



# **Right medicine, right patient?**

An exploratory study of medication  
safety in nursing homes

17-04-2013

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## Introduction

Patient safety is one of the most important health care issues of our time. The report “To err is human” (Kohn, 1999) is one of the matters that brought more attention to research of patient safety. This publication in 1999 estimated that up to 98.000 deaths per year in the United States were due to medical errors.

This publication was a motivation for further research internationally. In 2004, the findings of the Canadian Adverse Events Study (Baker et al.) were released. They concluded that the three most common areas for adverse events to occur in hospitals in Canada include surgery, medication and infection. A percentage of 37% of the adverse events were highly preventable, of which 24% were related to medication error.

Problems associated with medication use have been identified in the patient safety literature internationally. The World Health Organization (WHO) declares that between 7.5% and 10.4% of patients in acute care settings in developed nations experience an adverse medicine event. The WHO declares that adverse events due to medicine treatment include errors of commission and errors of omission, the latter meaning that a patient fails to receive a medication that is both indicated and necessary. These events cost billions of dollars to health-care systems around the world and result in 140.000 deaths annually in the United States alone. An estimated 28–56% of adverse medicine events are preventable (WHO, 2008).

In 2002, the Dutch researchers Beijer and De Blaey did a meta-analysis to investigate the hospital admissions as a result of adverse effects of medicines. They used international literature. Because the used literature was based on different countries and different research designs, there still was no reliable insight in the magnitude of this problem in The Netherlands. This was the reason to start the HARM (Hospital Admissions Related to Medication) study (van den Bemt, 2006).

The HARM study is a case control study in 21 hospitals in The Netherlands. Van den Bemt et al. concluded that yearly 16.000 medication related hospital admissions in The Netherlands can be avoided. Another conclusion was that the occurrence of medicine related hospital admissions of patients older than 65 years was twice as much as those of younger patients due to several risk factors. Some of the risk factors for hospital admission described in the report are pertinent to facilities providing long term care.

The Dutch Health Care Inspectorate (IGZ) therefore conducted its study to gain insight in the main risks associated with pharmaceutical care in institutions providing long-term residential or domiciliary care. Between May 2009 and March 2010, the Inspectorate visited a total of 208 institutions. In the care homes and nursing homes visited, most aspects of medication safety were found to be satisfactory. Nevertheless, the majority of the homes were instructed to improve their pharmaceutical care.

The Netherlands Institute for Social Research / SCP is a government agency which conducts

research in the social aspects of all areas of government policy. In 2010, SCP made an overview of the elderly living in nursing homes and care homes in The Netherlands. The majority of the residents in nursing homes and care homes lives there because of increasing health problems; physical, cognitive or psychological. Almost 90% of the residents suffer from a chronic disease. Even 62% of the residents has multiple chronic diseases. Almost all residents, 95%, is using medication.

Elderly people are at increased risk for adverse events (WHO, 2008). Several factors affect the increased risk, including the atypical presentation of disease, multiple chronic medical conditions, cognitive deficits and receiving care by health care providers. Also the WHO concluded that medication is the most common medical intervention used in the care of elderly people.

In this study, the current management of medication distribution and the most common incidents in nursing homes will be analyzed to investigate the medication safety.

There's a lack of knowledge about incidents in medication distribution in nursing homes in the Netherlands. Internationally, some researches have been done in nursing homes. In The Netherlands, most researches about medication safety were conducted in hospital care. This study explores the medication safety in Dutch nursing homes, to gain a general insight and find indications for further research.

Safety is defined by the WHO (2005) as freedom from accidental injuries. Health care providers report failures that threaten the safety of patients. Reporting failures is fundamental to detecting structural patient safety problems. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the system. Errors can be provoked by weak systems and often have common root causes which can be generalized and corrected (WHO, 2005).

To gain a first insight in the medication safety in the Dutch nursing homes, the organization Carintreggeland contributes by giving access to data of their nursing homes. This includes the error reporting system, protocols and cooperation of employees.

Herewith the safety of medication distribution will be investigated. All stages, including activities and involved actors are identified. Also the critical stages in the process will be investigated by studying the error reports. These reports were divided in three categories: near misses, mild adverse events and severe adverse events. The definition of these events are defined for this study as following:

#### Near miss

A threat to right and safe medication distribution, caused by a failure in the execution or planning of a planned action. This failure was identified and corrected in time though, and thereby didn't

result in any impact for the patient

#### Mild adverse event

An unintended event that affected the patient, but of which the consequences had no visible adverse results on the physical, psychological or social functioning of the patient.

#### Severe adverse event

An unintended outcome that is caused by a (non)action of a care provider or by the system, that has harmed the physical, psychological or social functioning of the patient.

### **Research questions**

The outcomes of this study have the intention to display a first insight in medication safety in nursing homes in The Netherlands. Besides that, for Carintreggeland, this will serve as a baseline measurement with which the situation after implementation of new medication instruments in 2011 can be compared in future research. In order to study the medication safety in nursing homes, primarily the process of medication distribution was explored. Secondly, the actual injuries or threats to safety arising from these risks will lead to gain insight in medication safety in nursing homes. To gain this insight, the following research questions and sub questions will be answered:

#### 1. How are the guidelines for the management of safety in medication distribution in nursing homes applied in practice?

- What legislation, regulations and guidelines are involved in medication distribution policy for caregivers?
- How is the process of medication distribution organized in the policy of the caregiver?
- What instruments are used to reduce risks that may harm safety in medication distribution?
- How are incidents registered and analyzed, and what actions are taken to prevent recurrence of the incidents?

#### 2. Which incidents in medication distribution are the most prevalent in nursing homes for elderly people and to which outcomes do they lead?

- In what stage of the medication distribution process do the most common incidents take place?
- To what outcomes do the incidents lead?
- Is there a difference in the occurrence of incidents between different populations?
- Is there a difference in the occurrence of incidents between different kinds of (combinations of) medicines?

# Setting of the research

## **Nursing homes in The Netherlands**

Both care homes and nursing homes deliver offer care to people who are no longer able to live independently on their own because of age, illness or disabilities. In care homes, mainly personal care is delivered. Nursing homes provide more intensive forms of personal care, nursing and complex medical care (SCP, 2010).

In the Netherlands, nursing homes are divided into two types, suitable for two different populations. Somatic nursing homes are designed for people with physical diseases or disabilities, psychogeriatric nursing homes are designed for people with psychological disorders. In 2009, there were about 300 somatic and 400 psychogeriatric nursing homes in The Netherlands. In the last decades a trend of extramuralising is seen in The Netherlands. This is caused by the fact that people remain living independently as long as possible in their own private homes. To make this possible, home modifications and receiving home care are increasingly common. This also means that people who live in institutions nowadays, suffer from more severe diseases and disabilities. This results in an increased average intensity of needed care in nursing homes (Sociaal Cultureel Planbureau, 2010).

## **Types of care**

Different types of care can be distinguished in nursing homes, described below .

### *Household*

Provides assistance in household activities, such as home cleaning and doing the laundry.

### *Counselling*

Provides assistance in managing and planning of daily activities and may contribute to learning new functions or activities.

### *Personal care*

Provides care assists in e.g. washing, showering and dressing people.

### *Nursing*

Nursing care includes more complex and specialised types of caregiving, such as medicine administration and wound care.

### *Treatments*

Treatments in nursing homes are focussed on recovery or preventing progressing of certain diseases and disabilities

### *Temporary residence*

People can stay temporary in nursing homes, e.g. for rehabilitation, or in case of temporary loss of voluntary care or family care.

(Sociaal Cultureel Planbureau, 2009)

All residents in care homes and nursing homes are dependent of help with activities of household, personal care or mobility. About 75% of the nursing home residents is in daily need of help with visiting the toilet. Help with eating, drinking, (un-)dressing, getting out of bed, washing and taking a shower are the most common activities that are given in the category of personal care. In nursing homes, the majority of the residents is dependent of help with these activities because of serious physical or mental disabilities.

**Table 1: Nursing home residents dependent of help in activities of daily life, 2004**

| Activity                           | Somatic<br>nursing home (%) | Psychogeriatric<br>nursing home (%) |
|------------------------------------|-----------------------------|-------------------------------------|
| Eating and drinking                | 16.1                        | 31.2                                |
| Washing face and hands             | 39.6                        | 61.2                                |
| Washing total body                 | 85.1                        | 90.4                                |
| Sitting down and standing up       | 68.6                        | 50.0                                |
| Getting in or out of bed           | 74.5                        | 56.1                                |
| Using the toilet                   | 74.5                        | 75.8                                |
| (Un-)dressing of clothes and shoes | 77.6                        | 80.8                                |
| Moving around indoors              | 47.4                        | 50.0                                |
| Moving around outdoors             | 69.6                        | 86.9                                |
| 10 Minutes continuous walking      | 88.4                        | 69.1                                |
| Walking the stairs                 | 94.9                        | 87.6                                |

(De Klerk SCP. Den Haag, 2011)

### **Nursing home residents**

In 2008, about 165.000 Dutch citizens lived in an institution, of which about 100.000 in care homes and 65.000 in nursing homes. The population that lives in an institution has declined in the last decade, while the Dutch population is ageing. This implicates that elderly remain living longer



independently in their private homes and that the intensity of care in institutions increases (Sociaal Cultureel Planbureau, 2011).

**Table 2: Population of residents by year and type of institution, 2000-2008**

| Population                    | 2000    | 2000 | 2004    | 2004 | 2008    | 2008 |
|-------------------------------|---------|------|---------|------|---------|------|
|                               | N       | %    | N       | %    | N       | %    |
| care homes                    | 118.082 | 67   | 109.328 | 65   | 99.631  | 61   |
| somatic nursing homes         | 26.391  | 15   | 26.157  | 15   | 28.017  | 17   |
| psychogeriatric nursing homes | 31.224  | 18   | 33.868  | 20   | 36.934  | 22   |
| total                         | 175.697 | 100  | 169.353 | 100  | 164.582 | 100  |

(De Klerk SCP. Den Haag, 2011)

### Grounds for nursing home admission

People are eligible for admission in a nursing home if they are not capable anymore to live independently, mostly caused by an illness or disabilities. For many residents it wasn't feasible to arrange the needed care or home modifications. The necessary facilities were not present to let the family, friends and/or home care provider be able to provide care.

As mentioned above, the main grounds for admission in a nursing home is a deteriorating health status, physical, cognitive or mental. Admissions in somatic nursing homes were often (67%) caused by an acute disease or accidents/falls. Gradually deteriorating health conditions were ground of nursing home admission for 45% of the psychogeriatric residents.

The grounds of admission were specifically identified, shown in Table 3.

**Table 3: Grounds for nursing home admissions, 2004**

|                                | psychogeriatric<br>nursing home (%) | somatic<br>nursing home (%) |
|--------------------------------|-------------------------------------|-----------------------------|
| Gradually deteriorating health | 44.6                                | 20.2                        |
| Acute disease                  | 5.0                                 | 17.8                        |
| Accident or fall               | 17.9                                | 49.8                        |
| Death of partner               | 4.2                                 | 3.2                         |
| Loss of social network         | 1.2                                 | 2.0                         |
| Other                          | 27.1                                | 7.1                         |

Sociaal Cultureel planbureau (2010)

For about 5% of the residents in nursing homes, death of the partner or another loss in the social network was a cause of not being able to live independently anymore (Sociaal Cultureel planbureau, 2005).

### Duration of stay in institutions

The Sociaal Cultureel planbureau researched the average duration of stay in institutions. In this research, the temporary residents were excluded. The average duration of residence in a nursing home in The Netherlands was 2.8 years, for both somatic and psychogeriatric nursing homes. Table 4 displays the durations of stay per type of nursing home.

About 20% of the somatic residents stayed in a nursing home for shorter than a year, which applies to 15% of the psychogeriatric residents. This high percentage of the somatic population may be caused by the acute diseases as a ground of admission.

**Table 4: duration of stay in nursing homes**

|                                     | somatic<br>nursing home (%) | psychogeriatric<br>nursing home (%) |
|-------------------------------------|-----------------------------|-------------------------------------|
| < 1 year                            | 20,2                        | 15,5                                |
| 1 year                              | 21,8                        | 21,0                                |
| 2-4 years                           | 38,1                        | 45,0                                |
| ≥ 5 years                           | 19,8                        | 18,5                                |
| Average duration of stay (in years) | 2,8                         | 2,8                                 |

(SCP, 2005)

The percentage of residents that lived in the nursing homes over 5 years was about 19% of the population, regardless of the type of nursing home (Sociaal Cultureel planbureau, 2005). The study does not provide information about the reasons why the residents left the nursing homes; because of death or moving out.

According to the Sociaal Cultureel Planbureau in 2011, the duration of stay in nursing homes will shorten in the coming years because of the transition of elderly people living longer in their private houses with home care. The admitted patients nowadays are older and suffer from more diseases and disabilities, which results in an increased intensity and complexity of care in nursing homes.

### Physical health and chronic diseases

In 2005, SCP studied the physical health of nursing home residents. About 80% of the patients suffers from two or more chronic diseases. Only 5% had no chronic diseases. The diseases of different types of nursing homes differ. In somatic nursing homes, the most common health issue

is a stroke. Of the somatic patients, 41.3% suffers from disabilities as a result of a stroke. Other diagnoses as cardiac and vascular diseases, diabetes and arthrosis are common in somatic nursing home residents. In psychogeriatric nursing homes, the percentages of physical chronic diseases are in general lower, as shown in Table 5 (Sociaal cultureel planbureau, 2005).

**Table 5: Prevalence of physical chronic diseases**

|  | somatic<br>nursing home (%) | psychogeriatric<br>nursing home (%) |
|--|-----------------------------|-------------------------------------|
| Arthrosis of knee or hip joint                   | 32.0                        | 34,3                                |
| Diabetes   | 22.8                        | 17,9                                |
| Stroke   | 41.3                        | 20,7                                |
| Respiratory diseases                             | 14.6                        | 12,3                                |
| Vascular disorders in stomach or legs            | 21.9                        | 9,3                                 |
| Cardiac diseases                                 | 17.1                        | 10,1                                |
| Serious back pain (e.g. hernia nucleus pulposis) | 14.2                        | 9,7                                 |
| Chronic (rheumatoid) arthritis                   | 12.8                        | 6,8                                 |
| Results of an accident                           | 8.3                         | 3,8                                 |
| Disease of nerve system (MS, M. Parkinson)       | 11.1                        | 5,9                                 |
| No chronic disease                               | 5.5                         | 4,6                                 |
| One chronic disease                              | 14.9                        | 15,0                                |
| Two or more chronic diseases                     | 79.6                        | 80,4                                |

(SCP, 2005)

### Medicine use

The use of medicines by nursing home residents was a rate of 95% in 2008. This means that almost all residents of an institution used medicines. This is actually obvious, given the often poor health conditions of these people.

According to Gurwitz (2003), in the United States of America cardiovascular medications were the most frequently used prescription medication class (53.2%), followed by antibiotics/anti-infectives (44.5%), diuretics (29.5%) and opioids (21.9%). Antidepressants and sedatives/hypnotics were used by more than 10% of the population.

## **Carintreggeland**

Carintreggeland is a healthcare organization in The Netherlands, that provides domiciliary care and residential care, mainly to elderly people. The services of Carintreggeland include: household and personal care, social care, nursing and various kinds of treatments. To provide these services, Carintreggeland employs several kinds of professions, with a total of 4.248 employees in 2010 (Carintreggeland, maatschappelijk jaarverslag 2010). Nurses, elderly care physicians, psychologists, physical therapists, occupational therapists and speech therapists, social workers are important caregivers in the organization.

The working area of Carintreggeland is located in the eastern part of The Netherlands, in a region with about 440.000 inhabitants. In 2010, Carintreggeland provided domiciliary care to 4.023 patients (patient years). The patients that received residential care in 2009 and 2010 were 1.809 patient years. This type of care is given in care homes (about 1.052 patient years) and nursing homes (757 patient years).

