# Medication Management in Homecare Patients

# **Carolien Sino**

#### Medication Management in Homecare Patients

Hogeschool Utrecht University of Applied Sciences

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# Medication Management in Homecare Patients

### Medicatie Management bij thuiszorg patiënten

(met een samenvatting in het Nederlands)

### Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht op gezag van de rector magnificus, prof. dr. G.J. van der Zwaan, ingevolge het besluit van het college voor promoties in het openbaar te verdedigen op donderdag 12 december 2013 des middags te 2.30 uur

door

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geboren op 20 maart 1968 te Valkenswaard

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Voor mijn ouders



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Chapter 1



#### Casus

Two times a week, I visit Mrs. J., a single woman of 81 years old, who needs assistance in shopping, cleaning the house and bathing. Mrs. J. had a stroke two years ago and is suffering from heart disease. She has to take a lot of pills every day. Sometimes, I find some pills on the floor, which I usually clean up with the vacuum cleaner. Mrs. J. believes that her medication is very important. While she was bathing, I saw a big bruise on Mrs. J.'s arm, which she could not explain. Mrs. J. is known to have impaired cognition. Every week, there are two bottles of gin on her shopping list. After a visit to her cardiologist, her medication was changed. It was now prepared in very handy little plastic bags for each dose. Due to her arthritis, I have helped her to open these packages and have also given her the usual medication. Lately, it struck me that she has been shaky on her legs. I have advised her to be more careful.

Last week Mrs. J. fell due to dizziness, and she broke her hip. In the hospital, double blood pressure medication intake was observed. Did I miss any signs or symptoms? Should I have recognized this problem earlier? I do feel guilty. Mrs. J. never returned to her home again.

Anonymous homecare nurse assistant

#### Introduction

Older people and drug-related problems (DRPs)

In the Netherlands, people aged 65 years and older use three times more medication, and people aged 75 years and older consume five times more than the average person<sup>[1]</sup>. In general, medication has been shown to improve health and quality of life and to increase life expectancy<sup>[2]</sup>. However, in combination with natural changes in age-related drug metabolism, impaired cognition, multiple morbidities, reduced renal function, polypharmacy and impaired compensating capacity (frailty), older people are particularly vulnerable to drug-related problems (DRPs)<sup>[3-6]</sup>.

A DRP has been defined as an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes<sup>[7]</sup>. DRPs are classified into the following categories:

- Adverse drug reactions: defined by the World Health Organization as a response to a drug that is noxious and unintended and that occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of diseases or for the modification of physiological function<sup>[8]</sup>;
- Drug choice problems: the patient receives or will receive the incorrect (or no) drug for his/her disease and/condition, including drug allergies and under treatment;
- Dosing problems: the patient receive more or less than the amount of the drug that he/she requires or for a shorter/longer period of time given his or her (patho)physiological status (e.g., renal function);
- Drug use problems: wrong or no drug taken/administered, wrong administration technique for the right drug or practical administration problems; and
- Interactions: there is a manifest or potential drug-drug or drug-food interaction<sup>[7]</sup>.

DRPs can be caused during various stages of the medication management process, including prescribing, dispensing, taking/administering, monitoring and evaluation, and can be caused by various actors in this process, such as healthcare professionals (physicians, nurses, pharmacists) and the patient him- or herself<sup>[7]</sup>. In primary care, medications are usually prescribed by a general practitioner or medical specialist, provided by a pharmacist, and then self-administered by the patient. Although this chain should be a well-controlled system resulting in optimal therapeutic outcomes, this is often not the case. Garfield and colleagues<sup>[9]</sup> demonstrated that error-free percentages were rather high during the prescribing and cashing/dispensing phases of medicines in primary care. However, these error-free percentages decreased enormously during the phases of taking medication and monitoring/evaluating clinical outcomes. It was estimated that only between 4% and 21% of patients achieved the optimal benefit from their medication in primary care. This analysis shows that medication management research in primary care and research regarding intervention strategies should focus on the medication taking/administering phase<sup>[10]</sup>.

In older patients, medication intake is influenced by physiological factors, cognitive factors, the number of medications and medication frequency, the patient's consent to the treatment and motivation for taking the medication, demographic variables, and social factors, such as the presence of family caregivers and social support<sup>[11]</sup>.

One could question how older people experience their (multiple) medication use, whether they are aware of potential DRPs and whether they are capable of managing their medications, including early recognition of DRPs.

#### Early recognition of DRPs

DRPs are responsible for 3% - 10% of acute hospital admissions, of which approximately half are potentially preventable<sup>[12-21]</sup>. Hospital admissions can lead to additional functional decline<sup>[22,23]</sup>, unintentional harm<sup>[24]</sup> and increased costs. Drug-related hospital admissions can be seen as the tip of the iceberg. In many cases, DRPs will not lead to admission but will cause (unnecessary) inconvenience for the patient or loss of quality of life. Early recognition of potential drug-related problems is an essential part of preventing serious complications of drug therapy, such as discomfort, hospital admission, or even death. Several studies have shown that physicians<sup>[25-28]</sup> and pharmacists<sup>[29-32]</sup> can contribute to the recognition of drug-related problems in patient care. However, to date, little attention has been paid to the process of early recognition of the observations indicative of potential DRPs in the home environment.

In 2008, the Dutch HARM study group established seven independent risk factors for medication-related hospital admissions: (a) impaired cognition; (b) four or more diseases in the patient's medical history; (c) a dependent living situation; (d) impaired renal function before hospitalization; (e) non-adherence to the medication regimen; (f) the use of five or more medications at the time of admission (polypharmacy); and (g) age older than 65 years old <sup>[21]</sup>.

#### Homecare patients

Impaired cognition, polypharmacy and ages older than 65 years old are highly prevalent in people receiving homecare services<sup>[33·35]</sup>. Furthermore, it is likely that patients receiving homecare have a higher prevalence of reduced renal function and multiple morbidity than the general population, which are also risk factors for medication-related hospital admissions<sup>[21,33,34]</sup>. Therefore, particular segments of the older homecare patient population are vulnerable to DRPs<sup>[33,36-39]</sup>.

Due to aging, shorter hospital stays and a greater emphasis on outpatient care, the number of older persons receiving homecare is growing<sup>[40]</sup>. Health policy encourages older people to remain in their own homes for as long as possible.

In the Netherlands, 95% of people age 65 year and over live in their own homes. This percentage changes with age; however, even in people aged 80 years and older, 85% are still not institutionalized and live at home<sup>[41]</sup>. Based on political views, the expectation is that this percentage will increase even further in the coming years<sup>[42]</sup>. In the Netherlands, the majority (82%) of patients who receive homecare are 65 years old or older<sup>[40]</sup>. In 2007, half a million older people received care without residence<sup>[43]</sup>, constituting, on average, 20% of all older people. Almost three quarters of older people who received care at home received domestic support. Half of this group also received nursing care<sup>[41]</sup>. In the recent U-PROFIT data set, collected for a large cluster of randomized clinical trials in Dutch primary care<sup>[44]</sup>, all of the patients aged 60 years old or older who used at least five different medications were selected. In this group of 3100 older patients (mean age 74.2; SD 8.4), 787 patients (26.6%) received homecare on a regular base (median 3 hours weekly). The older the patients were, the larger the percentage was that was receiving homecare.

#### Homecare workers

Homecare workers help people to live independently for as long as possible, given the limits of their medical conditions. Most homecare is delivered to older people, covering a wide range of services, such as help with bathing and getting dressed, intravenous therapy and injections, wound care, education on disease treatment or assistance with medication intake. Because of this wide range of services, homecare workers are divided by their education levels and corresponding responsibilities into: registered (homecare) nurses (RNs; in Dutch: 'verpleegkundigen'); licensed practical nurses (LPNs; in Dutch: 'verzorgenden'); nurse assistants (NA; in Dutch: 'helpenden'); and housekeepers. In the Netherlands, the differences among these professionals are determined by the level of responsibilities and complexity of care<sup>[45]</sup>. For Dutch RNs and LPNs, medication education is part of their training. Medication is not part of the education for NAs. Despite their lack of education in medication, NAs work with increasingly older patients who use many drugs. Detecting changes in a patient's situation is certainly part of their training.

#### Window of opportunity?

Prevention and early recognition of potential DRPs could possibly be enhanced by including homecare workers in the chain of medication safety. Homecare workers are very well positioned to recognize the signs and symptoms of potential DRPs because of their frequent patient contact and their education to observe changes in the patient's state, despite a lack of extensive medical and pharmacological knowledge. In addition to the general practitioner and pharmacist, homecare workers who visit their patients in their homes on a regular basis might be able to facilitate early recognition of potential DRPs. Furthermore, one could question how patients can contribute their own medication safety.

#### **Objectives of the thesis**

Because it is important to recognize those homecare patients early who are at risk for DRPs, to prevent unnecessary discomfort, hospital admission or even death, the general aims of this thesis, described in three objectives, were as follows:

- Exploring the beliefs of older people regarding their medications and their medication management capacity relative to their self-management ability skills and cognition;
- 2.Describing the medication management practices, knowledge and attitudes regarding medication among homecare workers; and
- 3. Determining whether standardized observations in homecare could result in early recognition of DRPs.

#### **Outline of the thesis**

To accomplish the general aims, this thesis consists of three parts. The first part of the thesis focuses on older patients and provides information about beliefs regarding medicines among older (homecare) patients receiving polypharmacy (chapter 2.1). Next, a study is described comparing the medication management capacity of homecare patients receiving polypharmacy relative to their cognition and self-management skills (chapter 2.2).

The second part of the thesis focuses on homecare workers concerning medication safety, and it presents their medication management practices (chapter 3.1). Next, the knowledge and attitudes regarding medication among homecare nurses are discussed (chapter 3.2).

The third part of the thesis focuses on the early recognition of DRPs. This part begins with a study that describes the associations among the frequency of prescription changes, chronic disease scores and hospital admission, based on the idea that the frequency of prescription changes can contribute to the identification of patients who are at especially increased risk of DRPs in primary care (chapter 4.1). Next, an observational study regarding the recognition of DRPs by homecare employees is presented. Then, signs and symptoms indicative of potential DRPs in homecare patients, observed with a standardized observation list (the Home Observation of Medication related problems by homecare Employees [HOME] instrument) are presented in a correlational study (chapter 4.3).

In the general discussion, the main findings of this research are placed within a broader perspective and are discussed (chapter 5).

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# Chapter 2

Patients' beliefs regarding medication and Medication Management Capacity in homecare patients



# Chapter 2.1

## **Beliefs of Community-dwelling older people regarding**

Carolien GM Sino, Linda Michiels and Marieke J Schuurmans

#### Abstract

#### **Background:**

Although elderly are frequent medication users, not much is known regarding their beliefs about medicines and factors influencing these beliefs.

#### Method

Cross-sectional survey using the Beliefs about Medicines Questionnaire (BMQ).

#### Results

The participants (N=91; median age = 71.0 years; 41.4% female) were convinced of the necessity of their medicines, while they did not show concerns regarding overuse and harm. Beliefs about medicines did not correlate with age. Women had stronger beliefs in the necessity of medicines than men. Participants with elementary school had stronger beliefs in the necessity of medicines compared to participants with high education. ATC category users A, D and S had stronger beliefs in the necessity of medicine than non-users.

#### Conclusion

The results indicate that elderly if well informed regarding their medication will be adherent and in the meantime there could be a risk of harm due to their neglect of the possibility of adverse events.

#### Introduction

In developed countries, older people represent 12-18% of the population and consume approximately 50% of all prescription medicines<sup>[1]</sup>. Due to their age-related medication use, older people are vulnerable to medication related problems<sup>[2,3]</sup>, like over- and under-use of (inappropriate) medicines, interactions and adverse events like hospital admission<sup>[4-8]</sup>. Several studies reported that adverse drugs events in older people are common and often preventable<sup>[9-11]</sup>.

General practitioners<sup>[12-15]</sup> and pharmacists<sup>[16-20]</sup> can play an important role in avoiding these problems by appropriate prescribing and regularly reviewing the medication of their older patients. Besides, nurses are increasingly involved in early recognition of signs and symptoms of medication related problems<sup>[21-24]</sup>. However, few studies have examined the role of the older patients themselves in preventing medication related problems<sup>[34,35]</sup>.

Several factors influence the medication intake in elders. Van Vliet et al.,<sup>[36]</sup> grouped these factors into six categories: 1) physiological factors, 2) cognitive factors, 3) polypharmacy and medication frequency, 4) patient consent to the treatment and motivation for taking the medication, 5) demographic variables, and 6) family caregivers and social support. Patients' beliefs and attitudes towards medicines play an important role in medicine taking and have been found to be associated with adherence<sup>[25,27]</sup>. Patients who accept drug therapy are more frequently adherent to their medication regimens than patients who are ambi-valent, indifferent or skeptical<sup>[29]</sup>. To gain more information about the patient's perspective, someone's beliefs have to be determined, which are part of a perspective and represent the information a person has about an object<sup>[37]</sup>.

Although much attention is given to medication problems, the number of published studies about elderly's beliefs about medicines is relatively small and results are inconclusive.

Insight in the patient's beliefs about medication is an important part of an individualized intervention<sup>[44]</sup> in early recognition of medication related problems.

#### Aim

The aim of this study was to assess the beliefs of community-dwelling elderly regarding medication in The Netherlands and to assess the influence of age, educational level, number of medicines and therapeutic indications of medicines on these beliefs.

#### Method

#### Design and setting

A cross-sectional survey was conducted between December 2011 and May 2012, in patients of five general practices in the Netherlands using the 'Beliefs about Medicines Questionnaire' (BMQ). The BMQ was developed in the UK to measure patients' beliefs about medicines in a range of diseases (asthma, diabetes, renal, cardiac, psychiatric, general medical). In this questionnaire the concept "belief" is divided into four components: necessity, concerns, overuse and harm<sup>[43]</sup>.

#### Participants

The target population consisted of community-dwelling elderly who are using medication. The inclusion criteria were that participants had a minimum age of 65 years, used two or more different prescribed medicines a day, and lived independently at home. Exclusion criteria were not being able to understand or answer questions (dementia or mental deficiency), being terminally ill, or not understanding and speaking Dutch.

#### Measurements

#### Beliefs about Medicine Questionnaire.

To answer the research question regarding elderly's beliefs about medicines, the BMQ <sup>[25,43]</sup> was used. The BMQ consist of two sections: the *BMQ-Specific* and the *BMQ-General*, with a total of 18 items focusing on specific beliefs about medicines. Both sections consist of two subscales. For the *BMQ-Specific* section, the *Specific*-*Necessity* scale (5 items) assesses beliefs about the necessity of medicines, and the *Specific-Concerns* scale (5 items) assesses concerns about potential adverse effects of medicines<sup>[43]</sup>. For the *BMQ-General* section, the *General-Harm* scale (4 items) assesses beliefs about addiction, poison, harm, and long term use.

The *General-Overuse* scale (4 items) can be used to assess beliefs about how medicines are used by doctors<sup>[43]</sup>. The answers to each item are scored on a 5-point Likert scale (1 means "Strongly disagree", and 5 means "Strongly agree"). Scores for the individual items within each subscale are summed to give a scale score. Total scores for the *Specific-Necessity* and *Specific-Concerns* scales range from 5 to 25, scores of the *General-Harm* and *General-Overuse* scales range from 4 to 20. Higher scores indicate stronger beliefs in the concepts represented by the scale, and each scale can be dichotomized at the scale midpoint, to divide the scores in strong and less strong beliefs<sup>[43]</sup>.

The reliability (Cronbach's alpha) was estimated for six different groups (asthma, diabetes, renal-, psychiatric-, and cardiac diseases, and general medical), and varied for these six groups from 0.55-0.86 (Specific-Necessity subscale), 0.63-0.80 (Specific-Concerns subscale), 0.60-0.80 (General-Overuse subscale), and 0.47-0.83 (General-Harm subscale). The criterion-related validity varied from P=0.23 to P=0.50. Although small in magnitude, the correlation was statistically significant<sup>[43]</sup>. Since the development, the BMQ was used worldwide to assess beliefs about medicines, also specifically for elderly patients, for example, in a study for elderly with hypertension in the United States<sup>[46]</sup>.

In the Netherlands, the BMQ was applied to measure the beliefs about medicines for several diseases<sup>[29,32,47-50]</sup>, but not specifically for elderly.

#### Associated factors

To study relations between beliefs about medicines and patient characteristics, the age, gender, country of origin, living situation (living alone and living with a partner) and educational level (elementary school, lower education, middle education, and higher education) of each patient were recorded. Further, the number of medicines a patient used, was recorded, including the therapeutic groups of these medicines, following the Anatomical Therapeutic Chemical classification system of the World Health Organization (WHO ATC classification)<sup>[51]</sup>.

#### Procedures

A list of patient numbers of all persons of 65 years and over from the five general practices was imported in the statistical computer program PASW, version 18.0. Then, participants were selected at random with the randomization function of this program. This type of selection could increase the representativeness of the sample, and therefore, its key characteristics are closely approximate those of the population<sup>[45]</sup>. It was technically not possible to select patients according to all eligibility criteria first, and then conduct the randomization. Subsequently, the patient files were screened by the researcher and each eligible patient received an information letter from the general practitioner. In the information letter, patients were asked to contact the researcher when wishing to participate, and then a home visit was planned.

After the selection and recruitment of participants in March 2012, the included participants were interviewed in their homes with the BMQ. During this visit, baseline characteristics and used medicines were also recorded by the interviewer. These interviews were conducted by the researcher and two trained research assistants.

#### Ethical considerations

Ethical approval for the study was obtained from the institutional review board of the University Medical Centre Utrecht. Informed consent was obtained prior to each interview, by signing an informed consent form.

#### Data analysis

First, the normality of the data was assessed. Because the data were not distributed normally, non-parametric tests were used. Data were summarized using descriptive statistics. The relation between beliefs about medicines (BMQ subscale scores) and educational level (ordinal measurement level) was analyzed using the Kruskal-Wallis test. Differences in BMQ subscale scores between men and women and between users and non-users of each ATC category (nominal measurement levels), were analyzed using the Mann-Whitney U test. The correlation between the BMQ subscales and respectively age and number of medicines (both ratio measurement level), was analyzed using the Spearman correlation coefficient. The data analysis was conducted using PASW, version 18.0. The level of significance was 0.05, and testing was two-tailed.

#### Results

#### Sample

The database contained 1297 patients. After an at random selection of 840 patients, 379 eligible patients received an information letter. From theses eligible patient, 73 (19.3%) wanted to participate in the study. The 306 patients who did not respond to the information letter were contacted by telephone by the researcher, and thus an additionally 12 patients were recruited. The response rate was therefore 22.4%. Further, 6 spouses of interviewees wanted to participate on their own initiative, although they were at first not selected. Because they were eligible based on inclusion criteria, they were also included. Finally, a total of 91 elderly gave their consent to participate in the study (figure 1).

Patient characteristics are given in table 1. The median age of the participants was 71.0 years, ranging from 65 to 91 years, 41.4% were female. The median number of medicines used was 6.0 (Interquartile Range (IQR) 4.0), most frequently used were medicines for cardiovascular diseases (ATC category C) (table 4).

#### Elderly's beliefs about medicines

Elderly showed strong beliefs in the necessity of their medicines, and less strong beliefs regarding concerns, overuse and harm (Table 2). However, a quarter of the patients indicated sometimes to worry of the long term effects of medication. In addition, almost a quarter of the patients agreed with the statement that all medicines are poison. Furthermore, 27.5% of the patients agreed with the statement that doctors use to many medicines. Finally, half of the patients (49.5%) agreed with the statement that if doctors had more time with patients they would prescribe fewer medicines.





Age (mean, sd)		72.7	6.2
		Ν	%
Age category	65-68	29	32
	69-75	31	34
	76-91	31	34
Sex	Male	53	58.2
	Female	38	41.8
Education	Elementary school	18	19.8
	Lower education	30	33.0
	Middle education	24	26.4
	Higher education	91	20.9
Living situation	Alone	18	19.8
	Not alone	73	80.2
Number of prescribed	6.7	3.6	

### Table 1 Characteristics of the participants (N=91)

# Table 2. Beliefs about medicines of community dwelling older people (N=91)Age (mean, sd)

#### Specific necessity (scale 5-25

- 1 My health at present depends on my medicines
- 3 My life would be impossible without my medication
- 4 Without my medication I would be very ill
- 7 My health in the future will depend on my medication
- 10 My medication protects me from becoming worse

#### Specific concerns (scale 5-25)

- 2 Having to take medication worries me
- 5 I sometimes worry about the long term effects of my medication
- 6 My medication is mystery to me
- 8 My medication disrupts my life
- 9 I sometimes worry about becoming too dependent on my medication

#### General harm (scale 4-20)

- 13 Most medicines are addictive
- 14 Natural remedies are safer than medicines
- 15 Medicines do more harm than good.
- 16 All medicines are poisons

#### General overuse (scale 4-20)

- 11 Doctors use to many medicines
- 12 People who take medicines should stop their treatment for a while every now and again.
- 17 Doctors place too much trust on medicines
- 18 If doctors had more time with patients they would prescribe fewer medicines.

Disagree		Neu	tral	Ag		
N	%	N	%	Ν	%	Median
						19.0
9	9.9	15	16.5	67	73.6	
23	25.3	31	34.1	37	40.7	
24	26.4	35	38.5	32	35.2	
11	12.1	15	16.5	65	71.4	
8	8.8	13	14.3	70	76.9	
						10.0
70	76.9	9	9.9	12	13.2	
60	65.9	8	8.8	23	25.3	
63	69.2	14	15.4	14	15.4	
81	89.0	4	4.4	6	6.6	
67	73.6	6	6.6	18	19.8	
						10.0
61	67.0	23	25.3	7	7.7	
35	38.5	37	40.7	19	20.9	
60	65.9	20	22.0	11	12.1	
38	41.8	32	35.2	21	23.1	
						12.0
45	49.5	21	23.1	25	27.5	
44	48.5	24	26.4	23	25.3	
26	28.6	32	35.2	33	36.3	
30	33.0	16	17.6	45	49.5	

Fable 3. Beliefs about Medicine	s Questionnaire Scores versus age,	, gender and educational level
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	BMQ subscales							
	Specific- Necessity Range 5-25		Specific- Concerns Range 5-25		<b>General-</b> Overuse Range 4-20		<b>General-</b> Harm Range 4-20	
<b>Score for N=91;</b> median (IQR)	19.0 (4.0)		10.0 (4.0)		12.0 (4.0)		10.0 (3.0)	
<b>Age;</b> ρ(Ρ)	.028 (NS)		182 (NS)		004 (NS)		.051 (NS)	
<b>Gender</b> Male (N=53); <i>median (IQR)</i> Female (N=38); <i>median (IQR)</i>	17.0 (5.0) 19.0 (4.0)	P=.014	10.0 (3.0) 10.0 (4.0)	P=NS	12.0 (5.0) 12.0 (4.0)	P=NS	10.0 (3.0) 10.0 (3.0)	P=NS
Education Elementary school (N=18); median (IQR) Lower education (N=30); median (IQR) Middle education (N=24); median (IQR) Higher education (N=19); median (IQR)	19.0 (4.0) 19.0 (4.0) 19.0 (3.5) 17.0 (5.0)	P=.016	9.5 (4.0) 10.0 (3.0) 10.0 (3.5) 10.0 (4.0)		13.0 (4.0) 11.0 (3.0) 12.5 (5.0) 10.0 (6.0)		10.0 (2.0) 10.0 (3.0) 10.0 (2.5) 9.0 (3.0)	

The cut-off point for the Specific-Necessity scale and the Specific-Concerns scale is 15, the cut-off point for the General-Overuse scale and the General-Harm scale is 12. These cut-off points differentiate between strong and less strong beliefs in the concept that is measured by each subscale<sup>25</sup>.N=number of participants; IQR= Interquartile Range; P=p-value, with level of significance 0.05. NS=not significant. Correlation with age: Spearman's rank correlation coefficient; with Gender: Mann-Whitney U test; With Education: Kruskal-Wallis test.

