GP, the GP service, the community pharmacist or the emergency department (112). In Belgium, patients can also contact the Belgian Poison Centre for advice in case of drug overdose (070/245.245) (**ExpB**).

The patient is using an improper administration route or technique

- 4.2.4. Indicate the route of administration on the medication schedule.^{78,79,82,83}
- 4.2.5. Avoid professional jargon (e.g. oral, nasal, cutaneous), and use simple language (e.g. by mouth, in the nose, on the skin).^{93,94}
- 4.2.6. If necessary, use pictograms to visualise the route of administration. Pictograms are available through bijsluiterinbeeld.nl (**ExpB**).
- 4.2.7. Provide instructions and advice on correct inhalation technique, nasal spray technique, administration of eye drops, injection technique and so forth.⁷⁸
- 4.2.8. Use the 'teach-back' method: Ask the patient to demonstrate the administration method or technique.^{74,78,85-87}

4.3. The patient does not want to take the medicines

- 4.3.1. Ask patients what they know and understand about their drugs. Ask patient about their beliefs concerning medication, about specific concerns or doubts with regard to drugs.⁷⁴ Engage with the patient to address concerns and reasons for not wanting to take drugs.^{74,81} Valid and reliable instruments are available for asking patients about their beliefs concerning medication (see Appendix B).¹⁰⁷
- 4.3.2. If a patient is not taking the drugs because of beliefs about medication:
 - Use motivating conversational techniques to change negative opinions and beliefs that patients have about the drugs.¹⁰⁸⁻¹¹⁰ Recommendations for conducting a motivating interview are presented in Appendix C.
 - Discuss the advantages of taking medication.⁸¹
- 4.3.3. If a patient is not taking the drugs because of a bad taste, an alternative form or method of administration can be considered in consultation with the pharmacist/prescriber (**ExpB**).
- 4.3.4. If a patient is not taking the drugs because of side effects:
 - In consultation with physician/pharmacist and patient, consider whether the medication regimen can be adjusted to reduce side effects.⁸¹
 - In consultation with physician/pharmacist and patient, review ways to manage side effects.⁸¹

5. Supervision of desired and adverse effects of medication

5.1. The patient lacks knowledge about the desired and adverse effects (side effects and interactions) of the drugs

- 5.1.1. Discuss the advantages and long-term effects of the drugs with the patient.⁷⁴
- 5.1.2. Discuss concerns about the occurrence of adverse effects with the patient and assess the patient's need for information about side effects and interactions of

medication. If desired, provide information about the most frequently occurring interactions and side effects.^{78,99}

- How side effects and interactions can be avoided
- How to recognise side effects
- What to do when side effects occur (see Section 5.2)
- When it is necessary to contact a healthcare provider (see Section 5.2)

Note: Try to coordinate the amount of information to the patient's needs. Do not overload a patient with information on adverse effects if the patient does not need this information. If too much information is provided, there is a risk that the patient will focus on possible adverse effects or not take the drugs. For this reason, limit the information to the most common and relevant adverse effects and alarm symptoms.

- 5.1.3. Indicate where patients can find reliable information on side effects, interactions with food and drink, precautionary (or other) measures (e.g. the drug package leaflet, the pharmacist, the GP) (**ExpB**).

5.2. The patient is having trouble taking appropriate measures when side effects occur

- 5.2.1. Discuss options for dealing with side effects with the patient. Ask patients in what way they would like to deal with side effects if several alternatives were to be available.⁷⁴
- 5.2.2. Some side effects result from the improper use of drugs. Work with the patient to explore whether the drugs are being taken as prescribed (e.g. with food), and review specific instructions for drug intake with the patient (**ExpB**).
- 5.2.3. In case of stomach discomfort, advise the patient to take the drug during or just after meals. However, some drugs should be taken on an empty stomach (e.g. thyroid hormone, bisphosphonates). If in doubt, always consult the package leaflet, physician or pharmacist before giving this advice (**ExpB**).
- 5.2.4. Advise patients to contact the GP or pharmacist in case of hypersensitivity or allergic reactions, such as the occurrence of itching and rash (**ExpB**).
- 5.2.5. Advise patients to contact the GP or pharmacist in case of severe or persistent symptoms that occur after taking medicine (**ExpB**).
- 5.2.6. Inform patients that adjusting the drug regimen or discontinuing drug intake should always be done in consultation with the GP or pharmacist (**ExpB**).