The population of patients of Carintreggeland include people with:

- somatic (physical) diseases or disabilities
- psychogeriatric diseases or disabilities
- psychiatric disorders
- psychosocial problems

## **Nursing homes of Carintreggeland**

In 2009 and 2010, Carintreggeland owned 17 nursing homes in different housing concepts and sizes. The largest nursing home accommodated 152 beds, while only 8 patient years were in the smallest nursing home. Not only the size, but also the housing concepts differ. In the nursing homes of Carintreggeland, 4 housing concepts could be distinguished in 2009 and 2010:

- traditional nursing homes
- small scale group living
- nursing units within care homes
- rehabilitation units

(Carintreggeland, 2011)

## **Traditional nursing homes**

In traditional nursing homes, about 10 to 30 residents live together in one unit. The set-up of the unit is comparable to a hospital unit. Most of the residents share bedrooms with 1 to 3 other persons. The unit has a shared meeting or living room, where the people can stay during the day. Depending on the size of the unit and the number of residents, two or more nurses are continuously providing care on a traditional nursing home unit. The concept of traditional nursing

home units, is in use for both somatic and psychogeriatric residents. There is a difference though, the somatic units are freely accessible whereas the psychogeriatric units are locked.

### **Nursing units within care homes**

The nursing units within care homes are as a concept comparable to traditional nursing homes. In reference to medication supply and distribution though, there are some differences. The care home residents are provided with medication by their own (local) pharmacy. The general practitioner of the care home resident is responsible for the pharmaceutical care, in contrast to the responsibility of the elderly care physician of Carintreggeland for nursing home residents. Medication for all nursing home residents, also within care homes, is supplied by the contracted pharmacist of the nearby hospital. This means that the contracted pharmacist only supplies medication for the nursing home unit, which is a small part of the house.

### **Small scale group living**

The concept small scale group living is a type of nursing home wherein 6, 7 or 8 residents live in a group in a small dwelling. This dwelling is set up as a normal home. Besides a shared living and kitchen, each resident has his or her own room. In the shared rooms, daily activities such as cooking, eating etc. are done here. The residents are people who suffer from severe dementia problems. Therefore they need intensive support, guidance and care in a protected environment. The problems of these patients include loss of self control and problems with cognitive functions as orientation, concentration and memory. In addition, these problems can be associated with physical diseases or disabilities. These problems result in a need of care or support in activities of daily life and supervision to guarantee safety. Because the group of residents is small, most of the day, there is only one nurse available in the dwelling.

### **Rehabilitation units**

These are units within a nursing home, where patients only stay temporary, to a maximum stay of about 6 months. Afterwards, the patients return to their private homes. The patients had an (mostly acute) disease or a surgery, for which the patients need physical recovery or rehabilitation and temporary nursing care. Most patients get to the rehabilitation unit after a hospital admission. Intensive therapies are given in a multidisciplinary approach.

The rehabilitation is primarily aimed at restoring independence or learning to cope with the new physical condition. The rehabilitation population is over 65 years and is eligible for rehabilitation. The nature of the problem is somatic, not psychogeriatric or psychiatric. The most common diagnoses of the patients are stroke, joint replacement surgery, traumatology, amputations and cardiac and pulmonary diseases. Within Carintreggeland, about 24-30 patients stay at a rehabilitation unit.

# 1. Methods

This study has an exploratory and descriptive purpose. It is undertaken in order to ascertain and be able to describe the process and the variables of interest in medication safety. The study has a retrospective approach because it looks back at events that already have taken place.

## 1.1. Data collection

### *Qualitative research*

The first research question is answered by qualitative research to investigate the process of medication distribution in nursing homes. Data is collected by studying national and international literature, Dutch legislation and regulations and the internal policy documents of medication distribution in Carintreggeland. As a result, the process of medication distribution is described in different stages, illustrated in a flow chart. Literature, legislation and regulations are obtained by searching in research databases and internet. The data of internal policy of Carintreggeland are gathered by searching for the protocol in the digital quality management system.

### *Quantitative research*

Quantitative research is done to answer the second research question. Carintreggeland uses a reporting system, VIM (Veilig Incidenten Melden). In this system, events that threaten or harm the safety of patients are reported by caregivers. These events include medication, falling, nutrition, aggression and some other items. The reports that concerned events in medication distribution were extracted from the VIM-system and were analyzed in this research by using the statistical program SPSS. With these reports, a description was made of the events in different stages and the system related risks of the medication distribution process.

A small sample study was achieved to investigate how the administrations of medication are spread over a day. A sample of 45 medication administration lists was studied. The sample was compiled by the sum of three random samples in different units of a traditional nursing home; one somatic, one psychogeriatric and one rehabilitation unit. The medication lists were selected by choosing the first 15 patients of a list that had put the patients names in alphabetical order.

To collect data about patient related risks and medicine related risks, further research in the medical record of patients was done. In the year 2009, electronic medical records were introduced in Carintreggeland. The implementation was not yet completed in 2010. Only the nursing staff was using the electronic medical records. The elderly care physician and other practitioners were not yet instructed and were therefore still using paper medical records. This means that research had to be done in both paper and electronic medical records.

## **1.2. Research population of quantitative research**

The reports of all patients that received care in the nursing homes of Carintreggeland in 2009 and 2010 were included. This is a population of 757 patients, including 250 patients with somatic disabilities and 507 patients with psychogeriatric disabilities.

The units of study were the reports of events in medication distribution of the patients in the nursing homes of Carintreggeland and the characteristics of the patients that suffered from an adverse event. By studying the reports of two years, enough data was available to be sure that seasonal or temporary organizational factors didn't influence the internal validity.

The Eindhoven Classification Model (Van Vuuren, 1997) was used to classify the causes of the events. Van Vuuren distinguishes technical, organizational and human factors playing a role in errors.

For the research in the medical records, the method of purposive sampling was applied. Only the patients that suffered from an adverse event were selected for further research in the electronic medical record. Because some patients suffered from more than one adverse event, this turned out to be a population of 36 patients. At the time of the research, 9 patients were still alive. They have signed an informed consent to give permission for access to their medical record. The medical records of the deceased patients were retrieved from the archive. Two of the 27 records were not found. This resulted in a total of 34 patient records to research.

### **Interviews**

An elderly care physician and the pharmacist were interviewed to gain more information about how the process of medication distribution is applied in practice and to validate the quantitative results of the data from the reporting system. The interviews therefore took place after the data collection of the reporting system.

The interview population consisted of a pharmacist and a physician, because they share great responsibilities in evaluation and improvement of the pharmaceutical care in nursing homes. Elderly care physicians have much knowledge about medication distribution in practice and failures in this process, the nursing staff is obliged to report these events to the physician according to the protocol.

There is only one pharmacist involved in the medication distribution system of Carintreggeland, so sampling was inapplicable. The physician was purposive selected because she is involved in the implementation of new medication instruments and knows the process of medication distribution very well. Both were asked the same questions:

- A printed flowchart of the process of medication distribution is discussed. The interviewee is asked to tell about every stage; how the stages are carried out in practice and what are critical points.

- The quantitative results from the reporting systems are presented. The interviewee is asked to explain how he/she interprets the results and what issues or circumstances play a role.



## 2. Results

### 2.1. Legislation and regulations

In this paragraph, the first research sub question is answered:

What legislation, regulations and guidelines are involved in medication distribution policy for caregivers?

The process of medication distribution in nursing homes is partly determined by legislation and regulations. In The Netherlands, several acts, regulations and directives are involved in medication distribution. These are described below.

#### **Exceptional Medical Expenses Act (AWBZ)**

The Exceptional Medical Expenses Act insures the long term costs of treatment, support, nursing and personal care, when these costs are extremely high. The act is a national insurance.

The AWBZ offers the following types of care:

- personal care; help with activities of daily living e.g. washing, dressing, eating and drinking
- nursing; e.g. giving medication, injections, dressing wounds
- guidance; focused on preservation or improvement of the ability of a patient to live as independent as possible, and to prevent admission into a residential institution
- treatment; e.g. medical care by a physician
- accommodation; payment for staying in an institution.

Not everybody can qualify for care under the AWBZ. It is necessary to ascertain whether care is really required and what type of care and how much care is needed. This is assessed by the Care Needs Assessment Centre (CIZ), an independent organization responsible for determining impartially, objectively and thoroughly what care is required.

<http://www.government.nl/issues/health-issues/exceptional-medical-expenses-act%5B2%5D>

#### **Health institution Quality Act**

The Health Institution Quality Act obligates health care organizations to monitor, control and improve their own quality. The act identifies four quality requirements in which an organization must comply: responsible care, quality-involved policies, the establishment of a quality management system and making an annual report.

An health care organization must provide responsible care. The quality management system should therefore be aimed at maintaining and improving quality of care. The organizations are obligated to inform the Health Care Inspectorate in case of serious calamities and abuse involving a patient or caregiver.

In an annual report, the organization accounts for their quality of care and quality management system.

<http://wetten.overheid.nl/BWBR0007850/>

### **Dutch Medicines Act (geneesmiddelenwet)**

The Dutch Medicines Act focusses on the medicine product itself, and its aspects of manufacturing, the marketing, distribution to the patient and the profession of the pharmacists.

The definition of a medicine is described as following:

A substance or combination of substances which is intended to be administered or used for:

- treatment or prevention of disease, defect, wound or pain in humans
- medical diagnosing
- recovering, improving or otherwise modifying physiological functions in humans by pharmacological, immunological or metabolic actions

According to the act, there must be a board that assesses medicines. Therefore, there is the Medicines Evaluation Board (MEB), which has influence on the manufacturing and marketing of medicines. The MEB is responsible for authorising and monitoring safe and effective products on the Dutch market and shares in responsibility for authorising medicinal products throughout the European Union. The Board evaluates the products and decides on the conditions under which it can be placed on the Dutch market (website MEB <http://www.cbg-meb.nl>).

The act describes which professions or institutions have the right to prescribe or provide medicines and under which conditions this must be conducted.

### **Dutch Medical Treatment Act (WGBO)**

The Dutch Medical Treatment Act regulates the physician patient contract. The contract is an agreement about the treatment between the physician and the patient.

Three topics are the most important in this act:

- Information and consent
- Patient record and retention period
- Access to patient data

Every patient should be well-informed about his situation and prospects before he can decide about his treatment. According to the act, the physician is obligated to inform the patient in a clear way about the proposed examination and treatment and the health status of the patient.

To carry out a treatment, there's consent of the patient required.

The physician compiles a medical record with regard to the treatment of the patient. In this, the data about the treatment and health status of the patient is registered. The medical record is kept for 10 years by the physician.

The patient has the right to inspect his record. Without the consent of the patient, the physician is not allowed to give others insight in the medical record.

### **The Psychiatric Hospitals (Compulsory Admissions) Act (BOPZ)**

People who pose a danger to themselves or their environment, can be compulsory admitted in an institution. In nursing homes, this applies to psychiatric or demented patients. The Psychiatric Hospitals (Compulsory Admissions) Act protects the rights of the compulsory admitted patients (website Government of the Netherlands <http://www.rijksoverheid.nl/onderwerpen/dwang-in-de-zorg>). In the Act is written under which conditions patients can be admitted against their will, how the judicial procedure must be conducted and what rights the patients have.

The process of medication distribution is part of the medical treatment. According to the act, every patient has the right to a proper treatment plan. The treatment plan is drawn up together with the patient. If the patient himself is not capable to make decisions about the treatment, a legal representative is involved in drawing up the treatment plan. A legal representative is a person who is given the authority to act on behalf of the patient, e.g. a family member.

According to the act, in principle treatment of the patient can only take place if:

- the patient is provided with a treatment plan
- there is agreement about the treatment plan
- the patient or the legal representative does not object to the treatment

If these conditions are not fulfilled, treatment can only take place if treatment is necessary to avert danger, caused by the patients physical or mental disorder.

### **Individual Healthcare Professions Act (BIG)**

The goal of the act is to secure safety and promote the quality of health care services. It protects patients against inexpert or negligent treatment by a healthcare provider (Website of Ministry of Health, Welfare and Sport: <http://www.bigregister.nl/en/registration/inthebigregister/>).

The Individual Healthcare Professions Act regulates qualification to practice a profession in the individual healthcare sector. Only professionals who comply with the training and education requirements can be included in the BIG register. This register applies to the following professions: physician, dentist, pharmacist, health psychologist, psychotherapist, physical therapist, obstetrician, nurse.

According to the act, the healthcare provider is obliged to work with due care and to provide care of good quality. This applies not only for the treatment itself, but also to the personal interaction with patients and their families.

The act includes a chapter of 'reserved procedures'. These are medical interventions which represent an unacceptable risk to patient safety if they are carried out by an unqualified and

incompetent person. These procedures include injections, punctures, catheterization, obstetric procedures, endoscopies and the administration of general anaesthetics. In the register is recorded which healthcare providers are authorized to carry out these interventions. (Website of Ministry of Health, Welfare and Sport: <http://www.bigregister.nl/en/registration/inthebigregister/>).

In The Hague is a Disciplinary Council settled to supervise medical care in the Netherlands. The Disciplinary Council can impose sanctions if there has been serious misconduct on the part of the healthcare provider and there is a high likelihood of repeat offending. Sanctions available to the Disciplinary Council are:

- a formal warning
- admonition
- a fine
- suspension of BIG-registration for up to one year
- partial revocation of entitlement
- permanent removal from the BIG-register

(Website of Ministry of Health, Welfare and Sport:

[http://www.igz.nl/english/enforcement\\_measures/disciplinary\\_measures/](http://www.igz.nl/english/enforcement_measures/disciplinary_measures/))

### **Quality framework “Pharmaceutical care in nursing homes”**

In 1998, a quality framework for pharmaceutical care in nursing homes was composed by a collaboration of the KNMP, NVVA, NVVz and NVZA. To improve the quality of pharmaceutical care in nursing homes and to clarify responsibilities in this process, these authorities composed a quality framework. In this framework, pharmaceutical care is defined as:

All activities, interventions and measures of involved professionals concerning the selection and distribution of medicines and other pharmaceutical products, as well as the guidance of the use.

The framework contains a description of the quality requirements and conditions of good pharmaceutical care in nursing homes

The central objective of the framework is to ensure that the right medication is administered to the right patient, that the critical moments in the distribution process are explicitly monitored so that the safety in the total pharmaceutical process is guaranteed and misuse is prevented.

The framework describes what should be regulated, not how it should be done. The way in which the implementation of the framework is designed is the responsibility of the nursing homes and should depend on the local situation and possibilities.

The framework is composed of four sections:

1. preconditions (responsibilities, staff and organization, premises and facilities)

2. individual medication distribution processes (prescription, distribution, provision, administration, evaluation)
3. supporting processes (pharmacotherapy consultation, formulary, product assortment management, stock management, logistics)
4. quality management (quality policy, dealing with failures, incidents and risks, management of (quality)documentation, evaluation of the quality management system).

These sections are regularly part of the protocols concerning medication distribution in nursing homes. The protocol of Carintreggeland is also built up by these sections, described in the next paragraph.

### **Safe principles in the medication chain**

In line of the quality framework, in 2012, a Task Force composed 'safe principles in the medication chain'. This Task Force is a cooperation of Actiz, NVZA, KNMP and Verenso. Also some patients', physicians' and nursing organizations participated. According to the Task Force, a proper coordination between all involved actors is important for a safe medication process. The actors are the patient (and his family caregiver), the physician, pharmacist, health care organization and care provider. The premise of the principles are the role and responsibilities of the actors and how they should work together to enhance safety. The process of medication distribution is described in 6 stages:

1. Prescription
2. Providing by pharmacist
3. Stock and management of the medication
4. Preparation and dispensing
5. Administration and registration
6. Evaluation

In each stage is described what safe principles are for the involved actors. These principles are consistent and form a chain. The intention of the principles is to support and inspire the involved actors on a safe medication process.

### **Directive Safe Transfer of Medication Details.**

To improve patient safety, careful medication data transfer is important. Therefore, the Ministry of Health, Welfare and Sport (VWS) and the Healthcare Inspectorate (IGZ) took initiative to develop a directive.