Table 4. E	<b>Beliefs about medicines</b>	versus ATC category	and number of	prescribed medication
lable 4. E	Seliers about medicines	versus AIC category	and number of	prescribed medication

ATC category	Users	Specific- Necessity		Specific- Concerns		General- Overuse		General- Harm	
	N (%)	P*		P*		P*		Р*	
A Alimentary tract and metabolism	59 (64.8%)	.018ª		ns		ns		ns	
B Blood and blood forming organs	63 (69.2%)	ns		ns		ns		ns	
C Cardiovascular system	85 (93.4%)	ns		ns		ns		ns	
D Dermatologicals	10 (11.0%)	.033ª		ns		ns		ns	
G Genito-urinary and sex hormones	9 (9.9%)	ns		ns		ns		ns	
H Systemic hormonal prep, excluding sex hormones	14 (15.4%)	ns		ns		ns		ns	
J General anti-infectives for systemic use	6 (6.6%)	ns		ns		.008 <sup>b</sup>		ns	
L Antineoplastic and immunomodulating agents	4 (4.4%)	ns		ns		ns		ns	
M Musculo-skeletal system	20 (22.0%)	ns		ns		ns		ns	
N Nervous system	45 (49.5%)	ns		ns		ns		ns	
R Respiratory system	28 (30.8%)	ns		ns		ns		ns	
S Sensory organs	2 (2.2%)	.034ª		ns		ns		ns	
Number of medicines	Users	Specific- Necessity		Specific- Concerns		General- Overuse		Gener Harm	al-
	N (%)	ρ	P**	ρ	P**	ρ	P**	ρ	P**
Prescribed medicines	91 (100.0%)	.501		.204	.052	038	ns	.080	ns

\*Mann-Whitney U test; \*\*Spearman's rank correlation; ns=not significant

ATC category = therapeutic groups of medicines, following the WHO ATC classification<sup>51</sup>

N=number of participants that used medicines for each category.

%=percentage;  $\rho$ =Spearman's rho; P=p-value, with level of significance 0.05. a=P<0.05; b=P<0.01.

# *Beliefs versus age, gender, education, number of medicines and therapeutic indication.*

Beliefs about medicines did not correlate with age. Men and women differed only significantly in beliefs about the necessity of their medicines, where women had stronger beliefs in the necessity (median= 19.0) than men (median = 17.0).

Further, only beliefs about the necessity of medicines were associated with education (P=0.016).

Post hoc analysis using the Mann-Whitney U test, showed significantly stronger necessity beliefs (P=0.007) among participants with elementary school (median 19.0), compared to participants with high education (median= 17.0) (Table 3).

Table 4 shows that users of medicines for alimentary tract and metabolism (ATC category A) had significantly stronger beliefs in the necessity of their medicines, compared to non-users (users: median =19; non-users: median= 17.0), as well as users of dermatologicals (ATC category D) (users: median= 21.5; non-users: median= 18.0), and users of medicines for sensory organs (ATC category S) (users: median= 23.5; non-users: median =18.0).

Regarding the beliefs about overuse of medicines, users of general anti-infectives for systemic use (ATC category J) had less stronger beliefs than non-users (users: median =9.0; non-users: median =12.0). For the number of medicines, a small positive correlation was found between the score for the Specific-Necessity scale and respectively the number of prescribed medicines (r=0.501;  $r^2=0.25$ ; P=0.000), and the total number of all medicines (r=0.469;  $r^2=0.22$ ;P=0.000), where high numbers of medicines were associated with higher scores on the Specific-Necessity subscale.

#### Discussion

The results of this study showed that the elderly in the sample had strong beliefs in the necessity of their medicines, while beliefs in concerns, overuse and harm were less strong. Women had stronger beliefs in the necessity of medicines than man and participants with elementary school had stronger beliefs in the necessity of medicines compared to participants with high education. These strong beliefs in the necessity of their medicine will enhance the adherence<sup>[25-33]</sup>. On the other hand, these strong beliefs could blind the elderly and the healthcare providers as well, for medication related problems which do occur frequently in this population<sup>[9,11,53-56]</sup>.

As suggested in an earlier study by Rogers<sup>[57]</sup>, heart failure patients had difficulties in differentiating disease- and drug related problems. And elderly patients in general tend to consider observed symptoms as an unavoidable part of aging instead of disease or drug related<sup>[58]</sup>. Therefore, in contrast with the participants in the present study, patients who have stronger concerns may be more aware of unpleasant reactions and be more prejudiced towards their medication. Symptoms may be reported by patients before the occurrence of an adverse drug event. Therefore, older people should be made aware by the prescriber and provider
of the signs and symptoms of potential adverse drugs events. Good information about the difference between symptoms from disease or age and adverse drugs events by the prescriber and provider is hereby essential. Besides, other healthcare workers like (homecare) nurses could play a role in educating patients about possible adverse drug events and helping them in differentiating adverse drugs events from disease symptoms and normal aging.

Previous studies from Sweden<sup>[38,39]</sup> and New Zealand<sup>[40]</sup>, reported strong beliefs about the necessity, and less strong beliefs about concerns, overuse and harm of medicines, as well as in the present study.

In the study of Modig 93% of the patients agreed with the statement; "my medicines protect me from becoming worse" (versus 76.9% in the present study) and 79% of the patients agreed with the statement 'my health depends on my medicines" (versus 71.4% in the present study). However, in the study of Modig only 34 patients were involved. In another study, from Germany<sup>[33]</sup>, also positive beliefs concerning the necessity of medicines were found with the help of the BMQ. However, also participants with ages lower than 65 years were included. These studies support the results of the present study.

On the other hand, there are studies demonstrating that elderly have negative beliefs, like medicines being expensive<sup>[28]</sup> and confusing<sup>[39,41]</sup>. Furthermore, elderly are concerned about long-term effects and dependency<sup>[41]</sup>, about interactions, whether medicines are 'good' for the body, and adverse effects<sup>[40,41]</sup>. Negative attitudes also referred to the negative impact of medication on quality of life<sup>[42]</sup>. These conflicting results with our study emphasis the important of individual insight in the patients' beliefs about medication.

The association between gender and attitudes about medicines was also subject in a previous study<sup>[59]</sup>. In that study, men and women did not differ in their positive attitudes (instead of beliefs), however, women were often more negative to drugs than were men. In another study, where the BMQ was used<sup>[39]</sup>, no association between gender was found. This could be due to differences in sample size, and differences in age of the included participants 20 years and over<sup>[59]</sup> against 65 years and over<sup>[39]</sup>.

In the same study<sup>[59]</sup> beliefs about medicines were associated with educational level. Participants with high education were more positive to medicines than participants with lower education, contrary to our results. However, attitude and beliefs are different constructs. Therefore, these results cannot be compared to the results in the present study.

The results of the present study indicate that for certain therapeutic indications of medicines, differences in beliefs exist between users and non-users. A possible reason for these findings could be the purpose of the medicines. For example, some medicines are prescribed for diseases that can give complaints when not treated, like diabetes mellitus. Hence, patients possibly are more aware of the need for these medicines, rather than, for example, treatment with medicines for cardiovascular diseases, which are often prescribed preventive. However, then the expectation would be that, for example, users of medicines for respiratory diseases also have other beliefs than non-users of these medicines. This result was not found in the present study, possibly due to the large differences in numbers of users for each ATC category.

The results of the present study must be interpreted with caution because of the fact that, although patients were selected at random, they were included by convenience, because they had to respond to an invitation letter. It is possible that more vital patients were included which could have lead to an overestimation of the results. Further, the response was small, which may have caused bias in the results, and it may have undermined the representativeness of the sample. However, our sample size was significant larger than earlier studies (Modig et al: n=34; Mahler et al: n=33).

The strength of the study was the use of a validated instrument during a personal interview. Interviews were chosen as the data collection method, because they form the most respected method to collect survey data, because of the quality of information they yield<sup>[45]</sup>. Further, self-administered questionnaires are not appropriate for certain populations, for example elderly<sup>[45]</sup>.

## Conclusion

Elderly have strong beliefs in the necessity of their medicines, with less strong beliefs in aspects like concerns, harm, and overuse. Women, low educated participants and users of ATC category A, D and S had stronger beliefs in the necessity of their medicine than man, high educated participants and non-users of ATC category A,D, and S. However, these strong beliefs could blind the elderly for adverse drug events. Good information about the difference between signs and symptoms of normal aging, disease or potential adverse drug events by the prescriber and provider is hereby essential as well as awareness of professionals of the possible neglect of elderly regarding medication related problems. Insight in the patients' beliefs about medication could be an important part of an individualized intervention in early recognition of drug related problems.

## **Conflict of interest:**

Nothing to disclose.

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# Chapter 2.2

# Medication Management Capacity in relation to cognition and self-management skills in community-dwelling older people with polypharmacy

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Accepted for publication Journal of Nutrition, Health and Aging, Published online July 2013 Objective: to determine the medication management capacity of independently living older people ( $\ge$ 75 years) on polypharmacy ( $\ge$  5 medications) in relation to their cognitive- and self-management skills.

Design: cross-sectional study

**Setting:** two homecare organizations in the Netherlands Participants: homecare clients aged 75 and older on polypharmacy (N=95).

**Measurements:** The primary outcome measure was medication management capacity, quantified as the number of 'yes' answers (range = 0-17) on the Medication Management Capacity (MMC) questionnaire. Other measures included self-management ability (assessed with the SMAS30) and cognitive skills (assessed with the clock drawing test).

**Results:** Overall, 48.4% (n= 46) of the participants were able to manage their medication by themselves at home. About 40% of the participants were unable to state the names of their medications, even with the aid of a medication list, and about 25% reported having problems with opening medication packages. Correlations were found between self-management ability (Rs = 0.473; p < 0.001), cognitive skills (Rs = 0.372; p < 0.001), and age (Rs = 0.216; p < 0.005) and Medication Management Capacity score. Self-management ability and medication management support were significantly associated with medication management capacity.

**Conclusion:** A considerable proportion of independently living older people who receive homecare and regularly use five or more medications lack the knowledge and skills needed to independently manage their own medications. Cognition and self-management ability were related to medication management capacity. Self-management ability and medication management support were predictors of medication management capacity.

## Introduction

In primary care, medications are usually prescribed by a general practitioner, provided by a pharmacist, and then self-administered by the patient. Although this should result in a well-controlled system, this is often not the case<sup>[1]</sup>. Older people often use multiple medications because of age-related morbidities<sup>[2]</sup> and are consequently more prone to developing medication-related problems<sup>[3,4]</sup>. Older people who live independently have to manage their medication themselves. There are no professionals to supervise their medication use to prevent the potential consequences of medication misuse, such as unintentional harm, hospital admission or even death<sup>[5]</sup>, as compared to the situation in hospitals or nursing homes. Managing one's medications has been recognized as an important everyday function and is essential for safe, independent living<sup>[6]</sup>.

The question is if older people are able to manage their medication.

According to Maddigan et al.,<sup>[7]</sup> the capacity to manage one's own medication can be defined as the cognitive and functional ability to self-administer a medication regimen as prescribed. In turn, a person's capability to do so is dependent on his/ her ability to carry out a complex task. In this case, the task includes obtaining and scheduling medications, dealing with changes in medication, knowing when to contact the healthcare provider regarding problems related to the medication, and understanding what to do in case of missed or late doses<sup>[8]</sup>. In a retrospective chart review study (n=301), cognition and medication regimen complexity were found to be important predictors of medication management capacity, evaluated as the number of medication errors made by patients<sup>[7,9]</sup>, with any deviation from the prescribed dosing schedule being considered a medication error. Another study found cognitive impairment to compromise the ability of older people to successfully manage medications after hospitalization<sup>[9]</sup>.

According to Bergman-Evans<sup>[10]</sup>, self-treatment, lack of coordinated care, recent discharge from hospital, impaired cognitive status, and a complicated medication regimen all contribute to medication mismanagement by older people. Although there is evidence of a relationship between cognition and medication-related problems<sup>[4,8-11]</sup>, to our knowledge little is known about the relationship between self-management ability and medication management capacity. If a person's self-management skills, defined as the ability to maintain control over one's life and well-being<sup>[12]</sup>, deteriorate, then that person may be more likely to make errors in complex tasks such as medication management.

The purpose of this study was to determine the medication management capacity of older old patients living at home and who were on polypharmacy (≥5 medications) in relation to their cognitive and self-management skills.

## Methods

#### Design, setting, and participants

This cross-sectional study involved older patients receiving homecare services from two different Dutch homecare organizations, one of which is located in the northern area of the country (rural area), while the other is in the middle of the country (urban area). The study population consisted of a random sample of 95 patients who regularly used five or more prescription drugs daily, who were 75 years of age or older, and who gave their informed consent. The homecare organizations provided lists of their clients aged 75 years or older, and then these patients were contacted at random by telephone, to obtain a representative sample. They were asked whether they used five or more different prescription drugs regularly, and if so, they were sent or given a newsletter about the study. Individuals willing to participate in the study were interviewed at home by a trained research assistant. Data were collected between January and April 2010.

#### Ethical aspects

Participation in the survey was voluntary, and the anonymity of the participants was guaranteed under the Data Protection Act. The newsletter provided patients with information about the study (aim, duration), expected benefits, data confidentiality, right to refuse to participate, and right to withdraw from the study at any time. The patients provided verbal consent during a telephone conversation.

#### Measurements

#### Medication management capacity (MMC)

Despite many attempts to develop a standardized, objective, quantitative measure of peoples' ability to manage their own medications<sup>[13]</sup>, there are currently no reliable and valid instruments available to assess this. In the Netherlands, the MMC (which is known as the Beoordeling Eigen Medicatie (BEM) instrument in Dutch) was developed for use in nursing homes by the Dutch Institute for Responsible Medication Use (IVM)<sup>[14]</sup>. Although this instrument has not been validated, it is used as standard practice in the Netherlands to determine what kind of medication support nursing home patients require. It is also used by many homecare organizations.

For these reasons, the MMC was used to assess knowledge and skills that are relevant to managing and using drugs correctly among elderly people living at home. The original Dutch BEM instrument consists of a general section and a specific section. The general section, which was used in this study, contains 17 statements addressing the management and use of medications (Table II). The statements can be answered with 'yes', 'no' or 'not applicable'. If the answer is 'yes', the patient is considered to have the required knowledge and/or is able to perform the act independently.

The total score on the MMC is the number of times the answer 'yes' is scored, which ranges from O-17, with 17 reflecting an optimal medication management capacity.

The patients were divided into two groups, based on a median MMC score of 13: capable (>50% yes on the MMC) and less capable (< 50% yes on the MMC).

#### Cognitive skills

The clock drawing test (CDT) was used to assess cognitive skills. The CDT is a validated instrument to screen cognitive function and it is the second most commonly used test to screen for dementia. In a meta-analysis, the sensitivity and specificity of the CDT scoring system were both found to be 85%, based on CDT scores documented between 1983 and 1998<sup>[15]</sup>. The CDT requires visual analysis, motor performance, attention capacity, semantic knowledge, and language comprehension. Patients were asked to draw a clock set to 10 past 11.

The results of the CDT were analyzed by two researchers independently and an assessment was reached based on consensus agreement. Scores range from O-5, with 1 point being awarded for correct clock shape, all figures in the correct order, all figures in the right place, two hands present, and the correct time depicted. There are several scoring systems for the CDT, with the dichotomous system (the clock is correct = 1 point or the clock is not correct = 0 points) being recommended for its simplicity. On the basis of study by Kørner et al.,<sup>[16]</sup> the CDT scores were dichotomized into CDT= 5 and CDT < 5.

#### Self-management ability

Self-management ability was measured using version 2 / 2008 of the Self-Management Ability Scale (SMAS30)<sup>[12]</sup>, an instrument developed and validated by Schuurmans et al.,<sup>[17]</sup>.

The SMAS30 is based on theories of successful aging and measures the ability of elderly adults to maintain control over their lives and wellbeing.

The SMAS30 contains 30 Likert-scale questions and is divided into six subscales: initiative, self-efficacy, investment behavior, perspective, multi-functionality, and variety. Each subcategory includes five questions. Although theoretically these six types of self-management ability can be distinguished, they are not assumed to be independent. The SMAS30 is internally consistent (Cronbach's  $\alpha = 0.90$ )<sup>[12]</sup>. The SMAS30 questions were presented to participants verbally.

For each of the six subcategories, the mean and the percentage of the maximum score were calculated. The total SMAS30 score is the mean of the six subscales and ranges from 0 to 100. It is expressed as a percentage of the maximum score, with 100% reflecting optimal self-management ability. The SMAS score was divided into a low score ( $\leq$  42.17), a medium score (> 47.17 and  $\leq$  55.0), and a high score (>55.00).

#### Statistics

Basic characteristics were quantified using descriptive statistics. Medication management support was dichotomized and measured as 'yes' (I receive support in medication management from (in)formal caregivers and/or homecare organization) or 'no' (I do not receive any support in medication management). Missing values in the CDT (N=8) were excluded from analyzes. Correlations between the total score on the MMC and age, gender, the number of medications received, the total SMAS30 score, the CDT score, and educational level were determined using Spearman's rank correlation coefficient (for ordinal variables) and Cramers V (for nominal variables). To gain a better understanding of medication management, the MMC was further analyzed using the biserial correlation coefficient. Because the MMC is not validated, Cronbach's  $\alpha$  was used to determine the internal consistency of the instrument.

The following variables were univariately analyzed in relation to MMC: age, gender, number of medications, self-management ability, cognition, living situation, medication support and educational level.

The criterion for statistical significance for the entry of variables into the final model was  $\alpha$  = 0.05; selected variables were examined in a univariate analysis using a logistic regression model with the Enter method.

The data were analyzed using SPSS software (version 20.0 for Windows).

#### Results

Of the 134 homecare patients who met the inclusion criteria (age  $\geq$ 75 years,  $\geq$  medications), 95 participated in the study (70%).

Thirty-nine patients did not give informed consent, but were not asked why they did not participate, as agreed with the homecare organizations.

Thirty-two participants were men, and the mean number of medications used was 9.3 (range 5-18) (Table 1). The Clock Drawing Test, used as an indicator for cognitive skills, was completed by 87 (91.5%) patients, and 46 (52.9%) had the maximal score. There were eight missing values: patients did not draw a clock for unclear reasons (n=3), arm paralysis (n=3), or poor vision (n=2). SMAS30 data were available for all 95 patients. The mean total score for all six items of the SMAS30 was 51.1 (SD 13.7, range 27.8–94.5) which means the half of the maximum self-management ability score. The subscales with the highest scores were 'Self-Efficacy' and a 'Positive Frame of Mind' which indicates confidence in own self-management abilities of the participants. 'Variety of resources' had the lowest score which indicates a lack of informal care (spouses, siblings and friends as resources for affection).

		Participants	%	
<b>Gender</b> Female		63	66.3	5
<b>Age category</b> 65-68 69-75 76-91 Mean age (range)		30 30 35 84.1 (75-101)	31.6 31.6 36.8	
Number of medications		<b>ک</b> تر	26.2	
8-10 >10 Mean number of medications (range)		25 41 29 9.2 (5-18)	26.3 43.2 30.5	
<b>Living situation</b> Alone Not alone (together with partner or chi	ild)	63 32	66.3 33.7	
<b>Highest education Level</b> Elementary school Lower education Secondary education Higher education		36 23 24 12	37.9 24.2 25.3 12.6	
Medication management support None Only from informal caregiver Only from homecare organization From informal caregiver and homecare	organization	43 16 31 5	45.3 16.8 32.6 5.3	
Self-management ability Overall Self-management ability score Mean subscales Self-efficacy Investment behave Positive frame of r Multi-functionality Variety	ior nind /	Mean 51.1 46.6 68.7 48.8 60.7 32.4 49.3	Range (0-100) 29-95 4-92 30-100 12-100 20-100 0-100 28-88	
CognitionClock Drawing Test Score 1Sub-Clock Drawing Test Score 2Clock Drawing Test Score 3Clock Drawing Test Score 4Clock Drawing Test Score 5	optimal cognition	<b>N=87</b> 4 8 12 17 66	% 4.2 8.4 12.6 17.9	

#### Table I Baseline characteristics of the study population (n=95)

Remarks:

The number of drugs includes the number of tablets, powders, injections, drops, potions, plasters, ointments and creams, sprays, patches, suppositories and shampoo

Education is divided into four categories: lowest (primary school), low (e.g., LEAO and home economics), secondary (including junior high school) and high (HBS & MMS).

Caregivers included: sons/daughters (n = 26), partners (n = 12), acquaintances (n = 6), sisters (n = 1) and cousins (n = 1) Medication support consisted of managing, controling, handling, preparing, ordering, restocking, contacting the general practitioner and pharmacy, and administering and collecting of medicines.

Clock Drawing Test Score: 1 point for correct clock shape, 1 point for all figures in the correct order, 1 point for all figures in the right place, 1 point for two hands present, 1 point for the correct time depicted. Five points means optimal cognition

#### Medication management capacity (MMC)

The internal consistency of the 17-item MMC was good (Cronbach's  $\alpha$  = 0.86). The median score was 13, 51.6% (n = 49) of the patients were capable to manage their own medication. About 40% of participants were unable to tell which medications they used, even with the aid of a medication list, and 50% did not check their medications after delivery. In addition, 50% of the patients did not contact their GP or pharmacy when they thought that something was wrong with their medication. Nearly 25% of the patients indicated having problems opening drug packaging. Fewer than 50% of the patients checked the medication expiry date; however, most patients said they never used medications past their expiry date (Table II).

Age was correlated with the MMC score (Rs = 0.216; p < 0.005), indicating that MMC decreases with increasing age. Self-management ability (Rs = 0.473; p < 0.001) as shown in figure 1 and cognitive skills (Rs = 0.372; p < 0.001) were correlated with the MMC score. Patients with medication support scored lower on the SMAS30 (46.9; sd=11.8) than did patients without medication support (SMAS30=56.2; sd=14.3) (Data not shown in table). A significant biserial correlation with self-management was found for 8 of the 17 questions (Table II). Patients receiving medication support from an informal caregiver or the homecare organization scored lower on the CDT (3.7; sd=1.4) than patients without medication support

(CDT=4.5; sd=0.8). For 13 of the 17 questions in the MMC, a significant biserial correlation with cognition was found. There were 31 participants who stated to take medications that do not have to be taken daily, but for example weekly. Therefore, for 64 participants the statement 13 was inapplicable (Table II).

In the univariate analysis, only self-management ability and medication management support were significantly related with the MMC score. A high self-management score (> 55.00) was associated with a 22.0-fold (CI 6.1–83.0) higher likelihood of being able to manage medications as compared with the reference SMAS score of  $\leq$  42.17.

Patients without medication management support had a 9.9-fold (CI 3.9-25.5) higher likelihood of being able to manage their medications compared with patients with medication management support from homecare personnel or family.

# Table II. Medication management capacity as related to cognition and self-management (n=95)

- 1 I know what medication I use (possibly using a drug list)
- 2 I know the names of my family doctor and pharmacy
- 3 I can easily operate my phone
- 4 I make sure I order the medication on time in my house
- 5 I contact the pharmacy if my medication is not delivered (on time) or ask somebody to contact the pharmacy for me
- 6 I can easily read the pharmacy label on the packaging
- 7 I make sure the right drugs are delivered
- 8 I know how to distinguish between the different drugs I use
- 9 I contact my family doctor or pharmacy when I think something is wrong with my medication (name, strength, dosage) or ask someone to contact them for me
- 10 I contact my doctor when I think that a drug does not work or ask somebody to contact them for me
- 11 I contact my family doctor if I get unusual symptoms or ask somebody to contact them for me
- 12 I can get my medication out of the package (open boxes, free medicines from blister print, open and close bottles or, (Baxter) bags)
- 13 If I do not take medication daily, I take it on the correct days
- 14 I use my medication at the right times
- 15 I check the expiry date of my medication after opening
- 16 I never use old drugs
- 17 I follow the instructions on the label exactly (E.g., to be taken during a meal, with no milk, or not in combination with grapefruit juice)

<sup>\*</sup>Correlation is significant at p < 0.05 level (2-tailed)

Yes (N)	%	Correlation with cognition	P-value	Correlation self- management	P-value
58	61.1	0.4	0.001*	0.4	0.000*
86	90.5	0.4	0.000*	0.2	0.064
88	92.6	0.2	0.025*	0.2	0.093
57	60.0	0.4	0.000*	0.2	0.024*
64	67.4	0.3	0.002*	0.3	0.001*
81	85.3	0.1	0.348	0.1	0.884
48	50.5	0.2	0.052	0.4	0.000*
49	51.6	0.3	0.013*	0.4	0.000*
52	54.7	0.3	0.004*	0.4	0.000*
64	67.4	0.3	0.004*	0.1	0.198
65	68.4	0.3	0.004*	0.2	0.061
75	78.9	0.3	0.002*	0.3	0.010*
28	29.5	0.0	0.875	0.0	0.833
76	80.0	0.3	0.002*	0.3	0.004*
37	38.9	0.3	0.005*	0.1	0.160
91	95.8	0.0	0.921	0.0	0.630
79	83.2	0.3	0.013*	0.175	0.091

Predictor variable	Unadjusted (univariate	)	
	OR	(	CI 95%
Age	0.94	0.87	1.01
Gender <sup>a</sup>	1.95	0.82	4.67
Number of medications	1.00	0.87	1.15
Self-management ability score in tertiles:			
Low (Score ≤ 42.17)	1	re	ference
High (Score > 55.0)	22.50	6.10	83.02
Medium (Score > 42.17 and ≤ 55.0)	5.40	1.66	17.56
Clock drawing test			
Score <5	1	re	ference
Score 5	2.01	0.85	4.72
Education			
Level:			
Lowest	1	re	ference
Low	2.04	0.71	5.91
Moderate	1.86	0.65	5.29
Highest	1.57	0.42	5.85
Medication Management Support <sup>b</sup>	9.90	3.85	25.50
Living situation <sup>c</sup>	1.61	0.68	3.81

## Table III Factors related to the medication management capacity (n=95)

a. Coding male as the reference in logistic regression analysis.

b. Coding no medication management support as reference in logistic regression analysis

c. Coding living alone as the reference in logistic regression analysis



Medication Management Capacity.