6. Maintaining correct and safe medication intake

6.1. The patient has discontinued taking the medication prematurely

- 6.1.1. Regularly discuss with patients medication adherence, difficulties regarding drug usage and reasons for discontinuing drug intake prematurely.
- In consultation with the patient, consider whether failure to take drugs (or failure to take them correctly) is due to practical problems with drugs or because of perceptual barriers (e.g. certain beliefs and concerns about medication).^{74,111} Depending on the difficulties identified, different recommendations from the guidance document can be applied.
 - Use motivating conversational techniques.^{108,109,111} Recommendations related to conducting a motivating conversation are presented in Appendix C.
- 6.1.2. Encourage patients to report problems regarding drug usage to the prescriber, GP, pharmacist and/or home nurse (**ExpB**).

Appendix 6.1

Scan the QR code to access the patient survey including the patient self-assessment and nurse section.



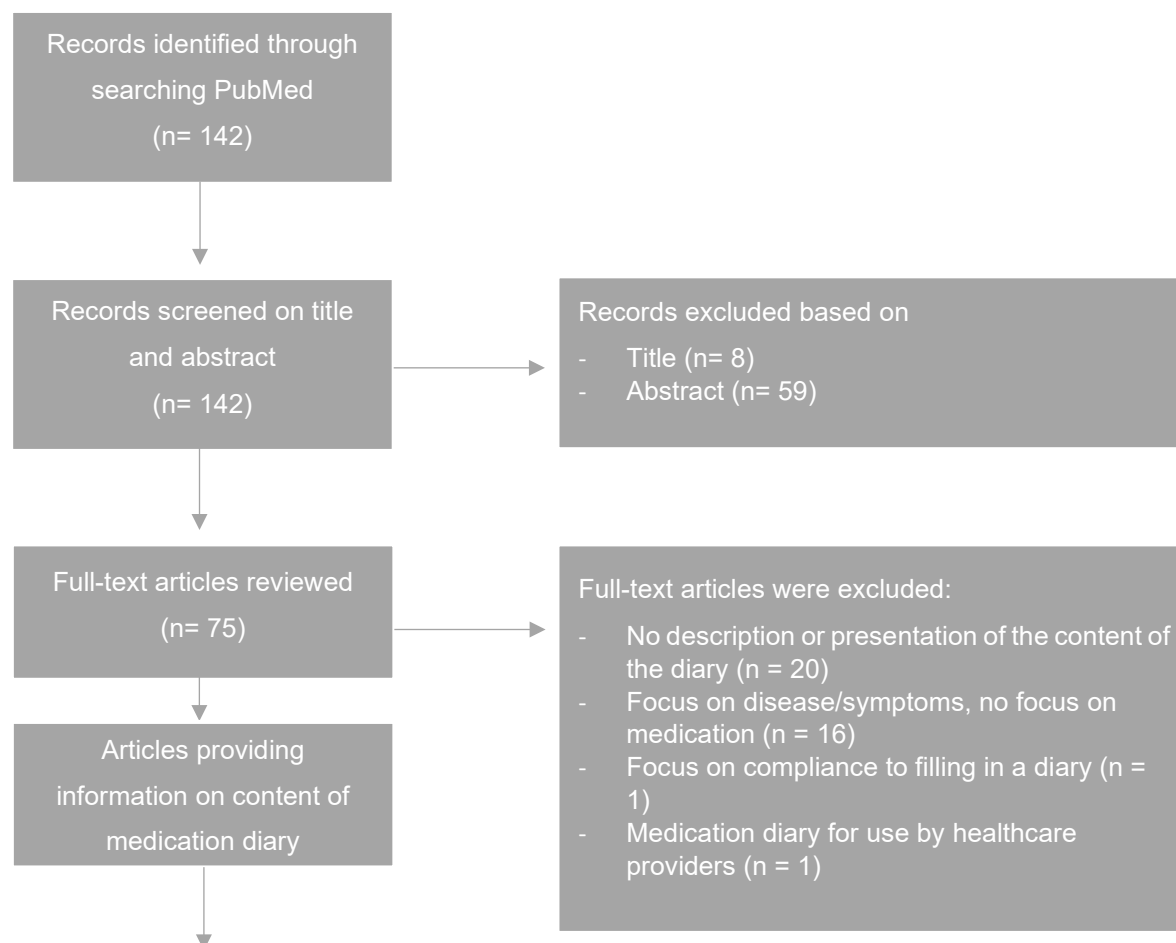
Appendix 6.2

Scan the QR code to access the nurses' survey.



Appendix 8.1

Figure: Flowchart of the selection process and results of PubMed search



Content of medication diaries used in research papers	Frequency
– Registration of:	
o Medication name	4x
o Dose of medication	3x
o Time of medication intake	7x
o Date of medication intake	3x
o Missed doses	4x
o Medication intake as prescribed	7x
o Number of pills/tablets taken	7x
o Intake of pro re nata medication	8x
o Reasons for omission	1x
o Side effects	3x
– List of current medication	1x
– Space for free text notes (reasons for not taking medicines, symptoms)	1x

369

Information for each medicine

Medication name:

What should I pay attention to when taking the medication?

What adverse reactions can this medication cause?

What other information about the medication is relevant to me?

01

Monthly overview January

Monthly overview January