The aim of the directive is to prevent errors in the transfer of medication data and increasing patient safety by letting professionals work together and let them inform each other proper and on time. Basis of the directive is that there is always a topical medication list of every patient available and that this list goes with the patient to other care providers.

## 2.2. Pharmaceutical care in nursing homes of Carintreggeland

This paragraph answers the question about how the process of medication distribution is organized in the policy of the caregiver and what instruments are used and/or what actions are executed to reduce risks.

Carintreggeland has developed a protocol that describes very precisely how the process of medication distribution should be operated. There is also defined which actors are involved and which authorizations and responsibilities they have. The protocol is adapted in the quality management system of Carintreggeland, and is reviewed annually by the responsible director.

In this chapter, the process of medication supply and medication distribution will be described according to the protocol (Carintreggeland, 2010).

### Protocol

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The central objective of the protocol is described as following:

*The right medication is administered by the right patient at the right time, and the critical moments in the distribution process are explicitly monitored, so that safety in the entire process is guaranteed and improper execution is prevented.*

To achieve this central objective, the protocol describes four sub-objectives relating to medication supply and distribution:

*1. Carintreggeland is provided with medicinal products of good pharmaceutical quality, at a reasonable price.*

The good quality of products is achieved by an adequate supply of medication by the pharmacy of the nearby hospital Ziekenhuisgroep Twente (ZGT) to the nursing home, with proper storage of these medicines and adequate medication distribution. This process operates under the supervision of the pharmacist in accordance with the agreement of Carintreggeland and ZGT, dated 2 June 1993.

*2. Carintreggeland is provided with an adequate stock in the medication depots of the nursing homes.*

In the medication depots at the nursing home is a standard stock of the medication that is the most commonly prescribed for patients in the nursing homes. The elderly care physician and pharmacist consult continuously when a choice has to be made on the basis of quality and price.

They also consult about the composition of the standard stock in the medication depots. This standard stock is regularly reviewed and if necessary adjusted.

*3. Carintreggeland is provided with an adequate medication distribution system.*

The design of the medication distribution process in the nursing home is fit to the guiding principles of the system of the hospital ZGT. Some adjustments were made for the nursing home.

*4. Carintreggeland provides adequate prescriptions of medication by the elderly care physician with sufficient feedback capabilities.*

This is achieved through various consultation and check moments in the process of medication distribution.

## **Involved actors**

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In the process of medication distribution for patients in the nursing homes of Carintreggeland, some specific actors influence the medication safety. In this paragraph, the responsibilities and authorizations of these actors are described.

### **The board**

Is ultimately responsible for pharmaceutical care in the nursing homes and ensures that this care is provided in accordance with relevant Dutch legislation and regulations. Therefore the board;

- Employs sufficient and qualified staff for all activities in the context of pharmaceutical care;
- Ensures that adequate space and facilities are available;
- Is responsible for contracting a registered public or hospital pharmacist for medication supply;
- Is responsible for granting the financial preconditions within the pharmaceutical care;
- Ensures that medication distribution policy is included in her quality management system for systematic evaluation and improvement of pharmaceutical care.

### **The elderly care physician**

- Is responsible for the substantive aspects of pharmaceutical care;
- Is responsible for adequate pharmacotherapy by appropriate medicine prescriptions, mutations and terminations of medicine use;
- Is responsible for the availability of adequate information and instruction regarding the way of administration of medicines by the nursing staff;
- The elderly care physician and the pharmacist share responsibility for a systematic review of the medication of patients;

- The elderly care physician and the pharmacist share responsibility for optimizing the efficiency of pharmacotherapy;
- Is involved in systematic evaluation and improvement of pharmaceutical care and the medication distribution policy.

### **The nursing staff**

- Is responsible for the proper way of administration of medicines in accordance with the medicine administration list;
- Follows the written instructions or the instructions given by the elderly care physician accurately;
- Is responsible for proper storing and handling of the medication on the unit;
- Is responsible for identifying relevant aspects of the medication use of patients and reporting these to the elderly care physician to support diagnosis and pharmacotherapy;
- Errors/incidents in the process of medication distribution must be reported to the elderly care physician and in the digital reporting system VIM.
- Outside office hours, in the absence of pharmacy assistants, high qualified nurses are responsible for providing necessary medication from the depot.
- Interns can also administer medicines to patients if they are competent and qualified.
- The BIG Act lists a number of 'reserved procedures'. These are medical interventions which would represent an unacceptable risk to patient safety if carried out by an unqualified, non-expert person. Carintreggeland handles protocols wherein is written who is authorized to carry out these interventions. The nursing staff is responsible for working with these protocols.

### **The pharmacist**

Carintreggeland contracted the pharmacist of nearby hospital Ziekenhuis Groep Twente (ZGT). He is supervising pharmacist for medication distribution in all nursing homes of Carintreggeland. In this position, the pharmacist is responsible for:

- The substantive aspects of pharmaceutical care, in accordance with involved legislation and regulations;
- Designing, implementing and maintaining a adequate medication distribution system;
- A good quality of all the medicines present in the nursing homes;
- The management of the medication depot and other stock locations in the nursing homes;
- The delivery of medication;
- The availability of instructions for the administration of medicines
- The design, implementation and maintenance of the components of the quality of the pharmaceutical care in the nursing homes;
- The pharmacist is involved in systematic evaluation and improvement of pharmaceutical care and the medication distribution policy;



- The pharmacist visits the nursing homes at least monthly, or more frequently if needed for adequate performance of his work;
- The pharmacist guarantees accessibility and arranges a substitute in case of absence. The substitute is familiar with the system of pharmaceutical care in the nursing homes.

The pharmacist and the elderly care physician share responsibility for:

- The availability of sufficient information about medicines and how to use them safely;
- The regular evaluation of medication use of the patients;
- Optimizing the efficiency of pharmacotherapy;

### **The pharmacy assistants**

The assistants in the nursing homes of the former Reggeland organization part are employed by Carintreggeland, but supervised by the pharmacist. The assistants in the nursing homes of former Carint organization are employed by the regional hospital.

The assistants are responsible for:

- Managing and completing the standard stock in the medication depot;
- Ordering and receiving of medication from the pharmacy, which is not included in the standard stock;
- Processing new medication prescriptions in the correct way.
- Allocating the medication per patient in the medication carts or cassettes;
- The transport of the medication carts or cassettes to the units

The pharmacists assistants perform a number of checks in the process of medication distribution. There are always two pharmacy assistants available. They check each other regarding the allocating of the medication per patient (double check).

### **Spatial and material matters**

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#### Medication depot

In two large nursing homes of Carintreggeland, there is medication depots located. In these depots, standard stock and a limited quantity of prescribed medications per patient are stored. The medication is supplied by the contracted pharmacist of the nearby hospital.

The pharmacy assistants work in the medication depots. The processing of medication prescription is done only there. New prescribed medication is checked by the pharmacy

assistants and can be supplied from the depot. The assistants bring medication to the units, or the nursing staff can collect the medication from the depot.

There is no storage of medication at the nursing units, with the exception of the emergency stock that is kept in a specific drawer of the medication carts. The emergency stock includes:

- 3 tablets of Noctamid
- 10 tablets of paracetamol
- 5 suppositories of paracetamol
- 1 rectiole of Stesolid
- 1 Micro lax
- 10 tablets of Isosorbidine dinitraat 5 mg.

This emergency stock is weekly checked and refilled by the pharmacy assistants.

The smaller nursing homes of Carintreggeland don't have their own medication depot. There is a smaller storage of medicines, the so called buffer stock. The assistants of the large nursing homes do the management of this stock. It is located in a locked cabinet of a room of the nursing staff. Again here, there is no medication storage on the units.

#### *Accessibility to the stock*

Not all employees of Carintreggeland are authorized to access the medication stock. Therefore, the following regulations are agreed:

In the large nursing homes:

The keys of the medication depot (totally 4 sets of keys) are only in possession of the pharmacy assistants and the high qualified nurse on duty. A spare set is kept by the manager facility services. These sets of keys are related to these professions and should never be given to others.

In the smaller nursing homes:

The keys of the buffer stock are in possession of the nurse on duty. A spare set is kept by the unit manager and the elderly care physician.

#### Medication cassettes and carts

Mainly in the large traditional nursing homes, medication carts are used for medication distribution. The medication carts are filled weekly by the pharmacy assistants in the medication depot. They allocate medicines per unit and per patient in cassettes. These cassettes are put in drawers of the medication carts. Depending on the medical condition, for each patient one or two drawers are in use.



**Figure 1: Medication cart**

The carts are refilled weekly, but the assistants put in medication for 8 days to reduce the risk of deficit if the depot can't supply medication for some reason.

### Medicine administration list

Every unit uses a folder with medicine administration lists for the patients. These folders are stored in the medication carts or locked cabinets. This list describes the medication that should be given to the patients, and is used by the administration. Afterwards, the medicine administration list is signed by the nurse.

The next details per patient are listed on the medicine administration list:

- name of the patient, possibly with maiden name and date of birth
- allergies
- the prescribed incidental medication
- the possible medication administered intravenously

## The process

The process of medication supply and distribution in Carintreggeland is displayed in figure “x”. The stages are described in activities and involved actors. In the following paragraph, these stages are explained in more details.

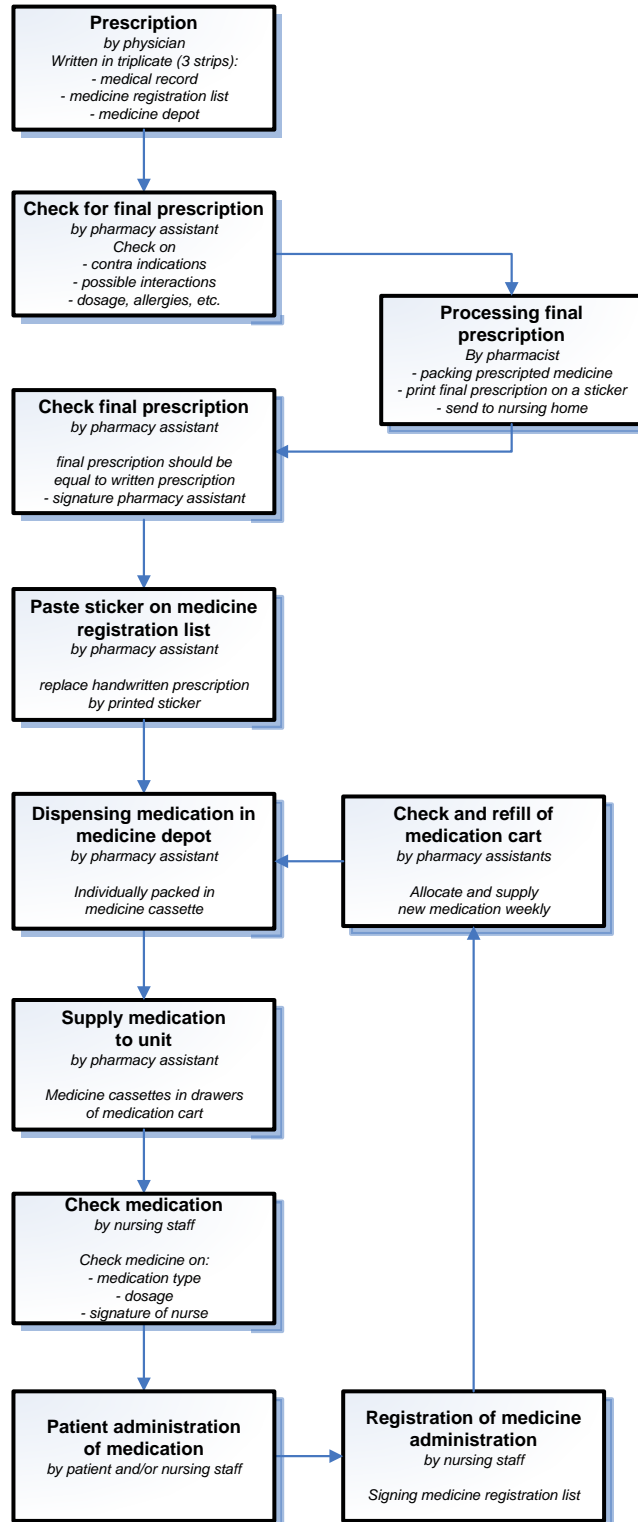


Figure 2: Process of medication supply and distribution Carintreggeland (protocol Carintreggeland, 2009-2010)

### Stage 1. Prescription

The prescription of the medicine is handwritten by the elderly care physician on a 3 layered carbonless paper strip. In this way, the prescription is triplicated in three strips, each with their own

purpose: one is attached on the patients medication list, one is put in the medical record and the last one goes to the medication depot for application at the pharmacy.

Because the prescription forms are made of carbonless paper, it is important to write with some pressure with a ball-point pen.

Patient related information that always has to be listed include:

- full name of the patient (in case of married women also the maiden name)
- date of birth
- the unit name

### **Processing the prescription**

a) The upper strip of the carbonless paper is used as provisional prescription and is pasted on the medicine administration list, using the adhesive strip at the left bottom. If a patient is prescribed two or more medicines, the provisional prescriptions are pasted together partly overlaying. The section where the medicine is mentioned should remain free, and the section of administration times should correspond to the horizontal lines of the medicine administration list.

b) The second strip of the carbonless paper is pasted on the medication prescription card in the medical record by the elderly care physician. All prescriptions of the same medicament are pasted together by the adhesive strip on the bottom of the paper (only the name of the occupant is thereby out of sight).

This means that there should be a sequence of overlaying: first the start prescription, followed by the mutation prescription and finally the stop prescription with a diagonal line over the prescription. For ointments, creams and other topical medicines, a separate medication prescription card is used in the medical record.

### **Prescriptions in different circumstances**

There are some different conditions in which medication is prescribed. In practice, the processing of the prescription can be executed in the following ways:

#### *a) The drug is prescribed for the first time*

This should be a prescription written by the physician, whereby the start date is listed in the left upper corner of the paper strip. Other items that must be listed are the patients name, dosage, way of administration, in case of antibiotics the stop date and the name of the prescribing

physician.

This is also the procedure for the medication that a newly admitted patient already used at home and should be continued, which was prescribed by another physician.

In addition, the planned times of administration (set times are 09.00am, 12.00am, 17.00pm and 21.00pm) and the way of administration should be listed in the right upper corner.

#### *b) Mutation*

If the medication that a patient uses has to change, e.g. in the dosage or way of administration, the physician should write a new prescription whereas the start date in the left upper corner is modified. To clarify that there was a mutation, the change is indicated by encircling the letter "W" in the left bottom corner of the paper ("W" of wijziging, which means mutation in Dutch). The rest is executed in accordance with procedure a).

#### *c) Stop of medication*

The medication has to be stopped. The physician writes a new prescription paper with the stop date. To clarify the mutation, a diagonal line is drawn over the entire paper.

#### *d) Prescription in absence of the physician*

If the physician is not present at the unit and a prescription should be given within a limited time, then the prescription can be arranged by phone. A high qualified nurse on duty writes the prescription. By phone, the nurse on duty reads the prescription out loud for the physician to check for accuracy. Subsequently, the physician himself writes a new, formal prescription at the first opportunity (at least on the next working day).

Note: The drug depot (pharmacy assistants or nurse on duty after office hours) provides the medication only on basis of a written prescription of the physician, or in exceptional situations as described under d), per physicians order.

### **Different types of prescriptions**

#### *'If needed' medication*

If needed medication means the medication that may be given regularly on patients request. This medication is prescribed by the elderly care physician with the notification of the minimum interval between two doses and/or the maximum dose per 24 hours. When the medication is administered by the patient, the time of administration is written on the medicine administration list by the nursing staff. The pharmacy assistants of the medication depot supply the unit with an amount of the medication by an estimation based on experience in practice, and the maximum dose of the prescription.

### *Incidental medication*

Incidental medication means the medication is administered only once. For that medication is no structural prescription given by the physician. Example: painkillers, sleeping tablets and medication in acute phases such as cardiac asthma or seizures.

If incidental medication is administered, it must be noted on the medicine administration list. If a medicine is given repeatedly, then the elderly care physician should write a prescription, possibly prescribed for 'if needed'.