## Discussion

Nearly half of the elderly patients included in this study were not able to manage their medications. If older homecare patients do not know what medication they use or do not know how to distinguish between the different drugs they use, they cannot be alert to signs or symptoms, which can lead to avoidable adverse events. Therefore, it continues to be an issue that requires rigorous alertness by general practitioners, pharmacists and homecare workers.

Cognitive and self-management skills were correlated with the ability to manage medications, only self-management ability and medication management support were significant independent predictors of medication management capacity. Several studies have addressed the association between cognitive skills and medication management capacity<sup>[4,7,9,18]</sup> in accordance with our study. Even mild changes in cognitive function can have impact on the person's ability to selfmanage medication<sup>[19]</sup>. This emphasizes the need for early recognition and good observation skills of impaired cognition by (home) health care professionals. In another study Edelberg et al.,<sup>[20]</sup> demonstrated an association between a change in medication management capacity with the need for increased homecare services, which compares to the results in this study. Lui et al., [21] suggested that abilities related to decisions on medication management are impaired before the clinical diagnosis of dementia is made. This also requires alertness from the (home) healthcare professional in an early stage. With higher levels of selfmanagement ability older people will better be able to maintain an independent and autonomous lifestyle for a longer period of time<sup>[22,23]</sup>.

To our best knowledge there are no other studies regarding the association between self-management ability and medication management capacity. Therefore, this should be examined in further research.

The study had some shortcomings that could have influenced our findings. Findings might be biased because patients were contacted by telephone, or because only patients with good cognitive skills participated in the study, which could have led to an overestimation of the medication management ability of homecare patients. Although most studies use the Mini-Mental State Examination (MMSE) <sup>[24,25]</sup>, we used the CDT to assess cognition because the test is easy to administer and has high sensitivity and specificity and minimal interviewer bias. Moreover, the CDT is highly correlated with the MMSE<sup>[15]</sup>. We measured patients' ability to manage their medication with the MMC, an instrument that is commonly used in clinical practice but which has not previously been used in research.

We used the median MMC value as the cut-off point in the logistic regression analyses because there is no information on acceptable cut-off scores for the MMC. However, it could be argued that answering one question with no on the MMC is an indication that additional medication support is required. In general, patients who responded with one to three no responses on the MMC had lower scores for cognitive and self-management abilities than did patients who had no no responses (i.e., they could manage their medication without assistance). Therefore, using a cut-off of 94% (one no response), 88% (two no responses), or 82% (three no responses) would not have significantly affected the results.

To our knowledge this is the first study to explore the medication management skills of the older old with polypharmacy. The strength of this study is the high average age of the population. Moreover, the association between self-management ability and medication management capacity give not only clues for further research but also for clinical practice indicating patients at risk for medication problems.

Self-management is suggested to help older people manage their own aging process by increasing the availability of coping resources so that their wellbeing is improved and maintained for longer<sup>[26]</sup>. Self-management interventions may best be aimed at older adults who are beginning to experience problems, rather than at those with serious problems that have already resulted in substantial loss<sup>[27]</sup>. For this reason healthcare providers should be alert to the deterioration of selfmanagement abilities among older adults on polypharmacy, which could be a sign of medication mismanagement.

The mean SMAS score in this study was slightly higher than 50% of the maximum possible score; which could be an explanation of the low medication management capacity scores. It could be argued that interventions that provide self-management support may be effective in improving the medication management capabilities of older patients. Homecare professionals, in their roles as caregivers, educators, and administrators of medication, are particularly well placed to act in a proactive manner to address potential medication-related problems<sup>[28,29]</sup>.

Practical problems with medication (distinction between different drug package, tablet swallowing and splitting, blister opening) could easily be resolved by health professionals by proactive enquiry<sup>[30]</sup>. Besides, these professionals should be trained to recognize a decrease in self-management abilities as a threat to safe, independent medication management. Such independence is desirable because it potentially avoids medication-related problems that can lead to infirmity, a decreased quality of life, hospitalization, or even death <sup>[5,31]</sup>. In our study, the patients without medication management support were better able to manage their medications than were the patients with medication management support from homecare personnel or family.

This implies that patients who were able to manage their medication themselves, in general did not use medication management support. Consequently, the patients with medication management support were less able to manage their medication themselves, which justifies this support.

Assessment of the capability of elderly homecare patients to manage their medications without help, should be an integral part of homecare, and a deterioration of this ability should be considered an alert for potential medication-related problems in these patients. A tool for the assessment of the capability is the MMC, which is widely used in senior and nursing homes in the Netherlands. However, it should be validated for homecare settings. The MMC is quick and easy to administer, which is important for use by homecare employees and other caregivers.

Further research is necessary to explore the effect of early recognition of potentially adverse drug events and deteriorated self-management ability by homecare workers.

## Conclusion

A considerable proportion of independently living older people who receive homecare and regularly use five or more medications lack the knowledge and skills needed to independently manage their own medications. Cognition and selfmanagement ability were related to medication management capacity. Selfmanagement ability and medication management support were predictors of medication management capacity.

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# Chapter 3

Homecare workers' knowledge and attitude and Medication Management Practices regarding medication



# Chapter 3.1

Homecare workers' Medication Management Practices and the association between Practices and self-reported knowledge and educational needs

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## Abstract:

Of the homecare workers who responded the cross-sectional survey (n=507) to assess medication management practices, 89.1% of the registered nurses, and 84.2% of the assistant nurses indicated that they provided information about medication to their patients' daily. Furthermore, 66.3% of the registered nurses and 53.1% of the assistant nurses indicated to observe their patients' non-adherence to their medication during regular care, and 46.1% of the registered nurses and 30.4% of the assistant nurses indicated to observe their patients' adverse drug reactions in their daily work. More than half (55.3%) of the registered nurses and 44.3% of the assistant nurses said their knowledge of medication was sufficient, and 65.3% and 60.8% respectively said they needed more education in medication. Homecare workers are involved in medication management in daily practice. Knowledge about medication-related problems and multidisciplinary collaboration in integrated care could be key issues in improving medication management by homecare workers.

## Introduction

In the Netherlands, the majority (82%) of patients who receive homecare are 65 years of age or older<sup>[1]</sup>. Due to their multi-morbidity associated with polypharmacy and diminished adaptive capacity, older homecare patients are especially vulnerable to medication-related problems<sup>[2-8]</sup>, like over- and under-use of (inappropriate) medicines, non-adherence and adverse drug reactions [5,9-12][9,10,13]. General practitioners and pharmacists can play an important role in preventing these problems by appropriately prescribing and regularly reviewing the medication use of their older patients<sup>[14-19]</sup>. Potentially inappropriate prescriptions for older people are a well-documented problem and have been associated with adverse drug reactions and hospitalization<sup>[20-25]</sup>. Beers' criteria<sup>[26,27]</sup>, Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP)<sup>[28]</sup> and Screening Tool to Alert doctors to Right Treatment  $(START)^{[29-31]}$ , are screening tools that have been developed to identify potentially inappropriate prescriptions and potential prescription. Medication reviews have been proposed as an important strategy to constrain the negative effects of polypharmacy, aiming at a safer and more effective use of medicines<sup>[25,32-35]</sup>.

Although considerable research has been done on how general practitioners and pharmacists can improve medication management, there has been only limited research on the role of homecare nurses in medication management. A few studies have shown that involving nurses in medication management can improve the identification rate of adverse drug reactions and patient outcomes<sup>[4,36-41]</sup>.

Two cross-sectional studies in homecare showed<sup>[4,42]</sup> that the most common side effects observed by homecare workers involved the central nervous system (confusion, drowsiness, stupor, weakness, depression and sleepiness).

A study by Griffith[43] examined the effect of how community nurses assessed medication regimen complexity, medication knowledge, medication management ability and uses of compliance aids and adherence in a small group of older people receiving homecare. This study demonstrated that community nurses identify clients experiencing problems with medications. Therefore, in their unique roles as caregivers, educators, and providers of medication management<sup>[44-46]</sup>. Due to regular contact with the patient in his or her own home, homecare nurses are able to observe changes in the patients' health status. However, it is less clear whether medication management activities such as providing medication information, monitoring medication adherence and ensuring drug safety are regularly performed by homecare workers in the Netherlands.

### Aim

The aim of this study was to examine the homecare nurses' medication management practices and to assess the association between these practices and the self-reported knowledge and educational needs of homecare nurses in the Netherlands.

### Methods

#### Design and participants

The target study population of this cross-sectional survey consisted of all Dutch homecare workers who were members of the national professional organization of primary care nurses (V&VN primary care department; n=1219) and homecare workers of the Dutch homecare organization 'Buurtzorg' (n=3750). There were 132 homecare nurses from "Buurtzorg" who were also members of the national professional organization of primary care nurses. Therefore, the target study population consisted of n=4837 homecare workers. Participation of the homecare workers in this study was entirely voluntary.

All participants were extensively informed about the study through a written introduction. Consent was assumed through the participants' submission of the electronic questionnaire. The anonymity of the respondents was guaranteed, and it was not possible to trace the answers back to the participants. The data obtained from the participants was used only for this study. Participants were informed that all findings would be reported as group results and would be submitted for publication.

## Questionnaire

The electronic questionnaire of nurses' practices regarding medication developed by Dilles et al.<sup>[47]</sup> was used with permission in the present study. This Flemish questionnaire, which was adapted to the Dutch situation, consists of 29 questions. After questions about age, gender, education, function level and work experience, the participants were asked about the frequency of contact with both general practitioners and pharmacists about the medication of their clients. Subsequently, the participants were asked about how they currently provided drug information, observed non-adherence and observed adverse drug reactions (ADRs). Homecare workers who provided drug information were further questioned about their sources of information. Those who had observed non-adherence or an ADR were queried about their ensuing actions. Finally, the respondents were asked to give their opinion on two propositions on a five-points Likert scale: "My knowledge about medication is sufficient" and "I need medication education". Multiple responses were permitted. The questionnaire was placed on two websites: the website of the Dutch national professional organization of primary care nurses and the website of the homecare organization 'Buurtzorg'. The homecare workers were notified of the questionnaire by a Twitter message and invited to open a link on the websites to the questionnaire. On average it took five minutes to complete the questionnaire.

### Data analyses

The data were processed and analyzed using SPSS 21.0 for Windows statistical software (SPSS Inc., Chicago, IL, USA). Descriptive statistics with frequencies and percentages were used to answer the objective of the study. Differences between function level, knowledge and education needs and medication management practices (providing information about a drug, observing non-adherence and observing ADRs) were calculated with Pearson's Chi square tests.

## Results

#### Characteristics of the convenience sample

A total of 507 (10.5 %) homecare workers answered the electronic questionnaire. The respondents were notified of the questionnaire by the website of the Dutch national professional organization of primary care nurses (9.6%), by the website of the homecare organization 'Buurtzorg' (35.9%), by colleagues (36.3%) or by different channels (18.2%). The mean age of the respondents was 44.8 (sd 10.8), with a range between 19 and 65. Most respondents were female (98.2%). The homecare workers were divided into registered nurses (RNs:n=349; secondary vocational education and bachelor nurses) and assistant nurses (ANs: n=158; licensed practical nurses, assistant nurses and students), as shown in Table 1. RNs and ANs did not significantly differ in mean age, work experience in nursing or work experience in homecare.

More than half of the respondents (55%) were engaged in continuing education (geriatric care, diabetic care, wound care, palliative care, stoma care, chronic obstructive pulmonary diseases care (COPD), heart failure care and several other courses). RNs were significantly more engaged in continuing education than ANs (Chi square: 0.263; p=0.03).

Table 1. characteristics of the sample (1-507)		
Age (years, sd)	44.8	10.8
Female (%)	498	98.2
<b>Assistants Nurses</b> (n, %) Licenced Practical Nurses Assistent nurses Students	<b>158</b> 144 4 10	<b>31.2</b> 91.2 2.5 6.3
<b>Registered Nurses</b> (n, %) Secondary vocational education Bachelor Nurse	<b>349</b> 142 207	<b>68.8</b> 40.7 59.3
Engaged in continuing education (n, %)	228	55.0
Years of experience in nursing (mean, sd)	19.5	11.3
Years of experience in homecare (mean, sd)	11.3	10.1
Working in rural area (n, %)	242	47.7
Working in urban area (n, %)	265	52.3

Table 1: Characteristics of the sample (n=507)

sd=standard deviation, n= number.
#### Current practice regarding medication management in homecare

In 50%-100% of the cases studied, almost half of the homecare workers (48.7%) gave medication to their patients. On average one in nine homecare workers (11.6%) said they prepared the medication for 50% to 100% of their patients. A few homecare workers (4.1%) said they filled pillboxes for 50%-100% of their patients. Respectively 89.1% and 84.2% of the RNs and ANs indicated that they provided information about a drug in their daily practice (Table 2). The patient's package insert was mentioned as the most frequently used source of information (respectively 80.7 % and 92.5 %) for the homecare workers, followed by consulting the pharmacist (respectively 65% and 69.9 %) and trusting in their own knowledge (48.2% and 57.1%). Almost half of the respondents mentioned internet as a source of information about a drug. There was no significant difference between function levels (RN or AN) and providing information about a drug (Chi<sup>2</sup>=2.434; df=1; p = 0.119).

Two-thirds of the RNs (66.3 %) and more than half of the ANs (53.1%) stated that they observed non-adherence by their patients during regular care. Threequarters of the homecare workers said they reported this non-adherence in the nursing record. When non-adherence was observed, more than a quarter of the RN respondents alerted the general practitioner or the primary nurse. Most homecare workers (respectively 69.6% of the RNs and 75.3% of the ANs) said that they had told their patients how important adherence was. More than half of the homecare workers who said they had observed non-adherence stated that they had checked drug intake. There was a significant difference among homecare workers between their function levels and observing non-adherence ( $Chi^2=6.774$ ; df=1; p = 0.009) as well as between observing non-adherence and their self-reported sufficient knowledge about medication ( $Chi^2=5.077$ ; df=1; p < 0.05). RNs indicated more often than ANs that they had observed non-adherence.

Almost half of the RNs (46.1%) and almost one-third of the ANs (30.4%) said they had observed possible ADRs in their daily work. Most of the homecare workers who indicated observing ADRs during regular care also reported this in the nursing record (respectively 80.7% and 68.8%). In addition, well over half of the RNs (62.1%) and 54.2% of the ANs said they had contacted the general practitioner about the observed ADR. Respectively, 8.1% of the RNs and 6.3% of the ANs advised the patient to stop taking drugs after having observed an ADR. Finally, about 15% of the respondents indicated that they had told the primary nurse about an observed possible ADR. There was a significance difference between the homecare workers' function levels and their observation of ADR ( $Chi^2=10.920$ ; df=1; p= 0.001); RNs indicated an observed ADR more often than did ANs. There was also a significant difference between homecare workers who observed ADRs and the continuation of education after graduation Homecare workers who stated to observe ADRs, significantly more often continued education after graduation ( $Chi^2=7.424$ ; df=1; p < 0.05).

Table 2. Hometare workers' metrication management practices							
	<b>Registered</b> Nurse n=349		Assistant Nurse n=158				
	n	%	n	%			
Providing information about a drug	311	89.1	133	84.2			
If yes: sources used to provide information to the patients and their families (multiple answers possible)							
Trusted in own knowledge Used patient package insert Consulted Repertorium Consulted internet Consulted the primary nurse Consulted the GP Consulted the pharmacist	152 251 67 139 17 79 202	48.9 80.7 21.5 44.7 5.5 25.4 65.0	76 123 28 66 4 48 93	57.1 92.5 21.1 49.6 3 36.1 69.9			
Observing non-adherence	230	66.3	85	53.1			
If yes: interventions following the observation of non-adherence (multiple answers possible)							
No intervention undertaken Pointed out importance of adherence to patient Checked drug intake Reported in nursing record Reported to the primary nurse Reported to the GP	7 160 119 168 65 65	3.0 69.6 51.7 73.0 28.3 28.3	1 64 44 64 23 16	1.2 75.3 51.7 75.3 27.1 18.8			
Observation of an adverse drug reaction	161	46.1	48	30.4			
If yes: interventions following the observation of an adverse drug reaction (multiple answers possible)							
No intervention undertaken Advised to stop taking drugs Reported in nursing record Reported to the primary nurse Advised the patient to contact GP Contacted the GP myself	7 13 130 26 78 100	4.3 8.1 80.7 16.1 48.5 62.1	1 3 33 7 20 26	2.1 6.3 68.8 14.6 41.7 54.2			

#### Table 2. Homecare workers' medication management practices

# *Contact between homecare worker, general practitioner and pharmacist about medication.*

Almost a quarter (23.8%) of the RNs and 13.9% of the ANs indicated having verbal contact with the general practitioner about medication at least once a week. The percentages of homecare workers who indicated having contact with the general practitioner about medication, at least once a month, are 42.7% (RNs) and 35.7% (ANs) respectively. More homecare workers stated having at least weekly contact with a pharmacist about their patients' medication (34.7% and 27.2% respectively), as shown in Table 3.

#### Assistant Registered Nurse Nurse n=349 n=158 % % n n Continuing education after graduation 22.8 144 41.3 36 I know which medications my patients 74.2 63.9 259 101 are using My knowledge about medication is 193 55.3 44.3 70 sufficient I need medication education 228 65.3 96 60.8

#### Table 3: Knowledge and education about pharmacotherapy (N=507)

#### Knowledge and education regarding medication management

More than half of the RNs (55.3%) and 44.3% of the ANs labeled their medication knowledge as sufficient. Respectively, 65.3% of the RNs and 60.8% of the ANs indicated a need for medication education. There was a significant difference (Chi<sup>2</sup>=5.418; df=1; p=0.020) between function level (RN or AN) and self-reported knowledge about medication. More RNs (41.3%) than ANs (22.8) continued their education after graduation. One-quarter of the RNs and one-third of the ANs said they did not know which medication their patients were using. Almost half of the homecare workers who said they provided information about drugs stated that they had insufficient medication knowledge (Table 4).

	<b>RN</b> n=349		<b>AN</b> n=158	
	n	%	n	%
<b>Verbal contact General Practitioner</b> at least once a week at least once a month less than once a month never	83 149 107 10	23.8 42.7 30.7 2.9	22 56 63 17	13.9 35.4 39.9 10.8
<b>Verbal contact with pharmacist</b> at least once a week at least once a month less than once a month never	121 148 69 11	34.7 42.4 19.8 3.2	43 54 51 10	27.2 34.2 32.3 6.3

# Table 4: Contact between homecare workers, general practitioners and pharmacists

RN; Registered Nurse. AN; Assistant Nurse

#### Discussion

This study demonstrates that homecare workers are involved in medication management by providing information about drugs and observing non-adherence and adverse drug reactions in their patients on a daily basis. However, a quarter of the RNs and a third of the ANs in the present study indicated not knowing which medication their patients were using, knowledge that is necessary in providing information and observing potential ADRs and non-adherence. In addition, on average half of the homecare workers did not trust their own knowledge about medication and indicated that their medication knowledge was insufficient. The majority of the homecare workers indicated a need for medication education. Previous studies have shown that nurses are inadequately prepared and lack sufficient knowledge to be capable of observing and recognizing medication-related problems <sup>[47-55]</sup>.

Although homecare workers are particularly well positioned in the home to act preventatively and alertly to their patients' non-adherence and adverse drug reactions, they need knowledge about drug-related problems to recognize these observations at an early stage in the home environment.

This study, which correlated continuing education after graduation and the observation of ADRs and non-adherence, shows that knowledge and education could be key issues in improving medication management by homecare workers.

In the present study, a considerable number of homecare workers said they had observed non-adherence and ADRs and had reported this in the nursing record.

Using the reports of homecare workers themselves, previous studies demonstrated that these nurses were able to recognize and report adverse drugs events<sup>[36,37,46]</sup>.

However, these studies lacked information about the nurses' self-reported medication knowledge or education needs. Observations of non-adherence or ADRs need to be reported to the prescriber and/or provider to be effective.

Remarkably, only half of the homecare workers who observed an ADR indicated having reported this to the general practitioner and primary nurse. Previous studies demonstrated the impact of collaboration between nurses and pharmacist on reporting ADRs<sup>[56,57]</sup>. Therefore, homecare organizations should invest in integrated care and train their nurses to collaborate with pharmacists and general practitioners. Homecare workers could function as the eyes and ears of the general practitioner and pharmacist. The homecare patient's primary nurse could play an active role in this collaboration.

As mentioned earlier, the questionnaire used in this study was developed and used before by Dilles and colleagues<sup>[47]</sup>. In a cross-sectional correlation survey, they included 82 community care nurses. A comparable percentage of 82.9% of the community care nurses in the Flemish study said they had provided information about a drug (versus an average of 86.7% in the present study). Furthermore, a comparable percentage (40.2 versus an average of 38.3 in the present study) said they had observed adverse drug reactions.

However, in comparison with the current study, a higher percentage of the Flemish community nurses said they had observed non-adherence. In both studies a higher education level coincides with a greater involvement in identifying adverse drug reactions.

#### Study strength and limitations

It is important to consider a number of study strengths and weaknesses when interpreting the findings. First, this study was a convenience sample. It is possible that the homecare workers who responded to the questionnaire were better informed and more up-to-date regarding medication management than the average Dutch homecare worker, which could implicate an overestimation of the homecare nurses' medication management practices. A clear description of nonrespondents is lacking.

Further, the response rate was low (10.5 %). This low response rate reduces the generalizability of the findings of the study. Theoretically, n = 4837 homecare workers could have been reached. However, it is very likely that not all potential participants read the invitation to complete the questionnaire on the website. On the other hand, 507 respondents is not a small population and is larger than other studies on homecare nurses' medication management practices, such as studies by Dilles (n=82) and Ellenbecker (n=101).

Further, the original questionnaire was kept quick and simple, which increased the response. However, information about other observations regarding medication-related problems, like intake problems, swallowing problems, or opening packaging, is lacking. Therefore, the questionnaire should be improved and extended.

Finally, we did not measure the current practice of homecare workers regarding medication management, but asked the respondents about their current practice. Therefore, despite the anonymity of the questionnaire and instructions, socially desirable answers are possible because of the self-report method.

#### Conclusion

Homecare nurses' medication management practices consist of handing over medication, providing information, observing non-adherence and observing ADRs. Almost all homecare workers said they provided information about drugs to their patients although their trust in their own medication knowledge was lacking and they said they needed medication education. Therefore, homecare organizations should consider their (educational) policy regarding medication safety. To be effective, the homecare nurses' observations of non-adherence or ADRs need to be reported to the prescriber and/or provider. Therefore, homecare organizations should intensify their collaboration with pharmacists and general practitioners. In summary, knowledge about medication and multidisciplinary collaboration in integrated care could be key issues in improving medication management by homecare workers. Further research is required into the effect of observations by homecare workers on non-adherence and potential ADRs in homecare patients.

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#### **Conflict of interest**

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#### Author contribution

CS, TE and MS were responsible for the study conception and design. CS performed the data collection. CS performed the statistical analysis, under supervision of MS. CS was responsible for the drafting of the manuscript. TE and MS made critical revisions to the paper for important intellectual content. TE and MS supervised the study.