Year: _____	I encountered PROBLEMS	I did NOT encounter any problems
1 Jan.	☐	☐
2 Jan.	☐	☐
3 Jan.	☐	☐
4 Jan.	☐	☐
5 Jan.	☐	☐
6 Jan.	☐	☐
7 Jan.	☐	☐
8 Jan.	☐	☐
9 Jan.	☐	☐
10 Jan.	☐	☐
11 Jan.	☐	☐
12 Jan.	☐	☐
13 Jan.	☐	☐
14 Jan.	☐	☐
15 Jan.	☐	☐
16 Jan.	☐	☐
17 Jan.	☐	☐
18 Jan.	☐	☐
19 Jan.	☐	☐
20 Jan.	☐	☐
21 Jan.	☐	☐
22 Jan.	☐	☐
23 Jan.	☐	☐
24 Jan.	☐	☐
25 Jan.	☐	☐
26 Jan.	☐	☐
27 Jan.	☐	☐
28 Jan.	☐	☐
29 Jan.	☐	☐
30 Jan.	☐	☐
31 Jan.	☐	☐

I did not manage my own medication from ____ / ____ / ____ to ____ / ____ / ____

Reason: _____

Problem sheet

Problem sheet

Date: ____ / ____ / ____ or period from ____ / ____ / ____ to ____ / ____ / ____

What problem did you encounter?	With which medication?	Did you take action?
a. Obtaining the medication		
☐ Medication not in stock ☐ Forgot to collect from the pharmacy ☐ I am unable to go get my medication (restricted mobility, no help from others, etc.) ☐ I cannot afford the medication ☐ I had no prescription (refill)	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:
b. Side effects		
	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:

Problem sheet

Date of completion: ____ / ____ / ____

What problem did you encounter?	With which medication?	Did you take action?
c. Problems with medication use		
☐ I took the wrong dose ☐ More than prescribed ☐ Less than prescribed ☐ Other: _____	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:
☐ Taken at the wrong time ☐ Too early ☐ Too late ☐ Other: _____	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:
☐ Administered the wrong way	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:

Problem sheet (continued)

What problem did you encounter?	With which medication?	Did you take action?
☐ Forgot to take the medication	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:
☐ Difficult administration (problems swallowing, inhaling, applying, injecting, etc.)	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:
d. Problems with packaging		
☐ Difficulty opening the packaging	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:

Problem sheet (continued)

What problem did you encounter?	With which medication?	Did you take action?
☐ Storage issues (e.g. packaging was thrown away)	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:
☐ I cannot read or understand all the information about my medication	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:
e. Other problems		
 	☐ Pertains to all medicines ☐ Pertains to specific medicines: ☐ I don't know	☐ No ☐ Yes:

Date of completion: / /

Problem sheet (continued)

Appendix 8.3

Scan the QR code to access the questionnaire on the user-friendliness of the medication diary (English translation). Please click on the supplemental information – multimedia component 4.



Appendix 8.4

Table: Reasons for drop-out during two months post-discharge (n = 16)

Reasons*	n
(Deteriorating) Health status	7
Problems in personal life	4
Diary not kept consistently	3
Getting nervous of participating in the study	2
Not wanting a home visit once returned home	1
Participating is too much of an effort	1
Not returned home	1
Did not want to participate once returned home	1
No medication self-management anymore	1

* Multiple reasons for drop-out per patient were possible.

Appendix 9.1

Table: Reasons for non-participation in part two of the study (n= 59)

Reasons*	n
Not willing to complete a medication diary	32
Not willing to preserve medication packages	20
Not willing to spend time on research	13
Because of health status	6
Did not want a home visit	3
Not willing to share personal data	2
Because of holidays	2
Because of moving	2
Difficult with current job	1
Going to forget to fill out medication diary	1
Already strict adherence	1
Already have to fill out diary	1
Personal worries	1
Too difficult	1
Did not want to give a reason	3

* Multiple reasons for non-participation per participant were possible.

Appendix 9.2

Table: Differences in population characteristics between dropouts and non-dropouts (study part 2)

	Non dropouts (n= 69)	Drop outs (n= 16)	P
Age in years – mean [SD, min-max]	68.9 [8.76, 43-86]	67.3 [11.37, 43-83]	0.263 ^a
Sex (male) (%)	72.5	50.0	0.082 ^b
Highest educational level (%)			0.703 ^b
No education	5.8	6.3	
Primary education	4.3	6.3	
Lower secondary education	20.3	25.0	
Higher secondary education	31.9	25.0	
Higher vocational education	18.8	31.3	
Bachelor's degree	14.5	0.0	
University (master's degree/PhD)	4.3	6.3	
Living alone (%)	24.6	25.0	0.976 ^b
Help needed to reside in own home (%)	34.8	43.8	0.502 ^b
Unexpected hospitalisation (%)	34.8	37.5	0.838 ^b
Reason for hospitalisation (%)			0.869 ^b
Surgery	53.6	56.3	
Treatment	21.7	25.0	
Examination	14.5	18.8	
Medication review	7.2	0.0	
Accident	0.0	0.0	
Observation	1.4	0.0	
Other	1.4	0.0	
Length of hospital stay (%)			0.863 ^b
1 to 3 days	31.9	25.0	
4 to 7 days	34.8	37.5	
8 days or more	33.3	37.5	
Number of chronic medicines at discharge	7.2	6.4	0.230 ^a
^d – mean [SD, min-max]	[2.47, 5-15]	[1.55, 5-10]	
Number of medication changes during two months post-discharge ^d – median [min - max]	1 [0 – 12]	1 [1 - 1]	0.971 ^c
Use of medication aids (yes) (%)	61.8	56.3	0.684 ^b

^a Independent T test. ^b Pearson Chi-square test. ^c Mann-Whitney U test. ^d Reported by participants.