The medication cart has a drawer with some incidental medication. Administered incidental medication should always be reported to the elderly care physician by the nursing staff.

### *'as planned' medication*

'As planned' medication means the medication whose dosage can vary daily, as planned. This only applies to the Sintrommitis (warfarin) medication, Insulin medication and medication on a reduction planning. On the prescription the words 'as planned' are written. The dosage of the Sintrommitis (acenocoumarol) and medication with a reduction planning, is signed on the medicine administration list by the physician. The dosage of Insulin is written on the diabetes list by the elderly care physician. This list is located in the same folder as the medicine administration list.

### *Mutations*

If the medication use should be changed or stopped, the physician writes a new prescription of the medicine with the new dose or just 'stop' (with the name of the medicine).

### Stage 2. Check for final prescription

The third strip of the carbonless paper is sent to the medication depot (if possible on Monday to Friday before 12.00am). There, the prescription will be checked on patient and medication related aspects, such as possible interactions, contra indications, dosage and allergies of the patient. Allergies are registered in the medical record by the physician and on the medicine administration list by the nursing staff.

This check of the prescription is performed by the pharmacy assistant. If the prescription is approved, the prescription is stated as final medication prescription (FMP).

Next, the assistants send the FMP to the pharmacy of the nearby hospital ZGT.

If the prescribed medication should start immediately while the medication depot is closed and the assistants are absent, the high qualified nurse on duty is authorized to get the medication from the depot.

### Stage 3. Processing final prescription

In the pharmacy, the handwritten prescription is processed into a digital final medication prescription. The medication is packed and sent back to the medication depot of the nursing homes, combined with a sticker of the printed digital FMP.

### Stage 4. Check on final prescription

After arrival in the medication depot of the nursing home, the assistants check the type of medication and dosage. They have to correspond to the handwritten prescription. If the FMP is correct, the pharmacy assistant signs the FMP. If the FMP is not correct, the assistants should contact the pharmacy.

The printed and signed FMP is pasted over the handwritten strip of the provisional prescription on the medicine administration list.

### Stage 5. Dispensing medication

The pharmacy assistants dispense the medication per patient in medication cassettes. They are also responsible for supplying the units with medication.

The dispensing of medicines per patient is executed weekly. The medication cart is collected from the nursing unit and refilled for the upcoming week. The dispensing of medicines is always done by two assistants in the depot. They check the dispensing that is done by the colleague to be sure that it is done correctly.

### Stage 6. Supply unit with medication

Once a week, the refilled medication carts will be delivered at the units by the pharmacy assistants. If there is a new prescription during the week, the assistants bring the new medication to the unit, or the nursing staff can collect them from the depot. The carts are stored in a room that is locked, and only accessible for the nursing staff and pharmacy assistants.

### Stage 7. Receiving and checking medication

In case of a new prescription during the week, whereas the medication is delivered at the unit by the assistants, the nurse that receives the medication has to check the type and dosage of the medicine.



### Stage 8. Patient's administration of medication

The medicine administration list is used by the nursing staff for the administration of medication to the patients. It describes per patient which medicine should be taken on which time.

Most of the time, the nurses use the medication cart with the cassette to go to the patient. Before the administration is carried out, the nurse will check if the medicines in the cassettes correspond to the prescription on the medicine administration list.

To work without being disturbed in the stage of administration of medication to the patients, the medication carts are provided with a sign "do not disturb".

### *Administration times*

The regular administration times are: 09.00am, 12.00am, 17.00pm and 21.00pm. The times are always listed on the prescription and the medicine administration list. If a different administration time should be applied, it is written on the prescription and medicine administration list.

### *Self management of medication*

For most of the patients in nursing homes, the medication is managed by the nursing staff.

It is however possible that a patient manages the medication himself. Whether this is safe and allowed for the patient, is determined by the elderly care physician. If a patient manages his own medication, a cassette with the medicines is handed over to the patient once a week. The patient must sign for receiving the cassette and is responsible for the correct medication intake. The cassette is stored in a locked cabinet in the room of the patient.

### Stage 9. Registration of administration

After administration of the medicine, the nurses sign the medicine administration list with their initials. This registration is carried out per patient, per medicine and per moment of administration.

If the medicine (in accordance to the prescription) is not given or cannot be given, the following three codes are used:

A: (Absence) if the patient is absent;

P: (Problem) if the medicine can not be given because of a problem of the patient;

W: Refusal (in Dutch: Weigering) if the administration is refused by the patient.

These letters are signed in RED on the medicine administration list.

## Medicines and administration forms under special attention

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### Medication

#### *Antibiotics*

Most medication is prescribed for an indefinite period, whereby predefined evaluation moments are planned that can lead to changes of prescriptions. Antibiotics on the other hand, are prescribed for a certain time. This means that not only the start of the medication use is known, but also the stop date should be indicated on the medicine administration list. Immediately after the start of medication use, the nursing staff therefore should put marks on the medicine administration list on the days that the antibiotics (no longer) should be given.

#### *Additional check insulin medication*

Insulin is prescribed by the elderly care physician, but in contrary to most medication, the prescription of insulin has no fixed dosage and is prescribed as "dosage by agreement". Within the nursing homes there's an extra check on the insulin medication per patient included in the process. The pharmacy assistants of the medication depot register per patient the amount of ampoules that is weekly (or more) provided. According to the protocol, pharmacy assistants make a notification to the elderly care physician if there is a discrepancy of two or more ampoules per week, per unit.

#### *Opiates*

A prescription of opiates is put on the medication list, with the dose (in letters). The opiates are stored in the drawer of the patient in the medication cart, with a measured dose of the medicine and medicine registration ticket with a number. The bottle or box and the medicine registration ticket have a corresponding number.

The nursing staff can take the necessary medication from the box or bottle and mark both the medicine administration list and the registration ticket, including the name of the patient.

#### *Medication storage in refrigerator*

If medication must be stored in the refrigerator, it should be indicated on the packaging of the medication. The temperature of the refrigerator is automatically and continuously measured. The pharmacy assistants monitor and register the temperatures.

### *Own medication of a newly admitted patient*

When a patient is admitted in the nursing home, mostly he brings his own medication to the nursing unit, prescribed by a general practitioner or a hospital physician. At the day of admission, the medicines should be handed over to the medication depot. The pharmacy assistants will consider whether this medication can be continued, depending on the prescription of the elderly care physician. The medicines are checked whether they comply with the expiration date and other standards.

## **Way of administration**

### *Ointments, creams and other topical medicines*

Most ointments and creams should be prescribed by the elderly care physician. This also applies to soap alternatives. There are some exceptions, such as Povidone ointment, zinc ointment and Vaseline. These can be collected from the medication depot by just filling in an application form. Also for other skin care products as Duoderm a medication prescription is written. For these products, a specific form is used, separate from the ordinary medicine administration list.

### *Drops and medical syrups*

Drops and medical syrups are usually stored in the lowest drawer of the medication carts. The preparation of the right dose takes place just before administration by the patient.

### *Bottles, vials*

When a bottle or vial is opened or punctured, the nursing staff writes the date on the bottle or vial.

### *Half a tablet*

In general, there are no half tablets given, because there are multiple dosages of tablets of many medicines.

If the prescribed dose is not available as a whole tablet, a half tablet can be given, but the unused half tablet should immediately be returned to the medication depot, in the original package.

### *Grinding medication*

Grinding of medication does not take place unless there is an explicit written instruction from the elderly care physician. The physician consults the Handbook Enteralia to check or find out whether or not grinding is possible. This can also be done by the pharmacy assistants, but the physician is responsible. If it is unclear whether it is possible to grind the medication, the physician consults the pharmacist. So only the physician determines whether the medication may be grinded.

## Evaluation of the process

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For the quality of the process of medication distribution in the nursing homes of Carintreggeland, some structural evaluation moments take place.

a) At least twice a year there is consultation of the following actors: the board, the physician that is ultimately responsible for medical care, the coordinating elderly care physician, the supervising pharmacist, the pharmacy assistant of hospital ZGT and the assistants of the medication depot. The subject of this consultation is to evaluate and if needed adjust the medication distribution system.

b) At least twice a year there is a consultation of the pharmacy assistants of the medication depot with the unit managers. The objective of the consultations is to evaluate the process and discuss adjustments or improvements, if needed.

c) At least six times per year there is the pharmacotherapeutic consultation. The elderly care physicians of Carintreggeland and another healthcare organization for elderly take part of this consultation with the supervisory pharmacist of hospital ZGT.

Discussion points in this consultation are:

- developing protocols for certain diagnostic groups;
- pharmacotherapeutic consultation about specific medication classes;
- developing and updating of the formulary of the nursing homes;
- discussion of signals relating to the drug distribution system;
- discussion of the reports of medication events from the VIM-registration system.

d) At least once a year a bilateral consultation of every elderly care physician with the supervisory pharmacist. Discussion and review of actual prescription medication per unit, based on relevant information from the pharmacist.

e) Individual feedback about the pharmaceutical care, provided by the pharmacist to the prescribing elderly care physician.

The pharmacist or the elderly care physician is obligated to make a report to the LAREB (stichting Landelijke Registratie Evaluatie Bijwerkingen) in case of serious adverse reactions or side effects of (new) medicines.

### 2.3. Reporting medication errors

This paragraph answers the research sub question about how reported events/incidents are registered, analyzed and what actions are taken to prevent recurrence.

Carintreggeland has implemented policy regarding to error reporting. There's a protocol called "Veilig Incidenten Melden", VIM abbreviated. Literally translated it means Safely Reporting Incidents. The protocol describes the obligation to report calamities and incidents that occur in caregiving of patients. The definition of calamities and incidents are formulated as following:

A calamity is any unintended or unexpected event in a medical, nursing or care action or the use of medical devices, equipment or drugs during transportation, diagnosis, treatment, nursing or care. This action led to death or a serious injury on the patient. For example fractures, hospital admission and burns.

An incident is defined as an event that was caused by a human action or omission, that could lead or has led to harmful consequences for the patient. For example a fall incident without consequences.

Converted to the definitions of this study, a calamity is similar to an adverse event. Reported incidents can be divided in adverse events, near misses and errors.

According to the protocol, all employees which are directly related to patients in their work, should report these calamities and incidents. The intranet of Carintreggeland gives all employees access to a digital VIM reporting system.

The system is connected to a database of patients data and a calendar that gives options to insert data in the system. Besides that, the system is built up with drop down questions.

Different variables are registered.

- Category of calamity/incident: medication, falling, aggression, nutrition, missing, burns, intake of harmful substances
- Place and time where it took place
- Name of the patient
- Location and unit where the patient lives
- Characteristic of the patient (psychogeriatric/somatic)
- Type of the calamity/incident
- Cause of the calamity/incident
- Result of the calamity/incident

- Action undertaken afterwards
- Name of the reporting employee
- Profession of the reporting employee

Open ended questions with an open comment box:

- Additional description about the calamity/incident
- Description of how the calamity/incident could have been prevented

The manager of the unit can monitor the reports of the staff and is responsible for making and deploying a plan of improvement according to the PCDA cycle (Plan Do Check Act). The manager must align the plan to the quality division and is also accountable to inform the director about the VIM reports every quarter of the year.

There is a VIM committee in the organization. Yearly, this group of employees analyses the VIM reports and draws conclusions. Together with the quality division of Carintreggeland they inform and advise the Board.

As described in the protocol of medication distribution in Carintreggeland, the VIM data are also evaluated in the pharmacotherapeutic consultation.

## 2.4. Results quantitative research

This paragraph describes the results of the second research question. It provides information about which incidents in medication distribution are the most common in nursing homes and to what outcomes they lead. Also some other variables are used to display a broad picture of incidents in medication distribution.

The data of the VIM-reporting system are used, complemented with data from research in patients medical records and medication administration lists.

Over the years 2009 and 2010, employees of the nursing homes of Carintreggeland reported 1156 failures in medication distribution. These reports represent the events in medication distribution of 757 patients in nursing homes. This indicates that on average 0,76 incidents were reported per patient per year.

### Time of the incidents

The reports of 2009 and 2010 were classified into months to evaluate certain patterns or specific times of the year where most errors take place. Most incidents were reported in February 2009, the least reports were made in September 2009. No clear trend is discernible.

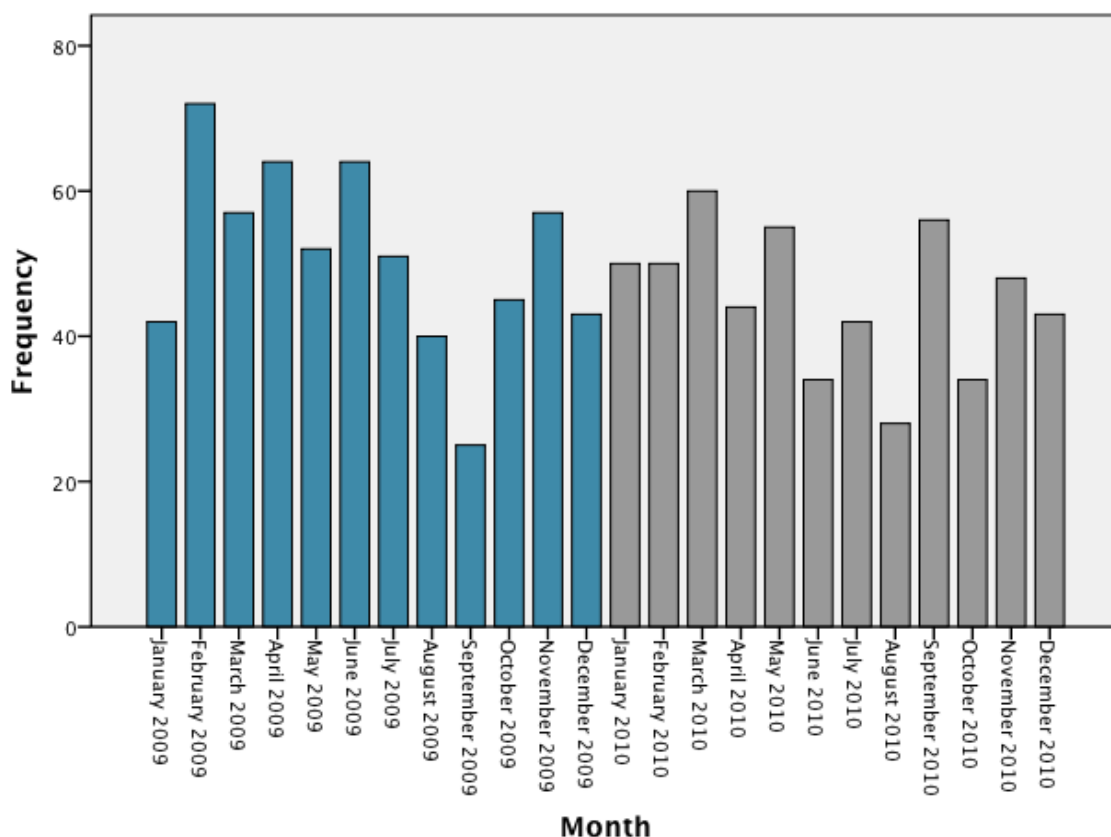


Figure 3: Reports of incidents per month

The reports were classified into the shifts of the nursing staff. Four shifts were operationalized;

- Morning shift (06.30am – 11.30am)
- Afternoon shift (11.30am – 04.30pm)
- Evening shift (04.30pm – 10.00pm)
- Night shift (10.00pm – 06.30am)

The reports have revealed that 53.1% of all incidents occur in the morning. To find out what percentage of the medicines are administered during different shifts over a day, a sample of 45 medication administration lists was studied. The sample shows a distribution of prescribed medication during the day, that fits to the distribution of de reports, shown in Table 6.