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## Chapter 3.2

# Knowledge and perspectives of Dutch home healthcare nurses regarding medication frequently used by older people

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#### Abstract

#### Background

Home healthcare nurses in their roles as caregivers, educators and administrators of medications are particularly well positioned to act on a preventive way to be alert of adverse drug reactions. However, knowledge about medication and a professional attitude is required.

#### Aim

To describe medication-related knowledge and perspectives of Dutch home healthcare nurses regarding frequent used medication by older people.

#### Method

A cross-sectional study was conducted among home healthcare nurses (n=146) in the Netherlands based on the ten most frequently used drugs by older people.

#### Finding

The mean score for total medication knowledge was 76.2% of the maximum score. Most home healthcare nurses (80.3%) felt responsible for improving older patients' medication use. Three-quarters of the home healthcare nurses agreed with the statement: "By taking appropriate action at the right time, I am able to prevent a medication-related hospital admission".

#### Conclusion

Although most home healthcare nurses felt responsible for their older patients' proper medication use and agreed with the statement that they played a role in preventing older patients' medication-related hospital admissions, their knowledge regarding medications could be improved.

#### Implications for practice

Home healthcare nurses should profit as a professional from gaining more knowledge of medication frequently used by older people.

#### Background

Due to increasing life expectancy, the proportion of the population over 65 years of age has increased significantly since the beginning of the twentieth century. The current 14% of older people in the Dutch population will have increased to 21% by 2025 (Blokstra et al., 2007). In the Netherlands, drug consumption in this group is three times higher than the national average. For people aged 75 and older, this consumption even increases to four times the level of the average Dutch person (SFK, 2008).

In the Netherlands the majority (82%) of the patients who receive home healthcare are 65 years of age or older (Velden van der et al., 2011).

Due to their age-related medication use, older (home healthcare) patients are vulnerable to medication-related problems, like over- and under-use of (in-appropriate) medicines, as described by Parsons and colleagues (Parsons et al., 2011). General practitioners and pharmacists can play an important role in avoid-ing these problems by regularly reviewing the medication of their older patients (Stuijt, 2008; Vinks, 2009).

Nurses' involvement in drug-safety monitoring is also believed to improve the identification rate of adverse drug reactions and patient outcomes (Ellenbecker et al, 2004, Nakanichi 2006; Ulfvarson, 2007; Backstrom, 2007). Besides, nurses can play a role in medication management in transitional care (Setter et al, 2009; Setter et al, 2012; Corbett et al, 2010). However, previous studies have shown that nurses are inadequately prepared and lack sufficient knowledge to be capable of observing and recognizing medication-related problems (Ives et al., 1997, King 2004, Grandell-Niemi et al., 2005, 2006, Offredy et al., 2008; Ndosi & Newel, 2008, Sulosaari et al., 2010; Dilles, 2011). Lim and colleagues (2010) identified the need to improve nurses' pharmacological knowledge, medication administration and management in healthcare facilities for older people.

As elaborated in the study of Arnold (Arnold, 1999) and Kovner and colleagues (2005), nurses in their roles as caregivers, educators and administrators of medications are particularly well positioned to act preventatively and alertly to adverse drug reactions in their older patients. However, knowledge about medication, side effects and interactions are required for nurses to recognize these adverse drug reactions at an early stage in older people at home. In the Netherlands there are two levels of home healthcare nurses: nurses with vocational education (bachelor's degree).

To our best knowledge, there is no information about the medication-related knowledge and perspectives regarding the medication of older people in the two levels of home healthcare nurses.

#### Objective

The aim of this study was to describe the current knowledge and perspectives among home healthcare nurses with regard to medication frequently used by older people. The results of this survey could give insight into the possibilities of the home healthcare nurses in recognizing medication-related problems at an early stage.

Table 1: Top 10 medicines most commonly used by persons 75+ years of age

1	Furosemide
2	Acetylsalicylic acid
3	Carbasalate calcium
4	Temazepam
5	Oxazepam
6	Paracetamol
7	Metoprolol
8	Omeprazole
9	Digoxin
10	Lactulose

Foundation of Pharmaceutical Statistics, 2003

#### Method

This paper is a report of a study to describe the level of knowledge and perspectives of Dutch home health care nurses regarding medication frequently used by older home healthcare patients.

#### Design

A cross-sectional survey was conducted using an electronic questionnaire administered via the internet.

#### Participants

The study population consisted of Dutch home healthcare nurses (with vocational education or with a higher vocational education/bachelor's degree) who were members of the national professional organization of primary care nurses and choose to participate in this study (N=146). These home healthcare nurses were asked by email, newsletters and website requests to participate in the study. The criterion for inclusion was that the nurses had to meet homecare patients on a daily basis.

#### The questionnaire

To gain insights into the knowledge of home healthcare nurses towards medication-related issues for older people, the 'Home Healthcare Nurses and Medication Questionnaire' was used. This questionnaire was developed in 2005 (Van Vliet & Rutgers); it contains twenty-nine questions on medication knowledge. The authors extended the questionnaire with nine statements of perspectives towards medication-related issues with a 5-point-Likert scale ranging from 'strongly disagree' to 'strongly agree'. The questionnaire in the Dutch language starts with questions regarding demographic characteristics such as sex, age, highest education level and years of work experience in home healthcare.

The basis for the knowledge questions in the questionnaire were the ten drugs most frequently used by persons older than 75 in the Netherlands according to the Dutch Foundation for Pharmaceutical Statistics *(Table 1)*. From these ten most commonly used medications, twenty-nine multiple choices questions about nurses' knowledge were formulated and divided into five questions about drug interactions (50 points), sixteen questions about side effects (160 points) and eight questions about (contra) indications (80 points). For the entire questionnaire, a maximum of 290 points could be scored (10 points per question). The contents of the perspectives statements were based on literature.

Statements on responsibility, self-confidence and fear regarding medication-related issues were formulated. The face validity of the questionnaire was judged by a panel of experts (five home healthcare nurses and two nursing scientists) and tested for feasibility in a pilot by nine bachelor nursing students in their fourth year just before graduation (Bouzariouh, 2006). After the questionnaire had been minimally modified, based on the judgement of the expert panel and the pilot, the developers of the questionnaire agreed on the appropriateness of the contents and the cut-off scores.

#### Data collection

The 'Home Healthcare Nurses and Medication Questionnaire' was introduced to the department of primary care nurses in December 2008 in several ways. Firstly, the introduction started with an announcement in the magazine for members of the primary care nurses association with a request to fill in the questionnaire. All members received this magazine in their mailbox. Secondly, members with an updated email address also received an electronic newsletter that highlighted the research and contained a direct hyperlink to the questionnaire. Finally, members who visit the website of the primary care nurses association were asked to fill in the questionnaire that was attached in a hyperlink. After one month (January) and after two months (February) a reminder was sent by email to all the members of the primary care nurses association. The data collection started in December 2008 and was completed in March 2009.

#### Ethical considerations

Participation of the home healthcare nurses in this study was entirely voluntary. All participants were extensively informed about the study through a written introduction. Consent was assumed through the participants' submission of the electronic questionnaire. The anonymity of the respondents was guaranteed, and it was not possible to trace the answers back to the participant. The data obtained from the participants was used only for this study. Participants were informed that all findings would be reported as group results and would be submitted for publication.

#### Data analysis

Data was analyzed using SPSS for Windows version 14.0. Demographic data and perspectives of home healthcare nurses regarding medication frequently used by older people were summarized using frequencies and percentages. The number of correct answers per category was calculated, including percentages, mean, range and standard deviation.

The relation between the outcome level of knowledge and age and years of experience was analyzed using linear regression. The association between level of education and level of knowledge was assessed with Spearman's coefficient. The relation between perspectives with regard to medication frequently used by older people (Fear yes/no, Responsibility yes/no and Self-confidence yes/no) and 'level of knowledge' of the home healthcare nurses was analyzed using logistic regression.

#### Results

#### Personal characteristics of sample

A total of 146 (18.25%) home healthcare nurses answered the questionnaire. The mean age of these nurses was 45 (sd 10.2), with a range between 18 and 61. The mean years of working experience in healthcare was 17.2 years (sd 11.0), with a range between 1 and 42 years. Almost all of the nurses (95.2%) were female. Most respondents (84%) had a bachelor's degree in nursing *(Table 2)*.

Table 2: Demographic characteristics (N=146)					
<b>Sex</b> Male Female	<b>N</b> 6 140	<b>%</b> 4.1 95.9			
<b>Age</b> 18 - 34 years 35 - 50 years 51 - 65 years	30 60 56	20.5 41.1 38.4			
<b>Nursing degree</b> Secondary Vocational Education Bachelor Degree Master Degree Other	18 123 3 2	12.3 84.2 2.1 1.4			
Working experience					
01 - 10 years 11 - 20 years 21 - 30 years 31 - 40 years 41 - 48 years	50 44 32 18 2	34.2 30.1 21.9 12.3 1.4			

Table 3: Knowledge of medication among home healthcare nurses (N=146)						
		N	%	Mean points	Range	sd*
A. Knowledg	e regarding interaction			38.8	26.5-47	4.7
5 Multiple Choice Questions (0-50 points)**						
Points	% Correct answers**					
0 - 25	(0-50)	0	0			
> 25 - 30	(>51-60)	5	3.4			
> 30 - 35	(>61-70)	33	22.6			
> 35 - 40	(>71-80)	35	24			
> 40 - 45	(>81-90)	66	45.2			
> 45 - 50	(>91-100)	7	4.8			
B. Knowledg	e regarding side-effects			123.8	100-152	11.3
16 Multiple (	Choice Questions (0-160	) point	s)**			
Points	% Correct answers**					
0 - 99	(>0-62)	0	0			
> 99 -110	(>63-69)	18	12.3			
>110 -120	(>70-75)	43	29.5			
>120 -130	(>76-81)	44	30.1			
>130 -140	(>82-88)	26	17.8			
>140 -150	(>89-94)	14	9.6			
>150 -160	(>95-100)	1	0.7			
C. Knowledge regarding (contra) indication			58.2	37.5-75	6.8	
		joints)	•••••			
Points	% Correct answers **	0	0			
0 - 34	(0-43)	0	0			
> 34 - 44	(>44-55)	4	2.1			
> 44 - 54	(250-08)	30 05	20			
> 54 - 04	(209-00)	0) 10	20.2 12.2			
> 04 - 74	(>01-93)	10	12.3			
> 74 - 00	(>94-100)	<u>+</u>	0.7	220.0	470 5 0 6 4 7	- 47 0
<b>10tal Knowledge (A+B+C)</b> 29 Multiple Choice Questions (0-290 points)**			220.9	1/3.5-204.5	) 1/.2	
Points	% Correct answers**					
0 - 170	(0-59)	0	0			
> 170 - 190	(>60-66)	5	3.4			
> 190 - 210	(>67-72)	32	21.9			
> 210 - 230	(>73-79)	65	44.5			
> 230 - 250	(>80-86)	37	25.3			
> 250 - 270	(>87-93)	7	4.8			
> 270 - 290	(>94-100)	0	0			

\*\*Min-Max score, \*\* Percentage correct answers on 'Home healthcare nurses and medication questionnaire'. \*sd: standard deviation

#### Level of knowledge of medication among home healthcare nurses

As shown in table 3 the mean score for total knowledge was 220.9 points (sd 17.2) out of a maximum score of 290 points, which implied 76% accuracy. The mean score for knowledge of drug interactions was 38.8 (sd 4.7) out of a maximum score of 50 points (77% accuracy), with a range between 26.5 and 47 points. The mean score for knowledge of side effects was 123.8 (sd 11.3) out of a maximum score of 160 points (77% accuracy). Finally, the mean score for knowledge of (contra)indications was 58.2 (sd 6.8) out of a maximum score of 80 points (73% accuracy).

#### Perspectives of home healthcare nurses regarding medication

The perspectives of home healthcare nurses regarding medication frequently used by older people were assessed by means of the answers to the nine statements related to feelings of fear, responsibility and self-confidence (*Table 4*). Almost half of the home healthcare nurses (47%) disagreed with the statement *"I sometimes experience actions involving medications as stressful"*, and almost a quarter (23%) of the respondents agreed with this statement. Most of the home healthcare nurses (80%) agreed with the statement *"When I observe that the medication is not being taken properly during a home visit, I feel responsible for improving this situation"*.

Most home healthcare nurses (82%) disagreed with the statement *"I am not the right person to identify the potential side effects of the medication"*.

Almost 60% of the home healthcare nurses agreed with the statement *"I feel confident when medication is part of the treatment visit"*. Another 18% the home healthcare nurses disagreed with this statement and 22% felt neutral. More than three-quarters of the nurses (78%) agreed with the statement *"By intervening in time, I can avoid a medication-related hospital admission"*.

#### Regression analysis and correlations

No linear relation was observed between the level of knowledge and age ( $r^2$ =0.00, p=0.945) and years of working experience ( $r^2$ =0.007, p=0.318). Also no association was observed between the level of knowledge and level of education (Spearman r=0.108, p=0.194). Nor was a relation observed between level of knowledge on the one hand, and perspectives of fear (p=0.942) responsibility (p=value 0.593) self-confidence (p=0.686). Effect of gender could not be analyzed because the home healthcare nurses were predominately female (95%).

### Table 4: Perspectives of home healthcare nurses (N=142) regarding older patients' medication use

	Disagree		Neutral		Agree	
Fear	N	%	N	%	N	%
I sometimes experience actions involving medication as stressful	67	47.2	42	29.6	33	23.2
I feel unsure if I unexpectedly have to help a patient take his/her medication	101	71.1	26	18.3	15	10.6
Sometimes I have the feeling that I incor- rectly inform patients about medication	95	66.9	32	22.5	15	10.6
Responsibility						
When I observe that the medication is not being taken properly during a visit, I feel responsible for improving this situation	17	12.0	11	7.7	114	80.3
It is the patient's own responsibility to take medication on time	37	26.1	52	36.6	53	37.3
I'm not the right person to identify potential side effects of the medication	117	82.4	11	7.7	14	9.9
Self confidence						
I feel confident when medication is part of the treatment visit	26	18.3	31	21.8	85	59.9
If I don't feel comfortable in a situation with medication, I will contact a general practi- tioner or a pharmacist immediately	10	7.0	5	3.5	127	89.4
By intervening in time, I can avoid a hospital admission for the patient	14	9.9	18	12.7	110	77.5

#### Discussion

Although the respondents were dealing with medication-related questions about the medication most frequently used by older people, only 30.1% of the nurses scored between 80%-100%.

These results are consistent with the findings of Ives et al. (1997), Kapborg and Svensson (1999), King (2002), Sohda et al. (2001), Sohda et al. (2002), Offredy et al. (2007). They found that the nurses' lack of knowledge in the areas of drug effects, side effects, indications, contra-indications and interactions could be improved.

This underscores the importance of emphasizing the need for better medicationrelated knowledge, particularly in home healthcare, where nurses typically work independently and polypharmacy related to the percentage of older patients is prevalent.

Knowledge of the interactions and side effects was better than the knowledge concerning the contra-indications. The lack of knowledge may make it more difficult for the home healthcare nurses to observe and instruct patients about their medications. Therefore, nursing education should prepare nurses to become competent professionals who can provide and improve the patients' quality of care (Banning, 2003). However, other studies have shown that pharmacological education is not at the required level (Latter et al., 2000b, Bullock & Manias, 2002).

Providing drugs information and monitoring drugs therapy are primarily seen as medical or pharmaceutical tasks. Medical doctors focus on making diagnoses and initiating therapy, whereas nurses focus on the consequences for the patient of these diagnoses and treatments. Medication-related problems can be seen as consequences of treatment. Therefore, observing the consequences of medication and giving early warnings of drug-related problems for the patient are definitely part of the nursing profession. According to Bulecheck et al (2007) medication management is pre-eminently a nursing intervention and described as the facilitation of the safe and effective use of prescription and over-the-counter drugs.

Dilles and colleagues (2010) demonstrated that nurses regularly engage in pharmacotherapeutic practices, such as providing drug information, monitoring treatment adherence and recognizing ADRs.

Based on the results, it appears that most home healthcare nurses feel responsible for their patients' medication use (80%). However, almost 20% of the home healthcare nurses did not agree with (12%) or were neutral (7.7%) toward the statement *"When I observe that medication is not being taken properly during a home visit, I feel responsible for improving this situation".* 

Almost a guarter (23%) of the home healthcare nurses sometimes experienced actions involving medication as stressful; this finding is consistent with what has been reported in the literature. Different studies have reported that nurses experience some fear when handling medication-related issues (Kapborg and Svensson, 1999; Grandell-Niemi et al., 2005; King, 2004). The results regarding self-confidence in relation to the patients' medication were comparable to other studies in the literature. It appears that home healthcare nurses did not have much selfconfidence with respect to medication. Previous studies have reported different findings in relation to the perspectives of nurses regarding medication. It was reported that nurses sometimes lacked self-confidence. Sohda et al. (2002) cited the number of years of experience as a probable cause of a lack of self-confidence regarding patients' medication use. We could not confirm this finding in our study. In our study, almost 60% agreed with the statement "I feel confident when medication is part of the treatment visit". Eighteen percent did not agree. A possible explanation for the nurses who disagree with the statement is that the system of medication administration is not clear to home healthcare nurses and needs to be improved. Most home healthcare nurses (77.5%) were convinced that they played a role in preventing patients' medication-related hospital admissions.

#### Limitations of the research

To appreciate the present results, a number of aspects need to be discussed with regard to the scope and limitations of this study. The Dutch Professional Association of Nurses and Caregivers (Verpleegkundigen & Verzorgenden Nederland) consists of several departments and groups including the Association of Primary Care Nurses. This study also included home healthcare nurses who were members of the Association of Primary Care Nurses. It is plausible that members of a professional association are better informed and more up-to-date on their medication knowledge than the average Dutch home healthcare nurse.

In addition, because of random sampling was not used, this could have introduced some selection bias in the results. The home healthcare nurse were invited collectively to participate, but the participants decided for themselves whether or not to participate. Because of this self-selection, it is plausible that more home healthcare nurses with greater interest, better knowledge and better perspectives on medication-related issues participated as compared to home healthcare nurses who were not interested in such issues. Consequently, the mean knowledge of the average home healthcare nurse in the Netherlands will likely be lower and the perspectives less positive than those of the average nurse in our study. In addition, the 'Home Healthcare Nurses and Medication Questionnaire' was electronically accessible. Because of this, the questionnaire could be opened at any time and place. This offered the respondents the chance to fill in the questionnaire with the help of outside information sources and colleagues. Because of this lack of control, there was the potential for information bias. We attempted to overcome this lack of control by collecting detailed, written participant information. Also, participants were asked not to fill in the questionnaire using extra sources of information.

Assuming the number of 800 members of the Association of Primary Care Nurses with an update email address, the response rate of 146 members (<20%) was low. This low response rate reduces the generalizability of the findings of the study, although this was expected given the similar response rate in the self-report survey of Mayo & Duncan (2003) and the questionnaire survey of Ives et al. (1996). Based on the description of the demographic characteristics of the respondents, the education levels were different from what was expected. For example, almost 80% of the respondents in this study had a bachelor's degree, unlike 5% of all of the home healthcare employees in the Netherlands (Velden van der et al, 2011). In addition, only 5% of the home healthcare nurses were male.

This is significantly lower than the national average of 15% male nurses (LEVV, 2008). This may have contributed to biased results.

We did not find a correlation between the demographic data and the knowledge or attitudes of the nurses regarding medication. It is possible that this was due to the small number of participants.

#### **Conclusion and recommendations**

Although most home healthcare nurses in this study feel responsible for promoting proper medication use by their older patients and agree with the statement that they play a role in preventing older patients' medication-related hospital admissions, their knowledge regarding medications could be improved. Nursing refresher courses, congresses, workshops and meetings are examples of venues where nurses can expand their knowledge of medication. The home healthcare nurses included are not always self-confident when taking actions to address their patients' medication-related issues. Further research in a larger population is recommended to investigate the association between medication-related knowledge and self-confidence in regard to handling medication-related issues.

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# Chapter 4

Early recognition of drug related problems



## Chapter 4.1

# The association between prescription change frequency, chronic disease score and hospital admission

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#### Abstract Backgroup

## Background

The aim of this study was to assess the association between prescription changes frequency (PCF) and hospital admissions and to compare the PCF to the Chronic Disease Score (CDS). The CDS measures comorbidity on the basis of the 1-year pharmacy dispensing data. In contrast the PCF is based on prescription changes over a 3-month period.

#### Methods

A retrospective matched case-control design was conducted.

10.000 Patients were selected randomly from the Dutch PHARMO database, who had been hospitalized (index date) between July 1, 1998 and June 30, 2000. The primary study outcome was the number of prescription changes during several three-month time periods starting 18, 12, 9, 6, and 3 months before the index date. For each hospitalized patient, one non-hospitalized patient was matched for age, sex, and geographic area, and was assigned the same index date as the corresponding hospitalized patient. We classified four mutually exclusive types of prescription changes: change in dosage, switch, stop and start.

#### Results

The study population comprised 8,681 hospitalized patients and an equal number of matched non-hospitalized patients. The odds ratio of hospital admission increased with an increase in Prescription Change Frequency (PCF) category. At 3 months before the index date from PCF=1 OR 1.4 [95%CI 1.3-1.5] to PCF= 2-3 OR 2.2 [95%CI 1.9-2.4] and to PCF  $\geq$  4 OR 4.1 [95%CI 3.1-5.1]. A higher CDS score was also associated with an increased odds ratio of hospitalization: OR 1.3 (95% CI 1.2-1.4) for CDS 3–4, and OR 3.0 (95% CI 2.7-3.3) for CDS 5 or higher.

#### Conclusion

The prescription change frequency (PCF) is associated with hospital admission, like the Chronic Disease Score (CDS). Pharmacists and other healthcare workers should be alert when the frequency of prescription changes increases. Clinical rules could be helpful to make pharmacists and physicians aware of the risk of the number of prescription changes.

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#### Background

Medication-related problems are responsible for 3–10% of acute hospital admissions, of which approximately half are potentially preventable<sup>[1-11]</sup>. Hospital admissions can lead to additional functional decline<sup>[12,13]</sup>, unintentional harm<sup>[14]</sup>, and increased costs. Medication monitoring and management are methods used to avoid medication-related complications.

In 2008, the Dutch HARM study group established seven independent risk factors for medication-related hospital admissions: (a) impaired cognition,

(b) four or more diseases in the patient's medical history, (c) dependent living situation, (d) impaired renal function before hospitalization, (e) non-adherence to medication regimen, (f) the use of five or more medications at the time of admission (polypharmacy), and (g) age over  $65^{[11]}$ . In the industrialized world, the proportion of the population that is 65 years or older is rapidly increasing. Elderly patients more often suffer from multiple morbidities, use more medications, and are treated by more healthcare professionals than younger patients<sup>[15]</sup>. Drug consumption is three times higher among people aged 65 years or older, and four times higher in people aged 75 years or older, than it is in people younger than 65 years. The majority of these drugs are taken chronically (www.SFK.nl). The increased use of prescription drugs by the elderly is a consequence of their longer lifespan, their increasing use of health services, and the availability of new drugs<sup>[16]</sup>. From a clinical perspective, prescription changes are a risk factor for medication-related hospital admission. During the course of a disease, it may be necessary to change the dosage of medication, to switch to a similar medication, to temporarily withdraw the drug, or to start a new drug. With the exception of the study of Koecheler<sup>[17]</sup>, who reported 'medication regimen changes in four or more times during the past 12 months' to be one of the six prognostic indicators for identifying ambulatory patients who need pharmacist monitoring, there have been no other studies that evaluated the association between the number of prescription changes and hospital admission. For this reason, we investigated whether the frequency of prescription changes is associated with hospital admission, and, if so, whether the strength of this association changes in the months before hospital admission.

The Chronic Disease Score (CDS), a well-established instrument to predict hospital admission, measures comorbidity on the basis of the 1-year pharmacy dispensing data for 17 (therapeutic groups of) somatic medications intended for chronic use<sup>[18]</sup>. The latter makes the CDS a static instrument. In contrast, the Prescription Changes Frequency (PCF) is based on prescription changes over a 3-month period. The objectives of this study were (1) to assess the association between the PCF and hospital admission at different times before admission and (2) to compare the PCF with the CDS for predicting hospital admission.