Appendix 9.3

Table: Percentage of participants agreeing with ProMAS statements

ProMAS items	Total population (n = 69)	
	n	(%)
It has happened at least once that I forgot to take (one of) my medicines.	29	(42.0)
It happens occasionally that I take (one of) my medicines at a later moment than usual.	41	(59.4)
I have never (temporarily) stopped taking (one of my) medicines.	27	(39.1)
It has happened at least once that I did not take (one of) my medicines for a day.	21	(30.4)
I am positive that I have taken all the medication that I should have taken in the previous year.	52	(75.4)
I take my medicines exactly at the same time every day.	48	(69.6)
I have never changed my medicine use myself.	24	(34.8)
In the past month, I forgot to take my medicine at least once.	21	(30.4)
I faithfully follow my doctor's prescription concerning the moment of taking my medicines.	56	(81.2)
I sometimes take (one of) my medicines at a different moment than prescribed (e.g., with breakfast or in the evening).	22	(31.9)
In the past, I once stopped taking (one of) my medicines completely.	11	(15.9)
When I am away from home, I occasionally do not take (one of) my medicines.	10	(14.5)
I sometimes take less medicine than prescribed by my doctor.	1	(1.4)
It has happened (at least once) that I changed the dose of (one of) my medicines without discussing this with my doctor	4	(5.8)
It has happened (at least) once that I was too late with filling a prescription at the pharmacy.	11	(15.9)
I take my medicines every day.	67	(97.1)
It has happened (at least once) that I did not start taking a medicine that was prescribed by my doctor.	7	(10.1)
I sometimes take more medicines than prescribed by my doctor.	4	(5.8)

Appendix 10.1

Scan the QR code to access the self-report survey on medication self-management problems (English translation).



List of tables and figures

List of tables

Chapter 1

Table 1.1: Definitions related to medication adherence	18

Chapter 2

Table 2.1: Sample characteristics	60
Table 2.2. Differences between patients who did fully self-manage medication after discharge and patients receiving help with medication management after discharge.	62
Table 2.3. Logistic regression of predictors of medication management deficiencies (general).	67
Table 2.4. Logistic regression of predictors of medication knowledge deficiencies.	67
Table 2.5. Logistic regression of predictors of deficiencies in medication-taking ability.	68

Chapter 3

Table 3.1: Participant characteristics	89
Table 3.2: Percentage of Participants Agreeing With 'Beliefs about Medicines Questionnaire' Statements.	91
Table 3.3: Correlations between Subscale Scores of the Beliefs about Medicines Questionnaire.	92
Table 3.4. Medication-related discharge management.	94

Chapter 4

Table 4.1: Sample characteristics	119
Table 4.2: Patient self-assessment	120
Table 4.3: Percentage of patients classified by MED-fLAG and SelfMED quartiles	124
Table 4.4: Influencing factors of the extent to which patients are considered capable of medication self-management	125

Chapter 5

Table 5.1. List of medication self-management problems.	151
Table 5.2. General characteristics of panelists of the e-Delphi study	152
Table 5.3. General characteristics of patients	154

Chapter 6

Table 6.1: Participant characteristics.	175
Table 6.2: The extent to which recommendations were applied by nurses	176
Table 6.3: Feasibility, user-friendliness and usefulness of the recommendations as reported by nurses	177

Chapter 7

Table 7.1. Sample characteristics.	194
Table 7.2. Shared decision making on medication use between nurses and patients in an oncology setting: a qualitative descriptive study	196

Chapter 8

Table 8.1: Sample characteristics	226

Chapter 9

Table 9.1: Sample characteristics	252
Table 9.2: Willingness to communicate medication adherence-related information	254
Table 9.3: Reported medication adherence-related problems	255

List of figures

Chapter 1

Figure 1.1: Relationship between concepts focusing on patients as active partners in healthcare, a concept map adapted from Hickmann et al.	15
Figure 1.2: Model of medication self-management as developed by Bailey et al.	16
Figure 1.3: Perceptions and Practicalities Approach (PAPA): motivation and ability as core intrinsic attributes for adherence	19
Figure 1.4: Overview of subsequent interventional SelfMED components	27
Figure 1.5: Overview of research objectives addressed in this PhD dissertation	31

Chapter 2

Figure 2.1. Prevalence of medication self-management before, during and after hospitalization.	61
Figure 2.2. Boxplots of medication management deficiency scores.	65