**Table 6: Distribution of prescribed medication and reports over a day**

| Shift           | Prescribed medication | Reports      |
|-----------------|-----------------------|--------------|
|                 | Percentage %          | Percentage % |
| Morning shift   | 54.0                  | 53.1         |
| Afternoon shift | 6.9                   | 14.4         |
| Evening shift   | 22.4                  | 27.4         |
| Night shift     | 16.7                  | 2.7          |
| Unknown         | 0                     | 2.3          |
| Total           | 100                   | 100          |

The table shows that the percentage of prescribed medication in the morning is nearly similar to the percentage of reports. The same applies to the data of the evening shift. The greatest difference was seen during the night shift. These numbers imply that the incidence of medication incidents during night shift is relatively low.

### Place of incidents

The staff has reported where the incidents have taken place. The living room and shared room were the places where most of the incidents occurred. Also the bedroom is a place where a great share of the incidents took place.

**Table 7: Place of the incidents**

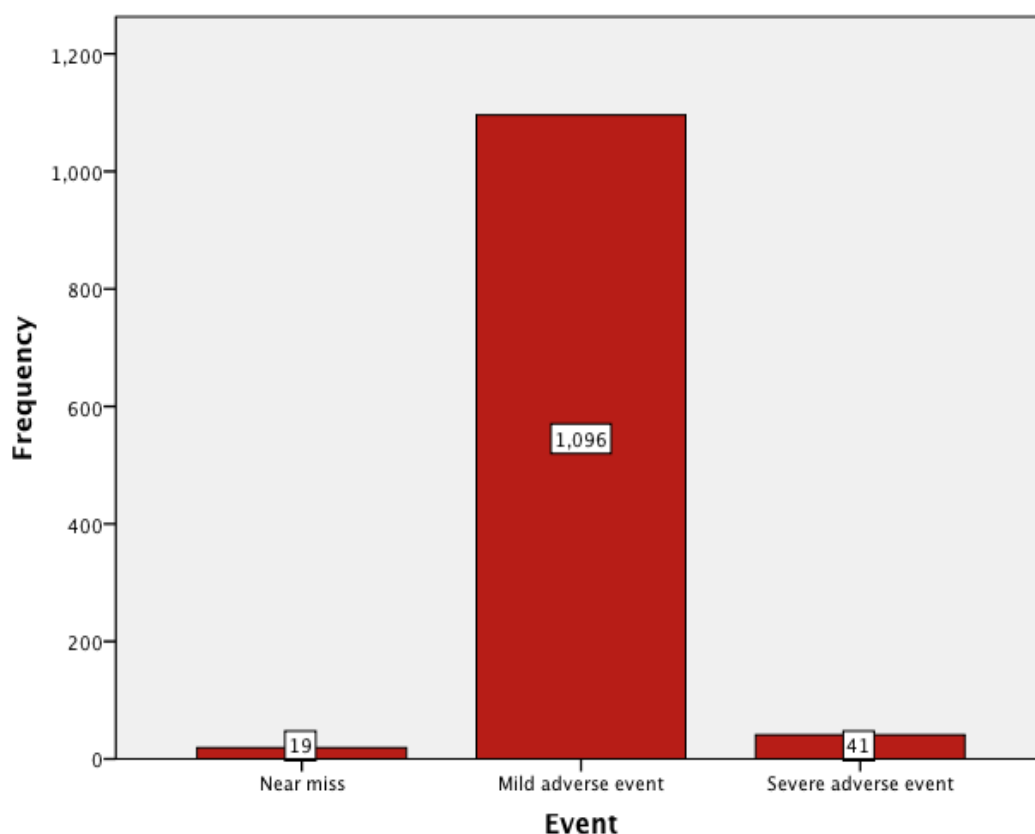
|                          | Frequency | Percentage % |
|--------------------------|-----------|--------------|
| Living room/ shared room | 809       | 70.0         |
| Bedroom                  | 233       | 20.2         |



|                      |    |     |
|----------------------|----|-----|
| Bathroom/toilet      | 3  | 0.3 |
| Kitchen              | 11 | 1.0 |
| Hallway              | 13 | 1.1 |
| Medicine cart/closet | 55 | 4.8 |
| Staff room           | 3  | 0.3 |
| Pharmacy             | 1  | 0.1 |
| Unknown              | 28 | 2.4 |

### Severity of the incidents

The severity of the incidents were classified into three types of events; near misses, mild adverse events and severe adverse events.



**Figure 4: Severity of the reported events**

Only 1.6% of the reports (19 cases) applies to the near misses. The majority of the reports, 1096 cases (94.8%), were mild adverse events. The events affected the patient, but did not lead to any visible adverse results on the physical, psychological or social functioning of the patient.

There were 41 reports (3.5%) of a severe adverse effect on the patient. As the severe adverse

events are the only reported incidents that really influenced the conditions of the patients, a relatively low proportion of the incidents seems to have harmed the patients.

To discuss the severity of the incidents, it is necessary to gain insight into the outcomes of the 41 severe adverse events. The conditions of the patients after the medication incidents were described in the reporting system and are displayed in Table 8. It appeared that no severe adverse event has lead to a hospital admission or death of a patient.

**Table 8: Outcomes of severe adverse events**

| Outcome                       | Frequency | Percentage % |
|-------------------------------|-----------|--------------|
| Pain or increased pain        | 5         | 12.2         |
| Abnormal blood pressure       | 1         | 2.4          |
| Abnormal blood glucose level  | 2         | 4.9          |
| Aggressive behaviour          | 1         | 2.4          |
| Restless behaviour            | 15        | 36.6         |
| Tiredness, drowsiness         | 8         | 19.6         |
| Much sleep                    | 4         | 9.8          |
| No sleep                      | 3         | 7.3          |
| Unresponsive/unconscious      | 1         | 2.4          |
| Increased urination           | 1         | 2.4          |
| Hospital admission or consult | 0         | 0.0          |
| Death                         | 0         | 0.0          |
| Total                         | 41        | 100.0        |

The most severe outcome of the incidents was a patient that temporary lost consciousness. The patient returned conscious within a few minutes and did not suffer from any permanent injury. Restless behaviour is the most common adverse effect.

### **Populations and housing types**

Two sub research questions are focussed on the possible differences in incidents between specific populations and housing types.

The population of the nursing homes of Carintreggeland was divided into three groups: psychogeriatric patients, somatic patients and rehabilitation patients.

The housing types of Carintreggeland as described in the background of this study were used;

traditional nursing homes, small scale group living, nursing units within care homes and rehabilitation units. The distribution of populations in the housing types was in 2010 equal to 2009. In Table 9 is displayed that the major part of the population lived in a traditional nursing home.

**Table 9. Population of nursing home residents of Carintreggeland in different housing types**

| Housing type:                 | Psychogeriatric |      | Somatic |      | Rehabilitation |     | Total |      |
|-------------------------------|-----------------|------|---------|------|----------------|-----|-------|------|
|                               | N               | %    | N       | %    | N              | %   | N     | %    |
| Traditional nursing home      | 289             | 57.0 | 151     | 74.8 | 0              | 0   | 440   | 58.7 |
| Small scale group living      | 176             | 34.7 | 39      | 19.3 | 0              | 0   | 215   | 28.4 |
| Nursing unit within care home | 42              | 8.3  | 12      | 5.9  | 0              | 0   | 54    | 7.1  |
| Rehabilitation unit           | 0               | 0    | 0       | 0    | 48             | 100 | 48    | 5.8  |
| total                         | 507             | 100  | 202     | 100  | 48             | 100 | 757   | 100  |

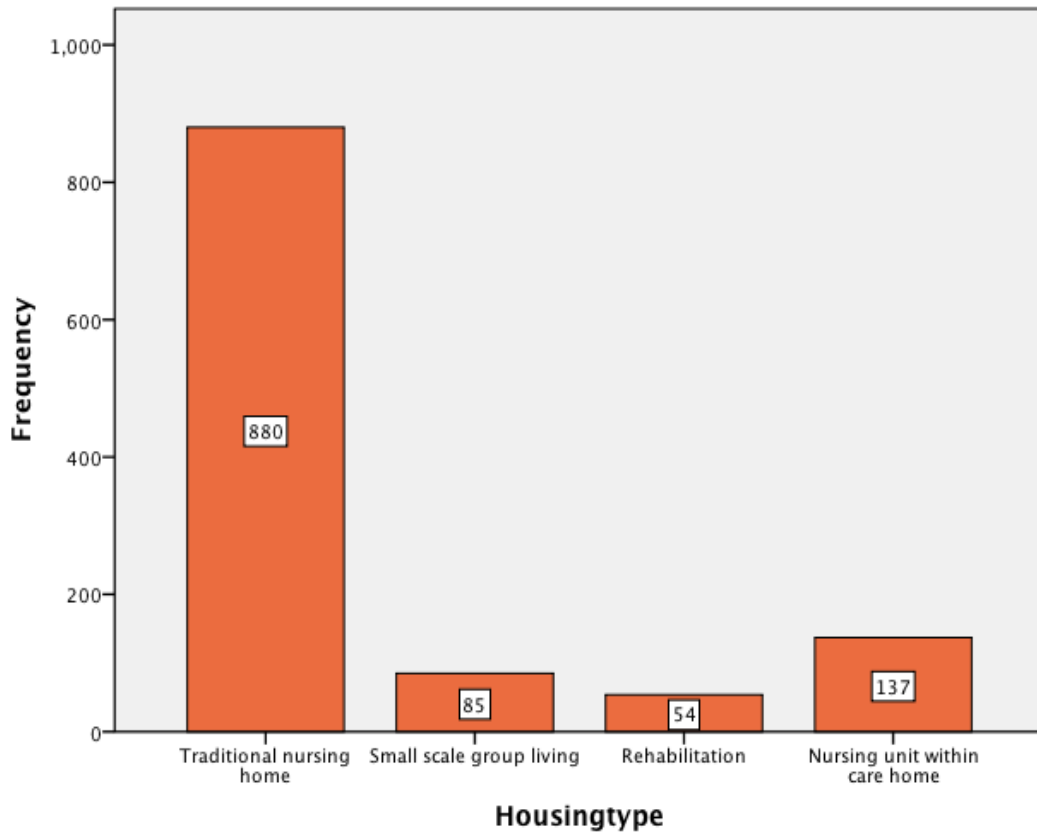
(Carint Reggeland Groep, maatschappelijk jaarverslag 2010)

There turned out to be a great difference in reports of the different populations of Carintreggeland. The largest representation came from the psychogeriatric units, these were 981 reports (84,9%). There must be notified that the group of psychogeriatric patients is the greatest proportion of the total nursing home population of Carintreggeland. But still, also relatively the most incidents take place in this group.

**Table 10: Population and reports divided by patient type**

| Population      | Patients |      | Reports |      | Reports<br>per patient<br>per year |
|-----------------|----------|------|---------|------|------------------------------------|
|                 | N        | %    | N       | %    | N                                  |
| Psychogeriatric | 507      | 67.0 | 981     | 84.9 | 0.97                               |
| Somatic         | 202      | 26.7 | 129     | 11.2 | 0.32                               |
| Rehabilitation  | 48       | 6.3  | 46      | 3.9  | 0.48                               |
| total           | 757      | 100  | 1156    | 100  | 0.76                               |

There's a housing type that has a remarkable high number of reports. Most reports were carried out in the traditional nursing homes (Figure 5). The 880 reports represent 76.1% of all reported incidents in medication distribution. Though, given the great population of patients in traditional



**Figure 5: Reports divided by housing types**

nursing homes (58.1%), a high number of reports is not unusual.

Looking at the proportion, most incidents were reported in nursing home patients in care homes. This population is small (7.1%) but the average amount of reports per patient per year is remarkable high. Compared to the average amount of reports of all housing types (0.76 reports per patient per year, as shown in Table 11, the rate of 1.27 reports per patient per year is very high.

A remarkable low number of reports is carried out in small scale group living units. With 85 reports, only 7.4% of the reports is derived from this housing type, while the population consists of 28.4% of the total nursing home population. This means that only 0.2 incidents per patient per year are reported.

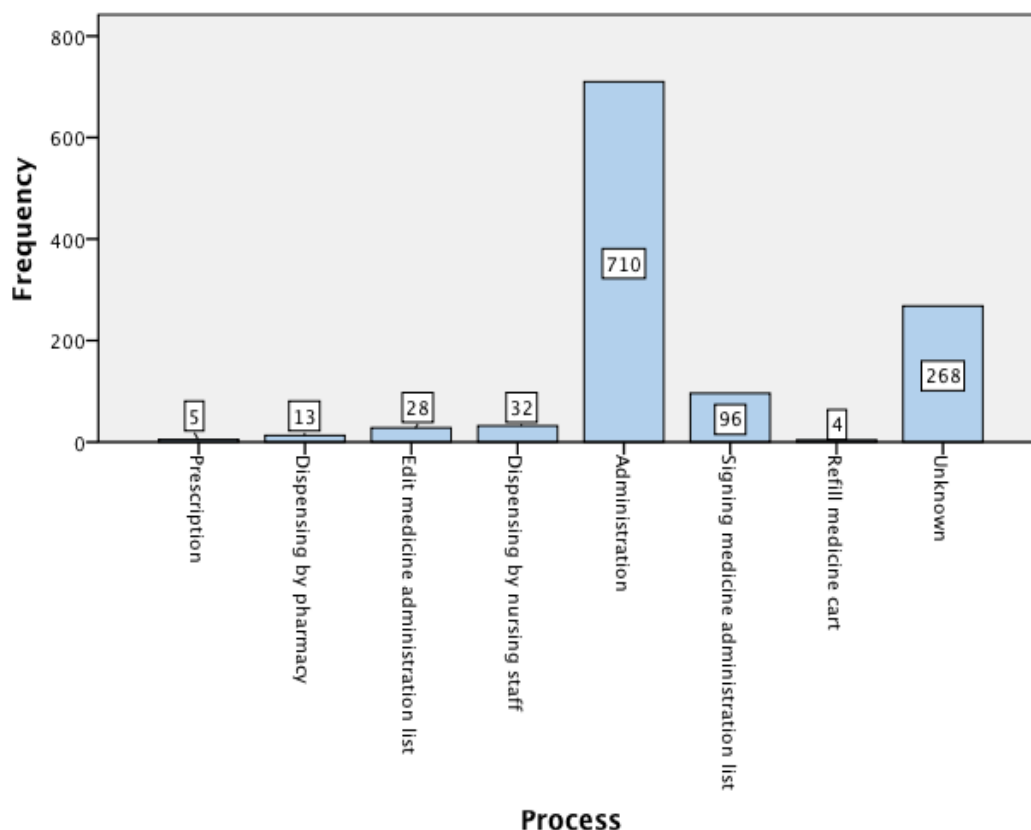
**Table 11: Distributions of patients and reports in different housing types**

|  | Patients | Reports | Reports per patient per year |
|--|----------|---------|------------------------------|
|  |          |         |                              |

| Housing type              | N   | %    | N    | %    | N    |
|---------------------------|-----|------|------|------|------|
| Traditional nursing home  | 440 | 58,1 | 880  | 76.1 | 1.0  |
| Small scale group living  | 215 | 28,4 | 85   | 7.4  | 0.2  |
| Rehabilitation            | 48  | 6,4  | 54   | 4.7  | 0.56 |
| Nursing unit in care home | 54  | 7,1  | 137  | 11.9 | 1.27 |
| total                     | 757 | 100  | 1156 | 100  | 0.76 |

### Characteristics of the incidents

The process of medication distribution is described in paragraph 2.2, according to the protocol of Carintreggeland. The stages in the flowchart are taken over to classify the incidents. By reading all descriptions in the open comment box in the VIM reporting system, the stage was determined. The data from the VIM reporting system show a striking distribution in Figure 6.



**Figure 6: Events in stages of medication distribution (N=1156)**

In 268 cases it was unknown in what stage the incident took place. These represent reports with too less information, but also events where at the end of the week medicines were left over in de medication cart, while they all were dispensed just to the needs of the patients for the week. This means that with faultless acting, the cart should be empty at the end of the week. Besides that,

the unknown cases also include situations where there were found medicines on the floor, in the patients bed, etc.

Without the unknown stages, 888 reports give information about in what stage of the process most incidents take place.