#### Methods

#### Study design and setting

This retrospective, matched case-control study used with permission data from the Dutch PHARMO Record Linkage System (RLS)(www.pharmo.nl). The PHARMO RLS includes the dispensing records of community pharmacies linked to hospital discharge records. It consists of a representative sample of more than 200 community pharmacies in more than 50 regions throughout the Netherlands and is representative for the Netherlands<sup>[19].</sup>

It currently includes data for more than 2 million residents (12% of the Dutch population) regardless of the type of medical insurance. The computerized pharmacy dispensing records contain information about drugs dispensed, dispensing date, prescribing physician, amount of drug dispensed, and prescribed dosage regimen. Patient information includes sex and date of birth.

Each patient is assigned an anonymous unique patient identification code and each medication is also given a unique code, according to the Anatomical Therapeutic Chemical (ATC) classification system. This makes it possible to track drug therapy and changes in drug therapy over time. The database does not record the indication for which a medicine is prescribed and neither does it include all medications used because non-prescription products can be purchased over-thecounter.

#### Cases and Controls

Initially, 10,000 patients who had been hospitalized for the first time of possible repeated hospitalizations between July 1998 and June 2000 were randomly selected from the PHARMO RLS. The date of hospital admission was considered the index date. Each hospitalized patient was matched (by age on birthday, sex, geographic area per pharmacy catchment area) with a control patient who was assigned the same index date. Patients were included if medication data were available for at least 24 months before the index date.

#### Prescription Change Frequency

A prescription is defined as one medication order. PCF is defined as the number of prescription changes made during a 3-month period, without distinguishing between intentional and unintentional changes. Four different types of prescription changes were distinguished: (1) change in dosage, (2a) product switch, (2b) generic brand switch, (2c) therapeutic switch, (3) stopping medication, and (4) starting medication (Table 1).
Classification	Definition
1. Change in dosage	Change in dosage means that, for the same drug, the daily dosage is increased or decreased (e.g., amitriptyline 25 mg changes in Metoprolol 50 mg plain tablet instead of metoprolol slow release tablet (Selokeen ZOC®).
2a. Product formulation switch	Metoprolol 50 mg plain tablet instead of metoprolol slow release tablet (Selokeen ZOC®)).
2b. Generic brand switch	Change to another product contain- ing the same active substance with the same strength and the same dosage (e.g., atenolol 50 mg tablet (generic product) instead of Tenormin® 50 mg tablet (brand) or Renitec® 10 mg tablet (brand) instead of enalapril 10 mg tablet).
2c. Therapeutic switch	Change to another active substance within the same therapeutic group; the first four characters of the ATC classification are the same (e.g. amitriptyline (NO6AAO9) instead of citalopram (NO6ABO4) or fluox- etine (NO6ABO3) instead of citalopram (NO6ABO4)).
3. Stop	No continuation 90 days after one of the five control time points and no generic- brand substitution (1), product formulation switch (2) or therapeutic switch (3).
4. Start	Start of a drug means prescription of a drug which had not been prescribed during the previous six months and which is not a generic brand substitution (1), product formulation switch (2) or therapeutic switch (3).

# Table 1: Classification of Prescription Changes

As we were interested in whether the PCF affects hospitalization over time, we calculated the PCF score for both patients and controls at 18, 12, 9, 6, and 3 months before the index date. The duration of use of each drug was estimated by dividing the number of dispensed units by the prescribed daily dose.

Drugs that had a theoretical end date beyond 18, 12, 9, 6, or 3 months before the index date were considered as being in use on these dates. Only drugs intended for systemic use were taken into account. PCF scores were categorized into 0 prescription changes

(PCF 0), 1 prescription change (PCF 1), 2 or 3 prescription changes (PCF 2 or 3), and 4 or more prescription changes (PCF≥ 4).

#### Chronic Disease Score

The CDS is calculated on the basis of the use over 1 year of medications for 17 medications for chronic somatic diseases. The CDS has been shown to be a valid measure of complications related to an individual patient's burden of chronic somatic diseases and is clearly associated with the probability of being hospita-lized[20-22].

To compare the PCF with the CDS, we calculated and categorized the CDS for the year preceding the index date into four categories: CDS score = 0, CDS score = 1 or 2, CDS score = 3 or 4, and CDS score 5 or higher.

#### Statistical analysis

The strength of the association between the PCF score and hospital admission was calculated by comparing the number of patients and controls in each PCF category at 18, 12, 9, 6 and 3 months before the index date with forced entry univariate logistic regression analysis; outcomes are expressed as the odds ratio (95% CI), using PCF O as reference. To assess the effects of other patient or hospitalization characteristics, we performed stratified analyses with age (< 65 years  $\geq$  65 years), admission type (emergency or planned), CDS score, and polypharmacy (the use of five or more drugs concomitantly) as variables.

To assess the strength of the association between the CDS score and hospital admission, the number of patients and controls per CDS category were compared (expressed as OR 95% CI), taking CDS O as reference. The nature of prescription changes was determined for each time period.

The correlation between the PCF and the CDS was measured with a two-tailed Spearman's correlation coefficient. Statistical analyses were performed using SPSS 16.0 (SPSS, Chicago, IL).

#### Results

The source population was a random sample of 10,000 patients admitted to a hospital and an equal number of matched non-admitted individuals (controls). Because 1319 matched patients had less than 24 months of exposure history available in PHARMO RLS, the final study population comprised 8681 patients and 8681 controls. The characteristics of the study population are displayed in Table 2. The mean age was 52.6 years (SD 21.8) and 58.7% of the participants were women. At the index date, 60.6% of the patients and 47.8% of the controls were using systemic medication; the mean number of drugs used at the index date was 3.0 for patients and 2.1 for controls. In both groups, the number of drugs used increased with age. The CDS was higher in the patients than in the controls. The most frequent reasons for prescription changes at all time points before the index date were stopping medication and changes in dosage (table 4).

The risk of hospital admission increased with the number of prescription changes. At 3 months before the index date, the likelihood of hospitalization increased with increasing PCF category: the odds ratio (OR) between patients and controls was 1.4 (95% CI 1.3-1.5) in the lowest PCF category (PCF 1) and 4.1 (95% CI 3.1-5.1) in the highest PCF category (PCF 4). This was also true for comparisons for 18, 12, 9, and 6 months before index date (table 3).

The risk of hospital admission also increased per CDS category. A higher CDS score was associated with an increased risk of hospitalization: OR 1.5 (95% CI 1.4-1.6]) for CDS 1–2, OR 1.7 (95% CI 1.6-1.9) for CDS 3–4, and OR 3.6 (95% CI 3.3-3.9) for CDS 5 or higher (table 5).

Stratification by age (< 65 years  $\geq$  65 years), admission type (planned or emergency admission), CDS score, and polypharmacy resulted in comparable increases in OR with increasing PCF score. For participants on polypharmacy, the OR of PCF 4 or more decreased between 9 and 3 months before the index date, from 3.5 (95% CI 1.9-6.67) to 2.2 (95% CI 1.0-5.4). When stratified by CDS, the likelihood of being hospitalized also increased with increasing PCF scores (Figure 1).

A two-tailed Spearman' correlation coefficient showed a significant but poor correlation between CDS 0 and PCI 0 (0.019, p= 0.01) and CDS 5 or higher and PCI 4 or higher (0.027, p=0.01) and no significant correlation between CDS 1 or 2 and PCF 1 and CDS 3 or 4 and PCF 2 or 3 at 3 months before the index date.

Characteristics	Hospitalized	%	Non- Hospitalized	%
	N=8681		N=8681	
<b>Sex</b> Male Female	3588 5093	41.3 58.7	3588 5093	41.3 58.7
Age (years at index date) 0 - ≥ 18 >18 - ≥ 45 > 45 - ≥ 65 > 65 - ≥ 79 > 79	574 2737 2246 2218 906	6.6 31.5 25.9 25.6 10.4	574 2737 2246 2218 906	6.6 31.5 25.9 25.6 10.4
Number of medications O 1 2 3 4 ≥5	3416 1794 985 767 544 1175	39.4 20.7 11.3 8.8 6.3 13.5	4534 2121 872 535 302 317	52.2 24.4 10.0 6.2 3.5 3.7
CDS category CDS score O CDS score 1-2 CDS score 3-4 CDS score ≥5	3671 1331 1731 1948	42.3 15.3 19.9 22.4	5206 1287 1415 773	60.0 14.3 16.3 8.9
<b>Duration of hospitalization</b> 1 day 2-5 days > 5 days	417 4374 3890	4.8 50.4 44.8		
<b>Admission type</b> Emergency Planned	3966 4715	45.7 54.3		
<b>Admission for surgery</b> Yes No	4360 4321	50.2 49.8		

Table 2: Characteristics of Hospitalized and Non-Hospitalized Patients at the

Table 3: T	Table 3: The association between Prescription Change TYPE and Hospital Admission at Different Time												
	-18					-12					-9		
	н	NH	OR	CI	95%	H	NH	OR	CI	95%	H	NH	
PC TYPE													
Change in Dosage	946	521	1.4	1.3	1.6	1183	699	1.3	1.2	1.4	1093	597	
Product Switch	211	127	1.6	1.3	2.0	329	187	1.6	1.3	1.9	325	202	
Generic Brand Switch	114	67	1.7	1.2	2.2	180	93	1.8	1.4	2.3	192	103	
Therap. Switch	221	100	1.9	1.5	2.4	230	117	1.7	1.4	2.1	256	96	
Stop	2735	1923	1.3	1.2	1.3	2961	1910	1.3	1.3	1.4	3122	1950	
Start	162	61	2.3	1.7	3.0	136	76	1.6	1.3	2.1	157	61	

H=hospitalized patients (N=8681), NH=Non=Hospitalized Patients (N=8681), OR=Odds Ratio,

CI 95%= Confidence Interval 95%,

PC Type=Prescription Change Type.

Points	oints before Index date												
		-6							-3				
OR	CI	95%	H NH C		OR	CI	CI 95%		NH	OR	CI	<b>95%</b>	
1.4	1.3	1.6	1162	639	1.4	1.3	1.5	1405	656	1.5	1.4	1.6	
1.5	1.3	1.8	349	217	1.5	1.3	1.8	422	245	1.6	1.4	1.8	
1.8	1.4	2.3	219	101	2.1	1.6	2.6	274	91	2.8	2.2	3.5	
2.3	1.8	2.9	300	111	2.3	1.8	2.8	345	117	2.6	2.1	3.1	
1.4	1.3	1.4	3122	1943	1.4	1.3	1.4	3102	2005	1.3	1.3	1.4	
2.3	1.8	3.1	186	75	2.2	1.7	2.8	227	71	2.9	2.2	3.7	

Table 4:	The asso	ciation b	etween	Prescrip	tion Ch	ange Fre	quency a	and Hosp	oital Adn	nission a	at Differe	ent Time
	-18						-12					-9
	H	NH	OR	CI 95	5%	Н	NH	OR	<b>CI 9</b>	5%	н	NH
PCF Cat												
0	6086	6736	1	ref		5844	6524	1	ref		5788	6556
1	1631	1418	1.3	1.2	1.4	1731	1564	1.2	1.2	1.3	1720	1561
2 or 3	760	451	1.9	1.7	2.1	853	514	1.9	1.7	2.1	899	490
≥ 4	204	76	3.0	2.3	2.4	253	79	3.6	2.8	4.6	274	74

H=hospitalized patients (N=8681), NH=Non=Hospitalized Patients (N=8681), OR=Odds Ratio, CI 95%= Confidence Interval 95%, PCF Cat=Prescription Change Frequency Category.

Points b	Points before Index date												
				-6					-3				
OR	CI 95	5%	H	NH	OR	CI 95	5%	H	NH	OR	CI 95	5%	
1	ref		5723	6570	1	ref		5591	6537	1	ref		
1.3	1.2	1.4	1751	1483	1.4	1.3	1.5	1743	1493	1.4	1.3	1.5	
2.1	1.9	2.3	923	542	2.0	1.8	2.2	1031	560	2.2	1.9	2.4	
4.2	3.3	5.4	284	86	3.8	3.0	4.8	316	91	4.1	3.1	5.1	



Figure 1. Stratification on age category, admission type, polypharmacy and cds score

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Admission						
	Indexdate					
	indezdate Hospitalized patients N=8681	Non Hospitalized patients N=8681)	OR	CI 9	95%	
CDS score						
0	3671	5206	1	ref		
1 or 2	1331	1287	1.04	0.96	1.13	
3 or 4	1731	1415	1.27	1.18	1.38	
≥ 4	1948	773	2.95	2.71	3.23	

 Table 5: The association between the Chronic Disease Score and Hospital

 Admission

OR=Odds Ratio, CI 95%= Confidence Interval 95%, CDS score=Chronic Disease Score at index date ref= reference

# Discussion

The main finding of this study is that the frequency of prescription changes (PCF) is associated with an increased risk of hospital admission. We also confirmed the known association between the Chronic Disease Score (CDS) and hospital admission. While the PCF and CDS were both associated with hospital admission, the correlation between the two instruments was poor. The CDS measures comorbidity on the basis of the 1-year pharmacy dispensing data. In contrast, the PCF is based on prescription changes over a 3-month period. The results showed that the PCF within a three month period is comparable with the one year period of the CDS. Therefore, the PCF is more useful in practice.

We found that among patients with a low CDS score, an increasing number of prescription changes was associated with an increased risk of hospital admission. Stratified analysis of the CDS scores into the four categories confirmed this finding: at each CDS category, we found a comparable increase in the risk of hospitalization caused by the number of prescription changes.

Stratification by age (<65 or  $\ge$ 65 year) and medication use (< 5 or  $\ge$ 5 medications used) showed an increasing risk of hospitalization with increasing PCF (figure 1). Several studies have reported age and polypharmacy as risk factors for hospital admission.

We found that, based on PCF scores, even patients younger than 65 years and patients without polypharmacy were at increased risk of hospital admission. It is plausible that the risk was lower for planned than for emergency admissions, but this was not confirmed after stratification by type of hospitalization. Unexpectedly, patients on polypharmacy had a decreased risk of hospital admission: PCF 4 or higher decreased between 9 and 3 months before the index date. On the basis of this finding, the most common reason for prescription changes, namely stopping medication, would appear to be protective against hospital admission in patients on polypharmacy. As we do not know which medications were stopped, this finding does not mean that stopping specific medications is protective.

The CDS has the disadvantage that it is based on information about medication history collected for at least 1 year prior to the event under investigation. We showed that it is possible to predict the risk of hospitalization on the basis of the number of prescription changes in 3 months. On the other hand, the CDS is based on the use of 17 medications, whereas the PCF is based on all medications and thus requires detailed medication histories. The CDS was developed to measure a patient's overall health status, but the PCF is not suitable for this. A potential weakness of the CDS, which was developed in 1992, is that it has never been adjusted to accommodate new medication classes, unlike the PCF, which is based on all medications used. Despite this, the CDS is still associated with hospital admissions.

# Limitations

This study had a number of limitations. The database does not provide information about the indication for which a drug is prescribed, so we cannot comment about the frequency of medication changes for specific indications. One could argue that more ill patients will have more prescription changes. However, this was not the aim of the study. The use of non-prescription medicines is not known as patients could also buy medications OTC. In addition, prescribers might not write out a new prescription each time drug use is changed.

Because the PCF is based on dispensing data from community pharmacies, this would mean that the association between PCF and hospital admission might have been underestimated. As the data set used in this study covered the period between July 1998 and June 2000, it is possible, but unlikely, that since then the prescribing behaviour of doctors has changed, influenced by medication reconciliation programmes, or indications for hospital admission might have become stricter, both of which would have led to overestimation of the association between PCF and hospitalization.

While the Dutch PHARMO database is complete, it does not provide information about the socioeconomic status or compliance of patients or their health status (the controls might have been ill less often than the patients); however, as the controls were sampled independently of exposure status, these factors would not influence our results. Lastly, it was outside the scope of this study to distinguish between the different reasons for changing medication in greater detail. To our knowledge, besides the study of Koecheler et al. <sup>[17]</sup>, no other studies have investigated prescription changes and the risk of hospital admission. Several other studies, like the HARM study, have described risk factors for medication-related hospital admission, but did not focus on prescription changes.

Further research should consider more detailed variables of the prescription changes like types of medications involved. In addition, it should be interesting to test the PCF model in a follow up study.

## Conclusion

This longitudinal study of a large group of patients over 24 months demonstrated that the frequency of prescription changes (PCF) over a 3-month period is associated with hospital admission, which suggests that the PCF could be used as an alternative to the CDS for predicting hospital admission. In the ambulant setting, the PCF score could function as a warning signal for an increased risk of hospitalization and as such contribute to medication safety programmes. The PCF might be particularly useful for older patients, who tend to use more medications. District nurses and social workers care should be alerted if the frequency of prescription changes increases in their patients. Community pharmacists can use the PCF as a clinical rule to facilitate early identification of potential drug-related problems. Further research is needed to determine the predictive value of the PCF in practice as a clinical rule.

### **Competing Interest**

Possible conflict of interest: nothing to disclose.

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# **Author's contribution**

All authors contribute the study conception and design and the study's analytic strategy (CS-RS-EH-MS-PS-TE). PS prepared the database for analysis. CS has done the statistical data analysis, supported by EH and PS. CS and RS conduct the literature review and have written the drafting of the manuscript.

Author MS and TE supervised the study and helped with critical revisions of the manuscript for important intellectual content. All authors read and approved the final manuscript.

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Chapter 4.2

# **Recognition of Drug Related Problems by Home healthcare Employees:**

# A Dutch observational study with self-reports

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# Abstract

**Background:** In the Netherlands, the majority (80%) of the older people (>65) use prescribed drugs. Besides, 82% of the patients who receive home healthcare is 65 years of age or older. Because of natural changes in age-related drug metabolism, these older home healthcare patients are particularly vulnerable to drug related problems.

**Purpose:** To describe how home healthcare Nurse Assistants (NA), home healthcare Licensed Practical Nurses (LPN) and home healthcare Registered Nurses (RN) rate their knowledge, monitoring skills and ability to recognize adverse drug reactions and drug interactions of the most commonly used medication in older people, aged 75 or older, in the Netherlands.

**Methods:** A survey design was conducted with the use of a questionnaire in a homecare organization in the Netherlands.

**Results:** Home healthcare workers most easily recognize side-effects of confusion, drowsiness and fatigue more easily than gastrointestinal disorders and dizziness. In addition, home healthcare Registered Nurses and home healthcare Licensed Practical Nurses were more likely than home healthcare assistants to recognize and report symptoms due to side-effects.

**Conclusion:** There are differences between Registered Nurses (RN), Licensed Practical Nurses (LPN) and Nurse Assistants (NA) in the knowledge and their skills to recognize adverse drug reactions and interactions in homecare. Consequently, the allocation of clients to RNs, LPNs or NAs should be arranged well throughout. Home healthcare workers are well positioned to act preventatively and alertly to potential drug related problems, if they have been adequately access to information on side effects and interactions of medication.

#### Background

It is a well-known fact that the proportion of the population that is 65 years or older is rapidly increasing. The older population more frequently suffers from multi morbidities, use more medication and are treated by a larger number of health care professionals than the younger population (Higashi et al. 2004). In the Netherlands drug consumption is three times higher among persons of 65 years or older, while people aged 75 years or older consume five times more than the average person (SFK. Foundation for Pharmaceutical Statistics 2010). Because of natural changes in age-related drug metabolism, older people are particularly vulnerable to medication-related problems (Gallagher 2001). Due to ageing, shorter hospital stays and an emphasis on outpatient care, the number of older persons receiving home healthcare is growing (Velden van der et al., 2011). Therefore, Drug Related Problems (DRPs) are an increasing challenge in homecare organizations as described by Meredith et al., (Meredith et al. 2001) and Parsons et al., (Parsons et al. 2011).

Home healthcare workers helps seniors to live independently as long as possible, given the limits of their medical condition. It covers a wide range of services such as help with bathing and getting dressed or intravenous therapy and injections, wound care, education on disease treatment or assistance with medication intake. Because of this wide range of services home healthcare workers are divided by their education level and corresponding responsibility into: Registered (home healthcare) Nurses (RNs), Licensed Practical Nurses (LPNs), Nurse Assistants (NA) and Housekeepers.

The differences between educational levels are determined by the degree of responsibilities, the level of complexity and the degree of transfer. The latter indicates the degree to which the professional is able to apply his or her knowledge and skills to different situations (van der Boom, 2008).

Medication is not part of the education for NAs. However, despite their lack of education in medication, NAs work with increasingly older clients using many drugs. For Dutch LPNs and RNs, medication education is part of their training.

In addition to the general practitioner and pharmacist, home healthcare workers, who visit their clients in their homes on a regular basis, may be able to help in early recognition of potential DRPs. Several authors stated that nurses play an important role in patient medication safety (Ndosi, Newell 2009),(Bergqvist, Ulfvarson & Karlsson 2009),(Lucero, Lake & Aiken 2010), (Sulosaari, Suhonen & Leino-Kilpi 2011). In their roles as caregivers, educators and administrators of medications, home healthcare Registered Nurses and Licensed Practical Nurses are particularly well positioned to be the most astute observers of adverse drug reactions (Arnold 1999),(Kovner, Menezes & Goldberg 2005). Notwithstanding the fact that homecare employees are in the right position to observe adverse drug reactions, it depends on their knowledge and self efficacy how they act in actual practice. Self-efficacy is defined as a person's belief to succeed in certain situations and can be viewed as the level of one's competence to complete tasks and to reach goals(Bandura 1977).

According to Meredith and colleagues(Meredith et al. 2001) nearly one-third of the home healthcare patients surveyed (n=6,718) had evidence of a potential medication problem or were taking a drug considered inappropriate for older people. Ellenbecker et al., (Ellenbecker, Frazier & Verney 2004) showed that more than three quarters of a homecare patient population (n=1467) were at risk for medication errors as a result of taking five or more different drugs.

Currently, for economic reasons and changes in the reimbursement of homecare, home healthcare nurses have often been replaced by less educated nurse assistants (Kunneman 2007; Hanrath 2010).

Medication, preventive tasks like patient education about their medication or early recognition of medication related problems, are not part of the education of the NAs.

In this study, we assessed whether homecare workers with different educational degrees are aware of, recognize and report (potential) Drug Related Problems and if so, what they subsequently do about them.

# Purpose of the study

This paper reports a study describing how home healthcare Nurse Assistants, home healthcare Licensed Practical Nurses and home healthcare Registered Nurses rate their knowledge, monitoring skills and ability to recognize adverse drug reactions and drug interactions of the most commonly used medication in older people, aged 75 or older, in the Netherlands.

# Methods

# Study Design

A survey was conducted using a questionnaire to answer the following research questions:

- 1. How do home healthcare workers rate their knowledge, monitoring skills and ability to recognize adverse drug reactions and interactions in their patients?
- 2. What are the differences between home healthcare nurses, home healthcare licensed practical nurses and home healthcare nurse assistants with regards to recognizing adverse drug reactions and interactions?

# Respondents

The study population consisted of 280 home healthcare employees (divided between five geographic areas) of a large homecare organization in The Netherlands. A convenience sample from the home healthcare workers was recruited. Respondents voluntarily took part in the study, which was presented and explained during a regular team meeting. The one inclusion criterion for participation in the study was that the home healthcare worker being employed in a direct patient care position for at least eight hours per week.

#### Instruments

To gain insight in how home healthcare workers rate their knowledge, monitoring skills and ability to recognize adverse drug reactions and interactions,

a questionnaire was developed. Starting point for this questionnaire were the potential side effects of the ten most frequently used drug products by people aged 75 years or older, according to the Dutch Foundation for Pharmaceutical Statistics (SKF, 2003). (table 1). Subsequently, from these ten most common drugs, the potential side-effects were divided in three categories: 1) gastrointestinal (GI) side effects such as diarrhea and nausea, 2) central nervous system (CNS) side effects such as confusion, drowsiness and fatigue and 3) dizziness. For each category, ten questions graded on a five point Likert-scale (from 1-strongly agree to 5-strongly disagree) were asked about respondents' (see below) knowledge and recognition of side-effects, the home healthcare worker's responsibility to discover the side-effects and her responsibility to report them to general practitioners (GPs) or pharmacists.