Chapter 3

Figure 3.1. Boxplots representing the BMQ-Subscales Scores.	92

Chapter 4

Figure 4.1: Nurse assessment regarding medication self-management by patients during hospitalisation	121
Figure 4.2: The extent to which a patient is considered capable for medication self-management during hospitalisation	122
Figure 4.3: Scatterplot of the relationship between medication literacy skills (MED-fLAG) and patients' medication self-management capacity	123

Chapter 5

Figure 5.1. Study design of the development of recommendations for healthcare providers supporting patients with medication self-management problems.	144
Figure 5.2. Selection of sources of evidence	146

Chapter 7

Figure 7.1. Integrative model of SDM according to Makoul and Clayman	192

Chapter 8

Figure 8.1: Flowchart of the methodology	221
Figure 8.2: Problems reported in the medication diary	227
Figure 8.3: Overall evaluation of the medication diary	228

Chapter 9

Figure 9.1: Willingness of patients with polypharmacy to apply different methods measuring adherence after discharge and the expected feasibility of the methods.	254

Chapter 10

Figure 10.1: Schematic illustration of study design.	274
Figure 10.2: Overview of subsequent interventional SelfMED components.	278
Figure 10.3: Overview of data collection and outcomes.	284

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Summer Course Nurses and Interprofessional Pharmaceutical Care <i>Nurse and Pharmaceutical Care, University of Antwerp</i>	2023
Online course Design and Interpretation of Clinical Trials <i>Authorized by John Hopkins University and offered through Coursera</i>	2022
Online masterclass Science Communication <i>University of Stellenbosch</i>	2022
Workshop Creating a Scientific Poster <i>Antwerp Doctoral School</i>	2021
Workshop Introduction to Data Management Plans <i>Antwerp Doctoral School</i>	2021
Online Course Systematic Review <i>Cochrane Belgium</i>	2021
Workshop Adherence Data Analysis <i>ESPACOMP</i>	2020
Workshop Implementation Science <i>ESPACOMP</i>	2020

Memberships

National Board Member Belgium Nurse and Pharmaceutical Care (NuPhaC), www.nuphac.eu	2019 – current
The International Society for Medication Adherence (ESPACOMP)	2020 – current

Scientific activities

▪ Peer-reviewed publications

Mortelmans L, Gentizon J, Dilles T. (2024) Medication Literacy and Medication Self-Management: A Cross-Sectional Study in Hospitalised Patients (65+) With Polypharmacy. *Journal of Nursing Management*, 2024(1):5430265. <https://doi.org/10.1155/jonm/5430265>.

Mortelmans L, Goossens E, De Cock AM, van den Bemt P, Dilles T. (2024) Nurses' responses to patients' medication self-management problems in hospital and the use of recommendations. *British Journal of Clinical Pharmacology*, 2024, 90(10):2684-2690. DOI: 10.1111/bcp.16204.

Mortelmans L, Goossens E, Dilles T. (2024) Effect of an in-hospital medication self-management intervention (SelfMED) on medication adherence in polypharmacy patients postdischarge: protocol of a pre-post intervention study. *BMJ Open*, 14(5):e083129. doi: 10.1136/bmjopen-2023-083129.

Mortelmans L, Goossens E, De Graef M, Van Dingenen J, De Cock AM, Petrovic M, van den Bemt ., Dilles T. (2024) Evaluation of methods measuring medication adherence in patients with polypharmacy: a longitudinal and patient perspective. *European Journal of Clinical Pharmacology*. doi: 10.1007/s00228-024-03661-1.

Mortelmans L, Dilles T. (2024) The development and evaluation of a medication diary to report problems with medication use. *Heliyon*, 10(4):e26127. doi: 10.1016/j.heliyon.2024.e26127.

Mortelmans L, Goossens E, De Cock AM, Petrovic M, van den Bemt P, Dilles T. (2023). The Development of Recommendations for Healthcare Providers to Support Patients Experiencing Medication Self-Management Problems. *Healthcare*, 11(11), 1545. <https://doi.org/10.3390/healthcare11111545>.