**Table 12: Distribution of events in known stages of the process (N=888)**

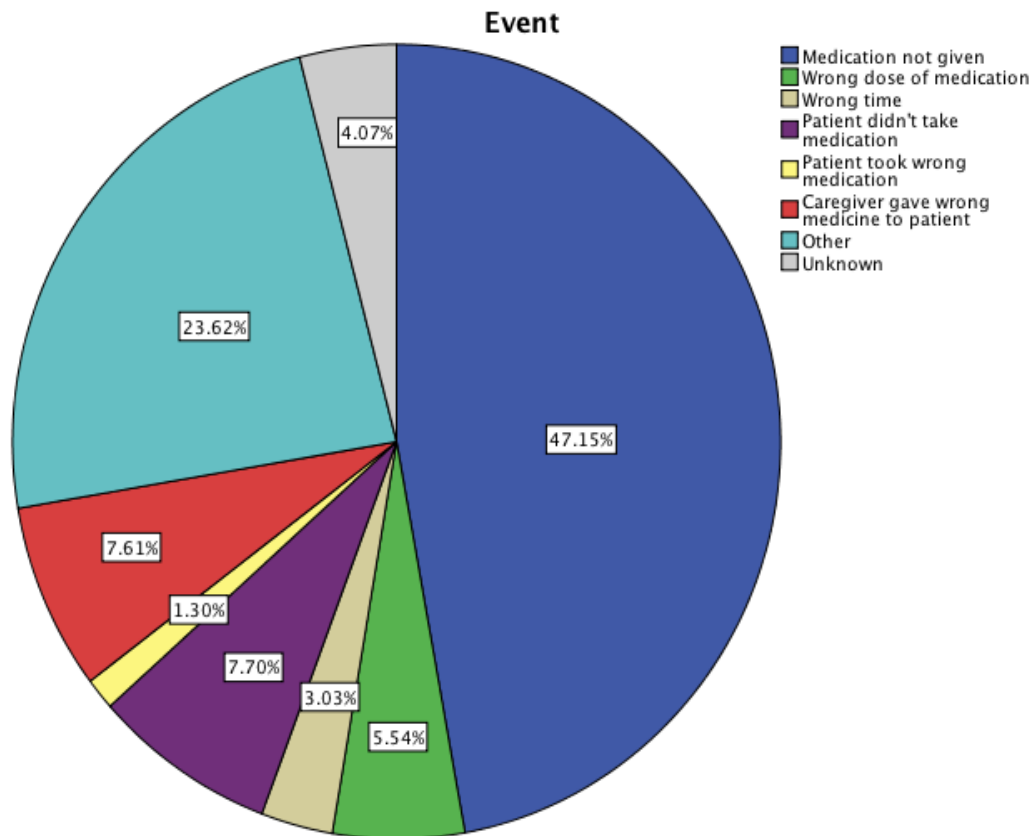
| Stage of the process                 | Reports |      |
|--------------------------------------|---------|------|
|                                      | N       | %    |
| Prescription                         | 5       | 0.6  |
| Dispensing by pharmacy               | 13      | 1.5  |
| Edit medicine administration list    | 28      | 3.2  |
| Dispensing by nursing staff          | 32      | 3.6  |
| Medicine administration              | 710     | 79.9 |
| Signing medicine administration list | 96      | 10.7 |
| Refill medicine cart                 | 4       | 0.5  |
| total                                | 888     | 100  |

It is very clear that medicine administration appears to be the stage with the highest rate of reported incidents. With 710 reports it can be called an outlier in the general overview.

With 10.7% of the reports, signing the medication administration list is the second stage where many incidents take place. In the open comment boxes is described that the nursing staff in the next shift didn't know whether the patients have administered their medicines, because the lists weren't signed.

Also an interesting fact is that there turned out to be an extra stage; 'dispensing by nursing staff'. This stage is not included in the protocol. From the descriptions in the open comment boxes, it appeared that the nursing staff in the unit dispenses the medicines from the cart into small cups. These cups are given to the patient. This extra action that is not supposed to be undertaken, lead to 32 reported incidents over the years 2009 and 2010.

What actually happened during the incidents is also reported by the employees. The distribution of the events is displayed in the pie chart of Figure 7.



**Figure 7: Description of the events**

In almost half of the reported incidents (47.2%), the medicines were not given by the nursing staff. Wrong medicines were given in 7.6% of the cases. Failures were made in the dose (5.5%) and timing (3.0%) of medicine administration. Two items were caused by the fact that the cup with medicines was put on the table in front of the patients. The nursing staff assumed that de patients would administer the medicines themselves, but didn't ensure that this was actually carried out. In 1.3% of the incidents, the patients administered the wrong medicines by taking the cup of another patient. The patients didn't administer their medicines in 7.7% of the reports. There's a great share of 23.6% undefined events where the reports didn't fit in one of the other values.

### Causes of the incidents

The Eindhoven Classification Model (ECM) was used to categorize the causes of the incidents. The model distinguishes four categories of errors; technical, human, organizational and other factors. The employees described the incidents in the open comment box in the reporting system. With these data, the incidents could be classified into the model of the Eindhoven Classification Model.

**Table 13: Causes classified by ECM**

|                | Frequency | Percentage % |
|----------------|-----------|--------------|
| Technical      | 0         | 0.0          |
| Human          | 1100      | 95.2         |
| Organizational | 0         | 0.0          |
| Other factors  | 53        | 4.6          |
| Unknown        | 3         | 0.2          |
| Total          | 1156      | 100.0        |

The incidents that were described, were not influenced by technical factors as defaulting equipment. Neither did organizational factors as policies, procedures and protocols play a role. In all well described reports, the incidents were affected by human actions. These human actions include behaviour of employees and patients.

**Table 14: Human failures caused by the staff, classified by ECM (N=1100)**

|                           |                   | Frequency | Percentage % |
|---------------------------|-------------------|-----------|--------------|
| Knowledge-based behaviour | Reasoning         | 0         | 0.0          |
| Rule-based behaviour      | Qualifications    | 3         | 0.3          |
|                           | Coordination      | 39        | 3.5          |
|                           | Verification      | 103       | 9.4          |
|                           | Intervention      | 943       | 85.7         |
|                           | Monitoring        | 9         | 0.8          |
| Skill-based behaviour     | Slips or tripping | 2         | 0.2          |
| External                  | External          | 1         | 0.1          |
| Total                     |                   | 1100      | 100.0        |

In 53 cases, the incident was caused by a patient related factor. This means that the incidents were related to the patient characteristics or conditions, which influence safety but are beyond the control of the nursing staff. These incidents include refusals of patients to take their medication. The other 1100 cases are caused by actions of the staff. According to the Eindhoven Classification model, human errors can occur on three behavioural levels; skill-based behaviour, rule-based behaviour and knowledge-based behaviour. Rule-based behaviour can be divided in five subcategories, as shown in Table 14.



In three cases there was an incorrect fit between the qualifications of the employee and the particular task. A nurse made a decision or carried out a task that should have been done by the physician. A lack of task coordination within a team resulted in 39 medication failures.

In a larger share, 9.4% of the failures, employees didn't assess the situation, conditions of the patient and/or the materials before starting the intervention, which lead to an incident in medication distribution.

With 85.7%, the majority of the reports were incidents that result from faulty task planning and execution from an individual employee. These also include the incidents wherein the staff forgot to administer the medication. In 9 cases wrong data were used.

Two cases represent a incident that concern the skills of the employee. An injection wasn't executed properly because of clumsiness or unskillfulness.

**Table 15: Cause of the incidents (N=943)**

| Cause                                       | Reports | Percentage % |
|---|---------|--------------|
| Wrong execution of instruction or procedure | 12      | 1.3          |
| Wrong use of equipment                      | 2       | 0.2          |
| Condition of the patient                    | 8       | 0.9          |
| Involvement of other patients               | 1       | 0.1          |
| Forgotten by caregiver                      | 765     | 81.1         |
| Not signing medicine administration list    | 96      | 10.2         |
| Wrong planning                              | 35      | 3.7          |
| Unknown                                     | 24      | 2.5          |
| Total                                       | 943     | 100.0        |

To take a closer look at the 85.7% of the reports that were caused by faulty task planning and execution, the causes that were registered by the reporting employees were investigated. The results are described in Table 15. It appears that forgetting to act in medication distribution is the main cause of the incidents. This cause represents 81.1% of the reported incidents. Also not signing the medicine administration lists causes a great share of the incidents (10.2%).

The VIM reporting systems contains an open ended question about how the incident could have been prevented. The suggestions that were described by the reporting employee were clustered into values to compute these data into quantitative data. There was no suggestion given in 166 reports. In 13 cases single answers were given that were not retrieved in other reports, these are displayed in Table 16 as 'not categorized'.

**Table 16: Suggestions for prevention given by nursing staff**

| Suggestion for prevention                      | Reports | Percentage % |
|--|---------|--------------|
| Improve check or double check by nursing staff | 554     | 47.9         |
| Don't leave medicines unattended with patients | 58      | 5            |
| Find a place without distraction by patients   | 199     | 17.2         |
| Improve communication                          | 58      | 5            |
| Improve planning                               | 30      | 2.6          |
| Improve performance of intervention            | 16      | 1.4          |
| Improve registration                           | 34      | 2.9          |
| No extra stage of dispensing by nursing staff  | 5       | 0.4          |
| Could not be prevented                         | 23      | 2            |
| No suggestion                                  | 166     | 14.4         |
| Other/not categorized                          | 13      | 1.1          |
| Total  | 1156    | 100.0        |

Over half of the given suggestions say that the nurse should have checked the situation better before administering the medication to the patient or a double check by a nursing colleague should have been done. This suggestion was given in 554 reports. Concentration in the task of medication distribution was a problem in 17.2% of the cases. The performance was done in an environment where the nurse was disturbed by patients or influencing events. Of a small percentage of 2.0% was stated that the incident could not have been prevented.

## Involved medication

The reporting system doesn't oblige the staff to register which medicine was involved in the incident. Nevertheless, in 654 reports (56.5%) the involved medicines were mentioned in the open comment box wherein the employee can write a description of the incident.

**Table 17: Involved medicines in events (N=654)**

| Medicine                      | Frequency  | Percentage % |
|-------------------------------|------------|--------------|
| Cardiovascular                | 82         | 12.5         |
| Antibiotics/anti-infectives   | 31         | 4.7          |
| Diuretics                     | 34         | 5.2          |
| Nonopioid analgesics          | 35         | 5.3          |
| Anticoagulants/anti platelets | 34         | 5.2          |
| Hypoglycaemics                | 98         | 15.0         |
| Steroids                      | 4          | 0.6          |
| Opioids                       | 35         | 5.4          |
| Antidepressants               | 24         | 3.7          |
| Anti seizure                  | 12         | 1.8          |
| Antihyperlipidemics           | 12         | 1.8          |
| Antineoplastics               | 0          | 0.0          |
| Gastrointestinal tract        | 54         | 8.3          |
| Nutrients/supplements         | 1          | 0.2          |
| Respiratory tract             | 11         | 1.7          |
| Sedatives/hypnotics           | 59         | 9.0          |
| Antipsychotics                | 49         | 7.5          |
| Hormones                      | 1          | 0.2          |
| Osteoporosis                  | 10         | 1.5          |
| Muscle relaxants              | 7          | 1.1          |
| Thyroid                       | 10         | 1.5          |
| Anti gout                     | 2          | 0.3          |
| Antiparkinsonians             | 17         | 2.6          |
| Dermatologic                  | 0          | 0.0          |
| Alzheimer disease             | 0          | 0.0          |
| Antihistamines                | 19         | 2.9          |
| Immunomodulators              | 0          | 0.0          |
| Ophthalmics                   | 9          | 1.4          |
| Vaccines                      | 4          | 0.6          |
| <b>Total</b>                  | <b>654</b> | <b>100.0</b> |

In 31.1% of the cases, the incident was involved with all medicines that the patient should have been given. All medicines of a patient were forgotten to issue, or all were given to the wrong patient. The involved medicine is unknown in 143 cases (12.4%). The distribution of the 654 mentioned involved medicines are shown in Table 17. The medicines are categorized in medication classes.

### Patients medical records

The 36 selected patients for the research in their medical records concerned 4 somatic, 29 psychogeriatric and three rehabilitation patients. Because two medical records were missing, these data are based on 34 files. The data that were retrieved from the records concerned their chronic diseases and medication. Also information about the time and way of administration and the amount of mutations in the period before the incidents was found.

The prevalence of chronic diseases was studied, specifically to congestive heart failure, renal insufficiency, Diabetes Mellitus, Rheumatoid Arthritis, COPD, dementia and cancer.

**Table 18: Prevalence of chronic diseases in research population medical records (N=34)**

| Chronic disease          | Frequency | Percentage % |
|--------------------------|-----------|--------------|
| Congestive heart failure | 10        | 29.4         |
| Renal insufficiency      | 2         | 0.06         |
| Diabetes Mellitus        | 13        | 38.2         |
| Rheumatoid Arthritis     | 3         | 0.09         |
| COPD                     | 5         | 0.15         |
| Dementia                 | 28        | 82.4         |
| Cancer                   | 3         | 0.09         |

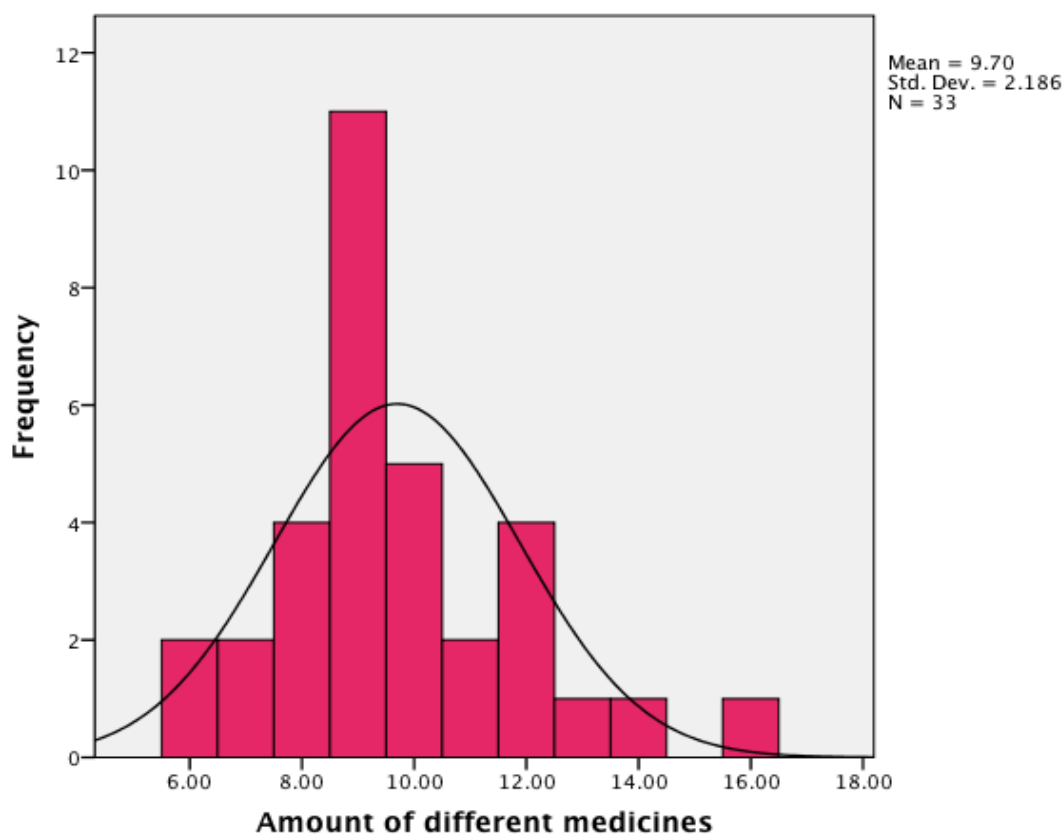
Mainly congestive heart failure, diabetes mellitus and dementia were common diseases.

Co-morbidity was seen in all of the selected patients. Besides these chronic diseases, other health issues were found. Health issues with a high occurrence are stroke, arthrosis of joints, anaemia, hypertension, hyper cholesterol, amputations and cataract. Focussing at only the chronic diseases, the distribution of co-morbidity is shown in Table 19.