1	Furosemide/Frusemide
2	Acetylsalicylic acid
3	Carbasalatecalsium
4	Temazepam
5	Oxazepam
6	Paracetamol
7	Metoprolol
8	Omeprazaole
9	Digoxine
10	Lactulose

#### Table 1: Top 10 medicines most commonly used by persons 75+

Foundation of Pharmaceutical Statistics, 2003

#### Validation of the questionnaire

To establish face validity, the questionnaire was assessed by a nursing scientist and a staff member of the homecare organization. Subsequently, a panel of two expert pharmacists judged the questionnaire. Finally, the feasibility of the questionnaire was discussed during a national congress of home healthcare services by 76 home healthcare nurses and 3 home healthcare licensed practical nurses. Based on the feedback from the pharmacists and the reactions of the home healthcare workers, the questionnaire was slightly adjusted.

#### Description of the questionnaire

The questionnaire started with two filter questions to select only participants who met the inclusion criteria of regular patient contact and at least eight working hours a week. The questionnaire included an introduction asking for demographic characteristics such as function, work experience in home healthcare in years, and actual working hours per week. Because of the small size of some teams within the healthcare organization and to guarantee anonymity, there were no questions about age or the team the respondent was working in. After the two filter questions, seven equal questions were asked per side effect category. Finally, there was one open question about possible tools that could support home healthcare workers' early recognition of (potential) side-effects and interactions.

#### Data collection

The questionnaire was distributed to 25 teams within the homecare organization. All home healthcare workers were informed about the study by means of the homecare organization newsletter. Eleven teams received the questionnaire through internal mail and arranged for internal distribution themselves. In fourteen teams, the questionnaires were personally distributed and orally explained by the independent researcher. There was no relation between the researcher and the homecare organization. In total, 280 questionnaires were distributed between December 2009 and January 2010.

#### Ethical considerations

In this study perceptions of home healthcare workers have been described about their daily practice. Permission from an ethics committee was not required. Participation was entirely voluntary. All participants were extensively informed about the study through a written introduction. The anonymity of the respondents was guaranteed, and it was not possible to trace the answers back to the participant. The data obtained from the participants was used only for this study. Consent was assumed through the participants' completion of the questionnaire. Participants were informed that all findings would be reported as group results and would be submitted for publication. Confidentiality was ensured through the use of code numbers to guarantee anonymity of the respondents.

#### Data analysis

Data were analyzed using SPSS for windows version 18.0. Descriptive statistics with frequencies and percentages were used to answer the research questions. Logistic regression was used because of a binary (yes/no) dependent variable to better understand the differences between home healthcare employees who agreed to the statements and who did not.

#### Results

#### Characteristics of the respondents

Almost 40% of the 280 home healthcare workers who received the questionnaire responded positively (N=107). The respondents were divided as follows: 25% home healthcare Registered Nurses (N=26), 41% home healthcare Licensed Practical Nurses (N=43) and 34% home healthcare Nurse Assistants (N=36).

Two respondents did not answer the question about their job function and were excluded (Table 2). Table 3 demonstrates the stated knowledge, reporting actions and respondents ability to recognize gastrointestinal disorders (1), confusion, drowsiness and fatigue (2) and dizziness (3) per care giver level. The homecare workers were poorly informed about medication changes of their patients. If these employees should be informed about these changes, they would be better able to monitor potential adverse reactions.

Home healthcare Registered Nurses recognized more (OR = 3.84; CI = 1.43-10.30) gastrointestinal disorders, diarrhea and nausea (Table 4) and also more (OR = 4.33; CI = 1.09-17.26) confusion, drowsiness and fatigue than home healthcare assistants. In addition, home healthcare Registered Nurses stated more often (OR = 4.44; CI = 1.10-17.03) than home healthcare assistants that they know that confusion, drowsiness and fatigue could be adverse drug reactions (Table 5). Respondents mentioned the following tools that could support the early recognition of (potential) side-effects and interactions: (1) information about side-effect and interaction in a handy pocketbook, (2) medication training on a structural basis and (3) information provided by the pharmacist.

Table 2 Characteristics of the Respondents (N=107)		
Position	N	%
Home Healthcare Registered Nurse	26	24.3
Home Healthcare Licensed Practical Nurse	43	40.2
Home Healthcare Assistant	36	33.6
Missing	2	1.9
Work experience in years		
0 - 5	18	16.8
6 - 10	23	21.5
11 - 10	17	15.9
>16	46	43
Missings	3	2.8
Working hours per week		
9 - 16	13	12.1
17 - 24	30	28
>25	56	52.3
Missings	8	7.5

Table 3 Recognition of side-effects							
Recognition of:	RN*		LPN**		NA***		
gastrointestinal disorders, diarrhea, nausea	n=25		n=42		n=33		
	N	%	N		Ν		135
	agree	agree	agree		agree		
I do recognize these complaints in my daily practice	15	60.0	32	76.2	15	45.5	
I do know that these complaints could be side effects	23	92.0	35	83.3	27	81.8	
I always report these complaints	24	96.0	38	90.5	27	81.8	
My colleagues always report these complaints	9	36.0	24	57.1	15	45.5	
I do recognize these complaints from the nursing report	13	52.0	27	64.3	20	60.6	
Clients always indicate these complaints to me	5	20.0	6	26.2	11	33.3	
It is my task to ask further about these kinds of complaints	25	100.0	40	95.2	29	87.9	
I do contact the general practitioner about these complaints	18	72.0	30	71.4	12	36.6	
I do contact the pharmacist about these complaints	7	28.0	22	52.4	7	21.2	
	n=25		n=42		n=36		
confusion, drowsiness, fatigue	N agree	% agree	N agree		N agree		
I do recognize these complaints in my daily practice	23	92.0	37	88.1	23	63.9	
I do know that these complaints could be side effects	23	92.0	40	95.2	27	75.0	
I always report these complaints	25	100.0	37	88.1	25	69.	
My colleagues always report these complaints	8	32.0	23	95.2	15	41.7	
I do recognize these complaints from the nursing report	11	44.0	30	71.4	20	55.6	
Clients always indicate these complaints to me	6	24.0	5	11.9	12	33.3	
It is my task to ask further about these kinds of complaints	25	100.0	38	90.5	27	75.0	
I do contact the general practitioner about these complaints	18	72.0	34	81.0	10	27.8	
I do contact the pharmacist about these complaints	19	76.0	22	52.4	6	16.7	
	n=25		n=42		n=36		
dizziness	N	%	N		N		
I de recognize these compleints in my deily prestice	agree	agree	agree	71 (.	agree	62.0	
I do recognize these complaints in my daity practice	10	09.2	30	(1.4	23	03.9	
I do know that these complaints could be side effects	24	92.3	35	83.3	23	03.9	
I always report these complaints	22	84.6	39	92.9	21	(5.0	
My colleagues always report these complaints	6	23.1	23	54.8	1/	47.2	
I do recognize these complaints from the nursing report	12	46.1	28	66.6	19	52.8	
Clients always indicate these complaints to me	(	26.9	9	21.4	15	41.7	
It is my task to ask further about these kinds of complaints	26	100.0	40	95.2	29	80.6	
I do contact the general practitioner about these complaints	17	68.0	31	73.8	15	41.7	
I do contact the pharmacist about these complaints	17	68.0	22	52.4	9	25.0	

\*RN= Registered Nurse,

\*\*LPN= Licensed Practical Nurse

\*\*\*NA=Nurse Assistant

Table 4:	Factors related to the recognition of Drug Related Problems:
	a logistic regression analyses (n=107)

Predictor variable	G <b>I, Dia</b> Nausea	irrhea,		Confus Drowsi	ion, iness, Fa	atigue	Dizziness			
	OR	CI 95%	6	OR	CI 959	6	OR	CI 95%	CI 95%	
Function										
Nurse Assistant	1	ref		1	ref		1	ref		
Licensed Practical Nurse	1.8	0.6	5.2	4.3*	1.1	17.3	1.3	0.4	3.7	
Registered Nurse	3.8*	1.4	10.3	4.2*	1.3	13.3	1.4	0.5	3.7	
Experience in years										
0 - 5	1	ref		1	ref		1	ref		
6 - 10	1.2	0.3	4.4	1.8	0.4	8.1	1.5	0.4	5.3	
11 - 15	1.8	0.5	7.4	0.9	0.2	4.0	1.9	0.5	7.8	
≥ 16	2.1	0.7	6.9	2.1	0.6	7.7	2.5	0.8	7.8	
Working hours per week										
9 - 16	1	ref		1	ref		1	ref		
17 - 24	0.3	0.1	1.4	1.2	0.2	7.4	0.8	0.2	3.4	
≥ 25	0.6	0.2	2.5	0.7	0.1	3.8	1.1	0.3	4.1	

OR=Odds Ratio GI=Gastrointestinal disorders Ref=reference

Predictor variable	G <b>I, Diarrhea,</b> Nausea			Confusion, Drowsiness, Fatigue			Dizziness		
	OR	CI 95%	5	OR	CI 95%	6	OR	CI 95%	)
Function									
Nurse Assistant	1	ref		1	ref		1	ref	
Licensed Practical Nurse	2.6	0.6	10.6	2.6	0.6	10.6	0.8	0.3	2.3
Registered Nurse	1.5	0.5	4.3	4.4*	1.1	17.0	1.7	0.7	4.1
Experience in years									
0 - 5	1	ref		1	ref		1	ref	
6 - 10	1.4	0.3	5.8	2.8	0.2	33.0	1.3	0.3	5.5
11 - 15	1.8	0.4	9.1	2.0	0.2	24.3	1.3	0.3	5.7
≥ 16	2.1	0.6	7.9	0.5	0.0	2.3	1.8	0.5	6.6
Working hours per week									
9 - 16	1	ref		1	ref		1	ref	
17 - 24	0.6	0.1	2.8	1.9	0.4	10.3	0.4	0.0	3.8
≥ 25	0.8	0.2	2.4	2.5	0.5	11.7	0.3	0.0	2.3

# Table 5: Factors related to the knowledge of Drug Related Problems: a logistic regression analyses (n=107).

OR=Odds Ratio GI=Gastrointestinal disorders Ref=reference

### Discussion

This study described how home healthcare workers assessed their own ability to recognize side-effects of the ten most common medications used by people 75 years or older. Although most home healthcare workers stated that they knew that confusion, drowsiness, fatigue, dizziness and gastrointestinal disorders could be side-effects of medicine use, a significantly lower percentage indicated that they recognize these types of complaints in their daily practice. The Central Nervous System (CNS) category (confusion, drowsiness and fatigue) was more often recognized than the gastrointestinal disturbances and dizziness categories.

This may be because clients rarely mention their complaints themselves, and it is possible that confusion, drowsiness and fatigue are easier to observe than GI disturbances and dizziness. Remarkably, the general practitioner was contacted more often than the pharmacist. It is possible that homecare workers are more familiar with the general practitioner than with the pharmacist. Function (RN, LPN or NA) appeared to be the only related factor to explain knowledge and recognition skills, which implies that years of experience and working hours per week were not related. This could be explained by the fact that positions are based on education level. As expected due to this education level, Registered Nurses estimated their recognition skills for gastrointestinal disorders higher than Licensed Practical Nurses and Assistant Nurses. There was no significant difference in the three positions in the rating concerning the knowledge of gastrointestinal disorders.

This may be because gastrointestinal disorders are the most common adverse drug events and therefore known by all homecare employees.

It is remarkable that Nurse Assistants report more often that clients mention complaints to them. It could be because of their kind of work (like housekeeping), which implicates a longer stay in company of the patient. Besides, a substantial part (20-25%) of the Nurse Assistants, do not regard it as their task to ask further about the complaints of a patient. Although medication is not part of their training, detecting changes in a patient situation certainly is part of their training.

Previous studies have shown that even nurses are inadequately prepared and lack sufficient knowledge to be capable of observing and recognizing medication related problems (Ives et al. 1996)(Grandell-Niemi et al. 2005)(Ndosi, Newell 2009) (Sino, Munnik & Schuurmans 2012)) Lim et al., (Lim et al. 2010) explained the need to improve nurses' pharmacological knowledge, medication administration and management in healthcare facilities for older people.

According to the Dutch law on professionals in healthcare (Wet BIG) and Act on quality of care in care institutions (Kwaliteitswet zorginstellingen) deploying Nurse Assistants in complex care does not decrease the quality of care. However, the Dutch professional association of nurses (V&VN) has recently taken position: "Stop with the deployment of Nurse Assistant regarding to medication", which we fully endorse.

#### *Limitations of the study*

To appreciate the present results, a number of aspects need to be discussed regarding the scope and limitations of this study. First, a voluntary survey from one home healthcare organization with 105 respondents cannot be considered representative of all home healthcare workers in the Netherlands. However, this is the first study about knowledge, reporting and ability to recognize Drug Related Problems and interactions of the most common used medication in older people. It does provide an in-depth, insiders' view of the perception of the homecare workers and points out the importance of the theme. Second, a response rate of nearly 40% is not adequate for generalizing to the entire population. Additionally, the questionnaire was developed specifically for this study. By means of an expert panel, only face validity could be guaranteed.

Because home healthcare workers were asked about their perceptions, the respondents may have overestimated or underestimated their recognition abilities, despite their answers being anonymous. In further research, the observation and recognition skills of home healthcare workers should be measured in "real life" instead of by self-reports.

This research was based on 2003 ranking of the ten most common medications used by individuals 75 years or older. Since then, this top-ten list has been changed. Acetylsalicylic acid, metoprolol, furosemide, omeprazole and temazepam are still in the top ten, according to the Foundation for Pharmaceutical Statistics, but new medications include simvastatin, pantoprazole, metformin, isosorbidemononitrate and hydrochlorothiazide (SFK. Foundation for Pharmaceutical Statistics 2010). Because of our interest in the recognition ability of homecare workers, we assume this finding did not influence our results. Over the counter (OTC) medications were not taken into account although these drugs could have side-effects and/or interact with prescribed medications as well. Most homecare workers stated that they always report the complaints of their clients in their daily report. Remarkably, less than half of the respondents declared that their colleagues always report complaints related to side effects in the daily report. There is a high probability that home healthcare workers overestimate their own reporting actions and underestimate those of their colleagues. Further, less than half of the respondents stated that clients mention their complaints to them. This result suggests that most clients do not speak about their complaints. Therefore, the personal observational skills of home healthcare workers are very important in detecting side effects or interactions.

Although other authors have stated that nurses are in a unique position and indeed can contribute to medication safety (Arnold 1999),(Kovner, Menezes & Goldberg 2005),(Molony 2009) only a few have focused on the role of home healthcare workers. Additionally, many solutions to medication problems focus on the pharmacist or general practitioner. Little attention is paid to the role of homecare workers regarding medication safety. Ellenbecker and colleagues (Ellenbecker, Frazier & Verney 2004) demonstrated by means of self-reporting that nurses in homecare were able to report adverse drugs events from medication errors. Our results are consistent with those findings.

Home healthcare employees should be aware of the added value they offer for observing drug-related problems in their patients through accurate reporting of their observations and contacting the physician or pharmacist when an observation of a potential medication-related problem occurs, home healthcare employees can contribute to medication safety in elderly clients.

#### Implications for practice

Homecare employees mentioned the following tools that could support in the early recognition of (potential) side-effects and interactions: (1) information about side-effect and interaction in a handy pocketbook. (2) medication training on a structural basis and (3) information provided by a pharmacist. These findings can be used in home healthcare practice to help prevent medication-related problems, such as conditions requiring hospital admissions. Home healthcare employees should be aware of their observational value in patients' home environments. Although the respondents in this study stated that they were generally able to recognize most of the common side-effects, continuous enhancement of both observation and reporting skills is necessary. Home healthcare workers should be aware of specific symptoms which could indicate a medication-related problem. These symptoms could function as a "red flag" for potential medication-related problems. Further research is necessary to assess these so called "red flags." Through accurate reporting of their observations and contacting the general practitioner or pharmacist when an observation of a potential medicationrelated problem occurs, home healthcare employees can contribute to medication safety for elderly clients. Nurse Assistants should be trained and supported in observing changes in homecare situations and educated in reporting their findings to the responsible Registered Nurse.

#### **Conclusion and recommendations**

Home healthcare workers stated that they recognized the CNS side-effects category (confusion, drowsiness and fatigue) better than gastrointestinal disorders and dizziness, although home healthcare Registered Nurses and home healthcare Licensed Practical Nurses were more likely to recognize and report symptoms than home healthcare assistants. These results lead to the following recommendations: (1) ensure comprehensive and easy to use information about medication, side-effects and interactions for the several jobs in home healthcare; (2) arrange clear job descriptions regarding medication management; (3) emphasize the importance of complete reporting without delay; (4) provide training and tools for the early recognition of medication-related problems; (5) implement good collaboration between the general practitioner, the pharmacist and the home healthcare organization and make clear communication agreements. Lastly, (6) appoint a Registered Nurse as coordinator for the pharmaceutical care within the homecare organization. This is de first study about the knowledge, reporting and ability to recognize Drug Related Problems and interactions of the most commonly used medication in older people in the Netherlands by home healthcare employees.

This first study points out the importance of the theme as we discussed. Therefore, further research is certainly needed.

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Chapter 4.3

# Signs and symptoms indicative of potential adverse drug reactions in homecare patients

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# Abstract

# Purpose

The purpose of this study was to determine whether homecare workers can detect signs and symptoms indicative of potential Adverse Drug Reactions (ADRs) in homecare patients, using a standardized observation list.

# Methods

This observational study involved 115 patients cared for by two homecare organizations in the Netherlands between April 2011 and August 2011. During routine home visits, homecare workers filled in a standardized observation list of signs and symptoms indicative of potential ADRs, namely, gastrointestinal and other bleedings, electrolyte disturbances, renal and heart failure, digoxin intoxication, constipation, disturbances of diabetic control, and falls. Their observations were compared against the medications that the patients were using, and their known side effects, by a panel of clinical pharmacology experts. Sensitivity, specificity, positive and negative predicted value of the standardized observations were calculated.

# Results

In total 234 signs and symptoms indicative of potential ADRs were observed by the homecare workers, 116 (49.6%) of which were considered drug related. More than half of the observed signs of gastrointestinal bleeding could be considered as drug related. Observed dizziness (64.1%) and drowsiness (53.3%) could be drug related in most cases, as could most cases (71.4%) of fainting spells (indicative of renal or heart failure). Seventeen of 20 observed falls could be drug related. The specificity of the standardized observation list was high, varying from 0.70 (CI: 0.62-0.77) to 0.97 (CI: 0.95-0.98).

# Conclusion

Signs and symptoms indicative of potential ADRs recorded by homecare workers using a standardized observation list can aid in the early recognition of ADRs in homecare patients.
### Introduction

Medication is one of the most common medical interventions used in healthcare. While medications improve health and quality of life and increase life expectancy <sup>[1]</sup>, they often cause adverse effects<sup>[2-4]</sup> and are a common cause of hospital admission. In the Netherlands and many other Western countries, 3% to 10% of all hospital admissions are caused by the suboptimal use of medication<sup>[5-8]</sup>, and about half of these admissions are considered preventable. Several risk factors for preventable medication-related hospital admission have been identified including: (a) impaired cognition, (b) multimorbidity, (c) dependent living situation, (d) impaired renal function, (e) non-adherence to medication, (f) polypharmacy, and (g) age older than 65 years<sup>[3]</sup>.

Impaired cognition, polypharmacy, multimorbidity, and age older than 65 years are typical of many people receiving homecare services<sup>[9-12]</sup>. Furthermore, it is likely that individuals who use these services have a higher prevalence of reduced renal function and non-adherence than the general population<sup>[11,13,14]</sup>. For these reasons, homecare patients are at high risk of preventable drug-related complications. Early recognition of a potential adverse drug reaction (ADR) is essential to prevent serious complications of drug therapy. Several studies have shown that physicians<sup>[15-19]</sup>, pharmacists<sup>[20-24]</sup> and nurses<sup>[25-28]</sup> can contribute to the recognition of (potential) ADRs in patient care. However, so far, little attention has been given to the early recognition of signs indicative of potential ADRs in the home environment. Homecare workers are well positioned to recognize signs and symptoms of potential ADRs because they frequently visit patients and are trained to observe changes in their patients' mental and physical condition even if they lack specific medical and pharmacological knowledge<sup>[11,13,29,30]</sup>. They help patients to live independently as long as possible, given the limits of their patients' medical condition, by providing a range of services, such as help with bathing and getting dressed or intravenous therapy and injections, wound care, education on disease treatment, or assistance with medication intake.

### Objective

The aim of this study was to determine whether homecare workers can detect signs and symptoms indicative of potential ADRs in homecare patients, using a standard observation checklist.

### Methods

### Setting and patients

This observational study was conducted among the homecare patients (n=115) of two homecare organizations in the Netherlands. Participants were included if they lived at home and used at least one medication long term. The Ethics Committee of University Medical Centre Utrecht (UMCU) approved this study. Patients received written information about the study and gave their oral consent to participation. They were able to refuse participation at any stage of the study. All data were rendered anonymous prior to analysis to ensure patient confidentiality. Data were collected from April 2011 to August 2011.

### Observations

The standardized observation list used in this study was part of the Home Observation of Medication related problems by homecare Employees (HOME) instrument (appendix). The HOME instrument is designed to identify signs and symptoms indicative of potential ADRs that homecare workers can observe during the provision of care. The HOME instrument is based on the Hospital Admission Related to Medication (HARM) Wrestling report<sup>31]</sup>, a Dutch advisory follow-up report of the Hospital Admission Related to Medication (HARM) study<sup>[32]</sup> describing preventable ADRs that would contribute the most to improving medication safety at a population level. These potentially preventable ADRs were translated into signs and symptoms that could be observed by homecare workers. The content validity of the HOME instrument was established by a panel of ten experts (three general practitioners, three pharmacists, three homecare nurses, and one geriatrician) using the method described by Lynn<sup>[33]</sup>. The HOME instrument consists of three parts: Process, Pill, and Patient (3xP). In this study, the observation list was focused on the second part (Pill) of the HOME instrument and contained seven categories of signs and symptoms of ADRs, presented in thirteen items: Gastrointestinal and other bleedings (stomach ache? very black feces? regularly occurring nosebleeds? bruises?), Electrolyte disturbances (dizziness when standing up? drowsiness? thirst?), Renal and heart failure (tightness of chest? fainting spells?), Digoxin intoxication (nausea, vomiting, and/or no appetite?), constipation (abdominal pain and no bowel movement for 5 or more days?), Disturbances of diabetic control (irregular heart rhythm, perspiration, and hunger?), and Falls (fallen recently/last year without a clear cause?). It may not always be easy to identify the underlying cause of dizziness, irregular heart failure or fainting spells. Irrespective of the cause of each individual observation, the expert panel concluded that the thirteen observation are relevant signs for homecare workers to report. The questions were answered yes or no.

### Reference standard

The likelihood that an observed sign or symptom could be drug related in that patient was established by a panel of ten pharmacists based on information gathered during an independent extensive medication interview carried out by a trained homecare nurse. This medication interview consisted of demographic questions, description of medication used, and structured questions matching the categories and items of the standardized observations.

### Procedure

Four teams of homecare workers (n=48) were instructed on the use of the HOME instrument. The instrument was filled in by the homecare worker on the basis of his or her observations during a visit while providing routine care. Within 2 weeks after inclusion, each patient was extensively interviewed about the medications they used by a qualified and specially trained homecare nurse who was blinded for the observations of the homecare worker. Subsequently, on the basis of this medication interview and the list of medications used by the patient, an expert panel of ten experienced clinical pharmacists assessed in couples: *certain, possible, probable, or unlikely* ADRs in each patient. If the assessments within the couples differed, consensus was sought, but if necessary a third pharmacist was consulted, who made the final decision. The members of the expert panel were blinded to the observations of the homecare workers. The ADRs were divided into certain, possible or probably (1) versus unlikely (2) drug related.

### Statistical analysis

Descriptive statistics were used to describe the demographic characteristics of the patients. To assess the homecare workers' ability to accurately observe signs and symptoms indicative of potential ADRs with the help of the standardized observation list, the sensitivity and specificity of this list were determined. In addition, the positive predicted value (PPV) and negative predicted values (NPV) were calculated per subcategory of the standardized observation list (except for potential ADRs, as they were not present in all categories). Data were analyzed and statistical calculations were performed using PASW for Windows version 18.0.