Dilles T, **Mortelmans L**, Loots E, Sabbe K, Feyen H, Wauters M, Haegdorens F, De Baetselier E. (2023). People-centered care and patients' beliefs about medicines and adherence: a cross-sectional study. *Heliyon*, 2023;9(5):e15795. <https://doi.org/10.1016/j.heliyon.2023.e15795>.

Mertens J, Weyler J, Dirinck E, Vonghia L, Kwanten WJ, **Mortelmans L**, Peleman C, Chotkoe S, Spinhoven M, Vanhevel F, Van Gaal LF, De Winter BY, De Block CEM, Francque SM. (2023). Prevalence, risk factors and diagnostic accuracy of non-invasive tests for NAFLD in people with type 1 diabetes. *JHEP Reports*, 100753. <https://doi.org/10.1016/j.jhepr.2023.100753>.

Mortelmans L, Bosselaers S, Goossens E, Schultz H, & Dilles T. (2023). Shared decision making on medication use between nurses and patients in an oncology setting: A qualitative descriptive study. *European Journal of Oncology Nursing*, 102321. <https://doi.org/10.1016/j.ejon.2023.102321>.

Vanwesemael T, **Mortelmans L**, Boussery K, Jordan S, & Dilles T. (2022). Self-Management of Medication on a Cardiology Ward: Feasibility and Safety of the SelfMED Intervention. *International Journal of Environmental Research and Public Health*, 19(24), 16715. <https://doi.org/10.3390/ijerph192416715>.

Dumitrescu I, Casteels M, De Vlieghe K, **Mortelmans L**, & Dilles T. (2022). Home care nurses' management of high-risk medications: a cross-sectional study. *Journal of Pharmaceutical Policy and Practice*, 15(1), 88. doi:10.1186/s40545-022-00476-2.

Mortelmans L, Goossens E, & Dilles T. (2022). Beliefs about medication after hospital discharge in geriatric patients with polypharmacy. *Geriatric Nursing*, 43, 280-287. <https://doi.org/10.1016/j.gerinurse.2021.12.007>

De Baetselier E, Dilles T, Feyen H, Haegdorens F, **Mortelmans L**, & Van Rompaey B. (2021). Nurses' responsibilities and tasks in pharmaceutical care: a scoping review. *Nursing Open*, 9(6), 2562 - 2571. doi:10.1002/nop2.984.

Mortelmans L, De Baetselier E, Goossens E, & Dilles T. (2021). What happens after hospital discharge? Deficiencies in medication management encountered by geriatric patients with polypharmacy. *International Journal of Environmental Research and Public Health*, 18(13), 7031. <https://doi.org/10.3390/ijerph18137031>.

▪ Non peer-reviewed publications

Mortelmans L. (2025) De teach-backmethode bij medicatiecounseling: werd mijn uitleg wel echt begrepen? *Netwerk Verpleegkunde*, 2025;5, 54.

Mortelmans L. (2024) Patiënten ondersteunen bij medicatiezelfmanagement. *Netwerk Verpleegkunde*, 2024;4,15.

Dumitrescu I, Casteels M, De Vlieghe K, **Mortelmans L** & Dilles T. (2022). Hoog-risico medicatie bij thuiswonende ouderen: wat gebeurt er na ontslag uit het ziekenhuis? *Overal Thuis*, 2(3), 6-9. <https://www.nptv.be/kwartaal-3-2022/>