**Table 19: Co-morbidity in research population medical records (N=34)**

| Amount of chronic diseases | Frequency | Percentage % |
|----------------------------|-----------|--------------|
| 1                          | 9         | 26.5         |
| 2                          | 20        | 58.8         |
| 3                          | 4         | 11.8         |
| 4                          | 1         | 2.9          |
| Total                      | 34        | 100          |

The medicine administration lists describe the amount of different medicines that are used by patients. The lists were studied to gain insight in medicine use. Although the data are retrieved from 34 files, the prescribed medication is only known from 33 patients, because the medicine administration list was missing in one of the files.



**Figure 8: Amount of different medicines (N=33)**

The mean of different medicines that was used by all patients of the medical record study was 9.7, with a minimum of 6 (psychogeriatric patient) and a maximum of 16 (somatic patient).

None of the patients managed the medicines themselves. This fits the protocol which describes that the medication for most of the patients is managed by the nursing staff. Elderly care

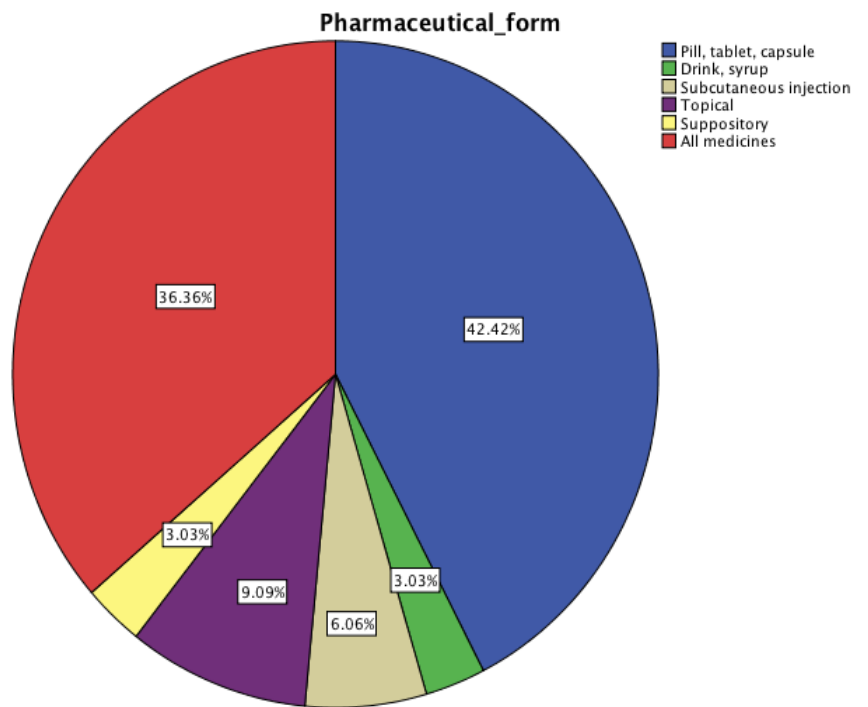
physicians determine whether self management of medication is safe for the patient.

The types of medicines that were prescribed on the medicine administration lists were studied. In Table 20 is displayed how many patients used the different classes of medicines.

**Table 20: Medication use of research population medical records (N=33)**

| Medicine                      | Patients<br>N | Percentage of<br>patients using<br>% |
|-------------------------------|---------------|--------------------------------------|
| Cardiovascular                | 15            | 45.50%                               |
| Antibiotics/anti-infectives   | 9             | 27.3                                 |
| Diuretics                     | 21            | 63.6                                 |
| Non opioid analgesics         | 12            | 36.4                                 |
| Anticoagulants/anti platelets | 23            | 69.7                                 |
| Hypoglycaemics                | 12            | 36.4                                 |
| Steroids                      | 5             | 15.2                                 |
| Opioids                       | 10            | 30.3                                 |
| Antidepressants               | 14            | 42.4                                 |
| Anti seizure                  | 2             | 6.1                                  |
| Antihyperlipidemics           | 4             | 12.1                                 |
| Antineoplastics               | 0             | 0                                    |
| Gastrointestinal tract        | 26            | 78.8                                 |
| Nutrients/supplements         | 6             | 18.2                                 |
| Respiratory tract             | 6             | 18.2                                 |
| Sedatives/hypnotics           | 25            | 75.8                                 |
| Antipsychotics                | 14            | 42.4                                 |
| Hormones                      | 2             | 6.1                                  |
| Osteoporosis                  | 8             | 24.2                                 |
| Muscle relaxants              | 0             | 0                                    |
| Thyroid                       | 2             | 6.1                                  |
| Anti gout                     | 2             | 6.1                                  |
| Antiparkinsonians             | 0             | 0                                    |
| Dermatologic                  | 5             | 15.2                                 |
| Alzheimer disease             | 0             | 0                                    |
| Antihistamines                | 6             | 18.2                                 |
| Immunomodulators              | 1             | 3                                    |
| Ophthalmics                   | 6             | 18.2                                 |
| Vaccines                      | 0             | 0                                    |

The medicines that were involved in the events were investigated for the pharmaceutical form. In 12 cases the incident concerned all medicines that should have been given. There's no specific pharmaceutical form mentioned in these reports. Evidently, the medicines of oral solid suspension are most involved in medication incidents with an adverse effect. The pill, tablet or capsule in the 14 incidents represent 66,7% of the 21 reports whereby the pharmaceutical form is known.



**Figure 9: Pharmaceutical form of involved medication in events**

According to the protocol, most medicines are administered at set times. These planned times are at 09.00am, 12.00am, 17.00pm and 21.00pm. Some medicines aren't prescribed for these times and depend on the situation of the patient. This means that these medicines cannot be given according to a certain planning. To find out if this unplanned medication is a risk factor for occurrence of an incident, the time of administration was investigated. From the description in the VIM-reporting system and the medical record of the patients, information was found for 34 of the incidents. A percentage of 82.9% of the incidents concerned scheduled medicines. The remaining 17.1% were medicines that should have been given at a random time, adapted to the patients condition.

Mutations in the prescribed medicines can play a role in incorrect carrying out the process of medication distribution. Therefore it is interesting to get insight in the mutations in the period before the incidents happened. In 33 of the medical records was found how long the period from the last mutation was until the incident had taken place. Also, the amount of mutations were studied. It appeared that in 11 cases (33.3%) the latest mutation had taken place within the preceding week. The other mutations were longer than a week ago.

In 4 cases, one mutation had found place in the preceding month. Two mutations per month goes for 11 cases. The majority (54.5%) of the selected patients experienced no mutation in the preceding month.

According to Field (2000), being a new resident in the nursing home is a risk factor that influences

medication safety. That is why the time between admission in the nursing home and the incident was studied. It appeared that no patient was a new resident on the time the incident took place.

**Table 21: Duration of stay in nursing home before occurrence of adverse event**

| Time from admission | Frequency | Percentage % |
|---------------------|-----------|--------------|
| 1 week              | 0         | 0            |
| 8 – 31 days         | 0         | 0            |
| 31 days – 6 months  | 12        | 35.3         |
| >6 months           | 22        | 64.7         |
| Total               | 34        | 100          |

No reliable data about medication reviews and physical examinations were found in the medical records. The intention was to find out how long the period was between the last medication review and the moment of the incident. It appears that the reviews were not registered in the medical records. The information of physical examinations weren't complete in the paper medical records of the deceased patients. Therefore no reliable data could be used for this study.

### Reporting behaviour

The reporting behaviour of the staff is of great influence on the number of incident reports. According to the VIM protocol, every employee that is directly involved in patients care should report incidents. That why this study investigated which employees reported the incidents. The results are displayed in Table 22.

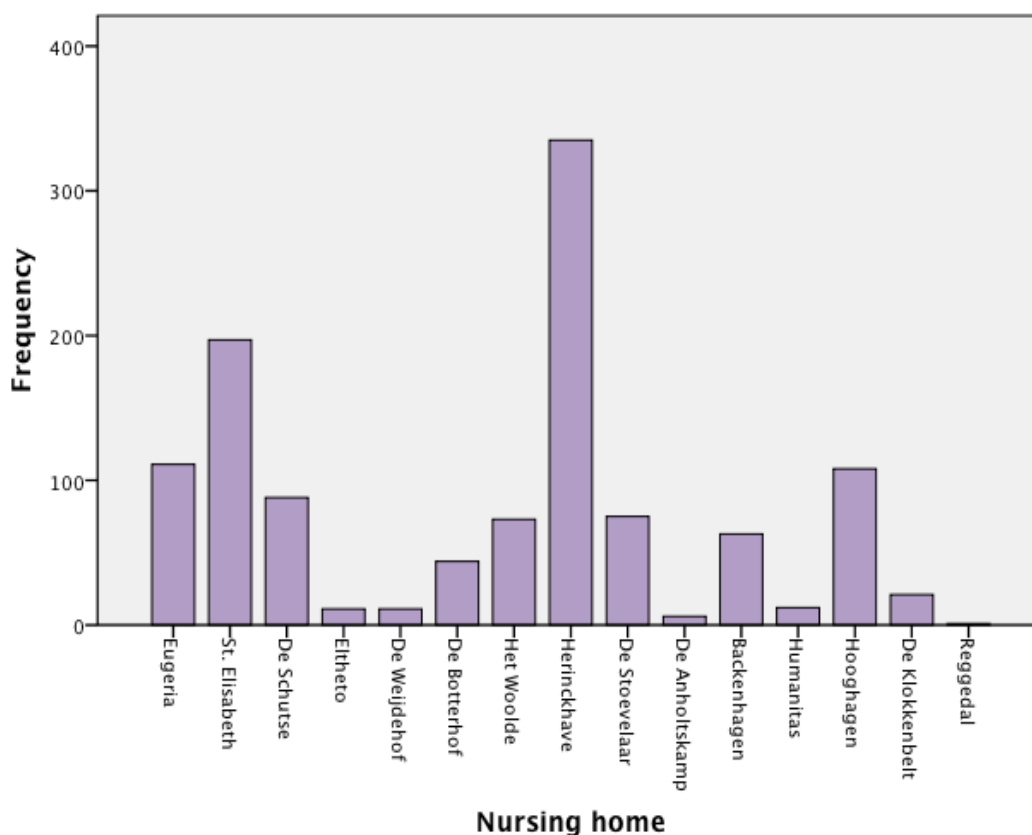
Some of the low percentages are reports of employees that are not authorized to administer medicines to patients. These employees concern the nurse level 2 and the welfare worker, representing both 0.3% of the reports. On the other hand, there are also employees that are very much involved in the process of medication distribution and show nevertheless a low number of reports. This applies to the elderly care physician and pharmacy assistant. Both only reported one incident over a period of two years. Most of the incidents were reported by nurses of level 3 (86.2%) and nurses of level 4 and 5 (8.0%).



**Table 22: Distribution of reporting caregivers**

| Reporting caregiver    | Frequency | Percentage % |
|------------------------|-----------|--------------|
| Nurse level 2          | 3         | 0.3          |
| Nurse level 3          | 996       | 86.2         |
| Nurse level 4-5        | 93        | 8            |
| Pharmacy assistant     | 1         | 0.1          |
| Elderly care physician | 1         | 0.1          |
| Flex worker            | 4         | 0.3          |
| Nurse intern           | 54        | 4.7          |
| Welfare worker         | 4         | 0.3          |
| Total                  | 1156      | 100.0        |

Besides the insight in the reporting employees, also the number of reports per nursing home was studied. The proportion of both the number of reports and the number of resident patients are charted.



**Figure 10: Distribution of reports of different nursing homes**

There is a large difference between the nursing homes in the number of reports, but they also differ in the number of resident patients. Figure 10 displays nursing home Herinckhave as an extreme outlier in number of reports.

To study for which nursing home applies the most reports per patient, the capacity of resident patients is compared to the number of reports. Table 23 shows the proportions.

**Table 23: Distribution of population and reports in different nursing homes (N=1156)**

| Nursing home   | Resident patients | Reports | Reports per patient<br>over period of 2 years |
|----------------|-------------------|---------|---|
| Eugeria        | 149               | 111     | 0.35  |
| St. Elisabeth  | 152               | 197     | 0.65  |
| De Schutse     | 63                | 88      | 0.65  |
| Eltheto        | 8                 | 11      | 0.65  |
| De Weijdehof   | 41                | 11      | 0.15  |
| De Botterhof   | 60                | 44      | 0.35  |
| Het Woolde     | 32                | 73      | 1.15  |
| Herinckhave    | 34                | 335     | 4.95  |
| De Stoevelaar  | 66                | 75      | 0.55  |
| De Anholtskamp | 12                | 6       | 0.25  |
| Backenhagen    | 23                | 63      | 1.35  |
| Humanitas      | 27                | 12      | 0.2   |
| Hooghagen      | 19                | 108     | 2.85  |
| Klokkenbelt    | 10                | 21      | 1.05  |
| Reggedal       | 12                | 1       | 0.05  |

Nursing home Herinckhave counts a remarkable high number of reported incidents per patient. Reggedal only reported one incident in 2009 and 2010 and is the nursing home with the lowest rate of reported incidents.

### 3. Discussion

In this paragraph, the results of the study are discussed and the study is critically reviewed. The discussion covers both issues of content and a methodological evaluation.

This study investigated medication safety in nursing homes by analyzing incidents in medication distribution. This has yielded new information about medication safety in nursing homes in the Netherlands. Preliminary, there has not been much research in medication safety in nursing homes with this focus. Some research was done in the United States. J.H. Gurwitz and T.S. Field et al researched incidence and preventability (2000) and risk factors (2003) of adverse drug events. They concluded that adverse events are common and often preventable. Other researches were focussed on hospital care and hospital admissions due to medication errors. For example the Hospital Admissions Related to Medication (HARM) in The Netherlands; P.M.L.A van der Bemt (2006) concluded that 5.6% of hospital admissions were caused by medication errors. This study focusses on the incidence, causes and outcomes of incidents in medication distribution in nursing homes.

The results are mostly based on the incident reports of the staff of the nursing homes of Carintreggeland. To validate the results of this study, the data were discussed in interviews with an elderly care physician and the pharmacist. Also, the protocol of medication distribution in nursing homes of Carintreggeland was discussed to gain information about the policy and how this is applied in practice.

The process of medication distribution in the nursing homes is applied in practice according to the flow chart in the protocol. Both interviewees stated that most incidents take place in the stage of administration. The physician is being contacted by the nursing staff to discuss what to do after an incident. That's why she has insight in the share of incidents in this stage. The pharmacist confirms this state, because he also works for nursing homes of other health care organizations, where administration of medicines is the most critical stage as well. The physician states that most common errors are caused by forgetting to administer the medicines, giving medicines to the wrong patient or giving the medicines at a wrong time. The pharmacist and physician expect that the greatest share of VIM reports with unknown stage also applies to errors in the stage of administration. These concern reports of left overs in the medication cart or a shortage of medicines. The patients might have got too much or too little medication. Remarkable are the conclusions of J.H. Gurwitz and T.S. Field (2005) that most of the errors take place in the stage of ordering and monitoring. In their study, the stage of medicine administration only applied to 19% of the adverse events.

The incidents are digitally reported by the staff in the so-called VIM system. The interviewees

explain their involvement in this procedure. The pharmacist is not involved in single VIM reports. Only in participating the yearly consultation, the pharmacist is involved to assess trends in VIM reports and evaluate policy of medication distribution in nursing homes. These consultations are based on a journal of the quality department. According to the pharmacist though, the information in this journal is very limited and therefore not suitable for a proper analysis and to really learn from incidents. The physician is involved in single VIM reports. The nursing staff mostly contacts the physicians to discuss the incidents and take measures. The physician determines what medication still will be administered, or which should be omitted. They also look at risks. If the physician feels insecure, some additional examinations are executed, for example measuring blood pressure a few times at the day of the incident.