### Results

The homecare workers recruited 115 homecare patients during a 5-month period. The mean age of the patients was 79.3 years and most were female (79.1%), widowed (54.8%), and lived alone (69.6%). The patients used an average of 8.8 (SD=3.9) prescribed medicines per day (table 1). In total, 234 signs and symptoms indicative of potential ADRs were recorded as occurring in 92 patients (median 2 per patient, 1–7 per patient); no signs were observed in the remaining 23 patients (see table 2). Overall, 116 of the 234 observations (49.6%) were considered by the experts as being potentially drug related.

The homecare workers recorded signs or symptoms indicative of potential ADRs related to gastrointestinal or other bleeding in 68 patients: stomach ache in 9 (7.8%), very black feces in 5 (4.3%), nosebleeds in 1 (0.9%)), and bruises in 53 (46.1%). The experts considered that more than half (55.6-100%) of the bleeding events observed by the homecare workers could be drug related. Stomach ache had a high NPV (0.98; 95% CI 0.95-0.99) and a moderate PPV (0.67; 95% CI 0.35-0.84).

Signs and symptoms indicative of potential ADRs regarding electrolyte disturbances were observed in 83 patients: dizziness when standing up in 39 (33.9%), drowsiness in 15 (13.0%), and thirst in 29 (25.2%). The experts considered that more than half of the reports of dizziness (64.1%) and drowsiness (53.3%) could be drug related. Drowsiness had a high NPV (0.70; 95% CI 0.66-0.73) and a moderate PPV (0.53, 95% CI 0.27-0.77). The experts considered that a high proportion of the fainting spells (71.4%), potentially indicative of renal or heart failure, could be drug related. Fainting spells had a high NPV (0.93; 95% CI 0.90-0.95) for an ADR. Signs indicative of digoxin intoxication (calculated for patients who used digoxin n=16), constipation, and disturbances of diabetic control (calculated for diabetic patients n=50) were seen in 18.8%, 7.8%, and 28.0% of patients. Twenty homecare patients reported falling down in the past 4 weeks. The experts

considered that in 17 patients (85%), the falls could be drug related. Falls had a high PPV (0.81; 95% CI 0.70-0.94) for an ADR. The results for sensitivity, specificity, PPV, and NPV of the homecare workers' observations compared with the experts' opinion are shown in table 3.

### Discussion

This study shows that homecare workers are able to observe signs and symptoms indicative of potential ADRs with the help of a structured observation list.

Previous studies investigating drug-related problems in homecare reported that 33%<sup>[9]</sup> to 100%<sup>[35]</sup> of homecare patients had a drug-related problem. In this study homecare workers reported signs or symptoms of potential ADRs in 80% of the patients. Three earlier studies that developed an assessment instrument for home health nurses<sup>[36-38]</sup> showed that nurses are able to identify patients experiencing problems with medication, as we did. However, these studies involved general assessments and were not focused on the observation of signs and symptoms of specific ADRs. Debrew et al. <sup>[36]</sup> developed an instrument for home health nurses to help them assess the medication knowledge and practice of older adults. One of

the questions was about medication problems ("Do side effects from your medication upset your daily routine?"). Gusdal et al.<sup>[38]</sup> developed the Safe Medication Assessment tool for district nurses in Sweden. Only one of the sixteen questions refers to the occurrence of ADRs ("Has the patient symptoms that can be presumed to be adverse effects of medication"). In another previous study, Lattanzio et al.<sup>[39]</sup> examined the association between geriatric condition and ADRs. The results of this study suggests that the presence of a fall history and loss of at least one Activity of Daily Living (ADL) increases the likelihood of the presence of ADRs in elderly patients. As demonstrated in our study, homecare workers are able to recognize a history of falls and can observe changes in the patients clinical condition.

### Strength and limitations

Half of the observed signs or symptoms were judged by experts as potentially medication related. The homecare workers were able to correctly identify patients who did not show signs or symptoms of ADRs (high specificity and NPV). A high specificity is important to avoid unnecessary alarms and potential unneeded medical attention. The sensitivity of findings recorded with the standardized observation list was moderate, as indicated by the lower sensitivity and PPV. However as the home care nurses frequently visit patients and filling the instrument requires a limited amount of time, it seems recommendable to incorporate the instrument in regular procedures.

The first aspect that deserves consideration is the lack of a formal reference test for ADR observations. We used the assessment of an expert panel as the reference standard. One of the most observed and reported symptoms was (easy) bruising, which belongs to the subcategory of gastrointestinal and other bleeding and which could be due to medication. Two thirds of the patients who reported bruising used a vitamin K antagonist or a platelet aggregation inhibitor, two major drug groups associated with gastrointestinal or other bleeding<sup>[3,4]</sup>. Corticosteroids should also be considered as a possible cause of easy or spontaneous bruising, although aging or an underlying medical condition, such as a bleeding disorder, could also cause this symptom<sup>[5-34]</sup>. Similarly, the normal aging process can be an explanation for several other observations such as dizziness or drowsiness. For example, a fall can be caused by reduced mobility, muscle weakness, or poor vision, in addition to an ADR caused by a drug acting on the central nervous system. The experts considered 85% of the falls to be potentially medication related. It was for this reason that the clinical expertise of the expert panel was used.

Another limitation of this study is the relatively small study population (n=115). The number of observations per patient, however, provides sufficient power to suggest that homecare workers using a standard observation list can recognize signs of potential ADRs when providing care. Lastly, assessment of the causality of signs and symptoms indicative of potential ADRs by the experts was restricted by the limited information available about demographics and disease background. The causality assessment of potential ADRs is a well-known methodological pro-

blem in clinical research, and it is often not clear what the exact contribution is of medication or of other disease related factors. This was another reason to include the expert panel.

### Future implications

Prevention starts with early identification, and the early identification of potential ADRs by homecare workers, using a standardized observation list, followed by effective interventions, could prevent or decrease the impact of these ADRs. The detection of relatively small changes, such an increase in dizziness with time, by homecare workers could prevent more serious consequences, such as an overall deterioration of the patients' situation or a fall due to dizziness which could lead to hospitalization. Effective collaboration between different health care providers (GPs, pharmacists, and homecare workers) is essential. Homecare workers can function as the 'eyes and ears behind closed doors' for GPs and pharmacists. Further research into the effect of early recognition of potential ADRs by homecare workers should be conducted.

### Conclusion

With the help of a standardized observation list, homecare workers are able to observe signs and symptoms of potential ADRs, thereby contributing to the early recognition of ADRs in homecare settings.

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### Table 1: Characteristics of the patients (n=115)

		N	%
Age, years	45-59	8	7.0
	60-74	18	15.7
	75-89	79	68.7
	≥ 90	10	8.7
Gender	Female	91	79.1
Living situation	Single	7	6.1
	Married	35	30.4
	Divorced	10	8.7
	Widowed	63	54.8
Level of education	No education	3	2.6
	Primary education	51	44.3
	Lower secondary education	41	35.7
	Higher secondary education	11	9.6
	University	7	6.1
	Missings: information not available	2	1.7
Chronic diseases*	Diabetes	50	43.5
	Heart diseases	53	46.1
	Renal dysfunction	16	13.9
	Pulmonary disease	39	33.9
Number of drugs	Prescribed medicines (mean)	8.8	3.9 (SD)
	OTC medicines (mean)	0.7	1.4 (SD)

\*As reported by the patient SD: Standard Deviation

OTC: Over The Counter

Table 2: Numbe Reacti	er of observations ir ons in homecare pat	ndicative of potential <i>I</i> tients	Adverse Drug
Observations indicative of potential ADRs	Patients (n=115)	Total observations indicative of potential ADRs	%
0	23	0	20
1	32	32	27,8
2	20	40	17,4
3	15	45	13
4	16	64	13,9
5	3	15	2,6
6	4	24	3,5
7	2	14	1,7
	Total	234	100%

\*ADR: Adverse Drug Reaction

### Table 3: Comparision of the observations indicative of potential ADRs from homecare workers and the

	Standa Observ (S	rdized /ations O)	Medie inter	cation view	Exp SO =Me rela	erts: dication ated	
	n	%	n	%	n	%	
<b>Bleedings: (gastrointestinal and others)</b> Stomach ache? Very black feces? Regularly occurring nosebleeds Bruises?	9 4 1 53	7.8 4.3 0.9 46.1	11 9 9 71	9.6 7.8 7.8 61.7	5 4 1 33	55.6 100 100 62.3	
<b>Electrolyte disturbances:</b> Dizziness when standing up? Drowsiness? Thirst?	39 15 29	33.9 13.0 25.2	48 55 31	42.6 47.8 27.0	25 8 9	64.1 53.3 31.0	
<b>Renal failure-heart failure:</b> Tightness of chest? Fainting spells?	31 7	27.0 6.1	39 13	33.9 11.3	4 5	12.9 71.4	
<b>Digoxin intoxication (n=16):</b> Nausea, vomiting and/or no appetite?	3	18.8	8	7.0	2	66.7	
<b>Constipation:</b> Abdominal pain/no bowel movement ≥ 5 days?	9	7.8	9	7.8	1	11.1	
<b>Disturbances of diabetic control</b> Diabetic (n=50): Irregular heart rhythm/transpiration/ hunger?	14	28.0	7	6.1	2	14.3	
Falls:Recently fallen without a clear cause?fallen last year?	20	17.4 *	14 61	12.2 53.0	17	85.0	
Total observations indicative of poten- tial ADRs	234				116	49.6	

ADR: Adverse Drug Reaction, CI: Confidence Interval, Sens: Sensitivity, Spec; Specificity, PPV: Positive Predicted Value, NPV: Negative Predicted Value, n:number of patients

\* not asked in standardized observations (HOME-instrument)

SO: standardized Observations

expert	panel as	sessment	t (n=115)								
Sens*	CI 9	5%	Spec*	CI 9	5%	PPV*	CI 9	5%	NPV*	CI 9	5%
0.75	0.40	0.95	0.97	0.95	0.99	0.67	0.35	0.84	0.98	0.95	0.99
0.67	0.57	0.79	0.70	0.62	0.77	0.62	0.52	0.71	0.76	0.67	0.84
0.51 0.21 0.43	0.40 0.13 0.24	0.61 0.30 0.63	0.79 0.91 0.77	0.71 0.86 0.72	0.86 0.96 0.81	0.64 0.53 0.29	0.50 0.29 0.16	0.76 0.77 0.43	0.68 0.70 0.86	0.61 0.66 0.81	0.75 0.74 0.91
0.57 0.39	0.20 0.17	0.88 0.55	0.74 0.97	0.72 0.94	0.76 0.99	0.13 0.63	0.05 0.28	0.19 0.89	0.96 0.93	0.93 0.90	0.99 0.95
0.33	0.07	0.49	0.90	0.74	1.00	0.69	0.13	0.98	0.36	0.57	0.77
0.10	0.01	0.40	0.92	0.92	0.95	0.11	0.01	0.44	0.92	0.91	0.94
0.33	0.06	0.73	0.82	0.78	0.87	0.20	0.04	0.44	0.90	0.86	0.96
0.34	0.25	0.39	0.94	0.87	0.98	0.81	0.70	0.94	0.65	0.60	0.68

Appendix 1 Homecare Observation of Medication related problems by homecare Employees (HOME) instrument.

Function: O Helper O nursing aid O Nurse Date: \_\_\_ / \_\_\_ / \_\_\_ / \_\_\_

					tner		
				○ Male / ○ Female	○ Living alone / ○ Living with part		
Name:	Address:	Telephone number:	Date of Birth:	Sex:	Living Situation:	Number of medicines:	

# Process

Is there a printout of the list of medication from the pharmacy?	🔿 Yes 🚩 🔿 No	
If yes: - Note the date: / / /		
If yes: - Does the patient take the medicines on the list?	O Yes ► O No O	20
Comments		

	_	
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- Nausea, vomiting and/ or no appetite?	0
- Abdominal pain and/or no bowel movement for more than 5 days?	
- For diabetes: Irregular heart rhythm and transpiration?	0
- For diabetes: Feeling of hunger?	0
Has the patient fallen recently without a clear cause?	
Patient	ΥES
Does the patient regularly forget to take his/her medication?	
- Does the week package contain medicine from previous days?	
- Does the robot-dispensed dosing aid contain pouches of	
medicine from previous days?	0
Is the supply of medicine in house:	
- Disordered? (is medicine left lying around?)	
- Regularly insufficient?	0
Does the patient have problems taking the medication? (for example, problems swallowing)	0
Does the patient have trouble opening the packaging?	0
Does the patient have pain?	0
Does the patient take more than 8 painkillers a dav without a prescription?	C

# Comments

Is the patient very different from usual? (for example, suddenly confused, very irritable or lethargic)

Does the patient use other painkillers without a prescription? Does the patient drink more than 3 glasses of alcohol a day?

Other comments about the medicines:

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Chapter 5





### **General discussion**

A growing number of older patients with multiple morbidities are dependent on medication to maintain their daily lives. In combination with natural changes in age-related drug metabolism, impaired cognition, multiple morbidities, reduced renal function, polypharmacy and impaired compensating capacity (frailty), older people are particularly vulnerable to drug-related problems (DRPs)<sup>[1-4]</sup>. DRPs can occur during various stages of the medication management process, including prescribing, dispensing, taking/administering, monitoring, and evaluation, and can be caused by various actors in this process, such as the healthcare professionals (physicians, nurses, pharmacists) and the patient him- or herself<sup>[5]</sup>. Scientific analysis has shown that research to prevent DRPs in primary care should focus on the medication taking/administering phase. Research on the prevention of DRPs has, in general, focused on general physicians<sup>[6-10]</sup> and pharmacists<sup>[11-14]</sup>.

Many older patients at risk for DRPs receive homecare as a result of declining daily functioning. In the area of research and in the scientific debate regarding the prevention of DRPs, the patients and professionals who support these patients at home, such as homecare workers, have largely been ignored.

The aim of this thesis was to explore the prevention and early recognition of potential DRPs by including homecare workers in the chain of medication safety.

In this thesis, a variety of studies were brought together highlighting the beliefs and medication management capacity of older people and the knowledge, attitude and observation skills of homecare workers regarding medication and DRPs.

The objectives of the thesis were as follows:

- To explore the beliefs to older people regarding their medication and their medication management capacity relative to their self-management skills and cognition;
- 2. To describe the medication management practices, knowledge and attitudes regarding medication of homecare workers; and
- 3. To determine whether standardized observations in homecare can lead to early recognition of DRPs.

### Main findings of the thesis

In general, the presented studies provided insight into the beliefs and medication management capacity of older (homecare) patients and into the medication management practices, knowledge and attitudes of homecare workers regarding DRPs. The main findings were as follows:

Concerning the patient

- Community-dwelling older patients viewed their medicines as necessary and showed little concern regarding harm and overuse (chapter 2.1).

- Nearly half of the older homecare patients in this study were not able to manage their medications by themselves (chapter 2.2).

### *Concerning the homecare worker*

- Almost all of the homecare workers stated that they provide information about drugs to their patients (chapter 3.1).
- A considerable percentage of the homecare workers indicated observing non-adherence and adverse drug reactions (ADRs) (chapter 3.1).
- Homecare nurses felt responsible for promoting proper medication use in their older patients (chapter 3.2).
- The knowledge of homecare nurses regarding medication was insufficient and should be improved (chapter 3.2).

### Concerning early recognition

- The frequency of prescription changes in an individual patient is associated with hospital admission. This relationship indicates that the prescription change frequency (PCF) can contribute to the identification of patients who are at especially increased risk of DRPs in primary care (chapter 4.1).
- Homecare workers indicated recognizing central nervous system side effects (confusion, drowsiness and fatigue) better than gastrointestinal disorders and dizziness (chapter 4.2).
- Registered nurses and licensed practical nurses indicated, more than less educated nurse assistants, recognizing and reporting symptoms of DRPs (chapter 4.2).
- Homecare workers are not informed about prescription changes (chapter 4.2).
- With the help of a standardized observation list, homecare workers are able to observe signs and symptoms indicative of potential DRPs (chapter 4.3).

In this final chapter, the main findings of this research will be placed within a broader perspective. First, reflections on practice-based research and education in homecare will be offered. Second, a closer look, enhancing the quality of medication management in homecare patients, will be described. Third, attention will be paid to the window of opportunity for early recognition by homecare workers of signs and symptoms that are indicative of potential DRPs. Based on these reflections, the implications of the findings and further research will be addressed.

### **Reflections on practice-based research in homecare**

A few years ago, the Dutch homecare organization Aveant (today called Careyn) asked the Hogeschool Utrecht University of Applied Sciences for help in improving medication safety in homecare. Homecare workers reported 'uneasy feelings' about their patients' medication; however, knowledge and tools to interpret these feelings were lacking. This question became the start of practice-based research, upon which this thesis is based, as well as follow-up research regarding older people receiving polypharmacy<sup>[15]</sup>. Given the challenges faced in homecare as a result of the growing number older multiple-morbidity patients, many similar questions will rise. For many questions, evidence from research to substantiate answers has been lacking. Practice-based research involves solving practical questions in a scientific manner, and it builds on strong collaboration between professionals and researchers. Within networks of professionals and researchers, validated instruments can be implemented in practice. These data enable an objective analysis of problems. Solutions for these problems can be built on subsequent studies, in which professionals and researchers combine their knowledge and experience. In the 'Medication Management in Homecare Patients Project', the following professional organization were involved: the (home)care organizations Careyn and

Buurtzorg; Expertise Centre Pharmacotherapy in Older Patients (Ephor); the Partnership of General Practitioners of Utrecht (Stadsmaatschap Huisartsen Utrecht); and the National Professional Organization of Primary Care Nurses (V&VN, afdeling eerste lijn). Addressed by these professionals, supplemented with teachers, students and researchers, the question of homecare organization could be answered. As a result, homecare workers are able to observe signs and symptoms indicative of potential DRPs, with the help of the HOME instrument.

### The roles of students and teachers

Practice-based research can also provide educational innovation by involving students in practice-based research and by integrating knowledge into education. Of the studies described in this thesis, there were 28 bachelor's degree in nursing students, 4 Master's degree in nursing sciences students, 4 bachelor's degree in pharmaceutical business administration students and 2 Master's of pharmacy students involved. Many of these students are currently active professionals who have graduated. Working in this project made these students (and their teachers) aware of the challenging role of homecare workers in medication safety. Given the challenges these professionals will face in the forthcoming years, their experience and ability to collaborate in practice-based research will prove valuable. In addition, practice-based research, in interaction with education, speeds up the velocity of bringing the results of research into practice. Today, bachelor's degree in nursing students in Utrecht are trained to work with the HOME instrument. In addition, several homecare organizations, for instance, those to which students report for their internships, are now working with this standardized observation list in practice. The HOME instrument is freely accessible via the Web site of the research center and is accompanied by a free demonstration film as well. By students conducting practice-based research while embedded in an university of applied sciences, the well-known gaps among research, education and practice will be reduced, and quality of care will be enhanced in an innovative manner. Moreover, future professionals will be prepared for evidence-based practice, even in those practices in which evidence has been lacking.

### Methodological considerations

One could argue that randomized, clinical trials (RCTs) provide the strongest scientific evidence. However, RCTs have serious limitations when developing knowledge for use in nursing practice<sup>[16,17]</sup>.

RCTs in nursing, and often also in medicine, do not provide evidence for general laws but allow for only probabilistic conclusions<sup>[18]</sup>. Heerdink et al<sup>[19]</sup> put it as follows: 'While clinical trials may form the foundation of evidence-based medicine, one should not neglect medicine-based evidence'.

All of the included studies in this thesis, except for the study described in chapter 4.1, had a cross-sectional design with self-reports, which precludes any attempt to establish the direction of causality. However, in the unexplored area of the patients' and homecare workers' roles in medication-related problems in homecare, observational studies are the preferred method for achieving the objectives. In addition, the study populations in chapter 2.1 (n=91), chapter 2.2 (n=95), chapter 3.2 (n=146), chapter 4.2 (n=105) and chapter 4.3 (n=115) were relatively small. These sample sizes could hamper the generalizability of the findings. However, the studies provided an in-depth insiders' view of the beliefs of communitydwelling older people and the perceptions of homecare workers regarding medication, indicating the importance of appropriate medication management in older homecare patients. Moreover, in this area of research, these sample sizes can be considered adequate. In this thesis, we attempted to use instruments that were already validated and used in other studies to enable the comparison of findings and to contribute to the accumulation of knowledge. Given the paucity of studies in this area, these goals were not possible to accomplish for all of the studies. Therefore, for the study in chapter 2.2, we used the Medication Management Capacity instrument (MMC, known as BEM in the Netherlands), which has been used in daily practice in the Netherlands. However, the MMC has not yet been validated. For the study in chapter 4.2, we developed a questionnaire that was based on potential side effects of the ten most frequently used drug products by people aged 75 years old or older. The face validity was established by experts. The feasibility was assessed during a national homecare congress.

### **Reflections on medication management in homecare patients**

### Homecare and the medication system: A window of opportunity

For a safe medication process in homecare, appropriate coordination among all important stakeholders is necessary, namely the patient (and caregiver), general practitioner or specialist (prescriber), pharmacist (provider), homecare organization and homecare worker<sup>[20]</sup>. The patient is responsible for providing relevant information to his or her general practitioner and pharmacist and for correct medication use. However, as reported in chapter 2.1, community-dwelling older people view their medicines as necessary and show little concern regarding harm or overuse. These strong beliefs in the necessity of their medicines enhance the adherence<sup>[21-29]</sup>. Nevertheless, it could blind them as well as healthcare providers to the DRPs that occur frequently in this population<sup>[30-35].</sup> Communitydwelling older people could consider observed symptoms as an unavoidable part of aging or disease, rather instead of drug-related events. Moreover, as reported in chapter 2.2, almost half of the homecare patients in this study were not able to manage their medications. Approximately 40% of them were unable to state the names of their medications, even with the aid of a medication list. In addition, only one quarter of the homecare nurses agreed with the statement that patients always indicated their complaints to them (chapter 4.2).

These problems emphasize the relevance of alertness by homecare workers to signs and symptoms indicative for potential DRPs and of proactive attitudes. The latter means that when signs or symptoms are observed, reporting in the nursing record is not sufficient. Contacting the general practitioner, first responsible nurse or pharmacist could also be necessary to improve the situation of the patient.

The medical prescriber is responsible for the diagnosis of illness or disease and the initiation of therapy. The pharmacist is responsible for the provision of drugs, counseling of patients, educating of healthcare professionals in drug use, and preparing of medications.

Nurses are responsible for drug administration and registration<sup>[36,37]</sup>. In addition, nurses are responsible for educating and coaching and for the observation and monitoring of their patients. Medical doctors focus on making diagnoses and initiating therapy, whereas nurses focus on *the consequences for the patient* of these diagnoses and treatments. Medication-related problems are consequences of treatment<sup>[37]</sup>. Therefore, observing the consequences of medication and providing early warnings of potential DRPs for the patient without a doubt constitute a part of the nursing profession. Signs and symptoms indicative of potential DRPs recorded by homecare workers, using a standardized observation list, aid in the early recognition of DRPs in homecare patients (chapter 4.3).

### Opportunities in timing

The first few weeks following hospital discharge are a particularly high-risk interval for DRPs<sup>[38,39]</sup>. Patients often experience changes in health state, and they do have frequently several prescription changes<sup>[40-43]</sup>. There might also be incomplete communication with community care providers reflecting these changes. Therefore, the medication management capacity (MMC) of the older homecare patient, defined as the cognitive and functional ability to self-administer a medication regimen as prescribed[44], should be measured with the MMC instrument at hospital discharge or homecare intake. If the MMC score is less than 13 (incapable of medication management), homecare or informal care should be incorporated for medication management support. Subsequently, medication management support should be an indication for homecare and should be reimbursed.

Prevention of (re)hospitalization is expected to lower the costs of healthcare and improve the quality of life of patients with multiple morbidities who are receiving polypharmacy.

### Opportunities for collaboration in integrated care

In this thesis, we demonstrated that homecare workers, using a standardized observation list, were able to observe signs and symptoms in homecare patients that were indicative of DRPs (chapter 4.3). Identification of these potential DRPs by homecare workers, followed by effective interventions, could prevent or decrease the impact of DRPs. The detection of relatively small changes by homecare workers, such as an increase in dizziness over time, could prevent more serious consequences, such as overall deterioration of the patient's situation or a fall due to dizziness, which in turn could lead to hospitalization. Homecare workers could assign homecare patients who should have a medication review by a pharmacist, based on the standardized observations.