▪ Conference presentations

Evaluation of methods measuring medication adherence in patients with polypharmacy. 2nd NuPhaC Winter Conference, Antwerp (Belgium). [Oral presentation]	December 2024
The effect of in-hospital medication self-management (SelfMED) on medication adherence in polypharmacy patients post-discharge: protocol of a pre-post intervention study. 28th ESPACOMP Conference, Naples (Italy). [Poster presentation]	November 2024
Recommendations for Healthcare Providers to support Patients with Medication Self-Management Problems. CARE4 International Scientific Nursing and Midwifery Conference 2024, Antwerp (Belgium). [Oral presentation]	February 2024
The development of recommendations for healthcare providers to support patients experiencing medication self-management problems. 27th ESPACOMP Conference, Budapest (Hungary). [Oral presentation]	November 2023
Evaluation of methods measuring medication adherence in patients with polypharmacy. European Drug Utilization Research Group Conference 2023, Bologna (Italy). [Oral presentation]	June 2023
Beliefs about medication after hospital discharge in patients with polypharmacy: are patients convinced of the benefits of their medicines? International Conference on Integrated Care, Antwerp (Belgium). [Oral presentation]	May 2023
Overtuigingen over medicatie na ontslag uit het ziekenhuis bij patiënten met polyfarmacie: zijn patiënten overtuigd van de voordelen van hun geneesmiddelen? 46 ^{ste} Wintermeeting Belgische Vereniging voor Gerontologie en Geriatrie, Oostende (Belgium). [Oral presentation]	February 2023
Evaluation of methods measuring medication adherence in patients with polypharmacy. 26 th ESPACOMP Conference, Berlin (Germany). [Poster presentation]	November 2022
What happens after hospital discharge? Beliefs about medication in geriatric patients with polypharmacy. Sigma's 33rd International Nursing Research Congress, Edinburgh (online). [Poster presentation]	August 2022

Medication management deficiencies in geriatric patients with polypharmacy after hospital discharge. Sigma's 33rd International Nursing Research Congress, Edinburgh (online). [Oral presentation]	August 2022

Medication management deficiencies in geriatric patients with polypharmacy after hospital discharge. 45 th Wintermeeting Belgian Society for Gerontology and Geriatrics , Oostende (Belgium). [Oral presentation]	June 2022

What Happens after Hospital Discharge? Deficiencies in Medication Management Encountered by Geriatric Patients with Polypharmacy. NuPhaC Winter Conference, Antwerp (Belgium). [Oral presentation]	December 2021

▪ **Science communication**

Mortelmans L. EOS blog: Waarom patiënten tijdens een ziekenhuisopname beter zelf de leiding nemen over hun medicatie. EOS Wetenschap.	February 2024

Interview: Gezamenlijke besluitvorming over medicatiegebruik tussen oncologiepatiënten en – verpleegkundigen. CancerCare.	November 2023

▪ **Organisational activities for scientific conferences**

Online Dutch NuPhaC Symposium 'Gespecialiseerd verpleegkundigen in farmaceutische zorg'	December 2024

2 nd NuPhaC Winter Conference, Antwerp (Belgium)	December 2024

NuPhaC Summer School, Antwerp (Belgium)	September 2023

NuPhaC Winter Conference, Antwerp (Belgium)	December 2021

▪ **Reviewer for international journals**

Geriatric Nursing
 BMC Geriatrics
 BMC Health Services Research
 BMC Medical Informatics and Decision Making
 Drugs – Real World Outcomes

Grants

PhD fellowship	2021 – 2023
Granted by Research Foundation Flanders (FWO)	
Grant reference: 11L0522N	

PhD fellowship	2023 – 2025
Granted by Research Foundation Flanders (FWO)	
Grant reference: 11L0524N	

Awards

Best oral presentation at the 2nd NuPhaC Winter Conference, awarded by Nurse and Pharmaceutical Care	December 2024

Best oral presentation in Health and Education at the CARE4 Conference, awarded by Netwerk Verpleegkunde	February 2024

Best oral presentation at the 46 th Winter Meeting of the Belgian Society for Gerontology and Geriatrics (BSGG)	February 2023

'Leo Bossaert' Honorary Award of University of Antwerp as most meritorious student	September 2019



University of Antwerp
Faculty of Medicine and
Health Sciences

**Thesis submitted for the degree of Doctor of Medical Sciences at the University of
Antwerp to be defended by Laura MORTELMANS**

Supervisors:

Prof. dr. Tinne Dilles

Prof. dr. Eva Goossens

Antwerp, 2025