According to the protocol, a half-yearly review of prescribed medicines of each patient should take place. This review should be executed by the pharmacist and the physician. This however is often not feasible because of various conditions. They try to do the reviews at least yearly. During this review, they discuss the medicines. Sometimes a more optimal combination of medicines is observed and changed. Risk full (combinations of) medicines are detected very rarely, because they have been filtered out already at the moment of prescribing.

The results of the study in medical records show that the average amount of use of different types of medicines is 9 medicines per day. The pharmacist and elderly care physician are aware of the high number. They state that it has to do with three conditions. Many patients suffer from co-morbidity. These different illnesses require different medicines. Also, some medicines cause other symptoms, such as gastrointestinal problems. To avoid these symptoms, other medication is prescribed preventively. The third cause of the high amount of medicines is that physicians are afraid to discontinue medicines. This is stated by the pharmacist and confirmed by the interviewed physician. Some patients take several medicines for years, while sometimes these aren't needed anymore. The pharmacist gives his opinion and advise during the review, but ultimately, it is the physician who determines whether or not to discontinue the medication. The physician, after all, is responsible for the medical care and physical health of the patients. In some cases medicines could be reduced, but the fear of the physicians stand in the way. The feelings of the physicians, patients and families have a major influence.

The results show some types of medicines that are most involved in medication incidents. In general, the pharmacist recognizes the distribution of involved medicines. Most of the incidents concern errors with 'al medicines'. The high percentage of cardiovascular medicines, sedatives and hypoglycaemics are logical, as they are medicines that are prescribed often to nursing home patients. The elderly care physician finds it a logical reflection of the medicines commonly used. The pharmacist though, is surprised by high rate of incidents with hypoglycaemics. The dosage of this medications may change more often than other medicines, but he doesn't expect that to be

the cause. He is interested in further research about incidents in this specific type of medicines. J.H. Gurwitz and T.S. Field (2003) concluded that use of multiple medications, non opioid analgesics, anticoagulants, diuretics, and anti seizure medications were risk factors for occurrence of adverse events. The sample of medical records in this study revealed that all patients used multiple medications. That risk factor applies to almost all nursing home patients. The types of medicines, differ from the results of J.H. Gurwitz and T.S. Field (2003). This study provides no explanation to this difference.

Most incidents seem to occur in the morning. According to both the elderly care physician and pharmacist, this is understandable given two reasons. During the morning shift, the nursing staff is very busy performing many activities of personal care; getting patients out of bed, washing, dressing up, getting breakfast, etc. Also, most medicines are administered in the morning. If medicines are prescribed for one administration per day, they mostly are prescribed for the morning. Remarkable is the low percentage of incidents during night shift. According to the elderly care physician, this is due to the calm conditions on the unit when most of the patients are asleep. The nurse is not being distracted and can take care of the medicine administration carefully.

There turned out to be a difference in the number of reported incidents between different populations. Relatively many incidents were reported in the psychogeriatric patients population. The physician and pharmacist cannot explain what the reason is. In fact, generally the somatic patients use more medicines than psychogeriatric patients due to co-morbidity and poor physical conditions. Therefore, this outlier of the psychogeriatric population is not logical. No literature is found to substantiate this result with population related arguments.

There also turned out to be a difference in the number of reported incidents between different housing types. A remarkable high number of reports were made in the nursing units of care homes. This can be declared by the involvement of many actors in the process of medication distribution. In some units of care homes, both the general practitioner and elderly care physician are involved, as well as both the local and general contracted pharmacist. This might influence the coordination of medication distribution. A low number of incident reports came from the housing type of small scale living. A study was done about small scale living (H. Verbeek e.a., 2008). The study concluded that patients in small scale dwellings use less medicines than patients in traditional nursing homes, this especially applies to sedatives and antipsychotics. Also, the small amount of VIM reports in the housing concept of small scale living can be explained by the small patient group and nursing team. The nurses know the patients and their conditions very well. In traditional nursing homes, the groups of patients are greater and the nursing team consists of more employees.

The differences of numbers of reports in different populations, housing types and nursing homes can also be explained by reporting behaviour. According to the interviewees, reporting behaviour

plays a great role. To draw conclusions from the the amount of VIM reports in different nursing homes might be biased. Therefore, reporting behaviour needs further research. Medication safety in a nursing home with many VIM reports is not necessarily lower than in a location with less reports.

According to this study, the incidents are practically only reported by the nursing staff. In 2006, Carintreggeland participated in a national project 'Zorg voor Beter'. Therefore, TNO Management Consultants conducted research on incidents in medication distribution. At that time also one of the conclusions that was drawn is that incidents weren't reported by elderly care physicians. TNO assumed that the protocol of VIM incidents reporting was not well implemented in this profession group. However, the interviewed elderly care physician stated that their profession is known with the protocol, and that their low rate of reports is just caused by their reporting behaviour. According to the physician, many scientific researches are conducted on the topic of reporting behaviour of physicians. She recognizes the low rates in her own behaviour and the behaviour of her colleagues. They feel like physicians are not allowed to make mistakes in their work and should function as a role model for other caregivers. This restrains them from reporting incidents. The physician also indicates that it is unclear what should be reported. It would be interesting to gain more information by not only including adverse events, but also near misses and deviations in the process. As an example, the physician mentions a case where a sleep medicine was not administered, because the patient was sleeping. The nurse decided not to wake up the patient. She also states that is debatable whether medicine refusals by patients should be reported. To gain a good insight in safety, the staff should also report errors in the process that don't affect the patients. Now generally only near misses and adverse events are reported, as the protocol asks. This might explain why this study shows a low amount of reports in the first part of the process. The near misses in the start of the process have no effect on the patient because the errors are corrected in time. The 1.6% of the near misses is therefore very likely an under registration. The interviewees both state that the evaluation of VIM-reports isn't carried out systematically according to the protocol. Therefore there will not optimally be learned from mistakes.

The outcomes of the incidents were reasonable mild. No permanent injuries were caused and no incident lead to a hospital admission or death of a patient. According to the interviewed elderly care physician it is logical that no patients were admitted to a hospital, because there is a lot of expertise and there are good facilities in the nursing homes. Equal to a hospital, in the nursing home the condition of the patient can be monitored all day. Nursing staff is present 24 hours a day. They monitor and carry out controls. Also the elderly care physician is present or on call to deliver medical care. Especially after a medication error, the patient will be monitored intensively. Only in exceptional situations, a patient is sent to a hospital.

Self management of medication by patients is very low according to this study. The interviewed

pharmacist and physician state this as a logical result. Because most of the patients in the population of the research in medical records are psychogeriatric patients, it is obvious that the management is taken over by the nursing staff. It is determined by the elderly care physician whether a patient can manage the medication himself. Because of the cognitive conditions and also the complexity of a great amount of medicines it is very rare that nursing home patients are judged capable of managing the medicines themselves.

### **Considerations of the study**

Because there was not much known about medication safety in the Netherlands, this study contributes to a first insight into this topic. The results are therefore very relevant for both science and Carintreggeland.

This exploratory research has provided much information about medication distribution in the nursing homes of Carintreggeland. According to Bell (2010), an exploratory study does not aim to provide the final and conclusive answers to research questions, but merely explores the research topic with varying levels of depth. The combination of the qualitative and quantitative parts of the study draws a comprehensive picture of medication safety in nursing homes.

Overall, the study was designed and performed properly. The objective to gain a first insight to medication safety in nursing homes in The Netherlands was achieved.

A weakness of this study is the dependence of reporting behaviour of the staff. The number of reports probably might give a biased reflection of the actual number of incidents. However, it does give a first insight. Literature confirms a reduced reliability due to reporting behaviour. Numerous factors may affect whether errors and adverse events are reported. Nevertheless, analysis of error reports provide rich details about latent errors that lead to active errors and adverse events (Eric J. Thomas, Laura A. Petersen, 2003). Carintreggeland attaches great importance to learn from errors and has developed policy to encourage reporting behaviour of their caregivers. A positive development for this study is the significant increase in reports in the last five years, shown in Table 24.

**Table 24: Number of reports, 2006 - 2010**

| Year              | 2006 | 2007 | 2008 | 2009 | 2010 |
|-------------------|------|------|------|------|------|
| Number of reports | 3571 | 3915 | 5412 | 5768 | 5616 |

(Carint Reggeland Groep, 2011)

According to Thomas (2003) high reporting rates may indicate an organizational culture committed to identifying and reducing errors and adverse events, rather than a truly high rate. The

increased reporting rates of Carintreggeland may also indicate an improved reporting behaviour, rather than a truly higher rate of events in patient safety.

This study was based on incident reports that were registered right after the incidents and provides no long term effects of adverse events.



## 4. Conclusions

In response to the results of this study, the conclusions are described in this paragraph.

There turned out to be many legislations and regulations concerning policy in medication distribution in nursing homes. Some acts concern necessary preconditions for medical treatment, but have no direct influence on the execution and safety of medication distribution in nursing homes. Other acts are strongly focussed on safety and quality of care and therefore are important acts. The regulations and directives turned out to be more important than the acts. They are focussed on the practice of medication distribution and thereby constitute an important base for the protocol of medication distribution in nursing homes.

In the protocol of Carintreggeland, the process of medication distribution in nursing homes is detailed defined. For each stage of the process of medication distribution, the involved actors are described, as well as their responsibilities and authorizations.

Several checks are performed and different materials are used to reduce risks in the medication distribution. Without these methods and materials, the safety of medication distribution in the nursing homes of Carintreggeland would be in great danger. These are very important for information provision, logistics and storing of de medication.

### ***Incident reports aren't systematically evaluated according to the protocol***

The board, the pharmacist and elderly care physicians are responsible for systematic evaluation and improvement of medication distribution policy. In practice, however, the evaluation isn't carried out systematically. Also, the annual report analysis by the VIM committee and quality department of Carintreggeland is carried out shallowly and therefore not sufficient for optimal improvement of medication safety.

This indicates that de protocol is developed on a good base, but because of a lack of evaluations of the practical use, there is not optimally learned from mistakes and the protocol is not systematically improved to adjust to the practice.

### ***Most reported incidents took place in the stage of administration and were caused by human errors.***

Most reported incidents took place in the stage of administration. This is a serious conclusion, as this stage directly influences the conditions of the patients. All incidents seemed to be caused by human errors.

### ***Under registration of reports of near misses***

Although clearly most reported incidents took place in the stage of administration, it is very likely that there's an under-registration of reports of near misses in the preceding stages. This is partly caused by the protocol of VIM reporting. The protocol demands employees to report calamities and incidents that influence the safety or conditions of the patients. Near misses though, which do not directly affect the conditions of the patient, are not obliged to report. They are not considered as a severe event, because the error is early detected and corrected. Nevertheless, this near miss in the stage of prescribing is a threat to right and safe medication distribution.

***The outcomes of the incidents turned out to be fairly mild.***

***No event had lead to death, hospital admissions or permanent injuries***

The outcomes of the incidents turned out to be fairly mild. The near misses and mild adverse events didn't lead to any visible adverse effects. Moreover, the more severe adverse events didn't lead to permanent injuries. Nevertheless, there is much attention to medication safety, because errors in medication distribution have the potential to lead to severe situations.

***A great difference in the number of reported incidents;***

***Many reports of incidents in the psychogeriatric population***

The staff of the psychogeriatric population reported significantly more incidents than the somatic and rehabilitation populations. A very low rate of reports was made in the small scale group dwellings, and a high number was found in nursing units within care homes. Some nursing homes made a striking high number of reports, there's a great difference between nursing home locations.

***No evidence for specific medicines with a higher risk***

Most of the incidents concerned all medicines that should have been administered to a patient. Furthermore, the medicines that were involved the most in the incidents seemed to be medicines that are prescribed the most. This study provides no evidence for specific medicines that are a risk factor.

### ***High number of prescribed medicines for nursing home patients***

The average number of prescribed medicines for nursing home patients turned out to be 9. The interviews revealed that physicians are afraid to discontinue certain medicines. This study does not conclude if the number of medicines is unnecessary high. Therefore, it would be interesting to explore overmedication in nursing homes.

### **Recommendations for Carintreggeland and further research**

The protocol of VIM reporting now only demands reporting adverse events. For a more complete insight it would be a gain to also report near misses. Therefore, also reporting behaviour of physicians, pharmacy assistants should be encouraged. Also, to learn from mistakes, Carintreggeland should evaluate the VIM reports systematically.

The great difference in the number of reported incidents in different populations, housing concepts and nursing homes is not reliable to declare. Reporting behaviour of employees is of great influence on gaining insight into these differences of the incidence of reports. It is important to find out whether truly more incidents occur or whether the willingness to report incidents is higher. Also it would be interesting to investigate what factors affect reporting behaviour of the staff.

This can give more insight in the differences of numbers of reports in populations, housing concepts and nursing homes.

The stage of administration is a critical point in the process of medication distribution. This study explored *what* incidents in medication distribution often occur, also in what stage and what the outcomes are. But even more important to know is *why* these incidents take place. To find out why the stage of administration is such a critical point, it would be useful to investigate what factors or circumstances affect proper medicine administration to a patient. If this context is made clear, Carintreggeland can take measures to improve medication safety in the stage of administration.

The studied reports of the incidents were made on the same day the incident took place. Slow effects or later appearing consequences are not included in the scope of these data. This means there's no insight in possible long term effects of an incident in medication distribution. Also, there's no information available about adverse drug reactions that are not caused by an error or incident, because it was excluded from the scope of this study. Further research focussed on the medication is therefore useful a completion.

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# Appendix

## Informed consent



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XXXXXXXXXXXXXXXXXXXX  
XXXX XX  
XXXXXXXXXX

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**betreft** inzage clientendossier

KvK 41027001

Geachte mevrouw XXXXXXXXXXXXXXXXXXXXXXX

Carintreggeland hecht grote waarde aan goede kwaliteit van zorg en veiligheid. Samen met Universiteit Twente wordt momenteel een onderzoek uitgevoerd naar de medicatieveiligheid in verpleeghuizen. Voor dit onderzoek wordt o.a. informatie verzameld over veel voorkomende chronische ziekten en voorgeschreven medicijnen. Om deze informatie te kunnen verkrijgen is inzage in medische dossiers van cliënten nodig.

Carintreggeland gaat zorgvuldig om met medische dossiers, conform de Wet bescherming persoonsgegevens. Dit betekent dat een onderzoeker zonder toestemming van de cliënt of diens eerste wettelijk vertegenwoordiger geen inzagerechten in medische dossiers heeft.

Op basis van een steekproef is het dossier van mevr. XXXXXXXXX XXXXX geselecteerd voor het onderzoek. Carintreggeland gebruikt de onderzoeksresultaten om de kwaliteit van zorg en veiligheid te bevorderen. Daarom wil ik u vragen toestemming te verlenen voor inzage in het medisch dossier. Deze toestemming kunt u geven door middel van het bijgevoegde toestemmingsformulier.

Met vriendelijke groet,

Henk Snijders  
Arts, medisch afdelingsverantwoordelijke  
Carintreggeland



## Toestemmingsverklaring

U bent gevraagd om mee te werken aan een wetenschappelijk onderzoek van Carintreggeland en Universiteit Twente door inzagerechten in uw medisch dossier te verlenen.

Alle informatie zal strikt vertrouwelijk behandeld worden en uitsluitend worden gebruikt voor het onderzoek. De gegevens zullen anoniem worden gebruikt voor het onderzoek. Dat wil zeggen dat geen persoonsgegevens of andere tot een persoon herleidbare gegevens zullen worden gebruikt.

Ondergetekende,

Naam: xxxxxxxxxxxxxxxxxxxx - xxxxxxxx  
Woonachtig te xxxxxxxx, xxxxxxxxxxxx

Wettelijk vertegenwoordiger/ 1<sup>e</sup> contactpersoon (indien van toepassing)

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Adres xxxxxxxxxxxxxxxxxxxxxxxxxxxx  
Postcode xxxx xx  
Woonplaats xxxxxxxxxxxxxxxxxxxx

verleent hiermee ten behoeve van het wetenschappelijk onderzoek toestemming aan de onderzoeker tot inzage van zijn/haar medisch dossier.

Handtekening: .....

Datum: .....