In chapter 4.1, we demonstrated that prescription change frequency (PCF) was associated with hospital admission. In current practice, as mentioned in chapter 4.2, homecare workers are often not aware of prescription changes. Prescribers should consider informing the homecare worker when the number of prescription changes increases. Moreover, the prescriber should ask for particular observations and feedback from the homecare worker. Effective collaboration is essential, whereby homecare workers can function as the 'eyes and ears behind closed doors' for GPs and pharmacists. With the help of standardized observations, homecare workers are able to observe signs and symptoms indicative of DRPs, as demonstrated in chapter 4.3. As of now, in the Dutch multidisciplinary protocol for polypharmacy in older people<sup>[45]</sup>, homecare workers have not been mentioned. The involvement of homecare workers in the next edition would improve this protocol.

Collaboration in primary care among general practitioners, pharmacists and homecare workers should be supported by communication appointments.

Moreover, standardized observations indicative of potential DRPs should be integrated into a digital file and transformed into a digital communication application ('app') for smart phones or tablets to facilitate this communication.

Multidisciplinary collaboration in integrated care can be seen as a key issue in the improvement of DRPs in homecare. The responsibilities, in summary, are as follows:

- the patient: providing relevant information to the prescriber and/or pharmacist, followed by proper intake after agreement on prescriptions;

- the medical prescriber: appropriate prescribing and shared decision-making
- with the patient;
  the pharmacist: accurate providing of drugs, counseling of patients, educating of healthcare professionals in all facets of drug use, and the preparing of medications:
- homecare organization: educating employees and facilitating collaboration among homecare workers, pharmacists and general practitioners;
- the homecare nurse assistant: observing and reporting changes in the patients' situation, and reporting this information in the nursing file and to the primary nurse;
- the licensed practical nurse: controlling, administering, advising and teaching patients, observing signs and symptoms indicative of the negative effects of medication, and reporting this information in the nursing file and to the primary nurse; and
- the homecare nurse: controlling, administering medication (also by airway, injection or drip and making solutions and dilutions), advising, teaching and coaching patients and LPNs and NAs, observing signs and symptoms indicative of potential DRPs, contacting LPNs and NAs as the primary nurse for the signs and symptoms indicative for potential DRPs, further assessment in case of potential DRPs by a medication interview, reporting this information in nursing file, referral to the prescriber or provider, and coordination of medication management care.

The study, as reported in chapter 3.1, demonstrated that almost all homecare workers indicated providing information about the drugs that their patients were using in daily practice. This duty is not arranged in current practice, given that medication management support is not reimbursed as an indication for homecare. This lack of reimbursement should be changed as part of the healthcare transition to care as closely for the patient as possible.

### Opportunities in education

In this study, as reported in chapter 3.1, on average, half of the homecare workers labeled their medication knowledge as insufficient, and two thirds of the homecare workers indicated a need for medication education. The observation of signs and symptoms indicative of DRPs requires knowledge and the correct attitude. Almost all of the homecare nurses (LPNs and ANs to a lesser extent) indicated knowing that gastrointestinal disorders, diarrhea, nausea, confusion, drowsiness, fatigue and dizziness could be side effects of drugs (chapter 4.2). In addition, a considerable number of homecare workers reported recognizing non-adherence and adverse drug reactions in their patients (chapter 3.1). However, in chapter 3.2, we demonstrated that the knowledge of homecare nurses regarding the ten most common medications used by older people could be improved. This deficit suggests that homecare nurses are overestimating their competence regarding medication. Therefore, homecare organizations should invest in permanent education for their staff regarding medication. In addition, nursing schools should embed medication management into their curricula. In addition to knowledge, which supports the awareness that particular signs and symptoms could be drugrelated, the willingness to provide excellent care is required and forms the basis of the correct attitude in homecare. Knowledge and attitude are also key issues in improving DRPs in homecare. Given that nursing students are not yet prepared for the growing number of multiple morbidity older patients[46], there is an urgent need for change.

### Implications for clinical practice, education and further research

- Prescribers and providers should improve their efforts in explaining and educating their patients to recognize important signs and symptoms indicative of DRPs.
- Homecare workers should support this improvement and arrange follow-ups.
- Systematic screening on patients' medication management capacity is necessary in homecare patients.
- Homecare workers should be aware of decreased self-management ability in their patients as a sign for decreased medication management capacity.
- The effects of communication between prescribers and homecare workers regarding prescription changes and prescription change frequency should be further investigated.
- The validity of the MMC instrument should investigated.
- The effect of medication education on the observation skills and on pro-active interventions regarding drug-related problems should be further investigated in a controlled intervention study.
- The effect of the identification of signs and symptoms indicative of DRPs by homecare workers on the quality of life of patients, as well on cost-effective-ness with regard to healthcare use, should be further investigated in a control-led intervention study.
- Conforming to the digital computer era, the standardized observation list on paper should be further developed as a digital integrated file or application, also called an 'app'.
- Nursing schools should enhance education regarding medication, DRPs and early recognition of DRPs.
- The evolution of 'hogescholen' into universities of applied sciences, in which practice-based research is connected with education, should be recognized as an important component of quality of education and quality of care.

### Conclusion

Older homecare patients are insufficiently aware of their vulnerability to DRPs. In addition, a considerable number of homecare patients are not able to manage their medications independently. Homecare workers are in an ideal position behind the front door, and they could contribute added value in the early recognition of DRPs by observing signs and symptoms indicative of potential problems. Knowledge, a pro-active attitude regarding medication, permanent education and multidisciplinary collaboration in integrated care are key issues in the improvement of drug-related problems in homecare.

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## Chapter 6

Summary

besilaat) Mylan 5 mg

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aren in de oorspronkelijke verpakking ter bescherming tegen licht. en het zicht en bereik van kinderen houden. voor gebruik de bijsluiter voor meer informatie.

Atorvastatine Mylan 40 mg 30 filmomhulde tabletten

Lot: EXP: In the Netherlands, people aged 65 years and older use three times more medication, and people aged 75 years and older consume five times more than the average person. In combination with natural changes in age-related drug metabolism, impaired cognition, multiple morbidities, reduced renal function, polypharmacy and impaired compensating capacity (frailty), older people are particular vulnerable to drug-related problems (DRPs).

Impaired cognition, polypharmacy and aged older than 65 years old are highly prevalent in people receiving homecare services. Therefore, particular segments of the older homecare patient population are vulnerable to DRPs.

Several studies have shown that physicians and pharmacists can contribute to the recognition of DRPs in patients care. However, to date, little attention has been paid to the process of early recognition of the observations indicative of potential DRPs in the home environment.

In addition to the general practitioner and pharmacist, homecare workers who visit their patients in their homes on a regular basis might be able to facilitate early recognition of potential DRPs.

The main objectives of this study were to:

- Explore the beliefs of older people regarding their medication and their medication management capacity relative to their self-management ability skills and cognition;
- 2. Describe the medication management practices, knowledge and attitudes regarding medication among homecare workers; and
- 3. Determine whether standardized observations in homecare could result in early recognition of DRPs.

**Chapter 1** describes how these aspects have led to the various studies and provides a general introduction including objectives and outline of this thesis. **Chapter 2** of this thesis describes the patients' beliefs regarding medication and medication management capacity in homecare patients.

In **chapter 2.1** we explored the beliefs about medicines and factors influencing these beliefs in community-dwelling elderly who were using medication. In a cross-sectional survey using the Beliefs about Medicines Questionnaire, 91 elderly were interviewed at their home. The participants were convinced of the necessity of their medicines, while they did not show concerns regarding overuse and harm. The results indicate that elderly if well informed regarding their medication will be adherent and in the meantime there could be a risk of harm due to their neglect of the possibility of adverse events.

In **chapter 2.2** the medication management capacity of 95 independent living older people on polypharmacy in relation to their cognitive- and self-management skills were determined, using the Medication Management Capacity questionnaire, Self-Management Ability Score and Clock-Drawing-Test. Almost half of the participants were able to manage their medication by themselves at home. Cogni-
tion and self-management ability were related to medication management capability. Self-management ability and medication management support were predictors of medication management capacity.

**Chapter 3** of this thesis describes the homecare workers' knowledge and attitude and medication management practices regarding medication.

The medication management practices of homecare workers (n=507) were assessed in a cross-sectional survey and described in **chapter 3.1**. Homecare nurses' medication management practices consist of handling over medication, providing information, observing non-adherence and observing ADRs. Almost all homecare workers said they provided information about drugs to their patients although their trust in their medication knowledge was lacking and they said they needed medication education. To be effective, the homecare nurses' observations of nonadherence or ADRs need to be reported to the prescriber/or provider. Therefore, knowledge about medication and multidisciplinary collaboration in integrated care could be key issues in improving medication management by homecare workers.

Knowledge and perspectives of Dutch homecare nurses regarding medication frequently used by older people was measured in a cross-sectional study (n=146) and described in **chapter 3.2**. Although most homecare nurses felt responsible for their older patients' proper medication use and agreed with the statement that they played a role in preventing older patients' medication related hospital admissions, their knowledge could be improved.

**Chapter 4** of this thesis presents three studies focusing on the early recognition of Drug Related Problems.

In **chapter 4.1** a retrospective matched case-control study was conducted (n=17362), to assess the association between Prescription Change Frequency and hospital admission. The odds ratio (OR) of hospital admission increased with an increase in PCF category. At 3 months before the index date from PCF=1 OR 1.4 [95%CI 1.3-1.5] to PCF=2-3 OR 2.2 [95CI 1.9-2.4] and to PCF  $\ge$  4 OR 4.1 [95%CI3.1-5.1]. Pharmacists and other healthcare workers should be alert when the frequency of prescription changes increases.

In **chapter 4.2** a survey (n=105) was conducted to describe how homecare workers rate their knowledge, monitoring skills and ability to recognize adverse drug reactions and drug interactions of the most commonly used medication in older homecare patients. Homecare registered nurses (RNs) stated to recognize more (OR = 3.84;CI 1.43-10.30) gastrointestinal disorders, diarrhea and nausea and also more (OR = 4.33; CI = 1.09-17.26) confusion, drowsiness and fatigue than lower educated homecare assistants. In general, homecare workers recognize side-effects of confusion, drowsiness and fatigue more easily than gastrointes-

tinal disorders and dizziness. There were differences between Registered Nurses (RN), Licensed Practical Nurses (LPN) and Nurse Assistants (NA) in the knowledge and their skills to recognize adverse drug reactions and interactions in homecare. Therefore, the allocation of homecare clients to RNs, LPNs or NA should be arranged well throughout.

To determine whether homecare workers can detect signs and symptoms indicative of potential ADRs in their patients, an observational study (n=115) was conducted and described in **chapter 4.3**. During routine home visits, homecare workers filled in a standardized observation list of signs and symptoms indicative for potential ADRs, namely, gastrointestinal and other bleedings, electrolyte disturbances, renal and heart failure, digoxin intoxication, constipation, disturbances of diabetic control, and falls. The observations were compared against the medications that the patients were using, and their known side effects, by a panel of clinical pharmacology experts. Half (49.6%) of the signs and symptoms were considered drug related. Observed dizziness (64.1%) and drowsiness (53.3%) could be drug related in most cases, as could most cases (71.4%) of fainting spells (indicative of renal or heart failure). Seventeen of 20 observed falls could be drug related. The specificity of the standardized observation list was high, varving from 0.70 (CI: 0.62-0.77) to 0.97 (CI: 0.95-0.98). Signs and symptoms indicative of potential ADRs recorded by homecare workers using a standardized observation list can aid in the early recognition of ADRs in homecare patients.

**Chapter 5** provides a general discussion of the results of the individual studies in thesis placed in a broader perspective. Three topics are discussed: reflections on practice-based research in homecare; reflections on medication management in homecare patients; and implications for clinical practice, education and further research. According to our findings, older homecare patients are insufficiently aware of their vulnerability to DRPs. Homecare workers are in an ideal position behind the front door, and they could contribute added value in the early recognition of DRPs by observing signs and symptoms indicative of potential problems. Knowledge, a pro-active attitude regarding medication, permanent education and multidisciplinary collaboration in integrated care are key issues in the improvement of drug-related problems in homecare.

## Chapter 6

## Samenvatting

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Atorvastatine Mylan 40 mg 30 filmomhulde tabletten

Lot: EXP: In Nederland gebruiken 65 plussers drie keer zoveel medicijnen als de gemiddelde Nederlander. Voor 75 plussers geldt dat zij vijf keer zoveel medicijnen gebruiken. In combinatie met leeftijdsgerelateerde natuurlijke veranderingen in het metabolisme, verminderde cognitie, multi-morbiditeit, verminderde nierfunctie, polyfarmacie en verminderde capaciteit tot herstel, zijn ouderen kwetsbaar voor medicatiegerelateerde problemen.

Thuiszorg cliënten zijn doorgaans ouder dan 65 jaar, waardoor er vaker sprake is van polyfarmacie en verminderde cognitie. Daarom bevinden zich vooral in deze populatie cliënten, die kwetsbaar zijn voor medicatiegerelateerde problemen.

Verschillende studies hebben aangetoond dat huisartsen en apothekers een bijdrage kunnen leveren aan het herkennen van medicatiegerelateerde problemen bij hun patiënten. Er is echter weinig aandacht besteed aan het vroegsignaleren van observaties die kunnen duiden op een medicatie gerelateerd probleem door thuiszorgmedewerkers. In aanvulling op de huisarts en apotheker zouden thuiszorgmedewerkers, die hun patiënten op regelmatige basis thuis bezoeken, een bijdrage kunnen leveren aan het vroegsignaleren van potentiële medicatiegerelateerde problemen.

Het doel van dit proefschrift is het:

- verkennen van de opvattingen van ouderen ten aanzien van hun medicatie en hun medicatie management capaciteit gerelateerd aan zelfmanagement vaardigheden en cognitie;
- 2. beschrijven van de kennis, houding en medicatie management praktijk van thuiszorgmedewerkers;
- 3. vaststellen of een gestandaardiseerde observatielijst leidt tot vroegsignalering van potentiële medicatiegerelateerde problemen in de thuiszorg

**Hoofdstuk 1** bevat een algemene introductie, doelen en korte beschrijving van het onderzoek gepresenteerd in dit proefschrift.

**Hoofdstuk 2** van dit proefschrift beschrijft de opvattingen van patiënten ten aanzien van hun medicatie en de medicatie management capaciteit van thuiszorg cliënten.

In **hoofdstuk 2.1** hebben we de opvattingen van ouderen ten aanzien van hun medicatie onderzocht en gekeken welke factoren deze opvattingen beïnvloeden. In deze studie hebben we bij 91 ouderen thuis, een vragenlijst afgenomen ('beliefs about Medicines Questionnaire', BMQ). De deelnemers in deze studie waren overtuigd van de noodzaak van hun medicijnen en toonden geen zorgen over bijwerkingen. Door deze overtuiging zullen deze ouderen hun medicatie trouw innemen. Het is echter mogelijk dat eventuele bijwerkingen door deze overtuiging niet (tijdig) worden herkend. In **hoofdstuk 2.2** hebben we de Medicatie Management Capaciteit van 95 thuiszorgcliënten met polyfarmacie onderzocht in relatie tot hun cognitieve en zelfmanagement vaardigheden. Hiervoor hebben we de BEM (Beoordeling van Eigen beheer Medicatie/Medication Management Capacity), de Self-Management Ability Score (SMAS) en de klok teken test gebruikt. Bijna de helft van de thuiszorgcliënten was in staat om zijn of haar medicijnen zelf te managen. Cognitie en zelfmanagement vaardigheden waren van invloed op de Medicatie Management Capa-citeit. De mate waarin de cliënt in staat was tot zelfmanagement van de medicatie en de mate van medicatie ondersteuning door familie of professionele zorg waren voorspellers van de Medicatie Management Capaciteit.

In **hoofdstuk 3** van dit proefschrift beschrijven we de kennis en houding van thuiszorgmedewerkers ten aanzien van medicatie en hun dagelijkse praktijk ten aanzien van medicatie management.

De dagelijkse praktijk ten aanzien van medicatiemanagement door thuiszorgmedewerkers (n=507) is gemeten met behulp van een vragenlijst en wordt beschreven in **hoofdstuk 3.1**. De dagelijkse praktijk van thuiszorgmedewerkers ten aanzien van medicatie bestaat grofweg uit: het aanreiken van medicatie, het geven van informatie en het observeren van therapie-ontrouw en bijwerkingen.

Bijna alle thuiszorgmedewerkers gaven aan informatie over medicijnen te geven aan hun cliënten, alhoewel zij eveneens aangaven dat hun kennis over medicatie tekort schoot en er behoefte was aan scholing.

Om de observaties van thuiszorgmedewerkers een effectief onderdeel te laten zijn van de medicatieveiligheid voor de cliënt, dienen deze observaties te worden ge-rapporteerd aan de voorschrijver of verstrekker van de medicatie. Medicatiekennis en multidisciplinaire samenwerking lijken sleutels tot het verbeteren van de medicatieveiligheid in de thuiszorg.

De kennis en houding van Nederlandse wijkverpleegkundigen (n=146) ten aanzien van medicatie die frequent door ouderen wordt gebruikt is gemeten met behulp van een digitale vragenlijst en beschreven in **hoofdstuk 3.2**. Hoewel de meeste wijkverpleegkundigen aangaven zich verantwoordelijk te voelen voor een juist gebruik van de medicatie door hun oudere thuiszorgcliënten, en het eens waren met de stelling dat zij een bijdrage konden leveren aan het voorkomen van medicatie gerelateerde ziekenhuisopnamen middels vroegsignalering van dreigende medicatiegerelateerde problemen, zou de kennis van wijkverpleegkundigen nog verder kunnen worden verbeterd.

In **hoofdstuk 4** van dit proefschrift worden drie studies gepresenteerd gericht op het vroegsignaleren van medicatie gerelateerde problemen.

In **hoofstuk 4.1** beschrijven we een gematchte retrospectieve case-control studie (n=17362) waarin de associatie tussen het aantal wijzigingen in medicatievoor-schriften en ziekenhuisopnamen is onderzocht.

De odds ratio op een ziekenhuisopname steeg naarmate het aantal wijzigingen in medicatievoorschriften steeg. Apothekers en andere gezondheidszorg medewerkers dienen daarom alert te zijn wanneer het aantal wijzigingen in medicatievoorschriften stijgt.

In **hoofdstuk 4.2** beschrijven we hoe thuiszorgmedewerkers (n=105) hun kennis, observatievaardigheden en mogelijkheden om bijwerkingen en interacties van medicijnen die ouderen veel gebruiken te herkennen, inschatten. Verpleegkundigen gaven vaker dan helpenden aan, dat zij gastrointestinale problemen, diarree en misselijkheid herkenden, als een mogelijke bijwerking van de medicatie. Daarnaast gaven verpleegkundigen vaker dan helpenden aan, dat zij verwardheid, slaperigheid en vermoeidheid herkenden als een mogelijke bijwerking. Over het algemeen werden door alle thuiszorgmedewerkers de bijwerkingen van verwardheid, slaperigheid en vermoeidheid beter herkend dan gastrointestinale problemen en duizeligheid. Verpleegkundigen, ziekenverzorgenden en helpenden schatten hun kennis en vaardigheden betreft het vroegsignaleren van signalen duidend op een medicatiegerelateerd probleem echter verschillend in. Het is daarom raadzaam om bij het toewijzen van cliënten aan medewerkers, rekening te houden met de kennis en vaardigheden van deze medewerkers.

Om vast te kunnen stellen of thuiszorgmedewerkers signalen en symptomen duidend op een mogelijke bijwerking van medicatie herkennen, beschrijven we in hoofdstuk 4.3 een observationele studie (n=115). Tijdens een routine huisbezoek vulden thuiszorgmedewerkers een gestandaardiseerde observatielijst in met signalen en symptomen die zouden kunnen duiden op bijwerkingen van medicatie, namelijk gastrointestinale problemen en bloedingen, verstoring van de elektrolyten balans, nier- en hart falen, digoxine-vergiftiging, obstipatie, verstoring van de controle van diabetes en vallen. Deze observaties werden, vergezeld van de medicatie die deze cliënten gebruikten, voorgelegd aan een expert panel van klinische apothekers. De helft (49.6%) van de signalen en observaties werden door dit panel als potentieel medicatiegerelateerd beschouwd. De observaties van duizeligheid (64.1%), slaperigheid (53.3%) en wegrakingen (71.4%) werden in de meeste gevallen als medicatiegerelateerd beschouwd. Van de 20 geobserveerde valpartijen werd bij 17 valpartijen een relatie met medicatie mogelijk geacht door het expertpanel. De specificiteit van de gestandaardiseerde observatielijst was hoog, variërend van 0.70 (BI: 0.62-0.77) tot 0.97 (BI: 0.95-0.98). Met behulp van een gestandaardiseerde observatielijst kunnen thuiszorgmedewerkers bijdragen aan het vroegsignaleren van signalen en symptomen die duiden op een mogelijk medicatiegerelateerd probleem.

Tenslotte wordt in **hoofdstuk 5** een algemene discussie gegeven waarbij de resultaten van de individuele onderzoeken in dit proefschrift in een breder perspectief worden geplaatst. Drie onderwerpen worden besproken: een reflectie op praktijkgericht onderzoek in de thuiszorg, reflectie op medicatie management van thuiszorg cliënten en tenslotte implicaties voor de klinische praktijk, onderwijs en vervolgonderzoek.

Gebaseerd op onze resultaten blijken oudere thuiszorgcliënten onvoldoende bewust van hun kwetsbaarheid ten aanzien van medicatiegerelateerde problemen.

Thuiszorgmedewerkers bevinden zich in de ideale positie achter de voordeur en kunnen hierdoor een bijdrage leveren aan het vroegsignaleren van signalen en symptomen die duiden op een potentieel medicatie gerelateerd probleem, met behulp van een gestandaardiseerde observatielijst. Kennis, een pro actieve houding ten aanzien van medicatie, permanente educatie en multidisciplinaire samenwerking in geïntegreerde zorg, lijken sleutels tot succes om medicatie gerelateerde problemen in de thuiszorg te verbeteren.

# Chapter 6



Het schrijven van een dankwoord is een moment van reflectie. Ik besef dat dit proefschrift nooit tot stand was gekomen zonder de hulp van vele anderen.

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# List of publications, interviews, presentations and awards

#### **Publications for practice**

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#### Lectures

Polifarmacie en medicatieveiligheid. COPD verpleegkundigen opleiding

Polifarmacie bij ouderen. Fysiotherapeuten eerste lijn.

Medicatie bij ouderen. Praktijkondersteuners Huisartsen.

Medicatieonderzoek bij ouderen. Bachelor Medische Hulpverlening opleiding

Medicatie bij chronisch zieken. Bachelor Verpleegkunde Opleiding

Ouderen in Nederland. Bachelor Mondzorgkunde Opleiding

*Multi farmacie en Screening*. Verpleegkundige Geriatrie en Gerontologie opleiding.

#### Abstracts

Sino, C. *The Home Observation of Medication related problems observed by homecare Employees instrument*. Posterpresentation EUGMS congress Brussel 2012

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#### Awards and nominations

Prijs beste verpleegkundige voordracht Vroegsignaleren van medicatiegerelateerde problemen achter de voordeur. Geriatrie congres 2012.

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Medicatie achter de voordeur: Genomineerd en geselecteerd voor de zorgveiligprijs 2012 van de Inspectie voor volks GezondheidZorg.

#### **Curriculum Vitae**

Carolien Sino was born in Valkenswaard, the Netherlands March 20th 1968. After graduating from the secondary school at the 'Thomascollege' in Venlo, she studied between 1986-1991 nursing at the Fontys Hogeschool Eindhoven. After gradua-ting she worked between 1991-1996 as a district nurse and team leader in Geldrop and Nuenen. During her work in homecare, Carolien studied Nursing Science at the Maastricht University from 1995-1999. In 1999, she graduated on a thesis about information methods about quitting smoking to be used by pulmonary

physicians. From 1996 until 2000 she worked as a prac-tical teacher at the Catherina Hospital in Eindhoven. In 2000, she started as a lecturer and later on as a team leader, at the Hogeschool Utrecht University of Applied Sciences, Institute for Nursing Studies. In 2007 she started her PhD-project within the Research Centre for Innovation in Healthcare of the Hogeschool Utrecht University of Applied Sciences. She obtained a Master in Science degree in Epidemiology at Utrecht University Graduate School of Life Sciences in April 2011. Currently, she is working as director of the Institute of Nursing Studies of Hogeschool Utrecht University of Applied Sciences and is editor of the journal 'Onderwijs en Gezondheidszorg'.